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A Study of Ambulatory Function and Complications in Adult Below Knee Amputees

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Background: Amputation not only causes a physical disability to the patient, it also has an effect on his social economic and psychological conditions. We undertook the study with an aim of assessing complications and ambulatory functions in below knee amputees.

Method: 10 years study was done including a total of 174 patients. Patients were grouped into diabetics and non-diabetics based on the primary cause of amputation. Various complications which were assessed included hematoma formation, wound healing problems, infections, phantom limb/pain, contractures, etc. Ambulatory functions were assessed before surgery and at follow-ups using modified ambulatory scale by Pinzur et al 1983.

Results: 41 (28.5%) had edema of the stump. Of these patients, 26 were in diabetes group. In 38 patients stump healing was prolonged with 21 patients in diabetes group and 17 patients in the non-diabetic group. 16 patients had wound dehiscence with 11 patients in diabetic group and 5 in non diabetic group. 15 (10.4%) patients developed contractures after below knee amputation, of which, 9 patients were in diabetic group and 6 were in non-diabetic group. In diabetes group, preoperatively 29 (46%) patients had grade 6 level of ambulation. In non-diabetics preoperative grade 6 was observed in 77 (95.1%) of patients. Post operatively 19 (30.2%) patients in diabetic group and 64 (79%) patients in the non-diabetic group had grade 6 ambulatory scale. 35 in diabetic group and 44 in non-diabetic group lost/changed their job. 33 patients (78.6%) in diabetes group and 48 (62.3%) in the non-diabetic group suffered an income loss. 34 (28.6%) had a psychological effect following below knee amputation. Of these 34, 10 patients were in the diabetic group and 24 were in the non-diabetic group.

Conclusion: Wound dehiscence is common in BK amputation performed due to diabetes. There is a higher incidence ofabove-knee amputation after BK amputation in diabetics. Preoperative and postoperative ambulatory grade is poorer in diabetics in comparison to trauma patients. Diabetics require additional support besides using the prosthesis. Manual labor class is worst affected due to loss of job. People employed in clerical/ desk jobs have minor changes. Younger people have psychological impact. The death rate is significant within one year of BK amputation and diabetics have a higher probability.

Keywords: Ambulatory function, complications below knee amputees

Introduction

Amputation is defined as a procedure that removes a part through one or more bones. Belowknee amputation is one of the commonest type of amputations. Common causes for below knee amputation include peripheral vascular diseases, trauma, infections, tumors, nerve injuries, congenital anomalies(1). In spite of the development of new surgical techniques amputation has many complications.

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The overall complication rate for below knee amputation is 43.5%, including 8.7% of systemic complications (2). Amputation of limbs is a very ancient procedure. Instruments belonging to the Neolithic period (8000-9000 B.C.) clearly indicate that amputations were practiced even at that time.

Tourniquet introduced by Ambrose Pare in the 16th century, artificial limbs in the 17th century and anesthesia in 19th century revolutionized the procedure of amputation and its outcome (3). Below knee amputation may be associated with a number of complications which can be broadly divided into local and general (4). These complications may further be categorized into early and delayed complications.

One of the early complications after below knee amputation includes patient's inability to mistreat post operatively, e.g. after a spinal anesthesia (5). Locally, even after meticulous hemostasis before closure, use of a drain, and a rigid dressing, a hematoma can form which can delay wound healing and serve as a culture media for bacterial infections. A local infection is a common cause for complications in amputees, especially in peripheral vascular disease and diabetes. There may be difficult, delayed closure of wound due to infection or edema. Sometimes even after a meticulous closure, skin necrosis may occur due to tight sutures, decreased blood or oxygen supply adding to the patient's agony (4).

Most of the times after amputation, the patient tends to keep his stump as immobile as possible in fear of pain. Often he may (more often his well meaning relatives help) put a pillow under his stump in order to support it, thus unknowingly predisposing to contracture of the stump (6). Inactivity is said to increase the incidence of phantom pains (7). Sometimes prolonged immobility after an amputation can cause contralateral deep vein thrombosis, chest infections, bed sores, ambulatory problems etc (8).

