



# Long-term outcomes of urethral catheterisation injuries: a prospective multi-institutional study

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## Abstract

**Purpose** There are no prospective data describing the incidence and spectrum of long-term complications associated with traumatic urethral catheterisation (UC). We prospectively monitored the long-term clinical outcomes and complications of patients with traumatic UC injuries.

**Methods** A prospective study at two tertiary university hospitals was performed to record all referrals for iatrogenic urethral injuries caused by UC. Long-term follow-up was prospectively maintained by regular outpatient department visits and by monitoring all urological interventions and their outcomes from urinary catheter-related injuries.

**Results** The incidence of traumatic UC was 13.4 per 1000 catheters inserted in male patients and 37 iatrogenic urethral injuries were recorded. The mean age was  $74 \pm 12$  years and the mean length of follow-up was  $37 \pm 3.7$  months. Urethral injuries were caused by inflating the catheter anchoring balloon in the urethra ( $n=26$ ) or by creating a false passage with the catheter tip ( $n=11$ ). In total, 29 patients (78%) developed urethral stricture disease during their follow-up; of which 11 have required at least one urethral dilation and two have required one urethrotomy. Three patients required long-term indwelling suprapubic catheter placement and seven patients opted for a long-term indwelling urethral catheter. There were eight patient mortalities; one of which was due to severe urosepsis resulting from catheter balloon inflation in the urethra.

**Conclusion** Catheter-related injuries are associated with significant long-term complications in this vulnerable patient cohort. In future, such injuries may be preventable if the safety profile of the urinary catheter is modified.

**Keywords** Urethra · Catheterisation · Urinary catheter · Iatrogenic injury · Urethral stricture

## Introduction

Urinary catheterisation (UC) is routinely performed in hospital and community settings. All newly qualified doctors are expected to be safe, confident, and competent at

performing UC at the end of their training. The incidence of iatrogenic UC injuries among male patients is approximately 13 per 1000 catheters [1, 2]. Predisposing factors for urethral trauma during UC are the length and tortuous anatomy of the male urethra and obstructing lower urinary tract conditions such as benign prostatic hyperplasia [3]. The most common methods of injury during UC are inadvertent balloon inflation in the urethra and/or false passage creation during insertion [4]. Short-term complications associated with traumatic UC are well described and include acute urinary retention, urosepsis, bleeding and acute kidney injury [1]. Conversely, there are no prospective data describing the incidence and spectrum of long-term complications associated with traumatic UC. In this prospective study, we present our long-term findings among patients with traumatic UC.

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## Materials and methods

### Overview of study design

A prospective study at 2 tertiary university hospitals during a 6-month period (July 2015 to January 2016) included all referrals for traumatic UC. Ethics approval was granted by each hospital's ethics approval process (REC reference: 16/78). Data were prospectively maintained in departmental databases. Traumatic UC was defined as a physician requesting a urological consultation after difficult/failed catheter placement and at least 1 of the conditions of hematuria, blood at the urethral meatus, perineal/urethral pain, cystoscopic evidence of urethral trauma and retrograde/antegrade urethrogram demonstrating urethral trauma. Study exclusion criteria were patient inflicted trauma and trauma from intermittent self-catheterisation.

### Recorded data

Prospectively maintained data included patient demographics, ASA grade, mode of urethral injury, setting of injury, number of catheterisation attempts, urological management provided, additional bed days due to urethral injury. The overall number of UCs performed was obtained from the procurement department in each hospital.

### Long-term follow-up

All patients were followed-up at 3–6 monthly intervals in the outpatients department with an interview, clinical examination, uroflowmetry and post-void residual measurement. Patients unable to attend outpatients' appointments due to underlying comorbidities and/or difficult homecare circumstances were followed-up with phone consultations through their residential care facility. Patients experiencing symptoms consistent with recurrent urethral stricture disease have direct access to a urology specialist so that they can be reviewed and investigated promptly as required. In addition, long-term follow-up on clinical outcomes and surgical intervention among patients with iatrogenic urethral injuries was monitored by reviewing each patient's electronic record (ER).

## Results

### Patient demographics

There are 1000 inpatient beds between both hospitals with 11,000 catheter insertions performed per year [1].

