KDUiRC
INTERNATIONAL RESEARCH CONFERENCE

14TH INTERNATIONAL RESEARCH CONFERENCE

" Security, Stability and National Development in the New Normal "

09TH - 10TH SEPTEMBER 2021

ALLIED HEALTH SCIENCES

PROCEEDINGS

GENERAL SIR JOHN KOTELAWALA DEFENCE UNIVERSITY

14TH INTERNATIONAL RESEARCH CONFERENCE

SECURITY, STABILITY AND NATIONAL DEVELOPMENT IN THE NEW NORMAL

Allied Health Sciences

PROCEEDINGS

General Sir John Kotelawala Defence University

Ratmalana, Sri Lanka

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Vice Chancellor, General Sir John Kotelawala Defence University

Keynote Speaker, Mr. Lalith Weeratunga Principal Advisor to H.E. President Gotabaya Rajapaksa, Secretary to the Ministry of Defence, General (Retd.) Kamal Gunaratne, DVC Administration and Defense, Brigadier Wipula Chandrasiri, DVC Academic, Prof Sanath Dhammika, Deans of the respective faculties, Centre Directors, Academics, Senior Military Officers, Administrative Staff, Students and all distinguished guests who are connected with us in the cyber space.
Good Morning to you all!

It is indeed with a great sense of responsibility that I deliver the welcome address at this 14th consecutive international research conference of General Sir John Kotelawala Defence University held on the timely theme, 'Security, Stability and National Development in the New Normal", at one of the most crucial times of our history.

To begin with, let me very warmly welcome our chief guest and keynote speaker, Mr. Lalith Weeratunga, the principal advisor to HE the President Gotabhaya Rajapakse. Of course, Mr. Lalith Weeratunga is not at all a stranger to KDU. He is one of the great personalities who clearly understands the role played by KDU for the betterment of the nation and who has long been assisting us in numerous ways to develop this institution to what it is today. As I remember Mr. Lalith Weeratunga was the keynote speaker of our 6th research conference in 2013. Sir, your keynote on our theme, "Sri Lanka as a Hub in Asia: the Way Foreword" still reverberate in our minds even after 8 long years.

And it is a remarkable coincidence that I welcome you once again to deliver the keynote address on our current theme, 'Security, Stability and National Development in the New Normal", which highlights the importance of stability created by the development and security nexus in the context of emerging new threats to national, human, and global security. Sir, we are looking forward to listening to your words of wisdom today as well.

Mr Weeratunga, it is also remarkable that eight years ago, you were accompanied by the Secretary Defence during that time, who has been destined to be President of our country today, H.E. Gotabaya Rajapaksa, and today you are accompanied by the present Secretary Defence and the Chairman of our Board of Management, General (Retd.) Kamal Gunarathne, and I am indeed honoured to welcome General Kamal to this conference as the Guest of Honour because he has been a tower of strength for KDU at this crucial time of its history.

Let me also welcome all distinguished invitees including the Tri-Service Commanders and other BOM members including the Chairman of the UGC, distinguished members of the diplomatic corps, Vice Chancellors and academics from other universities, senior tri-service and police officers, and national and international participants joining this event on line.

Ladies and gentlemen, this year's conference is significant to us at KDU on several accounts. First, 2021 is the year in which we mark the 40th year of KDU's existence in the higher education landscape of Sri Lanka, and we are proud of the role we have been playing therein, whilst continuously growing in its stature as a national university doing its call of

duty towards the nation with fullest commitment and dedication.

Secondly, this year's conference is the one that we hold under the most trying circumstances in our history. Last year too, we conducted our research conference in a hybrid mode due to the first wave of the COVID 19 pandemic that took us all by surprise.

But we hoped that we would be able to conduct the 2021 conference freely and in the usual glamour. But this year, it turned out to be even a worse scenario with the third wave of the pandemic hitting us harder. So we consider that this is a more challenging test of our resilience as the nation's defence university.

Ladies and gentlemen, we always believe in the dictum that a quitter never wins and a winner never quits. So we were determined to challenge the challenges, how hard they may be. And we ensure the continuity of the conference adjusting and amending the circumstances, while taking the highest precautions against the pandemic scenario. We were able to slowly but steadily accept the prevailing danger, assess the situation realistically, and to see the best options for the best interest of our University. Therefore, we finally decided that this year's conference will a hybrid one with a major virtual orientation.

Ladies and gentlemen, the reason why we conduct this conference somehow or the other is because of our belief that we need to set an example for the nation to stand on its feet at times of crises. We as a nation cannot afford to continue to play the waiting game for ever. As our theme highlights, we need to find ways to ensure security and national development in the new normal adjusting ourselves to the new normal conditions sooner than later.

And thirdly, we believe that this is the time in which a nation's intellectual community must come forward to engage in serious and meaningful research to help overcome innumerable issues and problems that crop up in diverse fields such as defence and security, economics, science, technology and engineering, medicine and health services, management, social sciences and humanities, law and so on and so forth. It is the responsibility of a university to create the necessary environment and enabling grounds for important research outcomes, which the nation yearns for.

Ladies and gentlemen, we are glad that the intellectual community of the country has very positively responded to our initiative. Despite some adverse comments and criticisms of KDU and its role in higher education in Sri Lanka from certain quarters in recent times, the large majority of fair thinking academics, professionals and ordinary people are with us fully, and that is evident from the large number of research papers submitted by researchers from all over the country representing various higher educational institutions.

Despite the difficulties in adjusting to the online mode, the organizers of the KDU international research conference have done their best to maintain the quality of the conference in the highest level. They intend to set the tone to initiate more collaborative research to face new global challenges. As I always point out these types of research conferences are ideal platforms to make connections nationally and internationally for mutual benefit.

I hope that authors of KDU and various other local and international universities will take the opportunity to interact and develop friendly relationships, establish networks, and explore opportunities to embark on productive research collaborations.

While assuring our commitment to providing best opportunities for research collaborations, I wish all the very best for the presenters and hope you will enjoy every moment of this academic fusion. Thank you.

Keynote Address

Mr Lalith Weeratunga

Principal Advisor to His Excellency the President of Sri Lanka

Secretary, Ministry of Defence, Chief of Defence Staff and Commander of the Army, Commander of the Air Force, Vice Chancellor of the KDU, Distinguished academics, Honoured guests, Friends, *Ayubowan!*

Once again, I am delighted to be with you this morning at this research conference. It gives me much pleasure to be at the KDU because it is one of the best universities we have in Sri Lanka. Since of late, there have been much attack on and criticism of the KDU. That's because the KDU is doing well and has brooked no nonsense. With a village background, my mind goes back to a famous Sinhala saying, which means "only those mango trees that have sweet fruits are attacked."

The entire world is undergoing a massive reorganization with the COVID-19 pandemic, and the traditional themes and arguments in security seems rather irrelevant in the present context. "Security, Stability, National Development in the New Normal" is a timely theme, giving us much food for thought in terms of the advancement of a country like Sri Lanka. If you take the first component, security, the bottom line of security is survival. *Survival,* is based on a number of factors. Barry Buzan, the veteran in international security rejected the practice of restricting security to just one sector and defined it as "a particular type of politics applicable to a wide range of issues."

As eminent representatives of the security sector, you are aware that the concept of security can somewhat vary from one country to another. When Mexico's major national security threat has remained to be organized crime for quite some time, Afghanistan's has been religious extremism. For a country like Somalia, it is the inbuilt corruption into their governance. For some countries, it might change abruptly. A few days ago, we all saw corruption and mismanagement which was the major security threat of the African nation Guinea, getting substituted by another – an armed unrest. In spite of these differences, almost all countries in the world have developed a commonality during the past year, where the health insecurity assumed a major role over and above all others.

The COVID-19 pandemic has caused the entire world to assume a 'new normal' to fight this common insecurity that is caused by a tiny, microscopic virus. Even during the new normal, however, certain fundamental features of the modern-day security have not changed. Security in the 21st Century was, to a great extent, focused on internal factors of a country, rather than external ones. The organization of the threat factor has changed from state militaries to terrorist organizations to even pirates. The underlying motivation for creating insecurities has shifted from being political to one that is economic.

Targets have shifted from soldiers to civilians. The distinction between 'high profiles' of national security and 'low profiles' of economic and social interactions have softened. This has given rise to new sources of global insecurity in the 21st Century which are essentially 'soft' in nature.

The 21st Century has continued to witness these new sources throughout its first two decades. Donald Rumsfeld, the onetime Defence Secretary of the United States said at a key decision-making point in the history of his country, "there are known knowns; the things we know we know, we also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns—the ones we don't know we don't know." Although stated in relation to a completely different scenario, when recalling this statement, I see that it resonates with the pandemic that we are facing now. In 'security

terms', COVID-19 is a 'wild card', an 'unknown unknown'. It is a security threat without a passport. It caused the 'health security' to assume the prime position in the security landscape of the modern day, surpassing the food security, water security and all other soft securities.

When we view the modern-day threats, we see that none of these is of a purely military nature, as those perhaps were, during the cold-war period. As a result, they also cannot be tackled by purely military means. There is another factor that contributes to the restriction of military means as a response to insecurities. In today's security landscape, States do not have the monopoly that they used to enjoy. Human beings have assumed that role. When the individual is considered as the central point in security rather than the 'State' as before, it gives a new insight into all our security related concerns. This helps us to understand the present-day global vulnerabilities with a new eye.

When the centre of focus in security becomes the individual, it changes the state-centric understanding of national, regional as well as global security. When a pandemic, which cannot be controlled by military means is plaguing the world, the human-centric understanding of security becomes vital to address it in order to ensure development of any country. This is why the 'soft component' of security, or the 'human security' gains more prominence over the 'hard component' of security during this new normal, created by the worst health pandemic in the recent history of the world.

The pandemic has given rise to a number of human security threats. To mention a few, the threat to economic security through unemployment, to health security through the deadly infectious virus and to environmental security through the mass accumulation of the waste generated in the health sector. It has also given a signal on food security as well, which is precisely when the Government declared essential services and appointed an authority to manage the situation in Sri Lanka. So you see, security in the new normal is connected with the stability of a country, but in a different way from how it did with conventional security under the normal conditions.

National development, as we all know, is an all-encompassing term. It includes both the individual and the nation. Therefore, national development can be considered as the process of development and reconstruction of all dimensions of the nation, along with the development of the individual. This concept is essentially linked with both the growth and the change where *change* can be socio-cultural or economic, tangible or intangible. National development involves activities through a planned national economy, application of modern technology in agriculture to enhance production, application of science and technology in the production sector, improving the human resource and providing education for all among many others.

During a disaster such as the COVID pandemic, it also includes providing facilities and assistance to the poorest segments of the society. In theory, addressing the security needs, especially those of soft security and implementing broad array of the previously mentioned key activities in national development ensures the stability of the country during the new normal. This theory is in practice in Sri Lanka today, in different sectors to different degrees.

Let us consider the vaccination drive for example. Two months ago, Sri Lanka was struggling with the inadequate human resource in the civilian component of the health sector to conduct the vaccination programme at its full length. Health sector employees were getting exhausted with the enhancing demand for services. At this point, the Government employed its military health professionals to assist their civilian component. That accelerated our vaccination drive to such an extent that Sri Lanka became the first country in the world to have the fastest vaccination drive to its population.

H.E. the President had first-hand supervision of this process, at times acting as a 'vaccination planner', which contributed to the success of the

whole programme. This measure addresses our health security, and at the same time contributes to our national development by making the workforce resistant to the pandemic. Together, the two outcomes contribute to enhancing the stability of the country during this new normal.

Now let us consider a few of the numerous initiatives that the Government has introduced to ensure food security. The Government recently decided to take a transition from inorganic agriculture to organic agriculture, in keeping with pledge given to our people by the President, H.E Gotabaya Rajapaksa, in his policy document, 'Vistas of Prosperity and Splendour." The primary aim was to safeguard the public, and especially the future generations from non-communicable diseases including renal diseases, again ensuring the health security. This also gave an added advantage where the imports of chemical fertilizers became minimal and that saved a considerable amount of money to our Treasury. This also resulted in enhancing organic and bio fertilizer production within the country, opening up new employment opportunities.

Linked with these two activities, the Government also launched 'Wari Saubhagya', a programme to rehabilitate 1000 small tanks across the country. This was to provide water for both irrigation and drinking purposes. These projects ensured irrigation water to a greater area of paddy and other field crop cultivations and also created additional employment opportunities within the country. Overall, those made a noteworthy contribution to the national development as well as to the soft security of the country during the new normal.

National development not only involves the infrastructure development, but also the human development. A developed human resource is a shield against certain soft threats. The programme 'connect Sri Lanka' was launched during the new normal, initially providing four remote areas with 4G connectivity. We are planning to expand it into all 9 provinces.

The pandemic period where schools had to be closed was also used to plan education reforms aiming at producing future generations that are better equipped with battling their way through the ever-changing global order. These enhance opportunities for the public, especially the children to gain access to knowledge that is amply available to children and citizens of many developed countries, and also to equip themselves better to assist with development initiatives of the Government.

Fruits of this labour will be reaped only in the future, where our country will continue to have a learned, open minded younger generations, and through them, smarter work forces. The activities that the Government has started today contribute to national development in the future on the one hand, security on the other, and to stability of the country, overall.

The last example that I wish to draw has a direct connection with all institutions in the public as well as the private sector, electricity. The Government spent over US$ 2.3 Bln for oil imports in 2020. We all know that a considerable amount of this is spent for generating electricity. This is an unbearable amount for a developing country like Sri Lanka, to be spent notwithstanding the prevailing health pandemic. It is also a waste of funds considering the vast and untapped potential that Sri Lanka has for renewable energy.

The Government gave due consideration to both these when establishing 'Thambapawani' the first wind power station owned by the Government of Sri Lanka. Another similar plant has been launched in Pooneryn. Use of solar power has been introduced to households. A waste-to-power plant was also declared open at Kerawalapitiya. It is not an easy task for a developing country like Sri Lanka to manage this shift while battling with a pandemic, but amidst all, the Government plans to increase the renewable energy component to 70% of the total consumption of the country by 2030. It Is an ambitious target, but it helps the country to reach a higher status in self-sufficiency and also prepares the country to face worse calamities than the present one that might arise in the future. The 'failure to prepare' as the old saying

goes, is 'preparation for failure'. We intend to avoid it.

Moving back to the concept of security with these examples, with special emphasis on human security, it is evident that the national development and security are inter-linked. These cannot be achieved separately. This is probably what caused the formerly known definition of security, 'freedom from fear', to be redefined as 'freedom from want', indicating the link between security and development. Human security, as we all know, is an integral part of State security, which in turn, has an equally strong connection with national development. This is why if you have a closer look at Sustainable Development Goals, you will see that all 17 goals are connected to human security.

In this context, I believe there is something vital that we all need to understand about security, development and the stability that those bring about. The new normal caused by the COVID-19 pandemic is calling us to re-think our actions, plans and concepts on security and development both.

Is it not high time for us to re-think our national security and national development?

Is this not the best time for us to redefine our development-security nexus?

Let me conclude by bringing back to your memory, extracts from a famous speech delivered by Robert F. Kennedy during his run for the Democratic nomination for the Presidency of the United States. Over 50 years later, his remarks about the measurements of development resonate with something that we need to re-discover with experience we had during this new normal. He said, and I quote,

"… the gross national product does not allow for the health of our children, the quality of their education or the joy of their play. It does not include the beauty of our poetry or the strength of our marriages, the intelligence of our public debate or the integrity of our public officials. It measures neither our wit nor our courage, neither our wisdom nor our learning, neither our compassion nor our devotion to our country, it measures everything in short, except that which makes life worthwhile."

Distinguished scholars, ladies and gentlemen, let us try to fathom the lesson that this global pandemic and the new normal is trying to teach us. Let us acknowledge the all-encompassing nature of national development and pay attention to the vital fact that has evaded our comprehension thus far – the fact that the individual, the human has assumed the central focus in security as well as in national development. Let us use that understanding to re-define our development-security nexus and bring a lasting stability to our country during the new normal.

Stay safe and take care of yourselves.

Thank you.

Address by Secretary, Ministry of Defence, Sri Lanka

General Kamal Gunaratne (Retd) WWV RWP RSP USP ndc psc MPhil

Secretary, Ministry of Defence, Sri Lanka

Chief Guest and Keynote Speaker of the 14th International Research Conference of KDU, Principal Advisor to the President Mr. Lalith Weerathunga, Ambassadors and High Commissioners, Foreign Secretary Professor Jayanath Kolombage, Chancellor of KDU General Jerry De Silva (Retd), Chief of Defence Staff and Commander of Army General Shavendra Silva, Commander of the Navy Vice Admiral Nishantha Ulugetenne, Chairman of University Grants Commison Professor Sampath Amarathunga, Vice Chancellors of other Universities, Vice Chancellor of KDU, Chief of Staff of Air Force, Director General at Institute of National Security Studies Professor Rohan Gunarathna, Deputy Vice chancellors, All Deans and Directors, former Chancellors and Commanders at KDU, Eminent Scholars, Senior Officers of the Armed forces and Police, distinguished guests joining us virtually from Sri Lanka and Overseas, Ladies and Gentlemen;

I consider it as a great pleasure and a privilege to be present here today at the inauguration ceremony of General Sir John Kotelawala Defense University's International Research Conference which is taking place for the 14th consecutive year and I would like to thank the Vice Chancellor and the conference organizers for the invitation extended for me to be present here to participate in this event. The International Research Conference of KDU is providing the opportunity for academics, professional researchers and practitioners to share their research findings and expertise addressing the mutual challenges in their fields. Therefore, this event has gained tremendous recognition among all interested parties around the world. Further, the provision of a wider interaction and networking with national and international scholars in respective fields would be absolutely beneficial for all the participants to broaden their horizons of knowledge through intellectual discussions. However, due to the global pandemic situation in effect, most participants may join the event through a virtual platform for this conference as same as the last year. Yet, I'm sure we will be able to achieve the desired objectives in a state amidst this pandemic situation.

Furthermore, I'm extremely pleased that the theme selected by the KDU for the conference this year security, stability, and the national development in the new normal is a timely theme capable of augmenting the significance and focus of the subject of strategic national importance. Further, I firmly believe that the endeavor towards warranting the national development and ensuring national security becomes further from achievement by undermining the routine activities due to the ill effects of the pandemic but becomes attainable by ensuring the adaptability to the new normal as widely accepted by all the countries in the world, today which is implied by the theme that you have selected. In fact, as comprehensively illustrated by the keynote speaker Mr. Lalith Weerathunga it is quite imperative that all of us understand and pursue the ways and means of adopting the circumstances embedded with the new normal. in order to coexist with the Covid 19 pandemic which has not shown any expiry date as of yet.

Ladies and Gentlemen in a context of globalization and further economic

integration, in recent decades the relationship between national development and national security of a country has become increasingly interlinked for Sri Lanka. These connections represent both opportunities and potential threats to the country's national security. The open and interconnected Sri Lankan economy creates vulnerabilities from potential international and external threats. Against this backdrop, national development has emerged as an important strategic priority for the Sri Lankan government with the connection between development and national security which will be orchestrated upon the vistas of prosperity and splendor, the national policy framework of our government headed by his excellency the president Gotabhaya Rajapaksha.

Ladies and gentlemen, the development generally depend on the stability of a country which should be achieved by ensuring national security. Sri Lanka being a country endangered by ruthless terrorism for almost three decades has experienced a lot of hardships during the past and was in the stage of eyeing its development in the last decade. Even though we were able to relieve the country from the menace of terrorism we have found another security threat in the form of a pandemic which has posed a greater threat to the entire world. The threat that we face today is progressing in its second continuous year without any indication of a possible termination we are yet to find a permanent solution for the same. However, we must always work towards reaching our development goals without letting our country at peril. In such a context our endeavor here as Sri Lankans should be to seek possibilities to find ways and means to steer the country towards development goals amidst said difficulties. Sri Lankan government is at the threshold of trying all possible methods to meet its economic growth and objectives yet with lots of empidements while ensuring human security. When the domestic affairs of a country are affected it is extremely difficult for a country to reach its desired end state. Sri Lanka is no exception in this, regard being a developing country Sri Lanka cannot accept any economic standstills for a protacted time frame. However, any plans to expedite the economic gains should never be at the expense of human lives. Therefore, his excellency the president himself has expressed his keenness on this aspect to see and inspire all possibilities available to ensure the maintenance of momentum in the economic sphere.

On the contrary, we should also note the other contemporary security concerns such as violent extremism, terrorism, piracy, drug, and human trafficking, smuggling, cybercrimes, and other organized crimes and natural disasters pose a grave threat to the stability of a country. Sri Lanka's geostrategic location is susceptible to such threats as it is located in the main sea routes in the Indian ocean. The same geopolitical significance has given a greater recoginition to the country, thus it has gained greater demand from the rest of the world. In such an instance, the possibility of Sri Lanka becoming susceptible to threats posed from violent extremism and organized crimes is very high and present the government has initiated several steps to curtail such illegal activities and such measures taken such as the demarcation of maximum security prisons concept and highly effective maritime domination programs launched by the Sri Lankan Navy which have become very effective in restricting such threats. However, the effects of such activities pose a moderate level threat to the stability of our country.

Ladies and gentlemen, a government alone cannot afford to force all these threats that are in concert ruining the stability of a country. Therefore, as responsible citizens, it

is our bounded duty to provide novel ideas, suggestions, and proposals to consider in regaining our country's stability and development. I hope the academic events of this nature will undoubtedly serve this national requirement. Such efforts are arranged to address emerging challenges. Promoting more research and development becomes a task of topmost priority for all of us.

Fortunately, as the Secretary of Defense, I feel tremendously proud and content to say that the Kotelawala Defence University is at the forefront of researching the development of security-related problems in the new normal. The approach adopted by the Kotelawala Defense University to understand the contempaty complex situations concerning the bigger picture rather than dwelling on the narrow passages will become far more effective in resolving the emerging complexity of future challenges. Therefore, I'm well certain that the faculties of General Sir John Kotelawela Defence University with their interest, commitment, dedication, and knowledge in diverse academic disciplines and outside rich researches inputs would contribute immensely to this year's conference theme. The knowledge that you are going to unearth and share during this conference would be of immense benefit not only to the academic community but to the entire humankind to make their lives better.

In conclusion ladies and gentlemen, I should express my most sincere appreciation to the Vice Chancellor and the organizers of the General Sir John Kotelawala Defense University's 14th International Research Conference 2021 for organizing this timely important event amidst the covid 19 pandemic concerns and I wish this event be successful in all way imaginable. Ladies and Gentlemen thank you very much for your patience, thank you.

Vote of Thanks

Dr Harinda Vidanage

Conference Chair, 14th International Research Conference, General Sir John Kotelawala Defence University

Mr Lalith Weeratunga, Principal Advisor to HE the President of Sri Lanka, Secretary to the Ministry of Defence, General Kamal Gunaratne, Vice Chancellor – Maj Gen Milind Peiris, Deputy Vice Chancellor (Defence & Administration), Deputy Vice Chancellor (Academics), Rector – Southern Campus, Senior Professors, Deans and Directors, Senior officers representing Tri Forces and Police, Distinguished guests, colleagues, Ladies & Gentlemen, Good morning!

In its 40th Anniversary since its inception the flagship academic conference of the KDU, the international research conference progresses to 14 years of continuity. I stand here to reflect and provide my gratitude to a team of individuals who despite every challenge in the form of material and the forces of nature has confronted us with, have managed to successfully bring us to where we are today.

Since 2019, the country has witnessed unprecedented upheavals from violent extremism to microbial threats that have forced a drastic rethinking of every aspect of social life. These challenges have made all of us believe in a reality that long established norms, traditions, beliefs do have their limits and if we are to survive and thrive in the new normal, we must adapt, adopt and innovate. The core fundamentals driving this year's IRC is based on this conviction and that the KDU as a leading force of defiance and a beacon of hope amidst such calamities.

On behalf of KDU, I would first and foremost like to extend a heartfelt appreciation to our Chief Guest and Keynote Speaker, Mr Lalith Weeratunga the Principal advisor to H E President Gotabaya Rajapaksa. Your presence today is a blessing to us as an institution and to the IRC as a process and your observations made at the keynote enriched us with knowledge and perspective. Your wise words of wisdom will have a bearing on the deliberations of all academic communities within and well beyond this conference. I also would like to thank Secretary to the Ministry of Defence, General Kamal Gunaratne for his presence, his insights and his towering leadership that has seen KDU through fair weather and through some rough storms.

I would like to highlight and appreciate the visionary leadership of the Vice Chancellor, Maj Gen Milinda Peiris and his belief in maintaining continuity of this apex academic event of the KDU. I must then appreciate the critical roles played by Deputy Vice Chancellor (Defence & Administration) Brigadier Wipula Chandrasiri in ensuring that the IRC will take place and in providing the administrative leadership towards the materializing of the conference. The support and blessing of the Deputy Vice Chancellor (Academic) Professor KAS Dhammika is highly appreciated, along with the support of all Deans of faculties who came together to make this event a success.

Even at a time when every institution is careful about its purse, our sponsors have stood by us, let me profoundly thank and appreciate the generosity of our Gold Sponsors, the Bank of Ceylon and the People's Bank and with Huawei Sri Lanka and National lotteries board being our silver partners. There are many more who have chipped in and do not want their names mentioned and a big thank you for all.

I must mention that this year it is the first time the faculty of Defense and Strategic Studies have been tasked with the overall IRC and holds the chair. I must with gratitude mention the hard work of my colleagues in both departments of Defense and Strategic

Studies under the leadership of Col Enoj Herath the Dean of the faculty. The FDSS represents the tip of the Spear of the KDU and bears testimony to the perfect convergence of civic-military relations.

