Comparative Study Of Silver Coated Urinary Catheter Vs Conventional Latex Catheter In Prevention Of Catheter Associated Urinary Tract Infection

by

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Dissertation submitted to

In partial fulfillment for the degree of

MASTER OF SURGERY

IN

GENERAL SURGERY

Under the guidance of

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DEPARTMENT OF GENERAL SURGERY

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2019

LIST OF ABBREVATIONS

HAI	Hospital Acquired Infections
CDC	Centre For Disease Control and Prevention
CAUTI	Catheter Associated Urinary Tract Infection
cfu	colony forming unit
UTI	Urinary Tract Infection
Fr	French Unit for Measurement; 1 Fr = 0.33 mm
PVC	Poly Vinyl Chloride
CIC	Clean Intermittent Catheterization
PTFE	Polytetrafluoroethylene
EAU	European Association Urology
IDSA	Infectious Disease Society of America
INICC	International Nosocomial Infection Control Consortium
BMI	Body Mass Index
AUA	American Urological Association
SSD	Silver Sulphadiazine
VAP	Ventilator Associated Pneumonia
AgO	Silver Oxide

ABSTRACT

AIMS & OBJECTIVES

Comparative study of silver coated urinary catheter vs conventional latex catheter in prevention of catheter associated urinary tract infection

MATERIALS AND METHODS-

Out of 240, 120 patients were treated with silver oxide coated Foley's catheter and 120 patients with conventional Foley's after baseline urine culture was found to be sterile and between age group 18- 89 yrs were included in the study. Patients with pre-existing UTI and urogenital abnormality were excluded from the study. The urine analysis and culture for bacterial count was assessed on day 1, day 3 and day7 or more and the results were compared.

RESULTS- in our study, we found that the mean age between the statistically not significant. Out of 240 study sample, 140 (59 %) were males and 99 (41 %) were females. On comparing the urine for pus cells, it was observed that there was significant decrease in the number of patients with positive urine for pus cells when there was an indwelling catheter for 7 days or more. It was also seen that the most common organism isolated was Escherichia. Coli, followed by Staphylococcus Aureus, Klebsiella Pneumonia, Pseudomonas species, and others.

CONCLUSION- In our study, there was no statistical difference in distribution of patients between the study group and control group with respect to age and sex.

Urine examination for evidence of pus cells was found significantly low in the study group on the Day 7 or more (up to 14 days) of urinary tract catheterization with P value – 0.027, whereas there was no difference on the incidence at the end of Day1 or Day3. Thus, we can infer from the above results that the Silver Oxide impregnated Foley's catheter was efficacious in reducing the occurrence of Catheter related urinary tract infections.

It was observed from our study that the Silver Oxide impregnation to plain Foleys catheter has the potential to prevent/reduce the incidence of catheter associated urinary tract infections in patients who need longer duration of catheterization for various reasons. It was also observed in our study that duration of study was a significant risk factor in predisposing a patient to infections.

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1. INTRODUCTION

Hospital-acquired infections (HAI) also known as health-care related infections are nosocomially (originating or taking place in a health care facility) acquired infections that occur up to 48 hours after hospital admission or up to 3 days after discharge or up to 30 days after an operation or in a healthcare facility when someone is admitted for reasons other than the infection[1].

About 1 in 10 people who are admitted to a hospital for any reason will develop a nosocomial infection. These healthcare-related infections include central line-associated bloodstream infections, catheter-associated urinary tract infections, and ventilator-associated pneumonia and surgical site infections[1]. These are potentially preventable infections which are under the surveillance of International Nosocomial Infection Control Consortium (INICC), which was founded in 1998. In developed countries nosocomial infections account for 7 % percent of the hospitalized patients and in developing nations, they account for 10 % percent. During hospital stay, these infections cause extended stay, disability and financial burden. Nosocomial pathogens include bacteria, viruses and fungal parasites. Pneumonia (21.8%) and surgical site infections (21.8%) are the leading causes, followed by gastrointestinal infections (17.1%), urinary tract infection (12.9%) and primary bloodstream infection (9.9%)[2].

“The Centers for Disease Control and Prevention (CDC) defines Catheter Associated Urinary Tract Infection (CAUTI) for those patients who have an indwelling catheter in place for 48 h or more with symptoms such as fever or chills, new onset of burning pain, urgency or frequency, change in urine character, flank or suprapubic pain or tenderness or change or decrease in mental or functional status in patients”. Diagnosis of CAUTI is considered when there is presence of at least 10Â³ colony-forming units cfu / ml of 1 or 2

micro-organisms by urine culture[3].

Urinary tract infections are the most prevalent form of Hospital Acquired Infection (HAI), accounting for over 30 percent of acute care hospital-reported diseases[3]. Virtually all health -care associated UTIs are caused by instrumentation of the urinary tract, which accounts approximately for about 80 %[4]. It leads to prolonged hospitalization and increased cost of treatment. It is seen that some of the causative agents are multi-drug resistant micro-organisms thus making it difficult to treat. The mortality rate of UTI following urinary catheterization is less than 5%[4].

Although number of bladder catheters inserted each year is more than 30 million, at least 6 times higher than the number of central venous catheters, catheter-associated UTI is the second most common cause of nosocomial bloodstream infection[5].

Although an indwelling intravascular and urinary catheter are key components of modern medical care, they significantly increase the risk of iatrogenic infection, particularly in the already fragile patient population. The risk of developing bacteriuria in a patient with an indwelling catheter is approximately 3% to 10% / day. Among them,10 to 25 % develop symptoms of local infection and about 1 to 4 % develop bacteremia[6]. 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[7].

In order to reduce the burden of catheter associated infections, various types of catheter coatings have been implemented. The word “catheter” comes from Greek, meaning “to let or send down.” Using catheters was known as early as 3,000 B.C. to alleviate painful retention of urine. In those times, many materials were used to form a hollow catheter shape, including straw, rolled up palm leaves, hollow tops of onions, as well as, gold, silver, copper, brass, and lead[8].

In the 11th century, malleable catheters were created. In time, silver was used as the basis of catheters as it could be bent to any required form and was felt to have an antimicrobial function[9]. In 18th century Benjamin Franklin, the inventor and colonial statesman, designed silver catheters to be used in his elder brother John, who was suffering from kidney stones and had to undergo a daily ritual of placing a bulky metal catheter into his bladder. To make this less painful, he worked with a local silversmith on his design for a flexible catheter. "It is as flexible as would be expected in a thing of the kind, and I imagine will readily comply with the turns of the passage," he wrote to John. To allow drainage, holes were bored into the sides of the catheter[10].

Coudé tip catheters were created in the 18th and 19th centuries to facilitate male catheterization and are in use for this purpose in current medical practice. Catheters made from rubber were introduced in the 18th century but were weak at body temperature, leaving debris in the bladder. With the introduction of rubber vulcanization by Goodyear in 1844 lead to increase in catheter's firmness and durability, encouraging mass production. In the 1930s, latex rubber was introduced into clinical practice[11]. Dr. Frederic E.B. Foley (a St. Paul urologist) introduced the latex balloon catheter at a urologic meeting in 1935. Though he lost a legal battle with Davol for the patent, this catheter has since been known as the “Foley”. The earliest self-retaining catheters had wing tips (known as Malecot) or flexible shoulders (known as Pezzer), attached to the male penis or sutured to the female labia[11]. The French scale of Charriere was used to define a catheter's internal diameter.

Thus, the term “French (Fr)” size was coined. Joseph-Frederic-Benoit Charriere was a 19th century Parisian maker of surgical instruments. A 12 French catheter is approximately 4 mm in external diameter (0.33 mm = 1 French [Fr]). Sir Ludwig Guttman introduced the idea of sterile intermittent catheterization in patients with spinal cord injury after World War II. Sterile method has been used for catheterization for many years since then. In 1971,

the clean intermittent catheterization method was initiated by Dr. Jack Lapides of Michigan University at Ann Arbor. Dr. Lapides believed that bacteria were not the only cause of infection. He thought that it was also because of chronic stagnant urine residuals and overdistention of the bladder[12].

Silver ion is known to have bactericidal effects and biocompatibility and is used as topical agent in other situations like burns wounds. Following impregnation of silver on catheters, there is migration of silver ions which has antimicrobial effects and is not toxic to patients[4].

Antibiotic coatings have been tried on catheters but its benefit is questionable as these remains risk of antibiotic resistance[13].

Since early 1990s, research has focused on different anti-infective catheter-coating materials but results have been generally inconclusive. Bactiguard-coated Foley catheters, an essential noble metal (gold, silver, and palladium) alloy and hydrogel–coated catheter, have been introduced to slow bacterial colonisation. In the early 2000s, a randomised cross-over study by Karchmer et al[13] demonstrated that the risk of UTI could be decreased by 21% in wards when a noble metal alloy catheter was used instead of a conventional catheter. Since then, more studies to compare anti-infective urinary catheters with conventional urinary catheters have been carried out. The noble metal alloy indwelling catheter has been shown in multiple large clinical trials and smaller case studies to reduce the incidence of CAUTI, when compared with conventional catheters. Therefore, by prevention of CA-UTI, a significant reduction in morbidity and mortality, as well as the health care economic burden can be anticipated.

Silver has known antimicrobial properties and has not been tested in association with Foley's catheter, AgO impregnation over conventional Foley's catheter has a potential to reduce UTI. There are very few studies done in our country on testing the properties of

silver as an antimicrobial agent, thus there is need for study in this area.

Our goal in undertaking this study was to assess and compare the efficacy of sliver impregnation over commercially available latex urinary catheters in prevention/ reduction of catheter related infections.

2. AIM AND OBJECTIVE OF THE STUDY

To compare and evaluate the efficacy of silver coated Foley's urinary catheter with conventional latex urinary catheter in prevention/reduction of catheter associated urinary tract infection.

3. RESEARCH HYPOTHESIS:

Silver coated Foley's urinary catheters reduce the risk of catheter associated urinary tract infection when compared with conventional Foley's catheter.

4. REVIEW OF LITERATURE

a) HISTORICAL ASPECT:

Since the primitive Egyptian civilization, there have been records of drainage of urinary retention. Other civilizations have also shown similar records like Asian, Chinese, Roman, Byzantine and Greek thus signifying the seriousness of this age-old issue. Various substances like straws, Reeds, Polished or Waxed rolled up leaves and hollow twigs have been used to drain the bladder[14].

Use of urinary catheter for draining urine was the principle procedure performed by any physician in ancient times and this was emphasized in Hippocratic writings, "On Diseases" (around 400 BC)[14,15]. It is surprising to note that the property of silver being an anti- microbial agent was suggested during medieval times, when a lean silver catheter was developed by Paulus Aegineta for draining bladder which later gained a lot of popularity[14], Until the initiation of use of natural rubber as catheter use of silver was still favoured.

