

## **May position of hemodialysis catheter tip have a direct effect on its patency? Positive results of a preliminary study on its rotation**

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### **Abstract**

Renal transplant therapy is essential in patients with End-Stage Renal Disease (ESRD). It is used in patients awaiting a kidney transplant or those who cannot be a transplant candidate. Central venous catheter is one of the most used access routes worldwide but has been recorded as the one with highest mortality and morbidity rate. Thromboembolic events have played a major part for that. This is a descriptive-analytical study, which conducted in a university treatment center in Tehran, Iran. A total of 225 patients were selected for this study that 108 were excluded because of our criteria. Statistical analysis was performed by SPSS v19 and a total of 117 patients were included in this study. The average age of the patients was  $51.62 \pm 11.26$ . 79 (67.5%) and 38 (32.5%) patients had medial and lateral tip direction, respectively. The catheter of 85(72.6%) and 32(27.4%) patients was patent and occluded, respectively. The average catheter tip occlusion time in both groups was 22.5 and 7.5 months. Three-month, six-month, twelve-month, and twenty-four-month patency rate were 99%, 94%, 88%, and 30%, respectively. our findings suggest that medial direction of the tip of the catheter reduces complications caused in CVS. Because our study has been conducted in a small scale and there is lack of similar studies, our team suggests extension to a larger scale to confirm or not our results.

**Key Words:** End-stage renal disease; renal replacement therapy; surgery; hemodialysis.

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Patients diagnosed with kidney failure formerly known as End-Stage Renal Disease (ESRD) or End-Stage Kidney Disease (ESKD) have a high incidence in the general population and their ultimate treatment would be a kidney transplantation. However, the majority of this patients (about 60%) who cannot be transplanted need other methods. On the other hand, even if a patient has the requirements for transplantation, before the procedure, the majority require hemodialysis (HM).<sup>1</sup> Permcath is an alternative vascular accesses for those patients in which arteriovenous fistula and graft or peritoneal dialysis are considered unsuitable for several reasons (e.g. exhaustion of vascular bed, previous steal syndrome in functional AVF, severe hypotension).<sup>2,3</sup> However, several problems have emerged following the widespread use of

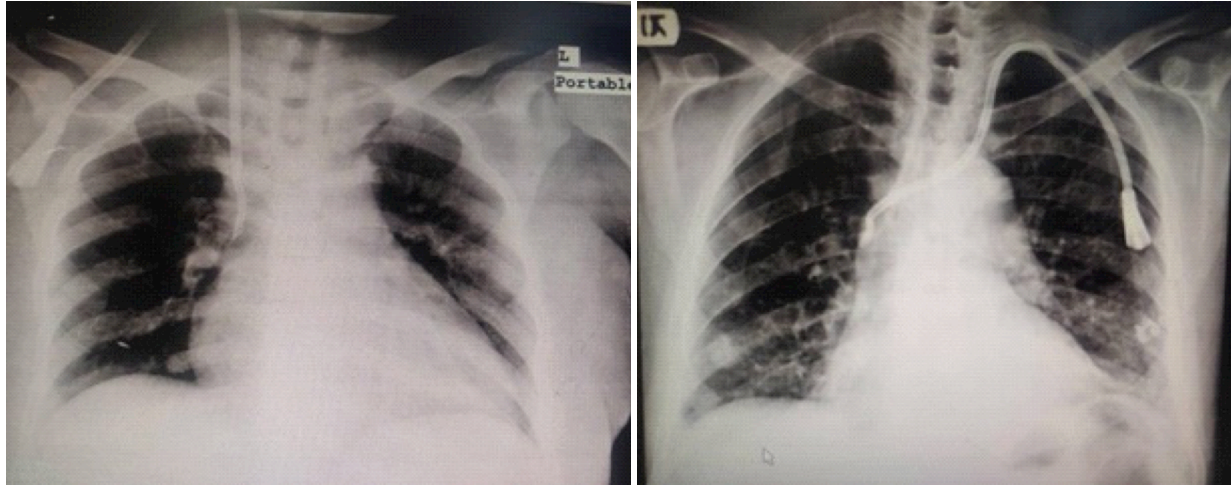
permcaths. These include higher risks of central venous stenosis,<sup>4</sup> increased morbidity for infection,<sup>5</sup> catheter thrombosis,<sup>6,7</sup> with decreased dialysis adequacy due to lower blood flow rate.<sup>8</sup> Thrombosis related to vascular access devices is common and has a significant impact on patient morbidity and mortality.<sup>9</sup> Over time, fibrin sheath forms on the tip of catheters which leads to catheter lumen obstruction and loss of function.<sup>10</sup> In fact, the most common reason of failure of dialysis catheters' long-term function is the formation of fibrin sheath. However, the term "fibrin sheath" is inaccurate to describe these phenomena, because the sheath can be composed of thrombus, endothelial cells, and finally collagen, depending on the time length of the catheter placement in the body.<sup>11</sup> Within a few weeks, collagen forms on the tip of the catheter as the smooth muscle cells of the venous wall migrate and the leukocytes

