Methods & Protocol

Functional rehabilitation in intensive care units for post craniotomy patients: study protocol

Reabilitação funcional em unidades de terapia intensiva para pacientes pós-craniotomia: protocolo de estudo

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ABSTRACT | INTRODUCTION: Craniotomy makes insight and approach towards the brain easier but accompanies ailments. Intensive care units are equipped with trained professional physical therapists working over these deleterious after-effects of this surgical program, but a progressive, defined, and evidence-supported protocol for such patients is lacking. **OBJECTIVE:** To assess the feasibility of a Neuro-rehabilitation protocol devised for post-craniotomy patients within their stay in the Intensive Care Unit (ICU) to improve their functional outcomes and reduce their length of stay (LOS). **MATERIALS AND METHODS:** It will be a single group pre-test post-test quasi feasibility trial. Fifteen patients undergoing craniotomy will be recruited for the trial and will be rendered with Neuro-rehabilitation protocol for 60 minutes from the first day of surgery up to 15 days of surgery. The primary outcome will be the Early Functional Abilities (EFA) Scale to measure functional outcomes like conscious level, sensorimotor abilities, cognitive-perceptual abilities, and oro-motor abilities of patients, which will be assessed first-day post craniotomy. Secondary outcomes will include Glasgow Coma Scale (GCS), Coma Recovery Scale-Revised (CRS-R), Sensory Modality Assessment Rehabilitation Technique (SMART), Modified Ashworth Scale (mMAS), Montreal Cognitive Assessment Score (MoCA), and Medical Research Council Scale (MRC). Assessments will be taken on the first and fifteenth days post-surgery. **PERSPECTIVES:** It is expected that this protocol might improve functional outcomes and may reduce the occurrence of comorbidities in patients after Craniotomy in ICUs.

KEYWORDS: Craniotomy. Coma. Intensive Care Unit. Length of stay. Physical Therapy.

ETHICAL APPROVAL: The study has been approved by Institutional Ethical Committee (MMIPR/IEC-1535) of a tertiary care teaching hospital. The trial is prospectively registered on Clinical Trial Registry-India and the CTRI number for the trial is CTRI/2020/03/024241 and the Universal Trial Registration Number is U1111-1248-9270. **PROTOCOL COPYRIGHTED REGISTRATION NUMBER:** L-94096/2020.

RESUMO | INTRODUÇÃO: A craniotomia torna mais fácil a compreensão e abordagem do cérebro, mas acompanha as doenças. As unidades de terapia intensiva são equipadas com fisioterapeutas profissionais treinados para lidar com esses efeitos deletérios após este programa cirúrgico, mas falta um protocolo progressivo, definido e apoiado por evidências para esses pacientes. **OBJETIVO:** Avaliar a viabilidade do protocolo de neuro-reabilitação elaborado para pacientes pós-craniotomia durante sua internação em Unidade de Terapia Intensiva (UTI) para melhorar seus resultados funcionais e reduzir seu tempo de internação (LOS). **MATERIAIS E MÉTODOS:** Será um ensaio de quase viabilidade pós-teste de pré-teste de grupo único. Quinze pacientes submetidos à craniotomia serão recrutados para o estudo e serão processados com protocolo de Neuro-reabilitação por 60 minutos do primeiro dia da cirurgia até o 15º dia da cirurgia. O resultado primário será a Escala de Habilidades Funcionais Precoces (EFA) para medição de resultados funcionais como nível de consciência, habilidades sensório-motoras, habilidades cognitivo-perceptuais e habilidades oromotoras de pacientes que serão avaliadas no primeiro dia após a craniotomia. Os resultados secundários incluirão Escala de Coma de Glasgow (GCS), Escala de Recuperação de Coma - Revisada (CRS-R), Técnica de Reabilitação de Avaliação de Modalidade Sensorial (SMART), Escala de Ashworth modificada modificada (mMAS), Pontuação de Avaliação Cognitiva de Montreal (MoCA) e Conselho de Pesquisa Médica Escala (MRC). As avaliações serão feitas no primeiro e no décimo quinto dia pós-operatório. **PERSPECTIVAS:** Espera-se que este protocolo melhore os resultados funcionais e reduza a incidência de ocorrência de comorbidades em pacientes após craniotomia em UTI.

PALAVRAS-CHAVE: Craniotomia. Coma. Unidade de Terapia Intensiva. Tempo de internação. Fisioterapia.

