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Comparison of Operative vs Non-operative Management of Ankle Fractures in Diabetic Patients: Prospective Randomized Trial

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Abstract

This study investigates the outcomes and complications associated with the management of ankle fractures in diabetic patients. A total of 44 diabetic patients with ankle fractures were enrolled, and they were randomly assigned to either conservative or operative treatment groups. The study evaluated demographic characteristics, diagnosis, complications, functional outcomes, and correlation with HbA1c and ankle brachial index. The results revealed a 29.5% complication rate among the patients, including superficial infections, Charcot neuroarthropathy, arthritic changes, loss of reduction leading to ankle fusion, and stiffness. Functional outcome scores (AOFAS and SF36) did not significantly differ between the conservative and operative groups. Correlation analysis showed a significant negative relationship between HbA1c levels and functional scores in the conservative group. Ankle brachial index demonstrated a negative correlation with the SF36 score in the conservative treatment group. The study emphasizes the importance of diabetic control and vascular assessment in guiding treatment decisions for diabetic ankle fractures.

Keywords: *Diabetes mellitus, ankle fractures, complications, functional outcome, HbA1c, ankle brachial index, conservative treatment, operative treatment, correlation analysis.*

1. Introduction

Ankle fracture and diabetes mellitus (DM) are two common pathologies in the outpatient clinics. Ankle fracture is a regular injury addressed by orthopaedic surgeons through standardised surgical procedures. With regards to DM, the World Health Organization calls it the epidemic of the 21st century, with a global prevalence of 4-6.5% and an exponential increase in the last decades. DM causes major complications that impact patient health and quality of life. Although it is known that diabetic patients who suffer a lower extremity fracture are prone to more complications due to diabetic comorbidity, such as neuropathy and peripheral arterial disease, there is little research that precisely estimated the rate of complications associated with diabetic ankle fractures. Similarly, there is a lack of investigation into whether there are certain subgroups of diabetic patients or modifying factors that make them more susceptible to various complications. (1)

The standard protocol of treating an unstable ankle fracture is open reduction and internal fixation (ORIF). In spite of ORIF and reaching a perfect anatomical reduction, some patients still complain enduring persistent pain and unsatisfactory functional outcomes. Around 1% of ankle fractures patients progress to an end-stage ankle osteoarthritis after ORIF requiring another surgical intervention (arthroplasty or fusion). (2,3,4,5)

Diabetes is considered a potential risk factor for complications in any fracture situation, but specially in any low extremity fracture, including ankle fracture. It was found that any diabetic ankle fracture is at a significantly higher risk of presenting any complication (approximately 2 times) independent to the

method of treatment. More-over, these complications tend to be fatal: infection (3 times), neuroarthropathy or non-union (5 times), amputation (3 times) and mortality (3 times). (1)

To understand the effect of diabetes on ankle fracture, it is recommended to understand the pathophysiology of diabetes mellitus and hyperglycemia. It can lead to neuropathy, retinopathy, nephropathy, and cardiovascular damage. Chronic hyperglycemia results in increased blood viscosity, impairing the ability of the red blood cell to deliver oxygen to the tissues, it affects nitric oxide, which acts as an antioxidant and neurotransmitter, leading to microvascular affection. It also can lead to coronary artery disease, stroke, peripheral artery disease, and produce nerve ischemia. Moreover, hyperglycemia also decreases the ability of immune cells, especially fibroblasts, from migrating and attaching to wounds, resulting in delayed healing that may last for up to 8 weeks. (6)

Chronic hyperglycemia also has an effect on physiology of the bone with the decrease in bone turnover, a functionally weaker bone and an increased risk of fracture. Advanced glycation end products (AGEs) accumulation interrupts cellular biology and the bony microarchitecture resulting in inflammation. This results from binding to the receptor for AGEs (RAGE). RAGE increases osteoclastic activity resulting in bone loss, leading to osteoporosis and demineralization. Additionally, AGEs also play a role interfering with development of osteoblasts, collagen, and osteocalcin production and increases osteoblast apoptosis. This results in decrease in formation of osteons and the bone ability to remodel. (7)