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adhere to the surface of the catheter creating a one-way valve mechanism (easy to inject, difficult to aspirate). It will also be associated with thrombosis and infection.<sup>12</sup>

database of all procedure data collected including age, gender, dialysis duration, catheter complications, and patency rates. Permanent tunneled catheters had two



**Fig 1.** A: Step-tip hemodialysis catheter with medially tip placed in right internal jugular B: A hemodialysis catheter placed in left internal jugular, with laterally placed tip.

Study of fluid dynamics, blood flow turbulence and local changes in the surface of the intravascular catheter can have a significant effect on preventing thrombosis and fibrin sheet formation. Given: i) the novelty of the idea; ii) the multiplicity of existing evidence; iii) the simplicity of modified surgical technique; iv) the potential of avoiding additional costs in the health sector; and v) the widespread use of step-tip catheters, our goal in this study is to answer whether the rotation of the dialysis catheter tip has or not a direct effect on its patency. Of course, in this study, standard locking solutions for systemic anticoagulation were also used to maintain catheter patency, i.e., sodium citrate (4%) or concentrated heparin solutions (1000 units per ml).<sup>13</sup>

### Materials and Methods

#### *Study Design and description of procedure*

The study was designed as descriptive-analytical and conducted in an university center for vascular surgery in Tehran, Iran. All procedures were aimed at restoring vascular access function for hemodialysis and life support therapy. The study was approved by the Shahid Beheshti Medical University. Informed consent was obtained from all the individual patients before every procedure. Two hundred and twenty-five patients underwent an indwelling hemodialysis catheter in the internal jugular vein from March 2019 to August 2021 in Taleghani hospital (Figure 1, A and B). After obtaining informed consent, an experienced vascular surgeon inserted all permanent catheters using ultrasound and fluoroscopy. We performed a follow-up for outcomes and complications and maintained a

lumens with a diameter of 14-15 F and were composed of silastic / silicon. The length varies depending on the size of the patient's body (19, 23 or 28cm). The permcath insertion site is washed, prepared, and then covered with a surgical cloth with the patient lying in a supine position, the distance between the point of puncture of the internal jugular vein and the end of the tunnel is measured using a guidewire. A small incision of about 5 mm was made on the pectoral area followed by the formation of a tunnel to the site of the entrance of the guidewire under the skin by a tunneling trochar attached to the end of the catheter and moving the catheter within this tunnel. After dilation of the soft tissues around the guidewire and insertion of the peel-away sheath, the catheter is inserted into the superior vena cava followed by peeling the sheath. After controlling the patency of both lumens and control of bleeding, lumens were saline flushed and filled with heparin and the catheter was fixed by sutures. All catheters are indwelled under a fluoroscopic guide. It has been tried from the beginning in such a way that the medial direction of the tip is maintained. Then patients were checked by chest X-ray for catheter tip direction (medial or lateral) and possible complications. The patency rate was defined as the number of days that the catheter is functional until patient death, catheter exchange, or removal.

