Incidence, Cost, Complications and Clinical Outcomes of latrogenic Urethral Catheterization Injuries: A Prospective Multi-Institutional Study



N. F. Davis,* M. R. Quinlan, N. R. Bhatt, C. Browne, E. MacCraith, R. Manecksha, M. T. Walsh, J. A. Thornhill and D. Mulvin

From the Department of Urology, St. Vincent's University Hospital (NFD, CB, EM, DM), Department of Urology, Tallaght Hospital (MRQ, NRB, RM, JAT), Dublin, and Centre for Applied Biomedical Engineering Research, Materials and Surface Science Institute, University of Limerick (MTW), Castletroy, Limerick, Ireland

Purpose: Data on urethral catheter related injuries are sparse. To highlight the dangers inherent in traumatic urethral catheterization we prospectively monitored the incidence, cost and clinical outcomes of urethral catheter related injuries. Materials and Methods: This prospective study was performed during a 6-month period at 2 tertiary referral teaching hospitals. Recorded data included method and extent of urethral catheterization injury, setting and time of injury, number of catheterization attempts, urological management provided, additional bed days due to urethral injury and clinical outcomes after followup. The additional cost of managing urethral injuries was also calculated.

Results: A total of 37 iatrogenic urethral injuries were recorded during the 6-month period. The incidence of traumatic urethral catheterization was 6.7 per 1,000 catheters inserted. Thirty (81%) patients sustained a complication Clavien-Dindo grade 2 or greater. The additional length of inpatient hospital stay was 9.4 ± 10 days (range 2 to 53). Of these patients 9 (24%) required an indwelling suprapubic catheter and 8 (21%) have an indwelling transurethral catheter. In addition, 9 (24%) are performing self-urethral dilation once weekly and 4 (11%) have required at least 1 urethral dilation due to persistent urethral stricture disease. The additional cost of managing iatrogenic urethral injuries was €335,377 (\$371,790).

Conclusions: Iatrogenic urethral catheterization injuries represent a significant cost and cause of patient morbidity. Despite efforts to educate and train health care professionals on urethral catheterization insertion technique, iatrogenic urethral injuries will continue to occur unless urinary catheter safety mechanics are altered and improved.

Key Words: urethra, catheterization, urinary catheter, iatrogenic disease, wounds and injuries

UP to 25% of hospitalized patients undergo routine urethral catheterization during their inpatient stay and approximately 0.3% will sustain iatrogenic urethral trauma during the insertion process. UC is more challenging in male patients due to the

tortuous anatomy of the male urethra and due to prostatic hyperplasia.² The most common methods of injury during traumatic UC are inadvertent balloon inflation in the urethra and/or false passage creation during insertion.³ Short-term complications

Abbreviations and Acronyms

ICU = intensive care unit

SPC = suprapubic catheter

UC = urethral catheterization

UTI = urinary tract infection

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* Correspondence: Department of Urology, St. Vincent's University Hospital, Elm Park, Dublin, Ireland (telephone: 00 353 1 221 4000; FAX: 00 353 1 221 4318; e-mail: nialldavis2001@yahoo.com).

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associated with traumatic UC include acute urinary retention, urosepsis, bleeding and acute kidney injury. Long-term complications include a predisposition to urethral stricture disease with subsequent reconstructive procedures. ^{1,3} Despite these preventable morbidities, mechanisms to prevent catheter related injuries receive little attention. ⁴ To highlight the dangers inherent with traumatic UC we prospectively monitored the incidence, cost and clinical outcomes of urethral catheter related injuries at 2 tertiary referral teaching hospitals.

METHODS

Overview of Study Design

A prospective study at 2 tertiary university hospitals in a 6-month period (July 2015 to January 2016) included all referrals for iatrogenic urethral injuries caused by UC. Ethics approval was granted by each hospital's ethics approval process. Data were prospectively maintained in departmental databases. Iatrogenic UC injury 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-catheterization.

Recorded Data

The data recorded included patient demographics, ASA® grade, mode of urethral injury, setting of injury, number of catheterization attempts, time of urethral injury (ie on call vs regular working hours), grade of health care professional causing injury, urological management provided, additional bed days due to urethral injury and clinical outcomes after followup. Additional length of stay was calculated based on the number of inpatient days from hospital admission to discharge for each patient under the urology service after an iatrogenic urethral injury caused by UC. The additional cost of initially managing urethral injury per inpatient stay was calculated from a resource and skill use model devised in conjunction with the hospital finance department. The overall number of catheterizations performed was calculated from data obtained from each hospital's procurement department. Statistical data are represented as mean \pm SD.