Studies have reported union times to increase to 163%, compared to non-diabetic patients, which is further increased to 187% when the fractures are displaced. This abnormal bony pathology also increases the chances of sustaining a more severe ankle fracture, along with increasing mortality rates, postoperative complications, lengths of hospital stay, and costs, than in the nondiabetic patient. Considering the aforementioned reasons, the use of nonoperative care is more often considered for management of the diabetic patient who presents with an ankle fracture. (8)

It was demonstrated that complications are mainly associated with advanced diabetic disease (approximately 8 times) rather than treatment modality (operative or non- operative). However, some complications are more frequent due to certain treatments, for example, infections (specifically deep infections) are associated with surgical management, whereas poor fracture healing is associated with non-surgical treatment. (1)

Although delayed fracture healing in diabetic patients has been demonstrated and it seems to be more likely in non-surgical treatments, it could be discussed whether malunion or non-union could be an acceptable outcome, especially in elderly or low- demand patients with risk to undergo a surgery. (1)

Over the past couple of decades, the risks and complications of diabetic ankle fractures have been recognized. Most of these patients also have additional comorbidities including peripheral arterial disease and diabetic neuropathy. Therefore, on one hand surgical intervention can pose challenges for wound healing, but non-operative management increases the risk for loss of reduction and therefore stresses the condition of the surrounding soft tissue. Both non-operative and operative management can increase the risk for Charcot neuroarthropathy. (9)

Hyperglycaemia plays a central role in the pathogenesis of complications, and measurement of HbA1c may provide a valid and easily available tool to diagnose the degree to which the human body has been affected by diabetes. It has been shown that values of HbA1c > 7%, are associated with increased complication rates following orthopaedic surgery, and has been used as a ‘cut off’ point over which elective surgery should be avoided. (10)

The trauma -itself- can elicit the onset of Charcot neuroarthropathy in diabetics, the pathophysiological mechanisms of which are not fully understood. In brief, pre-existing neuropathy and trauma can cause rapid ‘softening’ of bone (osteopenia) and cartilage degeneration, and/or can initiate a neuroinflammatory response resulting in joint collapse and deformity. The latter can result in catastrophic complications and following a pathway of lower leg and foot deformation, ulceration, and deep infection which may lead to amputation. This might occur both after non-operative management of ankle fractures, and also after failure of operative fixation. (11)

Whether the management was conservative or surgery, the treatment goals are to achieve a stable and congruent ankle, restore the function, and to prevent any further complications. Surgical goals should embrace obtaining an anatomic reduction of the mortise, providing a stable fixation that sustain the reduction till adequate healing has been achieved, avoiding the creation of pressure areas to the ankle, and prevent complications that may lead to limb loss or even death. An extra goal is to avoid instability or an early reduction loss that leads to the development of a Charcot joint. Nevertheless, whether patient

has been treated operatively or conservatively, a debate should also include whether prolonged immobilization and non- weight bearing of the patient will be needed as well as whether supplementary (nonoperative) forms of treatment will be necessary to obtain adequate healing. The decision driving treatment should be based on the injury pattern and the patient's physiology. Unfortunately, there is no clear algorithm to guide the treatment, based on displacement of the fracture, for this population. (12)

Ultimately, McCormack (13) recommended conservative treatment because of a high rate of major complications with operative treatment (such as deep infection, amputation, and wound breakdown), whereas Schon et al (14) recommended operative treatment in addition to an external fixator because of a 100% complication rate with non-operative treatment. (15)

The complications that have been reported in these studies of nonoperative management have included malunions, due to a loss in the initial reduction, nonunions, Charcot neuroarthropathy development, infections, and ulcers development. Risk factors for developing a complication include infrequent patient visits, early weight bearing and patient's noncompliance, history of long duration of diabetes, the presence of neuropathy, insulin dependence, and patients with a history of Charcot neuroarthropathy. All these factors contribute in a considerably increased rate of mortality, postoperative complications, hospital stay lengths, and costs, when compared to non-diabetic ankle fractures patients.

