Feasibility and efficacy of balloon disruption of fibrin sheath in hemodialysis catheters: A prospective study

Original Article

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ABSTRACT

Background: Tunneled hemodialysis catheter malfunction is often attributed to thrombotic blockages and the formation of catheter-related fibrin sheaths.

Patients and Methods: The study investigates the feasibility, safety, and efficacy of balloon disruption of fibrin sheath in hemodialysis patients with malfunctioning central venous catheters. The research spans from January 2023 to September 2023, evaluating 30 patients.

Results: Technical and clinical success rates were 100 and 93.33%, respectively. Despite promising initial outcomes, primary patency rates decreased over time, highlighting the need for further investigation. Factors like advanced age and previous interventions significantly influenced catheter patency.

Conclusion: Balloon disruption of the fibrin sheath has demonstrated safety and efficacy in preserving vascular access. Questions exist about the durability of such an intervention.

Key Words: Balloon disruption, catheter malfunction, central venous catheter, fibrin sheath, hemodialysis.

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INTRODUCTION

While native arteriovenous fistula (AVF) stands as the preferred hemodialysis access, catheter-based hemodialysis remains an adequate alternative, particularly when immediate dialysis is required, in patients awaiting the establishment or maturation of AVF, and in patients who have exhausted all options for fistula construction. Additionally, it serves patients requiring hemodialysis while awaiting soon transplantation. Moreover, it benefits fragile patients with limited tolerance to hemodynamic changes associated with AVF creation, and patients who possess a limited life expectancy[1].

Like other central venous devices, hemodialysis catheters are frequently prone to the development of catheter malfunction attributable to partial or complete thrombotic blockages and the formation of catheter-related fibrin sheaths (CRS)[2]. Catheter malfunction is defined as the catheter incapacity to sustain the prescribed extracorporeal blood flow necessary for the adequate delivery of hemodialysis dose without extending the duration of the hemodialysis session[1]. In a study involving 1 075 701 hemodialysis sessions, catheter malfunction was estimated to occur in 7.1% of sessions. Additionally, 65% of patients experienced one or more malfunction sessions, with 30% encountering one or more malfunction sessions/month[3]. In the United States, almost one-third of all hospital admissions for hemodialysis patients is attributed to catheter-related complications. This leads to an annual hospitalization duration of an additional 17 days/patient[4,5]. The rate of catheter malfunction resulting from the formation of a fibrin sheath has been reported to range between 13 and 57%[6]. Catheter malfunction may result in significant recirculation with a magnificent reduction in the delivered dialysis dose, and if left untreated may eventually end up in loss of the access site[7,8].

Fibrin sheath formation typically begins within 24 h of the catheter implantation at the venous insertion site. Over 5 to 7 days, it may progress to completely enclose the catheter. The distal end of the fibrin sheath then migrates centrally and ultimately envelops the catheter tip. This can lead to catheter malfunction by creating a flap valve effect, permitting injection but impeding the withdrawal of blood flow[2,9].

Restoration of flow in malfunction catheters can be accomplished through pharmacologic lysis or mechanical interventions; the latter is followed by catheter exchange. Mechanical techniques include transfemoral stripping of the fibrin sheath using a snare or endoluminal disruption with various devices such as a guide wire, catheters, or balloons[6,10]. Although thrombolytic therapy has shown a high immediate success rate of over 80%, the 2-month patency rate can be relatively low, ~36%[11]. Based on

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available evidence, mechanical disruption of fibrin sheath seems to be as effective as the pharmaceutical thrombolytic agents for the immediate management of malfunction catheters, with superior results in terms of catheter longevity[12]. The various approaches for mechanical fibrin sheath disruption exhibit variable outcomes of dialysis adequacy and the risk of adverse events[12].

PATIENTS AND METHODS:

Our study was conducted in the vascular surgery department of Cairo University Hospitals, spanning from January 2023 to September 2023. The objective was to assess the feasibility, safety, and efficacy of balloon disruption of fibrin sheath in hemodialysis patients with malfunction tunneled central venous catheters.

Catheter malfunction was diagnosed when the patient experienced either of the following conditions:

(a) Three dialysis treatments within the last 30 days, exhibiting a mean blood flow of less than 300 ml/min.

(b) A single dialysis treatment with a mean blood flow of less than 200 ml/min.

