Major Lower Extremity Amputation in Diabetics
Khartoum Teaching Hospital and Gabir Abu El Izz Center

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مقال تعالى:

اللَّهُ الَّذِي جَعَلَ لَكُمُ الْأَرْضَ قَرَارًا وَالسَّمَاءَ بِنَاءً وَصَوْرَكُمْ فَأَحْسَنَ صُوْرَكُمْ وَرَزْقَكُمْ مِنَ الطَّيِّبَاتِ ذَلِكُمُ اللَّهُ رَبُّكُمْ فَتَبَارَكَ اللَّهُ رَبُّ الْعَالَمِينَ

صدق الله العظيم
غافر (الاية 63)
Dedication

To my family for their support and encouragement over the prolonged period in which I was preoccupied with (this thesis) and this to the exclusion of normal family life.

To my teachers, who gave me faith to challenge the unknown.

To my dear patients who have trusted me to do something, even minor to alleviate their pains suffering.

To them all I dedicate this work.
Acknowledgment

I owe a very great debt to my supervisor Professor Mohammed El Makki Ahmed for his tolerant acceptance to supervise this work, for his constructive criticism, for provision of stimulating discussions and for his willingness to work extended hours and still provide me cheerful encouragement.

I would like also to acknowledge my indebtedness to Mogahid Osman and EL Farazdag Ahmed Yousif for their skilful help in computer work, for their tolerance in dealing with the editing and frequent reediting of the manuscript.

It is also a pleasure to thank the administration, physicians, technicians, and dear patients at KTH and Gabir Abu EL Izz Diabetes center.
ABSTRACT

This is a prospective hospital-based study on the clinical patterns of major LEAs in diabetic patients in KTH and Gabir Abu El Izz center during the period July 2002 to January 2003.

Objectives: The aim was to identify the anatomical levels and indications of major LEAs in diabetic patients undergoing major LEAs in KTH and Gabir Abu El Izz center during the period July 2002 to January 2003. The study also explored the rates of primary healing, post operative complications, reoperation, morbidity and mortality at the various levels of major LEA.

Methods: Consecutive seventy diabetic patients underwent major LEA during the study period, were included. A data sheet was completed by interviewing, examining, investigating and following up all patients.

Results: Seventy patients were included in this study. Their age ranged between 35-92 years with a mean age of 61.5 years ± SD 11.85. The male to female ratio was 1.5:1. Ninety-six percent had NIDDM while (4%) had IDDM. The mean duration of diabetes was 18.3 years ± SD 9.04. Sixteen percent were hypertensive and nineteen percent were regular smokers.
Eighty-six percent of our patient did not have previous foot education. Thirty patients (42.85%) had history of previous foot ulceration and thirty-one had history of previous minor or major LEA.

Fifty-two patients (74.28%) had transtibial amputation and 18 had transfemoral amputation. No Symes, through knee or hip disarticulation were encountered. The ratio of transtibial to transfemoral amputation was (2.9 :1).

The indication of major LEA was control of sepsis in 27 (37.14%) patients, gangrene of the foot in thirteen patients and extensive tissue loss in (18.55%), followed by various combination of sepsis, gangrene and extensive tissue loss in the remaining patients.

Forty-seven LEAs (67.00%) were done under spinal anesthesia, 19 (27.00%) were done under general anesthesia and only 4 (6.00%) were done under local anesthesia.

The wound was closed primarily in sixty-one patients (87.14%) and was left open in 9 patients (12.86%). The wound was closed without a drain in fifty-six patients (80.00%) and with a drain in 5 patients (7.14%).

Compared to transtibial amputation transfemoral amputations were associated with statistically significant: lower primary healing rate, higher postoperative complications rate, higher reoperation rate, and higher
mortality rate. The rate of in-hospital mortality was (20%). The mean duration of hospital stay was 30.14 days±21.87 with no significant difference in the hospital stay in relation to the level of the amputation.

Conclusion: Transtibial and transfemoral amputations are the main types of major LEA in diabetic patients in KTH and Gaber Abu El Izz diabetes center. The most common indication of major LEA is control of sepsis followed by gangrene of the foot and various combinations of sepsis, gangrene and extensive tissue loss. Transfemoral amputations are associated with higher rates of complications, reoperation, delayed healing and mortality.
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<td>2HPP</td>
<td>2 Hours Postprandial Blood Glucose</td>
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<td>ABI</td>
<td>Ankle Brachial Index</td>
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<td>DM</td>
<td>Diabetes Mellitus</td>
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<td>DSF</td>
<td>Diabetic Septic Foot</td>
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<tr>
<td>FBS</td>
<td>Fasting Blood Sugar</td>
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<td>IDDM</td>
<td>Insulin Dependent Diabetes Mellitus</td>
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<td>KHT</td>
<td>Khartoum Teaching Hospital</td>
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<td>LEA</td>
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<td>NIDDM</td>
<td>Non Insulin Dependent diabetes Mellitus</td>
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<td>PDV</td>
<td>Peripheral Vascular Disease</td>
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<td>RBS</td>
<td>Random Blood Sugar</td>
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Chapter One

Introduction & Literature Review
1.1 INTRODUCTION

Diabetes mellitus is a common condition. It is a serious, chronic disease caused by both hereditary and environmental factors. The 1996 global diabetes prevalence of 120 million is predicted to more than double to 250 million by the year 2005, due to the increasing age, obesity, sedentary lifestyles, changing dietary patterns and adoption of more strict criteria for diagnosis (1). Using strict diagnostic criteria (blood glucose more than ten mmol/L at two hour following a standard glucose tolerance test) between 1 and 2 percent of the population is affected (2). According to their absolute requirement for insulin in order to remain ketosis free, diabetic patients may be classified into two groups, insulin dependant (IDDM) and insulin non dependant (NIDDM). Insulin dependant diabetics represent one-fifth of diabetic patient's (3).

Following the introduction of insulin and more recently the oral hypoglycemic agents, the control of diabetes has markedly improved, and the major problem facing diabetic patients, is the development of the long term complications of the disease, such as neuropathy, angiopathy and ocular complications.

A further cause of illness and disability in diabetes is the development of foot complications. Diabetes -related foot problems result in significant social, medical and economic consequences, and constitute the most frequent reason for hospitalization in patients with diabetes, accounting for up to 25 percent of all diabetes related admissions in the United States and Great Britain (4, 5).
Accurate population-based statistics concerning the current incidence and prevalence of foot ulcers in developed countries is not available. Most of the available data are based on cross-sectional studies of selected patient populations of diabetic subjects. The point prevalence of foot ulcer in developed countries has been estimated to be approximately 4-10% of diabetic individuals (1). A corresponding incidence of 2.2-5.9% has also been reported (1).

Lower limb amputation is one of the most feared complications of diabetes. It is associated with a high mortality rate and considerable loss of the walking ability and independence among survivors. If an amputation has been performed, the risk of further ulceration is greatly increased, there is also an increased risk that the other limb will also require amputation and the patient 5-year survival will be reduced.

The United States National Commission on Diabetes estimates that (5%) (16 million) of the United State population are diabetics, (15%) of diabetic United State population will develop a foot ulcer at some time in their life. About 1 in 150 diabetic patients per year will require an amputation of some sort. These Figures agree well with the Oxford Diabetes Study where amputation rate was 8 per 1000 person years. Data from the United States National Hospital Discharge Survey found an annual average of 110,000 amputations for the period 1989-1992. Of all the discharge listing lower limb amputation, about (51%) are also listed diabetic (6).

Patients who have undergone a major lower limb amputation have a high risk of a subsequent ipsilateral or contralateral amputation. It has been estimated that (9%) to (20%) of diabetic individual experience a second amputation during a separate hospitalization (7). The postoperative mortality
is significantly higher in transfemoral amputation (10-40 %) than in transtibial amputation (5-20 %), probably because more fragile patients are selected for primary transfemoral amputation. The 5-year risk of a second leg amputation after an initial amputation is (28-51%) (1). The 5-year mortality rates after LEA among the diabetic population is (68 %) (1).

In the United Kingdom, around (2%) of the whole population are affected by diabetes. The Oxford Community Diabetes Study found a 7 % prevalence of active foot ulceration and a (3 %) prevalence of amputation of all or part of a foot (8). Problems associated with the diabetic foot account for (50 %) of bed use due to diabetes in UK (9). Further, median survival post-amputation is less than 2 years (10).

There is a lower incidence rate of lower extremity amputation in patient with diabetes mellitus of Asian ethnic origin (3-4 cases per 10,000 per year) compared to 14.2 cases per 10,000 in white Caucasians (11). This is mostly explained by low rates of PVD and neuropathy in south Asian and in part associated with low rates of smoking (12).