Operative diabetic ankle fracture treatment has centered around standard open reduction internal fixation (ORIF) with small or mini fragment (locking or nonlocking) plates following principles advocated by Arbeitsgemeinschaft für Osteosynthesefragen (AO). However, with the increased awareness of the fragile soft tissue envelope and the lack of adequate biology at times, recently it has been endorsed for alternative fixation methods to help increase rates of limb salvage. Minimally invasive approaches including percutaneous cannulated screws or Minimally Invasive Plate Osteosynthesis (MIPO) have been described as techniques to avoid large surgical incisions and avoid disruption of periosteal blood supply. (16)

It is known that the postoperative infection rate in patients undergoing foot and ankle surgery is higher in diabetics. Wukich et al analysed the outcomes of 1000 patients undergoing foot and ankle surgery and found a surgical site infection rate of 13.2% in diabetics, compared to 2.8% in non-diabetics. (17)

The challenging task of diabetic patients with ankle fracture is to determine the method of treatment, suitable timing of surgery, fixation means of the fractures, and postoperative rehabilitation protocol and risk factors identification and predictive values for the complications which can be managed to get the ideal anatomical and functional outcomes after surgical treatment of ankle fracture in diabetic patients. (18,19,20)

2. Materials and methods

After approval of the Institutional Review Board (IRB) of Mansoura faculty of medicine, this randomized double blinded clinical study was conducted on 44 patients. During the period from May 2020 to November 2021, any diabetic patient having history of significant trauma resulting in ankle fracture that requires fixation, and they came to accident and emergency department within 24 hours of the trauma, was included in this study after revising the exclusion criteria.

Randomized double blinded clinical trial.