APROVAÇÃO ÉTICA: O estudo foi aprovado pelo Comitê de Ética Institucional (MMIPR / IEC-1535) de um hospital universitário de atendimento terciário. O teste é prospectivamente registrado no Clinical Trial Registry-India e o número CTRI para o estudo é CTRI / 2020/03/024241 e o número de registro do teste universal é U1111-1248-9270. **NÚMERO DE REGISTRO PROTEGIDO POR DIREITOS AUTORAIS DO PROTOCOLO:** L-94096/2020.

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Introduction

A craniotomy is a surgical procedure that incorporates removing and replacing a bone flap of the skull after removing the anomaly within it.[1] It is a single-time procedure that aims to control the intracranial pressure and prevent the complications of reoccurring surgeries as in Decompressive Craniectomy followed by Cranioplasty, enhancing the incidence of post-traumatic hydrocephalus, prolonged hospitalization, unfavorable outcomes, and infections of the neural tissues.[2] Removing the skull to get an insight into the brain is generally termed as craniotomy, and the followed procedure determines the comorbidities which may persuade.[3] Conditions like stroke, traumatic brain injury, dural sinus thrombosis, aneurysms, intracranial infections, subarachnoid hemorrhage, and other severe inflammatory conditions require neurosurgical interventions like craniotomies, craniectomies, or Cranioplasty, depending upon the case. These techniques, however, have a risk percentage of around 12%-50% and result in extended use of medications, prolonged duration of the hospital of Intensive Care Unit (ICU) stay, governing the functional outcomes of patients.[4]

There are various detrimental consequences of prolonged hospitalization. Extensive hospitalization results in vast exposure to mechanical ventilation, development of venous thrombosis, sustained immobilization, probability of urinary tract infections owing to continued use of catheters, and hike in the cost of daily expenditure on healthcare.[5] This elongated period of ICU exposure of neurosurgical patients escalates the prospect of infections like ICU sepsis and ICU-acquired weakness, enhancing the disbursements of hospitalization by 40% leading to obstruction in return of consciousness from comatose state.[6] Excessive and prolonged exposure to mechanical ventilation elicits VAP (ventilator-acquired pneumonia), facilitates the ICU costs, and leads to AECOPD, respiratory failure, sputum accumulation, and atelectasis. As a direct consequence of critical illness, patients suffer from diverse disabilities and poor quality of life.[7]

Neurological ICUs incur common impairments like delirium, neuromuscular weakness, polyneuropathy, and myopathies, which impair the quality of life.[8] Studies suggest that the average mean duration in ICUs for surgical patients is 12-25 days, shortest being 7-12 and longest being 49-72 days depending upon the variability of services and procedures along with pathologies.[9,10]

According to Patient Protection and Affordable Care Act, it has been emphasized to consider the quality of life of patients and value-based treatment options to be made available to the patients while choosing the treatment administered to patients who require critical care.[5] Physical therapy has shown some amazing effects on patients' conditions in Intensive care units and is considered an important component of ICU teams in many countries worldwide. Early professional mediated rehabilitation has proved to effectively reduce hospital or ICU stay by combating the effects of prolonged immobilization.[11] Interventions like early active mobilization, positional changes, goal-directed mobilization have proven effective in reducing muscle weakness, muscle wasting, and immobility.[12] Chest physical therapies including mechanical vibration percussion lead to early extubation, which significantly improves the condition of ventilator-dependent patients in their early weaning off and mobilization of collected sputum within their lungs.[13,14]

Around the world, early mobilization for ICU patients is a regular regime to be followed, but to date, there is no single protocol that is implemented with modifications according to different craniotomy patients in neurological ICUs.[15] However, advancements like Transcranial direct current stimulation (tDCS) are proven to be safe for patients, and their results demand strong evidence to be implied in future practices and have shown positive effects on consciousness and motor re-education in patients.[16,17]

The basic objectives to commence this study are to evaluate the feasibility and applicability of the rehabilitation protocol, assess the protocol's effect on patients' functional outcomes, and estimate the length of stay in the ICU of such patients. Thus, the null hypothesis states that this rehabilitation protocol may not affect functional outcomes of patients with craniotomies in neurological ICUs.

Methods

Study design

The study design will be single group pre-test post-test quasi feasibility trial.

