مستشفى باقدو والدكتور عرفان العام
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Intermediate Results of Percutaneous Endovascular Therapy and Bypass Surgery of Femoropopliteal Occlusive Disease: Retrospective Non-Randomized Study

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Objective:-
This non-randomized retrospective study was designed to evaluate the effectiveness of treating of superficial artery occlusive disease percutaneously with balloon dilatation with / without stents and surgical femoral to above knee popliteal bypass with synthetic materials.

Material and Methods:-
Femoro-popliteal PTA and femoro-popliteal bypass (synthetic graft) were performed on 118 consecutive limbs (109 patients) from March 2003 to March 2007. Patients had symptoms ranging from claudication to rest pain with or without tissue. The limbs that were treated with angioplasty with / without self expandable stents (n=56). The limbs were treated surgically with PTFE or Dacron grafts (n=62). The length of occlusion or stenosis ranging from 2cm to 24 cm. follow up evaluation with ankle brachial index and color duplex were performed at 1,3, 6 and 12 months.

Results:-
Patients were monitored for a median of 12 months. No statically difference was found between the two groups in primary patency (p=.895). In surgical group Technical success was achieved in 94% of patients while in PTA group 91%. The 12-month patency, in surgical group primary patency was 73% while in PTA group, primary patency was 77%.

Conclusion:-
The choice of open surgical bypass vs. percutaneous angioplasty and stenting for femoro-popliteal segment is still of controversial. Nevertheless, in our study shows no significant difference in synthetic bypass vs. endovascular fashion provided you apply the TASC recommendations for the SFA treatment. However still we need longer period follow up and do randomized comparative study between endovascular & bypass surgery

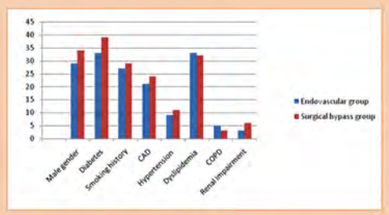
Materials and methods:-
The study was retrospective, non-randomized trial conducted at Kasr Eni hospital, Cairo university and private institution (DR. Erfan and Bagedo general hospital, Jeddah, KSA), between March 2003 to March 2007.
All patients had preoperative measurement of their Ankle Brachial Index (ABI). Baseline ABIs were 0.57 ± 0.19 for the angioplasty group and 0.46 ± 0.22 for the surgical bypass group. All patients were categorized according to revised version of the Joint Council of the Society of Vascular Surgeons and North American Chapter of the International Society of Cardio Vascular Surgeons (SVS/ISCVS) scale for chronic lower limb ischemia. Patients risk factors and co-morbidities, including sex, age, smoking history, diabetes mellitus, hypertension, dyslipidemia, and renal impairment or End Stage Renal Disease (ESRD), all were determined according to the Society of Vascular Surgery reporting standards. Preoperative lesion evaluation was obtained by either MRA or Ultra Fast Multi-axial CT angiography.

To be included in the study, patients had to have atherosclerotic stenotic or occlusive of superficial femoral artery, with no significant aorto-iliac disease. In addition, in the infra-popliteal segment had to be patent and at least one single vessel run off to the ankle.

Enrolled patient were divided into two treatment groups: percutaneous treatment +/- stents or open surgical femoro- AK popliteal bypass with synthetic graft (PTFE and Dacron). The categorization into each group according to TASC 2000 classification for femoropopliteal segment, according to its recommendation in which angioplasty was best solution for TASC A and preferred to B lesions. TASC C and D with associated co-morbidities in whom surgery is contraindicated, angioplasty also used. While bypass group includes TASC C and D lesions or TASC A and B with contraindications to angioplasty, (e.g. high incidence for renal failure with contrast)

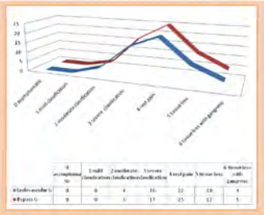
Study population. Between March 2003 and March 2007, 118 consecutive limbs in 109 patients met the inclusion criteria. The limbs that were treated with angioplasty with and without self-expandable stents (n=56) in 50 patients. The limbs were treated surgically with PTFE or Dacron grafts (n=62) in 59 patients. In six patients, one limb was treated by angioplasty and the other by bypass surgery. The demographic and associated co-morbidities are summarized in table **1. The two groups, no** significant difference was found in the patients co-morbidities.