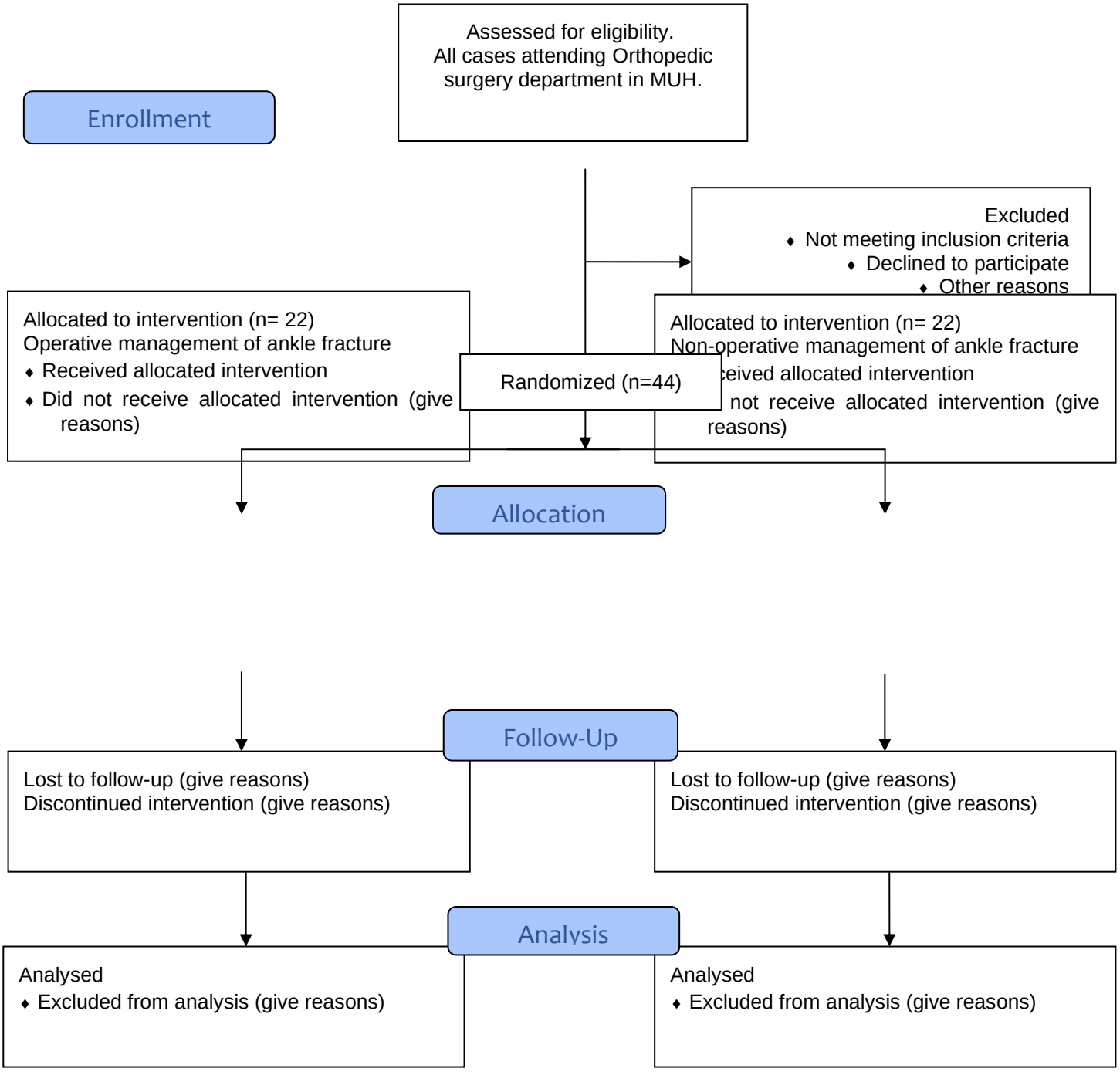

Figure (1): Consort flow chart

Each patient who was admitted to the accident and emergency hospital with a diabetic ankle fracture had the routine radiographs pre-reduction and post reduction (Anteroposterior and lateral and mortise views). Neuropathy and sensation were examined. Ankle brachial index was measured. Hgb A1c and random blood sugar was measured.

Method of management:

Patients underwent a closed reduction – under anesthesia if needed- and a well-padded cast. Then the patient was randomly directed to operative or conservative management by simple random sample using sealed envelopes technique.

Conservative management was through a well-padded below knee cast. Operative management was through ORIF by plate and screws or tension band. Operative method was under anesthesia whether general or spinal anesthesia (according to status of the patient and anesthesia specialist). All surgeries were done using a torniquet without exsanguination but only limb elevation for 5 minutes before

elevation the tourniquet according to its guidelines. Lateral malleolus was fixed using one third tubular plate through the direct lateral approach of the fibula, while medial malleolus was fixed by 2 partial cancellous 4.0 mm screws with washers or by a tension band technique by cerclage and k wires according to size of the fractured fragment. The medial malleolar fixation was made through the medial approach of the medial malleolus. After fixation of both malleoli tibio-fibular syndesmosis was examined under c arm fluoroscopic imaging and syndesmotic screw was applied whenever it is needed. Wounds were closed in layers and the patient was put in a below knee slap.

Post-operative care and evaluation.

Outcomes data included a patient interview, physical examination, radiographs, and subjective scales of functional performance.

Clinical Evaluation

Patients were followed up at the OPC with interval of every other week until union.

Plain radiographs: every other week until union

Antero-posterior, Lateral and mortise view of ankle

Computed tomography

it was ordered when needed.

Specific scores for foot and ankle:

The American Orthopedic Foot and Ankle Score (AOFAS)

A score for the general physical and mental health of patient (36-Item Short Form)

3. Results and Discussion

The present study is to assess the functional outcome of different methods of managing diabetic ankle fractures.

