

**COMPLICATIONS AMONG THE SPINAL CORD INJURED PATIENT
AFTER RETURNING THE COMMUNITY**

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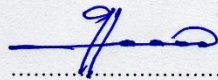
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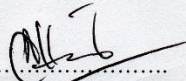
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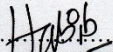
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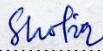
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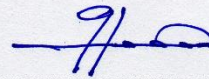
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Declaration

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 department of Physiotherapy of Bangladesh Health Profession Institute (BHPI).

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Acronyms

AD	: Autonomic Dysreflexia
BHPI	: Bangladesh Health Professions Institute
BMRC	: Bangladesh Medical and Research Council
CRP	: Centre for the Rehabilitation of the Paralysed
DVT	: Deep Venous Thrombosis
HO	: Heterotrophic Ossification
IRB	: Institutional Review Board
MDD	: Major Depressive Disorder
RTA	: Road Traffic Accident
RTI	: Respiratory Tract Infection
SPSS	: Statistical Package of Social Science
SCI	: Spinal Cord Injury
UK	: United Kingdom
USA	: United States of America
UTI	: Urinary Tract Infection
WHO	: World Health Organization

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Abstract

Purpose: To explore the complications among the spinal cord injured patients after returning the community. *Objectives:* To find out socio demographic information of spinal cord injured patients, to find out the nature of pressure sore, to find out the nature of pain, to find out the complications of muscle & joint, to find out the nature of tone, to find out the urological complications, to find out the cardio-respiratory complications, to find out the other complications (fall, poor transferring & bed mobility, psychological complications) with the SCI patients after returning the community. *Methodology:* Cross sectional type of study design was used to conduct the study where 50 participants with SCI who had completed their rehabilitation from Centre for the rehabilitation of the paralysed (CRP). The data were collected by using a semi structure questionnaire form and analysed by descriptive statistics using percentages, pie chart and bar chart. *Result:* Out of 50 most of the participants were 31-40 years range that was almost 32% (n=16), among them females were 20% (n=10) whereas males were 80% (n=40). So this result shows that males were more vulnerable than females. In rural area 74% (n=37) were more affected than the people who lived in urban 26% (n=13). About 34% (n=17) had pressure sore, 92% (n=46) patients had pain, most the patients had moderate pain 74% (n=37). About 44% (n=22) patients had spastic tone, 10% (n=5) had flaccid tone. There were 80% (n=40) had muscle and joint related problem. 50% (n=25) patients had no control in bowel & bladder, 52% (n=26) were suffering from UTI. About 18% (n=9) patients had cardio-respiratory problems, 68% (n=34) patients had psychological complication. And 14% (n=7) patients were falling complications, 24% (n=12) were poor transferring & bed mobility, 26% (n=13) had both falling and poor transferring & bed mobility complications after returning the community. *Conclusion:* The result of the study demonstrates that spinal cord injured persons are more prone to develop complications. So only awareness like- early hospitalization, early initiation of the complications and prevention of complications and proper care can help to survive after SCI returning the community.

Keywords: Spinal cord injury, complications after returning the community.

1.1 Background

To the mankind spinal cord injury (SCI) was one of the most devastating conditions (Rathore et al., 2008). Razzak (2013) stated that within a few seconds, SCI may happen but in the last period of lifetime the devastating effects could be stayed. Now a days road traffic accidents, gunshot injuries, knife injuries, falls and sports injuries are the most common causes of SCI in the world. In the developing countries like road safety situation was deteriorating day by day and the number of road traffic accident (RTA) is increasing in recent year (Razzak, 2013). In the developed country, RTA was the major cause of spinal cord injury followed by fall and sports injury (Rathore, 2010). Spinal Cord Injury brings impairment of person independence and physical function, as well as take in many complications because of the injury. There was a strong relationship between functional status and whether the injury was complete or not complete, along with the level of the injury. Spinal cord injury (SCI) was often followed by complications, which lead to the critical effect that loss of motor, sensory and autonomic function had on a person's health, quality of life and social participation (Haisma et al., 2007). Neurogenic bladder and bowel dysfunction, urinary tract infections, fall, pressure ulcers, pain, fractures, deep vein thrombosis, spasticity, autonomic dysreflexia, pulmonary and cardiovascular complications, and psychotic disorders were the common complications after SCI. Loss of work because of serious disability in the patient after SCI, which brings psychosocial and economic problems (Nas et al., 2015).

In one study had identified over 64 papers from 28 countries that the incidence SCI was about 25.5/million/year of in developing countries. Males (82.8%) were more likely to sustain SCI than females. The mean age of SCI occurrence was 32.4 years. The relative frequency for following subgroups of SCI was: MVC 41.4% and falls 34.9%; complete and incomplete SCI were 56.5 and 43.0%, respectively; paraplegia and tetraplegia were 58.6 and 40.7%, respectively. However, there was no significant difference between MVC and falls, complete and incomplete SCI, paraplegia and tetraplegia. The most commonly reported complication was the development of pressure ulcers (Rahimi-Movaghar, et al., 2013). About 24% history of spinal cord injury in the United States

occurred due to motor vehicle accident, along with the significant technological development, make important risk factor for incidence of SCI. Incidence rate ranges between 10.4 and 83 cases per million in one year, worldwide. In Europe, the incidence rate is from 10.4 per million per year to 29.7 per million per year, while in Asia was reported 27.1 (Trgovcevic et al., 2014). Recently published data indicate the incidence of 10.5 per million per year in Tehran, Iran (Sharif-Alhoseini et al., 2014). Incidence between 27.1 per million per year and 83 per million per year was noticed in Northern America (Trgovcevic et al., 2014). Cervical spine injury which was lead to neurological deficits more than 40% cases and carry significant public health impact because of its unwanted events on personal and family level, high cost of patient care, loss of productivity and reduce quality of life (Shrestha et al., 2008).. This injuries increasing in number day by day, though the actual incidence of spinal cord injuries was not known in most of the developing countries. In India it was estimated that 20000 new patients of spinal cord injuries were added every year, mostly were from village and illiterate (Shrestha et al., 2008). The incidence rate of SCI, In USA was 11000-14000 per year and annual cost of patients care was 4 billion dollars for 200000 alive patients in each year (Shrestha et al., 2008).

In one study had described that many patients live at distant villages in rural Nepal and India where existence farming was the primary source of income, and where abrupt environment, limited road access and distant housing were often obstacles to using mobility devices (Scovil et al., 2012). About 48.3% patients of SCI had problems due to the default structure of their housing, needing a ramp, lift or elevator to exchange stairs, or needing restorations to provide adequate space to move about in a wheelchair (Khazaeipour et al., 2014). Free movement within the home and safe outlet from the home, greatly reducing autonomy and independence were prevented by these problems (Khazaeipour et al., 2014). Incidence and prevalence rate of SCI in Nepal were unknown (Scovil et al., 2012). Complications had a considerable impact on those with SCI. A high incidence of complications was associated with a lower level of health-related aspects, such as physical capacity, activities and functional outcome (Haisma et al., 2007). Start of active rehabilitation may interfered by complications, can form unsatisfactory set-back

during rehabilitation, and frequently lead to re-hospitalization and complications were an important cause of mortality following SCI (Haisma et al., 2007).

In 2012 Chhabra showed in his study, 93.4% deserted spinal cord injury patient's rehabilitation had not been initiated early and result in significant poor functional outcome. Higher incidence of complications due to lack of or inadequate awareness, thus results in prolong hospitalization, increase cost of hospitalization and severely affect functional outcomes. In his study, represent 10.4% patients were admitted after 3 of injury. Evidence of Chhabra focused that interval between injury and correct diagnosis actually more than 3 weeks (Chhabra & Arora, 2012). Lack of awareness among 52.5% patients and others were lower economic status, distance of definitive hospital(16.4%) acts as a predisposing factors to increase incidence of complications (Chhabra & Arora 2012). Amatachaya1 et al. (2011) had shown that Patients with spinal cord injury (SCI) had suffered from a broad range of medical, social, psychological and economic problems, often because of the fact that the injury commonly occurs in young individuals. The reduction of motor performance and physical activity while engaging in the same environmental conditions may induce less or poor active lifestyle, risk of injury and secondary health complications after returning their community, thus raise a negative impact on the persons with SCI. A high incidence of complications is associated with a lower level of health-related aspects, such as physical capacity, activities and functional outcome (Haisma et al., 2007).

Until now, this information has received little attention in literatures. There had only been a few studies that reported the changes in physical performance, incidences of complications and falls of SCI patients after discharge or returning their community (Amatachaya et al., 2011). Therefore, this studies aims to find out the incidences of medical complications of patients with SCI after returning their community. The findings of this study would provide important insight into treatment modification to optimize the ability of the patients to be independent (Amatachaya et al., 2011). We all know that prevention is always better than cure. When there is arise any type of complication of spinal cord injured patients, the patient faces lots of problems those always try to decline the patient condition. Early detection prevent the chance of decline and helps to make

awareness among the population and will be helpful to prevent all type complications due to complications of spinal cord injury.

1.2 Rationale

Spinal cord injury (SCI) was very disruptive period in the life of an individual and requires a considerable coping process. Shortly after the injury, all attention is put into stabilizing the patient and from that moment the individual had to cope with challenges at physical, social, environmental, and psychological levels (Lude et al., 2014). Spinal cord injury (SCI) results loss of ability to control functions of body systems that leads the patients unable to control their movements. After discharge functional level can be worse due to inappropriate circumstantial conditions such as lack of home adaptation and assistive devices, by which falls and risks of medical complications can dramatically increase. Thus, outpatient and community rehabilitation may have a vital role to reduce the problems (Amatachaya et al., 2011).

In SCI the common cause of morbidity and mortality mostly depend on complications. Kawu et al., (2011) stated that 44.4% patients die due to respiratory failure, 26.4% for septicemia, 11.8% for DVT. Amatacheyal et al. (2011) had shown in his study that, among 44 patients experienced at least one complication and 11 of them re-admitted and encountered 1-5 times during 6 months. Complications were more frequent among tetraplegic than paraplegic and men are 4 times more common than women (Nair et al., 2005). Common secondary complications were urinary tract infections and pressure sores, as reported by 47% and 36% of the population at respectively. 49% and 36% of the population were affected mostly by the complications during the year after discharge (Haisma et al., 2006).

Now a days the evidence of SCI is increasing in Bangladesh with increasing the population and people are involved in different risky occupation. In case of spinal cord lesion there is no possibility to regenerate the neuron of CNS in human and once the lesion is stable, the neurologic deficit does not change. Patients with spinal cord injury reduces motor functional control and self-care activities. As a result, the patient become more likely to develop complications after SCI. This study will find out the amount of the patients who have complications after taking treatment and returning their community. This study will find out the people with spinal cord injury who are suffering badly from this various kind of secondary complications. This evidence will help the patient and others to know, how much prone they are, to develop complications after SCI, without

proper care and management. In this study also focus what should be the proper living environment, hygiene of patient, food habit, activities of daily living of persons with spinal cord injury. This evidence focus the importance of patient education to prevent the complications and awareness program. Finally it will be helpful to reduce the morbidity and mortality rate due to complications of SCI.

1.3 Research question

What are the complications among the spinal cord injured patients after returning the community?

1.4 Aim of the study

The aim of the study is to find out the complications among the spinal cord injured patients after returning the community.

1.5 Objectives

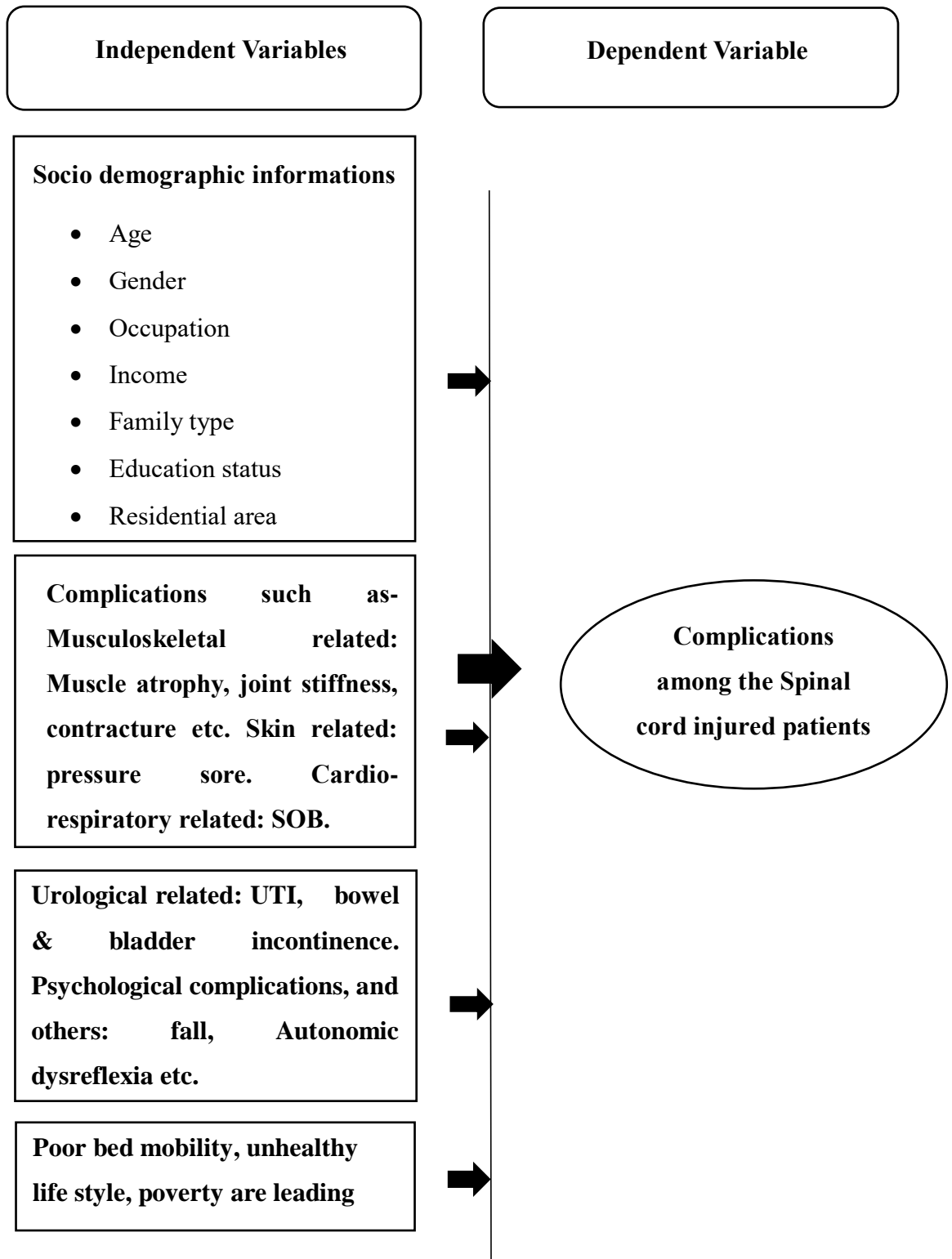
1.5.1 General objective-

To identify the complications among the spinal cord injured patients after returning to the community.

1.5.2 Specific objectives-

- To find out socio demographic information of spinal cord injured patients;
- To find out the nature of pressure sore;
- To find out the nature of pain;
- To find out the complications of muscle & joint;
- To find out the nature of tone;
- To find out the urological complications;
- To find out the cardio-respiratory complications;
- To find out the other complications (fall, poor transferring & bed mobility, psychological complications, Autonomic dysreflexia).

1.6 Conceptual framework



1.7 Operational definition

Traumatic spinal cord injury

A direct or indirect trauma to spinal cord following complete or incomplete cut off of the spinal cord. Complete cut injuries defect in total loss of motor and sensory function, incomplete injuries result in the loss of some motor and sensory function.

Paraplegia

Paraplegia refers to impairment or loss of motor and/or sensory function in the thoracic, lumbar or sacral (but not cervical) segments of the spinal cord, secondary to damage of neural elements within the spinal canal. Through paraplegia, arm functioning is spared but the trunk, legs and pelvic organs may be involved depending on the level of injury. The term is used in referring to cauda equine and conus medullaris injuries, but not to lumbosacral plexus lesions or injury to peripheral nerves outside the neural canal (Nas et al., 2015).

Tetraplegia (preferred to “quadriplegia”)

This term refers to impairment or loss of motor and/or sensory function in the cervical segments of the spinal cord due to damage of neural elements within the spinal canal. Tetraplegia results in impairment of function or paralysis of the arms, usually in the trunk, legs and pelvic organs, with including the four extremities. It does not include brachial plexus lesions or injury to peripheral nerves outside the neural canal (Nas et al., 2015)

Complete injury

Loss of sensory and motor function in the lowest sacral segment resulting in bowel-bladder control.

Incomplete injury

Preservation of sensory or motor function below the neurological level of injury that included the lower sacral segment.

Skeletal level

The level of vertebra of mostly injured.

Neurological level

The most caudal level, where both sensory and motor function are intact.

Complete-A

No sensory or motor function in the sacral segment.

Incomplete-B

Sensory but not any function preserved below the neurological level and includes the sacral segments.

Incomplete-C

Motor function is preserved below the neurological level, and more than half of the key muscles below the neurological level have a grade less than 3.

Incomplete-D

Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscles grade 3 or more.

Normal-E

Motor and sensory functions are intact.

Complication

Complications is a process or event that interrupted or changes the prognosis of the disease and its treatment and kill the time of patient's recovery (The free medical dictionary, 2009).

Stages of pressure sore: 4 stages are most commonly used.

