86045_Auto_Edited.docx

Name of Journal: World Journal of Clinical Cases Manuscript NO: 86045 Manuscript Type: MINIREVIEWS Lower Limb Amputation Rehabilitation Status in India: A Review Lower Limb Amputation Rehabilitation Status in India Raktim Swarnakar, Shiv Lal Yadav, Darshana S

Abstract

Rehabilitation of lower limb amputation in developing countries is quite challenging. Though there are basic to high advanced prosthesis available in India but in broader perspectives in developing country set-up it is still facing difficulties. Prosthetic management is difficult due to lack of availability of prothesis, reduced affordability among population with low income. In this review we have highlighted the lower limb amputation and prosthetic rehabilitation status in India. There is currently India is prospering in rehabilitation field but future further studies are required to build evidences and recommendation.

Key Words: Amputation; Lower limb amputation; Prosthesis; Rehabilitation; Lower limb prosthesis; Prosthetic rehabilitation

Swarnakar R, Yadav SL, S D. Lower Limb Amputation Rehabilitation Status in India: A Review. *World J Clin Cases* 2023; In press

Core Tip: Rehabilitation of lower limb amputation in developing countries is quite challenging. Prosthetic management is difficult due to lack of availability of prosthesis, reduced affordability among population with low income. In this review we have highlighted the lower limb amputation and prosthetic rehabilitation status in India.

INTRODUCTION

Amputation refers to the removal of a body extremity due to various factors such as blunt trauma, medical conditions, prolonged constriction, or surgical intervention [1]. Historical evidence reveals that limb amputation is among the oldest surgical procedures, dating back over 2500 years to the era of Hippocrates [2].

Carefully performed amputations with ideal stump may give very good results where depending upon the level of amputation individuals may learn jumping and running. Poorly healed amputation sites can lead to delays in fitting prostheses, impede rehabilitation, and potentially confine patients to wheelchairs. In some cases, patients with suboptimal stumps are transferred to rehabilitation units for prosthesis fitting. However, due to the possibility of requiring revision amputation, they may need to be referred to higher-level medical centers. This delay in rehabilitation and additional burden on resources can significantly impact the overall outcome [3].

Achieving a successful amputation and initiating early rehabilitation is of utmost importance for the patients, their families, and society. In particular, inadequate soft tissue coverage over exposed bone poses significant challenges in above-knee amputations, as it necessitates the use of an end weight-bearing prosthesis [4].

METHODOLOGY

As there is a lack of studies on this topic, a narrative review of reviews, systematic reviews, and meta-analyses was performed. We cited high-quality articles in the *Reference Citation Analysis* (https://www.referencecitationanalysis.com).

Eligibility criteria

PICOS model: (1) Studies on lower limb amputation in those who got rehabilitation in India (population); (2) Studies where the primary aim was to evaluate rehabilitation status in LLA in India (interventions); (3) Studies with a control group or without a control group (comparisons); (4) Studies that reported rehabilitation outcomes (outcomes); and (5) relevant original articles and reviews (study designs). From January 1947 to mid-March 2023 (10 years), studies that are following the PICOS model here and that reported rehabilitation in lower limb amputation in India were eligible for inclusion.

Search technique

The search was performed by two researchers independently in all electronic databases, primarily MEDLINE, EMBASE, Web of Science, and Google Scholar within this time period. We combined search terms and keywords related to the population (e.g., "Leg amputation OR Transfemoral amputation OR Transtibial amputation OR Lower limb loss OR Lower extremity amputation OR lower limb amputation) and outcomes (e.g.

rehabilitation OR exercise OR physiotherapy OR physical therapy). We additionally filtered study designs 'in humans'.

Inclusion and exclusion

All articles, reviews, and meta-analyses on our above-mentioned PICOS model were included. We included only studies that mentioned Indian status on the basis of the PICOS model. After the preliminary search, we extracted the studies outside India and who those did not receive rehabilitation.

