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Original Research Article

Sodium Bicarbonate versus Heparin as Catheter Lock Solution to Reduce Hemodialysis Catheter Loss due to Catheter Related Thrombosis and Blood Stream Infection

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ABSTRACT

Background
The aim of the study is to determine the safety and efficacy of using sodium bicarbonate catheter lock solution (SBCLS) as a means of preventing HD catheter loss due to catheter related thrombosis (CRT) and catheter related blood stream infection (CRBSI).

Methods
Patients aged > 18 years of age who needed HD treatment through central venous catheters (CVC) were included in the study. Total of 120 patients were given either Sodium bicarbonate or Heparin, post-dialysis in a 1:1 randomisation as a catheter lock solution. Catheter loss due to CRT or CRBSI was evaluated.

Results
Total of 120 patients were included in the study. There were no significant differences between groups in co-morbidities at the outset. The Heparin group had CRT and CRBSI rates of 3.3% and 10% respectively, compared with 20% (CRT) and 11.6% (CRBSI) for both outcomes in the Sodium bicarbonate group.

Conclusion
The incidence of CRBSI in Sodium bicarbonate group was similar to Heparin group, its efficacy in preventing thrombosis is notably lower than that of heparin, making it a less favourable option

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for catheter maintenance in chronic kidney disease (CKD) and acute kidney injury (AKI) patients who are already at a higher risk for thrombotic events.

Keywords: Sodium bicarbonate catheter lock solution, CVC, CRT, CRBSI, AKI, CKD.

INTRODUCTION

Hemodialysis patients are at a heightened risk of infections and thrombosis due to the regular use of central venous catheters (CVCs) for vascular access. Catheter-related bloodstream infections (CRBSIs) and catheter-related thrombosis (CRT) are two major contributors to catheter failure, which can result in increased hospitalizations, higher healthcare costs, and negative outcomes for patients. Identifying and implementing more effective catheter lock solutions may help to mitigate these risks.[1]

Heparin has traditionally been the go-to catheter lock solution for preventing thrombosis in hemodialysis catheters because of its strong anticoagulant properties, which prevents thrombosis inside the catheter. Its effectiveness in keeping catheters open and reducing the occurrence of catheter-related thrombosis (CRT) has established its widespread use in clinical settings.[2] However, heparin is associated with certain risks, including the potential for heparin-induced thrombocytopenia (HIT), an adverse immune reaction that lowers platelet counts, and an increased risk of bleeding. Despite these issues, heparin continues to be widely used because of its effectiveness in reducing thrombosis. Additionally, heparin lacks antibacterial properties, limiting its effectiveness in preventing catheter-related bloodstream infections (CRBSIs). In contrast, sodium bicarbonate, which is commonly used in various medical applications, has shown promise due to its buffering capabilities and potential antibacterial effects.[3,4]

Sodium bicarbonate provides both anticoagulant and antimicrobial effects, which can substantially reduce the occurrence of catheter-related thrombosis (CRT) and catheter-related bloodstream infections (CRBSIs).[5] Its alkaline properties neutralize bacterial acids, which may inhibit bacterial growth and prevent biofilm formation inside the catheter. Additionally, the anticoagulant effects of sodium bicarbonate help to keep the catheter open by preventing blood clots from forming and causing blockages. This combined effect offers a more thorough approach to maintaining catheter function and minimizing complications, potentially resulting in fewer catheter replacements, reduced hospitalizations, and better outcomes for hemodialysis patients.[6,7]

Conducting this study was essential to inform clinical practices and guidelines for hemodialysis catheter management. This could help us understand the potency of sodium bicarbonate proves to in reducing catheter-related complications, it could lead to a shift in standard care practices, potentially decreasing the incidence of CRT and CRBSIs. This could result in fewer catheter replacements, reduced hospital admissions, and overall improved patient outcomes. Moreover, this research could stimulate further investigations into other novel catheter lock solutions, broadening the scope of preventive strategies against catheter-related complications in hemodialysis patients.

AIM & OBJECTIVES

To determine the safety and efficacy of using sodium bicarbonate catheter lock solution as a means of preventing HD catheter loss due to CRT and CRBSI.