- Stage-I: Affects skin, results in redness and coloration of the area.
- Stage-II: Skin is broken both epidermis and dermis.
- Stage-III: Damage skin and involve fat and muscle tissue.
- Stage-IV: Extends up to bone and joint structures

Spinal cord injury (SCI) results in long-term complications and had a negative impact on patients' lifestyles in different levels such as their social and family relationships, education, employment, and financial status. In young adults SCI occurs most when they were in their primary and are experiencing a productive life and social role. (Botticello et al., 2012). In Razzak study (2011) had shown that carrying heavy load on the head causes of falling is the second most common cause (16%), usually resulting in tetraplegia. This is common in Bangladesh and India. Usually the day laborers, who were regularly carrying 60-100 kg loads on their heads, those persons had attained such injuries. By spreading awareness among workers and employers, as well as by the proper imposition of existing laws, we need to be stopped this unacceptable work like- heavy weight-bearing on the head. In contrast, in developed countries like USA, motor vehicle accidents were the leading cause.

Khazaeipour, (2014) state that many factors such as personality and the social, cultural, and economic situation that affect recovery from the persons with SCI, Persons with spinal cord injury (SCI) often face serious health problems, such as bladder and bowel disorders, pressure ulcers, self-care, sexuality and neuropathic pain. These secondary health conditions (SHCs) had been defined as: physical or psychological health conditions that are influenced directly or indirectly by the presence of a disability or underlying physical injury (Adriaansen et al., 2013). SHCs hamper an active lifestyle and quality of life on top of the primary motor and sensory impairments due to the SCI. They are a frequent cause of mortality and re-hospitalizations (Adriaansen et al., 2013). In Razzak (2011) study was found that only 16.4% of the study population survived for 10 years, which was much lower than figures for various developed countries where a 10 year survival rate was observed in around 80% of affected persons. This inconsistency may be due to different causes of injury, inadequate acute management, lack of proper social reintegration, less attention or care by family & community and inability to treat the co-morbidity of persons with SCI. The study showed that more than 80% of the persons with SCI had died at home. This finding was inconsistent with those of other studies regarding place of death. During spinal cord injury rehabilitation effort was put

into the treatment of complications and into the improvement of the physical fitness. Therefore, the period of this rehabilitation not only depends on the severity of the injury, but also depends on the rate of complications and on rehabilitation goals (Post et al., 2005).

Complications were the common causes of interfering with fruitful rehabilitation and although fitness improves during rehabilitation, it remains little (Haisma et al., 2007). There was a complex relations between fitness, the occurrence of complications and the duration of rehabilitation that need to be unravelled and this will provide tools to enhance individual outcome and rehabilitation strategies. A recent study report that, complications were high both during and after inpatient rehabilitation, had mostly occurred (Haisma et al. 2007). Complications were common among tetraplegic than paraplegic. But in paraplegic patients urinary tract infection and bowel & bladder incontinence were more common than tetraplegic patients (Nair et al. 2005). About 74.7% of patients with spinal cord injury were mostly committed pain, spasticity, contractures and heterotopic ossifications (Nair et al. 2005).

Traumatic SCI (TSCI) was defined as an acute, traumatic lesion of the spinal cord, with varying degrees of motor and/or sensory deficit or paralysis. Although injuries of cauda equine were included, the definition excluded isolated injuries of other nerve roots (Gupta et al., 2008). Traumatic SCI occurs mostly in young adults with more than half life between 16 to 30 years of age. Men account for about 80% of cases. Represents a significant proportion of individuals were admitted for SCI re-habilitation (Gupta et al., 2008). Spinal stenosis, primary and metastatic tumors, ischemia, infection and congenital diseases were the common causes of non-traumatic SCI. Non-traumatic SCI may be as high as 8 per 100000 in annual incidence (Gupta et al., 2008). It was found that the majority of persons were paraplegic rather than tetraplegic (79.75% vs 20.25%), which was different from findings in other studies. Razzak (2011) stated in his study that in France, tetraplegic were found 52% and paraplegic 48%. This distinction in finding might be because of the higher mortality of people with cervical cord damage therefore of various reasons for harm in different nations, improper evaporating from injury sites, thoughtless transportation to doctor's facility, insufficient intense administration and absence of pre-doctor's facility mind.

About 50 to 900 per million population was prevalence and traumatic SCI ranges from 9 to 174 per million population in global incidence (Scovil et al., 2012). In this manner a measure of yearly incidence of traumatic SCI in Nepal is 300–5000, and prevalence 1500–25000. One hospital in eastern Nepal reported that from 2001 to 2004 there were 149 traumatic SCI patients admitted and 233 were from 1997 to 2001. There were no reports of numbers of non-traumatic SCI in Nepal; one Indian hospital reported that 13% of 207 SCI patients were admitted in 2003–2004 and they were non-traumatic (Scovil et al., 2012). SCI patients outcomes after discharge from rehabilitation at (Green Pastures Hospital and Rehabilitation Centre) GPHRC have been a concern that, for the secondary complications about one-third of patients were found to require readmission for treatment. Nair et al, (2005) showed that individuals with lesions of spinal cord were vulnerable to several medical complications that increase the duration and cost of hospitalization and that result in loss of therapy time, delay with the rehabilitation program, and add to disability. Nontraumatic injuries represent about 30–50% of spinal cord injuries and make a major risk factor for medical complications during rehabilitation. Pain (naturopathic as well as musculoskeletal), contracture, pressure ulcers, spasticity, urinary tract infection (UTI), depression, autonomic dysreflexia and deep vein thrombosis were the most common complications observed in patients suffering from NTSCl during rehabilitation or after returning community (Gupta et al., 2009).

However, because of the challenges involved in completing follow-up in rural Nepal, formal evaluation had been limited. Patients are more likely to get or face secondary health complications, such as pressure ulcers, urinary tract infections (UTI), heterotrophic ossification, DVT, respiratory complications etc. are resulting in re-hospitalization or even death, without good community reintegration (Scovil et al., 2012). In the west, according to GPHRC, pressure ulcer represent adjacent one-fourth of the cost of tend to people with SCI, and 7–8% die from related complications (Scovil et al., 2012). Amatachaya1 et al. (2011) reported in his study that recurrent medical complications and falls may attribute negative impacts on functional ability of the subjects, particularly with chronic SCI after discharge. In addition, the alteration of functional ability may be affected by the related constrictions that the subjects come across after discharge. Most of

the patients were lived in rural areas in the northeast of Thailand and had economic problems. These areas were rarely confined places that were specifically modified for individuals with physical disability. Financial issues likewise kept them from having mobility aids helps and home adjustment. It was sensible to expect that the lessening of motor capacity, however captivating in the same ecological conditions may incite a hypoactive way of life that improves danger of optional medical issues and influences capacity to independently do day by day exercises. Most of the patients had to be faced medical complications from one to five times during 6 months. The three complications that were most widely reported included neuropathic pain, UTI and pressure ulcers, of which the next two were the leading causes of re-hospitalization (Haisma et al., 2007). Joseph et al. (2016) had shown in his study that about 50.3% (n= 71) patients had one or more secondary complication. PUs (n=42; 29.8%) was the most common followed by pulmonary complications 23.4% (n=33) and UTIs 17% (n=24) (Joseph et al., 2016).

Rathore et al. (2008) showed that in the developing country like Bangladesh, Turkey, India and Nigeria and in developed countries like Canada, United Kingdom, fall is the major cause of spinal cord injury. In Nigeria 48% case because of fall and 36% case happens for street car crash. In Romania 59% give history of fall and 13% for street car crash. In Bangladesh, 72% cases are traumatic and among them 43% because of tumble from tallness, 20% reason for spinal rope harm are convey substantial load on head and 18% spinal line happen because of street activity accident. In an Indian review reports, 90.62% patients report no less than one inconvenience and among them normal half patients suffer with urinary tract disease (Gupta et al., 2009) and another review highlights on the commonness of embarrassments, in these report confirm that 70% patients endure with neurogenic bladder brokenness, 60% report spasticity, 45% with agony, 25% weight ulcer, 20% heterotopic hardening, 10% urinary tract contamination, 10% for autonomic dysreflexia, 10% edema and 10% report disability (Vijayakumar and Singh, 2004).

In Bangladesh Razzak (2013) had shown that (N=53) Spasticity 52.8%, UTI 22.6%, Pressure ulcer 7.5%, Pain 45.2%, Depression 16.9%, Dependent edema 30.1%, No complication 15.0% are the common medical complications during rehabilitation.

Krause (2007) discovered some particular gatherings of issues in individuals with SCI living in the community, and these were (a) mental issues including loneliness, depression and stress, (b) reliance and control issues, (c) health issues such as pain and others and others (d) natural issues, for example, openness. Plainly, SCI can show obstacles to mental strength of those influenced.

According to the study of Anthony, after spinal cord injury most of the patients felt pain or had complained pain (Chiodo et al., 2007). As the cause of re-hospitalization in patients with SCI, pain as the highest incidences of medical complications. Pain was connected with psychosocial factors such as depression, anger and negative cognition (Perry et al., 2009). The quality of life and physical function of patients with SCI was also affected chronic pain (Haisma et al., 2007). According to a study of New Delhi approximately 45% patients suffers with pain (Vijayakumar & Resident 2004). Most patients reported neurogenic and musculoskeletal pain, or had spasticity at each assessment (Haisma et al., 2007). In the rates ranging from 63 to 91% at 1-year post injury following a SCI, pain has been found to be dominant. About 2–4 of those individuals reporting pain in the first year, up to 71% had reported that pain interfered with daily activities (Donnelly et al., 2005). Pain among the spinal cord injury patients can categorize into musculoskeletal pain and neuropathic pain. Aching and throbbing type are described as musculoskeletal pain and sharp, shooting and burning sensation were considered as neuropathic pain. According to a study on pain, average 25% pain were musculoskeletal origin, 15% referred pain and 5% report central cord pain (Vijayakumar et al., 2004). About 64-80% patients were reported pain and among them 38% characterized the pain as severe pain. When the patient feels pain in upper extremities, shoulder(75%), wrists(53%), hands(43%) and 35% in elbows may involve (Chiodo et al., 2007). In a study of Netherland found that, the severity of degree of pain was correlated the development of degree of spasticity (Haisma et al., 2007). Adriansen et al. (2013) had reported that neuropathic pain (83.7–92.1%) and UTIs (56.5–58.9%) were the most secondary health complications. In a study using a similar follow-up period, in 40% of the participant musculoskeletal pain was present at 6 months following SCI (compared with 62.3% at our first follow-up year) and in 59% of the participants 5 years after SCI (compared with 87.1% in our study). They also found that, at 5 years

following SCI, 25% reported their musculoskeletal pain as severe and they found a slightly higher percentage of 34.7%. What related was the increase in musculoskeletal pain during the 5-year follow-up period, which can be explained by the physiological age-related decline in the musculoskeletal system and the chronic overuse of the upper extremities due to their wheelchair-dependent life. There was a significant decrease in the occurrence of problematic spasticity and the occurrence of neuropathic pain between 1 and 2 years after discharge. Psychosocial factors such as depression, anger and negative cognition were associated with pain (Perry et al., 2009). Quality of life and physical function of patients with SCI also affected by chronic pain (Amatachaya et al., 2011).

Brotherton et al. (2007) had reported that the occurrences of falls in his study were higher than other reported and the researchers inspected that falls in independent ambulatory subjects with SCI and found that 75% of the patients were sustained at least one fall in a year. In his study, he found that in 6 months 24 patients (55%) experienced falls. Wheelchair-bound patients fell from wheelchair (7 in 21 subjects: 33%, range 1–8 times) where in upright activity the ambulatory persons fell while they performed (17 in 23 subjects: 74%, range 1–24 times). This indicated a high risk of falls, specially in more mobile patients. For frequently perform daily activities, higher functional ability might encourage the patients. However, loss of motor control and inappropriate environmental conditions might be increased the risks of injury to the patients. Amatachaya et al. (2011) had shown that with the chronic motor incomplete persons of SCI significant differences were found in the reduction of self-care, transfer and mobility scores of persons. During this follow-up time, patients were reported a high incidence of medical complications (91%) and falls (55%). During the 6 months follow-up, more than half of all subjects experienced at least one fall (range 1–24 times/subject). During upright, mostly walking and activities, the falls were mostly found in persons with incomplete SCI (Amatachaya et al., 2011). Chen et al. (2016) stated that according to National Spinal Cord Injury Database (NSCID), during 2010–2013 the percentage of falls was 31% but in the 1970s that was 17%, so the difference of the percentage showed that how the increasing percentage of SCI cases caused by falls. In the elderly people, fall-induced SCI was

particularly common, about 75% of SCI cases occurring among persons 76 years of age and older are due to falls (Chen et al., 2016).

“Autonomic Dysreflexia (AD) was defined as a sudden reaction of the autonomic nervous system triggered by a stimulus below the level of the lesion (e.g. bladder distension, UTI) which caused an increase in blood pressure associated with symptoms such as: (a) below the level of the lesion: Piloerection, pallor, cool extremities, abundant sweating; (b) above the level of the lesion: severe headaches, nasal congestion, flushing of the skin and bradycardia” (Adriaansen et al., 2013). Kirshblum et al. (2007) stated that risk for developing autonomic dysreflexia in those people who had injury levels at T6 and above T6. “AD is a symptom complex that arises from a noxious or intense stimulus below the level of injury that leads to an unopposed discharge of the sympathetic nervous system. This sympathetic discharge is unable to be modulated from higher cerebral centers and often results in hypertension”. Many people with SCI had a baseline systolic blood pressure in the 90- to 110-mmHg range, and an increase the blood pressure of 20 to 40mmHg may be a sign of AD. It was estimated that within the first year after their injury 92% of people who develop AD will have their first episode. Bladder dysfunction such as an over distended bladder, detrusor sphincter dissynergia, and kidney and bladder stones were the most common causes of AD and some other causes were included ingrown toenails, menstrual cramps, infections, bowel impaction, pressure ulcers, or undetected musculoskeletal conditions (Kirshblum et al., 2007).

“UTI was operationalized as a symptomatic subject (e.g. fever, malaise, incontinence, increased spasms of legs, abdomen or bladder, gritty particles or mucus in the urine or cloudy urine, foul-smelling urine) which was treated with antibiotics”. Pulmonary infections were also only included when they were treated with antibiotics. Because of the reduction of structured training and proper feedback in bladder management the persons with subacute SCI to have a high risk of UTI after discharge (Amatachaya et al., 2011). In an Indian study reports that, 90.62% patients report at least one complication and among them average 50% patients suffered with UTI (Gupta et al., 2009). In another study the researcher had found that an incidence of UTI at 1, 2 and 5 years following SCI of 56.5%, 58.3% and 58.9%, respectively who were in community or home after

taking treatment (Adriansen et al., 2013). Haisma et al. (2007) were found that Common secondary complication was urinary tract infections, reported by 47% of the population.

In the study of Divanoglou, in the SCI patients the symptomatic UTIs and pneumonia affected in similar proportion (Divanoglou et al., 2010). Respiratory complications exposed as shortness of breath, fever, excess secretion that were yellow or greenish in color. In spinal cord injury patients who had Long-term respiratory complications characterize a major source of morbidity and mortality. During chronic SCI pneumonia was often mentioned as the primary cause of death. Pulmonary or respiratory complications are influenced by respiratory muscle paralysis, restrictive ventilation, and ineffective cough (Cardenas et al., 2004).

In Cardenas et al. (2004) study showed that risk of respiratory-related re-hospitalization were increased at ASIA grade A, B, or C tetraplegia patients and that these groups were most prominent during 1 year post injury and then dropped in subsequent years. It was known that with increasing level of spinal cord injury there was a progressive effect on lung volumes. About 72.3% patients had died due to respiratory complications and majority of them were tetraplegic patients (Chiodo et al., 2007) and in Nigeria 44.4% patients of spinal cord injury had died due to respiratory failure (Kawu et al., 2011). Another study states that, due to inability to cough effectively and expectorate secretions with previous history of heavy smoking, intrinsic lung disease or general anesthesia, tetraplegic and high paraplegic patients were more vulnerable for respiratory complication and almost 20% are at risk for respiratory complication after some time of injury. In both motor complete and incomplete, the scores of persons with subacute SCI were increased in self-care, transfer and mobility items, but after discharge decreased in respiration and sphincter management items. (Amatachaya et al., 2011)

Pressure ulcers are a serious, lifelong secondary complication of spinal cord injury (SCI) that had the potential to “interfere with physical, psychological and social wellbeing and to impact overall quality of life” (Regan et al., 2010). The significant morbidity and mortality related with spinal cord injury (SCI) remain, in spite of many advances in spine surgery and rehabilitation medicine Even in SCI the ulcers (PUs) were remaining a

common complication (Zakrasek et al., 2015). Divanoglou et al. (2010) stated that the second most common medical Complication was Pressure ulcers & the rates of pressure ulcers on the first annual follow-up year after injury to range between 12 and 36% and it was the most frequent medical complication, with an increasing rate in later follow-ups. In Zakrasek et al. (2015) study reported that the developing world like ‘low-income’ and ‘middle-income’ Countries, PUs were affected ‘practically 100%’ of people with SCI. SCI make individuals with SCI uniquely vulnerable to PU development because of the sensory loss, motor impairment and skin changes of the patients. PUs were not particular to SCI but were frequent complications of immobilized and hospitalized patients in various clinical situation (Zakrasek et al., 2015). Hossain et al. (2016) had reported that wheelchair-dependent (26%) and (2%) who were walking had a pressure ulcer at the time of interview. In the preceding 3 months, more than 75% of participants who were wheelchair-dependent indicated the secondary conditions that pressure ulcers had been a ‘mild to severe problem. Importantly, for the formation of PU there were responsible some external and modifiable risk factors. In developing countries, these modifiable risk factors were more noticeable. In developing countries PUs were more challenging to prevent and treat for the risk factors such as poverty, low education, low household income, limited activity level and malnutrition, were more strong (Zakrasek et al., 2015). Haisma et al. (2007) were found that pressure sores were common secondary complication reported by 36% of the population. Secondary complication like- diseases of the skin was the second most common etiology at most time intermissions (years 1, 10, 15, 20) and was the most common at year 5 and causes re-hospitalization. Contributions from moisture, sheering forces, poor nutrition, and cigarette smoking and continuous pressure to the skin can lead to the formation of pressure ulcers. Pressure ulcers may cause secondary effects, such as- pain (in incomplete lesions), increased spasticity, and wound infections which may further impact medical morbidity and re-hospitalization. Pressure ulcers occur most commonly over the sacral and ischial regions in people with SCI (Cardenas et al., 2004). Zakrasek et al. (2015) suggested that in developing countries the prevalence of PUs was greater than in the developed world. In United States the prevalence of PU 1 year after injury was 11.5% and at 15 years after injury was 21%. In his study was also reported that the prevalence of PU were 26.7–46.2%, mean of 35.2%.