Table (1): demographic characteristics of all studied cases

	N	%
Age / years mean±SD (min-max)	56.57±10.74 (30-81)	
Sex		
Male	8	18.2
Female	36	81.8
Occupation		
Housewife	33	75.0
Manual worker	8	18.2
Sedentary	2	4.5
Farmers	1	2.3
Residence		
Urban	27	61.4
Rural	17	38.6
Special habits		
Nonsmokers	40	90.9
Smokers	4	9.1

Table (1): Mean age of the studied cases is 56.57±10.74 years ranging from 30 to 81 years, 81.8% are females, 75% housewives, 18.2% manual worker, 4.5% sedentary and 2.3% Farmers, 61.4% urban residence & 38.6% rural residence and 9.1% are smokers.

Table (2): diagnosis of the studied cases

Diagnosis	N=44	%
Uni-malleolar	4	9.1
Bi-malleolar	36	81.8
Tri-malleolar	4	9.1

Table (2) demonstrates that 81.8% bimalleolar, 9.1% uni-malleolar and 9.1% Tri-malleolar.

Table (3): Complications of the studied patients.

Complications	N=13	%

Superficial infection with stiffness	1	7.7
Superficial infection	3	23.1
Stiffness	1	7.7
Loss of reduction leading to ankle fusion	2	15.4
Charcot	3	23.1
Arthritic	3	23.1

Table (3) shows that 13 cases have complications: 23.1% superficial infection, 23.1% Charcot, 23.1% arthritic, 15.4% Loss of reduction leading to ankle fusion, 7.7% Stiffness and 7.7% Superficial infection with stiffness.

Table (4): Comparison of AOFAS score between studied groups.

	Conservative N=22	**Operative N=22**	**Test of significance**
AOFAS Mean±SD	75.0±19.19	78.82±18.66	t=0.669 P=0.507

t: Student t test

Table (4) demonstrates no statistically significant difference between studied groups as regard AOFAS score.

Table (5) Comparison of short form 36 score between studied groups

	Conservative N=22	**Operative N=22**	**Test of significance**
Short form 36 Mean±SD	62.5±16.81	61.36±21.45	t=0.196 p=0.846

t: Student t test

Table (5) demonstrates no statistically significant difference between studied groups as regard short form 36 score.

Table (6) comparison of complications between studied groups.

Complications	**Conservative N=5**	**Operative N=8**	**Test of significance**
Superficial infection with stiffness	0	1(12.5)	
Superficial infection	0	3(37.5)	
Stiffness	1(20.0)	0	χ2MC=10.18
Loss of reduction leading to ankle fusion	2(40.0)	0	P=0.07
Charcot			
Arthritic	0	3(37.5)	
	2(40.0)	1(12.5)	

MC= Monte Carlo test

Table (6) demonstrates that there is no statistically significant difference between studied groups as regard incidence of complications.

Table (7): correlation between HBA1C, ankle brachial index with AOFAS score and SF36 among cases with conservative therapy.

Conservative	**AOFAS score**		**SF36**	
	r	P	r	P
HbA1c	-0.656	0.001*	-0.714	<0.001*
Ankle brachial index	-0.353	0.107	-0.656	0.001*

r: Spearman correlation coefficient, *statistically significant

Table (7) illustrates statistically significant negative correlation between AOFAS score & HbA1c (r=-0.656), between SF36 & HbA1c (r=-0.714) and between SF36 & ankle brachial index (r=-0.656)

