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Original Research Article

Comparative Study Between Application of NeomycinOintment at External Meatus to Foleys Catheter and the Conventional Catheter Care in Prevention of Catheter Associated Urinary Tract Infection.

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Abstract

The study was conducted in a tertiary healthcare centre, on the patients who had urinary catheter. Criteria for the selection of the patients were prerecorded and accordingly the participants for the study were selected. The patients whose baseline urine analysis came out to be normal were selected. The participants were clearly toldabout the research and informed written consent was cordially taken.

They were allotted either a conventional (group A) or interventional(group B) method by block randomization. Patients were informed about their role and the procedure they need tofollow. Patients of both the groups A and B respectively were subjected to urine analysis and the routine vitals checkup, every 7 days. The data obtained was systematically recorded. The patients who had a positive urine analysis test result were then subjected to urine culture to determine the presence of catheter associated urinary tract infection. Urine culture was selected as confirmatory test as it is gold standard. The patients whose urine culture came out to be positive were labelled as positive for CAUTI presence.

The severity of the manifestations was also checked simultaneously. The data obtained was cordially put to the Z test and chi square test.

The observations were recorded. Among the 120 patients participated in the study, 60were under the CONVENTIONAL (group A)and 60 were under the INTERVENTIONAL (group B). 8 of 60 belonging to the conventional group and 2 of 60 belonging to the interventional group were found positive for the presence of CAUTI. This suggests that there is significant decrease in the rates of the presence of urinary tract infection by doing a simple intervention of neomycin ointment at the junction of urethral meatus and Foleys catheter. The null hypothesis is thus rejected.

The results of the z test and the chi square test came out to be significant. The primaryobjective was thus fulfilled. We were successfully able to compare between the conventional and interventional methods for prevention of CAUTI. The duration of sustainment of catheter is increased in the patient receiving intervention. Thus, from the above results it is seen that, the intervention of the application of neomycin ointment at the junction of urethral meatus and Foleys catheter, is a good option to reduce the rates of CAUTI.

It is a simple, cheap and effective method to reduce CAUTI and improve patient compliance. The some exceptional cases who acquired infection inspite of the intervention, acquired a milder form of infection having reduced severity of manifestations. Majority of the latter cases belonged to a age group>40 years, this presents to us an opportunity for further research on the topic ofreducing the rates of CAUTI in the older age group.

Keywords: CAUTI, Neomycin, Foley's catheter

Introduction

Catheter associated urinary tract infection (CAUTI) is defined as the presence of significant bacteriuria in a catheterized patient. It is a nosocomial infection allowing microorganisms to be inoculated in the urinary tract during its insertion or post placement manipulation . In addition, these devices promote colonization by forming a biofilm for adhesion of bacteria as well as by producing mucosal irritation [1]. Urinary tract infections (UTIs) because of
an indwelling catheter is one of the most common infections acquired by patients, in a hospital setting . Approximately 12%-16% of adult patients in hospital possess an urinary catheter during their stay, and the risk of acquiring infection increases by 3-7% each day catheter remains. [2]. In a study it was found that out of 679 patients 73 (10.75%) ICU patients suffered from episodes of UTI [3]. The patient manifested as : fever, chills ,headache, cloudy urine due to pus, burning sensation in urethra or genital area, blood in urine, foul smelling urine, lower back ache and achiness.(CDC) These manifestations add on to the suffering in already traumatized patients, and reduce their compliance. It increases the stay of the patient, recovery time and the cost of treatment. Also, predisposes the patient to renal complications.

