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Editorial for: Outcomes after endovascular mechanical thrombectomy in occluded vascular access used for dialysis purposes

# Outcomes after endovascular mechanical thrombectomy in occluded vascular access used for dialysis purposes

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#### **Abstract**

Purpose: Endovascular mechanical thrombectomy using the AngioJet™ system can be considered to reestablish patency in occluded vascular access. The aim of this study was to review our results for endovascular mechanical thrombectomy using the AngioJet™ system in patients with arteriovenous fistulae (AVF) and arteriovenous grafts (AVG).

Methods: Data collected in a database of patients requiring hemodialysis for renal failure were analyzed. Patients who underwent endovascular mechanical thrombectomy procedures with the AngioJet™ system for occlusion of vascular access were included. Clinical and technical success rates and patency rates were calculated. Multivariate analysis was used to identify factors of influence.

**Results:** A total of 92 AngioJet<sup>™</sup> procedures in 60 patients with thrombosed vascular access were reviewed during a mean follow-up period of 21.5 months in patients with an AVF and 11.9 months in patients with an AVG. Technical and clinical success was achieved in 92.6% of AVF cases and 92.0 and 90.8% of AVG cases with an AVG, respectively. Significantly higher primary and primary-assisted patency rates were observed in the AVF group. Multivariate regression analysis indicated that left-sided vascular access and female sex were independent predictors for failure regarding primary patency in AVG patients. Immunosuppressive drugs and older age were negative predictors for secondary patency in AVG patients.

Conclusions: The AngioJet™ system can be deemed an effective technique to reestablish patency in occluded vascular access with minimal use of central venous catheters for dialysis. Good technical and clinical success rates were achieved with acceptable patency rates, especially in AVF patients.

#### **KEYWORDS**

endovascular, outcomes, thrombectomy, vascular access

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758

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#### 1 | INTRODUCTION

Adequate blood flow through hemodialysis arteriovenous (AV) access is mandatory to perform hemodialysis and prevent thrombosis in patients with end-stage renal disease. After creating arteriovenous fistula (AVF) or arteriovenous graft (AVG), prospective monitoring is performed to ensure functionality. 1 Regular follow-up in a protocolized surveillance program and aggressive treatment of access site stenosis to maintain patency of vascular access seem to be of paramount importance. Still, thrombosis of an AVF or AVG is not uncommon. with a higher incidence in AVGs compared with AVFs. For native fistulae, only one-third of the access events is observed compared with grafts. In surveillance programs, fistula thrombosis should not exceed 0.25 episodes per patient year, in grafts this number should not exceed 0.5.1 A variety of techniques have been described for the treatment of vascular access thrombosis. Thrombus removal and treatment of the underlying stenosis are the main goals in reestablishing and maintaining patency.<sup>2-4</sup> The outcomes of surgical and endovascular intervention for vascular access thrombosis are comparable. 4 Surgical thrombectomy, pharmacological thrombolysis, balloon-assisted thrombectomy, aspiration, mechanical thrombectomy, or a combination of these techniques can be considered.<sup>5</sup> Endovascular mechanical thrombectomy using the AngioJet™ Peripheral Thrombectomy system (Boston Scientific, Natick, MA) can be deemed an effective technique, as described in a large multicenter registry for treatment of deep vein thrombosis.<sup>6</sup> Experience with this system in occluded vascular access is relatively limited though, especially in native AVF, with varying clinical success and patency rates.<sup>2-4,7-12</sup> Moreover, the quality of the evidence fluctuates.<sup>13</sup>

The aim of this study was to review our 8-year experience in endovascular mechanical thrombectomy using the AngioJet™ system in patients with AVF and AVG, and to determine whether this can be deemed an effective technique. Outcomes were technical and clinical success and patency rates. Factors of influence on the patency after the AngioJet™ procedure were also identified.

#### 2 | MATERIALS AND METHODS

#### 2.1 | Study design

Data collected in a database of patients with chronic renal dysfunction requiring hemodialysis were retrospectively analyzed. From April 2009 to December 2017, a total of 81 patients underwent either surgical or endovascular interventions for occluded vascular access. Of these patients, 65 were considered for endovascular mechanical thrombectomy procedures with the AngioJet™ system for occlusion of vascular access at our center; five patients were not treated; in three patients the procedure was aborted due to local pain and chest pain during the puncture procedure (these patients did not develop myocardial infarction afterwards); and in two patients, endovascular mechanical thrombectomy was not performed due to primary nonfunction of the vascular access caused by an anastomotic problem.