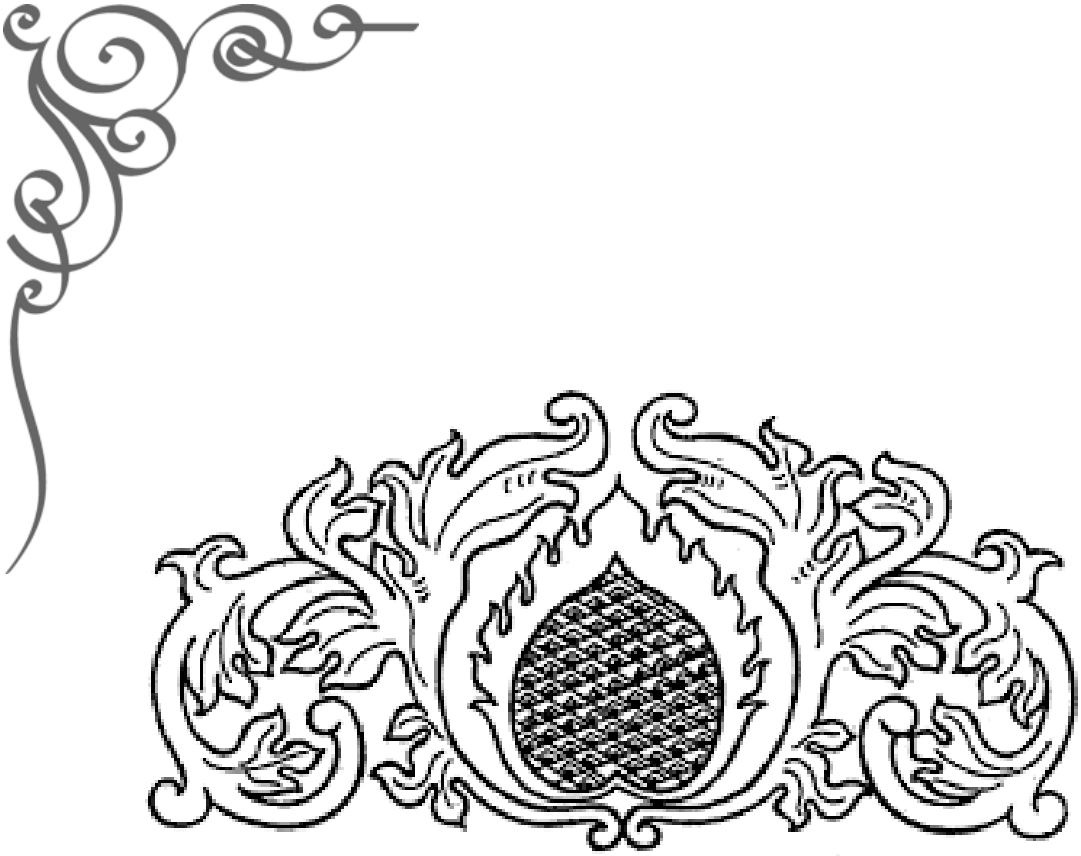
Towards the buildup to the conference the shutdowns became lockdowns and lockdowns became enforced quarantined curfews, yet the main committee of the IRC 2021 managed to work tirelessly around the clock. We knew it was all for a greater cause and I must appreciate the gargantuan task that was handled by the secretary of the IRC committee Ms Lihini De Silva who virtually was my prime buffer and the tremendous work done by the three co secretaries, Maj Ranushka Ferdinandesz, Ms Isuri Uwanthika and Captain Abeetha Athukorala. We were all supported by the dynamic team of faculty coordinators who labored hard and were endowed with patience.

It is with sincere gratitude I appreciate the services of Mr Kithsiri Amaratunga the president of the Editorial committee and Dr Faiz Marikar the deputy editor. I also want to mention the prudent actions taken by Commander Bogahawatte, the president of the publication committee. I would like to thank all committee presidents, committee members, faculty committees, the office of Bursar, Registrar, Adjutant and C/O Admin and the staff at the Vice Chancellor's office.

New normal pushed us to the limits, yet we managed to overcome as we functioned as a collective team. Yet, finally the work would be incomplete if not for the researchers who had put faith in us and submitted papers and reviewers who filtered them. This year's IRC is the most decentralized event out of all IRCs, facilitating intellectual deliberations of this scale is no easy task. To keep this grid alive and robust the contributions made by Director IT and his team needs a special word.

We have truly embraced the new normal. We have not run away from it, instead we have transcended it. Thank you all for accepting and believing in us. We shall prevail and we shall overcome.
Thank you very much!

ALLIED HEALTH SCIENCES



PLENARY SESSION

US Experience with the COVID-19 Pandemic

Prof Steven M Albert

Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh, USA.

Greetings to everyone. Thank you very much for the invitation to your conference. I'm only sorry that we can't be together in person. I send greetings from the United States and the University of Pittsburgh, which is my home base. I think I need to share my slides, so maybe give me one second to do that, and in my brief time here I will try to give you a picture of the pandemic in the United States and some of what we've learned so far and it is a very challenging time for us.

I will cover the following four topics and beginning now with the slide, I hope you can see from Northern Italy in March of 2020 already a long time ago, you can get a sense of the exponential growth of SARS-CoV-2 or the COVID-19 virus really within a month, from late February to late March of 2020, in Northern Italy saw 60 000 cases in a month. A really striking exponential growth, and if you can look at the slide, you will see that there were many attempts to mitigate or slow down the spread of the disease, and they failed. You can see there were lockdowns and school closures, stay-at-home measures, the closing of the economy, suspension of non-essential economic activities, but all of them together did not slow the growth of the infection and this raises the question, could we have done things differently earlier in February? would that have changed the course of the infection? Or perhaps the timing of these closures was not optimal? and a lot of our thinking in the pre-vaccine period was to determine what is the right approach for mitigation so I'll talk a little bit about that, give you a sense of the severity of the epidemic in the United States, and then talk a little more about infection versus vaccination-based community immunity, which we sometimes call herd immunity, and then end with where we are today. I won't have time to talk about the "infodemic" which is a new word which refers to the spread of information about the pandemic and some of the damages and challenges that come from wrong information getting out to our populations.

So, to go back to the beginning, In February of 2020, we have our first publication from China about the coronavirus and already something very alarming emerged that is that infection was possible even before the indexed case showed signs or symptoms of disease. In this first publication from the New England journal of medicine, the authors estimated about 9 or 10 percent of patients were infectious before they showed symptoms. In fact, now we know that the percentage is more like 30 or even 40 present of the transmission occurs before the index patient develops frank symptoms and that makes control of this infection extremely difficult.

And also, to go back already to what seems like ancient history, back in February in 2020, in my own hospital, we were very frightened and really struck by the intensity and the morbidity and mortality of COVID 19. In our emergency care units, two-thirds of older patients were dying with this disease. We did not know how to treat even in the ICU an advanced case of pneumonia from SARS. Very quickly, shortages of medical care became apparent our hospital system, which normally has about 80 to 90 percent of ICU bed occupancy was overwhelmed very, very quickly.

Looking at the population perspective, this is a very nice graphic which shows really the situation in the first months of the infection the plotting the exponential growth the side of the straight lines to the left indicate doubling time so the line furthest to the left indicates doubling every day and the line to the right doubling every month and you can see just how fast and how consistent the growth of the infection was. However, you can also see that some countries did quite well with early mitigation strategies. So China and South Korea and Japan, at the beginning of the infection, flattened their curves very quickly, unlike Spain, Italy, France, and the United States, and the other European countries which continue to see exponential growth and we're too little too late in mitigation strategies now China if you remember was very very severe in their mitigation closing down whole

cities, shutting down internal transportation, shutting down its airports and schools very very quickly the other countries were slower to respond, and the implication for the infection is here you can see the growth rate of the infections.

And where are we today well this is a dashboard from the United States that Johns Hopkins University prepares We have now crossed 40 million cases in the United States and over 650 000 deaths striking infection which we have not seen probably since the influenza pandemic of the early part of the 20th century, but a silver lining is over now 400 million vaccine doses administered if you look at the bottom, you'll see the plots which speak volumes, the red plot on the bottom is weekly cases, the middle is deaths, and the far right is vaccine. And unfortunately you can see on the left in the red curve that we are now facing our fourth or fifth wave with the delta variant, and there is a story to be told here of the uneven impact of the infection now in the United States, where regions with high vaccination are seeing much lower incidence than regions with low vaccination and unfortunately low vaccination is tied to some political movements in the United States which are very complex and require a lecture in themselves.

But here is I think the picture of mortality for the United States. The gray curves show a prior year mortality 2015 to 2019 over each week of the year and you can see there's a seasonal effect where in the early months sorry the early week zero to 10 or winter months we always have higher mortality but the red is the COVID year and you can really see the excess mortality due to this disease some of it is COVID itself, and some of it is people dying of other diseases because they could not get to the hospital for medical care. So we have seen 10 and 20 percent increases in mortality from diabetes or cardiovascular disease as well as the more immediate effect of COVID and of course in that early period centered around week 15 that was our first wave the alpha variant and mostly older adults in the United States took the brunt of the infection especially residents of long-term care facilities and unfortunately you can see our later waves toward the end of 2020 the red line is of course elevated again and if you look at the purple or whatever that color that line is that's 2021 and you it looked like we had the infection well under control from a combination of mitigation and vaccination strategies but the this this unfortunately is not complete data we are now back in our next wave.

And I just want to remind you also that despite a hundred years of modern medicine our early experience with the disease was not very satisfying we had very very high death rates this is a comparison of death rates from New York City in the influenza period from 1918 compared on the right with mortality from COVID. And you can see that overall, prior to the pandemic, yes, mortality is much lower in fact it's half but once we enter the COVID pandemic unfortunately our mortality rate went from 50 to about 200 per hundred thousand person years and at the height of the Spanish flu influenza 100 years ago it was about 275 deaths per hundred thousand. So, our experience was not good. And it took us some time to learn how to handle this disease medically and how to roll out proper public health precautions.

In my own area Pittsburgh Pennsylvania, the region around the University of Pittsburgh I can give you a feel for the law the widespread impact of COVID apart from effect infection. So here in the United States we have what we call emergency medical services or EMS calls you can dial 9-1-1 on your telephone and an ambulance will come with the police to investigate a health issue. And what I've plotted here are quarterly the volume of EMS calls, and you can really see that following the lockdown which occurred between quarter one and quarter two in 2020 we really did see a decline in EMS service calls. That's not because of COVID that was because people change their behavior in huge ways and lowered the risk of things like falls or accidents or injuries but also people did not call EMS when they had an episode of tachycardia or atrial fibrillation huge huge effects of COVID on health more generally as shown here.

And so we have had to recognize the limitations and the inadequacies of our data collection just showing you all the different components in the course of a disease like this and all the different data streams we need to effectively treat and anticipate control of such a disease. And the good news from our modeling efforts and now our empirical data is with vaccination we really have changed the course of the infection and with proper mitigation strategies, some the right combination of vaccination and mitigation, will allow us to control this infection. And by mitigation

remember I mean people distancing wearing face masks and rationally controlling the opening and closing of schools, airports, transportation, and commerce and how to do that well is the real challenge.

We have our modeling efforts here's one shown which we're now bringing behavior into our infectious disease models.

And also we are working out important effective public health communication strategies here's one from my own university, the University of Pittsburgh, where we have a dashboard of cases that students can see levels of infection and change behavior accordingly and we also have all kinds of infographics this was from last November, our Thanksgiving holiday trying to educate people that it's possible for someone to be infectious even though they're asymptomatic, and testing at the wrong time will not solve that problem, so we have had to learn very quickly about effective communication as well.

Here is something from my own department where we do, we develop videos for our health clinics on masking on, social distancing, and on quarantine and isolation when people develop symptoms.

So I don't have a lot of time, but I want to give you a taste of some of the most advanced thinking going on in the United States now about mitigation and one of the things we can do now with smartphones and GPS tracking is link movements of populations to places I don't know if you can see this well but this is a comparison of March and April of 2020 using data from safe graph which tracks movement on cell phone on smartphones and you can see that there's a little less thick lines here this is connecting people's movement and networks to places on the ground and that represents the lockdown of Chicago in 2020.

And one of the most interesting things we've learned is that you don't need to shut down 100% to have a radical impact on transmission with clearer data and understanding we see there's a non-linear relationship between people attending, let's say, commerce, a store and the risk of infection that curve is not a straight line it may be possible to open up a site at 30 percent or 20 rather than 0 and have a very strong gain in reduction of infections. And we can even target this by small geographic units and with the proper data system, it may be possible to mitigate transmission and yet not shut down the economy as a whole. So, we are very interested in new data systems that will allow us for rational control over population movement to minimize infection.

I also want to raise for you one large controversy we've had in the United States but also in the UK and other places you know it's a contrast of infection-based immunity versus vaccine-based immunity. And there was a group of academics who put out a declaration called the Great Barrington Declaration which said that we should really let the infection burn through a population that is the quickest way to have community immunity or what sometimes called herd immunity and it would be possible to do this by protecting those who are at higher risk. Well it sounds seductive and it sounds reasonable, but this approach turns out to be wrong.

And a number of us try to show why this is a bad idea. I myself published paper on this as well and it's really really quite difficult to segment a population to protect those at highest risk while letting the remainder of the population move at will. And the reasons are here the at-risk group in any population is quite large. For example, in the United States, 6% of people over age 65 have two or more medical conditions well that's two million people it's impossible to protect those folks, many of whom live in the community also it was not just the older sicker population that developed COVID and required hospitalization we are suffering with this now with the delta variant where many young people are in hospital and dying and as I showed you already the high stress on hospital care compromises care for the whole population, not just those affected by COVID. On the behavioral side, it is impossible we have learned to separate low and high risk groups they live together they interact the high-risk group is transmitting disease even before there are symptoms and our testing protocols are just not good enough right now to get those tests out in a timely way with results to people and not everybody is willing to self-isolate and quarantine. So, it is a real challenge and the Great Barrington resolution really was not an effective approach the more rational strategy is to combine vaccination and mitigation in rational ways.

And so, this is where we are in the United States right now. The red areas indicate census tracts and zip codes in the United States that have high infection rates. You can see it's the southern United States, in particular the the southern built from Texas to Louisiana to Florida and then up into Missouri, Virginia, West Virginia this is the hot spot of infection in the United States these are the areas with the lowest vaccination rate, these are the areas with the lowest mitigation efforts and unfortunately as we've learned from our studies of infectious disease, just having 50 or 60 percent of the population vaccinated is not enough to control the course of an infection.

And unfortunately, as I mentioned a second ago we have all kinds of lack of unity right now in the response to the infection and lots of mistrust in science and in government which is making it very difficult to protect the public's health.

And so, here's where we are today, and I will conclude here. I'm sorry if I went a minute or two over COVID in September 2021 over a month now we have uneven vaccination uptake in the United States, uneven acceptance of mitigation hot spots of infect and overwhelming of hospital surge capacity in some parts of the country on the other hand new knowledge and new strategies for redesigning environments both for ventilation and also for mitigation and probably beginning shortly in the United States following the example of Israel and some other countries we will see a third vaccination effort and I think that's probably where we're going today. So, I would like to thank you very much for this opportunity to address you I'm sorry for going quickly through a very complicated story but I'm I hope I've piqued your interest and I hope to see more collaboration and of course greater vaccine accessibility across the globe. Thank you very much.

The Use of Artificial Intelligence in Radiological Diagnosis

Prof Meng Liang

School of Medical Imaging, Tianjin Medical University, China

Good afternoon, everyone, first of all, let me send my best regards to all of you to stay safe and well protected in COVID-19 pandemic. Today I am going to talk about use of artificial intelligence in Radiological Diagnosis. I am Going to talk about four aspects. First one, when medical imaging meets AI, because my background is AI engineer mainly working on how to use AI technique in the medical imaging area. Then, how AI help in the COVID-19 pandemic, I am only just going to touch this point using two research work recently published how AI can help in this severe situation. In the third part, this is actually my own research interest is about AI in pain and schizophrenia research, lastly, I am going to talk about some challenges AI is facing.

I don't know if you know that first issue of nature medicine 2019, they published more than ten articles all of them are focusing on application of AI in medicine in medical area. It shows that artificial intelligence is a hot topic in medical area. Well, among these AI applications in the medical area using AI in radiological diagnosis one of the most important area. In China, there are two sentences in this area meanings are 'Imaging leads the way towards the precision medicine' and 'technology leads the way towards precision medicine'. So, we are trying to express the idea that advance techniques such as AI which can really push the medical imaging move forward.

OK. We want use AI to help human doctors to assist doctors to take their decisions on disease diagnosis. This is actually the computer vision and human vision and who will win? We all know that the machine and human have their own advantages what we should do is to combine these two different types of intelligence together to make a better ability to diagnose disease.

Medical imaging actually a perfect area for AI to be used for the diagnose of diseases. Because of some realities in the clinical practice or medical imaging diagnosis for an example in many countries such as in China I think probably a similar situation in Sri Lanka there is a shortage of radiographers and radiologists. Even with the shortage medical imaging examinations are rapidly increasing and we have a lot of medical images to examine every day. Also, the distribution of radiographer and radiologists are very unbalanced across the country. For example, in some hospitals in some areas you can find very good doctors with very good experience some areas you cannot find, and you can only see less experienced doctors. Fortunately, in the medical imaging, image format and image protocols are mostly already standardized which is very good condition AI to be used in this area.

So, this realty provides AI excellent opportunities to excel in assisting radiological diagnosis. So, what AI can do for example big database radiological diagnosis using AI and AI can be perfect in quantitative lesion measurements and evaluation. These are the things the computer good at. And also, the intelligent optimization of image quality or they can help us to get better quality images. And also less scanning time and dosage while keeping good image quality. So, AI can do so many things and also, we are trying to translate AI system products to clinical practice. In US, FDA has already approved quite few AI based products in clinical practice. Also in China for example last year in China government approved the first medical imaging AI system which is computing software for coronary artery based on CT scans and for lung cancer screening. These are the signs showing that AI has a great potential to be translated and to be actually used in the clinical practice.

Secondly, how AI can help in the COVID pandemic. I am only going to show you an example actually if you search on the pubmed there are so many papers about using AI for the detection of COVID 19 pneumonia patients. For example, there is one paper published last year is about clinical application of AI system for accurate diagnosis, measurements and prognosis COVID 19 pneumonia using CT scans. So, these AI systems ware developed using 40880 slices of 83 NCP patients and 91 common pneumonia patients and

86 normal controls. So, AI models performed very well in distinguishing different patients, so they can identify successfully NCP patients from common pneumonia patients and also healthy controls with very high classification accuracy. And also, there is another example which is a paper published last year in nature medicine, this work integrates the chest CT findings with clinical symptoms and other clinical data such as exposure history and laboratory testing data, and based on this multi-source data developed a machine learning algorithm model which also perform very well. The performance is comparable with senior thoracic radiologists and this shows AI shows great potential to be used in future.

OK. In the third part I am going to talk about my own interest is about using AI in pain. So, pain is a common problem among so many clinical diseases and which is very difficult to treat. So, pain by definition is a subjective feeling and can be easily affected by emotion, environment and culture and also for some special populations like babies and also some patients with language problems, for these people we cannot really tell you whether they are in pain or how painful they are. We need a tool to objectively assess pain. So, what can we do? Although the pain is a subjective feeling in the end pain is generated by our brain. So can we use neural activity of imaging data to identify pain. So, what you are seeing in my slides the brain activation maps. First row by painful stimuli, second one is the brain activation map elicited by the touch stimuli or non-painful stimuli. You can see that these activation maps are very similar. It turns out that we cannot really see any differences between painful and non-painful activation maps using our human eye. But if we apply AI technique, we can distinguish brain activation maps elicited by pain and touch.

Similarly for schizophrenia it is one of the severe mental disorders worldwide, but the diagnosis of schizophrenia is very problematic in clinical practice. So usually how the schizophrenia is diagnosed, doctors ask questions from patients based on guidelines. So, this way of diagnosis is very subjective. It strongly relies on doctors' experience and often patients are misdiagnosed. Based on this situation can we develop a tool how to diagnose schizophrenia. So, my idea also to use brain imaging data to diagnose schizophrenia. We found that schizophrenia patients they have alterations in grey matter and white matter and, we can see alterations in functional brain network both functional connectivity and effective connectivity network. It shows that schizophrenia patients have abnormalities in their brains. We use their abnormality patterns to check whether this patient have schizophrenia or not. So, we attempted to do that using AI model to diagnose schizophrenia and we found by fusion of different data together significantly improved the classification accuracy. In these two examples, in the first example of pain assessment trying to move from a subjective report by patients to objective evaluation, for example in schizophrenia diagnosis we are trying to move from a subjective report by doctors to objective evaluation to make their decisions.

Ok. Lastly, I am going to talk about some challenges in facing in the application in medical imaging diagnosis. Can we really trust AI? Or can radiologists replace by AI? My answer will be yes and no. Can we really trust AI? I personally know there is long way to go accurately and successfully to use in the real clinical practice. I don't think every radiologist will be replaced by AI because human has some advantages but some of the work currently will be replaced by radiologists. So, to really get that point that the AI can be successfully use and translated in the clinical practice still facing many challenges. We have to find the right scenario to apply AI system to make it successful, to make it really helpful and also, we need better algorithms, we need faster machines, we need big data to train our model. And need better quality data to train model. We often find data are missing and could be problem and issue of data safety, also patient privacy and often we lack gold standard to train our model. There are so many challenges AI is basing but AI can be developed very fast, will have to do system and products to really help radiologists to do that work.

OK let me conclude and finish saying in Chinese.

'While prospects are bright, the roads are twists and turns'- Mao Zedong

This is how AI will progress in the medical imaging diagnose. OK that s all for my talk. Thank you very much.

Radiological Technologists' Role in Global Health for COVID-19 Pandemic

Asst Prof Napapong Pongnapang

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Hello everyone and Ayubowan. First of all, I would like to thank the organizing committee for inviting me to be one of the speakers at the event. The topic of my talk is radiologic technologist's role in global health for COVID-19 pandemic. During my talk, I would like to have a short introduction of the organization that I belong, the International Society for Radiographers and Radiologic Technologist (ISRRT) and our activities in response to this COVID-19 pandemic including how we set up the standards and how we do international collaboration. We respond to what members need last but not least. As the International organization for radiological technologist and all radiographer professionals, the ISRRT was founded in 1952 and at present we represent over 500 thousand radiographers and radiologic Technologist globally to work closely with the World Health Organization. In this talk I will show a couple of activities we did together with the WHO in regard to the COVID-19 pandemic. And also, if we focus on radiation protection aspects of the practice we have a collaboration closely with the International Atomic Energy Agency (IAEA) and European Federation of Radiological Societies (EFRS). Also recently, we have had a lot of activities with the International Commission for Radiological protection (ICRP). As I mentioned earlier, the ISRRT is the voice of half a million radiography and radiation therapist professionals worldwide. We have a mission statement to improve the standards of delivery and practice of medical imaging and radiation therapy throughout the world by acting as an internationally liaison organization for medical radiation technology and by promoting quality patient care, education and research in the radiation medicine science. At present the board members we have is Miss Donna Newman from the USA as the president and three vice presidents, three regional directors, one treasurer, the director of education, the director of a professional practice and the director of the public relations. I am the vice president taking care of the Asia and Australasian region. Looking into our practice, we know that the radiography or radiological technology profession practice varies from one place to another and there are also different terminologies for what we do and who we are. So, to this end I just made a reference to Jill Yeilder from Australia who published in the journal of radiation science. According to this New Zealand colleague, it is unfortunate that the New Zealand internal technologists are still used along with the massive essence. Again, when we look into a global perspective even our practice may vary from one place to another but when it comes to the time of this COVID-19 pandemic, we all face the same situation. I know that our colleagues in China face it first and we have a lot to learn from you as we know that at first, we did not know much about this COVID-19 at all, and then we learned from experience from the Chinese colleagues. When the pandemic goes further beyond China to other countries then we have a lot of new things to learn also as the virus mutates. So, the things that we have as an issue around this COVID pandemic includes, limited access to practice standards for the profession. We may have the general guideline for radiation protection and infection control but not specific to this COVID-19 which is the very new pandemic disease. Also, in terms of infection control and patient care in special circumstances in many places we have problems with limited access to the personal protective equipment or PPE. This happens because when we first encountered this pandemic we did not have enough supplies because the demand was so high. One of the very important issues is the front-line status: who we are? We know that we are in a frontline, but how would we be recognized by other professional workers working along with us? The first thing that we did was set up the standard with the World Health Organization who contacted us as their colleague. Since we are an NGO, a nonprofit non-government organization that has an official relationship with the World Health Organization we were contacted by them

when the COVID-19 virus continued to evolve. They knew that the ISRRT members worldwide were trying to prepare and respond to this pandemic. So in this regard we are looking for a standard on how to deal with this kind of pandemic. Therefore, we collaborated with the World Health Organization in response to this. If you look into our collaboration with the World Health Organization, there were two documents published. Already you can check on our website, www.isrrt.org that includes COVID-19 resource update. The ISRRT members contribute to the development of COVID-19 educational resources. The first document we contributed to was on the WHO document on COVID-19 use of chest imaging, rapid advice guide. This multidisciplinary team consists of radiologists and us, the radiographers. We worked together and came up with this guideline and we also have published with the IAEA, the International Atomic Energy Agency. This document on COVID-19 pandemic technical guidance for the nuclear medicine department is a very important document which you can get access to online.

When we look at the COVID-19 guidelines what comes to us first was that how would we dress. We learnt a lot from our Chinese friend when we first encountered this disease. But the standards vary from one place to another and also from one profession to another. So what it means is the medical doctors, nurses and radiographers may have different needs depending on the procedures that you're involved with the COVID patient or a suspected COVID patient. Therefore, we published together with the World Health Organization, "the ISRRT COVID-19 guidelines" which was a kind of outline that you can check from our website. We have a control checklist for preparation of the patient during procedures and also post procedures. We have included step by step of this task and a clear instruction so that the radiographers and the technologists worldwide can adopt. Also, we have all the necessary details that anybody can check on our website.

On top of this collaboration with the World Health Organization and International Atomic Energy Agency among radiographers and radiological Technologist professions, we have international collaboration in terms of networking. We have members from more than 80 countries and territories. We implement a platform called Facebook live social media to promote collaboration and reach ISRT member societies together in the current best practice. This event, Facebook live, is just one of the platforms pretty similar to what you have here in China. We gathered using Facebook live every two weeks following a webinar as the talk show on the topic of interest. Finally, a real webinar was held as the educational webinar. So, during the first four to five episodes that we started a couple months ago, we first focused on issues around COVID-19 pandemic. We got a good response. One of the episodes that we did was to give responses to what members need. As I mentioned before, since we have more than eighty member societies from around the World, our members have different challenges and we do listen to them. For one episode we invited four representatives from four regions, including each from Europe, America, Asia and sometimes Africa also.

This episode was entitled to respond to what members needed and the role of radiography professional organization during COVID-19 pandemic. We got a lot of feedback and there were a couple of things in common among our member societies. The first issue is the standard of practice in dealing with COVID-19. Most of the member's need this either form their national organization or form the International organization, in case they don't have the national guidelines. The second issue is the access to surgical masks, N-95 masks and personal protective equipment (PPE). This is a very common problem across the world that we don't have enough access to these equipment to protect ourselves when we do have to contact the COVID-19 patient. One of the most important issues is the recognition of the profession as a front liner. Why is this important? Because when we are recognized as front liners, there should be a necessity showing other professions what we need to have in terms of protective equipment when we deal with the patient and our input on the processes that the patient comes for investigation or treatment. Finally, in some place you have surplus of the technologies already aggressive but in many places we have shortage of manpower. When we practice in this COVID-19 pandemic according to the guideline it is very clear that we have to separate the group of technologists or radiographers into two groups. Some countries call clean and dirty technologists, but we would

prefer to be called as contact and noncontact technologists. Contact technologists means the technologists that position the patient or perform the procedure with the patient. Noncontact technologists or non-contact radiographers are those who sit in the console and control the X-ray machine without contacting the patient at all. We got some responses from the ISRRT as I mentioned before. For the first issue the ISRRT response was the document on appropriate and safe use of medical imaging in radiation therapy with infection control measures considered, in addition to standard radiation protection procedures.

