Urethral Stents. Indications, Complications and Adverse Effects

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1 Introduction

Urine produced in kidneys should freely flow out through the ureters, bladder and urethra. Bladder outlet obstruction [BOO] by benign or malignant processes leads to Lower urinary tract symptoms [LUTS], reduced quality of life, and if left untreated it may damage kidneys and lead to loss of kidney function. BOO in the urethra is more prevalent in males compared to females, as the male urethra is much longer and can be caused by several conditions at different anatomical locations.

In this review we focus on the entire male urethra. Since no stents are used in female urethral obstructions, they will be excluded from this review [1].

At the prostatic urethra, the major cause for BOO is benign prostatic hyperplasia [BPH]. About 105 million men are affected globally of BPH [2]. Development of BPH typically begins after the age of 40, around half of males aged 50 and over are affected [3] with the majority [~90%] of males affected after the age of 80 [3]. Prostate cancer can also lead to BOO. More distal in the urethra, the major cause of

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obstruction is strictures of the urethra. Urethral strictures due to fibrosis occur in approximately 1% of the male population over 55 years of age [4].

2 Brief History of Lower Urinary Stents

The 1980s can be seen as the decade of various stent inventions in medicine, especially for use in vascular occlusions but also for prostatic obstructions. These stents were either self expandable or balloon expandable stents [5]. The use of urethral stents starts in 1980 with the introduction of the “partial catheter”/‘urological spiral’ invented by Fabian [6]. This was a 21F stainless steel coil for inserting into the occluded prostatic urethra, instead of an indwelling catheter. For reducing the risk of stone formation on the stainless steel, in 1987 a group in Denmark gold-plated the ‘urological spiral’ and named it Prostakath [7]. Since then, a variety of metals and biostable and biodegradable polymers have been used to produce temporary or permanent stents for the management of infravesical obstructions such as benign or malignant prostatic enlargement, bladder neck stenoses, urethro-vesical anastomotic stenoses or urethral strictures. Some stents originally developed for vascular use were also adapted for use along the urethra. Examples are: The balloon expandable Palmaz Stent [only for the prostatic urethra], the self-expanding Memotherm and the Urolume which was an adaptation of the vascular Wallstent. The Wallstent was developed by Hans Wallsten as a vascular stent and later adapted to urological use under the name Urolume Wallstent [8]. The design of this stent was based on a wire braiding technology similar to the “Chinese finger trap”; an old Chinese trick in which one can insert a finger that is trapped when the finger is retracted. This braiding technology allowed the stent to self-expand and apply radial force to the surrounding tissues. The Urolume Wallstent became a very popular stent for urethral stricture. Despite the initial enthusiasm for the use of permanent stents in recurrent urethra strictures, on longer follow up they could not prove themselves as a good alternative to urethroplasty and now they are used only in selected, frail, poor surgical risk patients.

The other self-expanding stent, the Memotherm was made of a nickel titanium alloy (nitinol) wire knitted to form a tube. This thermo-sensitive stent expanded to its maximal caliber at body temperature [9]. This stent also lost its initial enthousiasm for the same Reasons as the Urolume Wallstent.

The ProstaCoil, a large caliber (24/30F), nitinol made self-expanding temporary prostatic stent was based on the UroCoil which was developed for use in frequently recurring urethral strictures [10].

Almost at the same time different polymer made stents started to appear: The polyurethane made small caliber [16F] prostatic stent named ‘intra-urethral catheter—IUC’ [11], a similar 16F Barnes stent [12], the larger caliber silicone made Trestle and the more recent Spanner [13].

During the same years the Biofix/SpiroFlow biodegradable prostatic coil stent made of self-reinforced polyglycolic acid [SR-PLA] was also introduced. However, it failed to support the expectations because, after losing their radial force, they crushed into the urethral lumen and caused an obstruction that had to be solved by endoscopic removal of its segments [14].

Stenting the lower urinary tract is minimally invasive approach to relieve BOO in patients unfit for surgery or in others as an alternative to surgery. What we need from a urinary stent is a patent lumen so it can support both micturition and sexual activity without serious adverse effects. The ideal urethral stent is flexible so it can support the urethral lumen in both the flaccid or erect status of the penis. In addition, the ideal stent is an off-the-shelf product, so that each patient can be treated directly.

