Comparative Study between Rate of Stenting after Mechanical Rotational Thrombectomy Using Rotarex® System versus Balloon Angioplasty for Treatment of Critical Limb Ischemia in the Femoropopliteal Segment

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Introduction: Balloon angioplasty in the femoropopliteal segment carries high success rates, especially for the short lesions, the primary patency after 1 year reaches a low rate of 47% to 65%. Selective stenting was done if there is flow-limiting dissection, or residual stenotic, were the primary patency increases to about 65 % at three years. The technique of Atherectomy depends on using a rotating cutting blade at its tip to excise the atheroma.

Pathients and methods: A total of 52 patients with CLI due to occlusions in the femoropopliteal segment. The patients were enrolled in a prospective non- randomized controlled study from February 2023 to March 2024. The first group was managed by Rotarex® device augmented by PTA if needed; the second group was managed by plain balloon angioplasty with selective stenting. Primary outcomes were safety, rate of stent application in each group and Secondary outcomes were technical success, clinical success, patency rates, limb salvage, rate of major adverse events.

Results: Primary assisted patency after six months was 80.77 % in Rotarex® group compared to 69.23 % in PTA group. Total number of major amputations were one case (3.85%) in Rotarex® group versus 5 cases (19.23%) in PTA group and the mortality at six months were 3 cases versus 2 cases in the Rotarex® group and PTA respectively.

Conclusion: Recanalization of chronically occluded femoropopliteal segment using Rotarex® system- is an advisable technique, with clinical and technical success better than traditional plain angioplasty with a lower rate of stenting.

Key words: Stenting, mechanical rotational thrombectomy, rotarex®, critical limb ischemia, angioplasty.

Introduction

It has been recorded that 1- and 5-year mortality rates of 20% and 50% in patients with Critical Lower Limb Ischemia, respectively.[1] And the untreated Critical Limb Ischemia patients have major amputation of 22% in 1 year.[2]

The concept of critical limb ischemia patients will include the group of patients with advanced lower limb ischemia, tissue loss, infection, and neuropathy. It also describes the severe form of peripheral arterial disease patients who suffer from rest pain, foot ulcers and gangrene above two weeks duration.[3]

The main target of revascularization in patients with critical limb ischemia is the wound healing, to minimize tissue loss and to decrease the comorbidities of amputation and mortality by treating arterial occlusion. In case of tissue loss, restoration of pulsatile flow to the foot is very important in limb saving.[4]

Treatment strategies for patients with Critical Limb Ischemia are not only depending on the lesion or the severity of ischemia. Society for Vascular Surgery Threatened Limb Classification system is considered the best tool depending on extension of wound, ischemia, and foot infection (WIfI) to guide revascularization strategies in these comorbid patients.[5]

Superficial femoral artery and popliteal artery occlusive lesions can be treated by endovascular techniques. Occlusive Lesions can be categorized by TASC and Global Limb Anatomic Staging System which may help to decide which of them can be treated successfully with endovascular techniques.[3]

Balloon angioplasty in the femoropopliteal segment carries high success rates, especially for the short lesions, the primary patency after 1 year reaches a low rate of 47% to 65%. Selective stent implantation was done If there is flow-limiting dissection, or residual stenotic lesion after ballooning, were the primary patency increases to about 65 % at three years.[6]

The technique of Atherectomy depends on using a rotating cutting blade at its tip to excise the atheroma. The device is usually used in the femoropopliteal arterial segment due to the risk of vessel perforation; however, it may be used in the below knee vessels.[7]

Thrombectomy devices are classified according to their physical action into two different divisions: the first, pure rotational mechanical atherectomy plus thrombectomy (MATH) systems and the second is only rheolytic thrombectomy devices. The first one (MATH) is the most commonly used and its example in the market as Rotarex® device.[8]

Rotarex® mechanical thrombectomy system was

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made for efficient and rapid extraction of the occluding thrombus material. The rotations of the blades produce a continuous vacuum inside the catheter, which leads to aspiration of the thrombus into the catheter and transportation into the collecting bag.[9]

On the contrary, it has many disadvantages like vessel perforation, dissection (May need covered stent), the high costs, distal embolization (May need thrombolysis) and inability to work well in the kinked or highly tortious vessel that makes the thrombectomy in-effective.[10]

Aim of work

This study aims to compare mechanical rotational thrombectomy using rotarex® System versus balloon angioplasty with or without stenting during the treatment of critical limb ischemia in the femoropopliteal segment as regard safety, feasibility and efficacy, also we aim to discuss low incidence of stent implantation in the mechanical thrombectomy based procedures over the plain angioplasty procedures.

