Midterm Results of Endovascular Management of Multilevel Arterial Disease in Lower Limb in Diabetic Patients

AHMED TAHA, M.D.**; AMR ABOU ELROUS, M.Sc.*; AHMED SAYED, M.D.**; MOURAD ELKHOLY, M.D.* and IHAB HANNA, M.D.*

The Department of Vascular Surgery, National Institute of Diabetes* and Deprtment of General & Vascular Surgery, Cairo University**

Abstract

Background: The most common cause of mortality and morbidity in diabetics is diabetic vasculopathy.

The multilevel arteriosclerosis leads to a massive decrease in blood perfusion distally.

Aim of Study: The aim of this retrospective review is to assess the midterm results of 1ry & 2ry patency & limb salvage rates after endovascular management of multilevel arterial disease in lower limb of diabetic patients suffering from incapacitating intermittent claudication or Critical lower limb ischemia (CLI).

Patients and Methods: Diabetic patients presented with incapacitating claudication or critical lower limb ischemia (CLI) due to multilevel vascular arterial disease with no history of previous attempts of lower limb revascularization, were included, whom angioplasty was done, from the beginning of January 2013 till the end of December 2013.

Results: 101 diabetic patients with multi-level arterial disease in lower limbs were studied. Their mean age was (64.4 ± 14 years) and 62.4% of patients were male. We classified the patients to sub-groups (A, B, C & D) depending on the level of the proximal lesion, Group A lesion start from level of the aorta or CIA to tibials 5.9%, Group B lesion start from level of EIA or CFA to tibials 5%, Group C lesion start from upper level of Popliteal artery to tibials 5.9%.

We also classified the patients to 2 group: Group (F) (n.=83) 82% which included all patients had full revascularization for all diseased arterial levels & group (P) (n.=18) 18% which included all patients had revascularization for proximal levels only.

The worst presentations were associated with worse morphological nature of the lesions & its level. (p=0.042). Initial technical success was significantly better in patients with Minor tissue loss (97.0%) & in patients with rest pain & intermittent claudication (94.7%) than patients with major tissue loss (75%) (p=.029). With no significant difference in comparison of sub groups (A, B, C&D) (p=.443). 1ry patency

at 3, 6 & 12 months showed no significant difference in comparison of sub groups (A, B, C & D). But 1ry patency was significantly higher in group (F) than in group (P), The 1ry patency rate decreased significantly in group (P) where we failed to deal with the distal level, 2ry patency at 6 months was (77.2%) & at 12 months was (71.3%) with no significant difference of 2ry patency between sub-groups (A, B, C & D) (p=.078), The 2ry patency was significantly higher in group F compared to group P (p=.001) at 6 month & (p=.001) at 12 month.

Patients achieved limb salvage in (81 patients) 80.2% & a major amputation rate was needed in (20 patients) 19.8% over 1 year. Group (F) patients showed significantly higher limb salvage rate & significant lower amputation rate than group (P). (p=.001). Complications were significantly higher in sub-groups A & C, which were mostly dissection (p-value =0.001). Mortality rate was 3%.

Conclusion: Full correction for multilevel arterial lesions with direct pulsatile flow to the foot shows better 1ry, 2ry patency & limb salvage rates than correction of the proximal level only.

Limb salvage & patency rates in management of multilevel arterial lesions were significantly affected by the increasing number of co-morbidities, risk factors & worse presentation of the patients.

Key Words: Multilevel arterial lesions – Critical limb ischemia – Diabetics – Angioplasty.

Introduction

DIABETES is one of the leading causes of chronic disease and limb loss worldwide, currently affecting 382 million people [1].

The multilevel arteriosclerosis leads to a massive decrease in blood perfusion distally & facilitate micro-thrombi formation so severe ischemia of the limbs had developed [2].

Lower extremity artery disease (LEAD) is a marker of a more advanced atherosclerotic process often affecting multiple vascular beds beyond the

Correspondence to: Dr. Amr Abou Elrous, E-Mail: drabouelrous@gmail.com

lower limbs, with a consequent increased risk for all-cause and cardiovascular mortality [3].

Amputation is a devastating but preventable complication of diabetes and peripheral arterial disease (PAD) [4].

Aorto-iliac disease is a common manifestation of atherosclerosis. Individuals with this condition may have limb symptoms ranging from claudication to limb-threatening ischemia. Revascularization is reserved for individuals with lifestyle-limiting claudication despite conservative therapy and in those with chronic limb-threatening ischemia [5].

More than 50% of all PAD cases involve the SFA due to multiple forces exerted on the SFA & induce significant stress which promoting more diffuse disease & occlusions more than stenosis so the SFA is the most commonly diseased artery in the peripheral vasculature [6].

The adductor canal has non-laminar flow dynamics, especially with walking in challenges for endovascular devices (stents) [6].

In diabetic patients with lower limb arterial disease, the vascular involvement is extremely diffuse and particularly severe in tibial arteries, with high prevalence of more than 10cm occlusion lesions [2].

Many studies of patients with multilevel disease showed a significantly improved 1ry patency, 2ry patency & limb salvage rates in group of patients with correction of all levels compared to group of patients who had correction for a single level [7,8].