RESULTS

Traumatic Urethral Catheterization

A total of 37 iatrogenic urethral injuries were recorded during the 6-month period. There are 1,000 inpatient beds between both institutions with 11,000 catheter insertions performed per year. The incidence of traumatic UC was 6.7 per 1,000 catheters inserted during the study period. All patients

were male with a mean age of 74 ± 12 years (range 42 to 93) and an ASA grade of 3.4 ± 0.9 . The indications for UC were urinary retention (28), monitoring urine output (5), change of long-term indwelling catheter (3) and UC at brachytherapy (1). The mean number of attempted catheterizations was 3.2 before urological consultation.

Initial Management of latrogenic Urethral Injuries

Urethral injuries were caused by inflating the catheter anchoring balloon in the urethra (26) or by creating a false passage with the catheter tip (11). There were 29 traumatic UCs during on call hours and 2 patients had a prior documented history of difficult catheterization secondary to benign prostatic hyperplasia. Overall 35 patients sustained an iatrogenic injury in the hospital and 2 patients in a primary care center who were subsequently referred to the emergency department for further treatment. There were 13 patients who underwent percutaneous insertion of a suprapubic catheter and 12 who underwent diagnostic flexible cystoscopy with catheter reinsertion over a guidewire (table 1). All SPC placements were performed in the event of failed endoscopic attempts. Other initial management strategies included successful transurethral reinsertion of a catheter by the urology department (10), antegrade and retrograde urethrogram to catheterize bladder (2), rigid cystoscopy and catheter reinsertion (1), and open cystotomy and SPC (1) (table 1).

Short-Term Complications

All patients experienced a short-term complication and 30 of 37 complications (81%) were Clavien-Dindo grade 2 or greater. Short-term complications and relevant Clavien-Dindo grades are summarized in table 2. Urosepsis developed in 12 of 30 patients (40%), of whom 2 required inotropic support in the ICU due to severe urosepsis resulting in septic shock (Clavien-Dindo grade 4a). Urosepsis was defined as a proven UTI confirmed by positive blood and urine cultures accompanied by systemic inflammatory response syndrome. Of the 30 patients 4 (13%) sustained an acute kidney injury due

Table 1. Initial urological management for traumatic UC

	INO.
Percutaneous insertion of SPC*	13
Flexible cystoscopy + guidewire to catheterize bladder	12
Transurethral catheter inserted by urology service	7
Catheter manipulated + pushed back into bladder	3
Rigid cystoscopy + guidewire	1
Open cystotomy + SPC	1
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Total	37

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^{*}Of these patients 2 also underwent antegrade/retrograde urethrography to characterize the urethral injury.

Table 2. Short-term complications and relevant Clavien-Dindo grade after traumatic UC

	N	lo.	Clavien-Dindo Grade
Urosepsis (requiring ICU management)	10	(2)	2 (4a)
Acute renal failure (requiring ICU management)	3	(1)	2 (4a)
Hematuria requiring continuous bladder irrigation	6		2
Repeat cystoscopy to catheterize bladder	4		3b
Epididymo-orchitis requiring intravenous antibiotics	2		2
Blood transfusion	2		2
Total	27+(3	3)=30	

to obstructive uropathy, of whom 1 required dialysis and monitoring in the ICU department due to severe uremia (Clavien-Dindo grade 4a).

Other short-term complications included hematuria requiring continuous bladder irrigation (6), repeat cystoscopy to catheterize the bladder after SPC insertion (4), blood transfusion (2) and epididymo-orchitis requiring intravenous antibiotics (2). Brachytherapy for prostate cancer was postponed in 1 patient due to an iatrogenic urethral catheter injury at the time of seed implantation. The additional length of inpatient hospital stay was 9.4 ± 10 days (range 2 to 53).

Clinical Outcomes

All patients with a catheter related injury were followed (table 3). Eleven patients were discharged to a residential facility after presenting from home. Residential care was required as patients in this group were unable to independently manage an indwelling catheter due to underlying comorbidities (eg dementia and/or neurodegenerative disorders). Overall 9 (24%) patients required a long-term indwelling SPC. Eight (21%) patients currently have a transurethral catheter in situ with an elective trial without catheter planned in 6, and 2 patients opted for a long-term indwelling urethral catheter. Nine (24%) are performing self-urethral dilation once weekly and 4 (11%) have required at least 1 urethral dilation due to persistent urethral stricture disease. The remaining patients (7, 19%) are asymptomatic and have attended followup outpatient appointments for clinical examination, uroflowmetry and post-void residual measurement.