Well, we know that when we practice, radiation protection is the key for patient safety but with this pandemic there is another issue about infectious control. So ISRRT developed resources for members to use in COVID-19 pandemic which are available on our website. When we talk about how important we are in the clinical environment, of course it is your profession, you say that you are important but how can you prove that? We got a lot of feedback from around the world about this recognition of the profession as a front liner. As I always mention, practice varies from one place to another, but it is evident that the radiography profession is among the front liners in this pandemic. Why is that? The patients come in and it's just X-ray, or they also need chest CT sometimes. So, we deal with the patient directly and what we want to have is the international perspective to provide evidence based feedback to the authority in many countries where the profession still struggles to get proper recognition. This episode was the most hit one. The episode was clicked more than 10000 times and watched. Also 78000 people reached this Facebook link. We had four speakers and two panelists. At that time, we had Philippe Gerson from France. He is our treasurer. Pearchy Luna from the Philippines representing Asia and for America we had Reshma Maheepat. She is the president of the society of radiographers from Trinidad and Tobago. Fourth one we got a radiographer from South Africa to present. Finally, we had Stuart Whitley who is the ISRRT director of professional practice who is also the panelist. I was the host for this event. We got a lot of feedback from this episode and we had managed to have somewhat a solution from experience sharing from advanced countries so that the countries that still struggle can learn from them and can adopt the situation and deal with the government in terms of recognition of the profession as the front liners.

Again, the communication during this COVID pandemic is very important. We had a lot of communication with our member societies. We published a good example on our news we got from Nigeria, a country in Africa. It is about the role of Nigerian radiographers as frontline workers. And also, from the Philippines Pearchy Luna also presented a part about the Philippines association of radiological technologist initiative to support recognition of the frontline workers during COVID-19 pandemic in the Philippines. This is a good example for other countries.

In conclusion, what we have learnt so far is that the COVID-19 has been a huge challenge to humans. The COVID-19 is also a new kind of pandemic that the medical professionals like us have learn how to deal with it quickly but sometimes it was not quick enough. Like what we have seen so far in so many countries, we have to struggle on how to deal with it, how to perform our duties and how to save ourselves from this contagious disease. Radiographers and radiological technologists are one of the front liners medical professionals who provide imaging services to COVID-19 and suspected COVID-19 infected patients. During the almost past two years the profession had globally contributed not only to the professional services but also academic and community services. We have learnt how to deal with the pandemic together and we hope to overcome this huge challenge in human history together. Thank you very much.

Health Outcomes Concerning Vulnerable Groups - A European Perspective

Prof Martin Persson

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I am going to talk today about the Health Outcomes concerning vulnerable groups – a European perspective. Health outcomes for vulnerable groups is also very much a global perspective. And if we put it in relation to COVID-19 there are being some recent status that in this current pandemic there is evidence that those individuals occupying low socioeconomic procession and or lower education or more prone to developing severe COVID-19 or dying from it. So, this is not keeping the society when we work with different segments of populations, we are at various risk. So, the European Union currently consists of 27 countries with a collective population of 446 million inhabitants. And our economic situations in Europe various quite differently.

And this map is expressing the relation to the European Union average set to a hundred. So, in other words if the countries are above hundred, they do the capture and consequently if the country is below a hundred, they real do works. As you can see on this map there are numerous countries.

This leads us to help inhabitance. If you look here from Romania for example is very low compared to Luxemburg or even Sweden or Switzerland and obviously these has a big impact in the relationship how we can provide our health care. The different resources that can have impacts on the provisional health care and can be important to determine the health and social outcomes. And then will start looking at determining health outcomes.

Not only the amount available to spend on health care that is influential in determining health outcomes, unequal distribution of wealth and one example is child mortality. Then will look at child mortality, In 2013, child mortality was 4.9 births per 1000 in the UK, which was about 25% higher than France, Germany, Italy and Spain and almost twice as high when compared to Sweden and one aspect of why the difference between child mortality rates between the United Kingdom (UK) and Sweden is due to the unequal distribution of wealth in the UK's society and this then leads us to inequalities and what are inequalities. Inequalities are variants which talks about different groups in our society.

And then will look at Social marginalised groups. Who are socially marginalised group in our society? For example (but not limited to), individuals who are unemployed, have a disability, experience mental health problems for example, low educational attainment, migrants or refugees. They are in a risk to be socially marginalized and being a member of socially marginalised group also increase the risk of health inequality, poverty and social exclusion. In 2017, 22.4% of the European population (112.8 million people) lived in households at risk of poverty or social exclusion. This has a big difference between the countries as you can see in this picture in Bulgaria 32.5% are at risk for poverty or social exclusion while Czechia is 12.5%. So, when we start looking at the health care we can obtain from different countries and also looking at the risk of poverty and social exclusion and students understanding a big difference. So, in Europe depend on where you were born also depends which kind of health care is in risk for poverty and social exclusion.

Looking at the indicators for poverty or social exclusion something we teach to health care professionals in Europe and also in the other parts of the world of course. We are going to specifically look at sex and age group, hours hold types, educational attainment and where you are from and reside matters.

So, if we start on sex and age group we are going to looking at people at risk of poverty or social exclusion, by sex and age group. We can see in total as we know now that women in Europe have a higher risk as to belong it to a group and if you are younger and even higher than the average and that goes on until 24 years of age. Then between 25-49 years it lowers up until you get older it starts again and so on. We have various age groups when taking into consideration and when we look at

children we see again. When you look at the different countries in Europe 35.8% children in Romania are at risk of poverty and social exclusion compared to almost 12% in Slovenia. For example, EU is 22.5% and United Kingdom is quite high as well almost 30%. So, these are the factors when we work globally or internationally but also locally you need to pay attention to. And then we start looking at household types for example. And we see depending on where you are living, and kind of household and we see single person with dependent children are at a higher risk to be in poverty or social exclusion. One adult younger than 65 years and over and see a big difference and as health care professionals we need to be aware of these factors. Because always considering men in household are young and unemployed people. In many cases, in this group had higher and average risk of poverty and social exclusion. A good thing is when we look at this the orange line is 2010 and blue line is 2017.

Education, when we look at education. When we look at the difference levels from less than primary, upper secondary or university tertiary and also risk for poverty and social exclusion. Are those that are in the highest degree to obtain less than primary, lower and secondary education and this has increased from 2010 to 2017 as long as upper secondary zone. Those in higher education as we know is at higher risk. To education level is a very important factor to consider and it also belongs to where our parents are. So, parents either have primary, lower, secondary education increase in risk for the child for poverty and social exclusion by almost 63% of primary, lower or secondary are at risk of poverty and social exclusion in contrast to parents with university education is only 9.5%.

It is also important where you are from and reside also has an impact. If we look at this data. If you were born in non-EU country and live in a country and work for example Sweden, if I am born in Sweden and working in Europe, I have a risk of 20.7% for being in poverty and social exclusion. If I am from another European country, If I am in Sweden and start working in Bulgaria my risk would go up to 22.7%. However, if I come from for example from Africa continent you go up to 38.3%. So, this becomes a big difference and when we look at across Europe you can see the EU average where reporting where person born and works and other EU countries close and if you come outside the European Union there is a much higher risk for being in poverty and social exclusion. And this is pretty much even across Serbia for example is almost the same or Bulgaria, if you're from another country outside of Europe is much higher risk. So again, as a health care professional you need to be aware of where your clients are from and how this interferes or affect.

So then impact on health, so for health care professionals it is essential to be aware of the indicators of poverty and social exclusion and who is at risk at in order to provide an adequate provisional care. It is so equal and important that health care professionals thoroughly understand that being at risk of poverty and social exclusion. For example, as we talked earlier, COVID, in European Union, those individuals with lower levels of education have lower life expectancy and are more likely to be in worse health than better-educated individuals. And this influence life expectancy and inequalities. Difference between life expectancy between individuals living in the most deprived areas versus the richest areas in England for example is women 7.1 years and for men 9.2 years but the important aspect is the differences have increased over the years and that is not just in England but also in Europe or most westernized countries such as US, Australia and most likely in Asia. So, then we look at the self-perceived health in the EU aged 16 and above. The share of people that describe their health as good or very good increases with the level of education and income. So, 20% of the richest population 3.9% bad or very bad. Health versus 20% of the poorest population is over 14%. So, this clearly shows that socio-economic statuses influence in EU and how we feel our subjective health. And again, when we look on the date across the board from the different countries blue is the highest income and grey is the lowest income. Percentage of the population aged 16 years and over reporting good or very good health. This is across all countries that reports lower socio-economic status report verse health.

And this has an impact because people with lower levels of education are at higher risk of suffering from certain illnesses than those at high level of education. Lower-level education increases the risk for depression 3.12 times higher, diabetes and obesity. So, this is an important fact for us to

consider. And access to care, In the EU, on average, individuals in the low-incomes group report four times (6.4%) more unmet medical needs for financial, geographic or waiting time versus the individuals in high-income groups (1.5%). There are though considerable differences across Europe, for instance in Latvia (25%) and Greece (17%) of the lowest income group states unmet needs. So again, the average in EU was a lower socio-economic group of four times more on medical needs but it depends on the countries.

Looking at the economic policy, the country, the PPS, then how much each country provides on health expenditure. Social determinants of health: the level of education, type of occupation and income. And these factors together generate a social gradient in health for us.

So, what are then the barriers to access health care for socially disadvantaged groups.

This is going to improve our health care provision. You need to know the barriers. These barriers are for example language and commination with health professionals, health professionals lack of experience in dealing with differences, structural inequalities, organizational barriers, culture and faith, mental health and fear and social stigma. So, all of these things we need to address in our health care settings and not just in Europe, this is a global phenomenon unfortunately.

So, then the question is how we evaluate access to care and how going to take wisdom we have from the projects and if we look at this diagram you need to have an available health care structure and that needs to be inclusive and the training in system work in the health care structure and what we need is these aspects. This is what the patients need. The patient's capacity is very important to understand is the ability to proceed with health literacy, health beliefs, how do we trust the profession what is the personal social values. How do we get to the hospital for example and so on. What is the income, how is the health system, is it private do you need to pay? Is it doll free and so on. And you cannot generate one model for everyone in this. You need to generate how does this work for high income patient and for low income, middle income and if they are from another country. And this is the only way we can address the health inequalities we have in our society. Need to generate a health system which is accommodating it needs to be inclusive everyone not just for a few. So in conclusion if you learn a good education in your living country your access to health inequalities but if you are from a lower socio-economic group or have even more burden from another country, unemployed or access to health is much more burdensome. That means more lot of people will fail like cannot understand being from any shellness or what to do. For example, when it pandemic, this is clear and that's why also some of the studies that shows higher mortality and lower socio-economic groups during this pandemic is because people don't have access to health care same way, they don't understand information provided and so forth. And we as health care professionals we have failed in a way. And we have to change this both on the bottom level and top level.

Anterior Cruciate Ligament (ACL) Rehabilitation and Outcomes

Asso Prof Gisela Sole

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Good Afternoon!

Thank you so much for inviting me to present at this conference and I'm delighted to be able to share some results of research we've done at University of Otago that is related to ACL rupture. I'm quoting the presentation 'Preparing a person with ACL rupture for 'Chaos and Confusion with Confidence'. I'm from Dunedin on the South Island of New Zealand which has a beautiful peninsula and we have a University, it is very much a University town with about 20,000 students making up a substantial part of the population of about 110,000 and 120,000. This is our main administration building which is quite a landmark in the campus.

My background in ACL rehabilitation started as a connection in Physiotherapy in the mid-1980s working in a hospital where we had many ACL surgeries and rehabilitation after the surgery. That stage was very conservative; we were not allowed to use active knee extension first six weeks' post-operative because there was a concern about the quality of the grafts that we were using at the time. We had the patients in braces for six weeks and due to the lack of active movements allowed at the time they had sever quadriceps weakness and stiffness post-operatively. In the 1990s, it started getting more accelerated rehabilitation based on experience that were coming from the USA and we were able to get some athletes back to basketball within six months. But we then found out about the high risk of re-injury, if people went back to the sports too soon. And then in the mid-2010s the shift was more moderate and more of a patient centered approach that we used, with more patience and individual specific milestones to guide the treatment. We now know that we should discourage early sports participation, for every month that we wait after nine months' post-injury. So if we add more and more months that will reduce the risk of re-injury.

So what I want to do here in this focus is to highlight the multi-dimensional influences and multi-dimensional approaches for rehabilitation of a person with an ACL rupture. I also want to talk about the importance of long term rehabilitation particular for maintenance of quadriceps strength and unpredictability associated with sports and also skills training.

So just a bit of context in New Zealand, approximately 80% of all people with an ACL rupture undergo a reconstruction and in fact one of the highest instances per 100,000 person years for ACL reconstruction. In the whole world we've got 58.2 people per 100,000 people compared to about 60 in the United States and Scandinavian slightly lower than the New Zealand. About 71% of those patients undergone reconstruction get a hamstring graft and about 24% get a patellar graft. These are just data from the New Zealand ACL registry, 2020. We have a national health insurance for accidents called the accident compensation co-operation or ACC. And the ACC covers medical care and surgery paid for all patients with ACL rupture. But patients usually have to pay a surcharge per Physiotherapy treatment. Now we found in the South Island study here, that many patients in New Zealand did not get enough Physiotherapy following ACL reconstruction and the thought was may be because they had to pay a surcharge for Physiotherapy. Over the last few years ACC has provided a mutual pathway that allows care to allow early surgery and also to encourage patients to take physiotherapy. So those patients need not pay a surcharge for Physiotherapy anymore. But it does depend on where in New Zealand the patient resides.

The problem with ACL rupture is that we offer reconstruction to improve quality of life and also to allow people to get back to the sports. Based on the systematic reviews done, around 55% of competitive athletes return to their pre injury level sports. And at the longer term there is a high incidence of knee osteoarthritis within 10-15 years post injury. So a soccer player who injures their knee in the age of 16, by the age of 30 they are most likely to have some symptoms of osteoarthritis, but on the other hand it does not

happen to every person with an ACL reconstruction. So we also need to be very realistic and not feed them the fear of long term knee disability. We need to empower them with powerful, positive wording. So based on those statistics we do need to consider strategies to improve them to work as well as return them to sports particular in terms of their physical work and also to minimize future disability. And to do this we need to consider their social aspect, their psychological state and also physical outcomes.

Our research at Otago started with a qualitative study done by an honors student Sarah Scott, a study of people with anterior cruciate ligament reconstruction 3 years prior to taking part in the study. Themes that she developed from her data was firstly the 'The journey' it's an arduous journey of recovery and it does represent and enormous injury; it is a very serious injury. The changes lie for some patients. And some of these participants described how the injury actually changed who they were as sportsperson or who they were in their workplace. It's never just an ACL rupture, it is a serious injury and the outcomes have to be worked for so hard and it will be by the patient and the team that surrounds him. For them the support system is really important to get them to the rehabilitation. And they mentioned their sports team, their family, their work place who either discouraged them or their barriers towards their rehabilitation or their support system or encouraged them on them along the way. Relationships with their clinicians was really important and they find their physiotherapists, orthopedic surgeons were either empowering them, encouraging and motivating them but could also be a little bit destructive to their rehabilitation by not providing information that the patient thought they needed, and not including them in decision making. So the relationship that we as clinicians have with our patients having ACL ruptures is critical for the success of their rehabilitation. It is not only about surgery; it is also about rehabilitation as well as our professional relationship with our patients.

In terms of longer than two years, this is Dr. Mandeep Kaur an honors student in our school and graduated few years ago, and she did a qualitative study with patients with ACL ruptures more than 2 years earlier. And she focused particularly on the fear of re-injury, that we know from other researches that it is an enormous problem. And from the data of her interview she found these main themes; the fear of re-injury and the other one the behavioral manifestations. And the reasons she asked why were you so fearful of the knee and what makes you feel fearful or anxious or makes you feel you have no confidence in your knee and the first sub theme that came was that they were very afraid of the pain that they had experienced. Having an ACL rupture is enormously painful experience and then they undergo that pain again with surgery so they even don't want to go through their pain again and avoid it if at all possible. But they are also fearful of the memory of the movements, they knew exactly what they were doing at the time they got the ACL rupture. Some of them were jumping and on landing they ruptured their ACL and they could not get that out of their mind and they tried to avoid that movement in most circumstances. They were also anxious and fearful of the rehabilitation which had taken them ages to get back the muscle strength and they did not want to lose their muscle strength again. And some of them had changed family responsibilities over those years post surgery. For example, some had children that they had to drive to school or pick up from school or they are heading another job. So they wouldn't have the chance to undergo another and recover with rehabilitation again. So all these factors were contributors to why they were being fearful. Because of the fear they were very concerned about playground conditions especially in the winter; was the playground icy or frosty in the evening or early mornings when they run. So they were more aware of the conditions of the ground that they were playing and being fearful of risks. They had low confidence on the sports and were hesitant particularly towards the movement that actually led them towards the injury. Some of them were using bracing to just bum up their confidence. So we know that the fear of re-injury and the anxiety of re-injury is an enormous point in these patients. And we can't say its just your thoughts, just your feelings because one can actually measure these changes.

For example, the frontal MRI of these individuals. I'll show you one of those studies. So this study was done by Kapreli in 2009, looked at people with ACL deficient knees with 17 males. While the patient was on MRI they were asked to do active knee

flexion and extension and those with ACL deficiency were compared with those that were healthy. For example, this is the sensory motor cortex. The blue column is the control and the red column is the injured. When comparing patients with ACL injury and controls, the controls had high levels of brain activity while the person was performing flexion and extension. May be that is because of the reduced proprioception in part coming from the injured knee. Therefore, has less activity in the sensorimotor region. In the same study they found that the visual cortex region the ACL injured person had higher activity in the brain compared to the controls. Perhaps these people compensate for the loss of proprioception of their knee by using more of the vision. So I wanted to show that these are the changes of the brain activity in a patient with an ACL injury. So it is not just an emotion.

In our quantitative studies at University of Otago we got people with ACL deficient, and people with ACL reconstruction and we compared them to controls and before Mandeep undertook a systematic review published in the journal called Sports Medicine and what this study showed was people with ACL reconstruction had less knee flexion angles and they used less flexion in walking up and down stairs, and running. When we had the people in our lab we also measured muscle strength on the dynamometer and we found decreased strength of the quadriceps and knee flexion muscles, possibly in both sides because the person after ACL reconstruction often do less physical activity the other side also gets weaker. But it should be compared to normative data. Some of them gain weight and becomes a vicious cycle that is at risk of developing osteoarthritis. And that is the group I think we need to find and that we need to identify in our clinical practice. And institute a program that maintain their physical capability. Now why is muscle strength important? What we did was we investigated the relationship between the muscle strength and weakness and compared a relationship between knee flexion moments. We found a very positive relationship so that people with weaker quadriceps were likely to have low knee flexion moments. Stronger quadriceps on the other hand it was a less of an asymmetry when they were walking. Up to 56% of the variance in knee flexion moment was explained by the knee flexion strength. And it was more for the women than for the men. Because women often have greater deficient after ACL deficit than men do. So its highlighted the importance of strength training for women following ACL rehabilitation, due to the relationship between knee moments and muscle strength.

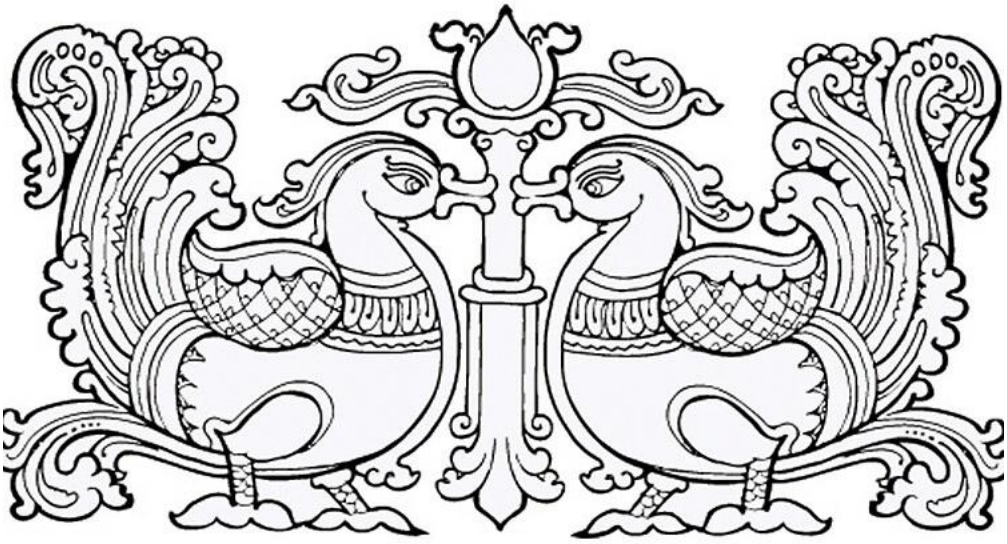
Looking into the data that has not been published yet but we are hoping to do so, looking to see if there is any correlation between muscle strength of the thigh and fear free injury in these people. And fear free injury is a scale of 80 indicates high level of fear or anxiety whereas lower scale indicates more confidence and less fear. This was also a significant relationship in that people who had high muscle strength had lower scales on the fear free injury scale. Basically meaning people with stronger muscles had greater confidence in the knee. People with fear or concern with re-injury can deal with them or we can suggest to them that they need to strengthen their quadriceps. They need to maintain their quadriceps strength in the long term. Our analysis was supported by a new study, published in Sports Health, 2021 will basically see the same. Relationship between the confidence to return to play after ACL Reconstruction with quadriceps strength. So strengthening the quadriceps is absolutely critical and long term following ACL reconstructions.

Caran Mahood was another honors student who listened to people who had ACL reconstruction, who had been really successful and we wanted to know what the most positive interventions were. And that study had 3 themes. We defined the drivers why they want to return to sport, they had to prepare not only the body but also their mind. And at the end of the day they had to exceed the risk. They had a very strong attitude, they definitely wanted to get back to their sport, they were confident. In terms of preparation of body and mind they had strong connections with their medical team and positive relationships with the Physiotherapists. They clearly described their physical rehabilitation as increasing muscle strength and very specific sports specific skills and some of them also used mental and cognitive skills that they may have learnt from psychologists or physiotherapists. So rehabilitation is not only about the physical aspect, it is also about the cognitive and the mental skills they need to get. In

terms of risk acceptance, a group of persons had identified what movement they had to avoid and what movements that they can use with confidence. And they described how they had to analyses the risk. We can use graded learning and skills based exercise to train them. Some of them were not fearful and they did not have fear of re injury. They just had the attitude when it happens it happens. They could just get lost in the moment and the team sports they were in. One of the subthemes chaos and confusion, we have to prepare our patient to the unpredictability of sports that give the confidence on the field without having to worry about the knee and immerse themselves into their sport without being fearful.

What does that mean for rehabilitation wise before we need to strength the quadriceps muscles. That is the main take home message. And it's not only for the rehab periods for last because somewhat central nerves system who's trying to protect the knee and therefore unlock the knee to certain extend. So getting back to your patient they need strengthening quadriceps muscle for life not in a day, not in a week, but every year a few hours a few weeks, a few months, focus on getting those muscles that muscle strength getting stress the work place and also for sports, and just for good quality of life. We need to prepare them for unpredictable scenes as exercise that happen unpredictable elements. For an example this exercise here with a stick sort of position in different directions for lunging forward with this small weight, started very slow and control to larger weight and also to progress faster and great percussions. We have to consider the mental and cognitive skills, help them to planning, help them with preparing for training to get back to training. Be aware on the on the field was same when they are giving back to training and Drayri introduced sports specific skills as soon as possible. Sports specific skills will not replace muscle strength but they need both. So basically we have to listen to the patient, listen to the beliefs, the anxiety and great deal with it likely go to an interviewing like self-motivational interviewing and some people those that can't get back to their hopes if they still consider the risk of their higher knee injury may need counselling in terms of alternative sports that they may also enjoy. If they get used to the idea that may be okay to change the sport. So it's not for every patient, every person with the ACL rupture, but we specially need them to guide to get through that. Rehabilitation is never completed after an ACL rupture, so people who do not work in any sports probably he boosts the session once in a while if it's you few months, if it's you few years. And they need to take responsibility for it. We may need to use behavioral change intervening system to take responsibility for managing their behavior change and for them to think about the what they eat and also whether they have enough general physical activity. So an ACL injury is more than just a knee injury. It also intervenes the brain, proprioception and all the other input mechanisms that come from the knee. So we could say there are changes in the brain as well but we need to tell our patients that if they have a serious injury in the knee even after ACL reconstruction that might change how they work at the shoulder and that in turn may change the performance and the accuracy of the throw if it's a throwing athlete. So an ACL injury has influence on the whole body, the whole person and on the mind and feelings as well. We need to consider and be very supportive also at some levels, be at the workplace or family; you are there to support the person. Coaches, Managers and team members can help the person as well because the team dynamics will also change and we need a very supportive help from the team regardless of what is available for the person. We need to be there and listen to the person what they can do in their context in their life to maintain that knee health over long term.

So in summary we need to think about the biological domain, the physical ability of muscle strength but we also have to consider the psychological and social domain, what commitments they have for their home, their family in spite of the knee injury and also their mental well-being and health. So that is all from me now.



TECHNICAL SESSIONS

The Relationship between Early Physiotherapy Intervention and Shoulder Joint Mobility among Breast Cancer Survivors in Sri Lanka

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Abstract - Breast cancer is the most common cancer among women worldwide, including Sri Lanka. Modified Radical Mastectomy (MRM) is the standard surgical management when the breast conservation is not considered as an option. However, common post-surgical complications of MRM include impairment of shoulder joint mobility and lymphedema which could be managed well with early physiotherapy intervention. This study was aimed to identify the relationship between shoulder joint mobility and early physiotherapy intervention among breast cancer survivors at Apeksha hospital, Maharagama, 74 female breast cancer patients referred to the Department of Physiotherapy for the first time were recruited for this study. Patients with history of shoulder joint injuries or other pathologies were excluded from the study. An interviewer-administered questionnaire was used to collect information of socio-demographic data and underwent surgical procedures. Shoulder joint Active Range of Motions (AROM) (flexion, extension, abduction, Internal Rotation (IR) and External Rotation (ER)) of the affected side was measured by universal goniometer following standard procedure. Delayed period to commence physiotherapy of the sample ranged from < 1 year to 17 years. According to the findings, the mean values of AROM of flexion, extension, abduction, IR, and ER were 1570±140, 510±50, 1370±220, 700±120, 750±80, respectively. A significant negative relationship showed between delayed physiotherapy intervention and shoulder joint AROM of flexion (p=0.05, r=-0.82), extension (p=0.05, r=-0.54), abduction (p=0.05, r=-0.75), IR (p=0.05, r=-0.76) and ER (p=0.05, r=-0.74). Therefore, shoulder mobility limitation increases with time of delayed physiotherapy intervention. Hence, it is advisable for patients to participate in early physiotherapy interventions to reduce the level of shoulder immobility.