Aim of the work:

The aim of this retrospective review is to assess the clinical effectiveness and related mid-term patency rate of percutaneous trans-luminal angioplasty (PTA) for atherosclerotic lesions affecting more than one level in lower limb arterial tree in diabetic patients.

Symptomatic Patients, who included in this study, are diabetic patients suffering from incapacitating claudication or patient with critical lower limb ischemia (CLI), due to different combination of iliac, femoral, popliteal & tibial arteries lesions.

This study focused on achieving limb salvage in patients with multilevel arterial disease who suffering from incapacitating claudication or Critical lower limb ischemia.

Patients and Methods

Diabetic patients presented with incapacitating claudication or critical lower limb ischemia (CLI) due to multilevel vascular arterial disease with no history of previous attempts of lower limb revascularization, who had admitted to the Department of Vascular Surgery at National Institute of Diabetes and Endocrinology & the Department of Vascular Surgery at Kasr El Aini Hospital from the beginning of January 2013 till the end of December 2013, were included in our study.

These patients underwent a follow-up period of about one year.

Inclusion criteria:

- 1-Diabetic patients of any age & sex.
- 2- Patients with atherosclerotic multilevel arterial lesions in lower limb.
- 3- Patients suffered from incapacitating claudication or Critical lower limb ischemia.

Exclusion criteria:

- 1-Non diabetic patients.
- 2- Patients who have one level arterial disease in lower limbs.
- 3- Asymptomatic patient.
- 4- Patient with previous history of lower limb revascularization.

This is a retrospective review of prospective collected data of 101 consecutive patients with symptomatic peripheral arterial disease, either incapacitating claudication, rest pain or tissue loss, who underwent PTA of multiple levels arterial stenosis or occlusion.

Clinical outcome, including improvement in rest pain and ulcer healing/resolution, were documented prior to discharge and at subsequent outpatient visits, with repeat ankle brachial index (ABI) and/or ankle peak systolic velocity (APSV) & arterial duplex performed within six weeks.

All patients had an arterial duplex performed for diagnosis and characterization of the lesions, Initial CTA was not standard practice in our department, ordered only as a protocol for aortic & Iliac arteries lesions, all patients had a full vascular assessment, including clinical history, physical examination, ABI, PSV, risk factor profile and serum creatinine. On the basis of this assessment, appropriate medical management was commenced to the patients, along with risk factor modification.

Procedure details:

Ipsilateral antegrade femoral arterial puncture was performed in patients with middle 1/3 SFA lesion or more distal lesions, contra-lateral femoral with cross over was performed in patients with EIA, CFA & proximal SFA lesions near to its origin & some times for CIA with good nipple for manipulation & brachial arterial puncture technique was used in aorto-iliac lesions.

In aorto-iliac lesions, primary stenting with balloon expandable stents for CIA & selfexpandable stents for EIA after predilatation of the lesion were done.

SFA lesions were crossed to the nearest run off vessel by intra-luminal or sub-intimal routes, in mild to moderate stenosis we confirm crossing & dilating the further distal vessels (popliteal & tibial arteries) from distal to proximal, in tight stenosis & occlusion we dilate the SFA first.

Residual SFA stenosis more than 30% or dissection are dilated and stented. Proximal revascularization of aorto-iliac level or SFA level is considered satisfactory alone in patient with intermittent claudication. For rest pain & tissue loss further lesions need to be dilated except if procedure extends for long time or patient has renal impairment or complaint of chest pain.

Finally, routine angiography was performed with the guide-wire remaining across the lesion and procedure outcome was recorded.

A dose of 0.1mg nitroglycerine was given as an intra-arterial bolus with arterial spasm, sheath removed after angiography done with appropriate hemostasis with manual compression.

After the intervention, ^{1 st} dose of LMWH used 6 hour after the procedure with therapeutic dose in 1st week for all patients in combination with an antiplatelet drug (clopidogrel 75mg daily followed by acetylsalicylic acid 150mg daily thereafter) & (cilostazol 200mg daily for non-cardiac PT) & naftidrofuryl 600mg daily for 3 months Together with lipid lowering agents (atorvastatin 40mg once daily) in dyslipidemic patients.

Case (1)



Fig. (1): Diagnostic angiography show occluded Lt. CIA, passage of wire subintimally, balloon dilatation.

IT CLA POST STENTING LT CFA POST

Fig. (2): Post Lt. CIA stenting with good flow through Lt. CIA, EIA, CFA & SFA.



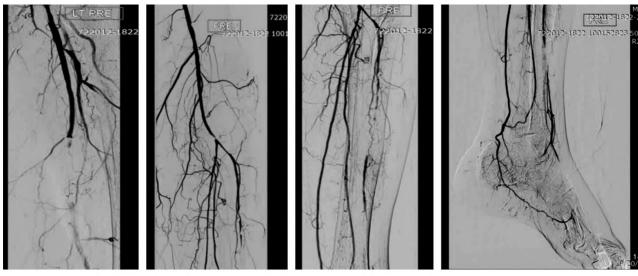


Fig. (3): Diagnostic angiography show total occlusion of SFA & ATA.

