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Risk factors for acute kidney injury after pharmacomechanical thrombolysis for acute deep vein thrombosis

Karim M. Salem, MD, Zein Saadeddin, MD, Catherine Go, MD, Othman A. Malak, MD, Mohammad H. Eslami, MD, Eric Hager, MD, Georges Al-Khoury, MD, Rabih A. Chaer, MD, MSc, *and* Efthymios D. Avgerinos, MD, *Pittsburgh, Pa*

CME Activity

Purpose or Statement of Need The purpose of this journal-based CME activity is to enhance the vascular specialist's ability to diagnose and care for patients with the entire spectrum of circulatory disease through a comprehensive review of contemporary vascular surgical and endovascular literature.

Learning Objective

- Advise patients who have iliofemoral DVT about the risks of renal injury when undergoing thrombolytic therapy

Target Audience This activity is designed for vascular surgeons and individuals in related specialties.

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ABSTRACT

Background: Pharmacomechanical thrombolysis (PMT) is an established treatment for selected patients with acute deep vein thrombosis (DVT). Despite significant clinical success, hemolysis can lead to acute kidney injury (AKI) with unknown longer term implications. Our aim was to characterize the rate of AKI after PMT and identify those patients at the greatest risk.

Methods: A retrospective medical record review of patients with acute DVT who had undergone PMT in our institution from 2007 to 2018 was performed. The baseline demographics, comorbidities, preoperative clinical characteristics, procedural details, postoperative hospital course, and follow-up data were reviewed. The primary outcome was postoperative AKI (≥1.5 times preoperative creatinine), and longer term renal impairment. Logistic regression modeling was used to identify associated factors.

Results: A total of 137 patients (mean age, 47 ± 16.6 years; 49.6% male) who had undergone PMT for treatment of acute DVT were identified (85.4% AngioJet system; Boston Scientific Corp, Marlborough, Mass). Of the 137 patients, 30 (21.9%)

From the Division of Vascular Surgery, University of Pittsburgh Medical Center, Presbyterian University Hospital.

Author conflict of interest: E.A. has been paid a consulting fee by BD Medical and Angiodynamics and is on the speaker's bureau for Boston Scientific. R.A.C. has been paid a consulting fee by Boston Scientific. K.M.S., Z.S., C.G., O.A.M., M.H.E., G.A.-K., and E.D.A. have no conflicts of interest.

Presented at the Thirty-third Annual Meeting of the Eastern Vascular Society, Pittsburgh, Pa, September 5-7, 2019.

Correspondence: Karim M. Salem, MD, Division of Vascular Surgery, University of Pittsburgh Medical Center, Presbyterian University Hospital, South Tower, Ste E370.5, 200 Lothrop St, Pittsburgh, PA 15213 (e-mail: salemkm@upmc.edu).

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2213-333X

Published by Elsevier Inc. on behalf of the Society for Vascular Surgery.

https://doi.org/10.1016/j.jvsv.2020.11.005

had developed AKI in the periprocedural period, 1 of whom had required hemodialysis in the perioperative period. The patients who had developed AKI had had significantly greater rates of preoperative coronary artery disease (23.1% vs 4.7%; $P = .002$), diabetes mellitus (19.2% vs 6.6%; $P = .045$), dyslipidemia (42.3% vs 17.9%; $P = .008$), and hypertension (53.6% vs 29.3%; $P = .018$). No significant difference was found in preoperative creatinine (0.99 vs 0.92 mg/dL; $P = .65$) or glomerular filtration rate (GFR; 96.9 vs 91.8 mL/min; $P = .52$) between the two groups. Multivariate analysis demonstrated bilateral DVT (odds ratio [OR], 4.35; 95% confidence interval [CI], 1.47-12.86; $P = .008$), single-session PMT (OR, 3.05; 95% CI, 1.02-9.11; $P = .046$), and female sex (OR, 2.85; 95% CI, 1.01-8.04; $P = .048$) were significant predictors of AKI. Of the 30 patients, 10 had had normal renal function at discharge and 15 and 25 patients had had normal renal function at the first and subsequent clinical follow-up visits, respectively. The remaining five patients (3.6%) had progressed to moderate (GFR, <60 mL/min) or severe (GFR, <30 mL/min) renal insufficiency, with one requiring long-term hemodialysis.