A recent audit of lower limb amputees in Scotland carried out by the Scottish Physiotherapy Amputee Research Group (SPARG) found that (30%) of cases undergoing LEA involved patients known to be diabetics (13). However, previous studies in Scotland suggested that these Figures might be low (14). Therefore, SPARG, in collaboration with the Scottish Vascular Audit Group (SVAG), conducted a 3-month (1/5/1995-31/7/1995) prospective study of the diagnosis of diabetes in patients presenting for lower limb amputation at vascular units throughout Scotland. This study suggested that significant proportion of patient currently presenting for (LEA) in Scotland have undiagnosed diabetes. The study concluded that the
true incidence of diabetes among amputees in Scotland is likely to be over (50 %). In this study all patients who were not known diabetic and presenting for a (LEA) had a fasting plasma glucose (FPS) test. Values above 6.6mmol/L (118.8mg\d) were considered diagnostic of diabetes. The positive predictive value (PV+) for a threshold of 6.6mmol/L is (45-55 %) in the general population .The (PV+), however is increased by the presence of one or more risk factors for diabetes, these risk factors include age over 50 years, obesity and physical inactivity (15). Patient presenting for amputation in Scotland are over 60, and many are likely to have other risk factors as well, thus significantly increasing the (PV+) in that study population.

In Poland a cross sectional study of the incidence of any non-traumatic and non-neoplastic (LEAs) in the population Krakow region (1,293,703) between (1/1/1996-31/12/1996) was done. A total of 290 non-traumatic and non-neoplastic (LEAs) were identified. (47.9%) of the (LEAs) were performed in diabetic's .An incidence rate of (LEAs) of 186.7 per 100,000 per year in diabetics were calculated (16).

In Germany, a study on the incidence of non-traumatic (LEAs) in residents of Leverkusen during the period (1994-1998) revealed an incidence rate of amputation in diabetic population of 463 per 1000,000 person-year (17).
1.2 LITERATURE REVIEW

Evolution of amputation surgery:

The earliest anthropological evidence of an amputee is that of a human skull in the Smithsonian institution 45,000 year old that shows the teeth shaped and aligned in such away that indicate he was an upper extremity amputee (18). Other evidence is found in cave printing in Spain and France, about 36,000 years old, which show the negative imprints of a mutilated hand. Late painting, like these were also found in New Mexico (19).

Early surgical amputation was a crude procedure by which a limb was rapidly severed from unanaesthetized patient; for haemostasis the open stump was crushed or was dipped in boiling oil (20). Surgery was performed without anesthesia, analgesia and fairly advanced tools. For judicial punishment no anesthesia was used and a guillotine technique with an ax was used. Analgesic plants such as asperic acid from Tree Park were used to relieve pain (21). Ligature of cotton fiber, human hair, or ant jaws may also have been used in weaving cultures. Tools such as bronze or stone axes were the standard surgical instrument (19).

The reason for amputation in ancient times varied. Congenital deformities have always been present. Wars were often the cause of traumatic amputation. Amputation was & is still used as a judicial punishment (21). Ancient cultures have knowledge of amputation for diseases such as gangrene, leprosy and ergotism (21). Amputation was feared more than death because of it is problems of wound healing, sepsis and mortality.
Around 400 B.C Hippocrates provided a classic description of the amputation of extremity in a patient who was most likely a diabetic- a painless amputation (peripheral neuropathy) of a gangrenous limb with little or no bleeding (peripheral vascular disease). \(^{(22)}\) Hippocrates (460 - 377) also advocated that the ablation of gangrenous tissue should be through the gangrenous part. The use of ligature to tie of bleeder was originally put forth by Hippocrates \(^{(18)}\). Celsus (25 B.C - A.D 5) described a circular amputation technique through healthy tissue, between sound and diseased tissue and also described ligation of blood vessels to stop bleeding \(^{(21)}\).

During the dark ages as their name implies, a time in which there was little scientific illumination, primitive techniques such as crushing the limb, dipping in hot oil or cutting with hot irons were used. The guillotine technique was used and the limb surface was allowed to granulate. Speed was of the essence. Most people died of blood loss, and those who didn't usually succumbed to infection from dirty surgical techniques. Pus was not only expected, but also thought of as an indication of normal healing \(^{(23)}\).

In 1517 Han Von Gersdoff of Strasbourg recommended the use of tourniquet with compression from a cow or pig bladder, cautery and dressing with warm rather than boiling oil \(^{(24)}\).

The greatest contribution to amputation surgery was made by Amhroise Pare (1510-1590), a French army barber-surgeon. He reintroduced the use of linen ligature originally put forth by Celsus and Hippocrates, when he ran out of cautery oil, during battle surgery. Time was still a limiting factor. A surgeon working with no anesthesia, tourniquet, or skilled aid hand, was limited to 30 seconds to amputate, and 3 minutes to complete the operation. There was no enough time for the surgeon to ligate
blood vessels and this is why Guillemeau, Pare student, again abandoned this method for direct cautery. Pare also invented upper & lower extremity prosthesis (25).

In 1593 Wilhelm Fabry, the first educated and scientific German surgeon popularized the use of linen ligature (24). In 1599 William Clows, described the above knee amputation, and in 1669 Pierre Verudin, described in detail the below knee amputation. In 1679 Clowdham of Exeter introduced the method of flap amputation making closure easy (23).

James Syme, chief of surgery at the University of Glasgow, Scotland performed his first innovative ankle disarticulation in 1842, and was followed by Pigoroff (Russian surgeon) with his own version in 1854. Rocco Gritty of Milan described knee disarticulation using the patella as a protective flap in 1857(24).

Still with all the advancement, a patient was susceptible to infection. In 1842 Paris hospitals were said to have a mortality of 26%. Mortality after amputation even of a digit was high. It was said that it was safer to have a limb amputated by gunfire than by a surgeon. As late as 1880, surgery assistant held sutures in their mouth (24).

The invention of tourniquet, anesthesia, analgesia, blood transfusion and antibiotics brought amputation to the modern era and made amputation an accepted curative maneuver rather than a last ditch effort to safe life. The surgeon had time to make residual limbs more functional, and therefore allowed the prosthetist to make better prosthesis.
The history of diabetes

Diabetes: Historical background:

Diabetes is one of many common diseases known long time ago. The earliest known record of diabetes was mentioned on Egyptian papyrus by physician Hesy Ra (1552-B.C); mention polyuria as a symptom \(^{(26)}\). In the first century A.D Arateus of Cappodiocia described diabetes as the melting down of flesh and limbs into urine. About the same time (164-A.D) Galen a Greek physician of Pergamum mistakenly attributed this disease to the inability of the kidneys to retain water, so that it passed through unchanged \(^{(27)}\).

The first account of sweet urine was probably reported from India about 500A.D \(^{(27)}\). Up to the eleventh century, diabetes was commonly diagnosed by water tasters, who drank the urine of those suspected of having diabetes. The Latin word mellitus (means honey) was added to the term diabetes as a result.

In the second half of the eighteenth century, significant advances were made. Robert Wyatt found a sugar-like substance in urine after evaporation. In the same period Frank classified the disease into two forms: diabetes insipidus (or spurious) in which there was no sugar in urine or diabetes mellitus (or Vera) in which the urine contained sugar.

Mc Gregor and Magendie separately found sugar, both in the blood of diabetics and in small quantities in blood from normal subjects. More detailed Knowledge of the metabolism of sugar has to await the studies of Claude Bernard a French researcher.
In 1869 Paul Langerhans (27), a German medical student announces in dissertation that the pancreas contains two systems of cells. One set secretes normal pancreatic Juice; the function of the other was unknown. Several years later these cells were identified as the islets of Langerhans.

In 1889 Oskar Minkowski and Joseph Von Mering at the University of Strasbourg, Austria first, removed the pancreas from a dog to determine the effect of an absent pancreas on digestion. At the same time it was observed that ablation of the pancreas with phloridzin was followed by glycosuria (27).

The link between the pancreas and diabetes was unknown. In 1908 a German scientist, George Zuelzer developed the first injectable pancreatic extract to suppress glycosuria; however, there were extreme side effects to the treatment. In 1892 Lepire proposed that diabetes be due to the absence of a glycolytic ferment in the pancreatic juice. In 1900 Opie demonstrated a connection between diseases of the islets Langerhans and diabetes. Sharpey Schafer in 1910 concluded that, the islands of Langerhans must secrete a substance, which regulates carbohydrate metabolism, and proposed the name insulin for this hypothetical substance (27).

In 1921 Dr. Banting assisted by Best, Collip and Macleod discovered insulin. In the same year a depancreatized dog was successfully treated with insulin. In 1922 insulin was first tested on a human being, a 14-years old boy, named Leonard Tompson. In 1923 Banting and his colleague Prof. Macleod were awarded Noble Prize in medicine.