Sometimes, an early period after an amputation may pass off uneventfully, but it may result in a number of late complications which include bony spurs, neuroma, joint contractures and deformities (8). Amputation not only causes a physical disability to the patient, it also has an effect on his social and economic conditions. Amputees often find it difficult to adjust themselves back into family and society. They often face discrimination in society. Due to physical disabilities they often lose their jobs or have to settle for a work which is paying less. Loss of a limb also has a direct psychological effect on the patient. The patient often feels helpless and considers himself at the mercy of society (9). Patients have been known to be depressed, neurotic or even violent as a result of this (10).

Rehabilitation is perhaps not easy at times, and takes some timeto succeed. As a consequence of this his general,physical and mental well being deteriorates (11).

A great many patients undergo below knee amputation each year in India and in our institution. Most of them are affected in one or more ways. Paucity of Indian studies on their ambulatory status and complications prompted us to undertake this study

Study Design

This retrospective as well as prospective study was carried out in the Department of Orthopaedics at Christian Medical College and Hospital, Ludhiana, Punjab on patients of below knee amputation.The retrospective period included the patients who underwent below knee amputation in the past nine years, from September 01, 2004 to August 31, 2013. The prospective period included the patients

who were operated upon from September 01, 2013 to August 31, 2014. These patients were followed up for a period of at least 6 months to 9 years with a mean follow up of 3 years. In case of the retrospective study medical records were studied and patients were reviewed. Patients were also contacted by phone, letters and personal visits.

Inclusion criteria

1. Adult patients who underwent below knee amputation between 18 and 80 years of age

Exclusion criteria

1. Patients who had a neurological deficit like paraplegia/quadriplegia before amputation
2. Patient with amputation of ipsilateral/contralateral upper limbs and lower limbs
3. Patients with any physical disability hampering mobility
4. Amputations for malignancy

Patients who were selected for this study included those patients who underwent amputation due to vascular insufficiency or gangrene. This study included cases which were done as either emergency or elective courses.

In this study a total of 190 patients operated were contacted and reviewed personally or by phone, letters and medical records. Out of these 190, 16 patients were lost to follow up and were excluded from this study. Patients were divided into two groups, diabetics and non diabetics. Patients in which primary cause of amputation was diabetes, were put intoa diabetic group and the rest were classified as non diabetics. They were reviewed for the effects of below knee amputation on their lives, especially with regards to ambulatory functions and complications followingsurgery. Various complications which were assessed included hematoma formation, wound healing problems, infections, phantom limb/pain, contracures, edema, suture abscess, wound dehiscence, blister formation, scarring, bony spurs, neuromas and deformities.

Ambulatory functions were assessed before surgery and at follow ups using modified ambulatory scale by Pinzur et al 1983.

Functional ambulation scale

Grade 6: unlimited community ambulator

Grade 5: limited community ambulator

Grade 4: unlimited household ambulator

Grade 3: limited household ambulator

Grade 2: supervised household ambulator

Grade 1: wheelchair ambulator

Grade 0: bedridden (12)

Patients were also inquired about when they started using prosthesis, how long they used prosthesis per day and whether they were happy or not with their post op life.

Statistical analysis

The collected data was tabulated and analyzed using following statistical methods

- Percentage: percentage value from total.
- Mean or average: average of all values in the group.
- Standard deviation: measure of how widely values are dispersed from the average value.
- Mean scores: to analyze the results
- P value: or the probability value was determined for all the tests to check for the level of significance

Results

A total of 174 people was studied with a mean age of 45.9 years. The majority of the patient were in the age group of 51 – 60 years (21.8). Male to female ratio was 8.1:1.80 (46%)patients underwent amputation following trauma. 78 (44.8%) patients had diabetic foot.

Ninety (52.1%) patients underwent below knee amputation in an emergency. 84 (47.9%) of patients were elective cases. Of the emergency surgeries 60 patients were in the non diabetic group (trauma, burns and peripheral vascular disease) and 30 were in the diabetic group. The result was statistically significant ($p<0.05$) for emergency cases in both the groups. Of 174 patients, 30 patients had to undergo above knee amputation later on.

Six (4.2%) patients developed hematoma. Of these, 6 below knee amputees with hematoma 5 were in diabetes group. Statistically the result was not significant ($p<0.05$). 41 (28.5%) had edema of the stump. Of these patients, 26 were in diabetes group. 15 patients had edema of stump in the non diabetic group. This result was statistically significant in both the groups ($p<0.05$)

Thirty-three (22.9%) patients had an infection of the stump. Of these, 19 were in diabetic group and 14 in non diabetic group. The result was statistically significant with $p<0.05$ for both groups. Both diabetics and non diabetics had a significant incidence of infection after below knee amputation.