	Endovascular group	Surgical bypass group
Patients (n)	50	59
Male gender	29	34
Age, mean +/-SD (range)	71+/- 9.9	65.9 +/- 10.7
Diabetes	33	39
Smoking history	27	29
CAD	21	24
Hypertension	9	11
Dyslipidemia	33	32
COPD	5	3
Renal impairment	3	6



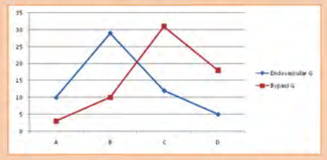
All patients were categorized according to revised version of the Joint Council of the Society of Vascular Surgeons and North American Chapter of the International Society of Cardio Vascular Surgeons (SVS/ISCVS) scale for chronic lower limb ischemia. Both groups were identical in the clinical assessment. Most of the patients were suffering of sever claudication to rest pain. None of both groups were asymptomatic and have mild claudication. Clinical grades of both groups are summarized in table 2.

Clinical grade	Endovascular group	Surgical bypass group
0 asymptomatic	0	0
1 mild claudication	0	0
2 moderate claudication	4	3
3 severe claudication	16	17
4 rest pain	22	25
5 tissue loss	10	12
6 tissue loss with gangrene	4	5



All patients with tissue loss and also with gangrene were diabetics, 25% and 27% in endovascular and bypass groups respectively.
By following the TASC grading system for femoro-popliteal lesions, each limb in both treatment groups was assigned a TASC classification as summarized in table 3. The TASC classifications between the two treatment groups were significantly different. Most of surgical group are TASC C (31/62= 50%) while in the angioplasty group the majority are TASC B (29/56= 51%).

TASC	Endovascular group	Surgical bypass group
A	10	3
B	29	10
C	12	31
D	5	18



Runoff score was calculated as described by Starr Registry. Each tibial vessel was assigned a score (0= <50% stenosis, 1= 50%-99% stenosis, and 2= occluded) the sum of which is total 0-6. No significant difference in both groups as regard the distal run off. None of both groups had score 5 or 6 as showed in table 4. At least one patent vessel distal run off should be present in all cases.

Starr Registry score	Endovascular group	Surgical bypass group
0	30	35
1	12	11
2	4	3
3	6	8
4	4	5
5	0	0

Clinical outcome was assessed with Society Vascular and International Society of Cardiovascular Surgeons assessment scale. The scale assigned a score of +3 for markedly improved symptoms combined with ABI >0.9 and +2 for improvement at least in a single chronic lower limb ischemia category combined with increase in ABI more than 0.15 above the preoperative measurement and +1 from either a single category improvement or an increase in ABI more than 0.15 or 0 for unchanged symptoms and -1 to -3 for deterioration of the symptoms and ABI (mild, moderate, and severe; respectively).
Duplex scanning of treated arterial segments was performed at 1, 3, 6 and 12 months. Stenosis free patency was defined by absence of stenosis more than 50% of treated arterial segment. Criteria of detection of restenosis greater than 50% are increase of peak systolic velocity (PSV) above 150 cm/sec.

Analysis of the data were performed using Fischer two sample of variance and Multiple Logistic regression analysis using the Analysis ToolPak of Microsoft Excel office 2007 application.

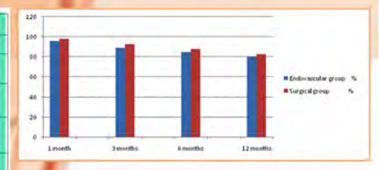
Results:-
Percutaneous angioplasty +/- stenting was technically successful in all treated limbs. Self-expandable stents were used in 38 limbs (38/56= 67%). Mean of 1.8 stents per limb. The mean diameter of the stent was 6 mm (4 to 7 mm). The mean total length of artery covered with the stent was 7.6 cm.
Femoral–AK popliteal artery bypass was successfully performed in all treated limbs in the surgical group. Dacron grafts were used in 18 limbs (29%), and ePTFE was used in 44 limbs (71%).
Immediate procedure-related and early postoperative, non-thrombotic complications were observed in seven limbs (12.5%) with the angioplasty group. In one patient, a dissection was created in the SFA at the entry point with extravasations of contrast. Cross over technique with retrograde contra-lateral femoral artery puncture and a stent was used to exclude the dissection. Another patient developed sub-intimal dissection with worsen distal run off in whom urgent bypass surgery is needed (femoro-lower popliteal bypass). One patient experienced transient severe leg edema in the treated limb. Deep venous thrombosis was ruled out, and the edema resolved by elevation of leg and bed rest. One patient reported severe thigh pain in the treated limb that required readmission to the hospital for pain management. The pain resolved ≤24 hours without any identifiable pathology. Two patients had a small groin hematoma that resolved without intervention. Last patient developed femoral pseudo aneurysm that required surgical repair.
In the surgical bypass group, early postoperative complications were observed in six (10%). Three patients developed a groin lymphocele, a groin seroma, and a small superficial groin wound dehiscence, respectively. The patient with a groin lymphocele was returned to the operating room for washout and re-closure of the wound. One patient developed gaped groin wound with severe infections and he required long hospital stay (27 days), in which several times of debridement and drainage were done and vacuum machine dressing was applied. One patient developed severe neurotic pain in the leg and foot that was treated by neurolipitic medications and improved. The last one developed persistent swelling in the leg and foot (acute lymphodema) that takes three months to resolve.

