Faculty of Medicine

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PROSTHETIC AMBULATION, UTILITY, RESIDUAL LIMB HEALTH AND SATISFACTION LEVEL FOLLOWING PATIENTS WITH LOWER LIMB AMPUTATION

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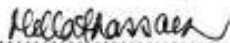Department of Physiotherapy

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We the undersigned certify that we have carefully read and recommended to the Faculty of Medicine, University of Dhaka, for the acceptance of this dissertation entitled.

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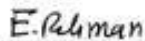
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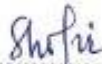
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DECLARATION

I declare that the work presented here is my own. All sources used have been cited appropriately. Any mistakes or inaccuracies are my own. I also declare that for any publication, presentation or dissemination of information of the study, I would be bound to take written consent from the Physiotherapy department, Bangladesh Health Professions Institute (BHPI).

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Acronyms

AHA   American Health Association

AKA   Above Knee Amputation

BHPI   Bangladesh Health Professions Institute

CRP   Centre for the Rehabilitation of the Paralysed

ICF   International Classification and Functioning

IRB   Institutional Review Board

LLA   Lower Limb Amputation

LLP   Lower Limb Prosthesis

P&O   Prosthetics and Orthotics

MDT   Multidisciplinary treatment

NGO   Nongovernment Organization

NOC   Nursing Outcomes Classification

PEQ   Prosthetic Evaluation Questionnaire

PWD   Persons with Disabilities

QoL   Quality of life

RTA   Road Traffic Accident

SCI   Spinal Cord Injury

TTA   Trans Tibial Amputation

TFA   Trans Femoral Amputation

WHO   World Health Organization

Abstract

Purpose: To explore the ambulatory condition, utility, residual limb heath and satisfaction level of lower limb prosthesis patients in Bangladesh. ***Methodology*****:** The cross-sectional study was chosen to carry out this study among 41 participants who were selected according to inclusion criteria from the Prosthetic and Orthotic department of CRP. Data was collected by using modified PEQ questionnaire Quantitative descriptive statistic was used for data analysis which focused through table, chart and discussion. ***Results:*** The study found that among the 41 participants the majority were younger (39%, n=16) people and most of them were male (82.9%, n=34) participants. 63.4% (n=26) were from rural area and unemployment was seen among them after amputation (26.8%, n=11) where there was no unemployment before amputation. Of all amputations, transtibial and transfemoral amputation were equal (46% each) others had knee disarticulation and partial foot (5%, 3%). In average ambulatory function were 77.29% and the younger partisans were responding more positively than the elder ones. The thinking about the utility of the prosthetic limb among the all ages people were almost average (75.15%). About their residual limb heath, almost every age group people answer those questions positively (86.27%). The older people were expressed their more satisfaction (94.67%) as they were still able to walk than the younger (86.85%). But there was statistically little positive correlation (r <0.01) present between age and satisfaction. ***Conclusion:*** From this study it could conclude satisfaction of the participants was approximately 88%, ambulation was good and felt the importance of prosthesis and participants had good residual limb health after using lower limb prosthesis at least 4 weeks. Future surveys are required to collect more specific information about LLA patients for their better prosthetic rehabilitation in Bangladesh.

Key words: Amputation, utility, residual limb health, prosthetic limb, lower limb prosthesis, satisfaction level, ambulatory function.

CHAPTER: I	INTRODUCTION

1.1 Background

Amputation is a devastating event and also known as a mutilating surgery and a public health problem (Chigblo et al., 2017). According to WHO (2005), more than 600 million people in the world experience disabilities of various types and degrees. Mishra (2015) stated that the word amputation is derived from the Latin amputare, "to cut away", from ambi- ("about", "around") and putare ("to prune"). By the end of the 17th century "amputation" had come to dominate as the accepted medical term.

Raichle et al. (2008) and Pezzin et al. (2004) both have mentioned that each year in the United States, an estimated 158,000 persons undergo amputation and limb loss may be the result of a series of complicated events. Like tumor, diabetes, vascular disease (not diabetes), injury, congenital, infection, gangrene, other dysvascular causes. Studies shows that the rising frequency of road traffic accidents and vascular pathologies as major causes of amputation in developing countries (Handy et al.,2018). Nearly 73.5% of limb losses were lower limb amputations (LLA) and the majority of which were caused by traumatic injuries and vascular disease. (Asano et al., 2008) Elsewhere, Sinha et al. (2011) mentioned that vascular complications are the major contributors to lower limb amputations in developed countries and on the contrary, traumatic accidents are the major cause of amputation in developing countries. The majority (53%) of amputation cases area unit classified as a transtibial (TT) or below knee amputation (BKA), in which there is a loss of one or both legs below the level of the knee (Ziegler-Graham et al., 2008).

Amputation leads to a permanent disability that brings a dramatic change in the life and function of the individual and lower limb amputees are more experienced of this situation than the upper limb amputees where the incidence of lower limb amputation is also higher than that of the upper limb (Sinha et al., 2011). In recent study in Kolkata, 94.8% of the amputation population consisted of lower limb amputees, the foremost common age group affected by amputation being those in their 20s and 30s (Pooja & Sangeeta, 2013).

Amputation can often be connected with anxiety, isolation, and depression that may change the social and free-time activities of lower-limb amputees (Deans et al., 2008). It seems a physical, emotional and social challenge for the patient with lower limb amputation (Unwin at el., 2009). Though limb loss can cause severe disturbance in locomotion and functional abilities, prosthetic rehabilitation has the potential to reclaim function and increase quality of life and is associated with a greater likelihood of returning to employment (Raichle et al. 2008). To restore or imbue some of the function and/or cosmesis of an anatomical limb, prosthetic limbs are commonly used by people with limb absence (congenital deficiency) and limb loss (acquired amputation). People with congenital limb absence and people with acquired amputations both will be encouraged to use prostheses by a variety of professionals as part of a rehabilitation process (Murray & Fox, 2002).

For the past decade, quality of life (QoL) has been avowed as an important outcome for rehabilitation programs for not only people with LLA but also for those who experienced stroke or traumatic spinal cord injuries (SCI) as they all face sudden changes and challenges in their life (Asano et al., 2008). Safer et al. (2015) defined Quality of life as individuals' perception of their position in life, in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. Besides, different factors including physical health, level of independence, psychological state, social relationships, personal beliefs, and their interactions to salient features of their environment are related to the quality of life. Quality of life (QoL) is increasingly being avowed as an important outcome of rehabilitation programs and also as a guide to assess adjustment to prosthesis (Sinha et al., 2011). An external prosthesis is an external orthopedic instrument designed to replace an absent limb or limb segment. So, external prostheses provide a means of compensating for losses incurred during amputation (Handy et al., 2018).

According to Kark (2011), Satisfaction has been defined as the difference between expectation and experience which is affected by interpersonal factors like lifestyle, previous experiences, values of the individual and the society and variability over time. In case of amputation, it is therefore important to know the satisfaction level of patients with external prosthesis as the satisfaction of a patient being defined as his/her opinion resulting from the difference between his/her perception of the prosthesis and his/her expectations (Handy et al., 2018).

A number of studies have published that the quality of life (QoL) of individuals with a lower limb amputation (LLA) is related to a number of characteristics absolute to this population including the condition of the residual and contra-lateral limbs, the fit of their prosthesis, and the time since amputation. In addition, common factors such as walking distance, mobility problems, symptoms of depression, and social support have also been suggested as important predictors of QoL (Asano et al., 2008). So, amputees can experience feelings of social discomfort and may avoid particular social scenarios and can exhibit symptoms of depression. In point of fact, concern about body image has been directly linked to depression in person with amputation. Sometimes the appearance or aesthetics of a prosthetic limb is important to amputees and can influence their opinion or acceptance of the prosthesis and increase their satisfaction level (Cairns et al., 2014).

Road accident is a global trauma. Like many other countries in the world, every year Bangladesh also suffers a great deal due to road accidents (Alam et al.,2011) and increase the rate of injury and amputation. Lower limb amputee people experience multiple challenges which can range from learning how to care for their amputated limb, how to walk, and how to adjust and cope with their limb loss. It seems plausible that given the associated challenges and adjustment that they may experience a change in their quality of life (QoL) (Asano et al., 2008). The purpose of this study is to find out the ambulatory capacity, utility of the prosthesis, residual limb health and satisfaction level among with the patients of lower limb amputation in Bangladesh as the ambulation, utility and residual limb health have been suggested as important predictors of quality of life.

1.2 Rationale

An accident is an unexpected occurrence of physical damage to living lifeless structure. In case of Bangladesh, the number of accidents on road are stepping up with the passage of time. Every year due to numerous types of accident (RTA, fall from height, crush injury, burn etc.) and diseases (tumor, infection, peripheral vascular disease, recurrent sepsis), many people go through the amputation. In recent years, disability caused by amputation has increased with the development of Bangladesh. Prosthetic services play a major role in enabling a person with a disability to change from being immobile to becoming mobile, a passive receiver to an active contributor, and isolation to inclusion. Lower extremity amputation is seen in clinical practice. With the improvement of clinical treatment, the survival rates of the patients will increase. But in Bangladesh, there is limited relevant published research that has been conducted in this field. This study describes the impact of lower limb amputation of different levels on patients' lives. The results indicate the level of functional performance of individual lower limb amputee patients after prosthetic rehabilitation and the satisfaction level with their prosthesis. The great majority of individuals with lower limb prosthetic have limitation in physical functioning especially problem in locomotion or mobility. In this manner, for their better future and integration in the social activity needs to give appropriate prosthetic training and rehabilitation. So, this kind of study is needed for the people with lower limb amputation.

1.3 Research Question

How satisfied are the lower limb amputee patients with their prosthetic ambulation, utility and residual limb health in Bangladesh?

1.4 Aim:

The aim of this study was to obtain information about the satisfaction level of the lower limb prosthesis user patients and evaluating identify their prosthetic ambulatory capacity, residual limb health condition, utility with their lower limb prosthesis.

1.5 Objectives

1.5.1. General objective

To identify the satisfaction level of lower limb amputee patients with their prosthetic ambulation, utility and residual limb health in Bangladesh.

1.5.2 Specific objectives

i. To identify the socio-demographic factors of the participants;
ii. To identify the patient who were using lower limb prosthesis for their ambulation;
iii. To identify the ambulatory capacity of the participant in different environmental condition;
iv. To find out how did the patients feel the utility of prosthesis using;
v. To identify the participants' residual limb health condition;
vi. To identify the overall satisfaction of the participants;

1.6 Operational definition

Ambulation

Ambulation is the act, action, or an instance of moving about or walking. Nursing Outcomes Classification (NOC) define ambulation as ability to walk from place to place with or without assistive device. The act, action, or an instance of moving about or walking is also known as ambulation.

Amputation

Amputation is the surgical removal of all or part of a limb or extremity such as an arm, leg, foot, hand, toe, or finger.

Prosthetics

The branch of medicine or surgery that deals with the production and application of artificial body parts.

Prosthesis

The word prosthesis came from Ancient Greek prosthesis, means addition, application, attachment. Prosthesis or prosthetic device, is an artificial device that replaces a missing body part. Prosthesis are typically used to replace parts lost by injury or missing from birth (congenital) or to supplement defective body parts. A prosthesis is intended to restore the normal functions of the missing body part.

Utility

Utility means the usefulness of something, especially in a practical way. It is an economic term referring to the total satisfaction received from consuming good or service.

Residual Limb

The term residual limb refers to the part of the body that remains after an amputation has been performed.

Health

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

| CHAPTER: II | LITERATURE REVIEW |

The surgical removal of a part or whole limb in an acquired condition such as injury, disease or surgery is called amputation (Adegoke et al., 2012). Arifin et al., (2017) stated that, according to International Classification of Functioning, Disability and Health (ICF), lower limb amputation is a form of physical disability which impairs body structures and results in activity limitation and participation restriction. It is also known as the most ancient of all surgical procedures. This procedure is mainly performed when any limb cannot function properly or due to arterial reconstruction failure (Adegoke et al., 2012). Da Silva et at., (2011) mention on their study about global statistics estimation of the incidence of amputation at around 2.8–43.9 cases per 100,000 people per year. One in nearly 200 Americans is living with the loss of a limb and by 2050, 3.6 million people in the United States will be living with limb loss (Ziegler-Graham et al., 2008). The total number of lower-limb amputations in Germany in the year 2001 was estimated to be over 43000 (Rümenapf & Morbach, 2017). Another study mentioned on their study that in Netherland approximately 3000 primary amputations of the lower limb are performed annually and among amputee patients most are older than 60 years (Schoppen et al., 2003).

Globally ratio of amputation by gender, male: female ratios from the UK, USA and Scandinavia are 2:1 (Kumar et al.,2016). Lower limb amputation (LLA) occurred approximately 91.7% because of traumatic injury, wherever men being at a considerably higher risk than female (Sahay et al., 2014). Amputation above the knee, below the knee or the foot amputation is defined as major lower limb loss. Causes of lower limb amputations varies from country to country and also varies among developing and developed countries. So, it seems difficult to find out the exact global burden of limb amputation due to poor record keeping in many countries. In USA, 1.6 million people were living with an amputated limb in 2005 and this is expected to rise to 3.6 million in 2050 (Ahmad et al., 2019). It ranges from 0.2 per 10,000 total population for first major amputation in Japan, to 115.7 per 10,000 population aged over 90 years in Sweden (Sansam et al., 2009).