In Brazil from a population only of persons with paraplegia PU prevalence was drawn less than 30% (26.7%) (Zakrasek et al., 2015).

Heterotopic ossification was defined as the presence of bone in soft tissue surrounding paralyzed joints confirmed by radiological examination. During the acute rehabilitation phase after SCI, Heterotopic ossification (HO) also usually present. Its incidence was between 16% and 53% in SCI, clinically important with 10% to 20% and developing into ankylosis in 3% to 5%. With the decrease in the range of motion of a joint Swelling of the extremities may be present. Most commonly, in the hips HO presents, followed by the knees, elbows, and shoulders. Deep venous thrombosis must also be ruled out, because there was an association between the 2 conditions. With a neurologically complete injury who present with spasticity HO was more common in that peoples (Kirshblum et al., 2007).

Spasticity may develop in people with upper motor neuron injuries, after the period of spinal shock. Spasticity may or may not be harmful for the patient. At times, spasticity may be beneficial; that was, a patient may use extensor muscle tone to perform stand pivot transfers. (Kirshblum et al., 2007)

Chen et al. (2006) had shown that without an appropriate adjustment for the dietary intake after injury, the energy intake easily exceeds daily energy requirements, which predisposes the affected individuals to weight gain. About 40% patients were overweight or obese found in a recent survey of 348 persons with chronic SCI.

Psychological issues affect outcome after SCI. Premorbid issues such as alcohol and other substance abuse, depression, psychosis or behavioral or learning disorders will affect rehabilitation and long-term outcome. Psychosocial issues such as relationship outcome, patrician group acceptance, and family resources had a greater impact on functional outcome and secondary conditions than does the neurologic level of injury. In the persons with SCI depression was one of the most common psychological conditions (Craig et al., 2009). Craig et al. (2009) had also found that there were significant gaps in our knowledge about SCI-related depression and how to manage it. Similar incidence rates emerged from depression screening studies of people undergoing SCI rehabilitation

(20%–43%) and community-residing people (11%– 60%). In contrast, the 1-year incidence of MDD (Major Depressive Disorder) was 6.7% in the U.S population (Fann et al., 2011). In Hossain et al. (2016) study stated that the participants had possible major depressive episode, 10 (6%) probable major depressive episode and 7 (4%) major depressive episode (Hossain et al., 2016). In Fann et al. (2011) study had reported that depression was associated with longer rehabilitation lengths of stay and less functional independence and mobility at discharge as well as fewer functional improvements. In addition, depression was related with incidence of greater pressure ulcer, poorer self-appraised health, 3 more days in bed and greater use of paid personal care, and poorer role functioning (Crisp et al., 2007). Krause et al. (2008) had found that possible major depression predicted all-cause mortality after SCI. Anxiety was one of the most common and disabling comorbid conditions associated with depression, (Kroenke et al., 2007) and they also said that still they know little about the comorbidity of anxiety and depression in persons with SCI.

Depression was the most common psychological problems in spinal cord injury (SCI) patients. The severity of depression ranges from minor depression to adjustment disorders and major depressive episodes (Shin et al., 2012). Their type, duration, symptoms and effect on functions were changeable (Shin et al., 2012). After SCI, the estimated prevalence of depression varies from study to study, depending on the type of measurement, the category of depression, and the period during which the measurement was actually taken (Shin et al., 2012). Depression may be included higher repetition rates, inadequate recognition, and barriers to treatment when depression was recognized and factors that may contribute to the low rate of mental health care for persons with SCI (Fann et al., 2011). Because of the heavy stressors after SCI, there may be a chance of higher rate of depression recurrence compared with other patient groups (Fann et al., 2011). As a result of the shared symptoms of depression and SCI, such as fatigue, sleep disturbance, and low appetite depression may not be recognized properly (Fann et al., 2011). An estimated showed that about 50% to 80% of patients with depressive or anxiety disorders present with physical symptoms, including headaches, pain, fatigue, or worsening chronic medical illness symptoms. Further morbidity, illness behavior, and vocational impairment can be possible due to inaccurate diagnosis and inappropriate

medical procedures (Fann et al., 2011). In Shin et al. (2012) study shown that, about (63.9%) patients with SCI suffered a higher rate of depression and higher overall level of depression (13.8 points) within 6 months of the occurrence of the SCI. It was also found that motor complete injuries had momentous effects on depression.

In Craig, (2009) study had shown that Kennedy and Rogers assessed after the initial week of the injury, and then every 6 weeks up to the time of discharge (mean 48 weeks), when assessments were performed 1, 3, 6, 12 and 24 months after discharge, about 25 the persons with SCI for state anxiety. They found that cruel anxiety levels steadily increased from the initial week after the injury to scores above those expected for a clinical anxiety disorder at approximately 36–48 weeks post-injury (just before discharge), after which mean levels fell below the clinical cut off score for a clinical disorder.

Complications after spinal cord injury had fallen negative impact for the family, whole community and rehabilitation program. Genitourinary complications, pressure sore and respiratory complications were considered as a most common for the re-hospitalization of patients (Chiodo et al., 2007). Higher age of injury manipulate to increase the rate of mortality and morbidity(Gupta et al., 2009). Amatachaya et al. (2011) have shown that mortality rates were higher among the patients those not admitted to a specialized hospital. Common causes of mortality after spinal cord injury consider as septicemia, pneumonia, pulmonary embolism and heart disease (Murthy, 2007). Among the 79.75% injured persons, approximately 56.4% patients was admitted and died within 5 years. 80.8% died at home, average one-third had pressure sore during death (Razzak et al., 2011). But it was good news for all that, over the last 50 years mortality and morbidity of spinal cord injury patients are decreased (Burns & Connell 2012).

3.1 Study design

This study aimed to find out the complications spinal cord injury patients after returning to their community. For that reason quantitative research model in the form of a cross sectional type of study design was used to perform the study. A quantitative research design was used, so that there were used large numbers of participants to collect data. Cross sectional study was one of the form of observational study and most commonly used to observe the section of population at community.

3.2 Study area

Data were collected from the persons with spinal cord injury at Dhamrai & Savar upozilla who return to their community after taking treatment or after discharge from hospital.

3.3 Study population

The study populations were all the Spinal cord injury patients, who are in the community after having treatment or discharge. The sample was taken by convenience sampling.

3.4 Sample size

The equation of sample size calculation were given below

$$n = \left\{ \frac{Z \left(1 - \frac{\alpha}{2}\right)}{d} \right\}^2 \times pq$$

Here,

$$Z \left(1 - \frac{\alpha}{2}\right) = 1.96$$

$$P = 0.49 \text{ (here, } p = \text{prevalence) (Haisma et al., 2007)}$$

$$q = 1 - p$$

$$= 1 - 0.49$$

$$= 0.51$$

$$d = 0.05$$

The actual sample size for this study was calculated as 384.

Actual sample size for the study was 384. Generally survey needs large number of sample that will represent whole population. But due to limitation of different conditions at least 50 samples was taken to make the study. As it was an educational research and the study was cross-sectional survey the number of the study sample was 50.

3.5 Inclusion criteria

- Patient with spinal cord injury at community.
- Both sex had got the priority.
- Spinal cord injury patients with complications.

3.6 Exclusion criteria

- Undiagnosed patient
- Patients who were admitted at hospital.
- Unconscious patient.

3.7 Sampling technique

The samples were selected through convenience sampling technique due to time limitation and it was one of the easiest, cheapest and quicker method of sample selection. Sample will meet the inclusion and exclusion criteria and participate in the study voluntarily.

3.8 Data collection method and tools

Data was collected by using a semi structured type of questionnaire paper, that was developed by the investigators and conducting interview to collect information. Questionnaire would provide information about demographic information (age, sex, educational status, occupations and residential area), injury related information, different types of complications after returning the community. The data collection tools used in collecting data were pen and pencils, paper, approved forms and consent forms and bag for storing these tools.

3.9 Data analysis

Data was entered into Statistical Package for Social Science (SPSS) software Version 20 and excel spread sheet. Data also analyzed by SPSS software. Semi structured type of Bengali questionnaire was analyzed and discussed about the socio-demographic factors such as age, gender, educational status, occupation, residential area etc. And this questionnaire was also discussed about injury related information, different types of complications after returning the community of the participation. Researcher found out the results by SPSS software-version 20 that analyzed in excel. In this questionnaire there were 34 questions. The data were analyzed by descriptive statistics and results were presented with the use of percentage (%). The collected data presented with tables, bar charts and pie chart etc.

3.10 Ethical Consideration

The proposal was submitted and prepared to the Institutional Review Board (IRB) and Bangladesh Health Profession Institute (BHPI) and approval was obtained from the board. The World Health Organization (WHO) and Bangladesh Medical Research Council (BMRC) guideline was al followed to conduct the study. A written/verbal consent was taken from participate before collecting of data. During the course of the study, the samples who were interested in the study had given consent forms and the purpose of the research and the consent form were explained to them verbally. The study did not interfere with their jobs. They were informed that their participation was fully voluntary and they had the right to withdraw or discontinue from the research at any time. They were also informed that confidentiality was maintained regarding their information. It should be assured the participant that his or her name or address would not be used. The participants were also informed that the research result would not be harmful for them.

The cross sectional study was conducted to achieve the research objective. In this study results were based on different types of variables such as socio-demographic variables, injury related variables and complications related variables. All the data was analyzed by SPSS v. 20 software. Here descriptive data were collected and presented by percentage, pie chart, bar chart and tables by using Microsoft excel office 2010.

❖ Socio-demographic Information-

4.1 Gender

Among the participants females were 20% (n=10), whereas males were 80% (n=40). So this result shows that males were more vulnerable than females.

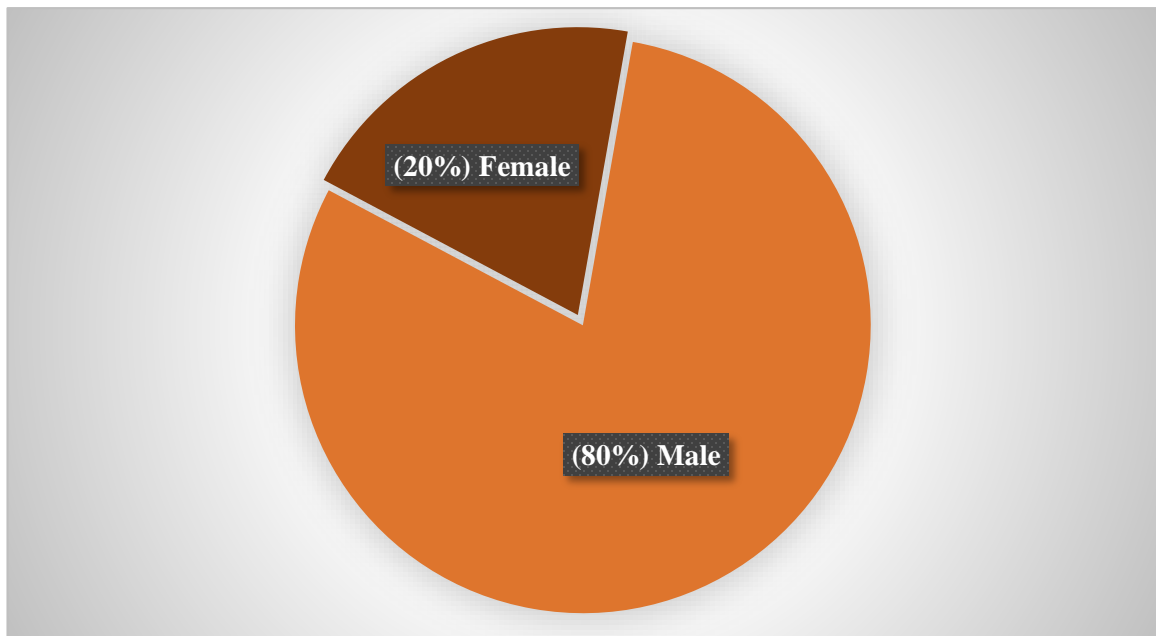


Figure-1: Gender distribution of SCI participants

4.2 Age group

The study was conducted with 50 participants. Among the participants most of them were 31-40 years range that was almost 32% (n=16), 20-30 years were 22% (n=11), 41-50 years were 26% (n=13), 51-60 years were 10% (n=5) and 61-70 years were 10% (n=5).

Table-1: Age of the participants

Age group(years)	Frequency(n)	Percent %
20-30	11	22.0
31-40	16	32.0
41-50	13	26.0
51-60	5	10.0
61-70	5	10.0
Total	50	100.0

4.3 Occupation

About 50 participants were involved as sample in this study. Among almost 42% (n=21) were employed and 58% (n=29) were unemployed.

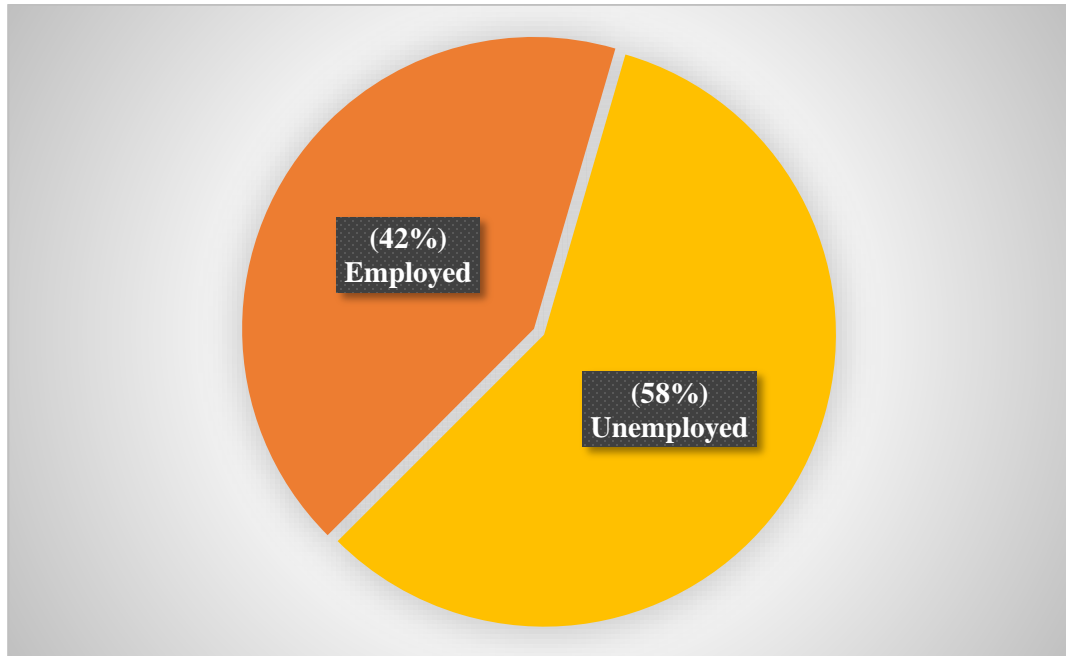


Figure-2: Occupational status

4.4 Family type

Among the 50 participants there were 52% (n=26) separated family and 48% (n=24) combined family.

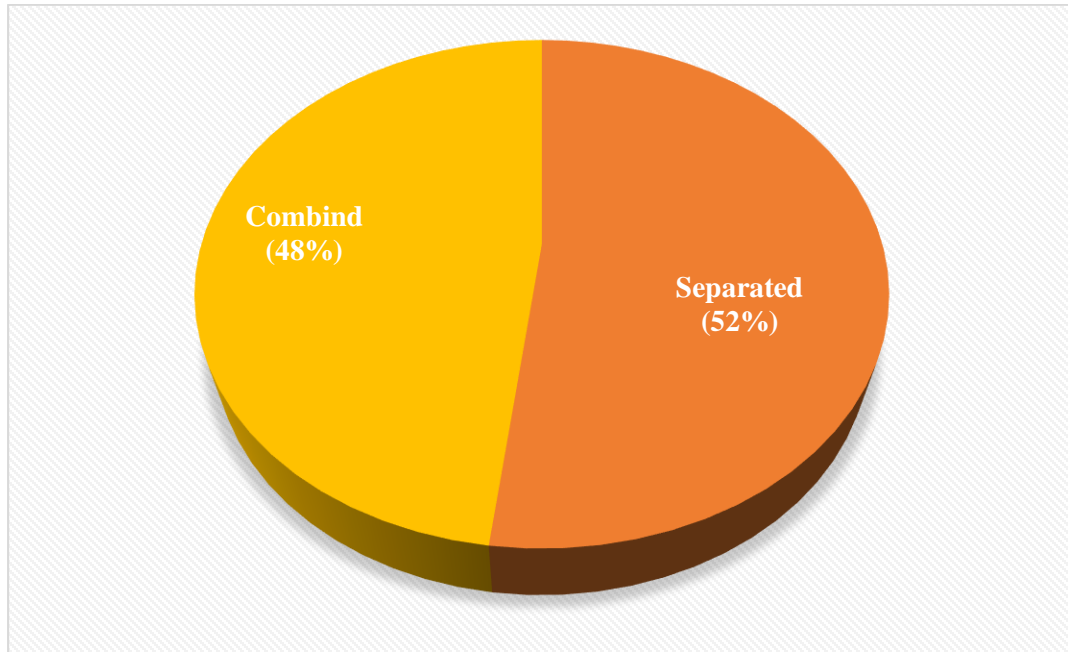


Figure-3: Family type of the participants

4.5 Educational status

The bar chart showed that among 50 (100%) participants in the study about 18% (n=9) illiterate, 22% (n=11) took primary education, 48% (n=24) took secondary education and 12% (n=6) were undergraduate. So the result shows that most participants were in secondary level.