Clinical outcome was assessed with Society Vascular and International Society of Cardiovascular Surgeons assessment scale in the first month postoperative. An improvement in clinical grade occurred in 52 limbs (92%) in the angioplasty group and in 54 limbs (94%) in the surgical bypass group. The overall mean clinical improvement was nearly equal in both groups (86%). Deterioration of vasculature in angioplasty and surgical groups was 7% and 8% respectively. No changes in hemodynamic after intervention in surgical and endovascular groups was 6% and 7% respectively. At 12 months, the mean improvement in ABI was the same in both groups with no significant statically different values. The clinical grade improvement showed in the table 5.

Clinical grade improvement	Endovascular group	Surgical bypass group
+3	33 (58.92%)	36 (58.06%)
+2	12 (21.42%)	14 (22.58%)
+1	3 (5.35%)	3 (4.83%)
0	4 (7.14%)	4 (6.45%)
-1	1 (1.78%)	2 (3.22%)
-2	2 (3.57%)	2 (3.22%)
-3	1 (1.78%)	1 (1.61%)

Correlation between the clinical improvement and demographic features for both groups showed that diabetes is an important factor that plays significant role in the outcome. All patients showed deterioration clinically were diabetic in both groups.
Median follow-up duration was 12 months for both treatment groups
During this period, 11/56 (20%) of the angioplasty failed secondary to thrombosis and significant restenosis (>50%). An early thrombosis occurred in the recovery room the same day of the procedure in one patient and he required immediate surgical thromboectomy and heparin infusion. One stent thrombosis occurred within the first month after stent implantation, angiography was done and thrombolytic therapy applied with successful recanalization and limb salvage. The other 9 significant stenosis (>50%) and occlusion were detected after a mean period of 7+/- 2.3 months after angioplasty.
Of these 9 patients, two were successfully recanalized with intra-arterial tissue plasminogen activator–mediated lysis followed by balloon angioplasty of underlying stent stenosis. Three were in need for re-intervention by angioplasty and stenting for significant in-stent restenosis. Three were converted to open surgical bypass (three to the AK popliteal artery) as they were suffered from total occlusion of the SFA with failure for recanalization. Finally, one of the patients was found to have heparin-induced thrombocytopenia and amputation eventually was performed owing to progressive tissue loss. This patient had tissue loss preoperatively.
Overall, 11 interventions had to be performed in the angioplasty group during 12 months. Interventions required for 6 patients with TASC D, 4 patients with TASC C and one patient with TASC B.
Major amputations were done for 6 limbs (6/56= 10.7%) during the 12 months period.
In surgical group, one patient developed graft thrombosis in the 1st month postoperative with critical limb ischemia. Immediate surgical re-intervention required in form of femoro- lower popliteal bypass with successful perfusion and limb salvage. This patient was TASC D category.
Nine patients (14.5%) developed graft stenosis and occlusion during mean of 6.9 ± 4 months after graft placement. Three patients showed significant stenosis at the proximal stenosis and balloon angioplasty for these lesions was done successfully with good re-perfusion of the ischemic limbs. Three required femoro-distal bypass. Last three patients required major amputations with failure for limb salvage.
Total major amputations needed for surgical group were 5 (5/62=8.6%) during 12 months period follow up.
Cumulative primary patency rates were calculated with use of the life-table method. At follow-up at 1,3, 6 and 12 months, the respective primary patency rates were 96.0%, 89.0%, 85%, and 80%, for the angioplasty group and 98.0%, 93.0%, 88.0%, and 83.0% for the surgical bypass group. Table 6 summarizes the cumulative primary patency rate in 12 months follow up.

Primary patency follow up	Endovascular group		Surgical group	
	N	%	N	%
1 month	54/56	96	61/62	98
3 months	50/56	89	58/62	93
6 months	48/56	85	55/62	88
12 months	45/56	80	52/62	83



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