Safety, procedural success and outcome of the Aspirex™S endovascular thrombectomy system[1]

In the treatment of iliofemoral deep vein thrombosis.

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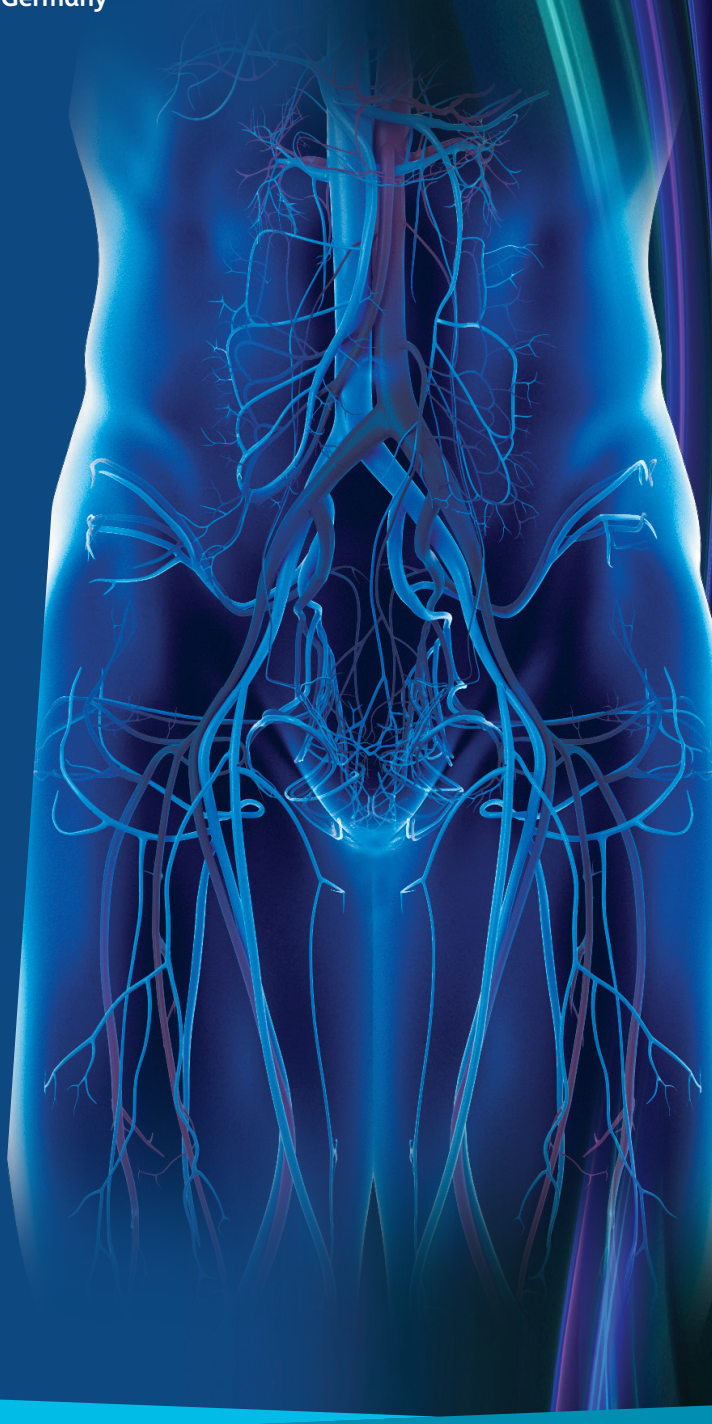

Objective

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

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Conclusion

> “The usage of the Aspirex™S PMT[2] 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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