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A STUDY OF SPECIALIZED TROCAR OF REMOVING CUFFED CATHETER AMONG PATIENTS SUFFERING FROM HEMODIALYSIS

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ABSTRACT: Background: Permanent cuffed catheter (permcath) is a method used to access the veins in hemodialysis. In those patients with catheter exit indication, a small incision is made on the skin after feeling the cuff under the skin and catheter is removed after disconnecting its tissue-cuff connection. In this study, the whole connection between catheter cuff and tissue is disconnected using a new tool named trocar; then the catheter is removed. **Materials and Method:** This is a clinical trial conducted on 104 patients candidate for catheter removal in two groups. The bleeding level, the operation length, the damages requiring intervention following catheter removal and the number of stitches made were all recorded. The patients' outcome regarding bleeding and surgical site infection was traced for 14 days following the operation, and the probable complications such as edema, fever, ecchymosis, *etc*. were recorded. **Results:** No significant difference was observed between the two groups regarding background diseases (P = 0.3). No significant difference was observed between the two groups in terms of the frequency of infection (P = 0.49), catheter damage (P = 0.614), hematoma (P = 0.5), and tissue damages (P = 0.32). The length of the operation (P = 0.0001), level of bleeding (P = 0.0001) and the number of stitches made (P = 0.0001) were significantly less than what was observed in the intervention group. **Conclusion:** Using catheter would result in shorter catheter removal time, less bleeding level, fewer stitches, and less scar following the removal.

INTRODUCTION: Chronic kidney failure is diagnosed through progressive and irreversible deterioration of kidney function [1]. The patients suffering from hemodialysis undergo dialysis three times a week, and each session lasts for 4 h [2]. Many patients who have received a kidney continue to live with dialysis [3]. Among the 300 million population of the US, 450 thousand patients are suffering from ESRD (end state renal disease) most of whom require dialysis.

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The following criteria have been defined to place an individual in the dialysis list: presence of uremic symptoms, hyperkalemia resistant against preserving treatments, greater extracellular volume resistant against Diuretics, treatment-resistant acidosis, bleeding tendency, creatinine clearance or GFR (Glomerular Filtration Rate) as much as 10 ml per minute for each 1.73 mm^2 body area [4].

The following therapeutic choices are available for those patients suffering from end-stage renal disease: hemodialysis, peritoneal dialysis (including chronic ambulatory peritoneal dialysis and chronic cyclic peritoneal dialysis) and kidney transplant. Hemodialysis is the most common method [4]. Fistula, graft, or the catheter through which blood runs into dialysis is known as dialysis vascular access [4].

Percutaneous venous catheterization (PVC) is a quick method to access blood circulation with its particular applications. It is a selective method among patients with chronic kidney failure where constant vascular access with peritoneal for them is not possible or arterial venous fistula can't be used (considering the time required for it) [5, 6]. Cuffed catheters with a larger diameter and greater flow are the most suitable catheters for hemodialysis [7, 8].

These catheters are preferred when we need the arterial path for more than three weeks (particularly when the patient has arterio-venous fistula), and we are awaiting its maturation for 4 weeks and, on the other hand, the patient requires immediate hemodialysis. These catheters are hidden, they never limit the patient's physical activity, and require no particular care by the patient. Thus they are preferred by doctors and patients [9]. However, implementation and removal of these devices are not without its complications. Bleeding, hemothorax, pneumothorax, tamponade, and arrhythmia are some early complications. The late complications include venous thrombosis, catheter's failure, and infection. Infection is the most common type of infection and accounts for the greatest number of catheter removals [10]. In some cases, catheter removal is so difficult and with many complications as it has stayed there for a relatively long time. Causing damage to the adjoining vessels, thrombosis and blood clotting, arteries rupture, and infection are some of these complications [11-14].