Conclusions: The use of PMT for treatment of acute DVT conferred a risk of AKI that will progress to chronic renal failure in a small fraction of affected patients. Patients with bilateral extensive DVTs have a greater risk of AKI; thus, longer priming with a thrombolytic drip before PMT should be preferred for this population. (J Vasc Surg Venous Lymphat Disord 2021;9:868-73.)

Keywords: Acute DVT; DVT lysis; Pharmacomechanical thrombolysis

In recent years, endovascular catheter-based interventions have been more frequently used in the treatment of acute deep vein thrombosis (DVT). The more rapid reduction of the thrombus burden allows for a faster resolution of symptoms and aids in the maintenance of valve function. Recent evidence has suggested that catheter-directed therapy (CDT) in the setting of acute iliofemoral DVT improves iliofemoral vein patency and post-thrombotic severity with an equivocal risk of bleeding.[1] Current guidelines recommend early thrombus removal in patients with acute and symptomatic proximal DVTs if they have a good life expectancy and low bleeding risks.[2]

Although the use of no-lytic alternatives has been increasing, catheter thrombolytic agents have remained the standard of care for DVT intervention. Catheter thrombolysis can be accomplished by dripping thrombolytic agents through a multiside-hole catheter over several hours or using pharmacomechanical thrombolysis (PMT) devices, which mechanically reduce the thrombus burden and simultaneously instill the thrombolytic agent. Plenty of evidence has supported the use of PMT over catheter thrombolysis because PMT can achieve faster lytic therapy at a lower tissue plasminogen activator (tPA) dose.[3-5] The AngioJet system (Boston Scientific Corp, Marlborough, Mass), in particular, has been, and still is, the most popular PMT device with distinct advantages and a high safety profile.[6]

Aggressive PMT, however, using the AngioJet system causes hemolysis, which can be complicated further by the development of acute kidney injury (AKI).[7,8] The present study evaluated the frequency, risk factors, and effects of AKI in patients undergoing PMT for acute DVT.

METHODS

Study design. The institutional review board of the University of Pittsburgh approved the present study and waived the requirement for patient informed consent. A retrospective medical record review of consecutive patients who had undergone PMT for acute DVT in our institution from 2007 to 2018 was conducted. All patients included in the present study had had acute symptomatic iliofemoral DVT. Baseline demographics, comorbidities, thrombotic risk factors, symptoms, procedural details, postoperative hospital course, and follow-up data were recorded and reviewed. The primary outcomes studied were the development of postoperative AKI, defined as an increase of ≥1.5 times the preoperative baseline creatinine, and long-term renal impairment or recovery.

Data were compiled in Excel (Microsoft, Redmond, Wash) and analyzed using Stata SE, version 15.1 (StataCorp, College Station, Tex). The patients were divided into two groups stratified by the development of AKI. Student's t tests (for continuous data) or χ^2 tests (for categorical data) were used to compare the baseline characteristics between the two groups. Logistic regression modeling was used to identify the risk factors associated with our primary outcome of AKI. The results are presented as odds ratios (ORs) and P values, with P values <.05 considered statistically significant.

Perioperative management and technique. Duplex ultrasonography was performed for all patients to confirm the diagnosis of DVT. Before intervention, intravenous unfractionated heparin was initiated, and a standard hospital-wide protocol was followed to maintain therapeutic partial thromboplastin time or antifactor Xa levels. Perioperatively, all nephrotoxic medications were withheld until discharge. Postoperatively, all patients were bridged to full oral anticoagulation therapy. Board-certified vascular surgeons performed all procedures during the study period.