Before enrollment, catheter malfunction was evaluated to eliminate causes other than CRS. Measures to restore the catheter function as patient repositioning, lumen reversal, and treatment with at least one dose of 2 mg of alteplase administered as a 1 h dwell for each lumen were all tried. Patients were not included in the study if catheter function was successfully restored by any of those measures. Patients were also deemed ineligible if they had an allergy to contrast material or exhibited any signs of active infection. Patients with dual-way obstruction of the catheter as well as cases of catheter malfunction due to mechanical issues such as kinking and malposition of the catheter tip were excluded.

The study protocol was approved by our institution research ethics committee. Written informed consent was obtained from all study participants. Patients' medical histories were collected, encompassing demographic and medical details, as well as the history of prior catheter insertion, duration of current catheter indwelling, and any previous interventions related to catheter issues.

Technique

Following antiseptic application and draping, a local anesthetic was infiltrated into the subcutaneous tissue at the vein puncture site (through which the catheter had initially been inserted) and a 1–1.5 cm skin incision was made to dissect free the catheter, which was then hooked and secured using a suitable artery forceps. Another injection of Lignocaine was administered into the subcutaneous tissue surrounding the Teflon cuff, and a small skin incision centered over the cuff was made to dissect the cuff off the surrounding tissues. The presence of a fibrin sheath was confirmed by withdrawing the catheter until the tip was near the vein entry site, followed by injection of undiluted contrast at a rate of 2–4 ml/min through the arterial port.

The hooked part of the catheter was clamped and severed beyond the clamp. The segment of the catheter beyond the cut was then extracted from the tunnel and discarded. The catheter stump was cannulated using a standard Terumo 0.035' wire through one of its lumens. The remaining portion of the catheter was then removed while the wire maintained the access. A 10 F sheath was then advanced over the wire into the vein, through which further injection of contrast medium allowed for identification of the extent of the CRS. An appropriately sized, in both length and diameter, the balloon was advanced over the wire and inflated to disrupt the fibrin sheath. A completion angiogram was obtained to verify sufficient disruption of the fibrin sheath. The procedure was concluded by over the wire insertion of a new 15.5 F dual-lumen cuffed catheter.

Technical success was achieved when free flow was expressed from both lumens of the newly inserted central venous catheter. Clinical success was confirmed by the restoration of target flow rates during subsequent hemodialysis sessions, ensuring uninterrupted flow for thrice-weekly dialysis doses.

Follow-up appointments were scheduled at 1 week, as well as at 1, 3, and 6 months postoperatively, and whenever there were any malfunction concerns. During each follow-up visit, the following criteria were evaluated:

(a) Manifestations suggesting catheter-related infection.

(b) Review the dialysis technician's notes on the dialysis flow rates and the necessity for lumen reversal.

Patients were excluded from further analysis if they experienced recurrent catheter malfunction. Those patients were categorized as having lost catheter patency following fibrin sheath disruption, irrespective of the subsequent catheter salvage intervention.

RESULTS:

Thirty consecutive chronic kidney disease patients on regular hemodialysis with malfunctional central venous catheters attributed to CRS formation were included in the study. The age of the patients enrolled in the current study ranged from 28 to 81 years, with a mean age of 62.73 years. Sixteen (53.33%) patients were males. Ten (33.33%) patients were smokers. Twenty-one (70%) patients had hypertension, and 19 (63.33%) were diabetics. Thirteen (43.33%) patients had ischemic heart disease (IHD), and 13 (43.33%) patients were dyslipidemics. The duration from hemodialysis treatment initiation ranged from 2 months to 7 years, with a median duration of 2 years.

Among the study population, 16 (53.33%) patients had previous catheters in the same location of current indwelling. Four (13.33%) patients were identified to have previous endovenous interventions for the management of fibrin sheath-related catheter malfunction. Three of them had balloon disruption while the remaining patient had fibrin sheath stripping.

The malfunctioning indwelling central venous catheters were inserted in right internal jugular vein in 14 (46.67%) patients, left internal jugular vein in nine (30%) patients, right subclavian vein in two 96.67%) patients, left subclavian vein in three (10%) patients and right femoral vein in two (6.67%) patients.

The median procedure time was 35.1±7.7 min. Patients were followed-up for a mean duration of 126.7 days.

Technical success was achieved in all the 30 (100%) patients.

There were no perioperative complications such as bleeding, pneumothorax, or pulmonary embolism. There was no procedure-related mortality.