Various papers have conducted through analysis of catheter insertion, but few studies have focused on catheter removal. Catheter removal usually causes no complications, but the formation of fiber cells in those areas of the catheter inside the arteries (which connect the catheter to the walls of the vein in several points) will impede the process of catheter removal and cause many complications [13, 15, 16]. In such cases, only the external part of the catheter is removed, and the internal part remains inside and makes the person prone to thrombosis formation [12, 13, 16]. A frequency of 16% has been reported for these complications among patients suffering from dialysis as a result of catheter removal [17]. In some other cases, the cuffed catheter is attached to the adjoining tissues. In cutting and disconnecting associated with this procedure, the possibility of causing damage to the surrounding tissues and body or cord tissue is so great. So much spinning of the scalpel around the tissue increases the possibility of permcath tube rupture and bleeding.

As a result, designing a highly accurate scalpel with the least error rate used to disconnect catheter from the surrounding tissue which causes the least damage possible to the tissue and correct and quick removal of the catheter is quite necessary. In spite of the rise in the number of patients suffering from hemodialysis that require permcath and the complications associated with removing this type of catheter, this problem still has its high priority, and no comprehensive method has ever been proposed on the national or international level to control this complication. As a result, the present research studies the modern specialized trocar used to removed tissue-cuff catheter.

MATERIALS AND METHOD: This is a randomized clinical trial. The population included all patients suffering from kidney diseases undergoing constant dialysis with permanent cuffed catheter resorting to outpatients' operation room of Shahid Beheshti Hospital of Kashan candidate for catheter removal which took part in our research from June 14th, 2016 to February 13th, 2017. The patients were divided into the intervention, and direct control groups and their catheters were removed by the principles of the usual and trocar method. In this study, a new instrument was used in the operating room **Fig. 1**.

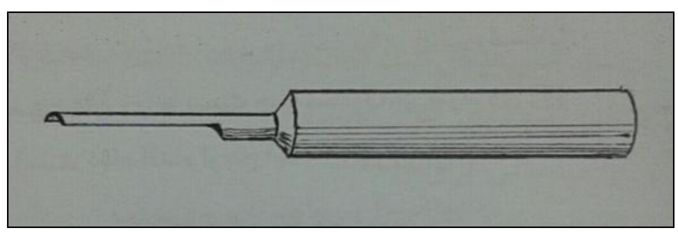

FIG. 1: A NEW INSTRUMENT USED IN THE OPERATING ROOM FOR THE REMOVAL OF THE CATHETER

Using Permuted black randomization method, the two groups were randomized. Having registered the patients based upon the exclusion and inclusion criteria, the person in charge of outpatients' operation room randomized them. The patients were completely blind about catheter removal method and knew nothing of intervention type. Both the researcher and the intervener were blind about the type of intervention.

Previous researches have reported a frequency rate of 16 to 20 percent for the complications caused by normal methods of catheter removal [16]. As the new trocar method has not been utilized yet and no complications were observed in the pilot conducted on patients, by considering the facts that α = 5%, power = 80%, p2 = 0%, and p1 = 20%, the sample size was set to 30 participants in each group.

$$n' = \left[\frac{\left(z_{1-\alpha/2}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_1(1-p_1)+p_2(1-p_2)} \right)}{p_1 - p_2} \right]^2$$

To enhance the accuracy, the initial sample size was increased to 50 individuals in each group, and finally, there were 51 participants in the control group, while 53 were selected for the intervention group.

Having obtained patients' informed consent, their demographic information including age, sex, chronic diseases such as diabetes, blood pressure, and causes of renal failure, and the length of catheter implantation (months) were recorded in special checklists. After controlling the inclusion and exclusion criteria, the patients were divided into intervention and control groups by selecting sealed envelopes in which the name of catheter removal methods was written. The length of catheter removal (minutes), the bleeding volume (regarding the number of gauzes used to stop bleeding), number of stitches, the distance between cuff and catheter's exit from under the skin and unwanted catheter damage were recorded for both groups. All these patients were visited one week following the procedure by a doctor who was blind about the type of intervention (to avoid information bias). The patients were traced regarding bleeding and infection up to 14 days following the operation, and the possible complications such as edema, fever, ecchymosis, *etc*. were recorded.