Rationale of Study

Previous Studies that have been conducted in that past mainly provided 4prevention strategies which notably are

- Maintenance of aseptic precautions while insertion and handling of the catheter [4,5,6]
- Maintenance of a system with closed drainage.
- Usage of catheters coated by silver alloy or other antibiotics
- Systemic antibiotic therapy prophylactically

Maintenance of aseptic precautions and a closed drainage system in Indian hospital setting is undoubtedly challenging. The CDC recommend the usage of silicone catheter [7],[8],[9], but not used in the government setting because of the highprice . Tested in vitro, these new coated catheters efficiently killed the microorganisms and prevented biofilm formation. However in clinical setting it was unsuccessful in curbing infections or yielded mixed results [10],[11],[12],[13]. Moreover, systemic antibiotic therapy prophylactically is not recommended by CDC as it promotes the development of resistant organisms [14]. This, study of neomycin topical application at junction of Foley's catheter and urethral meatus may be useful in preventing the CAUTI as compared to the conventional cathetercare .As this study does not alter the drugs used in treatment ,possibility of any deterioration in the preexisting condition may be ruled out.

Objectives:

1. To compare the prevalence of CAUTI between conventional catheter careand topical application of neomycin ointment to Foley's catheter at its junction with urethral meatus.

2. To determine maximum duration of indwelling catheter placement after application of neomycin to Foley's catheter at catheter- meatus junction.

Methodology:

- Type of Study: this is a hospital based clinical interventionalstudy .
- Duration of Study: 2 months.
- Study Settings: the study was conducted in the ward and ICU of a tertiary health care centre.
- The participating patients was properly informed about the study ,and
- Written informed consent is taken .
- The base line urine analysis (PYURIA) is done to maintain theinclusion criteria (as a screening test). This urine analysis is done within 24hrs of the catheter insertion (preferably). But, as it is little tedious to identify each patient within 24hrs of catheterization, urine analysis wouldbe done whenever the patient is identified.
- The reports must contain a normal range of pus cell in urine .
- The normal range of pus cells confer to ≤10leukocytes/mm^3.[15] Thus,
- rise above this level was considered as UTI and the identified patient was not included in the study .
- The patients confining to the above criteria of normal reports of screening
- test were considered for the study .

After taking a written informed consent, patients in intervention group were informed and shown the correct technique of application of neomycin ointment at the catheter- meatus junction as:

1. confirm the ointment name and dose as written in prescription
2. wash hands and follow aseptic precautions
3. apply the ointment at the catheter-meatus junction .(without touching ointment tube to catheter- meatus junction)
4. apply daily at the frequency suggested.
5. If any discomfort occurs inform immediately.

The application of neomycin and monitoring of the patient was doneby the concerned staff of the hospital.
A checklist was maintained on daily basis regarding the same .
The remaining patients were informed about the conventional catheter care protocol.

- Conventional catheter care involves : AS STATED BY CDC:

A. After aseptic insertion of the urinary catheter, a closed drainage system is maintained.

1. If aseptic technique is not followed or leaked, replace the catheter and collecting system using aseptic technique and sterileequipment.
2. Use preconnected, sealed catheter-tubing junctions.

B. Unobstructed urine flow must be maintained.

1. Kinking should be avoided in the catheter and collecting tube .
2. Collecting bag must be below the level of bladder.
3. Collecting bag must be emptied regularly, in a clean and separate container . Avoid splashing.

C. During manipulation of catheter or collecting system use glovesand gown, follow standard precaution.

D. Change the catheters or drainage bags only on infection,obstruction or compromised closed system.

- The selection of the patients for either conventional catheter care orneomycin drug intervention was done by following SIMPLE BLOCK RANDOMISATION.

A	B	A	B	B	A
A	B	B	A	A	B
B	A	A	B	A	B
B	A	B	A	B	A

Here A: Conventional Catheter Care; B: Neomycin Drug Intervention

- No alteration in the ongoing prescription was done.
- Half the participants were told to apply the ointment at the catheter- meatus junction twice(BD) a day (morning and night respectively)for the period until catheter is removed .
- The other half participants were advised to follow the conventional catheter care protocol.
- The urine analysis of both the types of patients were done every 7days or if the patients manifest the symptoms given below, until the catheter is removed .
- Presence of pus cells , white blood cells, red blood cells was checked in the urine report.