Since their introduction in the late 1980s, stents have been studied in the urinary tract to prevent scaring contraction and re-modelling of the strictured urethral segments. Although the first reports seemed to promise excellent outcomes, longer follow-up began to cast doubts on the usefulness of urethral stenting as a primary treatment modality for urethral stricture disease [15]. Especially permanently implanted stents lead to tissue ingrowth and re-stenosis. Temporary stents prevented tissue ingrowth in their lumen but induces tissue ingrowth at their ends. Resection of this tissue or removal of the stent opened the obstructed lumen.

3 Classification of Stents

First use of a stent in the urinary tract was the permanent use of a 22F catheter for 1–4 years in a small group of 19 patients [16]. Later vascular stents were used ‘off label’. The Palmaz stent, Wallstent and the Memotherm were supposed to be completely covered by urothelial tissue within a few weeks after their implantation like in the vascular tract. Less than satisfying results with these stents especially in the prostatic urethra led to development of urethral specific stents. Most of these stents had either a fixed caliber, or are self-expandable or thermo-expandable.

Differing from other tubular organs, the cross section of the prostatic urethra is rarely round. For this reason, some of the permanent stents could not become fully covered with tissue as they were supposed to become and stones could develop on the uncovered bare metal wires. Despite this drawback both the Urolume and the Memotherm are still used in selected high surgical risk patients [17]. The Palmaz stent dropped from use because its lack of radial self-expanding force.

Urethral stents can be classified in several groups. First, we can make a distinction on anatomical location. We have prostatic urethral stents—both for benign and malignant obstructions and bulbar and distal urethra stents, these are used to open the urethral lumen after traumatic pelvic bone fractures, endoscopic manipulations related and in case of recurrent infection (e.g. lichen sclerosis, gonorrhoea). An additional classification is based on the type of stent, there are permanent and removable stents, mesh stents can be either balloon expandable and self-expandable. Examples of the removable stents are among others Fabian stent/Prostacath, InStent’s ProstaCoil and UroCoil, Allium’s TPS, BUS and RPS. Lastly few experimental trials are reported on degradable stents.

The use of a permanent stent positioned in distal urethra may look to be an attractive treatment in the treatment of strictures. The Urolume/Wallstent and the Memotherm which are permanent stents were used as an alternative approach in such stenoses [18]. Time showed that the use of permanent stents is a contraindication in these cases because of intra-stent obstructive tissue proliferation [19, 20]. Significant complication rates were also observed when such stents were used for benign prostatic obstructions [21].

4 Aim of This Chapter

In the present chapter we provide an overview of the current literature to summarize the most common complications seen with different urethral stents for male patients with benign or malignant urethral obstruction of the urethra. Full data extraction is ongoing, this is our initial report.

5 Materials and Methods

5.1 Literature Search

Following search string: *[[[[urethra] OR urethral]] AND [[[[stent] OR endoprothesis] OR endoprosthesis] OR stents]]* was initially used both in Embase and PubMed, in February 2019 and a re-run in March 2020. Cross references were added. Figure 1 presents an outline of the literature search in a Prisma Flow Diagram [22]. Prospective, retrospective, comparative studies, case reports and case series were included.

5.2 Study Selection

Results from PubMed and the Embase were imported in Rayyan [https://rayyan.qcri.org/], where duplicates were removed. The title and abstract screen was performed by two authors independently [PdG, DR]; the full text screen was performed by the same authors, also independently of each other. Any differences in the screening results were solved by discussion. Studies were excluded when written in languages other than English, non-original papers [abstract, comment or review paper], when describing pre-clinical studies and non-human use, when studying wrong