The remaining 60 patients underwent endovascular thrombectomy procedures with the AngioJet<sup>™</sup> system and were included in this study based on the per-protocol principles.

Approval of the Institutional Review Board was obtained (METc 2018/015). As retrospective patient file research does not fall under the scope of the Dutch Medical Research Involving Human Subjects Act, informed consent was not required. All patient-related data were analyzed anonymously.

#### 2.2 | Access creation

For the creation of a radiocephalic AVF, cephalic vein and radial artery diameters of 2 mm were considered appropriate for fistula creation. For the creation of brachiocephalic AVF and basilic vein transposition, vein diameters and brachial artery diameters of 3 mm were considered appropriate for fistula creation. For AVG creation, a standard wall PTFE graft (Gore-Tex, WL Gore & Associates, Flagstaff, Arizona) with 6 mm diameter and 0.5 mm wall thickness was used in a forearm loop configuration, vein diameters of 4 mm were considered appropriate. All anastomoses were created with a running polypropylene 6–0 suture (Prolene®, Ethicon Inc., Somerville, NJ).

# 2.3 | Indication for thrombectomy

In case of suspected vascular access thrombosis, patients were referred to the emergency ward or the dialysis clinic to confirm the diagnosis. Thrombosis was defined as a lack of thrill or pulse of the vascular access on physical examination, confirmed by the absence of flow on duplex ultrasound examination. Patients with proven access thrombosis were admitted to the hospital and prepared for an intervention with routine blood chemical analysis to determine serum potassium. When serum potassium was within normal range (3.5–5.0 mEq/L), patients were scheduled for an intervention as soon as possible. For patients with elevated serum potassium levels, pharmacological correction or dialysis was performed using a temporary central venous catheter.

#### 2.4 | Thrombectomy procedure

For endovascular mechanical thrombectomy, a 50-cm AngioJet™ AVX™ 6F or 90-cm Solent™ Proxi catheter was used (Boston Scientific, Natick, MA). Systemic heparization was performed by administering 50 IU/kg of heparin at the start of the procedure. No other thrombolytic drugs or antibiotics were given. The Seldinger technique was used to obtain access under ultrasound guidance. The puncture location was determined by localization of the thrombus and type of vascular access. A single 6F sheath was introduced, either proximal or distal to the occlusion, and the occlusion was passed with a 0.035-in. wire. Thrombectomy was performed by retracting the AngioJet™ catheter through the thrombus with a flow rate of 60 mL/

min. A maximal run time of 300 s was used to prevent hemoglobinuria due to hemolysis. The saline supply bag was heparinized with 2,500 IU of heparin. Complete angiography was performed and remaining significant stenotic segments (>50%) were treated with balloon angioplasty. In case of residual stenosis after balloon angioplasty, a self-expanding nitinol stent was placed. In case of failed endo-vascular treatment, additional surgical treatment was performed. Low-dose acetylsalicylic acid was started in patients who did not receive antiplatelet or anti-thrombotic drugs.

#### 2.5 | Definitions

Technical success was defined as the restoration of blood flow, combined with a residual stenosis of less than 30%, as reported by the Society of Interventional Radiology.<sup>14</sup> Clinical success was defined as the completion of at least one hemodialysis session after treatment.<sup>1</sup>

Primary patency was defined as the interval from the time from the first successful AngioJet™ procedure until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency. Primary-assisted patency was defined as the interval from the time from the first successful AngioJet™ procedure until access thrombosis or the time of measurement of patency, including intervening manipulations designed to maintain the functionality of a patent access. Secondary patency was defined as the time from the first successful AngioJet™ procedure until access abandonment, thrombosis, or the time of patency measurement including intervening manipulations designed to reestablish functionality in thrombosed access.¹