Subjects

Inclusion criteria

Patients between 18 to 55 years after their craniotomy procedure, i.e., Post-Operative Day 1 (POD) will be recruited in the study, which may be mechanically ventilated, or on oxygen, support has undergone tracheostomy. Since craniotomy is a surgical procedure, the patient undergoing decompressive craniotomy for pathologies like cerebral aneurysm, stereotactic aspiration, extended bi-frontal craniotomy, minimal invasive supra-orbital craniotomy, removal of blood clot from blood vessels, drainage of brain abscess, repairing of fractures of the skull, subarachnoid hemorrhage, and subdural hemorrhage will be recruited before the development of any secondary infection. Thorough knowledge about the patient's condition and rehabilitation will be made available to the nearest relatives of patients, and after their approval, recruitment will be preceded. In addition, patients with dura and skin flap repaired post craniotomy will be recruited.

Exclusion criteria

Patients will be excluded if there will be the development of any infection post craniotomy procedure, fluctuation in the vital parameters, like heart rate, blood pressure, respiratory rate, oxygen saturation, and pulse rate, of patients, post 12 hours of craniotomy, abnormalities in intracranial pressure and CSF circulations and presence of secondary infections like ventilator acquired pneumonia (VAP). Patients will also abstain from recruitment if consent is denied from family members, patients with meningioma, malignant skull-based tumor, acoustic neuroma, tear in Dura-mater, hearing and visual loss, previous history of fatal injuries, agitated and patients with amputations. In addition, Retro-sigmoid, trans-labyrinthine, and orbital-zygomatic craniotomies will be excluded. Patients with implanted stimulators will also be excluded from the study.

Patient recruitment

Post-surgery family members of patient's undergoing craniotomy procedure will be asked for their approval, and then if they will fulfill the criteria of the study, a detailed informed consent will be taken and post their consent, baseline measurements of the primary and secondary outcomes will be taken, and the physiotherapist will perform the intervention in neurosurgical ICU after 24 hours of craniotomy.

Study setting

The study will be conducted in Neurosurgical ICU in a tertiary care teaching hospital in Ambala, Haryana of India.

Outcome measures

Primary outcome

The primary outcome measure will be the Early Functional Abilities (EFA) scale. It is a 20-point scale comprising of measures of wakefulness, cognitive abilities, and activities of daily living.[18] Its total scoring ranges from 20 to 100 depending upon the 20 points considered. Meant to measure the neurological progress in any neurosurgical patient and will be assessed at the baseline, i.e., POD 1, and at the end of the 15th day of surgery.

Secondary outcomes

Secondary outcomes that will be evaluated include scales specialized for different domains. Glasgow Coma scale, Coma Recovery Scale-Revised, and Sensory Modality Assessment and Rehabilitation Technique scales will be evaluated along with the EFA scale on POD 1 and after the complete intervention. Scales like the Montreal Cognitive Assessment scale, modified Modified Ashworth scale, and Medical Research Council scale for muscular strength will be assessed on the day patient regains consciousness, i.e., reaches GCS level ≥ 8, and on the 15th day of the intervention.

• Glasgow Coma Scale (GCS) is a 3-point scale comprising eye-opening, verbal, and motor responses. The maximum scoring for GCS is 15, denoting normal and lowest being 3, describing severe brain injuries.[19]

• Coma Recovery Scale-Revised (CRS-R) is an effective tool to measure neurobehavioral assessment of disordered consciousness, especially in coma patients with a maximal score of 23 and a minimum score of 0.[20]

• Montreal Cognitive Assessment Scale (MoCA) is used to assess the cognitive impairments domain in patients post craniotomy. Normal scoring of this test ranges from 0 to 30 and depicts the level of dementia or cognitive impairments.[21] Patients who are intubated or have tracheostomy will not be assessed using this scale, and the cognitive domain thus will be evaluated through the Cognitive domain present within the EFA scale.

• Modified Ashworth Scale (mMAS) is a measure of spasticity and helps predict the tone of muscles of extremities. It is a 5-point scale ranging from 0 to 5 depending upon muscle response on movement.[22] Six primary muscle groups, namely elbow flexors, elbow extensors, wrist flexors, knee flexors, knee extensors, and ankle plantar flexors, will be assessed on both sides, making it a total score of 60.

• Medical Research Council Scale (MRC) measures the strength of extremity muscles, ranging their scores from 0 to 5.[23] The marking of this scale will be done according to mMAS scoring, i.e., a total of 60 points will be evaluated for both extremities.

