

Safety, procedural success and outcome of the Aspirex™S endovascular thrombectomy system¹

In the treatment of iliofemoral deep vein thrombosis.

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Objective

To determine the safety, patency and short-term outcome of the Aspirex™S catheter as a rotational mechanical thrombectomy device in the endovascular treatment of iliofemoral DVT

In terms of:

- Technical success
- Device complications, procedure complications
- Device malfunction
- Prevention of Post-Thrombotic Syndrome (PTS) at 1, 6, 12-months follow-up
- Patency rates at 1, 6, 12-months follow-up

Methods

Retrospective, single-centre, investigator-initiated registry

56 patients, with acute, subacute or acute-on-chronic, ascending and descending iliofemoral DVT occlusions, were treated with Aspirex™S system



Total patients



Acute



Subacute



Acute-on-chronic

Conclusion

“ The usage of the Aspirex™S PMT² in treatment of acute and subacute iliofemoral DVT turned out to be safe without any device-related complications or technical failure. ”

“ 87% primary patency rate with <50% restenosis at 12 months follow-up.³ ”

Results

Patient demographics	N(%)
Smoker	13 (23)
Hypertension	28 (50)
Malignancy	9 (12)
Oral contraceptive	21 (38)

Lesion Characteristics	N(%)
Acute	40 (71)
Subacute	13 (23)
Acute-on-Chronic	3 (6)
May-Thurner syndrome	30 (53)
Mean Occlusion Length	15.6 ± 7.2 cm

Notable points

- Acute, subacute and acute-on-chronic lesions were treated
- Over half of the patients had an underlying May-Thurner syndrome as the cause of the thrombosis
- Mean occlusion length of over 15 cm

Procedural Outcomes	N(%)	Notable points
Technical success	56 (100)	100 % technical success
Mean treatment duration	94.2 min	Mean treatment time just over 1.5 hours
Adjunctive stenting	56 (100)	All patients had a dedicated venous stent implanted
Adjunctive lysis	4 (7)	Thrombolysis not needed in 93 % of patients

Safety Outcomes	N(%)	Notable points
Minor adverse events (procedure-related)	11 (20)	Puncture site bleeding complication or hematoma
Serious adverse events (procedure-related)	8 (14)	Rehospitalization, re-occlusion of target vein, prolonged hospitalization due to AV-Fistula operation
Device-related complications	0 (0)	0% device-related complications
Device malfunction	0 (0)	0% device malfunction

12-months Results	N(%)	Notable points
Patency rate	39/45 (87)	Patency rate of 87% sustained out to 12-months follow-up
Low PTS ⁴	34/53 (64)	“Severe PTS could be prevented in all patients after 1 year of follow-up; moderate PTS in 64%”
Moderate PTS	19/53 (36)	
Severe PTS	0/53 (0)	
No rehospitalisation/reocclusion	48/56 (86)	86% patients required no further hospitalisation

Summary

- Acute, subacute and acute-on-chronic lesions of mean length > 15 cm were treated with over half of the patients having an underlying May-Thurner syndrome as the cause of the thrombosis
- 100 % technical success, within treatment time of around 1.5 hours
- 87 % patency rate with reduction in PTS severity and no recorded severe PTS at 12-months follow-up

1. Lichtenberg M, Stahlhoff WF, Özkapi A, de Graaf R, Breuckmann F. Safety, procedural success and outcome of the Aspirex®S endovascular thrombectomy system in the treatment of iliofemoral deep vein thrombosis - data from the Arnsberg Aspirex registry. *Vasa*. 2019 Jul;48(4):341-346.

2. PMT = Percutaneous Mechanical Thrombectomy

3. Combined patency rate measured by duplex ultrasound with a definition of <50 % restenosis of target vessel was 87% at 12 months and was calculated using survival analysis with the Kaplan-Meier method.

4. Definition of Post-thrombotic Syndrome: Low PTS: CEAP Score <3, rVCSS Score <3; Moderate PTS: CEAP Score >3, rVCSS >3; Severe PTS: CEAP score > 4, rVCSS > 6

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