All the patients had undergone conscious sedation in a hybrid operating room at the University of Pittsburgh Medical Center. Venography was performed via 6F to 8F sheaths via percutaneous femoral or popliteal venous access. During the study period, the treatment techniques used had evolved with experience. Initially, instillation of tPA (Alteplase; Genentech, San Francisco, Calif)

was performed for 24 to 48 hours, after which repeat venograms were performed at the second and/or third sessions to evaluate the degree of thrombus clearance. PMT was performed during the second or third session to complete thrombus removal before venoplasty or stenting. As the venous treatment experience evolved, PMT was used as first-line treatment with selective use of CDT overnight if adequate thrombolysis could not be achieved in a single session at the discretion of the treating physician. Our practice primarily uses PMT with the AngioJet catheter (Boston Scientific) with 6 to 10 mg of tPA. A small proportion of patients underwent PMT using the Trellis device (Covidien Vascular, Mansfield, Mass) before its removal from the market. A standard multiside-hole catheter, most often a Cragg-McNamara Valved Infusion Catheter (Medtronic, Minneapolis, Minn), was used for CDT at a tPA infusion rate of 0.25 to 1.00 mg/h. Hemoglobin, hematocrit, and fibrinogen levels were measured every 6 hours throughout thrombolysis, with the patients monitored in the intensive care unit.

RESULTS

We identified 137 patients who had undergone PMT for acute DVT (85.4% using the AngioJet system; Boston Scientific). The mean age was 47 ± 16.6 years, 49.6% were men, and 86.1% of the patients were white. The patients were divided into two groups according to the development of postoperative AKI (≥1.5 times the baseline creatinine). Of the 137 patients, 30 (21.9%) had developed postoperative AKI. The mean age, sex, and indication for treatment (pain and/or edema or phlegmasia) did not differ between the two groups. However, the patients who had developed AKI were more likely to be obese, with a body mass index of ≥30 kg/m^2 (76.2% vs 51.5%; $P = .02$). Patients in the AKI cohort also had greater rates of coronary artery disease (23.1% vs 4.7%; $P = .002$), diabetes mellitus (19.2% vs 6.6%; $P = .045$), dyslipidemia (42.3% vs 17.9%; $P = .008$), and hypertension (53.6% vs 29.3%; $P = .018$). The baseline characteristics and comorbidities are presented in Table I. Of the patients who developed postoperative AKI, 89.5% had been treated with the AngioJet device (Boston Scientific). The use of the AngioJet device increased throughout the study period. In the first quartile of the study period, 74.5% of the treatments had been with the AngioJet device. In the last quartile, it was used for 100% of treatments. No significant associations were found between the development of AKI and known nephrotoxic medications, because all had been withheld during the perioperative period.

The preoperative creatinine levels (0.99 vs 0.92 mg/dL; $P = .65$) and glomerular filtration rates (GFR; 96.9 vs 91.8 mL/min; $P = .52$) did not differ between the two groups. The mean creatinine increase observed in the AKI cohort was 1.68 ± 1.47 mg/dL (range, 0.40-5.90 mg/dL).

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective comparative review
- **Key Findings:** Pharmacomechanical thrombolysis (PMT) for the treatment of acute deep vein thrombosis (DVT) in 137 patients conferred a risk of acute kidney injury (AKI) in 21.9% of patients. Bilateral DVT (odds ratio [OR], 4.35; $P = .008$), single-session PMT (OR, 3.05; $P = .046$), and female sex (OR, 2.85; $P = .048$) were significant predictors of AKI.
- **Take Home Message:** PMT has been shown to cause AKI during treatment of DVT. Patients with a significant clot burden might require slow lytic drips to reduce this risk.

The AKI cohort had had greater rates of bilateral DVT on presentation (40.7% vs 16.5%; $P = .005$) and were more likely to undergo a single-session intervention (30% vs 10.3%; $P = .007$).