• Sensory Modality Assessment and Rehabilitation Technique (SMART) - It measures the domains of arousal and sensations which could be elicited through stimulations. It is a 5 point scale ranging from 1 to 5 in ascending order of progress of patients.[24]

Study Procedure (Table 1)

Table 1. Procedure fo the study

	Study Period							
	Enrolment	**Allocation**	**Protocol (Treatment)**				**Final Assessment**	
Timepoint	**Day of Surgery**	**-**	**Day 1-4**	**Day 5-7**	**Day 8-11**	**Day 12-24**	**Day 15**	**Prior to discharge**
Enrolment:								
Eligibility screen	X							
Informed consent	X							
Interventions:								
Regain consciousness			X	X	X	X	X	
Chest physiotherapy			X	X	X	X	X	
Sensory reeducation			X	X	X	X	X	
Limb physiotherapy			X	X	X	X	X	
Motor reeducation					X	X	X	
Assessments								
Demographic data	X	-						X
Baseline characteristics	X	-						X
Early Funcional Abilities EFA scale	X	-					X	X
Secondary outcomes	X	-					X	X

Interventions

Patients recruited will be administered with a 15 days rehabilitation protocol (Table 2) which will be rendered from POD 1 up to POD 15 according to 5 different domains. The protocol's objective is to enhance the overall functional improvement, which will not only improve health benefits for them but will also reduce the chances of occurrence of comorbidities which indirectly elongates the ICU stays. The major five domains include regaining consciousness, chest physiotherapy, sensory re-education, limb physiotherapy, and motor re-learning.

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (to be continued)

Sections	Goals of treatment	Intervention	Method	Dosage
Section 1 (Day1 to Day4)	To promote recovery from unconscious state	Transcranial direct current stimulation	An anodal electrode placed at F3 (over the left DLFPC), Cathodal electrode placed at FP2 (over the right supraorbital area)	Current intensity 2mA for 20 minutes.
		Music therapy	The earphone would be inserted into the patient's ear lobes. The music chosen would be the patient's favorite, according to relatives of the patient	The time allotted is 10 minutes.
		Coma stimulation therapy	Tapping- Continuous rhythmic taping over the upper and lower extremity from distal to proximal. Brushing – Continuous brushing over the upper and lower extremity from distal to proximal with the help of fine brush. Auditory- The patient will be administered with earphones and will be hearing his/her family's voices	Repetitions- 5 sets* 2sets. Repetitions- 5 reps * 2 sets The time allotted for auditory stimulation is 5 minutes.
	To prevent pulmonary complications and accumulation of secretions within lungs	Mechanical vibration	A mechanical vibrator is used to administer vibrations to the chest anteriorly, posteriorly, and bilaterally. It depends upon the lobe most affected .	In alternation with the percussion.
		Percussion	Given anteriorly and posteriorly. Primary focus on the lobe of the lung involved	300 repetitions per minute. In alternation with the vibration.
		Intercostal muscle stretches	The therapist palpates the intercostal space on both sides of the chest with the help of two fingers placing both the fingers in the fashion of the muscle fiber present. A distracting stretch is applied by spreading the fingers at the end of expiration.	5 reps * 2 sets
		Suction	As required, nasal suction with the removal of nasal prongs. Endotracheal suctioning when endotracheal route available. Oral suctioning when advisable.	As per required when there is presence of secretions within the airway passage.
	To promote mobility in the upper and lower extremities and reduce the risk of developing pressure sores	Passive range of motion exercises	Performed for the joints of upper and lower limbs. The dominant hand of the therapist is to be placed above the next distal joint according to the joint which is being moved, and the non-dominant hand of the therapist is below the distal next joint in accordance with the joint being moved.	Repetitions- 10 reps * 2 sets
		Positioning	Supine lying- Patient must be positioned as a pillow beneath the head, both the elbows such that forearm is supinated and palm facing upwards. Pillows are placed below both knees. Side-lying- Patient must be positioned as a pillow beneath the turned head, a pillow placed between both the hands on each other, a pillow between both the knees such that upper knee lies over the pillow placed latitudinally, for both sides right as well as left.	Every 2 hours change in position.

