Original Article

Blood Pressure and Risk of Bleeding During Permcath Insertion

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Abstract

Background: The tunnelled double-lumen cuffed catheter (TDLCC) is commonest route of vascular access with risk of bleeding from its insertion site.

Objective: To assess the effect of blood pressure on the risk of bleeding during tunnelled double-lumen catheter placement for haemodialysis.

Methods: This study was carried out on patients who were ≥ 18 years old and required vascular access for haemodialysis. Patients having patent arteriovenous fistula, coagulopathy, and thrombocytopenia were excluded. All the patients were observed for haemodynamic instability and bleeding from the site of TDLCC insertion.

Results: There were one hundred and forty (n=140) individuals, including 97 (69.29%) males, with a mean age of 56.21±14.86 years. The bleeding during TDLCC insertion was observed in 24 (17.14%) patients. The mean systolic blood pressure was 138.69±19.09 mmHg, while the mean diastolic BP was 85.89±12.31 mmHg. The receiver operating curve analysis of systolic blood pressure for the risk of bleeding showed the area under curve 0.792(95% confidence interval 0.697 - 0.886, p<0.001) and for diastolic blood pressure, the area under curve came out to be 0.767(95% confidence interval 0.662 - 0.871, p<0.001). The area under curve for serum creatinine was 0.654(95% confidence interval 0.536 – 0.772, p=0.017). The best cut-off values for systolic and diastolic blood pressure and serum creatinine for predicting bleeding risk were 142.50 mmHg, 92.50 mmHg, and 691.50 µmol/L, respectively.

Conclusion: The blood pressure has a significant effect on the risk of bleeding during the insertion of a tunnelled double-lumen catheter in haemodialysis patients.

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Introduction

Central venous catheters (CVC) have been life-saving for end-stage renal disease (ESRD) patients requiring haemodialysis. Central venous catheters are used not only for haemodialysis but also for medications, blood product transfusions, cardiac catheterisation, and many other procedures/ conditions.[1] The type of access, either arteriovenous fistula (AVF) or tunnelled double lumen cuffed catheters, is mostly dictated by the circumstances under which patients report to the hospital, for example, urgent haemodialysis, AVF is

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not mature or cannot be made and many other reasons as dictated by vascular access scenarios.[2,3] For haemodialysis patients, the most recommended and supported method of vascular access is arteriovenous fistula (AVF) as it is recognised by the Kidney Disease Outcome Quality Initiative (KDOQI) and others.[4,5] However, the TDLCC is more widely used among central venous catheters.

Due to the increase in the population affected with diabetes mellitus (DM) and hypertension (HTN), the clientele for haemodialysis has also increased, causing an indirect increase in the use of CVCs, i.e. TDLCC.[6,7] The central venous access is most commonly maintained through the internal jugular vein (the right is preferred over the left) by using TDLCC, but other large lumen veins can also be used. The malposition of CVC has been reported in 13.4%.[8] Apart from malposition, arterial injuries have also been reported along with pleural space mishaps. The placement of TDLCC or CVCs is associated with many complications like bleeding, haematoma, pleural effusion (traumatic), and damage to arteries and nerves.[9,10] An analysis of TDLCC and AVF showed that TDLCC is associated with higher morbidity and mortality than AVF.

There is a risk of bleeding during tunnelled catheter placement for HD.[11] Raised arterial blood pressure leads to various vascular accidents. This study was planned to observe the risk of bleeding with changes in patient's blood pressure during the placement of tunnelled double-lumen catheters. This study will help clinicians provide better, safer management for patients with raised blood pressure, which is often seen in patients with kidney failure.

Methods

This prospective observational cohort study was conducted at the Department of Nephrology, Pakistan Emirates Military Hospital, Rawalpindi, Pakistan, from 1st January 2024 to 30th October 2024 over 9 months. The study followed the ethical code of the Declaration of Helsinki and got ethical approval from the Ethical Review Board vide certificate # A/28/ERC/192/24. The easyROC: a web-tool for ROC curve analysis (ver. 1.3.1) was used for sample size calculation, by using type-I error of 0.05, power of 0.8, assuming area under curve (AUC) of 0.8 and allocation ratio of 14.65 using results of Hamid et al., the sample size came out to be 94 individuals.[12] The participants were enrolled using a convenient consecutive sampling technique, and informed consent was taken after explaining the study protocol and pro-cedure. The study included participants of both genders who were ≥ 18 years old, consented to participate, had ESRD, and required vascular access for HD in the absence of, or due to, a malfunctioning arteriovenous fistula. Exclusion criteria included patients with a patent AVF, coagulopathy, platelets < 50000/µL, anticoagulants, and anti-thrombotic therapy. Moreover, the patients having TDLCC site infection, sepsis, or another systemic infection were also excluded from the study.

