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First Time Sodium Bicarbonate Catheter Lock Solution is Found to be a Safe and Effective Lock Method in Preventing Hemodialysis Catheter Loss due to Lumen Clot Formation

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Keywords
- Hemodialysis
- Catheter lock
- Clotted catheter
- Sodium bicarbonate
- ESRD

Abstract

Background: Central venous catheters, originally introduced as vascular access for short-term dialysis, have become an acceptable form of permanent vascular access. Both non-tunneled, non-cuffed and cuffed, tunneled hemodialysis catheters are used for vascular access in HD patients who have no alternative access or are awaiting placement or maturation of AVF. One of the major causes of catheter loss is clot formation in catheter lumen. Locking catheter with heparin has been associated with increased risk of bleeding in some dialysis patients. Hence, the effective of sodium bicarbonate (8.4 %) solution used as an alternative method for catheter lock solution is considered because it is easily available, inexpensive and easy to be popularized. Its anticoagulant principle is still unclear. It can be speculated that its mechanism of action includes binding calcium and removing it from the many enzymes of the coagulation system that require it as a cofactor.

Method: One hundred patients with inserted HD catheter were randomly divided into two groups: SBCLS (Sodium Bicarbonate Catheter Lock Solution) and NSCLS (Normal Saline Catheter Lock Solution), over a period of six months. After the hemodialysis treatment had been completed, each lumen of the catheter in 50 patients of the NSCLS group was flushed with 18 ml of 0.9 % sodium chloride and locked with the 2 ml of locking solution. Three patients were excluded from NSCLS group and the analysis due to removal of catheters for catheter related sepsis.

For the 50 patients in the SBCLS group, each lumen of the catheter was flushed with 18 ml of Na HCO_3 8.4% and locked with the 2 ml of locking solution. Heparin free HD was used for both groups during the study. The incidence of catheter thrombosis was followed up at each time of HD. Thrombosis was evaluated by resistance or complete occlusion to inflow or out flow of catheter ports before initiation of heparin free HD or during HD treatment if blood flow is less than 200 ml/min in the early time of HD.

Results: The incidence of catheter retention rate (RR) in NSCLS group 78.72% and in SBCLS group 98%. In the NSCLS group 10 catheters were removed due to clot formation and three catheters were removed due to catheter related sepsis. The three infected catheters are excluded from the study. However, in the SBCLS group only one catheter was removed (due to resistance of the outflow of red catheter port). The Chi-Square test was used to determine whether there was a significant difference between the two groups. In the NSCLS group 10 catheters were removed due to clot formation and 37 catheters continued functioning while in the SBCLS group 1 catheter was lost and 49 continued functioning ($P = 0.003$).

Conclusion: SBCLS is an effective and safe lock solution for both non-tunneled, non-cuffed and tunneled, cuffed catheters that may provide prolonged catheter use with a diminution in catheter occlusion.

ABBREVIATIONS

HD: Hemodialysis; $NaHCO_3$: Sodium Bicarbonate; SBCLS: Sodium Bicarbonate 8.4% Catheter Lock Solution; NSCLS: Normal Saline 0.9% Catheter Lock Solution; HS: Heparin Solution; RR: Retention Rate; mEq: Milliequivalent; L: Liter; AVF: Arterio-Venous Fistula; IJV: Internal Jugular Vein; ESRD: End Stage Renal Disease; NSAID: Non-Steroidal Anti-Inflammatory Drug

INTRODUCTION

Central venous catheters, originally introduced as vascular access for short-term dialysis, have become an acceptable form of permanent vascular access [1]. It is common practice to provide patients with ESRD, three-times-weekly hemodialysis (HD) for 3-4 hours to be effective with blood flows in the adult patient of at least 300 mL/minute [2]. Today so many diabetic and elderly patients developing end-stage renal disease (ESRD) and the veins of their arms are too small or too jugular vein and the 6 month tunneled dialysis catheter patency rate was 37% for left IJV catheters, versus 54% for right IJV catheters [3].