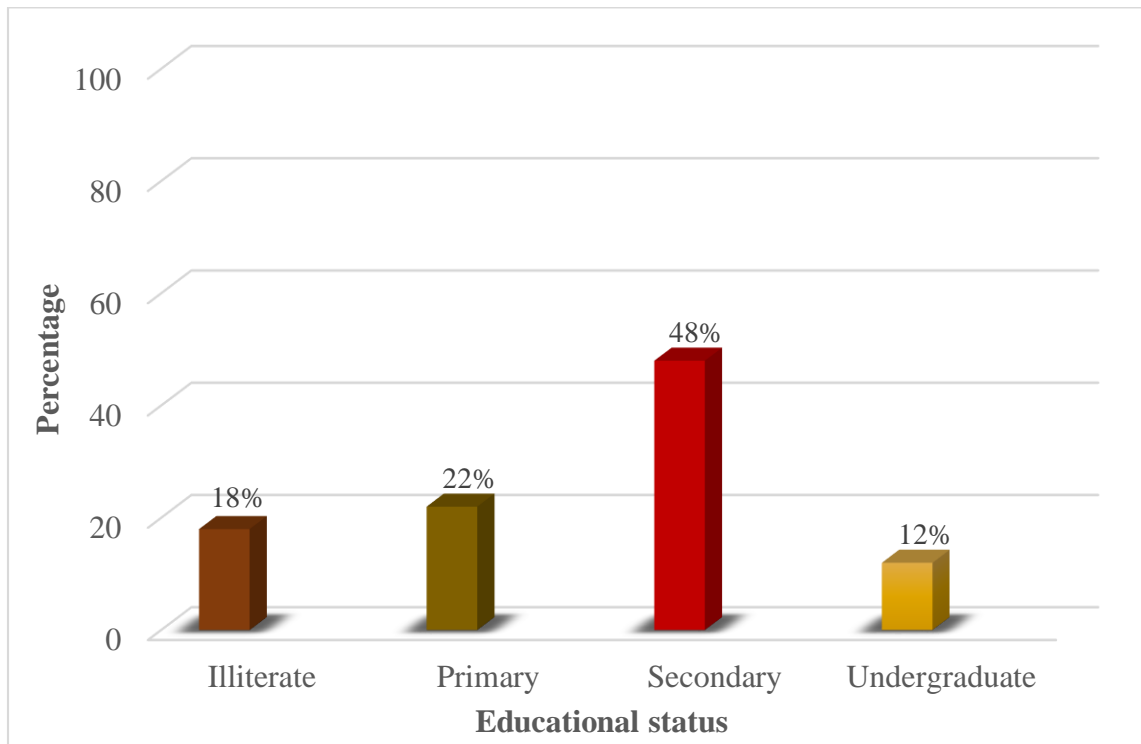


Figure-4: Educational status

4.6 Residential Area

In this study patients who lived in rural were more affected than the people who lived in urban. Among these approximately 74% (n=37) were in rural and 26% (n=13) were in urban area.

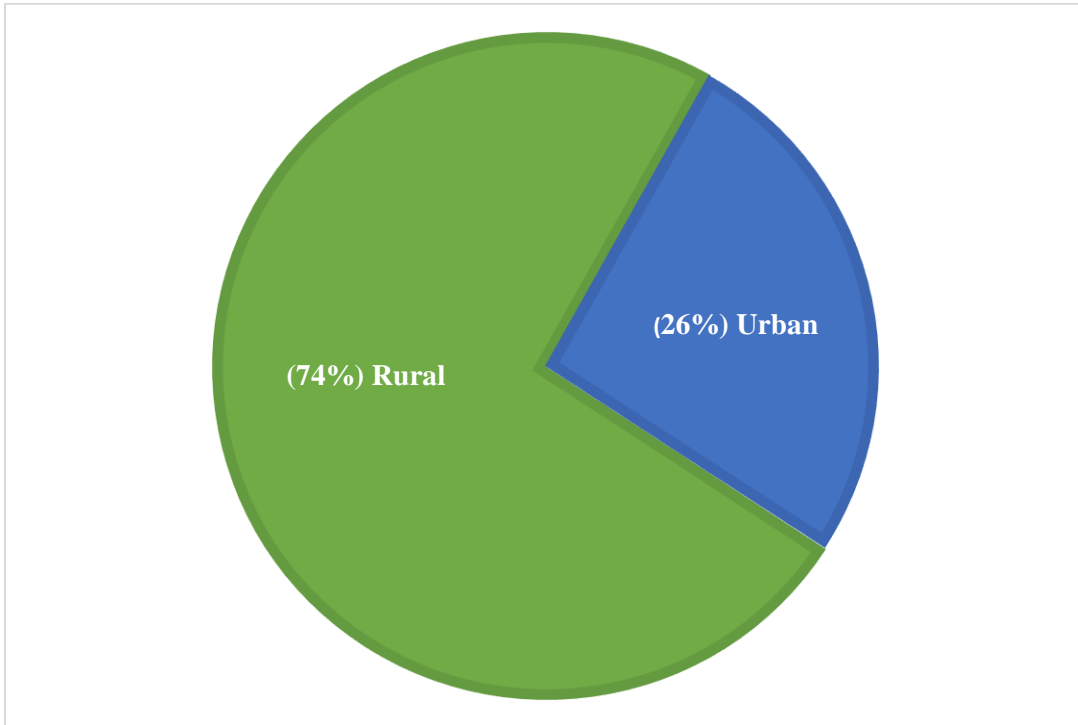


Figure-5: Residential Area

4.7 Causes of injury

The pie chart showed that most of the injuries were caused by traumatic 94% (n=47) and 6% (n=3) were non traumatic cause.

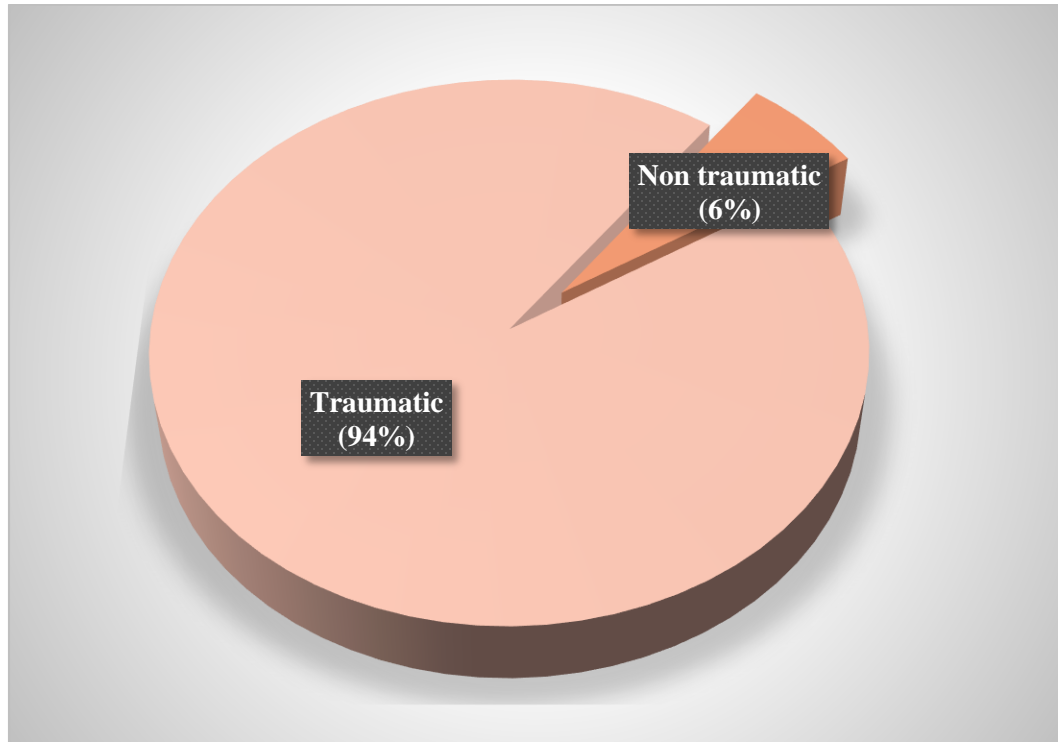


Figure-6: Causes of injury

4.8 Types of paralysis

Among the participants almost 64% (n=32) were paraplegia and 36% (n=18) were tetraplegia.

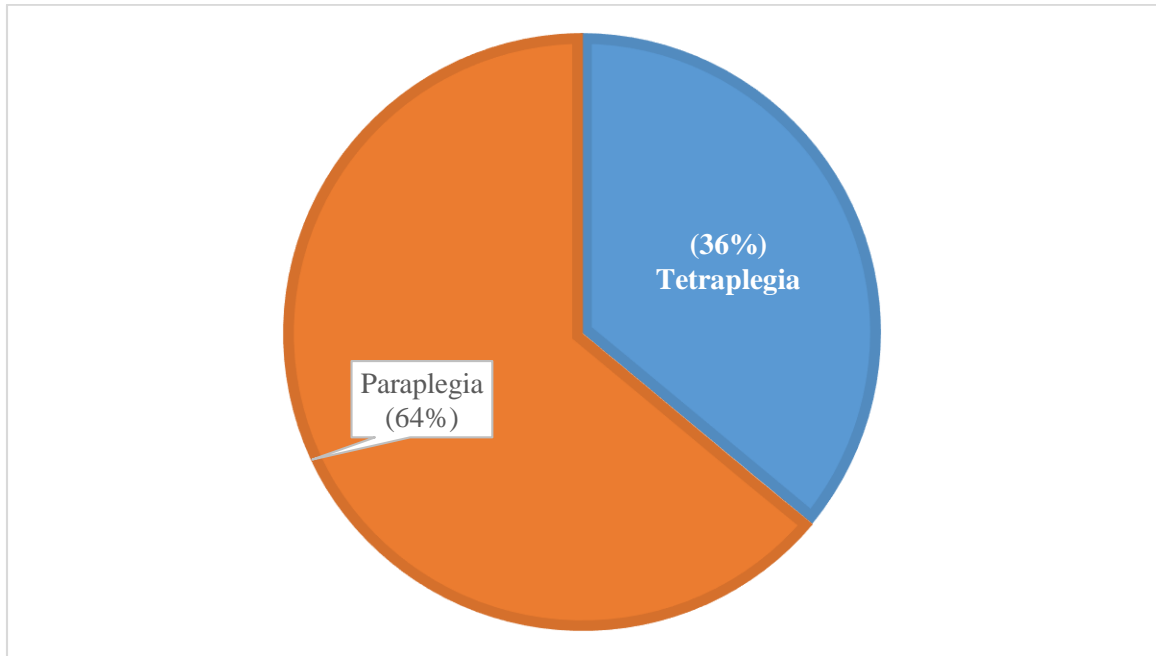


Figure-7: Types of paralysis

4.8 Pressure sore

In this study it was found that about 34% (n=17) were suffering from pressure and 66% (n=33) had no pressure sore.

Table-2: Pressure sore

Pressure sore	Frequency(n)	Percent %
Yes	17	34.0
No	33	66.0
Total	50	100.0

4.9 Number of pressure sore

In this study shows that about 24% (n=12) had at least one pressure sore, 6% (n=3) had two pressure sore, 4% (n=2) had three pressure sore and 66% (n=33) had no pressure sore.

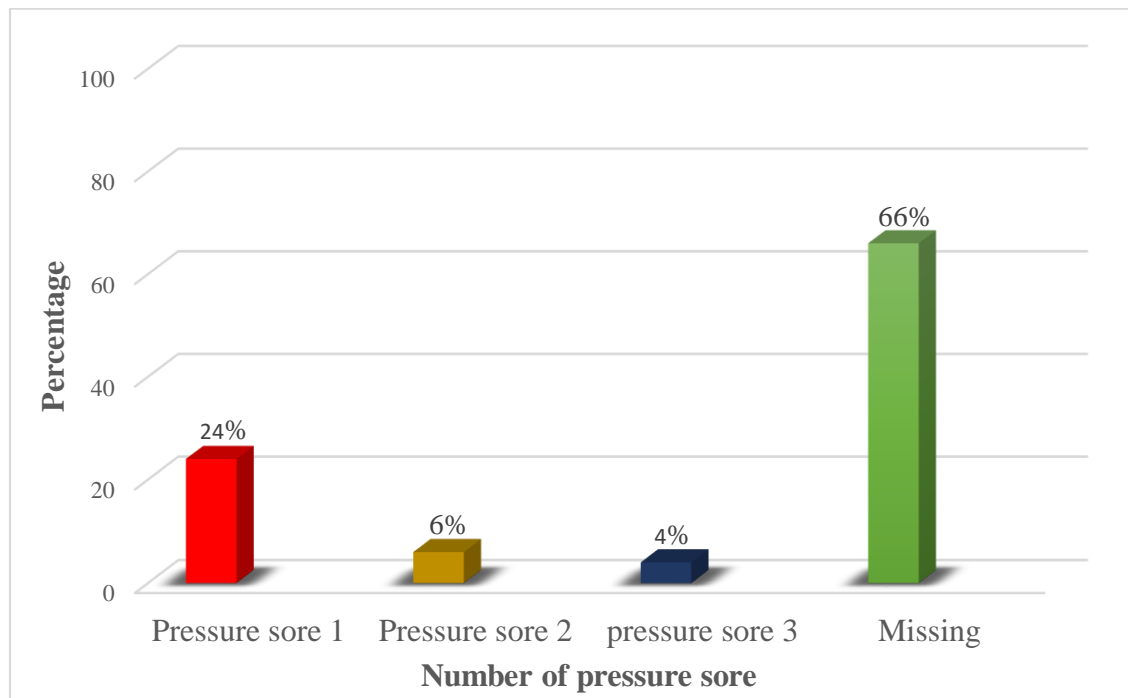


Figure-8: Number of pressure sore

4.10 Area of pressure sore

The pie chart showed that about 2% (n=1) patient had pressure sore at elbow region, 30% (n=15) patients had at gluteal region, 2% (n=1) had at ankle region and 66% (n=33) had no pressure sore.

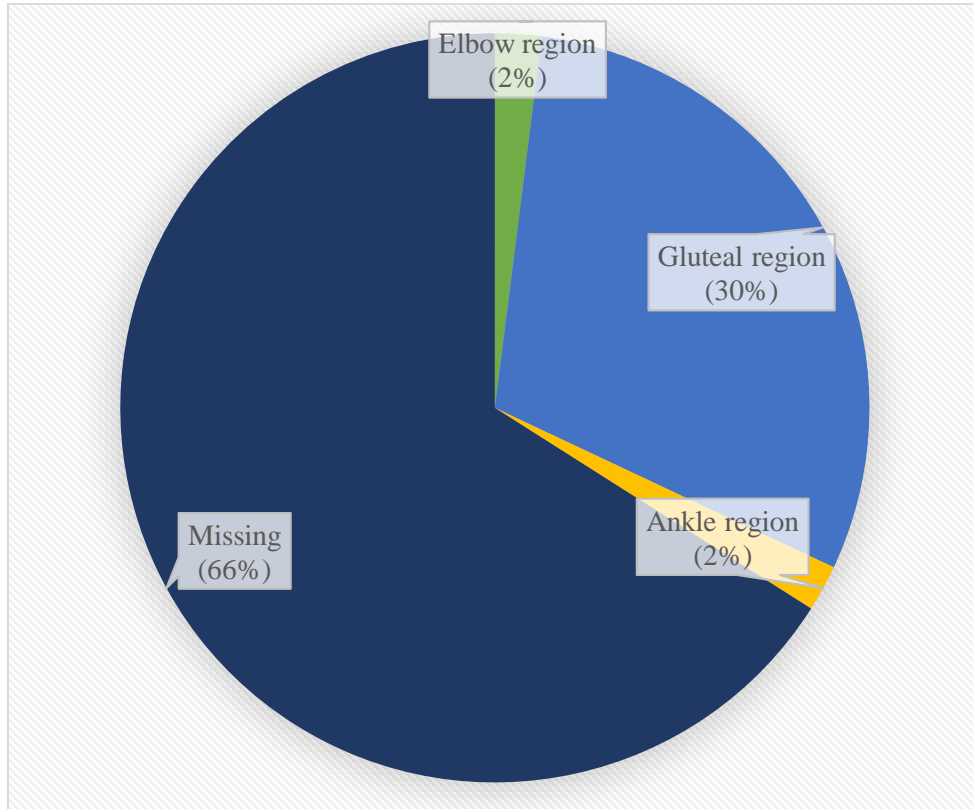


Figure-9: Area of pressure sore

4.11 Grade of pressure sore

The pie chart showed that almost 16% (n=8) patients had in grade-1, 18% (n=9) patients had grade-2 and 66% (n=33) patients had no pressure sore.

