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Investigating the Rotarex®S Catheter in Femoropopliteal In-Stent Occlusion – 6-Month Results in the Robinson (Rotarex Belgian In-Stent Occlusion) Study

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Abstract

Background

To evaluate the safety and effectiveness of percutaneous mechanical thrombectomy (PMT) using Rotarex®S in the treatment of acute limb ischemia (ALI) in femoropopliteal in-stent occlusions in a prospective, non-randomized study, conducted in 5 hospitals in Belgium. This manuscript reports the findings up to 6-month follow-up for the total cohort. The primary endpoints of this study were technical success (efficacy endpoint) and absence of complications (safety endpoint).

Methods

Between March 2015 and March 2016, 30 patients with ALI because of in-stent occlusion of the femoropopliteal arteries were included.

Results

The mean lesion length was 170.50mm. Procedural success was 100% for the total procedure. In 53.33% technical success was achieved after Rotarex®S treatment. In 46.67% of the cases, additional treatment was necessary to obtain <30% residual stenosis. Perforation was seen in 3.33% of the cases. Without the use of a distal embolization filter, distal embolization was seen in 3 single cases.

Conclusions

PMT with the Rotarex®S catheter seems to be a safe and effective treatment method in the treatment of ALI in stent-occlusions in the femoropopliteal arteries. There is an absolute need for a future randomized controlled study with larger sample size and longer follow-up period comparing chemical thrombolysis versus mechanical thrombectomy for the treatment of infra-inguinal acute limb ischemia, looking into the safety, efficacy and economical endpoints.

Introduction

Acute Limb ischemia (ALI) is a common vascular surgery emergency associated with high rates of morbidity and mortality. Rutherford RB et al described the different clinical categories of acute limb ischemia in 1999 (Table 1) [1]. The treatment of acute and subacute thromboembolic and local thrombotic ischemic lesions of the iliaco-femoral segments in the lower extremities has undergone considerable changes over recent years. The standard modality of surgical thrombectomy with the Fogarty balloon catheter technique for acute arterial occlusions has been largely replaced by percutaneous catheter techniques, i.e. percutaneous aspiration thrombectomy (PAT) for thrombus aspiration [2, 3]. Alternatively, if not facing Acute Limb Ischemia Rutherford IIb or III,catheter-directed pharmacologic thrombolytic therapy with or without additional catheter aspiration is used, particularly if the occlusion is already a few days or weeks old [4, 5]. These techniques obtain the best results in acute occlusions of less than 2 weeks' duration [2].

Both techniques have limitations such as the application of fibrinolytic substances and technical, the impossibility of rapid and complete thrombus extraction. Therefore, various mechanical devices have been introduced which involve maceration or fragmentation and removal of the thrombus. The two categories of devices for mechanical thrombectomy (MT) are: (1) rotational recirculation devices which work by the vortex principle, such as the Amplatz thrombectomy catheter (ATD, Microvena, White Bear Lake, MN) or the Arrow-Trerotola PTD (Teleflex, Morrisville, NC, USA); and (2) hydrodynamic (rheolytic) recirculation devices which operate on the principle of the Venturi effect, such asthe Angiojet (Boston Scientific, Marlborough, Massachusetts, USA) [6–11]. These devices are not suited for subacute occlusions of more than 7–14 days' duration. Recently, a new rotational mechanical debulkingcatheter, the Straub Rotarex®S / Aspirex®S (Straub Medical, Wangs, Switzerland) has been introduced to Belgium. This device combines the two essential effects of mechanical clot fragmentation and removal of the fragmented clot material from the vessel by negative pressure [12, 13]. Two studies using the Rotarex®S system with 38, resp. 98 patients showed a primary patency rate of 62%, resp. 54% at 6 months and described the Rotarex®S / Aspirex®S systems as an efficient and quick technique for revascularization of acute femoropopliteal in-stent reocclussions [14, 15]. A more recent publication dating from 2011 reports results from using Rotarex®S® catheters for the treatment of in-stent reocclusions of femoropopliteal arteries. In 78 patients, the restenosis rate was calculated as 18.4% after 12 months [16].

The purpose of this Belgian multi-center study is to follow-up patients after recanalization with the Rotarex®Scatheter system (Straub Medical) for acute and subacute femoropopliteal in-stent occlusions.