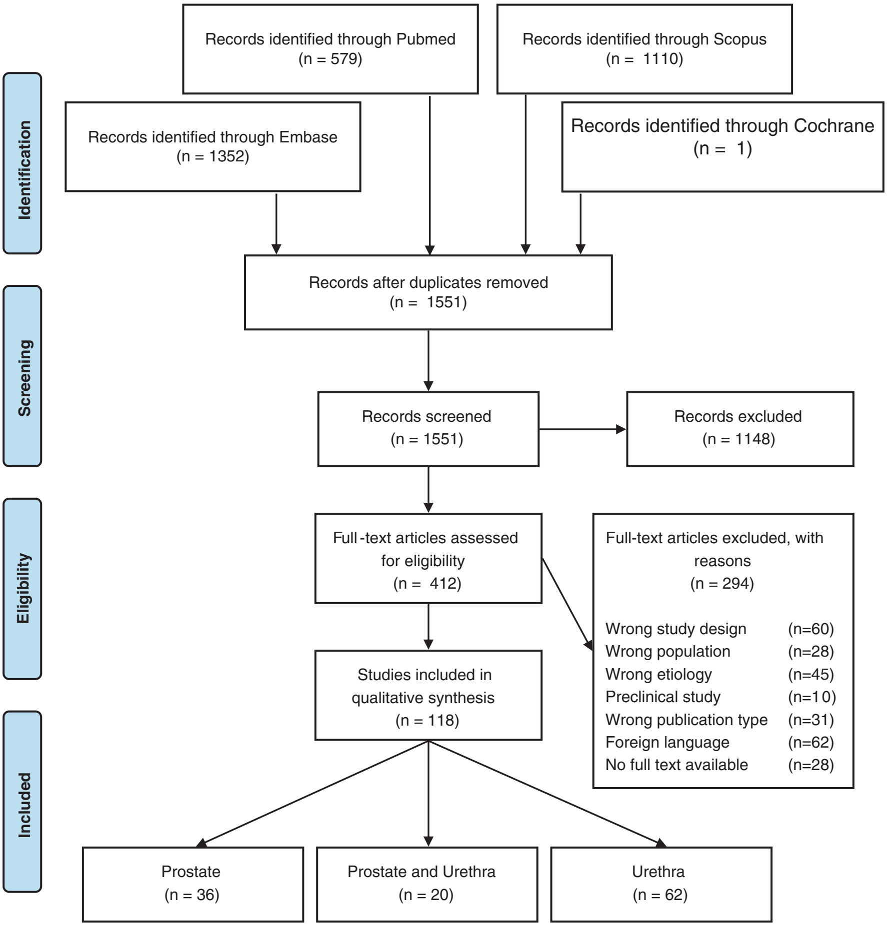

Fig. 1 Study selection process [22]. For more information, visit www.prisma-statement.org

population, e.g. wrong etiology of the urethral obstruction [mainly detrusor sphincter dyssynergia] or stenting by catheter after reconstruction surgery. The primary endpoint was cause [restricture, infection, migration and other causes for stent failure] and rate of complications and secondary endpoint was patency rate. Stent patency was calculated as number of failed stented urethra over number of total stented urethra and failed stented urethra is defined as stent not being able to do as expected so an unplanned stent removal.

6 Results

After search has been run, 1551 publications were identified and their abstracts were screened independently by two authors [PdG, DR] resulting in consensus on 412 acceptable full text papers which were thoroughly read by same authors and of those 118 were finally included in systematic review. Reasons for exclusions were listed in Fig. 1.

Over 4000 patients are described, with varying follow up. Several different stents were used, including o*ff label* use of covered metal stents designed for vascular use, drug eluting stents, biodegradable stents.

Papers were divided on use in anatomical location [prostate, urethra or report on both locations]. In total, 94 papers recorded on results, 24 papers on complications only. Here we summarize the results based on this division.

6.1 Prostatic Stents

Thirty-six studies report on stent use in the prostatic urethra. Of these, 34 reported on results, 2 on complications. An overview of the studies is given in Table 1. At the prostatic region the UroLume was the most used stent, used in 8 studies, other stents used were MemoKath (3), Memotherm (2), 4 reported on ProstaKath, 3 on ProstaCoil, 2 on Urospiral, 4 on Spanner and a variety of others, including 4 studies on biodegradable stents. As a full data extraction and analysis is currently performed by the authors, we can only preliminary summarize the common adverse effects, including dislocation of the stent, dysuria, retention, recurrence of obstruction and urinary incontinence. Meta-analysis cannot be performed due to different endpoints, differences in stents and most of all, differences in follow up. Overall, in studies with short follow up, success rates are much higher than in studies with longer follow up.