Table 3. Clinical outcomes after traumatic UC

	No.
Indwelling SPC	9
Indwelling urethral catheter	8
Intermittent self-catheterization	9
Urethral dilation/direct vision internal urethrotomy	4
Outpatient $uroflow + post-void residual measurement$	7
Total	37

Cost

The calculated cost of managing 37 iatrogenic urethral injuries in an acute inpatient hospital setting was €335,377 (\$371,790) (table 4). These costs are exclusive of managing the long-term complications, repeated urological interventions and followup appointments.

DISCUSSION

In this study the incidence of iatrogenic urethral catheter injury was 6.7 per 1,000 catheter insertions, consistent with the literature. Although educational initiatives reduce the incidence of iatrogenic UC injuries, they are not fail-safe and successful UC remains fully dependent on the operator. 4-6 Considering introgenic UC injuries are potentially avoidable and operator dependent, the medicolegal implications of these injuries are becoming more relevant. Urologists must be willing to advocate for urethral catheter design modifications to further decrease or eliminate the risk of injury due to operator error. In addition to shortterm and long-term morbidity and monetary loss, urethral injuries lead to an increased burden on urological resources, inpatient beds and skill use.³

The complications sustained in this group were significant, and included invasive urological intervention, urosepsis, severe hematuria requiring blood transfusion and urethral stricture disease. The mean number of attempted catheterizations was 3.2 before urological consultation and based on these findings we would suggest a "one gentle attempt only rule" for junior health care professionals. This may prevent a false passage or at least decrease the likelihood of making an iatrogenic false passage worse by repeating attempts.

Table 4. Breakdown of initial financial burden due to iatrogenic urethral injury during UC

	No.	Cost (€)	Total Cost (€)
Inpatient stay in ICU Inpatient stay at ward level Flexible cystoscopy	3 (17 nights total) 34 (330 nights total) 13	2,936/Night 832/Night 130	49,912 274,560 1,690
SPC Surgical theatre (open cystotomy)	12 1	150 3,000/Hr	1,800 3,000
Surgical theatre (endoscopic access to bladder)	1	3,000/Hr	1,500
Retrograde/antegrade urethrogram	2	225	500
Guidewire Catheters	17 37	42—70 20—65	935 1,480
Total cost			335,377

These initial costs are exclusive of managing long-term complications such as urethral stricture disease and followup outpatient appointments which lead to an even greater cost burden on the department.

Source: Finance departments at St. Vincent's University Hospital and Tallaght Hospital, Dublin, Ireland.

Disturbingly, 3 patients had severe morbidities that required inotropic support in an intensive care environment. Furthermore, autonomy was severely compromised in 11 patients who presented from home and were discharged to short-term or long-term residential care for management of an indwelling catheter after traumatic UC. This group of patients was unable to independently manage a suprapubic or transurethral catheter due to underlying comorbidities and had a prolonged inpatient stay.

Our study cohort is representative of a typical hospital inpatient population as our data were gathered prospectively. The majority of injuries were caused by senior house officers/junior residents, and occurred out of hours in high volume, rapid turnover environments (ie emergency departments). Only 2 patients had a history of difficult UC. These findings suggest that environmental settings and grade of health care professional performing UC are potential risk factors for an iatrogenic urethral injury as opposed to underlying urological patient abnormalities. The total cost of managing these complications was €335,377 during the 6-month study period. Notably these costs were exclusive of repeat procedures, outpatient appointments, medicolegal fees and residential care costs which are ongoing. Therefore, the overall cost of managing iatrogenic urethral injuries is likely to be significantly greater than the figures presented here.

Contemporary catheters and catheter syringes have been unchanged for decades and can generate enormous inflation pressures (greater than 700 kPa).⁵ We recently reported safer UC with a prototype safety syringe that allowed fluid in the syringe to decant through an activated safety threshold pressure valve.⁵ The introduction of safety mechanisms could potentially prevent injury related to inadvertent balloon inflation in the urethra, thereby reducing iatrogenic catheter morbidity and financial penalties. While inadvertent filling of the catheter balloon in the urethra may cause an iatrogenic injury, trauma may also occur during catheter

removal if the balloon is not completely deflated. Wu et al demonstrated that urethral balloon inflation pressures are 1.9 times greater than bladder pressures and this increases nonlinearly 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.