Materials and Methods

Study Design

This prospective, non-randomized, multi-center study was conducted at the vascular departments of A.Z. Sint-Blasius, Dendermonde, Belgium; Imelda Hospital, Bonheiden, Belgium; OLVHospital, Aalst, Belgium; RZ Heilig Hart, Tienen, Belgium & the University Hospital Antwerp, Edegem, Belgium.

The study was conducted in accordance with the Declaration of Helsinki. The local ethics committees at the participating sites approved the study protocol, and all patients provided written informed consent before undergoing any procedures. Patients who provided informed consent and met the study entrance criteria were considered enrolled.

In total, 30 patients were selected between March 2015 and March 2016, based on the investigator's assessment and evaluation of the underlying disease.

Patients were eligible for study inclusion when all general and angiographical inclusion criteria were met and when none of the exclusion criteria were fulfilled. Tables 2 and 3 give an overview of the in- and exclusion criteria.

Device description

The Rotarex®S family of catheters are over-the-wire, single-use, percutaneous devices for the treatment of occlusions in the arterial vasculature. The catheters consist of a flexible outer covering, a rotating head, and a rotating helix which runs the length of the catheter. A lumen for the passage of the supplied guidewire runs the entire length of the helix and through the head of the catheter.

The catheter head is made up of two overlying metal cylinders, with two side openings. The outer cylinder is connected to the rotating helix and the inner cylinder to the catheter shaft. The helix and the catheter head rotate at approximately 40,000-60,000 rpm depending on the model, by means of a gear box in the catheter housing and a motor contained within the catheter handle driven by the Drive System.

When in operation, both the helix and the outer catheter head, rotate and are advanced along the guidewire toward

		Findings		*Doppler signals*	
Category	*Description / prognosis*	*Sensory loss*	*Muscle weakness*	*Arterial*	*Venous*
I. Viable	Not immediately threatened	None	None	Audible	Audible
II. Threatened					
a. Marginally	Salvageable if promptly treated	Minimal (toes) or none	None	Inaudible	Audible
b. Immediately	Salvageable with immediate revascularization	More than toes, associated with rest pain	Mild, moderate	Inaudible	Audible
III. Irreversible	Major tissue loss or permanent nerve damage inevitables	Profound, anesthetic	Profound, paralysis (rigor)	Inaudible	Inaudible

Table 1 : Clinical categories of acute limb ischemia

1.	Patient is willing to comply with specified follow-up evaluations at the specified times
2.	Patient is >18 years old
3.	Patient understands the nature of the procedure and provides written informed consent, prior to enrolment in the study
4.	Patient has a projected life-expectancy of at least 6 months
5.	Symptomatic acute or subacute stent or bypass occlusion in the femoropopliteal artery
6.	Target vessel diameter ≥ 3 mm and ≤ 8 mm
7.	Patient is candidate for thrombolytic or anticoagulation medication
8.	Patient is able and willing to comply with study follow-up requirements

Table 2 : Inclusion criteria

1.	No patent artery until the foot
2.	Inability of crossing lesion with guidewire
3.	Known active infection at the time of intervention
4.	Untreated flow-limiting inflow lesions
5.	Perioperative unsuccessful ipsilateral percutaneous vascular procedure to treat inflow disease just prior to enrolment
6.	Aneurysm in the target vessel
7.	Severe medical comorbidities (untreated CAD/CHF, severe COPD, metastatic malignancy, dementia, etc) or other medical condition that would preclude compliance with the study protocol
8.	Major distal amputation (above the transmetatarsal) in the study limb or non-study limb
9.	Septicemia or bacteremia
10.	Any previously known coagulation disorder, including hypercoagulability
11.	Contraindication to anticoagulation or antiplatelet therapy
12.	Patient with known hypersensitivity to heparin, including those patients who have had a previous incidence of heparin-induced thrombocytopenia (HIT) type II
13.	Currently participating in another clinical research trial
14.	The patient must be excluded in case any of the contraindications as listed in the IFU is present

Table 3: Exclusion criteria

an arterial occlusion. When occlusion is met, the rotating head, with its small, blunt facets in its forward aspect, breaks down the occlusive material. Concomitantly, the rotation of the catheter head creates a vortex in the blood which assists to further erode occluding material from the vessel lumen. The rotating helix produces a negative pressure inside the catheter tube and acts as a conveyor screw upon which the ablated material is transported. The detached particles are drawn into the catheter through side windows in the head where they are further broken down and drawn out of the body and into the attached collecting bag under continuous aspiration. At no time is it necessary for the catheter or rotating head to come into contact with the vessel wall to be effective. The catheter is designed in such a manner that when used as directed, over a guidewire and with adequate proximal blood flow, no wall damage would result if contact with a vessel wall should unintentionally occur.