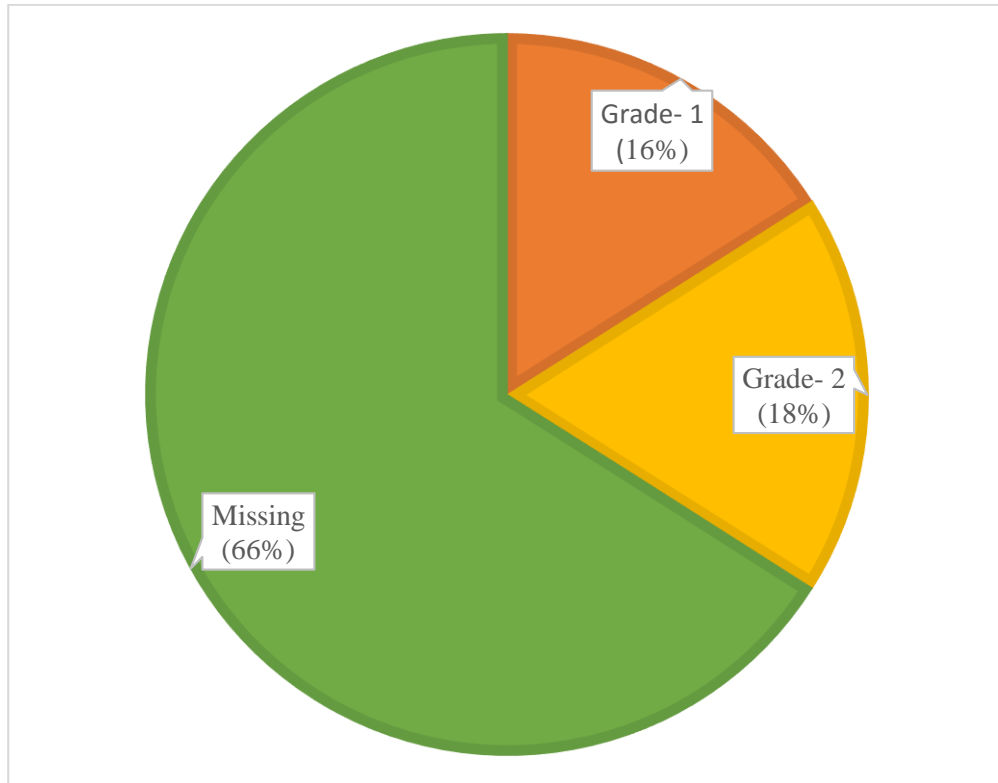


Figure-10: Grade of pressure sore

4.12 pain among the participants

Out of the all participants nearly 92% (n=46) patients were suffered from pain and 8% (n=4) patients had no pain.

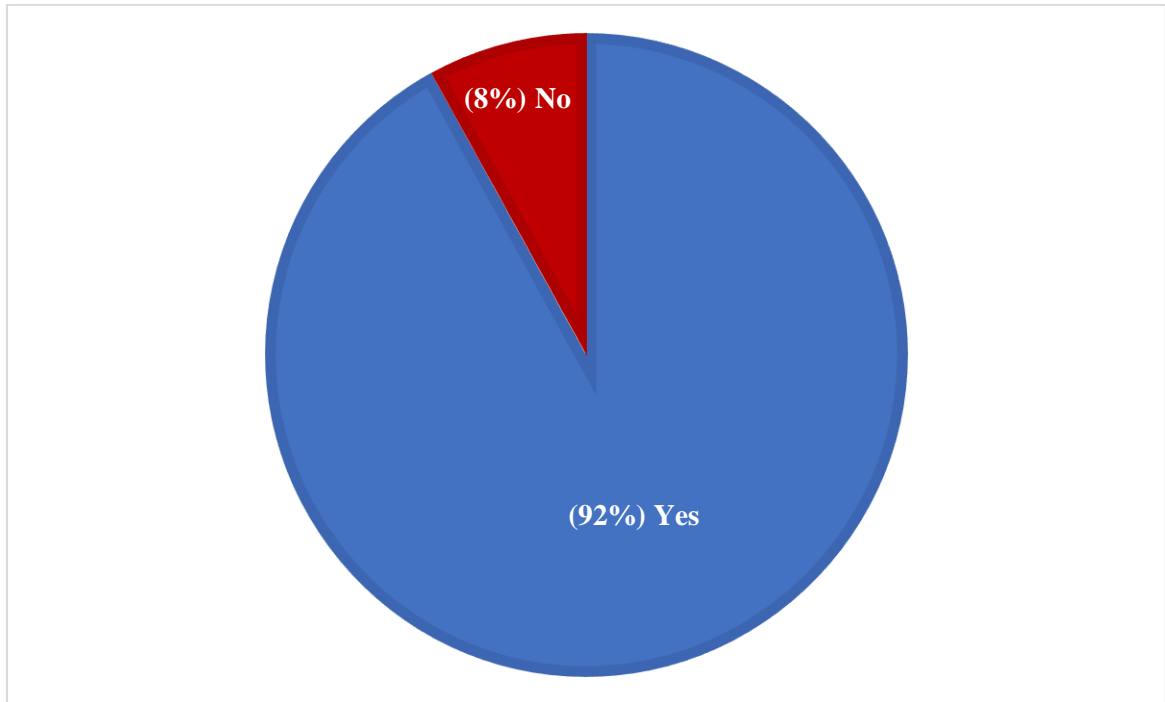


Figure-11: pain among the participants

4.13 Severity of pain

In this study most the patients were suffered by moderate pain 74% (n=37), followed by 14% (n=7) mild pain, 4% (n=2) severe pain and 4% (n=2) no pain.

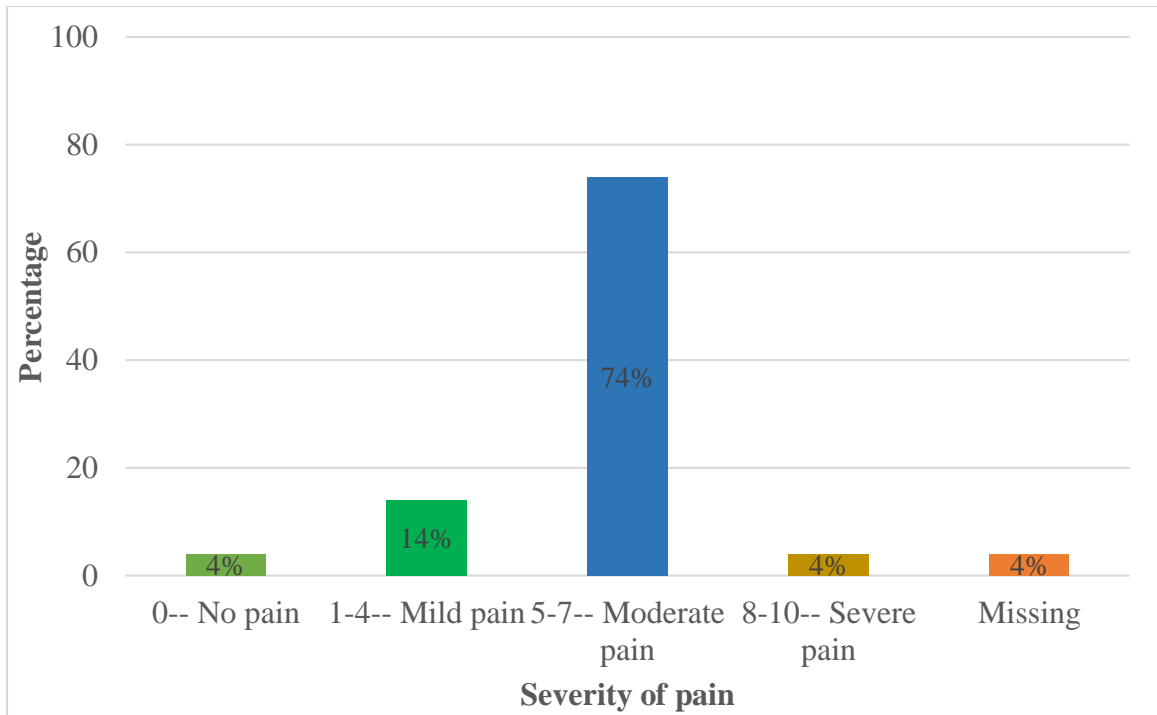


Figure-12: Severity of pain

4.14 Area of pain

In this study most of the patients had suffered pain at lumber region 48% (n=24), followed by 12% (n=6) were at cervical region, 12% (n=6) were at shoulder region, 10% (n=5) lower limb region and 8% (n=4) had no pain.

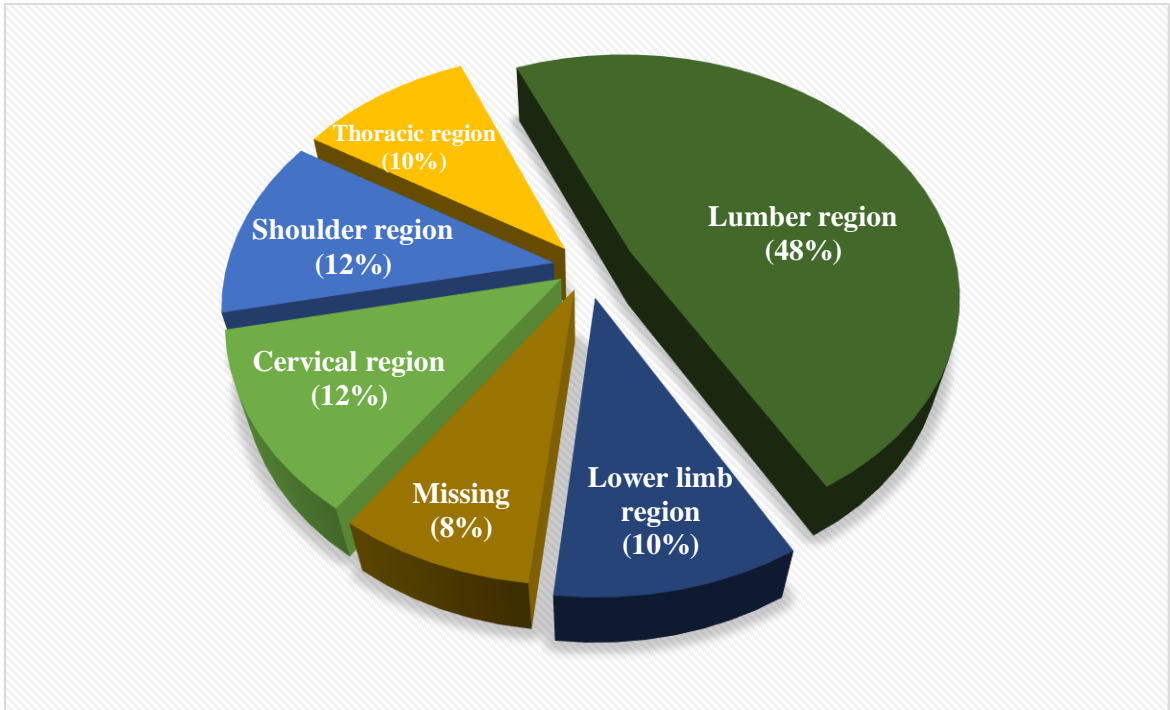


Figure-13: Area of pain

4.15 Muscle tone

From the data of the present study found that about 44% (n=22) patients had spastic tone, 10% (n=5) had flaccid tone and 35% (n=23) had normal tone.

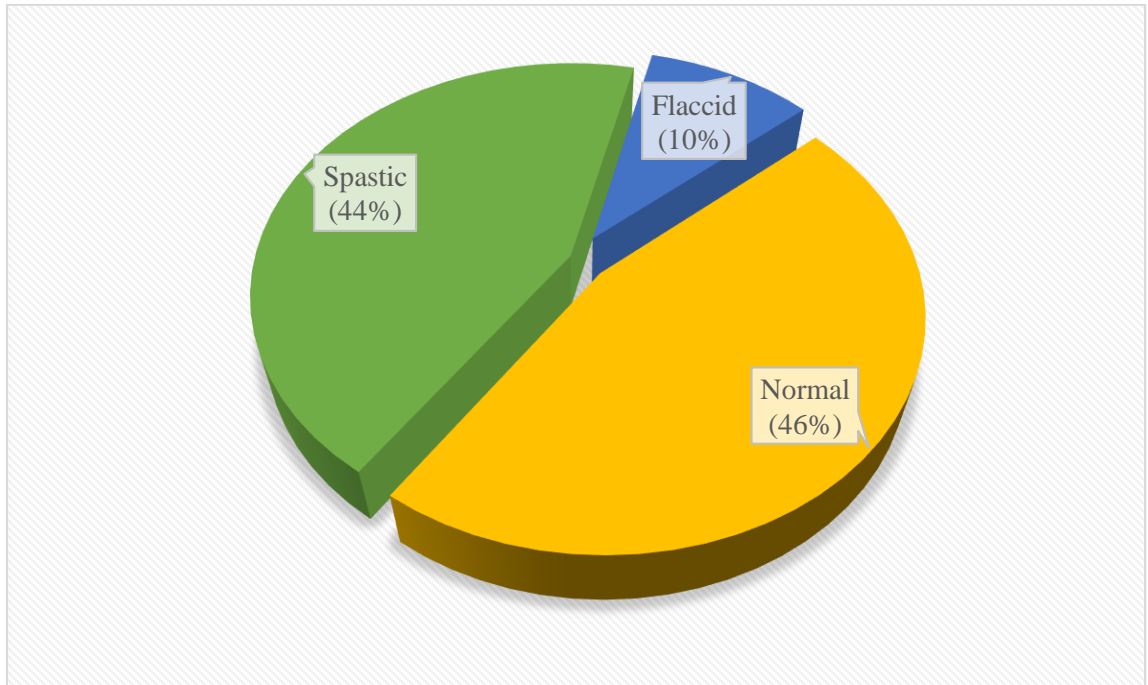


Figure-14: Muscle tone

4.16 Complications of muscle and joint

Among the participants there were 80% (n=40) had muscle and joint related problem and 20% (n=10) had no problem.

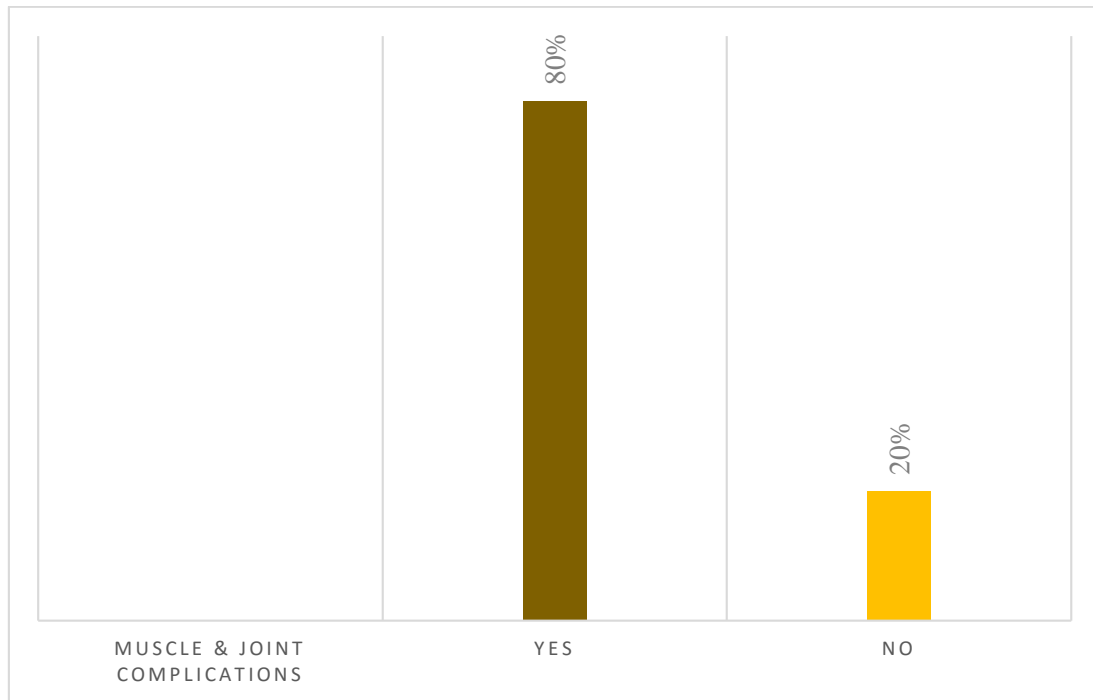


Figure-15: Complications of muscle and joint

4.17 Joint stiffness

In this pie chart shows that about 46% (n=23) had joint stiffness and 54% (n=27) had no joint stiffness.

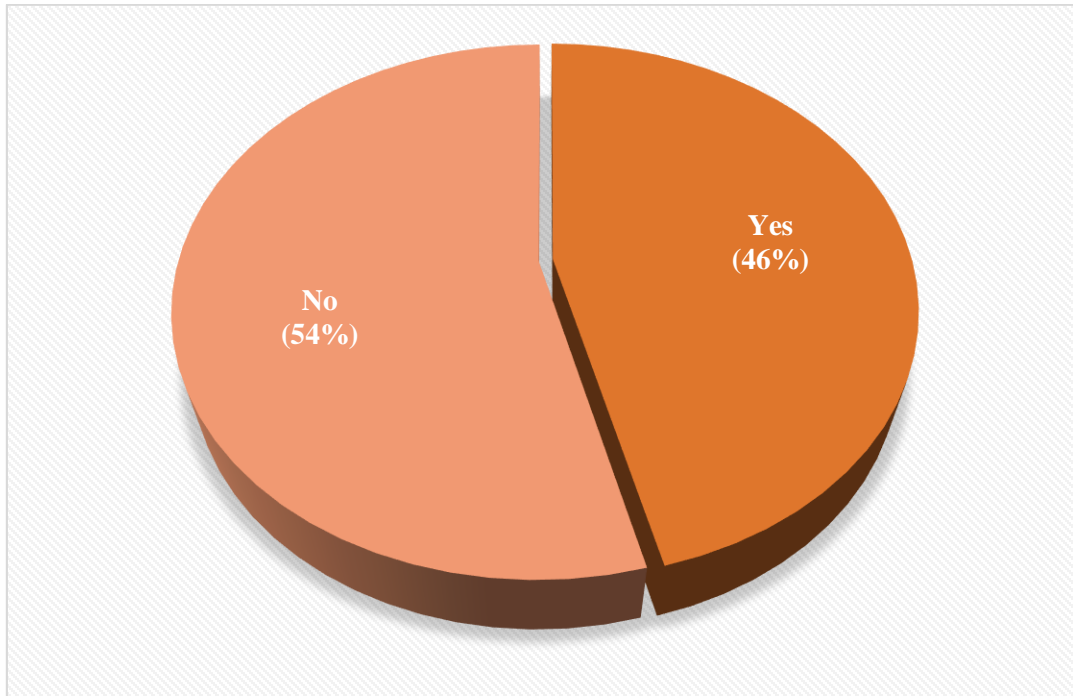


Figure-16: Joint stiffness

4.18 Area of joint stiffness

In this study 22% (n=11) of patients had knee joint stiffness, followed by 12% (n=6) of ankle joint, 8% (n=4) wrist joint, 2% (n=1) hip and 2% (n=1) at elbow joint and 54% (n=23) had no joint stiffness.