Study selection and data extraction

The titles and abstracts of studies were reviewed to identify potentially relevant ones. After the initial screening, the full texts of potentially eligible studies were obtained to undergo a thorough evaluation, ensuring the removal of any duplicate articles.

To supplement the search strategy, a manual scan of key articles and review papers was conducted to identify any additional articles that may have been missed. Two reviewers independently assessed the articles, and in the event of any disagreements, the opinion of a third reviewer was sought for resolution.

Analysis

We performed a narrative and descriptive analysis.

RESULTS

As this was a narrative review, potentially relevant articles have been added and given references in the below discussion section.

DISCUSSION

Below we have discussed the topic with appropriate subheadings:

EPIDEMIOLOGY

In 1983, the prevalence of amputees in India was approximately half a million, with an estimated annual addition of 23,500 amputees. The majority of amputees in India are

males from rural backgrounds, living in poverty, and belonging to the working-age group. A significant number of these individuals have undergone amputations due to injuries sustained in railway and road accidents, as well as agricultural equipment-related incidents [5].

An epidemiological study conducted in Kolkata, India, involving 155 amputees, found that trauma was the most common cause of amputation (70.3%), followed by peripheral vascular disease (27.7%). Among the group aged over 60 years, peripheral vascular disease accounted for a higher proportion of amputations (34.9%). Lower limb amputations constituted 94.8% of all amputations [6].

Diabetic foot/gangrene was responsible for 32% of lower limb amputations [7]. Diabetic foot is a leading cause of disability worldwide, and amputations in patients with diabetes account for a significant portion of all amputations, with an average percentage of 68.6% [8]. The age group most affected by amputations was the 20s and 30s, which represents the productive population of the country [9].

According to a survey by the World Health Organization (WHO), the estimated number of amputees in the developing world is 40 million. In India, as per the 2011 Census, the population of persons with disabilities is approximately 2.68 crore, which accounts for 2.22% of the total population. Amputation is a major cause of disability in India, but only a small percentage (around 5%) have access to prosthetic devices [10]. Conditions such as severe crush injuries, cancer ablation, diabetes, peripheral vascular disease, and neuropathy pose a significant threat of lower limb loss. In the long run, limb salvage is more cost-effective than amputations [11].

IMPACT OF LOWER LIMB AMPUTATIONS

The impact of lower limb amputations is substantial, leading to increased illness-related costs and a significant change in the patient's quality of life and functionality. After an amputation, patients experience a reduced quality of life compared to the general population [12]. Losing the ability to walk and perform daily activities causes inconvenience, along with psychological and social challenges. Properly designed prosthetic systems play a crucial role in restoring walking ability and facilitating

activities of daily living (ADL). The successful integration of sensory systems, actuators, and control schemes greatly influences the amputee's ability to achieve normal gait biomechanics [13]. However, developing countries face issues related to the durability and failure of prosthetic foot, discomfort due to inadequate prosthetic socket fit, and poor alignment and functioning of components, including knee joints [14].

Although various options exist for prosthetic components, prescription criteria rely primarily on the subjective experiences of physicians, therapists, and prosthetists [15].

Psychological aspects: The psychological impact of amputation is profound, leading to a high prevalence of psychiatric disorders among amputees, ranging from 32% to 84%. Rates of depression vary from 10.4% to 63%, while post-traumatic stress disorder rates range from 3.3% to 56.3%, compared to the general population's rates of 10-15%. Amputation can have adverse psychological effects, including a decrease in self-confidence, a sense of inadequacy, the development of a negative self-concept, and a distorted perception of body image, ultimately affecting overall quality of life.

Depressive disorders often arise due to various factors, such as feelings of loss, self-stigma, role limitations, and difficulties in adapting to the physical impairment and lifestyle changes. Amputees also face challenges related to impaired physical function, persistent pain, changes in employment and job status, which can significantly impact their emotional well-being.