Adjustments and improvements to catheter mechanics will likely result in an incremental decrease in iatrogenic urethral trauma. However, education on a safe catheterization technique remains the most important preventive step.4 Educational measures decrease some of the avoidable complications associated with traumatic UC as demonstrated by Kashefi et al, where the number of iatrogenic urethral catheter injuries were monitored before and after the commencement of a nursing education program. After comparing data from a 6-month period the authors noted a 4.9-fold decrease in urethral injuries in the post-education phase of the study. Similarly, a mandatory training course for all health care professionals performing urethral catheterization has been introduced in both institutions in the current study. However, it is notable that our study was performed in the postcatheter education period, thereby demonstrating that traumatic UC remains a persistent and unclinical problem among health solved professionals.

CONCLUSIONS

Iatrogenic UC injuries represent a significant cause of patient morbidity and have medicolegal implications. In addition, managing UC related injuries places a significant and potentially avoidable cost burden on the health care system. Despite efforts to educate and train health care professionals on catheter insertion technique, iatrogenic urethral injuries will continue to occur unless the safety mechanics of the conventional urinary catheter are altered in the future.

REFERENCES

- Kashefi C, Messer K, Barden R et al: Incidence and prevention of iatrogenic urethral injuries. J Urol 2008; 179: 2254.
- Manalo M, Lapitan MC and Buckley BS: Medical interns' knowledge and training regarding urethral catheter insertion and insertion-related urethral injury in male patients. BMC Med Educ 2011; 11: 73.
- 3. Thomas AZ, Giri SK, Meagher D et al: Avoidable iatrogenic complications of urethral catheterization

- and inadequate intern training in a tertiary-care teaching hospital. BJU Int 2009; **104:** 1109.
- Simhan J: Reducing iatrogenic urethral trauma. J Urol 2015; 194: 871.
- Davis NF, Mooney RO, Cunnane CV et al: Preventing urethral trauma by inadvertent inflation of catheter balloon in the urethra during catheterization: evaluation of a novel safety syringe after correlating trauma with urethral
- distension and catheter balloon pressure. J Urol 2015; **194:** 1138.
- Davis NF, Mooney RO, O'Brien MF et al: Attitudes among junior doctors towards improving the transurethral catheterisation process. Ir J Med Sci 2015; 184: 365.
- Wu AK, Blaschko SD, Garcia M et al: Safer urethral catheters: how study of catheter balloon pressure and force can guide design. BJU Int 2012; 109: 1110.

EDITORIAL COMMENT

Traumatic catheterization and its association with clinical outcomes at 2 tertiary care centers were reported in this study, and fortunately the rate of injury was low (6.7 per 1,000 catheters inserted). However, the short-term morbidity after traumatic catheterization was significant, with 30 of 37 patients experiencing Clavien 2 or greater complications. In addition, at an average cost of more than \$10,000 per patient, traumatic catheterization was associated with significant expense during the study period. The long-term burden to individuals who experience these complications is potentially life altering.

Catheter associated UTI has received considerable scrutiny from national and international regulatory

agencies. However, traumatic catheterization may contribute to catheter associated morbidity as significantly as catheter associated UTIs,² thus representing another important argument for the judicious use of catheterization. When catheterization is required, simple educational interventions can reduce the incidence and severity of iatrogenic catheterization injuries (reference 1 in article). Organized urology must assume a leadership role in the management of these linked complications.

Joshua A. Cohn, W. Stuart Reynolds and Roger R. Dmochowski

Vanderbilt University Medical Center Nashville, Tennessee

REFERENCES

- 1. Eliminating CAUTI: Interim Data Report, 2013. Available at http://www.ahrq.gov/professionals/quality-patient-safety/cusp/cauti-interim/cauti-interim1.html. Accessed May 26, 2016.
- 2. Leuck AM, Wright D, Ellingson L et al: Complications of Foley catheters—is infection the greatest risk? J Urol 2012; 187: 1662.

REPLY BY AUTHORS

We agree with the comment that traumatic catheterization contributes to catheter associated UTI. This point is highlighted by the fact that urosepsis developed in 12 of 37 patients in our study, of whom 2 required inotropic support in the ICU after a misplaced urinary catheter.

We also agree that judicious use of catheterization and simple educational interventions will reduce the incidence of iatrogenic catheterization injuries in our hospitals. One recent national

prevention program decreased catheter use from 20.1% to 18.8% (incidence rate ratio 0.93; 95% CI 0.90 to 0.96; p <0.001) and catheter associated UTI rates from 2.28 to 1.54 infections per 1,000 catheter days (incidence rate ratio 0.68; 95% CI 0.56 to 0.82; p <0.001) in nonICUs after 12 months. The main program features were education and guidance on technical and socio-adaptive factors in the prevention of catheter associated UTI.

REFERENCE

1. Saint S, Greene MT, Krein SL et al: A program to prevent catheter-associated urinary tract infection in acute care. N Engl J Med 2016; 374: 2111.