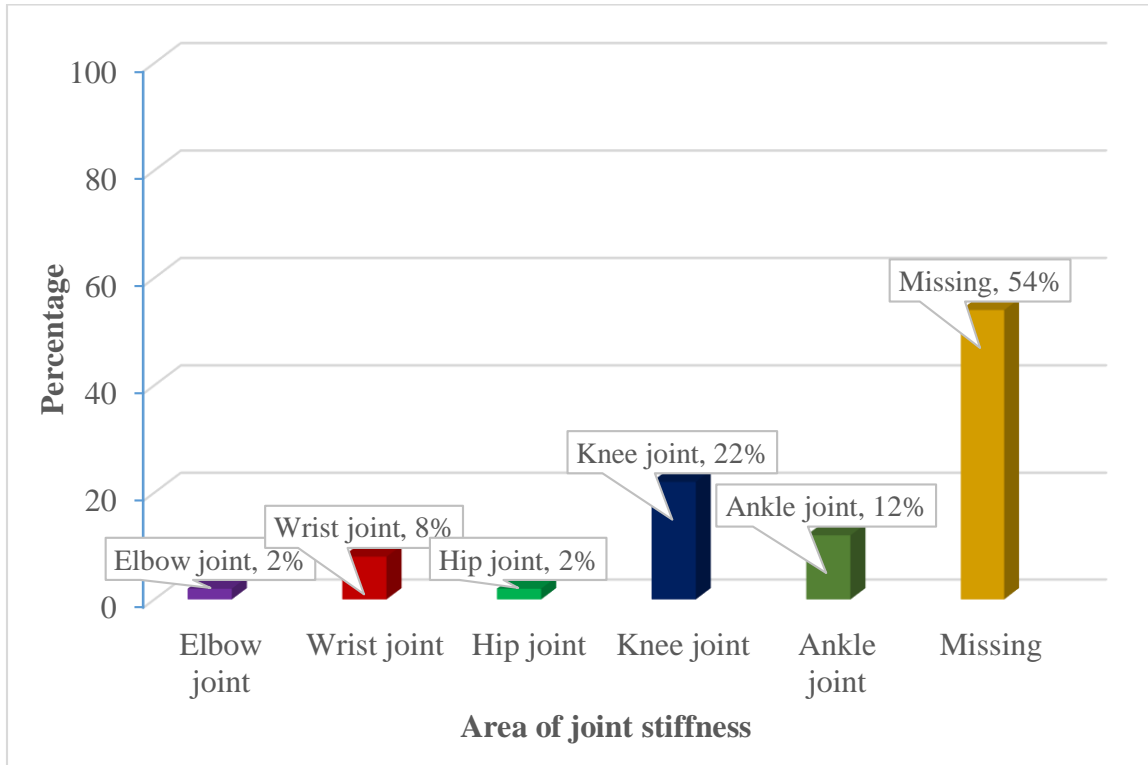


Figure-17: Area of joint stiffness

4.19 Muscle atrophy

This study showed that approximately 46% (n=26) patients had muscles atrophy and 54% (n=27) patients had no muscles atrophy.

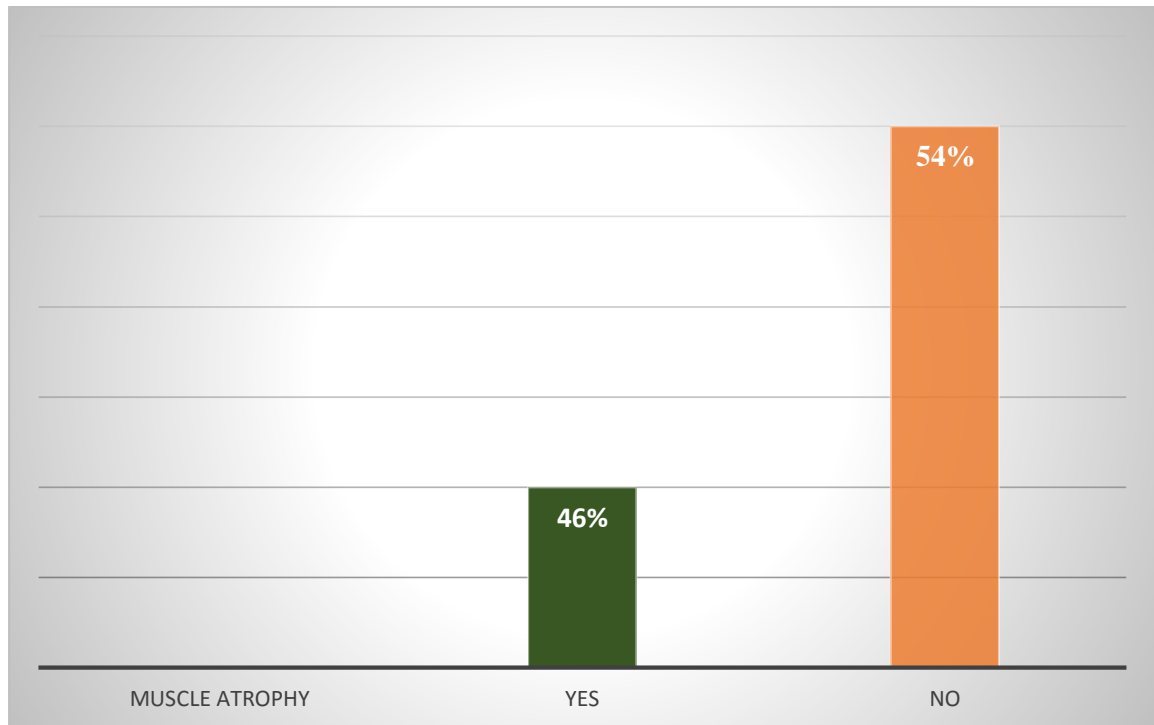


Figure-18: Muscle atrophy

4.20 Area of muscles atrophy

This study showed that 44% (n=22) patients had muscles atrophy at lower limb, 2% (n=1) had back muscles atrophy and 54% (n=27) had no muscles atrophy.

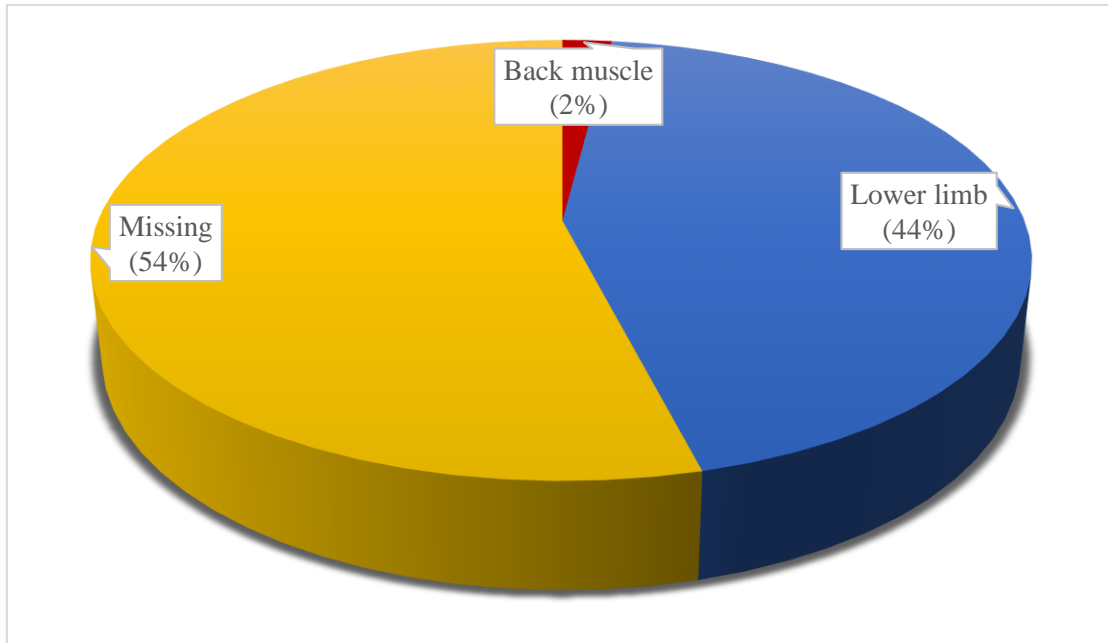


Figure-19: Area of muscles atrophy

4.21 Muscle contracture

Among the participants there were 50% (n=25) patients had muscle contracture and 50% (n=25) had no muscle contracture.

Table-3: Muscle contracture

Muscle contracture	Frequency(n)	Percent %
Yes	25	50.0
No	25	50.0
Total	50	100.0

4.22 Area of muscle contracture

In this bar chart there were 32% (n=16) patients had lower limb muscle contracture, followed by 4% (n=2) gluteal region, 10% (n=5) back muscles, 4% (n=2) upper limb muscles and 50% (n=25) had no muscle contracture.

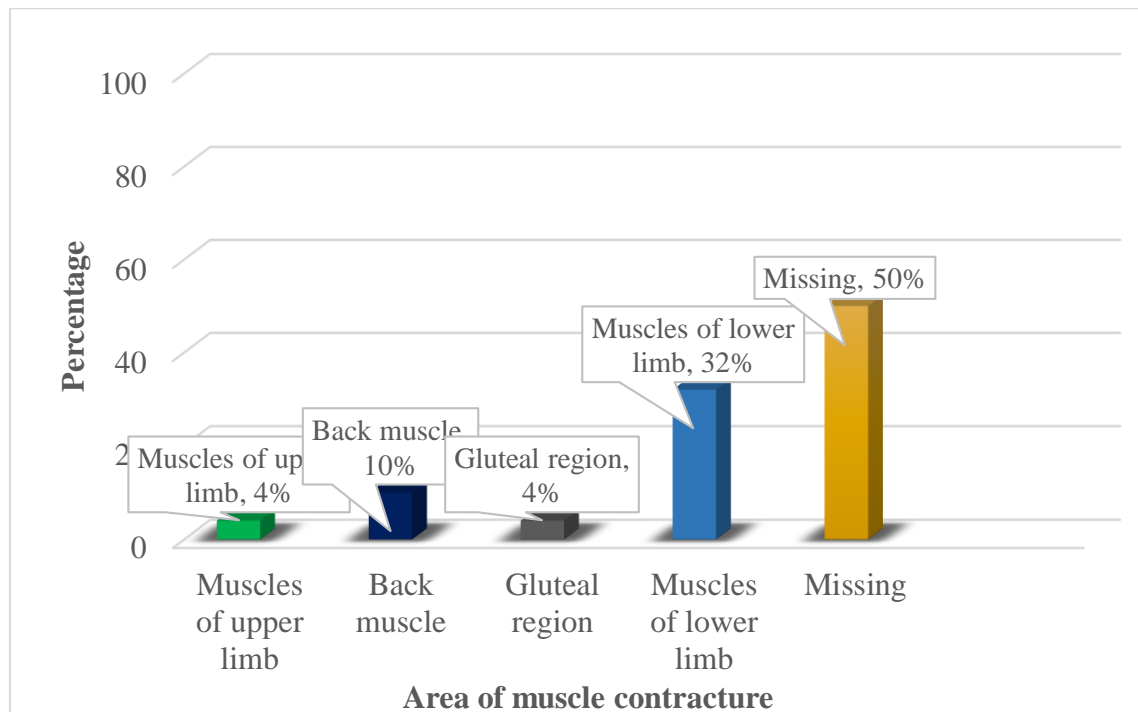


Figure-20: Area of muscle contracture

4.23 Urological complications

The study showed that about 70% (n=35) patients had urological complications and 30% (n=15) had no urological complications.

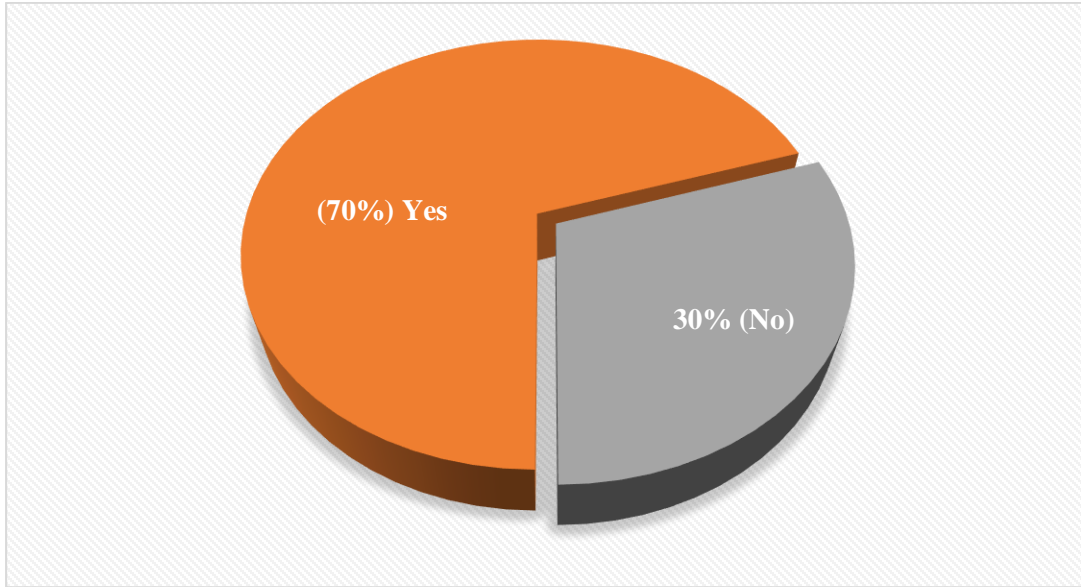


Figure-21: Urological complications

4.24 Bowel & bladder incontinence

In this table showed that 50% (n=25) patients had control in bowel & bladder and 50% (n=25) had no control.

Table-4: Bowel & bladder incontinence

Bowel & bladder incontinence	Frequency(n)	Percent %
Yes	25	50.0
No	25	50.0
Total	50	100.0

4.25 Urinary tract infection

This study showed that among the patients 52% (n=26) were suffering from UTI and 48% (n=24) had no UTI.

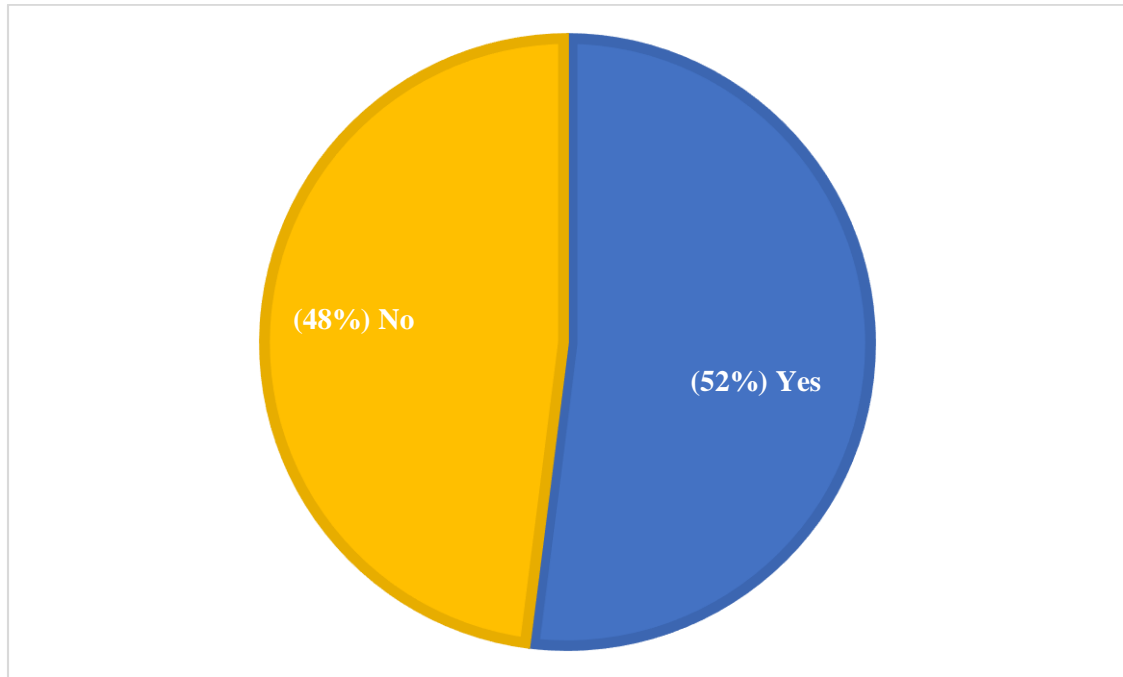


Figure-22: Urinary tract infection

4.26 Cardio-respiratory complications

In this bar chart showed that about 18% (n=9) patients had suffering from cardio-respiratory problems and 82% (n=41) patients had not cardio-respiratory problem after returning the community.

