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Title: A Scoping Review of Important Urinary Catheter Induced Complications

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Abstract:

This study presents a scoping review of the literature on the morbidity and mortality associated with several common complications of urinary catheterization. Data gathered from the open literature were analyzed graphically to gain insights into the most important urinary catheter induced complications. The results reveal that the most significant catheter complications are symptomatic bacterial infection, severe mechanical trauma (perforation, partial urethral damage and urinary leakage) and anaphylaxis, catheter toxicity and hypersensitivity. The data analysis also revealed that the complications with the highest morbidity are all closely related to the mechanical interaction of the catheter with the urethra. This suggests that there is a strong need for urinary catheter design to be improved to minimize mechanical interaction, especially mechanical damage to the urinary tract, and to enhance patient comfort. Several urinary catheter design directions have been proposed based on tribological principles. Among the key recommendations is that catheter manufacturers develop catheter coatings which are both hydrophilic and antibacterial, and which maintain their antibacterial patency for at least 90 days.

Keywords: *Urinary catheters, catheter induced complications, urinary catheter coatings, biomaterial applications in urology, indwelling catheters, mechanical interaction, mechanical trauma, morbidity rate, mortality rate, tribology, biotribology*

1 Introduction

Urinary catheters have been used to treat patients with urological problems such as urinary incontinence and retention since Greco-Roman times [1–4]. Today over 4 million patients undergo urinary catheterization in the United States [5] with more than 30 million urinary catheters inserted annually [6]. Currently there are three main types of urinary catheters which are commonly used in clinical settings: condom (i.e., external) catheters, indwelling (i.e., long-term; typically up to 90 days) catheters and intermittent (i.e., short or medium-term; typically between 14 to 30 days) catheters [7–8]. Condom catheters are most often used in elderly males with severe functional disabilities such as dementia or restricted mobility [4, 9]. Indwelling and intermittent catheters are indicated for use in patients with chronic urinary incontinence and retention, as well as in individuals who have undergone surgical operations or are suffering from conditions such as multiple sclerosis, enlarged prostate and spinal cord injury [7–8, 10–12]. Urinary catheters are also indicated for intermittent use for the measurement of bladder residual volume, obtaining uncontaminated urine for microscopy and culture, intravesical installation of drugs, urodynamic assessment and the treatment of acute urinary retention [7, 13–14].

Adult urinary catheters come in a wide range of sizes (between 10 - 24 Fr [7, 15–16]) and lengths (23-26cm, 30 cm and 40-45 cm [16]) which are chosen for a patient based on such factors as gender, age, clinical application (e.g., irrigation vs. drainage) and urinary tract health (e.g., debris, mucous, blood clots, may occlude small catheter lumens) [16]. There are also two main shapes of urethral catheter tips: Foley (i.e., straight tip) and Coudé (i.e., elbowed tip; also referred to as a Tiemann tip) [17]. Urinary catheters are made from many different biomaterials which often have surface coatings to enhance their biocompatibility, functionality (e.g., friction reduction) and resistance to bacterial infection. Among the most widely used biomaterials are C-flex®, latex, nylon, percuflex®, polyethylene, polyvinylchloride (PVC), polyurethane, silicone, silitek®, tecoflex®, teflon® (polytetrafluoroethylene or PTFE), silver, and stainless steel [15–16, 18–20]). Several different material coatings may be also applied to the surface of urinary catheters to improve their biocompatibility and minimize bacterial infection. These include coatings containing antibiotic liposome (ciprofloxacin liposome) hydrogel, cephalothin, chlorhexidine, ciprofloxacin (also called ciprofluoxacin); dibekacin, gendine (an antiseptic coating containing Gentian Violet and chlorhexidinehydrogel), gentamicin sulphate, halofuginone, kanamycin, minocycline, nitric oxide, nitrofuroxone (also called nitrofurazone), polymixin, rifampicin, silicone elastomer, silver hydrogel, silver oxide, silver alloy, silver sulfadiazine, teflon® coatings and triclosan [15–16,18,21–36].