Stenosis was defined as the presence of a peak systolic velocity greater than 310 cm/s in AVG and greater than 375 cm/s in AVF, with a vessel diameter smaller than 2.0 mm.<sup>15</sup> Indications for interventions were standardized; in patients with an AVF with flow rates <500 ml/min and patients with an AVG with flow rates <600 ml/min, or with a consistent monthly decrease of 25% or more with a flow rate < 1,000 ml/min, angiography was scheduled and a percutaneous transluminal angioplasty (PTA) was performed in the case of stenosis.<sup>1</sup>

### 2.6 | Follow-ups

All patients were monitored in the postprocedural period. Patients were generally discharged the day after thrombectomy. After discharge, routine physical examination and ultrasound dilution flow measurements were performed with either a Transonic HD01 plus Hemodialysis Monitor (Transonic Systems Inc., Ithaca, NY) or a Fresenius 5008S CorDiax dialysis machine (Fresenius Medical Care, Bad Homburg, Germany).

# 2.7 | Statistical analysis

Data are presented as means including standard error of the mean (SEM) or medians including range. Differences in incidence rates

between groups were calculated with Pearson's chi-square test or Fisher's exact test. Distribution was tested with the Kolmogorov–Smirnov test. Differences between the groups were calculated with the Mann–Whitney U test since data were skewed. Kaplan–Meier survival analysis and the life table method were used to calculate patency rates. The log-rank test was used to compare patencies between the different procedures and to determine significant factors of influence on survival. Following univariate analysis, all significant factors with a p value lower than 0.10 were then entered into a multivariate Cox regression model with backward elimination. The p values lower than 0.05 were considered statistically significant. SPSS 24 (SPSS, Chicago, IL) was used for analysis.

#### 3 | RESULTS

#### 3.1 | Characteristics

A total of 92 AngioJet<sup>™</sup> procedures for vascular access thrombosis were performed in 60 patients: 27 thrombectomies in occluded AVFs and 65 in occluded AVGs. Characteristics are listed in Table 1. Significant differences between groups were found in the presence of diabetes mellitus (p = .026) and total follow-up time, with 21.5 months in the AVF group and 11.9 months in the AVG

**TABLE 1** Characteristics

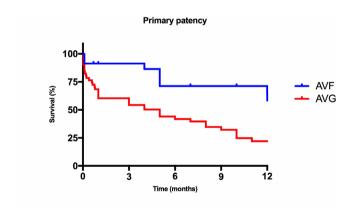
|                                      |                |                | р      |
|--------------------------------------|----------------|----------------|--------|
| Variable                             | AVF (27)       | AVG (65)       | values |
| Age (year)                           | 58.6<br>(19.6) | 59.4<br>(13.0) | .986   |
| Sex                                  |                |                |        |
| Male                                 | 36 (55%)       | 20 (74%)       | .094   |
| Female                               | 7 (26%)        | 29 (45%)       |        |
| BMI (kg $m^{-2}$ )                   | 25.9 (5.2)     | 27.9 (9.0)     | .534   |
| Diabetes mellitus                    | 4 (15%)        | 25 (39%)       | .026*  |
| Hypertension                         | 21 (78%)       | 53 (82%)       | .679   |
| Access type                          |                |                |        |
| Radiocephalic AVF                    | 13 (48%)       | NA             |        |
| Brachiocephalic AVF                  | 10 (37%)       | NA             |        |
| Basilic vein transposition           | 4 (15%)        | NA             |        |
| Straight PTFE AVG                    | NA             | 20 (31%)       |        |
| PTFE loop AVG                        | NA             | 45 (69%)       |        |
| History of thrombosis                | 9 (33%)        | 32 (49%)       | .162   |
| Time to AngioJet™ procedure<br>(day) | 0.4 (0.6)      | 0.6 (1.3)      | .502   |
| Follow-up time (month)               | 21.5<br>(22.4) | 11.9<br>(13.3) | .040*  |

Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; BMI, body mass index; NA, not applicable; PTFE, polytetrafluorethylene. *Note*: Data are presented as numbers including percentages or means including SDs; \*p < .05.