1944 Standard insulin syringe is developed.

1955 Oral hypoglycemic drugs were introduced.
1959 Two types of diabetes identified (type 1 IDDM) and type II (NIDDM).

1966 First pancreatic transplantation was performed.

1983 First biosynthetic human insulin was introduced (27).

Pathophysiology of Foot ulceration:

It is firstly important to appreciate that the etiology of diabetic foot disease, (infection, ulceration and/or destruction of deep tissue, associated with neurological abnormalities and various degrees of peripheral vascular disease in the lower limb), (1) is truly multifactorial. Factors to be considered include neuropathy, macro vascular disease, micro vascular disease, infection, connective tissue and hematological disturbances. Identification of the dominant causative factors is essential in planning treatment, and the concept of the neuropathic, the neuro-ischemic and the ischemic foot is very useful. In cross sectional, population based studies the proportion of neuropathic, neuro-ischemic and ischemic lesion was 55%, 34% and 10% respectively. Only 1% of the ulcers were considered not to be diabetes-related (1).

The natural history of the diabetic foot:

Edmonds and Foster (1994) have divided the natural history of diabetic foot into six stages (28).

1- Stage one: The foot is normal and not at risk, the patient doesn't have the risk factors that render him or her vulnerable to foot ulcers. These are neuropathy, ischemia, deformity, callus and edema.
2- Stage two: High risk factor, the patient has developed one or more of the risk factors for ulceration of the foot.

3- Stage three: Foot with ulcer. The foot has a skin breakdown. Ulceration is on the plantar surface in the neuropathic foot and on the margin in neuro-ischemic foot.

4- Stage four: Foot with cellulitis. The ulcer has developed infection with the presence of cellulitis, which can complicate both neuropathic and neuroischemic foot.

5- Stage five: Foot with necrosis. Necrosis has supervened. In the neuropathic foot infection is usually the cause. In neuro-ischemic foot infection is still the most common reason for tissues destruction, although ischemia also contributes.

6- Stage six: The foot can not be saved, and will need major amputation.

**Historical background:**

The association between diabetes and symptoms in the lower limb was first recognized by John Rollo (1798). His patients had pain and paraesthesia. Indeed before 1850, the frequency of neurological changes in diabetic led to suggestion that neuropathy was a cause of diabetes (26).

Oakley et al. (29) in 1956 drew attention to the importance of peripheral neuropathy as a cause of plantar ulceration and described the three factors, arterial disease, neuropathy and sepsis as being essential causes of foot lesions in diabetics. This concept was extended by Duplessis who emphasized the importance of inter-relationship between three principal etiological factors-vascular disease, hematological changes and neuropathy-and development of lesion, in the diabetic foot (26). In 1959-vascular disease rose to prominence as a principal etiological factor in
diabetic foot ulceration following the publication of a paper that retrospectively examined amputated limbs from diabetic patient. A material that stained positive with periodic acid-Schiff reaction was found to fill the arteriole, in the specimen studied (30). In this study Goldenberg et al (1959) found no clear difference, in the distribution and severity of atherosclerosis in amputated limbs (30). This may be because limbs, which require amputation, whatever the cause, are likely to have severely diseased arteries.

**The Epidemiology of the Diabetic foot:**

The point prevalence of foot ulcers in developed countries has been estimated to be approximately 4-10% of diabetic individual. A corresponding incident of 2, 2 - 5, 9% has also been reported (1). Diabetic foot complication, account for up to 25% of diabetes related hospital admissions in the United States and Great Britain (4). Foot ulcers are documented to precede approximately 85% of all diabetic amputations (1).

Numerous factors have been suggested to be related to the development of food ulcers. There is a general agreement that the most important risk factor for developing a foot ulcer is the presence of Peripheral sensorimotor neuropathy (1).

**Diabetic neuropathy:**

Diabetic neuropathy is defined as the presence of symptoms and/ or signs of peripheral nerve dysfunction in people with diabetes after exclusion of other causes (1). 60% to 70% of diabetic patients have neuropathy. Diabetic neuropathy can be further classified according to the clinical manifestations into sensorimotor and peripheral sympathetic neuropathy.
Causes of neuropathy:

There are essentially two theories as to the causation of diabetic peripheral neuropathy. One related to metabolic factors and the other associated with micro vascular disease \(^{(31,32)}\).

Effects of neuropathy:

1. Extrinsic neuropathic foot ulceration. Loss of somatic sensation over the plantar aspect of the food can lead to extrinsic neuropathic foot ulceration following trauma. The trauma can be varied- ill-fitting footwear, thermal, foreign bodies in shoes and toenail cutting are merely examples. The initial trauma is often minor, but in the absence of somatic sensation it is not perceived, so allowing tissue damage to continue, once started.

2. Intrinsic neuropathic foot ulceration. The etiology here is more complex. Somatic motor neuropathy result in weakness of the intrinsic muscle of the foot which in turn allows abnormal movements of the small bones of the foot and Joint subluxation occurs. Ligament and Joint capsules are stretched further and the bony structure of the foot is altered permanently.

As time goes on, these changes lead to foot deformities such as a claw foot with prominent metatarsal heads, or a rocker bottom foot with collapse of the longitudinal arch and prominence of the tarsal bones. These bony changes produce Localized areas of high pressure on the sole of the foot, particularly under the metatarsal heads, on the tips of toes, on the heel and under the midfoot. These high-pressure areas are associated with ulceration.

Autonomic neuropathy:
It causes loss of normal sweating, so that the skin become, dry, scaly and stiff, leading to formation of fissures through the dermis that serve as portal of infection. Sweat contains keratinolytic enzymes, which help break down hyperkeratotic areas. In the absence of sweating, the skin becomes inelastic and more prone to trauma.

**Clinical manifestation and assessment of diabetic neuropathy:**

Symptoms of peripheral neuropathy include burning pain, stabbing pain, paraesthesia, hot and cold sensation, and hyperesthesia: all symptoms prone to nocturnal exacerbation.

Signs include reduced sensation to pain, temperature, vibration, small muscle wasting, absent sweating and distended dorsal foot veins.

Neuropathy can be tested by the traditional clinical methods examining the various sensory modalities, muscle power and knee and ankle reflexes. More reproducible and meaningful information can be collected by the nylon monofilament.

The Semmes Weinstien l0g monofilament is pressed onto the skin of the foot until it buckles. If the patient is unable to feel this, then it is assumed that protective sensation is lost\(^1\).

The vibratory sense can be tested using a 128 HZ tuning fork or better still by a biothesiometer. Pain sensation can be tested by a pin brick and deep sensation by a tendon hammer.

**Peripheral vascular disease and diabetes:**

Peripheral vascular disease (PVD), causing arterial insufficiency, is the most important factor related to the outcome of a diabetic foot ulcer in diabetic patients \(^1\). Atherosclerosis and medial sclerosis are the most
common arterial diseases. Atherosclerosis causes Ischemia by arterial narrowing and blockage. Medial sclerosis (Moenckeberg sclerosis) is calcification of the tunica media producing a rigid conduit without, however, encroachment on the arterial lumen.

There is no peripheral arterial lesion specific to diabetes, but the pattern of atherosclerosis is somewhat different. The characteristics of atherosclerosis in diabetic patients as opposed to non-diabetic patients\(^{(1)}\):

1. More common.
2. Affect younger individuals.
3. No sex difference.
4. Multisegmental.
5. More distal.

**Symptoms:**

When adequate collateral vessels compensate for arterial occlusion, there may be no symptoms at rest, but when the demand for blood flow increases, claudication may occur. End stage symptoms are rest pain and ulceration/gangrene. There are thus four stages according to *Fontaine*\(^{(1)}\):

- Stage 1: Occlusive arterial disease without clinical symptoms.
- Stage 2: Intermittent claudication.
- Stage 3: Ischemic pain.
- Stage 4: Ulceration-gangrene.

**Clinical examination:**

Experts recommend that the vascular status in diabetic patient should be examined on an annual basis paying particular attention to: \(^{(1)}\)

1. A history of intermittent claudication or ischemic rest pain.
2. Palpation of pulses of the posterior tibial and dorsalis pedis is mandatory. If pulse is absent, the popliteal and femoral pulsation should be examined. If foot pulses are present significant vascular disease is unlikely. The dorsalis pedis artery may be congenitally absent. When pedal pulses are absent, ankle blood pressure should be measured with a hand-held ultrasound Doppler device. An ankle brachial index (ABI) below 0.9 indicates occlusive disease.

3. Potential signs of critical ischemia e.g. Skin necrosis and gangrene.

**Chronic critical ischemia:**

Critical ischemia indicates risk of amputation of a major part of the limb, unless reversed by a revascularization procedure. Chronic critical ischemia is currently defined by either one of two of the following criteria:\(^1\):

1- Persistent ischemic rest pain requiring analgesia for more than two weeks.