In spite of the ubiquity of urinary catheters several complications arise from their use which often limits their clinical effectiveness. Among the most common urinary catheter complications are: anaphylaxis (allergic reaction to latex), cytotoxicity and hypersensitivity [37–40], symptomatic bacterial infection [19,41–51], catheter blockage (due to calculi and encrustations) [52–60], catheter fracture and malignancy [61], hematuria (blood in urine) [52,59, 62–64], intravesical knotting [4, 65–67], inflammation (due to pyelonephritis and epididymitis) [44,56,58-59,62,68], erosion and periurethral abscess [56, 59, 62], mechanical trauma (partial damage, perforation and urinary leakage) [11–12, 52, 55, 69–73], urethral fistulae [59, 62], urethral stenosis and stricture [56, 62, 72], and urosepsis [62–63, 74–76]. While several studies have investigated the morbidity and mortality associated with urinary catheters [52, 62], to date no comprehensive review has been performed which has focused specifically on identifying and analyzing important complications caused or exacerbated by the mechanical interaction (i.e., physical contact) between the catheter and urinary tract.

The aim of this paper is therefore to investigate and identify the most important catheter induced complications associated with urinary catheterization by performing a scoping review of the literature. In addition, using the insights gained from this analysis, recommendations will be made for engineering and design improvements to urinary catheters which are aimed at reducing the morbidity (i.e., prevalence) and mortality associated with urinary catheterization. This study has been undertaken as part of the European Union Framework Programme 7 project, Understanding Interactions of Human Tissue with Medical Devices (UNITISS, FP7-PEOPLE-2011-IAPP / 286174). UNITISS focuses on catheterization procedures involving acute (< 24 hours) to more sustained (< 30 days) usage, where the catheters are inserted into blood vessels and the urinary tract. Among the main objectives of the UNITISS project is the development of device design guidelines, including the use of improved materials and coatings that minimize complications such as patient discomfort, irritation, inflammation, infection and tissue damage. This is vital in order to meet the needs of today's healthcare industry as well as social expectations.

2 Materials and methods

2.1 Methodology

A scoping review of the literature on adult urinary catheterization complications was performed using several online search engines and databases including “Google,” “Pubmed,” “MEDLINE,” “Wiley Online Library” and “ScienceDirect.” Emphasis was placed on recent papers (i.e., published within the last 25 years) which quantitatively report morbidity and mortality data from randomized controlled trials, cohort and case-controlled studies, individual case reports, meta-analyses and previous reviews. In particular, this study has focused on bibliographic references which provided information and insight into complications caused by the mechanical damage (i.e., urethral erosion, friction, inflammation, perforation and partial damage) of catheters with the urinary tract, as well as studies which report important co-morbidities and risk factors such as advanced age, diabetes mellitus, gender, immobility, institutionalization, length of hospitalization, recurrent urinary tract infections and spinal cord injury [14, 77–78].

The literature review excluded studies on pediatric and neonatal urinary catheterization since the morbidity and mortality rates of complications in infants are significantly different from adults. It also important to note that clinician error could not be accounted for in the current study, since this information is not reported widely in the literature and may be difficult to interpret due to variations in clinical practice. In addition, in cases in which studies report different (morbidity and mortality) statistics associated with the same complication, a data range has been specified.

For simplicity and to facilitate data management, closely or semi-related complications were grouped under a single complication heading. For example, perforation, partial urethral damage and urinary leakage were all classified as forms of severe mechanical trauma to the urethra. Similarly, anaphylaxis (allergic reaction to latex), cytotoxicity and hypersensitivity have been grouped together. It is also important to note here the definition of symptomatic bacterial infection, and in particular catheter associated urinary tract infection (CAUTI), which is used in the current study. A CAUTI occurs when there is a systemic or local response to a bacterial agent associated with the urinary catheter which triggers edema (i.e., swelling), erythema (inflammation), pain or fever.