#### *Exclusion and inclusion criteria*

Of these 225 patients, 38 patients were excluded from this study because they had a history of hyper coagulopathy or were treated with anticoagulants before the study period and 17 were excluded because they had

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**Table 1.** Clinical characteristics of patients (N=117)

Characteristics	Mean $\pm$ SD / Frequency (%)
<b>Age, y</b>	51.62 $\pm$ 11.26
Missing	0 (0)
<b>Gender</b>	
Male	31 (26.5)
Female	86 (73.5)
Missing	0 (0)
<b>BMI</b>	
18.5-24.9	16 (13.7)
25-29.9	42 (35.9)
30-34.9	59 (50.4)
Missing	0 (0)
<b>Bevel</b>	
Medial	79 (67.5)
Lateral	38 (32.5)
Missing	0 (0)
<b>Patency Status</b>	
Patent	85 (72.6)
Occluded	32 (27.4)
Missing	0 (0)
<b>Time of patency</b>	14.10 $\pm$ 5.93
Missing	0 (0)

a body mass index higher than 35. We also excluded 4 patients who underwent renal transplantation, arteriovenous grafting (18 patients), died of catheter-unrelated diseases (6 patients) and removal of the hemodialysis catheter because of infection (25 patients). The remaining 117 patients underwent placement of an indwelling tunneled catheter in the right internal jugular vein. For 79 patients, the catheter tip was placed medially, and the rest were placed laterally. The primary patency rate of catheters and catheter-related problems, including catheter dysfunction and infection, were investigated at 3, 6, 12 and 24 months after catheter insertion. Catheter dysfunction was defined when the blood flow rate was  $<120$  mL/min. When infection was diagnosed, the site was washed with normal saline

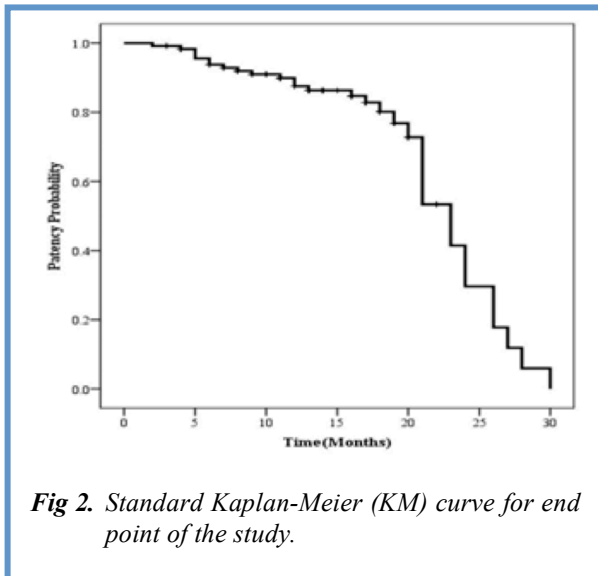
solution. A bloodstream infection that ends in catheter removal is diagnosed when a positive blood culture for bacterial pathogens is detected and other infectious sites were not observed or not likely to be the origin of the bacteria.

### *Statistical analysis*

The categorical variables with frequencies and percentages are reported. The endpoint of this study was to calculate the number of days the catheters were left open regardless of their tip direction (patency). Continuous variables were compared using the student's *t*-test. The univariate and multiple linear regression models were applied for patients with occluded catheter tips. The patency probability of the patients was

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calculated using the Kaplan-Meier (KM) method. The univariate and multiple cox proportional hazard models were employed for the occlusion of the catheter tip as an outcome. The significance level in models was set at 0.05. The calculations were carried out using SPSS version 19. A value of  $p < 0.05$  was considered significant.