The patients having significant pyuria (≥10 leukocytes/mm^3) or are symptomatic for UTI (fever, chills , headache, cloudy urine due to pus, burning sensation in urethra or genital area, blood in urine, foul smelling urine, lower back ache and achiness were are subjected to urine culture

The gold standard for the diagnosis of UTI is detection of pathogens and presence of clinical symptoms. The pathogen is detected by URINE CULTURE using midstream urine. The defining level of SYMPTOMATIC UTI is $\geq 10^3$CFU/ml (COLONY FORMIMG UNITS), [16,17] and, for ASYMPTOMATIC UTI is $\geq 10^5$CFU/ml. [18]

Clinical Examination :

The basic clinical examination is done every 7 days along with the urine analysis. This involves the TEMPERATURE, RESPIRATORYRATE, PULSE, BLOOD PRESSURE.

Sampling Techniques:

A small volume of fresh urine is aspirated from needleless sampling port with asterile syringe/cannula adapter after cleansing the port with a disinfectant.
Midstream urine is collected by this procedure.
Sample Size: 60/group.
Total: 120.
Selection CriteriaInclusion Criteria:
The patients who have an indwelling catheter due to some underlying etiologyin the ward and ICU of surgery department of a tertiary healthcare setting.

1. Patient of age group 18 to 65 years.
2. Base line urine analysis test results in normal range

Exclusion Criteria:

1. Patient not interested to participate.
2. Patient not giving consent
3. Patients having uncontrolled diabetes mellitus (random blood sugar level ≥200g/dl)
4. Patients allergic to neomycin ointment.
5. Immunocompromised patients
6. pregnant and lactating patients
7. Patients whose baseline admission urine pyuria is ≥10leukocytes/mm^3.
8. Patients receiving higher urinary antibiotics specifically CARBAPENEMSAND COLISTIN.

Discontinuation :

1. Patients who develop a allergic reaction to the neomycin ointment.
2. patients who die during the study

3. patients who leave the study abruptly due to any underlying cause.

Study Setting :

As CAUTI is the most prevalent hospital acquired infection, some measures should be taken to curtail it. The already existing CDC guidelines of conventional catheter care are inefficient, mainly because of faulty enforcement. Studies that have been conducted in that past mainly provided 4 following prevention strategies which notably are:

- Maintenance of aseptic precautions while insertion and handling of the catheter. (CDC)
- Maintenance of a system with closed drainage. (CDC)
- Usage of catheters coated by silver alloy or other antibiotics [19]
- Systemic antibiotic therapy prophylactically (CDC)
- Neomycin polymyxin sulfate bladder wash [20]
- Polyantiobiotic cream containing neomycin, polymyxin b, gramicidin at the catheter -urethral meatus junction.

Maintenance of aseptic precautions and a closed drainage system in Indian hospital setting is undoubtedly challenging. The CDC recommend the usage of silicone catheter, but not used in the government setting because of the high price. Tested in vitro, these new coated catheters efficiently killed the microorganisms and prevented biofilm formation. However in clinical setting it was unsuccessful in curbing infections or yielded mixed results. Moreover, systemic antibiotic therapy prophylactically is not recommended by CDC as it promotes the development of resistant organisms. [21] The neomycin polymyxin sulfate bladder wash is efficient in reducing the CAUTI rates but, rarely used as it is COSTLY, more chances of REFLUX IN URETERS, DIAMETER of catheters used is LARGER which may produce occlusion of secretions posing threats of infection, possibility of SYSTEMIC ABSORPTION in cases of denuded bladder surface, Ototoxicity, nephrotoxicity, and neuromuscular blockade may occur if Neomycin and Polymyxin B Sulfate Solution used for irrigation are systemically absorbed , irrigation of the bladder with Neomycin and Polymyxin B Sulfate Solution for Irrigation may result in overgrowth of no susceptible organisms, including fungi, CONTRAINDICATED IN PREGNANCY because of teratogenicity if systemically absorbed.