According to the World Health Organization's report on disability (Geneva, 2011), assistive devices play a crucial role in improving an amputee's independence and enhancing their participation in society. Such devices are recognized as powerful tools that can positively contribute to an amputee's overall well-being and quality of life [16].

INDIAN SCENARIO

In lower- to middle-income countries like India, a significant number of individuals with disabilities face challenges in accessing proper rehabilitation services and necessary assistive devices. According to the World Health Organization (WHO), the availability and utilization of assistive products remain limited, with only one in ten individuals having access to the assistive products they require [17].

This lack of access to assistive devices further exacerbates the difficulties faced by people with disabilities, hindering their ability to perform daily activities, participate in society, and achieve a good quality of life. Addressing this issue and improving the availability and affordability of assistive products is crucial in ensuring equal opportunities and enhancing the well-being and independence of individuals with disabilities.

According to national sample survey on disabled person conducted in July 2018, for locomotor disability aid/appliance was not acquired in 7.1% people due to affordability issue. Among locomotor disabled persons an artificial limb was used as aid by 3.9%.

The cost of lower limb prosthesis is in the range of rupess 20,000 for a trans tibial prosthesis to 75,000/- for a hip disarticulation prosthesis depending on the complexity. Many centres like including Regional limb fitting and Rehabilitation Research Centre in Jaipur and centres in Bombay, Lucknow, Calcutta, Artificial limb manufacturing corporation of India (ALIMCO), and Madras are experimenting with designs of prostheses. One of the main challenges faced by prosthetic centers in India is the lack of availability and high cost of appropriate materials for prostheses. Additionally, there is a lack of expertise in utilizing newer synthetic materials. Many amputees in India have to use prostheses that are not specifically designed for local conditions and habits. While most centers provide a valuable service, there is room for improvement in terms of both quality and quantity.

The cost of prosthetic aids is often prohibitive for the majority of amputees, making them inaccessible without government subsidies. Despite the need, long waiting lists exist at all centers in India. Even though many amputees do not attempt to obtain a prosthesis, the waiting time could be reduced by streamlining and making the limb fitting process more efficient. Increasing facilities and staff may help but would come with increased operating costs. In Jaipur, the fabricating and fitting time has been significantly reduced, and similar facilities in other locations could be beneficial.

Prostheses should be designed for easy fitting with minimal moving parts to reduce the likelihood of failure and minimize the need for repairs. The use of wrong or overly

expensive materials has been a common factor contributing to the lack of success of certain prosthetic designs. The cost of a prosthetic limb mainly consists of material costs, with some nominal labor costs involved ^[5].

An important focus in India has been developing prostheses that allow individuals to squat and sit cross-legged. While the Jaipur foot enables squatting, there is currently no optimal design for an above-knee prosthesis that accommodates sitting cross-legged. The All India Institute of Medical Sciences has developed an above-knee prosthesis that permits both squatting and sitting cross-legged, but it is of the exoskeletal type and has a hard external surface. Its practicality depends on patient acceptance, ease of maintenance, and manufacturing cost [18]. Table 1 here shows where crucial consideration have to be given regarding prothesis usage in India and how to utilize available resources effectively.

GAPS IN LITERATURES

Lack of knowledge of prothesis; ack of availability; cost of prosthesis and its affordability all lead to lacuna in evidence-based literature. There are scarcity of studies that exist in developing countires due to these hindrances.

REHABILITATION

Instead of perceiving amputation as a failure to preserve the limb, it can be viewed as a step towards enhancing the patient's mobility and independence. Prosthetic rehabilitation consists of four phases:

Pre-prosthetic management: This involves assessing the patient's functional status before the amputation, considering factors such as comorbidities, social support, goals, and expectations. Activities in this phase include range of motion exercises, conditioning, correct positioning of the residual limb, ambulation with assistive devices, relaxation techniques, and activities of daily living (ADL) training.