Keywords— Breast cancer, Shoulder mobility, Physiotherapy

I. INTRODUCTION

Breast cancer is a malignant tumor that develops from the cells in the breast and usually originates in the cells of the lobules or the ducts of the breast. With the time cancer cells have a potential to grow into nearby healthy breast tissue and make their way into the underarm lymph nodes, enabling the cancer cells to spread in the other distant parts of the body; metastasis (Cheifetz, 2010).

The Global cancer observatory estimated that there are nearly2.3 million new cases representing breast cancer as the commonest type of cancer in worldwide in 2020. According to the Fernando *et al*. (2018) data from National Cancer Registry revealed a gradual, significant increase in the incidence of female breast cancer in Sri Lanka which also recorded that the cases was hundred times higher in women compared to men (Siegel *et al*.,2019).

In general, there are many treatments options carry out to manage breast cancer such as local treatments and systemic treatments. (Nounou *et al.* 2015). Among local treatments, surgical management option Modified Radical Mastectomy (MRM) preferred as one of the standard surgical managementfor most of the stages in breast cancer that has been used for years since 1948, due to its better survival effect (Najeeb *et al.,* 2019). This surgery removes the entire breast tissue including skin, areola, nipple and most of the axillary lymphe nodes. Following MRM with axillary clearance, breast cancer survivors have to struggle with post-

surgical complications that directly affect their quality of life (Merchant and Chen 2015). Shoulder joint mobility impairments are lying as the front liner complications post-surgically.

Shoulder joint is the most movable joint in the body and main joint that can be affected its functions by MRM due to its proximity to the chest. Since the human could stand up with the erect position, functions of upper limb provide maximal advantages to the day today life activities. With relevant to the shoulder mobility implications, upper limb movements potentially affect and lead to experience difficulties to perform movements and engage in activities using upper limb to maintain a comfortable quality of life.

Relative to shoulder mobility, Active Range of Motion (AROM) measures the available amount of movement of a joint which briefly shows the ability to move. Basic movements of the shoulder joint are flexion, extension, abduction, adduction, Internal Rotation (IR) and External Rotation (ER). Losing the ability to use the shoulder joint movements appropriately results in considerable difficulty in daily activities (Sugden*et al.*, 2013).

Early physiotherapy interventions help to prevent and reduce complications such as, limitations in shoulder movements among patients after breast cancer surgery (Reyes, 2018). Breast cancer survivors refer to the physiotherapy department within a short period post surgically or after ages and there is a clear variation for period from surgery to commence physiotherapy.

The purpose of this study was to identify whether is there any relationship between shoulder joint mobility and delaying physiotherapy among the breast cancer survivors who had undergone MRM with axillary clearance in Sri Lanka.

II. METHODOLOGY

This study is a a cross sectional study. 74 female newly referred breast cancer survivors following MRM with axillary clearanceto the department of physiotherapy, Apeksha hospital, Maharagama, Sri Lanka during the study period of July 2020 - February 2021 were recruited forthis study.

Patients with history of shoulder joint injuries or other pathologies before conducted the MRM were excluded from the study. A pretested Interviewer-administered questionnaire which was evaluated in a pilot study was used to collect the information of socio-demographic data.

The timeperiodfrom the surgery performed date to the very first date of attending to the department of physiotherapy was calculated as the delayed period to commence physiotherapy for each participant.

AROM of the shoulder movements of shoulder flexion, extension, abduction, internal rotation and external rotationwere measured to assess shoulder mobility. Each movement was measured three times according to the standard procedure by Clarkson (2000) and Reese and Bandy (2009) using a universal goniometer and average values were calculated to get the exact AROM of each type of movement.

Shoulder flexion AROM was measured in comfortably seated position of the participant, palm facing medially while investigator stabilized the scapula and goniometer axis was placed at the lateral aspect of center of humeral head about 2.5cm inferior to the lateral aspect of acromion process along with stationary arm placed parallel to the lateral midline of trunk and moveable arm was placed parallel to the longitudinal axis of humerus, and participant was asked to move the arm in an anterior and upward direction in the available full range.

Same procedure as in shoulder flexion AROM measurement was followed to measure shoulder extension AROM along with participant was asked to move the arm in posterior direction in the available full range and for shoulder abduction participant was asked to move limb laterally and upward in the available full range.

In order to measure shoulder IR AROM participant was asked to lie on bed in facing upward; in supine position with shoulder abducted to 90^0, elbow flexed to 90^0 and forearm in mid position while goniometer axis was placed on the olecranon process of ulna and stationary arm was placed perpendicular to floor along with movable arm was placed parallel to the longitudinal axis of ulna, pointing toward ulnar styloid process and participant was asked to move palmar side of hand towards the floor to the available full range.

Shoulder ER AROM was measured when participant was positioned same as for the shoulder IR measurement and was asked to move dorsum of hand towards the floor to the limit of motion.

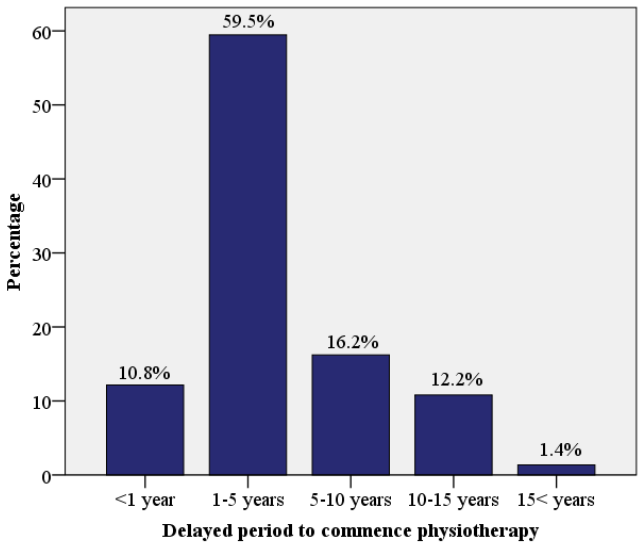
Figure 1. Measuring AROM of the shoulder joint abduction

The investigators wore the personal protective equipment kits, face masks, face shields, gloves during the whole procedure and equipment and beds were disinfected by participant to participant following the safety precautions. The Statistical Package for Social Sciences version 23 was used in data analysis purposes. Shapiro-Wilk test was used to assess the normality with the assumption made under the Sig. value > 0.05. Pearson correlation coefficient test was used to investigate the relationship between the shoulder joint mobility and delayed period to commence physiotherapy.

III. RESULTS AND DISCUSSION

Age of total study sample ranged from 35-70 years and mean age was 54±8. Delayed period to commence physiotherapy after surgery varied from less than 1 year to 17 years. Distribution of delayed period to commence physiotherapy among the participants shown in the Figure 2 and Table 1.

Figure 2. Distribution of delayed period to commence physiotherapy



	Frequency	Percentage
<1 year	9	12.2
1 – 5 years	44	59.5
5 – 10 years	12	16.2
10 – 15 years	8	10.8
15 < years	1	1.4
Total	74	100.0

Table 1. Distribution of delayed period to commence physiotherapy

Majority of the breast cancer survivorsreferred to the department of physiotherapy for their treatments within the 1-5years of time post surgically. Similar findings were recorded by Bernas*et al.,* (2018). The longest delayed time period to commence physiotherapy was 17 years in this study while a similar study of case reports review in America by Brennan and Weitz, (1992) recorded a new referral even after 30 years following MRM.

AROM of shoulder flexion ranged from 123^0 to 178^0 with the mean value of 157^0±14^0, extension ranged from 42^0 to 60^0 with the mean value of 51^0±5^0, abduction ranged from 89^0 to 175^0 with the mean value of 137^0± 22^0, IR ranged from 41^0 to 90^0 with the mean value of 70^0±12^0 and ER ranged from 56^0 to 88^0 with the mean value of 75^0±8^0.

Hence the data was normal, in order to identify the relationship between two variables, parametric test Pearson correlation coefficient was used to investigate the relationship between the shoulder joint mobility and delayed period to commence physiotherapy. According to the statistical analysis a significant negative relationship was observed between delayed period to commence physiotherapy from surgery and AROM of the shoulder joint movements among the study population (see Table 2). The level of significant relationships were 0.7< with the movements; flexion, abduction, ecternal rotation, internal rotation whereas moderate relationship was found with extension.

	Period from surgery	
	Pearson Correlation	Sig. (2-tailed)
Period from surgery	1	0.00*
Flexion AROM	-0.82*	0.00*
Extension AROM	-0.54*	0.00*
Abduction AROM	-0.75*	0.00*
ER AROM	-0.76*	0.00*
IR AROM	-0.74*	0.00*

*correlation level significant at the 0.05 level

Table 2. Relationship between period from surgery to commence physiotherapy and AROM of shoulder joint movements

Similar results were reported by some others studied conducted by Oliveira *et al.*,(2009) and Mohammed (2016).

IV. CONCLUSION

In conclusion a significant negative relationship identified between the delayed period from surgery to commence physiotherapy with shoulder mobility in shoulder flexion, extension, abduction, internal rotation and external rotation. Accordingly, shoulder mobility limitations increase with time when there is a delay in commencing physiotherapy. These consequences are not being diagnosed or treated as often as they require. Hence, the patients are advisable to participate in early physiotherapy interventions to reduce the level of shoulder immobility.

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Relationship between Craniovertebral Angle with the Long-Term Usage of Electronic Devices among Undergraduates of General Sir John Kotelawala Defence University

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Abstract - Long term usage of electronic devices among undergraduates have become a growing problem all around the world. Prolong usage of these devices can result in malalignment of the normal posture. Forward head posture (FHP) is known as the commonest postural abnormality resulted due to long term usage of smartphones and laptops. The purpose of this study was to determine the relationship between craniovertebral angle with duration of smartphone and laptop usage among undergraduates, Faculty of Allied Health Sciences, General Sir John Kotelawala Defence University. This is a descriptive cross sectional study. 228 undergraduates, within 19- 24 years of age, using smartphones and laptops for more than 1 year were recruited by the consecutive sampling method. Those who had previous cervical injuries/congenital deformities and who didn't grant informed consent were excluded. Self-administered questionnaire was given to collect information. Craniovertebral Angle was measured by lateral view photographs using KINOVEA app. According to the results the mean values of age, BMI and CVA were (21.83±1.57 years), (22.86±4.39kg/m-^{2}), (46.53±5.49degrees). Pearson correlation coefficient was used to quantify the linear relationship of CVA with duration of smartphone, laptop usage and BMI. A statistically significant negative correlation was obtained between CVA and duration of smartphone usage (p = 0.033, r = -0.35), duration of laptop usage (p = 0.003, r = -0.047) and BMI (p > 0.01, r = -0.55). Findings of the study concluded that long term usage of electronic devices could result in reducing the craniovertebral angle. Furthermore, BMI has a statistically significant negative relationship with CVA.

Keywords— Craniovertebral angle, Smartphone usage, Laptop usage

I. INTRODUCTION

Nowadays prolong usage of smartphones and laptops are prevalent among young adults and students, especially including university undergraduates who spend a large amount of time on mobile devices for social leisure or academic purposes. The negative consequences that might be caused by long-term usage of these electronic devices can be highlighted in terms of both the psychological and musculoskeletal systems. In relevant to musculoskeletal system the cervical region, elbow, and wrist joints are mainly affected due to prolong duration in unsupported positions (Yalcinkaya, Sengul Salik and Buker, 2020). Forward Head Posture (FHP) is the commonest postural abnormality related to musculoskeletal system. Craniovertebral Angle is commonly used in anlaysing FHP (Lee, Chung, and Park, 2015). Craniovertebral angle (CVA) is interpreted as the angle formed between the horizontal line passing through the C7 spinous process and the tragus of the ear (Kim, Kim and Son, 2018). Photogrammetry is an extensively used non-invasive technique for postural evaluation (Furlanetto, Sedrez, Candotti and Loss, 2016). With regard to the high reliability and validity of the photogrammetry method, this has been used as the easiest and the simplest way of measuring Craniovertebral Angle for postural evaluation (Furlanetto, Sedrez, Candotti and Loss, 2016). Body Mass Index (BMI) is known as one of the most vital factors which could influence the changes of CVA. Kinovea software has been used in measuring the CVA, which is a valid, precise, and reliable (both inter- and intra-rater) tool in obtaining angles and distance data (Hazar,

Karabicak and Tiftikci 2015). The main objective of this study was to determine the relationship between craniovertebral angle and the duration of smartphone and laptop usage among university undergraduates of Faculty of Allied Health Sciences, Kotelawala Defence University. Specific objectives of the study was to evaluate the relationship between craniovertebral angle with the smartphone usage time duration per day among undergraduates, to evaluate the relationship between craniovertebral angle and laptop usage time duration per day among undergraduates, to determine the difference of craniovertebral angle between males and females, to determine the difference between duration of smartphone/laptop usage among males and females, to evaluate the relationship between craniovertebral angle with BMI and to investigate the compiling factors which influence the smartphone/laptop addiction among undergraduates.

II. METHODOLOGY

A descriptive cross-sectional study was conducted under the consecutive sampling method. In total 228 university undergraduates (158 Female, 70 Males) who fulfilled the inclusion criteria within the age group of 19-24 years were included in the study. Participants who had previous history of cervical spine deformities, injuries to the cervical spine and surgeries were excluded from the study while undergraduates who have been using smartphones and laptops for more than 1 year, aged between 19 to 24 years and who granted written informed consent were included. Ethical clearance was attained from the Ethical Review Committee of General Sir John Kotelawala Defence University. An information sheet containing all the details of the study was distributed among the undergraduates and their consent was obtained via a written consent form prior to the study participation. Demographic characteristics including age, gender, duration of smartphone and laptop usage and most preferred posture of the participants were obtained using a self-administrated questionnaire. The BMI was calculated by measuring the height and the weight of the respondents and craniovertebral angle was measured by a lateral view photograph using the KINOVEA app. Three stations were allocated for data collection with a responsible investigator for each station. Prior to data collection, a pretesting was conducted with 15 randomly selected university undergraduates in order to train the main procedures of three stations. After that data collection was initiated.

Procedure

The Station 1 was responsible for taking the written consent and for screening purpose. A reference number was assigned and the height and the weight of the participants were measured. After reading the information sheet and listening to the study procedure explained by the investigators, participants gave their consent for the participation or denied the participation. Then the self-administrated questionnaires were filled by the participants who gave their consent.

Height measurement

The height of the participants was measured using the stadiometer. They were instructed to remove their footwear and stand in erect position. Then the moveable head part of the stadiometer was kept on the upper most part of the head to take the measurements. Three measurements were taken for each participant and the mean value of those three measurements were taken as the final height of the particular participant.

Weight measurement

With bare foot, participants were asked to step on to the weight scale and instructed to stand straight and to keep both feet on the center of the scale to confirm that the body weight was evenly distributed between both legs. They were asked to keep their hands on either side of thebody. Three measurements were taken and the mean value of those three were taken as the final value of that participant's weight. BMI was then calculated.

Marking the bony landmarks for the required measures were taken at the Station 2. Palpation of the 7th cervical vertebrae, marking the vertebrae and right Tragus using adhesive markers were performed. In this station, participant's spinous process of the 7th cervical vertebrae and the tragus were marked using adhesive markers. The angle between the above-mentioned points were marked in the photo and was taken as the craniovertebral angle.

Palpation and confirmation of the spinous process of the7th cervical vertebrae

The participants were instructed to expose their neck and cervical area to mark the spinous process of the 7th cervical vertebrae. The palpation was done using the flexion-extension method (Povoa, Ferreira & Zanier, 2018; Shin, Yoon & Poon, 2011). The examiner was at the side of the participant and

passively flexed the subject's neck. Then the pulp of the middle finger of the examiner's dominant hand was on the prominent desired vertebrae. Following that subject's neck was passively returned to the neutral position. According to the assumptions, C6 spinous process of the cervical spine is the lower last vertebrae to move freely during the test. The below vertebrae which acts as stationary should be C7.

Palpation of the tragus:

The tragus is a small pointed eminence of the external ear, positioned in front of the concha, and projecting backward over the meatus. The right-side tragus was marked using adhesive markers. The three points were marked using adhesive double-sided tapes of 0.5mm x 0.5 mm and plastic pearls to make the marks visible on the photographs.

Station 3 was responsible for the measurements of the craniovertebral angle and capturing the participant's photographs. In this section, the investigator was responsible in positioning the participant in front of the calibration board and capture the photograph. Calibration board allowed referencing of horizontal and vertical axes of the photographs. A mark was set on a particular place on the floor and participants were instructed to stand on that mark in order to maintain the standardized method of the procedure.

To maintain the same distance between the tripod and the participant, marks were placed in those two positions and made sure that any distance changes were not happened between those two points. The position of the camera and the tripod was also fixed for standardization throughout the data collection procedure. The plumb line was set 1 m away from the participants and the camera was fixed on a tripod which was placed 2m away from the lateral border of the footmark (Akodu, Akinbo and Young, 2018). The height of the camera was adjusted so that the tragus of the participant was the focus point (Yousuf, 2016). When capturing the CVA, the participants were asked to stand comfortably in his/her anatomical position with head in erected position (Akodu, Akinbo and Young, 2018) His/her feet were closed to each other and arms were hanging relaxed on either side of the body. Participants were asked to focus on a relevant point at his/her eye level (Figure 1 and 2). This procedure was repeated three times in order to take the mean values. All photographs were captured by one researcher in order to reduce the bias. Photogrammetry method for the analysis of craniovertebral posture was highly recommended in previous studies as it is an accurate and objective method (Worlikar, Apurva & Mayuri, Rajesh & Shah, Mayuri, 2019).

At the analysis part, all the photographs were transferred to the Kinovea software and angles were measured between the horizontal line passing through the spinous process of 7th cervical vertebrae and the tragus. Angles which were lesser than 49.9° were considered as decreased CVA (Figure 1) wheareas angles which were more than 49.9° were considered as increased CVA (Figure 2).

Collected data were statistically analyzed using IBM SPSS software, version 20. Before the data analysis the normality tests were performed. Parametric tests were used for further analysis since our data distribution stated normal (Barton & Peat, 2014). Pearson's correlation coefficient test was used to determine the relationship between CVA and the duration of using smartphones and laptops and to identify the relationship between CVA and BMI.

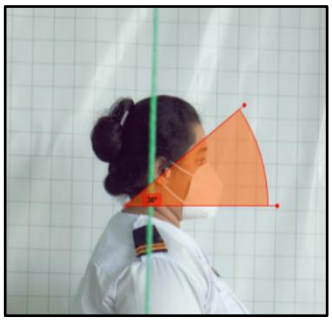


Figure 1. Decreased CVA

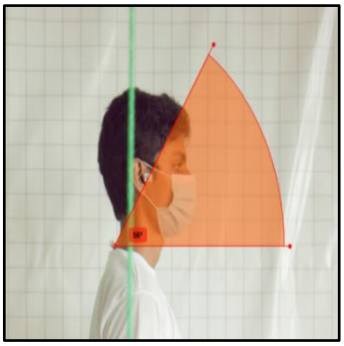


Figure 2. Increased CVA

III. DISCUSSION AND ANALYSIS

The study included 228 participants comprised out of 158 females and 70 males within the age range of 19-24 years. The mean values of age, BMI and CVA were (21.83±1.57years), (22.86±4.39kg/m^{-2}) and (46.53±5.49degrees).

Table 1. Descriptive statistics of the demographic data of the study sample

	N	Minimum	Maximum	Mean	Std. Deviation
Age	228	19.00	24.00	21.83	1.57
BMI	228	12.60	36.41	22.86	4.39
Duration of years using smartphones	227	2.00	8.00	4.93	1.51
Duration of years using laptops	206	1.00	7.00	3.91	1.38

Comparable results were manifested by previous studies which have been aimed to investigate the correlation between craniovertebral angle and smartphone addiction among undergraduates. According to the results of the study conducted by Akodu, Akinbo and Young (2018), the mean CVA value was (51.83 ±5.7degrees). Pearson correlation coefficient was used to quantify the linear relationship of CVA and long-term usage of smartphones, laptops, and BMI.

Table 2 shows the correlation between CVA and duration of years using smartphones. There was a statistically significant negative relationship between CVA and long-term usage of smartphones among the respondents (p = 0.03, r = -0.35).

Table 3 demonstrates the correlation between CVA and duration of years using laptops. A statistically significant negative linear relationship between CVA and long-term usage of laptops among participants (p = 0.03, r = - 0.47).

Table 2. Correlation between CVA and duration of years using smartphones

		CVA	Duration of years using smartphones
CVA	Pearson Correlation	1	-0.35*
	Sig. (2-tailed)		0.03
	N	228	227
Duration of years using smartphones	Pearson Correlation	-0.35*	1
	Sig. (2-tailed)	0.03	
	N	227	227

Table 3. Correlation between CVA and duration of years using laptops

		CVA	Duration of years using laptops
CVA	Pearson Correlation	1	-0.47*
	Sig. (2-tailed)		0.03
	N	228	206
Duration of years using laptops	Pearson Correlation	-0.47*	1
	Sig. (2-tailed)	0.03	
	N	206	206

According to the above statements, it was evident that participants who had lower craniovertebral angles were long-term users of smartphones and laptops, while the participants who had relatively higher craniovertebral angles were short-term users of the above-mentioned devices. A previous research conducted by Park et al (2015) supported the above statement by mentioning that people who use smartphones for a long period of time usually keep their neck flexed downwards to stare at smartphones and to maintain head in the forward posture for a prolong time. According to the study conducted by Kang et al (2012) with the aim of estimating effects of a relatively protruded head and neck posture in computer-based workers, concluded that forward head posture associated with reduced craniovertebral angle was influenced by the prolong laptop usage.

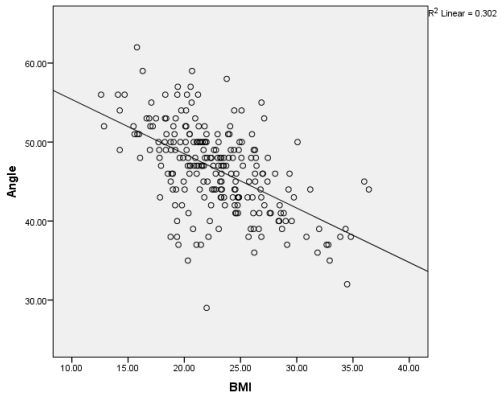
Table 4. Correlation between CVA and BMI

	CVA	BMI

CVA	Pearson Correlation	1	-0.55**
	Sig. (2-tailed)		0.01
	N	228	228
BMI	Pearson Correlation	-0.55**	1
	Sig. (2-tailed)	0.01	
	N	228	228

According to Table 4, a moderately negative significant correlation was observed between CVA and BMI ($p > 0.01$, $r = -0.55$).

Figure 3. Scatter plot demonstration of correlation between CVA and BMI



The findings of the study conducted by Kocur et al (2019) has stated that there is a significant moderately negative correlation among BMI and CVA which strongly relates to the current study results. A significant relationship was obtained between CVA and duration of time using smartphones ($p = 0.02$, $r = -0.15$). A statistically significant relationship was identified between CVA and duration of time using laptops ($p = 0.32$, $r = -0.07$). The independent t-test was used to analyze the association between CVA and gender. It was revealed that there was no statistically significant difference between duration of time using both smartphones ($p = 0.50$, $t = 2.18$) and laptops ($p = 0.55$, $t = 0.58$) in relevant to their gender. Further, no statistically significant difference was observed between craniovertebral angle with regard to their gender ($p = 0.49$, $t = -1.36$).

IV. CONCLUSION

The study concluded a significant negative correlation between craniovertebral angle and the long-term usage of smartphone and laptops among university undergraduates. Further, it emphasized a significant negative correlation between craniovertebral angle and the BMI among the participants. Further studies could be conducted with large scale sample sizes to verify the results. This study results can be used as a warning indication to minimize the excessive usage of smart phones and laptops, and its dependency in undergraduate's population as it has negative impact on musculoskeletal system.

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The Correlation between Incidence of Falls and Quadriceps Muscle Strength among Patients with COPD from Two Selected Government Hospitals in Colombo District

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Abstract— Skeletal muscle dysfunction is one of the extrapulmonary manifestations in patients with chronic obstructive pulmonary diseases (COPD). Quadriceps muscle strength plays an important role in maintaining the postural stability of a human. The objectives of the study were to determine the incidence of falls and to identify the probability of risk of falls among COPD patients in relation to quadriceps muscle strength among patients who presented to the National Hospital for Respiratory Diseases, Welisara, and the Chest Clinic at the Medical Research Institute, Sri Lanka. This descriptive cross-sectional study was conducted among 35 COPD patients between 40-60 years of age. The quadriceps strengths of bilateral lower limbs were measured using the one repetition-maximum (1RM) strength test and the incidence of falls was assessed using an interviewer-administered questionnaire. The test results indicated a significant positive correlation between the incidence of falls and right side 1RM ($p=0.019$, $r=0.395$) and left side 1RM ($p=0.033$, $r=0.362$). The results showed a significant positive relationship between the probability of risk of falls and right side 1RM ($p=0.030$, $r=0.601$) and left side 1RM ($p=0.040$, $r=0.537$). According to the results of the study, a significantly positive correlation between the incidence of falls and the quadriceps muscle strength of COPD patients was identified. Further, the results show an increase in the probability of falls risk with the reduction of quadriceps muscle strength.

Keywords: quadriceps muscle strength, COPD, falls Incidence

I. INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a combination of diseases which is characterized by limitation of lung airflow that restricts normal breathing (Devine, 2008; Celli et al, 2015; World Health Organization, 2020). Even though COPD is defined as a preventable and treatable disease, it is not a completely reversible disease (Celli et al, 2015). It is a life-threatening chronic inflammatory lung disease with progressive, debilitating clinical symptoms (World Health Organization, 2020).

COPD is one of the worldwide main causes of morbidity and mortality. It has been identified as the worldwide third leading cause of mortality by the Burden of Disease Studies (Celli et al, 2015). Global initiative for Chronic Obstructive Lung Diseases, (2018) has shown that, the global prevalence of COPD is 11.7% reference to the results of 384 million of COPD cases in 2010 Skeletal muscle dysfunction is one of the main extra-pulmonary manifestations found in patients with COPD. The skeletal muscle function plays an important role in maintaining the quality of life of a person.

Skeletal muscle dysfunction can be identified with reduced muscle strength and reduced endurance of a patient. In COPD, Skeletal muscle dysfunction involves both respiratory and peripheral muscles. Even though the peripheral muscle functions of both upper and lower limbs are affected in patients with COPD, the lower limb muscles are more severely affected than the upper limb muscles. Gea et al, (2015) In consideration of the lower limb muscle dysfunction in patients with COPD, the most affected muscle group is the Quadriceps muscle group of the lower limbs (Kharbanda, 2015). Also, Shah et al, 2019 has mentioned that there is a significant reduction in unilateral or bilateral quadriceps muscle strength in COPD patients. Degree of the muscle weakness changes according to the severity of the COPD (Kharbanda, 2015).