- ❖ The junction of the external urethral meatus and the Foley's catheter is considered appropriate site for application of the neomycin ointment in order to prevent the CAUTI as, the junction itself is the PORTAL OF ENTRY for the microorganisms causing UTI. ALSO, EASE of application and NON INVASIVE.

Taking the above in consideration application of neomycin at external meatus to Foley's catheter can prove to be an effective way in preventing CAUTI.

Results

The study started with the identification of patients in the age group 18 to 65 those had urinary catheter after taking approval of the IEC. Data was collected from 120 patients, 50% of them underwent the conventional method of catheter care and the remaining 50% received an intervention with neomycin ointment at the junction of urethral meatus and the catheter. The results of the study were derived from the collected data, which came out to be, bacteriuria was acquired in 8 of 50 (16 percent) from the conventional group and 2 of 50 (4 percent)from interventional group. The rate of bacteriuria was found out to be lower in the treated group by the statistical methods used.

The main objective of the study was to determine the rate of CAUTI between the conventional and interventional group, which came out to be:

Table 1:

	Presence Of UTI (CAUTI)		
Method To Be Followed	Absent	Present	Total
Conventional	52	8	60
Interventional	58	2	60
Total	110	10	120

Table 2:

Age (Binned) *Method to BeFollowed					
		Conventional	Interventional	Total	
AGE	<=40	43	45	88	
	>40	17	15	32	
	Total	60	60	120	
		Chi-Square Tests			
	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	0.170a	1	0.68		
Continuity Correctionb	0.043	1	0.836		
Likelihood Ratio	0.171	1	0.68		
Fisher's Exact Test				0.837	0.418
N of Valid Casesb	120				
a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 16.00.					
b. Computed only for a 2x2 table					

The number of patients that participated in the study were divided according to therange of age as follows,

Table 3:

		Age			
	Age Group	**Frequency**	**Percentage**	**Valid Percent**	**Cumulative Percent**
Valid	20-30	31	25.8	25.8	25.8
	30-40	55	45.8	45.8	71.7
	40-50	26	21.7	21.7	93.3
	50-60	8	6.7	6.7	100
	Total	120	100	100	

The result found by comparing the age group and the presence of CAUTI was as follows .

Table 4:

Age (Binned)* Presence of UTI(CAUTI)					
	Age (Binned)	Presence of UTI (CAUTI)	Total		
		Absent	Present		
	<=40	84	4	88	
	>40	26	6	32	
	Total	110	10	120	
		Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	6.198a	1	0.013		
Continuity Correctionb	4.478	1	0.034		
Likelihood Ratio	5.412	1	0.02		
Fisher's Exact Test				0.022	0.022
N of Valid Casesb	120				
a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 2.67.					
b. Computed only for a 2x2 table					

Result obtained by considering the sex and presence of CAUTI

Table 5:

Sex* Presence of UTI(CAUTI)				
		Presence of UTI(CAUTI)		
		Absent	Present	Total
Sex	F	63	3	66
	M	47	7	54
Total		110	10	120
		Chi-Square Tests		

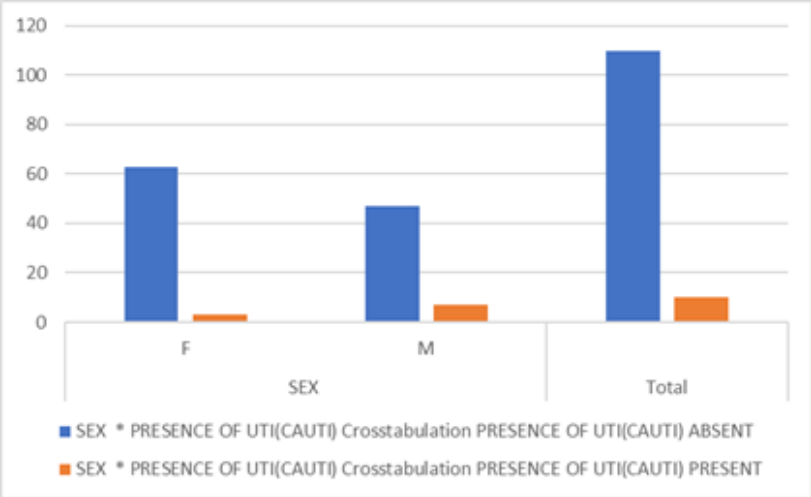

Figure 1:

