Effect of Early Pre-Ambulatory Training on Functional Mobility Skill and Quality of Life in Low Paraplegia: A Research Protocol

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Abstract

Background: Paraplegia defined as near total dysfunction of the entire or part of the trunk and both lower limbs, caused by lesions of the thoracic or lumbar spinal cord or cauda equina. 43% of SCI results in paraplegia for thoracic, lumbar, or sacral lesion. The purpose of physical therapy management is to make the patient relaxed and to achieve pre-ambulatory preparations, pre-ambulatory activities and ambulation activities.

Methods/Design: The study will be designed as experimental study. Total 60 participants will be selected as per inclusion and exclusion criteria from AVBRH, Sawangi Meghe for the study. The duration of study will 6 months with intervention. Physiotherapy intervention includes respiratory care, skin protection, range of motions and early reinforcement, early mobility activity, bed mobility skills, transfer activities and wheelchair skills. ASIA Impairment Scale, Functional Independent Measure, Wheelchair Skill Test, WHOQOL-BREF will be major outcome measure for the patient.

Discussion: The study protocol details, in people with SCI the intervention strategy selected is largely based on the amount of preserved motor function. Independence in functional skills in patients with complete motor SCI (ASIA A and B) is largely achieved through compensatory mechanisms and interventions are developed accordingly. Expected outcome from the study will be the effects of early pre-ambulatory training on functional mobility skills and quality of life in low paraplegia.

Key Words: Spinal cord injury, paraplegia, pre-ambulatory training, quality of life, rehabilitation

Introduction

Spinal cord injury is a moderately low – rate, high – cost injury that outcomes in huge change in a person’s life. Traumatic and non-traumatic injuries are two specific etiological categories of spinal cord injury. Trauma is the most common cause of injury in adult recovery settings. Injury occurs from damage caused by traumatic situations such as road traffic accidents(40.4%), falls(27.9%), crime (15%), and athletics (8.0%).

In adult populations non-traumatic injury generally results from illness or pathological effect. Tetraplegia and paraplegia are two specific functional categories of spinal cord injury. Paraplegia defined as to complete paralysis of the entire or part of the trunk and both lower limbs, caused by lesions of the thoracic or lumbar spinal cord or cauda equina. Approximately 1.5 million people live with SCI in India. Every year approximate 20,000 new cases of SCI...
are combined and 60-70% of them are illiterate, poor.\textsuperscript{3} 43% of SCI results in paraplegia for thoracic, lumbar, or sacral lesion\textsuperscript{2}. The ability to strengthen results is with combinatorial strategies, and the effects on functional outcomes that support the recovery and quality of life. Life expectancy for people without a SCI has improved over the years but is still lower than that. Age at the onset and level and extent of neurological injury are variables that affect life expectancy. Patients with incomplete neurological SCI have a longer life expectancy than those with complete injuries, and patients with more serious injuries often have a higher life expectancy. Individuals with SCI may benefit from recent neurotechnology advances designed to enhance function and quality of life.\textsuperscript{1}

The neurological conditions are spinal shock, sensory and motor impairment, autonomic dysreflexia, spastic hypertonia, postural hypotension, coronary heart disease, impaired temperature control, pulmonary impairments, bowel and bladder dysfunction, sexual abnormality. Secondary medical complications are developed in 82% patients by rehabilitation. After one year of injury, pressure ulcers (15%), pneumonia (4%), and deep vein thrombosis (2.5%) are the most common secondary complications.\textsuperscript{1}

The summary purpose of physical therapy management is to make the patient relaxed and to gain functional freedom necessary for daily life, jobs and recreation.\textsuperscript{4} 5 During this early stage of recovery the primary focus areas are the evaluation of sensory and motor control, respiratory function, skin integrity, PROM, and early mobility ability performance. Early pre-ambulatory training includes strengthening, isokinetic strength testing exercises, resistance training program, endurance training, bed mobility skills, sitting stability, transitions, mat-to-wheelchair transfers, locomotive training.\textsuperscript{1}

Improvements in functional damage, the capacity to carry out tasks that are significant to the individual and a return to engaging in regular, preferred social roles can be achieved through therapies based on compensatory approaches, restorative approaches or a mixture of the two. In people with SCI the intervention strategy selected is largely based on the amount of preserved motor function. Independence in functional skills in patients with complete motor SCI (ASIA A and B) is largely achieved through compensatory mechanisms and interventions are developed accordingly.

**Aim & Objective**

To study the effect of early pre ambulatory training on functional mobility and quality of life in low paraplegia. The objectives are to achieve pre-ambulatory preparation, pre-ambulatory activities and ambulation activities.

**Methodology**

**Study setting**

The study shall be incorporated at ICU setup of Acharya Vinoba Bhava Rural Hospital Sawangi Meghe, Wardha, after approval from Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences, Sawangi Meghe, Wardha.