In 38 stumps, healing was prolonged. Of these 38, 21 patients were in diabetes group and 17 patients in the non diabetic group. The result was statistically significant in both the groups ($p<0.05$). In non diabetics out of 17 patients who had prolonged stump healing, 11 patients were above 51 years of age. Of these 11 patients, 4 patients were of peripheral vascular disease. This result was significant ($p<0.05$) for peripheral vascular disease.

Sixteen (11.1%) patients had wound dehiscence. Of these 11 patients were in diabetic group and 5 were in the non diabetic group. This result was statistically significant ($p<0.05$) in the diabetic group.

96 (66.7%) patients of below knee amputees had phantom limb sensations post operatively. Out of these 96, 38 were in the diabetic group and 58 (71.6%) were in non-diabetic group. The result was highly significant ($p<0.05$) for both the groups.

Three (2.1%) patients developed blisters after amputation. 1 patient was in diabetic group and 2 patients were in the nondiabetic group. The result was statistically not significant for both groups. One patient out of 81 in the non diabetic group developed neuroma. None of patients indiabetic group developed neuroma. The result was statistically not significant. 15 (10.4%) patients developed contractures after below knee amputation. Of these 15, 9 patients were in diabetic group and 6 were in the non diabetic group. The result was statistically significant ($p<0.05$) in diabetic and not significant in non-diabetics.

Out of total 15 patients with contractures 2 patients (13.3%) developed extension contracture and 13 (86.7%) had flexion contracture. 2 patients with extension contractures were post burns. Out of 13 patients with flexion contracture 2 (13.3%) patients had fixed flexion deformity of the knee.

In the diabetes group, preoperatively 29 (46%) patients had grade 6 level of ambulation (unlimited community ambulatory) and 4 (6.3%) had grade 0 level of ambulation (bedridden). In non diabetics preoperative grade 6 was observed in 77 (95.1%) of patients and none of the patients had grade 0 level of ambulation. The result is significant ($p< 0.05$). Diabetics had a lower preoperative ambulatory grade as compared to non diabetics

Post operatively 19 (30.2%) patients in diabetic group and 64 (79 %) patients in the non diabetic group had grade 6 ambulatory scale. Grade 0 was in 1 (1.4%) patient in diabetic group and 0 patients in the non

diabetic group. The result was statistically significant ($p<0.05$) in both the groups.

In none of the patients in the present study, Pylon fitting was done. Postoperatively, 92 (63.9%) patients initially used crutches for mobilization. 40 (27.8%) patients were using walker, 7 (4.9%) used wheelchair and 5 (3.4%) remained bed ridden before they died. It was observed that of 92 patients who were using crutches, 22 were in diabetic group and 70 in non diabetic group. 31 patients with diabetes and 9 patients of non diabetic group used a walker. 5 patients in diabetic group and 2 patients in the non diabetic group could mobilize only in a wheelchair. 5 patients in the diabetic group remained bedridden posto-peratively before they died. Younger patients with no Co morbidities preferred crutches. Patients in older age groups and those in the diabetic group preferred a walker.

One hundred four (72.2%) patients started using a prosthesis for mobilization once their stumps had healed adequately. Of these 104, 80 patients were initially using crutches and 24 were using a walker. 40 (27.8%) patients never used prosthesis postoperatively. Of 104 patients, 30 were in diabetic group and 74 in the non diabetic group who used prosthesis. The result was statistically significant for both groups. It was observed that of 104 prosthesis users, 32 were unhappy while using it. 33.2% of patients with Burgess flap closure were unhappy with their prosthesis and 29% patients with skew flap closure were unhappy with their prosthesis. The result was not significant ($p>0.05$).

Of 104 prosthesis users, 43 (41.3%) were using it for less than 6 hours per day, 55 (52.9%) were using 6-12 hours per day and 6 (5.8%) patients were using it for >12 hours per day.

Of 104 prosthesis users, 10 (9.6%) patients used an additional single crutch/stick for walking. 4 (3.8%) patients used two crutches and 3 (2.9%) patients had a walker with prosthesis for mobilization.