Thirty-seven iatrogenic urethral injuries were recorded during the study period and the overall incidence of traumatic UC was 6.7 per 1000 catheters inserted (i.e., male and female catheterisation). The relevant patient demographics and clinical information are summarised in Table 1. All injured patients were male, and the incidence of traumatic UC was 13.4 per 1000 catheters inserted in male patients. The mean age was  $74 \pm 12$  years (range 42–94 years) and the mean ASA grade was  $3.4 \pm 0.9$ . Notably, 2/37 patients had a prior documented history of difficult catheterisation secondary to benign prostatic hyperplasia (BPH).

### Urinary catheterisation injuries

The mean number of attempted catheterisations was 3.2 before urological consultation was sought (Table 1). There were 29 traumatic UCs during on call hours and two patients had a prior documented history of difficult catheterisation due to benign prostatic hyperplasia. Urethral injuries were caused by inflating the catheter anchoring balloon in the urethra ( $n=26$ ) or by creating a false passage with the catheter tip ( $n=11$ ). All injuries occurred proximal to the penile urethra. The additional length of inpatient hospital stay due to iatrogenic urethral injuries was  $9.4 \pm 10$  days (range 2–53) and the mean length of follow-up was  $37 \pm 3.7$  months (Table 1).

### Long-term complications and management

Long-term management due to catheter-related urethral injuries are summarised in Table 2. Twenty-nine patients (78%) developed cystoscopic and radiological evidence of urethral stricture disease during their follow-up and 8 (22%) remained asymptomatic after their catheter-related injury. Follow-up cystoscopy and/or retrograde urethrography were performed on patients based on deteriorating LUTS. Currently, 6/37 (16%) patients require ongoing care in a long-term residential facility after presenting from home. Residential care is required in these patients as they are unable to independently manage an indwelling suprapubic or transurethral catheter due to underlying cognitive or neurodegenerative comorbidities.

### Urethrotomy/urethral dilatation

Thirteen patients (48%) are performing self-urethral dilation once weekly in the form of intermittent self-catheterisation (ISC). Among these 13 patients, 11/13 (85%) have required at least 1 urethral dilation and 2/13 (15%) have required 1 internal urethrotomy under direct vision due to bulbar urethral strictures. Two patients have required 4 urethral dilations under general anaesthetic since their iatrogenic urethral injury due to recurrent urethral stricture disease.

**Table 1** Summary of demographics and clinical information for patients undergoing traumatic urethral catheterisation

Patient no.	Age	Indication for catheter	Hx of difficult catheterisation (yes = Y; no = N)	No. of catheter attempts	Location of injury	Nature of injury	Initial urological management	Total duration of inpatient stay (days)	Length of follow-up (months)
1	56	Acute urinary retention	N	4	Dialysis unit	Catheter balloon in urethra	SPC for 6 weeks	10	41
2	76	Acute urinary retention	N	3	Medical ward	Catheter balloon in urethra	Long-term SPC	5	43
3	76	Chronic urinary retention	N	3	Dialysis unit	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	8	42
4	78	Acute urinary retention	N	3	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	5	43
5	84	Acute urinary retention	Y (known BPH)	5	ED	Catheter balloon in urethra	Catheter manipulated and pushed back into bladder	21	43
6	65	Acute urinary retention	N	4	ED	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	10	43
7	84	Change of long-term catheter	N	4	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	21	38
8	81	Acute urinary retention	N	4	ED	Catheter balloon in urethra	Long-term SPC	7	42
9	92	Change of long-term catheter	N	2	ED	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	15	41
10	56	Acute urinary retention	N	5	ED	False passage	Long-term SPC (pt. desire)	7	39
11	73	Acute urinary retention	N	2	ED	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	28	39
12	74	Monitoring urine output	N	2	Gen. surg ward	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	5	37