Treatment strategy and follow-up

All patients enrolled into the clinical investigation underwent a baseline clinical examination: medical history and medication record, physical examination, clinical category of chronic limb ischemia, resting an ankle-brachial index and preoperative Colour Flow Doppler Ultrasound (CFDU).

Since the Rotarex®S / Aspirex®S is an over-the-wire system (0.018"/0.025") any occlusion needs first to be recanalized by conventional guidewire techniquevia a common femoral artery approach (retrograde/antegrade). After assessment of the lesion by angiography, the occlusion is intraluminally crossed with the wire. The Rotarex ®S device is introduced 10 mm proximal to the lesion. The catheter is activated while its tip is still proximal to the occlusion to allow lubrication of the spiral inside the catheter with the aspirated blood. The catheter is then slowly (1cm/sec.) advanced into the occlusion with occasional retraction into the already recanalized lumen (to allow cooling of the catheter by the inflowing fresh blood). Care must be taken to achieve sufficient cooling of the catheter tip and evacuation of the debris to get an appropriate blood flow along the catheter. To minimize peripheral embolization of clot, the distal end of the occlusion should not be passed before all loose material has been sucked back into the catheter. The distal part of the occlusion should be passed more slowly to allow the aspiration of fragmented debris into the catheter. The device allows the reopening of approximately 10 cm of occlusion within 10 -20 sec. Several passages of the occlusion may be needed to clean out all wall-adherent thrombotic material. Angiography post-Rotarex®S treatment is necessary to evaluate the residual stenosis. If the residual underlying stenosis of >30% persists, additional endovascular treatment can be performed according to the physician's discretion. Post-procedural angiography was necessary to evaluate the full lesion treatment.

Endpoints

The primary efficacy endpoint was the technical success of the Rotarex®S device, defined as the removal of all thrombotic material, documented by angiography pre- and post-procedure: residual stenosis of the lesion had to be less than 30%.

The primary safety endpoint was the absence of procedure-related complications: embolization, amputation, perforation or hemorrhage.

The secondary endpoints were: primary patency at 6-month, defined as absence of restenosis (≥50% stenosis) or occlusion within the originally treated lesion based on duplex ultrasound (systolic velocity ratio no greater than 2.4) and without Target Lesion Revascularization (TLR); TLR, defined as a repeat intervention to maintain or re-establish patency within the region of the treated, stented, artery plus 5mm proximal and distal to the treated lesion edge ; Clinical success at follow-up, defined as an improvement of Rutherford Classification at 6-month follow-up of one class or more as compared to the pre-procedure Rutherford Classification ; Serious Adverse Events (SAE's), defined according to ISO 14155:2011 as any clinical event that is fatal, life-threatening, or judged to be severe by the investigator, resulted in persistent or significant disability, necessitated surgical or percutaneous intervention, or required prolonged hospitalization.

Statistical analysis

In the descriptive statistical analysis, the continuous variables are shown as their mean value with their minimum, maximum and standard deviation. The categorical variables are shown as their mean with its corresponding percentage. The primary patency rates were estimated using the Kaplan-Meier survival analysis. All statistical analysis was completed with IBM SPSS Statistical Software (IBM Corporation. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, New York).

Results

Subject enrollment

Between March 2015 and March 2016, a total of 30 eligible patients were enrolled in 5 different centers in Belgium.

Patient Demographics

Most of the patients were male (76.67%) with a mean age of 71.24± 9.39 years old. The most prominent risk factors were nicotine abuse (80.00%), hypertension (73.33%) & hypercholesterolemia (70.00%), Half of the patients were Critical Limb Ischemia patients, resulting in Rutherford 2 (3.33%), Rutherford 3 (46.67%), Rutherford 4 (40.00%) and Rutherford 5 (10.00%). A detailed overview of the patient demographics can be found in Table 4. Nicotine abuse was defined as an addiction to or history of addiction to tobacco products caused by the drug nicotine. Nicotine dependence means you can't stop using the substance, even though it's causing you harm.