2.2 Data Analysis

The morbidity and mortality data extracted from the literature were input into Microsoft Excel (Redmond, WA) for analysis. In the current paper the morbidity rate is defined as the percentage of patients in a given sample population who have experienced a specific complication during urinary catheterization; while the mortality rate is defined as the percentage of patients in a given sample population who have died after experiencing a specific catheterization related complication. To gain insight into the relative importance of each complication the morbidity and mortality data were plotted graphically. For each complication the highest morbidity and mortality rate has been plotted, in order to present the worst-case scenario. In general this was not found to have a significant effect on the results obtained since most studies report data that are fairly consistent. The data were also analyzed to differentiate between complications which are directly related to mechanical interaction or trauma between the urethra and the catheter and those which are indirectly related. This distinction was made by carefully considering the causes of each complication with respect to the influence of urinary catheter biomaterial interaction, friction, geometry and stiffness.

3 Results

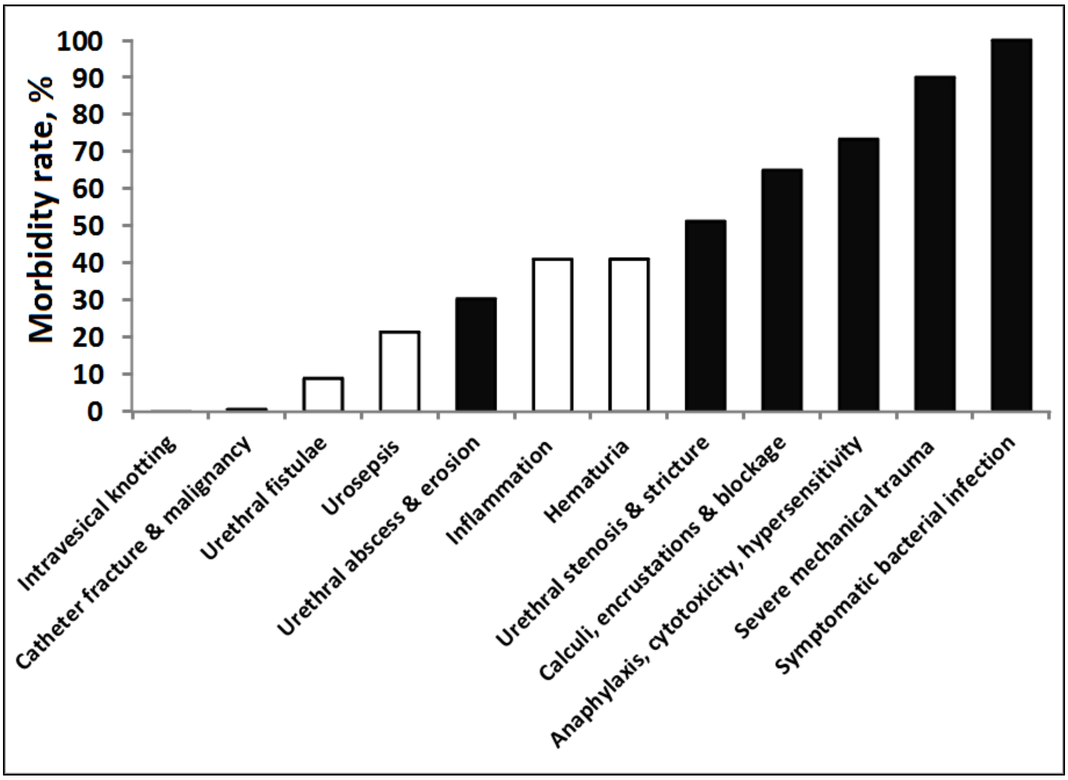

Fig. 1 Morbidity rate (%) of common complications arising from urinary catheterization procedures. Filled and unfilled bars indicate complications which are directly related and indirectly related to mechanical interaction or trauma between the urethra and the urinary catheter, respectively.