Patients and methods

We reviewed our study on a total of 52 patients with critical limb ischemia due to occlusions in the femoropopliteal segment. The patients were enrolled in a prospective non- randomized controlled study which was done in Ain Shams University hospitals and Air Force hospital from February 2023 to March 2024. The first group was managed by mechanical rotational thrombectomy (Rotarex® device Straub Medical AG, Wangs, Switzerland) augmented by balloon angioplasty if needed, the second group was managed by plain balloon angioplasty with selective stenting.

The inclusion criteria includes patients with chronic (>3 months) onset of ischemia with an occlusive lesion in the femoropopliteal segment, Rutherford Becker classification (RBC) from IV to VI. Transluminal crossing of the lesion by the wire is mandatory for the mechanical thrombectomy group; also, primary or secondary lesions after previous vascular interventions were included as previous balloon angioplasty or stent implantation or previous open thrombectomy. Also, Patients accepting the risk of the procedure and sign the detailed informed consent.

Exclusion criteria includes acute limb ischemia, contraindications for the anti-platelet therapy or haemorrhagic tendency, vasculitis, and trauma patients, Patients with CKD and elevated serum creatinine level or hypersensitivity to contrast ,critically ill patients including pulmonary diseases, insufficient cardiac and hepatorenal functions, systemic infection, Sub-intimal crossing of the lesion by the wire (For mechanical thrombectomy group) and patients who don't accept the risk of our procedure or refuse to sign the detailed informed consent.

Study procedure

The procedure was done in the vascular catheter lab or an operating room with C-arm. Puncture site was prepared with antiseptic solution then the patient was draped before the procedure. The procedure was done under local, regional, or general anesthesia according to the general condition and cooperability of the patients.

Puncture site was either ipsilateral common femoral artery, contra-lateral common femoral artery or trans-brachial using Seldinger needle then sheath (6 French, 8 French, cross-over sheath or long sheath) was used. 5000 IU of heparin was given IV throw the sheath. Complete diagnostic angiography of the affected limb was done.

In the first group: Rotarex® device was used with its special guide wire 0.018 after transluminal crossing of the lesion, the rotational thrombectomy device will be slowly advanced and retracted to avoid embolic complications down- stream of the occlusion and may be repeated, if necessary, till complete restoration of the arterial lumen, completion angiography was done to determine the need of additional ballooning and/or stenting.

In the second group: After crossing of the lesion by the wire balloon dilation of the lesion using appropriate size balloon +/- stenting was done.

All patients were routinely scheduled to return for ambulatory follow-up visits at 30 days and then at 3, and 6 months. Technical Success was defined as restoration of the luminal patency during completion angiography with residual stenosis less than 50 % while the clinical success was defined by symptomatic relief as rest pain and signs as regaining of distal pulses.

Our Primary outcomes were safety, rate of stent application in each group and Secondary outcomes were technical success, clinical success, patency rates, limb salvage, rate of major adverse events (MAE) defined as death, myocardial infarction (MI), stroke, renal failure, and major complications (Requiring hospitalization and/or reintervention) including dissection, perforation, bleeding, re-thrombosis, distal embolization, false aneurysm, and infection during the period of follow-up.

Statistical Analysis & Package: Statistical analysis was performed using SPSS version 28.0.0 (SPSS, IBM, Chicago, IL, USA). Descriptive statistics was used for patient demographics, Chi square test was used to compare demographics, technical success, and complications between patients with different fiber tip configurations. T-test was used to compare means of Laser energy, vein parameters and VCSS

between the different laser fiber tip configurations. P-values was considered significant if <0.05.

Results

We conducted our study on 52 patients, 40 males and 12 females, 76.92 % and 23.08% respectively. Patients were divided into two groups first group (n=26) included 17 males and 9 females the second group (n=26) included 23 males and 3 females. Mean age of our population was 60.1 years old, population age ranged from 30 to 85 years. All the younger age population symptoms were due to premature atherosclerosis not due to vasculitis which was an exclusion criterion. Risk factors including DM, HTN, CAD, smoking all were written down and compared between both groups **(Table 1).** We noticed that P-value was non-significant which means good distribution of risk factors between the two study groups which allow fair comparison of the studied techniques.