Eventually people such as Galen (2th century AD), Paulus (7th century AD), Avicenna (11th century AD) and others established the use of catheter for treatment of diseases such as Pyocyctitis, Hematuria, Inflammation by introducing it into the bladder[16].

The evolution of various equipment that we use in present day have been attributed to the crucial 19th century inventions. The Charrie`re unit to calculate catheter size came into existence and soon was accepted worldwide. This was initiated by Joseph F. B. (1 French unit equaling 0.33 mm)[14].

Coudé tipped catheter (coudé means "elbow" in French) was introduced in 1836 by Mercier[14]. The Nelaton catheter, that is, a vulcanized rubber catheter which is soft, tubular and made with a solid straight tip with a hole at the side was developed by Auguste Nelaton in 1860[14]. Frederick E B Foley in 1930 came up with a novel idea of an expandable balloon attached to catheter tip as an anchor[17]. This became a fundamental concept for the rationale

of most of the lower urinary tract catheters used in current clinical practice[17].

b) ANATOMICAL CONSIDERATIONS

MALE URETHRA

Average length of male urethra varies from 17.5 – 20 cms, as suggested from postmortem studies[18]. These values have been proven to be precise in recent studies by measuring urethra in vivo with a bladder catheter[19].

Parts of the male urethra include, bladder neck or pre-prostatic urethra, prostatic urethra, membranous urethra and penile or spongy urethra. spongy urethra is sub divided into bulbous urethra, pendulous urethra and fossa navicularis. Another way of categorizing the male urethra are posterior segment comprising the prostatic and membranous urethra and anterior including the penile urethra. The diameter is variable in its entire length. A 24 F catheter can be passed through a normal healthy external meatus. Larger diameter is noticed in its proximal parts specially the prostatic which is the largest with 32 F diameter. Bladder neck admits 28 F device[20]. The male urethra crosses the prostate followed by its course through deep perineal pouch, perineal membrane after which it enters the erectile tissues of penis finally ending at external urethral meatus (Fig. 1).

The two angles of penile urethra include;

1) Following its course through perineal membrane, the urethra curves anteriorly at the root of the penis, forming the **fixed angle**.
2) Another angle occurs distally where the unattached part of the penis curves inferiorly- when the penis is erect, this second angle disappears.

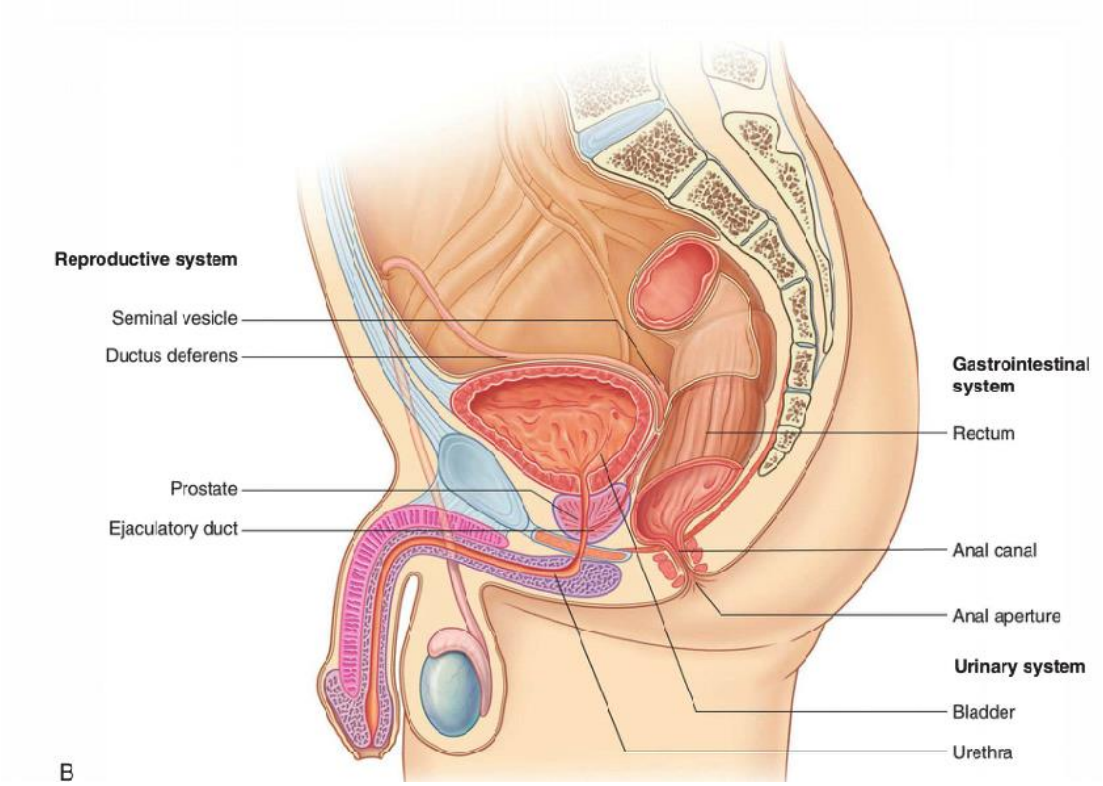


Figure- 1. Course of Male Urethra

Source- Gray's Anatomy for Students – 3rd ed. 2015; page no.424

FEMALE URETHRA

Urethra and bladder neck are usually present in the connective tissue of anterior vaginal wall in nulliparous women. Female urethra is about 4 cms, has three parts: Distal segment, Mid urethra, and the proximal segment[21]. There is an inferior angulation horizontally about mid-way in supine position the mean diameter being 22 F[22]. The female urethra is short, opens from bladder directly into perineum after crossing pelvic floor (Fig.2).

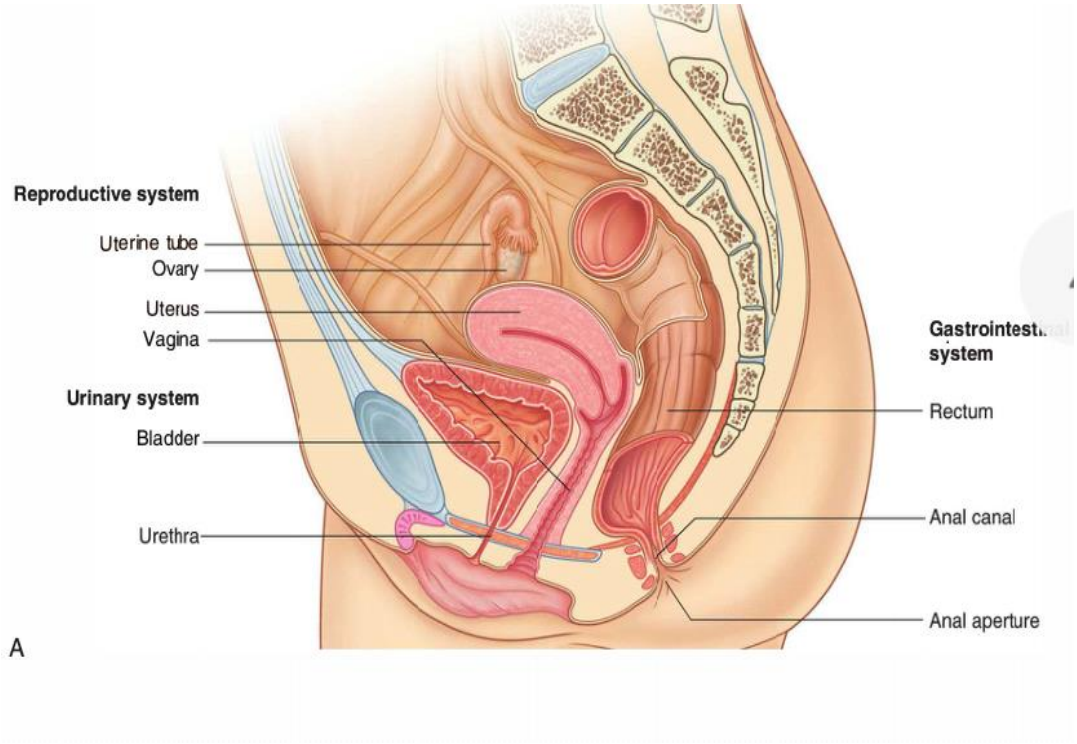


Figure- 2 Course of Female Urethra

Source- Gray's Anatomy for Students – 3rd ed. 2015; page no.424

c) INDICATIONS FOR URINARY CATHETERIZATION

THERAPEUTIC INDICATIONS

- Acute/ chronic urinary retention.
- Monitoring urinary output.
- Gross hematuria, to drain blood and clots
- Primary treatment in the management of urethral strictures[24].
- Intravesical instillation of drugs
    - For interstitial cystitis- dimethyl sulfoxide[23],
    - For intractable hematuria- Alum[23],
    - Invasive bladder cancer – Mitomycin C or Bacilli Calmette-Guérin (BCG) solution[23].
- Urogenital trauma

DIAGNOSTIC INDICATIONS

- Retrograde cystography, to inject contrast agent.
- To obtain an uncontaminated urine sample.
- Urodynamic studies to measure the intravesical and urethral pressure.
- Thermometer-tipped catheters – In lengthy surgeries providing both continuous thermometry and adequate drainage for urinary output measurement.

d) CATHETER SELECTION

A vast range of catheters are accessible for urinary catheterization. Variations in substance for manufacturing, length, diameter, appearance of catheter tip, number of channels, different coatings add to a wide range of choices.

Indications for use, amount of fluid required to drain, duration of catheter use, age, gender, previous history, anatomy decide the option of catheter design. Smallest size available should be chosen based on the following parameters (Table 1).

Table 1.

Catheter Size Based on Age

AGE IN YEARS	CATHETER SIZE (Fr)
<5	5-8
5-10	8-10
10-14	10
>14	10-14

Source: Campbell- Walsh UROLOGY. 11th ed. 2016, page no 120

The first trial of catheterization in an adult with no previous urinary complaints or known allergies should be attempted with a 16 F latex catheter.

Feeding tube insertion should be avoided due to their length and stiffness which may give rise to complications such as ischemic ulcers, urethral stricture, knotting of tube[25].

e) CATHETER DESIGN

Indwelling urinary catheter is a semi rigid, flexible tube which is used to drain the bladder but in turn block the urethra. there are mainly two types of urinary catheters available in current practice.

a. Single lumen catheter

   It has only one lumen running its whole length open at both ends to facilitate urine drainage for single use and cannot be used for continuous urinary drainage. The advantage is that the intraluminal diameter of the catheter is large but cannot be used to keep the catheter in bladder for urinary drainage.

b. Double lumen/ Two-way catheter

   It is the mostly widely used variety in clinical practice, it has two lumens running down its whole length. One of the lumen opens at both ends and allows for urine drainage. The other lumen has got a valve on the outside end and is connected to a balloon at the tip. The balloon is inflated with sterile water once it lies inside the bladder and thus predisposes for retention in bladder. Advantage in this type of catheter is that the intraluminal diameter of draining channel is larger as only two channels are accommodated. The disadvantage is that there is no channel for irrigation and other procedures[26] (Fig 4.).

c. Three -way catheter

   The distal end of the catheter is provided with three ports/ lumens, one is a funnel

shaped channel for draining urine, other one is for inflation of balloon with sterile water for anchorage. The last one is for facilitating continuous bladder irrigation or for instillation of medication. This type is primarily needed following urologic surgery or in a case of bleeding from the bladder or prostate malignancy, where the bladder may need continuous or intermittent irrigation to clear blood clots or debris[27] (Fig 4.)