**TABLE 2** Angiojet<sup>™</sup> procedure specification

| Variable                              | AVF (27) | AVG (65) | p<br>values |
|---------------------------------------|----------|----------|-------------|
| Technical success                     | 25       |          |             |
| (92.6%)                               | 60       |          |             |
| (92.0%)                               | .963     |          |             |
| Clinical success                      | 25       |          |             |
| (92.6%)                               | 59       |          |             |
| (90.8%)                               | .777     |          |             |
| Adjuvant periprocedural interventions |          |          | .362        |
| None                                  | 2 (7.4%) | 2 (3.1%) |             |
| PTA arterial anastomosis              | NA       | 6 (9.2%) |             |
| PTA venous anastomosis                | NA       | 14       |             |
| (21.5%)                               |          |          |             |
| Multiple PTAs                         | 24       |          |             |
| (88.9%)                               | 36       |          |             |
| (55.4%)                               |          |          |             |
| Arterial stent                        | 0 (0%)   | 0 (0%)   |             |
| Venous stent                          | 1 (3.7%) | 7        |             |
| (10.8%)                               |          |          |             |
| Additional surgery                    | 5        |          |             |
| (18.5%)                               | 9        |          |             |
| (13.8%)                               | .391     |          |             |

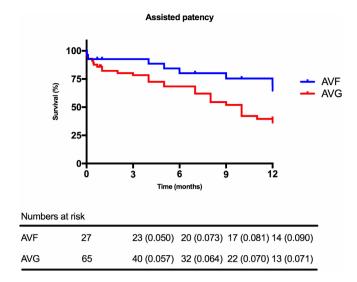
Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; NA, not applicable; PTA, percutaneous transluminal angioplasty.



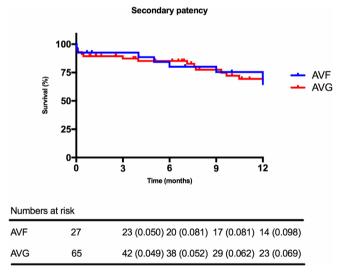
| Numbers at risk |    |  |  |  |
|-----------------|----|--|--|--|
| AVF             | 27 | 19 (0.08) 14 (0.098) 12 (0.098) 11 (0.098) |  |  |
| AVG             | 65 | 28 (0.064) 19 (0.063) 13 (0,060) 7 (0.055) |  |  |

**FIGURE 1** Primary patency rates of AVF and AVG after AngioJet<sup>™</sup> procedure. AVF, arteriovenous fistula; AVG, arteriovenous graft [Color figure can be viewed at wileyonlinelibrary.com]

group (p = .04). Time from thrombosis to AngioJet<sup>m</sup> procedure was 0.4 days in the AVF group and 0.6 days in the AVG group (p = .502).



**FIGURE 2** Primary-assisted patency rates of AVF and AVG after AngioJet™ procedure. AVF, arteriovenous fistula; AVG, arteriovenous graft [Color figure can be viewed at wileyonlinelibrary.com]



**FIGURE 3** Secondary patency rates of AVF and AVG after AngioJet<sup>™</sup> procedure. AVF, arteriovenous fistula; AVG, arteriovenous graft [Color figure can be viewed at wileyonlinelibrary.com]

# 3.2 | AngioJet™ procedure

Results and specifications of AngioJet<sup>™</sup> procedures are shown in Table 2. Technical success was achieved in 92.6% of AVF cases and 92.0% of AVG cases (p = .963). Clinical success was achieved in 92.6% of AVF cases and 90.8% of AVG cases (p = .777). A periprocedural adjuvant intervention during the thrombectomy procedure was performed in 92.6% of the AVF and 96.9% of the AVG cases (p = .362). The types of additional interventions are shown in Table 2. An additional PTA was most frequently performed at varying sites (88.9% in the AVF group and 55.4% in the AVG group). Additional surgical intervention due to residual stenosis or thrombosis was indicated

