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HEPARIN OR 0.9% SODIUM CHLORIDE TO MAINTAIN CENTRAL VENOUS CATHETER PATENCY: A RANDOMISED TRIAL

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ABSTRACT: BACKGROUND: Maintaining the lumen patency of Central venous catheters (CVCs) using low dose Heparin is recommended in many guidelines of CVC maintenance. This study is to compare the efficacy of low-dose Heparin 3ml (10U/ml) and 0.9% Sodium chloride (10ml) flush solutions to maintain Central venous catheter (CVC) lumen patency. **METHODS:** We studied 100 adult patients between March 2012 and August 2012 who required short-term CVC insertion to compare two flush solutions, Heparin and 0.9% Sodium Chloride on catheter lumen patency. **RESULTS:** The crude catheter non patency was 4% (two lumens) in Heparin group and 8% (four lumens) in the Sodium Chloride group. There was no incidence of thrombocytopenia in both the study groups. **CONCLUSION:** This study has demonstrated no significant difference between Heparin and 0.9% Sodium Chloride flushes with regards to catheter patency in adult patients with short-term use of CVCs.

KEYWORDS: central venous, heparin, sodium chloride, vascular patency.

INTRODUCTION: Venous catheters generally develop a fibrin sheath at the tip, which evolve into a clot due to body's physiological response to the vein injury and the foreign catheter¹ and subsequent catheter obstruction. Flushing a catheter lumen used for intermittent infusions is important. After an infusion or a flush, the reflux of blood into the lumen increases the risk of thrombus formation. Thrombus formation leads to loss of functionality of that lumen. Loss of lumen functionality due to thrombosis requires costly thrombolytic therapy or catheter removal². Interventions to prevent catheter thrombosis occlusion & maintain function of CVCs vary from unit to unit & institute to institute. Heparin is the standard flush recommended in various CVC maintenance guidelines³⁻⁵. The switch to 0.9% Sodium Chloride may be due to the concerns of Heparin induced complications like Heparin induced thrombocytopenia (HIT) or bleeding (6). Therefore, we conducted a study to compare the efficacy of low-dose Heparin 3ml (10U/ml) and 0.9% Sodium chloride (10ml) flush solutions to maintain Central venous catheter (CVC) lumen patency in the Respiratory intensive care unit (RICU) of our tertiary referral hospital. The primary objective of this study is to compare the efficacy of low-dose Heparin 3ml (10U/ml) and 0.9% Sodium chloride (10ml) flush solutions to maintain Central venous catheter (CVC) lumen patency.

METHODS: After obtaining institutional ethical committee's approval, 100 patients aged between 18 to 58 years of both sexes who are admitted into the RICU (Respiratory Intensive Care Unit) with various disease processes were selected. They were assigned randomly into two groups consisting of 50 in each group, within 12 hrs. after CVC insertion. To be enrolled in the study, patients had to have a newly inserted triple lumen CVC (<12hrs), and all the lumens had to be patent. Heparin group (group H) who received Heparin flush solution and 0.9 % sodium chloride group (group S) who

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received 0.9 % sodium chloride flush solution. All the CVCs used for the study were triple lumen catheters (Certofix®Trio of B.Braun, made of Polyurethane).The size and length of the CVCs were same in all the patients. Distallumen was exclusively used for the study purpose only, while the other lumens were being used for the infusions. Exclusion criteria were Known Heparin allergy, diagnosis of Heparin induced thrombocytopenia (HIT), bleeding risk identified by attending physician, Age < 18 yrs. OR > 58 yrs., patients requiring prolonged ICU stay with ailments like terminal illness, severe septicemia, Multi Organ Dysfunction Syndrome (MODS) etc....

After obtaining consent within 12 hrs. after insertion of CVC, the patient received either heparin (3 mL, 10 U / mL) or 0.9 % NaCl(10 mL) flushes every 8 hours. Daily at 8:00 AM, 4:00 PM and 12:00 AM the patency assessment was done. Therefore three patency assessments per day were possible for every case. All the RICU Residents were educated on study purpose, protocol, data collection, and the importance of adhering to regular flushing intervals. When a CVClumen non-patency was encountered, it was reported and noted in the study. These assessments were performed until the patients were shifted out of the RICU or, the CVC was removed, whichever came first, with an average duration of 1 week.

Study outcome and definitions: The primary outcome of the study was lumen non-patency defined as inability to both withdraw blood and flush through a lumen. The conclusion of lumen non-patency was arrived only after the following interventions:1. if the lumen could not be flushed, the patient was repositioned and flush reattempted.2.If still unable to flush, the syringe was changed and flush was reattempted. As a secondary outcome, heparin induced thrombocytopenia (HIT) was assessed with daily platelet count, starting on day 4 from the time of giving heparin flushes for all the patients in Group H.