Figure 1 is a plot showing the morbidity rate (%) associated with the occurrence of twelve common urinary catheterization complications. The filled and unfilled bars correspond to the complications which are directly related and indirectly related to mechanical trauma or interaction associated with urinary catheterization, respectively. The figure shows that the most common urinary catheterization complications are symptomatic bacterial infection (100%), severe mechanical trauma (90%) and anaphylaxis, cytotoxicity and hypersensitivity (80%). The least morbid complications are intravesical knotting (0.0002%), catheter fracture and malignancy (0.6%) and urethral fistulae (8.9%).

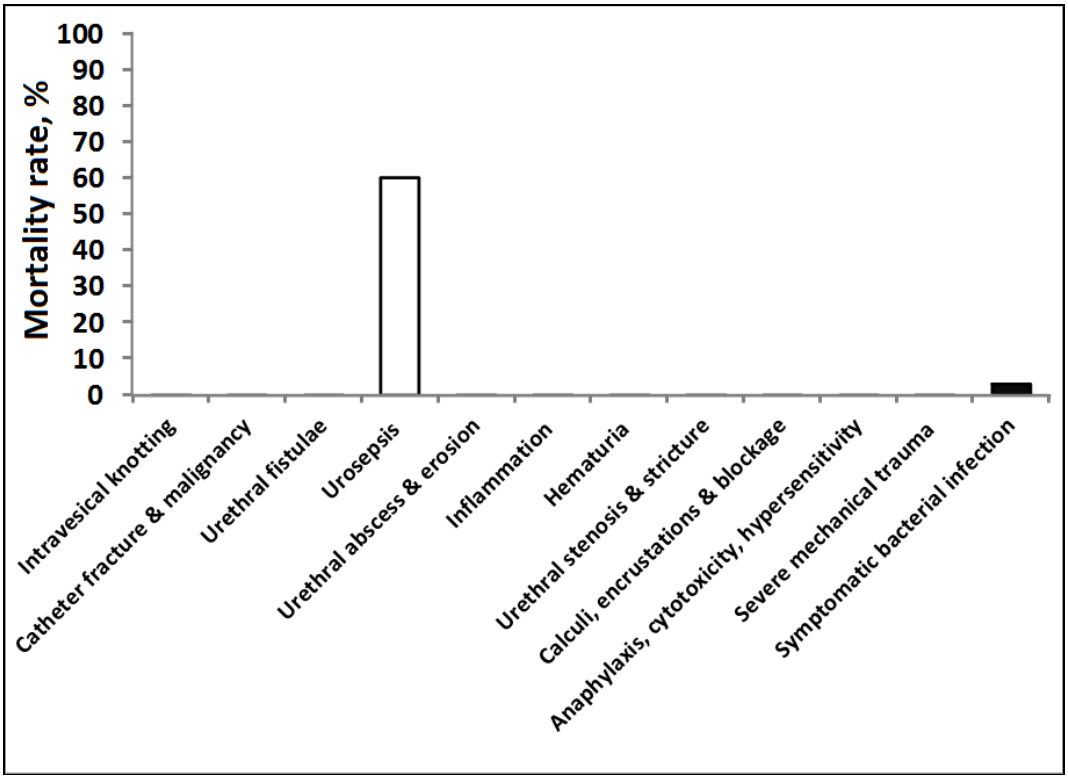

Fig. 2 Mortality rate (%) of major complications arising from urinary catheterization procedures. Filled and unfilled bars indicate complications which are directly related and indirectly related to mechanical interaction and trauma between the urethra and the urinary catheter, respectively.

Figure 2 is a plot showing the mortality rate (%) associated with the occurrence of twelve common urinary catheterization complications. The filled and unfilled bars correspond to the complications which are directly related and indirectly related to mechanical trauma and interaction associated with urinary catheterization, respectively. The most fatal urinary catheterization complications are urosepsis (60%) and symptomatic bacterial infection (3.1%).

Table 1 Summary of urinary catheter complication morbidity and mortality rates.