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (continuation)

Sections	Goals of treatment	Intervention	Method	Dosage
	To promote sensory re-education	Quick stretches	Calf stretch: The dominant hand of the therapist cuddles the foot of the extremity with the therapist's elbow supporting the patient's sole. Non-dominant hand to be placed just before the ankle joint of the extremity anteriorly. Biceps Stretch: The dominant hand of the therapist to be placed over the wrist, anteriorly grasping the whole wrist. Non-dominant hand to be placed on the posterior aspect of the elbow grasping in a half-cup shape.	Repetitions- 10 reps*2 sets on each extremity.
		Tapping	Upper extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from fingers to the shoulders. Lower extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from toes to the hips.	Repetitions- 10 reps along with movement of the extremity × 2 sets.
		Brushing and Stroking	Brushing and stroking over the entire length of extremity from distal to proximal fashion with the help of bristle brushes.	Soft brush strokes brushing at the velocity of 1-10 cm/sec. on an average 43 brushing stimuli rendered.
Section 2 (Day5 to Day7)	To promote recovery from unconscious state	Transcranial direct current stimulation	An anodal electrode placed at F3 (over the left DLFPC), Cathodal electrode placed at FP2 (over the right supraorbital area)	Current intensity 2mA for 20 minutes.
		Music therapy	The earphone would be inserted into the patient's ear lobes. The music chosen would be the patient's favorite, according to relatives of the patient.	The time allotted is 10 minutes.
		Coma stimulation therapy	Tapping- Continuous rhythmic taping over the upper and lower extremity from distal to proximal. Brushing – Continuous brushing over the upper and lower extremity from distal to proximal with the help of a fine brush. Auditory- The patient will be administered with earphones and will be hearing his/her family's voices .	Repetitions- 5 sets* 2sets. Repetitions- 5 reps * 2 sets Time allotted for auditory stimulation is 5 minutes.
	To prevent pulmonary complications and accumulation of secretions within lungs	Mechanical vibration	A mechanical vibrator is used to administer vibrations to the chest anteriorly, posteriorly, and bilaterally, depending upon the lobe most affected.	In alternation with the percussion.
		Percussion	Given anteriorly and posteriorly. Primary focus on the lobe of the lung involved	300 repetitions per minute. In alternation with the vibration.
		Intercostal muscle stretches	The therapist palpates the intercostal space on both sides of the chest with the help of two fingers placing both the fingers in the muscle fiber present. A distracting stretch is applied by spreading the fingers at the end of expiration. .	5 reps * 2 sets
		Suction	As per required. Nasal suction with the removal of nasal prongs. Endotracheal	As per required when there is

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (continuation)

Sections	Goals of treatment	Intervention	Method	Dosage
			suctioning when endotracheal route available. Oral suctioning when advisable.	presence of secretions within the airway passage.
	To promote mobility in the upper and lower extremities and reduce the risk of developing pressure sores To prevent muscle wasting To enhance the muscle tone	Passive range of motion exercise	Performed for the joints of upper and lower limbs. The dominant hand of the therapist is to be placed above the next distal joint in accordance with the joint which is being moved and the non-dominant hand of the therapist below the distal next joint in accordance with the joint being moved.	Repetitions- 10 reps * 2 sets
		Quick stretches	Calf stretch: The dominant hand of the therapist cuddle the foot of the extremity with the therapist's elbow supporting the patient's sole. Non-dominant hand to be placed just before the ankle joint of the extremity anteriorly. Biceps Stretch: The dominant hand of the therapist to be placed over the wrist, anteriorly grasping the whole wrist. Non-dominant hand to be placed on the posterior aspect of the elbow grasping in a half-cup shape.	Repetitions- 10 reps*2 sets on each extremity.
		Positioning	Supine lying- Patient must be positioned as a pillow beneath the head, both the elbows such that forearm is supinated and palm facing upwards. Pillows are placed below both knees. Side-lying- Patient must be positioned as a pillow beneath the turned head, a pillow placed between both the hands-on each other, a pillow between both the knees such that upper knee lies over the pillow placed latitudinally. For both sides, right as well as left	Every 2 hour change in position.
	To promote sensory re-education	Tapping	Upper extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from fingers to the shoulders. Lower extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from toes to the hips.	Repetitions- 10 reps along with movement of the extremity × 2 sets.
		Brushing and Stroking	Brushing and stroking over the entire length of extremity from distal to proximal fashion with the help of bristle brushes.	Soft brush strokes brushing at the velocity of 1-10 cm/sec. on an average 43 brushing stimuli rendered.
Section 3 (Day8 to Day11)	To promote respiratory independency.	Mechanical vibration	A mechanical vibrator is used to administer vibrations to the chest anteriorly, posteriorly and bilaterally. Depending upon the lobe most affected.	In alternation with the percussion.
		Diaphragmatic breathing exercise	The patient is made to sit in semi fowler's position, i.e., sitting supported at the back with flexed hips and knees. The patient is asked to keep his hand at the lower portion of his chest over the stomach and is asked to inhale deeply to inflate his stomach. Then the patient is asked to exhale slowly with his mouth.	5 repetitions, 3 minutes