2- Ulceration or gangrene of the foot or toes, both associated with an ankle systolic pressure of \(< 50\, \text{mm Hg}\), or a toe systolic pressure of \(< 30\, \text{mm Hg}\).
Non invasive vascular testing:

The commonly used techniques include ankle pressure, toe pressure and less frequently transcutaneous oxygen pressure measurements. Any measurement less than the following values is considered abnormal (0.8, 45 mmHg, 40 mmHg) for the above mentioned test respectively\(^{(33)}\).
Major Amputations of the lower extremity

General surgical principles:

Today amputation has come to be regarded as a form of treatment and not a purely life saving procedure. It is a carefully planned operation, which is followed by intensive rehabilitation, medically, vocationally and socially so that the amputee can adopt the use of the prosthesis and the significant alteration of body image. Meticulous attention to the detail and gentle handling of tissues are important for creating a well healed and highly functional amputation stump.

The stump:

This has been defined by Day H J (1980), as being the terminal segment remaining after amputation. Day's criteria for a healthy and efficient stump are as follows:

1. Well nourished skin with a healed pain free mobile scar.
2. Rounded bone ends, stabilized by strong balanced muscles, with well-protected high nerve endings.
   1. Proximal joints should be normally mobile and without any contracture.

Tourniquet:

The use of tourniquet is contraindicated in major amputations of the lower extremity in diabetic because these limbs are ischemic and infected.
**Level of amputation:**

In remote past amputation through specific levels was necessary for proper prosthetic fitting. With modern types of prosthesis and sophisticated prosthetic-fitting technique, the level of amputation is less important. Rather, any well-healed, non-tender, and properly constructed amputation stump can now be satisfactorily fitted with prosthesis. The amputation should be through tissues that will heal satisfactorily and at a level that will remove the diseased or otherwise abnormal part. The cardinal rule is to preserve all possible length consistent with good surgical judgment\(^{(20)}).  

**Skin flaps:**

Regardless of the level of amputation, the stump should be covered with good skin. The skin should be mobile and normally sensate. Atypical flaps should always be preferred to amputation at a more proximal level. The location of the scar is rarely important with modern total-contact prosthetic sockets, but the scar should not be adherent to the underlying bone because adherent scars make prosthetic fitting extremely difficult and because this type of scar often breaks after prolonged prosthetic use\(^{(20)}).  

**Muscles:**

The muscles should be divided just distal to the level of intended bone section. It should be pointed out that myodesis is specifically contraindicated in diabetic patients with peripheral vascular disease or ischemia. Beveling or other contouring of the muscles may be necessary to obtain a stump that is shaped properly\(^{(20)}).
Nerves:

Most surgeons currently agree that nerves are best treated when isolated, gently pulled distally into the wound, and divided cleanly with a sharp knife so that the cut end will retract well proximal to the level of bone section. Strong tension on the nerve should be avoided during this maneuver. Large nerves contain relatively large arteries and should be ligated before being divided (35).

Blood vessels:

Major blood vessels should be isolated and individually ligated with absorbable or non-absorbable sutures before being divided. The larger ones should be doubly ligated (20).

Bone:

Excessive periosteal stripping is contraindicated and may result in the formation of ring Sequestrum. Bony prominence should always be resected. This is especially important in locations such as the anterior aspect of the tibia in transtibial amputation. Hampton (1972) (20) has pointed out the need for beveling the lateral aspect of the femur in transfemoral amputation.
Situation in Sudan

In Sudan despite the fact that amputation is a common surgical procedure, there is little published data. The subject of diabetic septic foot was first studied by Ahmed-M.E (36). He found that the incidence of major limb amputation rate of (DSF) is (38%). Mohamed I A, et al in 1994, found that diabetic septic foot is the main cause of major lower amputation comprising (24.1%) (37). Ali EA, et al (22), in 1999, studied prospectively the clinical presentation, management and outcome of 150 patients presenting to (KTH) with (DSF). 59 patients (39.3%) underwent major lower limb amputation.
1.3 OBJECTIVES

1. To study the indications and anatomical levels of major lower Limb amputations in diabetic patients in KTH and Gabir Abu Izz Center.

2. To identify:
   a- The healing patterns of major lower limb amputation at various levels
   b- The rate of postoperative stump infection.
   c- The rate of reoperation.
   d- The in hospital mortality and mean hospital stay.
Chapter Two

Patients & Methods
PATIENTS AND METHODS

This is a prospective analytic hospital based study on the clinical patterns of major lower limb amputation in diabetics.

This study was performed in 70 patients with diabetes, who underwent major lower limb amputation in KTH and Gabir Abu Izz Specialized Center for Diabetes, during the period between July 2002 and January 2003. The aims and methodology of the study were explained to the patients, and their consent was obtained.

Patient data were collected using a unified clinical protocol of database consisting of a questionnaire, clinical examination and investigations (appendix 1).

The clinical protocol included:

A- Patients' personal data.

B- History:

i. Type of diabetes.

ii. Duration of diabetes.

iii. Mode of control of diabetes.

iv. Compliance.

v. History of previous foot education.

vi. History of hypertension and smoking.

vii. History of previous foot ulceration.

viii. History of previous amputation.
C- Amputation surgery:

The following data concerning the amputation surgery were recorded for each patient:

(i) Date.

(ii) Caliber of the surgeon.

(iii) Anatomical level and dexterity.

(iv) Type of anesthesia.

(v) Indication for amputation.

(vi) Wound management.

(vii) Use of drains.

D- Investigations:

a- The following investigations were done for each patient preoperatively and their results were obtained from the records of the patients:

(i) Hb.

(ii) RBS.

(iii) FBS.

(iv) 2-hour postprandial blood glucose.

(v) Blood urea.
b- The following investigations were done for some patients preoperatively and their results were obtained from their records:

(i) Serum creatinine.

(ii) Radiological studies for the affected limb.

(iii) Microbiological studies in the form of wound swab for culture and sensitivity from the foot ulcer before surgery.

c- The following postoperative events were recorded:-

1. Post operative complication.

2. Microbiological studies in the form of wound swab for culture and sensitivity from the stump in-patients who developed postoperative wound infection.

3. Pattern of wound healing after amputation at different levels.

4. Requirement and indication of re-operation.

5. Development of contralateral lower limb ulceration.

6. Duration of hospital stay.

Chapter Three

Results
RESULTS

A total of 70 diabetic patients underwent major lower limb amputation, between July 2002 and January 2003, at KTH and Gabir Abu El Izz center. Forty-nine patients (70%) were seen in KTH and twenty-one patients (30%) were seen in Gabir Abu El Izz center.

This group comprised 28 females (40%) and 42 males (60%). The male to female ratio was 1.5:1. The level of lower limb amputation did not differ significantly between males and females (P=0.655) (Figure 1).

Their age ranged between 35 and 92 years. The mean age was 61.5 ±11.85 years. Fifty-six patients (79.99%) were in the age group 50-80 years (Table 1). The age in years was not significantly related to the level of amputation (P=0.097) (Figure 2).

Sixty-seven patients (95.72%) were having NIDDM, three patients (4.28%) were having IDDM, and the ratio of NIDDM to IDDM was 22.3:1.

Sixty-one patients (87.15%) had diabetes for more than 10 years. Twenty-nine patients (41.42%) had diabetes for 10-19 years. The mean duration of diabetes was 18.3 ± SD =9.04 years. All patients were known diabetics; no newly diagnosed diabetics were reported in this series (Table 2). In this series the level of LEA was not found to correlate significantly with the duration of the disease (Figure 3).

The diabetes was controlled by oral hypoglycemic drugs in 64 patients (92%), by insulin in 3 patients (4%) and by diet only in 3 patients (4%). However all patients were shifted to soluble insulin.

The majority of patients 51 (72.86%) were found to be irregular in their treatment.
History of hypertension was obtained in 11 patients (16%). Thirteen patients (19%) were regular smokers. Three patients were current smokers, while 10 patients already stopped smoking. Hypertension was significantly more prevalent among transfemoral amputees compared to transtibial amputees (P=0.017) (Figure 4). On the other hand no significant correlation was encountered between smoking and the level of amputation (P=0.345) (Figure 5).

Ten patients (14%) had previous foot education, while 60 patients (86%) did not have previous foot education.

There was a past history of previous foot ulceration in thirty patients (42.85%). Thirty-one patients (44%) had history of previous minor and /or major LEA. The previous LEA was ipsilateral, contralateral and bilateral in 20 (64.51%), 7(22.58%) and 4 (12.91%) patients respectively (Figure 6). History of previous ulceration and / or amputation was not found to correlate significantly with the level of LEA in this series (P=0.693) (Figure 7, 8).

Forty-seven LEAs (67.15%) were done by surgical registrars and 23 LEAs (32.85%) were done by consultants.

The majority of the LEAs forty-seven (67%) were done under spinal anesthesia, Nineteen (27%) were done under general anesthesia and only 4 (6%) were done under local anesthesia.