Inclusion Criteria: Patients with a cuffed catheter with tissue connection candidates for catheter removal.

Exclusion Criteria:

1. Cuffless catheter with tissue connection.
2. Patients with cuffed catheter whose catheters were removed without the need for any tools.

The present research uses mean and SD to describe quantitative variables; however, qualitative variables are presented using frequency and percentage of frequency. Chi-square was used to compare qualitative outcomes across the two groups while independent T-test (for variables with normal distribution) or Kruskal-Wallis (for variables with abnormal distribution) were used to compare quantitative factors in both groups. To study the effect of the therapeutic method on the formation of each outcome, the confounding effect of the catheter's presence was controlled using multivariable linear and Poisson regression statistical models. SPSS v.19 was used to conduct statistical analysis and P-value less than 0.05 was considered significant.

RESULTS: As many as 104 patients took part in the research where 53 of them (51%) were assigned to the intervention group and the remaining 51 (49%) were put in the control group. The mean age of individuals was 62.56 years with an SD of 13.23. 53.8% of the patients were male, and the remaining 46.2% were female.

59.6% of patients had a background of diabetes, 28.8% were suffering from high blood pressure, 7.7% had a history of Glomerulonephritis, and the rest had a history of other diseases.

48% of the participants in the intervention group and 46% in the control group were male, and no significant difference was observed between the two groups regarding sex (P = 0.8).

Diabetes and high blood pressure had a frequency of 66% and 28% in the intervention group, while these frequencies in the control group were 56% and 26% respectively. No significant difference was observed between the two groups regarding the background diseases (P = 0.3).

The average age in the intervention and control group was 63.78 and 61.24 years old respectively which exhibited no significant difference (P = 0.3).

No significant difference was observed between the two groups regarding catheterization indication **Table 1**.

TABLE 1: FREQUENCY OF THE CAUSES OF CATHETERIZATION AMONG PATIENTS

Cause of catheterization		Control group	Intervention group	P-value
No veins	Number	7	9	
	Percentage	13.7%	17.0%	
Emergency	Number	23	19	
	Percentage	45.1%	35.8%	
Transplantation	Number	10	11	0.909*
	Percentage	19.6%	20.8%	
No consent	Number	3	4	
	Percentage	5.9%	7.5%	
Other causes	Number	8	10	
	Percentage	15.7%	18.9%	

*: chi-square test

The outcomes traced in both groups were compared against one another. A frequency rate of 86% and 90% were reported for Fibrotic band incidence in the intervention and control group respectively. This difference was not statistically significant (P = 0.5). While 2% of those in the control group experienced infection, none of those in intervention groups suffered from any infections. This difference was not statistically significant (P = 0.5).

Catheter damage was observed among 2% and 4% of those in the intervention and control group respectively, and this difference was not statistically significant (P = 0.5). The average catheter removal time in intervention and control group was 4.92 min and 33.96 min respectively indicating a statistically significant difference between them (P = 0.0001).

The average amount of blood loss in the intervention group was 5.15 cc, while this level in control group was 18.20 cc with a significant difference observed between the two groups regarding the amount of blood loss (P = 0.0001).

The average number of stitches in intervention and control group was 0.22 and 5.18 indicating a statistically significant correlation (P = 0.0001). The cuff depth in the intervention group was 2.24, while this depth in the control group was 2.14. This difference was not statistically significant (P = 0.4) **Table 2**.

TABLE 2: A COMPARISON OF INTERVENTION AND CONTROL GROUPS REGARDING FINAL OUTCOMES

Outcomes studied			Control	Intervention	P-value
	No	Number	5	7	
		Percentage	9.8	13.2	0.587**
Fibrosis	Yes	Number	46	46	
		Percentage	90.2	86.6	
	No	Number	50	53	
Infection		Percentage	98	100	0.409**
	Yes	Number	1	0	
		Percentage	2	0	
	No	Number	49	52	
Catheter damage		Percentage	96.1	98.1	0.614**
	Yes	Number	2	1	
		Percentage	3.9	1.9	
Tissue destruction	Yes	Number	3 (6%)	0 (0%)	0.32**
	No	Percentage	48 (94%)	53	
Catheter removal time	Mean ± SD		33.59 (7.90)	4.74 (4.70)	< 0.001*
Bleeding level	Mean ± SD		18.14 (7)	5.25 (2.91)	< 0.001*
Number of stitches	Mean ± SD		5.16 (1.47)	0.21 (0.41)	< 0.001*
Depth of catheter’s cuff	Mean ± SD		2.14 (0.63)	2.23 (0.70)	0.463*