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MATERIALS & METHODS

The study was conducted after obtaining approval from the Ethics Committee of our institute. Informed consent was obtained from each patient before the study. This randomized control trial was conducted over a period of 2 years from June 2022 to June 2024, at department of nephrology at KIMS Hubballi. A total of 120patients undergoing HD were included in the study. All patients were randomly assigned in 1:1 ratio based on the computer-generated random sequences into two groups:

Group A: Sodium bicarbonate group
Group B: Heparin group

Demographics, co-morbidities, clinical and treatment related data was recorded in the study performa. Patients were checked for patency of catheter on regular basis. Rate of CRT and CRBSI in each group were recorded. Patients who had patent HD without both CRT and CRBST were followed upto 1 year.

Definition

- CRBSI: It was diagnosed when clinical sepsis symptoms (clinical manifestations) and empirical evidence of an infection related to catheter were present.
- Acceptable empirical evidence of CRBSI was defined as "two peripheral venous blood samples drawn from the patient producing positive quantitative (more than 1000 cfu/segment) culture results. Alternatively, one positive culture obtained from a peripheral vein and one catheter culture with a positive semi quantitative (>15 cfu/segment). Result was acceptable.
- In concordance with national kidney foundation guidelines, catheter dysfunction was defined when extra corporeal blood flows <=300 ml/min or the pre pump arterial pressure was >=250 mm Hg.
- Malfunctioning catheters were recorded when the catheter showed a visible kink or repositioning maneuvers such as ipsilateral arm raising, sitting, standing, or rolling the patient onto one side led to catheter dysfunction reversibility.
- Catheter loss due to CRT was defined as persistent catheter malfunctioning, irreversible difficulty with line aspiration or infusion despite repositioning before or during HD.

Statistical Analysis

Data was analyzed using Microsoft excel sheet and Vassar Stats. The data collected were subjected to descriptive analysis to evaluate the rate of CRT and CRBST in both groups. Results were expressed as percentages, as mean ± standard deviation for continuous variables. Comparisons between sodium bicarbonate group and herparin group was performed using Chi-square, to test the association between groups. A p-value <0.05 id considered statistically significant.

RESULTS

Total of 120 patients were included in the study. Mean age of the patients was 50.49 years and included 64 males and 56 females (table1). 69.39% of the patients had hypertension and 30.61% had both diabetes and hypertension. Mean duration of the catheter was 3.5months. 10.31%

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patients has catheter related blood stream infection, 11.67% had Catheter related thrombosis and 11.66% had positive blood culture. 79.17% of the patients had chronic kidney disease and 20.83% had acute kidney injury.

In the present study there was no significant difference between the groups regarding age, sex, co-morbidities, catheter related blood stream infection and blood culture positive infection (Table 2). 20% of the bicarbonate group of CRT compared to 3.33% in heparin group. There was statistically significant difference in catheter related thrombosis between the group.

The heparin group had CRBSI and CRT rates of 10 % (6 out of 60) and 3.3% (2 out of 60). Among the CRBSI cases 2 patients had IJV and 4 patients had permanent catheter. CRT patients had permanent catheter and CRT was with resolved with inj. Streptokinase.

Sodium bicarbonate group had CRBSI and CRT rates of 11.6% (7 out of 60) AND 20% (12 out of 60). Among the CRBSI cases 2 patients had IJV and 5 patients had Permanent catheter. Among the 12 CRT patients, 11 patients had permanent catheter and 1 patient had IJV. Among the 12 CRT, 10 patients with CRT were salvaged with inj. Streptokinase and 1 permanent catheter were removed as we couldn't salvage.

Variable	Number of patients	Percentage
Age in years (mean)	50.49± 14.13 years	
Gender 1. Male 2. Female	 64 56	 53.33% 46.67%
Co-morbidities 1. Hypertension 2. Hypertension and diabetes	 90 30	 75% 25%
Duration of catheter	3.5 ±1.9 months	
Access 1. Permcath 2. IJV	 95 25	 79.17% 20.83%
CRBSI 1. Yes 2. No	 13 107	 10.83% 89.17%
CRT 1. Yes 2. No	 14 106	 11.67% 88.33%
Blood culture 1. Positive 2. Negative	 14 106	 88.33% 11.66%
Diagnosis 1. Chronic kidney disease 2. Acute kidney injury	 95 25	 79.17% 20.83%

Table 1: Characteristics of the Patients Assessed for catheter related thrombosis and blood stream infection

