



## LEVOFLOXACIN A FIRST LINE DRUG IN THE PREVENTION AND MANAGEMENT OF LOWER EXTREMITY AMPUTATION RESIDUAL LIMB INFECTION IN RURAL NORTH INDIAN POPULATION

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**ABSTRACT** **BACKGROUND:** In lower extremity amputation residual limb infection is the most common complication accounting 53.5% in India. There are very few published studies on preventive and therapeutic management of these infections. **METHODS:** This cross sectional retrospective study include all the patients presenting with lower extremity amputation residual limb infection from 2010 to 2015. Confirmation of diagnosis were done by clinical, radiological, hematological and microbiological culture of wound and treatment was started based on sensitivity report. **RESULT:** This study include sixty two patients with eighty lower extremity amputation residual limb infection. Sinus tract (54.8%) was the most common presentation of residual limb infection. Pseudomonas Aeruginosa (39%), was the most common cultured pathogen and Piperacillin + Tazobactam (82.25%), followed by Imipenem (75%) and Levofloxacin (58.75%) were the most sensitive antibiotic. **CONCLUSION:** In India where more than 60% population live in rural area, peripheral health centers are the primary mode of healthcare services. Levofloxacin can be given as first line drug therapy in prevention and management of lower extremity amputation residual limb infection

### KEYWORDS :

#### INTRODUCTION

In the global population estimated prevalence of limb amputations is 0.7%. Amputations complicated by residual limb wound infections, leads to morbidity, poor quality of life, and additional health care costs<sup>1</sup>. Thirteen to forty percent wound infections occur following major lower extremity amputation<sup>2</sup>. Residual limb infection is the most common complication accounting 53.5% following lower limb amputation in Chhattisgarh<sup>4</sup>. Twenty five percent of wound infection following major lower limb amputation require revision amputation<sup>5</sup>. However, there are very few published studies on the preventive and therapeutic management of these infections. We carried out a cross sectional retrospective study at King George's Medical University, Lucknow. It is the major tertiary referral center not only for North India but also for neighboring country like Nepal and Bhutan. The main objective of this study was, (i) To find most common presentation of infection. (ii) To find most common pathogen. (iii) To find most sensitive antibiotic. (iv) To select most appropriate first line antibiotic for lower extremity amputation residual limb infection management.

#### MATERIAL AND METHODS

The records of all the patients from the Dept. of Physical Medicine and Rehabilitation with lower extremity amputation residual limb infection were analyzed for recording relevant information for the said objectives from January 2010 to December 2015. After taking written and inform consent from head of department to analyze the patient's treatment records, this cross sectional study was performed. This study included, all the patients treated for lower extremity amputation residual limb infection in the Dept. of Physical Medicine and Rehabilitation at King George's Medical University, Lucknow, from January 2010 to December 2015. King George's Medical College is the major tertiary referral center not only for North India but also for neighboring country like Nepal and Bhutan.

A soft tissue infection was defined as extensive inflammation, or a subcutaneous or muscular abscess confirmed by ultrasonography<sup>6</sup>. Infectious osteomyelitis was suspected on physical examination, based on bone contact achieved with a sterile metal probe and also by radiologic and/or computed tomography anomalies<sup>7</sup>.

In this study, diagnosis of infection was confirmed by microbiological culture of soft tissue and / or bone samples. Sample collection was done by open wound swab method and by needle aspiration method from discharging sinus. X - Ray of residual limb was done to see bony changes and sinography was performed to determine the extent of abscess cavity or sinus.

Sensitivity of all the residual limb were tested for fourteen Antibiotic viz. Ampicillin, Amoxiclav, Piperaciline + Tazobactam, Cephalexin, Ceftriaxone, Ceftazidime, Cefipime, Cefaperazone + Sulbactam, Imipenem, Gentamicin, Amikacin, Cefprofloxacin, Levofloxacin, Gatifloxacin. Most sensitive antibiotic was selected for treatment of infection. Residual limb infection in the form of open wound were treated by regular dressing and course of antibiotics. Residual limb infection in the form of discharging sinus were treated by course of intravenous antibiotic, surgical debridement followed by oral antibiotics. Residual limb infection in the form of osteomyelitis were treated with course of intravenous antibiotic, surgical excision of infected bone followed by oral antibiotics.

