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Randomized Comparative study between Reversed and Insitu Great Saphenous Vein Grafts in Infrapopliteal Revascularization

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ABSTRACT

Background: Foot ulcer is a disabling complication and not uncommon among patients with DM, the predictive factors for diabetic foot ulcer development were peripheral neuropathy, duration of diabetes, poor glycemic control, and peripheral vascular disease which was a major significant risk factor.

Aim of the study: to determine whether Reversed or Insitu Great Saphenous Vein Grafts is the optimum In Infrapopliteal Revascularization. **Patients and Methods:** diabetic patients referred to Vascular Surgery department of Al-Azhar University Hospitals and Nasr City Hospital were included if they had foot lesions such as ulcers, gangrene or tissue necrosis and had no palpable pedal pulses. End points were healed, healing, non healing or amputation. Fifty diabetic foot patients were included.

Results: twenty-four patients reached the end point of adequate healing or complete healing, whereas twenty-six patients had nonhealing lesions. The Ankle Peak Systolic Velocity (APSV) was significantly higher in patients with Reversed Great Saphenous Vein Grafts compared with patients with Insitu Great Saphenous Vein Grafts: 57.8cm/s (±12.72) versus 24.9 cm/s (±9.55), $p < 0.001$. At a cutoff point of 40 cm/s, the APSV showed sensitivity of 90.91%, specificity of 100%, positive predictive value of 100%, negative predictive value of 92.3%, with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions. There was a significant difference between the APSV before and after revascularization: 23.4 cm/s (±6.5) versus 58.8 cm/s (±12.3), $p < 0.001$. **Conclusion:** both reversed and insitu great saphenous vein grafts have good patency in infrapopliteal revascularization.

Keywords: Diabetes mellitus, Diabetic foot ulcer, Ankle Peak Systolic Velocity, Peripheral vascular disease.

INTRODUCTION

Foot ulcer is a disabling complication and not uncommon among patients with DM, the predictive factors for Diabetic foot ulcer development were peripheral neuropathy, duration of diabetes, poor glycemic control, and peripheral vascular disease which was a major significant risk factor [(1)].

The ankle-brachial index (ABI) is widely used for the assessment of the degree of peripheral ischemia[(2,3)]. However, this parameter is not accurate in the presence of arterial wall calcification as it gives falsely high results[(4)]. The toe-brachial index (TBI) has been used as an alternative because digital arteries are less affected by calcification[(5,6)]. However, the incidence of digital artery calcification among diabetics is still significant[(7)]. In addition, it is impossible to measure toe pressures in a substantial number of patients presenting with diabetic foot lesions because the toes are affected by ulcers or gangrene or have been amputated, which makes the TBI invalid or impossible to use[(8)].

PATIENTS AND METHODS

This study included 50 diabetic foot patients who presented to the Vascular Surgery department of Al-Azhar University Hospitals and Nasr City Hospital, Cairo, Egypt, during the period from April 2017 to April 2019.The patient population consists of 28 males and 22 females with a mean age 62.2 years (± 7.2).

Written informed consent:

An approval of the study was obtained from Al- Azhar University academic and ethical committee. Every patient signed an informed written consent for acceptance of the research.

Inclusion criteria:

Diabetic Patients with absent pedal pulses and complaining of foot lesion (tissue necrosis, ulcer, or gangrene).

Exclusion criteria:

Venous ulcers, malignant ulcers and autoimmune ulcers, ischemic limbs (i.e. rest pain) but without foot lesion.

Clinical examination:

At the initial clinical presentation full history was taken from every patient and the clinical data were prospectively collected regarding age, gender, risk factors and comorbidities, ABI and full details of duplex scanning, including APSV. Lesions were treated by daily dressings and followed up monthly. Post management, wound dressing protocol was standardized. Patients were followed up until they reached one of the end points of the study, which were a healed wound, a healing wound, non healing wound and major amputation. A wound was considered completely healed if it was fully covered with intact skin. It was considered adequately healing if it was completely covered with healthy granulation tissue, with absence of tissue necrosis or infection. It was considered nonhealed if it did not show signs of healthy granulation tissue during follow-up.

During follow-up, data were collected regarding wound status, the details of the management plan, details of duplex scanning including APSV, ABI.

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Statistical methodology:

The data collected were tabulated and analyzed using statistical package for social science.

Descriptive statistics:

Number (No.), percentage (%), mean (X), and standard deviation (SD) were determined. Significance level (P) value: P value >0.05 was considered nonsignificant (NS) and P value <0.05 was considered significant (S).

RESULTS

The study included 50 limbs, belonging to 50 patients, Their mean age was 62.2 years (± 7.2). All patients were diabetic, The demographic characteristics and risk factor distribution are shown in Table (1).