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (continuation)

Sections	Goals of treatment	Intervention	Method	Dosage
		Segmental breathing exercise	Depends on the segment infiltrated with sputum. In this procedure, the hand is held around the ribs semi-circularly from both sides and is manually contracted; a quick stretch is applied at the end of every exhalation.	5 repetitions intermittently.
		Incentive spirometry	An incentive spirometer with three different colored balls is taken. A mouthpiece attached to the instrument is taken inside the mouth, and deep inspiration raising the balls is achieved.	5 repetitions × 2 sets
		Huffing and coughing facilitation technique	The patient is made to sit in high sitting posture and is asked to huff (enact as to cough) multiple times. With expiration deflating the stomach.	5 repetitions
	To promote mobility and enhance tone and strength in extremities To prevent development of synergy patterns	Active assisted range of motion exercises	The patient is asked to attempt a full range of motion for every joint movement, and the therapist assists	10 repetitions × 2 sets (intermittent or continuous as comfortable for the patient)
		Positioning	Supine lying- Patient must be positioned as a pillow beneath the head, both the elbows such that forearm is supinated and palm facing upwards. Pillows are placed below both knees. Side-lying- Patient must be positioned as a pillow beneath the turned head, a pillow placed between both the hands-on each other, a pillow between both the knees such that upper knee lies over the pillow placed latitudinally. For both sides, right as well as left.	Every 2 hour change in position.
	To promote sensory re-education	Tapping	Upper extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from fingers to the shoulders. Lower extremity: Therapist taps over the whole extremity from distal to proximally, i.e., from toes to the hips.	Repetitions- 10 reps along with movement of the extremity × 2 sets.
		Brushing and Stroking	Brushing and stroking over the entire length of extremity from distal to proximal fashion with the help of bristle brushes.	Soft brush strokes brushing at the velocity of 1-10 cm/sec. on an average 43 brushing stimuli rendered.
	To improve cognition	Tactile discriminating exercises	The therapist moves different texture materials over the extremity with the patient's eyes closed, and the patient needs to identify the objects. The objects which could be used are cotton whips, gloves, blunt end of a pen, etc., discriminating two distant points.	At least 10 repetitions.
		Music therapy	The earphone would be inserted into the patient's ear lobes. The music chosen would be the patient's favorite, according to the patient's relatives, along with the voices of the family members.	The time allotted is 10 minutes.

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (continuation)

Sections	Goals of treatment	Intervention	Method	Dosage
	To promote motor re-education	Transcranial direct current stimulation	The anodal and cathodal placement of electrodes is done at C3 and C4 point.	Intensity being 1.5mA administered for 15 minutes.
		Assisted sitting	The patient is made to sit with support from the therapist.	For 3 minutes
		In bed mobility exercises	The therapist asks the patient to perform functions like picking up something from the side table, choosing the color the therapist says, and handling objects from one hand to another.	For 1 minute
		Wheelchair mobilization	The patient is ambulated with the help of a wheelchair	For 2 minutes
Section 4 (Day 12 to Day15)	To improve respiratory functions	Diaphragmatic breathing exercises	The patient is made to sit in semi fowler's position, i.e., sitting supported at the back with flexed hips and knees. The patient is asked to keep his hand at the lower portion of his chest over the stomach and to inhale deeply to inflate his stomach. Then, the patient is asked to exhale slowly with his mouth.	5 repetitions, 3 minutes
		Incentive spirometer	An incentive spirometer with three different colored balls is taken. A mouthpiece attached to the instrument is taken inside the mouth, and deep inspiration raising the balls is achieved.	5 repetitions × 2 sets
		Paper blowing exercises	A napkin or tissue paper is held in front of the patient's face, and the patient is asked to blow the paper by mouth after deep inspiration.	5 repetitions
		Thoracic expansion exercises	With every inspiration, the patient is asked to raise his/her hand in full flexion and bring it back with every expiration. With every inspiration, the patient abducts the hand at 90 degrees and, on expiration, adducts the hand back.	5 repetitions × 2 sets
	To improve muscle tone and strength	Active assisted range of motion exercises	The patient is asked to attempt a full range of motion for every joint movement, and the therapist assists	10 repetitions × 2 sets (intermittent or continuous as comfortable for the patient)
		Prolonged stretching of involved extremity	Prolonged stretching of distal muscles. Calf stretching- place the right hand over the heel of the patient in cradle position and left hand over the distal leg to stabilize the leg. Stretch by performing passive dorsiflexion of the foot for 30 seconds bilaterally. Biceps stretch- place the extremity of the patient in 90-degree abduction with the elbow extended and supinated. Place right hand over the palm and left hand over the distal elbow. Stretch by extending the fingers	5 repetitions × 2 sets
		Self-stretching of uninvolved extremity	Patient is advised to perform self-stretching of distal muscles like biceps brachii, triceps brachii and calf.	For 2 minutes
		Active movements	The patient is asked to move his extremities in all movements of the joint available.	10 repetitions

