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SURGICAL TECHNIQUES AND INNOVATIONS

Non-randomized Clinical Trial of In-house Silver-Coated Foley's Catheter Reduces Urinary Tract Infections—a Low-Cost Innovation

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Abstract
Catheter-associated urinary tract infections account for 80% of hospital-related urinary tract infections. Attempts are being made to improvise catheters to reduce the infective burden. A non-randomized clinical trial was conducted on two hundred and forty patients who required catheterization. The aim was to assess the efficacy of silver ion–impregnated Foley catheters in reducing urinary tract infections. They were divided equally with 120 patients in each group. The control group received standard Foley catheter insertion and patients in the study group received in-house-prepared silver ion–impregnated catheters. Urine was examined for the presence of pus cells on days 1, 3, and 7. Culture and sensitivity were carried out on days 1, 3, and 7. Though the initial results were similar in both groups, there was a significant reduction in the number of pus cells in urine and a decrease in positive cultures on day 7 ($P=0.0277$ and $P=0.0497$), respectively suggesting the efficacy of silver ion impregnation. This is a simple and easy-to-perform technique with potential for routine use in the future with adequate validation. Routine use minimizes antibiotic usage due to reduced incidence of urinary tract infections and hospital expenses.

Keywords Catheter-associated urinary tract infections · CAUTI · Silver-coated urinary catheters · Hospital-acquired infections · Silver ion impregnation

Introduction

An infection is considered a healthcare-associated infection (HAI) "if the date of the event of National Healthcare Safety Network (NHSN) site-specific infection criterion occurs on or after the 3rd calendar day of admission to an inpatient location where the day of admission is calendar day" [1]. Hospital-acquired infections (HAI) include central line–associated infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, and surgical site infections [1]. Developing countries have 10% hospital-acquired infections leading to extended hospital stay and financial burden. Urinary tract infections (UTIs) account for 12.9% of HAI [2]. The CDC defines catheter-associated urinary tract infection (CAUTI) in those patients as having "an indwelling catheter for 7 or 8 h." UTIs are the most common HAI in acute care setup, almost amounting to 30%, and about 80% of them are caused by instrumentation of the urinary tract [3, 4]. Though mortality due to CAUTI is less than 5%, it leads to prolonged hospitalization and increases cost and the development of multidrug-resistant strains.

Urinary catheterization is part of standard care for management for many medical or surgical conditions. Attempts are being made to improvise the quality of catheters towards reducing the infective burden. One of the methods is to coat the catheter with a material that either reduces or prevents infection. Silver has been known to have antimicrobial properties. AgO impregnation over conventional Foley catheter has the potential to reduce urinary tract infections and in turn reduces stay and cost of care. There are very few studies done in our country where the efficacy of silver as an antimicrobial agent coating is assessed [4, 5].

Various agents like Bactigaurd-coated Foley catheter (gold-silver palladium alloy, hydrogel-coated catheters, antibiotic-coated catheters) have all been tried with variable success rates. However, experience related to those is limited [6]. Production-related issues, cost, etc. have been the issues for routine use. Simple, cost-effective impregnation is necessary for widespread use. Hence, a variety of attempts are made in preparing such a catheter, used in clinical trials to

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assess the infection reduction rate [4, 7]. One or two varieties of silver-coated urinary catheters are available, but the costs are significantly high and not easily available in the market. Currently, in the USA, the available silver hydrogel–coated Foleys' catheters are very costly [8].

Keeping in mind the limitations of conventional Foley catheters (Latex), this study was taken up to assess the effectiveness of silver-impregnated latex Foley catheters in reducing CAUTI and assess the efficacy of the silver oxide impregnation method adopted by Nandakumar et al. [4]. The method is easy and feasible and is a low-cost innovation.

Patients and Methods

A non-randomized clinical trial was conducted on 240 patients catheterized for various conditions after obtaining written informed consent and Institutional Ethics Committee clearance. They were divided into study and control groups. The technology applied is patented; hence, written permission was taken from the corresponding author [4].