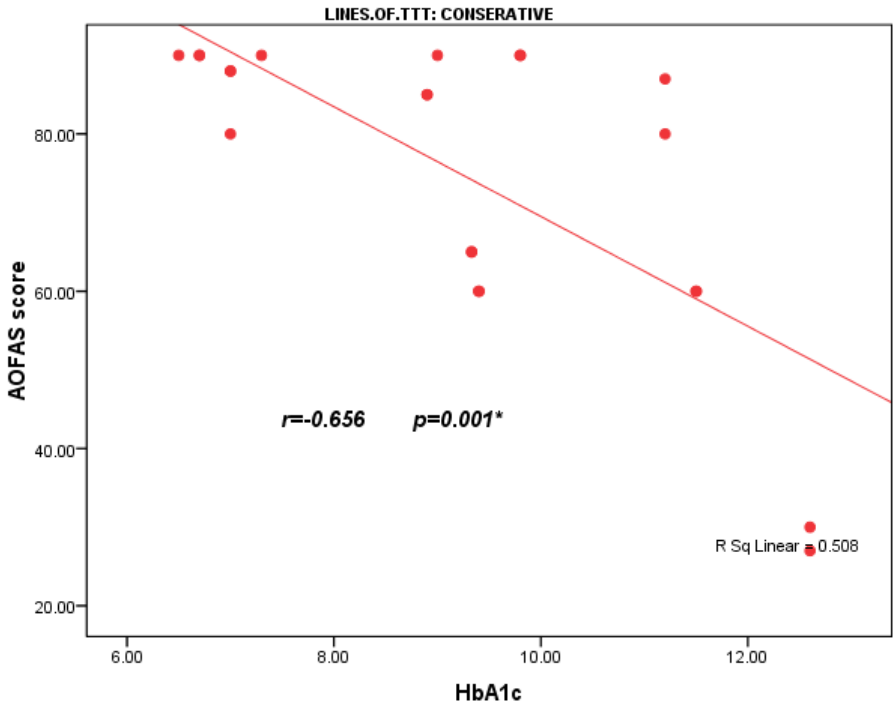

Figure (2): scatter diagram showing correlation between HBA1C & AOFAS score among cases with conservative treatment.

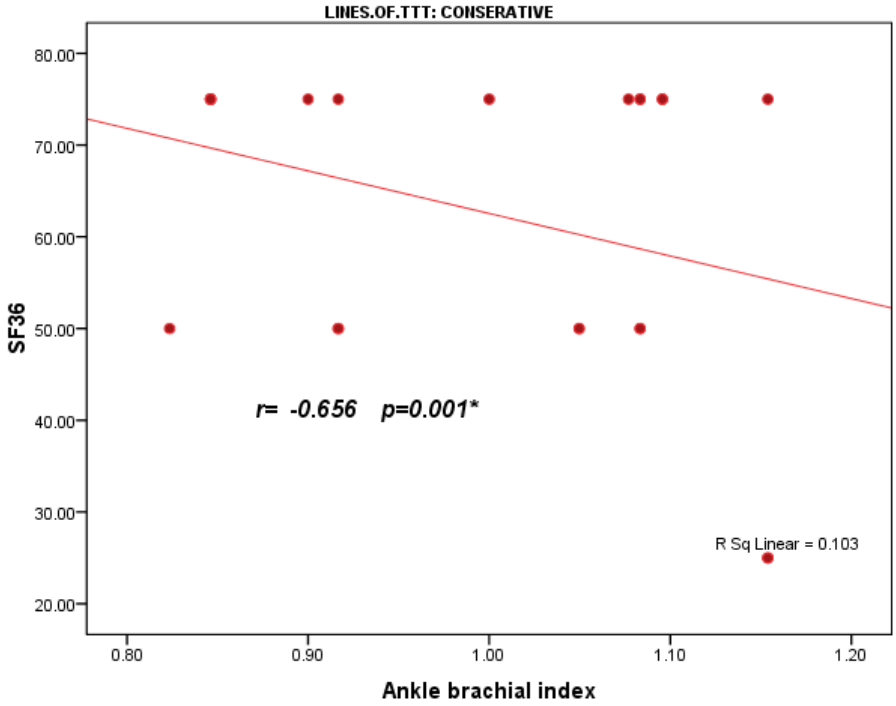

Figure (3): scatter diagram showing correlation between SF35 & ankle brachial index among cases with conservative treatment.

