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Review

REVIEW ON COMPLICATIONS AND ADVERSE EFFECTS OF METALLIC URINARY STENTS

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SUMMARY – Urinary stents, be it urethral or ureteral, polymeric, metallic or biodegradable, are one of the most frequently used tools in urology and they have been used for decades in prophylactic and therapeutic setting. Although relatively low invasive, they are prone to complications and adverse effects so much that complication rates up to 100% have been described. Many reviews have focused either on specific groups of patients or particular stent types, materials or designs but so far, no comprehensive review on complications has been published. To tackle this issue, a working group was set up within ENIUS (European Network of multidisciplinary research to Improve Urinary Stents) tasked with literature search in order to screen for and systematically review published stent complications in urethra (male only) and ureters (polymeric and metallic ureteral stents in both sexes) when used in obstructed systems. In this paper, we review, catalogue and summarize complications published for metallic urethral and ureteral stents.

Key words: *Complications; Metal; Alloy; Metallic; Stent; Urethral; Ureteric; Ureteral; Urinary; Review*

Introduction

In order to function properly, free flow of urine from kidneys through ureters into urinary bladder and out through urethra should be secured. Impaired drainage through ureters can cause hydronephrosis and excessive intrarenal pressure, which leads to cortical thinning and subsequent loss of function. Ureteral obstruction can be described as internal or external, and can be caused by malignant or benign disease, or due to previous radiotherapy. Obstructed renal units can be unblocked by means of ureteral stent (internal) or nephrostomy (external) to secure uninterrupted urinary drainage. Outflow from the bladder can also be obstructed by benign or malignant conditions which can impact the quality of life by lower urinary tract symptoms (LUTS) and, if left untreated, cause kidney damage with loss of function.

Urinary stents can be utilized in several clinical scenarios and we will divide them to prophylactic and therapeutic use.

Prophylactic Use – Stone Interventional Treatments

Ureteric stent is often placed prior to or after extracorporeal shock wave lithotripsy or ureteroscopy to secure free urine outflow minimizing the risks of obstruction from residual stone fragments, blood clots or edema[1].

Prophylactic Use – Renal Transplantation

Stenting transplanted kidney decreases anasto-

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motic leakage, which therefore aids in prevention of stricture formation[2]. Lower overall complication rates for stented anastomosis were demonstrated in a meta-analysis of 5 randomized controlled trials[3].

Prophylactic Use – Upper Urinary Tract Reconstructions

The idea behind stenting after endopyelotomy, pyeloplasty, pyelolithotomies and repairs due to ureteric trauma or strictures is to aid in healing by preventing leakage and urinoma formation, as well as functioning as a scaffold[4,5].

Prophylactic Use – Non-Urologic Procedures with Ureteral Mobilization

It is widely shown that prophylactic ureteric stenting prior to some abdominal and gynecologic procedures reduces the risk of ureteric injury, while aiding in ureter visualization and identification during dissection[6-8].

Therapeutic Indications – Decompression of an Obstructed Collecting System

Ureteric stenting and percutaneous nephrostomy remain the gold standards for decompression and this indication is the most frequent one. To date, no definitive data on superiority of one approach over another have been demonstrated[9-11].

Therapeutic Indications – Conservative Management of Upper Urinary Tract Trauma

Many traumatic injuries to upper urinary tract can be managed conservatively by stenting depending on damage severity. In that scenario, JJ stents reduce urinary leakage and urinoma formation, secure patency and decrease the risk of stricture[12,13].

Therapeutic Indications – Enlarged Prostate and Urethral Strictures

Enlarged prostate due to benign prostatic hyperplasia (BPH) is the major cause of compression to prostatic urethra, even though prostate cancer can also be a potential cause. Estimated 105 million men worldwide could be affected by BPH, which typically develops in their 40s with close to 50% of males aged 50 and above being affected and 90% in their 80s[14,15]. A major cause of obstruction in penile and bulbar urethra is stricture disease with fibrosis occurring in 1% of males over 55[16].

A wide list of indications for use of urinary stents inevitably leads to a variated spectrum of complications and adverse effects some of which are due to stent material or coating or inherent to stent design, patient characteristics or related to pathophysiology of disease.