Lesion Characteristics

Mean lesion length was 170.50± 46.29 mm with lesions treated up to 500 mm. All lesions were longer than 150 mm. All lesions were in-stent occlusions (100.00%) and in 73.33% of the lesions, thrombus was present. A detailed description of the lesion characteristics can be found in Table 5.

Treatment Characteristics

All patients were treated with femoral access (100.00%). 29 patients (96.67%) were treated using a contralateral access side. The average procedure time was 62.03± 24.47 minutes. With a mean scopy time of 19.21± 8.31 minutes, 79.23 ± 33.46 cc of contrast was used. If Rotarex®S-catheter would not be available in these 30 cases, all of these 30 cases would have been treated with thrombolysis (24h). Depending on the outcome of the thrombolysis, additional treatment might have been necessary. According to the participating physicians' discretion, preferred additional treatment post-thrombolysis would be covered stenting, PTA, DCB, DES.

Primary and Secondary Endpoints

The primary efficacy endpoint was described as a technical success, defined as residual stenosis of less than 30% in the study lesion after Rotarex®S treatment. In 16 out of 30 cases (53.33%) less than 30% was achieved after Rotarex®S treatment. In 14 cases (46.67%) additional treatment after Rotarex®S treatment was necessary. For additional treatment, covered stenting (4 out of 14 ; 28.57%) was the most preferred strategy, followed by bare-metal stenting (3 out of 14 ; 21.43%), drug-coated balloon (2 out of 14 ; 14.29%) , drug-eluting stenting (2 out of 14 ; 14.29%), thrombolysis (1 out of 14; 7.14%) , combined drug-coated balloon with bare-metal stenting (1 out of 14 ; 7.14%) and vascular mimetic implantation (1 out of 14 ; 7.14%).

The primary safety endpoint was defined as the absence of procedure-related complications (embolization, amputation, perforation or hemorrhage). Perforation was seen in one single case (3.33%). Distal embolization was seen in 3 cases. Further detailed analysis showed that of these 3 cases, in-stent occlusion lengths were 35 mm, 170 mm and 420 mm and all 3 were occluded by significant amounts of thrombus. In 2 cases, thrombus aspiration has been performed and in one patient the operators opted for thrombolysis. Unlike the Jet registry, where distal embolization filters were deployed in 22.4% of cases, this study did not use distal embolization filters. Neither perforation nor hemorrhage was seen in a single case.

The 6-month primary patency rate was 63.9%. Freedom from target lesion revascularization (TLR) rate at 6-month follow-up is 67.9%. Primary patency & freedom from TLR curves are displayed in Graph 1 and Graph 2 respectively.

Clinical success during follow-up, defined as an improvement of Rutherford classification at 6-month follow-up of one class or more as compared to the pre-procedure Rutherford classification, was remarkable. We noticed an important shift from Rutherford 3 and 4 categorizations towards 0 categorizations, resulting in a clinical success rate of 94.74%. More detailed information on Rutherford Classification is displayed in Graph 3.

Discussion

Among current reasons for amputation, acute and subacute ischemia of the lower extremity remains common. In randomized studies, Fogarty thrombectomy was associated with a high rate of perioperative complications and low technical success rates [17-20].

Over the past few years, the treatment of acute and subacute thrombus-containing lesions in the lower limbs has undergone important changes. Nowadays, endovascular treatment is well established for thrombus-containing ischemic lesions. Thrombolysis, clot aspiration, mechanical thrombectomy, and revascularization techniques (such as balloon angioplasty or stenting) are well-accepted techniques worldwide [21-26].