Table (1): Baseline clinical characteristics of patients

		No.	Percent (%)
Gender	Male	28	56
	Female	22	44
Age (year)	Mean ± SD	62.6 ± 7.2	
	Min.	44	
	Max.	82	
Ischemic heart disease (IHD)	Negative	32	64
	Positive	18	36
End stage renal disease (ESRD)	Negative	46	92
	Positive	4	8
Hypertension (HTN)	Negative	31	62
	Positive	19	38
Diabetes	Negative	0	0
	Positive	50	100
Smoking	Negative	30	60
	Positive	20	40
History of previous Amputation	Negative	37	74
	Positive	13	26

Twenty-four limbs with diabetic foot lesions reached the end point of adequate healing or complete healing: (23 patients undergo angioplasty revascularization and 1 was candidate for conservative treatment).

Twenty-two limbs (44%) did not heal: Three limbs (6%) ended with nonhealing lesions (all had endovascular intervention), Six limbs (12%) had below knee amputations following failed revascularization (5 endovascular interventions and 1 Bypass surgery, 13 limbs (26%) had above knee amputation following failed revascularization (2 Endarterectomy and 11 Bypass surgery).

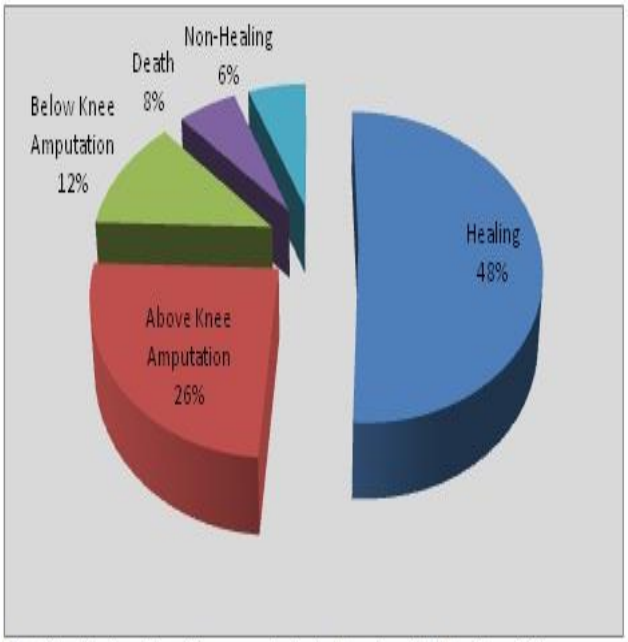

Fig.(1) : End points of the current study showing 48% healing , 6% nonhealing , 12% below knee amputation , 26% above knee amputation , 8% death

Four patients (8%) died, shown in Figure 1.

The average mean APSV of the 24 limbs with healed or adequately healing lesions was significantly higher than that of the 26 limbs with non-healing lesions: 57.86cm/s (±12.72) versus 24.90 cm/s (±9.55), p < 0.001, shown in table 2, figure 2.

Table 2: Comparison between patients as regard APSV

APSV (mean±SD)	Healed patients	Non healed patients	T-test	P-value
Pre	23.04 ±6.51	20.96 ±6.21	1.156	0.253
After 1 week	57.46 ±13.62	25.00 ±8.91	9.912	**<0.001**
After 4 weeks	57.83 ±12.61	24.65 ±11.41	9.071	**<0.001**
After 8 weeks	58.00 ±12.61	22.65 ±10.41	9.071	**<0.001**
After 24 weeks	59.31 ±11.85	23.97 ±10.87	9.888	**<0.001**
Average APSV	57.86 ±12.72	24.90 ±9.55	10.284	**<0.001**

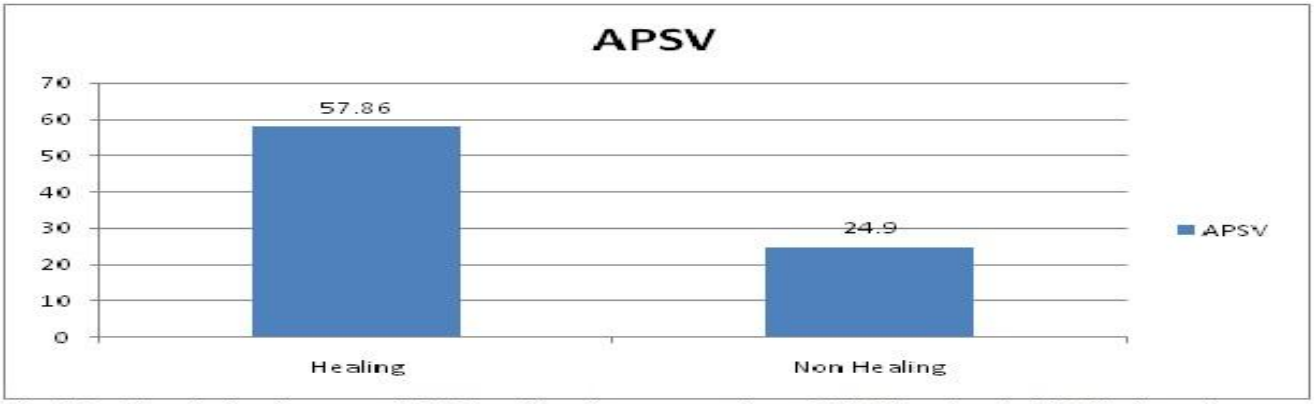

Fig.(2) : Correlation between APSV and healing , at a value of 57.86 cm/sec(±12.72) the patient healed while, at a value of 24.91 cm/sec(±9.55) the patients neither healed nor showed any progression of healing.