Even the patients with mild severity of the disease, can develop quadriceps muscle weakness (Seymour, 2010; Kharbanda, 2015). One Repetition Maximum (1RM) is described as the maximum weight that an individual can lift only in one

attempt, using a correct lifting method (Seo et al, 2012) with completing full range of motion (Rydwik et al, 2007). Levinger et al, (2009) and Seo et al, (2012) state that 1RM is a gold standard measurement to assess the muscle strength of individuals in non-laboratory situations. The 1RM test is a well-tolerated test by the patients who have undergone pulmonary rehabilitation program (Zanini, 2015).

Impaired balance increases the risk of falls among the patients with COPD (de Castro LA et al, 2016; Marla, 2018). Orr, (2010) in his study mentions the

contribution of muscle power to postural instability in the elderly people, tibialis anterior, gastrocnemius, hamstrings, and quadriceps muscle groups have major influence on maintaining the postural stability. According to Crişan et al, (2015), COPD patients of acute stage (Specifically GOLD severity stage 2) and patients with exacerbation suffer impaired balance and greater risk of falls.

This paper examines the correlation between the fall's incidence and the quadriceps muscle strength of COPD patients. In addition, this paper identifies the probability of risk of falls among COPD patients in relation to quadriceps muscle strength of patients with COPD.

II. METHODOLOGY

This descriptive cross-sectional study was conducted with 35 COPD patients in age between 40-60 year who attended the National Hospital for Respiratory Diseases, Welisara and the Central Chest Clinic at Medical Research Institute of Sri Lanka within the course of one month. Both male and female patients with COPD, Age group between 40 to 60 years, Patients who had been diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Diseases, patients who extended their consent having complied with the information about the research study were included in the study. Patients with lower extremity joint replacement surgeries and spinal surgeries, Patients with a history of neuro-muscular conditions (example: Parkinson disease, Arthritic conditions, Osteoporosis) and Patients who did not give their consent were excluded from the study.

In order to measure the quadriceps muscle strength, 1RM strength test was conducted (Gosselink, n.d.) with the use of free weights which could be strapped round the ankle. Prior to the quadriceps muscle strength testing, all the participants were given instructions as to how the techniques should be performed correctly. The participants were instructed to engage in warm up activities of walking with arms and leg movements for about 5 min prior to the test (Rydwik et al, 2007; Seo, 2012). The test was performed in the seated position. The chair was with a fixed height which had no armrests, back rest with an angle of 90-degrees. The subjects who were unable to reach the floor were given a foot stool. The starting position of the test was sitting position with the straight back, hip, knee and ankle flexed in the angle of 90-degrees. The subject was then instructed to stretch forward the testing leg up to the angle 180 degrees, (through full ROM) with the corresponding weight (Zanini, 2015). Quadriceps muscles strength of both the sides were tested in this manner (Figure 1)

Figure 1- Testing 1 Repetition Maximum

Number of incidences of falls during the last 3-6 months were collected using the interviewer administered questionnaires.

III. RESULT

The mean value and standard deviation of age were 55.63 ± 4.222 years whereas the gender distribution of the study was 08 women and 27 males. Spearman's correlation coefficient test was used to measure the correlation between falls incidence and quadriceps muscle strength. The test results indicated a significant moderate positive correlation between falls incidence and right side 1RM ($p=0.019$, $r=0.395$) (table 1) and left side 1RM ($p=0.033$, $r=0.362$) (table 2). The logistic regression test was used to measure the probability of risk of fall in relation to quadriceps muscle strength. The results showed a significant positive relationship between the probability of a patient not falling with increased quadriceps muscle strength of the right side ($p=0.030$, $r=0.601$) (table 3) and left side ($p=0.040$, $r=0.537$) (table 4).

Table 1- The relationship between right side quadriceps muscle strength and risk of falls among the COPD patients

			Right side 1RM¯ (kg)	Falls' History (within 3 to 6 months)
Spearman's rho	Right side 1RM¯ (kg)	Correlation Coefficient	1.000	.395*
		Sig. ¯¯ (2-tailed)	-	.019
		N¯¯¯	35	35

*. Correlation is significant at the level of 0.05 (2-tailed). ¯One Repetition Maximum ¯Significance ¯¯Total number of participants

Table 2- The relationship between left side quadriceps muscle strength and risk of falls among the COPD patients.

			Left side 1RM¯ (kg)	Falls' History (within 3 to 6 months)
Spearman's rho	Left side 1RM¯ (kg)	Correlation Coefficient	1.000	.362*
		Sig. ¯¯ (2-tailed)	-	.033
		N¯¯¯	35	35

Table 3- The probability of risk of falls among COPD patients in relation to the level of right quadriceps strength.

		B	S.E.	Df	Sig.
Step 1a	Right side 1RM (kg)	.601	.276	1	.030
	Constant	-3.823	2.054	1	.063

Table 4- The probability of falls risk among COPD patients in relation to the level of left side quadriceps strength.

		B	S.E.	Df	Sig.
Step 1a	Left side 1RM (kg)	.537	.262	1	.040
	Constant	-3.179	1.868	1	.089

IV. DISCUSSION

This chapter contains a detailed discussion of the research findings based on the prevailing literature. The objective of this research was to identify the correlations between Incidence of falls and quadriceps muscle strength among patients with COPD from two selected government hospitals in Colombo district. All the patients with COPD, who presented themselves to the Chest Clinics within a period of one-month were recruited for the research study. A total number of 35 patients who satisfactorily completed the requirements relevant to the exclusion and exclusion criteria were selected for recruitment. They all belonged to the age group ranging from 40 to 60 years.

The results of this research revealed that there is a correlation (p=0.019 in right side and p=0.033 in left side) between quadriceps muscle strength and falls incidences with the patients of COPD. According to the research conducted by Loughran et al, 2020, it has highlighted that there is a significant

balance impairment associated with reduced quadriceps muscle strength which increases the risk of falls among patients with COPD. The results of this research study indicate that there is a significant moderate positive correlation between left (p=0.033) and right (p=0.019) quadriceps muscle strength with falls incidences of patients with COPD. Accordingly, the results indicate an increased probability of not falling of patients, in relation to the increased quadriceps muscle strength.

V. CONCLUSION

According to the result of the study a significantly positive correlation between falls incidence and

quadriceps muscle strength of COPD patients was identified. Further, the results show an increase of probability of not falling in parallel to the improvement of bilateral quadriceps muscle strength with increasing

severity from moderate, severe to very severe stage of COPD respectively.

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Medication Practices in the Management of Upper Respiratory Tract Infections among Undergraduates of University of Jaffna, Sri Lanka

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Abstract - Upper respiratory tract infections (URTIs) are one of the most commonly encountered diseases in both paediatric and adult populations and they represent a significant cause of antibiotic abuse which contributes to antibiotic resistance. This study mainly aimed to evaluate the medication practices of URTIs among undergraduates at the University of Jaffna. A descriptive cross-sectional study was conducted among 382 undergraduates of University of Jaffna from July 2019 to November 2020. Stratified random sampling was performed to recruit the participants and the data were collected using a self-administered questionnaire and analysed using SPSS version 23. The response rate was 82.1% (n=314) for this survey. The majority of the respondents were female (64.0%) and unmarried (97.1%). Almost 45.0% of participants had URTIs at least once in the last three months and the common cold was the most frequently reported URTI symptom. Most of the students had antipyretics (74.8%), Vitamin C (73.8%), herbal remedies (72.0%), antibiotics (63.7%), cough syrups (55.0%) and antihistamines (54.4%) to treat their URTIs. A considerable number of students, 42.0% had self-medicated with antibiotics. Compared to Health Science students, Non- Health Science students significantly shared their antibiotics with friends or family members ($p<0.05$) and kept leftover antibiotics to be used in similar disease conditions in the future ($p< 0.05$).This study concluded that majority of the undergraduates at the University of Jaffna had inappropriate antibiotic usage in URTIs and it suggested that educational programs should be designed to educate undergraduates irrespective of course of study regarding rational usage of antibiotics.

Keywords: URTIs, Practices, Undergraduates, University of Jaffna

I. INTRODUCTION

Acute URTIs refers to acute infections of the nose, sinus, pharynx, middle ear, larynx and epiglottis, airway and bronchus (Simoes et al., 1995). URTIs are one of the most commonly encountered diseases in both pediatric and adult populations, who generally experience an acute URTIs 2-5 times a year (Yoon *et al.*, 2017; Shuhayb, Al and Khawaja, 2018). Although URTIs are rarely fatal, they compose a great economic burden on health systems. 20–30% of all hospital admissions and 30–60% of practitioner visits in the developing countries are related to respiratory tract infections. URTIs are leading to unnecessary absence from school and unnecessary medical care (Shuhayb, Al and Khawaja, 2018).

Treatment of URTIs can be classified as symptomatic treatment, antibiotics treatment, complementary and alternative treatment and other practical interventions. Antipyretics, anti-inflammatory agents, first generation antihistamines, expectorants, antitussives and decongestants are some of medications which are used in the symptomatic treatment. Antibiotics usage in URTIs remains contentious since more than 90% of the infections are of viral etiology (Cotton, Innes and H Rabie, 2011). Herbal remedies are used as complementary and alternative treatments of URTIs (Cotton, Innes and H Rabie, 2011). Although URTIs are usually self-limiting and numerous over the counter medications used for URTIs have no effect on outcome (Shuhayb, Al and Khawaja, 2018).

Antibiotics are effective in bacterial infections but not in viral infections. As viral invaders are responsible for most of acute URTIs, early antibiotic treatments for URTIs are not recommended. But it is recommended when symptoms are worsening and existing for a long time period. But there is an evidence that URTIs are the reason for 60% of all antibiotic prescribing in general practice. So misuse

and overuse of antibiotics in URTIs leads to loss of bacterial sensitivity to antibiotic agents and emergence of antibiotic resistance bacterial strains, which is current global crisis (National institute for health and clinical science, 2008; O'Connor et al., 2019).

In Sri Lanka, only a few studies were carried out on university students focusing on their drug treatment patterns (Rathnayake *et al.*, 2016; Sakeena *et al.*, 2018). Irrational use of antibiotics has been a common problem among university students and is supported by previous studies conducted in Sri Lanka (Gunawardhana, Sakeena and Sivayoganthan, 2015; Rathish and Wijerathne, 2017; Sakeena *et al.*, 2018). This study mainly aimed to evaluate the knowledge and practices regarding medication usage in URTIs, in order to develop educational and awareness programmes for university students, as they are representing the educated adult population which may help them in promoting the proper practices in URTIs. The proper knowledge and practice regarding the management of URTIs among undergraduate students will significantly reduce the misuse of the drugs especially antibiotics and also reduce antibiotic resistance crisis in near future.

II. METHODOLOGY

A. Study design and setting

This study was an institutional based descriptive cross sectional study conducted from July 2019 to November 2020, investigating the knowledge and practices on the management of URTIs among undergraduate students of University of Jaffna, Srilanka. This study was conducted in eight faculties of University of Jaffna including Faculty of Medicine, Faculty of Allied Health Sciences, Faculty of Arts, Faculty of Management studies and Commerce, Faculty of Science, Faculty of Engineering, Faculty of Agriculture and Faculty of Technology. In this study, students who were studying in Faculty of Medicine, Faculty of Allied Health Sciences were considered as "Health Science students" and those who were studying in Faculty of Arts, Faculty of Management studies and Commerce, Faculty of Science, Faculty of Engineering, Faculty of Agriculture and Faculty of Technology were considered as "Non-Health Science students".

B. Sample size

The sample size for this study was calculated based on p value (0.34) from a previous study conducted among Pakistan university students (Saleem *et al.*, 2016). From this, a total of 382 undergraduates of University of Jaffna from various degree programmes were enrolled for the study. Second year students (2016/2017 intake) of University of Jaffna were included in this study. Students who were not willing to take part in this survey, voluntarily excluded from the study.

C. Sampling technique

Among the 2586 second year students of University of Jaffna, stratified random sampling method was performed to select the undergraduate students from each course.

D. Study instrument

The data was collected by using a self-administered questionnaire. The questionnaire was developed in English and it was translated into Tamil and Sinhala by trilingual experts. Again the questionnaire was back translated into English and equivalency of questions was ensured. The content and format of the questionnaire used in this study were evaluated using a pre-test involving 25 students from University College of Jaffna. According to the feedback of the students, questionnaire was modified with the help of supervisors without affecting the objectives of this study.

The questionnaire consisted of three sections. Section A was designed to collect socio- demographic factors (Gender, age, marital status, ethnicity, religion, faculty, course of study, current living status) of undergraduates. Section B and C were designed to collect data on knowledge and practice in the management of URTIs respectively. The section B consisted of ten questions. It was designed in a view of assessing the ability of undergraduates on identification of drugs used in the management of symptoms of URTIs, the ability to identify the cause of URTIs and the knowledge on antibiotic usage in URTIs. The section C consisted of sixteen questions regarding the practices on the management of URTIs.

E. Data collection method and ethical considerations

Data collection was done after obtaining the ethical clearance from the Ethics Review Committee, Faculty of Medicine, University of Jaffna. After the ethical clearance, the permission for data collection was obtained from Vice Chancellor, University of Jaffna and Deans of respective faculties. Data collection was done among selected undergraduate students from July 2020 to September 2020. The voluntary participation was ensured. Before sending the questionnaire, consent form was sent to the selected

undergraduate students and after obtaining their informed written consent, the questionnaire was sent to the respective student via google forms through E-mail.

F. Data analysis

The collected data was entered in to Statistical Package for Social Sciences (SPSS-23 version) and data was analyzed based on research specific objectives. Results were presented as frequency, percentage, mean, median and standard deviation and the results were elucidated as tables and diagrams.

When analyzing knowledge section, score of one was given for correct response while zero was given for wrong and "don't know" responses. Total knowledge score was calculated in percentage. The level of knowledge was determined by pre-determined cut-off marks and it was categorized as "Good knowledge" and "Poor knowledge". A total of 14 marks was given for section B. The score from 8 to 14 was considered as "Good knowledge" and score from 0 to 7 was considered as "Poor knowledge".

When analyzing practices section, data was analyzed descriptively and the responses of each questions in practice section were described in frequency and percentage individually. Chi- square test and Fisher's exact test were used to determine the significant association between socio-demographic factors and level of knowledge and practices. $p < 0.05$ was used as level of significance.

III. DISCUSSION AND ANALYSIS

A. Distribution of sociodemographic factors

A total of 314 students completed the study with a response rate of 82.1%. Table 1 depicts a descriptive summary of students' socio demographic characteristics. The students' age range was between 21 to 26 years and were predominately female (64.0%) and unmarried (97.1%). This is similar to other differential studies conducted earlier (Parimi et al., 2004; Saengcharoen, Lerkiatbundit and Kaewmang, 2012; Saleem et al., 2016).

B. Knowledge on identification of drugs used in the management of symptoms of URTIs

Students were given with five drugs including antihistamines, antibiotics, antipyretics, cough syrups and Vitamin C and were asked to identify the drugs which can be used to treat URTIs. Only 2.5% had correctly identified all five drugs while 4.8% of them were not able to distinguish none of the drugs.

Table 1. Students' sociodemographic characteristics

Sociodemographic factors	**Categories**	**Frequency (N=314)**	**Percentage (%)**
Age	21-23 yrs	225	71.7
	24-26 yrs	89	28.3
Gender	Male	114	36.0
	Female	200	64.0
Marital status	Unmarried	305	97.1
	Married	9	2.9
Ethnicity	Sinhalese	71	22.6
	Sri Lankan Tamil	210	66.9
	Sri Lankan Moors	33	10.5
Religion	Buddhism	68	21.7
	Hinduism	177	56.4
	Christianity	36	11.5
	Islam	33	10.4
Faculty	Agriculture	14	4.5
	AHS	30	9.6
	Arts	94	29.9
	Engineering	17	5.4
	Management	54	17.2
	Medicine	23	7.3
	Science	45	14.3
	Siddhamedicine	10	3.2
	Technology	27	8.6

C. Knowledge on the antibiotic usage in URTIs:

Table 2 shows the statements related to antibiotic usage in URTIs which were analysed using X^2 test among Health Science and Non-Health Science students. It illustrates that overall Health Science students scored remarkably better than Non-Health Science students on knowledge regarding antibiotic usage in URTIs (X^2= 119.093, p< 0.0001). The same pattern of results was observed for most of the statements related to the antibiotic usage.

Table 2. Students' knowledge on antibiotic usage

Statements (Correct responses)	Total% (n/N)	Whole %			
		Health Science %	Non-Health Science %	X^2	p
Antibiotics speedup the recovery of acute URTIs (No)	25.6 (79/309)	26.7 (16/60)	25.3 (63/249)	0.047	0.828
Antibiotics cure bacterial infections (Yes)	49.5 (154/311)	93.5 (58/62)	38.6 (96/249)	60.057	**< 0.0001***
Antibiotics cure viral infections (No)	49.2 (154/313)	67.7 (42/62)	44.6 (112/251)	10.634	**0.001***
Antibiotics for URTIs can be taken from a pharmacy without prescription of a doctor (No)	48.1 (151/314)	77.8 (49/63)	40.6 (102/251)	27.827	**< 0.0001***
Leftover antibiotics of URTIs from previous course can be used if I have the same condition in the future (No)	56.1 (174/310)	61.9 (39/63)	54.7 (135/247)	1.071	0.301
The prescribed course of antibiotics can be stopped if the symptoms are improved (No)	42.9 (134/312)	71.0 (44/62)	36.0 (90/250)	24.791	**< 0.0001***
Inappropriate use of antibiotics leads to antibiotic resistance (Yes)	41.5 (130/313)	92.1 (58/63)	28.8 (72/250)	82.935	**< 0.0001***

D. Level of knowledge of study participants

Table 3 depicts the categorized distribution of level of knowledge among the participants. Majority of the respondents 194 (61.8%) had poor knowledge and 120 (38.2%) of the entire participants had good knowledge on the management of URTIs. It is in line with a study conducted among Thai students, where the 66% of the participants had inappropriate knowledge (Saengcharoen, Lerkiatbundit and Kaewmang, 2012).

Table 3. Level of knowledge among students

Level of knowledge	Frequency (n)	Percentage (%)
Good knowledge	120	38.2
Poor knowledge	194	61.8

E. Influence of socio demographic factors on level of knowledge

Table 4 describes the influence of socio demographic factors on level of knowledge regarding the management of URTIs among the students. Among the Health Science students, 85.7% had good knowledge and only 14.3% had poor knowledge. Among the Non-Health Science students, only 26.3% had good knowledge and 73.7% had poor knowledge. So that the faculty of the participant showed stastically significant influence on level of knowledge ($p < 0.001$).

Table 4. Students' level of knowledge and socio demographic factors

Socio demographic factors	Level of knowledge		tastical est
	Good knowledge N (%)	Poor knowledge N (%)	
Age 21-23 years 24-26 years	 80 (35.6) 40 (44.9)	 145 (64.4) 49 (55.1)	Chi-square test $X^2 = 2.381$ df = 1 p = 0.123
Gender Male Female	 37 (32.5) 83 (41.5)	 77 (67.5) 117 (58.5)	Chi-square test $X^2 = 2.515$ df = 1 p = 0.113
Marital status Married Unmarried	 2 (22.2) 118 (38.7)	 7 (77.8) 187 (61.3)	Fisher's exact test X^2= - df = - p = 0.491
Faculty Health Science Non-Health Science	 54 (85.7) 66 (26.3)	 9 (14.3) 185 (73.7)	Chi-square test $X^2 = 75.30$ df = 1 **p < 0.001***

F. Distribution of practice among participants

1) Distribution of recent history of URTIs among participants: Table 5 describes the recent history and associated symptoms of URTIs. Majority of the participants, 44.9% had URTIs atleast once for the last three months. Common cold was the most frequently reported URTI symptoms (74.1%) followed by cough (33.7%) and sneezing (27.0%). It is incoherent with another study conducted in Pakistan which revealed that cough (51.9%) was most commonly observed symptom followed by fever (32.3%) (Saleem et al., 2016).

Table 5. Recent history of URTIs among students

Questions	Responses	N	n	%
How many times did you have URTIs in past 03 months	None	314	59	18.8
	Once		141	44.9
	Twice		44	14.0
	Three times		28	8.9
	More than three times		42	13.4
Symptoms that you had during the last episode of URTIs	Common cold	255	189	74.1
	Cough		86	33.7
	Runny nose		67	26.2
	Sneezing		69	27.0
	Sorethroat		31	12.1
	Nasal blockage		53	20.7
	Fever		55	21.5

2) Distribution of practices regarding the symptomatic and alternative treatment of URTIs: Most of the students had taking antipyretics (74.8%) followed by Vitamin C (73.8%), cough syrup (55.0%) and antihistamines (54.4%) to treat their URTIs.

When considering the alternative treatment of URTIs, majority of them tried steaming (87.6%), herbal remedies (72.0%) and gargling with salt water (61.5%).

3) Distribution of practices regarding the antibiotic usage in URTIs: Majority, 63.7% had taking antibiotics to treat their symptoms of URTIs. However, a previous study conducted among Pharmacy and Non-Pharmacy students in Pakistan stated that 79.5% of the participants took antibiotics for their URTIs (Saleem et al., 2016). In this study, almost 42.0% of them got the antibiotics from pharmacy without prescriptions and 71.3% of them completed their antibiotic course as prescribed by the doctor. The present study stated that there was irrational usage of antibiotics for URTIs among the undergraduates.

Table 6. Students' antibiotic usage in URTs

Variables (Responses)	n	%
I get antibiotics from pharmacy without prescriptions for my URTIs (always, often)	132	42.0
I complete my antibiotic course as prescribed by the doctor (always, often)	224	71.3
I suggest antibiotics which cured my disease to my friends in similar conditions (always, often)	143	45.5
I share antibiotics with my friends or family members if they have similar disease conditions that I had in the past (always, often)	126	40.1
I keep leftover antibiotics to be used in similar disease conditions in the future (always, often)	100	31.8

IV. CONCLUSION

The findings of the study revealed that the knowledge on the management of URTIs was inadequate among the undergraduates of University of Jaffna and faculty of the participant had significantly influenced the level of knowledge. Furthermore, irrational usage of antibiotics in URTIs among the undergraduates irrespective of faculty of study was observed. This findings of the study suggested that educational programs should be designed to educate the undergraduate students irrespective of course of study regarding the hazards of self medication, duration of antibiotic theraphy in URTIs and significance of antimicrobial resistance.

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Gender-wise Variation in the Delivered Radiation Dose during Common X-ray Procedures. A Preliminary Study

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Abstract - The increased radiosensitivity in women compared to men is a greater concern in diagnostic radiology, which uses ionization radiation for the purpose of diagnosis. However, radiation protection authorities, such as the international commission on radiation protection (ICRP) have only focused on the average adult when giving radiation protection recommendations, such as diagnostic reference levels (DRL). The present study aimed to evaluate the gender wise variation in delivered radiation dose during common X-ray projections. The dose area product (DAP) values of six X-ray projections were recorded for 658 adult patients (393 male and 265 female) of same age range of 18 to 83 years who underwent routine X-rays at two hospitals. A gender wise comparison between the resultant average DAP values showed that the females received a higher mean dose than the males during abdomen anteroposterior (AP) (230.0 µGy.m^2), kidney-ureter-bladder (KUB) (323.8 µGy.m^2) and pelvis AP (268.3 µGy.m^2). In addition, males also received higher doses of 124.1 µGy.m^2, 388.0 µGy.m^2 and 16.3 µGy.m^2 respectively for lumbar spine AP, lateral and chest posteroanterior (PA). However, these differences were significant only in chest PA and lumbar spine lateral projections (P=0.000 and 0.001). Therefore, the authorities should focus on subpopulations rather than consider an average adult when providing dose recommendations and guidelines on radiation protection. However, in-depth and large-scale studies are required to support the idea of gender-based DRLs in the future.

Keywords: X-ray procedures, radiation dose, gender difference, dose area product, DAP, DRL

I. INTRODUCTION

Ionizing radiation is well known for its deleterious effects on human life. The identification of radiation exposure risk is important for the implementation of protective measures. Demographic factors such as age, sex and genetic susceptibility influence radiosensitivity. However, the influence of gender-differences on radiation sensitivity has given less attention compared to other factors. An animal study had proven that there is a gender-related difference in radiation-induced cataractogenesis (Henderson *et al.*, 2009).

Moreover, a controversary exists regarding the long-term risks following the exposure to ionizing radiation during medical diagnosis, particularly in women than men (Institute of Medicine (US) Committee on Women's Health Research., 2010). The Institute of Medicine USA, claims that the ionizing radiation from computed tomography (CT) scan is a contributing factor for breast cancer in women (Smith-Bindman, 2012).

The increased radiosensitivity in women compared to men is a greater concern in diagnostic radiology, which uses ionization radiation for diagnosis. Therefore, it is being highly demanded to have dedicated imaging protocols with a special focus on radiation dose optimization in women. In fact, the international radiation protection authorities such as International Commission on Radiological Protection (ICRP) and International Atomic Energy Agency (IAEA) had given their recommendations for a population average (e.g. for a standard average adult of 70-75 Kg of body weight) without considering the subpopulations (Vañó *et al.,* 2017)(IAEA, 1998). These guidelines includes sensitive radiation protection aspects such as diagnostic reference levels (DRL) which helps in identify abnormally low or high radiation doses that are beyond the clinical requirement. Therefore, in this study we aimed to analyze the gender-wise variation in radiation dose delivered during

common X-ray procedures to determine the validity of using an average adult irrespective of gender in the DRL process.

II. METHODOLOGY

This cross-sectional study was conducted in three X-ray rooms belongs to two hospitals (state-owned (A) and private (B)). The head of the institution of the hospital B and the institutional review board of hospital A waived the individual patient informed consent since patient identification data or their direct involvement was not required for the study. A total of 658 adult patients (393 male and 265 female) of the same age range (18 to 83 years) were included in the study. Patient morphometric data (age and gender) together with dose area product (DAP) were recorded for each patient for six X-ray projections (chest posteroanterior (PA), kidney, ureter and bladder (KUB), abdomen anteroposterior (AP), lumbar spine AP/lateral and pelvis AP). In hospital A, the data collection was done at the site using a commercially available ion chamber manufactured by "Vacu Tec" Germany with dose area product (DAP) resolution of 0.01 μGym^2 and active area of 147x147 mm. In hospital B the DAP values were automatically displayed on the image footer so that no any external device was required for the dose data collection. The statistics were done using Minitab® 17.1.0 statistical software. Independent sample T-test was used to test for the significant differences between the mean DAP values of two gender for different X-ray projections at the level of significance (α) of 0.05. Finally, 11 subjects were excluded from the analysis after identifying them as outliers.