Postoperative management: After the surgery, pain control, edema therapy, proper positioning of the patient and the residual limb, mobilization, strengthening of the residual limb, scar treatment, stump hygiene, patient education, and psychosocial

support are provided. The ideal postoperative dressing or the use of immediate postoperative prosthesis (IPOP) is a topic of debate in the literature, with no consensus reached. IPOP involves using a rigid dressing with a basic prosthesis to allow early weight bearing and stability [19].

Prosthetic fitting and training: Once the surgical wounds have sufficiently healed, usually within 6 to 8 wk of amputation (with exceptions for certain patients), prosthetic fitting and training can begin. Initial fitting and training may take approximately 2 wk. During the initial 6 to 18 mo, there may be continued loss of residual limb volume, requiring frequent follow-up visits for adjustments to the prosthetic socket or the addition of limb socks.

Follow-up visits: Regular follow-up visits are conducted to assess the condition of the residual limb, the functionality of the prosthesis, the individual's gait, and overall level of function. These visits help monitor progress and make any necessary modifications or improvements.

It is crucial to educate and inform patients about the prosthetic options and potential outcomes they can achieve. Preamputation counseling, conducted by an experienced prosthetist, can involve using realistic outcome videos or facilitating peer interactions to prepare the patient and their caregivers for the prosthetic fitting process and help them understand the possibilities ahead. This allows them to be in the right frame of mind and make the most of the time leading up to the prosthetic fitment [20].

PROSTHESIS

Lower limb amputations are performed at different levels, and prostheses are developed accordingly. The types of prostheses include:

Hemipelvectomy prostheses: Designed for hemipelvectomy surgeries.

Hip disarticulation prostheses: Specifically for hip disarticulation procedures.

Above knee prostheses (Transfemoral/Above knee amputation): Designed for individuals with above-knee amputations.

Below knee prostheses (Transtibial/below knee amputation): Developed for those with below-knee amputations.

Symes prostheses: Intended for Symes amputations or ankle disarticulations.

The prosthetic socket encloses the residual limb and is categorized as either "Patellar tendon bearing," which distributes weight across multiple pressure tolerance areas including the patellar tendon, or "Total surface bearing," which provides more equal weight distribution throughout the entire socket.

Endoskeletal prostheses, also known as modular prostheses, are the most commonly used type. They have an internal supporting structure resembling the human skeleton. The tube frame of the endoskeletal prosthesis functions as a weight-bearing element, while a foam cover gives it a more natural appearance. The pylon, connecting the socket and prosthetic foot, is typically made of aluminum, titanium, or stainless steel. Endoskeletal prostheses can be customized with joint components to suit the needs of individual amputees.

Advantages of endoskeletal prostheses include the ability to make changes at any time, lightweight and comfortable weight bearing, cosmetically acceptable appearance closely resembling a natural limb, suitability for all levels of amputation, and good dynamic alignment adjustment. Disadvantages include less resistance to external wear, shorter lifespan of the foam cover necessitating frequent replacements.

Exoskeletal prostheses, also known as conventional or crustacean prostheses, have a rigid outer shell as their supporting structure, providing shape and weight-bearing capability. The weight is borne through the outer shell, which can be constructed using materials such as wood or rigid polyurethane covered with a rigid plastic lamination. Advantages of exoskeletal prostheses include longer lifespan, greater resistance to external wear, and cost-effectiveness. However, they can be heavy and uncomfortable to wear, require longer fabrication time, lack adjustability and alignment changes, and are not suitable for through-knee amputations.

Prosthetic Materials: Prostheses are designed using various materials that possess specific characteristics such as strength, lightweightness, thermal resistance, durability, and biocompatibility to avoid allergic reactions in the body. These materials include:

Metals: Titanium, aluminum, and stainless steel are commonly used in both exoskeletal and endoskeletal prostheses. They are utilized in components such as sockets and pylons.