In order to help the quest for 'perfect stent', a multidisciplinary working group was established within the European Cooperation in Science and Technology (COST) Action 16217, named European Network of multidisciplinary research to Improve Urinary Stents (ENIUS), to research the causes of stent complications and failure rates. Their task was literature search to screen for and systematically review published stent complications in order to create a starting point for other working groups and researchers with data on stent failure rates, complications and culprits of commonly available stents[17]. In order to do such mammoth task, the working group was functionally split into three subgroups led by one of the authors (PDG for male urethral stents, FS for polymeric ureteral stents, and DR for metallic ureteral stents). Results from two subgroups dealing with metallic stents are presented here.

Methods

Literature search

For male urethra search string [[[[urethra] OR urethral]] AND [[[[stent] OR endoprosthesis] OR endoprosthesis] OR stents]] was used in Embase and PubMed in March 2020. For metallic ureteral stents search string [[[[[ureter] OR ureteric] OR ureteral]] AND [[[[stent] OR endoprothesis] OR endoprosthesis] OR stents]] AND [[[[metal] OR metallic] OR metallic] OR alloy] was conducted on PubMed database only in March 2020. Results were then limited to prospective, retrospective and comparative studies, case reports and case series limited to English language only.

Study selection

Papers retrieved from PubMed (and Embase where used) were then imported in Rayyan interface (https://rayyan.qcri.org/) and duplicates removed. Three authors or contributors screened titles and abstracts independently. Inclusion differences were then solved by a series of discussions (with the rule two out of three in favor to accept) followed by independent full-text reading by the same authors/contributors to retrieve

data. Exclusion criteria were non-original papers (no full text available, comments, etc.), pre-clinical studies, animal and *in vitro* studies, and articles dealing with non-intended use of stents or splints (e.g., after genitourinary reconstructive surgery). Our endpoints included the causes of stent failure (compression, migration, infection, restricture, etc.) and rates of published complications *per* number of stents used; therefore, only papers reporting complications or adverse effects were included.

Results

For urethral stents, 1551 publications matched the search criteria and two authors independently screened titles and abstracts resulting in 412 acceptable papers which were retrieved and read by the same authors. Only 118 were subsequently included in the database but only 21 papers actually reported on stent complications or adverse effects with 399 patients in total suffering 366 complications[18-37].

Regardless of the metallic stent used (Wallstent, Urolume, Prostakat, Urospiral, Memotherm, Urospiral), most commonly they exhibited obstructive (207 cases, 56.6% of all complications) and irritative (83 cases, 22.7% of all complications) symptoms. Most documented obstructive scenarios included fibrous stenosis or obstruction in 103 cases, recurrent stricture in another part of urethra in 81 cases, retention in 20 patients, panurethral stricture in two patients, and one candida obstruction. Irritative symptoms were mostly in the form of LUTS in 49 patients, perineal discomfort in 19 patients, incontinence in seven, bleeding in five, and sexual dysfunction in three patients. Other complications were mainly infections (41 cases, 11%), encrustations (19 cases, 5%), migration (14 cases, 4%), and two bizarre complications, one case of transitional cell carcinoma of the urethra after >10 years of successful stenting and urethral stripping in one patient during endoscopic stent removal due to recurrent obstruction.

For metallic ureteric stents, we identified 319 publications with 111 acceptable papers which (after reading) led to 88 papers included in final analysis. That accounts for 2394 stents placed in 2194 ureters in 1749 patients with documented 1188 complications[38-130].

Twenty-nine papers have reported complications with the use of 457 (mostly vascular or biliary) bare metal stents in 345 patients (98 stents for benign conditions in 87 patients and 359 stents in 258 patients with malignant disease) resulting in 277 reported complications. That translates to 4 out of 5 patients being at risk of complication or 60% complication risk *per* stent used.

Our dataset included 5 papers with data on the use of covered metallic stents (two with Passager stents manufactured by Boston Scientific from the USA, one for ePTFE covered nitinol stent developed by Hemobahn Endoprosthesis and W. L. Gore and Associates from the USA, another on Dacron covered nitinol mesh stent from Stanford Nanture from

France and one using polyurethane tube reinforced with metal wire by Heidelberg University and Mannheim hospital in Germany). Sixty-nine complications were documented with 86 stents in 72 patients (56 stents in 49 patients with malignant disease and 30 stents in 23 patients with benign conditions).

In 707 patients with malignant (n=462) and benign (n=245) condition, Resonance™ stent was used on 1085 occasions in 944 ureter units (621 for malignant and 323 benign disease) with 449 complications recorded.

Another 21 studies reported a total of 230 complications with the use of Memokath 051™ stent in 469 episodes (214 for malignant and 255 benign disease) in 423 patients (188 and 235, respectively).