Amputation can be performed as a disarticulation of a joint or as a transection through a long bone. The level of amputation is usually named by the joint or major bone through which the amputation has been made (Shurr & Michael, 2000). Arifin, et al., (2017) mentioned on their article that approximately 84% are lower limb amputations among the total amputations whereas upper limb amputations are only 16%. Another research also shows that the occurrence rate of lower limb amputation (LLA) is more than the upper limb amputation and most of the adult people are go through the amputation (Murry & Fox, 2002). Disease, injury, surgery, congenital limb loss that present at birth, vascular insufficiency, cancer these are mainly responsible for acquired limb loss (Arifin et al., 2017 and Murry & Fox, 2002). Worldwide, the reported incidence of major amputation between 1989 and 2010 ranged from 3.6 to 68.4/100 000 in the normal population but in diabetics, it shows higher incidence rate from 5.6 to 600/100 000 (Rümenapf & Morbach, 2017 and Moxey et al., 2011). In South India territory hospitals report, Diabetes mellitus was the most common cause for Amputation: 39.5%, and chronic NDMVI - 33.3% (Unnikrishnan et al., 2017).

On a study it is mentioned that in Scotland around 82.9% of lower limb amputation have lost their limb due to peripheral vascular disease (Deans et al., 2008). In England annually around 7000 lower limb amputations occur in people with diabetes (Kerr et al., 2019). Tumors and trauma were the leading causes of lower limb amputation in Sub-Saharan Africa. Whereas peripheral vascular disease and diabetic foot infection were reported to be major indications for lower limb amputation in Kenya. Every 20 second a lower limb is lost to diabetes in the world and it is the most common cause of non-traumatic lower limb amputation (The International Working Group on the Diabetic Foot, 2017). The incidence of amputation (excluding toe amputation) in diabetics in the year 2011 varied between 1 and 18.4/100 000 among 26 OECD (Organization for Economic Cooperation and Development countries) (Rümenapf & Morbach, 2017).

It is estimated that approximately 45,000 lower limbs are amputated every year in India (Jain & Viswanath, 2016). In India, 70% of the amputees were victims of trauma and among the traumatic cases majority suffered a road traffic accident (Hassan Al Imam et al., 2019). There are approximately 0.62 amputees per 1000 population in India, and the prevalence of psychiatric disorders among amputees' patients has been found to be in the range of 32%–84% (Sahu et al., 2016).

Amputation marked as a major cause of permanent disability (Deans et al., 2008). An amputation that involves the lower extremity can affect an individual's ability to stand and walk, requiring the use of prosthetics and, often, an assistive device for mobility (Lusardi & Nielsen, 2007). On an official statistical study in India shows that, 2.2% of the general people are disable and among them 20% have a movement disability (Magnusson et al., 2019). In A study on Malaysia, the researchers found that 81.5% of study population were male amputees. Among them 67.7% were unemployed and 38.5% had to comorbidities at the time of study. More than half of the subjects were below knee amputees (61.5%) and lower limb problems due to diabetes mellitus (DM) was the most common cause of amputation (63%) (Htwe et al., 2015).

Like other county in Pakistan amputation is also common. Road traffic accident and bomb bursting is a common cause of amputation. In a recent study in Pakistan shows that 5820 patients with LLA registered during the study period and 87.9% among them were males and 12.1% were females. 37±19 years was the mean age of patients and about 67.6% (n=3933) patients were ≤40 years of age. Overall, trans-tibial amputations were common (n=3582/5820; 61.6%), followed by trans-femoral amputation (n=1496; 25.7%). Generally, an increasing trend in frequency of patients with LLA was observed over four years. Major causes of LLA were trauma (61.9%), reconstructive surgeries (15.4%), various diseases (8.2%) and congenital (2.1%). In 12.4% cases, cause of LLA was not documented. Bomb blast injuries (21.6%) and road traffc accidents (14.6%) were main traumatic causes of LLA and diabetes mellitus (4.6%) was the commonest disease-related cause of LLA (Ahmad et al., 2019).

On a study that studied at Nigeria, Adegoke et al., (2012) mention that 66.0% of the participants were male, 83.0% were using prostheses, 57.4% had dominant lower limb affectation, 61.7% had below-knee amputation and 51.1% were engaged in skilled occupation. It's also mentioned that there was no significant difference (p = 0.78) between the ages of male (50.58 ± 12.90 years) and female (51.68 ± 13.67 years) participants. There was also no significant difference (p = 0.06) between time since amputation. According to Asano et al., (2008), 71.1% of the subjects were male, 61.9% were married, and 74.2% unemployed on a study among the amputee patients of Canada. 73.0% amputates were below knee amputation and the cause of amputation was more commonly related to vascular (53.0%) than non-vascular (47.0%) etiology. The incidence of LLA is for seen by gender, age, marital status, and level of education,

socio-economic standing and therefore the presence of diabetes. However, in some components of Africa wherever there is violence and wars, trauma is that the leading explanation for LLA (Godlwana et al., 2008).

However, to access basic rights along with food, shelter, education, job/income or to obtain the equal opportunities and equal citizenship mobility is known as a first step (WHO,2005). A recent study also shows the physical activity is needed to earn his livelihood and to perform daily life activity. But it becomes difficult to earn income and daily activities due to physical disability (Magnusson et al., 2019).It is estimated that around 65% of all extremity amputations are lower limb amputation, with the ratio of major lower limb amputation to major upper limb amputation estimated to be as high as approximately 15:1. As all individuals that experience a lower limb amputation will require a prosthetic ankle-foot mechanism, this component category impacts the lives of more individuals with amputation than any other prosthetic technology (Wurdeman et al., 2019). Arifin et al., (2017) mentioned that according to WHO, on a developing country 0.5% of the population are disable and they will require a prosthesis or orthosis related rehabilitation services. Orthoses, prostheses and mobility aids are some of assistive device that play an important role for the restoration of the mobility and contribute to make the disable person into mobile (WHO,2005) whereas mobility is considered an important to achieve rehabilitation goal (Sinha et al., 2011). When the removal of a diseased limb and therefore the application of an appropriate prosthesis, the patient will resume being an energetic member of society and maintaining a freelance lifestyle. The patient should learn to walk with a prosthesis, apply and take away the prosthesis, look after the prosthesis, monitor the skin and therefore the presence of any pressure points, walk on tough surface, and use the commode at the night. The result is directly affected by level of amputation, stump length and therefore the age of patients (Anjum et al., 2016).

Lower limb amputation is a permanent surgical procedure that has important functional and sequelae that can influence the daily activity of the person with amputation (van Twillert et al., 2014). Although rehabilitation aims to address these measuring the effect of these interventions on rehabilitation outcomes of people who have had an LLA remains a challenge (Coffey et al., 2014). The selected outcomes must be related to rehabilitation goals that are specific to each person and associated with premorbid function (Horne & Neil, 2009). This is surprising given that amputee rehabilitation

programs have common goals to improve mobility and functioning through prosthetic fitting to assist community reintegration and to ultimately improve the overall functional activity of persons with an LLA (Zidarov et al., 2009). The best possible restoration of mobility and locomotor function represents the cornerstone of rehabilitation programs (Franchignoni et al., 2007).

Functioning is an umbrella term that enclosed with all body functions and structures, activities and participation whereas disability is known as the overarching term for impairments, activity limitations and participation restrictions. The importance of excellent gait training cannot be immoderate. In reality, most new amputees need months of practice with their prosthesis. Walking with a prosthetic limb is that the primary goal of rehabilitation once a lower limb amputation. A person's functioning and disability including the participation are considered to arise from the interaction among health conditions and environmental factors and personal factors. According to ICF frame work, 'Impairments' are defined as problems in body function or structure; 'activity limitations' are difficulties a person may have in carrying out daily activities; and 'participation restrictions' are problems a person may experience when involved in life or social situations (McDougall et all.,2010). So, Functional ability requires the physical, social and mental ability to perform activities of daily living. Therefore, rehabilitation following prosthesis prescription must focus on mobility and as well as on rehabilitation in other health domains because this has been advocated for several decades. Maximizing satisfaction requires the refocusing of amputee opinion on their own functional ability, importantly, promoting patient independence and social acceptance of limb loss by patients as well as family and friends (Kark and Simmons, 2011). Sometimes additional factors affect the functioning and well-being of amputees. Quality of life (QoL) is increasingly being recognized as an important outcome of rehabilitation programs and also as an indicator to assess adjustment to prosthesis (Sinha et al., 2011).

Lower-limb amputee patients may also suffer from anxiety, isolation, and depression that may affect the social and daily activities of life. Eventually they tried to avoid social activities and change their life style. Physical activity is used as an ancient concept to treat and prevent disease for those who faces psychological or physical challenges, or

a combination of these two (Deans et al., 2008). In this manner, assistive devices of lower-limb play a major role to increase mobility, and positive correlation has been shown between mobility and quality of life. (Magnusson et al., 2019). Rehabilitation practitioners should keep up with quality of life of the patients while creating intervention targets for rehabilitation program (Safer et al., 2015) that brings the patient satisfaction. Satisfaction encompasses the patient's experience and because of its subjective nature. It needs to be subdivided in order to be accurately measured (Handy et al., 2018). The aim of this work was to describe the level of satisfaction of lower limb amputee patients wearing external prostheses by evaluating the physical, psychological and social aspects of satisfaction. So, it is important to find out satisfaction, ambulatory capacity, utility, residual limb health level through prosthetic evaluation questionnaire (PEQ). Frustration level of the amputees will also be evaluated.

Da Silva., (2011) did a study that about Physical activity and quality of life of amputee patients of southern Brazil. On their study they resulted this by measuring of central tendency in this sample showed appropriate values for all physical activities. And on that study men had higher scores in all physical activity groups and women had values below the recommended level for health in the physical activities. Men showed higher scores in all types of sedentary behavior than the women. On the satisfactory scores for quality of life, men having higher values in the social domain while women had higher values in the psychological domain. However, gender comparison did not show significant differences in physical activities, level of physical activity or quality of life and its domains. It was also noted that there were no significant gender differences in quality of life and level of physical activity among this intentionally selected amputee sample.

Kark & Simmons (2011) stated that patient satisfaction is an important measurement in healthcare for administrators, healthcare providers and patients. From an administrative perspective, the primary reason to measure satisfaction is that patient satisfaction and quality of care, although distinct, are highly correlated. This correlation is so well recognized that healthcare providers view satisfaction as a fair measure of quality of care, making it a necessary component of quality management systems. Research has also shown that satisfied patients are more likely to seek medical assistance, comply with treatment and continue using medical services. Quality of life and satisfaction can

be measured by the healthcare provider, but a discord between the perceptions of the healthcare provider and those of the patient may be present.

Patient satisfaction is a key indicator of the quality of care Satisfaction with the prosthesis plays a key role in regaining mobility and is important for optimizing use of the prosthesis, preventing rejection, and increasing compliance with the medical regimen (Baars et al., 2018). A study with lower limb amputees over Cotonou city of Benin, in West Africa from 2009-2015 was published on 2017. On that study researcher showed the result with sociodemographic and clinical characteristics, prosthetic fitting, social impact etc. In this study involved male to female ratio was 2.7. They were mean aged of 42.4 ± 18.8 years (15–85 years). 24% (17 patients) had a prosthesis fitting and among them 11 transfemoral amputees and 06 transtibial amputees. In developed countries, the prosthesis fitting is 100% covered by social security. Transfemoral amputation (11/11) had unsatisfactory rehabilitation; 3/6 fitted after a transtibial amputation had satisfactory rehabilitation. There was a statistically significant in relationship between the amputation level and the Houghton score (Chi2 = 6.7; p-value = 0.009): the higher the level of amputation was, the greater was the risk of unsatisfactory rehabilitation. Fitting prosthesis wasn't linked to the sex, the age, the cause of amputation. Over the study population 70% had a walking aids, 54% were using walking stick, 16%, crutch and 4%, wheelchair. In the view of social impact, the lower limb amputation had the negative impacted that mentioned on the study.

Eusufzai et al., (2019) mention on their study more than one billion people are living with some form of disability in this world and among them 0.2 billion have functioning difficulties. It is estimated that in Bangladesh disabled population is approximately 16 million that is 10 percent of total population whereas approximately 10-15% of the world's population lives with a disability. Bangladesh is a low-and-middle-income-country with a population of 160 million. According to World Health Organization (WHO) estimates, the number of people who suffer from non-fatal injuries are about 20–30 times more relative to fatalities in developing countries. WHO also reported that there are 21,316 fatalities from road accidents in Bangladesh. Thus, it can be estimated that about 426,320–639,480 people suffer from road traffic related injuries annually in Bangladesh (Hassan Al Imam et al., 2019). A recent study by Eusufzai et al., (2019) found that 83%, majority of participant were male and rest of them were female with the mean age of 35 years with minimum age 22 years and maximum

age 50 years. 96.2% had fair level QOL score in physical domain. In psychological domainmore than half (53.2%) had fair level whereas nearly half (47.0%) had fair level of Quality of life (QOL) score in Social domain. In environmental domain more than half (52.6%) had fair and good level of QOL score.

Another recent study in Bangladesh resulted that in their study participation with 332 respondents, aged 5 to 76 years (mean 37.5± SD 13.8), with lower limb amputation. Of the respondents, the majority were male (87.7%) and lived in rural areas (64.8%). Road traffic accidents were the leading cause (58.7%) of amputation followed by peripheral vascular diseases (7.5%) and hit by sharp objects (7.2%). Age (odds ratio: 0.9) and driving as occupation (odds ratio: 7.3) were found to be statistically significant covariates for amputation from road traffic accidents. 30.7% lost their jobs after amputation and their mean monthly income reduced significantly ($p<0.01$) (Hassan Al Imam et al., 2019).

| CHAPTER: III | METHODOLOGY |

3.1. Study design

The study was conducted by using quantitative method that is cross sectional study with interview conducted with patient with lower limb amputation. This design was chosen because it was carried out at one center and with short duration time frame (Levin, 2006). Survey methodology was chosen to meet the study aim as an effective way to collect data.