Discussion

The study was conducted on the patients of age group 18 to 65 to compare the prevention of CAUTI by conventional catheter care and the interventional care by application of neomycin ointment at the junction of urethral meatus and the Foleys urinary catheter. 50 percent each that is 60 patients underwent conventional and 60 underwent interventional care during the study. The allocation of the method used for the patients was done by block randomization method. Blinding was not done. Among the 120 patients who participated in the study, 8 out of 60 from the conventional group and 2out of 60 from the interventional group developed bacteriuria (CAUTI). By application of the z test we find the result to be significant (p= 0.0477). that is there was significant decrease in the incidence of CAUTI by application of the neomycin ointment at the junction of the foleys catheter and the urethral meatus. Thus, this can be an efficient, cheap intervention to reduce the rates of CAUTI prevalence and Improve the patient compliance.

The chi square test applied shows presence of significant association. The secondary objective of the study was to determine the maximum duration of catheter prevalence in patients without developing urinary tract infections.

The study results showed that after application of the neomycin ointment the duration for which the patients sustained the catheterisation without developing catheter associated urinary tract infection was in a range of 21 to 28 days. This, as compared to the conventional group, the average maximum days that the patient could sustain the urinary catheterization without developing urinary tract infection was only 10 to 12 days. Thus, the time for which the patients can sustain the catheter without any infection was increased. The difficulty of changing the catheter after some duration to prevent infections is thus minimized by minimal application of the neomycin ointment twice in a day at the urethral meatus and Foley's catheter junction.

Out of the 120 patients, 66 were females and 54 were males, 3 of 66(4.5%) and 7 of 54(12%) females and males respectively, were found positive for presence of urinary tract infection post catheterization. The participants were divided according to the age groups, 6 of 10 found positive for CAUTI presence belonged to the age group >40 years. Thus, the infection is acquired more in the older age. Most probable reason for the same could be the reduced immunity required to fight infection and lack of ability to maintain the aseptic precautions and hygienic conditions during the presence of indwelling urinary catheter.

The manifestations of the UTI were present in 8 of the 10 found positive for CAUTI but the severity was greatly reduced. The intervention was successful in reducing the rates of catheter associated urinary tract infection among the catheterized patients. The junction between urethral meatus and the foleys catheter is the portal forentry of the organisms that cause urinary tract infection. Thus, intervention of application of neomycin ointment at the junction to prevent the entry of the organismsproved to be successful in reducing the rates of CAUTI in patients.

Conclusions

It could be concluded from the present study that the application of the neomycin ointment at the junction of the urethral meatus and Foleys catheter may successfully help in the reduction of the rates of catheter associated urinary tract infection.

Thus, the primary objective of comparing the conventional catheter care and the interventional neomycin ointment application suggests that the interventional method is better to reduce the rates of presence of CAUTI.

Also, the time duration of catherised patients to develop urinary tract infection can also be extended significantly when neomycin is applied to the junction of urethral meatus and Foleys catheter (21 to 25 days vs. 10 to 12 days in conventional group) this could be helpful in patients with catheterization. Such interventions should be practiced in wards and ICUs in the best interest of our patients.