Plastic: The socket, which connects the residual limb to the prosthesis, is often made of plastic. Thermoplastic materials like polypropylene, polyethylene, polyurethane, and acrylic are commonly used. Thermosetting plastic is also employed in laminated sockets, where resin is combined with reinforcing materials like glass fiber, nylon, or carbon fiber.

Wood: Wood is utilized in lower limb prostheses for foot assembly. For example, the SACH foot (Solid-Ankle Cushion Heel) incorporates an interior hardwood heel that provides structural strength. This wooden heel is bolted to the rest of the prosthesis.

Leather: Leather is employed for suspension straps and socket linings, providing comfort and support.

Rubber: The foot component of some prostheses is made from vulcanized rubber, which offers flexibility and shock absorption.

Fabric/Cotton: Socks, typically made of cotton, serve as an interface between the residual limb and the socket. They provide comfort and help prevent friction.

Fiber Reinforcement: High-strength fiber reinforcements, such as glass and carbon, are utilized in prosthetics to enhance strength and durability [21].

The Artificial Limbs Manufacturing Corporation (ALIMCO) has introduced lower limb polypropylene prostheses that combine both functional and cosmetic features. The mechanical components made of polypropylene are designed to fit inside a cosmetic foam cover. The joints and adapters are modular, allowing for exchangeability during the lifespan of the prosthesis.

Polypropylene Prosthesis: These prostheses are lightweight, weighing almost half as much as conventional ones. They are also cost-effective, easier to fabricate, and require less fabrication time. Additionally, they offer comfort, restore a natural appearance, and have excellent cosmetic appeal. Moreover, they reduce the energy consumption for the amputee.

In 1982, the Regional Limb Fitting and Rehabilitation Research Centre in Jaipur achieved remarkable success with the development of a rubber vulcanized foot known as the Jaipur Foot, combined with an aluminum shank. This breakthrough has enabled them to provide prostheses to numerous amputees. The Jaipur Foot incorporates two blocks of microcellular rubber, a lightweight willow wood ankle section, and embedded nylon cords. Additional rubber is used to cover these components, giving the prosthetic flexibility, shock absorption, and the appearance of a natural human foot, including a cosmetic rubber cushion compound for a realistic color and texture.

The Solid Ankle Cushion Heel (SACH) foot is a basic, durable, and cost-effective prosthetic foot option suitable for individuals with limited walking needs and minimal variation in speed and terrain. SACH feet consist of a soft material molded over a rigid inner piece that mimics the shape of a human foot. This type of foot is commonly used as the initial prosthesis after amputation [22].

Stanford University has developed a four-bar linkage polycentric knee joint called the Stanford Jaipur knee specifically for above-knee amputees.

Despite being nearly 50 years old, the Jaipur Foot remains widely used and beloved in many parts of the world, even in today's high-tech era [23]. This relatively simple prosthetic continues to make a significant difference for needy and disadvantaged amputees in India and worldwide.

In individuals with above-knee amputations, the prosthetic knee joint is a crucial component that significantly impacts overall walking performance and activities of daily living [24].

Lower limb prostheses for above-knee amputations vary based on the type of thigh and shank joint (single-axis and polycentric) and control methods. Polycentric knee joints, due to their complexity, associated costs, repairs, and maintenance requirements, are considered less suitable for use in developing countries [25]. Efforts have primarily focused on establishing prosthetic programs that encompass services, personnel training, and the provision of suitable prosthetic technologies [26].

Among various knee devices, the four-bar linkage polycentric knee mechanism remains the most widely used as it is a simple device that provides stability and accurately replicates the natural motion of the joint [27].

The four-bar linkage comes in three types: the elevated instantaneous center, the hyperstabilized knee mechanism, and the voluntary control mechanism [28]. The elevated instantaneous center provides stability during heel contact, while the hyper-stabilized knee functions as a locked mechanism, offering alignment stability for less active amputees. The voluntary control mechanism provides stability during heel contact and push off, offering more control and is preferred by highly active amputees [29].

