Study Protocol

Official title of the study: Arteriovenous Fistula Cannulation Practices and Dialysis Adequacy

NCT number: NCT04270292

Date of document: 20 April, 2020

Objective: The aim of this study was to investigate the effect of the cannulation technique used during needle insertion into the arteriovenous fistula (AVF), the direction of the fistula needle, the rotation of the needle, the AVF insertion area, and whether the artery and vein needle are on the same vascular line on the adequacy of the hemodialysis (HD).

Design: Descriptive and cross-sectional study

Methods: The study was conducted in accordance with the Declaration of Helsinki. The approval of the local ethics committee approval (Meeting no: 08/042019, Decision no: P0139R00), permission from the institutions where the study was conducted, and the verbal consent of the patients were obtained.

This study was conducted between May and December 2019 at the a total of four HD centers, including one private dialysis center, one private hospital and two state hospitals in two provinces. The study sample consisted of 164 patients who had received HD treatment with an AVF for at least six months, at three days a week and four hours a day, were aged 18 years or older, had no problem communicating, and volunteered to participate in the study. All patients were treated with a high-flux synthetic type dialyzer at the dialysis unit where the study was conducted. The same dialysate solution was used for each session with a dialysate temperature of 36°C, a standard bicarbonate concentration 30-35 mmol/l, a dialysate flow rate 500 ml/minute and a pump speed 300-450 ml/minute. All needles placed into the AVF were of the back eye type. A semi-structured questionnaire form developed by the researchers as a

result of a literature survey was used to collect the data. The form included questions on the patients' socio-demographic and clinical data and AVF cannulation. The Kt/V and urea reduction rate (URR) that were used to evaluate dialysis adequacy were regularly evaluated at the HD centers every month and recorded in the patient's chart. The mean three-month Kt /V and URR values starting from the date the study was started were calculated by the researchers and entered into the data form. The questionnaire was then completed by the researchers interviewing the patients with the face-to-face method during the second hour of HD treatment. Completing the forms took about 5 minutes. STROBE check-list was used for reporting the study.

Statistical Analysis Plan

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Outcome measures

Number of fistula needle direction: The hemodialysis nurse who cannulate the patient's fistula fill the data form. There is two options about fistula direction as antegrade or retrograde.

Number of cannulation method: The hemodialysis nurse who cannulate the patient's fistula fill the data form. There is three options about cannulation method as puncture, buttonhole, and rope ladder methods.

Number of fistula needle rotated: The researchers look to the fistula needle while it inserts to the fistula. There is two options as needle rotation is yes or no.

Number of arterial and venous needle been on the same line: The researchers look to the arterial and venous line whether they are the same venous line.

Results

Title:	Number of Fistula Needle Direction
Description:	The hemodialysis nurse who cannulate the patient's fistula fill the da...
Time Frame:	up to 12 weeks

Outcome Measure Data ✓

Analysis Population Description

Arm/Group Title	Arteriovenous Fistula Cannulation Group	
Arm/Group Description:	The cannulation practices' of patie...	
Overall Number of Participants Analyzed	164	
Measure Type: Count of Participants Unit of Measure: participants		
Row Title		
Antegrade direction	72	43.9%
Retrograde direction	92	56.1%

Title:	Number of Cannulation Method
Description:	The hemodialysis nurse who cannulate the patient's fistula fill the da...
Time Frame:	up to 12 weeks

Outcome Measure Data ✓

Analysis Population Description

Arm/Group Title	Arteriovenous Fistula Cannulation Group	
Arm/Group Description:	The cannulation practices' of patie...	
Overall Number of Participants Analyzed	164	
Measure Type: Count of Participants Unit of Measure: participants		
Row Title		
Area puncture	87	53.05%
Rope ladder	54	32.93%
Buttunhole	23	14.02%

Title:	Number of Fistula Needle Rotated
Description:	The researchers look to the fistula needle while it inserts to the fis...
Time Frame:	up to 12 weeks

Outcome Measure Data ✓

Analysis Population Description

Arm/Group Title	Arteriovenous Fistula Cannulation Group	
Arm/Group Description:	The cannulation practices' of patie...	
Overall Number of Participants Analyzed	164	
Measure Type: Count of Participants Unit of Measure: participants		
Row Title		
Yes	104	63.41%
No	60	36.59%

Title:	Number of Arterial and Venous Needle Been on the Same Line
Description:	The researchers look to the arterial and venous line whether they are ...
Time Frame:	up to 12 weeks

Outcome Measure Data ✓

Analysis Population Description

Arm/Group Title	Arteriovenous Fistula Cannulation Group	
Arm/Group Description:	The cannulation practices' of patie...	
Overall Number of Participants Analyzed	164	
Measure Type: Count of Participants Unit of Measure: participants		
Row Title		
Yes	25	15.24%
No	139	84.76%

Statistical analysis

The Statistical Package for Social Sciences (SPSS Inc., Chicago, IL., USA) v. 22.0 software program was used for the statistical analysis of the data from the study. The compliance with a normal distribution of the measurements obtained within the scope of the study was investigated with the "Shapiro-Wilk Test". Mean±standard deviation, median, and interquartile range (IQR) were used to present the descriptive statistics of the continuous numerical variables and number (n) and percentage (%) to present the categorical variables. Values not showing a normal distribution were compared with the "Mann-Whitney U Test" and "Kruskal-Wallis Test", while data with a normal distribution were compared with "Student's *t* Test" and "One-Way ANOVA". The homogeneity of variances was evaluated with the "Levene test". Pairwise post-hoc comparisons were made by using the "Tukey and Tmahane T2" tests in cases where there was a significant difference between the groups. Independent predictors affecting the Kt/V and URR values were investigated with logistic regression analysis using the possible factors identified with multivariate analysis previously. A p level of 0.05 was accepted as statistically significant in statistical decisions.