* Mann-Whitney test; ** Chi-square test

83% of those in the intervention group and 80.4% of those in the control group experienced no complications. However, 9.4% of those in the intervention group and 9.8% in the control group complained of bleeding.

The frequency of hematoma in the intervention and control group was 3.8% and 3.9% respectively. Statistically, there was no significant difference between the two groups regarding catheter complication (P = 0.981) **Table 3**.

TABLE 3: THE FREQUENCY OF COMPLICATIONS AMONG PATIENTS IN EACH GROUP

Complications		Groups studied		P-value
		Control	Intervention	
No complications	Number	41	44	
	Percentage	80.4%	83.0%	
Bleeding	Number	5	5	
	Percentage	9.8%	9.4%	
Hematoma	Number	2	2	
	Percentage	3.9%	3.8%	0.981*
infection	Number	1	0	
	Percentage	2.0%	0.0%	
Re-improvement	Number	2	2	
	Percentage	3.9%	3.8%	

* Exact test

Multivariable models have shown that the effect of the intervention on each of these complications exhibited no change after controlling the possible confounding effect of catheter implantation time **Table 4**. In other words, the new method will reduce the risk of catheter damages 46%, while the risk of infection increases 3.5 times. None of these deteriorating or protective effects was statistically significant.

TABLE 4: A COMPARISON OF THE TWO GROUPS REGARDING THE LENGTH OF CATHETER REMOVAL IN THE ADJUSTED LEVEL

Model	Coefficients of non-standardized effect		Standardized effects coefficient	T	sig
	B	Std. error	Beta		
Fixed	37.967	3.894		9.750	.000
Age	-0.068	0.050	-0.057	-1.368	0.174
Sex	0.183	1.295	0.006	0.141	0.888
Disease	-0.291	0.830	-0.015	-0.351	0.726
Group	-28.749	1.297	-0.911	-22.172	0.000

a. dependent variable: exit time

After removing the effect of age and sex and disease, the difference between the two groups regarding catheter removal decreased 28.7 units, and this difference is still significant ($P<0.001$).

TABLE 5: A COMPARISON BETWEEN THE TWO GROUPS REGARDING THE LEVEL OF BLEEDING IN THE ADJUSTED MODEL

Model	Coefficients of non-standardized effect		Standardized effects coefficient	T	sig
	B	Std. error	Beta		
Fixed	18.688	3.298		5.666	.000
Group	-12.666	1.055	-7.61	-12.010	.000
Sex	-0.491	1.053	-0.029	-0.467	0.642
Disease	0.671	0.675	0.064	0.994	0.323
Age	0.018	0.040	0.028	0.440	0.661
Time	-0.222	0.113	-0.123	-1.957	0.053

a. dependent variable: bleeding volume

After removing the effect of age and sex, disease, and the time of the procedure, the difference between the two groups regarding bleeding volume decreased 7.12 units, and this difference is still significant ($P < 0.001$).

TABLE 6: A COMPARISON OF THE TWO GROUPS REGARDING CUFF DEPTH IN THE ADJUSTED MODEL

Model	Coefficients of non-standardized effect		Standardized effects coefficient	T	sig
	B	Std. error	Beta		
Fixed	1.845	0.412		4.477	0.000
Group	0.086	0.132	0.065	0.653	0.515
Sex	-0.054	0.131	-0.040	-0.407	0.685
Disease	0.032	0.084	0.039	0.385	0.701
Age	0.009	0.005	0.177	1.759	0.082
Time	-0.025	0.014	-0.171	-1.737	0.086

a. dependent variable: depth

After removing the effect of age and sex, disease, and the time of the procedure, the difference between the two groups regarding catheter's depth increased 0.86 units, and this difference is not significant (P<0.51).