Variables	Bicarbonate group	Heparin Group	P value

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Age 1. <60years 2. >60years	 45 (75%) 15(25%)	 40 (66.67%) 20(33.33%)	 0.2110
Sex 1. Female 2. Male	 31(51.67%) 29(48.33%)	 33(55%) 27(45%)	 0.4274
Co-morbidities 1. Hypertension **2.** Hypertension & Diabetes mellitus	 48 (80%) 12 (20%)	 42(70%) 18(30%)	 0.1459
Catheter related blood stream infection. 1. YES 2. NO	 7(11.67%) 53(88.33%)	 6(10%) 54(90%)	 0.50
catheter related thrombosis YES NO	 12(20%) 48(80%)	 2(3.33%) 58(96.67%)	 **0.0041***
Blood culture positive Positive negative	 7(11.6%) 53 (88.33%)	 7(11.6%) 53 (88.33%)	 0.6114

Table 2: Comparison of the Patients Assessed for catheter related thrombosis and blood stream infection between bicarbonate group and heparin group

Analysed using Chi square test, *P- value < 0.05 considered as significant

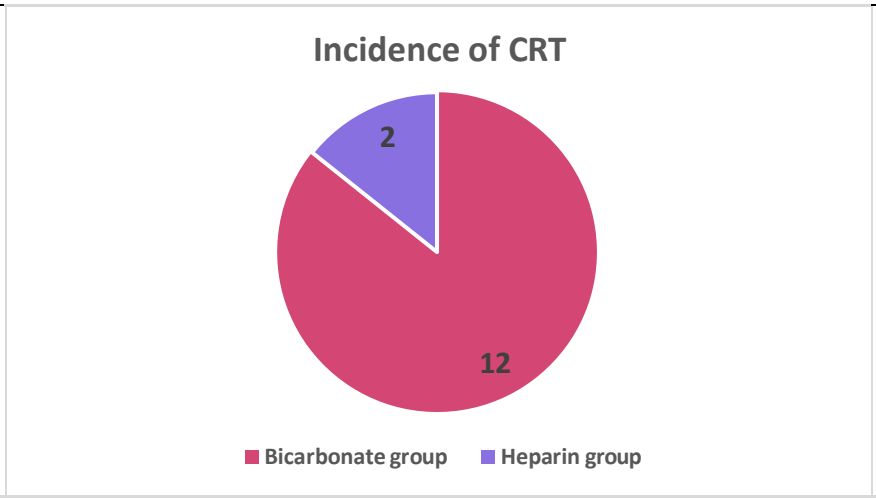

Figure 1: Comparison of CRT incidence between bicarbonate group and heparin group

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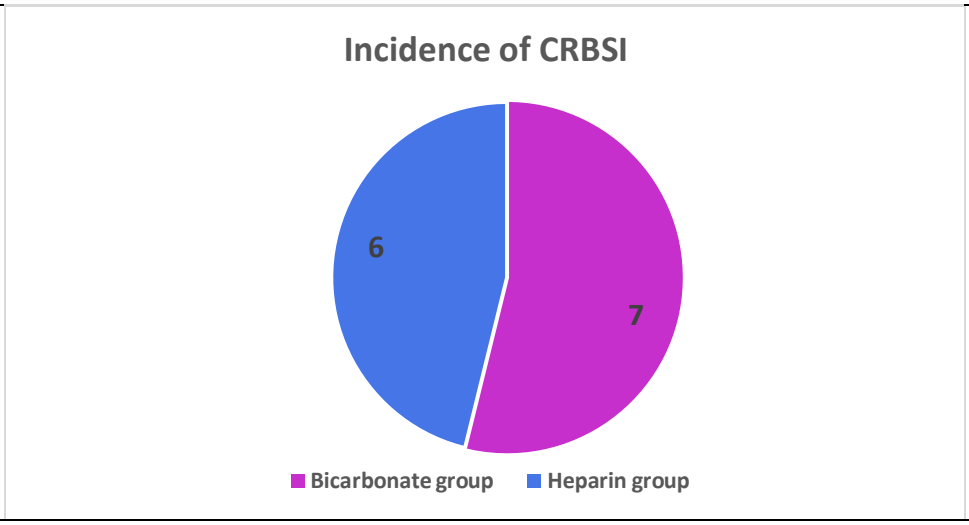

Figure 2: Comparison of CRBSI incidence between bicarbonate group and heparin group

DISCUSSION

Temporary vascular access is essential for patients undergoing acute hemodialysis. Heparin lock solutions being the globally accepted standard for prevention of thrombosis of catheter. While various lock solutions have been explored for their ability to prevent thrombosis and catheter-related infections, heparin remains the preferred choice. This study was therefore designed to assess the effectiveness of sodium bicarbonate-a widely available and cost-effective alternative-compared to heparin in tunnelled and non-tunnelled hemodialysis catheters.