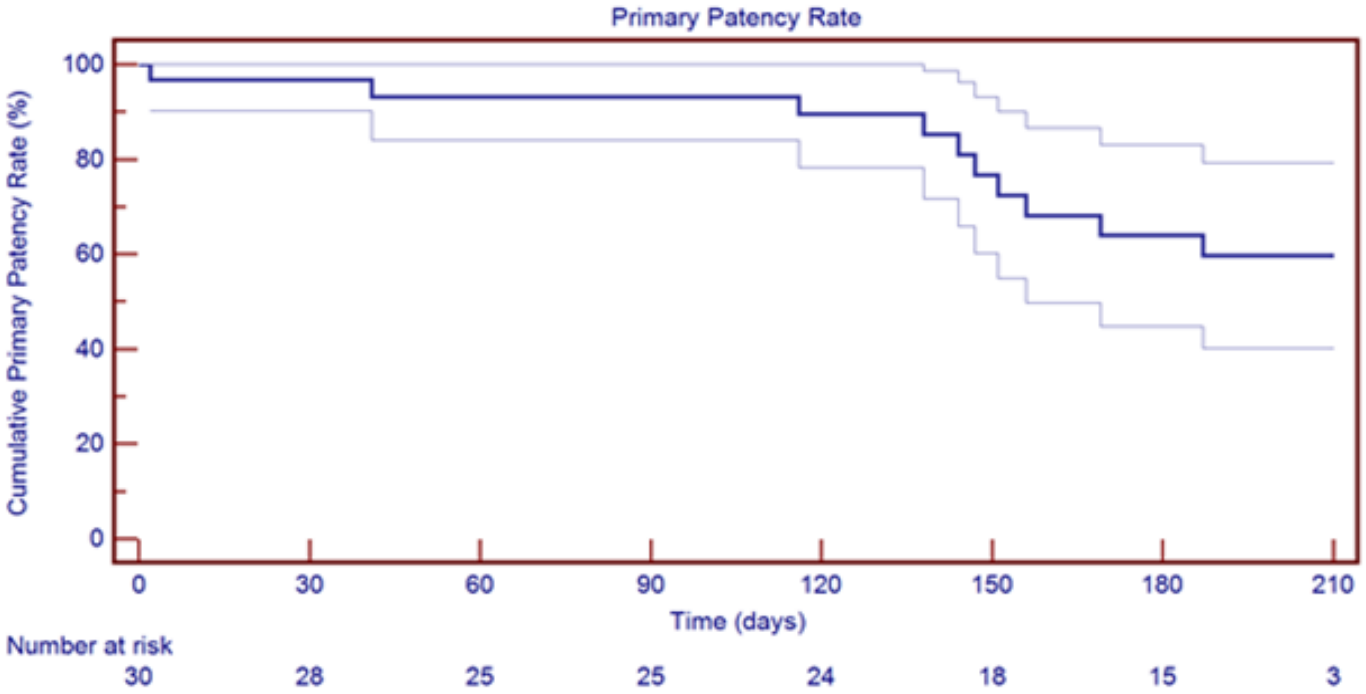
When using local thrombolysis, the investigator has to choose between either lower costs but very high risk of haemorrhage and morbidity, or high costs related to intensive care monitoring but a much lower risk of haemorrhage and morbidity. Percutaneous mechanical thrombectomy in patients with acute limb ischemia avoids time spent in an intensive care unit, reduces

Age (min-max; ±SD) (years)	71.24 (51.75-87.33 ± 9.39)
Gender (%)	
-Male	23 (76.67%)
-Female	7 (23.33%)
Nicotine abuse	
-Never	6 (20.00%)
-Former	8 (26.67%)
-Current	16 (53.33%)
Hypertension	
-Yes, medicated	20 (66.67%)
-Yes, not medicated	2 (6.67%)
-No	8 (26.67%)
Diabetes	
-Yes, type I	5 (16.67%)
-Yes, type II	5 (16.67%)
-No	20 (66.67%)
Renal insufficiency	
-Yes, on dialysis	2 (6.67%)
-Yes, not on dialysis	2 (6.67%)
-No	26 (86.67%)
Hypercholesterolemia	
-Yes	21 (70.00%)
-No	9 (30.00%)
Obesity	
-Yes	9 (30.00%)
-No	21 (70.00%)
History of coronary intervention	
-Yes	8 (26.67%)
-No	22 (73.33%)
History of cerebrovascular intervention	
-Yes	5 (16.67%)
-No	25 (83.33%)
Rutherford 2	1 (3.33%)
Rutherford 3	14 (46.67%)
Rutherford 4	12 (40.00%)
Rutherford 5	3 (10.00%)