**Table 1** (continued)

Patient no.	Age	Indication for catheter	Hx of difficult catheterisation (yes = Y; no = N)	No. of catheter attempts	Location of injury	Nature of injury	Initial urological management	Total duration of inpatient stay (days)	Length of follow-up (months)
13	78	Monitoring urine output	N	2	Medical ward	False passage	Urethral catheter with cystoscopy and guide-wire	7	37
14	81	Acute urinary retention	N	5	ED	False passage	SPC	14	37
15	81	Acute urinary retention	N	3	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	5	36
16	81	Monitoring urine output	N	3	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	10	36
17	81	Acute urinary retention	N	4	ED	False passage	SPC	28	35
18	77	Acute urinary retention	N	4	ED	False passage	Urethral catheter with cystoscopy and guide-wire	7	33
19	87	Monitoring urine output	N	2	Gen. surg ward	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	6	31
20	83	Acute urinary retention	N	3	ED	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	7	33
21	70	Acute urinary retention	N	3	ED	False passage	Flexible cystoscopy and long-term SPC	6	39
22	88	Acute urinary retention	N	2	ED	Catheter balloon in urethra	Catheter manipulated and pushed back into bladder	7	39
23	69	Acute urinary retention	N	3	Community	Catheter balloon in urethra	Catheter manipulated and pushed back into bladder	3	39
24	50	Acute urinary retention	N	2	ED	Catheter balloon in urethra	SPC	3	39
25	76	Acute urinary retention	N	1	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	7	39

**Table 1** (continued)

Patient no.	Age	Indication for catheter	Hx of difficult catheterisation (yes = Y; no = N)	No. of catheter attempts	Location of injury	Nature of injury	Initial urological management	Total duration of inpatient stay (days)	Length of follow-up (months)
26	94	Acute urinary retention	N	3	ED	Catheter balloon in urethra	Flexible cystoscopy and long-term SPC	10	34
27	42	Monitoring urine output	N	3	Theatre	False passage	Flexible cystoscopy: failed. Required open cystotomy and SPC	53	37
28	82	Acute urinary retention	N	5	ED	False passage	Flexible cystoscopy and long-term SPC	2	35
29	81	Acute urinary retention	Y (known BPH)	5	ED	False passage	Urethral catheter with cystoscopy and guide-wire	6	35
30	78	Acute urinary retention	N	2	Medical ward	Catheter balloon in urethra	SPC	5	39
31	82	Acute urinary retention	N	3	Medical ward	False passage	SPC	2	32
32	65	Change of long-term catheter	N	5	Community	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	5	33
33	74	Acute urinary/ clot retention	N	2	ED	Catheter balloon in urethra	3-way urethral catheter with cystoscopy and guide-wire	3	33
34	63	Acute urinary retention	N	5	ED	False passage	SPC	2	33
35	85	Chronic urinary retention	N	3	Medical ward	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	2	32
36	67	Prior to brachy-therapy	N	2	Radiotherapy dept	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	2	32
37	69	Acute urinary retention	N	3	ED	Catheter balloon in urethra	Urethral catheter with cystoscopy and guide-wire	5	32

No. number, ED Emergency Department; SPC suprapubic catheter, BPH benign prostatic hyperplasia

**Table 2** Summary of management strategies for patients that developed urethral stricture disease ( $n=29$ ) after traumatic urethral catheterisation

Long-term management	Number ( <i>N</i> )
Indwelling suprapubic catheter	3
Repeat urethral dilatation with ISC	11
Repeat DVIU with ISC	2
Long-term transurethral catheter	7
No complication	6
RIP since urethral injury	8 (urethral stricture disease $n=6$ )
Total	37

In general, patients sustaining injuries from traumatic urethral catheterisation have been managed with less invasive urological procedures as they are either unwilling or deemed unfit for urethroplasty due to their underlying comorbidities

ISC intermittent

### Long-term catheter

Three patients required long-term indwelling suprapubic catheter (SPC) placement due to recurrent urethral stricture disease and an inability to appropriately manage with self-dilatation. Seven patients opted for a long-term indwelling transurethral catheter, again due to inability to appropriately manage recurrent urethral strictures with regular self-dilatation. Patients opting for repeated endoscopic procedures, long-term SPC or long-term transurethral catheterisation were either unwilling or deemed unfit to consider primary

anastomotic urethroplasty due to preference and/or underlying comorbidities.