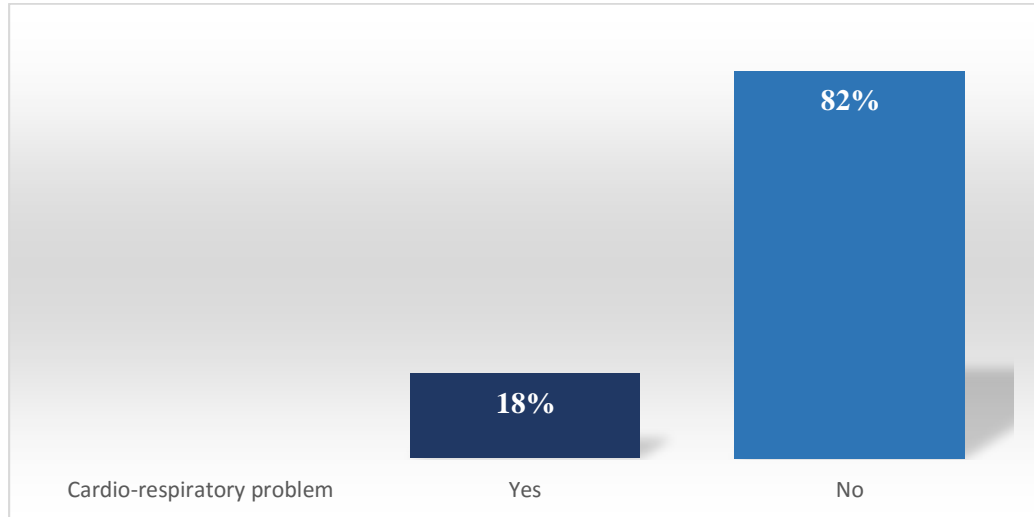


Figure-23: Cardio-respiratory complications

4.27 Type of cardio-respiratory problem

In this table 18% (n=9) patients had shortness of breathing (SOB) and 82% (n=41) had no problem.

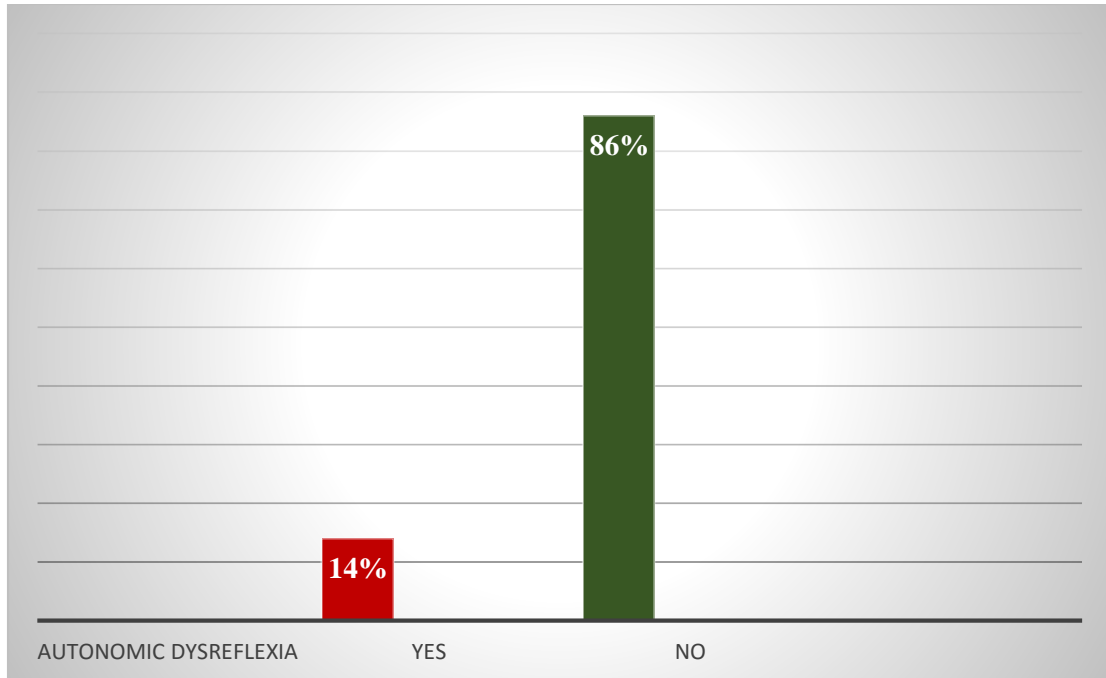
Table-5: Type of cardio-respiratory problem

Type	Frequency(n)	Percent %
SOB	9	18.0
Missing	41	82.0
Total	50	100.0

4.28 Autonomic dysreflexia

Following figure showed that around 14% (n=7) had developed autonomic dysreflexia and 86% (n=43) had no autonomic dysreflexia after returning the community.

Figure-24: Autonomic dysreflexia



4.29 Psychological complications

In the pie chart about 68% (n=34) patients had psychological complication and 32% (n=16) had no psychological complication after returning the community.

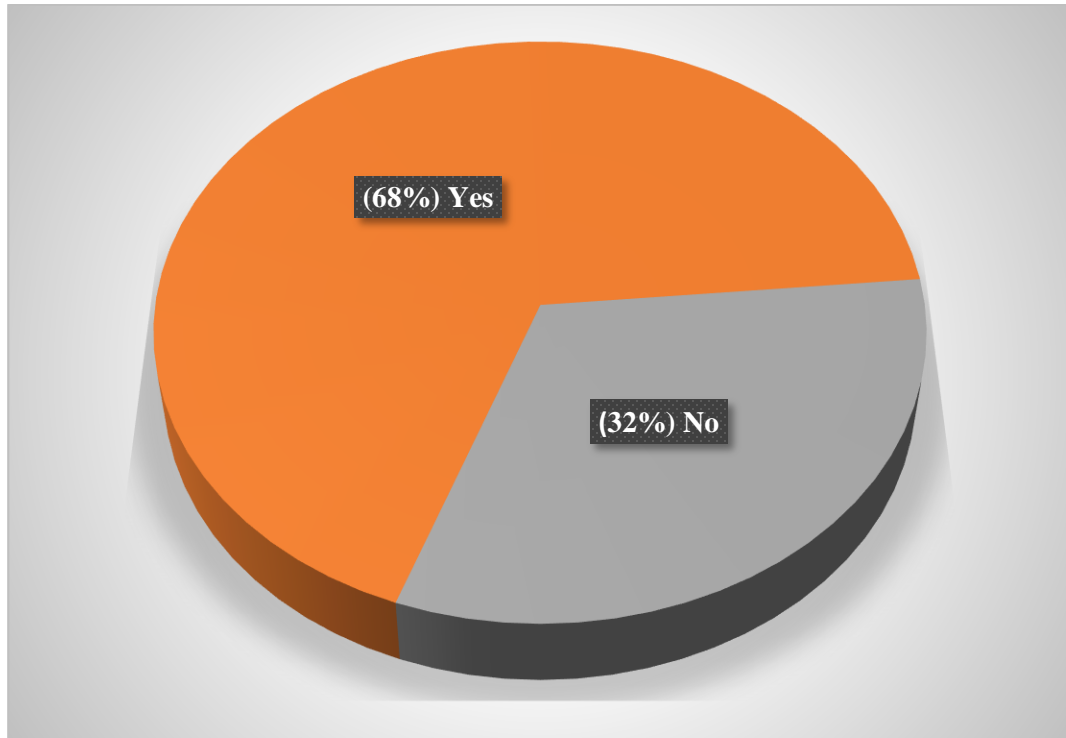


Figure-25: Psychological complications

4.30 Type of psychological complications

In this pie chart there were 58% (n=29) patients were in depression, 8% (n=4) were in tension, 2% (n=1) were in other problem and 32% (n=16) had no psychological complications after returning the community.

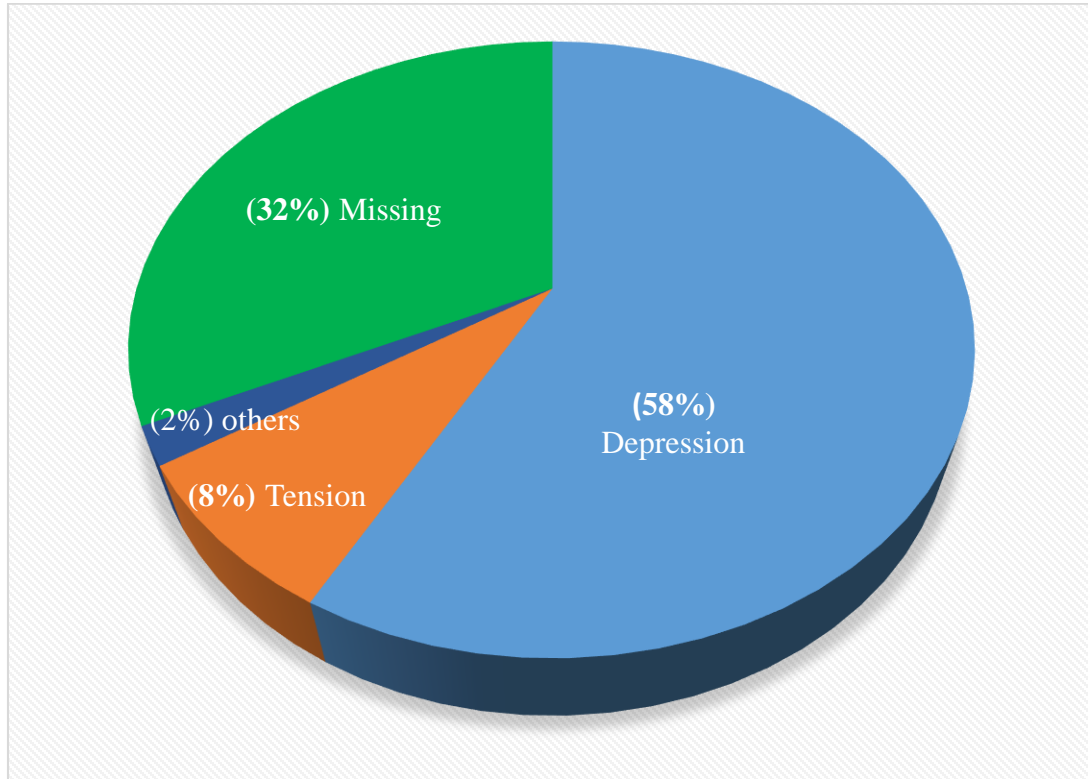


Figure-26: Type of psychological complications

4.31 Other complications

In the bar chart 14% (n=7) patients were falling complications, 24% (n=12) were poor transferring & bed mobility, 8% (n=4) were others like- constipation, swelling, 26% (n=13) had both falling and poor transferring & bed mobility complications after returning the community.

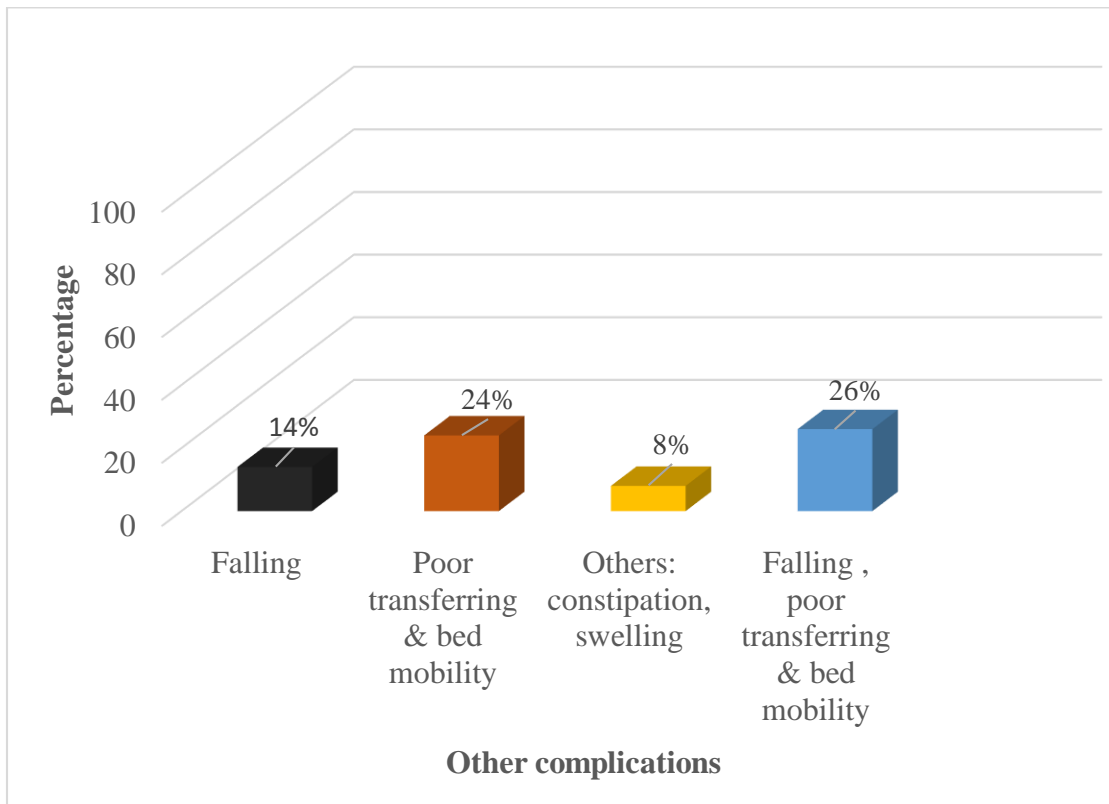


Figure-27: Other complications

4.32 Complications after returning the community

Complications	Number (n)	Percent %
Pressure sore	17	34
Pain	46	92
Spasticity	22	44
Flaccidity	5	10
Joint stiffness	23	46
Muscle atrophy	23	46
Muscle contracture	25	50
Bowel & bladder incontinence	25	50
UTI	26	52
Cardio-respiratory problem (SOB)	9	18
Autonomic dysreflexia	7	14
Psychological complications	34	68
Falling	7	14
Poor transferring & bed mobility	12	24
Others: constipation, swelling	4	8
Both falling , poor transferring & bed mobility	13	26
Total	50	100

Table-6: Complications after returning the community

The aim of the study was to find the socio-demographic information's, injury related information and complications among the spinal cord injured patient after returning the community. In this study 50 patients with SCI, who were in community most of them were 31-40 years range that was almost 32% (n=16), 20-30 years were 22% (n=11), 41-50 years were 26% (n=13), 51-60 years were 10% (n=5) and 61-70 years were 10% (n=5). So it was found that biggest sample contains in age range 31-40 years and lowest sample range was 51-70 years. Among the study of Bangladeshi most common age group between 25-29 years in spinal cord injured patients (Islam et al., 2011).

From this study were found that females were 20% (n=10), whereas males were 80% (n=40). So this result shows that males were more vulnerable than females. In one study reported data of 44 patients. There were 35 males and 9 females whose average age was 45.23 ± 13.78 years (Amatachaya et al., 2011).

In this study patients who lived in rural were more affected than the people who lived in urban. Among these approximately 74% (n=37) were in rural and 26% (n=13) were in urban area. Among 50 (100%) participants in the study about 18% (n=9) illiterate, 22% (n=11) took primary education, 48% (n=24) took secondary education and 12% (n=6) were undergraduate. So the result shows that most participants are in secondary level. A study of India showed that almost 60-70% was illiterate. A Brazilian study showed that of the 60 patients, 38 (63.3%) had complete or incomplete primary education, 19 (31.7%) had complete or incomplete secondary education and 3 (5%) had college education (Blanes et al., 2009).

About 50 participants were involved as sample in this study. Among them almost 42% (n=21) were employed and 58% (n=29) were unemployed. Among the employed participants most of the patients had monthly income within 5000-12000tk. So this study had also showed that the views of the economic status of the SCI patients in our country. Among the 50 participants there were 52% (n=26) lived as a separated family and 48% (n=24) combined family. Among the participants almost 64% (n=32) were paraplegia and

36% (n=18) were tetraplegia. In Canadian study had showed that paraplegia was more prone rather than tetraplegia, this study 58% were paraplegia and 42% were tetraplegia (Rouleau et al., 2011). In this study, most of the injuries were caused by traumatic 94% (n=47) and 6% (n=3) were non traumatic cause. In the developed country, road traffic accident is the leading cause of SCI followed by fall and then sports injury (Rathore, 2010).

According to this study the incidence of pressure sore, pain, spasticity, joint stiffness, muscle atrophy, contracture, urological problems, psychological complications, fall were increased after returning the community. Pain, spasticity, muscle atrophy, pressure sore, UTI and psychological problems were highly incited. Lack of awareness among 52.5% patients and other lower economic status, inaccessibility of definitive hospital (16.4%) acts as a predisposing factors to increase incidence of complications (Chhabra & Arora, 2013). Most often the complications were reported like as pain, spasticity and pressure ulcers, as well as complications associated with bladder, bowel and sexual dysfunction (Hossain et al., 2016).

In this study it was found that about 34% (n=17) were suffering from pressure and 66% (n=33) had no pressure sore, among them about 24% (n=12) had at least one pressure sore, 6% (n=3) had two pressure sore, 4% (n=2) had three pressure sore and 66% (n=33) had no pressure sore and there were about 2% (n=1) patient had pressure sore at elbow region, 30% (n=15) patients had at gluteal region, 2% (n=1) had at ankle region and 66% (n=33) had no pressure sore. Out of the all participants nearly 92% (n=46) patients were suffered from pain and 8% (n=4) patients had no pain, most the patients were suffered by moderate pain 74% (n=37), followed by 14% (n=7) mild pain, 4% (n=2) severe pain and 4% (n=2) no pain. About 44% (n=22) patients had spastic tone, 10% (n=5) had flaccid tone and 35% (n=23) had normal tone. There were 80% (n=40) had muscle and joint related problem and 20% (n=10) had no problem. About 46% (n=23) had joint stiffness and 54% (n=27) had no joint stiffness. Approximately 46% (n=26) patients had muscles atrophy and 54% (n=27) patients had no muscles atrophy. 70% (n=35) patients had urological complications and 30% (n=15) had no urological complications, among them 50% (n=25) patients had control in bowel & bladder and 50% (n=25) had no control,

52% (n=26) were suffering from UTI and 48% (n=24) had no UTI. In an Indian study reported that, average 50% patients suffered with UTI (Gupta et al., 2009). About 18% (n=9) patients had suffering from cardio-respiratory problems and 82% (n=41) patients had not cardio-respiratory problem. 14% (n=7) had developed autonomic dysreflexia and 86% (n=43) had no autonomic dysreflexia. 68% (n=34) patients had psychological complication and 32% (n=16) had no psychological complication. And 14% (n=7) patients were falling complications, 24% (n=12) were poor transferring & bed mobility, 8% (n=4) were others like- constipation, swelling, 26% (n=13) had both falling and poor transferring & bed mobility complications after returning the community.