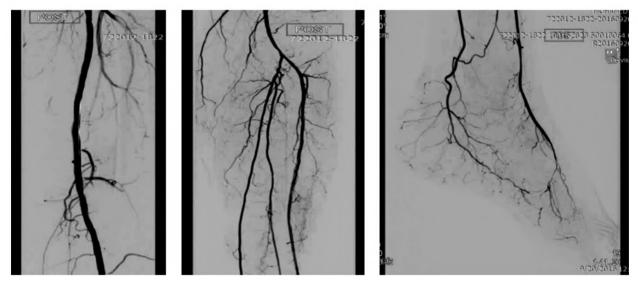


Fig. (4): Angiography post procedure with successful balloon angioplasty of SFA, ATA, Dorsalis artery.

Clinical improvement & follow-up:

Clinical improvement was judged by:

- 1-Palpable peripheral pulse.
- 2- Increase of claudication distance.
- 3- Disappearance of rest pain.
- 4- Wound healing.
- 5- Limb salvage.

Control of infection & wound care management were done parallel to the revascularization procedure.

Clinical improvement was documented prior to discharge and at subsequent outpatient visits, Wound closure & Limb salvage are our main target & the end point of our study. Follow-up was done at 3,6,12 months after the procedure with clinical examination and duplex study.

Primary patency was defined as patent treated arteries without recurrent stenosis or occlusion & the need for further intervention.

2ry patency was defined as recurrent stenosis or occlusion in treated vessels which interfere with wound healing & need for re-intervention.

Technical failure was defined as an inability to cross the lesion at the time of the primary procedure or by the presence of an occlusion or 50% restenosis within the first 30 days after the initial procedure.

Results

This is retrospective review included 101 diabetic patients of different age & sex with Overall the mean age was (64.4 ± 14 years) and 62.4% of patients were male.

We classified our patients to sub-groups (A, B, C & D) depending on the level of the proximal lesion, Group A lesion start from level of the aorta or CIA to tibials 5.9%, Group B lesion start from level of EIA or CFA to tibials 5%, Group C lesion start from level of SFA to tibials 83.2%, Group D lesion start from upper level of Popliteal artery to tibials 5.9%.

We also classified our patients to 2 group: Group (F) (n.=83) 82% which included all patients had full revascularization for all diseased arterial levels & group (P) (n.=18) 18% which included all patients had revascularization for proximal levels only.

In our study Overall the mean age was $(64.4\pm14$ years) and 62.4% of patients were male.

The initial technical success showed no significant difference in comparison of sub groups (A, B, C & D) (p=.443).

Initial technical success was significantly better in patients with Minor tissue loss (97.0%) & in patients with rest pain & intermittent claudication (94.7%) than patients with major tissue loss (75%) (p=.029).

Table (1): Initial technical success according to presentation.

| Presentation | Intermittent Claudication | Rest Pain | Minor Tissue Loss | Major Tissue Loss | Total |
|----------------------|------------------------------|--------------|-------------------------|-------------------------|-------|
| Initial technical | 94.7% | 94.7% | 97.0% | 75.0% | 94.1% |

success

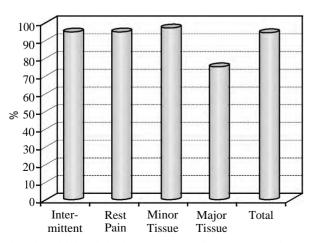


Fig. (5): Initial technical success according to presentation.

75% of patients presented with major tissue loss, all of them had their most proximal lesion an occlusion.

100% of patients presenting with intermittent claudication & 73.7% of patients presenting with rest pain had their proximal lesion in the form of stenosis.

So the worse morphological nature of the lesions were associated with the worse presentations. (p-value=0.042).

Table (2): Morphology and presentations.

| Mor- phology | Inter- mittent Claud- ication | Rest Pain | Minor Tissue Loss | Major Tissue Loss | Total |
|------------------------|--|--------------|-------------------------|-------------------------|------------|
| Occlusion | 0 (0.0%) | 2 (10.5%) | 6 (50.0%) | 25 (37.3%) | 33 (32.7%) |
| Occlusion, stenosis | 0 (0.0%) | 3 (15.8%) | 3 (25.0%) | 13 (19.4%) | 19 (18.8%) |
| Stenosis | 1 (33.3%) | 2 (10.5%) | 0 (0.0%) | 9 (13.4%) | 12 (11.9%) |
| Stenosis, occlusion | 2 (66.7%) | 12(63.2%) | 3 (25.0%) | 20 (29.9%) | 37 (36.6%) |

In this retrospective study 1ry patency rates for patients with critical limb ischemia at 0, 3, 6 and 12 months were 93.1%, 84.2%, 70.3% & 65.3%, respectively.

1ry patency at 3, 6 & 12 months showed no significant difference in comparison of sub groups (A, B, C & D).