Clinical demographics of the CLI patients were compared as rest pain, foot ulcer, and gangrene. 16 patients have rest pain in the first group in comparison to 9 cases in the second group, 5 cases have ulcers in their feet in the first group in comparison to 9 cases in the second group and 9 cases have gangrene both groups. From the study group, some patients had previous vascular interventions. Nine patients In the Rotarex® group and seven patients in Balloon angioplasty group. One case had previous amputation in each group, one case of EVAR in first group and two cases had previous tibial angioplasty, in the second group two cases underwent embolectomy procedure and two cases had CIA stenting and none of the second group had tibial angioplasty nor EVAR before **(Table 2).**

There was no statistically significant difference between two groups regarding number of occluded vessels or diagnostic modality. SFA was the main site of occlusion in both groups it represents 88.46% (23 cases) and 84.62% (22 cases) in the 1st and 2nd group respectively. CFA occlusion was noticed in 4 cases 15.38% in the 1st group in comparison to 8 cases 30.77% in the 2nd group. Popliteal artery occlusion was noticed in 16 and 15 cases in the 1st and 2nd groups respectively. We can notice that the total number of occluded arteries in each case was the same in both study groups **(Table 3).**

Endovascular procedures were done via transfemoral assess in total of 42/52 patients (19 case in Rotarex® group versus 23 patients in Balloon Angioplasty group), while contralateral access was used in 6 cases in the Rotarex® group, trans-popliteal access was used in one case in each group **(Table 3).**

Technical and clinical success were achieved in 26 cases (100%) in Rotarex® group and in 23 cases (88.46%) in PTA group. Although efficacy of the procedure wasn't statically different between each group, we can notice that failure rate is slightly higher among the second group. Primary failure occurred in 3 cases treated by balloon angioplasty 11.54% primary failure in 2nd group. After one month we lost two cases previously treated by Rotarex® technique due to mortality, not related to our procedure, the second group we lost two cases in that first month of follow up too. After three months of follow up patency rates were 84.62% in the 1st group and 73.08% in the 2nd group **(Table 4).**

Primary assisted patency (Final patency after six months) was 80.77 % in Rotarex® group compared to 69.23 % in PTA group , the Final patency rate and final failure rate weren't statistically significant, although numbers are in favorite of Rotarex® group **(Fig. 1)**, total number major amputations were one case(3.85%) in Rotarex® group versus 5 cases(19.23%) in PTA group and the mortality at six months were 3 cases versus 2 cases in the Rotarex® group and PTA respectively(figure 2) ,all mortalities from both groups were not related to the procedure **(Table 5).**

We compared different complications encountered in post-operative period with no big difference between both groups **(Fig. 2)**. Complication rates were 6 patients (23%) in the first group and 7 patients (26.9%) in the second one. First group had 3 cases with anemia that required blood transfusion, two cases of small puncture site hematomas treated conservatively, one cases of perforation that was managed by prolonged balloon inflation and another case of AKI , and one cases had distal showering treated with anticoagulation .The second group had one case of pseudoaneurysm treated by US guided compression and two cases of arterial dissection treated by stenting, one case of puncture site hematoma also treated conservatively. There were neither major adverse event like cardiac complications or stroke nor mortalities related to the procedures **(Table 6).**

Stenting was done in 2 cases in Rotarex® group in comparison with 9 cases in the angioplasty group, all stent implantation was in the SFA and was selective stenting after multiple trials of balloon dilatation **(Fig. 3)**, so the rate of stenting is significantly higher in angioplasty group than Rotarex® group with P-value 0.017 **(Table 5).**