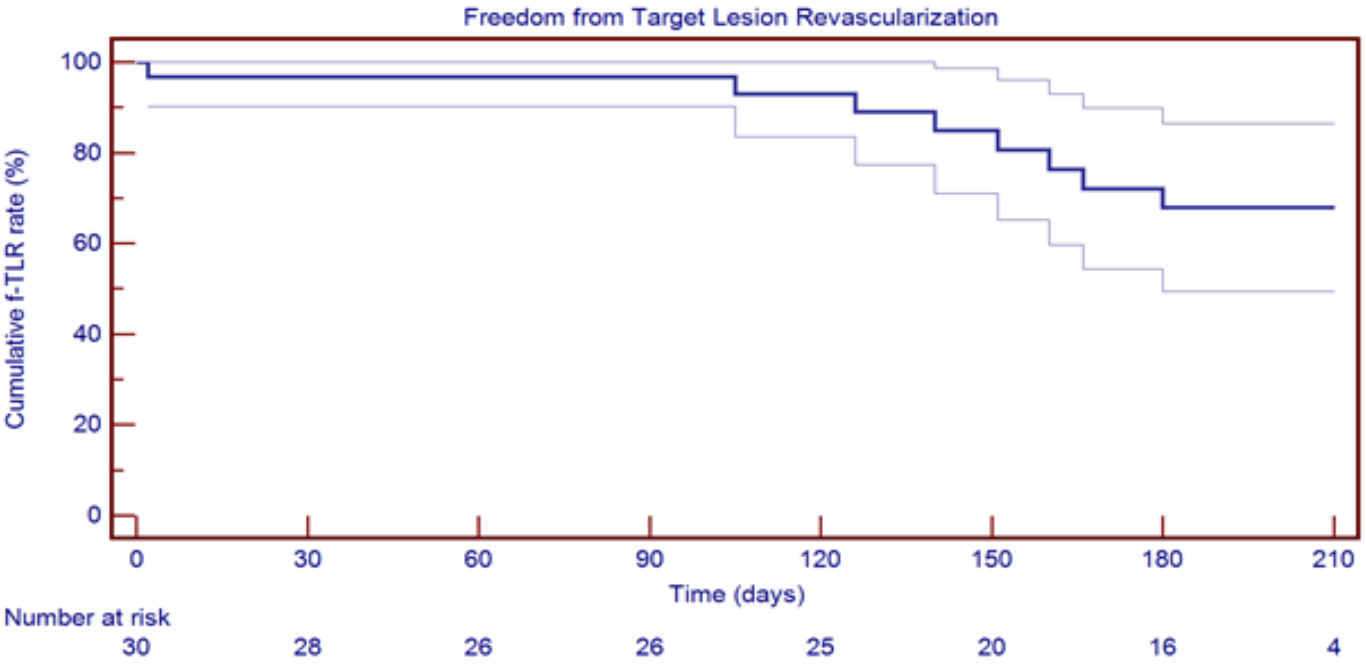
Table 4 : Patient demographics

Lesion side (N=30)	
- Left (%)	19 (63.33%)
- Right (%)	11 (36.67%)
Lesion Type	
- Stenosis	0 (0.00%)
- Occlusion	30 (100.00%)
Lesion length (min-max; ±SD) (mm)	170.5 (15.0-500; ± 146.29)
Proximal reference vessel diameter (min-max; ±SD) (mm)	5.43 (4.0-7.0; ± 0.63)
Presence of calcification (%)	6 (20.00%)
Presence of dissection (%)	1 (3.33%)
Presence of thrombus (%)	22 (73.33%)
Presence of ulceration (%)	1 (3.33%)