Table (3): Primary patency rates.

| 1 ry patency rate | А | В | С | D | Total | <i>p</i> ⁻ value |
|---|--------------------------|-------------------------|-------------------------|--------------------------|-------------------------|--------------------------------|
| Initial technical success | 100.0% | 100.0% | 91.7% | 100.0% | 93.1% | 0.443 |
| At 3 month At 6 month At 12 month | 100.0% 50.0% 50.0% | 80.0% 80.0% 80.0% | 82.1% 71.4% 65.5% | 100.0% 66.7% 66.7% | 84.2% 70.3% 65.3% | 0.217 0.516 0.669 |

1ry patency was significantly higher in group (F) than in group (P), The 1ry patency rate decreased significantly in group (P) where we failed to deal with the distal level of occlusions, such distal level of occlusion was the Femoro-Popliteal segment in Aorto-iliac lesions or the tibials in SFA lesion.

Table (4): Shows the comparison of 1ry patency of different follow-up durations of groups (F) & (P).

| 1 ry patency rate | F | р | Total | <i>p</i> -value |
|----------------------|-------|-------|-------|-----------------|
| Initial success rate | 97.6% | 72.2% | 93.1% | p-value = 0.002 |
| At 3 month | 91.6% | 50.0% | 84.2% | p-value = 0.001 |
| At 6 month | 77.1% | 38.9% | 70.3% | p-value = 0.002 |
| At 12 month | 72.3% | 33.3% | 65.3% | p-value = 0.002 |

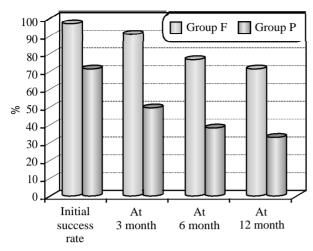


Fig. (6): The comparison of 1ry patency of different followup durations of groups (F) & (P).

In this study increasing numbers of risk factors & co-morbidities had drawback on 1ry patency rate at 3 month (*p*-value=0.006) & 12 month (*p*-value=0.012).

2ry patency re-intervention was needed in 8 patients due to re-stenosis or total occlusion of the lesions with lost pulses; appearance of claudication or rest pain or deterioration of the wound healing.

2ry patency rate at 6 month was: 77.2% & at 12 month was: 71.3%.

This study showed no significant difference of 2ry patency between sub-groups (p=.078).

Table (5): 2ry patency rate in different sub-groups.

| Sub-group | А | В | С | D | Total | <i>p</i> -value | | |
|--|----------------|------------------|----------------|----------------|----------------|-----------------|--|--|
| At 6 month At 12 month | 83.3% 83.3% | 100.0% 100.0% | 76.2% 69.0% | 83.3% 83.3% | 77.2% 71.3% | 0.62 0.38 | | |
| 100 90 80 70 60 \$50 40 30 20 10 0 | | | | | | | | |
| Subgroup Subgroup Subgroup Subgroup A B C D | | | | | | | | |
| Fig. (7): 2ry patency rate in different sub-groups. | | | | | | | | |

The 2ry patency was significantly higher in group F compared to group P (p=.001) at 6month & (p=.001) at 12 month.

Table (6): 2ry patency rate in different groups.

| Group | F | р | Total | <i>p</i> -value |
|-------------|-------|-------|-------|-----------------|
| At 6 month | 84.3% | 44.4% | 7.2% | 0.001 |
| At 12 month | 78.3% | 38.9% | 71.3% | 0.001 |

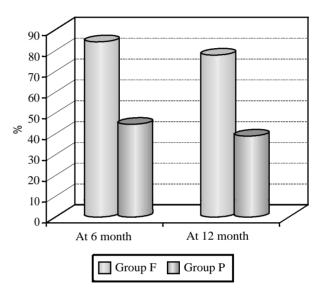


Fig. (8): 2ry patency rate in different groups.

Limb salvage was achieved in 81 patients (80.2%) & in 20 patients (19.8%) a major amputation was needed, above knee amputation (AKA) was done for 7 patients 6.9% & below knee amputation (BKA) was done for 13 patients 12.9% in this retrospective study.

There were no significant differences in limb salvage rate or major amputations rate between the different subgroups (A, B, C & D). (p=.245).

Table (7): Major amputations & limb salvage in different subgroups.

| Ampu- tations | А | В | С | D | Total |
|---------------------------|------------|-----------|------------|------------|------------|
| AKA | 0 (0.0%) | 1(20.0%) | 6 (7.1 %) | 0 (0.0%) | 7 (6.9%) |
| BKA | 0 (0.0%) | 0 (0.0%) | 13 (15.5%) | 0 (0.0%) | 13 (12.9%) |
| Total ampu- tations | 0 (0.0%) | 1(20.0%) | 19 (22.6%) | 0 (0.0%) | 20 (19.8%) |
| Limb Salvage | 6 (100.0%) | 4 (80.0%) | 65 (77.4%) | 6 (100.0%) | 81 (80.2%) |

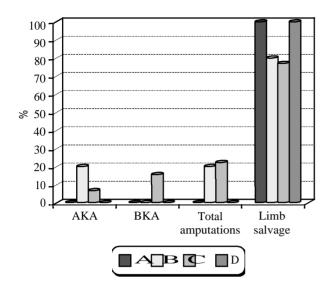


Fig. (9): Major amputations & limb salvage in different subgroups.

Group (F) patients showed significantly higher limb salvage rate & significant lower amputation rate than group (P). (p=.001).