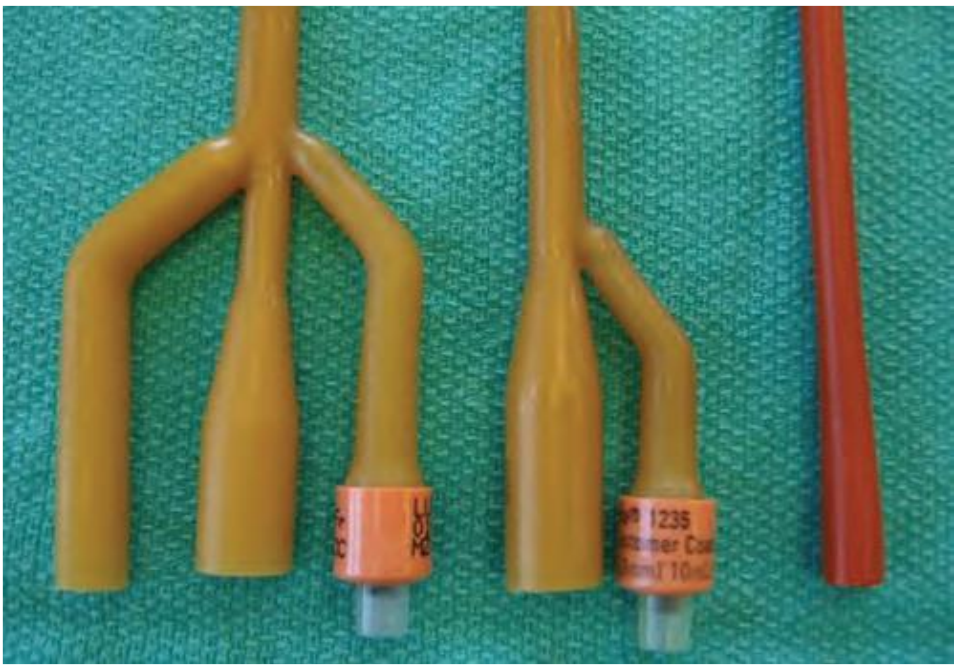


Figure. 3- Three-way, Two- way and Single lumen catheter

Source: Campbell- Walsh UROLOGY. 11th ed. 2016, page no 121

However, the addition of channels to single catheter design has several disadvantages. The extra channel reduces the internal diameter of catheter. Hence the internal diameter of a 24 F single channel catheter is more than that of a two-way 24 F which is again more than that of a 24 F three-way catheter.

There are two tip shapes of catheters- Nelaton blind ending straight tip and the Coude` tip/ elbowed/ Tiemann tip. Variations such as tapered tips or multiple side holes are present in a vast range of available catheters.

f) MATERIALS AND COATINGS

For day to day use catheters made of latex, rubber, silicon, Poly Vinyl Chloride (PVC) are preferred. For short term duration latex or rubber catheters are used because of their less cost and accessibility[23]. For long duration silicon is favoured over latex due to less tissue inflammation.

As compared to others silicon is stiffer and has less risk of buckling in the presence of resistance[28]. Various attempts for coating have been done to reduce trauma, urethritis and catheter associated urinary tract infection (CAUTI). Hydrophilic coated catheters can be used for intermittent catheterization. Advantages include more compliance, less trauma, reduced chance of UTI[23].

A current study by Bermingham showed that there was not much difference in risk of UTIs on comparing different catheter types used for Clean Intermittent Catheterization (CIC). In another study by Li and colleagues, with focus on spinal cord trauma patients documented that hydrophilic catheter usage in CIC significantly reduced UTI and Hematuria rates[23]. Since uncoated catheters were most cost effective for CIC and the use of gel reservoir was 2nd most cost effective in Bermingham study, the routine use of hydrophilic catheters for CIC in non-spinal cord injury patients is not recommended[23, 28].

For short term use antibiotic coating may delay UTI chance (< 1 week). However, it is not much beneficial in long term use[24]. Also, in some trials use of bacterial coated catheters with a non-virulent strain of E. Coli have shown good results. Although its effectiveness is still doubtful[23, 25].

In 2008, a meta-analysis published in Cochrane documented that use of silver coated catheters remarkably reduced the occurrence of UTI in both short- and long-term usage (>1

week)[24]. In another recent RCT involving 6 thousand patients, antimicrobial impregnated catheters showed a notable benefit in minimizing CAUTI incidence as compared to polytetrafluoroethylene (PTFE) catheters, on the other hand, silver catheters showed no significant change. Since remarkable benefit couldn't be appreciated in short term use with either groups, the routine use cannot be suggested[28].

Newer methods to impregnate catheter to amplify the biocompatibility are still being tried so as to prevent UTI and encrustation[29].

g) TECHNIQUE OF URETHRAL CATHETERIZATION

After gathering information regarding requirement of catheterization and taking a through history, previous urologic history, allergies catheterization should be attempted. This is required to decide upon correct catheter choice and for evaluation of risks and complications.

During catheterization, the doctor should stand at the side of patient which corresponds to the doctor's dominant hand. Materials required for the procedure should be kept ready on the sterile tray. Patient is placed in supine position and in case of female patients, lithotomy position is preferred. Under sterile precautions cleaning and draping are done. Before catheterizing, the balloon is checked for proper functioning. According to current American Heart Association protocols, there is no requirement of prophylactic treatment for infective endocarditis even in high risk patients for any urological procedure[30].

Before insertion, catheter should be lubricated properly for reducing chance of urethral trauma. Four types of lubricants are there; plain, lubricant anesthetic, lubricant disinfectant, lubricant anesthetic disinfectant.

Two percent lidocaine gel prior to catheterization has been considered safe and

effective since mid-20th century and has been in practice till now[31]. The absorption of 2 % lidocaine attains a very low peak concentration which is never toxic (i.e. up to 550 mg, which is 27 ml of 2% lidocaine)[32]. Although in patients with distorted mucosal barrier, absorption is found to be more which causes high peak serum concentration in minutes causing toxicity. Side effects documented are confusion, lethargy, seizures, disorientation, anaphylactic shock[33].

According to Chitale and Mc Farlane, pain scale was similar for plain versus anesthetic lubricant for flexible cystoscopy[34]. However, Ho and colleagues stated that anesthetic lubricant usage is paradoxically more painful than plain lubricant[23]. On the other hand, if we decrease the temperature of lubricant up to 4 degree centigrade, it notably reduces pain in comparison with lubricant at room or body temperature most probably due to cryo-analgesic effect[35].

Application of the anesthetic lubricant for more than 10-15 mins is needed for its action to start[36]. Also, it has been seen that little delay (< 15 mins) will not cause any benefit in comparison to no delay[23]. In females, the action of anesthetic lubricant starts few minutes after its insertion[23]. Various studies show contradictory conclusions with respect of usage of anesthetic versus plane lubricant. This was supported by Patel and colleagues. Whereas Aaronson and colleagues documented a favorable effect with respect to anesthetic lubricants.[23, 36]

Hence depending on this information regular use of anesthetic lubricant is questionable, but when indicated it has to be applied slowly (3-10 secs) and about 20 ml cooled lubricant should be used and allowed to act for about 15 mins[23].

After retracting the prepuce, the external meatus is visualized. If there is phimosis, catheter can be inserted blindly with smaller flexible catheter. In patients with hypospadias where

there is blind ending navicular fossa catheter should be avoided. If there is a stricture or a stenosis, a smaller size catheter should be tried initially. If catheterization is unsuccessful, careful dilatation is tried.

Under aseptic precautions, skin and meatus are cleaned and draped. First the penis is to be held with the non-dominant hand. This hand is now considered unsterile. The penis is straightened by pulling the shaft upward. Following lubrication catheter is introduced into the meatus and pushed to about 7-12 cms. Penis is made parallel to the patient by making it horizontal. There may be minimal resistance at the membranous urethra. Catheter is inserted up to the Y junction. There should be spontaneous drainage of urine if bladder is full. If not, slight suprapubic massage is done or by flushing with sterile fluid followed by aspiration should drain urine. If after all efforts there is no urine in catheter, either bladder is empty or catheter is not in position. Pus / blood/ lubricant jelly may block the catheter.

Once the catheter is in the bladder, balloon is filled with sterile water. Sterile water has been considered ideal for inflation of balloon if catheter requirement is for many days[37]. Saline or glucose fluids if used for inflation can cause precipitation, however not proven evidently[23]. After catheterization, prepuce is retracted back to prevent paraphimosis. In order to avoid pressure ulceration at the pendulous curve of urethra and iatrogenic hypospadias, the catheter must be fixed at an upright position. Iatrogenic hypospadias leading to deformities can happen if it remains unattended.[23, 37]

Catheter should be connected to sterile urine collecting bag so as to ensure a closed drainage circuit, to be kept in dependent position for urine to be drained. It is important to note that even though it is a belief that there might be problems like hematuria, hypotension, pain, due to sudden emptying of bladder, but drainage has been proved to be efficacious and safe[38].

h) COMPLICATIONS

Urinary catheterization is a routine procedure in hospital. Although it is very important it can have various complications.

It has been seen that at any point during their stay, 15-25% of patients require catheterization[23]. UTI is commonly seen, about 35 % of Nosocomial infections. About 95% of UTI is seen in ICU set up from catheters[39]. Urinary catheterization has been documented up to 15-40 % of cases and is associated with longer hospital stay. The cost of CAUTI accounts to about $ 300 million in United States. Various projects have been undertaken to improve the quality which have led to the reduction in CAUTI incidence.[23, 39]

In 2009, CAUTI definition has been changed according to which asymptomatic bacteriuria is excluded[40]. In recent guidelines, "CAUTI is defined as significant bacteriuria in a patient with symptoms/ signs indicating a UTI, whereas asymptomatic bacteriuria refers to significant bacteriuria in asymptomatic patients." Antibiotics are not required for asymptomatic bacteriuria. Since sufficient proof is not there regarding benefit following treatment of asymptomatic bacteriuria to reduce mobility and mortality, the European Association of Urology (EAU) and Infectious Disease Society of America (IDSA) does not recommend any antibiotic therapy for the same[23]. Indwelling catheter for long duration of 6 days or more, is a significant risk factor for CAUTI. Catheterization outside the operation theatre, female, body mass index (BMI) more than 30, diabetes and any evidence of foci of infection are to their risk factors for CAUTI[41].