Seventy patients underwent major LEAs. Fifty-two patients (74.28%) had transtibial amputations and 18 patients (25.72%) had transfemoral amputations. No Symes, through knee or hip disarticulation were encountered in this series (Figure 9). Of the seventy major LEAs, the majority 42 (60.0%) were on the left side, whereas 28 (40.0%) were on the right side (Figure 9).
In fifty-six patients (80%) the indication for LEA was control of sepsis. This was followed by ischemia in 31 patients (44.2%) and extensive tissue loss in thirteen (18.55%) patients (Figure 10). The indication of LEA according to the anatomical level is illustrated in (Table 3).

Information about glycemic control before amputation was obtained by reviewing the results of measurement random blood sugar (RBS), fasting blood sugar (FBS) and 2 hour postprandial (2HPP). Accordingly only (1%, 4%, 4%) had good glycemic control (Figure 11, 12 and 13).

Preoperative investigations from patient’s records showed that 35 patients (50.0%) had Hb level below 10-g / dl.

The results of preoperative microbiological studies were obtained from the patients' records. These were in the form of wound swab for culture and sensitivity and were done in 44 patients (62.85%). The swab was taken from the infected ulcer before surgery. The most frequent isolates were staphylococcus aureus in twenty-two patients (50.00%), followed by Gram negative organisms in 17 (38.64%) patients and in three cases (4.45%) no growth was obtained (Figure 14). Twenty-four (54%) isolated organisms were found sensitive to ciprofloxacin. 15 isolates (36.6%) were sensitive to Gentamycin and 13 isolates (31.7%) were sensitive to Amikacin (Figure 15).

The results of preoperative renal function assessment by measuring the blood urea & serum creatinine level were obtained from patients' records. Only 7 (10.0 %) patients had creatinine level above 1.5 mg/dl.

Preoperative radiological investigations were done in thirty-four patients (48.57%). The most frequently diagnosed radiological abnormalities were periosteal reactions, cortical erosions and radiolucent areas (Figure 16).
The wound was closed primarily in Sixty-one patients (87.14%) and was left open in 9 patients (12.86%). The wound was closed without a drain in 56 patients, (80%) and with a drain in 5 patients (20%).

The most frequently encountered post operative complication was wound infection in 11 patients (15.71%), followed by ischemia of the stump in 6 (8.56%) patients (Figure 17). The rate of postoperative complication was significantly higher in patients undergoing transfemoral amputation (P=0.04) (Table 4).

Wound healing occurred primarily in the majority of patients forty-five (64.29%). Fourteen patients (20.00%) died before the occurrence of wound healing. Wound healing occurred after debridement in 6 patients (8.56%), after delayed suturing in 1 patient (1.42%) and after refashioning in one (1.42%) patient (Figure 18). The difference in the rate of primary healing in transtibial (76.9%) and transfemoral (27.78%) amputation was found to be statistically significant (P=0.000) (Table 5).

From the eleven patients who developed postoperative wound infection staph was isolated from 4 patients, Gram-ve organisms from 3 patients. No microbiological studies were done in the remaining 4 cases (Table 6).

Nineteen patients (27.14%) required reoperation. The most frequent type of reoperation was debridement in 16 patients (21.86%). The requirement of reoperation was significantly higher among transfemoral (55.6%) over transtibial amputees (17.4%) (P=0.008) (Table 7).

Fourteen patients (20.0%) died in hospital. The most common causes of death were septicemia and MOF in 10 patients followed by myocardial infarction in 3 patients and uremia in 1 patient (Table 8). The mortality rate
for transfemoral amputation (50.00%) was statistically higher than that of transtibial amputation (9.62%) \((P= 0.000)\) (Figure 19, Table 8).

Three patients developed contralateral lower limb ulceration while in hospital. This was managed by debridement in two cases and by a transtibial amputation in one case.

Forty-six patients (65.9%) stayed in hospital for 10-40 days. The mean hospital stay was 30.14 ± SD -21.87 days (Table 9). No significant difference in the hospital stay according to the level of LEA was noted in this series \((P=0.497)\) (Table 10).
Table (1) Age distribution of diabetic patients who underwent major LEA (n= 70).

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 – 40</td>
<td>2 (2.86%)</td>
</tr>
<tr>
<td>41 – 50</td>
<td>8 (11.43%)</td>
</tr>
<tr>
<td>51 – 60</td>
<td>20 (28.57%)</td>
</tr>
<tr>
<td>61 – 70</td>
<td>18 (25.71%)</td>
</tr>
<tr>
<td>71 – 80</td>
<td>18 (25.71%)</td>
</tr>
<tr>
<td>81 – 90</td>
<td>3 (4.29%)</td>
</tr>
<tr>
<td>91 – 100</td>
<td>1 (1.42%)</td>
</tr>
</tbody>
</table>

Mean age = 61.5 ± 11.85 years
Table (2) Duration of diabetes in patients who underwent major LEA (n= 70).

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Numbers of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – 10</td>
<td>9 (12.85%)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>29 (41.42%)</td>
</tr>
<tr>
<td>21 – 30</td>
<td>20 (28.57%)</td>
</tr>
<tr>
<td>31 – 40</td>
<td>11 (15.71%)</td>
</tr>
<tr>
<td>41– 50</td>
<td>1 (01.45%)</td>
</tr>
</tbody>
</table>

Mean duration of diabetes = 18.3 ± 9.04 years
Table (3) Level of LEA in relation to indications of LEA in diabetic patients who underwent major LEA (n =70).

<table>
<thead>
<tr>
<th>Indications of LEA</th>
<th>Levels of LEA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
<td>Transfemoral</td>
</tr>
<tr>
<td>Extensive tissue loss</td>
<td>1 (1.42%)</td>
<td>0 (.00%)</td>
</tr>
<tr>
<td>Ischemia</td>
<td>4 (5.71%)</td>
<td>9 (12.86%)</td>
</tr>
<tr>
<td>Control of sepsis</td>
<td>26 (37.14%)</td>
<td>1 (1.43 %)</td>
</tr>
<tr>
<td>Ischemia + control of sepsis</td>
<td>11 (15.71 %)</td>
<td>6 (8.57%)</td>
</tr>
<tr>
<td>Extensive tissue loss + control of sepsis</td>
<td>9 (12.86%)</td>
<td>2 (2.85%)</td>
</tr>
<tr>
<td>Extensive tissue loss + control of sepsis + Ischemia</td>
<td>1 (1.43%)</td>
<td>0 (0.00)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>52</strong></td>
<td><strong>18</strong></td>
</tr>
</tbody>
</table>
Table (4) Level of LEA in relation to types of post operative complications in diabetic patients who underwent major LEA (n= 20) .

<table>
<thead>
<tr>
<th>Indications of LEA</th>
<th>Levels of LEA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Wound infection</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>Ischemic stump</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Septicemia</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Wound infection + ischemia</td>
<td>1 (5%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9</strong></td>
</tr>
</tbody>
</table>

*P value = 0.371*
Table (5) Level of LEA in relation to wound healing after amputation in diabetic patients who underwent major LEA (n = 70).

<table>
<thead>
<tr>
<th>Indications of LEA</th>
<th>Levels of LEA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
<td></td>
</tr>
<tr>
<td>Occurred primary</td>
<td>40 (57.14%)</td>
<td>45</td>
</tr>
<tr>
<td>Occurred after refashioning</td>
<td>0 (0.00%)</td>
<td>1</td>
</tr>
<tr>
<td>Patient died before healing</td>
<td>4 (5.71%)</td>
<td>12</td>
</tr>
<tr>
<td>Didn’t occur by the end of the observation period</td>
<td>1 (42%)</td>
<td>3</td>
</tr>
<tr>
<td>Occurred after debridement</td>
<td>4 (5.71%)</td>
<td>6</td>
</tr>
<tr>
<td>Occurred after delayed suturing</td>
<td>3 (4.28%)</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>52</strong></td>
<td><strong>18</strong></td>
</tr>
</tbody>
</table>

*P value < 0.000*
Table (6) Isolated organisms from diabetic patients who developed stump infection following major LEA (n=11).

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Numbers of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staph.</td>
<td>4 (5.71%)</td>
</tr>
<tr>
<td>Coliform</td>
<td>2 (2.85%)</td>
</tr>
<tr>
<td>Proteus</td>
<td>1 (1.43%)</td>
</tr>
<tr>
<td>Not done</td>
<td>4 (5.71%)</td>
</tr>
</tbody>
</table>
Table (7) Level of LEA in relation to requirements & types of reoperation in diabetic patients who underwent major LEA (n = 70).

<table>
<thead>
<tr>
<th>Requirement and types of reoperation</th>
<th>Levels of LEA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
<td>Transfemoral</td>
</tr>
<tr>
<td>Debridement</td>
<td>8 (11.42%)</td>
<td>8 (11.24%)</td>
</tr>
<tr>
<td>Refashioning</td>
<td>0 (0.00%)</td>
<td>1 (1.42%)</td>
</tr>
<tr>
<td>Proximal major amputation</td>
<td>0 (0.00%)</td>
<td>1 (1.42%)</td>
</tr>
<tr>
<td>Others</td>
<td>1 (1.42%)</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>52 (74.66%)</strong></td>
<td><strong>18 (25.34%)</strong></td>
</tr>
</tbody>
</table>

P value < 0.008
Table (8) Level of LEA in relation to causes of death in diabetic patients who underwent major LEA (n = 14).