3.2. Study area

The study was conducted in Prosthetics and Orthotics Department at CRP, which is situated in Savar, about 25 km away from the capital city of Dhaka. CRP is a Non-government Organization (NGO) and tertiary level rehabilitation hospital that treats and rehabilitates persons with disabilities (PWD) regardless of their socio-economic means and aims to improve the quality of life of PWD in Bangladesh. It is specialized in the management of person with prosthesis. In CRP, there is a Prosthetics and Orthotics Department. Management is based on a multidisciplinary treatment (MDT) approach. Many people with lower limb amputation come here for their lower limb prosthesis and follow-up after 2 to 3 months interval or more from different district of Bangladesh, which is easily accessible for the researcher.

3.3 Study population

Unilateral lower limb amputee patients in Bangladesh, currently use lower limb prosthesis for ambulation those who attend at CRP for their treatment and rehabilitation management.

3.4 Sample selection

The inclusion criteria for participation in this study were the persons with lower limb prosthesis in Prosthetics and Orthotics Department, who took their prosthesis and rehabilitation care from CRP, Savar, Dhaka. The researcher selected the participant by purposive sampling because researcher had specific requirements and chose those who met the selection criteria. At first permission was sought from the incharge of P&O Department and a discussion about the study was held with the responsible physiotherapist. And then collected the data according to inclusion criteria from follow up patient who had come from different area of Bangladesh.

3.5 Inclusion criteria

   i.   Age between 15 to 60 years.

  ii.   Both male and female

 iii.   Only unilateral prosthesis user

 iv.   Only lower limb prosthesis user.

  v.   At least 4 weeks continuously prosthesis user person after rehabilitation processes.

 vi.   Persons who were willing to fill the consent form and participate.

3.6 Exclusion criteria

  i.   Persons who were filled the consent but family members did not allow to participate.

3.7 Sample size

2.8% prevalence was considered as prevalence of lower limb amputee patients (Pooja et al., 2013) to calculate the desired sample size in this study by using the following formulae: - (Daniel, 1999)

$$n = \frac{Z^2 p(1-p)}{d^2}$$

$$= \frac{(1.96)^2 \times 0.03 \times (1-0.03)}{(.05)^2}$$

$$= \frac{3.84 \times 0.03 \times .97}{.0025}$$

$$= 44.68 \,(\sim 45)$$

Where: n = the desired sample size.

Z = the standard normal deviation, set at 1.96, which corresponds to 95% confidence level.

p = the prevalence proportion set at 2.8 %

d = degree of accuracy desired, here set at 0.05 corresponding to the 1.96.

While substituting the values in the formula, the sample size was ∼45. However, 41 participants were included in the study because they were matched with the inclusion criteria during the study period.

3.8 Method of data collection

By following the instruction, the Prosthetic Evaluation Questionnaire (PEQ) with some standard demographic questions; a modified questionnaire was used to collect the data. The questions in the PEQ use a visual analog scale format. Each visual analog scale was scored as a continuous numerical variable measured as the distance in millimeters from the left endpoint of the line to the point at which the respondent's mark crosses the line. Each line was 100 mm long and was always measured from the left (0-100). The questions were all worded so that a higher number (toward the right) would correspond with a more positive response. This guide contains coding instructions for all the questions. Note that the questions that offer the option of making a check mark to indicate that the question was not applicable to the respondent are sometimes coded

"100" and sometimes "nr (no response)". Patients were requested to follow the instructions and mark on the line as they really feel.

3.9 Data collection

3.9.1 Data collection tools

Pen, paper and clip board was used to write down observation notes. An information sheet and consent form were used for taking permission from the participants. A close-ended question sheet was used to conduct the data.

3.9.2 Data collection procedure

The data was collected after approval of the study by Dhaka University, Institutional Review Board of Bangladesh Health Professional Institute (BHPI) along with permission from incharge of Prosthetics & Orthotics Department of CRP. All the subjects received explanations regarding the purpose and procedure of the study before voluntarily agreeing to take part. All questions and information were developed into Bangla. Data were collected through face to face administration of prepared questionnaires. The data conducted during daytime and the duration was approximately 10-15 minutes for each participant. Venue of data collection was Prosthetics and Orthotics Department of CRP, but the place of interview depended on situation and permission of regarding authority. Before proceeding for the study, a pre-test was conducted to find out possible drawbacks in the study tools and procedure and necessary correction was made to the best of possible knowledge and effort.

3.10 Duration of data collection

Duration of data collection for research was 10th July to 4th September, 2019.

3.11 Data Analysis

After the completion of data collection, quality control was checked for accuracy, utility and completeness and stored systematically and scientifically. Any errors, incompleteness and inconsistencies in data affecting the study result was excluded. The data entry and analysis were done by using Statistical Package for Social Science (SPSS 20.0). Researcher analyzed the data by descriptive statistics using Frequency, Percentage (%), Pie diagram, Bar diagram, Scatter diagram and also shown the association by non-parametric test which was Chi-Square test.

Chi square ($\chi 2$) Test

Chi square ($\chi 2$) Test is the most popular discrete data hypothesis testing method. It is a non-parametric test of statistical significance for bivibrate tabular analysis with a contingency table. In this study Chi square ($\chi 2$) test was done to measure the associations between two variables. It was used to test the statistical significance of results.

3.12 Ethical Consideration

The researcher maintained ethical consideration in all aspect of the study. Before starting the study, a formal project proposal was submitted to the department of physiotherapy and after verifying the proposal, permission was taken from Institutional Review Board (IRB) of BHPI to continue the study. For maintaining confidentiality and guideline, this study followed Bangladesh Medical Research Council (BMRC). This study also followed the World Health Organization (WHO) guideline. The researcher took permission to conduct the research project from the supervisor and Head of the Department, the academic institute of CRP for data collection. Informed consent was used to take permission from all participants. Participants' rights and privileges were ensured. All the participants were aware about the aim and objectives of the study. Findings of the study were disseminated with the approval of regarding authority.

3.13 Quality Control and Quality Assurance:

The rigorous manner was maintained to conduct the study. The study was conducted in a clean and systemic way. During the data collection it was ensured that participants were not influenced by own value, experience, perception and biases. The answer was accepted whether they were in negative or positive impression. No leading questions were asked. Then the questionnaires that was filled out was kept safely. The participant information was coded accurately checked by the supervisor to eliminate any possible errors. The entire information was handled with confidentiality. In the result section, outcome was not influenced by showing any personal interpretation. Every section of the study was checked & rechecked by research supervisor.

Patients' socio demographic information:

Age: Among 41 participants, the mean age of the participants was 28.88 years. The youngest participant was 16 years old and the oldest one was 60 years. The participants were divided into 5 groups. The range of the age and the frequency of the participated patients showed on the figure-1. Among 41 participants, around 16 participants (39%) were in between age 15 to 24 years old. 14 participants (34 %) were 25-34 years old, 8 participants (20%) were in 35-44 years old. 2 participants (5%) were in 45-55 years old and 1 participant (2%) were in 55-64 years old.
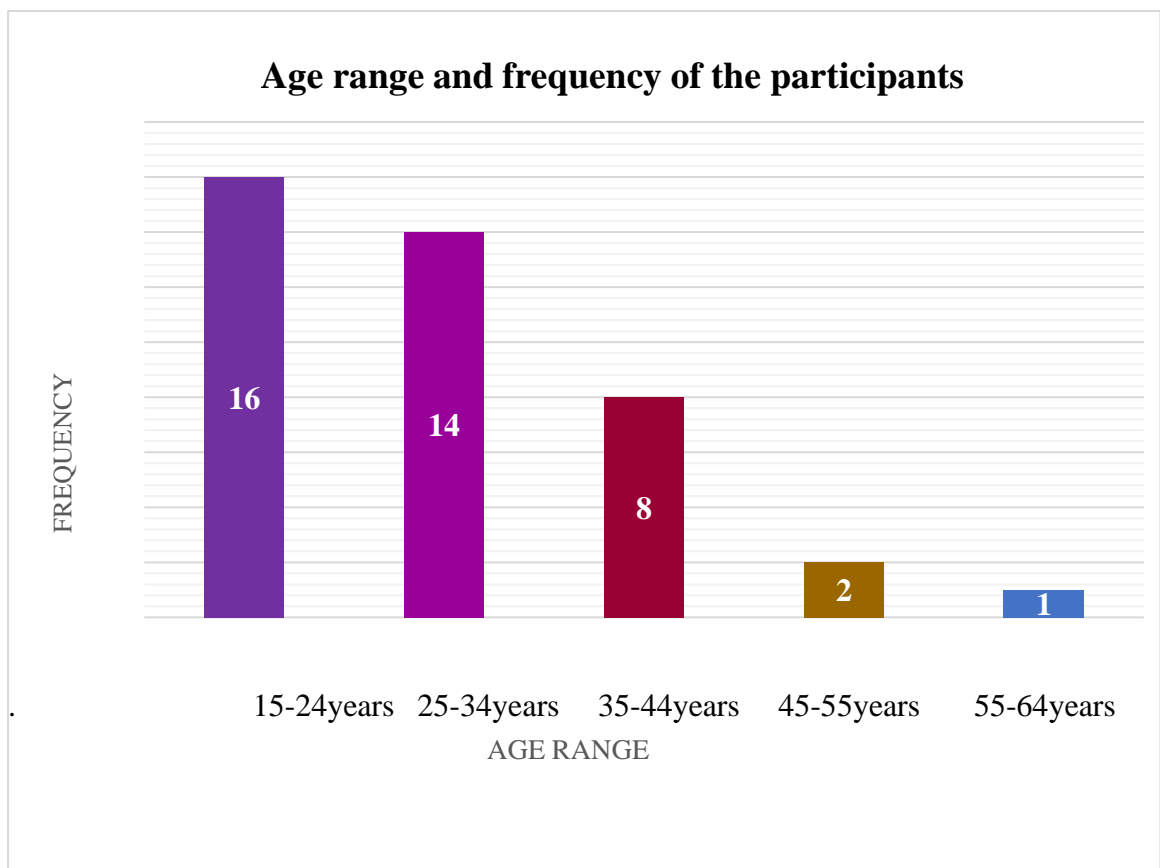
Figure 1: Age of the participants

Sex:

Among the participants, majority population were male. 83% (n=34) of the participants were male and the rest 17% (n=7) of the participants were female.

GENDER

Female, 17.1%

Male, 82.9%
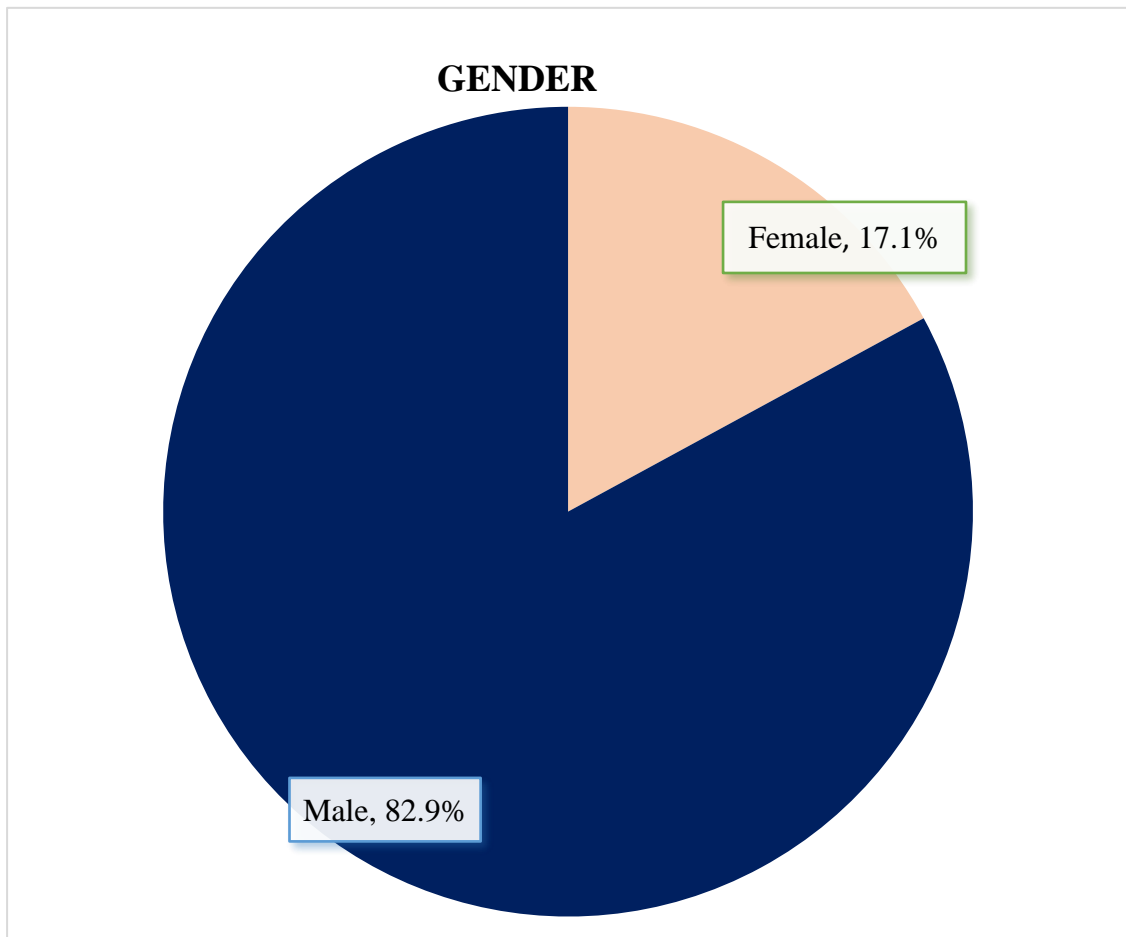
Figure 2: Sex of the participants

