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Feasibility Study to Assess the Effect of Immediate Post-Operative Prosthesis in Patients with Below Knee Amputation following Trauma

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Abstract

Background: The concept of immediate post-operative prosthesis (IPOP) is not a new one rather dates back to 1893. To the best of our knowledge and after wide literature review this study which we plan to conduct on post trauma amputee is a unique one in a way that patients will be evaluated for their balance and psychological adjustment after application of IPOP.

Objective: To see the effect of IPOP versus conventional prosthesis on balance, Quality of Life & psychological status in below-knee amputation patients following trauma.

Methods: A randomized controlled trial with sample size of 60 patients (30 in each group) with traumatic below knee amputation will be randomized in two groups using computer-generated list of random numbers with a block of 4. Group A will be intervention group who will receive IPOP within 24 hours of amputation and group B will be control group in which patients will be treated according to the standard protocol of the institute and will apply conventional prosthesis post maturation of the stump. Outcome measures will be postural stability test, limits of stability, WHO Qol Bref, Hospital Anxiety and Depression Scale (HADS), Trinity Amputation and Prosthesis Experiences Scales (TAPES), Amputee Mobility Predictor (AMP).

Results: Descriptive analysis will be done using means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Student's t-test will be used to compare the normal variables, whereas the Mann–Whitney U-test to compare the non-normal variables.

Conclusion: The study will present data for the impact of immediate post-operative prosthesis in relation with balance and quality of life in patients with posts traumatic below knee amputation.

Keywords: Limb Loss; IPOP; Below Knee IPOP; Traumatic Amputation; Feasibility

Abbreviations: IPOP: Immediate Post-Operative Prosthesis; IPD: Inpatient Department; HADS: Hospital Anxiety and Depression Scale; TAPES: Trinity Amputation and Prosthesis Experiences Scales; AMP: Amputee Mobility Predictor.

Introduction

Amputation patients' postoperative care differs from centre to centre. Applying a soft dressing and elastic bandages to the residuum and waiting for complete tissue healing and swelling reduction before applying the initial temporary prosthesis is a common standard of treatment. Recent advances in the care of patients needing amputation of the lower extremities show a lot of promise for better outcomes. The use of prosthetic-oriented amputation surgical methods and the application of immediate post-operative prosthesis (IPOP) are examples of these innovations [1]. Immediate postoperative prosthesis (IPOP) is not a novel concept. In 1893, German surgeon von Bier reported that within days of amputation, patients were fitted with temporary prosthesis that permitted them to stand and walk [2]. Berlemont M [3,4] reported fitting patients with prosthesis right after amputation surgery and starting gait training in 1 to 2 days in 1961. Burgess EM [5] reported positive results in 193 lower extremity amputations for peripheral arterial insufficiency in 1971; by 1978, he and his team had conducted more than 1500 unselected amputations using the IPOP technique.

The rehabilitation procedure after amputation is frequently lengthy, which is expensive for both the patient and the healthcare system. This is largely owing to the practice of 'coning' the residual limb to make the primary prosthesis application easier. A number of studies [6-8] have shown that IPOP systems are beneficial. These benefits include pain relief, edema control, less complications, a faster time to customized prosthesis fitting, lower costs, shorter rehabilitation periods, and shorter hospital stays. Muscle strength, tone, overall fitness, and coordination are additional benefits of immediate postoperative prosthesis (IPOP) [9]. Wound healing and rehabilitation progress in tandem, reducing muscle atrophy and a removable, tailor-made, prefabricated IPOP; allowing for early mobilization is the primary aim of this current study. There is growing evidence that amputation can provide a comparable or better functional outcome than limb salvage surgery in patients with severe lower limb injury, with a shorter, less complex treatment pathway and decreased risk of complications [10].

Hypothesis of the study is to compare the standard protocol (conventional application of prosthesis) with the IPOP; which is a detachable, adjustable, prefabricated prosthesis and would reduce postoperative problems, prevent falls, and allow controlled ambulation without affecting the stump maturation. The primary objective of our study is to see the effect of immediate post-operative prosthesis versus conventional prosthesis on balance, Quality of Life & psychological status in below-knee amputation patients following trauma. The secondary objective is to compare the period of recovery in patients of below-knee amputation.

Methods/ Designs

Ethical Statement and CTRI Registration

The study protocol is approved by the Institute's Ethics Committee, (Ref no IEC-727/07.08.2020, RP-52/2020) and registered under CTRI with reference no - CTRI/2020/09/027742.