In North America, the creation of the arteriovenous fistula (AVF) is the optimal form of access for patients on hemodialysis (HD). However, the majority of patients start HD with a hemodialysis catheter, and many continue to use a catheter 90 days after placement. Additionally, as the population of patients on HD grows older, the number of patients dependent on a catheter as their permanent mode of HD access increases. When catheters are used with the proper care, they may decrease patient morbidity and mortality [4]. In one prospective study involving 108 tunneled catheter-dependent hemodialysis patients, the cumulative likelihood of catheter-related bacteremia was 35 percent within three months and 48 percent within six months of catheter insertion [5]. The outcomes of tunneled femoral hemodialysis catheters in comparison with internal jugular vein catheters showed IJV is preferred [6]. In the United States, high-efficiency dialysis as practiced requires dialyzer-delivered blood flow rates greater than 300 mL/min to achieve the target single-pool Kt/V of 1.2 [7]. The consequences of catheter dysfunction are many, including increases in morbidity and mortality [8]. In some studies, clotted catheter accounts for 10%-42% of catheter malfunctioning depending on catheter site [9]; for which thrombolytic agents, such as recombinant tissue plasminogen activator (rt-PA), are effective [10]. Heparin is routinely used as a "locking" solution for preventing thrombosis-related catheter malfunction [11]. Many other agents, such as warfarin [12], sodium citrate [13,14], low-molecular weight heparin [15] and concentrated sodium chloride [16] have been studied for the same purpose. Since there was no ideal catheter lock solution, it was reasonable to evaluate an alternative catheter lock solution and we selected $NaHCO_3$ solution because it is found to be cheap, available and easily popularized. Furthermore, empiric testing of blood of 10 normal volunteers by drawing 1.5 cc of blood from each one and putting 0.5cc in one empty tube, second 0.5 cc in tube with 1 cc NaCl 0.9 % and third 0.5 cc in tube with 1 cc $NaHCO_3$ 8.4 %. Following tubes visually for 30 min showed formation of clot in the 10 empty tubes and in the 10 tubes with NSS. No formation of clot in the 10 tubes with $NaHCO_3$. The results were very encouraging and supported our theory. However, we could not find any literature related to $NaHCO_3$ lock solution; Its anticoagulant principle is still unclear. It can be speculated that its mechanism of action is through binding calcium and removing it from the many enzymes of the coagulation system that require it as a cofactor. For first time, easily available $NaHCO_3$ 8.4% solution is used as an effective alternative catheter lock solution method for all patients who are receiving HD by both non-tunneled, non-cuffed and cuffed, tunneled hemodialysis catheters with remarkable success. There was no increase in rate of infection or bleeding in patients in $NaHCO_3$ group.

SUBJECTS AND METHODS

Sodium bicarbonate description

Sodium Bicarbonate is a sterile, non pyrogenic solution with a concentration of 8.4%. The solution contains no bacteriostatic or antimicrobial agent. Concentration selection was based on the molecular weight of $NaHCO_3$. Each ml contains Sodium Bicarbonate, 84 mg with an osmolarity of 2 mOsmol/ml and pH 8.0 (7.0 to 8.5).

Sodium chloride solution description

Sodium chloride 0.9% is a sterile non pyrogenic solution contains 9g/L Sodium Chloride (NaCl) with an osmolarity of 308 mOsmol/L at pH 5.5 (4.5 to 7.0).

Dialysis machine

4008K2 Fresenius dialysis machine.

Dialyzer

Optiflux single use unit of polysulfone membrane. There is no reuse program in our dialysis center.

Catheters

Both non-tunneled, non-cuffed and tunneled, cuffed hemodialysis catheters are included in the study. Catheters were used for hemodialysis treatment only. Non-tunneled, non-cuffed catheter: Mahurkar Acute Dual Lumen Catheter right or left tunneled, cuffed catheter: Palindrome Precision Chronic Catheter right or left. All catheters are inserted by an expert operator under strict asepsis. Catheter exit site dressing changes after each HD treatment. Catheter manipulation was performed by a trained dialysis staff wearing masks and non-sterile gloves. Use of dry gauze dressings at the catheter exit site was implemented.