Complication(s)	Study population(s)	Cause(s)	Morbidity Rate (%)	Mortality Rate (%)	Reference(s)
Intravesical knotting	Pediatric male patients	Clinician error	0.0002	0	[4, 65–67]
Catheter fracture & malignancy	Adult male and female patients	Mechanical weakness of catheter	0.6	0	[61]
Urethral fistulae	Male patients with spinal cord injuries	Injury to the urethra	2.0-8.9	0	[59, 62]
Urosepsis	Adult male patients with spinal cord injuries [62]; Adult male and female patients of all ages [63, 74–76]	Derivative complication of a CAUTI	15.8-21.4	25.0-60.0	[62–63, 74–76]
Urethral abscess & erosion	Adult male patients with spinal cord injuries	Catheter impingement on the urethra leading to urethral necrosis [79]	7.0-30.4	0	[56, 59, 62]
Inflammation (pyelonephritis & epididymytis)	Adult male patients with spinal cord injuries [56, 58–59, 62]; Adult male and female patients of all ages [44, 68]	Derivative complication of a CAUTI;	10.0-41.0	0	[44, 56, 58–59, 62, 68]
Hematuria	Adult male patients with spinal cord injuries [59, 62]; Adult male and female patients of all ages [52, 63–64]	Derivative complication of a CAUTI	14.1-41.1	0	[52, 59, 62–64]
Urethral stenosis & stricture	Male patients with spinal cord injuries [56, 62]; Male and female patients with bladder injuries [72]	Injury to the urethra	23.0-51.2	0	[56, 62, 72]
Calculi, encrustations & blockage	Adult male patients with spinal cord injuries [54–56, 58–59] Adult male and female patients of all ages [52, 53, 57, 60]	Precipitation of calcium phosphate on catheter surface; derivative complication of a CAUTI [79]	20.0-65.0	0	[52-60]
Anaphylaxis, cytotoxicity and hypersensitivity	Adult male patients with spinal cord injuries [37–38]; Adult male and female patients of all ages [39–40]	Physical contact between catheter surface and the urethra	18.0-80.0	0	[37–40]
Severe mechanical trauma (partial damage, perforation and	Adult male patients with spinal cord injuries [12, 55]; Adult male and female patients of	Friction between catheter surface and the urethra	19.0-90.0	0	[11–12, 52, 55, 69-73]

urinary leakage)	all ages [11, 52, 69-72]; Elderly adult male and female patients [73]				
Symptomatic bacterial infection (CAUTI)	Adult male and female patients of all ages [19, 41–42, 44, 49–51, 57]; Elderly adult male and female patients [43, 45–48]	Introduction of uropathogens into the urinary tract via the catheter surface [80]; bacterial adherence to catheter surface leading to biofilm formation [80–81]; injury to the protective uroepithelial mucosa creating new bacterial binding sites [82–83].	90.0-100.0[a]	3.1 (21.0[b])	[19, 41–51, 57]

[a] For indwelling catheters after 30 days.
[b] Klevens et al. (2007) [48] report a 21.0% mortality rate in elderly patients only.

4 Discussion

The morbidity data presented in Fig. 1 and Table 1 provide many valuable insights into urinary catheter complications and how they are related to various aspects of catheter design (i.e., material composition, coatings, catheter shape and physical properties). In particular, Fig. 1 highlights the fact that, including symptomatic bacterial infection, the five most common urinary catheter complications (with > 45% morbidity) are caused by the mechanical interaction (i.e., physical contact) between the catheter and the urethra. This is important since it emphasizes the key role that catheter design plays in the occurrence and aggravation of complications during urinary catheterization. Moreover, the figure reveals that severe mechanical trauma (i.e., partial damage, perforation and urinary leakage), which is strongly correlated with patient discomfort and increased risk factors for other urinary complications, occurs in as many as 90% of urinary catheterization procedures. This is consistent with expectation since catheter insertion into the urethra involves the generation of friction between the catheter and the urethra, which can lead to the application of excessive forces that can injure the urinary tract. Furthermore, other mechanically related damage including urethral stenosis and stricture, as well as urethral abscess and erosion occur very frequently (in more than 30% of catheterization procedures). Taken together this suggests that there is a strong need for urinary catheter design to be improved to minimize mechanical damage to the urinary tract and to enhance patient comfort.