Table 2. Neurorehabilitation protocol for post craniotomy patients for 15 days (conclusion)

Sections	Goals of treatment	Intervention	Method	Dosage
	To improve sensory re-education	Task oriented reaching out exercises	The therapist asks the patient to perform functions like picking up something from side table, choosing the color said by the therapist, handling object from one hand to another.	For 1 minute
	To improve cognition	Tactile discriminating exercises	The therapist moves different texture materials over the extremity with the patient's eyes closed, and the patient needs to identify the objects. The objects which could be used are cotton whips, gloves, blunt end of a pen, etc., discriminating two distant points.	At least 10 repetitions.
		Music therapy	The earphone would be inserted into the patient's ear lobes. The music chosen would be the patient's favorite, according to the patient's relatives, along with the voices of the family members.	The time allotted is 10 minutes.
	To improve motor re-education To improve mobility	Transcranial direct current stimulation	The anodal and cathodal placement of electrodes is done at C3 and C4 points.	Intensity being 1.5mA administered for 15 minutes.
		Assisted standing	The patient is made to sit with support from the therapist.	For 2 minutes
		Weight transfer activities	Transfers from supine to high sitting position, high siting to wheelchair transfer, wheelchair transfer to standing with support, standing with support to standing upright, standing upright and double stance standing to single leg stances.	For 10 minutes
		Assisted gait training	The patient is ambulated with the help of 2 helpers, followed by a wheelchair behind the patient.	For 5 minutes

a. Transcranial direct current stimulation (tDCS) - s a low-intensity electrical stimulation that is proved to be efficient in improving various anomalies in humans and is also considered safe within the selected parameters.[25] It has been shown to improve consciousness, memory and cognitive deficits, motor skill learning, motor functions, etc.[26] At the beginning of the protocol, patients will be administered tDCS to regain consciousness, however as the protocol progresses and assuming regain of consciousness, later the tDCS will be used for motor re-education.

b. Chest physiotherapy- It is an eminent part of any physiotherapeutic intervention being followed in intensive care units. It is majorly administered to prevent the complications like sputum accumulation, atelectasis, VAP, early weaning off, etc. Techniques like percussion, mechanical vibration, intercostal stretches, suction, and segmental expansion exercises will be administered until patients remain unconscious. When patients progress consciousness, interventions like diaphragmatic breathing, incentive spirometer, huffing coughing facilitation, thoracic expansion, segmental expansion, and paper blowing exercises will be taught.[27] However, the administration of sets and repetitions of the above interventions can be modified according to the needs of the patient.

c. Limb physiotherapy- According to protocol, initially, when the patient will be unconscious, exercises like the passive range of motions, positioning, and prolonged stretching will be administered.[28] As patients regain consciousness, i.e., GCS, â• 8, exercises like the active-assisted range of motion exercises, strengthening, stretching, wheelchair mobilization assisted standing, and teaching of self-stretching and active movements along with positioning will be followed.

d. Music therapy- Music therapy intervention is not a new technique to be followed in ICUs.[29] In this protocol, music therapy will initially be rendered to patients to stabilize their vitals, as hypertension is the key complication following any brain surgery. In later stages, music therapy will help patients to attain relaxation and boost their cooperation.

e. Coma stimulation therapy- The therapy is to restore consciousness post-surgical intervention. It consists of interventions like taping, brushing, and auditory stimulation.30 It will be used alongside tDCS to improve conscious regain and continue until the patient returns to consciousness.