III. DISCUSSION AND ANALYSIS

Assuming equal variances, the obtained P values for the independent sample T-tests which compares the difference in means of DAP of six X-ray projections are given in table 1. The level of significance was kept at 0.05 and the outliers were removed from the samples due to their influence on the calculated statistics. . Figure 1 illustrated the dose distribution using boxplots. According to table 1 and figure 1, it is seen that the females received higher mean dose than that of males during abdomen AP (230.0 μGy.m^2), KUB (323.8 μGy.m^2) and pelvis AP (268.3 μGy.m^2). In addition, males also received a higher dose of 124.1 μGy.m^2, 388.0 μGy.m^2 and 16.3 μGy.m^2 respectively for lumbar spine AP, lateral and chest PA. However, these differences were significant only in chest PA and lumbar spine lateral projections (P=0.000 and 0.001).

Figure 2 (a) and (b) illustrates the distribution of tube potential (kVp) and tube current (mAs) utilization among males and females for the above X-ray projections. The kVp and mAs used for chest PA projection were nearly similar for males and females although the corresponding mean DAP values were significantly different. Since DAP accounts for both dose and the radiation field area, the difference in obtainedDAP values can be attributed to the vriyng X-ray field sizes used for the same projection of the different genders.

Table 1. The mean DAP values obtained for different X-ray projections and the resultant P values after analysing the sample means using the independent sample T test. (α = 0.05)

X-ray	Mean DAP (μGy.m^2)				P value	% change
	(n)	Female	(n)	Male		
Chest PA	126	13.8	202	16.3	0.000	+15.3%
KUB	03	323.8	17	314.5	0.817	-2.95%
Abdomen AP	18	230.0	51	203.6	0.336	-12.96%
Lumbar Spine AP	47	117.8	54	124.1	0.619	+5.07%
Lumbar Spine LAT	50	255.0	61	388.0	0.001	+34.2%
Pelvis AP	10	268.3	08	219.4	0.096	22.29%

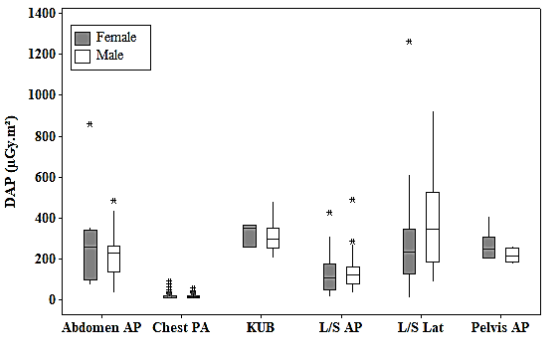

Figure 1. Box and whisker plots illustrates the distribution of DAP values obtained for various projections for males (M) and females (F) separately.

However, a clear difference was seen between the kVp and mAs used for rest of the projections similar to the difference in DAP. This can be attributed to differences in their body sizes where the exposure parameters are adjusted to provide optimum quality image

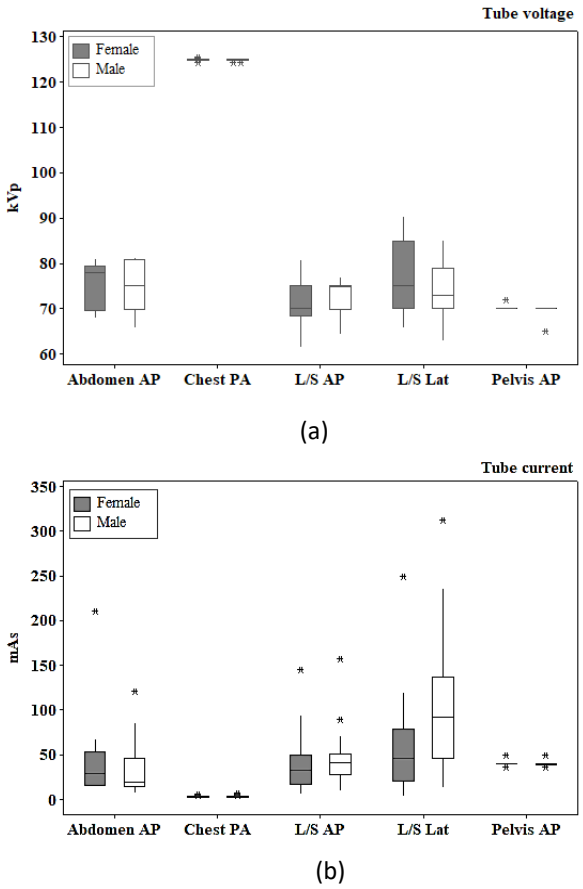

Figure 2. Box and whisker plots illustrates the distribution of (a): tube potential (kVp) and (b): tube current (mAs) utilization for males and females during various projections separately.

The United States nuclear information and resources services (NIRS) data suggest that the radiation risk associated with women is comparatively higher than men since cancer and death incidents reported were 50% higher in women, among men and women who are being exposed to same amount of the radiation (NIRS, 2011). Despite these differences, similar protection standards were still applying for both genders by ICRP and IAEA. The results of the present study, indicates that females received considerably higher doses than males for the same X-ray procedure.

In addition, all the above projections irradiate the most radiosensitive tissues of the female body such as the breasts and ovaries which increase the risk of breast cancer. Breast cancer is the most common cancer among females in Sri Lanka and each year 3000 new cases are diagnosed. Hence the contribution of medical exposures for the above elevation cannot be neglected (Balawardena *et al.,* 2020). Therefore, when providing recommendations, it is essential to consider this gender-wise variation in the radiation dose whenever appropriate

IV. CONCLUSION

The increased radiosensitivity in women compared to men is a greater concern in diagnostic radiology. Therefore, it is being highly demanded to have dedicated imaging protocols with a special focus on radiation dose optimization in women and children, as they do not fall under the reference man. The results of the present study suggest that a gender-wise variation exists among the delivered radiation doses during common X-ray projections. The females received a higher mean dose than that of males during abdomen AP, KUB and pelvis AP that were 230.0, 323.8 and 268.3 $\mu Gy.m^2$ respectively. In addition, males also received a higher dose of 124.1, 388.0 and 16.3 units respectively for lumbar spine AP, lateral and chest PA. However, these differences were significant only in chest PA and lumbar spine lateral projections (P=0.000 and 0.001). Overall, more studies are needed to fully conclude the gender-differences in the delivered radiation dose during X-ray based medical imaging procedures and radiation protection authorities should focus on subpopulation rather than considering an average adult irrespective of gender when giving recommendations and guidelines on radiation protection.

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Comparative Evaluation of Metformin Hydrochloride Brands Available in Sri Lanka

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Abstract - Metformin, being noteworthy, is used in the management of Type 2 Diabetes. It is available in different brands in Sri Lanka. Several studies have shown that different brands of the drug varied qualities, which could impact the treatment efficacy. This study was conducted to analyse the quantity of different brands of metformin hydrochloride tablets available in the Jaffna municipal area, Sri Lanka. It was a laboratory-based exploratory study conducted in State Pharmaceutical Manufacturing Corporation, Sri Lanka. Based on most available brands at pharmacies in the Jaffna Municipal area, fifteen brands of conventional metformin tablets were selected for this study. They were coded as M_1, M_2, M_3,... M_{15}. The uniformity of weight, hardness, friability, disintegration, uniformity of content, and dissolution tests were performed in accordance with the British Pharmacopeia (BP). Two out of fifteen brands were locally manufactured, and the remaining were imported. All brands were conformed to BP specifications in uniformity of weight. The hardness test showed optimum withstanding strength in all brands. All brands excluding M_1 (108.95%), M_6 (111.58%), M_7 (94.27%) and M_{11} (93.91%) were comprised of values falling under monograph specifications (95% -105%) for uniformity of content. Twelve brands satisfied Pharmacopeia requirements in the friability test, while two brands, M_7 (40.45 min) and M_{10} (34.5 minutes), failed in the disintegration test. The dissolution of one brand showed the least drug release (61.40%), and the remaining passed the dissolution test. In conclusion, of all the metformin hydrochloride brands, nine brands passed all the official tests according to BP specifications.

Keywords: metformin, brands, evaluation, quality analysis

I. INTRODUCTION

Diabetes mellitus is a chronic, non-communicable metabolic disease distinguished by increased blood glucose levels. It is categorized as Type 1 and Type 2 Diabetes (WHO, 2006). Metformin, an oral hypoglycaemic drug belonging to the biguanides group, serves as the first-line treatment in managing Type 2 diabetes (International Diabetes Federation, 2005). Maintaining a steady-state plasma concentration of the drug is vital in drug therapy and is enhanced by the amount of drug available in metformin tablets in accordance with the amount prescribed. Different brands of the similar drug may express discrepancy from the prescribed amount, and it might alter the plasma steady state when a patient switch from one brand to another (Sougi et al., 2016).

Generally, the drugs are given with two different names: Generic name or Non-proprietary name and Brand name or Proprietary name (Thakkar and Billa, 2013). The generic name is the name of the active ingredient in the medicine decided by an expert committee and internationally understood and accepted. It is well-known that generic drugs are usually intended to be interchangeable with an innovator product which is formulated and marketed after the termination of the patent (WHO, 2013a). The most crucial aspect of generic drug development is the concepts of bioavailability and bioequivalence (Howland, 2009). The essential criterion utilized in confirming the interchangeability of a generic drug to the corresponding brand-name drug. The drug approval will be given when the generic drug meets the exact amount and type of active ingredient, route of administration, and therapeutic effectiveness as the original drug (Borgheini, 2003).

The drugs of the self-same group are considered to be chemically and bio pharmaceutically equivalent to each other when they are alike in quality, strength,

purity, and active ingredient release profile (Adegbolagun et al., 2007). Quality control parameters are remarkable kits for maintaining the quality of different brands of Metformin (Awofisayo et al., 2010). Test for uniformity of weight ensures the consistency of dosage form while hardness test determines the physical strength of the tablet. Friability is the propensity of tablets to break into fragments, influencing product appearance and consumer acceptance. Apart from that, a disintegration test is essential in identifying the time taken for complete disintegration of tablets or capsules (Hettiarachchi et al., 2015). The dissolution test, as a surrogate marker for bioequivalence, plays a crucial role in monitoring the consistency of drug release among batches (Awofisayo et al., 2010).

Counterfeiting with inappropriate or insufficient ingredients, absence of active ingredients, or fake packaging is common in generic and branded products (WHO, 1999). Furthermore, substandard drugs are the products that are encountered with low specified qualities at laboratory testing (Taylor et al., 2001). Consumption of these under-quality medicines may result in treatment failure and lead to detrimental consequences (Petralanda, 1995). Metformin is one of the fast-moving oral hypoglycaemic drugs, with a wide range of different brands prescribed, especially for diabetes and other indications. This study aims to assess the quality control parameters of different brands of metformin hydrochloride conventional tablets available in the Jaffna municipal area, Sri Lanka, and compare them with the reference brand.

II. METHODOLOGY

This laboratory-based analytical study was carried out in the State Pharmaceutical Manufacturing Corporation (SPMC), Sri Lanka. Fifteen different brands of metformin hydrochloride tablets with a strength of 500 mg were selected for this study. A mini-survey was used to select brands. Metformin brands were selected based on mostly available brands in all registered pharmacies in the Jaffna municipal area. A total of 15 brands, including reference brands, were used in the study. The tablets with near expiry dates (within two months) were excluded. The samples were coded as M1, M2, M3, M4, M5, M6, M7, M8, M9, M10, M11, M12, M13, M14, and M15. Brand M2 was used as a reference brand.

A. Uniformity of weight

Twenty tablets were randomly selected from each brand and weighed collectively and individually. The average weight of each tablet and percentage deviation was determined for each brand (British Pharmacopoeia, 2017).

B. Hardness test

Ten tablets of each brand were randomly taken and placed between the spindles of the Pharma Test (Germany) hardness tester. It was diametrically compressed until fractured. The crushing strength of tablets from each brand was read and recorded

C. Friability test

The samples, each containing ten tablets from each brand, were used for this test. Tablets were dedusted and weighed together, and placed in the friabilator (Pharma test, 920, Germany). It was operated at 25 revolutions per minute for 4 minutes. The tablets were again dedusted and weighed. The percentage weight loss was calculated (British Pharmacopoeia, 2017). This test was done in triplicate for each brand.

D. Disintegration test

Three sets of samples, each containing six tablets, were used from each brand, and the disintegration time was determined at 37^{o}C using distilled water in the disintegration apparatus (Toyama Sangyo, NT4H5, Japan). The disintegration time of tablets was recorded (British Pharmacopoeia, 2017). Test was done in triplicate for all brands.

E. Dissolution test

USP 2 (basket type) digital tablet dissolution test apparatus (Pharma Test Apparatus, Germany) is operated at 100 revolutions per minute(rpm) using 900 mL of pH 6.8 Potassium dihydrogen orthophosphate buffer at 37 ± 0.50^{o} C. Six metformin tablets were taken, and one tablet was placed in each basket. The apparatus was operated at the interval of 10, 30 and 45 minutes. 10 mL of the sample was withdrawn at the interval of 10, 30, and 45 minutes and 10 mL of fresh dissolution medium was immediately added. The withdrawn sample was filtered by 0.45 µm syringe filter and diluted to 100 mL with distilled water. Again, 10 mL of the resultant diluted solution was diluted up to 100 mL with distilled water. The drug content of each sample was analyzed using UV – visible spectrometer, and the absorbance values were taken at a maximum wavelength of 233 nm (British Pharmacopoeia, 2017).

F. Uniformity of content test

Twenty tablets from each brand were used for this test. Tablets were crushed to powder. The tablet powder equivalent to 0.1 g of metformin hydrochloride was accurately weighed and added into 70 mL of distilled water. Then it was shaken for 15 minutes and made up to 100 mL with distilled water. It was filtered through Whatman filter paper (no 5), and initial 20 mL was discarded. 10 mL of the filtrate was taken and diluted to 100 mL with distilled water. 10 mL of the resulting solution was diluted again to 100 mL with distilled water. The absorbance of the final solution was determined at a wavelength of 232 nm using a UV spectrometer (British Pharmacopoeia, 2017). This test was done in triplicate for each brand.

All test readings were presented as mean with standard deviation. The data were computed and analyzed by using SPSS 21 (Statistical Package of Social Science). One-way ANOVA was used to determine the significant difference between the brands and reference. 95% confidence interval was used in this study, and a p-value less than 0.05 was considered a statistically significant difference.

III. DISCUSSION AND ANALYSIS

The metformin tablets included in the study were used before their expiry dates. Among the selected brands, eleven brands were from India (M1, M3, M5, M6, M7, M8, M9, M10, M11, M13, and M14) and one brand from Pakistan(M2), and one brand from Bangladesh (M4) while two brands were manufactured locally in Sri Lanka (M12 and M15). Tables 1 and 2 show the quality parameters of different parameters of metformin brands. All tests were done in triplicate, and the results of all tests were presented as mean with the standard deviation.

The weight uniformity test revealed that all the brands were conformed to British Pharmacopoeia, as the percentage weight deviation of tablets was not greater than 5% for all brands. In order to pass the uniformity of weight, not more than two of the individual weight of the tablets can deviate from the average weight by more than a percentage deviation of ±5%, and none should deviate by more than 10% (British Pharmacopoeia, 2017). Similar studies in Sri Lanka (Hettiarachchi et al., 2015), Syria (Mansour and Isbera, 2016), and West Indies (Gupta and Gupta, 2016) also showed that all brands of Metformin were within BP limit. However, another study in Sri Jayewardenepura, Sri Lanka, reported that one batch out of fifteen batches from five brands failed to comply with the uniformity of the weight test (Nelumdeniya et al., 2012).

Table 1. Quality evaluation parameters of Metformin tablets

Code	Uniformity of Weight (g)	Hardness (Kgf)	Friability (%)
M_1	0.5605 ± 0.016	9.7 ± 0.636*	0.0214 ± 0.0004
M_2 Ref	0.5246 ± 0.006	15.74 ± 0.838	0.0172 ± 0.0002
M_3	0.6063 ± 0.019	10.36 ± 0.835*	0.0435 ± 0.0006*
M_4	0.6223 ± 0.008	8.26 ± 0.802*	0.0433 ± 0.0012*
M_5	0.5664 ± 0.014	12.46 ± 1.999*	0.0248 ± 0.0008
M_6	0.5763 ± 0.011	12.36 ± 0.635*	1.1111 ± 0.1540*
M_7	0.5595 ± 0.015	17.24 ± 0.684	0.0214 ± 0.0014
M_8	0.5643 ± 0.006	8.82 ± 1.112*	1.2888 ± 0.1890*
M_9	0.5463 ± 0.010	7.94 ± 0.152*	1.2288 ± 0.0230*
M_{10}	0.5826 ± 0.012	9.82 ± 0.277*	0.0274 ± 0.0015
M_{11}	0.7004 ± 0.007	18.26 ± 1.119*	0.0057 ± 0.0011
M_{12}	0.6254 ± 0.004	17.26 ± 1.547	0.0064 ± 0.0006
M_{13}	0.6439 ± 0.009	12.28 ± 1.381*	0.0197 ± 0.00023
M_{14}	0.5834 ± 0.011	22.4 ± 0.656*	0.0103 ± 0.0005
M_{15}	0.6065 ± 0.009	13.32 ± 1.794*	0.0049 ± 0.0007

*Statistical significance ($p < 0.05$)

Brands manufactured from India showed both the highest hardness (M14, 22.4 Kgf) and the lowest hardness (M9, 7.94 Kgf). The crushing force of 6 ± 2 Kgf was considered as the minimum force for a quality tablet (Uddin et al., 2017). Statistical significance was observed between all brands excluding M7 and M12 to reference brand, M2 at $p < 0.05$. According to the Pharmacopoeial limit, tablets should not have a friability value larger than 1.0% w/w (British Pharmacopoeia, 2017). Out of all brands, M6, M8, and M9 failed the friability test. Statistically, a difference was observed among M3, M4, M6, M8, and M9 with reference brand M2 ($p < 0.05$). The failure of these three brands could be due to the use of an insufficient binder or inappropriate compaction force, making the tablets friable (Afifi et al., 2013).

Table 2. Disintegration and dissolution profile of Metformin tablets

Code	Disintegration Time(min)	Drug release (%) in 45 minutes
M_1	9.65 ± 0.778	94.53 ± 2.31
M_2 Ref	12.1 ± 0.990	92.29±0.57
M_3	11.3 ± 1.697	99.82±1.75*
M_4	2.50 ± 0.566*	97.97±2.64
M_5	8.55 ± 2.192	96.49±1.76
M_6	16.45 ± 0.212*	95.45±3.16
M_7	40.45 ± 1.909*	61.40±0.99*
M_8	9.2 ± 1.273	88.45±1.56
M_9	19.15 ± 1.061*	86.32±8.99
M_{10}	34.5 ± 0.849*	87.36±1.32
M_{11}	3.575 ± 0.530*	92.14±1.76
M_{12}	12.3 ± 0.707	99.63±2.24*
M_{13}	9.5 ± 0.849	92.41±2.56
M_{14}	10.1 ± 0.849	91.65±1.91
M_{15}	9.55 ± 1.202	101.02±1.37*

*Statistical significance ($p< 0.05$)

The disintegration time measures the time required for a tablet to disintegrate into particles when in contact with the gastrointestinal fluid (Giri et al., 2012). According to this study, the maximum disintegration time was 40.45 minutes for a brand from India (M7), and the minimum was 2.5 minutes for a brand from Bangladesh (M4). British Pharmacopoeia (2017) stipulated that the disintegration time should be within 15 minutes for an uncoated tablet and 30 minutes for film-coated tablets. The tablets tested in this study were film-coated, and it is clear that M7 (40.45 min) and M10 (34.5 minutes) failed to achieve the standard. Although M11 and M14 had considerably higher values for hardness than the innovator brand (M2), they showed a significantly low disintegration time. This could be due to different disintegrants employed to improve the penetration of aqueous liquids (Afifi et al., 2013)). Identical studies were manifested with all brands passing the disintegration test in accordance with BP (Nelumdeniya et al., 2012; Hettiarachchi et al., 2015).

The British Pharmacopoeia (2017) specifies that the content of active pharmaceutical ingredients should not be less than 95% and not more than 105%. All brands except M1 (108.95%), M6 (111.58%), M7 (94.27%), and M11 (93.91%) comprised values within the monograph specifications. A Study in India reported that all four brands of Metformin were within the BP limitation (Sachan, Kumar, and Gupta, 2016). A dosage form having a higher percentage of drugs than it claimed may lead to adverse reactions while lower percentages pave the way to treatment failure (Uddin et al., 2017). Dissolution is pharmaceutically defined as the mass transfer rate from a solid surface into the dissolution medium (Singhvi and Singh, 2011). According to British Pharmacopeia, Active Pharmaceutical Ingredient should be released from the tablet is not less than 70% of the stated amount within 45 minutes. Only one brand (M7 61.40%) failed to meet with BP limit while other brands passed the dissolution criteria. It could be due to defective formulation, compression pressure used, and binder effect (Akinleye et al., 2012). The dissolution of brands M3, M7, M12, & M15 were showed significant diferences compared to reference brand M2.

Among all quality parameters, uniformity of content, friability, and dissolution time were considered as official tests by British pharmacopeia. According to these official tests, out of 15 brands, nine brands (M2, M3, M4, M5, M10, M12, M13, M14, and M15) were within the pharmacopoeial limits. Since Metformin is a first-line drug used in diabetes treatment, the quality of Metformin is essential for its efficacy in controlling diseases. Treating with low-quality medicines could lead to therapeutic failure and progression of the disease. Special attention should be taken to imported medicines and ensure their quality before releasing to the market by relevant authorities.

IV. CONCLUSION

Among the tested brands of metformin hydrochloride, nine out of fifteen brands passed the all quality parametes according to British Pharmacopeia. Imported medicines should be strictly monitored for their quality.

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Relationship between Unexplained Infertility and Sedentary Lifestyle among Women in the Urban City of Colombo; Infertile Female vs. Fertile Female

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Abstract - Infertility is defined as the absence of conception after 12 months of regular, unprotected intercourse. The objective of this study was to identify the relationship between unexplained infertility and sedentary lifestyle behaviour among the young female population in the urban city of Colombo. A case-control study was conducted among 250 women (125-fertile group/125- infertile group) in the age group of 18 – 32, who were clinically diagnosed with infertility and fulfilled the inclusion criteria at Infertility clinics and Gynaecology wards at 3 hospitals in the Colombo district. A convenient sampling method was used to recruit cases and controls upon completion of clinical diagnosis by the Visiting Obstetrician and Gynaecologist. The study tools and measurement tools were an interview-administered female infertility questionnaire form, International Physical Activity Questionnaire (IPAQ), Body Mass Index (BMI), and Skin Fold Thickness (SFT). Significant positive associations ($P<0.05$) were explored between the obesity category and female infertility. There was a significant influence of over fat (30.4%) level measured using SFT for female infertility. A significant positive correlation ($P<0.01$) was emphasized between the low level of IPAQ score (36.4%) and female infertility. Women aged ≥28 years, sedentary occupations, and age at menarche were found to be associated with infertility ($P<0.01$). Sedentary lifestyle behaviour among women of reproductive age, living in the urban city of Colombo was found to be associated with female infertility.

Keywords: unexplained infertility, international physical activity questionnaire, BMI (Body Mass Index)

I. INTRODUCTION

Infertility is defined as the absence of conception after 12 months of regular, unprotected intercourse, (Larsen, 2005). Unexplained infertility is infertility that is idiopathic, meaning that the cause is unknown even after a thorough examination. Infertility affects 15 percent of reproductive-age couples worldwide. A 2006-2010 National Family Growth Survey study reported that in the United States, 6% of married females aged 15-44 years are infertile, and 12% have impaired fecundity, described as the inability to conceive and bring a baby to term. And also, in China, the prevalence of infertility was 25 percent among reproductive-age couples. Some research has shown that female infertility prevalence is comparatively higher than male infertility prevalence. (Sun et al., 2019) Any waking activity, such as sitting or leaning, with an energy expenditure of 1.5 metabolic equivalent task (MET) or less is considered as sedentary behaviour. Sedentary LifeStyle Behaviour causes infertility in women. Female infertility can be an outcome old enough, physical issues, hormonal issues, and way of life or natural components. Any condition that interferes with one or more of these factors will cause infertility. The relative prevalence of the aetiologies of infertility in a couple was defined by Burney et al in 2007. They revealed percentages are Male factor 25-40%, Female factor 45-50%, Both10%, Unexplained 10%. The prevalence of the causes of female infertility are Ovulatory dysfunction 30-40%, Tubal/peritoneal 30-40%, Unexplained10-15%, Miscellaneous10-15%. The couple were never able to conceive in primary infertility and there is trouble in conceiving after once conceived in secondary

infertility. Our research mainly focuses on infertility and association of sedentary lifestyle among adult females in Sri Lanka. There are several studies done under sedentary lifestyle and infertility.

Gudmundsdottir, S. L., Flanders, W. D., & Augestad, L. B. (2009). Physical activity and fertility in women: doi:10.1093/humrep/dep337, Homan GF1, Davies M, Norman R.et al, Influence of lifestyle factors on fertility of the general population and those receiving fertility: a review. Kelly R. Evenson et al., (2016) conducted a study on the "Complex Relationship between Physical Activity and Infertility." They also consider a sedentary lifestyle as a potentially important, unexplored, volatile behavior that may be associated with infertility. In addition, they found that various types of physical activity (e.g., resting, caring for home, caring for a child or adult, transportation, work) or physical exercise (e.g. aerobic exercise, strengthening, mild effects) are differently related to infertility.

To attain our objective on how well the females are aware about their fertility difficulties, we will provide a standard questionnaire to females who are at Castle street hospital for women at Colombo, De Soysa Maternity Hospital for women at Colombo and Colombo South Teaching Hospital, Kalubowila.

The main objective of this study was to identify the association between unexplained infertility and sedentary lifestyle behavior among young female population in urban city of Colombo to assess and evaluate the fertility state of the case study and the control study population and to identify the association between unexplained infertility and sedentary lifestyle behavior among women in the urban city of Colombo.

One in four couples in the developing countries have been affected by infertility and 180 million couples are affected by either primary or secondary infertility in developing countries (WHO). The level of infertility care differs from Country to country such as level of education, economic and political situation of the country, reproductive health care, culture, also depends on number of hospitals and their quality, the available equipment and facilities and facilities to perform surgeries in complications, the level of maternity care (Ombelet et al., 2011).