6.2 Stents in Both Prostatic and Urethral Region

Twenty studies reported on urethral stents both in the prostatic and the bulbar urethral region, without making clear distinction or made a combinations of results/complications in both regions. Of these, 16 reported on results, and 4 on complications. An overview of these studies is given in Table 2. Again, the Urolume was used most in this combined region (8), the other 12 studies were using a variety of stents, including a 22F catheter [16] and some titanium alloys based stents [see Table 2 for description]. Success rate in up to 50% of cases, however, short follow up may bias these results, as some complications take longer to develop.

Table 1 Data extraction prostate

Authors	Year	Report on	Number of patients	Type of stent
Van Dijk et al. [26]	2006	Results	108	Bell- shaped nitinol prostatic stent
Petas et al. [27]	1997	Results	45	Biodegradable
Laaksovirta et al. [28]	2002	Results	50	Biodegradable, self-expandable SR-PLGA copolymer stent
Talja et al. [29]	1995	Results	22	Biodegradable, self-reinforced polyglycolic acid spiral stent
Petas et al. [30]	1997	Results	72	Biodegradable, self-reinforced polyglycolic acid spiral stent
Morgentaler and DeWolf [31]	1993	Results	25	Gianturco-Z stent
Nissenkorn et al. [32]	1996	Results	15	IUC intraurethral catheter
Poulsen et al. [33]	1993	Results	30	MemoKath
Williams and White [34]	1995	Results	48	MemoKath
Kimata et al. [35]	2015	Results	37	MemoKath
Tseng et al. [36]	2007	Complications	1	Memotherm
Gesenberg and Sintermann [37]	1998	Results	123	Memotherm
Guazzoni et al. [38]	1994	Results	135	Modified Urolume
Yachia et al. [39]	1995	Results	65	ProstaCoil
Yachia and Aridogan [40]	1996	Results	27	ProstaCoil
Ovesen et al. [41]	1990	Results	1	Prostakath
Thomas et al. [42]	1993	Results	64	Prostakath
Sofer et al. [43]	1998	Complications	107	Prostakath or Urospiral
Yachia and Aridogan [44]	1996	Results	117	Prostakath vs Prostacoil
Song et al. [45]	1995	Results	13	Self-expandable metallic Z-stent
Mori et al. [46]	1995	Results	17	Shape memory alloy
Henderson et al. [47]	2002	Results	5	Spanner
Corica et al. [48]	2004	Results	30	Spanner
Tyson et al. [49]	2012	Results	20	Spanner
Goh et al. [50]	2013	Results	16	Spanner
Porpiglia et al. [51]	2018	Results	32	Temporary implantable nitinol device [TIND]
Van Dijk et al. [52]	2005	Results	35	Thermoexpandable hourglass-shaped nitinol prostatic stent
Milroy and Chapple [53]	1993	Results	54	UroLume
Williams et al. [54]	1993	Results	96	Urolume
Oesterling et al. [55]	1994	Results	126	UroLume

(continued)

Table 1 (continued)

Authors	Year	Report on	Number of patients	Type of stent
Schneider et al. [56]	1994	Results	70	UroLume
Anjum et al. [57]	1997	Results	62	Urolume
Lallas et al. [58]	2001	Results	1	UroLume
McLoughlin et al. [9]	1990	Results	19	Unclear [UroLume]
Özgür et al. [59]	1993	Results	31	Urospiral
Adam et al. [60]	1990	Results	21	Wallstent