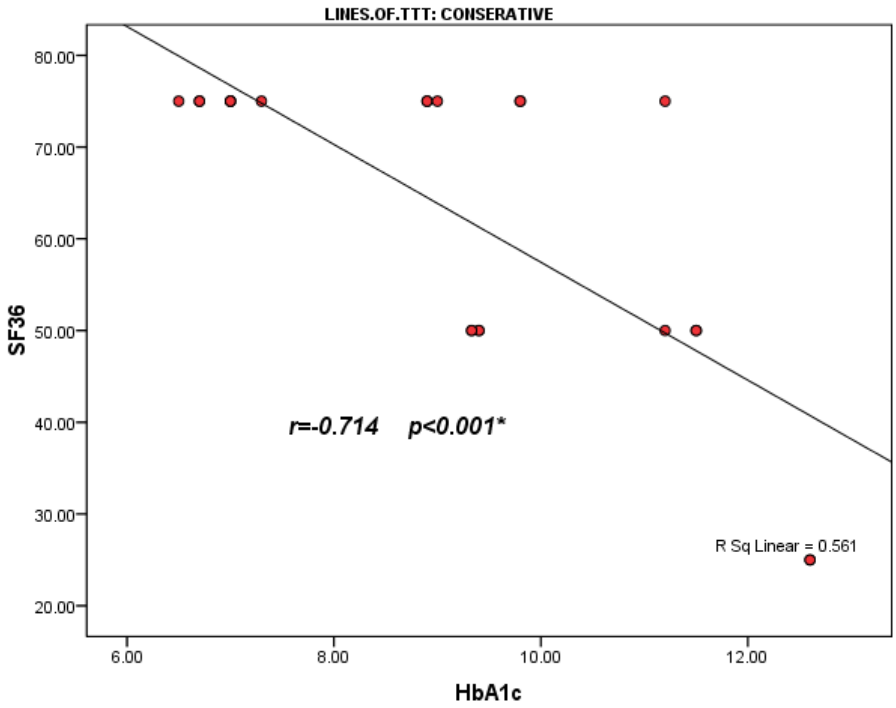

Figure (4): scatter diagram showing correlation between SF36& HBA1C among cases with conservative treatment.

Table (5): correlation between HBA1C, ankle brachial index with AOFAS score and SF36 among cases with operative therapy.

Operative	**AOFAS score**		**SF36**	
	r	P	r	P
HbA1c	-0.311	0.159	-0.407	0.06
Ankle brachial index	-0.076	0.736	-0.144	0.522

r: Spearman correlation coefficient, *statistically significant

Table (5) illustrates no statistically significant correlation between AOFAS, SF36 with HBA1c& ankle brachial index (p>0.05)

McCormack and Leith reported 26 diabetic patients with ankle fractures, 19 of which were treated operatively, they noted one wound complication and four infections with two transtibial amputations in their operatively treated group, with an overall complication rate of 47%, they did not have any complications in their non-diabetic group. (13)

Lanzetti et al. analyzed ninety patients retrospectively, with surgically treated ankle fracture, patients were classified in two groups: diabetic and non-diabetic patients, 38.9% of patients showed wound complications (6 wound infection requiring revision surgery, 12 wound infections treated with antibiotics, seven cases of delayed wound healing), of them. 17.1% were non-diabetics and 82.9% were diabetics (21)

According to our study we had 13 patients (29.5%) with complications. Four cases had superficial infection but only one case required debridement and removal of the implant while the other cases were treated with antibiotics only. 3 cases developed Charcot neuroarthropathy and thy were all from the operative group.

Zakaria et al. (20) conducted a study in 2022 that was carried out on 34 diabetic patients with ankle fractures with 15 (44%) patients having controlled diabetes (HbA1c<7) and 19 (56%) patients having uncontrolled diabetes (HbA1c≥7). During the follow-up period, all patients were evaluated regarding the postoperative complications (including superficial wound infection, delayed wound healing, delayed union, nonunion, arthritis, and unplanned surgery for revision or hardware removal) and functional outcome using the AOFAS-Hind-foot score. The complication rate in this study was 47.1% of all studied patients, with 26.7% in the controlled diabetes group and 63.2% in the uncontrolled diabetes group. With a statistically significant increase in complications rate in the uncontrolled DM group, it was found that complications of delayed wound healing, superficial wound infection, and

delayed union were more in the uncontrolled diabetes group, whereas other complications like arthritis and unplanned surgeries were almost equal in both groups. All cases of postoperative wound complications were treated with frequent dressing and antibiotics with no cases requiring readmission or surgical debridement.