II. METHODOLOGY

A case-control study was conducted among 250 women (125-fertile group/125- infertile group) in the age group of 18 – 32 years, infertile women who were clinically diagnosed as infertility and fulfilled the inclusion criteria at Infertility clinics and Gynecology wards and 1st trimester pregnant mothers who fulfilled the inclusion criteria of the control study as fertile women at 3 hospitals in Colombo district ; De Zoysa Maternity Hospital, Colombo, Castle Street Hospital for women (Teaching) and Colombo South Teaching Hospital, Kalubowila. We got the participant characteristics for both case study and control study populations. Inclusion criteria for case study population is only female subjects, age group between 18-32 years, females who will give the consent only and females who not diagnosed a proper medical reason for infertility. Exclusion criteria for case study population is women diagnose with PCOS and other medical reasons, females with Family planning, females above age 32 years, females who will not give the consent, Illiterate females, females with mental illness and couples with infertility due to male partner's medical reasons. Inclusion criteria for control study population is only female subjects, age group between 18-32 years, females who will give the consent only and females with pregnancy positive. Exclusion criteria for control study population is females above age 32 years, females who will not give the consent, females who cannot read or write and females with mental illness. For the study, our sample size would be 125 infertile women as a control group and 125 fertile women as a case group who fulfill the inclusion and exclusion criteria. Since we do not have statistics from the prevalence of infertility among women in Sri Lanka, we referred to the journal article on, Safarzadeh, A., Ansari, H. and Arbabisarjou, A., 2016. Comparison the LifeStyle between Secondary Infertile and Fertile Women: Considering Potential Socio-Demographic and Reproductive Confounding Factors in A Case-Control Study. And we consider the same sample size for our study.

The patient who has fulfilled the inclusion criteria and been referred by the consultant will be included in the study. A consent form and the information sheet containing all the necessary information regarding the research will be provided to the participants in all three languages Sinhala, Tamil, and English. The information sheet contains the necessary details about the research, aim of the research, methods of the research, and ethical issues which will be protected throughout the research. Data collection will be performed under the supervision of the consultants, chief physiotherapist,

and the chief nutritionist in the hospital. Convenient sampling method was practiced to recruit cases/ and controls upon completion of clinical diagnosis by Visiting Obstetrician and Gynecologist. Demographic details and medical history of the women was collected in an interview-administered female infertility questionnaire form. To evaluate activity level, International Physical Activity Questionnaire (IPAQ) short form was used. IPAQ is validated in Sri Lanka by Dr. Charukshi Arambepola. For that granted permission from Dr. Charukshi Arambepola prior to use the IPAQ questionnaire. Height and weight were measured in all participants according to the standard methods then Body Mass Index (BMI) was calculated according to the standard equation and Skin Fold Thickness (SFT) was measured by using skin fold caliper. Data were statistically analyzed using SPSS software version 23.0 using Pearson Chi-Square test. Before conducting the data, collection and performing the test procedures on our study sample, a pre testing session was carried out to overcome the bias while performing tests and collecting data. This session was conducted using a randomly selected 10 infertile patients, from Colombo South Hospital, Kalubowila under the supervision of expert in the field of obstetrics and gynaecology. This procedure was mainly aimed to improve the accuracy and the quality of the study by familiarizing the researchers regarding the performance of the measures; BMI and SFT and Infertility Interviewer administered questionnaire and IPAQ (short form) we used it in categorical method. This helped the Investigators to overcome the possible inconveniences and bias that could arise during obtaining data from patients and throughout the study period.

III. DISCUSSION AND ANALYSIS

A. Socio – demographic characteristics of study population (n=250)

The study included 125 infertile females and 125 fertile females with the age of 18-32 years old. Sedentary life style among female groups based on age, occupation, ethnicity and religion.

As per age, majority of respondents (both infertile and fertile women) were in 28-32 years' age category. Majority of infertile population were sedentary occupation category (47.6%). Most of the participants are Sinhalese (Case- 46% and Control – 40.4%) with a majority of Buddhist. (Case- 40.4% and Control – 36.4%)

Table 01: Association of socio demographic characteristics with female regarding fertility state (n=250)

Characteristics	Category	Case - Infertile		Control - Fertile		
		Frequency	Percentage (%)	Frequency	Percentage (%)	P Value
Age	18 – 22 years	6	2.4	12	4.8	0.0486
	23 – 27 years	49	19.6	47	18.8	
	28 – 32 years	70	28.0	66	26.4	
Ethnicity	Sinhala	115	46	101	40.4	0.029
	Tamil	5	2	9	3.6	
	Muslim	5	2	15	6	
Religion	Buddhist	101	40.4	91	36.4	0.051
	Catholic	14	5.6	10	4	
	Hindu	5	2	8	3.2	
	Islam	5	2	16	6.4	
Occupation	Sedentary	119	47.6	45	18.0	0.000
	Non sedentary	6	2.4	80	32.0	

Below Table 2 demonstrate the frequency and percentages of case and control population's independent variables of the 250 cases which are including infertility interviewer administered questionnaire. Here we have mentioned independent variables: Age at 1st menarche, Interval between periods, regular or irregularity of menstrual cycle, contraceptive consumption and history of infertility.

When we consider about an age at 1st menarche according to the results among 125 of case study or infertility population, No one in the < 8 year category of age at 1st menarche, 50%(125) of infertility females are in the 8-16 years category of age at 1st menarche, and no one in the >16 years category of age at 1st menarche. And when we consider about the control study or fertile female population among 125, 1.6%(4) fertile females are in the < 8 year category of age at 1st menarche, 48.4%(121) of fertility females are in the 8-16 years category of age at 1st menarche, and no one of fertile females in the >16 years category of age at 1st menarche.

When we consider about an interval between periods, according to the results among 125 of case study or infertility population, No one in the less than 24 days category and 24-26 days category,

30%(75) of infertility females are in the 27-29 dayscategory, 13.2%(33) are in the 30-32 days category, and 6.8%(17) are in the more than 32 days category. And when we consider about the control study or fertile female population among 125, No one in the less than 24 day category and 2.4%(6) of fertile females are in 24-26 days category, 40%(100) of fertile females are in the 27-29 days category, 4.8%(12) are in the 30-32 days category, and 2.8%(7) are in the more than 32 days category.

When we consider about regularity of menstrual cycle, according to the results among 125 of case study or infertility population, 26% (65) of infertile females are in irregular menstrual cycle category and 24% (60) of infertile females are in regular menstrual cycle category. And when we consider about the control study or fertile female population among 125, 8.4% (21) of infertile females are in regular menstrual cycle category and 41.6% (104) of infertile females are in regular menstrual cycle category.

When we consider about contraceptive consumption, according to the results among 250 of case and control population no one use combined hormonal contraception, Vasectomy, IUCD – Intrauterine Contraceptive Device and Depo - Provera. According to the results among 125 of case study or infertility population, 35.6% (89) of infertile females are not use any contraceptive method, 5.2% (13) of infertile females are using fertility awareness-based method and 9.2% (23) of infertile females are using male condom. According to the results among 125 of control or fertile population, 46% (115) of fertile females are not use any contraceptive method, 1.2% (3) of fertile females are using fertility awareness-based method and 2.8% (7) of infertile females are using male condom.

All those results are described below Table 02.

Table 02: Association of Fertility state of study population (n=250)

Independent variables	Categories	Cases- Infertile		Controls - Fertile		P
		Frequency	Percentage	Frequency	Percentage	
Age at 1st menarche	<8 years	0	0	4	1.6	0.044
	8-16 years	125	50	121	48.4	
	>16 years	0	0	0	0	
Interval between periods	Less than 24 days	0	0	0	0	0.000
	24-26 days	0	0	6	2.4	
	27-29 days	75	30	100	40	
	30-32 days	33	13.2	12	4.8	
	More than 32 days	17	6.8	7	2.8	
Menstrual cycle	Irregular	65	26	21	8.4	0.000
	Regular	60	24	104	41.6	
Contraceptive consumption	1. No	89	35.6	115	46	0.000
	2.Fertility awareness-based method	13	5.2	3	1.2	
	3. Male condom	23	9.2	7	2.8	
	4.Combined hormonal contraception	0	0	0	0	
	5. Vasectomy	0	0	0	0	
	6. IUCD – Intrauterine Contraceptive Device	0	0	0	0	
	7.Depo - Provera	0	0	0	0	
	8. Others					

B. Physical characteristics of study population (n=250)

BMI- Body Mass Index and SFT- Skin Folder Thickness were analyzed under the descriptive statistics of physical characteristics of the study sample. (n=250)

Descriptive statistics of mean values for BMI- Body Mass Index

Below table is mentioned the BMI classification according to the Sri Lankan cut off values which have modified by the Sri Lankan guideline committee. (Somasundaram et ai. 2014).

Table 03. BMI classification according to the Sri Lankan cut off values which have modified by the Sri Lankan guideline committee

Nutritional status	Sri Lankan BMI cut off levels
Underweight	<18.5
Normal	18.5-22.9
Overweight	23.0-24.9
Obesity	Above 25

Mean of BMI of Infertility patients is 30.57 (SD – 3.05) and the mean of BMI of Fertility females - 23.87 (SD- 4.583). Mean value of the BMI of the case study population (Infertility females) is 30.57(SD=3.05). So that most of the infertile females are in obese category. Mean value of the BMI of the control study population (Fertility females) is 23.87(SD=4.583). So that most of the fertile females are in obese category.

Descriptive statistics of mean values for Skin Folder Thickness (SFT)

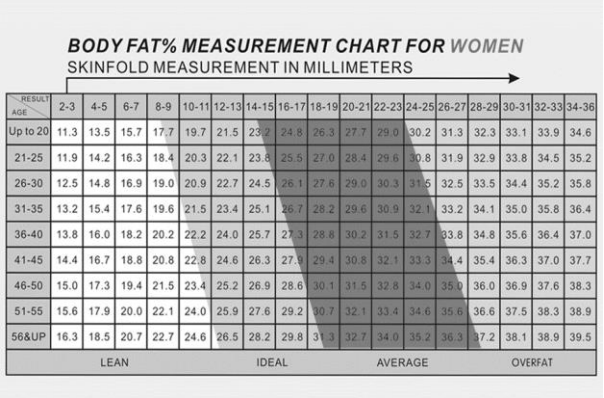

Figure 1. Skin Folder Measurements Scale

Source: Amazon.com

Mean value of the infertile or case population is 2.55. (SD=0.602) Among 125 of case study population high frequency of infertile females are distributed in overfat range and mean value of the fertile or control population is 1.62. (SD=0.982) Among 125 of case study population high frequency of fertile females are distributed in average range.

Descriptive statistics of IPAQ - International Physical Activity Questionnaire score (Short form)

Then we have categorized IPAQ results using categorical score given below Table 04.

Table 04. IPAQ – Categorical Score

Category	Intensity
Category 1	**Low**
Category 2	**Moderate**
Category 3	**High**

Analysis of IPAQ score and infertility relation, mean value of the IPAQ score of the case study population is 1.29(SD=0.489). Among 125 of case study population high frequency of females are distributed in low IPAQ score. Mean value of the IPAQ score of the case study population is 1.83(SD=0.416). Among 125 of case study population high frequency of females are distributed in moderate IPAQ score.

Finally, we demonstrate the IPAQ score levels of case study and control study population. According to that among 125 of infertility population 36.4% of infertility females are in the low level of IPAQ score, 12.8% infertility females are in the moderate level of IPAQ score and the 0.8% infertility females are in the high level of IPAQ score. So that there is a significant influence of low level of IPAQ score for infertility in females. And when we consider about the control study or fertile female population among 125 of fertile female population 9.2%of fertile females are in the low level of IPAQ score, 40.0% fertile females are in the moderate level of IPAQ score and the 0.8% fertile females are in the high level of IPAQ score. So that there is a high number of fertile females are in moderate level of IPAQ score.

Pearson correlation test was performed statistically to find out the relationship between BMI and infertility, SFT and infertility, and IPAQ score and infertility.

Table 05. Pearson correlation test to find out the relationship between BMI and infertility, SFT and infertility, and IPAQ score and infertility

Variable	P Value	Confidence Interval
BMI and Infertility	0.011	95%
SFT and Infertility	0.000	95%
IPAQ score and infertility	0.000	95%

BMI, SFT and IPAQ had significantly associated with infertility ($P < 0.05$). Significant positive correlations ($P<0.05$) were emphasized between obesity category of BMI and infertility in females. There was significant influence overfat (30.4%) category of SFT for infertile females. Significant positive correlations ($P<0.01$) were emphasized between low level of IPAQ score (36.4%) and infertility. Age at 1st menarche, interval between periods, regularity/ irregularity of the menstrual cycle, contraceptive consumption family history of infertility had significantly associated with infertility. ($P < 0.05$)

C. Relationship between sedentary lifestyle behavior and unexplained infertility in women.

According to the IPAQ categorical score sample population we categorized as a sedentary and non-sedentary as below Table.05.

Table 05.

Life style behavior according to the IPAQ scores	Sample Population					
	Infertile - Case		Fertile – Control		Total	
	Count	%	Count	%	Count	%
Sedentary	91	79.8%	23	20.2%	114	100.0%
Non-sedentary	34	25.0%	102	75.0%	136	100.0%
Total	125	50.0%	125	50%	250	100.0%

Then calculate the odd ratio. We can use an "odds ratio" to determine if there is a relationship between the infertile women vs sedentary life style behavior and the fertile women vs sedentary life style behavior. Odd ratio of the study population is 11.87. [log (11.87) =1.07] The odd ratio and the log (odds ratio) are like R-squared; they indicate a relationship between the infertility and sedentary life style behavior. In here odd ratio is 11.87. It's a larger value. That mean the sedentary lifestyle behavior is a good predictor of unexplained infertility in women.

Pearson Chi-Square test was performed statistically to find out the relationship between sedentary life style behavior and infertility in women. In this case, p value is 0.000. (Significance level was defined as $p < 0.05$). So that p value is Since $p< .05$, there is a significant relationship and further need to investigate. According to the results of this study sedentary life style behavior was a significantly associated with infertility in women. (P=0.000, 95%CI – Confidence interval)

IV. CONCLUSION

The study concluded that significant positive relationships were emphasized between infertility and sedentary lifestyle behaviour including activity level, the study conducted a sample of 250 subjects (125-Infertile females and 125 – Fertile females) based on the inclusion and exclusion criteria. Significant positive Association ($P<0.05$) were explored between the obesity category and female infertility. There was a significant influence of over fat (30.4%) level measured using SFT for female infertility. A Highly significant positive correlation ($P<0.01$) were emphasized between low level of IPAQ score (36.4%) and female infertility. Women aged ≥28 years, sedentary occupations were found to be associated with infertility ($P<0.01$). The odd ratio and the log (odds ratio) are like R-squared; they indicate a relationship between the infertility and sedentary life style behavior. In here odd ratio is 11.87. Though it's a larger value, that mean the sedentary lifestyle behavior is a good predictor of unexplained infertility in women in urban city of Colombo. A highly significant positive relationship was determined between unexplained infertility and sedentary life style behavior. ($P<0.01$) Finally, we determined our primary objective which is there is a relationship between unexplained infertility and sedentary life style behaviour among women in urban city of Colombo.

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Factors Associated with Early Post-Partum Haemorrhage among Mothers during Postpartum Period at Castle Street Hospital for Women in Colombo, Sri Lanka

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Abstract- Early Post-Partum Hemorrhage (early PPH) is the leading cause of maternal mortality worldwide, where nearly one-quarter of all maternal deaths in most low-income countries. The study aimed to assess the factors associated with early postpartum hemorrhage among mothers during the postpartum period at Castle Street Hospital for Women. A retrospective Cohort Study was conducted among a sample of 300 mothers in the post-partum period to identify and evaluate the risk factors for early PPH at Castle Street Hospital for Women in Sri Lanka. Data was collected using a systematic sampling method and extracted from the delivery records during the 2017 and 2018 years into a data extraction sheet. It consisted of, Part A- Demographic data, Part B - Current antenatal and obstetric history, Part C - Past obstetric history, Part D - Past medical and surgical history, Part E - History of current delivery. Data were analyzed using SPSS 23 version in percentages and Chi squire. The mean age of the sample was 30.39±5.17 years. The majority, 39.9% of mothers, were educated up to secondary level and 33% of mothers were "O positive" in the blood group. Among the sample anemia, diabetes, hypertension, heart disease, renal diseases, and hyperthyroidism were presented respectively 12.0%, 15.3%, 11.0%, 1.0%, 0.7%, and 4.3%. In conclusion, the identified risk factors for early PPH have shown a significant association with anemia, diabetes hypertension (p=0.001) and hyperthyroidism (p=0.009) conditions of the mothers' method of delivery (p=0.001), duration of labour in normal vaginal delivery (p=0.001), vaginal tears (p=0.001), retained placenta (0.001), and prostaglandin administration (p=0.001).

Keywords— risk factors, early postpartum haemorrhage

I. INTRODUCTION

Early Post-Partum Hemorrhage (PPH) one of the major health concerns in maternal and child health (Nyfløt et al., 2017) contribute to 6% of global prevalence (Ononge et al., 2016; Ngwenya, 2016). Also, acts as a leading cause for premature maternal motility with an estimate of 500,000 global deaths per year (Knight et al., 2009; Ononge et al., 2016). According to the American College of Obstetricians and Gynecologists (ACOG) practice bulletin, the estimated death rate is reported as one death per every four minutes and 140,000 deaths per year (Zelop, 2006; Dahlke et al., 2015). But some literature has reported 25% of annual global (Biguzzi et al., 2012; Driessen et al., 2011).

PPH is usually an unpredictable event (Zelop, 2006; Biguzzi et al., 2012); where both known (maternal and obstetric) and unknown risk factors are contributed (Nyfløt et al., 2017; Ngwenya, 2016). The incidence and mortality rate are high in lower-income countries compared to the developed countries (Ononge et al., 2016; Lu et al., 2005), and Driessen et al., 2011 is reported that PPH is the leading cause of maternal mortality in sub-Saharan Africa. Respectively, according to the conducted prospective cohort study in Uganda, is revealed that 9% of overall PPH incidence with 1.2% of severe PPH (Ononge et al., 2016). While Smith and Mousa, in 2007 are reporting 6.7 of severe PPH per 1,000 deliveries in the UK, Biguzzi et al., 2012 is reporting that the current incidence of PPH is increasing in developed countries also compared to its past. PPH incidence is high among nulliparous and multiparous women compare to the other parity

(Nulliparous incidence - 19% of PPH, 4.2% of severe PPH in the Netherlands) (Bais et al., 2004; Biguzzi et al., 2012; Sosa et al., 2009).

A single definition for PPH is not available and generally, it is defined as bleeding from the genital tract of 500 ml or more following the delivery (WHO,1990; Smith and Mousa, 2007). But the alternative definitions have developed after considering the volume of blood loss after delivery through the genital tract in different amounts. According to that, PPH is considered as loss of 500 ml of blood after vaginal delivery or 750 ml after the caesarian delivery (Australian definition) (Knight et al., 2009).

PPH is classified as primary PPH which presents within the first 24 hours and secondary PPH which is clinical presents between after the first 24 hours to 12 of the weeks of postpartum (Zelop, 2006). But the standard classification is available as international classification of disease, 9th revision, clinical modification (ICD-9-CM code classification).

The causes of PPH are multifactorial. The etiology of primary PPH has undergone four categories including uterine atony, tissues, trauma, and coagulation disorders (Zelop, 2006). The specific etiology for the secondary PPH; referred to as persistent or delayed PPH, is usually unknown and clinically presents with 1% -3% of pregnancies (Ngwenya, 2016; Zelop, 2006). Although exact etiology is unknown, secondary PPH has shown an association with the identified risk of uterine inversion, secondary sub involution of placental site, maternal infections, retained placental products and inherited coagulation defects (Zelop, 2006). Other than this classification, causes and risk factors can be classified as the individually affect and medical management related to the risk factors (Dahlke et al., 2015).

Also, Driessen et al., 2011 have identified three characteristic categories of risk factors of severe PPH including, (1) factors associated with the women and aspects of labor and delivery (primi and multiparas, previous PPH and cesarean delivery, labor induction by cervical ripening, prolonged labor, episiotomy, prophylactic uterotonics), (2) factors associated with the initial management of the PPH (delayed diagnosing, senior obstetric care delayed oxytocin administration and manual examination of the uterine cavity), and (3) organizational characteristics (being a non-teaching (non-university) public hospital and delivery unit, secondary level caring unit, annul the number of delivery in the unit and 24-hour availability of obstetrician and anesthesiologist) (Driessen et al., 2011; Kanchana, 2018). The epidural analgesia, non-delayed obstetric and anesthetic care had associated with a significant risk reduction of severe PPH. Also, it was revealed that 51% of severe PPH cases minimally present three of the identified risk factors (Driessen et al., 2011).

Maternal age (>35 or < 18 years), multiple pregnancies, (Bateman et al., 2010) gravida and parity (prim gravida, nulliparous and grand multiparty (Ononge et al., 2016), fetal macrosomia (>4 kg) body mass index (BMI)- (<25 or >35 kg/m^2), gestational age, pre-existing or current pregnancy-related overwhelming maternal disorders (hypertension, severe pre-eclampsia, HELLP syndrome, anemia and low platelet level, diabetes mellitus), unhealthy behaviors (smoking during pregnancy) (Kramer et al., 2011) previous antepartum hemorrhage, miscarriages and previous PPH incidences, uterine anomalies or uterine disorders (fibroma), previous surgery (caesarian or uterine surgeries), ethnicity (especially Asian and Hispanic ethnicity) and marital status have identified pre-pregnancy and current pregnancy related risk factors (Knight et al., 2009; Biguzzi et al., 2012; Zelop, 2006; Nyfløt et al., 2017; Bateman et al., 2010; Ngwenya, 2016; Kramer et al., 2013; Reyal et al., 2004; Sheiner et al., 2005; Wetta et al., 2013; Farine , 2015; Anderson, 2007 & Kanchana, 2018).

Furthermore, current pregnancy is in the identified risk of PPH with the assisted reproduction technologies, over distended uterus with poly-hydroaminosis or multiple gestations or macrosomia, Premature Rupture Of Membrane (PROM), placental abnormalities (abnormal placental attachment such as placenta previa accrete, increta, percreta, placental abruption), maternal infections (eg: chorionamnionitis, HIV), coagulation disorders and anticoagulant treatment during pregnancy (Zelop, 2006; Nyfløt et al., 2017; Bateman et al., 2010; Biguzzi et al., 2012; Ngwenya, 2016). It is reported that HIV positive patients are more likely to PPH compared to negative patients (Reyal et al., 2004).

The incidence and severity of PPH associated with the cesarean deliveries are high compared to the vaginal deliveries (Oyelese et al., 2007; Ononge et al., 2016; Bateman et al., 2010; Knight et al., 2009) and with the cesarean surgery the specific obstetric

management, care, and close monitoring need to be taken to minimize the complications (Nyfløt et al., 2017). The assessment of Early Warning Systems to obstetric practice (Modified Obstetric Early Warning Scoring System MOEWS) is important and correct hemodynamic assessment through MOEWS significantly reduces the severity of PPH (Knight et al., 2009).

The complications of PPH are included, organ failure (acute renal and respiratory failure), sepsis, hysterectomy, prolonged mechanical ventilation, and coagulopathy (Bateman et al., 2010). Furthermore, Bateman et al., 2010 are reported that PPH is relatively common in their study; highly associated with uterine atony, causes maternal mortality and morbidity.

In Sri Lanka, PPH accounted for 12.7% of maternal deaths in 2008. Therefore, identifying Factors associated with early post-partum hemorrhage is important its proper management.

II. METHODOLOGY

A retrospective cohort study was conducted for six months of duration at Castle Street Hospital for Women (CSWH) in Colombo, Sri Lanka to assess the factors associated with early Post-Partum Haemorrhage. The study sample included 300 mothers who have undergone delivery during the years 2017 and 2018. Data was extracted from the preserved delivery records in the Bed Head Ticket (BHT). The systematic sampling method was used to achieve sample size and a pre-test was performed before the main study. The data extraction sheet consisted of, Part A- Demographic data, Part B - Current antenatal and obstetric history, Part C - Past obstetric history, Part D - Past medical and surgical history, Part E - History of the current delivery. Data was analyzed using SPSS 23 version using descriptive and interferential statistics. The ethical approval was obtained from Ethics Review Committee at KIU (KIU/ERC/20/04) and hospital permissions were obtained from Director and Chief Nursing Officer at Castle Street Hospital for Women, Sri Lanka.

III. DISCUSSION AND ANALYSIS

Out of 300 participant's majority was Sinhalese (79.7%) and others while Muslim, Tamil 7% (21) and Burger respectively represent 12.3%, 7% and 1%. Point seven percentage (0.7%) was unmarried, 0.3% are divorced. Even though 62.7% were unemployed and 39.7% of post-natal mothers have been educated up to A/L (Figure 01).

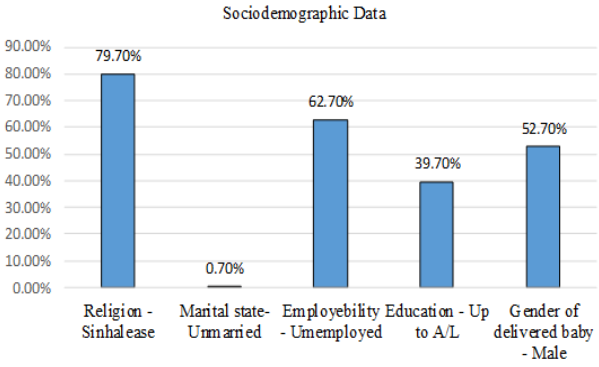

Figure 1: Sociodemographic Data

The majority of participants had delivered baby boys (52.7%) while only 2% of them had multiple pregnancies. Labor method included, normal vagina (17.3%), instrumental vacuum (7.3%) caesarean (62.3%) and forceps (13.0%) while duration of labor included, 0-5 hours (21.9%), 5-10 hours (54.7%) and 10-15 hours (23.4%). In the study sample, 8% of first-degree genital tract trauma and 2% second-degree genital tract trauma were reported (Figure 2).

The majority of early postpartum hemorrhagic mothers (33%) had "O positive" blood group and retained placenta was seen among 26% of them (Figure 3). The anemia (12%), diabetes mellites (DM) (15.3%), hypertension (11%), hyperthyroidism (4.3%), perineal tears (10%), prolong labor duration (23.40%), retained placenta (26.0%), and labor induction with prostaglandin (7%) was identified as associated risk factors for early PPH (Figure 2).

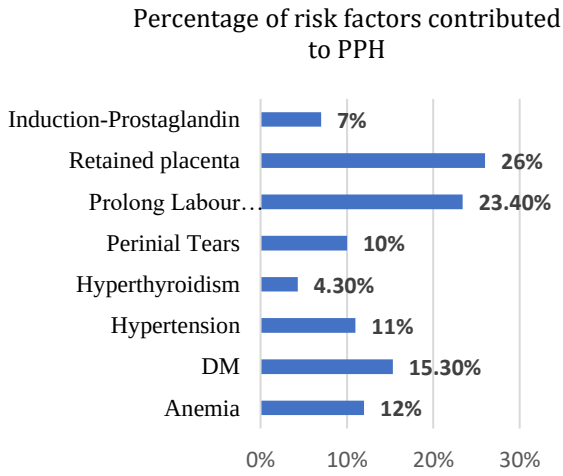

Figure 2: Percentage of risk factors contributed to PPH

In this research study identified risk factors for PPH were shown significant association between anemia, diabetes hypertension (p=0.001) and hyperthyroidism (p=0.009) conditions of the mothers', method of delivery (p=0.001), duration of labour in normal vaginal delivery (p=0.001), vaginal tears (p=0.001), retained placenta (0.001) and prostaglandin administration (p=0.001) (Table 01).