### Results

A total of 117 patients were included in this study. Their clinical characteristics are shown in Table 1. The average age of the patients was  $51.62 \pm 11.26$ . 79 (67.5%) and 38 (32.5%) patients had medial and lateral tip direction, respectively. The catheter of 85 (72.6%) and 32 (27.4%) patients was patent and occluded, respectively. The average catheter tip occlusion time in both groups was 22.5 and 7.5 months. Three-month, six-month, twelve-month, and twenty-four-month patency rate were 99%, 94%, 88%, and 30%, respectively. Catheter patency probability is shown in Figure 2. The results of the linear regression model are demonstrated

in Table 2. As shown, based on the univariate analysis of the risk factors for patients with occluded catheter tip, gender, body mass index (BMI), and catheter tip direction were influential on occlusion time of catheter and were entered to the multiple models. Catheter tip occlusion time was expected to increase about 8 months for male patients in comparison with female patients [Beta: 7.74; 95% CI:(4.18-11.31); p-value= 0.008] and expected to increase 10 months for patients with BMI of between 25-29.9 in comparison with patients with BMI of between 30-34.9 [Beta: 10.26; 95% CI:(6.49-14.03); p-value= 0.001]. Also, the lateral tip direction group patients were expected to decrease occlusion time catheter tip by 15 months compared to the medial patients [Beta: -15; 95% CI:(-16.72 - -13.27); p-value<0.001]. Based on multiple models, the direction of the catheter tip was significant. Therefore, the lateral tip was expected to decrease catheter occlusion time by 14 months compared to the medial patients [Beta: -13.66; 95% CI:(-17 - -10.34); p-value<0.001]. The results of the cox proportional hazard model are demonstrated in Table 3. As shown, based on the univariate analysis of the risk factors for patency probability, BMI and direction of catheter tip were influential and were entered into multiple models. The risk of occlusion in patients with BMI of between 25-29.9 in comparison with patients with BMI of between 30-34.9 was less by 65% [Hazard ratio (HR): 0.35; 95% CI:(0.20-0.62); p-value= 0.01]. Medial tip direction group had lower risk of occlusion in comparison with the lateral tip direction group by 77% [HR: 0.23; 95% CI:(0.13-0.40); p-value= 0.001]. Also, based on multiple models, the effect of BMI and direction of catheter tip were reported significant again. The risk of occlusion regarding BMI was similar to the results of univariate analysis. The Medial tip direction group, holding the effect of BMI, decreased the occlusion risk by 76% in comparison with the others.

### Discussion

**Table 2.** Univariate and multiple linear regression models for patients with occluded catheter tip (N=32)

Variables	Univariate		Multiple	
	Beta (95% CI)	p -Value	Adjusted Beta (95%)	p-Value
Age	-0.05 (-0.26 - 0.78)	0.78		
Gender		0.008*		
Male	7.74 (4.18-11.31)	0.008*	2.70 (-0.14 - 5.55)	0.062
Female (RL) <sup>1</sup>	0	-	0	-
BMI		0.004*		0.43
18.5-24.9	6.93 (1.11-12.94)	0.12	1.61 (-3.10 - 6.33)	0.48
25-29.9	10.26 (6.49-14.03)	0.00*	0.69 (-2.92 - 4.30)	0.69
30-34.9 (RL) <sup>1</sup>	0	-	0	-
Bevel		<0.001*		<0.001*
Lateral	-15 (-16.72 - -13.27)	<0.001*	-13.66 (-17 - -10.34)	<0.001*
Medial (RL) <sup>1</sup>	0	-	0	-

\*. Significant at  $p < 0.05$ ; 1: Reference Level

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**Table 3.** Univariate and multiple cox regression models for patency probability (N=117)

Variables	Univariate		Multiple	
	HR <sup>2</sup> (95%)	p-Value	AHR <sup>3</sup> (95%)	p-Value
Age	1 (0.97- 1.04)	0.98		
Gender		0.61		
Female	1.21 (0.73-2.01)	0.61		
Male (RL) <sup>1</sup>	1	-		
BMI		0.03*		0.048*
18.5-24.9	0.44 (0.20-1.65)	0.19	0.50 (0.14 – 1.70)	0.48
25-29.9	0.35 (0.20-0.62)	0.01*	0.37 (0.15 – 0.88)	0.02*
30-34.9 (RL) <sup>1</sup>	1	-	0	-
Bevel		0.001*		0.001*
Medial	0.23 (0.13-0.40)	0.001*	0.24 (0.1 -0.57)	0.001*
Lateral (RL) <sup>1</sup>	1	-	0	-