**TABLE 3** Factors of influence on patency at univariate analysis

|                                     | AVF             |                          |                      | AVG             |                          |                      |
|-------------------------------------|-----------------|--------------------------|----------------------|-----------------|--------------------------|----------------------|
| Factor                              | Primary patency | Primary assisted patency | Secondary<br>patency | Primary patency | Primary assisted patency | Secondary<br>patency |
| Age                                 | 0.445           | 0.281                    | 0.148                | 0.409           | 0.616                    | 0.060*               |
| BMI                                 | 0.983           | 0.542                    | 0.663                | 0.434           | 0.625                    | 0.269                |
| Sex                                 | 0.217           | 0.780                    | 0.947                | 0.010*          | 0.139                    | 0.003*               |
| Left- or right-handedness           | 0.555           | 0.685                    | 0.413                | 0.377           | 0.234                    | 0.659                |
| Diabetes mellitus                   | 0.576           | 0.151                    | 0.098*               | 0.742           | 0.134                    | 0.648                |
| Hypertension                        | 0.884           | 0.353                    | 0.451                | 0.489           | 0.912                    | 0.470                |
| Immunosuppression therapy           | 0.041*          | 0.143                    | 0.160                | 0.092*          | 0.221                    | 0.005*               |
| Preoperative anticoagulant therapy  | 0.031*          | 0.001*                   | 0.001*               | 0.353           | 0.880                    | 0.004*               |
| History of thrombosis               | 0.745           | 0.239                    | 0.147                | 0.412           | 0.428                    | 0.537                |
| Time to procedure                   | 0.350           | 0.282                    | 0.386                | 0.012*          | 0.495                    | 0.630                |
| Type of access                      | 0.553           | 0.203                    | 0.156                | 0.419           | 0.075                    | 0.188                |
| Side of vascular access             | 0.679           | 0.906                    | 0.822                | 0.032*          | 0.267                    | 0.992                |
| Postoperative anticoagulant therapy | 0.390           | 0.003*                   | 0.003*               | 0.009*          | 0.623                    | 0.010*               |
| Additional PTA                      | 0.728           | 0.493                    | 0.383                | 0.868           | 0.609                    | 0.240                |
| Additional stent                    | 0.671           | 0.370                    | 0.370                | 0.880           | 0.969                    | 0.327                |

Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; BMI, body mass index; PTA, percutaneous transluminal angioplasty. *Note*: p values are presented; p < .10.

in five cases (18.5%) in the AVF group and nine cases in the AVG group (13.8%) (p = .391).

#### 3.3 | Patency

Primary, primary-assisted, and secondary patency rates are shown in Figures 1–3. A significantly higher primary patency rate after the Angiojet<sup>TM</sup> system was found for the AVF group than for the AVG group (p < .001). Also, primary-assisted patency was significantly higher in the AVF group than in the AVG group (p = .001). Secondary patency rates were comparable between the two groups (p = .262). The results of univariate analysis of factors influencing patency are shown in Table 3.

Use of immunosuppressive drugs was significantly associated with primary patency and type of postoperative anticoagulant therapy was significantly associated with primary assisted patency in AVF patients. Types of preoperative and postoperative anticoagulant therapy were significantly associated with secondary patency in AVF patients. Type of postoperative anticoagulant therapy, time to procedure, and side of vascular access were significantly associated with primary patency in AVG patients. Sex, use of immunosuppressive drugs, and type of preoperative and postoperative anticoagulant therapy were significantly associated with secondary patency in AVG patients.

Following univariate analysis, univariate factors with p < .10 were entered into a multivariate Cox regression model. No significant

independent predictors for failure were found in AVF patients. Female sex (HR 2.02, 95% CI 1.14–3.59, p = .016) and left-sided AVG (HR 1.92, 95% CI 0.29–0.95, p = .032) were independent predictors for failure in primary patency of AVG patients. Use of immunosuppressive drugs (HR 10.3, 95% CI 3.01–34.44, p < .001) and older age (HR 5.91, 95% CI 1.92–18.22, p = .002) were independent predictors for failure in secondary patency of AVG patients.

#### 4 | DISCUSSION

This study shows that excellent technical and clinical success rates can be achieved using the AngioJet™ pharmacomechanical thrombectomy device in occluded vascular access with a short interval from diagnosis to treatment. Promising patency rates were observed during follow-up in both AVF and AVG patients. The AVF group did display higher primary and primary-assisted patency rates. With regard to the outcomes of the multivariate regression model, decreased patency in female patients might be attributed to their usually smaller vessel diameter. Patency of left-sided vascular access was not associated with left- or right-handedness of patients nor with the use of central venous dialysis catheters. However, only five patients were left-handed in the AVG group so this might not be representative. Age had been previously identified as predictor for survival,<sup>5</sup> but the use of immunosuppressive drugs had not. In our study, 12 patients used immunosuppressive drugs in the AVG group and had a significantly lower secondary patency rate than patients who did not use

them. The lower secondary patency rate might be attributed to the negative effect of such drugs on these patients' vascular system.

