Utilization of Rotational Mechanical Thrombectomy In AV Fistuals and Synthetic Grafts:

A Review of Published Literature on 324 Procedures

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ARGON MEDICAL DEVICES

INTRODUCTION

Arterial venous fistulas and synthetic grafts have become a mainstay in the provision of hemodialysis in patients with chronic renal failure. Unfortunately, greater than 18% of fistulas and grafts thrombose less than 14 months after creation or surgical implantation.[1] Fistula and graft thrombectomy via balloon mediated or mechanical based thrombectomy devices has proven vital for long term care and preservation of adequate vascular conduit for performance of hemodialysis. Traditional thrombectomy has been performed both open via surgical thrombus extraction and percutaneously utilizing venoplasty balloons or Fogarty style embolectomy catheters.

Newer devices designed specifically for use in the treatment of AV fistula and graft thrombosis have been developed to reduce and macerate thrombus burden faster and more efficiently than standard balloon maceration alone. One of these devices, the Cleaner XT™ (Argon Medical Devices, Plano, TX) utilizes a mechanical maceration wire that spins at 4,000 RPM to morcellate thrombus while creating a fluid vortex effect to facilitate extraction of thrombus from the native AVF or graft wall to aid in restoration of flow and circuit patency.

OBJECTIVES

The objectives of this study is to perform a literature review utilizing established research literature data bases with the goal of identifying safety and efficacy data specifically pertaining to the Cleaner/Cleaner XT™ rotational mechanical thrombectomy system.

Specifically, this study is designed to identify the benchmarks surrounding such parameters as post procedural patency, time frame for total thrombus resolution, as well as safety parameters such as procedural related complications.

Utilization of investigator-initiated studies will hopefully allow for unbiased evaluation of general performance characteristics of this device based on what is considered the current standard of care which by varying stake holders is designated as balloon facilitated maceration and extirpation of thrombus burden from the hemodialysis circuit.

METHODS

This study utilizes published peer review data readily available via research data base access and as such was deemed to be excluded from the need to seek IRB approval.

Research databases such as Embase (embase.com) and Research Gate (researchgate.com) were utilized for performance of initial research review. Search parameter words such as Cleaner, Cleaner XT™, thrombectomy, complications, and patency were utilized in the search engine to identify suitable research articles discussing the used of mechanical rotational thrombectomy utilization in the dialysis access circuit. Once appropriate studies were identified, initial data was scrubbed to identify the studies that included post procedure patency rates, procedural times, and cited procedural or post procedural complication data. Four studies stood out with regards to having all the parameters for evaluations after data scrub was performed for comparative benchmarks.

Fig 1. Cleaner XT™ Rotational Thrombectomy Device.

A sum was extrapolated by adding the individual studies patient populations and procedural numbers. The combined studies were also totaled together using basic mathematical equation to calculate the overall post procedural patency, average procedural time and total procedural complication rates.

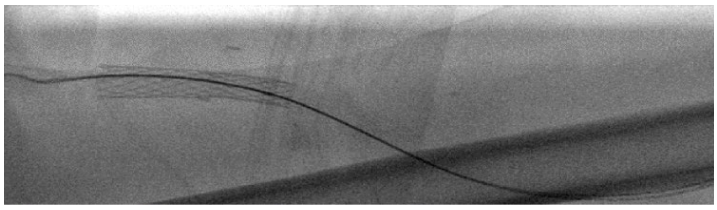

Fig 2. Cleaner Device in a Stented AVF.

With consideration to the respective cited studies, a sum of 324 thrombectomy procedures were performed utilizing the Cleaner XT™. Out of those procedures a total patency rate of 96.12% was achieved upon initial conclusion of procedure.

RESULTS

STUDY

Utility of Rotational Thrombectomy for the Management of Thrombosed Arteriovenous Shunts

PROCEDURES	TIME	COMPLICATION
34	30 +/- 20 minutes	0 Device Related

97% patency

February 2020, The Arab Journal of Interventional Radiology 04(3) DOI: 10.1055/s-0041-1729018

STUDY

Abstracts 099 Safety and Efficacy of the Argon Cleaner Rotational Thrombectomy System for Hemodialysis Access Interventions

PROCEDURES	TIME	COMPLICATION
216	35 +/- 20 minutes	15 | 0 Device Related

95% patency

Presented at International Symposium on Endovascular Therapy 2020

STUDY

Single-centre experience with endovascular rotational thrombectomy for single session salvage of thrombosed arteriovenous fistulas and grafts

PROCEDURES	TIME	COMPLICATION
40	40 +/- 20 minutes	0 Device Related

92.5% patency

J Vasc Access, 2021 Nov 29; 11297298211060964. DOI: 10.117/11297298211060964.

STUDY

Cleaner XT™ Rotational Thrombectomy: An Efficacious Endovascular Technique for Salvage of Thrombosed Arteriovenous Access and a 12 Month Outcome Analysis

PROCEDURES	TIME	COMPLICATION
34	62 +/- 20 minutes	0 Device Related

100% patency

J Endovasc Ther, 2022 Mar 11; 15266028221083222. DOI: 10.117/15266028221083222.

TOTAL

PROCEDURES	TIME	COMPLICATION
324	41.75 minutes	0.69% Adjusted to 0% for Device Related*

96.1% patency

Fig 3. Results Table.

The average procedural time from fistula/graft access with needle to completion was approximately 41.75 minutes with a total complication rate of only 0.69 %. This complication rate can be adjusted to 0 percent in relation directly to utilization of the thrombectomy device. The most frequent complication being cited as bleeding or hematoma at the sheath access site.

For reference and comparison, literature comparing balloon maceration thrombectomy and/or maceration thrombectomy with administration of lytic agents cite patency rates of 73% with procedural times exceeding 60 minutes and a general overall complication rate of 7%.[2]

CONCLUSION

Based on an overall literature reviews looking at safety and efficacy data points, the Cleaner XT™ demonstrates efficacy and safety with regards to the parameters of post procedural patency, procedural time reduction, and device related complication rates in comparison to balloon maceration thrombectomy.

Further study may be warranted in prospective design comparing treatment methodologies in a true comparative therapy arms study.

This study is limited to published literature in retrospective written format. There is also limitations attributed to varying methods of data collection between the individual retrospective studies.

AUTHOR AND CONTACT

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