Some of the recommended protocols to prevent CAUTI are to ensure to a closed drainage system, avoid catheter use as much as possible, to remove catheter early and to avoid irrigation routinely. Catheterization should be done under aseptic precautions and using sufficient lubrication. According to a recent study there was not much difference in

incidence of UTI for prolonged duration when compared with respect to various types of catheter[23, 42]. There is lack of proof to suggest the use of a particular catheter type. Short course of antibiotics for 5 days along with change of catheter versus long course (10 days) without change are equally effective[42].

In patients with CIC (Clean Intermittent Catheterization) use of long course of antibiotics as prophylaxis has not been seen to reduce the incidence of UTI notably. However, in patients with spina bifida, disruption of long course antibiotic prophylaxis leads to insignificant rise in UTI without clinical significance. After short term use and removal of catheter, prophylactic antibiotic course even for short term duration has been encouraged as well as disapproved[23]. According to American Urological Association (AUA) recommendations in 2008, use of prophylactic antibiotics following removal of catheter has been suggested if there is presence of bacteriuria especially in patients like older age, immunosuppression, corticosteroid use[43]. The IDSA has disapproved the use of antibiotic course as prophylaxis before catheter is removed or changed in 2010[23]. A recent study documented reduced incidence of UTI on administration of prophylactic antibiotics after removal of catheter post-surgery[23]. If about 25 % of in- patients are considered to be catheterized at any point in the course of their stay, suggesting antibiotics routinely after removal of catheter would lead to increased risk of antibiotic resistance and drug related adverse effects. Therefore, considering antibiotic prophylaxis only in patients with risk factors is advisable as recommended by AUA panel.

A recent study showed that complications other than CAUTI are more frequently seen in long term catheterized patients i.e. four-fold times. They include peri catheter urine leakage, accidental removal, catheter block, hematuria, bladder calculus, bladder cancer. Patients with spine injuries are at increased risk for these complications[44].

One of the important complications is difficulty in removing catheter. Following urethroplasty or radical prostatectomy catheter entrapment with in anastomotic sutures is one of the serious post-operative complications. If sutures are absorbable catheter can be removed one to two weeks following procedure. If they are non- absorbable, they can be divided by laser with the help of semi rigid ureteroscope[23, 44]. There is a possibility of catheter being bound to bladder neck due to balloon cuffing following deflation which usually depends on the material of the catheter, duration of usage, method of deflation, UTI. Among these duration of usage is the most important factor. This can be avoided by using hydrogel coated or PTFE catheters or deflating the balloon slowly[45]. A method was suggested by Gonzalgo in which of 0.5 – 1 ml of fluid can be infused in the balloon due to which the cuff gets smoothened as a result of which catheter can be easily removed[46].

There can be instances where it is difficult to deflate the balloon. It can be resolved by infusion of an extra 1-2 ml fluid in balloon and retry to aspirate. Letting the balloon burst by over inflating it might be painful to the patient and could lead to retained catheter bits in the bladder and hence to be avoided. Another alternative is to cut off the inflation valve if not working properly. In case of failure guided wire can be passed through the inflation channel and balloon can be perforated. If all attempts fail, ultrasound guided needle puncture of balloon is the ultimate choice. The balloon deflation is difficult due to encrustation which can be because of prolonged catheterization. There are reports suggesting that one of the main reasons for encrustation is infection due to Proteus mirabilis. As a result of this there can be repeated catheter block[47]. Gentle traction to the catheter may help to remove encrustation and hence aid removal of catheter. Even after this if it is not solved, ultrasound or X- Ray can be done for confirmation of encrustation. Semi rigid ureteroscope guided Holmium: YAG Laser can be used to dislodge the encrustation. Asking the patient to increase fluid intake and intake of citrate may prevent this issue in

known calculus and chronic catheterized patients[23, 47].

Another common problem is stricture urethra. About 11.2 % of strictures which need urethroplasty are due to catheterization in patients as reported by Lumen and coworkers. It causes multifocal or pan urethral strictures[23].

According to Fenton and colleagues about 32 % of strictures were caused by iatrogenic trauma, among which 36.5 % were due to longer duration of catherization. The suggested reason being inflammation and ischemia of urethra finally leading to stricture[23]. Also, if the balloon is inflated in the prostatic urethra, it can cause severe hematuria, urethral rupture and finally stricture[48].

i) PREVENTION OF IATROGENIC TRAUMA

When catheter balloon is kept in wrong position the pressure exerted is much higher. As compared to 10 ml, 5 ml causes much less force of extraction in balloon[49]. While inflation if resistance is encountered, we should suspect that catheter is in wrong position. If patients are at risk of trauma, balloon has to be inflated with 5 ml to reduce the trauma risk.

For longer duration of catheterization 16 F size catheter is preferred. When longer duration of catheterization is required, a low threshold suprapubic catheter can be used[23]. There can be a reduction in trauma due to catheterization by 5-fold with proper training, knowledge and skill[50].

A study conducted by A. Maya Nandkumar, titled **'Antimicrobial Silver Oxide Incorporated Urinary Catheters for Infection Resistance' in 2010[4]** has described a method of incorporating Silver oxide into finished Latex Foley's catheters without substantially altering its properties. The method is easy to perform, does not need special equipment and can be

easily incorporated into the manufacturing process. It has effective antimicrobial activity which prevents both bacterial adhesion and subsequent biofilm formation and is non-cytotoxic, thus fulfilling its promise of an effective anti-microbial surface.

In a study conducted by Patrick HY Chung et al, titled '**A prospective interventional study to examine the effect of a silver alloy and hydrogel−coated catheter on the incidence of catheter-associated urinary tract infection' 2017**[51] found that the incidences of catheter-associated urinary tract infection per 1000 catheter-days were 6.4 and 9.4, in silver coated and uncoated catheters respectively (P=0.095). There was a 31% reduction in the incidence of catheter-associated urinary tract infection per 1000 catheter-days in the silver-coated group. Silver alloy and hydrogel−coated catheters appear to be effective in preventing catheter-associated urinary tract infection based on the latest surveillance definition. The effect is perhaps more prominent in long-term users and female patients.

A study conducted by James W. Lederer, William R. Jarvis, Lendon Thomas, Jaime Ritter, titled '**Multicenter Cohort Study to Assess the Impact of a Silver-Alloy and Hydrogel-Coated Urinary Catheter on Symptomatic Catheter-Associated Urinary Tract Infections' 2014**[52] found 47% relative reduction in the CAUTI rate was observed with the silver-alloy hydrogel catheter compared to the standard catheter (0.945/1000 patient days Vs 0.498/1000 patient days) (odds ratio = 0.53; P < .0001; 95% CI: 0.45-0.62) thus use of a silver-alloy hydrogel urinary catheter reduced symptomatic Catheter Associated UTI occurrences.

A study conducted by David Roe1, Balu Karandikar1, Nathan Bonn-Savage1, Bruce Gibbins1 and Jean-Baptiste Roullet2 titled '**Antimicrobial surface functionalization of plastic catheters by silver nanoparticles' 2008**[53] found that sustained release of silver was demonstrated over a period of 10 days. Coated catheters showed significant in vitro

antimicrobial activity and prevented biofilm formation using Escherichia coli, Enterococcus, Staphylococcus aureus, coagulase-negative staphylococci, Pseudomonas aeruginosa and Candida albicans. Because of the demonstrated antimicrobial properties of silver, it may be useful in reducing the risk of infectious complications in patients with indwelling catheters.

A study conducted by Tobi B. Karchmer, Eve T. Giannetta, Carlene A. Muto, Barbara A. Strain, Barry M Farr, titled **'Randomised cross over study of silver coated urinary catheters in Hospitalised patients' in 2000**[13] found that the relative risk of infection per 100 silver coated catheters used on study ward with uncoated catheters was 0.68(95% CI, P= .001). The incidence of catheter associated urinary tract infection was found to be 2.13 per 100 silver coated catheters Vs 3.12 per 100 uncoated catheters.

5.MATERIALS AND METHODS:

SOURCE OF DATA:

All patients coming to B.L.D.E (D.U)'s Sri B M Patil Medical College, Hospital and Research Centre, admitted and had an indication for Urinary Bladder Catheterization.

Period of the study was from November 2017 to May 2019.

METHOD OF COLLECTION OF DATA

The Patients admitted in B.LD.E. (DU)'s Shri. B. M. Patil Medical College, Hospital and Research Centre, Vijayapur in Surgery Department during period November 2017 to May 2019 with a sample size of 120 in each group comprising of a total 240 patients were allotted to either of the group to ensure that the two groups are adequately matched with respect to age, sex ratio and patients on systemic antibiotics. The patients were explained in detail about both the procedure and complications. Data collection included indication for catheterization, type of catheter used and duration of catheterization, urine for pus cells, organisms isolated, and demographic information. Bacteriuria as evaluated by urine culture and urine pus cells were the outcome variables used to indicate urinary tract infection (Catheter associated), which is defined by centers for disease control and Prevention (CDC) as "In patients with indwelling catheter in place for 48 h or more with presence of at least 10 A^3 colony forming units (cfu)/ ml of 1-2 micro-organism by urine culture[3].

INCLUSION CRITERIA

Adult patients aged between 18 and 89 years admitted for surgical conditions which needed intervention or prolonged stay with requirement of monitoring of urinary output or catheterization for various reasons who will need catheterization for 3 or more days, such as,

- ✓ Patients with negative urine culture
- ✓ Patients who had an indwelling urinary catheter for 3 or more calendar days after hospital admission were included in the study.

EXCLUSION CRITERIA

- ✓ Patients with urinary diversions.
- ✓ Certain pre-existing conditions affecting the bladder (E.g. active bladder cancer, chronic indwelling urinary catheter in place.
- ✓ Those undergoing an invasive urologic surgery.
- ✓ Patients with pre-existing UTI.
- ✓ Patients with sterile Bacteriuria.

METHOD OF PREPARING CATHETER:

The methodology described here is a patented technology, where in commercially available Foley's urinary catheter made up of latex material were used in silver impregnation[4]. It is a simple to perform procedure and the necessary substrates and materials required are,

1. FOLEY'S CATHETER

   It is a flexible rubber tube catheter used for drainage of urine. It was named after Dr. Frederic Eugene Basil Foley, an American Urologist who first came up with the original design in 1929. It is made up of either latex material, silicon or can be made from Teflon. It has two lumens, one for inflating the balloon and the other for drainage, running down its whole length with a retention balloon near the tip. Foley's catheter is available with short and long nosed tips. The size of the retention balloon ranges between 5-50 ml and the diameter (luminal) ranges from 12 to 30 F. It is found that the

balloon can be overinflated (at least up to twice their stated capacity) without breakage[54]. The silver oxide impregnated Foley's catheter was sterilized using an Ethylene Oxide sterilisation for 48 hrs.