Statistics analysis: Differences between the groups were assessed using student's t test or chi-square test as appropriate. All statistical analyses were performed using SPSS version 17.0.

RESULTS: The demographic characteristics of the patients undergoing study are shown in the table. Baseline demographics and catheter and lumen characteristics were similar in both the groups.

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AGE DISTRIBUTION	GROUP H (n=50)	GROUP S (n=50)
18-28	6	6
29-38	12	14
39-48	16	12
49-58	16	18
SEX DISTRIBUTION		
MALE	24	22
FEMALE	26	28
TYPE OF LUMEN	GROUP H (n=50)	GROUP S (n=50)
TRIPLE LUMEN	TRIPLE LUMEN	TRIPLE LUMEN
LOCATION	GROUP H (n=50)	GROUP S (n=50)
IJV	40	36
SUBCLAVIAN	10	14
NON-PATENCY (LOSS OF BLOOD STREAM& FLUSH FAILURE)	GROUP H (n=50)	GROUP S (n=50)
	4%(n=2)	8% (n=4)

Table 1

The crude catheter non patency was 4% (two catheters) in heparin group and 8% (four catheters) in the sodium chloride group.

There was no incidence of **thrombocytopenia** in both the groups.

DISCUSSION: Central venous catheters (CVC's) are widely used in critical care to administer a variety of blood products, intravenous (IV) fluids & medications, to monitor hemodynamic indices, to obtain blood samples, & for pacing or dialysis. Heparin is the standard flush recommended in various CVC maintenance guidelines. However 0.9% NaCl is also used for the same purpose. This study demonstrated no difference between Heparin and 0.9% NaCl flushes on maintaining patency of short-term CVC's in adults. Conflicting results were found in a randomized comparison of Heparin (5000 IU / ml), Vitamin C (200 mg / ml), or 0.9 % NaCl flush solutions used in distal lumens of triple

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lumen catheters⁷. Attempts to aspirate blood was performed every 48 hrs. The authors observed significant difference between the three groups, and concluded that Heparin is superior for maintaining catheter patency⁷. One major difference in this study was the flushing frequency of every 48 hours as compared to every 8 hours, and may partly account for the different findings. Systemic reviews of various CVCs have demonstrated insufficient evidence for superiority of flushing with Heparin compared to 0.9% NaCl. Likewise, a Cochrane review that analyzed the heparin bonded catheters with non-heparin bonded catheters found no significant difference in patency⁸. Matthew D. Mitchell¹, Barbara Jo Anderson, Kendal Williams, Craig A. Umscheid² concluded that the evidence base on heparin flushing and other interventions to prevent catheter occlusion is small, and published studies are of low quality. There is insufficient evidence on which to conclude that flushing catheters with heparin is more effective than flushing with saline solution.

In this study, 100 patients were randomly selected who have a newly inserted CVC (<12hrs) & divided into two groups group H & group S, with 50 patients in each group. One lumen in each CVC was exclusively used for study. Flushes with heparin or sodium chloride solutions were done every 8hrs. This study demonstrated no difference between heparin & 0.9% NaCl flushes on maintaining patency of short-term CVCs in adults. Simple interventions like position changing can sometimes correct loss of patency, thus eliminating the need for catheter removal. Systematic reviews of various CVCs have demonstrated insufficient evidence for superiority of flushing with heparin compared to 0.9% NaCl.^{2, 9, and 10}. The primary outcome of the study was lumen non-patency defined as inability to both withdraw blood and flush through a lumen. The lumen was declared non-patent only after flushing with a position change and change in the syringe. Proper flushing/clamping sequence performed every 8 hours and catheter flushes after medication administration are worthwhile interventions to help maintain catheter patency. In our study, the primary outcome i, e; lumen non-patency was encountered in one catheter of heparin group (4%) and in 2 catheters of sodium chloride group (8%). None of them had complications during insertion or when the catheter was in situ. Thrombocytopenia was not found in both the groups.

CONCLUSION: In conclusion, this study has demonstrated no significant difference between heparin and 0.9% NaCl flushes with regards to catheter patency in adult patients with short-term use of CVC's. Although measures of safety were similar in these two groups, saline flushes may be preferred to reduce exposure to heparin and its potential complications. Regular intervals of flushing, proper flushing/clamping sequence are likely the most important interventions to maintain catheter patency.

Previous presentation: The results of this study were presented as a free paper at the South zone conference of the Indian society of Anesthesiologists, Coimbatore 2012.

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