ROC curve was used to determine the cutoff APSV value with the maximum sensitivity and specificity. A cutoff value of 40 was with sensitivity of 90.91% specificity of 100% positive predictive value of 100%, negative predictive value of 92.3% with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions, shown in figure (3).

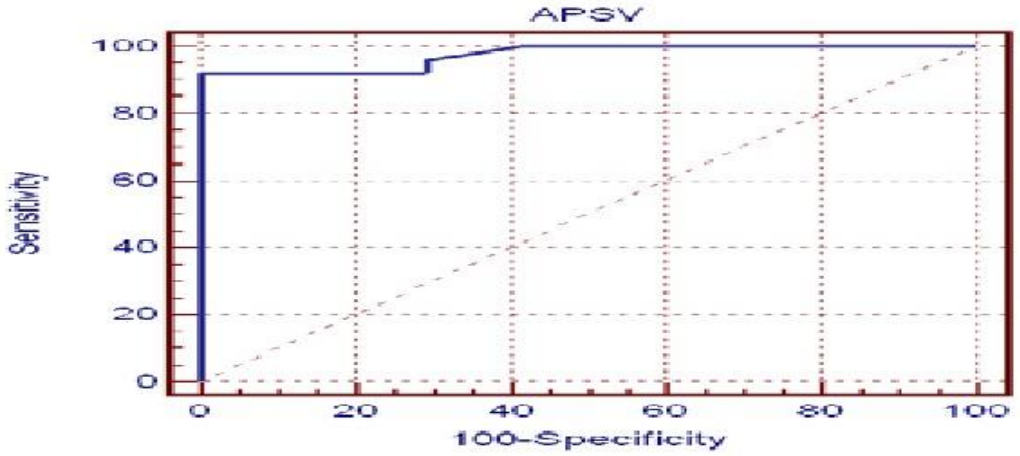

Fig.(3) : ROC curve determine the cutoff APSV value with the maximum sensitivity and specificity . a cutoff value of 40 was with sensitivity of 90.91% , specificity of 100% ,with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions .

This table shows that smoking, renal failure and history of previous amputation have a significant effect especially on the non healed patients.

Table (3): Logistic regression of factors affecting the patients

Demographic and Risk factors	B	Sig.	Exp(B)	95.0% C.I. for EXP(B)	
				Lower	Upper
Age	-0.07	0.204	0.93	0.84	1.04
Sex	1.37	0.111	3.93	0.73	21.13
DM	-0.33	0.840	0.72	0.03	18.16
Smoking	-2.13	**0.015**	0.12	0.02	0.66
Hypertension	-0.47	0.494	0.62	0.16	2.42
IHD	-0.52	0.475	0.60	0.15	2.45
ESRD	-1.26	**0.049**	0.28	0.03	2.50
History of previous amputation	-2.13	**0.015**	0.12	0.02	0.66
Dyslipedemia	-0.39	0.544	0.68	0.19	2.40

DISCUSSION

Many noninvasive methods have been described to predict wound healing of foot lesions in diabetic patients. These include ankle-brachial pressure[9], toe-brachial pressure [9,10], transcutaneous oxygen[10], skin perfusion pressure [11-13], radioisotope clearance [14], photoplethysmography [15] and laser Doppler ultrasonography[12]. The utility of the ankle-brachial pressure measurement is limited by the fact that a significant proportion of diabetic patients suffer some degree of arterial wall calcification [16,17]. The utility of toe pressure measurement is also limited by the possibility of calcification of the digital arteries [8]. APSV is not affected by such limitations[18].

Skin perfusion pressure at a cutoff value of 40 mm Hg has a sensitivity of 72% and a specificity of 88% in predicting wound healing.(11) Transcutaneous oxygen measurements at a cutoff value of 34 mm Hg have a sensitivity of 78.6% and a specificity of 83% in predicting wound healing[19]. The sensitivity and specificity of APSV in our study compare favorably with previously reported results of ankle peak systolic velocity (APSV), skin perfusion pressure and transcutaneous oxygen.

If foot perfusion is significantly impaired as indicated by a low APSV, healing is unlikely. However, if foot perfusion is adequate, as indicated by a high APSV, wound healing is highly suspected. Using the ROC curve, it was found that the cutoff value of 40 cm/sec. gives the highest specificity and sensitivity to predict healing in this cohort of patients: sensitivity of 90.91%, specificity of 100%, positive predictive value of 100%, negative predictive value of 92.3%, with diagnostic accuracy of 97.4% in predicting healing of diabetic foot lesions.

Bishara *et al.* [18] stated that APSV at a cutoff value of 35 cm/s showed a sensitivity of 92.9%, a specificity of 90.6%, a positive predictive value of 92.9%, and a negative predictive value of 90.6%.

CONCLUSION

Both reversed and insitu great saphenous vein grafts have good primary and secondary patency in infrapopliteal revascularization.

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