Basic details, including age, gender, cause of ESRD, prior dialysis history, and serum creatinine at the time of TDLCC placement, were recorded. Blood pressure (BP) was recorded on the procedure table 5 minutes before the commencement of the procedure and 5 minutes after its completion. The average of three pre-procedural readings was used for statistical analysis. A digital sphygmomanometer (Dräger Vista 120S, Drägerwerk AG & Co., Germany) was used to measure BP. The procedure was delayed or postponed in patients with BP ≥180/120 mmHg. In these patients, blood pressure control was optimised, and then the procedure was performed. The TDLCC was placed by a team of trained doctors, assisted by paramedical staff, in a procedure room. The patients were draped under aseptic measures. TDLCC was placed under ultrasonographic guidance as per standing operating procedures. The flow was checked in both lumens, and the catheters were locked using a catheter-lock solution. The catheter placement was confirmed on a posteroanterior chest x-ray due to the unavailability of fluoroscopy. All the patients were kept in the recovery room for 6 hours to observe for haemodynamic instability and bleeding from the site of TDLCC insertion. The bleeding was referred to as clinically significant oozing of blood from the catheter insertion site, requiring pressure, suturing, or intervention. The bleeding was recorded as a binary variable (yes/no).

The data was processed using Statistical Package for Social Sciences (SPSS) version 25.0. Data normality was assessed using the Shapiro-Wilk Test. The conti-

Table 1: *Basic demographic and clinical characteristics details of the study population*

Variable	Values
Age (years)	56.21±14.86
Gender	
• Male	97 (69.29%)
• Female	43 (30.71%)
Bleeding	
• Yes	24 (17.14%)
• No	116 (82.86%)
Serum Creatinine (µmol/L)	763.43±370.44
Blood Pressure	
• Systolic	138.69±19.09
• Diastolic	85.89±12.31
Haemodialysis History	
• Yes	91 (65.00%)
• No	49 (35.00%)

nuous variables were presented using mean or median with standard deviation or interquartile range, respectively. The categorical data was presented using frequency and percentages. The ROC curve analysis was used for statistical analysis. The p≤0.05 was taken as significant.

Results

In this study, there were one hundred and forty (n=140) individuals with a mean age of 56.21±14.86 years. This was a male predominant sample population with males 97 (69.29%) and females 43 (30.71%). The bleeding during TDLCC insertion was observed in 24 (17.14%) patients. 91 (65.00%) individuals were already on dialysis while 49 (35%) had TDLCC for their first haemodialysis. The mean systolic blood pressure (SysBP) was 138.69±19.09 mmHg while the mean diastolic BP (DiaBP) was 85.89±12.31 mmHg. Details are shown in Table 1.

The receiver operating curve (ROC) analysis of the effect of SysBP on the risk of bleeding showed the area under curve 0.792(95% confidence interval 0.697 - 0.886, p<0.001). For DiaBP, the area under came out to be 0.767(95% confidence interval 0.662 - 0.871, p< 0.001). the area under curve for serum creatinine was 0.654(95% confidence interval 0.536 – 0.772, p= 0.017) as shown in Figure 1.

