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Original Article / Özgün Makale

Comparison of pharmacomechanical and surgical interventions for thrombosed native arteriovenous fistulas

Nativ arteriyovenöz fistül trombozlarında farmakomekanik ve cerrahi girişimlerin kıyaslanması

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ABSTRACT

Background: This study aims to compare success and patency rates of pharmacomechanical thrombectomy versus open surgical thrombectomy for thrombosed native arteriovenous fistulas.

Methods: A total of 96 patients (56 males, 40 females; mean age 61±11.7 years; range, 26 to 82 years) with a thrombosed native arteriovenous fistula between January 2016 and December 2018 were retrospectively analyzed. The patients were divided into two groups as pharmacomechanical thrombectomy (n=42) and open surgical thrombectomy (n=54). Primary failure rate and primary patency rate at 6 and 12 months were recorded.

Results: Of 42 patients in the pharmacomechanical thrombectomy group, 41 (98%) had additional interventions, and primary failure occurred in four patients (10%). Primary failure was seen in 15 (28%) patients in the surgical group. The primary patency rates at 6 and 12 months were significantly higher in the pharmacomechanical treatment group than the surgical group (85% vs. 67% and 78% vs. 55%, respectively; p<0.05).

Conclusion: Pharmacomechanical thrombectomy procedure yields higher primary patency rates than open surgical thrombectomy for thrombosed native arteriovenous fistula.

Keywords: Arteriovenous fistula, endovascular intervention, thrombosis.

ÖZ

Amaç: Bu çalışmada nativ arteriyovenöz fistül trombozunda farmakomekanik trombektomi ile açık cerrahi trombektominin başarı ve açıklık oranları karşılaştırıldı.

Çalışma planı: Ocak 2016 - Aralık 2018 tarihleri arasında nativ arteriyovenöz fistül trombozu olan toplam 96 hasta (56 erkek, 40 kadın; ort. yaş 61±11.7 yıl; dağılım, 26-82 yıl) geriye dönük olarak incelendi. Hastalar farmakomekanik trombektomi (n=42) ve açık cerrahi trombektomi (n=54) olmak üzere iki gruba ayrıldı. Altı ve 12. ayda primer başarısızlık oranı ve primer açıklık oranı kaydedildi.

Bulgular: Farmakomekanik trombektomi grubundaki 42 hastadan, 41'ine (%98) ek girişim yapıldı ve dört hastada (%10) primer başarısızlık izlendi. Açık cerrahi grupta 15 hastada (%28) primer başarısızlık görüldü. Altı ve 12. ayda primer açıklık oranları, cerrahi gruba kıyasla, farmakomekanik grupta anlamlı düzeyde daha yüksek idi (sırasıyla, %67'ye kıyasla %85 ve %55'e kıyasla %78; p<0.05).

Sonuç: Nativ arteriyovenöz fistül trombozunda farmakomekanik trombektomi işlemi, açık cerrahi trombektomiye kıyasla, daha yüksek primer açıklık oranı sağlar.

Anahtar sözcükler: Arteriyovenöz fistül, endovasküler girişim, tromboz.

Native arteriovenous fistulas (AVFs) still remain the preferred method of maintaining long-term hemodialysis access and its use is associated with fewer complications, improved access survival, and a lower mortality risk, compared to an arteriovenous graft (AVG) or central venous catheter (CVC).[1-4]

Arteriovenous fistula thrombosis, which is one of the leading causes of significant morbidity, has been shown to result in a large economic burden on healthcare resources and, therefore, they should be managed urgently to restore the AVF and optimize the outcomes.[5-8]

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Currently, access thrombosis can be managed by endovascular techniques or open surgical interventions. A variety of thrombectomy methods are available; however, the most optimal treatment in restoring and maintaining AVF functions is still unclear.[9,10]

There are previous randomized-controlled studies conducted more than a decade ago mostly included only AVGs with a small sample size.[11-13] Since then, there have been significant advances and improvements in endovascular equipment and techniques which are used for the treatment of thrombosed AVF.[14]

To the best of our knowledge, there is no randomized study comparing surgical versus endovascular interventions for native AVFs.[15] In addition, a meta-analyses of randomized studies comparing surgical versus endovascular treatments for thrombosed AVGs reported conflicting results.[10] In another study, surgery yielded superior patency rates, compared to repeated endovascular interventions.[16]

Hydrodynamic mechanisms such as the AngioJet™ Hemolytic Thrombectomy Device (Boston Scientific, Malborough, MA, USA) or rotational mechanisms using rotational instruments are the main two categories for endovascular mechanical thrombectomy procedure.[17] The AngioJet™ thrombectomy system is a rheolytic thrombectomy device which can be used in the treatment of hemodialysis AVF and AVG thrombosis. Thrombosis is often provoked by an underlying stenosis such as a juxta-anastomotic or a needle site stenosis or outflow stenosis.[18,19]

In the present study, we aimed to compare the success rate and patency outcomes of pharmacomechanical thrombectomy using the AngioJet™ rheolytic system versus open surgical thrombectomy.