Clinical success was achieved in 28 (93.33%) patients. However, two patients had an early loss of patency and were classified as early clinical failures. One of these patients developed recurrent catheter malfunction 5 days following the procedure, while the other experienced recurrence 9 days postprocedure. In both instances, management necessitated catheter removal, followed by the insertion of a new catheter at a different location.

In 1 month, one patient was lost to follow-up.

During the subsequent follow-up period, at 3 months, five additional patients experienced recurrent catheter malfunction. Re-intervention was performed for all of them. One patient underwent fibrin sheath stripping, one received lytic therapy infusion, and the remaining three underwent redo balloon disruption of the fibrin sheath.

At 6 months, two additional patients were lost to follow-up and seven additional patients experienced recurrent catheter malfunction. Re-intervention was required for all seven patients. Three patients underwent catheter removal followed by insertion of a new catheter at a different location, and four patients underwent successful balloon disruption in conjunction with catheter exchange. The type of the procedure offered to all patients with recurrent catheter malfunction was determined by the attending operator's preference.

The patency rates were 90, 73.3, and 43.3% at 1, 3, and 6 months, respectively. Overall, re-intervention was necessary in 14 (46.7%) patients. The mean time to first re-intervention was 78 days, with a range of 5–166 days (median 157 days). The cumulative rates of preserved patency are depicted in the Kaplan–Meier survival estimate (Fig. 1).

Demographic and clinical criteria were correlated with their effect on the patency of the newly inserted central venous catheters. Among all studied demographic criteria, only the age above 60 years had a significant relationship to the loss of patency of the catheters [hazard ratio (HR)=0.94, 95% confidence interval (CI) 0.89–0.99, *P=0.02*].

Previous catheter-related interventions had a highly significant relationship to the loss of patency of the catheters (HR=12.15, 95% CI 2.91–50.70, *P=0.001*). Previous catheters in the same dwelling location had a highly significant effect on the loss of patency of the catheters (HR=5.4, 95% CI 1.67–17.4, *P=0.005*).

Other criteria such as female sex, diabetes mellitus, hypertension, dyslipidemia, smoking, ischemic heart disease, time from indwelling catheter insertion, and duration from the start of hemodialysis affected the loss of patency of the catheters, yet this effect did not reach a statistical significance (Table 1).

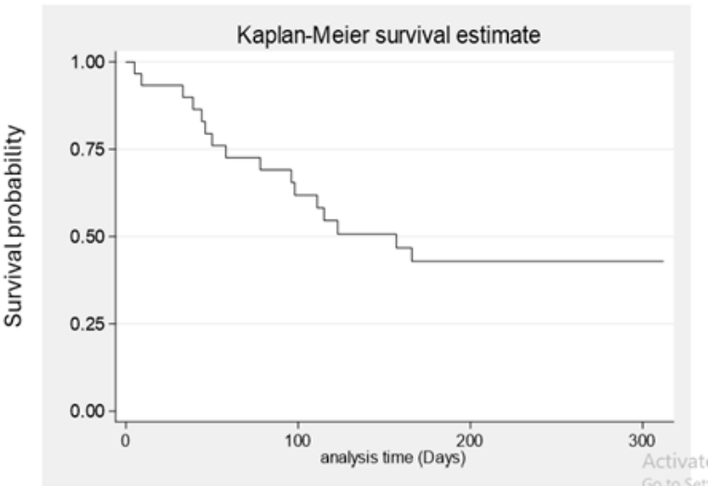

Fig. 1: Kaplan–Meier survival estimate showing time to re-intervention (Median time: 157 days).

Table 1: Cox proportional hazard regression analysis for predictors of reintervention

	Hazard ratio (95% CI)	*P*
Age above 60 years	0.94 (0.89–0.99)	**0.02**
Female Gender	1.17 (0.45–3.11)	0.7
DM	1.91 (0.61–5.96)	0.3
HTN	0.70 (0.24–2.03)	0.5
Dyslipidaemia	0.64 (0.23–1.77)	0.4
Smoking	0.56 (0.18–1.73)	0.3
IHD	0.46 (0.16–1.35)	0.2
Previous catheter-related interventions	12.15 (2.91–50.79)	**0.001**
Time from indwelling catheter insertion	0.99 (0.99–1.003)	0.4
Previous catheters in the same location	5.40 (1.67–17.40)	**0.005**
Duration from the start of HDx	0.97 (0.77–1.21)	0.8

DISCUSSION

Despite decades of research in the development of dialysis catheters, the persistent issue of catheter-related complications remains unresolved and warrants further research. Among various catheter-related complications, the development of fibrin sheaths continues to be a significant factor influencing the long-term performance of catheters. Fibrin sheath; the fundamental structural component of the thrombus; ultimately results in the malfunction/occlusion of the catheter, necessitating catheter exchange, and ultimately leading to the premature loss of the access site. Therefore, the preservation of catheter patency remains a significant concern in the routine care of hemodialysis patients[12].