This study found that using a 7.5% sodium bicarbonate solution alone as a catheter lock in patients with CKD or AKI resulted in a significantly higher incidence of CRT compared to the standard heparin locking solution. Similar evidence when evaluating the use of sodium bicarbonate solution as a catheter lock in patients with Chronic Kidney Disease (CKD) or Acute Kidney Injury (AKI), research indicates a concerning increase in catheter-related thrombosis (CRT) rates compared to the standard use of heparin as a locking solution.

However, studies have shown that while sodium bicarbonate may offer some protective benefits against infection, its use as a sole locking solution is associated with a significantly higher incidence of CRT, potentially due to the lack of anticoagulant properties that heparin provides. As A review by Cochrane,[8] showed similar results with frequent occurrences of CRT in sodium bicarbonate lock solution. Our study findings underscore the importance of considering the balance between infection prevention and thrombosis risk when choosing a catheter locking solution. Bicarbonate group.

Catheter-related bloodstream infections (CRBSIs) are a significant concern in patients requiring long-term catheterization, particularly those undergoing hemodialysis or receiving parenteral nutrition. Traditionally, antimicrobial solutions such as heparin, ethanol, or antibiotic locks have been used to prevent CRBSIs.

Studies conducting by Lee et al[9] and Jognson P et al[10] on the efficacy on prevention of CRBSI by sodium bicarbonate showed significant reduction in CRBSIs in the sodium bicarbonate group. Literature also demonstrates Sodium bicarbonate (NaHCO3) that anti-infective and anticoagulation properties with a good safety profile, making it an ideal lock solution development target.[11] A study by Lee et al[10] on biofilm formation demonstrates that sodium bicarbonate disrupts biofilm formation, thereby reducing the potential for bacterial colonization and subsequent infections. Sodium bicarbonate is relatively inexpensive and readily

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available, making it a cost-effective option for long-term catheter maintenance. Sodium bicarbonate is generally well-tolerated and does not carry the same risks as anticoagulants like heparin, such as bleeding complications.[11]

Traditionally, heparin has been widely used as a catheter lock solution to maintain patency and prevent clotting. However, concerns about heparin's association with bleeding complications and its limited antimicrobial properties have led to the exploration of alternative solutions, such as sodium bicarbonate. A study by Smith et al demonstrates that, heparin locks were associated with a certain rate of CRBSIs.[1] Lee et al,[9] suggest that heparin may inadvertently promote biofilm formation, providing a surface for bacterial colonization, which can increase the risk of CRBSIs.

However, in the present study though the incidence of CRSBI is similar in both groups with no statistical difference. Studies like smith J et al[12] Brown T et al, compared between sodium bicarbonate and heparin as catheter lock solutions highlights important differences in their ability to prevent CRBSIs. While heparin remains a standard choice for maintaining catheter patency, its limited antimicrobial properties and potential complications make it less effective in reducing infection rates. Sodium bicarbonate, with its antimicrobial and biofilm-disrupting properties, offers a promising alternative that could enhance patient outcomes by lowering the risk of CRBSIs.

In the present study Heparin demonstrated superior efficacy in maintaining catheter patency and reducing the incidence of CRT but not with catheter-related bloodstream infections (CRBSIs) The study's findings suggest that, despite the growing interest in sodium bicarbonate as an alternative lock solution, heparin remains the more effective option for preventing CRT. These results underscore the importance of continued research into optimizing catheter lock solutions, balancing the need for infection prevention with ensuring catheter functionality. While sodium bicarbonate may have applications in other settings, its use in CRT should be carefully considered, and heparin should remain the standard of care for this patient population based on current evidence.

The study had few limitation. Generalizability of the results is limited as it was conducted in a single center and in a specialty clinic. Further large-scale studies are needed to establish standardized protocols and confirm its efficacy across diverse patient populations.

CONCLUSION

We can conclude that the incidence of CRBSI in Sodium bicarbonate group is similar to Heparin group, its efficacy in preventing thrombosis is notably lower than that of heparin, making it a less favorable option for catheter maintenance in CKD and AKI patients who are already at a higher risk for thrombotic events.

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