### Mortalities

To date, there have been eight patient mortalities in patients who have been prospectively followed with a urinary catheter-related urethral injury. Their details are summarised in Table 3. The mean age at mortality was  $78.5 \pm 7.9$  years and the mean duration between catheter-related urethral injury and mortality was  $3.9 \pm 3.7$  months. One patient required inotropic support in the intensive care unit (ICU) due to severe urosepsis resulting from catheter balloon inflation in his urethra and ultimately died 4 weeks later. Urosepsis leading to septic shock was confirmed by positive blood and urine cultures accompanied by progressive systemic inflammatory response syndrome. A second patient required emergency suprapubic catheter insertion due to a false passage sustained during urethral catheterisation for acute urinary retention. This patient developed urosepsis and was managed with antibiotic therapy. As an inpatient, he was undergoing extensive treatment for respiratory and cardiovascular issues and died 4 weeks later from multiorgan failure.

### Asymptomatic

The remaining six patients are asymptomatic and are still attending regular follow-up outpatient appointments at 3–6 month intervals for clinical examination, assessment of uroflowmetry and post-void residual measurement.

**Table 3** Cause of mortality during follow-up of patients in patients undergoing traumatic urethral catheterisation

Patient number	Age (years)	Cause of mortality	Duration between catheter injury and mortality (months)	Urological issues
1	74	Progressive dementia	8	Discharged to residential care with long-term urethral catheter
2	87	Cardiovascular	4	Asymptomatic
3	83	Multiorgan failure	3	Asymptomatic
4	70	Metastatic cancer	1	Discharged to residential care with suprapubic catheter
5	82	Cardiovascular and dementia	2	Discharged to residential care with suprapubic catheter
6	65	Urosepsis leading to multiorgan failure	1	Urosepsis caused by catheter injury
7	85	Multiorgan failure	11	Discharged to residential care with long-term urethral catheter
8	82	Multiorgan failure	1	Died in hospital 4/52 after urethral trauma with SPC in situ
Mean $\pm$ SD	$78.5 \pm 7.9$	NA	$3.9 \pm 3.7$	N/A

The mean duration between catheter-related urethral injury and mortality was  $3.9 \pm 3.7$  months. Among patients that died, 6/8 had sequelae of iatrogenic urethral injury cause by traumatic catheterisation

SD standard deviation, N/A non-applicable

## Discussion

Every year millions of urinary catheters are inserted and  $\leq 25\%$  of hospitalised patients are catheterised during their inpatient stay. Among these, approximately 0.3–1.3% will experience an iatrogenic traumatic UC injury resulting in immediate complications such as pain, haematuria, urosepsis or urinary retention [1, 2]. Despite the potential for such morbidities; mechanisms to prevent catheter-related injuries receive little attention and there is a complete absence of data on the long-term complications and implications of iatrogenic urethral injuries [5].

In the present study, we prospectively followed the clinical outcomes of 37 patients that sustained urinary catheter-related urethral injuries for  $37 \pm 3.7$  months in 2 tertiary referral centres. Our main finding was that 78% ( $n = 29$ ) of patients developed cystoscopic and/or radiological evidence of urethral stricture disease that have required multiple ongoing urological interventions during this follow-up period. This finding is concerning and clinically relevant as traumatic UC injuries are a preventable source of iatrogenic morbidity in patients [3]. In addition to short-term morbidities and monetary loss, the present study clearly demonstrates that urethral injuries lead to an increased burden on urological resources, inpatient beds, theatre time and skill usage [1].

Furthermore, complications due to traumatic UC have medicolegal implications, financial penalties and longer inpatient stays in an acute setting. Previously, we reported on the incidence, cost and short-term complications in this cohort of patients. The cost of managing immediate inpatient complications was €335,377 and this cost is likely to have increased considerably during the ensuing 3-year follow-up period [1]. To decrease or eliminate the risk of urethral injury during UC, urologists must be willing to support the advancement of improved training programmes and safer urethral catheter design modifications, particularly in patients with risk factors (e.g., prior history of urethral stricture disease, known BPH) for difficult UC [6].