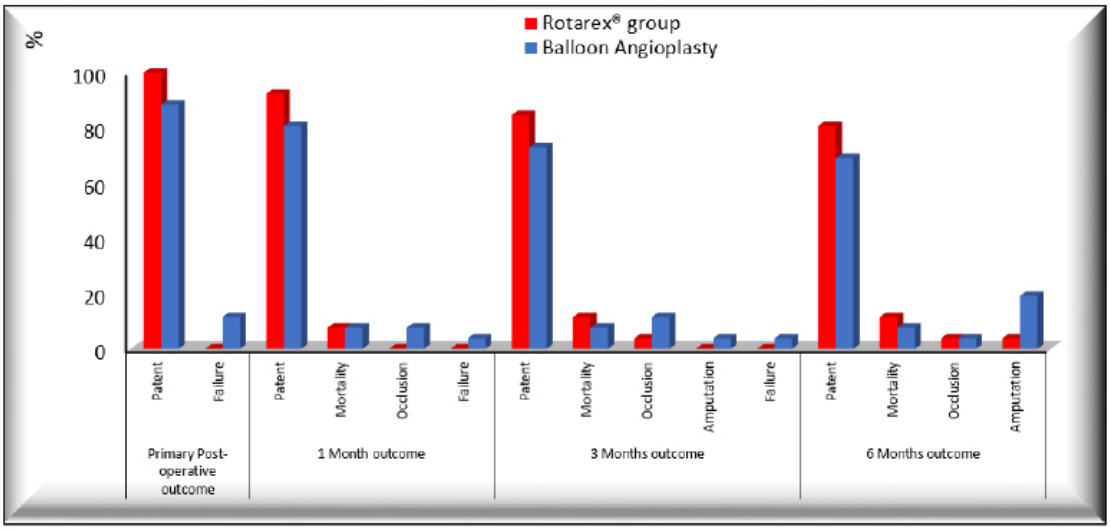

Fig 1: Bar chart descriptive for patency rates over 6months between patients in each group.

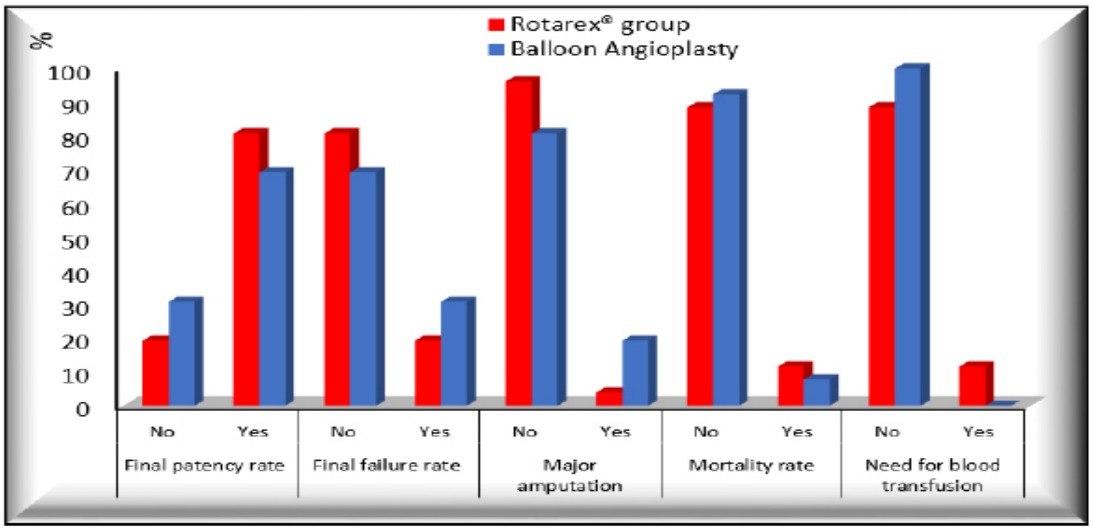

Fig 2: Bar chart descriptive for failure rate, amputation rate, and mortality rate in each group.