<table>
<thead>
<tr>
<th>Indications of LEA</th>
<th>Levels of LEA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
<td>Transfemoral</td>
</tr>
<tr>
<td>Septicemia &amp; MOF</td>
<td>3 (21.43 %)</td>
<td>7 (50.00%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1 (7.14%)</td>
<td>2 (14.28%)</td>
</tr>
<tr>
<td>Uremia</td>
<td>1 (7.14%)</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>9</td>
</tr>
</tbody>
</table>

P value = 0.3377
Table (9) The duration of hospital stay in days in diabetic patients who underwent major LEA (n = 70)

<table>
<thead>
<tr>
<th>Hospital stay in days</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>7 (10.00%)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>19 (27.14%)</td>
</tr>
<tr>
<td>21 – 30</td>
<td>18 (25.71%)</td>
</tr>
<tr>
<td>31 – 40</td>
<td>9 (12.85%)</td>
</tr>
<tr>
<td>41 – 50</td>
<td>5 (7.14%)</td>
</tr>
<tr>
<td>51 – 60</td>
<td>5 (7.14%)</td>
</tr>
<tr>
<td>61 – 70</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td>71 – 80</td>
<td>2 (2.85%)</td>
</tr>
<tr>
<td>81 – 90</td>
<td>2 (2.85%)</td>
</tr>
<tr>
<td>91 – 100</td>
<td>3 (4.28%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>70</strong></td>
</tr>
</tbody>
</table>
Mean hospital stay is $30.14 \pm 21.87$ days

Table (10) Level of LEA in relation to hospital stay in days in diabetic patients who underwent major LEA (n = 70).

<table>
<thead>
<tr>
<th>Indications of LEA</th>
<th>Levels of LEA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transtibial</td>
<td>Transfemoral</td>
</tr>
<tr>
<td>1-11</td>
<td>4 (5.71%)</td>
<td>3 (4.28%)</td>
</tr>
<tr>
<td>11 – 20</td>
<td>16 (22.85%)</td>
<td>3 (4.28%)</td>
</tr>
<tr>
<td>21 – 30</td>
<td>15 (21.42%)</td>
<td>3 (4.28%)</td>
</tr>
<tr>
<td>31 – 40</td>
<td>7 (10.00%)</td>
<td>2 (2.28%)</td>
</tr>
<tr>
<td>41 – 50</td>
<td>3 (4.28%)</td>
<td>2 (2.28%)</td>
</tr>
<tr>
<td>51 – 60</td>
<td>4 (53.71 %)</td>
<td>1 (1.42%)</td>
</tr>
<tr>
<td>61 – 70</td>
<td>0 (0.00%)</td>
<td>0 (0.00%)</td>
</tr>
<tr>
<td>71 – 80</td>
<td>1 (1.42%)</td>
<td>1 (1.42%)</td>
</tr>
<tr>
<td>81 – 90</td>
<td>1 (1.42%)</td>
<td>1 (1.42%)</td>
</tr>
<tr>
<td>91 – 100</td>
<td>1 (1.42%)</td>
<td>2 (2.28%)</td>
</tr>
<tr>
<td>Total</td>
<td><strong>52</strong></td>
<td><strong>18</strong></td>
</tr>
</tbody>
</table>
P value = 0.497
Figure 1: Level of LEA in relation to gender in diabetic patients who underwent major LEA (n = 70).

Gender & Level of LEA

- Males: 32 Transitibial, 10 Transfemoral
- Females: 20 Transitibial, 8 Transfemoral

P value = 0.655
Figure 2: Level of LEA in relation to the age in diabetic patients who underwent major LEA (n = 70).

Age in years
P value = 0.097
Figure 3: Level of LEA in relation to duration of diabetes in years in diabetic patients who underwent major LEA (n=70).

Duration of diabetes in years

Number of patients

<table>
<thead>
<tr>
<th>Duration</th>
<th>Transitibial</th>
<th>Transfemoral</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>11-20</td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td>21-30</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>31-40</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>41-50</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*p value = 0.206*
Figure 4: Level of LEA in relation to presence of hypertension in diabetic patients who underwent major LEA (n = 70).

- Yes: 5 (Transitibial) vs. 6 (Transfemoral)
- No: 47 (Transitibial) vs. 12 (Transfemoral)

Presence of hypertension
P value = 0.017
Figure 5: Level of LEA in relation to smoking in diabetic patients who underwent major LEA (n = 70).

<table>
<thead>
<tr>
<th></th>
<th>Smokers</th>
<th>Non smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smokers</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Non smokers</td>
<td>41</td>
<td>16</td>
</tr>
</tbody>
</table>

P value = 0.345
Figure 6: Dexterity of previous amputation in diabetic patients who underwent major LEA (n=31).
Figure 7: Level of LEA in relation to history of previous LL ulceration in diabetic patients who underwent major LEA (n = 70).

P Value = 0.693
Figure 8: Level of LEA in relation to history of previous LEA in diabetic patients who underwent major LEA (n=70).
Figure 9: Anatomical Level & dexterity of amputation in diabetic patients who underwent major LEA (n=70).

Number of patients

<table>
<thead>
<tr>
<th></th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfemoral</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Transitibial</td>
<td>32</td>
<td>20</td>
</tr>
</tbody>
</table>

p value = 0.655
Figure 10: Indications of amputation in diabetic patients who underwent major LEA (n = 70).
Figure 11: Preoperative mean RBS as indicator of diabetic control in diabetic control patients who underwent major LEA (n=70).
Figure 12: Preoperative mean FBS as indicator of diabetic control in diabetic patients who underwent major LEA (n=70).
Figure 13: Preoperative mean 2 hour postprandial blood sugar as indicator of diabetic control in diabetic patients who underwent major LEA (n = 70).
Figure 14: The isolated organisms in wound swabs taken from the infected primary lesion before surgery in diabetic patients who underwent major LEA (n = 70).
Figure 15: Sensitivity of the isolates from the infected primary lesion before surgery in diabetic patients who underwent major LEA (n=41).
Figure 16: Preoperative type of radiological abnormalities in diabetic patients who underwent major LEA (n= 32).
Figure 17: Postoperative complications in diabetic patients who underwent major LEA (n = 70).
Figure 18: Pattern of wound healing in diabetic patients who underwent major LEA (n = 70).
Figure 19: Level of LEA in relation to in-hospital mortality in diabeti patients who underwent major LEA (n = 70).
Chapter Four

Discussion, Conclusion & Recommendations
4.1 DISCUSSION

The major adverse outcome of diabetic foot problems, are foot ulcers and amputation. Diabetic foot complications are the most common cause of major LEA in Sudan, accounting for (24.1%) \(^{(37)}\). The risk of lower extremity amputation is 15 to 46 times higher in diabetics than in nondiabetics \(^{(38)}\). Major amputations are associated with a high mortality rate \(^{(39)}\). Recent studies have shown that very few amputees from (12%-26 %) achieve normal mobility \(^{(40)}\).

This prospective analytic hospital-based study included seventy diabetic patients who underwent major LEA in KTH and Gabir Abu El Izz diabetes center in the period July 2002 - January 2003.

The male to female ratio in this series was (1.5:1). \(\text{Ebskov B et al}^{(41)}\) in a series of 2848 major LEAs in diabetic individuals reported a similar ratio of (1.18:1). A higher ratio of (2.2:1) was reported by \(\text{Turney BW et al}^{(42)}\). A sex difference in diabetes-related major lower limb amputation rates of (2:1) was reported by \(\text{Armstrong D G et al}^{(43)}\). A ratio of (2.6:1) was reported from KTH for forty diabetic patients with transtibial amputation by \(\text{Mohammed IM et al}^{(26)}\). The slight male predominance in our series can be explained by the fact that male have a more active lifestyle and therefore have a high risk of foot injuries. Furthermore, males sex has been associated with increased risk of foot ulcer and amputation in most studies of type 2-diabetes \(^{(1)}\).

Although more diabetic males were encountered in our series, the level of lower limb amputation did not differ significantly between males and females (\(P = 0.655\)).
The age of our patients ranged between thirty-five and ninety-two years. The mean age was 61.1 years ± SD 11.85. Eighty percent of our patients were in the age group (50-80) years.