Method of Silver Oxide Impregnation

The materials used were latex Foley catheters, toluene or methylbenzene, silver nitrate, and formamide. The commercially available latex Foley catheter was first dipped in toluene for 30 s. Silver nitrate powder was mixed (1 g/catheter) with formamide solution and catheters were placed in it. This solution was heated in a temperature-controlled water bath at about 70–80 degrees centigrade for 15 min. After cooling, the catheters were washed in distilled water to remove excess formamide and dried. Later, these dried catheters were sterilized using ethylene oxide sterilization for 48 h. Then they were used on patients (Fig. 1a and b).

Patients with negative urine culture on insertion of the catheter and who needed catheterization for more than 3 days were included. Patients with renal diseases, pre-existing catheters, who underwent invasive urosurgery, prior positive urine culture, and sterile pyuria were excluded.

Catheterization was done by surgery residents as per standard practice, i.e., cleaning and retracting prepuce/vulva with povidone-iodine and insertion with aseptic precautions. After ensuring the catheter in situ, few milliliters of urine were drained and the urine samples were collected directly and sent for microscopy and culture sensitivity. Later, samples were collected on day 3 and day 7 directly by aspirating the catheter for the presence of pus cells and culture sensitivity. Patients were observed for clinical symptoms of UTI and documented. Pyuria was considered significant if pus cells were more than 10 per hpf. Urine cultures were considered significant if organisms were more than 10^5 (Chart 1).

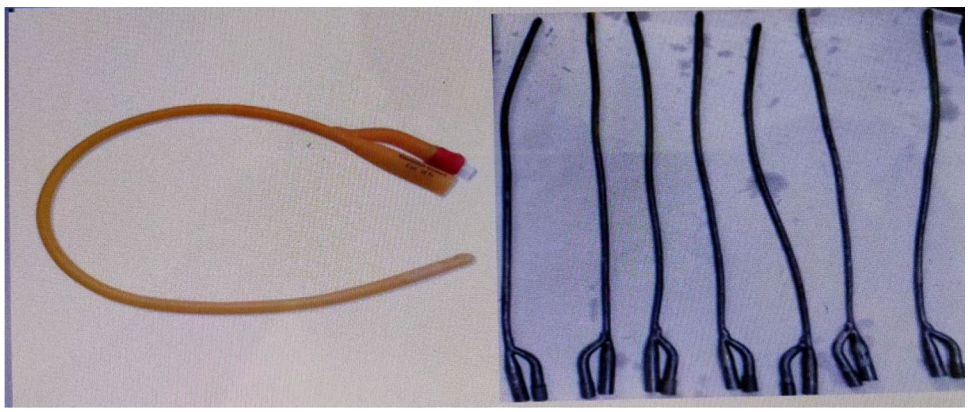
The results were recorded in a Microsoft excel sheet and analysed with appropriate statistical methods. A P value of <0.05 was considered significant.

Results

A total of 240 patients with 141 men and 99 women were included. The study group had 66 men and 54 women patients. The control group had 75 men and 45 women. Age ranged from 18 to 70 years. Maximum patients (53 and 67) were in the age group of 30–39 and 40–49 years' range respectively. The mean age of the study group was 47.63 SD 15.04 and the control group 47.73 SD 13.07. Both groups were comparable demographically. Indications for urinary catheterization are tabulated in Table 1.

Urine routine examination and cultures were done on day 1, day 3, and day 7 of catheterization.