Living area:

Among the participants around 63% (n=26) people were lived in rural area and the rest of the participants 37% (n=15) were from urban area (Figure:3).
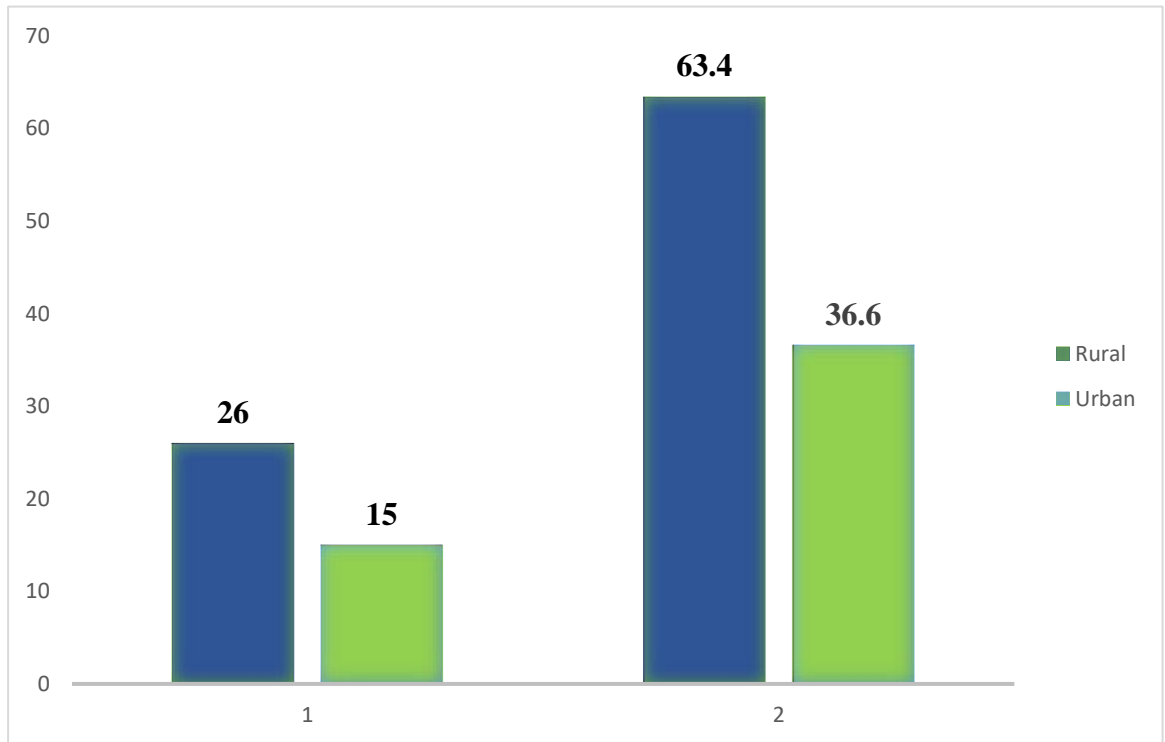
Figure 3: Living area of the participants

Occupation:

People with different kind of occupation participated on this study. The majority of this population were student. Analysis shows that around 46% (n=19) were student before amputation and among them 34 % (n=14) still continue their study. 20% (n=8) were service holder before the amputation and after it decreases into 12% (n=5). 34% (n=14) people were with different types of work like driving car, shopper, rickshaw puller, farmer. Some of them switch their work to others after amputation. 27% (n=11) do different kind of work after their lower limb amputation. But the major thing of notice that there was no unemployment among these patients while they were able to walk. But after amputation 27% (n=11) turns to unemployed (Table:1).

occupation	Before amputation		After amputation	
	Frequency	Percent (%)	Frequency	Percent (%)
Service holder	8	19.5	5	12.2
Student	19	46.3	14	34.1
Unemployed	0	0	11	26.8
Others	14	34.1	11	26.8
Total	41	100	41	100

Table 1: Occupation before &after amputation

Amputation level:

In this study the ratio of the transfemoral and the transtibial amputees were equal. Among 41 participants, 19 (46%) were transfemoral and 19(46%) were transtibial. 2 (5%) had knee disarticulated and 1 (3%) had partial foot (Fig: 4).
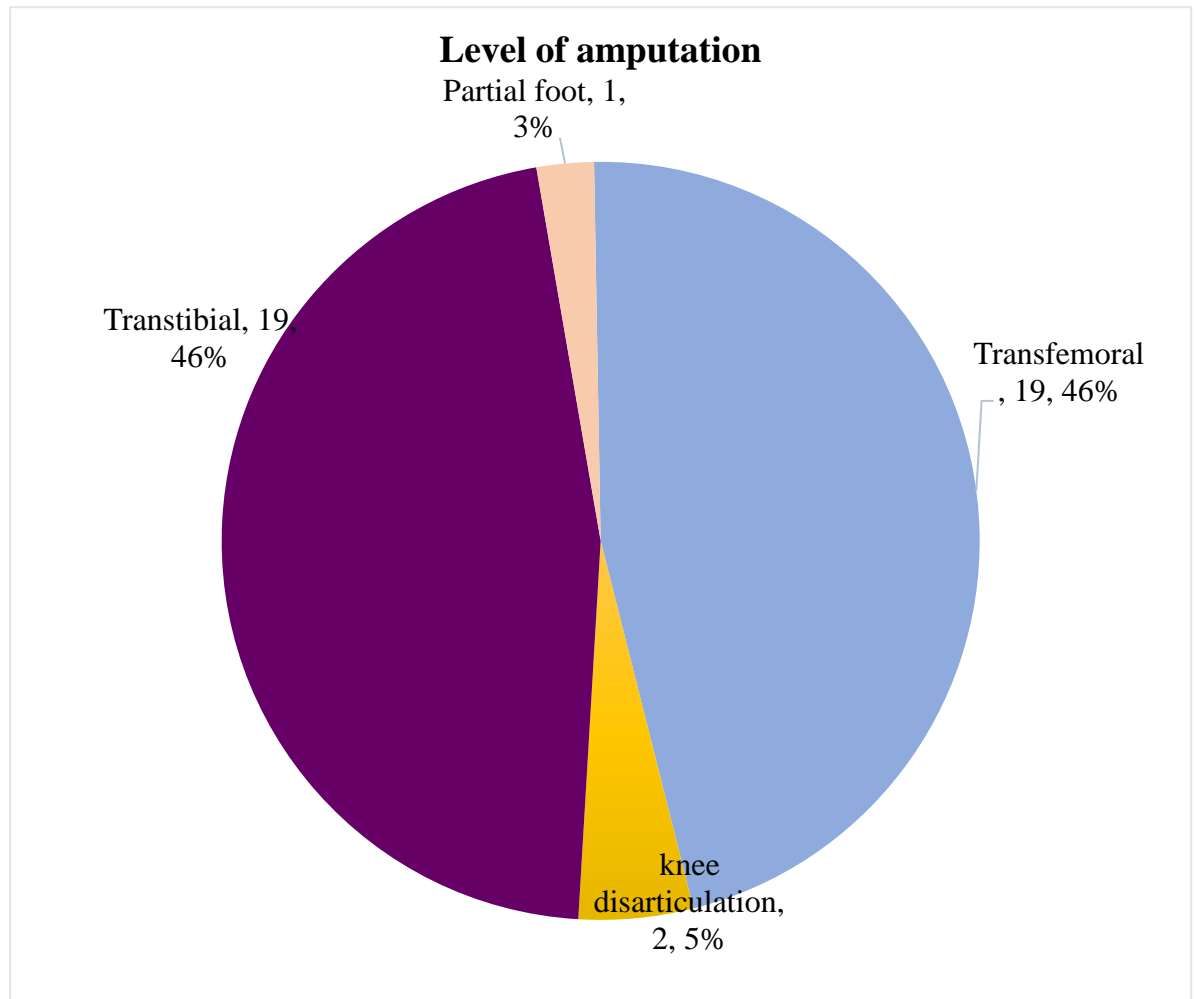
Figure 4: level of amputation of the participants

Educational level:

39% (n=16) were educated at secondary level. Among the whole participant 17% (n=7) were illiterate; 24% (n=10) were taken higher secondary education and only 5% (n=2) were graduate (Fig.5).
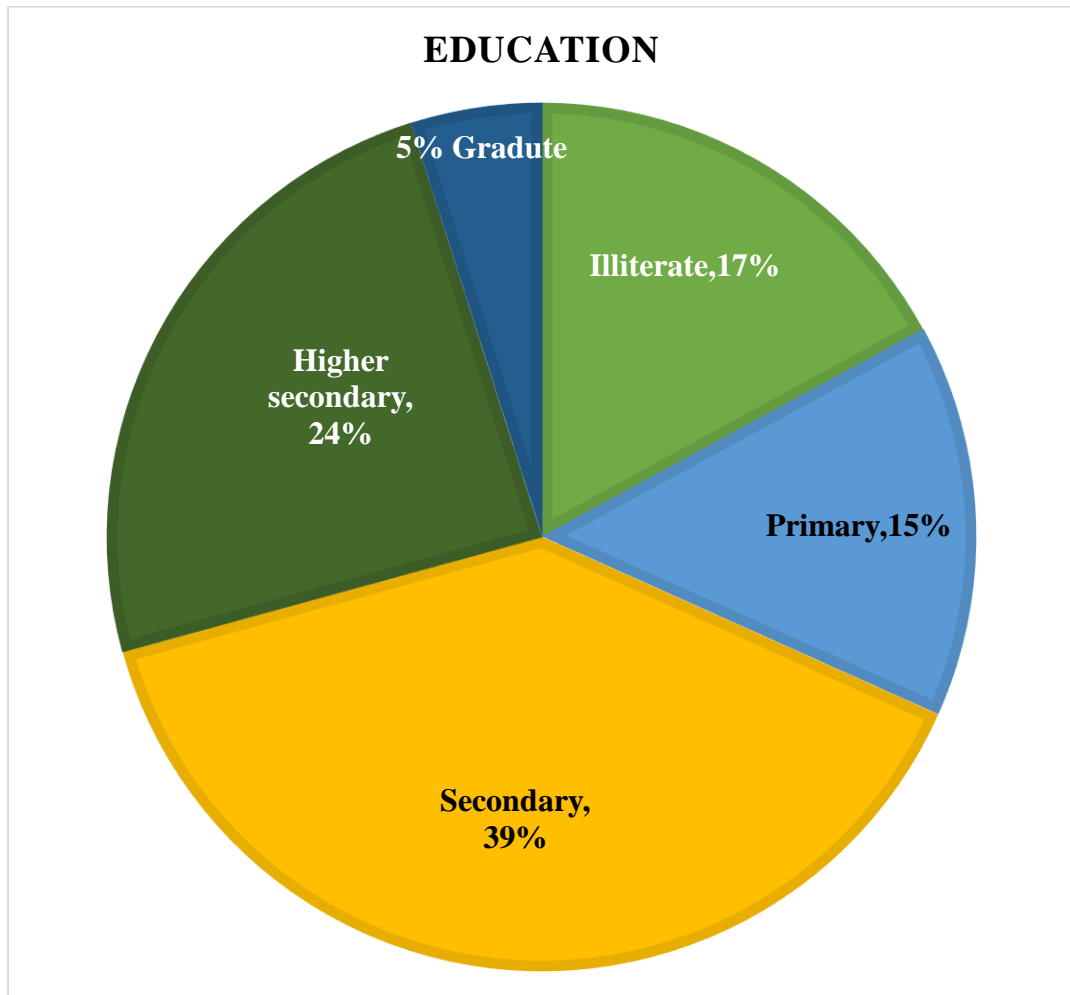
Figure 5: Educational level of the participants

Marital status:

Among the participants 44% (n=23) were married and the 56% (n=18) were married (figure:6).
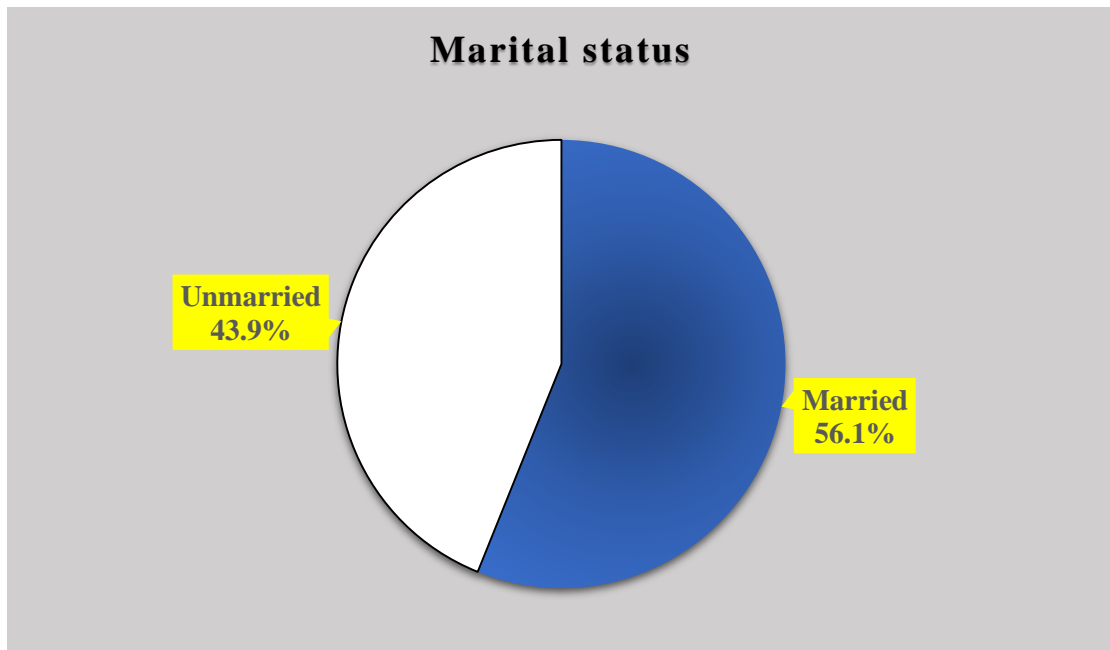
Figure 6: Marital status of the participants