Out of total 119 patients in whom data was documented, who were asked about loss/ change in their job, 35 in diabetic group and 44 in the non diabetic group lost/changed their job. This result was statistically significant ($p<0.05$) for both the groups.

The worst affected were those of the manual labor class group who had to give up their job after amputation. On the other hand patients who were previously employed in government or permanent private service suffered a change of their job. Worth mentioning is one general surgeon who had to give up his practice
after his limp got amputated due to diabetes and because of his inability to stand for prolonged hours.

Out of 119 patients 33 (78.6%) in diabetes group and 48 (62.3%) in the non diabetic group suffered an income loss. The result was statistically significant ($p<0.05$) in both the groups.Out of 119 patients 34 (28.6%) had a psychological effect following below knee amputation. Of these 34, 10 patients were in the diabetic group and 24 were in the non diabetic group. The result was statistically significant ($p<0.05$) for both the groups. Of the total 34 patients, 20 (58.8%) had immediate depression after amputation and 14 (41.2%) had delayed/late onset depression.

Of 144 patients, 25 (17.4%) died within one year. Of these 25 patients, 21 patients were in diabetic group and rest 4 in the non diabeticgroup.The result was highly significant ($p<0.05$) for diabetics.

Discussion

In this study, we found that development of a hematoma was not related to the cause of amputation. If the proper bleeding profile analysis is done preoperatively and adequate hemostasis is achieved during surgery, the chances of hematoma formation, decrease and are not related to cause of amputation 41 (28.5%) patients developed stump edema postoperatively. This complication occurred despite giving adequate elevation and anti-inflammatory medications. Out of 41 patients, 26 (63.4%) were in diabetic group who developed postoperative edema after amputation. 15 (36.6%) patients were in the non diabetic group. The result is statistically significant ($p<0.05$) for both the groups and diabetics were found to be more associated with development of edema. Important causes of this difference is increased vulnerability to infection in diabetics, leading to development of stump edema and cellulitis and also restricted use of anti-inflammatory due to associated renal problems. Hoover (1964) reported that many diabetics had other medical problems like renal failure, cardiac failure, electrolyte imbalance, anemia, protein energy malnutrition and hypoproteinaemia which caused venous congestion and thus edema. Prolonged intake of anti diabetic drugs also resulted in the development of edema as a side effect.

33 (22.9%) patients had an infection of the stump. Of these, 19 were in diabetic group and 14 were in the non diabetic group. The result was significant ($p<0.05$) in both the groups which signifies that infection is commonly associated with both the groups. Diabetics (30.2%) were however found to have a higher incidence of developing infection at the stump site as compared to non diabetics (17.3%). In this study a list of factors associated with diabetes, which predisposed to infection of stump included decreased generalized immunity because of old age, cardiac failure, renal failure, anemia, hypoproteinaemia, restricted ambulation, pulmonary involvement, hypostatic pneumonia and septicemia. Our results were comparable to studies by Jonathan (2006) and Vinsent et al (2006) who reported rates of infection i.e. 18% and 26% respectively. It was also found that the incidence of deep infection and abscess formation was more in diabetics. In case of non diabetics superficial infection and cellulitis were commoners.

16 (11.1%) patients in this study suffered a wound dehiscence after stump closure. 11 (17.5%) patients in diabetic group had wound dehiscence which is significant ($p<0.05$). This means that diabetics have a higher incidence of wound dehiscence after closure. The result was not significant ($p>0.05$) in non diabetics where incidence was 6.1%. The increased rate of wound dehiscence in diabetics was due to higher incidence of infection, edema and poor blood supply. Study by Thomas et al (1965) reported a comparable incidence of wound dehiscence of 15%. Miller et al (1985) stressed on immediate mobilization of patient post operatively. However, it increases chances of edema at stump site and thus wound dehiscence. The present study has less incidence of wound dehiscence in diabetics as compared to that of Miller et al (1985) because post operatively stump was kept elevated and immobilized to reduce edema and thus wound dehiscence. 96 (66.7%) of the total amputees complained of phantom limb sensation after amputation. 60.3% patients in diabetic group and 71.6% in the non diabetic group had phantom limb sensation. The result was highly significant ($p<0.05$) in both the group, however non-diabetics had higher

incidence of phantom limb perception as compared to diabetics. The results were comparable to Larrson et al (1997) who reported an incidence of 80% phantom limb sensations. Larrson et al (1997) reported that most diabetics also suffered from various neuropathies.These neuropathies weakened sensory perception from lower limb which resulted in lower incidence of phantom limb in diabetics.