The first limitation of this study was sample size. It was taken only 50 samples. As the study was done in the community, so transporting system was one of the limitation. Another major limitation was time. The period was very limited to conduct the research project on this topic. As the study period short so the adequate number of sample could not arrange for the study.

Spinal cord injury is one of the most devastating event in human life. Annual of incidence of SCI occurs in various countries average up to 15-40 cases per million. But in Bangladesh there is no well proper documents about spinal cord injury and also lake of specialized care of SCI patients. Bangladesh is a developing country. Most of them live with low economic level and poor educational level. In this country there is also lack of awareness about injury especially caused by SCI. But spinal cord injury causes a bad impact on quality of life results in long term disability, mortality & morbidity and burden for the community.

In this study 50 patients with SCI, who were in community most of them were 31-40 years range that was almost 32% (n=16). Females were 20% (n=10), whereas males were 80% (n=40). So this result shows that males were more vulnerable than females. Patients who lived in rural were more affected than the people who lived in urban. Among these 74% (n=37) were in rural and 26% (n=13) were in urban area. Among 50 (100%) participants in the study about 18% (n=9) illiterate, 22% (n=11) took primary education, 48% (n=24) took secondary education and 12% (n=6) were undergraduate. And the study also found that the complications which commonly develop within the SCI patients are pressure sore, pain, spasticity, UTI, muscle atrophy, psychological problem etc. So the result shows that most participants are in secondary level. So it is necessary to raise awareness and take steps to reduce the risk of complications.

Spinal cord injury is a catastrophic, devastating and life changing event. Most of the patients with SCI do not come under specialized care and follow up care, as a result they become more prone to develop complications and this complications are major factor of mortality & morbidity. So only awareness and proper care can help to survive after SCI returning the community. Awareness should be early hospitalization, early initiation of the complications and prevention of complications.

Comparative study to find out the complications among before admission, during admission and after admission at specialized rehabilitation center will be better one. But

during further research it is recommended to take more samples with adequate time to solve the recent problems areas for better result and perspectives. Needs to arrange awareness program among the community based populations about specialized care, proper hygiene and prevention of complications.

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APPENDIX

সম্মতিপত্র

আসসালামুয়ালাইকুম/ আদাব,

আমি মোঃ শফিকুল ইসলাম, আমি এই গবেষণা প্রকল্পটি বাংলাদেশ হেলথ প্রফেশনস ইনস্টিটিউট (বিএইচপিআই)- এ পরিচালনা করছি যা আমার ৪র্থ বর্ষ বিএসসি ইন ফিজিওথেরাপী কোর্সের অধিভুক্ত। আমার গবেষণার শিরোনাম হল- “ মেরুরজ্জুতে আঘাত প্রাপ্ত রোগীদের সম্প্রদায়ে ফিরে যাওয়ার পর জটিলতা ” এর মাধ্যমে আমি মেরুরজ্জুতে আঘাত প্রাপ্ত রোগীদের সম্প্রদায়ে ফিরে যাওয়ার পর কি কি জটিলতা হয় সে সম্পর্কে জানতে চাই। আমি এখন আপনাকে কিছু ব্যক্তিগত এবং শারীরিক ও মানুসিক জটিলতা সম্পর্কে আনুষঙ্গিক কিছু প্রশ্ন করতে চাচ্ছি। এতে আনুমানিক ২০- ৩০ মিনিট সময় নিবো।

আমি আপনাকে অবগত করছি যে, এটা আমার অধ্যয়নের অংশ এবং যা অন্য কোন উদ্দেশ্যে ব্যবহৃত হবে না। এই গবেষণায় আপনার অংশগ্রহণ বর্তমান জীবনে কোন প্রকার প্রভাব ফেলবে না। আপনি যেসব তথ্য প্রদান করবেন তার গোপনীয়তা বজায় থাকবে এবং আপনার প্রতিবেদনের ঘটনা প্রবাহে এটা নিশ্চিত করা হবে যে এই তথ্যের উৎস অপ্রকাশিত থাকবে।

এই অধ্যয়নে আপনার অংশগ্রহণ স্বেচ্ছাপ্রণোদিত এবং আপনি যেকোন সময় এই অধ্যয়ন থেকে কোন নেতিবাচক ফলাফল ছাড়াই নিজেকে প্রত্যাহার করতে পারবেন এছাড়াও কোন নির্দিষ্ট প্রশ্ন অপছন্দ হলে উত্তর না দেয়ার এবং সাক্ষাৎকারের সময় কোন উত্তর না দিতে চাওয়ার অধিকারও আপনার আছে।

এই অধ্যয়নে অংশগ্রহণকারী হিসেবে যদি আপনার কোন প্রশ্ন থাকে তাহলে আপনি আমাকে অথবা/এবং আমার সুপারভাইজার মোহাম্মদ ওবাইদুল হক, সহযোগী অধ্যাপক ও প্রধান, ফিজিওথেরাপী বিভাগ, বিএইচপিআই, সিআরপি, সাভার, ঢাকা- ১৩৪৩ এ যোগাযোগ করতে পারেন।

সাক্ষাৎকার শুরু করার আগে কি আপনার কোন প্রশ্ন আছে?

.....

সুতরাং আমি আপনার অনুমতিতে এই সাক্ষাৎকার শুরু করতে পারি ?

হ্যাঁ

না

১। অংশগ্রহণকারীর স্বাক্ষর ও তারিখ _____

২। উপাত্ত সংগ্রহকারীর স্বাক্ষর ও তারিখ _____

৩। সাক্ষীর স্বাক্ষর ও তারিখ _____

Verbal Consent Statement
(Please read out to the participants)

Assalamualaikum / Adab,

I am Md. Shafiqul Islam. I am conducting this study as a part of my academic work of 4th professional B.sc in Physiotherapy under Bangladesh Health Professions Institute (BHPI), which is affiliated by University of Dhaka. My dissertation title is **“COMPLICATIONS AMONG THE SPINAL CORD INJURED PATIENT AFTER RETURNING THE COMMUNITY”**. I would like to know about spinal cord injured persons complications after returning the community. Now I want to ask some personal and complications related questions. This will take approximately 20 to 30 minutes.

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 life. All information provided by you will be kept in 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 any query about the study or your right as a participant, you may contact with me and or my Supervisor Md. Obaidul Haque, Associate Professor & Head of the Department of Physiotherapy, BHPI, CRP, Savar, Dhaka-1343.

Do you have any questions before I start?

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

Yes

No

Signature of the Participant and date _____

Signature of the Data collector and date _____

Signature of the witness and date _____

Questionnaire in Bangla:

পার্ট- ১ :সামাজিক -জনসংখ্যা তাত্ত্বিক তথ্যসূত্র	
১.১	রোগীর নাম:
১.২	লিঙ্গ: বয়স:
১.৩	ঠিকানা-
১.৪	টেলিফোন নম্বর:
১.৫	পেশা:
১.৬	পারিবারিক ধরণ:
১.৭	মাসিক আয়:
১.৮	শিক্ষাগত যোজ্ঞতাঃ
১.৯	আবাসিক এলাকা:

পার্ট-২: আঘাত সংশ্লিষ্ট প্রশ্নাবলী

২.১০	আঘাতের কারণ:
২.১১	পক্ষাঘাতের ধরন: ১। টেট্রাপ্লেজিয়া:----- ২। পেরাপ্লেজিয়া:-----

পার্ট -৩: জটিলতার সম্পর্কিত প্রশ্নাবলী (সম্প্রদায় ফেরত যাওয়ার পরে)

৩.১২	সম্প্রদায়ের কাছে ফিরে যাওয়ার পর, আপনি কি কোন জটিলতায় ভুগছেন? যেমন- চাপ জনিত ক্ষত। ১। হ্যাঁ---- ২। না---- (অনু। ৩.১৩,৩.১৪,৩.১৫ নং বাদ)
৩.১৩	চাপ জনিত ক্ষতের সংখ্যাঃ
৩.১৪	চাপ জনিত ক্ষতের স্থানঃ
৩.১৫	চাপ জনিত ক্ষতের গ্রেড ? ১। গ্রেড – 1 ২। গ্রেড – 2

	৩। গ্রেড – 3 ৪। গ্রেড – 4											
৩.১৬	আপনি সম্প্রদায় ফিরে যাওয়ার পরে কোন ব্যাথায় ভুগছেন? ১। হ্যাঁ---- ২। না---- (অনু। ৩.১৭, ৩.১৮ নং বাদ)											
৩.১৭	ব্যাথার তীব্রতা: <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> </table> ০ ১ ২ ৩ ৪ ৫ ৬ ৭ ৮ ৯ ১০ ০ = ব্যাথা নাই।- হ্যাঁ----/না---- ১-৪ = অল্প ব্যাথা।- হ্যাঁ----/না---- ৫-৭ = মাঝারি ব্যাথা।- হ্যাঁ----/না---- ৮-১০ = তীব্র ব্যাথা।- হ্যাঁ----/না----											
৩.১৮	ব্যাথার স্থানঃ											
৩.১৯	মাংসপেশীর টোন: ১। স্পাস্টিক বা খিঁচুনির মতো- হ্যাঁ----/না---- ২। ফ্ল্যাসিড বা নরম – হ্যাঁ----/না---- ৩। নরমাল -----											
৩.২০	আপনি কি কোন মাংসপেশি এবং জয়েন্ট এর জটিলতায় ভুগছেন? ১। হ্যাঁ---- ২। না---- (অনু। ৩.২১, ৩.২২, ৩.২৩, ৩.২৪, ৩.২৫, ৩.২৬ নং বাদ)											
৩.২১	আপনার কি জয়েন্ট শক্ত হয়ে গেছে? ১। হ্যাঁ----- ২। না---- (অনু। ৩.২২ নং বাদ)											
৩.২২	জয়েন্ট শক্ত হয়ে যাওয়ার স্থান:											
৩.২৩	আপনার কি কোন মাংসপেশী শুকিয়ে গেছে? ১। হ্যাঁ----- ২। না---- (অনু। ৩.২৪ নং বাদ)											
৩.২৪	আক্রান্ত মাংসপেশীর স্থান :											
৩.২৫	আপনার কি কোথাও মাংসপেশী শক্ত হয়ে গেছে ? ১। হ্যাঁ----- ২। না---- (অনু। ৩.২৬ নং বাদ)											

৩.২৬	মাংসপেশী শক্ত হয়ে যাওয়ার স্থান:
৩.২৭	আপনি কি পুস্রাব-পায়খানা সংক্রান্ত জটিলতায় ভুগছেন? ১। হ্যাঁ----- ২। না---- (অনু। ৩.২৮, ৩.২৯ নং বাদ)
৩.২৮	আপনার কি মূত্রাশয় এবং মলাশয়ে কোন নিয়ন্ত্রণ আছে? ১। হ্যাঁ----- ২। না----
৩.২৯	আপনি কি মূত্রনালীর সংক্রমেণে ভুগছেন? ১। হ্যাঁ----- ২। না----
৩.৩০	আপনি কি কোন হৃৎযন্ত্র-শ্বাসযন্ত্রের জটিলতায় ভুগছেন? ১। হ্যাঁ----- ২। না---- (অনু। ৩.৩১ নং বাদ)
৩.৩১	কি ধরনের হৃৎযন্ত্র-শ্বাসযন্ত্রের জটিলতায় ভুগছেন? ১। শ্বাস কষ্ট- হ্যাঁ----/না---- ২। অন্যান্য:
৩.৩২	অটোনমিক ডিসরিফ্লেকশিয়া? ১। হ্যাঁ----- ২। না----
৩.৩৩	আপনি কি কোন মানসিক জটিলতায় ভুগছেন? ১। হ্যাঁ----- ২। না-----
৩.৩৪	আপনি কি অন্য কোন জটিলতায় ভুগছেন - যেমন: ১। পড়ে যাওয়া - হ্যাঁ----/না---- ২। স্থানান্তর এবং বিছানায় নড়াচড়াতে জটিলতা- হ্যাঁ----/না---- ৩। অন্যান্য:

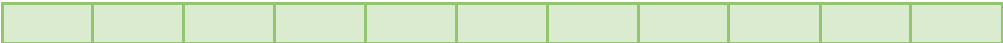
Questionnaire in English:

Part-1: Socio- demographic informations	
1.1	Patients name:
1.2	Gender: Age:
1.3	Address-
1.4	Telephone number:
1.5	Occupation:
1.6	Family type:
1.7	Monthly Income:
1.8	Educational status:
1.9	Residential area:

Part-2: Injury related questionnaire

2.10	Cause of injury:
2.11	Type of paralysis: 1. Tetraplegia----- 2. Paraplegia-----

Part-3: Complications related questionnaire (After returning community)

3.12	<p>After returning to community, are you suffering from any complications, like-pressure sore?</p> <ol style="list-style-type: none"> 1. Yes----- 2. No----- (skip Q.no 3.13,3.14,3.15)
3.13	Number of pressure sore:
3.14	Area of pressure sore:
3.15	<p>Grade of pressure sore?</p> <ol style="list-style-type: none"> 1. Grade –I 2. Grade –II 3. Grade –III 4. Grade –IV
3.16	<p>Are you suffering from pain?</p> <ol style="list-style-type: none"> 1. Yes----- 2. No----- (skip Q.no.3.17,3.18)
3.17	<p>Severity of pain:</p>  <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>0= no pain. Yes-----/No----- 1 - 4= mild pain. Yes-----/No----- 5 – 7= moderate pain. Yes-----/No----- 8 – 10= severe pain. Yes-----/No-----</p>
3.18	Site of pain:
3.19	<p>Muscles tone:</p> <ol style="list-style-type: none"> 1. Spastic – Yes-----/No----- 2. Flaccid – Yes-----/No----- 3. Normal-----
3.20	<p>Are you suffering from any complications of muscle & joint?</p> <ol style="list-style-type: none"> 1. Yes----- 2. No----- (skip Q.no. 3.21,3.22,3.23,3.24,3.25,3.26)
3.21	<p>Have your any stiffness of joint?</p> <ol style="list-style-type: none"> 1. Yes----- 2. No----- (skip Q.no 3.22)
3.22	Location of joint stiffness:
3.23	<p>Is there present any muscle atrophy?</p> <ol style="list-style-type: none"> 1. Yes----- 2. No----- (skip Q.no 3.24)
3.24	Area of affected muscles:

3.25	Is there any muscle contracture? 1. Yes----- 2. No----- (skip Q.no 3.26)
3.26	Area Muscle contracture:
3.27	Are you suffering any urological complications? 1. Yes----- 2. No----- (skip Q.no 3.28,3.29)
3.28	Have your any control of bowel and bladder? 1. Yes----- 2. No-----
3.29	Are you suffering from UTI? 1. Yes----- 2. No-----
3.30	Are you suffering with any Cardio-respiratory complications? 1. Yes----- 2. No----- (skip Q.no.3.31)
3.31	What type of respiratory problem? 1. SOB- Yes-----/ No----- 2. Other:
3.32	Autonomic Dysreflexia? 1.Yes----- 2.No-----
3.33	Are you suffering from any psychological complications? 1.Yes----- 2.No-----
3.34	Are you suffering from any other complications- such as: 1. Fall- Yes-----/No----- 2. Poor transferring & bed mobility- Yes-----/No----- 3. Others-



বাংলাদেশ হেল্থ প্রফেশন্স ইনষ্টিটিউট (বিএইচপিআই)
BANGLADESH HEALTH PROFESSIONS INSTITUTE (BHPI)

(The Academic Institute of CRP)
CRP-Chapain, Savar, Dhaka. Tel: 7745464-5, 7741404 . Fax: 7745069
BHPI-Mirpur Campus, Plot-A/5, Block-A, Section-14, Mirpur, Dhaka-1206. Tel: 8020178,8053662-3, Fax: 8053661

তারিখ : ০৩.০৫.২০১৭

প্রতি
সহকারী ব্যবস্থাপক
রিহ্যাবিলিটেশন উইং
সিআরপি, সাভার, ঢাকা।

বিষয় : রিসার্চ প্রজেক্ট (dissertation) প্রসঙ্গে।

জনাব,

বিএইচপিআই'র ৪র্থ পেশাগত বিএসসি ইন ফিজিওথেরাপি কোর্সের ছাত্র মোঃ সফিকুল ইসলামকে তার রিসার্চ সংক্রান্ত কাজের জন্য আগামী ০৪.০৫.২০১৭ তারিখ থেকে ০৪.০৬.২০১৭ তারিখ পর্যন্ত সময়ে আপনার নিকট প্রেরণ করা হলো। তার রিসার্চ শিরোনাম

“ Complications among the spinal cord injured patient after returning the community.”

তাই তাকে সার্বিক সহযোগীতা প্রদানের জন্য অনুরোধ করছি।

ধন্যবাদান্তে

মোঃ ওবায়দুল হক
সহযোগী অধ্যাপক ও বিভাগীয় প্রধান
ফিজিওথেরাপি বিভাগ
বিএইচপিআই।



বাংলাদেশ হেল্থ প্রফেশন্স ইনস্টিটিউট (বিএইচপিআই)
BANGLADESH HEALTH PROFESSIONS INSTITUTE (BHPI)
(The Academic Institute of CRP)

Ref: CRP-BHPI/IRB/04/17/103

Date: 15/04/2017

To
Md. Shafiqul Islam
B.Sc.in Physiotherapy
Session: 2012-2013, Student ID 112120020
BHPI, CRP, Savar, Dhaka-1343, Bangladesh

Subject: "Complications among the spinal cord injured patient after returning the community".

Dear Md. Shafiqul Islam,

The Institutional Review Board (IRB) of BHPI has reviewed and discussed your application on 16/08/2016 to conduct the above mentioned thesis, with yourself, as the Principal investigator. The following documents have been reviewed and approved:

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

Since the study involves a structured questionnaire and VAS scale that takes 20 to 30 minutes and have 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 09:00 AM on August 17, 2016 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,

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