Causes of amputation:

80% (33) of the patients' loss their lower limb due to accident and complication after surgery like gangrene, vascular disease etc. Rest of the participants 20% (8) loss their limb due to other causes like tumor, ulcer due to diabetics, violence etc.
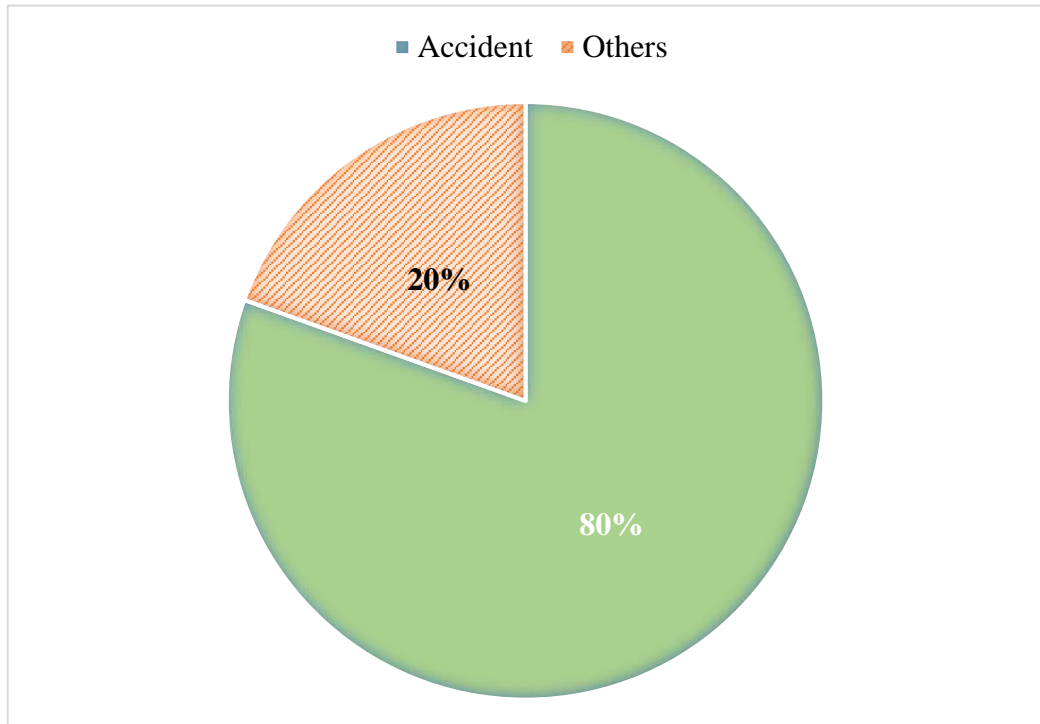
Figure 7: Causes of amputation

Prosthetic ambulation:

The mean prosthetic ambulation was 77% (n=41) among all age's participants. The ambulatory capacity among the age range 15-24 years old (n=16) were 81%; 25-34 years old (n=14) were 76%; 35-44 years old (n=8) were 76%; 45-54 years old (n=2) were 72% and 55-64 years old (n=1) were 55% (Figure 8).
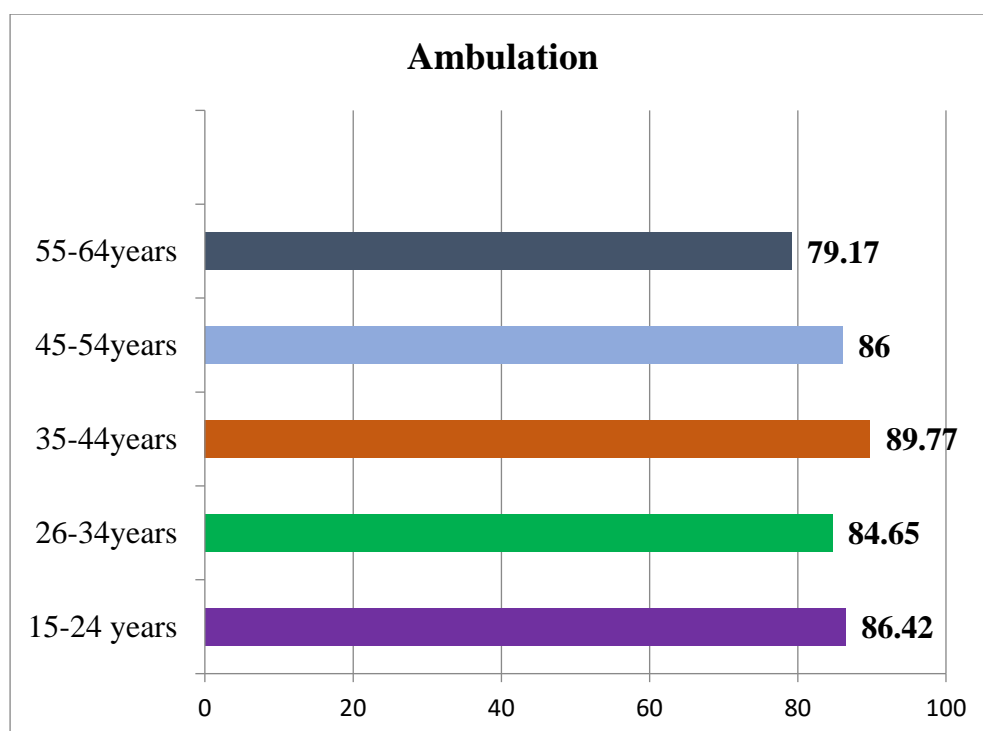
Figure 8: Prosthetic ambulation between age groups

Utility:

Among all age's participants (n=41) the mean utility of the lower limb prosthesis was 75%. The feel of prosthetic utility among the age range 15-24 years old (n=16) were 81%; 25-34 years old (n=14) were 77%; 35-44 years old (n=8) were 78%; 45-54 years old (n=2) were 90% and 55-64 years old (n=1) were 77% (Figure 9).
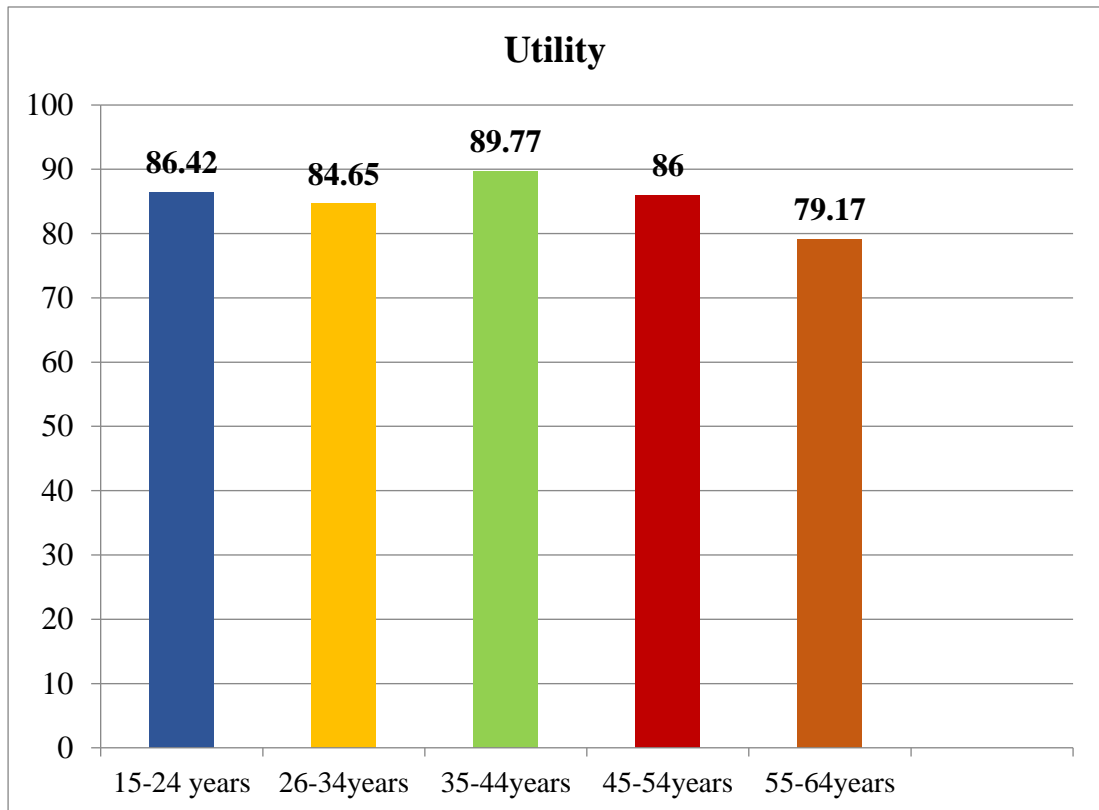
Figure 9: Utility of the prosthesis between the age groups

Residual limb health:

The mean residual limb health condition of the lower limb amputee patients was 86% (n=41) among all age's participants. The feel of prosthetic utility among the age range 15-24 years old (n=16) were 86%; 25-34 years old (n=14) were 85%; 35-44 years old (n=8) were 90%; 45-54 years old (n=2) were 86% and 55-64 years old (n=1) were 79% (Figure 10).

Residual limb

Age group	Value
15-24 years	86.42
26-34years	84.65
35-44years	89.77
45-54years	86
55-64years	79.17

Figure 10: Residual limb health condition between the age groups

Satisfaction:

The mean satisfaction with the lower limb prosthesis was 88% among all age's participants (n=41). The satisfaction level among the age range 15-24 years old (n=16) were 87%; 25-34 years old (n=14) were 88%; 35-44 years old (n=8) were 88%; 45-54 years old (n=2) were 91% and 55-64 years old (n=1) were 95 % (Figure 11).
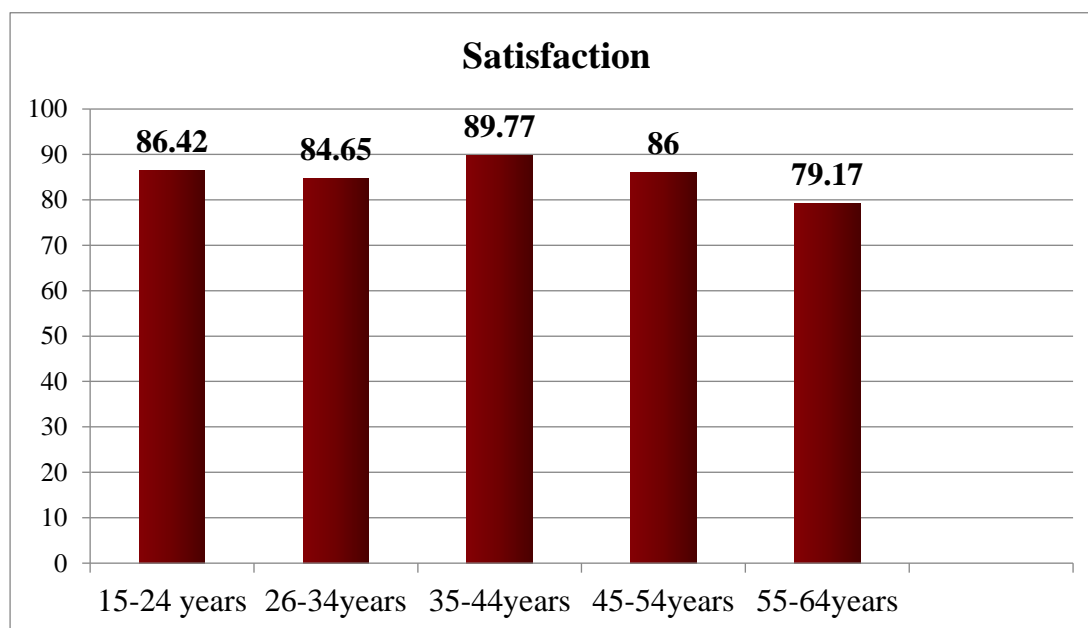
Figure 11: Satisfaction level between the age groups

Table 2: Ambulation, Utility, Residual limb health and satisfaction level among genders

Gender	Rate of Satisfaction	Ambulation	Utility	Residual limb health	Satisfaction
Male	Satisfaction	77%	79%	86%	72%
	Not satisfied	23%	21%	14%	28%
Female	Satisfaction	77%	80%	90%	63%
	Not satisfied	23%	20%	10%	38%

Among male and female, the percentage of the ambulatory power was almost same. The Female (n=7) had the capacity 77% whereas the male (n=34) ambulatory power was 77%. Decreased satisfaction rate of ambulation, 23% on female and 23% on male.

The percentage of the utility measure of the lower limb prosthesis was also nearly the same. Between female (n=7) the mean of the utility feel was 80% whereas the male (n=34) was 79%. Decreased satisfaction of utility on female were 20% and the male were 21%.