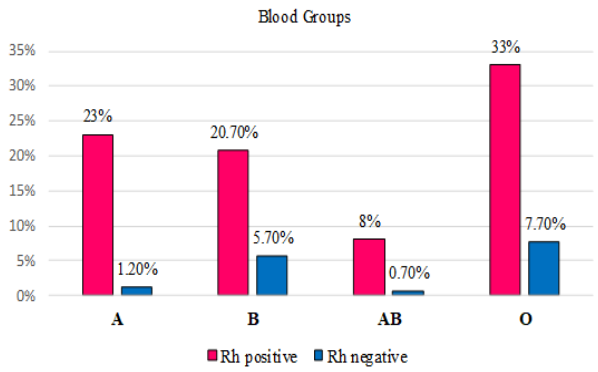

Figure 3: Blood Group Percentages

Table 1: Association between the identified risk factors and PPH

Parameter	Chi value	P value
Anemia	20.455	.001
Diabetes	27.165	.001
Hyperthyroidism	6.794	.009
Method of delivery	18.511	.001
Duration of labour in normal vaginal delivery	40.678	.001
Vaginal tears	16.667	.001
Retained placenta	52.703	.001
Prostaglandin administration	11.290	.001

CI - 95%, P <0.05

PPH is a leading cause of global maternal morbidity and mortality and (Nyfløt et al., 2017) contribute to 4% - 6% of global prevalence (Ononge et al., 2016; Nyfløt et al., 2017). Incidence and mortality rate related to PPH is high in lower-income countries compared to the developed countries (Ononge et al., 2016; Driessen et al., 2011; Kramer et al., 2011).

According to Bais et al., 2004, 61% of the severe PPH are reported among nulliparous women and Biguzzi et al. reported the high PPH incidence among nulliparous women to compare to the other party. The incidence is high with the cesarean than normal vaginal delivery (Driessen et al., 2011).

Due to the PPH being a global health concern, many studies had done to identify the risk factors, prevention, and management (Ononge et al., 2016; Dahlke et al., 2015; Kramer et al., 2013). The current study also conducted as a retrospective cohort study focusing to identify risk factors affecting the early PPH.

According to the available literature, even though definitions are varied generally, loss of > 500 ml blood after the following delivery is considered as PPH (Bais et al., 2004; Smith and Mousa, 2007). A loss of > 500 ml blood or more as standard PPH and exceeding amount of 1000 ml or more as a severe PPH and loss of > 500 ml blood after following vaginal and >1000 ml blood following the caesarian (Zelop, 2006; Bais et al., 2004; Bateman et al., 2010; Dahlke et al., 2015; Driessen et al., 2011; Biguzzi et al., 2012; Ononge et al., 2016; Bais et al., 2004; Dahlke et al., 2015).

Many studies have reported the risk factors for PPH as anemia, diabetes, hypertension, and hyperthyroidism, maternal age, multiple pregnancies, gravida and parity, fetal macrosomia, BMI, previous antepartum hemorrhage and previous PPH incidences, uterine anomalies or uterine disorders, previous caesarian, polyhydroaminosis, PROM, placental abnormalities, maternal infections, coagulation disorders and anticoagulant treatment (Knight et al., 2009; Biguzzi et al., 2012; Zelop, 2006; Nyfløt et al., 2017; Bateman et al., 2010; Ngwenya, 2016; Ononge et al., 2016; Sheiner et al., 2005).

The current study identified that antepartum risk factors were associated with PPH (P < 0.05) and it included anemia, hypertension, hyperthyroidism, perineal tears, prolong labor duration, and labor induction. Similar findings are given by the many of the studies and they were included the prolonged or obstructed labor, maternal fever and infections, obstetric management including labor induction, labor augmentation with oxytocin, using epidural analgesia, malposition, deep engagement, mode of delivery (especially caesarian and assisted deliveries with forceps or vacuum extractor), genital tract trauma, PROM and blood disorders (Nyfløt et al.,

2017; Bateman et al., 2010; Dahlke et al., 2015; Knight et al., 2009).

Many studies have shown the association between the identified risk factors with the PPH. The current study also, all identified risk factors anemia, diabetes hypertension, hyperthyroidism, vaginal tears, retained placenta, and prostaglandin administration; method of delivery and labor duration were significantly associated with the PPH. Although, labour induction is highly associated with the PPH still the usage of tocolytic agents such as oxytocin and prostaglandin (misoprostol) are common. The incidence of PPH is reported at a higher rate by using misoprostol versus oxytocin (Ononge et al., 2016).

As the limitation of the current study women who delivered by cesarean section had measured the blood volume by visual can be presented since visual estimation has a higher probability to underestimate the true volume of blood loss.

IV. CONCLUSION

Many factors are associated with PPH. While concerning the stage of labor pre-pregnancy is at risk of pre-existing maternal disorders such as hypertension, anemia, diabetes, and hyperthyroidism. Prolong duration of labor. The identified risk factors for PPH were retained placenta, tears, perineal teas, prostaglandin administration, and duration of vaginal labor interfered with the intrapartum and postpartum period for PPH.

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Evaluation of Performance Characteristics of an In-house Glucose Reagent Compared to Analyzer Specific Commercial Glucose Reagent

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Abstract - Blood glucose level is the most frequently analyzed parameter in a routine clinical laboratory in order to assess diabetes mellitus. Currently, commercial reagent kits with high costs are used for this test. However, the same reagent can be prepared in the laboratory at a lower cost. The aim of this study was to examine the performance of an in-house reagent method under standard laboratory conditions with the analyzer specific commercial glucose reagent. An evaluation study was carried out at the Clinical Pathology Laboratory, Teaching Hospital, Karapitiya using 200 randomly selected retained blood samples. Glucose values were determined by in-house glucose reagent and commercial glucose reagent. Correlation and the agreement between the two methods were determined. Accuracy, sensitivity, specificity, precision, and stability was checked for the in-house method. Daily IQC and monthly EQA samples were run to assure precision and accuracy. The results were significantly correlated (r=0.9993; p=0.001), and the two methods indicated a good agreement with a positive bias of 0.835±0.488 mg/dL in Bland Altman analysis. There was a good agreement between 0-300 mg/dL. At concentrations above 300 mg/dL, a tendency towards increasing scatter was observed, which could be due to the low number of sample size in this range. Accuracy, sensitivity, and specificity were 96.5%, 96.15% and 97.14% respectively. The in-house method was linear up to 1000mg/dL. An intra-assay precision (CV) of 6.88 and 2.38% and an inter -assay precision of 2.21 and 3.34% were obtained for normal and high levels of glucose respectively. The reagent was stable for a period of three months at 2-8˚C.The in-house glucose reagent is more cost-effective and possesses similar performance characteristics and good stability, compared to the analyzer specific glucose reagent. Thus, it can be adopted for analysis of plasma glucose in routine laboratory checkups.

Keywords: glucose, performance characteristics, correlation coefficient

I. INTRODUCTION

Glucose is the primary source of energy for the body. Mainly, the body obtains glucose through the digestion of sugar and starch in carbohydrates, in the fed state. In the fasting state, gluconeogenesis and glycogenolysis maintain glucose concentration. Glucose is vital for life and interacts with the digestive and endocrine systems. Due to this, it is imperative to maintain glucose level within the normal range under physiological condition which would otherwise leads to hyperglycemia or hypoglycemia. (Mallick and Ahsan, 2017)

For identifying these conditions, plasma glucose measurement is used. Commonly, it is widely measured for the diagnosis and management of diabetes mellitus. (Mallick and Ahsan, 2017)

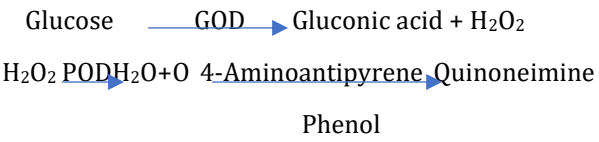
Diabetes mellitus is a chronic disease caused by inherited and/or acquired deficiency in production of insulin by the pancreas, or by the ineffectiveness of the insulin produced. Good control of blood glucose levels in diabetics helps to prevent or delay the development of complications which may lead to premature disability or death from blindness, kidney failure, coronary thrombosis, stroke, bacterial and fungal infections. (Buzanovskii, 2015)

A. Methods of glucose measurement

Enzyme assays commonly used for this in vitro diagnosis are Glucose oxidase method (GOD/POD method), Hexokinase method and Glucose dehydrogenase method (Dohnal et al., 2010)

Based on the reagent stability and accuracy, glucose oxidase method is considered as the most commonly used method for plasma glucose measurement.(Mallick and Ahsan, 2017)

B.Principle of the Glucose Oxidase Method



In this reaction, glucose present in plasma is oxidized by glucose oxidase to gluconic acid with liberation of hydrogen peroxide. Hydrogen peroxide is converted to water and molecular oxygen by peroxidase. In the presence of 4- aminoantipyrene together with phenol and molecular oxygen a pink color quinoneimine is formed which is detected by measuring absorbance at 505 nm at 37°C.(Duxbury, 2004)

Most of the laboratories use commercial glucose reagent kits with traceability to international reference material for plasma glucose measurement. They are quite expensive. However, preparation of in-house glucose reagent with row materials is very convenient and cost- effective. (Zafar and Syed, 1992) When a large number of samples need to be performed, properly validated in-house reagents can be prepared and used in clinical laboratories for analytical and diagnostic purposes. The composition of in-house reagents may slightly vary from laboratory to laboratory depending on the circumstances. But, results they produced should fall within a clinically acceptable range.

The recommended formula as per the Standard Operating Procedure (SOP) in manual published by Medical Research Institute (MRI), Colombo for preparation of in – house glucose reagent (100 mL) is as follows. This is actually defined for manual method of glucose estimation.

$Na_2HPO_4.2H_2O$	1.295 g
KH_2PO_4	0. 495 g
NaN_3	0. 05 g
4-Aminophenazone	16 mg
Glucose oxidase	1800 units
Peroxidase	100 units
Phenol	105 mg
Tween 20	50 µL

Formula designed to make glucose reagent to be used on the automated analyser is given below.

Na_2HPO_4	1.25 g
KH_2PO_4	0.53 g
Glucose oxidase	2 mg
Peroxidase	2 mg
NaN_3	0.1g
4-Aminoantipyrene	15 mg
Phenol	0.11 g
Distilled water	100 mL

In this reagent, Na_2HPO_4 and KH_2PO_4 are used as buffering agents. NaN_3 is used for chemical preservation.

There are significant differences in reagent composition between these two formulas. MRI reagent is stable for about 1 month at 2-8°C whereas there stability data for the modified procedure is not checked.

The same analytical settings used on the fully automated biochemistry analyzer for commercial glucose reagents are used for in-house glucose reagent.

In this study, the above in- house glucose reagent will be compared with the commercial glucose reagent (mention the method) as the reference method or the gold standard method.

II. METHODOLOGY

A. Study design and settings

This was an evaluation study performed at Chemical Pathology Laboratory, Teaching Hospital, Karapitiya, Sri Lanka and at students' laboratory of Medical Laboratory Science department, Faculty of Allied Health Sciences, Galle, Sri Lanka. Ethical approval was obtained from the Ethics Review Committee of the Faculty of Allied Health Sciences, University of Ruhuna, Galle.

B. Study population and sample size

200 retained samples which were received to Chemical Pathology Laboratory, Teaching Hospital, Karapitiya for fasting plasma glucose measurement were used for the study, the samples were analysed within 6 hours of collection.

C. Procedure

In- house glucose reagent (500 ml) was prepared by modifying the formula developed by MRI (Medical Research Institute) stated below.

Na_2HPO_4	6.25 g
KH_2PO_4	2.65 g

Glucose oxidase	10 mg
Peroxidase	10 mg
NaN_3	0.5 g
4-Aminoantipyrene	75 mg
Phenol	0.55g
Distilled water	500mL

The fully automated biochemistry analyzer (Mindray BS-300) in Chemical Pathology Laboratory, Teaching Hospital, Karapitiya, Sri Lanka was programmed for both in-house glucose reagent and commercial glucose reagent. It was simultaneously loaded with both reagents and calibrated for both methods with the same commercial multi-calibrator from Mindray. 200 Left over samples were analyzed using in-house glucose reagent and the commercial glucose reagent in fully automated analyzer at Chemical Pathology Laboratory.

Two levels of commercial, lyophilized, assayed IQC materials were run with each batch to assure the stability and the precision of the assays. Monthly EQA samples were run to assure the accuracy of the test results.

Standard stock solution of glucose was prepared using anhydrous glucose (1000 mg/dL). An independent dilution series was prepared with 10 standards using the standard stock solution (20, 50, 100, 200, 300, 400, 500, 600, 800, 1000 mg/dL). Glucose assay was performed with each glucose standard using in-house glucose reagent and commercial glucose reagent. Calibration curves were generated separately. Linearity of the two methods were determined.

Two pools of samples were prepared and aliquoted into 20 tubes respectively in normal and pathological ranges. Glucose levels were measured using in-house reagent. Mean, standard deviation and co-efficient of variation were calculated to get the intra assay precision within batch. To obtain the inter assay precision, IQC results were obtained in 20 consecutive days.

Sensitivity, specificity and accuracy of the in-house method were checked compared to the commercial glucose reagent as the reference method.

Stability of the in-house glucose reagent was checked by assessing the performance of the in-house reagent stored at 2-8 °C, using freshly prepared QC materials over a period of three months.

Data was analyzed using SPSS version 20.0 and Microsoft Excel 2013. Paired t-test was used to calculate the significance of the mean. P value less than 0.05 was considered significant. Pearson Correlation coefficient was determined to show the correlation between two methods. Bland Altman plot was generated to evaluate the agreement of the two methods.

III. DISCUSSION AND ANALYSIS

A. Comparison of plasma glucose measurements

Total of 200 blood samples were analyzed by both in-house and commercial glucose reagents. The statistical parameters calculated for both the methods are summarized in the Table1.

Table 1. General characteristics of the two methods of glucose values of patients at Teaching Hospital, Karapitiya, Sri Lanka

Parameters	In-house Method (mg/dL)	Commercial Method (mg/dL)
Minimum	43	44
Maximum	478	454
Mean	142.28	141.44
Standard deviation (SD)	62.066	59.383
Coefficient variance (CV)	4.389	4.199

The measurements of in-house reagent showed slightly higher glucose levels as compared to the commercial reagent.

Based on the glucose concentrations obtained by both methods, the results were divided into 3 groups as follows in order to find whether there were any statistically significance in between them.

Group 1: Plasma glucose concentration below 60 mg/dL

Group 2: Plasma glucose concentration between 60 to 300 mg/dL

Group 3: Plasma glucose concentration above 300 mg/dL

The mean glucose concentrations and significance values determined by both methods are summarized in Table 2.

Table 2. Table comparing the mean glucose concentrations by both methods

	Mean plasma glucose concentration		**Significance (P value)**
	In-house method (mg/dL)	**Commercial method (mg/dL)**	
All the patients (n=200)	142.28	141.44	0.001
Group 1 (n=3)	51.5	55.0	0.395
Group 2 (n=192)	136.88	136.34	0.05
Group 3 (n=5)	386.8	373.0	0.007

The measurements of in-house reagent showed slightly higher glucose levels as compared to the commercial reagent. It was statistically significant.

Although the in-house reagent showed a lower glucose concentration in patients with glucose levels below 60 mg/dL and slightly higher concentration was observed in patients with glucose concentration 60-300 mg/dL, these differences were not statistically significant. The in-house reagent showed a higher glucose concentration compared to the commercial reagent in patients with glucose levels above 300 mg/dL, which was statistically significant. This contributed to the overall statistical significance in above table 1. This could be due to the small sample size in these groups 1 and 3 (n=3 and n=5).

Pearson correlation coefficient analysis showed very good, positive correlation between the two methods (Figure 1).

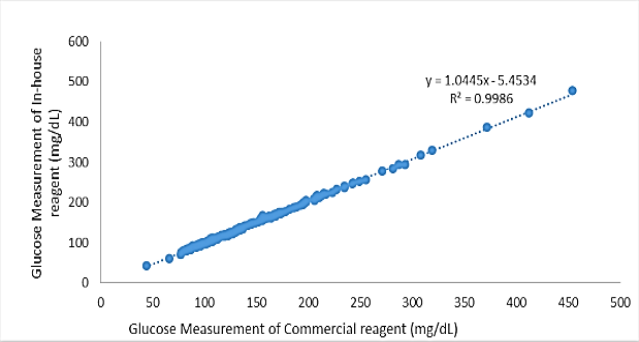


Figure 1: Linear regression graph of in-house reagent measurement vs. commercial reagent measurement

The two methods showed a strong correlation of 0.9993 according to the Pearson correlation.

Bland Altman statistical technique compares the agreement of the two methods by calculating the mean and 95% range of the differences (upper and lower limit of agreements) between the data points of the methods.

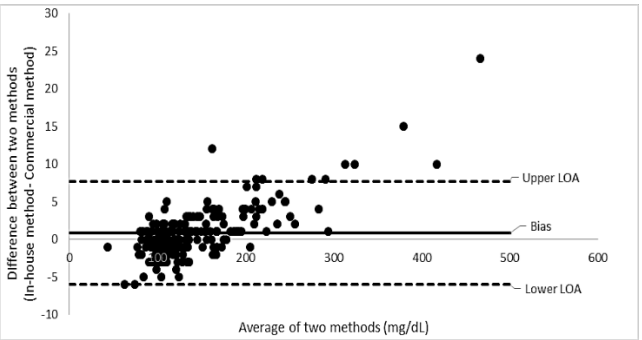


Figure 2: Bland-Altman plot

The black solid horizontal line corresponded to the bias of the two methods while the dashed horizontal lines corresponded to the 95% confidence limits of agreements (LOA). The mean measurement of in-house reagent was 142.28 mg/dL, while the mean measurement of commercial reagent was 141.44 mg/dL. The mean difference between measurements (bias) was 0.835 mg/dL. (95% CI 0.347- 1.323 mg/dL). There was thus a clear tendency for the glucose measurement of the patients to over-report their glucose measurements, by an average of 0.835 mg/dL.

The dashed horizontal lines showed 95% limits of agreement, given by the mean differences plus or minus twice the standard deviation of the differences. Approximately 95% of differences lied within this range, we could determine that the differences are normally distributed. 95% limits

were from -6.03 to 7.70 mg/dL. The differences were positively skewed after 200 mg/dl. There was a good agreement between 0-300 mg/dL.

After 300 mg/dL, the differences between two methods were dispersed beyond the upper limit of the agreement. A tendency towards increasing scatter was observed which could be due to low number of sample size in this range.(n=5)

B. Analysis of Performance characteristics

1) Determination of linearity: The reaction was linear up to 1000 mg/dL in both methods. Concentrations above the 500 mg/dL are calculated after diluting by saline automatically by the automated analyzer.

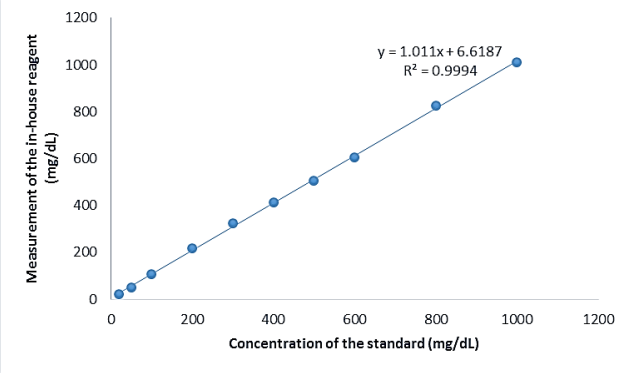


Figure 3: Calibration curve of in-house reagent

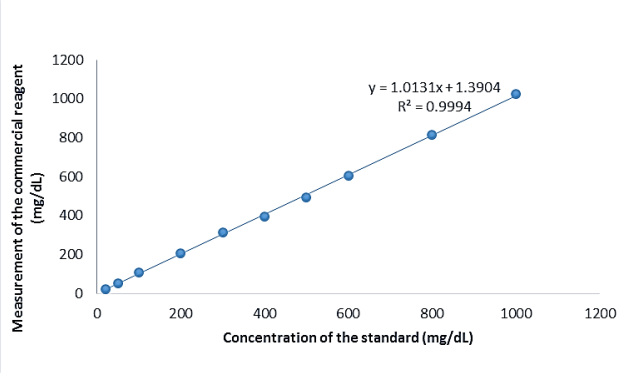


Figure 4: Calibration curve of commercial reagent

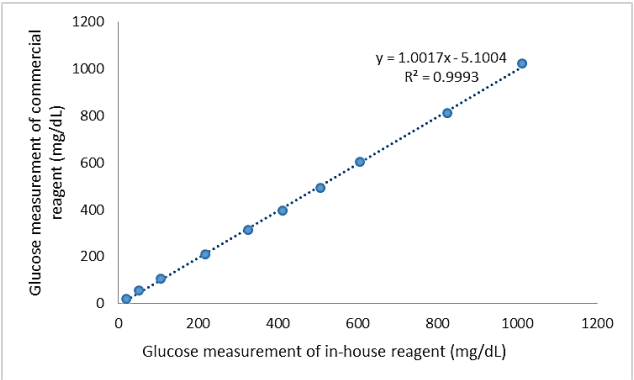


Figure 5: Correlation of the two methods using the dilution series of the standard

2) Analytical range: Analytical range is from 60 mg/dL to 300 mg/dL for in-house glucose reagent.

3) Intra- assay and Inter- assay Precision: Two pools of samples were prepared in normal and pathological levels and measured in the same day per 20 times for Intra assay precision. Quality control samples were measured in 20 consecutive days for Inter assay precision. According to that data below parameters were calculated.

Table 3.Intra -assay and Inter -assayprecision data for in-house reagent

	Intra Assay (n=20)		**Inter Assay (n=20)**	
	Normal Level	**High level**	**Normal level**	**High level**
Mean (mg/dL)	92.95	261.1	87.35	276.75
SD (mg/dL)	6.39	6.21	1.93	9.24
CV %	6.88	2.38	2.21	3.34

*4) Sensitivity, specificity and Accuracy:*According to the normal fasting plasma glucose range (60-110 mg/dL), values from both methods were categorized into 2 groups as positives and negatives.Values that are more than 110mg/dL and below 60 mg/dL were included into the positive group.Values that are within the normal range included into the negative group.Reference method was the commercial method. If from both methods values were positive, they became the real positive values and if both methods values were negative , they became the real negative.

Sensitivity, specificity and accuracy were 96.15%, 97.14% and 96.5% respectively.

Table 4.Other Characteristics in the population

	Reference Method		**Total**
	Real positive	**Real negative**	
Test positive	125	5	130
Test negative	2	68	70
Total	127	73	200

5) Stability: Stability of the reagent was checked by assessing the QC materials using the in- house reagent for a period of three months . In that three months period, reagent was stable with good performance at 2-8˚C.

C. Discussion

Glucose oxidase /peroxidase is the most commonly used method for estimation of plasma glucose in practice, due to it's a stability, reliability, (Fischl et al, 1975). It requires only small volumes of plasma and minimum reagent consumption (Sonowane et al., 1976).

Not many studies have been performed to compare the glucose measurements on in-house and commercial reagents for GOD/ POD method.

Mean values of the in-house glucose reagent and the commercial glucose reagent were 142.28 and 141.44 mg/dL; respectively for the 0- 500 mg/dL range. The measurements of in-house reagent showed slightly higher glucose levels as compared to the commercial reagent. Also, this increase was statistically significant. Other studies also suggest that slightly higher values for glucose measurements are reported for in-house reagent measurements. (Zafar and Syed, 1992). However, the mean values for 60-300 mg/dL range were 136.88 and 136.34 mg/dL. The differences were not statistically significant,

The agreement between two methods was compared using Bland-Altman plot and it showed a positive bias of 0.835 in the range from 0-500 mg/dL. It showed comparable results when compared with the commercial reagents to the manufacturers' assigned mean and range.Accuracy, sensitivity and specificity of the in-house reagent were 96.5%, 96.15% and 97.14%; respectively. Other studies have also shown similar results. (Zafar and Syed, 1992)

This in-house reagent showed a linearity up to 1000 mg/dL with the standard glucose values. However, other studies showed lower detection ranges for glucose standards with concentration up to 300 mg/dl (Passey et al., 1977) and 400 mg/dL (Sonowane et al., 1976). In this tudy, CV values for intra assay precision were 6.88% for normal level and 2.38% for pathological level. CV values for inter assay precision were 2.21% and 3.34%; respectively for normal and pathological levels.

Therefore, the prepared in-house reagent has proven better performances than previously prepared in-house reagents.

The two methods showed a strong correlation of 0.9993 according to the Pearson correlation. Taylor and Pannock, 1982 showed positive good correlation in between two methods (r=0.990).

Many studies have shown that home -made reagents are on the average 100 to 500% cheaper (Zafar and Syed, 1992). A Commercial kit (250 ml) costs Rs.1125.00 but for in-house reagent (250 ml) it costs Rs.650.00. Therefore, in-house reagents are more cost-effective than commercial reagents.

Zafar and Syed, 1992 stated glucose in-house reagent was stable for 6 weeks. This in-house reagent, has better stability over proper storage conditions over three months.

Although, the linearity has showed upto 1000 mg/dL, analytical range was from 60 mg/dL to 300 mg/dL for this method. One limitation of the study was that 192 samples were in 60-300 mg/dL range and only 8 samples were below 60mg/dL(n=3) and above 300 mg/dL(n=5). Therefore, only the results in 60-300 mg/dL range can be interpreted statistically.

IV. CONCLUSION

Although the in-house reagent showed a good linearity upto 1000 mg/dL, analytical range for this in-house reagent can be confirmed to be 60mg/dL to 300 mg/dL from this study.

Therefore, this in-house reagent can be used to measure plasma glucose level in clinical chemistry laboratory from 60 mg/dL to 300 mg/dL. Accuracy, sensitivity and specificity of the in-house reagent are

96.5%, 96.15% and 97.14%; respectively. This in-house reagent is stable for a period of three months.

Therefore, performance of in-house glucose reagent is well correlated with that of commercial reagent for the range from 60 mg/dL to 300mg/dL with good precision, accuracy and stability. The cost-effectivenes and feasible preparation procedures makes it a good candidate to assess plasma glucose levels at hospital setups where a large quantity of analyts are evaluated daily.

In this study samples with very high (>300 mg/dL, n=5) and very low (<60 mg/dL, n=3) plasma glucose values were limitted. Therefore, to validate the method for above ranges more data need to be collected. Therefore, it is recommended to expand the study for high and low values of plasma glucose levels with increased sample size in further studies to validate the method for very high and very low ranges of plasma glucose.

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