Study Design and Sample Size Calculation

A prospective randomized controlled trial. Patients who will meet the inclusion criteria will be enrolled in the study after obtaining informed consent either from patient or next of kin. Random sequence generation will be done with a computer-generated list of random numbers. Allocation concealment will be achieved with sequentially numbered and sealed opaque envelopes opened by a person who will not be directly involved in the trial. Since the study is a pilot randomized controlled trial, a small sample size of 60 patients is planned to be taken (30 in each group).

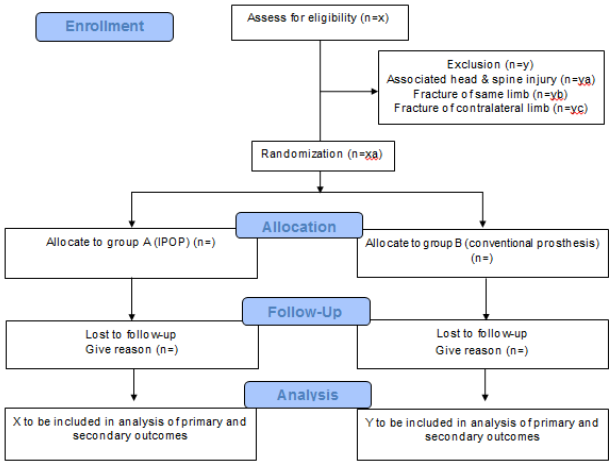

Figure 1: Depicts Consort Chart.

Inclusion Criteria

IPD patients
Hemodynamically stable patients
Unilateral below knee amputation patient
Age 18-65
All gender
Patient not necessitating ICU care for more than 24 hours

Exclusion Criteria

- Revision amputation patients.
- Children and pregnant women.
- Patient with co-morbidity like cardiac condition, malignancies, bleeding disorder.
- Patients on antiepileptic and thyroid drugs.
- Patient with premorbid history of infection.
- Patient with associated fracture of the same or contra lateral lower limb.
- Patient with head or spine injury.

Procedure

As per our current practice all patients are recommended definitive limb prosthesis during hospital stays which are later procured by the patients themselves usually within six to eight weeks following amputation. To measure the effect of IPOP in post-traumatic below knee amputees on their rehabilitation, temporary prosthesis (immediate post-operative prosthesis) will be given to group A (Intervention group) for the study purpose. The study is funded by the intramural fund from the institute to procure temporary prosthesis for patients enrolled in study group. Both groups of patients will get the same standard of post-operative care, which will include pain management, physiotherapy, balance exercises, muscle strengthening, counseling etc. The conventional way of treating amputations postoperatively involves the application of a soft dressing while awaiting wound healing. Thereafter the stump is coned, producing shrinkage of the residual limb, before fitment and mobilization with prosthesis can be achieved. However, with the IPOP technique, immediate measurements to be taken for a prosthesis postoperatively within 24 hours and prosthesis will be applied.

Outcome Assessment

All the outcomes will be assessed at baseline for all the three psychological scales which includes Quality of life, Hospital anxiety depression scale, and Trinity Amputation & Prosthesis Experience Scale and Amputee Mobility predictor which is to be done within 48 hours of amputation for both the groups. Postural stability test and limits of stability will be done using Biodex for group A (IPOP) patients. 2nd and third assessment which are the follow up assessment is to be done at 6 weeks and 12 weeks of amputation respectively, for all the three psychological tests, amputee mobility predictor along with postural stability and limits of stability tests.

WHOQoL-Bref: The WHOQoL-Bref is a thorough research tool with 26 items scored on a 5-point Likert scale. The person's quality-of-life perception ranges from 1 to 5, with 5 being the best. Scoring includes four domains: Physical, psychological, social, and environmental health. Q1 and Q2 enquire about the subject's quality of life and health satisfaction.

Hospital Anxiety and Depression Scale (HADS): The 2–5minute questionnaire has seven anxiety and seven depression questions which are graded independently. For quantification, a score of 8 or more for anxiety has a specificity of 0.78 and sensitivity of 0.9, and for depression, a specificity of 0.79 and a sensitivity of 0.833.

Trinity Amputation and Prosthesis Experiences Scales (TAPES): TAPES measures four sections of psychological adjustment (General Adjustment, Social Adjustment and Adjustment to limitation subscales); Activity restriction; satisfaction with the prosthesis (functional and aesthetic); exploration of phantom limb pain, residual limb and other medical conditions not related to amputation. It is designed to in variegate different aspects of having prosthesis.