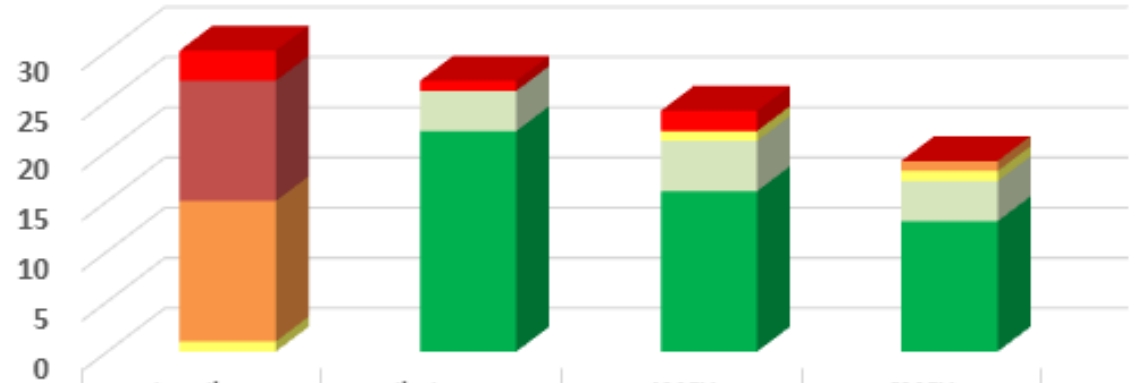
Table 5: Lesion characteristics



Graph 1 : 6-month primary patency rate



Graph 2 : 6-month freedom from Target Lesion Revascularization



	baseline	discharge	1MFU	6MFU
RF5	3	1	2	0
RF4	12	0	0	0
RF3	14	0	0	1
RF2	1	0	1	1
RF1	0	4	5	4
RF0	0	22	16	13

Graph 3: Evolution in Rutherford Classification

risks of bleeding complications, and makes endovascular therapy of acute limb ischemia a one-stage procedure in the majority of the cases. In terms of cost-effectiveness, the above-listed benefits more than compensate for the additional cost of the device [27].

Studies demonstrated the Straub Rotarex®S system was a successful alternative therapy option, not only in terms of amputation-free survival but their use was also associated with low complication rates [27].

The Rotarex®Ssystem is reported to be a safe tool for the treatment of acute and subacute or chronic peripheral arterial thromboembolic occlusions. It can be used for both short and long occlusions with similar success, given that the obstruction is not heavily calcified and a guidewire has been safely passed through the obstruction. In contrast with chemical thrombolysis, the Rotarex®S system can also be used in chronic thrombus, including patients suffering from RutherfordAcute Limb Ischemia I to IIb.

In our study, we achieved a total technical success rate of 100.0%. With the use of Rotarex®S alone in 53.33% of the cases, in 46.67% of the cases, additional treatment was necessary. Perforation was seen in 3.33% of the cases. Distal embolization was seen in 3 cases, which is higher than seen in the literature [15,27,28,29]. Possible explanations for this higher rate of distal embolization are the fact that we treated very long (up to 500 mm), occluded, thrombotic lesions, without the use of a distal embolization filter.

Primary Patency rate at 6-month follow-up is 63.90%. These results support earlier findings that percutaneous mechanical debulking is a safe and effective treatment method in treating In-stent occlusions with acute and subacute lower limb ischemia. When looking into patients that had the Rotarex®S treatment as a stand-alone treatment versus patients with additional treatment after Rotarex®S, there was no significant difference (p=0.4993) with patency rates after 6-months of respectively 64.90% and 52.540%. Although sample sizes were very small, there was a big difference when looking deeper into the 6-month patency rates for the different additional treatment methods: covered stent (4 out of 4 ; 100%), thrombolysis (1 out of 1 ; 100%), DCB + BMS (1 out of 1 ; 100%), VMI (1 out of 1 ; 100%), BMS (2 out of 3 ; 66.67%) , DES (1 out of 2 ; 50%), DCB (0 out of 2 ; 0%). A limitation of this study is the small sample size and the fact that it is a non-randomized study.

Conclusion

In-stent restenosis remains one of the most challenging areas to treat, without clear evidence on the gold standard of treatment. This study, in a small cohort of a severely diseased patients with very long, challenging lesions, seems to show that mechanical atherothrombectomy as first-line treatment of in-stent occlusion in infra-inguinal acute limb ischemia, is safe and effective, with lower risks of amputation, lower morbidity and

mortality rates as compared to previous studies on traditional techniques such as balloon embolectomy or chemical thrombolysis. Mechanical atherothrombectomy should be considered as a treatment of choice in experienced high-volume centers for the treatment of in-stent occlusions in infrainguinal Acute Limb Ischemia Rutherford I to IIb. There is an absolute need for a future randomized controlled study comparing chemical thrombolysis versus mechanical thrombectomy for the treatment of in-stent occlusions in infra-inguinal acute limb ischemia, looking into the safety, efficacy and economic endpoints.

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