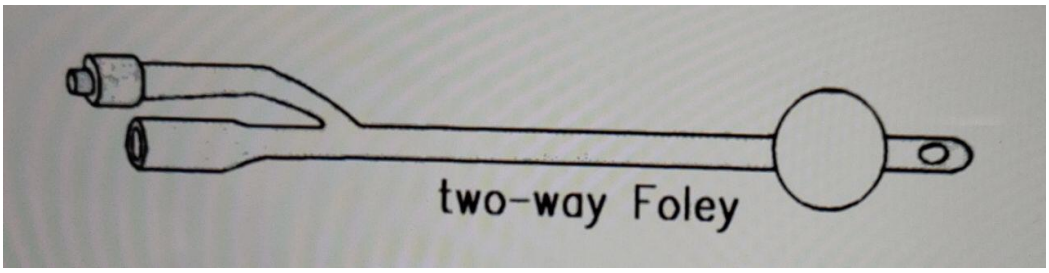


Figure 4- Classical two- way Foley's catheter.

Source: Handbook of Urology: Diagnosis and Therapy. 3rd ed. 2004; p-65

2. TOLUENE (METHYLEBENZENE)

   It is an aromatic hydrocarbon, which is colourless liquid, water insoluble, chemically it is CH3 group attached to a phenyl group. It is predominantly used as an industrial feedstock and a solvent. In our study it was used as a solvent[55].

3. SILVER NITRATE

   Silver as silver nitrate is a chemical element with symbol Ag, derived from the Latin word argentum; meaning "shiny" or "white" with atomic number 47. Silver and its compounds have an oligodynamic effect and toxic for bacteria, algae, fungi. Its antibacterial function is dependent on Ag+ ions. Effectiveness of silver compounds as an antiseptic is based on the ability of biologically active silver ions to irreversibly damage key enzyme systems in the cell membranes of pathogens. It was observed that, on applying an electric current across silver electrodes enhances antibiotic action at the anode, likely due to the release of silver ions into the bacterial culture[56].

   Silver and its applications in current clinical practice

- ❖ Silver is in use since 1960, Silver Sulphadiazine (SSD) is used as a topical antibiotic agent in wounds/ burns to prevent infection[57].
- ❖ Its application in specific wound management was strongly supported by a 2018 Cochrane's review, which concluded that silver compounds containing dressings may have increased the probability of healing for venous ulcers[58].

  Another meta-analysis in 2017 over 15 years (2000-2015) concluded that "the evidence base for silver in wound management is significantly better than perceived in the current scientific debate" and if applied selectively for short periods of time, silver has antimicrobial effects, produces an improvement in quality of life and shows good cost effectiveness[59].

- ❖ A 2015 system systematic review suggested silver coated endotracheal tubes reduced the risk of contracting Ventilator Associated Pneumonia (VAP)[60].
- ❖ Its role in application to urinary catheters is supported by a 2014 cohort study, which observed that using a silver alloy hydrogel urinary catheter did reduce symptomatic CAUTI occurrences[52].

4. DIMETHYL ACETAMIDE/ FORMAMIDE

   Formamide (also known as methanamide) is an amide derived from Formica acid. It is a clear liquid with a pungent (ammonia) like odour, which is used as a solvent for preparing silver nitrate solution[61].

PROCEDURE

Foley's catheter commercially available is dipped in an organic solvent such as Toluene for about 30 secs. Silver Nitrate is then mixed in Formamide liquid to prepare a solution of silver nitrate. For every catheter prepared, 1 gram of silver nitrate was used. Following which the

catheter is then placed in the solution prepared. The solution is then heated in a temperature-controlled water bath at about 70- 80 degree for 15 mins.

Figure 5 - Temperature Controlled Water Bath

Source – *BLDE (DU) Central Research Laboratory*, Vijayapur

This will lead to silver oxide impregnation over the intra-luminal and extra-luminal surfaces of catheter. Further the Catheter is washed with distilled water to remove excess of formamide. Catheter is then air dried and is further subjected to Ethylene Oxide sterilization for 48 hours.

Figure 6- Ethylene Oxide Sterilizer

Source- *Shri B. M Patil Medical College*, Hospital, Vijayapur, Karnataka

Figure 7- Conventional Foley 'S Catheter

Source- *Shri B. M Patil Medical College*, Hospital, Vijayapur, Karnataka.

Figure 8- Silver Oxide Impregnated Foley's Catheter

Source- *BLDE (DU) Central Research Laboratory*, Vijayapur.

SAMPLING

A study conducted by **Sanjay Saint et al[6]**. titled 'The Efficacy of Silver Alloy-coated Urinary Catheters in Preventing Urinary Tract Infection: A Meta-Analysis' published in 1998 is taken as reference study.

With the incidence of UTI by silver coated catheter- 11% and that of conventional Foley's catheter- 24%, at 99% confidence level and with 80% power in the study, total sample size of 240 was taken. Thus, study group had 120 and control group had 120 patients (240/2).

Formula for estimating sample size: $n = \frac{(z\alpha + z\beta)\ 2*P*Q}{d2}$

Where,

n= estimated sample size

d= difference between two proportions

Zα = confidence level (99%)

Zβ=Power (80%)

P = incidence of infection

Q= 100-P

STATISTICAL ANALYSIS-

The data obtained were recorded in a Microsoft Excel sheet, and statistical analysis was performed using statistical package for the social sciences (Version 17). Results are presented as drawings, Mean±SD, counts and percentages.

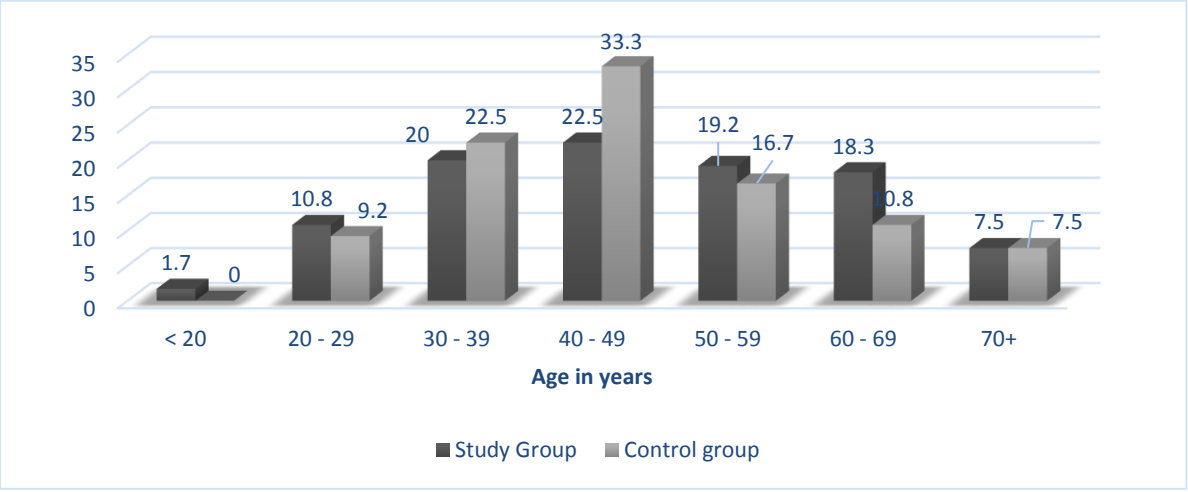
Categorical variables were compared using chi square test, quantitative variables were compared using Mann Whitney U test. For all tests, significance was achieved at $p<0.05$. All statistical tests performed were two tailed.

6.RESULTS:

Table 2. Distribution of patients according to Age in study and control group.

Age (Years)	Study group		Control group	
	No. of patients	Percentage	No. of patients	Percentage
< 20	2	1.7	0	0
20 - 29	13	10.8	11	9.2
30 - 39	24	20.0	27	22.5
40 - 49	27	22.5	40	33.3
50 - 59	23	19.2	20	16.7
60 - 69	22	18.3	13	10.8
70+	9	7.5	9	7.5
Total	120	100.0	120	100.0

Figure 9- Distribution of patients according to **Age** in study and control group.



The above table shows the distribution of age between the two groups **Study** (silver oxide coated catheter) and **Control** (conventional latex catheter). There were only two patients in the study group with less than 20 yrs of age. 13 patients were between 20-29 years in study group and 11 in control, 24 patients were between 30-39 years in study group and 27 in control group ,27 patients were in between 40-49 years of age group in study and 40 in control group , 23 patients were between 50-59 years in study and 20 in control group, 22 patients were between 60-69 years of age in study group and 13 in control group, 9 patients were above 70 years in each study and control group.

Table 3. Distribution of patients according to Gender in study and control group.

Gender	**Study group**		**Control group**		**Chi square test**	**P value**
	No. of patients	**Percentage**	**No. of patients**	**Percentage**		
Female	54	45.0	45	37.5	X^2=1.393	P=0.2380 NS
Male	66	55.0	75	62.5		
Total	120	100.0	120	100.0		
NS: Not significant						

Out of 120 patients, 66 were males and 54 were females in Study group.

Out of 120 patients, 75were males and 45 were females in no drain group.

Figure- 10. Distribution of patients according to Gender in study and control group.

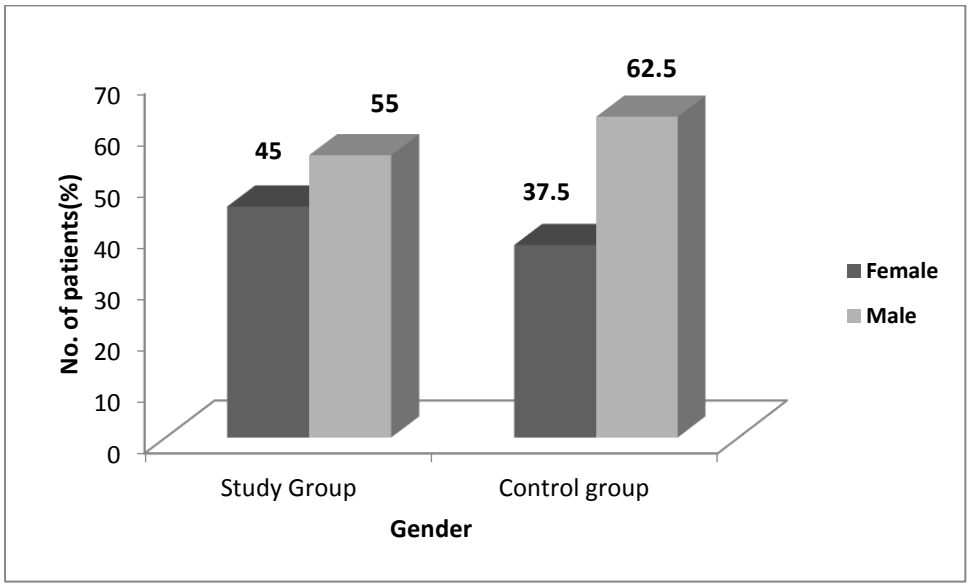


Table 4. Mean age between study and control group.