PATIENTS AND METHODS

A total of 96 patients (56 males, 40 females; mean age 61±11.7 years; range, 26 to 82 years) with a thrombosed native AVF admitted to a referral center for vascular and vascular access surgery between January 1st, 2016 and December 31st, 2018 were included in this retrospective study. Of the patients, 56 were males and 40 were females with a mean age of 61±11.7 (range, 26 to 82) years. Inclusion criteria were as follows: age between 18 and 85, adult hemodialysis patients with a thrombosed native arteriovenous fistula within three days after last hemodialysis session. Exclusion criteria were as follows: age less than 18 and over 85 years, having an arteriovenous graft, those who were not eligible for tissue plasminogen activator (t-PA) usage and thrombosed fistulas for more than three days. Data were retrospectively retrieved from the databases of the hospital center. A written informed consent was obtained from each patient. The study protocol was approved by the Istanbul Medeniyet University, Faculty of Medicine, Göztepe Training and Research Hospital Ethics Committee (2019/0271). The study was conducted in accordance with the principles of the Declaration of Helsinki.

The patients were divided into two groups as pharmacomechanical thrombectomy (n=42) and surgical thrombectomy (n=54). The primary outcome measures included primary failure (PF) rate and primary patency rate at 6 and 12 months. Strict and clear definitions were used as described by Lambert.[10] The use of functional hemodialysis was defined as six consecutive dialysis sessions on two needles after the intervention as a measurement of successful dialysis.[20,21] The PF was defined as an AVF used for less than six consecutive hemodialysis sessions after the initial intervention. Primary patency was defined as the duration of AVF patency without revision.

All patients presenting with an occluded access underwent a clinical and ultrasonographic examination by the vascular surgeons to identify the location and extent of the thrombosis. The majority of patients with a thrombosed access were admitted for surgery the same day or the next day. Low-molecular-weight heparin (LMWH; enoxaparin sodium) was administered preoperatively to all patients. The mean duration of access thrombosis before the treatment was one to five days for both groups.

A small minority of patients with an established complete solid fistula thrombosis received a CVC and excluded to create a new AVF. The patients were censored at the last needling date, if they died, lost to follow-up, underwent successful renal transplantation, or switched to peritoneal dialysis. Patients with thrombosed AVGs were excluded from the study.

Operative procedures

The choice of operative method (pharmacomechanical versus surgical thrombectomy) was decided by the vascular surgeons at the center. In routine practice, there is no formal treatment protocol for access thrombosis at the study center. Both open and endovascular surgeons are available and the choice is at the discretion of the surgeon.

Endovascular protocol

All endovascular procedures were performed under local anesthesia. A standard Seldinger technique

under the ultrasound guidance was performed with retrograde access from more proximal part of the thrombosed vein and, if retrograde access failed or the vein segment became inadequate for retrograde cannulation, antegrade brachial artery was punctured. A 6F sheath was inserted, and angiographic images were obtained which detailed the AVF anatomy and thrombus structure. Systemic heparin (up to 5,000 IU) was used intraoperatively for all patients. A 5F angled catheter was passed over the thrombus with a 0.035-inch wire. Pharmacomechanical thrombectomy, using the rapid lysis technique with an AngioJet™ catheter (with 5 to 10 mg t-PA in 250 mL of saline) was performed for 2 min. After waiting for half an hour for lysis, the AngioJet™ was introduced across the thrombosis with a flow rate of 60 mL/min for 480 sec total run time according to the instructions for use. Following completion of pharmacomechanical thrombectomy, venography was performed to identify any residual thrombus load and potential stenosis. Subsequently, Angiojet™ thrombectomy was performed, if needed. Completion of venoplasty of causative stenosis was performed as routine in all endovascular interventions. Vein preparation was done with plain balloons, and paclitaxel was delivered for restenosis prevention with drug-coated balloons.