Table (8): Major amputation & limb salvage vs. patient groups.

| Group | F | р | Total |
|---------|-----------|------------|------------|
| AKA | 4 (4.8%) | 3 (16.7%) | 7 (6.9%) |
| BKA | 6 (7.2%) | 7 (38.9%) | 13 (12.9%) |
| Amp | 10 (12%) | 10 (55.6%) | 20 (19.8%) |
| Salvage | 73 (88%) | 8 (44.4%) | 81 (80.2%) |
| Total | 83 (100%) | 18 (100%) | 101 (100%) |

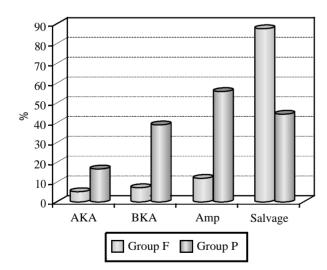


Fig. (10): Major amputation & limb salvage vs. patient groups.

Patients presented with major tissue loss showed higher amputation rates & patients presented with intermittent claudication or rest pain showed significantly higher limb salvage rates. (p=.003).

Table (9): Major amputations & limb salvage in different presentations.

| Ampu- tations | Inter- mittent Claud- ication | Rest Pain | Minor Tissue Loss | Major Tissue Loss | Total |
|---------------------------|--|-----------------------|-------------------------|-------------------------|------------------------|
| AKA BKA | 0 (0.0%) 2 (10.5%) | 0 (0.0%) 2 (10.5%) | 4 (6.0%) 6 (8.9%) | 3 (25.0%) 5 (41.7%) | 7 (6.9%) 13 (12.9%) |
| Total ampu- tations | 2(10.5%) | 2 (10.5%) | 10 (14.9%) | 8 (66.7%) | 20 (19.8%) |
| Limb Salvage | 17(89.5%) | 17 (89.5%) | 57 (85.1%) | 4 (33.3%) | 81 (80.2%) |

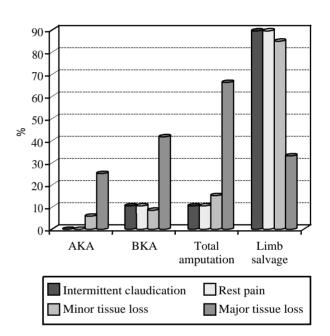


Fig. (11): Major amputations & limb salvage in different presentations.

In our study increasing numbers of risk factors & co-morbidities had drawback on limb salvage rate (p-value=.001) & followed with increasing the amputation rate (p-value=.025).

Complications occurred in 47 patients (46.5%), Dissection was the most common complication occurred in 40 patients (39.6%) & mostly in (groups A & C) (p-value=0.001).

Stent were used in 44 patients (43.6%) as a bailout stenting in 40 patients & primary stenting in 4 patients.

Perforations occurred in 3 patients, elastic recoil occurred in 2 patients & arterial spasm occured in 2 patients with no significant differences.

Mortality rate was 3%, 3 patients died during the period of follow-up.

Discussion

Diabetic vasculopathy is the most common cause of mortality and morbidity in diabetes and is responsible for high incidence of vascular diseases including PVD [2].

Amputation is a devastating but preventable complication of diabetes and peripheral arterial disease (PAD) [4].

Pathological changes of major blood vessels leads to functional and structural abnormalities in diabetic vessels including endothelial dysfunction reduced vascular compliance and atherosclerosis [10,11]. The duration and severity of diabetes correlate with incidence and extent of PAD [12]. Diabetics are up to 15 times more likely than nondiabetics to suffer a major amputation. Diabetes is also associated with decreased primary patency following endovascular interventions [13].

In our study, 101 diabetic patients of different age & sex were retrospectively studied for angioplasty with multi-level arterial disease in lower limbs & presented with incapacitating claudication or CLI.

Claudication has a relatively benign natural history & associated with a low risk of limb loss [14].

Miura et al., considered superficial femoral plus iliac lesions in addition to age, dialysis, left ventricular dysfunction, diabetes, hematoma prolonging hospitalization & coronary artery disease as positive predictors of all-cause mortality [15]. Almost 70% diabetic patients with critical limb ischemia in study done by Kassaian et al., had a positive history of hypertension and were under antihypertensive treatment, and 4% of their study populations were current smokers [16]. In our study increasing numbers of risk factors & co-morbidities, (e.g. hypertension, ischemic heart disease (IHD), smoking, renal impairment, stroke or chest disease), had drawback on 1ry patency rate at 3 month (pvalue=0.006) & 12 month (p-value=0.012) & on limb salvage rate (p-value=.001) & followed with increasing the amputation rate (*p*-value=.025). Abularrage et al., reviewed that DM is an independent predictor of decreased long-term primary patency after PTA/stent in 920 patients underwent 1075 PTA/Stent procedures & long-term limb salvage remains inferior in diabetic patients compared with non-diabetic patients due to a more severe clinical presentation and poor runoff [13]. In our study overall the mean age was 64.4 ± 14 years and 62.4% of patients were male. In a study

done by Ghoneim et al., which included 511 cases of chronic atherosclerotic critical lower limb ischemia (CLI), the mean age was 64.5 years [17]. Sadek et al., mentioned in his study about multilevel disease, which included 85 patients. The Age was 72.4±13.1 years & 67% were men [7]. Guo et al. reported in his study, Endovascular treatment for patients with TASC II D femoropopliteal occlusive disease, the mean age of patients were 74.2±8.2 (range, 58.0-91.0 years) [18]. In a study of 45 diabetic patients, Kassaian et al., found (76 %) of the patients were men [16]. Endovascular interventions for critical limb ischemia (CLI) continue to have variable reported results, adequate rates of limb salvage can be achieved in patients undergoing multilevel interventions for CLI, and improved patency is seen with multilevel compared to isolated tibial interventions [8].