Among the gender variation, the residual limb health condition of the lower limb prosthesis varies a little. Between female (n=7) the mean of the residual limb health condition was 90% whereas the male (n=34) was 86%. Residual limb health condition decreased 10% on female and 14% on male.

Between the female participants (n=7) the overall satisfaction of their prosthesis mean was 63% and male (n=34) had the satisfaction level 72%. And the dissatisfaction rate was 37% on woman participants and 28% on man participants. (figure:11.2)

Table 3: <u>The prosthesis evaluation questionnaire scale summary:</u>

Scale name	Mean±SD
Ambulation	**77.29±11.58**
Utility	**79.15±11.09**
Residual limb health	**86.27±8.63**
Satisfaction	**87.88±9.66**

Table 4.1: Association between satisfaction and age of the participants.

Satisfaction with prosthesis and age of the participants	Chi-Square	P value
	120.5	0.57

This observed Chi-square value was 120.5 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's age and satisfaction level with prosthesis.

Table 4.2: Association between satisfaction and sex of the participants.

Satisfaction with prosthesis and sex of the participants	Chi-Square	P value
	32.76	0.38

This observed Chi-square value was 32.76 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's gender and satisfaction level with prosthesis.

Table 4.3: Association between ambulation and age of the participants.

Ambulation with prosthesis and age of the participants	Chi-Square	P value
	861.0	0.30

This observed Chi-square value was 861.0 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's age and ambulation with prosthesis.

Table 4.4: Association between ambulation and sex of the participants.

Ambulation with prosthesis and sex of the participants	Chi-Square	P value
	41.0	0.42

This observed Chi-square value was 41.0 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's sex and ambulation with prosthesis.

Table 4.5: Association between utility of prosthesis and age of the participants.

Utility of prosthesis and age of the participants	Chi-Square	P value
	861.0	0.15

This observed Chi-square value was 861.0 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's age and utility of prosthesis.

Table 4.6: Association between utility of prosthesis and sex of the participants.

Utility of prosthesis and sex of the participants	Chi-Square	P value
	41.0	0.38

This observed Chi-square value was 41.0 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's sex and utility of prosthesis.

Table 4.7: Association between residual limb health with prosthesis and age of the participants.

Residual limb health with prosthesis and age of the participants	Chi-Square	P value
	694.15	0.26

This observed Chi-square value was 694.15 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's age and residual limb health with prosthesis.

Table 4.8: Association between residual limb health with prosthesis and sex of the participants.

Residual limb health with prosthesis and sex of the participants	Chi-Square	P value
	18.63	0.97

This observed Chi-square value was 18.63 and 5% level of significant state chi-square was 1.96 which is more than the observed chi-square value. The result means Null-hypothesis was accepted and alternative hypothesis was rejected. So, there was no association between participant's sex and residual limb health with prosthesis.

Correlation between Satisfaction and Age:
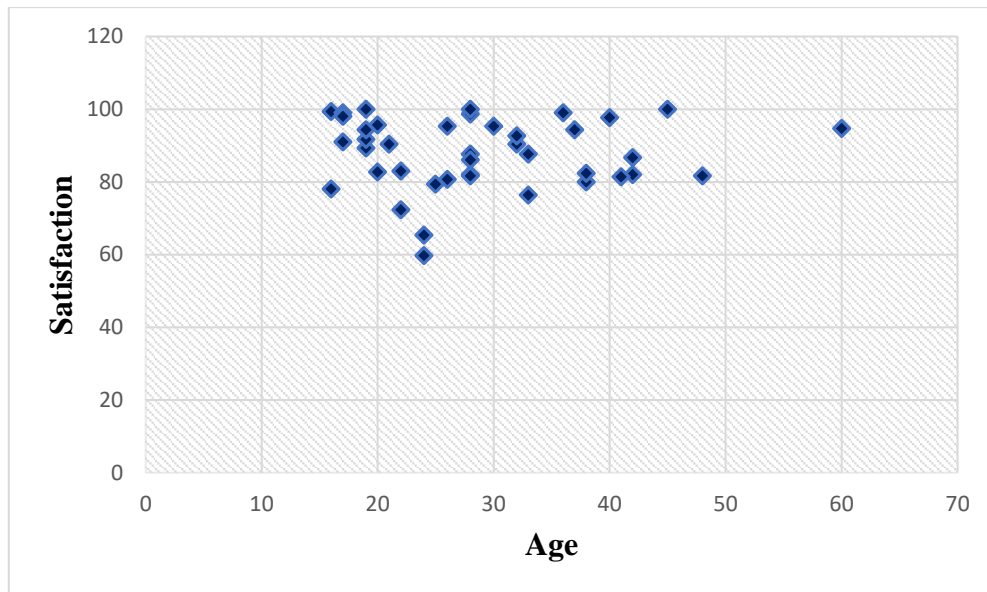
Figure: 12

The correlation between satisfaction and age was found to be positive, weak and linear relationship (r <0.01) (figure:12).

Correlation between Residual limb health and Age:
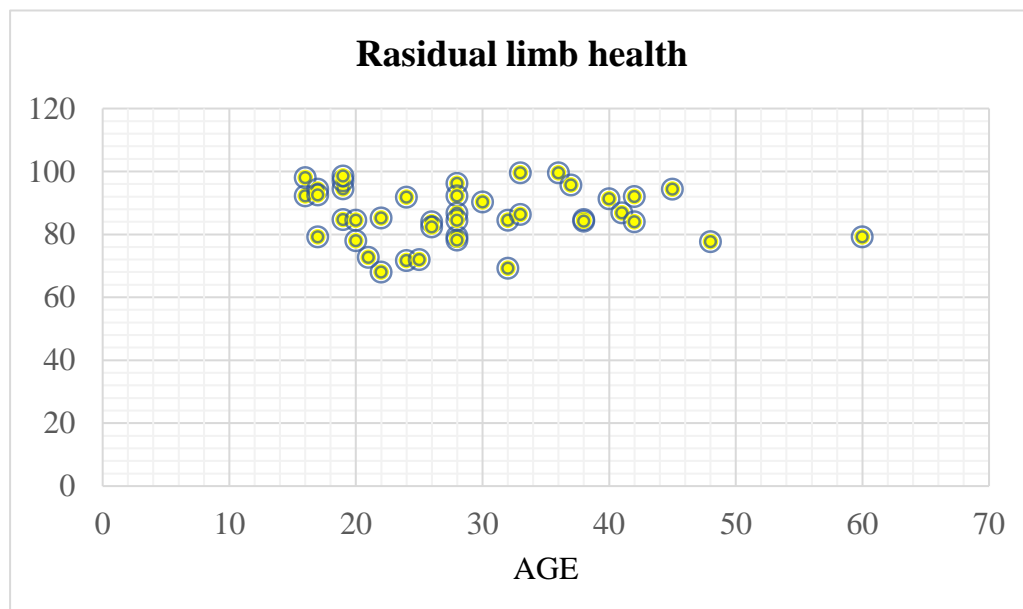
Figure: 13

There was negatively (r < 0.48) correlation between residual limb health and age; and there was a fair linear relationship between them (figure:13).

Correlation between Ambulation and Age:
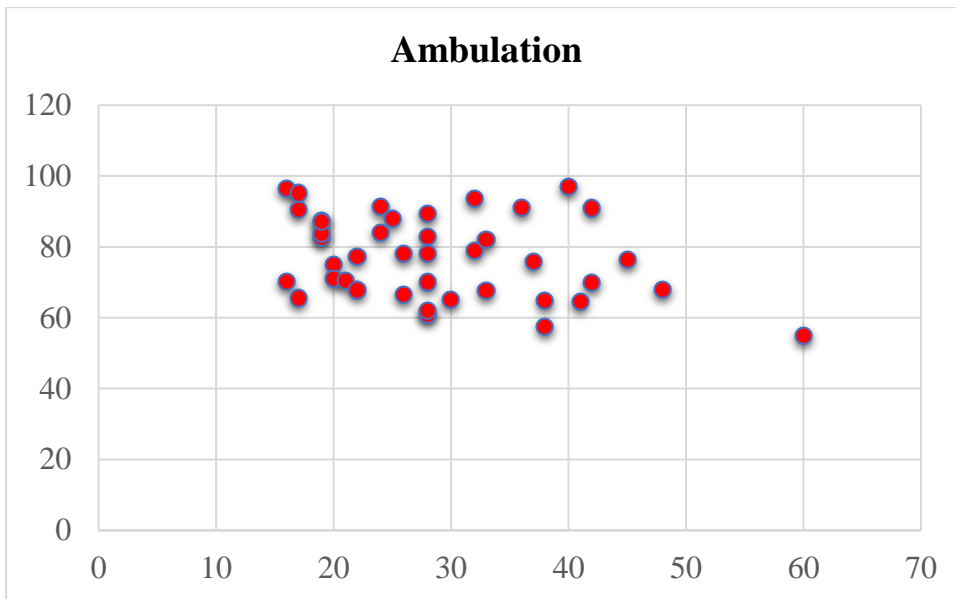
Figure:14

There was negatively (r < 0.33) correlation between ambulation and age; and there was a fair linear relationship between them (figure:14).

Correlation between Utility and Age:
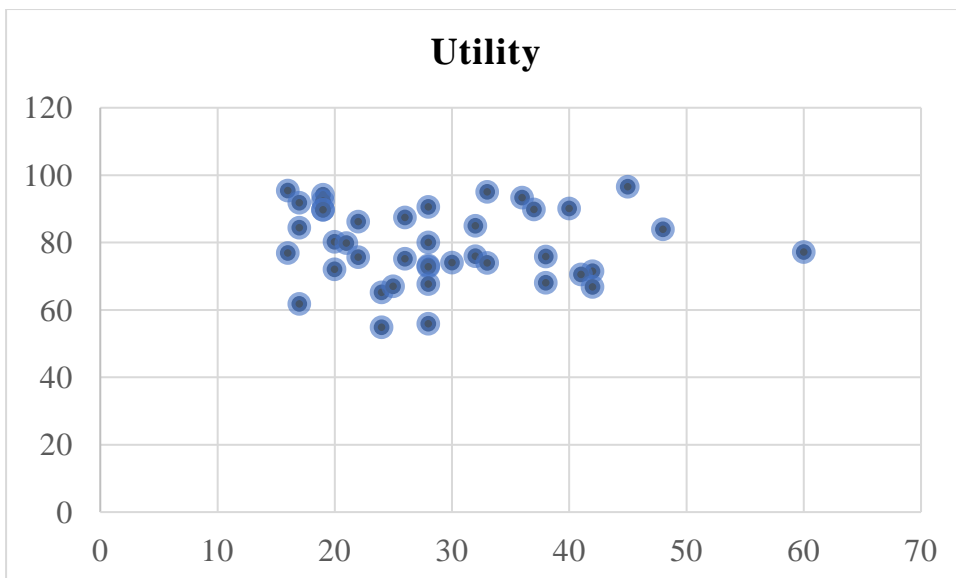
Figure:15

There was negatively (r < 0.05) correlation between ambulation and age; and there was a little or no linear relationship between them. (figure:15)

5.1 Discussion

In this chapter the results of the study are discussed in relation to the research questions and objectives of the study. The discussion focus on satisfaction of lower limb prosthesis for ambulatory function, utility, residual limb health and overall satisfaction of the participants.

Safer et al., (2015) mentioned on their study that the Prosthetic Evaluation Questionnaire (PEQ) was specifically developed to assess prosthesis-related changes in quality of life of lower limb amputee patients. The Prosthetic Evaluation Questionnaire (PEQ) is organized into nine functional domain scales that may be used individually to measure a specific domain of interest. Prosthetic Evaluation Questionnaire (PEQ) is composed of 82 questions with 9 subscales including frustration (FR), perceived response (PR), social burden (SB), ambulation (AM), utility (UT), residual limb health (RL), appearance (AP), sounds (SO), and well-being (WB). On this study researcher used twenty seven of 82 questions in PEQ use a visual analog scale with scores expressed in millimeters (0–100 mm) to find out the ambulation (AM), utility (UT), residual limb health (RL), and satisfaction level of lower limb amputee patients.

In this study the researcher found that among the study population (n=41) the most participants were younger; between the age 24 (n=16) and sequentially the number of the participants decrease according to increase of age. Rezai., (2017) also found on his study, majority of amputee patients were from the younger group of population in Afghanistan. Another study also showed that the majority population (42%) were younger on their study. Chigblo et al., (2017) and Handy Eone et al., (2018) mentioned, their study was dominated with youth lower limb amputees. In this study, majority population were male (83%). Other study also mentions on their study, sex ratio of the lower limb amputees in favor of men (Handy Eone et al., 2018; Dillingham et al., 2001). But there was no association between the satisfaction and age & sex of the participants (p< 0.57; p< 0.38). But there is statistically a little positive correlation (r <0.011) present between age and satisfaction. On this study the majority domain was transtibial and transfemoral and they were equal in number (n=19,19; 46%, 46%); partial foot (3%),

knee disarticulation (5%). So transtibial and transfemoral amputation are the most common in lower limb amputee patients. But Dillingham et al., (2001) found on their study that transtibial amputation was more common (51.3%) thereafter transfemoral (20.5%). Deans et al., (2008) also showed the transtibial amputation was more common (80%) on their study.