Amputee Mobility Predictor (AMP): Amputee mobility predictor (AMP) is a fast and simple assessment technique for lower-limb amputees with and without prostheses. AMP can predict post-prosthetic mobility before fitting. The AMP can be administered with or without a prosthesis, although the AMPnoPRO is best for prosthetic prescription. The AMP also assessed the specific tasks of 5-level Medicare functional classification system (MFCL K0–K4).

Postural Stability Test (PST)

Postural stability test measures the ability to maintain center of balance. This test measures deviations from the center, thus a lower score is better. The Biodex Balance System's Dynamic Balance test was employed. Protocol used for testing was duration: 20 seconds with stability level: 8 (platform instability, static (0–12); and stance of two legs. The score ranges from 0-20.

Limits of Stability (LOS)

A balance and stability test which refers to the points at which the center of gravity approaches the boundaries of the base of support (BoS) and necessitates the use of a corrective measure to move the center of mass back inside the BoS. To put it another way, LOS is the furthest point one can purposefully sway in either direction without losing balance.

Intervention

Patients of the group A which is the intervention group will be provided with immediate post-operative prosthesis within 24 hours of below knee amputation. The components of IPOP includes adjustable post-operative preparatory prosthetic system (APOPPS) is a three part Prosthetic Socket which includes FLO-TECH-TOR, VCSPS & UFOS. This three-part post-operative preparatory prosthesis allows to provide a continuum of care, from the time of amputation, through early weight bearing, until the patient is ambulating independently. The IPOP system to be used in our study will be customized. Each of these sockets will be a one-piece, polyethylene, clamshell designed having

anatomically trimmed overlapping sides. During critical period of rehabilitation, the system is designed specifically to resist knee flexion contractures and maintain good knee alignment. The UFOS attached with either the FLO-TECH-TOR or the VCSPS offers opportunity for ambulatory training from post-operative amputation to definitive prosthesis. The UFOS are connected with foot and pylon components which can be removed without removing the inner socket, offering practitioners a versatile rehabilitation system. Before discharging, the patient will be educated regarding the donning and doffing of the prosthesis by themselves.

Conventional therapy

Patients of the group B which is the control group will be treated postoperatively for pain management, range of motion exercises, strengthening exercises, sensory training, balance and coordination, stump care, limb management, gait training and prosthetic counseling. Thereafter the stump is expected to be coned, producing shrinkage of the residual limb, before fitment and mobilization with a prosthesis was achieved.

Data Collection and Statistical Analysis

All the data collected will be recorded in MS Excel spreadsheet program. The data will be coded and analyzed using SPSS v 29 (IBM Corp.) Descriptive analysis will be done using means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Student's t-test will be used to compare the normal variables, whereas the Mann–Whitney U-test to compare the non-normal variables. For comparison of categorical data, the Chi-square/Fisher's exact test will be used. Intention to treat analysis will be done for primary outcomes Statistical significance will be kept at p value <0.05.

Results

It is expected that patients who will receive immediate post-operative prosthesis will have shorter duration of recovery phase along with better quality of life.

Discussion

Limb loss is a traumatic and debilitating affliction that causes amputees' lives to change dramatically. Treatment of limb loss focuses on the physical and psychological repercussions of amputation and typically involves the supply of prosthesis to enhance mobility [11]. Prosthesis use is related with greater employment, better quality of life, and fewer secondary health concerns [12]. The unemployed status of male family member can have a direct effect on the family's income and level of living, because in India male is generally the bread earner. This may explain the significance of employment status in influencing QoL in amputees, given that unemployment can be distressing for an individual and may influence his mental functioning [13]. A study from other low-income nations highlights the low socioeconomic status of PLLA and their inability to afford the cost of fixing their prosthetic devices [14]. Lower limb amputees without prosthesis have seen their physical functioning and quality of life diminish at the individual, family, and society levels [15]. When the fitting of a prosthetic device is delayed, the patient's muscle strength, tone, general fitness, and coordination all suffer, which slows down the rehabilitation process even further. Our study aims to fasten the process of rehabilitation along with minimizing the rate of complications associated with delayed rehabilitation.

Conclusion

The study will present data for the impact of immediate post-operative prosthesis in relation with balance and quality of life in patients with post traumatic below knee amputation. Our findings will guide the feasibility of application of immediate post-operative prosthesis in traumatic above knee amputation patients.

Study Site: The study will be conducted in the Division of Trauma Surgery and Critical Care, Jai Prakash Narayan Apex Trauma Centre, All India Institute of Medical Sciences, New Delhi, India. Clinical trial registration number, if applicable: CTRI/2020/09/027742.

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