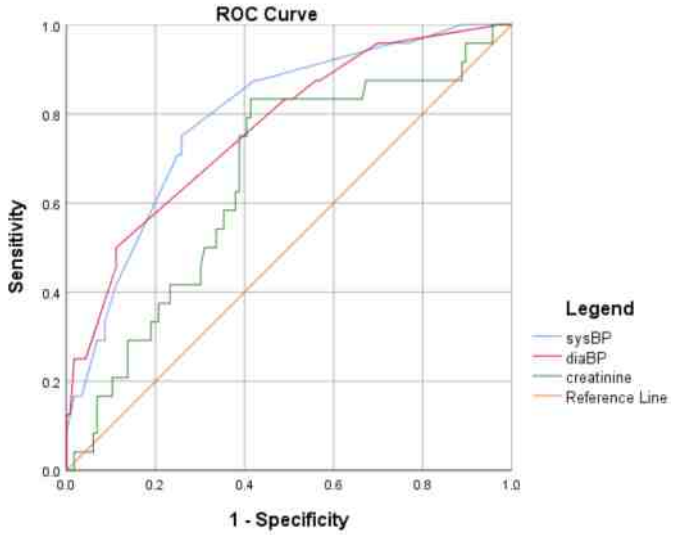

Figure 1: *ROC curve for risk of bleeding during TDLCC insertion in patients*

The subset ROC analysis of HD groups showed the area under the curve of 0.0.830 (95% confidence interval 0.722 – 0.938, p<0.001) for SysBP, and for DiaBP, the area under the curve was 0.822 (95% confidence interval 0.721 - 0.923, p<0.001). The area under the curve for serum creatinine was 0.672 (95% confidence interval 0.527–0.817, p=0.024) in patients already on HD, as shown in Figure 2. In the case of patients who were not previously haemodialyzed (NHD), the area under the curve was 0.723 (95% confidence interval 0.537 – 0.909, p=0.079) for SysBP, and for DiaBP, the area under the curve was 0.667 (95% confidence interval 0.406 - 0.927, p=0.190). The area under the curve for serum creatinine

Table II: *Best cut-off values for predicting the risk of bleeding*

Parameter	Best cut-off value	AUC	Sensitivity	Specificity	p-value
SysBP	≥142.50 mmHg	0.792	75.0%	74.1%	<0.001
DiaBP	≥92.50 mmHg	0.767	50.0%	88.8%	<0.001
Serum Creatinine	≥691.50 µmol/L	0.654	83.3%	58.6%	<0.017
HD Patients					
• SysBP	≥142.50 mmHg	0.830	72.2%	83.6%	<0.001
• DiaBP	≥82.50 mmHg	0.822	83.3%	60.3%	<0.001
• Creatinine	≥685.50 µmol/L	0.672	77.8%	65.8%	0.024

SysBP: Systolic blood pressure; DiaBP: diastolic blood pressure; HD: Haemodialysis

was 0.721 (95% confidence interval 0.536–0.906, p= 0.082) in NHD patients.

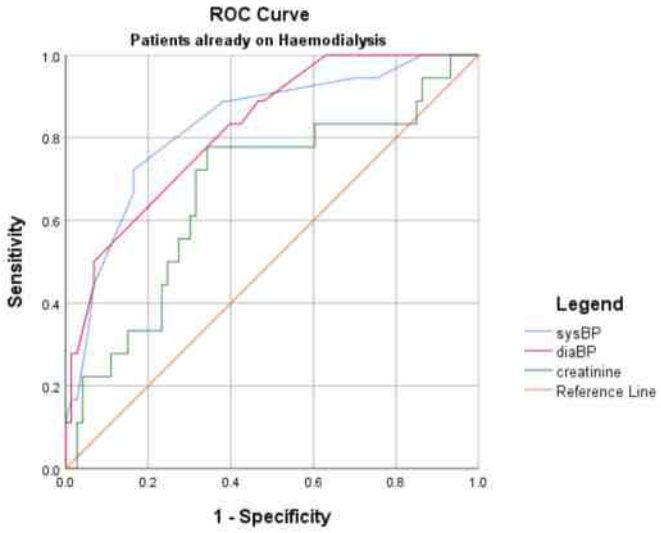

Figure-2: *ROC curve for risk of bleeding during TDLCC insertion in patients already on haemodialysis.*

The systolic blood pressure of 142.50 mmHg or more had a sensitivity of 75.0% and specificity of 74.1%, and the diastolic BP of 92.50 mmHg had a sensitivity of 50.0% and specificity of 88.8%. Similarly, the best cut-off value for creatinine was 691.50 µmol/L, with a sensitivity of 83.3% and specificity of 58.6%. Details are shown in Table-II.

Discussion

The raised blood pressure has long been known for cardiovascular accidents and has always been a concern for surgeons for intervention, as raised blood pressure has been associated with vascular misadventures and haemodynamic instability. The incidence of complications and arterial injuries are under-reported and often limited to reporting of once-in-a-while complications.[13] This study was also planned to see the effect and impact of blood pressure on the risk of bleeding during TDLCC (also known as permcath) insertion. There were 140 patients in this study with a mean age of 56.21±14.86 years. The serum creatinine levels were at the higher end 763.43±370.44 µmol/L. The mean systolic blood pressure was 138.69±19.09 mmHg while the mean diastolic pressure was 85.89±12.31 mmHg. The area under the curve (AUC) for Sys BP was 0.792(95% confidence interval 0.697 - 0.886, p<0.001) showing a statistically significant impact. Similarly, the AUC for the DiaBP was 0.767(95% confidence interval 0.662 - 0.871, p<0.001) with a statistically considerable result. Out of 140 patients, only 24 (17.14%) had a bleed due to TDLCC insertion. The bleeding at the catheter site was 5.4% in a study conducted by Hamid et al. and similarly, 5% was reported in another research.[12,14] The difference in our local site bleed from these studies is due to the difference in study population and parameters observed. The SysBP of 142.50 mmHg or more and DiaBP of 92.50 mmHg or more was associated with increased risk of bleeding in our study population. Moreover, we observed serum creatinine value of 691.50 µmol/L or more was associated with increased risk of bleeding during permcath (TDLCC) insertion in patients requiring maintenance haemodialysis. Furthermore, the patients already in HD and requiring permcath placement had a lower threshold for DiaBP (182.50 mmHg or more) and serum creatinine (685.50 mmHg), except for SysBP (142.50 mmHg), which was similar to the general population. This difference might be due to coagulopathy, platelet dysfunction and heparin use during haemodialysis.