Age (Years)	Mean (Median)	±SD	Mann Whitney U test	P value
Study	47.63(48)	15.04	U=7103	P=00.8763 NS
Control	47.73(47)	13.07		
NS: Not significant				

The mean age was 47.63± 15.04 years in study group and 47.1± 13.07 years in control group.

Table 5. Comparison of **Body Mass Index (BMI)** between Study and Control groups

Comparison of	**Study group**		**Control group**		**Mann Whitney U test**	**P- value**
	Mean (Median)	**±SD**	**Mean (Median)**	**±SD**		
BMI	20.03(19.4)	1.83	20.18(19.4)	2.20	7189.5	P=0.9852 NS
NS: Not significant						

It was observed in our study that, the Mean & Median BMI in study group was found to be 20.3 and 19.4 respectively. In control group, the Mean & Median was found to be 20.18 and 19.4 respectively.

Table 6. Indications for catheterization in study and control group

SL NO	**Indications**	**Study**	**Control**	**Total**
1	Split Thickness Skin Grafting	22	14	36
2	Necrotising Fascitis	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	Chronic Kidney Disease	1	2	3
14	Thoracotomy	0	1	1

Out of the various causes for monitoring urine output urinary catherization done, most common indication was in patients who were immobilised following Split thickness skin grafting surgery (36 patients), followed by Necrotising Fascitis (35 patients), fracture of the lower limbs such as fracture of femur, tibia, hip joints, calcaneum and etc.

Other indications for catheterization were as followed, Exploratory Laparotomy (25 patients), Deep Venous Thrombosis (25 patients), Resection anastomosis of the small bowel for various reasons (18), patients immobilised due to pressure sores (16 patients), Blunt trauma abdomen (15 patients), Sub- acute Intestinal Obstruction (11 patients), neurogenic bladder (6 patients), Sepsis (5 patients), Chromic kidney disease (3 patients) and one patient was catheterized pre operatively in a case of Open thoracotomy.

Figure 11- Indications for Catheterization in study group

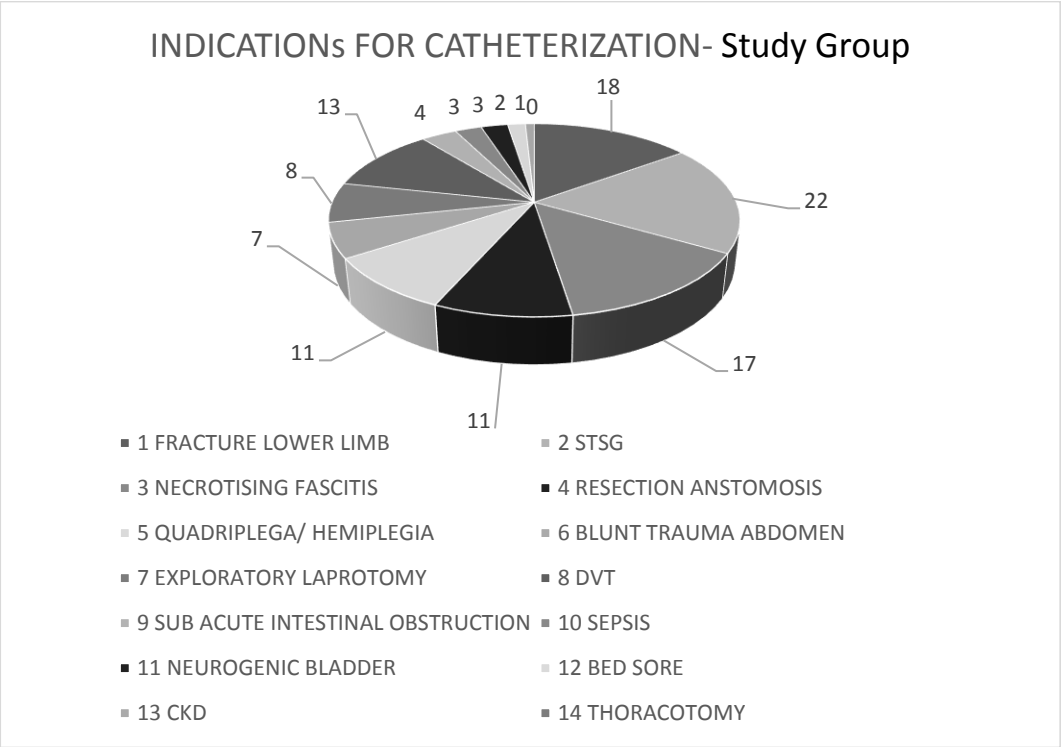


Figure 12- Indications for Catheterization in study group

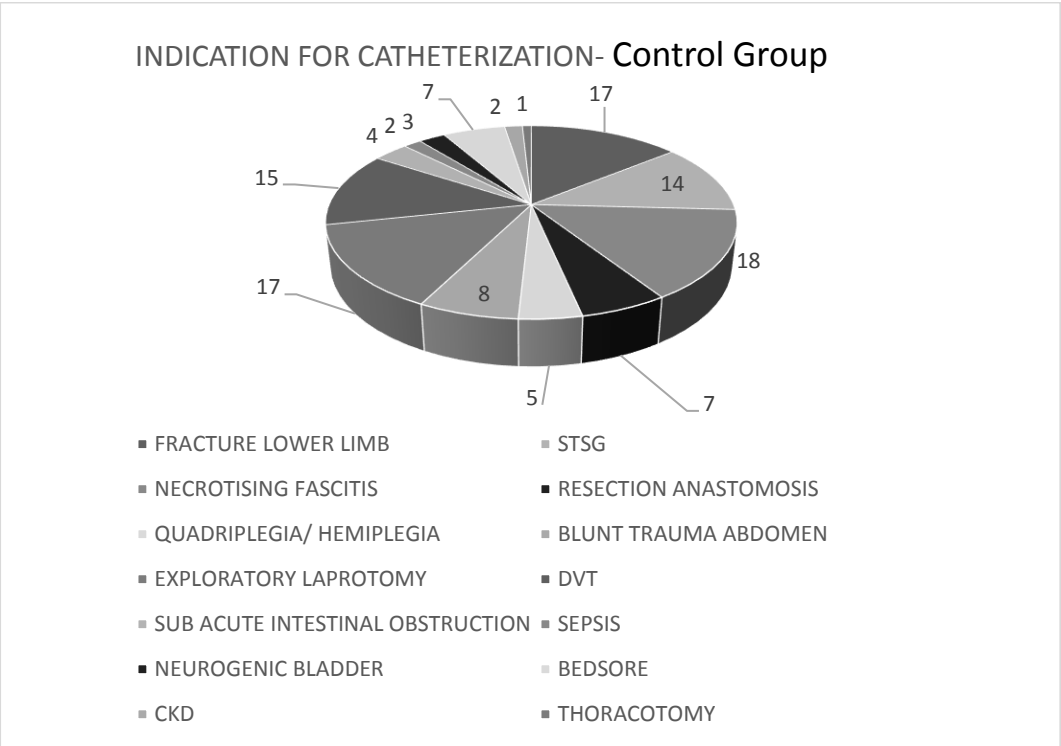


Table 7. Comparison of urine for **pus cells** in patients between study and control group

Urine pus cells	**Study group**		**Control group**		**Chi square test**	**P value**
	No. of patients	**Percentage**	**No. of patients**	**Percentage**		
Day 1						
Present	7	5.08	9	7.5	X^2=0.0803	P=0.7768
Absent	113	94.2	111	92.5		NS
Day 3						
Present	26	21.7	29	24.2	X^2=0.2123	P=0.6450
Absent	94	78.3	91	75.9		NS
Day 7						
Present	47	39.2	64	53.3	X^2=40.844	**P=0.0277**
Absent	73	60.08	56	46.7		**HS**
Total	120	100.0	120	100.0		
NS: Not significant HS: Highly significant						

In the present study, urine for pus cells was taken as positive when the count was more than 10 pus cells per hpf[62]**.** It was observed that the number of patients with significant pus cells (pus cells > 10 /hpf) in urine on day 7 was significantly lower in study group **P value 0.0277**. There was no difference in p value between study and control group at the end of day 1 (after 48 hrs of catheter insertion) and on day 3, with p value of 0.77 and 0.64 respectively.

Figure 13- Comparison of urine for **pus cells** in patients between study and control group.

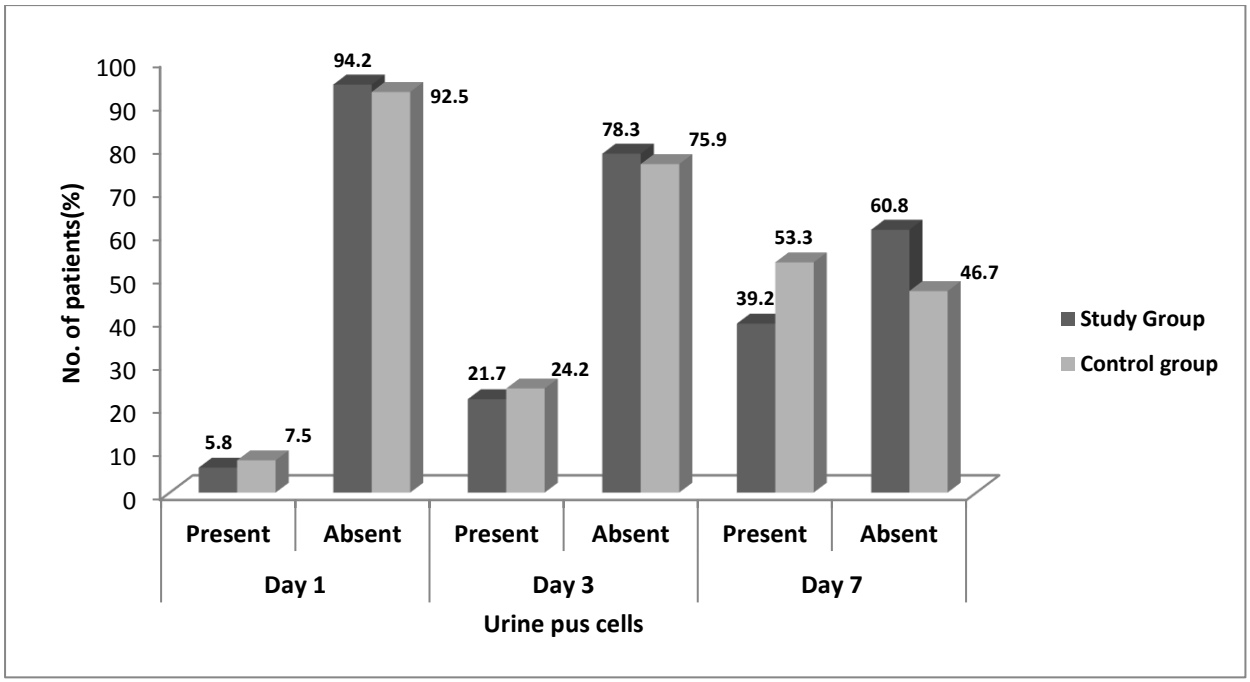


Table 8. Comparison of **Urine Culture between study** and control group

Urine Culture	**Study group**		**Control group**		**Chi square test**	**P value**
	No. of patients	**Percentage**	**No. of patients**	**Percentage**		
E. COLI	13	27.6	23	33.3	X^2=7.397	
S. AUREUS	11	23.4	13	18.8		
K. PNEUMONIA	6	12	15	21.7		
P. AUREUGINOSA	8	17	5	7.2		