We classified our patients to sub-groups (A, B, C & D) depending on the level of the proximal lesion, Group A lesion start from level of the aorta or CIA to tibials 5.9%, Group B lesion start from level of EIA or CFA to tibials 5%, Group C lesion start from level of SFA to tibials 83.2%, Group D lesion start from upper level of Popliteal artery to tibials 5.9%.

We also classified our patients to 2 group: Group (F) (n.=83) 82% which included all patients had full revascularization for all diseased arterial levels & group (P) (n.=18) 18% which included all patients had revascularization for proximal levels only.

Guo et al., classified patients with multiple segmental lesions to groups from iliac to tibial arteries 26 patients (19.8%) patients, from SFA to tibial arteries 86 patients (65.6%) patients, from Popliteal to tibial arteries 19 patients (14.5%) patients and found the vascular involvement is extremely diffuse and particularly severe in tibial arteries, with high prevalence of more than 10cm occlusion lesions [2].

In our study the aortoiliac disease constitutes approximately 10.9% of total patients group A&B while infra-inguinal was 89.1%. In 511 patients studied by Ghoneim et al., aortoiliac disease constitutes approximately 16% of total patients, while infra-inguinal was 84% & multilevel arterial disease were diagnosed in 92% patients [17]. We reported that 69.3% of the below the knee lesions were occlusion among our 101 diabetic patients with critical lower limb ischemia & among more proximal lesions occlusions constituted 51.5% of our patients. Graziani et al., reported that 66% of all below the knee lesions were occlusions in 417 diabetic patients with critical lower limb ischemic & foot ulcer, vascular involvement is extremely diffuse and particularly severe in tibial arteries, with high prevalence of long occlusions [19]. Our study showed that the worse presentations were associated with worse morphological nature of the lesions (*p*value=.042).

In our study the technical success rate was 9 1. 1 %, on 12 month follow up primary patency, secondary patency, and limb salvage were 65.3, 71.3. 80.2%, respectively. Our initial technical success was significantly better in patients with Minor tissue loss (97.0%) & in patients with rest pain & intermittent claudication (94.7%) than patients with major tissue loss (75%) (p-value=.029).

Although, there are no significant differences in primary patency rates between sub-groups (A, B, C & D) at 12 month follow-up, 1ry patency was significantly higher in group (F) with full revascularization for all diseased arterial level than in group (P), The 1ry patency rate decreased significantly in group (P) where we failed to deal with the distal level of occlusions. Such distal level of occlusion was the Femoro-Popliteal segment in Aorto-iliac lesions or the tibials in SFA lesion.

Sadek et al., reported technical success rate for all procedures 91 %. On 12 month follow up primary patency & secondary patency rate were $(50\% \pm$ 8%) & $(71\% \pm 7\%)$, respectively [7]. The technical success rate was 94% On 24 months follow-up, primary patency & secondary patency were 77.8 & 84.7, respectively, in the study done by Ghoneim et al. & his results were higher than our results due to involvement of a single level lesion in the total results [17].

Our 2ry patency rate was 71.3% & we noticed significantly higher 2ry patency rate in group F compared to group P (p=.001) at 6month & (p=.001) at 12 month but We didn't notice significant differences of secondary patency rates between the different sub-groups (A, B, C & D).

Similar to our results, two studies of patients with multilevel disease showed a significantly improved 2ry patency rate of multilevel intervention compared to single level intervention [7,8].

In a study included 53 patients with TASC II D femoro-popliteal occlusive disease, Gue at al., showed a technical success rate of 95% & the mean follow-up time was 12.2±6.1 months (5-38 months). Primary patency rate at 1 year was 63%, assisted primary patency rate at 1 year was 77% & Secondary patency rate at 1 year was 96% & these results were better than ours because they included femoropopliteal segment only which was treated by 1ry stenting. Other levels were not included [15]. In another study of multilevel diseases, the presence of major tissue loss showed a significantly worse limb salvage rate (p-value=0.001) with total limb salvage rate 90.7% at 2 year follow-up [17].

In this retrospective study stents were used in 44 patients (44/101) 43.6%, patients with morphological nature of proximal occlusions showed high rate of stenting in comparison to patients with proximal stenosis which treated successfully with ballooning only (PTA).

Guo et al., used 1ry stenting in SFA for TASC II D femoro-popliteal occlusive disease in 53 patients (100%) [18]. Ghoneim et al., Performed SFA stenting in 97 patients (48%), while iliac artery stenting was used in 36 patients (90%). No stents were used in tibial vessels [17].