Table 2 Data extraction prostate and urethra

Authors	year	Report on	Number of patients	Type of stent
Fair [16]	1982	Results	21	22F catheter
Perez-Marrero and Emerson [61]	1993	Results	9	Balloon expanded titanium prostatic urethral stent
Qiu et al. [62]	1994	Results	25	Chinese titanium-nickel alloy with shape memory
Choi et al. [63]	2007	Results	33	Covered nitinol stent
Boullier and Parra [64]	1991	Results	20	Expandable titanium stent
Takahashi et al. [65]	2013	Complications	4	MemoKath
Ricciotti et al. [66]	1995	Results	49	Memotherm
Egilmez et al. [67]	2006	Complications	76	Nitinol
Inoue and Misawa [68]	1997	Results	1	ProstaKath
Parra [69]	1991	Results	5	Titanium endourethral stent
Yachia and Beyar [70]	1993	Results	20	UroCoil
Corujo and Badlani [71]	1998	Complications	2	Urolume
Milroy [72]	1991	Results	45	UroLume
Oesterling [73]	1993	Results	N/A	UroLume
Sweetser et al. [74]	1993	Results	23	UroLume
Bailey et al. [75]	1998	Results	14	UroLume
Wilson et al. [76]	2002	Results	10	UroLume
Shah et al. [77]	2003	Results	465	UroLume
McNamara et al. [78]	2013	Results	45	UroLume
Chapple and Bhargava [19]	2008	Complications	14	Variety of stents

6.3 Urethral Stents

The largest set of studies was found for urethral stenting, 62 studies were selected, 44 reported on results, 18 on complications. An overview of these studies is given in Table 3. Urolume was used in 26 studies, 3 of these studies compared the stent to the Wallstent. 10 studies reported on Wallstent alone. Six studies reported on the use

Table 3 Data extraction urethra

Authors	Year	Report on	Number of patients	Type of stent
Shental et al. [79]	1998	Complications	1	Porges Urethrospiral-2 stent [as second stent, over a UroLume]
Culha et al. [80]	2014	Results	54	Allium
Silagy et al. [81]	2017	Results	15	Allium
Temeltas et al. [82]	2016	Results	28	Allium
Yachia and Beyar [83]	1991	Results	18	Biocompatible metal alloy
Isotalo et al. [84].	2002	Results	22	Biodegradable
Isotalo et al. [85]	1998	Results	22	Biodegradable
Song et al. [86]	2003	Results	12	Covered nitinol stent
Jordan et al. [87]	2013	Results	92	MemoKath
Jung et al. [88]	2013	Results	13	MemoKath
Wong et al. [89]	2014	Results	22	MemoKath
Abdallah et al. [90]	2013	Results	23	MemoKath
Barbagli et al. [91]	2017	Results	16	MemoKath
Sertcelik et al. [92]	2011	Results	47	MemoKath
Atesci et al. [93]	2014	Results	20	Memotherm
Takenaka et al. [94]	2004	Results	1	Metal
Gujral et al. [95]	1995	Results	7	Modified Z-stent, Gianturco type
Na et al. [96]	2012	Results	59	Nitinol
Eisenberg et al. [97]	2008	Complications	22	Several types
Kotsar et al. [98]	2009	Results	10	PLGA
Nissenkorn [99]	1995	Results	22	Polyurethane
Nissenkorn and Shalev [100]	1997	Results	42	Polyurethane
Kim et al. [101]	2017	Results	54	Retrievable self-expandable metallic stents
Yachia et al. [102]	1990	Results	26	Self-retaining stent
Saporta et al. [103]	1993	Results	16	UroCoil
Sikafi [104]	1996	Results	18	UroCoil
Fisher and Santucci [105]	2006	Complications	1	UroLume
Gupta and Ansari [106]	2004	Complications	1	UroLume
Paddack et al. [107]	2009	Complications	1	UroLume
Tahmaz et al. [108]	2009	Complications	1	UroLume
Cimentepe et al. [109]	2004	Results	1	UroLume
Parsons and Wright [110]	2004	Complications	3	UroLume
Rodriguez Jr. and Gelman [111]	2006	Complications	2	UroLume

(continued)

Table 3 (continued)