C. FRUEIDI	3	6.3	4	5.7	P=0.4945 NS
C.NON-ALBICANS	3	6.3	3	6.3	
E. SAPROPHYTICUS	2	4.2	4	5.7	
PROTEUS	0	0	2	2.8	
C. ALBICANS	1	2.1	0	0	
NS: Not significant					

It was observed in that the most common organism isolated was found to be E. Coli with 27 .6%, followed by S. Aureus with 23.4 %. Other organisms isolated with lesser frequency were P. Aeruginosa and K. Pneumoniae with 17 % and 12 % respectively. Other rare organisms isolated were C. Albicans, C. Non- Albicans and E. Saprophyticus.

In Control group, K. Pneumoniae (21.7 %) was the most common organism after E. coli (33.3 %), followed by S. Aureus being 18.8 %. Two patients were found to be positive with proteus species being 2.8 %.

Figure 14- Organisms isolated in Study group

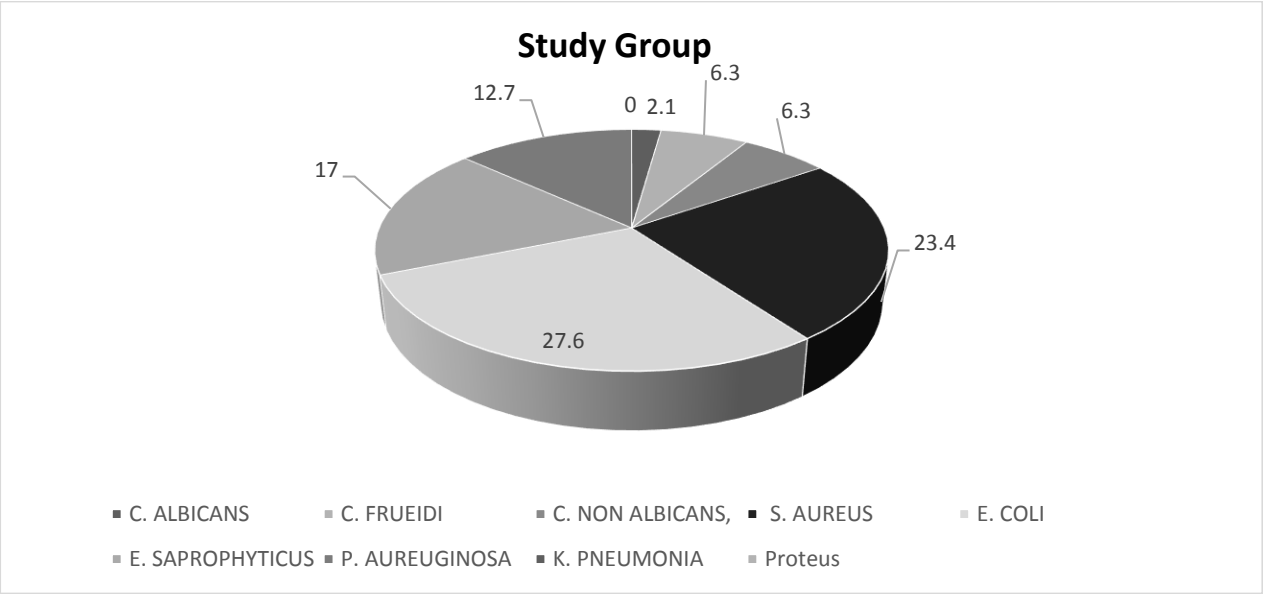
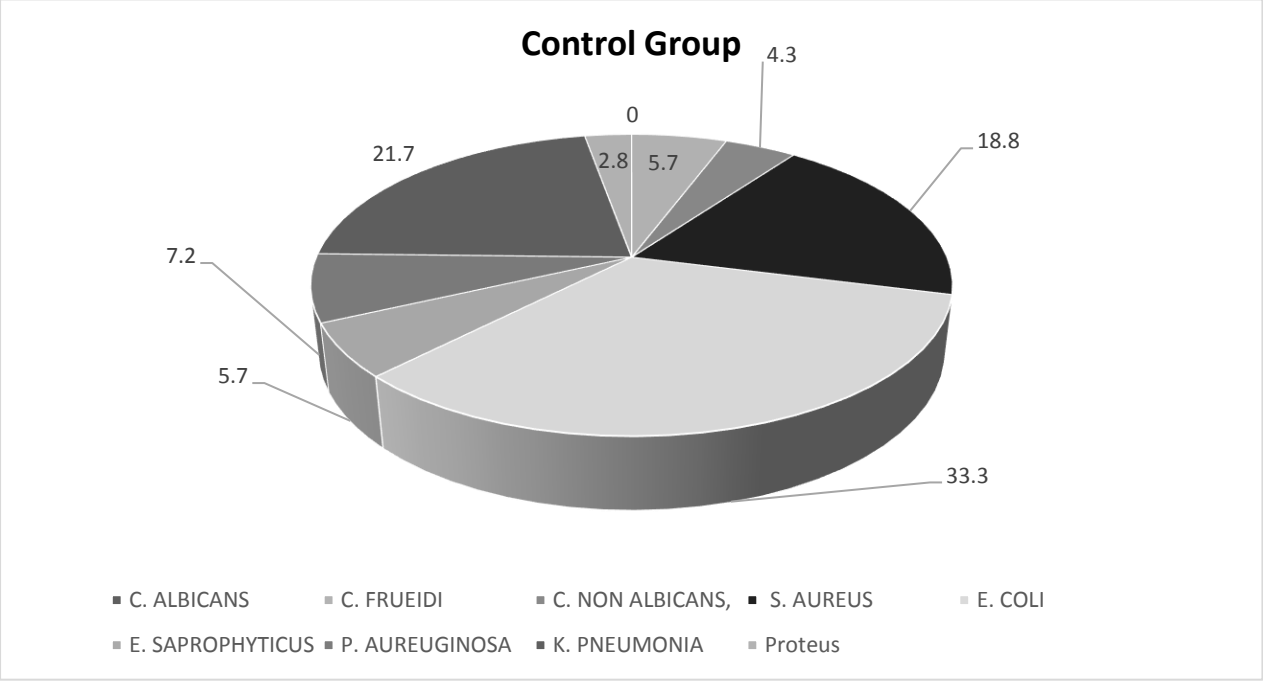


Figure 15- Organisms isolated in control group.



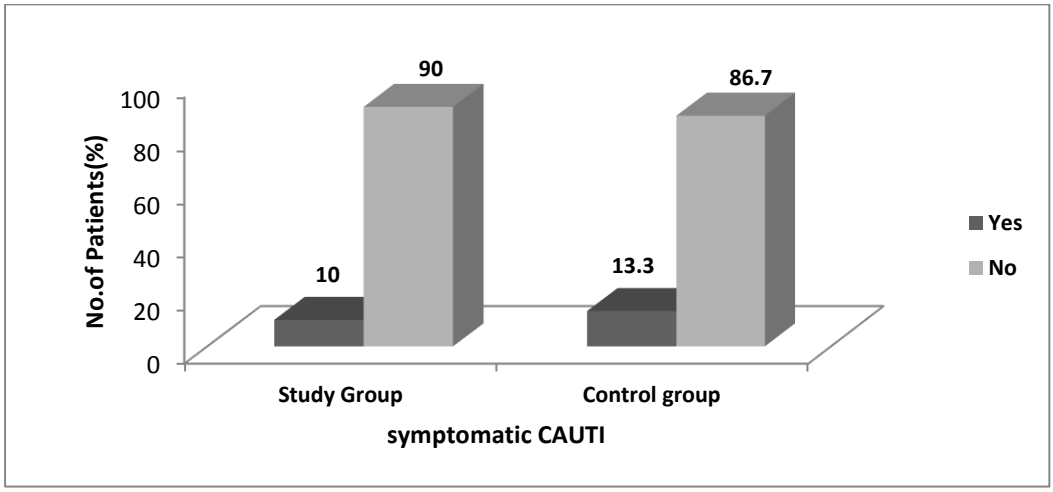
However, Comparison for the difference in the incidence of type organisms isolated between study and control group revealed no statistical difference with P- value 0.49.

Table 9. Comparison of **symptomatic CAUTI** between study and control group.

SYMPTOMS (fever/ suprapubic pain, etc.)	**Study group**		**Control group**		**Chi square test**	**P value**
	No. of patients	**Percentage**	**No. of patients**	**Percentage**		
Yes	12	10.0	16	13.3	X^2=0.6469	P=0.4212
No	108	90.0	104	86.7		NS
Total	120	100.0	120	100.0		
NS: Not significant						

It was observed that out of 49 patients positive for urine culture, only 12 patients had symptoms like fever, suprapubic pain/ tenderness. Whereas 16 patients were symptomatic out of 69 patients positive for urine culture. However, there was no statistical difference between the study and control groups with P- value 0.42.

Figure- 16. Comparison **symptomatic CAUTI** between study and control group.



7.DISCUSSION

In this study a total of 240 patients were included, of which 120 patients with Silver Oxide impregnated Foley's catheter were placed in study group and 120 patients with Conventional Foley's catheter were in control group**.**

AGE GROUP & GENDER

In our study, 22.5 % of patients in the study group were in the age group between 40- 49 years, followed by 20 % of patients in the age group 30-39 years, followed by 19.2 % in 50-59 years and 18.3 % in the age group 60-69 years. It was observed that 10.8 % of the patients were in the age group 20-29 years, 7.5 % of them were above 70 years of age and 1.7 % in the age group less than 20 years.

On the other hand, 33.3 % of patients in the control group belonged to the age group 40- 49 years, followed by 22.5 % of patients between age group 30-39 years. 16.7 % of the patients belonged to age group 50-59 years, 10.8 % patients in the age group 60-69 years, 9.2 % of them between 20-29 years and 7.5 % of the control group patients were more than 75 years of age.