It is also imperative to discuss the high morbidity (100% after 30 days) of symptomatic bacterial infection during urinary catheterization. Several complications with high morbidity rates (>40%), including inflammation (due to pyelonephritis and epididymytis), catheter blockage (due to calculi and encrustations), as well as urosepsis are also derived from catheter associated urinary tract infections (CAUTIs). This finding highlights not only the ubiquity of urinary catheter associated bacterial infection, but also the indirect, yet significant role played by mechanical (tribological) interactions (which contribute to the initiation of CAUTIs), in the morbidity of several common urinary catheter complications. Although considerable research effort has been applied over the past 30 years towards reducing CAUTIs during long term catheterization by the application of antibacterial catheter coatings, this finding underscores the need for further research to be undertaken to develop catheter coatings which can maintain their patency for extended periods of time (>30 days). Urinary catheters with enhanced bacterial resistance would greatly reduce the morbidity (i.e., prevalence) associated with CAUTIS as well as several other derivative complications such as urosepsis.

Consideration of Figure 2 indicates that most urinary catheter complications are non-fatal. This is consistent with expectation since mortality is generally not considered a major risk from urinary catheterization except in elderly patient populations [43]. It is therefore, very striking to note the very high mortality rate (25-60%) reported for patients suffering from urosepsis; which is a complication that is aggravated by the mechanical interaction between the urethra and the urinary catheter [83]. However, this high mortality rate can be explained by the fact that urospesis is a systemic inflammatory response to a urinary tract infection that has spread to the bloodstream [84]. It is therefore a derivative complication of an initial CAUTI. Since CAUTIs, have a morbidity of 100% (after 30 days), it can be inferred that if the prevalence of CAUTIs is reduced through improved catheter design (in particular enhanced antibacterial coatings) and better clinical management, this will likely also significantly reduce the morbidity and overall mortality rate (i.e., the morbidity multiplied by the mortality rate) of urosepsis.

From tribology principles it is known that mechanical (i.e., friction) forces govern the friction behavior and damage occurring on surfaces. Depending on the tribological system in question, different friction mechanisms can be active, such as mechanical ploughing, adhesion, deformation (hysteresis) and (elasto-) hydrodynamic friction [85]. Under non-hydrodynamic lubrication conditions, with relatively smooth surfaces sliding against very soft surfaces that are capable of significant deformation at the micro-scale, adhesion friction dominates. This is known to be the case with human skin friction [86–87], and it is reasonable to assume that it will also be the case with the catheter-urethra contact, where the conditions are unlikely to be such that hydrodynamic lubrication occurs. Thus, reducing the adhesion friction between the catheter surface and the relatively soft urethral tissue may help to reduce tissue damage and discomfort caused during catheter insertion and removal.

The adhesion friction force, $F_{f(adh)}$, is given by:

$$F_{f(adh)} = \tau_i \cdot A_R \tag{1}$$

where τ_i is the Interfacial shear strength ($N.m^{-2}$), i.e. shear strength of the interface between the two surfaces; A_R is the real area of contact (m^2), i.e., the sum of individual contact areas at all physical points of contact between the two surfaces.

Consideration of Eq. (1) clearly shows that by reducing either τ_i or AR or both will result in a lower adhesion friction force.

Reduction of the interfacial shear strength can be achieved through the use of coatings that provide a lubricating effect. Hydrophilic coatings are typically applied for this purpose in catheters. Such coatings interact with water to produce gel-like substances, providing a smooth semi-solid surface that is easily sheared. If this shearing occurs within the coating, it will necessarily lead to displacement and wearing of the coating material, which raises durability issues.