The univariate risk factors for the development of AKI included coronary artery disease, hypertension, dyslipidemia, obesity, bilateral DVT, single-session treatment, postoperative hematuria, and use of the AngioJet device (Table II). Female sex, diabetes mellitus, and a >20% decrease in postoperative hemoglobin showed a trend toward statistical significance.

Multivariable analysis demonstrated bilateral DVT (OR, 4.35; 95% CI, 1.47-12.86; $P = .008$), single-session PMT (OR, 3.05; 95% CI, 1.02-9.11; $P = .046$), and female sex (OR, 2.85; 95% CI, 1.01-8.04; $P = .048$) were significant predictors for development of AKI (Table II). A subgroup analysis was performed of the 37 patients without bilateral DVT, single-session PMT, or female sex. The results revealed a 2.7% incidence of postoperative AKI in the subgroup.

Postoperative follow-up of the 30 patients who had developed AKI revealed that the renal function of 10 had returned to baseline by discharge. The renal function of 5 additional patients had returned to baseline by the 1-month follow-up visit and 10 at later follow-up visits. Eventually, three patients had experienced progression to moderate (GFR <60 mL/min) and two to severe (GFR <30 ml/min) renal insufficiency, for a 3.6% rate of progression to moderate or severe renal failure. One patient required long-term hemodialysis, which was started during the perioperative period. The patients who had experienced long-term renal dysfunction were older (mean age, 61.8 ± 16.9 years), had had a greater body mass index (mean, 36.5 ± 5.3 kg/m^2), and had had more frequent caval thrombus involvement. Also, the treatment was more likely to have been completed in a single session (50%) compared with the remainder of the study cohort.

Table I. Demographics and comorbidities

Variable	AKI		*P* value
	Yes (n = 30)	No (n = 107)	
Age, years	47.2 ± 18.7	47.0 ± 16.2	.94
Male sex	33.3 (9/27)	57.3 (57/106)	.058
BMI class			**.02**
Normal	19.1 (4/21)	19.1 (28/99)	
Overweight	4.8 (1/21)	20.0 (20/99)	
Obese class I	14.3 (3/21)	22.2 (22/99)	
Obese class II	23.8 (5/21)	13.1 (13/99)	
Obese class III	38.1 (8/21)	16.2 (16/99)	
Smoker	19.2 (5/26)	22.1 (23/104)	.75
CAD	23.1 (6/26)	4.7 (5/106)	**.002**
DM	19.2 (5/26)	6.6 (7/106)	**.045**
HLD	42.3 (11/26)	17.9 (19/106)	**.008**
HTN	53.6 (14/26)	29.3 (31/106)	**.018**
Hypercoagulable state	40.7 (11/27)	30.8 (33/107)	.33
Malignancy	7.4 (2/27)	13 (14/107)	.42
DVT	37.4 (12/27)	37 (40/107)	.50
CKD	33.3 (10/30)	41.1 (44/107)	.44
Iliofemoral plus caval	46.2 (12/26)	47.7 (51/107)	.89
Iliofemoral only	23.3 (7/30)	30.8 (33/107)	.42

AKI, Acute kidney injury; *BMI,* body mass index; *CAD,* coronary artery disease; *CKD,* chronic kidney disease; *DM,* diabetes mellitus; *DVT,* deep vein thrombosis; *HLD,* hyperlipidemia; *HTN,* hypertension.
Data presented as mean ± standard deviation or % (n/N). Boldface *P* values represent statistical significance.