Dialysis treatment

91 Patients receive HD treatment three times /week. 9 patients received HD treatment 5 times /week. All dialysis patients were receiving heparin free-HD therapy. Duration of each HD session is 3 Hours. Remove and discard the last SBCLS or NSCLS before connecting HD catheter to machine. After HD treatment catheter blood is rinsed back thoroughly with normal saline solution. Catheter is flushed and locked with 20 ml in each port with either isotonic sodium chloride in NSCLS group or $NaHCO_3$ 8.4% solution in SBCLS group.

Patients

One hundred acute or chronic renal failure patients were enrolled. 90 of them received right internal jugular veins, 9 left internal jugular veins and one patient left femoral vein catheterization with both non tunneled, non-cuffed and cuffed, tunneled hemodialysis catheters from July 1, 2014 to December 31, 2014. Patients were randomized to either NSCLS or SBCLS regardless of their age, gender, Diabetes Mellitus, hypertension or any other medical condition.

Patients with the following criteria were excluded from the study:

1- Patients who are receiving Coumadin or thrombolytic agents.

2- Patients with abnormal PTT, PT and INR.

3- Patient with infected catheter before or during the 6 months period of the study.

Patients in both groups were closely monitored for any evidence of adverse reaction each time a catheter lock solution was removed or infused to the catheter. Due to withdrawal of urokinase from the market since June 1999, the routine practice in our dialysis unit is to change dialysis catheter if a catheter showed evidence of occlusion. In HD unit it is our routine to keep venous pressure less than 200 mmHg and blood flow more than 300 ml/min. Nurses and technicians wear masks and non sterile gloves and the patient wears a mask while the catheter is opened. New, sterile caps are placed on the catheter following each procedure. Catheters and connections are inspected for leaks or evidence of damage during each treatment. Other than the change in locking solution, there was no change in procedures for catheter use or care.

Study design

This is a prospective, randomized controlled study. One hundred patients with an inserted HD catheter were randomly divided into two groups: SBCLS (Sodium Bicarbonate Catheter Lock Solution) and NSCLS (Normal Saline Catheter Lock Solution), over a period of six months. After the hemodialysis treatment had been completed, each lumen of the catheter in 50 patients of the NSCLS group was flushed with 18 ml of 0.9% sodium chloride and locked with the 2 ml of locking solution. Three patients were excluded from the NSCLS group and the analysis due to removal of catheters for catheter related sepsis.

For the 50 patients in the SBCLS group, each lumen of the catheter was flushed with 18 ml of $NaHCO_3$ 8.4% and locked with the 2 ml of locking solution. Heparin free HD was used for both groups during the study. The incidence of catheter thrombosis was followed up at each time of HD. Thrombosis was evaluated by resistance or complete occlusion to inflow or out flow of catheter ports before initiation of heparin free HD or during HD treatment if blood flow is less than 200 ml/min in the early time of HD.

Statistical analysis

Results are expressed as mean (standard deviation) or as n (%). Chi Square or Fisher's exact test was used to compare the differences in categorical variables between the NSCLS and SBCLS groups. Independent t-tests were used for comparison of continuous variables. Kaplan-Meier life table analysis was used to document and test for any differences in the time to the catheter removal event. P-values less than 0.05 were deemed statistically significant; no multiple-test adjustment to the p-value was done. All analyses were conducted using SAS 9.4 (SAS Institute, Inc, Cary, NC).

RESULTS

The randomization was effective in that there were no statistical differences between the two groups with respect to demographic, biochemical or clinical characteristics. See Tables 1 and Table 2. The mean age was 67 (15) years, 54% were male, and the race distribution was almost identical (62% white, 11% black, 5% Asian 16% Hispanic and 5% other (p=0.95).