\*. Significant at  $p < 0.05$ ; 1: Reference Level; 2: Hazard Ratio; 3: Adjusted Hazard Ratio

Central venous catheters are used for hemodialysis initiation in patients requiring this treatment or patients awaiting other routes of access such as arteriovenous fistula (AVF) and arteriovenous grafts (AVG). Moreover, when every other option is out, central venous catheter (CVC) can be the last resort choice for the patients in need. Despite convenience and broad accessibility of this method, CVC has the highest morbidity and mortality rate among accesses.<sup>14</sup> Our hypothesis was that when a CVC is placed medially in the vein of use, because of less contact with vessels inner surface, thrombotic events will be lower in incidence and thus, less complications will occur for patients. This study demonstrated that the direction of the permanent dialysis catheter tip (medial to lateral) was significantly effective on the rate of catheter patency in patients undergoing dialysis. We evaluated the factors that may have affected the patency rate; gender, BMI, and bevel of needle. These three factors proved to be influential on occlusion time of catheter resulting in alteration of the mean patency of jugular accesses. The right internal jugular vein was selected as the first-choice access because it has high accessibility and a straight route in the neck, resulting in high patency and fewer catheter-related complications such as catheter dysfunction and infections. In patients with occlusion of the right internal jugular vein, insertion of a pacemaker in the right chest, or difficulty maintaining the required surgical position for placement of an indwelling tunneled hemodialysis catheter, the left jugular vein was selected as the second option. From the beginning, we tried to locate the catheter tip 3-4 cm upper than the intersection of the right bronchus with the SVC, the starting point of the atrium, or slightly above the right atrium. Theoretically, if the tip catheter is medial, it is exposed more to the intraluminal space, therefore, the possibility of obstruction is less than if it is lateral. In the latter case it is more likely for its adhesion to the wall, which potentially results in

thrombosis and fibrin sheet formation. The primary patency rate of the tunneled hemodialysis catheters and catheter-related problems, including catheter dysfunction and infection, were investigated at 3, 6, 12, and 24 months after catheter insertion. As mentioned before, the mean time of occlusion for CVC catheters monitored in this study, has shown a wide difference between two groups that used medially directed catheters in comparison with the other group.

Among 18 patients, AV fistula was indwelled at the same time as insertion of a permanent catheter and for 11 patients the tip was placed medial while for 7 patients were placed laterally. By following the patients until their fistulas became mature, 3 were occluded. One patient had a lateral catheter tip and 2 patients had medial catheter tip and there was no statistically significant difference in the direction of the permanent catheter tip (p-value: 0.34) which suggests the same outcome for the occasions that there is alternative dialysis access and the need for the catheter is not long-term. The catheters used were all Palindrome (n=68) and Medcomp (n=49), but the analysis of the subgroups did not show any significant difference between the two types of catheters and their patency. In previous studies,<sup>1-5</sup> less attention was paid to role of gender on catheter occlusion that in our statistical analysis showed significantly higher rates in men (Table 2). The limitations of the present study are: i) related to the registration system which lengthened the data collection times; all cases were investigated individually instead of in a systematic search; iii) the lack of published studies examining the direction of catheter tip did not allow comparison with independent studies.

In conclusion, our data suggest a new and safer technique for CVC implantation in patients in need. Indeed direction of the catheter tip is a factor that should be brought into account. Due to the lack of similar studies, we suggest designing and implementing clinical

trials with large patient groups to verify the data reported here.

### List of acronyms

AVF - arteriovenous fistula  
 AVG - arteriovenous graft  
 BMI - Body mass index  
 CVC - Central venous catheter  
 ESKD - End-Stage Kidney Disease  
 ESRD - End-Stage Renal Disease  
 HM - Hemodialysis  
 KM - Kaplan-Meier  
 SVC - Superior vena cava

### Contributions of Authors

MH, MMo, MT, SMRHN, MMi, RH participated in conception and design of the study, acquisition, analysis and interpretation of data, wrote the manuscript, performed literature review, article drafting and revision, reviewed and edited the manuscript critically, all authors read and approved the final version.

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### Conflict of Interest

The authors declare no conflict of interests.

### Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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