Correction of all hematological inflammatory markers and abolition of radiological sign of infection was considered as complete cure from infection and indication to stop drug. A prior inform consent was taken from the head of department to conduct this study.

#### RESULTS

There were 62 patients (44 unilateral and 18 bilateral) with 80 lower extremity amputation residual limb infection of which 48 were male (77.4%) and 14 were female (22.6%) with male to female ratio 3.4: 1. The mean age of presentation was 30 years (range: 2 – 60 years). Cause of primary amputation were traumatic in 43 limbs (54.8%), infection in 14 limbs (17.5%), peripheral vascular disease in 10 limbs (12.5%), leprosy in 8 limbs (10%) and malignancy in 5 limbs (6.3%).

The level of amputation was transfemoral in 29 limbs (36.6%), transtibial in 38 limbs (47.5%), at knee level in 6 limbs (7.5%) and at ankle level in 7 limbs (8.8%). The presence of a sinus tract was the most common presentation of lower extremity amputation residual limb infection, which was observed in 43 limbs (54.8%). Other sign of infection were, ulceration in 20 limbs (25%), abscess in 12 limbs (15%), and pain during the prosthetic fitting in 5 limbs (6.3%) at the initial evaluation.

On radiological examinations, X - ray of all the residual limbs showed, bony spur in 32 residual limbs and changes of osteomyelitis in 11 residual limbs. Sinography of discharging sinus showed soft tissue infection in 32 residual limbs.

Microbiological culture showed six type of pathogen viz. Pseudomonas Aeruginosa, E.coli, Staphylococcus Aureus, Acinobacter, Proteus and Klebsiella, out of which Pseudomonas

Aeruginosa (39%) as the most common cultured pathogen. Sensitivity testing with all the fourteen drugs showed Piperacillin + Tazobactam as the most sensitivity antibiotic followed by Imipenem and Levofloxacin. Piperacillin + Tazobactam was found sensitive against all pathogen with 81.25% sensitivity. Imipenem was found sensitive against all pathogen except Staphylococcus Aureus with 75% sensitivity. Levofloxacin was found sensitive against all pathogen except Klebsiella with 58.75% sensitivity.

## DISCUSSION

There are very few published studies available on the preventive and therapeutic management of lower extremity amputation residual limb infection. Most of these patients required surgical procedure in the form of excision of necrotic soft tissues and resection of infected bone in addition to antibiotic treatment.

The presence of a non-healing discharging sinus tract is the most frequent clinical sign indicating chronic infection<sup>7</sup>, as in this study. Ultrasonography can be used in early detection of soft tissue abscess and sample collection for microbiologic culture, but CT scan with or without sinography is very sensitive to detect soft tissue as well as bony infection and guide for surgical decision, thus diagnostic radiology play a vital role in management of residual limb infection<sup>9</sup>. In this study, only X-ray of residual limb and sinography were used as radiological parameter due to poor financial condition of patients.

In lower limb infections Staphylococcus is the most frequent isolated bacteria<sup>10</sup> but, in traumatic lower extremity amputation residual limb infection Pseudomonas Aeruginosa is the most frequent isolated bacteria<sup>11</sup>. Similarly in this study, Pseudomonas Aeruginosa was the most common isolated bacteria from lower extremity amputation residual limb infection and trauma was the most common cause of lower limb amputation.

There are very few published studies dealing with antibiotic therapy after amputation. Antibiotics play vital role in prevention and control of lower extremity amputation residual limb infection<sup>7</sup>. In this study Piperacillin + Tazobactam, followed by Imipenem, and Levofloxacin were the most sensitivity antibiotic. When we compare all the three drug, Piperacillin + Tazobactam, and Imipenem has following drawback, they are costly, not freely available, administered only by intravenous route and require monitoring. Whereas Levofloxacin is, cost effective, freely available even in rural part of India, available in both oral as well as infusion formulation.

In Indian condition where more than 60% population live in rural area and peripheral health centers are the only mode of primary healthcare services, neither Piperacillin + Tazobactam, nor Imipenem can be considered as first line drug therapy in lower extremity amputation residual limb infection management. Whereas Levofloxacin can be start as even on outdoor basis till the availability of culture and sensitivity report in lower extremity amputation residual limb infection management.

## CONCLUSION:

In India where more than 60% population live in rural area, peripheral health centers are the primary mode of healthcare services. Levofloxacin can be started as first line drug therapy in prevention and management of lower extremity amputation residual limb infection.

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