TABLE 7: A COMPARISON OF THE TWO GROUPS REGARDING STITCH NUMBERS IN THE ADJUSTED MODEL

Model	Coefficients of non-standardized effect		Standardized effects coefficient	T	sig
	B	Std. error	Beta		
Fixed	5.613	0.667		8.415	0.000
Group	-4.875	0.213	-0.905	-22.859	0.000
Sex	-0.037	0.213	-0.007	-0.173	0.863
Disease	0.172	0.137	0.051	1.259	0.211
Age	-0.007	0.008	-0.035	-0.877	0.383
Time	-0.27	0.023	-0.047	-1.191	0.236

a. dependent variable: depth

After removing the effect of age and sex, disease, the and the time of the procedure, the difference between the two groups regarding the number of stitches decreased 4.87 units, and this difference is still significant (P<0.001).

TABLE 8: A COMPARISON BETWEEN THE TWO GROUPS REGARDING DIFFERENCE COEFFICIENTS IN THE ADJUSTED *vs.* NON-ADJUSTED MODEL

Variable	Crude B	Adjusted* B
	Logistical regression	
Catheter removal time	-28.85	-28.74
Bleeding volume	-12.89	-12.67
Depth of cuff	-0.089	-0.086
	Logistical regression	
Infection	3.23 (0-90)	0.156 (0-90)
Destruction	0.471 (0.041-5.36)	0.528 (0.041-6.72)

*Adjusted on age, sex, time and disease

The difference between the two groups in the model following adjustment on the possible confounders showed that other personal information such as age, gender and the length of dialysis and the type of background diseases do not affect the intervention studied.

DISCUSSION: Although our ability to conduct dialysis technique is always increasing, the number of patients suffering from dialysis is also on the rise [18]. Kidney transplantation is the preferred treatment for most of these patients, but the limited number of kidney donors has reduced the growth of kidney transplantation operations. What's more, many kidney transplantation patients continue using dialysis technique. For this reason, hemodialysis is still considered one of the most important therapeutic methods to treat renal problems [19]. The permanent cuffed catheter (Permcath) is an arterial access method in hemodialysis. Using these catheters may have short-term or long-term complications.

In some cases, as the catheter remains in its place for a relatively long time, removing it will be difficult and causes many issues. Causing damage to surrounding arteries, thrombosis and blood clotting, arterial rupture and bacterial infections are some of these complications. The most important type of infection is *Staphylococcus aureus* [20, 21, 22]. As we observed in the present research, using the new method of catheter removal has significant differences with old methods concerning catheter removal time, bleeding level, and the number of stitches required. However, no significant difference was observed between the two methods concerning other complications. A review of various databases by researchers failed to find any similar studies concerning catheter removal. Only one case which deals with the removal method has discussed surgical incision and forceful pulling and removal of the catheter.

This research has reported that the above-said method has 10% frequency rate of complications caused by the cuff left in the duct. However, no reference is made to other complications such as infection, bleeding, hematoma, *etc.* [22] As it turned out in our research, utilization of this tool helps shorten the time required for catheter removal compared to usual methods.

This tool will also reduce bleeding significantly compared to common methods. This tool will also reduce the need for stitches. Because the length of catheter's presence in fistula may have a confounding effect on the correlation between the new method and the resulting outcomes, we tried to neutralize the effect of this variable in multivariable methods which yielded similar results. Regarding causing infections, there was no difference between the tools used in our research and common methods. The Institutional Ethical Committee (IEC) approval number for our study was IR.KAUMS.REC. 1395.25.95.3.23.

CONCLUSION: Using the catheter studied in this research will help the dialysis catheter be removed in a shorter time with less complication and greater ease for the surgeon. This method is also of great benefit for the patients, and they can ask less skilled people to help them remove the permcath.

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