India has several prosthetic dealers, including the Artificial Limb Manufacturing Corporation of India (ALIMCO), Ottobock, National Orthotic Centre, Innovative Trading Company, N L Healthcare, W Fitness, State Surgical Agencies, Vijay Mediequip Pvt Ltd, and Endolite India Ltd. These dealers provide a range of prosthetic solutions.

DISABILITY

According to the guidelines and gazette notifification issued by Ministry of Social Justice and Empowerment, Govt. of India on july 8th 2015, The Permanent Physical Impairment (PPI) percentages for various levels of amputation are as follows [30]:

Hind quarter amputation: 100% PPI

Hip disarticulation: 90% PPI

Trans Femoral (Above knee) up to upper 1/3 of thigh: 85% PPI

Trans Femoral (Above knee) up to lower 1/3 of thigh: 80% PPI

Through knee amputation: 75% PPI

Trans Tibial (Below Knee) up to upper 1/3 of leg: 70% PPI

Trans Tibial (Below Knee) up to lower 1/3 of leg: 60% PPI

Through ankle amputation: 55% PPI

Syme's amputation: 50% PPI

CONCLUSION

In India, rehabilitation of lower limb amputation has improved in the last 10 years. Life after lower limb amputation will be challenging. Understanding India's current situation is important for future planning and for making newer developments in the areas of prosthetics and technologies. Moving forward, it remains crucial to foster close collaboration between developed and developing countries. This collaboration should focus on undertaking and sharing formal research, development, and evaluation activities. These activities play a pivotal role in the process of improving and advancing various aspects related to prosthetic care.

By engaging in collaborative efforts, countries can pool their expertise, resources, and knowledge to address the challenges faced by individuals in need of prosthetic devices. This collaboration facilitates the exchange of best practices, innovative solutions, and advancements in prosthetic technology.

Furthermore, formal research, development, and evaluation activities are essential for driving progress in prosthetic care. They enable the exploration and implementation of new ideas, technologies, and materials that can enhance the quality, affordability, and accessibility of prosthetic devices. The findings and outcomes of such activities should be widely disseminated to benefit the global prosthetic community.

By embracing this collaborative and research-focused approach, countries can collectively work towards improving the lives of individuals in need of prosthetic care. This includes developing more suitable and affordable prosthetic solutions, addressing the gaps in access and availability, and continuously advancing the field to meet the evolving needs of amputees worldwide. The availability of prostheses and prosthetic materials and advanced prostheses has been coming up. The setting up of Physical Medicine and Rehabilitation has changed the spectrum of services to amputees. But there is a severe lack of studies on this domain, especially rehabilitation intervention in lower limb amputees and as a result recommendations and guidelines are also absent. Further studies are the key unmet need in this area.

ORIGINALITY REPORT

PRIMARY SOURCES		
2	www.researchgate.net Internet	112 words — 3%
3	link.springer.com Internet	62 words -2%
4	www.ijesm.co.in Internet	53 words — 1%
5	hangerclinic.com	44 words — 1 %
6	Emad Rabie, Yousria Salem, Maha Salem, Rasha Yakout, Wael Shaalan. "Effect of a Rehabilitation Program on the Quality of Life of Patients with Lo Amputation", Alexandria Scientific Nursing Journa Crossref	
7	Ghosh Das Pooja, Lahiri Sangeeta. "Prevalence and aetiology of amputation in Kolkata, India: A retrospective analysis", Hong Kong Physiotherapy Crossref	15 words — < 1% y Journal, 2013

Harish Mysore. "The \"Jaipur Foot\": India?s Most Popular Prosthetic for Amputees Is Not the Latest 15 words — <1%8

in Technology, but It's Still the Most Suitable Option for Many Patients Almost 50 Years after Its Development", IEEE Pulse, 2016

Crossref

EXCLUDE QUOTES ON EXCLUDE BIBLIOGRAPHY ON

EXCLUDE SOURCES

< 12 WORDS

EXCLUDE MATCHES

< 12 WORDS