The incidence of catheter retention rate (RR) in the NSCLS group 78.72% and in SBCLS group 98% as seen in Figure 1. In NSCLS group 10 patients (out of the 47 followed) had catheters removed due to clot formation. By comparison, in the SBCLS group only one patient's catheter (among the 49 followed) was removed due to resistance of the outflow of red catheter port (Fischer Exact P= value of 0.003) see Figures 1 and Figure 2.

Table 1: Comparison of categorical demographic and clinical characteristics.

Variable	Total sample N=97	SBCLS N=50	NSCLS N=47	P-value
Sex (% male)	55 (53.5%)	30 (60%)	23(46.9%)	0.19
HTN	89 (89.9%)	46(92%)	43(87.8%)	0.48
CAD/CHF	67 (68.4%)	36(73.5%)	31(63.3%)	0.27
DM	54 (55.1%)	27(55.1%)	27(55.1%)	1

Table 2: Comparison of continuous demographic and clinical characteristics.

	Total Sample N=97	SBCLS N=50	NSCLS N=47	t-test
Variable	Mean (stddev)			P-valve
Age	67.0 (15.2)	66.8 (16.2)	67.2 (14.3)	0.91
Height	164.0 (9.4)	164.1 (11.1)	163.8 (7.4)	0.89
Weight	75.8 (20.4)	74.7 (17.6)	77.0 (23)	0.58
SBP	129.9 (17.4)	133.3 (15.8)	126.5 (18.4)	0.0502
DBP	68.6 (8.8)	69.6 (8.4)	67.6 (9.3)	0.26
#CATH	1.1 (0.3)	1.1 (0.3)	1.1 (0.3)	0.77
# HD TX	6.1 (4.4)	5.9 (4)	6.2 (4.8)	0.71
ALB	3.1 (0.6)	3.1 (0.7)	3.1 (0.6)	0.8
BICARB	23.73 (3)	24.66 (2.5)	22.84 (3.1)	0.002
GFR	9.37 (2.6)	9.42 (2.7)	9.33 (2.6)	0.86
HB	9.16 (1.3)	9.19 (1.1)	9.14 (1.5)	0.84
INR	1.11 (0.1)	1.12 (0.2)	1.11 (0.1)	0.83
PHOS#	4.01 (1.4)	4 (1.3)	4.03 (1.5)	0.89
PT	11.93 (1)	11.94 (1.1)	11.93 (1)	0.92
PTT	30.01 (2.8)	30.46 (2.4)	29.54 (3)	0.10

DISCUSSION AND CONCLUSION

Central venous catheters, originally introduced as vascular access for short-term dialysis, have become an acceptable form of permanent vascular access. Both non-tunneled, non-cuffed catheters and tunneled, cuffed catheters are available.

These catheters are also used for permanent vascular access in some patients, particularly those with limited alternative options for vascular access [4]. Approximately 17-18% of HD patients select tunneled cuffed catheter as long-term vascular access [17]. The common method to ensure patency of HD catheter is locking them with heparin whose concentration is from 1000U/mL to 10,000 U/mL. Each HD unit uses different concentration and there is no unified standard [18]. However, heparin lock alters coagulation studies and the risk of heparin lock-related bleeding when using in dwelling venous catheter in hemodialysis and bleeding complications related to heparin lock have been

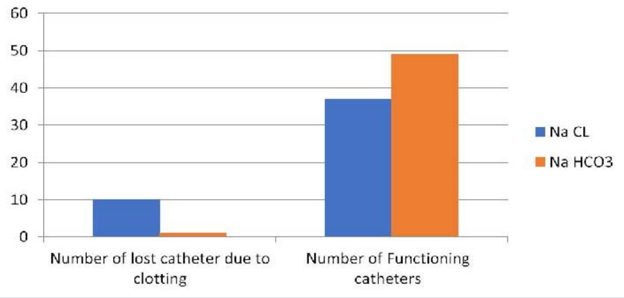

Figure 1 Shows in blue Catheter Retention Rate (RR) in normal saline catheter lock solution (NSCLS) group 78.72% versus in red catheter RR in sodium bicarbonate catheter lock solution (SBCLS) group 98% in over 6 months.