The incidence of blister formation in present series was 2.1%, which was not significant ($p<0.05$). 2 patients developed blisters due to defective prosthetic fitting and in 1 patient due to bony impingement of the skin. The patient with bony impingement had to undergo a revision at the site of amputation. Newton (1986) reported an incidence of 2% in his patients after BK amputation.

In our study,one patient (0.7%)had neuroma formation at stump site. In this case, Norma had to be excised as it was causing pain and difficulty in prosthetic fitting. Chauhan et al (2008) reported that careful severing of the nerve endings while amputating a limb greatly reduces chances of neuroma formation later on. In the present study the major nerves were identified carefully, drawn distally and cut sharp as high as possible to retract deep into the soft tissues of the stump. Delblenco et al (1972) reported a 1% incidence of neuroma formation in his study, which is comparable to the present study. Ninon (1998) reported a 10% incidence of neuroma formation using ultrasonography to scan neuromas in the stump which picked up even those neuromas which were not palpable or painful. In the present study neuroma formation was assessed on clinical grounds and hence a lower incidence.

15 (10.4%) patients developed contractures after BK amputation. Of these 15, 9 (14.3%) patients were in diabetic group and 6 (7.4%) were in the non diabetic group. The result was statistically significant ($p<0.05$) in diabetic group and not significant in non-diabetics. Fearon (1983) reported 16.6% of contractures in below knee amputation due to diabetes. He reported these contractures develop in diabetics due to weak quadriceps muscle, tendency to keep the knee flexed for pain relief, immobility and lack of exercises. Newton (1986), and Jonathan (2006) documented incidence of contractures after BK amputation at 2.2%, and 2% respectively. These studies included traumatic patients only in whom mobilization can be started early and muscle power is good enough and lesser incidence of contractures. Present study includes burns patients (6) along with trauma patients, hence a relatively higher incidence of contractures. 2(33.3%) burn patients developed contractures in present study. Chen et al (2000) reported a contracture incidence of 28% in post burns.

In this study, 17.2% of the patients had to undergo above the knee amputation after BK amputation. Major causes for this included infection, unhealthy or dead muscles and decreased vascularity. Results were comparable to studies by Dormandy (2005) and Lim (2006) who reported incidence of 19% and 17.6% respectively. It was observed that out of 30 patients who underwent above knee amputation, 20 patients were in the diabetic group.

Out of 10 patients in the non diabetic group, 3 patients had peripheral vascular disease. Diabetics and peripheral vascular disease patients were found to have a higher incidence of above knee amputation. This was because of the fact that both these groups have a poor blood supply in peripheral parts of the body. Decreased blood supply delays healing and increases rate of infection, which can predispose the limb to be amputated at a higher level.

In the present study, diabetics had a poor preoperative ambulatory status as compared to non diabetics. 34.9% of diabetics had a preoperative ambulatory grade of 3 or less than that. Only 1.2% patients in the non diabetic group had less than 3 preoperative ambulatory grades. Important causes were high incidence of co-morbidity in diabetics and old age. Collin et al (1988) also reported that diabetics come with a poor preoperative ambulatory grade because of associated medical problems. On the other hand patients with trauma come with fresh wounds before which they were fully mobile. In the present study another group of patients who had a lower ambulatory status preoperatively in the non diabetic group were peripheral vascular disease patients. 24% of peripheral vascular disease patients in the present study had an ambulatory grade of 3 or less than that Collin et al (1988) has also reported a lower pre-operative ambulatory grade in diabetics because of associated co-morbid conditions and old age.