**Study design and sample size**

The number of participants enrolled in this experimental study is 60. Clarify to the participants before inclusion about the study’s goals and methods. The patients will be screened and random allocation shall be done; written consent form will be obtained from all participants’ family.

**Participants**

**Inclusion Criteria:** Subjects of both genders from the age of 18 to 65 years, neurological level of injury from T12 or below, motor complete and incomplete injury, medically stable patients, sufficient upper extremity and range of motion.

**Exclusion Criteria:** Spinal instability, deep vein thrombosis, heterotopic ossification, cognitive deficits, contractures, osteoporosis and skeletal fracture, pain, skin injury, upper extremity soft tissue injuries like contusion, sprain and strain.

**Participant timeline**

The study duration is of 6 months with intervention. Simple random sampling (envelop) method will be done. Before the initial examination, the patient must be stable enough to undergo analysis. Assessment will be done on 1\textsuperscript{st} day of visit then in last of intervention. In patients,
the treatment process varied from 8 weeks to 12 weeks, respectively. The evaluation (FIM and WHOQOL-BREF) will be performed initial to the last session.

**Recruitment**

Regular visit to neuro ICU, neurosurgery wards will be done and contact will maintain with doctors, record maintaining office for cases that will enrolled in hospital so that can be taken for the study. The patient who are already undergoing rehabilitation in our in-patient department (IPD) and diagnosed with low paraplegia will be systematically assessed for the eligibility in the study as per the inclusion and exclusion criteria.

**Implementation & Blinding:** Randomization will be supervised by the research coordinator and principal investigators. Tester(s) will be blinded.

**Physiotherapy interventions:**

Management of physical therapy in an acute recovery period: In physical therapy assessment examination of skin integrity, sensory and motor function, respiratory function, passive range of motion and performance of early mobility activity will be done. Physical therapy intervention will be respiratory care, skin protection, range of motions and early strengthening, recent flexibility interventions, education.

In active rehabilitation, physical therapy strategies include strengthening, cardiovascular/ Endurance, bed mobility activities, rolling, progression supine to/ from sitting, sitting stability, transitions, mat-to-wheelchair transitions, locomotive exercise, locomotive training for individuals with motor full SCI and locomotive training for individuals with partial SCI. Wheelchair Skills are forward and backward propulsion, turning, ascending and descending inclines, guess and continue to maintain wheelie, propulsion on uneven terrain.

**Study procedure**

The physiotherapy program focused mainly not just on patient recovery but also on improving their quality of life. In patients, the treatment process varied from 8 weeks to 12 weeks, respectively.

**Treatment plan will be followed in some key steps:**

Pre-ambulatory preparation, Pre-ambulatory activities, Ambulatory activities. (Time duration will vary according to patient’s condition).

Pre-ambulatory preparation will be: Postural hypotension and cardiovascular impairments. In postural hypotension: When an erect or vertical position is assumed there is a decrease in blood pressure that is called orthostatic hypotension. It is due to a lack of sympathetic regulation of the vasoconstriction. The problem is compounded by lack of muscle tone, causing pooling of the peripheral venous and splanchnic beds. The vital signs should be closely monitored. Using compression stocking and an abdominal binder should reduce these symptoms further. In cardiovascular impairments: Below the level of lesion this causes bradycardia, and peripheral vasculature distension. Due to the disturbed equilibrium from sympathetic to parasympathetic device, and lack of active muscle contraction and extended bedtime. Cardiovascular preparation provides major safety advantages for SCI sufferers. A variety of studies have shown that aerobic fitness may be improved by strength training. The most popular form of aerobic training is upper limbs - based movements such as arm ergometry, wheelchair movements and swimming. Another form of endurance training is in people with SCI with adequate walking ability locomotive training on an TM with or without BWS.

Pre-ambulatory activities will be as follow: Rolling, Progression supine to/from sitting, sitting stability. To facilitate functional mobility independence bed mobility skills are required. It involves rolling, transition from sitting at the bedside to / from the supine and lower limb management. Independence is also required for dressing, placement in bed and screening of the skin. Basically, two methods of progression “walking” on bent elbows and going straight up, from supine. Independent sitting stability, in both the low sitting and the high sitting, is an important ability for several various basic activities like transitions, dressing and mobility in the wheelchair. Number of surfaces should undergo balance treatments. Surfaces are: rigid mat, bed, thick mattress, soft sofa and so on. Balance interventions should also be practiced while sitting in the patient’s wheelchair.

Ambulatory activities will be as follow: transitions, mat-to-wheelchair transfers, and locomotive training
and wheelchair skills. In transitions, the sitting-pivot has three components: Preparatory step; away from the transferring surface trunk is flexed forward and laterally, lift phase; buttocks are lifted off the seating surface as the trunk rotates and end of the descent phase when the buttocks are on the other sitting surface. Locomotive training will be: Locomotive Training for Individuals with Motor full SCI and locomotive Training for Individuals with partial SCI. Basic wheelchair mobility skills will be included.