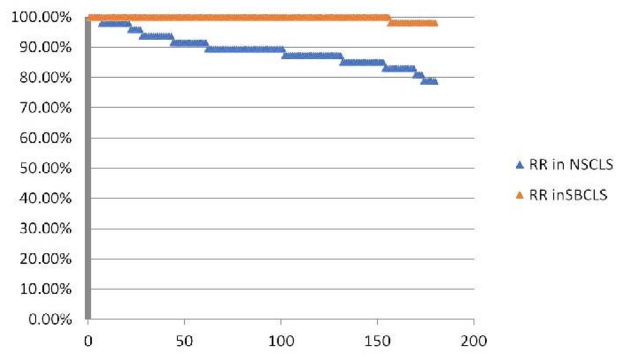

Figure 2 Shows the Kaplan-Meier survival curves for the time course of the lost and functioning catheters in both NaCl Lock solution and NaHCO3 Lock solution groups due to clot formation during a period of 6 months. P= 0.003.

reported [19,20]. American Diagnostic and Interventional Society of Nephrology recommended that locking catheter with low concentration (1000 U/mL) HS or 4% citrate was the method with relatively lower bleeding risk [20]. Even after removing and discarding the last HS catheter lock solution, the left heparin attaching to the wall of lumens could have anticoagulation effect at start of HD and APTT of 5 min. after starting HD was also extended by 13.6% longer than the last baseline [21]. Therefore, the overflowing heparin from catheter is an important reason of increased bleeding risk after HD [22].

We propose that $NaHCO_3$ 8.4% solution might be used as catheter lock solution for locking both non-tunneled, non-cuffed and cuffed tunneled hemodialysis catheters. Since it is not an anticoagulant and will not increase bleeding risk even overflowing into circulation, it appears that SBCLS is very effective in preventing clotting of catheters. Effectiveness of SBCLS appears to be superior to NSCLS in preventing catheter clotting in our clinical study. Using SBCLS to flush and lock catheters is very safe and there was no evidence of transient hypocalcemic symptoms. Due to the risk of using heparin and citrate solution, SBCLS is clearly a safe way to lock catheters. So it would be a safer catheter lock method for patients with high bleeding risk.

Our study evaluated this new alternative catheter lock method because SBCLS is inexpensive, available and easily popularized. Furthermore, empiric testing of blood of 10 normal volunteers by drawing 1.5 cc of blood from each one and putting 0.5 cc in one empty tube, second 0.5 cc in tube with 1 cc NaCl 0.9% and third 0.5 cc in tube with 1 cc $NaHCO_3$ 8.4%. Following tubes visually for 30 min showed formation of clot in the 10 empty tubes and in the 10 tubes with NSS. No formation of clot in the 10 tubes with $NaHCO_3$. The results were encouraging and supported to our theory.

Since we have not found any literatures related to $NaHCO_3$ lock solution, its anticoagulant principle still cannot be definitely explained. It can be speculated that its mechanism of action is by binding calcium and removing it from the many enzymes of the coagulation system that require it as a cofactor [23].

Safety of using citrate solution as a catheter lock solution became an issue when the FDA reported death due to cardiac arrest shortly after an ESRD patient received a rapid injection of 5 mL 47% citrate into one lumen of a central vein, tunneled catheter, just after placement, for the purpose of anticoagulation [22]. However, the Medical Device Report (MDR) indicated that the patient did not expire immediately, but more than 24 hours later after receiving citrate catheter lock solution [23,24].

CONCLUSION

Sodium Bicarbonate solution may provide significant advantages for catheter lock in patients with all types of central venous catheters, reducing catheter clotting and increasing retention rate without going into risks of using citrate or heparin.

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