Authors	Year	Report on	Number of patients	Type of stent
Scarpa et al. [112]	1997	Results	2	UroLume
Gelman and Rodriguez Jr. [113]	2007	Complications	10	UroLume
Elkassaby et al. [114]	2007	Complications	13	UroLume
Milroy [115]	1993	Results	6	UroLume
Angulo et al. [116]	2018	Complications	63	Urolume
De Vocht et al. [117]	2003	Complications	15	Urolume
Hussain et al. [118]	2004	Complications	60	UroLume
Badlani et al. [119]	1995	Results	175	UroLume
Breda et al. [120]	1994	Results	82	UroLume
Donald et al. [121]	1991	Results	33	Urolume
Granieri and Peterson [122]	2014	Results	4	UroLume
Milroy and Allen [123]	1996	Results	50	UroLume
Sertcelik et al. [124]	2000	Results	60	UroLume
Shah et al. [20]	2003	Results	24	UroLume
Tillem et al. [125]	1997	Results	41	UroLume
Eisenberg et al. [126]	2007	Results	13	UroLume [11], endovascular [2]
Morgia et al. [127]	1999	Results	99	Wallstents [94], 5 other
Verhamme et al. [128]	1993	Complications	1	Wallstent
Krah et al. [129]	1992	Complications	1	Wallstent
Pansadoro et al. [130]	1994	Results	1	Wallstent
Baert et al. [131]	1993	Complications	7	Wallstent
Baert et al. [132]	1991	Results	6	Wallstent
Beier-Holgersen et al. [133]	1993	Results	10	Wallstent
Kardar and Lindstedt [134]	1998	Results	8	Wallstent/UroLume
Milroy et al. [135]	1989	Results	8	Wallstent/UroLume
Katz et al. [136]	1994	Complications	2	Wallstent/UroLume
Oosterlinck and Talja [137]	2000	Results	N/A	Various stents
Milroy et al. [138]	1989	Results	8	Various stents
Palminteri et al. [23]	2010	Complications	13	Various stents

of MemoKath, 1 on MemoTherm, 2 on UroCoil and 3 on Allium stents. The other 17 studies used other stents, described a variety of stents or the stents used were ill-defined. Reported complications included stent migration, haematuria, recurrent strictures or obstructed stents by encrustation, urinary tract infections, perineal pain and sexual dysfunction. Despite their relatively high complication rates, externally covered stents seemed more effective with fewer complications than either uncovered or internally covered stents. However, all stents intrinsically generate the risk to turn a simple stenosis into a complex stenosis requiring a staged urethroplasty, a definitive urethrostomy, or a permanent suprapubic diversion [23].

7 Discussion

In total, we analyzed 118 studies on urethral stenting, 94 on results and 24 on complications. In the studies analyzed, the UroLume was used most frequently. Full extraction of the data is in progress, we will report later on this based on this book chapter.

In modern urological practice, ureter stents and bladder catheters have become indispensable tools. The use urethral and prostate stents was introduced with optimism and hope; however, these latter stents have not shown their benefits over current procedures to treat urethral obstruction. Over the course of time, many improvements in designs and constitutive materials for urinary stents have taken place in an attempt to improve their efficacy. Nevertheless, they remain associated with several adverse effects that limit their value as tools for long-term urinary drainage. Infection, encrustation, migration, hyperplastic epithelial reaction, and patient discomfort are the most common problems [24] and, especially for urethral stricture disease, open urethral reconstruction is the treatment of choice for patients with traumatic strictures and those with previously failed urethroplasty [19]. For patients unfit for this major open surgery, research for better stents, potentially biodegradable or a combination of materials and cells will be a better option [25].

8 Limitations and Risk of Bias

The included studies used different approach on reporting complications therefore a quantitative report on the adverse effects was not possible. Publication bias is likely on the included reports, both biased on complication in the case reports, as well as bias on the outcome due to short follow up.

9 Conclusion and Future Perspectives

It is clear from papers we have analyzed that purpose-built urethral stents have outperformed off-label vascular stents, but still the ideal stent has not been identified. Despite many adverse effects, urethral stents may still be useful, in particular to the elderly unfit patient in whom a major operation is contraindicated, providing a rapid treatment that can be performed with the patient under local anesthesia. For this we need to develop better stents that can avoid the current complications and disadvantages. Cross pollination is needed between basic, translational, preclinical and clinical research, thereby combining knowledge on materials, cells, rheology, tissue, pathophysiology and pathology, with the ultimate aim better treatment options for our patients.

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