OUTCOME

Primary outcome measures:

The primary outcome measures will be ASIA Impairment Scale and Functional Independent Measure. ASIA standards should be used to assess the level of lesions and preserved motor function. In sensory examination key points in each of the dermatomes is tested bilaterally and in motor examination key muscle functions of the myotomes are tested bilaterally. Motor and sensory examination of the standards can be reliable if carried out by professional examiners. For classification of injury ASIA standards are validated. The Measurement of Functional Independence (FIM) is an 18-item measure of physical, psychological and social dimensions functionality. The FIM uses an individual’s level of assistance to rate the functional status from complete independence to complete assistance.

Secondary outcomes measures:

The secondary outcome measures will be the Wheelchair Skill Test. To evaluate a manual wheelchair user’s skill performance WST 4.1 is a reliable tool. The wheelchair circuit is a appropriate and valid instrument for assessing the manual functionality of wheelchairs in subjects with SCI. The main objective of this review is to evaluate record, examine and critically assess the performance-based wheelchair skills assessments currently available in international literature for manual wheelchair users, particularly those with spinal cord injury. The WHOQOL-BREF will be used to determine the quality of life (QoL) of paraplegic people and their self-esteem. It contains 26 items, assessing the following specific domains: physical and psychological health, social relations, and environment. It has been shown that WHOQOL-BREF exhibits strong discriminating validity, material validity and reliability for test-retest.

DATA COLLECTION AND MANAGEMENT

Data collection

The data of assessment will be collected from the pre-established spread sheet with variable baseline characteristics. In a secure REDCap database testing data will be stored. The non-electronic data, such as hard copies of assessment forms, signed consent forms, etc. will be stored securely in the study setting.

Data management

Data collection and documentation will take place in the context of principal investigators guidance. For accuracy will being evaluated thoroughly by the study documentation. To prevent missing data due to inappropriate staff procedures checklists are used.

Statistical Analysis Plan

Data analysis will be undertaken utilising qualitative and interpretation statistical data through using Chi-square test and the student’s unpaired t test. The device used for interpretation will be SPSS24.0 version, Graph pad prism version 7.0 and p<0.005 are considered to be of relevance (p>0.005).

Bias

Measures will be taken to prevent this from happening attrition bias by giving reminder calls prior to each intervention and by providing travel assistance to those who need it. So, we expect a low percentage of dropouts.

Discussion

The study protocol details, in people with SCI the intervention strategy selected is largely based on the amount of preserved motor function. As the average life expectancy of people with SCI has increased due to improvements in medicine, the HRQL of persons with SCI should be examined more thoroughly because quality of life (QoL) provides a good prediction of survival 15 years after injury. As the average life expectancy of people with SCI has increased due to improvements in medicine, the HRQL of persons with SCI should be examined.
more thoroughly because quality of life (QoL) provides a good prediction of survival 15 years after injury. The study protocol details, in people with SCI the intervention strategy selected is largely based on the amount of preserved motor function. Because of advances in medicine, the average life expectancy of people with SCI has improved, the HRQL of people with SCI should be studied more closely because quality of life (QoL) offers a strong predictor of survival 15 years after injury. The individuals and their families seems to have a substantial impact from the sudden onset of spinal cord injury.

Exercise and gait training in persons with paraplegia and its potential impact on mass and strength assets. The connection between changes in the muscle properties and factor of gait of paraplegic people using orthotics are investigated by the authors. For developing countries with environmental barriers, these results are significant and relevant. Reinforcement of the upper extremity will be used in the recovery of paraplegic patients qualified for orthotics ambulation.

Expected outcome from the study will be the effects of early pre-ambulatory training on functional mobility skills and quality of life in low paraplegia. Rehabilitation measures may be compensatory or recovery-based depending on the patient’s appearance. The physiotherapist, recovery team and patient will use these projected outcomes to set goals and expectations.

**Ethical Approval and Dissemination:**

Ethical approval will be taken from institutional ethical committee. The DMIMS who will fund for research and the subjects who will participate in the study can access the main findings of the research. Data held safely for the enrolled subjects a minimum of five years. After completion of data collection, statistical analysis a completion report will be formed and after review by institutional research cell will be send for publication.

**Patient consent**

Principal Investigators will obtain the informed consent from the patient and one of the relatives on a printed form with signatures and give the proof of confidentiality.

**Confidentiality**

The research plan will be explained to the participants and personal details will be taken from one of his / her relative and the principal investigator. The consent form must contain a statement of confidentiality and the principal investigator, patient and 2 witnesses’ signatures. If needed to reveal any details for the analysis, the patient’s consent will be taken with full confidentiality guarantee.

**Declaration of interest**

The authors declare no conflicting interest.

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