References :

1. Stickler DJ. Bacterial biofilms in patients with indwelling urinary catheters. Nat Clin Pract Urol. 2008;5(11):598-608
2. Lo E, Nicolle LE, Coffin SE, Gould C, Maragakis LL, Meddings J, et al. Strategies toprevent catheter associated urinary tract infections in acute care hospitals: 2014 update. Infection Control and Hospital Epidemiology. 2014; 35:464-79.
3. Health-care-associated infections: Risk factors and epidemiology from an intensive careunit in Northern India
4. Parker V, Giles M, Graham L, et al. Avoiding inappropriate urinary catheter use and catheter associated urinary tract infection (CAUTI): A pre-post control intervention study. BMC Health Services Res. 2017;17(1):314.
5. Ternavasio-de la Vega HG, Barbosa Ventura A, Castano-Romero F, et al. Assessment of a multimodal intervention for the prevention of catheter associated urinary tract infections. J Hosp Infect. 2016; 94(2): 175-181.
6. Meddings J, Rogers MA, Krein SL, Fakih MG,Olmsted RN, Saint S. Reducing unnecessary urinary use and other strategies to prevent catheter associated urinary tract infection: An integrative review. BMJ Qual Safety. 2014;23(4):277-289.
7. Ha US, Cho YH. Catheter-associated urinary tract infections: New aspects of novel urinarycatheters. Int J Antimicrob Agents. 2006;28(6):485-490.
8. Singha P, Locklin J, Handa H. A review of the recent advances in antimicrobial coatings for urinary catheters. Acta Biomaterialia. 2017;50:20-40.
9. Gould C, Umscheid CA, Agarwal PK, Kuntz G, Pegues DA, Healthcare Infection Control Practices Advisory Committee. Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009. 2017 updated:1-61. Centers for Disease Control and Prevention. https://www.cdc.gov/infectioncontrol/guidelines/cauti/index.htm
10. Pickard R, Lam T, Maclennan G, et al. Types of urethral catheter for reducing symptomaticurinary tract infections in hospitalized adults requiring short-term catheterisation: Multicenterrandomized controlled trial and economic evaluation of antimicrobial- and antiseptic-impregnated urethral catheters (the CATHETER trial). Health Technol Assessment. 2012; 16(47):1-197.
11. Tenke P, Koves B, Nagy K, et al. Update on biofilm infections in the urinary tract. World J Urol. 2012; 30(1):51-57.
12. Ha US, Cho YH. Catheter-associated urinary tract infections: New aspects of novel urinarycatheters. Int J Antimicrob Agents. 2006;28(6):485-490
13. Tenke P, Koves B, Johansen TE. An update on prevention and treatment of catheter- associated urinary tract infections. Curr Opin Infect Dis. 2014; 27(1):102-107.
14. Gould C, Umscheid CA, Agarwal PK, Kuntz G, Pegues DA, Healthcare Infection Control Practices Advisory Committee. Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009. 2017 updated:1-61. Centers for Disease Control and Prevention. https://www.cdc.gov/infectioncontrol/guidelines/cauti/index.html
15. Measurement of pyuria and its relation to bacteriuria WE Stamm - The

American journal of medicine, 1983 - Elsevier
16. Schmiemann G, Gebhardt K, Matejczyk M, Hummers-Pradier E. *DEGAM*-Leitlinie Nr Brennen beim Wasserlassen - Update 2009. Düsseldorf: Omikron publishing; 2009
17. EAU (European Association of Urology) Guidelines on Urological Infections. European Association of Urology.
18. Lin K, Fajardo K. Screening for asymptomatic bacteriuria in adults: evidence for the U.S. preventive services task force reaffirmation recommendation statement. Ann Intern Med. 2008;149:20–24.
19. S Saint, J G Elmore, S D Sullivan, S S Emerson, T D Koepsell. The efficacy of silver alloy-coated urinary catheters in preventing urinary tract infection: a meta-analysis. Meta-Analysis Am J Med. 1998 Sep;105(3):236-41.
20. Sulfate solution bladder wash for prevention of catheter associated urinary tract infection: A prospective randomized study. Neeraj Int J Crit Illn Inj Sci. 2018 Jan-Mar; 8(1):17-21. Disclosure: This study was approved and funded by Indian Council Of Medical Research vide their reference number Reference ID: 2022-10697.
21. Demir Hulya & Oyman B. U. Essential Oil Essential Oil Analysis of Some Plants. Journal of Medical Research and Health Sciences, 2022; 5(8): 2197–2202.