Our study also demonstrates that most incidences of long-term complications due to traumatic UC occur in a similar pattern; in high-risk, comorbid older male patients (ASA grade  $> 3$ ) with difficult catheterisation scenarios such as during ‘on-call’ hours. This comorbid inpatient male patient population appear particularly vulnerable as evident by the fact that there were 8 mortalities (22%) within  $3.9 \pm 3.7$  months of a catheter-related urethral injury. Worryingly, in the present study, 1 mortality was directly related to severe progressive urosepsis that was provoked by inflating the catheter’s anchoring balloon in the patient’s urethra (Table 3).

Although supervised training programmes and education on proper catheterisation technique are important initial steps for avoidance of urethral injuries; one study demonstrated that the anchoring balloon is still mistakenly inflated in the urethra in approximately 10% of patients by trained doctors [7]. Another study investigated the ‘confidence’ and ‘experience’ of first year UK interns at performing urinary catheterisation and found that one in five had never performed male catheterisation and nearly half (45%) had never performed a female catheterisation after 1 year of medical practice [3]. We advocate simulation-based training for certain procedures; however, there are no data or audits that demonstrate a benefit with simulation-based UC training in its current form [8]. For male catheterisation, it is difficult to replicate regular challenges that encountered in male patients requiring catheterisation such as urethral tortuosity, with non-visible urethral angulations, obstructing prostate tissue, prior urethral stricture, high bladder neck and possibility of false passage with greater insertion forces [8].

Limitations with conventional simulation models emphasise the role for a safer urethral catheter system in conjunction with supervised training programmes for newly qualified healthcare professionals in future. Interestingly, the most commonly used urethral catheter was devised by Foley in 1929 and since its conception 89 years ago, no significant modification has occurred to advance the safety design of urethral catheters [8]. Furthermore, contemporary catheters and their connecting inflation syringes have also remained unchanged despite the fact that the anchoring balloon can generate enormous pressures during the inflation process ( $> 700$  kPa) [9, 10].

In view of the significant morbidity caused by urinary catheters, there is an obvious clinical need to provide a research program for developing a safer alternative [5, 8]. We recently prospectively piloted a ‘safety-valve’ device for preventing catheter balloon inflation-related urethral injuries in 100 male patients requiring UC [11]. The device allowed fluid in the catheter system to decant through an activated safety threshold pressure valve if the catheter anchoring balloon is misplaced [9]. Wu et al. [12] demonstrated that urethral balloon inflation pressures are 1.9 times greater than bladder pressures and this increases non-linearly during intraurethral filling in cadavers and ex vivo models. They suggest incorporating differences in bladder and urethral pressures and forces into a safer urethral catheter design. Most recently, Bugeja et al. [13] reported on a new urethral catheterisation device (UCD) to manage difficult catheterisation involving an integrated hydrophilic Nitinol guide wire which allows for guiding the catheter blindly into bladder utilising the Seldinger technique principle in 100 patients. The authors found that their catheterisation device was easy to integrate into standard catheterisation training programs for managing difficult urethral catheterisation scenarios [13].

It is likely that the costs of the safety devices described for UC will need to be analysed with appropriate cost–benefit analyses before they can be commercially integrated into catheter kits.

There is a limitation to our study. It is arguable that some patients may have had an undiagnosed history of urethral stricture disease prior to traumatic UC. However, past medical and surgical history was extensively reviewed for every patient that sustained a urinary catheter-related urethral injury. We found that only 2/37 patients had a prior history of difficult catheterisation due to BPH and no patients had a documented prior history of urethral stricture disease.

## Conclusions

We followed the clinical outcomes of 37 patients with iatrogenic urinary catheter-related urethral trauma and found significant long-term complications that required multiple urological interventions. Managing long-term catheter-related injuries places a significant and potentially unnecessary burden on the healthcare system and on this vulnerable patient cohort. In future, iatrogenic urethral injuries may be prevented if the safety profile of the conventional urinary catheter is modified.

**Author contributions** NFD: data collection, data analysis, manuscript writing. NRB: data collection, data analysis. EM: data collection, data analysis. HF: manuscript writing, supervision. RM: project development. GL: project development. MW: manuscript writing, supervision.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflicts of interest.

**Research involving human rights and animal participants** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standard.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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