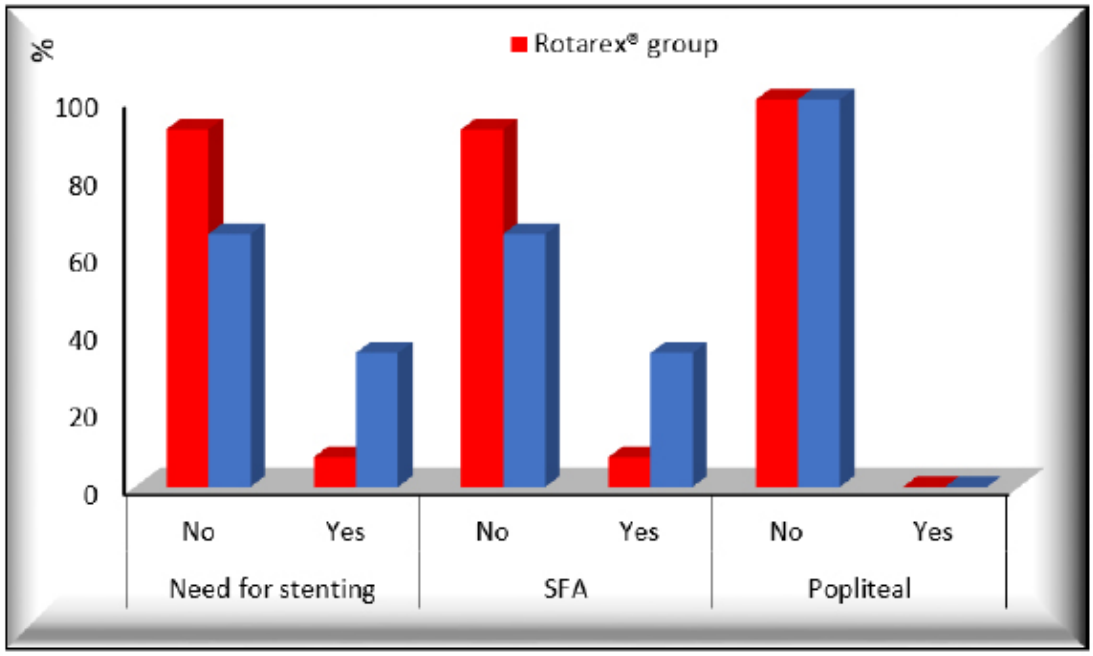

Fig 3: Bar chart descriptive for need of stenting in each group.

Table 1: Demonstrate patients' demographic data

Basic clinical data		Used technique									T-Test	
		Rotarex® group			Balloon Angioplasty			Total			t	P-value
Age	Range	41	-	85	30	-	81	30	-	85	2.804	0.007*
	Mean ±SD	64.808	±	10.000	55.423	±	13.828	60.115	±	12.853		
Chi-Square		**N**		**%**	**N**		**%**	**N**		**%**	**X^2**	**P-value**
Sex	Male	17		65.38	23		88.46	40		76.92	2.708	0.100
	Female	9		34.62	3		11.54	12		23.08		
DM		18		69.23	13		50.00	31		59.62	1.997	0.158
HTN		20		76.92	16		61.54	36		69.23	1.444	0.229
CAD		11		42.31	11		42.31	22		42.31	0.000	1.000
Smoking		14		53.85	20		76.92	34		65.38	3.059	0.080

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant.

Table 2: Clinical and previous vascular data of the patients

Ischemic symptoms	Used technique						Chi-Square	
	Rotarex® group		Balloon Angioplasty		Total			
	N	%	N	%	N	%	X^2	P-value
Rest pain	16	61.54	9	34.62	25	48.08	2.773	0.096
Gangrenous change	9	34.62	9	34.62	18	34.62	0.000	1.000
Foot ulcer	5	19.23	9	34.62	14	26.92	1.564	0.211
Previous vascular intervention	9	34.62	7	26.92	16	30.77	0.361	0.548
Tibials ballon angioplasty	2	7.69	0	0.00	2	3.85	2.080	0.149
EVAR	1	3.85	0	0.00	1	1.92	1.020	0.313
CIA stent	0	0.00	2	7.69	2	3.85	2.080	0.149
Embolectomy	0	0.00	2	7.69	2	3.85	2.080	0.149
Amputation	1	3.85	1	3.85	2	3.85	0.000	1.000

No statistically significant difference between both groups as regard their symptoms.

Table 3: Imaging modality, number of occluded vessels and access site

Diagnostic data		Used technique						Chi-Square	
		Rotarex® group		Balloon Angioplasty		Total			
		N	%	N	%	N	%	X^2	P-value
Diagnostic imaging modality	Duplex	8	30.77	10	38.46	18	34.62	0.340	0.560
	CTA	18	69.23	16	61.54	34	65.38		
Number of occluded vessels	1	7	26.92	7	26.92	14	26.92	0.000	1.000
	2	13	50.00	13	50.00	26	50.00		
	3	5	19.23	5	19.23	10	19.23		
	4	1	3.85	1	3.85	2	3.85		
SFA occlusion		23	88.46	22	84.62	45	86.54	0.165	0.685
POP occlusion		16	61.54	15	57.69	31	59.62	0.080	0.777
CFA occlusion		4	15.38	8	30.77	12	23.08	1.733	0.188
PFA occlusion		1	3.85	2	7.69	3	5.77	0.354	0.552
TIBIALS occlusion		8	30.77	5	19.23	13	25.00	0.923	0.337
Contra-lateral femoral access		6	23.08	0	0.00	6	11.54	6.783	0.009
Trans-femoral access		19	73.08	23	88.46	42	80.77	1.981	0.159
Trans-popliteal access		1	3.85	1	3.85	2	3.85	0.000	1.000