It was observed that the presence of pus cells on days 1 and 3 was similar in both groups with a P value of 0.77 and 0.64 respectively. Pus cells were significantly low in



a Regular Foley's catheter **b** Silver impregnated Foley's catheter

Fig. 1 **a** Regular Foley catheter. **b** Silver-impregnated Foley's catheter

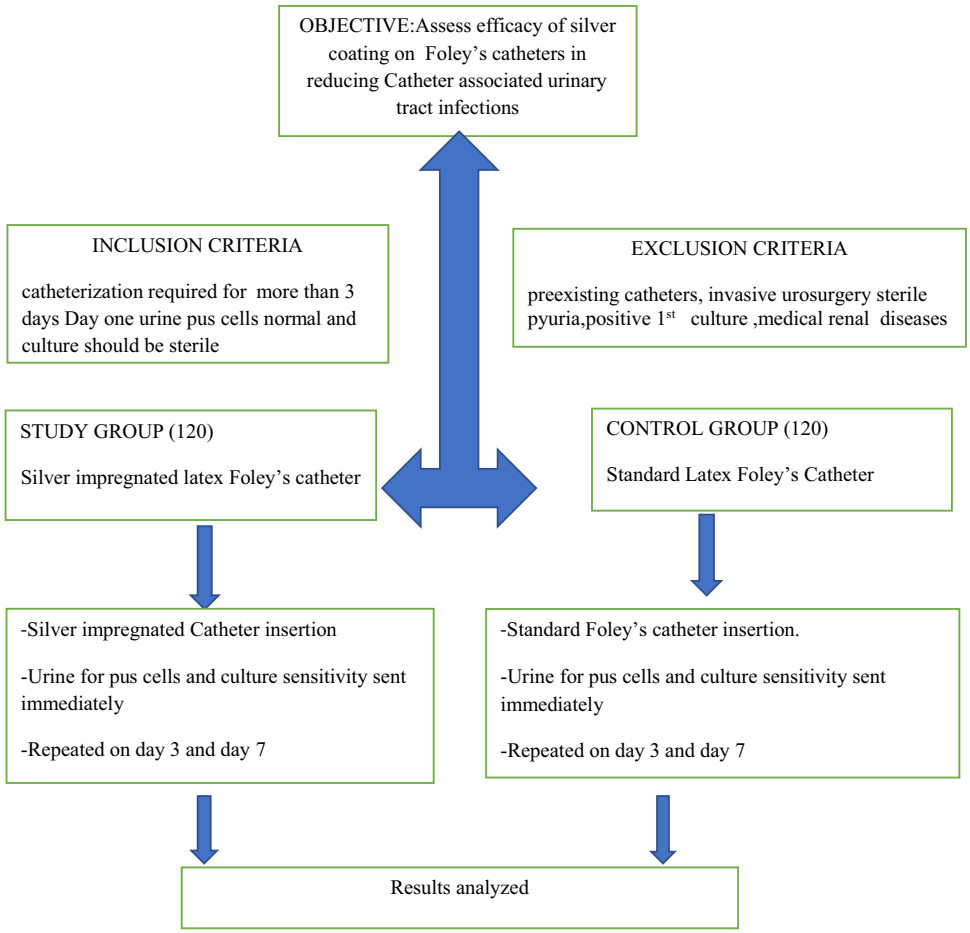


Chart. 1 Flowchart of patients and methods

Table 1 Indications for catheterization

Sl. no	Indications	Study	Control	Total
1	Split thickness skin grafting in the lower limbs or surrounding areas where urine contamination was expected	22	14	36
2	Necrotising fasciitis	17	18	35
3	Fracture of lower limb	18	17	35
4	Exploratory laparotomy	8	17	25
5	Deep venous thrombosis	13	15	25
6	Resection anastomosis of small bowel	11	7	18
7	Quadriplegia/hemiplegia	11	5	16
8	Blunt trauma abdomen	7	8	15
9	Sub-acute intestinal obstruction	4	7	11
10	Bedsores	2	7	9
11	Neurogenic bladder	3	3	6
12	Sepsis	3	2	5
13	Thoracotomy	1	3	4

the silver-coated catheter group on day 7 with a *P* value of 0.0277 (Table 2).