In contrast to previous findings, the type of additional intervention during the AngioJet™ procedure was not a predictor for survival.<sup>8</sup> This might be attributed to an aggressive adjuvant periprocedural treatment policy to ensure adequate outflow. Only two patients in each group did not receive adjuvant periprocedural interventions. It has also been suggested that long-term patency is dependent on effective treatment of underlying stenosis and not on the thrombectomy technique.<sup>9</sup>

Time to intervention was not a predictor for survival in our study either in contrast to other findings.<sup>8</sup> This might be explained by the short interval between diagnosis and treatment, with a mean of 0.6 days for the AVG group and 0.4 days for the AVF group. This is reflected in our data, where 92% of the patients were treated within 1 day of diagnosis and only four patients needed a central venous catheter for dialysis. This short interval might be related to the intensive follow-up scheme and logistic facilitations in our hospital that help minimize treatment delay.

One of the first randomized multicenter studies to compare AngioJet™ with surgical thrombectomy in patients with a thrombosed AVG was performed by Vesely et al. in 1999. Technical success rates and patency rates were lower than previously reported studies with other interventions and lower than that indicated by the 2006 KDOQI guidelines. 1,2 Still, this study was the first to define success as effective completion of at least one hemodialysis session and to report standardized patency rates. The outcomes might be hampered by the use of an older AngioJet™ system with lower power and lacking a standardized treatment protocol and expertise. More recent studies, including ours, were conducted with the newer, more powerful, AngioJet™ AVX system and show improved results, reporting clinical success rates of up to 97%. 3.8.9.11,12.16

Kakkos et al. reported their results in the largest population to date. AngioJet™ thrombectomy was performed in 261 AVG cases and 24 AVF cases. Clinical success rate was 95%, which was comparable to our findings. Three-month functional primary patency rate of 55% was comparable to our patency rate in the AVG group. A relatively small number of patients with AVF access thrombosis were included and compared with the AVG group, and success rates were not specified for AVF patients.<sup>8</sup> Experience and comparison of different endovascular thrombectomy devices in AVF is described by Yang et al.9 The AngioJet<sup>™</sup> thrombectomy device was compared with the Arrow-Trerotola™ percutaneous thrombectomy device 275 thrombectomy procedures in patients with occluded AVF. They concluded that the PTD had a significantly higher success rate than the AngioJet<sup>™</sup>, 91% versus 76% (p = .002), with analogous patency rates. Our clinical success rate with the AngioJet™ did resemble the clinical success rate of the PTD group in their study; the patency rates were likewise similar. This might be explained by the type of AngioJet™ catheter, as only 31 of the 134 procedures were performed with the latest, more powerful AVX catheter.

A recent systematic review compared the outcomes of different endovascular devices in percutaneous treatment of thrombosed

vascular access, mainly divided into two categories: thrombectomy dependent and thrombolysis dependent. No significant differences were found in vascular access survival between the different treatments. However, a shift toward thrombectomy-dependent devices to reduce the amount of hemorrhagic complications associated with thrombolytic drugs was observed over time.<sup>5</sup>

The strength of this study is that we provide detailed information about the procedures and outcomes with the latest AngioJet™ system, especially in occluded AVFs. Patency rates were compared between AVF and AVG groups and multivariable analysis was performed to define predictors for failure after treatment. Limitations of the current study are its retrospective nature and the fact that the total number of included AVFs was relatively small compared with the included AVGs.

#### 5 | CONCLUSIONS

Based on the results of our retrospective study, the AngioJet™ system can be deemed an effective technique to reestablish patency in occluded vascular access, with minimal use of central venous catheters for dialysis. Good technical and clinical success rates were achieved with acceptable patency rates, which improved in patients with an AVF compared with patients with an AVG. Furthermore, this study identified several factors that influenced patency after the AngioJet™ thrombectomy procedure.

#### **CONFLICT OF INTEREST**

The authors declare no conflicts of interest.

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