Table 4: Demonstrating efficacy of each procedure

Efficacy outcome data		Used technique						Chi-Square	
		Rotarex® group		Balloon Angioplasty		Total			
		N	%	N	%	N	%	X^2	P-value
Primary Post-operative outcome	Patent	26	100.00	23	88.46	49	94.23	3.184	0.074
	Failure	0	0.00	3	11.54	3	5.77		
1 Month outcome	Patent	24	92.31	21	80.77	45	86.54	3.200	0.362
	Mortality	2	7.69	2	7.69	4	7.69		
	Occlusion	0	0.00	2	7.69	2	3.85		
	Failure	0	0.00	1	3.85	1	1.92		
3 Months outcome	Patent	22	84.62	19	73.08	41	78.85	3.420	0.490
	Mortality	3	11.54	2	7.69	5	9.62		
	Occlusion	1	3.85	3	11.54	4	7.69		
	Amputation	0	0.00	1	3.85	1	1.92		
	Failure	0	0.00	1	3.85	1	1.92		
6 Months outcome	Patent	21	80.77	18	69.23	39	75.00	3.097	0.377
	Mortality	3	11.54	2	7.69	5	9.62		
	Occlusion	1	3.85	1	3.85	2	3.85		
	Amputation	1	3.85	5	19.23	6	11.54		

Table 5: Demonstrating patency rates, safety measurements and need for stenting

Safety outcome data		Used technique						Chi-Square	
		Rotarex® group		Balloon Angioplasty		Total			
		N	%	N	%	N	%	X^2	P-value
Final patency rate		21	80.77	18	69.23	39	75.00	0.923	0.337
Final failure rate		5	19.23	8	30.77	13	25.00	0.923	0.337
Major amputation		1	3.85	5	19.23	6	11.54	3.014	0.083
Mortality rate		3	11.54	2	7.69	5	9.62	0.221	0.638
Need for blood transfusion		3	11.54	0	0.00	3	5.77	3.184	0.074
Need for stenting	No	24	92.31	17	65.38	41	78.85	5.650	0.017
	Yes	2	7.69	9	34.62	11	21.15		
SFA	No	24	92.31	17	65.38	41	78.8	5.650	0.017*
	Yes	2	7.69	9	34.62	11	21.15		
Popliteal	No	26	100.00	26	100.00	52	100.00	-	-
	Yes	0	0.00	0	0.00	0	0.00		

P-value > 0.05: Non- significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant.

Table 6: Demonstrates different post-operative complications reflecting safety of each method

Safety outcome data	Used technique						Chi-Square	
	Rotarex® group		Balloon Angioplasty		Total			
	N	%	N	%	N	%	X^2	P-value
Complications (total)	9	34.6	8	30.77	17	32.7	0.103	0.749
Anemia	3	11.54	0	0.00	3	5.77	3.184	0.074
Hematoma	2	7.69	1	3.85	3	5.77	0.354	0.552
Artery perforation	1	3.85	0	0.00	1	1.92	1.020	0.313
AKI	1	3.85	0	0.00	1	1.92	1.020	0.313
Distal shower	1	3.85	0	0.00	1	1.92	1.020	0.313
Dissection	0	0.00	2	7.69	2	3.85	2.080	0.149
Pseudoaneurysm	0	0.00	1	3.85	1	1.92	1.020	0.313
Gangrene	1	3.85	4	15.38	5	9.62	1.991	0.158

Discussion

In our study we have demonstrated that the majority of chronically occluded arterial segments can be treated and reopened using either mechanical rotational thrombectomy augmented by balloon angioplasty or by plain angioplasty alone with or without stenting .the primary patency in our patients was greater in Rotarex® group (80.77%) compared to Balloon Angioplasty group (69.23 %).both groups are safe and effective with mild failure rate (3 cases) in the angioplasty only group .the amputation rate is also lower in Rotarex® group 1 case (3.85%) compared to 5 cases (19.23%) in the second group ,but slightly greater in-hospital mortality by 3 cases (11.54%) in Rotarex® group compared to 2 cases (7.69%) in the second group, but all cases of mortality are not linked to the procedures. the rate of stenting is much lower in the Rotarex® group by only 2 cases (7.69%) versus 9 cases (34.62) in the angioplasty only group.