f. Sensory re-education- To elicit sensory responses in unconscious patient therapies like quick stretches, brushing, stroking, and tapping[30] will be performed, and on regaining consciousness, tactile discriminative tasks and music therapy will also be included in the protocol.

g. Motor re-education - Once patients are out of a minimally vegetative state or coma, training their extremities for better functional capacities becomes important. Thus, interventions like in-bed, bed-side, task-oriented exercise will be initiated for patients to overcome ICU acquired weakness. Then assisted sitting, standing, and walking will be initiated to ensure mobility in such patients.[31] Later, patients will be allowed and asked to mobilize through wheelchairs under full guidance and safety measures.

Sample Size

Since it will be a feasibility study and aims to test the aptness of protocol devised for craniotomy patients, the sample size will be 15, including 30% of drop out, and the power of the study will be calculated post completion of the study.

Statistical Analysis

Baseline data characteristics which will be evaluated and depicted using mean (standard deviation) or median (Interquartile range), will depend upon the normality of data. Data analysis for testing the hypothesis will be done by either Wilcoxon signed ranked test or paired t-test to compare pre-test and post-test intervention scores of the above-given outcomes.

Discussion

In order to reduce brain anomalies, it becomes necessary at certain stages of the diagnosis to perform such a complex neurosurgical procedure. That, in turn, gives rise to various complications which, when not dealt with as early as possible, may take the shape of fatal severe problems which in latter stages leaves a permanent disability or deformity with which the patient has to live for the rest of his/her life.[32,33] According to WHO, worldwide brain injuries alone stand responsible for 1/3 of the total global financial burden.[3] It can also be stated that extensive application of heavy-priced medical equipment and severe critical illness costs have led to an increased burden on medical facilities. It is thus proven that optimizing the length of hospital or ICU stay can globally affect the increasing trends of disability and financial burden, which these days go hand in hand.[34]

It is already significantly evident that physiotherapists' role in neurosciences and their active participation with the team of surgery can have life-changing effects on humankind. Lesser time to physiotherapist consultation post surgeon's referral significantly decreases the length of hospitalization and reduces the number of ventilation days.[35] The trends of the modern era suggest that the use of efficient but affordable treatment is the need of the hour. In neurosurgery cases where no outcome is predictable, the application of regimes that reduce the burden on the patient's family is the basic amenity these days. Various studies have correlated length of stay in hospitals, ICUs, and physiotherapeutic interventions, suggest that the length is reduced with trained and well equipped cooperative staff and a complete rehabilitation team, some suggest early extubation of patients reduces their LOS, others strongly approve early, and effective mobilization in ICUs decreases stay duration, etc.[6,15,37] Unfortunately, despite many studies, there is no protocol to be followed in neurosurgical ICUs as per our knowledge.[10] Hence, this study will be conducted to evaluate the validity of this rehabilitation protocol.

Around 60 minutes of treatment will be given to patients depending upon their condition, and the whole procedure will be documented for further insight of relatives or neurosurgeons, along with the signatures of the therapist. In addition, the treatment regime will be updated with the effects seen on the patients of prior treatment methods.

The protocol is devised from the available knowledge of physical therapy interventions to treat complications regarding prolonged hospitalization and craniotomy. Physiotherapeutic interventions which are commonly followed in Intensive care units like early mobilization, resistance training, use of incentive spirometers, secretion clearance techniques, goal-directed tasks and exercises, range of motion exercises[31], etc. are included in the protocol and practices which are evidence-based yet not so frequently used in ICUs like application of tDCS, music therapy, sensory stimulations, and coma stimulation therapy are also included in the protocol because they are advised only on the presence of specific symptoms.

Thus, the concept of this protocol is to restrict the complications before their emergence. To our best knowledge, there has not been a single protocol studied for craniotomy or neurosurgical patients, which would directly enhance their functional outcomes by preventing the development of postoperative complications. The establishment of such a rehabilitative protocol will encourage physiotherapy in neurosurgical units and substantiate it as a mainstay treatment regime.

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Author contributions

Srivastava A will be completing the study and has drafted the manuscript. Sharma N helped participate in study planning, the design provided the research material and reviewed the final version of the manuscript. Srivastav AK provided the literature review and will also be contributing to the statistical analysis. Gehlot A supervised the research project and helped in planning and conceptualization. All the authors approved the final version of the manuscript.

Competing interests

No financial, legal, or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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