Reduction of the real area of contact could in principle be achieved by applying an appropriate surface topography or texture to the catheter surface. The catheter surface should be such that the degree of deformation of the human tissue surface is not sufficient to result in full conformity, under all usage conditions. However, care should be taken here to design the applied surface topography or texture so that it does not result in higher friction through the ploughing mechanism and increased tissue damage through abrasion.

Based on the above and the results as well as insights gained from Figures 1 and 2 the following recommendations can be made as generic design directions to improve long and short-term urinary catheters, especially with regards to reducing the detrimental effects of mechanical interaction between the catheter and the urinary tract:

• A durable, lubricious, hydrophilic and antibacterial coating should be applied to the surface of urinary catheters, to reduce the likelihood of severe urethral trauma by improving the ease of insertion of the catheter into the urethra. Hydrophilic coatings capable of being combined with antibacterial agents are currently under development [88], and have become commercially available in recent years [89–91]. Studies have shown that the use of low friction, hydrophilic-coated urinary catheters reduces the incidence of urethral strictures and fistulae [92]. However, challenges still remain with regard to durability, since these coatings have been shown to wear away with repeated use and also to become sticky if inserted over extended periods of time [93].

• Catheter coatings should be designed to maintain 95% of their antibacterial patency over a period of at least 90 days (i.e., spanning the maximum duration of long term catheterization). This will reduce the frequency of CAUTIs which will in turn diminish the likelihood of severe complications such as urosepsis. Slow release antibacterial coatings show potential in this regard [94–95], however, problems associated with the development of drug resistant bacteria still need to be overcome [35, 96].

• Manufacturers should eliminate the use of latex and any other anaphylactic or irritating materials in the fabrication of urinary catheters in order to eradicate the problem of hypersensitivity and anaphylaxis during urinary catheterization. This can be achieved by fabricating catheters from materials such as silicone (polydimethylsiloxane), aromatic polyurethane and Teflon (polytetrafluoroethylene). This can also be achieved by applying silicone and silver-hydrogel coatings to catheters. These coatings have been clinically shown to cause less irritation [40, 72, 97]. However, some challenges remain since silicone catheters, for instance, are known to suffer from more rapid fluid loss than other types of catheters which increases the risk that the catheter is dislodged after insertion [98].

• Catheter manufacturers should explore the use of slow release anti-inflammatory coatings (in combination with antibacterial agents, lubricious behavior and hydrophilic properties) which can suppress a patient's inflammation response during long term catheterization and enhance patient comfort.

• Urinary catheters should be designed to reduce the contact surface area (A_R) between the catheter and the urethra which may help to reduce discomfort caused by friction during insertion of the urinary catheter. This can be achieved through the development of novel surface geometries which minimize the contact area between the urethra and the catheter, while also maintaining appropriate draining and flushing performance.

5 Conclusions

Based on the review of the literature on the morbidity and mortality rates associated with several common complications of urinary catheterization it was determined that the most significant complications are symptomatic bacterial infection, severe mechanical trauma (perforation, partial urethral damage and urinary leakage) and anaphylaxis, catheter toxicity and hypersensitivity. In addition, it was found that the complications with the highest morbidity (with a morbidity of > 45%) are all strongly influenced and aggravated by the mechanical interaction of the catheter with the urethra. This suggests that there is a strong need for urinary catheter design to be improved to minimize mechanical interaction with the urethra, particularly mechanical damage to the urinary tract, and to enhance patient comfort. Several generic urinary catheter design directions have been proposed based on the insights gained from the data analysis and on tribological principles. Among the key recommendations is that catheter manufacturers utilize catheter coatings which are both hydrophilic and antibacterial, and which maintain their antibacterial patency for at least 90 days.

Abbreviations

CAUTI = catheter associated urinary tract infection

Fr = French gauge

PVC = polyvinylchloride

PTFE = polytetrafluoroethylene

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