The most participants (63%) were from rural area of Bangladesh. On their occupational status, before amputation majority domains (46%) were student and their percentage decreased after amputation. And the researcher also found that lower limb also effects on unemployment. Before amputation there was no unemployment status among the study population but after amputation it's increased into 26.8%. Asano et al., (2008) also found unemployment (74%) in their study. Htwe et al., (2015) mentioned on their study that among the study population 67.7% were unemployed. So, lower limb loss causes an unemployment to the lower limb amputee (LLA) patients. In this study the researcher also found that trauma or accident is the major cause of lower limb amputation. 80% of the study population were injured due to accident or trauma. Safer et al., (2015) also showed the trauma as a major of amputation. Around 71% of their study population had the reason of amputation and its trauma.

77% prosthetic ambulation were there among the lower limb amputee patients on this study. The younger partisans were responding more positively than the elder ones. Wurdeman et al., (2019) found on their study,93% probability of being an unlimited community ambulator after using a lower limb prosthesis. So, prosthetic acts positively over the lower limb amputee (LLA) patients. But the researcher found the negative fair correlation (r <0.48) between the age and ambulation.

The thinking about the utility of the prosthetic limb among the all ages people were almost average (75%). Among the group ranged people, adult people (90%) were response more positively than the others.

The use of prosthetic lower limb may not cause any big trouble to the participant's residual limb. Through the PEQ questionnaire, the participants answered about their residual limb health. And almost every age group people answer those questions positively (86%). But fair negative correlation (r <0.48) was found between the residual limb health of the participants and age.

In this study the researcher also tried to find out the overall satisfaction of the lower limb amputee (LLA). This study showed that the satisfaction was positively increased according to the increase of age range. The participants of this study answered about their satisfaction with their prosthesis and walking with the prosthetic limb. The older people were expressed their more happiness (95%) as they were still able to walk at that stage. On the other hand, the younger ones were also happy (87%) but that were comparatively lower than the older ones.

5.2 Limitations

The result of the study should not be generalized all over the country as it is carried out within only one centre and the centre were selected based on personal judgement. The data was imitated because there was not much patients of lower limb amputation for follow up. So, the sample size was small. With quantitative measures it is really difficult to measure satisfaction of lower limb amputee (LLA) patients, a mix method quantitative and qualitative would have being better. And if the researcher uses the both research methods then the results might be different. The price of prosthesis was too high in context with their economic status so that they were not much interested on follow up session. There were very few researches focused on similar topic.

CHAPTER:VI   CONCLUSION & RECOMMENDATION

6.1 Conclusion

The loss of a limb is a shocking experience. Amputation is one of the major causes of permanent disability. Limb loss can be a result of vascular disease, trauma or congenital anomalies. But accident or trauma is the major cause of amputation in Bangladesh. Person with a new amputation face a complex set of tasks to return to adaptive mobility status. The prosthesis affects the patient's physical & mental ability of the adaptation. Frustration can be seen with them. The satisfaction of the patients with an amputated lower limb, with the respect to their prosthesis was positive over some criteria like the appearance of the prosthesis, weight, donning, limb condition, environmental factor. Although amputation is one of the most serious problem that a person can survive, it is possible to return to a healthy, happy and productive life even completing prosthesis. By using prosthesis lower limb amputee patients can lead their more positively by using it. So, the amputee patients were feeling the utility of prosthesis effectively. Psychological and social support needs to be improved to face the employment challenges. Nevertheless, patients were almost satisfied. The amputation of the lower limb is a physical, emotional and psychological challenge for the patient, their family and services aiming to assist them.

6.2 Recommendation

This study put forward that it is important to use lower limb prosthesis for more of their function completing easily in everyday life, CRP needs to supervised and ensure available materials to improve the service and also minimize difficulties for ambulation during bad weather. We should arrange many health camps to inform the unaware people more and inspire them to come for follow up. Some new activities can be added and should apply for other patients nicely. More research needed in this sector for better improvement of the patient. A better policy on prosthetics fitting choice, with laws voting to improve everyone in socio-economic reintegration and empowerment of these amputees is necessary.

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APPENDIX

CONSENT STATEMENT

Assalamualaikum/Namaskar, I am Suraiya Akter, 4th professional B.Sc. in Physiotherapy student of Bangladesh Health Professions Institute (BHPI) affiliated to the Faculty of Medicine, University of Dhaka. To obtain my Bachelor degree, I have to conduct a research project and it is a part of my study. My research titled is "Prosthetic ambulation, utility, residual limb health and satisfaction level following patients with lower limb amputation in Bangladesh." To make this study successful I need your information. So, I requested you to participate on this study. Now I want to ask some personal and related question.

I would like to inform you that this is a purely academic study and will not be used for any other purpose. Your participation in the research will have no impact on your present or future treatment in this area. All information provided by you will be treated as confidential and in the event of any report or publication it will be ensured that the source of information remains anonymous.

Your participation in this study is voluntary and you may withdraw yourself at any time during this study without any negative consequences. You also have the right not to answer a particular question that you don't like or do not want to answer during interview.

If you have query about the study or your right as a participant, you may contact with me and /or my research supervisor Muhammad Millat Hossain, Assistant Professor, Project & Course Coordinator of Department of Rehabilitation Science, Bangladesh Health Professions Institute (BHPI), CRP, Savar, Dhaka-1343

Do you have any question before I start?

So, may I have your consent to proceed with the interview?

Yes   No

Signature of participant………………………

Data …………………………………

TITLE: "Prosthetic ambulation, utility, residual limb health and satisfaction level following patients with lower limb amputation."

Questionnaire (English), this question is developed to identify the ambulatory capacity, utility, residual limb health and satisfaction level of lower limb prosthetic patients in Bangladesh.

Please give a tick (√) mark on the left side of the box of correct answer and mark on the line according to your feeling.

Patient's Information:

Name: **Age:**

Gender: 1. Female   2. Male

Living area: 1. Village   2. Town

Educational level: 1. Illiterate   2. Primary

                   3. Secondary   4. Higher secondary

                    5.Graduate

Occupation:

Before amputation: 1. Service holder   2. Teacher   3. Student   4. Unemployed   5. Others….

After amputation: 1. Service holder   2. Teacher   3. Student   4. Unemployed   5. Others….

Marital status:

1. Married
2. Unmarried
3. Divorce

Cause of amputation: 1. Accident   2. Others……

About your prosthesis:

1. Over the past four weeks, rate how happy you have been with your current prosthesis.

|⊢—————————————————————————————⊣|

Extremely unhappy   Extremely happy

2. Over the past four weeks, rate the fit of your prosthesis.

|⊢—————————————————————————————⊣|

Terrible   Excellent

3. Over the past four weeks, rate the weight of your prosthesis.

|⊢—————————————————————————————⊣|

Terrible   Excellent

4. Over the past four weeks, rate your comfort while standing when using your prosthesis.

|⊢—————————————————————————————⊣|

Terrible   Excellent

5. Over the past four weeks, rate your comfort while sitting when using your prosthesis.

|⊢—————————————————————————————⊣|

Terrible   Excellent

6. Over the past four weeks, rate how often you felt off balance while using your prosthesis.

|⊢—————————————————————————————⊣|

All the time   Not at all

7. Over the past four weeks, rate how much energy it took to use your prosthesis for as long as you needed it.

|⊢—————————————————————————————⊣|

Completely exhausting   None at all

8. Over the past four weeks, rate the feel (such as the temperature and texture) of the prosthesis (sock, liner, socket) on your residual limb (stump).

Worst possible   Best possible

9. Over the past four weeks, rate the ease of putting on (donning) your prosthesis.

Terrible   Excellent

10. Over the past four weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket).

Extreme amount   Not at all

11. Over the past four weeks, rate how smelly your prosthesis was at its worst.

Extremely smelly   Not at all

12. Over the past four weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.
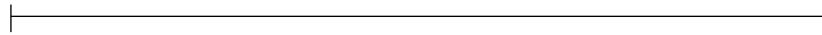
All the time   Never

13. Over the past four weeks, rate any rashes that got on your residual limb/ I had no rashes on my residual limb in the last month.

Extremely bothersome   Not at all

14. Over the past four weeks, rate any ingrown hairs (pimples) that were on your residual limb/ I had no ingrown hairs on my residual limb in the last month.

|—————————————————————————————————————|

Extremely bothersome   Not at all
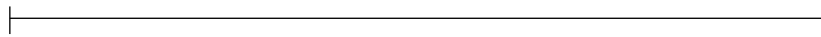
15. Over the past four weeks, rate any blisters or sores that you got on your residual limb/ I had no blisters or sores on my residual limb in the last month.

|—————————————————————————————————————|

Extremely bothersome   Not at all
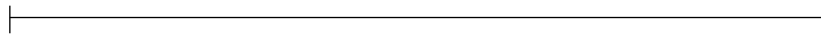
16. Over the past four weeks, rate how frequently you were frustrated with your prosthesis.

|—————————————————————————————————————|

All the time   Never

17. If you were frustrated with your prosthesis at any time over the past month, think of the most frustrating event and rate how you felt at that tune/ I have not been frustrated with my prosthesis.

|—————————————————————————————————————|

Extremely frustrated   Not at all
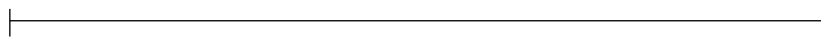
18. Over the past four weeks, rate your ability to walk when using your prosthesis.

|—————————————————————————————————————|

Cannot   No problem

19. Over the past four weeks, rate your ability to walk in close spaces when using your prosthesis

|—————————————————————————————————————|

Cannot   No problem

20. Over the past four weeks, rate your ability to walk upstairs when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem
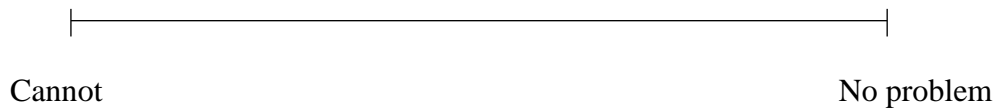
21. Over the past four weeks, rate how you have felt about being able to walk down stairs when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem

22. Over the past four weeks, rate your ability to walk up a steep hill when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem

23. Over the past four weeks, rate your ability to walk down a steep hill when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem

24. Over the past four weeks, rate your ability to walk on sidewalks and streets when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem

25. Over the past four weeks, rate your ability to walk on slippery surfaces (e.g. wet tile, snow, a rainy street, or a boat deck) when using your prosthesis.

|———————————————————————————————————|

Cannot   No problem
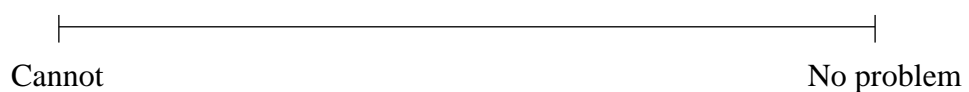
26. Over the past four weeks, rate how satisfied you have been with your prosthesis.

|—————————————————————————————————|

Extremely dissatisfied   Extremely satisfied

27. Over the past four weeks, rate how satisfied you have been with how you are walking.

|—————————————————————————————————|

Extremely dissatisfied   Extremely satisfied

<div align="center">**সম্মতিপত্র**</div>

আসসালামুআলাইকুম/নমস্কার, আমি সুরাইয়া আক্তার, ঢাকা বিশ্ববিদ্যালয়ের চিকিৎসা অনুষদের অধীনে বাংলাদেশ হেলথ প্রফেশন্স ইন্সটিটিউট (বিএইচপিআই) এর ফিজিওথেরাপি বিভাগের ৪র্থ বর্ষের ছাত্রী। আমার ব্যাচেলর ডিগ্রী অর্জনের জন্য আমাকে একটি গবেষণা সম্পাদন করতে হবে এবং এটা আমার অধ্যয়নের একটি অংশ।

আমার গবেষণার শিরোনাম, " **নিম্নাংশে কৃত্রিম পা সংযোজিত রোগীদের চলাচল,কার্যকারিতা,অবশিষ্ট অঙ্গের স্বাস্থ্য এবং সন্তুষ্টির হার নির্ণয়।** " এই গবেষণা প্রকল্প বাস্তবায়ন এর জন্য আপনার কিছু তথ্য সংগ্রহ প্রয়োজন। আপনাকে গবেষণার একজন অংশগ্রহণকারী হওয়ার জন্য অনুরোধ করছি। এ জন্য আমি আপনার কিছু ব্যক্তিগত এবং আনুষাঙ্গিক তথ্য জানতে চাচ্ছি।

আমি আপনাকে জানাতে চাই যে, ইহা একটি সম্পূর্ণরূপে প্রাতিষ্ঠানিক গবেষণা এবং অন্যকোন উদ্দ্যেশে ব্যবহৃত হবে না। গবেষণায় আপনার বর্তমান বা ভবিষ্যত চিকিৎসায় কোন খারাপ প্রভাব পরবে না। আপনার সকল উপাত্তসমূহ গোপণীয় রাখা হবে। আপনার অংশগ্রহণ সম্পূর্ণ ঐচ্ছিক। আপনি যেকোন সময় আপনাকে গবেষণা থেকে প্রত্যাহার করতে পারেন।

একজন অংশগ্রহণকারী হিসেবে, অধ্যয়ন সম্পর্কে যদি কোন প্রশ্ন থাকে তাহলে আমাকে বা আমার সুপারভাইজার মোহাম্মাদ মিল্লাত হোসেন , সহকারী অধ্যাপক, প্রকল্প এবং কোর্স সমন্বয়কারী, পূনর্বাসন বিজ্ঞান বিভাগ, বিএইচপিআই, সি আর পি, সাভার, ঢাকা, ১৩৪৩ এর সাথে যোগাযোগ করতে পারেন।

আমি শুরু করার আগে আপনার কোন প্রশ্ন আছে?

আমি কি শুরু করতে পারি?

হ্যাঁ ▢   না ▢

অংশগ্রহণকারীর নামঃ......................................