46.5% of our patients developed complications, dissection occurred in 39.6% & treated with stenting. Perforation occurred in 3.0%, recoil occurred in 2.0% & spasm occurred in 2.0%. Ghoneim et al., reported that the morbidity was 23% in the angioplasty group. Flow limiting dissection was the main complication in about 20% of endovascular cases (All were treated by stents except one requiring surgery). Other complications were 4%, which included extra-vasation, embolization, retroperitoneal hematoma, acute pulmonary edema, and failed endovascular revascularization [17].

Our overall mortality rate was 3%, early mortality rate was 1% due to myocardial Infarction, all died from other causes not related to the procedure. Miura et al., reported that the mortality rate was 2.8% at 1 year & the cause of death was cardiovascular in 42.8% of cases [15]. Ghoneim et al., reported that the mortality rate was 5.3%; this higher percentage was due to including patients who had open vascular surgical interventions [17].

Conclusion:

Full correction for multilevel arterial lesions with direct pulsatile flow to the foot shows better 1ry, 2ry patency & limb salvage rates than correction of the proximal level only.

Limb salvage & patency rates in management of multilevel arterial lesions were significantly affected by the increasing number of co-morbidities, risk factors & worse presentation of the patients.

References

- 1- HINGORANI A., LAMURAGLIA G.M., HENKE P., M.D., MEISSNER M.H., LORETZ L., ZINSZER K.M., DRIVER V.R., FRYKBERG R., CARMAN T.L., MARSTON W. and MURAD M.H.: The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, J. Vasc. Surg., 63 (2): 3S-21S, 2016.
- 2- GUO X., SHI Y., HUANG X., MENG YE, XUE G. and ZHANG J.: Features Analysis of Lower Extremity Arterial Lesions in 162 Diabetes Patients, J. Diabetes Res., 2013: 781360, 2013.
- 3- Mislav Vrsalovic & Victor Aboyans, Antithrombotic Therapy in Lower Extremity Artery Disease, Current Vascular Pharmacology, 18 (3): 215-222, 2020.
- 4- SAMANTHA DANIELLE MINC, BRIAN HENDRICKS, RANJITA MISRA, YUE REN, DYLAN THIBAULT, LUKE MARONE and GORDON STEPHEN SMITH: Geographic variation in amputation rates among patients with diabetes and/or peripheral arterial disease in the rural state of West Virginia identifies areas for improved care, J. Vasc. Surg. May, 71 (5): 1708-1717, 2020.
- 5- ISMA N. JAVED and BEAU M. HAWKINS: Aorto-iliac peripheral artery disease, Prog Cardiovasc Disease. Mar-Apr., 65: 9-14, 2021.
- 6- MADASSERY S., TURBA U.C. and ARSLAN B.: Role of Stent Grafts and Helical-Woven Bare-Metal Stents in the Superficial Femoral and Popliteal Arteries, Tech. Vasc. Interv. Radiol. Jun., 19 (2): 153-62, 2016.
- 7- SADEK M., ELLOZY S.H., TURNBULL I.C., LOOK-STEIN R.A., MARIN M.L. and FARIES P.L.: Improved outcomes are associated with multilevel endovascular intervention involving the tibial vessels compared with isolated tibial intervention, J. Vasc. Surg. Mar., 49 (3): 638-43, 2009.
- 8- FERNANDEZ N., MCENANEY R., MARONE L.K., RHEE R.Y., LEERS S., MAKAROUN M. and CHAER R.A.: Multilevel versus isolated endovascular tibial interventions for critical limb ischemia, J. Vasc. Surg. September, 54 (3): 722-729, 2011.
- 9- RUPERT BAUERSACHS, MARIANNE BRODMANN, CHRISTOPHER CLARK, SEBASTIAN DEBUS, MAR-CO DE CARLO, JORGE FRANCISCO GOMEZ-CEREZO, JURAJ MADARIC, LUCIA MAZZOLAI, JEAN-BAPTISTE RICCO, HENRIK SILLESEN and VICTOR ABOYANS: International public awareness of peripheral artery disease, Vasa. Jul., 50 (4): 294-300, 2021.