Interventions for catheter malfunction encompass the use of thrombolytic agents administered directly into the catheter lumen, as well as mechanical disruption of fibrin sheath. Thrombolytic agents evaluated thus far include urokinase, streptokinase, and recombinant tissue-type plasminogen activators[1]. Various protocols involving different doses of different thrombolytic agents have been implemented. Cumulatively, the use of thrombolytic agents demonstrates reasonable immediate success rates approaching 80%. However, recurrent catheter malfunction is common, occurring in 30–50% of patients within two months[13–17].

Catheter exchange over a guidewire is a simple, safe, and effective method for treating catheter malfunction. Possible complications of this approach include bleeding and hematoma formation along the tunnel track, and the risk of infection[18].

There is evidence that elimination of the fibrin sheath prevents early recurrent catheter malfunction[19,20], especially in patients with limited central venous access sites[21].

Based on expert opinion, National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) considers it reasonable that catheter abandonment and using a different access site should be considered as the last resort after failure of all other measures to restore catheter patency[1].

Percutaneous transfemoral loop snare stripping of the fibrin sheath has been reported to yield favorable early results, with technical success rates of 95.5–100%[22–24]. However, predictors for the success of the procedure are not well understood. One study demonstrated a median duration of primary patency after stripping of 89 days[23]. In other studies, 1 month patency rates ranged from 52 to 72%[10,25]. In another randomized controlled trial comparing fibrin sheath stripping versus catheter exchange, it was found that malfunctioning tunneled hemodialysis catheters treated using catheter exchange are significantly more likely to remain patent for up to 4 months compared with those treated using fibrin sheath stripping[26]. Although rarely documented, there exists a theoretical risk of a potential pulmonary embolism due to fibrin fragments dislodging into the pulmonary vasculature[18].

Using a method involving passing a wire through an established catheter track, followed by balloon disruption is preferable to other methods of managing CRS. This approach offers the potential advantage of revamping precious central venous access in patients with limited access options. Restoring central venous access not only helps in maintaining catheter function but also re-establishes the possibility of future ipsilateral AVF creation, especially when a subclavian vein is restored to function[27].

Our study is consistent with previous reports[10,19,27], we achieved a technical success rate of 100%.

The early clinical success rate was 93.33%, slightly lower than previous reports[27] which showed early

clinical success of 100%. Nonetheless, these high rates of technical success and early clinical success underscore the feasibility and reproducibility of the procedure. Even in cases of early clinical failure, although excluded from the current analysis, patients can undergo repeated balloon disruption of their fibrin sheaths, especially when other suitable sites for new catheter insertion are lacking.

Congruent with the previous studies[19,27], we report no significant procedure-related morbidities.

Despite the technical feasibility and promising early results, it appears that this procedure may not provide long-lasting effectiveness. In the current study, primary patency rates were 90, 73.3, and 43.3% at 1, 3, and 6 months, respectively. In the study by d'Othée *et al*.[10], catheter patency rates following balloon disruption of fibrin sheath were 65, 39, and 39% at 1, 3, and 6 months, respectively. Advanced age, previous interventions and previous catheters in the same location were found to have a significant relationship to the loss of patency of the catheters.

The study underscores the importance of preserving vascular access in hemodialysis patients and calls for larger studies to investigate the long-term efficacy of balloon disruption in extending catheter patency. This research sheds light on a critical aspect of hemodialysis care and provides valuable insights for clinical practice and future research endeavors.

CONCLUSION

Balloon disruption of the fibrin sheath has demonstrated safety and efficacy in preserving vascular access. However, larger-scale studies are necessary to validate whether angioplasty disruption significantly prolongs catheter patency.

CONFLICT OF INTEREST

There are no conflicts of interest.

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