In none of the patients in the present series, Pylon fitting was done. Post operatively 30.2% patients in diabetic group and 79% patients in the non diabetic group had grade 6 ambulatory scale. Grade 0 was in 1.4% patients in diabetic group and 0% in the non diabetic group. The result was statistically significant ($p< 0.05$) in both the groups. It was observed that 90.1% patients in the non diabetic group had an ambulatory grade of 4 or more postoperative. In case of diabetics only 44.4% patients had ambulatory grade of 4 or more postoperative. The result was poorer in case of diabetics than non diabetics. Condie et al (1996) in their study reported a significant poor grade of ambulation in diabetics as compared to non diabetics. Major causes for this difference was preoperative lower ambulatory grading in diabetics, old age,co-morbid conditions, increased incidence of infection and prolonged stump healing time. In the present study maximum patients (63.9%) used crutches for ambulation before their stumps were ready for a prosthesis fitting. 27.8% used a walker and 4.9% utilized a wheelchair. Condie et al (1996) reported that older and less fit patients take smaller steps while walking and feel secure with a walker. On the other hand, with crutches patients can take longer steps. He reported that diabetics or patients with other co-morbidities prefer a walker and younger people prefer crutches. In his study, 50% patients preferred using crutches and 50% preferred a walker. The reason for higher walker use in his study was that it had a higher number of diabetic patients as compared to non diabetics.

72.2% of the total below knee amputees utilized prosthesis and 27.8% patients never used a prosthesis. Non diabetics were found to be more compliant with prosthesis usage, which has also been reported by Goldberg (1984). Of 104 prosthesis users, 74 (91.3%) were in the non diabetic group. Goldberg (1984) reported that important reasons for high prosthesis utilization were that it keeps upper limbs free from holding a support while walking, aesthetic reasons, brings the mechanical axis of body to normal, increases loading on pressure tolerant areas (ischial tuberosity, patellar tendon) and reduces loading in pressure important areas (adductor longus tendon and head of the fibula). 52.9% of prosthesis users wore it for 6-12 hours per day. Out of 104 patients, 17 (16.3%) were still using additional support like cruches and walker for mobilization. 12 (28.6%) of these patients were diabetics. Results were comparable to Hays et al (1998) who reported use of additional support in 30% patients of below

knee amputation due to diabetes. He reported that reason for need of additional support was weak lower limb muscles due to prolonged immobility and lack of confidence. Pinzur et al (1993) reported that 86.7% patients in his study were using prosthesis post operatively. Reason for a higher percentage of prosthesis users in his study in comparison to the present study is that Pinzur et al (1993) did not include diabetics in his study. In the present study, 49% diabetics used prosthesis after below knee amputation.

In this study, 66.4% patients after BK amputation suffered either a loss or change of their job. This result was highly significant ($p<0.05$). Whyte (2002) reported that after a BK amputation working capacity, especially in people employed in heavy work, was greatly reduced. On the other hand amputees who were previously employed in clerical/desk jobs continued with their original jobs with minor changes/ adaptations. Huevel (2002) reported in his study that 64% patients had to change their jobs after amputation because they had to commute long distances to reach their job places or were working in day/ night shifts. Our results were comparable to findings of Huevel (2002) and Whyte (2002) who reported loss/change of job in 64% and 63.4% BK amputees respectively.

In the present study, 68.1% patients reported a difference in income between pre and post BK amputation surgery. All these patients suffered a loss of income. Reason for loss of income was either loss of job or change in a profession which was less paying. It was further noted that in diabetics 35 people had a change of job and 33 had a loss of income. This was because of the fact that government employees continued to earn the same despite a change in their job. Our results were comparable to findings of Huewel (2002) and Whyte (2002) who reported a loss of income in 66% and 68% BK amputees respectively.

In our study BK amputation surgery caused a psychological effect in 28.6% of the patients. This result was highly significant ($p<0.05$) and is comparable with that of Singh (2007) who reported an incidence of 26% in his study. 20 patients in our study had immediate depression after amputation and 14 patients had delayed/late onset depression. It was also analyzed that out of 34 people who had a psychological effect post surgery, 15 patients were less than 40 years of age. Thus, it was observed that younger patients had a greater chance of post surgical depression than their older counterparts. A study conducted by Othman et al (2008) reported 37% patients with depression after amputation. Othman et al (2008) study was conducted in post traumatic patients, most of whom were in younger age groups.

In the present study 25 (17.4%) patients died after BK amputation within a period of one year. Of these 25 patients, 21 patients were in diabetic group and rest 4 in non diabetic group. The result was highly significant ($p<0.05$) for diabetics. The results were comparable to Jonathan (2006who reported one year mortality of 16% respectively after below knee amputation. Jonathan (2006) reported that increased mortality in diabetics was due to prolonged immobility, comorbid complications e.g., congestive heart failure, chronic renal disease, liver diseases, encephalopathies, mental illness, stroke, previous myocardial infarction,hypostatic pneumonia and infections.

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