The mean age for diabetic amputees reported from the west ranged between (64.1-70.9) years \((44, 45, 46)\). This is a marked age difference. Similar age discrepancies were reported by other workers from this country \((37, 27)\). This can be partly explained by the fact that diabetic patients in western communities are more aware of the control and treatment of diabetes, and therefore they lose limbs from diabetic sepsis at a much older age if that becomes necessary. Moreover, the widespread implementation of arterial reconstruction resulted in a substantial decrease \((40-80\%)\) in amputation rates in western communities \((46)\).

The age in years was not significantly related to the level of LEA in our series \((P = 0.097)\). This may be difficult to explain, because with the advancement of age, the effects of diabetes on the feet, and peripheral vascular disease become more evident. But during the last 3 decades there is a growing tendency to preserve the knee joint even in elderly diabetic patients with peripheral vascular disease \((20)\). This tendency is based on two reasons, one: preservation of the knee joint is very important in postoperative rehabilitation \((20)\), two: after amputation through the LE for PVD with diabetes, the stump usually heal even when the level of amputation is below the knee \((20)\).

Sixty-seven patients \((95.72\%)\) were having NIDDM, 3 patients \((4.28\%)\) were having IDDM. A similar ratio among diabetic amputees (with NIDDM comprising 93\%) were reported by Morrise AD et al \((47)\). NIDDM accounts for 66.1\% - 84.6\% of diabetes in Sudan \((48, 49)\). This
predominance of NIDDM among our patients is consistent with the fact that patients with NIDDM are more prone to develop foot ulceration and LEA \(^{(50, 51)}\).

The duration of diabetes in our patients ranged from 1 to 40 years. The mean duration of diabetes was 18.3 year ± SD 9.04. The majority of our patients (87.15%) had the disease for more than 10 years. It is known that, the longer the duration of diabetes, the higher is the degree of neuropathy, which is the main cause of foot sepsis \(^{(52)}\). Humphrey AR et al \(^{(53)}\) reported that LEAs are associated significantly with longer mean duration of diabetes.

In our series the level of LEA was not found to correlate significantly with the duration of the disease (\(P = 0.206\)). No newly diagnosed diabetics were encountered in this series, in contrast to other workers who reported that in up to (15%- 19%) of diabetic patients undergoing major LEA, diabetes was first diagnosed at the time of surgery.

Fifteen percent of our patients were hypertensive. The prevalence of hypertension among Sudanese diabetic patients undergoing major LEA is not available. Ali SM et al \(^{(54)}\) reported systemic hypertension in (18%) of patients presenting to KTH with diabetic foot sepsis (\(n = 150\)). Allaham YR et al \(^{(50)}\) studied the risk factors for development of diabetic foot in a symptomatic Sudanese diabetic patients and they reported systemic hypertension in twenty-five percent of their patients (\(n = 100\)). Hypertension was less prevalent in our series, but it was significantly more prevalent among transfemoral amputees compared to the transtibial
amputees (P= 0.017). This is very interesting, since hypertension is a potentially modifiable risk factor.

Thirteen patients in our series were regular smokers (18.6%). This Figure is lower than that reported by Mohamed IM et al (26), which was (35%). Smoking was not significantly related to the level of LEA in our patients (P=0.345). Moss SE et al (55) and Selby JV et al (56) reported similar results.

Eighty-six percent of our patients did not have any previous foot education. Relatively little research has been performed into the specific effect of education on the incidence of ulcers and amputations in diabetic subjects. Although some studies suggested that education results in a reduction of ulcers and amputations, in most of these studies education was in fact part of a comprehensive foot-care program (1). Ezio F et al (57) reported that the use of therapeutic shoes and intense educational training have contributed to the low incidence of new ulceration and major amputation in their study population.

To be effective, education should be simple, relevant, consistent and repeated. It should also target the high risk groups, patients, and health care professionals. Unfortunately inspite of the clear guidelines and recommendations incomplete foot examination is reported in up to (50%) of patients undergoing LEA (1).

Among individuals with diabetes identified in the 1989 US National Health Interview Survey, (22%) stated they never checked their feet, and (53%) of them reported no foot examination by a health care professional within the past six months (58).
Forty percent of our patients reported history of previous ulceration and /or amputation. This is expected because (85%) of diabetes-related LEAs are preceded by a history of foot ulceration (1). It is also known that diabetic patients with history of previous ulceration and / or amputation are at increased risk of subsequent amputation (59, 60, 61).

History of previous ulceration and / or amputation was not found to correlate significantly with the level of LEA in our series (P= 0.693).

Preoperative glycemic control was graded as good, moderate and bad according to the blood sugar level. Three indices were considered: FBS, RBS and 2HPP. Our results showed that (59% -75%) of our patients fall into the bad control group according to the three indices combined. This is very serious because hyperglycemia together with vascular dysfunction is a direct cause of diabetic neuropathy (62). However these in the same time highlight potential therapeutic approaches.

Preoperative renal function was assessed by measuring blood urea and serum creatinine level. (10%) of our patients had creatinine levels above 1.5 mg/dl. The prevalence of chronic renal insufficiency in our patients is higher than that described by Al Laham YR et al (50) (7%). Apelqvist J et al (63) reported a prevalence of diabetic nephropathy of (26%). Eggers PW et al (64) reported that amputation rate among diabetic patient with end stage renal disease (ESRD) is 10 times higher than that among diabetic patients at large.

Wound swabs were taken from the infected primary lesion before surgery in forty-four patients (62.9 %). The specimen sent was a wound swab in all patients. Sapico FL et al (65) reported that cultures obtained by
curettage of the base of ulcers correlated better with deep tissue cultures than did needle aspiration or swabs of the ulcers.

Most of our bacteriological assessment was qualitative rather than quantitative i.e. no information about the bacterial count per gram of tissue was reported. The drawback of such studies is that it may not differentiate between contamination and deep infection. Staphylococcus aureus was isolated in (50%) of patients. It was followed in frequency by coliforms (38.63%), streptococci in (4.55%) and no growth was obtained in 3 cases (6.8%). Jones EW et al (66) in a study of the microbiology of diabetic foot lesions, reported staph aureus to be the most frequent incriminated organism.

No anaerobic organisms were reported in our cultures. This is most probably due to the lack of special transport media and proper culture setup.

Radiological assessment before surgery was done on thirty-four patients (48.57%). The imaging study used was a plain radiograph. Radiographs were obtained in anteroposterior and lateral projections. The most frequently diagnosed radiological abnormalities were periosteal reactions, cortical erosions and radiolucent areas. No soft tissue gas or foreign bodies were encountered in this series.

MRI and CT scan although they are important were not done in our patients because they are expensive. Morrison WE et al (67) reported that MRI may still be needed even if conventional radiographs are diagnostic for osteomyelitis, because it demonstrates clearly the extent of infection in the bone, and to see if neighboring bones are involved.
Fifty-two patients (74.28%) had transtibial amputation and 18 patients (25.72%) had transfemoral amputation. No Symes, through knee or hip disarticulation were encountered in our series. The ratio of transtibial to transfemoral amputation in our patients was (2.9:1).

A similar ratio of (3:1) was reported by Ali EA et al (22) (n=59). Mohemed I A et al (37) in a series of forty-one diabetic patients with major LEA reported a ratio of (1.5:1). No Symes, through knee or hip disarticulation were reported in both series.

Our ratio is higher compared to that reported by Tourkissian B et al (68) which was (1.5:1). Their lower ratio can be explained by the higher prevalence of PVD among their patients.

Dormandy J et al (69) reported that transtibial to transfemoral amputation ratio of (2.5:1) is the minimum acceptable for units providing LEA service.

The method of anesthesia used in the majority of our patients was spinal anesthesia in (67%), followed by general anesthesia in (27%) and local anesthesia in (6%). Minchev B et al (70) in series of 296 major LEAs reported that the type of anesthesia used were general anesthesia in (55%), epidural in (29%) and spinal in (14%). Epidural anesthesia is now gaining more grounds because it can provide postoperative analgesia as well.

The commonest indication for major LEA in our series was control of sepsis in (38.57%); this was followed by ischemia in (18.57), extensive tissue loss and sepsis in (24.28%). In the remaining (18.58%) the indication was a various combination of ischemia, sepsis and extensive tissue loss.
Van Damme H et al (71) in a series of 186 diabetes-related major LEAs reported that the most common indications for major amputation were extensive tissue loss, intractable infection and non-reconstructable occlusive vascular disease. Morris AD et al (47) reported in their series of 258 non traumatic major LEAs in diabetic patients, infected non healing ulcers (31%) and gangrene (29%) as the two main indications for amputation. Pecoraro RE et al (4) in a series of (80) consecutive LEAs in diabetic subject's reported that (46%) of the LEAs were due to ischemia and (59%) were due to infection.

The wound after amputation was closed primarily in sixty-one patients (87.14%) and was left open in 9 patients (12.86%). Open amputation as the name implies, is one in which the skin is not closed (20). The operation is only the first of at least two operations required to construct a satisfactory stump. The indication of this type of amputation is to prevent or eliminate infection (26). The wound was closed without a drain in fifty-six patients (80.00%) and with a drain in 5 patients.