Surgical protocol

Surgical thrombectomies were performed under local anesthesia with standard balloon embolectomy catheters (LeMaitre® Fogarty catheter; LeMaitre Vascular, Burlington, MA, USA) and systemic heparin (5,000 IU) was used intraoperatively for all patients. A surgical revision of the anastomosis was mostly planned for a juxta-anastomotic stenosis, and a secondary fistula was created by forming a new anastomosis more proximal on the artery. On-table fistulogram was not available in the surgery group. After thrombectomy for outflow or cannulation site thrombus, a short interposition graft (polytetrafluoroethylene [PTFE] or saphenous vein) was used for a revision of the suspected stenotic segment in selected cases.

Statistical analysis

Statistical analysis was performed using the STATA for Macintosh version 12.0 software (STATA Corp., College Station, TX, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max), or number and frequency. The Fisher's exact test was used to compare categorical data, while the Student's t-test was used to compare continuous variables. A p value of less than 0.05 was considered statistically significant.

RESULTS

Of a total of 96 thrombosed AVFs, 42 (44%) underwent pharmacomechanical thrombectomy and 54 (56%) underwent surgical thrombectomy. There was no significant difference in demographic and clinical characteristics between the treatment groups (Table 1).

Of 42 pharmacomechanical thrombectomies, 41 (98%) had additional interventions and all were balloon angioplasty procedures for underlying stenosis with drug-coated balloons. The PF occurred in four (10%) patients and 38 (90%) patients had a successful dialysis use.

In all study population, 43 of 54 surgical thrombectomies had additional treatment, seven (13%) had a surgical revision of the anastomosis, 29 (53%) had a PTFE graft, four (7%) had saphenous vein interposition, and three (5%) had resection and side-to-side reanastomosis for the stenotic segments. Additional interventions for both groups and their

Table 1. Demographic and clinical characteristics of study groups

	Pharmacomechanical group (n=42)				Surgical group (n=54)				Total (n=96)			
	n	%	Median	Range	n	%	Median	Range	n	%	Mean±SD	*p*
Age (year)			58	32-78			62	36-81			61±11.7	0.64
Sex												
Male	25	59			31	57			56	58		0.81
Diabetes mellitus	30	71			37	68			67	69		0.78
CHF (EF <40%)	8	19			11	20			19	19		0.89
PVD	12	22			15	27			27	28		0.68
Forearm	26	62			35	65			61	64		0.85
Upper arm	16	38			19	35			35	36		0.74

SD: Standard deviation; CHF: Chronic heart failure; EF: Ejection fraction; PVD: Peripheral vascular disease.

Table 2. Primary failure and success rate according to type of treatment with additional interventions

		Primary failure		Success (dialysis use)	
	n	n	%	n	%
Pharmacomechanical (%)	42	4	10	38	90
No additional intervention (%)	2	1	50	1	50
Additional balloon angioplasty (%)	41	3	7	37	93
Surgical (%)	54	15	28	39	72
No additional intervention (%)	11	9	82	2	18
Additional surgical revision (%)	43	4	9	37	89

Table 3. Primary failure and primary patency of access after interventions at six and 12 months

	Pharmacomechanical group		Surgical group		
	n	%	n	%	*p*
Primary failure	4	10	15	28	0.18
Primary patency (month 6)	36	85	36	67	<0.05
Primary patency (month 12)	33	78	30	55	<0.05

effect on PF or successful dialysis use are summarized in Table 2.

A total of 77 (80%) of all thrombosed AVFs were needled following successful thrombectomy and 19 of those failed to achieve six consecutive dialysis sessions on two needles and classified as PF. Therefore, the PF rate was higher in the surgical group, compared to the pharmacomechanical group, although it did not reach statistical significance (15 [28%] vs. 4 [10%], respectively; p=0.18) (Table 3). The primary patency rate at six months was significantly higher in the pharmacomechanical treatment group compared to the surgery group (85% vs. 67%, respectively; p<0.05) with significantly higher rates at 12 months (78% vs. 55%, respectively; p<0.05) (Table 3).

There was no in-hospital mortality in any of the treatment groups. None of the patients had major bleeding requiring transfusion in the surgical group; however, there was a vein rupture requiring surgical revision and transfusion in the pharmacomechanical group. Three patients developed postoperative infection and all were in the surgical group; however, none of them required reoperation, and all were treated with oral antibiotics. Two patients suffered from an access site hematoma in the pharmacomechanical group and recovered without any intervention. Time to restart hemodialysis ranged from one to nine days for both groups and central vein catheters were used, if necessary.