DISCUSSION

Endovascular treatment of acute iliofemoral DVT has become more common in recent years with improvement in experience and a better definition of appropriate patient selection. Thrombolysis can achieve a rapid reduction in the thrombus burden, and high quality evidence has shown that a faster resolution of symptoms and reduction of post-thrombotic syndrome (PTS) severity can be achieved.[9] Minimizing residual thrombus is key for an overall successful outcome and in particular for PTS severity reduction.[10,11]

Several trials have been performed to evaluate the efficacy of interventional therapies for acute iliofemoral DVT. The CaVenT (catheter-directed thrombolysis in acute iliofemoral vein thrombosis) and ATTRACT (acute venous thrombosis: thrombus removal with adjunctive catheter-directed thrombolysis) trials showed that CDT achieves faster pain relief, reduces the rates (CAVENT) or severity (ATTRACT) of PTS development, and improves patients' quality of life.[1,12] Since 2012, the Society for Vascular Surgery guidelines have suggested early thrombus removal for patients with an initial episode of acute iliofemoral DVT, symptoms lasting <14 days, and a low risk of bleeding, provided the patients are ambulatory with good functional capacity.[2]

More contemporary studies have reported the results of more rapid and aggressive thrombolysis protocols that can be completed in a single session.[13] The fast-track thrombolysis protocol (FTTP) reported by Ascher et al[13] studied 38 patients with acute iliofemoral DVT. Successful single-session FTTP was accomplished in 81.5% of the cases with a median dose of 10 mg of tPA infused. They achieved this with low rates of 30-day repeat thrombosis, pulmonary embolism, significant hemorrhage, limb loss, or mortality.[13] Their findings suggested that their protocol would be safe, clinically effective, and cost-effective in the treatment of iliofemoral DVT. Treating patients using a rapid and single-stage method requires more aggressive use of pharmacomechanical therapies compared with an infusion and multiple-stage treatment. The aggressive use of PMT, however, has been associated with a development of acute renal failure owing to the hemolysis caused by these devices, mainly the AngioJet peripheral thrombectomy system (Boston Scientific).[14]

Within our institution, the most commonly used device for PMT has been the AngioJet peripheral thrombectomy system, specifically the ZelanteDVT catheter (Boston Scientific). The device works in two modes. The power pulse lytic delivery mode directly delivers the lytic into the thrombus. After the dwell time, active aspiration

Table II. Univariate and multivariate predictors of AKI after PMT

Variable	OR	95% CI	*P* value
Univariate			
Female sex	2.32	0.96-5.65	.060
CAD	6.06	1.68-21.80	**.006**
DM	3.37	0.97-11.64	.055
HTN	2.82	1.17-6.79	**.020**
HLD	3.36	1.33-8.45	**.010**
Bilateral DVT	3.7	1.44-9.55	**.007**
Single session	3.74	1.38-10.16	**.010**
Multiple sessions	0.27	0.10-0.72	**.010**
CDT first	0.57	0.24-1.37	.210
BMI	1.06	1.00-1.12	**.039**
Phlegmasia	1.58	0.51-4.91	.430
Caval involvement	0.94	0.40-2.22	.890
Iliofemoral alone	0.68	0.27-1.75	.430
Postoperative anemia (>20% decrease)	2.38	0.95-5.94	.063
AngioJet use	2.32	1.01-5.32	**.048**
Multivariate			
Bilateral DVT	4.35	1.47-12.86	**.008**
Single session	3.05	1.02-9.11	**.046**
Female sex	2.85	1.01-8.04	**.048**

AKI, Acute kidney injury; *BMI,* body mass index; *CAD,* coronary artery disease; *CI,* confidence interval; *CDT,* catheter-directed therapy; *DM,* diabetes mellitus; *DVT,* deep vein thrombosis; *HLD,* hyperlipidemia; *HTN,* hypertension; *OR,* odds ratio; *PMT,* pharmacomechanical thrombolysis.
Boldface *P* values represent statistical significance.

is achieved using backward-flowing saline jets, which create a low-pressure zone and, ultimately, a vacuum effect. The thrombus is drawn into the catheter by this vacuum and evacuated into a collection bag.[15] Careful consideration is required to not surpass a total thrombectomy volume of 300 mL in accordance with the instructions for use. Multiple studies have demonstrated hemolysis resulting from AngioJet therapy in animal models.[7,8] This intravascular hemolysis results in acute tubular necrosis due to hemoglobinuria and, ultimately, AKI. The presence of hematuria, decreased haptoglobin levels, elevated serum lactate dehydrogenase, and elevated urine bilirubin can aid in the diagnosis of intravascular hemolysis.[16]