Analysis of the clinical outcomes of our patients at 6 months revealed that using mechanical thrombectomy augmented by balloon angioplasty in cases of chronic arterial occlusions is not inferior to plain angioplasty. Actually, the results of Rotarex® in our study is better as regard complication rate, limb salvage and also rate of stenting.

Pawel Latacz at al. demonstrated in his post-hoc analysis that most of femoropopliteal occlusions due to atherothrombotic lesions leading to acute or chronic critical limb ischemic problems, with low calcification, may be treated by mechanical rotational thrombectomy. He postulated in his study that the primary-assisted patency rate after thrombectomy followed by balloon angioplasty with stenting was as high as 97.1%, and an amputation rate of 4.1 %. Such type of management was safe as well. 30 days mortality was 2.0 % and was much lower than that of open surgical correction. Moreover, using drug balloons after mechanical thrombectomy in such patients reduced stent implantation in about 49% of cases.[11]

Cochrane Database of Systematic Reviews (2020) on Atherectomy for peripheral arterial disease showed that during 6 to 12 months follow up, there is no sufficient and clear evidence to support the efficacy of atherectomy on primary patency or mortality compared to balloon angioplasty or primary stenting (Very low-certainty evidence). Cardiac complications were reported in two trials comparing atherectomy versus balloon angioplasty, in the first trial it was not clear to witch arm this event belongs and in the second trial, there was no clear difference between the two groups (Very low-certainty evidence).[12]

Although Rotarex® system as mechanical thrombectomy device is a safe tool and also effective, it should be optimized as a treatment modality.[13]

In spite of the relatively good short-term results of plain balloon angioplasty that may be associated with stent implantation in the femoropopliteal segment, its long-term results are not encouraging with an approximately one-year reocclusion rate of balloon angioplasty is 60 %.[14,15] Stents is not a good choice especially in the distal SFA and popliteal artery because high rate of occlusion due to stent fracture, thrombosis or intimal hyperplasia.[16]

Christoph Artzner et al., 2022 underwent a large retrospective study on 193 patients and 397 interventions and showed the Rotarex® system a safe and also effective option of treatment, with high rate of clinical and technical success about 90%, ABI improvement and significant improvement in claudication symptoms. This study includes about 50% acute and 30% chronic lesions in the iliac or femoropopliteal segments, 60 % of patients presented with critical limb ischemia. Most of lesions are Complex TASC-C and TASC-D with more than 20 cm in length. The length of lesion is not considered a predictor of clinical success.[17]

Artzner C et al., postulated in his recent study about Rotarex® in long SFA lesions 89.5 % of occluded vessels had underlying residual stenosis, so Rotarex® needs associated therapy to complete the procedure. The most common adjunctive therapy was plain balloon angioplasty followed by drug balloon and to very minimal extent is the implantation of stents.[18]

Our results align and are similar to these studies specially in the low stent implantation rate post Rotarex usage as only 2/24 cases (7.69%) fixed SFA stent compared to 9/17 cases (34.62%) in the balloon angioplasty group. Thrombo-atherctomy of iliac and femoropopliteal arteries seems to be safe and effective using Rotarex® device and comparable or even superior to plain balloon angioplasty due to low stenting rate and better patency rates.

Being in a developing country, we found it very expensive to use the rotarex device, but on the other hand it was beneficial as it lowers the rate of using endovascular stents which are very expensive too.

However, it was a retrospective study, and the two groups were not fully comparable, and we need a larger prospective study with a larger sample size in order to fully compare the clinical outcomes of Rotarex® and balloon angioplasty as regard limb salvage, complications, patency and rate of stenting.

Conclusion

Although previous studies proved that using mechanical thrombectomy augmented by balloon angioplasty in cases of chronic arterial occlusions is not inferior to plain angioplasty, in our study we concluded that recanalization using mechanical rotational thrombectomy - Rotarex® system- is an advisable technique for arterial occlusions in femoropopliteal segment, with clinical and technical success better than traditional plain angioplasty. It also has higher patency rate without statistical increase of adverse effects. The rate of stenting is much lower with Rotarex® device than traditional plain angioplasty inspite of its high cost. Moreover, further studies should be done with larger data while taking in account long term patency rates and risk factors for post operative re-occlusion.

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