In our study we had 44 diabetic patients with mean HbA1c is 8.63±1.98 gm%, mean random blood sugar is 261.74±155.36. Cases were randomly grouped to conservative and operative groups. Patients were followed up and evaluated for complications and their functional outcome by the use of AOFAS-hindfoot score and 36-Short form scoring system. Complication rate was 29.5%: 22.7 % of the conservative group and 36.4% of the operative group.

In Zakaria et al (20) study, the AOFAS score was used to assess the functional outcome, and it was found that the mean difference was 67 points in the controlled diabetes group, whereas the mean difference was 60 points in the uncontrolled diabetes group. Hence, the functional outcome was superior in the controlled diabetes group. This study concluded that there was a statistically significant increase in complications rate in the uncontrolled DM group with high HbA1c≥7%. These complications were mainly related to wound problems, such as surgical site infection and delayed wound healing. While the number of cases with poor radiological outcome was greater in the high HbA1c group than in the low HbA1c group, whereas unplanned reoperation and arthritis show almost near equal numbers.

Liu and colleagues studied 21 diabetic patients with ankle fractures treated surgically. They divided them in two groups: controlled diabetes group (HbA1c<6.5) and uncontrolled diabetes group (HbA1c≥6.5). They found that the overall complication rate was 76.2% among all studied patients, where 88.9% in the uncontrolled diabetes group had postoperative complications, whereas 66.7% of the controlled diabetes group had postoperative complications. Regarding radiological outcome, 100% of uncontrolled diabetes group showed poor outcome (delayed union, nonunion, or malunion), whereas only 33% of the controlled diabetes group showed poor radiological outcome. Thus, HbA1c levels were inversely correlated to radiological union; high HbA1c levels were associated with lower rates of union, whereas low HbA1c levels were associated with higher rates of union. The percentage of revision was 55.6% in the uncontrolled diabetes group and only 5% in the controlled diabetes group; however, there was no correlation between HbA1c level and the revision rates. At 6-month follow-up, HbA1c was inversely proportional to the AOFAS score as high HbA1c level was associated with poor AOFAS score, whereas low HbA1c was associated with high AOFAS score . (10)

Meanwhile in our study the mean AOFAS score was 76.91 showing no statistically significant difference between the two studied groups. While the 36 SF score mean was 61.93 showing no statistically significant difference between studied groups. When correlating the HbA1C in the two study groups it has been demonstrated that there is a statistically significant negative correlation between AOFAS score & HbA1c, between SF36 & HbA1c in the conservative group of patients. Ankle brachial index was assessed as an indicator for vasculopathy showed that it has a statistically significant negative correlation with 36 SF scoring system in the conservative group only.

Lovy et al. (2016) concluded that conservative treatment was accompanied with increased rate of complications compared with surgical treatment (75% vs 12.5%). Complication rate following unintended ORIF for persistent nonunion or malunion in nonoperatively treated patients was significantly greater compared with immediate ORIF (100% vs 12.5%,). They stated that conservative treatment of ankle fractures in diabetic patients was accompanied with a high unacceptable rate of complications when compared to surgical treatment. (15)

In our study we had 13 cases with radiological nonunion studied groups as the following: 27.8% of the patients of conservative group versus 27.3% of the patients of operative group have shown radiological nonunion. On the other hand, the mean of AOFAS score in the conservative group was 75 and in the operative group was 78.82. while the 36 SF score mean in the conservative group was 62.5 and in the operative group was 61.36. Thus, the complication rate and functional outcome from both operative and conservative line of treatment is nearly equal.

4. Conclusion

Diabetic ankle fracture is a debatable situation. Diabetic control and vascular affection (in ankle brachial index) can guide to management. With a controlled blood sugar level and good peripheral vascularity operative treatment can be done. While in uncontrolled diabetes and poor vascularity conservative treatment can be done.

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