Urine cultures were repeated on day 3, day 7, and weekly until the catheter was removed. The duration considered for the study was 7 days. Both the plain catheter group and the silver-impregnated group had 13 cultures positive on day 3. The number increased to 33 in the silver-coated catheter group and 47 in the plain catheter on day 7. Though similar in the initial results, there was a significant increase in the number of positive cultures (47) after 7 days of insertion in

Table 2 Details of results and comparison of the incidence of pyuria and positive cultures in both groups

	Siver oxide–coating group				Plain latex group				*P* value	
	Pus cells (no of patients)	%	Positive urine culture	%	Pus Cells (no of patients)	%	Positive Urine culture	%	Pus cells	Positive Urine culture
Day 1	7	5.8	-		9	7.5	-		0.77	
Day 3	26	21.6	13	10.8	29	24.1	13	10.8	0.64	1.1O
Day 7	47	39.1	33	27.5	64	53.3	47	39.1	**0.02**	**0.049**
Sympto-matic CAUTI	No of patients			%	No of patients			%	*P* value	
	12			10	16			13.3	**0.042**	
Male	66			55	75			62	**0.23**	
Female	54			45	48			37		

< 0.05 is significant *p* value

the plain catheter group compared to the silver-impregnated catheters, with 33 positive cultures and a significant *P* value of 0.049 (Chart 2).

The average cost of impregnating silver ion wasRs 100 + catheter cost, i.e., 80 + 100 = 180/- with a cost price of the standard catheter being Rs 80/-. This impregnation was possible in-house in the central research laboratory with basic facilities for temperature-controlled water bath and ETO sterilization facilities.

Discussion

CAUTI has been one of the important reasons for increased morbidity, hospital stay, and overall cost. It can become the cause of mortality if sepsis is significant. Routine urinary catheterization for various indications has many advantages and often a source of infection. CAUTI has been ranked number 2 in the incidence of HAI [9]. With extensive use of bladder catheterization, related complications and morbidity have increased too. The risk of developing pyuria in a patient with an indwelling catheter is approximately 3 to 10% per day. Among them, 10 to 25% develop symptoms of local infection and about 1 to 4% develop bacteremia [10]. Various studies emphasize that even if other co-morbidities are taken care of, there is three times increase in mortality and morbidity associated with urinary catheter–related infections [11]. Access to the sterile urinary tract to the exterior through a catheter enhances susceptibility to infections. Regular cleaning and following aseptic precautions in handling catheters reduce the chances of CAUTI. But multiple hands, prolonged duration of catheterization, and contamination from the genital tract, perineal organisms, and general condition