DISCUSSION

In the present study, we compared the success rate and patency outcomes of pharmacomechanical thrombectomy using the AngioJet™ rheolytic system versus open surgical thrombectomy. Our study results demonstrated that pharmacomechanical thrombectomy yielded better outcomes with lower PF rates and higher primary patency rates than surgical thrombectomy.

Access thrombosis should be managed as soon as possible to optimize outcomes.[5] In general, underlying stenosis within the access circuit is the main reason for AVF thrombosis and procedures for detecting and treating these lesions is critical.[18] Endovascular approaches such as AngioJet™ system may help more to identify these stenotic segments. In a review regarding the AngioJet™ system for thrombosed AVFs and AVGs, Chan and Goh[22] Reported that endovascular thrombectomy method was a safe and effective treatment option. The adjusted mean primary patency rates at 1, 3, 6, and 12 months were reported as 64.6%, 43.8%, 42.5%, and 30.5%, respectively and the adjusted mean secondary patency rates at 3, 6, and 12 months were reported as 76.5%, 75.1%, and 74.5% respectively. Our study results are also consistent with

this report showing higher primary patency rates with AngioJet™ system, compared to surgical methods.

Thrombectomy alone without revision procedures have poor outcomes for both endovascular and surgical methods due to the underlying stenosis. Endovascular approaches provide more opportunity to identify this problem by performing an arteriovenous fistulogram and enable to make total correction of the stenosis of the AVF circuit.[10] In our study, however, we were unable to perform fistulogram during surgical procedures and, therefore, this might have adversely affected our results in this patient group. In addition, in surgical thrombectomies, we were unable to identify and treat more proximal and central vein problems.

In open surgical thrombectomy, the repair of cephalic arch syndrome is not possible for most cases, and brachiocephalic AVF thrombectomies produce higher PF rates; however, for endovascular thrombectomy interventions, balloon angioplasty should be performed and patency should be achieved.[23-26] Surgical and endovascular thrombectomy interventions have shown similar patency rates for particularly thrombosed AVGs.[27] In a meta-analysis of thrombosed AVFs and AVGs, endovascular techniques achieved comparable results to surgical thrombectomies.[13] However, there is no randomized study comparing surgical and endovascular treatment options for thrombosed AVFs in the literature.[28] Nonetheless, there is some evidence that forearm fistulas have slightly better long-term patency rates following surgical thrombectomy than endovascular procedures.[27]

Improved overall outcomes of endovascular interventions may be explained by the rapid improvements in endovascular techniques and skills over the past years. On the other hand, this accelerated gain in the field of endovascular treatment results in the discovery of numerous intervention methods with different endovascular devices and techniques, leading to a lack of evidence regarding the factors which influence the choice of treatment. As different endovascular techniques and devices were performed in previous studies, it is difficult to make a direct comparison of the patency rates of the treated thrombosed vascular accesses.[29-32] In their study, Sadaghianloo et al.,[6] showed a higher technical success rate, if surgical thrombectomy was performed less than 6 h after the diagnosis of thrombosed access. The exact duration of access thrombosis before treatment is of utmost important for achievement, although it is not possible to identify it for most cases.

The main limitations of the present study are its retrospective design and small sample size. In addition, the reasons of failure after procedures were unable to be identified; however, most of these were AVF thrombosis. In the surgical group, short interposition PTFE grafts were used for the suspected stenotic segment which may have caused a lower patency rate; therefore, the low success rate can be attributed to the use of these grafts. Also, we were unable to perform fistulography during surgical thrombectomies. The location of the underlying stenosis and occlusion may have influenced the patency of both procedures; however, we have no clear data about the location of the treated lesions. This study had no information about detailed preoperative pathological state of the disease (i.e., hypotension, critical stenosis or occlusion in the fistula circuit). Decision-making process for the treatment procedure was based on the surgeon discretion, we had no selection criteria for both endovascular and surgical methods, and the patients were not randomized. Therefore, further large-scale, long-term, prospective studies are needed to establish a definite conclusion.

In conclusion, arteriovenous fistula is a long-term, well-functioning vascular access and is important for hemodialysis-dependent patients, as it affects the mortality and morbidity. Thrombosis is one of the most common complications of AVF and can be treated by surgical thrombectomy or endovascular methods using pharmacomechanical thrombectomy systems. Our study results suggest that AngioJet™ pharmacomechanical thrombectomy system yields higher primary patency rates than surgical thrombectomy for primary thrombosis of a native arteriovenous fistula.

Declaration of conflicting interests

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