- 10- ZHANG H., DELLSPERGER K.C. and ZHANG C.: The link between metabolic abnormalities and endothelial dysfunction in type 2 diabetes: An update, Basic Res. Cardiol., 107 (1): 1-11.
- 11- ZHANG H., DELLSPERGER K.C. and ZHANG C.: The link between metabolic abnormalities and endothelial dysfunction in type 2 diabetes: An update, Basic Res. Cardiol., 107 (1): 237, 2012.
- 12- BOSEVSKI M.: Peripheral arterial disease and diabetes, Prilozi, 33 (1): 65-78, 2012.
- 13- ABULARRAGE C.J., CONRAD M.F., HACKNEY L.A., PARUCHURI V., CRAWFORD R.S., KWOLEK C.J., LAMURAGLIA G.M. and CAMBRIA RP.: Longoutcomes of diabetic patients undergoing endovascular infrainguinal interventions term. J. Vasc. Surg., 52 (2): 314-22, 2010.
- 14- TANNER I. KIM, GATHE KIWAN, ALAA MOHAMED ALI, YAWEI ZHANG, ALAN DARDIK, RAUL J. GUZ-MAN and CASSIUS IYAD OCHOA CHAAR: Multiple Reinterventions for Claudication are Associated with Progression to Chronic Limb-Threatening Ischemia, J. Annals Vascular Surgery. Apr., 72: 166-174, 2021.
- 15- MIURA T., SOGA Y., MIYASHITA Y., IIDA O., KAWA-SAKI D., HIRANO K., SUZUKI K. and IKEDA U.: Fiveyear prognosis after endovascular therapy in claudicant patients with iliofemoral artery disease. J. Endovasc. Ther., 21 (3): 381-8, 2014.
- 16- KASSAIAN S.E., MOHAJERI-TEHRANI M.R., DEH-GHAN-NAYYERI A., SAROUKHANI S., AN-NABESTANI Z., ALIDOOSTI M., SHIRANI S., SHO-JAEI-FARD A., MOLAVI B., POORHOSSEINI H., SALARIFAR M., ABOEE-RAD M., PASHANG M. and LARIJANI B.: Major adverse events, six months after endovascular revascularization for critical limb ischemia in diabetic patients, Arch. Iran. Med. May, 16 (5): 258-63, 2013.
- 17- GHONEIM B., ELWAN H., ELDALY W., KHAIRY H., TAHA A. and GAD A.: Management of Critical Lower Limb Ischemia in Endovascular Era: Experience from 511 Patients, Int. J. Angiol. Sep., 23 (3): 197-206, 2014.
- 18- GUO X., XUE G., HUANG X., XIE H., LIANG W., ZHANG J., LIN F. and YAO T.: Outcomes of endovascular treatment for patients with TASC II D femoropopliteal occlusive disease: A single center study, BMC Cardiovasc Disord. May, 29 (15): 44-50, 2015.
- 19- GRAZIANI L., SILVESTRO A., BERTONE V., MAN-ARA E., ANDREINI R., SIGALA A., MINGARDI R. and DE GIGLIO R.: Vascular involvement in diabetic subjects with ischemic foot ulcer: A new morphologic categorization of disease severity, Eur. J. Vasc. Endo. Vasc. Surg. Apr., 33 (4): 453-60, 2007.

النتائج متوسطة المدى للعلاج بالقسطرة الطرفية للإصابات متعددة المستوى بشرايين الساق لمرضى السكر

تعتبر إصابة الشرايين جزء من الإصابات التى تنتج عن مرض السكر وتعتبر السبب الشائع لحدوث الإصابات والوفيات بين مرضى السكر ومسئولة عن إرتفاع معدلات الإصابة با لأمراض الناتجة عن أمراض الشرايين كجلطة المخ والذبحة الصدرية وأمراض الشرايين الطرفية.

أمراض الشرايين الطرفية تميل بطبيعتها لإصابة الشريان في عدة مستويات أعلى وأسفل الركبة وبزيادة المرض يعانى المريض من القصور الحرج في الدورة الدموية للساق وإذا لم تعالج قد تنشأ القرح التي لا تلتئم وقد تصل إلى البتر في بعض الأحيان.

هذه الدراسة ضمت مئة وواحد مريض من مختلف الأعمار والأجناس والتى تم إدخالهم قسم جراحة الأوعية الدموية بالمعهد القومى لأمراض السكر والغدد الصماء وقسم جراحة الأوعية الدموية بمستشفى قصر العينى وقد تم التخطيط لعمل توسيع للمستويات المتعددة من إصابات شرايين الساق وذلك فى الفترة من أول يناير ٢٠١٣ وحتى نهاية ديسمبر ٢٠١٣ وقد تم عمل متابعة للمرضى لمدة عام.

يعانى مرضانا من إصابات شرايين متعددة المستوى وتتوزع على إمتداد الشريان حيث تبدأ من الشريان الأورطى بالبطن تحت مستوى الشرايين الكلوية وحتى مستوى شرايين الساق تحت الركبة مع إختلاف طبيعة الإصابات من حالة لأخرى.

وقد تم تقسيم المرضى إلى عدة مجموعات معتمدين على مستويات أصابات الشرايين وكذلك مستويات إعادة فتح الشرايين لجميع المستويات المصابة أو للمستوى العلوى فقط.

لم نجد أي فروق ملحوظة في المعدلات الأولية والثانوية لإنفتاح الشرايين ومعدلات المحافظة على الساق بين المجموعات المختلفة.

فى المجموعة التى تم علاج جميع مستويات الإصابة بها تلاحظ زيادة المعدل الأولى والثانوى لإنفتاح الشرايين ومعدلات المحافظة على الساق بالمقارنة بالمجموعة الأخرى والتى تم بها إصلاح المستوى العلوى فقط.

لاحظنا أن نسبة المحافظة على الساق ومعدلات إنفتاح الشرايين تتأثر بزيادة عدد عوامل الخطر والإعتلال كما تتأثر بمدى سوء الحالة عند مناظرتها أول مرة.

المرضى الذين يعانون من أعراض سيئة كفقد جزء كبير من الأنسجة لوحظ زيادة نسب البتر فيما بينهم أما المرضى الذين يعانون من ألام عند المشى أو ألام مع الراحة أظهروا زيادة فى نسب المحافظة على الساق.