We elected to further explore the risk factors for the development of AKI in patients who had undergone PMT. The rate of AKI development in our cohort was 21.9%, similar to the rates reported by other studies (20%-30%).[7,14,16] Although the vast majority had recovered, 3.6% had eventually developed new-onset long-term moderate (GFR, 60-90 mL/min) to severe (GFR, <60 mL/min) renal dysfunction without renal recovery. Univariate risk factors for the development of AKI included coronary artery disease, hypertension, dyslipidemia, obesity, bilateral DVT, single-session treatment, postoperative anemia, and the use of the AngioJet device (Boston Scientific). In our multivariable model, patients with bilateral DVTs, those who had undergone aggressive single-session PMT, and women had had the greatest risk of developing postoperative AKI. Similar studies have noted these findings. However, these studies had focused on hemolysis and subsequent anemia as risk factors for AKI and had not addressed preoperative risk factors for the development of AKI. A recent study by Shen et al[14] suggested that major surgery within the 3 months before PMT was associated with postoperative AKI. However, no further risk factors were identified.[14] Our focus was to identify the preoperative factors that might influence our decision to pursue aggressive single-stage intervention, similar to the previously discussed FTTP, rather than multistage CDT. With the results of the present study, we avoid single-stage intervention for this high-risk group (women with bilateral extensive DVT), if clinically appropriate, to minimize the risk of postoperative AKI. Lytic drips or alternative aspiration devices can be used, depending on the indication, anatomy, and extent of the disease.

The study limitations included its retrospective and single-institution nature. The patients included in the present study did not undergo single- or multiple-stage

procedures according to a protocol, and the treatments differed by physician preference and level of experience. The present study was performed during a 12-year period (2007-2018), which possibly introduced bias into the study regarding the diagnostic and therapeutic protocols. On average, we treated 11 patients annually, although a greater proportion of these treatments were performed in the early portion of the study period. We did not find any statistically significant association between the development of AKI and the year of treatment or study period. Despite this, bias was likely introduced into the study as we became more experienced with our patient selection and treatment method. The thrombectomy volume and time were not recorded by the operating team, which could significantly affect the risk of AKI. Because of the prolonged study period, the hydration protocols varied and had not been recorded appropriately in the medical records. Contrast administration was also not accurately recorded. Within our institution, we generally use half-strength iodixanol for venography. The 2020 Radiologic Society of North America guidelines have stated that the risk of AKI from iodinated contrast media is overstated and that a significant risk exists for patients with an estimated GFR <30 mL/min/1.73 m^2. Only two such patients were included in our study, and no significant association was noted between the development of AKI and the preoperative estimated GFR. Therefore, procedural contrast administration data were not recorded.[17]

CONCLUSIONS

PMT has become a more frequently used treatment for patients with acute iliofemoral DVT. The use of PMT has been shown to confer a risk of AKI, which can progress to chronic renal failure in a small fraction of patients. Our series has shown that patients with bilateral extensive DVTs, with more aggressive intervention and greater operative blood loss, have the greatest risk of AKI. Alternative techniques or longer priming with lytic drips before PMT should be considered for these patients.

AUTHOR CONTRIBUTIONS

Conception and design: KS, EA
Analysis and interpretation: KS, EA
Data collection: KS, ZS, CG, OM, ME, EH, GAK, RC, EA
Writing the article: KS, ZS, CG, EA
Critical revision of the article: KS, ZS, CG, OM, ME, EH, GAK, RC, EA
Final approval of the article: KS, ZS, CG, OM, ME, EH, GAK, RC, EA
Statistical analysis: KS, EA
Obtained funding: Not applicable
Overall responsibility: EA

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Submitted Jul 7, 2020; accepted Nov 1, 2020.

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