There is always a small risk of bleeding during central venous catheter insertion. It has been reported to variable degrees from 0.5% – 1.6% in different studies.[15] Similarly, the bleeding was reported by Beathard et al. in the control group (0.46%).[11] The blood pressure has a significant role in increasing mortality and morbidity. Shimamura et al. in their study reported that TDLCC placement is associated with increased all-cause mortality when SysBP is less than 100mmHg, when compared to SysBP greater than 100mmHg.[16] They also reported instruction/ decreased catheter blood flow in patients who had SysBP<100 mmHg. Similarly, an increased complication rate was reported by Coeckelenbergh et al.[17] In this study, elevated blood pressure was associated with increased bleeding during and after TDLCC placement (p<0.001). This difference in reporting outcome might be due to differences in parameters observed. They assessed complications like lumen blockade, bacteraemia, and others, while this study saw if patients bleed from the TDLCC insertion site when TDLCC is placed at a higher blood pressure. This increased risk of bleeding can be explained by increased intraluminal vascular pressure, as it would not allow the venous lumen close in the absence of external pressure. This rise in venous pressure can be explained by the change in mean arterial pressure (MAP) due to increased SysBP and DiaBP. The MAP increases the cardiac output, indirectly increasing the central venous pressure.[18]

In this study, raised serum creatinine levels were also found to be associated with increased risk of bleeding (p=0.017). It is widely believed that elevated serum creatinine levels do not directly increase the risk of bleeding. But it does show the impairment in kidney

functions, i.e., increased uraemia, which leads to coagulopathy, thus serum creatinine indirectly affects the bleeding haemostasis and procedure.[19,20] Though the Fistula-First initiative and NKF-KDOQI guidelines are in place, 82.6% of new haemodialysis patients begin HD with a CVC rather than an arteriovenous graft (AVG) or arteriovenous fistula (AVF). Moreover, the cost-effectiveness analysis and the mortality rates are also remarkably different between AVF and CVC groups.[21] In a study by Ocak et al., the researchers observed the decreased kidney functions, i.e., decreased estimated glomerular filtration rate and increased creatinine, which increases the risk of bleeding.[22] Somewhat similar to our proposition that the increased serum creatinine levels increase the risk of bleeding above a certain threshold during TDLCC placement.

It is one of the initial studies to see the effect of blood pressure on the risk of bleeding during TDLCC placement. This study has certain limitations. Firstly, it is a single-centre study with a modest sample size. Secondly, it is a prospective observational cohort study, a randomised clinical trial with a large sample size, and analysis of all covariates will give better and broader insight into the relationship. Moreover, the study lacks multivariable adjustments for confounders due to data limitations.

Conclusions

The raised blood pressure either systolic or diastolic increases the risk of bleeding during tunnelled double-lumen catheter insertion in patients requiring haemodialysis. However, a large multicentre study is required to establish the relationship between blood pressure and the risk of bleeding.

Ethical Approval: The Ethical Committee, Pakistan Emirates Military Hospital, Rawalpindi approved this study vide letter No. A/28/ ERC/192/ 24.

Conflict of Interest: The authors declare no conflict of interest.

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Authors' Contribution:

ZS, ARA: Conception and design, acquisition of data, analysis & interpretation of data, revising it critically for important intellectual content, final approval of the version to be published

MNAK: Conception and design, analysis & interpretation of data, final approval of the version to be published

MI: Conception and design, acquisition of data, revising it critically for important intellectual content, final approval of the version to be published

KM: Conception and design, analysis & interpretation of data, final approval of the version to be published

SS: Acquisition of data, revising it critically for important intellectual content, final approval of the version to be published

RMUE: Conception and design, acquisition of data, final approval of the version to be published

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