There was only one identified paper reporting complications after the use of three Allium stents (Allium™ Medical, Caesarea, Israel) in two patients with one obstructed stent. There were 163 complications on UventaTM stents (Taewoong Medical, Seoul, Korea) identified in ten articles including 238 stents used in 202 patients, of whom 158 had malignant and 44 benign conditions.

Discussion

Initially, prostatic and urethral stents were welcomed with hope to provide patients with yet another, possibly even more convenient option compared to reconstructive surgery. Unfortunately, over time, they have failed to provide sustained relief for most of the patients and all of their potential benefits were lost soon. Surprisingly, only 21 out of 118 papers on urethral stenting met our inclusion criteria and had sufficient data regarding complication reporting, which in turn demonstrates poor reporting on complications. The most frequently used urethral stent in our dataset was UroLume. Of course, over time, attempts to improve tolerability, patency, efficacy, etc., have been made

by changes in materials and design, however, however, to date it has not been translated to their longevity. Still, the most commonly encountered complications include migration, patient reported discomfort, rate of infections and encrustrations, and epithelial hyperplasia[131]. Therefore, open urethral reconstruction still remains the gold standard for failed urethrotomies, urethroplasties and post-traumatic strictures[132]. This should not discourage future research for better (maybe biodegradable) stents and cellular or acellular scaffolds because there will always be patients unfit for major open surgery[133].

The authors are aware of the likely publication bias secondary to inclusion criteria, difference and lack of standardization in complication reporting, as well as the usually short follow ups, and all these must have also led to the inability to produce quantitative report.

In contrast to scarce data on urethral stents, much more complications have been recorded with the use of metallic ureteral stents. Based on our comparison, the purpose-built metallic ureteral stents clearly outperform all other bare metal or covered off-label (mostly biliary or vascular) prostheses used in the ureters. Still, they carry approximately 50% risk of complications and 2.6% were severe on Clavien-Dindo scale[134].

The question which metallic ureteral stent is better is hard to answer, as it depends on disease characteristics, patient demographics and their expectations, local availability and financial reimbursement, provider (urologist or interventional radiologist) experience or preference, and many more[135]. Wide variations in complications mostly come from stent design and materials used. Despite their cost, poor availability in some areas and high rates of complications, metallic ureteral stents still represent a valuable tool, especially for palliative patients with short life expectancy, those unwilling or unfit for major surgery, and as a salvage option. All of these should motivate further research seeking improvement. Problems with adequate complication reporting (especially using standardized tools) were evident in this subgroup as well and should be addressed in future publications.

Stemming from this research, the need of adequately powered, prospective, multi-institutional, randomized controlled trials is identified. It should be designed as a comparative, head to head study of available metallic ureteral stents with long enough (at least 12 months) follow up. Patients should be stratified according to disease cause in at least three groups (malignancy, benign conditions, postradiotherapy). That type of study should provide us with high quality data on stent adverse effects and complication and failure rates and causes. Patients receiving metallic ureteral stents should have close follow up due to high failure and complication rates, as well as burdensome symptoms.

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Sažetak

PREGLED KOMPLIKACIJA I NEŽELJENIH DOGAĐAJA METALNIH URINARNIH STENTOVA

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Urinarni stentovi, bilo uretralni ili ureteralni, polimerni, metalni ili biorazgradivi, jedan su od najčešće korištenih alata u urologiji i u primjeni su već desetljećima u profilaksi ili kao terapija. Iako su minimalno invazivni, česte su komplikacije i neželjeni učinci do te mjere da su u nekim studijama stope komplikacija do 100%. Mnogi pregledni radovi su orijentirani na specifičnu skupinu bolesnika ili određeni tip, materijal ili dizajn stenta, ali dosad nije objavljen pregledni rad o komplikacijama upotrebe stentova. Stoga je oformljena radna skupina unutar grupe ENIUS (*European Network of multidisciplinary research to Improve Urinary Stents*) sa zadatkom probira literature i sistematskog pregleda objavljenih komplikacija stentova u muškoj uretri te polimernih i metalnih ureteralnih stentova (kod oba spola) korištenih kod opstrukcije. U ovom radu iznosimo pregled objavljenih komplikacija u katalogiziranom i sažetom obliku za metalne uretralne i ureteralne stentove.

Ključne riječi: *Komplikacije; Metal; Legura; Metalni; Stent; Uretralni; Ureteralni; Mokraćni; Pregledni rad*