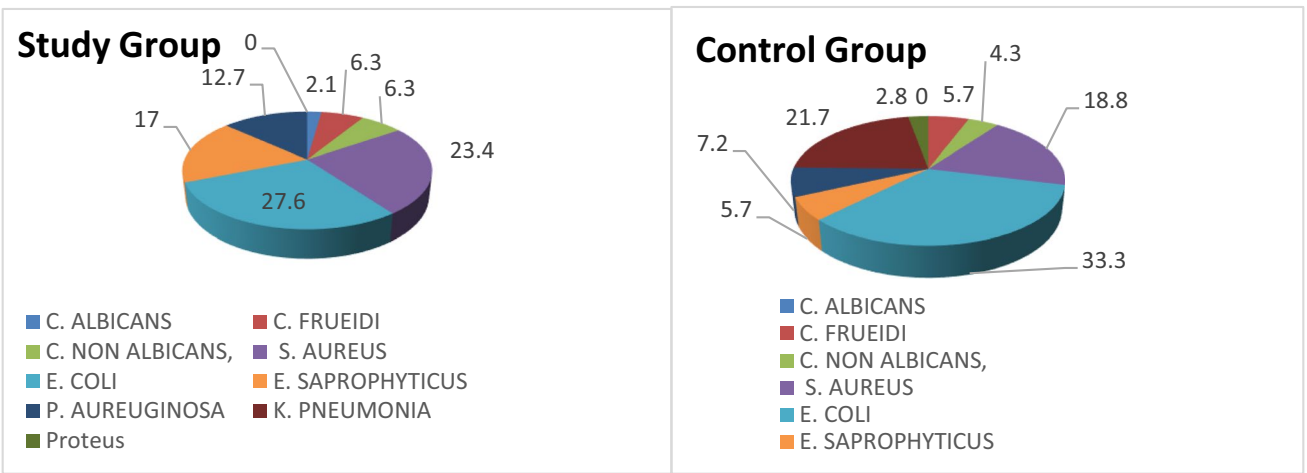


Chart. 2 Organisms isolated

of the patient all predispose to CAUTI. Hence, this led to attempts in modifying the catheter quality, use of different materials, and attempting coating of catheters to reduce contamination. At present, all are in trials [4, 7]. The standard latex catheters are soft, easily usable, and cost-effective. Latex catheters, in favorable conditions, can develop biofilms which in turn are a source for chronic infections [12, 13]. Silver ion is known to have bactericidal effects and biocompatibility and is used as a topical agent in other situations like burns wounds. Following impregnation of silver on catheters, there is a migration of silver ions which has antimicrobial effects and is not toxic to patients [4]. Since the early 1990s, research has focused on different anti-infective catheter-coating materials, but results have been generally inconclusive [7]. Bactiguard-coated Foley catheters, an essential noble metal alloy and hydrogel-coated catheter, have been introduced to slow bacterial colonization [6, 7]. In the early 2000s, a randomized crossover study [12, 13] demonstrated that the risk of UTI could be decreased by 21% in the wards when a noble metal alloy catheter was used instead of a conventional catheter. But access to such catheters which are easily prepared, available, and cost-effective has not been possible. Silver ion–based hydrogels are now increasingly being used as a surface coating for wounds to reduce biofilm development [14, 15]. With the technique proposed here, silver ion coating can be easily impregnated to the existing available latex Foley catheters without an increase in toxicity or reduced quality. Though the results regarding the number of pus cells in the urine and urine cultures were similar in both groups during the initial period of catheterization, there was a significant difference in the incidence of pyuria and positive cultures in the samples obtained on day 7, suggesting its effectiveness in patients who need prolonged catheterization. Though there are variable results, there is risk reduction [12, 13]. Reviews suggest there is an emerging tilt towards the benefit of using silver alloy–coated catheters [16], but clear conclusions are lacking. The overall clinical implications will be significant as any reduction in the incidence of CAUTI will reduce morbidity and mortality cost-effectiveness in the long run.

Presumptive Cost Analysis

With the present results, the anticipated incidence of positive urine cultures for 1000 patients on day 7 would be silver oxide catheter group—Rs 392/1000 and simple latex catheter group—Rs 533/1000. Considering the cost of antibiotic therapy for one patient at Rs 140/-0 (considering the average cost of standard antibiotic ceftriaxone as protocol with Rs 50/ per dose for 7 days' therapy twice a day), the expenses would be $1400 \times 392 = 548{,}800$ for the silver oxide catheter group and $1400 \times 533 = 746{,}200$ for the simple latex catheter group.

Total cost burden in both the groups:

Silver oxide catheter group—Rs $180{,}000 + 548{,}800 =$ Rs 728,800/-
Simple latex catheter group—Rs $80000 + 746{,}200 =$ Rs 826,200/-
The anticipated difference—Rs $826{,}200 - 728{,}800 =$ Rs97400/-

The cost reduction per 1000 catheterization will be around one lakh or Rs 97,400/-.

Conclusion

This study, an open-label non-randomized non-practice that changes usual unsupervised urinary catheterization of self-retaining Foley's catheter, if simply impregnated with silver, showed a reduction in CAUTI when catheterization was required for a week or more. There was no difference in short-duration catheterization. This low-cost innovation can reduce the overall cost of hospitalization and financial burden to hospitals cumulatively.

Declarations

Conflict of Interest The authors declare no competing interests.

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