স্বাক্ষরঃ...........................   তারিখঃ.....................

বিষয়ঃ "নিম্নাংশে কৃত্রিম পা সংযোজিত রোগীদের চলাচল,কার্যকারিতা,অবশিষ্ট অঙ্গের স্বাস্থ্য এবং সন্তুষ্টির হার নির্ণয়।"

অনুগ্রহপূর্বক নিচের প্রশ্নগুলোর মধ্যে সঠিক উত্তরের বাম পাশে টিক (√) চিহ্ন দিন এবং দাগের মধ্যে আনুভূতি অনুযায়ী চিহ্নিত করুন।

পরিচিতিঃ

নামঃ   বয়সঃ

লিঙ্গঃ   ১।মহিলা   ২।পুরুষ

বসবাসের এলাকাঃ   -গ্রাম   -শহর

শিক্ষাগত যোগ্যতাঃ

   -অশিক্ষিত   -প্রাথমিক

   -মাধ্যমিক   -উচ্চ মাধ্যমিক

   -স্নাতক

পেশাঃ

পা কেটে যাওয়ার পূর্বেঃ

পা কেটে যাওয়ার পরেঃ

বৈবাহিক অবস্থাঃ

   -বিবাহিত

   -অবিবাহিত

   -বিচ্ছেদ

পা কাঁটার কারণঃ

   -দুর্ঘটনা

   -অন্যান্য....................।

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আপনার প্রোথেসিস সম্পর্কে :

১। গত চার সপ্তাহ ধরে, আপনি আপনার বর্তমান প্রোথেসিস সঙ্গে কতটা খুশি?

|————————————————————————————|

খুবই অখুশি   খুবই খুশি

২। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস কতোটা ফিট ?

|————————————————————————————|

খুবই খারাপ   খুবই ভালো

৩। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ওজন কেমন মনে হয়েছে?

|————————————————————————————|

খুবই বেশি   উত্তম

৪। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করার সময় দাঁড়িয়ে আপনার কতোটা আরাম বোধ হয়?

|————————————————————————————|

খুবই খারাপ   খুবই ভালো

৫। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করার সময় বসে আপনার কতোটা আরাম বোধ হয়?

|————————————————————————————|

খুবই খারাপ   খুবই ভালো

৬।গত চার সপ্তাহের মধ্যে আপনার প্রোথেসিস ব্যবহার করার সময় আপনি কত বার ভারসাম্যহীনতা অনুভূব করেছেন?

|————————————————————————————|

সব সময়   কখনই না

৭। গত চার সপ্তাহের মধ্যে , আপনার প্রোথেসিস ব্যবহার করার জন্য কত শক্তি প্রয়োজন হয়েছে?

|————————————————————————————|

সম্পুর্ন ভাবে ক্লান্ত   মোটেও না

৮। গত চার সপ্তাহের মধ্যে, আপনার অবশিষ্ট অংশের উপর অনুভূতিটি কেমন ছিল (যেমন তাপমাত্রা এবং, সকেটের ধরণ)?

├───┤

খুবই খারাপ   খুবই ভালো

৯। গত চার সপ্তাহের মধ্যে, আপনি প্রোথেসিস পড়তে কতোটা স্বাচ্ছন্দ্য বোধ করেছেন ?

├───┤

খুবই খারাপ   খুবই ভালো

১০। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিসের ভিতরে কতটা ঘামে (মুজা, লাইনার, সকেটে)?

├───┤

সবসময়   কখনই না

১১। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস কতটা দুর্গন্ধ যুক্ত হয়ে গিয়েছে ?

├───┤

খুবই   মোটেও না

১২। গত চার সপ্তাহের মধ্যে, আপনার প্রোথেসিস পরিবর্তন করার সময় আপনার অবশিষ্ট অঙ্গটি কতটা ফুলে উঠেছিল ?

├───┤

সবসময়   কখনই না

১৩। গত চার সপ্তাহের মধ্যে, কোন লাল ফুস্কুড়ির মতো হয়েছিলো কি?/ গতো মাসে আমার কোন ফুস্কুড়ির মতো হয় নি।

├───┤

খুবই বিরক্তিকর   মোটেও না

১৪।গত চার সপ্তাহ ধরে, আপনার অবশিষ্ট অংশে যে কোনও অভ্যন্তরীণ চুল (পিম্পল) হয়েছিলো কি রেট দিন

?/ গতো মাসে আমার কোন পিম্পলের মতো হয় নি।

|—————————————————————————|

খুবই বিরক্তিকর   মোটেও না

১৫। গত চার সপ্তাহ ধরে, আপনার অবশিষ্ট অংশে আপনার যে কোন ফোস্কা বা ফুসকুড়ি বা ঘা হয়েছিলো কি?/ গতো মাসে আমার কোন ফোস্কা বা ফুসকুড়ি বা ঘা এর মতো হয় নি।

|—————————————————————————|

খুবই বিরক্তিকর   মোটেও না

১৬। গত চার সপ্তাহ ধরে, কত বার আপনি আপনার প্রোথেসিস নিয়ে হতাশায় ছিলেন?

|—————————————————————————|

সবসময়   কখনই না

১৭। যদি আপনি গত মাসে কোনও সময়ে আপনার প্রোথেসিস নিয়ে হতাশ হয়ে থাকেন , তাহলে সবচেয়ে হতাশ ঘটনা চিন্তা করুণ এবং তার আনুভুতি কেমন ছিল?

|—————————————————————————|

খুবই হতাশ   কখনই না

১৮।গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করে হাঁটতে আপনি কতোটা সক্ষম ?

|—————————————————————————|

পারিই না   কোন সমস্যাই নেই

১৯।গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করে সরু জায়গায় হাঁটতে আপনার সক্ষমতার রেট?

|—————————————————————————|

পারিই না   কোন সমস্যাই নেই

২০। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করার সময় সিঁড়িতে উঠতে আপনার সক্ষমতার রেট?

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পারিই না   কোন সমস্যাই নেই

২১। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করার সময় সিঁড়িতে নামতে আপনার সক্ষমতার রেট?

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পারিই না   কোন সমস্যাই নেই

২২। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করে সময় খাড়া পাহাড়/উঁচু জায়গায় উঠতে আপনার সক্ষমতা রেট?

|--|

পারিই না   কোন সমস্যাই নেই

২৩। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করে সময় খাড়া পাহাড়/উঁচু জায়গায় নামতে আপনার সক্ষমতা রেট?

|--|

পারিই না   কোন সমস্যাই নেই

২৪। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করে ফুটপাত এবং রাস্তায় হাঁটায় আপনার সক্ষমতা রেট?

|--|

পারিই না   কোন সমস্যাই নেই

২৫। গত চার সপ্তাহ ধরে, আপনার প্রোথেসিস ব্যবহার করার সময়, পিচ্ছিল জায়গায় হাঁটতে আপনার দক্ষতার রেট দিন (উদাঃ ভিজা টাইলস, বৃষ্টির রাস্তায় বা নৌকা ডেকে)।

|--|

পারিই না   কোন সমস্যাই নেই

২৬। গত চার সপ্তাহ ধরে, আপনি আপনার প্রোথেসিস নিয়ে কতটা সন্তুষ্ট ?

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খুবই হতাশ   খুবই সন্তুষ্ট

২৭।গত চার সপ্তাহ ধরে, আপনি যেভাবে হাঁটছেন তার সাথে আপনি কতটা সন্তুষ্ট ছিলেন তা রেট করুন।

|———————————————————————————————|

খুবই হতাশ   খুবই সন্তুষ্ট

বাংলাদেশ হেল্থ প্রফেশন্স ইনস্টিটিউট (বিএইচপিআই)
Bangladesh Health Professions Institute (BHPI)

(The Academic Institute of CRP)

Ref.

Date: 26/08/2019

CRP-BHPI/IRB/08/19/1317

To
Suraiya Akter
B.Sc. in Physiotherapy
Session: 2014-2015 Student ID: 112140251
BHPI, CRP, Savar, Dhaka-1343, Bangladesh

Subject: Approval of the thesis proposal **"Prosthetic ambulation, utility, residual limb health and satisfaction level following patients with lower limb amputation in Bangladesh"** by ethics committee.

Dear Suraiya,
Congratulations.
The Institutional Review Board (IRB) of BHPI has reviewed and discussed your application to conduct the above-mentioned dissertation, with yourself, as the Principal investigator. The Following documents have been reviewed and approved:

Sr. No.	Name of the Documents
1	Dissertation Proposal
2	Questionnaire (English & Bengali version)
3	Information sheet & consent form.

The purpose of the study is to identify the satisfaction level of lower limb prosthesis patients and about their prosthetic ambulation, residual limb health and utility in Bangladesh. The study involves use of a prosthetic evaluation questionnaire to find out their prosthetic ambulation, utility, residual limb health and satisfaction level that may take 10 to 15 minutes to answer the questionnaire for collection of specimen and there is no likelihood of any harm to the participants. The members of the Ethics committee have approved the study to be conducted in the presented form at the meeting held at 08.30 AM on 11th August, 2018 at BHPI.

The institutional Ethics committee expects to be informed about the progress of the study, any changes occurring in the course of the study, any revision in the protocol and patient information or informed consent and ask to be provided a copy of the final report. This Ethics committee is working accordance to Nuremberg Code 1947, World Medical Association Declaration of Helsinki, 1964 - 2013 and other applicable regulation.

Best regards,

Millat Hossain

Muhammad Millat Hossain
Assistant Professor, Dept. of Rehabilitation Science
Member Secretary, Institutional Review Board (IRB)
BHPI, CRP, Savar, Dhaka-1343, Bangladesh

Date: 20th August 2019

The Chairman
Institutional Review Board (IRB)
Bangladesh Health Professions Institute (BHPI)
CRP-Savar, Dhaka-1343, Bangladesh

Subject: **Application for review and ethical approval.**

Sir,

With due respect I would like to draw your kind attention that I am a student of B.Sc. in Physiotherapy at Bangladesh Health Professions Institute (BHPI)- an academic institute of CRP under Faculty of Medicine of University of Dhaka (DU). I have to conduct a thesis entitled **"Prosthetic ambulation, utility, residual limb health and satisfaction level following patients with lower limb amputation in Bangladesh"** under honorable supervisor, Muhammad Millat Hossain, Assistant Professor, Project &Course Coordinator of Department of Rehabilitation Science, Bangladesh Health Professions Institute(BHPI),CRP,Savar,Dhaka-1343.The purpose of the study is to identify the satisfaction level of lower limb prosthesis patients and about their prosthetic ambulation, utility and residual limb health in Bangladesh.

The study involves use of a prosthetic evaluation questionnaire to find out their prosthetic ambulation, utility, residual limb health and satisfaction level that may take 10 to 15 minutes to answer the questionnaire for collection of specimens. There is no likelihood of any harm to the participants and / or participation in the study may benefit the participants or other stakeholders. Related information will be collected from the patients' guide books. Data collectors will receive informed consents from all participants. Any data collected will be kept confidential.

Therefore I look forward to having your kind approval for the thesis proposal and to start data collection. I can also assure you that I will maintain all the requirements for study.

Sincerely,
Suraiya Akter
Suraiya Akter
4th Year, B. Sc. in Physiotherapy,
Roll no: 19, Session: 2014-15,
Bangladesh Health Professions Institute (BHPI),
(An academic institution of CRP)
CRP, Chapain, Savar, Dhaka-1343.

Recommendation from the thesis supervisor:

Millathossain

Muhammad Millat Hossain

Assistant Professor, Project & Course Coordinator of Department of Rehabilitation Science

BHPI, CRP, Savar, Dhaka-1343, Bangladesh

Permission Letter

9th July, 2019

The Head of the Department

Department of Prosthetics & Orthotics

Centre for the Rehabilitation of the Paralysed (CRP)

Chapain, Savar, Dhaka-1343.

Through: The Head of the Department, Department of Physiotherapy, BHPI.

Subject: Prayer for seeking permission to collect data for research project.

Sir,

With due respect I state that I am a 4th year student of B. Sc. in Physiotherapy Department of BHPI, the academic Institute of CRP. I sincerely seeking your permission to collect the data for my research project as the partial fulfillment of the requirement for the degree of B.Sc. in Physiotherapy. The title of this research project is **"Prosthetic ambulation, utility, residual limb health and satisfaction level following patients with lower limb amputation in Bangladesh"** under the supervision of **Muhammad Millat Hossain**, Assistant Professor, Project & Course Coordinator of Department of Rehabilitation Science, Bangladesh Health Professions Institute (BHPI), CRP, Savar, Dhaka-1343. I would like to assure you that anything of my research project will not be harmful for the participants.

So, I therefore, pray and hope that you would be kind enough to grant my application and permit me to collect data to accomplish this research project.

Sincerely yours,

Suraiya Akter

Suraiya Akter
4th Year, B. Sc. in Physiotherapy,
Roll no: 19, Session: 2014-15,
Bangladesh Health Professions Institute (BHPI),
(An academic institution of CRP)
CRP, Chapain, Savar, Dhaka-1343.

Recommended & forwarded to Head, Dept. of PT BHPI & Head Dept. of Prosthesis & orthosis for appraisal & help in data collection

permitted

S.M. IMRAN SHOAIB
Clinical Prosthetist & Orthotist (In-Charge)

Prof. Md. Obaidul Haque
Head, Department of Physiotherapy
BHPI, CRP, Savar, Dhaka-1343

Muhammad Millat Hossain
Assistant Professor
Project & Course Coordinator
Dept. of Rehabilitation Science
BHPI, CRP Savar Dhaka-1343 Bangladesh