In our study, 45 % of the patients in the study group were females and 55 % were males, where as 37.5 % of the patients in the control group were females and 63.5 % were males. It was observed that there was no statistical difference between the groups with respect to gender with P value 0.238. Overall, 41 % of the patients were females and 59 % of them were males.

Sangamithra. V et al[3] in their study reported 65% of patients were males and 37 % were females.

MEAN AGE

The mean age was found to be 47.63± 15.04 in study group and 47.1± 13.07 in the control group. There was no statistical difference of age between the groups with P value of 0.087.

A study conducted by Patrick H. Y Chung et al reported a mean age of 81.1 %[51].

COMPARISION OF BODY MASS INDEX (BMI)

On comparing the BMI between the study and control group, it was observed that, there was no statistical difference between the study and control group with P- value being 0.98.

INDICATIONS FOR CATHETERIZATION

On comparing the various indications for catheterization, it was seen that the two groups were statistically not significant.

COMPARISON OF URINE FOR PUS CELLS

In our study, it was seen that the urine examination for pus cells at the end of Day1 (48 hours after admission) was found positive (urine pus cells more than 10/ hpf was taken as cut off in our study[65]) in 5.08 % in study group and 7.5 % in the control group. There was no statistical difference between the incidence of urine for pus cells between the study and control group with p value of 0.77. Similarly, there was no statistical difference between the two groups with incidence of 21.7% positive in study group and 29 % in the control group (p value- 0.64).

Whereas, urine for pus cells was found positive in 39.2 % in study group and 53.3 % positive in control group in a sample size of 120 in each group. There was difference in the incidence of patients with positive urine analysis with significantly less patients in study group with p value 0.027.

In a study conducted by Sangamithra V. et al observed that incidence of Urinary Tract Infection in a tertiary care set up was found 10 % during first three days of urinary tract catheterization, followed by 29 % between 4- 7 days and 52 % between 7-14 days[3].

In a study conducted by Thibon, P. et al[65] observed that, the mean cumulative incidence of UTI related to catheterization was 11.1 %, 11.9 % in the group with classical catheter and 10 % in the group with hydrogel and silver salts coated catheter. The overall incidence density was 19 per thousand days of catheterization, 21 in the classical catheter and 18 per thousand days of catheterization in the other group. The differences between the two groups were not significant concluding that there is not enough number of studies to support the role of silver coated catheters in prevention of CAUTI.

URINE CULTURE

It was observed in our study that most common organism isolated was Escherichia Coli (27.6 % in study group, followed by Staphylococcus Aureus (23.4%), Pseudomonas Aeruginosa (17%), Klebsiella Pneumoniae (12 %), Candida Non-albicans (6.3 %), Citrobacter freundii (6.3 %) and Candida Albicans (2.1 %) respectively in decreasing frequency.

Whereas, most common organism isolated in control group was Escherichia Coli (33.3%), followed by Klebsiella Pneumoniae (21.7 %), Staphylococcus Aureus (18.8%), Pseudomonas Aeruginosa (7.2%), Citrobacter freundii (5.7 %), Enterococcus Saprophyticus (5.7%), Candida Non-albicans (4.3 %), and Proteus species in 2.8 % cases.

Overall the most common organisms isolated were Escherichia Coli, Staphylococcus Aureus, Klebsiella Pneumoniae, Pseudomonas Aeruginosa, Citrobacter freundii and Candida species in decreasing frequency.

In a study conducted by Sangamithra V et al[3] found that the most common organism isolated was Escherichia Coli, followed by Enterococcus Saprophyticus, Klebsiella species and Pseudomonas species in decreasing order of frequency. Whereas, Proteus species and Acinetobacter were found in 3-4 % cases.

In a study conducted by Thibon, P. et al revealed that, from 22 cases of infection there were 23 microbial isolates found; one patient was found to be infected with more than one type of microorganism. There was no significant difference between the types of organisms isolated with the two types of catheter[63].

SYMPTOMATIC CAUTI

In our study, it was observed that 10 % of the patients were symptomatic although they were found to be significantly positive for urine pus cells/ urine culture on urine analysis. They had presented with symptoms of fever/ chills, suprapubic pain, or change in urine character. Whereas, 13 % of the patients among 120 patients had symptomatic CAUTI. There was no reported case of complicated UTI or reaction to the silver oxide impregnated Foley's catheter in our study.

In a study conducted by Tambyah PA et al titled "Catheter-associated urinary tract infection is rarely symptomatic: a prospective study of 1,497 catheterized patients" found that, out of 235 new cases of nosocomial CAUTI during the study period, More than 90% of the infected patients were asymptomatic; In the subset analysis, there were no significant differences among patients with and without CAUTI in signs or symptoms commonly associated with urinary tract infection—fever, dysuria, urgency, or flank pain—or in leucocytosis[64].

8. CONCLUSION:

In our study, there was no statistical difference in distribution of patients between the study group and control group with respect to Age and Gender.

Urine examination for evidence of pus cells was found significantly low in the study group on the Day 7 or more (up to 14 days) of urinary tract catheterization with P value – **0.027**, whereas there was no difference on the incidence at the end of Day1 or Day3. Thus, we can infer from the above results that the Silver Oxide impregnated Foley's catheter was efficacious in reducing the occurrence of Catheter related urinary tract infections.

It was observed from our study that the Silver Oxide impregnation to plain Foleys catheter has the potential to prevent/reduce the incidence of catheter associated urinary tract infections in patients who need longer duration of catheterization for various reasons. It was also observed in our study that duration of study was a significant risk factor in predisposing a patient to infections.

9.SUMMARY:

Catheter Associated Urinary Tract Infection is the most prevalent form of Hospital Acquired Infections (HAI), causing significant morbidity and mortality. It leads to prolonged hospitalization and increased cost of treatment.

Our goal in undertaking this study was to assess and compare the efficacy of sliver impregnation over commercially available latex urinary catheters in prevention/ reduction of catheter related infections.

Period of the study was from November 2017 to May 2019, with a total sample size of 240.

Urine for pus cells was used as the end variable for diagnosing CAUTI and on comparing the values at the end of day 1 (48 hours after admission), on Day3, and Day seven or more, we observed that there was significant difference in the incidence of CAUTI between the study and the control group on the Day 7 or more.

There was no difference between the groups compared with respect to Age and Sex. The most common organism isolated in our study was Escherichia. Coli, followed by Staphylococcus Aureus, Klebsiella Pneumonia, Pseudomonas species, and others.

The incidence of symptomatic CAUTI was found to be between 10-13 % in our study.

Thus, we can conclude that the current research hypothesis of silver coated urinary catheters reducing risk of CAUTI holds good with a positive result on the incidence of CAUTI on Day 7 group with significant P- value of 0.0277, but there is a greater need for further studies on this topic as CAUTI is a potentially preventable condition.

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11. ANNEXURE I – ETHICAL CLEARANCE CERTIFICATE

12. ANNEXURE II – SAMPLE INFORMED CONSENT FORM:

TITLE OF THE PROJECT : **COMPARATIVE STUDY OF SILVER COATED URINARY CATHETER VS CONVENTIONAL LATEX CATHETER IN PREVENTION OF NOSOCOMIAL CATHETER ASSOCIATED URINARY TRACT INFECTION**

PURPOSE OF RESEARCH:

I have been informed that this study is conducted to compare and evaluate the efficacy of silver coated urinary catheter with conventional latex urinary catheter in prevention/ reduction of catheter associated urinary tract infection.

PROCEDURE:

I am aware that in addition to routine care received I will be asked series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

Patients who met the inclusion criteria were randomly assigned a Study group (Group A) or Control group (Group B).

RISK AND DISCOMFORTS:

I understand that I may experience some pain and discomforts during the examination or during my treatment. This is mainly the result of my condition and the procedures of this study are not expected to exaggerate these feelings which are associated with the usual course of treatment.

BENEFITS:

I understand that my participation in the study will help to predict to evaluate the efficacy of placement of drains in the thyroid surgeries and to compare it without placing drains.

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of hospital records and will be subject to the confidentiality. Information of sensitive personal nature will not be part of the medical record, but will be stored in the investigations research file.

If the data are used for publication in the medical literature or for teaching purpose, no name will be used and other identifiers such as photographs will be used only with special written permission. I understand that I may see the photograph before giving the permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study to **Dr. XXX** in the Department of General Surgery who will be available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice. I also understand that **Dr. XXX** may terminate my participation in the study after he has explained the reasons for doing so.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, the appropriate treatment would be available to me. But no further compensation would be provided by the hospital. I understand that by my agreements to participate in this study and not waiving any of my legal rights.

I have explained to _____the purpose of the research, the procedures required and the possible risks to the best of my ability.

_____ _____

Dr.XXX Date

(Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that **Dr. XXX** has explained to me the purpose of research, the study procedure, that I will undergo and the possible discomforts as well as benefits that I may experience in my own language. I have been explained all the above in detail in my own language and I understand the same. Therefore, I agree to give consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(Witness to signature) Date

13. ANNEXURE III – PROFORMA

SL NO

NAME

AGE IP NO

SEX UNIT

RELIGION DOA

OCCUPATION WARD

ADDRESS DOD

SOCIO-ECONOMIC STATUS

Complaints:

HISTORY OF PRESENT ILLNESS

SYSTEMIC SYMPTOMS

PAST HISTORY:

PERSONAL HISTORY:

GENERAL PHYSICAL EXAMINATION

BUILT: WELL/MODERATE/POOR

NOURISHMENT: WELL/MODERATE/POOR [BMI=]

PALLOR

ICTERUS

CYANOSIS

CLUBBING

PEDAL EDEMA

GENERAL LYMPHADENOPATHY

VITAL DATA:

TEMPERATURE:

PULSE

RESPIRATORY RATE

BLOOD PRESSURE:

SYSTEMIC EXAMINATION

PER ABDOMEN:

RESPIRATORY SYSTEM

CARDIOVASCULAR SYSTEM

CENTRAL NERVOUS SYSTEM

PER RECTAL EXAMINATION

CLINICAL DIAGNOSIS:

INDICATION FOR CATHETERISATION

TYPE OF CATHETER

LABORATORY TESTS

HB%

TOTAL COUNT

DIFFERENTIAL COUNT

N/L/E/B/M:

URINE ROUTINE:	DAY 1	DAY 3	DAY 7
Pus cells-			

URINE CULTURE AND SENSITIVITY:	DAY 1	DAY 3	DAY 7
Organisms isolated-			
Culture sensitivity pattern-			

DATE OF URINARY CATHETER REMOVAL

URINARY CATHETER TIP CULTURE AND SENSITIVITY

RBS

B. UREA

S. CREATININE

HIV

HBsAg

CHEST X RAY