The most frequently encountered postoperative complication was 'wound infection in 11 (15.71%) patients, followed by ischemia of the stump in (8.5%). The occurrence of postoperative complication was significantly related to the level of LEA (P< 0.00). The rate of postoperative complications for transfemoral amputation was (61.11%) while that for transtibial amputation was (17.3%). Toursarkissian B et al (68) in a series of 113 diabetes-related major LEAs reported a postoperative complications rate of forty percent. The majority of these were wound-related (22%). In their series wound complications were more frequent with transfemoral than transtibial amputation (P = 0.04).
The requirement of reoperation rate in our series was (27.14 %). The most frequent type of reoperation was debridement in (84.2%) followed by delayed suturing in (5.3%) refashioning in (5.3%) and a more proximal amputation in (5.3%).

The requirement of reoperation was significantly higher among transfemoral (55.6%) over transtibial amputees (17.4%) (P = 0.008).

Primary healing occurred in (76.9 %) of patients who underwent transtibial amputation and in (27.78) in those who underwent transfemoral amputation. This difference in primary healing patterns was found to be statistically significant (P <0.000). Similar healing patterns were reported by Dormandy J et al (69).

The overall in-hospital mortality in our series was (20%). The mortality rate for transfemoral amputation (50%) was statistically higher than that of transtibial amputation (9.62%) (P < 0.00). Our mortality rate figures are comparable to those reported by the International Working Group on the Diabetic Foot: (10-40 %) for transfemoral amputation Vs (5 - 20 %) for transtibial amputation (1). The most common causes of death were septicemia and multiorgan failure, followed by myocardial infarction and uremia. Amputation of the lower limb is generally viewed as an ominous event portending poor survival, with four-year survival ranging from (22% -76%) (71). Survival is affected by age, level of amputation and co-morbid conditions. Jennifer A et al (72) reported a twenty percent mortality rate before discharge for patients undergoing transtibial amputation.

The mean duration of hospital stay in our patient was 30.14 days ±SD 21.87. This duration is comparable to that reported by Turney BW et
al (42). Payne C P (39) studied diabetes related lower limb amputations in Australia and reported a mean hospital stay of (24.7 days). A mean hospital stay of forty-two days was reported from the Netherlands (73).

No significant difference in the hospital stay according to the level of LEA was noted in our series (P = 0.497).
4.2 CONCLULSION

Major LEA had prevalence upon type II DM.

The majority of patients had history of previous ulceration and | or minor or major LEA.

Most patients had poor glycemic control.

Transtibial and transfemoral amputations are the main types of major LEA in diabetic patients in KTH and Gabir Abu El Izz diabetes center.

The most common indication of major LEA is control of sepsis followed by gangrene of the foot and various combinations of sepsis, gangrene and extensive tissue loss.

Postoperative stump infection rate is (15.71%) with significantly higher rates of postoperative stump infection in transfemoral amputations.

The overall primary healing rate is (76.9%); with significantly lower rates for transfemoral amputation.

The rate of reoperation is (27.14%). The most common type of reoperation is debridement. Requirement of reoperation is significantly higher in transfemoral amputation.

The in-hospital mortality in our patients is (20%), with significantly higher mortality rates in transfemoral amputation.

There is considerable morbidity due to long hospital stay and the mean hospital stay is 30,14days ± SD21.87.
4.3 RECOMMENDATION

There is a need for setting up multidisciplinary foot-care team. Here a step by step approach, introducing different elements of the team one by one should be considered to create the full team at the outset.

Education should be an integral part of foot-care program. Education needs to be directed to professionals as well as patients.

Patients who have undergone a major amputation should join a surveillance program of the other foot.

Patient selected for transfemoral amputations are more fragile should be assessed carefully for concomitant co morbidity.

Vascular status in diabetic patients should be examined to pick up cases that can benefit from revascularization and arterial reconstruction before major amputation.

There is a need to implement and institute certain principles and guidelines to reduce the rate of postoperative stump infection. The use of broad-spectrum intravenous antibiotics, early postoperative wound inspection, performance of open amputations when indicated can be considered in this context.

Surgeons performing amputations should be more aware about the basic prosthetic principles and should be more involved in amputee rehabilitation.

There is a need for accurate registration of amputations.
REFERENCES


Appendix
University of Khartoum  
Faculty of Medicine  
Postgraduate Medical Studies Board  
Clinical MD Surgery  
Major Lower Extremity Amputation in Diabetics  
Clinical patterns  

Serial No. :  

(1) Personal Data:  
1. Name:  
2. Age:  
3. Sex:  
4. Origin:  
5. Occupation:  
6. Address & Telephone:  

(2) Hospital:  

(3) Unit:  

(4) Date of admission:  

(5) Date of Discharge:  

(6) History:  
(i) Type of DM  
   IDDM:  
   NIDDM:  
(ii) Duration of DM:  
(iii) Treatment of DM:  
   - Diet:  
   - Insulin:  
   - Oral hypoglycaemi:  
(iv) Patient compliance:  
Yes  
No
(v) History of hypertension   Yes    No

(vi) History of smoking   Yes    No
   If yes:
   1. Duration of smoking: ........................................
   2. Number of cigarettes or packs/ day : ......................
   3. If stopped time since abstinence: ..........................

(vii) History of previous foot education   Yes    No

(viii) History of previous ulceration     Yes   No

(ix) History of previous amputation        Yes   No
   If yes:
   1. No of previous amputation .........................
   2. Level of previous amputation ........................
   3. I psi lateral or contra lateral .....................

(7) Amputation:
   1. Date
   2. Operator
      • Consultant.
      • Registrar.
      • Medical officer
      • House officer
   3. Anesthesia:
      • General: ..................................................
      • Spinal : .................................................
      • Local: ..................................................

2
4. Amputation level & dexterity:

<table>
<thead>
<tr>
<th>Dexterity</th>
<th>Rt</th>
<th>Lt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Transtibial</td>
<td>........................................</td>
<td>........................................</td>
</tr>
<tr>
<td>2) Transfemoral</td>
<td>........................................</td>
<td>........................................</td>
</tr>
<tr>
<td>3) Through knee</td>
<td>........................................</td>
<td>........................................</td>
</tr>
<tr>
<td>4) Hip disarticulation</td>
<td>........................................</td>
<td>........................................</td>
</tr>
<tr>
<td>5) Others</td>
<td>........................................</td>
<td>Specify ...............</td>
</tr>
</tbody>
</table>

(8) Preoperative investigation:

a. Hb.................................................................

b. Blood glucose:
   - RBG □
   - Fasting □
   - 2 hour postprandial □

c. Blood urea.
   □

d. Serum creatinine ............... □

(9) Microbiological studies done:

Yes □
No □

a. What was specimen
   1. Needle aspirate □
   2. Wound swab… □
   3. Tissue biopsy □

b. What was the, result of C & S
   - Organism .........................................................
   - Sensitivity ........................................................

(10) Radiological studies before surgery:

Yes □
No □

If yes:
   - Normal □
   - Abnormal □
If abnormal what was the abnormality?

1. Cortical erosion
2. Radiolucent areas
3. Periosteal reaction & new bone formation
4. Soft tissue gas
5. Sequestration
6. Neuropathic arthropathy
7. Others ................................

(11) What was the indication for LL amputation?

i. Extensive tissue loss

ii. Ischemia that cannot be revascularized

iii. Control of sepsis

iv. Others........................................

(12) Wound management after amputation

Closed primarily

Left open

(13) Use of drains

Yes ☐ No ☐

(14) Postoperative complications

1. Bleeding

2. Wound infection

3. Ischemic stump

4. Ring Sequestrum

5. Septicemia

6. DVT

7. Others ................. ☐ Specify ......
(15) Healing of the wound after amputation
  a. Occurred primary
  b. Occurred after refashioning
  c. Occurred after another major amputation
  d. Patient died before healing
  e. Did not occur by the end of the observation period

(16) In Cases of postoperative wound infection what was the result of culture & sensitivity?
    Organism .................................................................
    Sensitive to ............................................................

(17) Requirement of reoperation during that same admission
    Yes ☐    No ☐
    If yes what was the indication
    1. Exploration ☐
    2. Debridement ☐
    3. Refashioning ☐
    4. Major amputation at a more proximal level ☐
    5. Others .........................................................

(18) Did the patient develop ulceration on the contralateral limb during that same admission?
    Yes ☐    No ☐

(19) If yes what type of treatment did it require?
    Debridement ☐
    Drainage ☐
    Dressing ☐
    Amputation ☐
    Others .............................................................
(20) Duration of hospital stay

(21) If death occurred what were the circumstances of death (possible causes)?

i. Intraoperative death

ii. Septicemia & multi organ failure

iii. Pulmonary embolism

iv. Myocardial infraction

v. Stroke

vi. Others