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Clinical evaluation of a safety-device to prevent urinary catheter inflation related injuries

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Abstract

Objective

To evaluate the feasibility of a novel 'safety-valve' device for preventing catheter related urethral trauma during urethral catheterisation (UC). To assess the opinions of clinicians on the performance of the safety-valve device.

Materials and Methods

A validated prototype 'safety-valve' device for preventing catheter balloon inflation related urethral injuries was prospectively piloted in male patients requiring UC in a tertiary referral teaching hospital (n=100). The device allows fluid in the catheter system to decant through an activated safety threshold pressure valve if the catheter anchoring balloon is misplaced. Users evaluated the 'safety-valve' with an anonymous questionnaire. The primary outcome

measurement was prevention of anchoring balloon inflation in the urethra. Secondary outcome measurement was successful inflation of urinary catheter anchoring balloon in the bladder.

Results

Patient age was 76 ± 12 years and ASA grade was 3 ± 1.4. The 'safety-valve' was utilised by 34 clinicians and activated in 7% (n=7/100) patients during attempted UC, indicating that the catheter anchoring balloon was incorrectly positioned in the patient's urethra. In these 7 cases, the catheter was successfully manipulated into the urinary bladder and inflated. 31/34 (91%) clinicians completed the questionnaire. 10% (n=3/31) of respondents had previously inflated a urinary catheter anchoring balloon in the urethra and 100% (n=31) felt that a safety mechanism for preventing balloon inflation in the urethra should be compulsory for all UCs.

Conclusion

The safety-valve device piloted in this clinical study offers an effective solution for preventing catheter balloon inflation related urethral injuries.

Abbreviations:

UC: Urethral catheterisation

TUC: Traumatic urethral catheterisation

1.0 Introduction

Approximately 25% of hospitalised patients undergo urethral catheterisation (UC) during their inpatient stay[1]. A misplaced urethral catheter, with subsequent inflation of its anchoring balloon in the patient's urethra, is a frequently encountered complication that can lead to debilitating long-term co-morbidities[2,3] Short-term complications associated with traumatic

UC are penile/perineal pain, urosepsis, acute urinary retention, urethral bleeding or urinary tract infection[1]. Long-term complications include urethral stricture disease requiring subsequent reconstructive procedures[3,4]. Despite these preventable iatrogenic morbidities, few studies examine mechanisms to prevent UC related injuries[5]. Of those that examine such mechanisms, none are based on data from human patients in a clinical environment[6]. The objective of the present study is to clinically evaluate a mechanism for preventing urinary catheter inflation related injuries in patients requiring UC. This is accomplished by prospectively performing a clinical trial of a novel 'safety-valve' device that is intended to prevent inadvertent inflation of the catheter's anchoring balloon in the urethra during UC. We also aim to assess the opinions of junior doctors on the clinical performance of the safety-valve device.

2.0 Methods

2.1 Overview of study design

Following hospital ethical research committee approval a previously validated prototype 'safety-valve' device, that allows fluid in the catheter system to decant through an activated safety threshold pressure valve, was prospectively evaluated in 100 male patients requiring UC in a tertiary referral teaching hospital (Beaumont Hospital, Dublin, Ireland) (Fig. 1)[6]. Written informed consent was obtained in every patient and a patient information leaflet was given to every patient. All clinicians that utilised the device were educated on its application through 'hands-on' demonstrations on silicone catheterisation models. Inclusion criteria included male gender, age >18 years, painless acute urinary retention, no previous history of urethral trauma and appropriately consented patients. Painless acute urinary retention was defined as a post void residual (PVR) volume measurement >400ml in the absence of suprapubic pain. Exclusion criteria included patients unable to provide informed consent, emergency catheterisations (e.g. painful acute urinary retention), paediatric patients and prior history of urethral trauma.

2.2 Safety-valve

The safety-valve comprises of a pressure valve and flow-restrictor that attach distally to an existing commercial syringe and proximally to any commercial urinary catheter (Fig. 1). The safety valve functions as a one-way pressure relief valve that allows pressurised fluid to flow from an auxiliary passage out of the system in a regulated manner. The purpose of the pressure valve is to prevent inflation of the catheter's anchoring balloon when inadvertently misplaced in the urethra and to allow inflation when correctly positioned in the urinary bladder. Once the valve has 'popped' it automatically deactivates so that it can be used repeatedly. The flow restrictor prevents rapid inflation of the anchoring balloon (an act which

has the potential to allow a portion of the fluid to bypass the pressure valve and cause partial inflation of the balloon even when mispositioned) in the urethra[7].The valve remains inactivated when the anchoring balloon is in the bladder allowing the anchoring balloon to inflate as normal.

2.3 Measurement outcomes

The primary outcome measurement was prevention of anchoring balloon inflation in the urethra. The secondary outcome measurement was successful inflation of the urinary catheter's anchoring balloon in the bladder without dispensing fluid (false-positive). Successful UC was defined as urine exiting the catheter's drainage port witnessed by the user with successful inflation of the catheter's anchoring balloon. Users were instructed not to repeatedly attempt to inflate the catheter's anchoring balloon if the safety-valve activated. Instead, they were advised to gently advance the deflated catheter until urine drained from the drainage port. Users that performed UC with the safety-valve were then requested to complete an anonymous questionnaire on their opinions of the device. The survey consisted of 5 questions and requested details pertaining to UC of male patients with the safety-valve. (Table 1). All questions required either 'Yes' or 'No' as an answer. Unless otherwise stated, data are represented as mean ± standard deviation (SD), and n represents the number of patients included in the analysis

3.0 Results

3.1 Safety-valve

In total, 34 interns utilised the safety device in 100 consenting male patients requiring inpatient UC. All patients underwent successful catheterisation with the 'safety-valve' device. The relevant UC patient demographics are demonstrated in Table 2. The mean patient age was 76 ± 12 years and the mean ASA grade was 3 ± 1.4. Indications for UC included monitoring of urine output (n=68), treatment of acute urinary retention (n=25) and requirement of long-term indwelling urethral catheterisation (n=7). No urethral injuries due to traumatic catheterisation were recorded during the study time-period. The 'safety-valve' activated in 7 patients during attempted UC, indicating that the catheter's anchoring balloon was incorrectly positioned in the patient's urethra (Table 3). In these 7 cases, the catheter was successfully manipulated into the urinary bladder by the user followed by successful inflation of the anchoring balloon.

3.2 Questionnaire response

The questionnaire was completed by 31/34 (91%) interns that utilised the safety-device (Table 1). No questionnaires were incomplete, and analysis was performed on every returned questionnaire. Among the respondents, 10% (n=3/31) had previously inflated the catheter's anchoring balloon in the urethra instead of the urinary bladder in a male patient. The majority (87 %; n = 27/31) of interns were interested in a safety mechanism for preventing urethral trauma during the catheterisation procedure and 100% (n = 31) felt that a safety mechanism for trauma prevention should be compulsory for all urethral catheterisations.

4.0 Discussion

UC is a routine procedure that is performed daily by healthcare professionals. Iatrogenic complications associated with UC have recently decreased due to advanced training programmes that are regularly provided by senior clinicians[8]. Junior doctors are supervised during their initial months when performing UC and a quota of catheterisations is usually required prior to complete independence. Although supervised training programmes have led to an overall decrease in the frequency of catheter-related complications, our questionnaire demonstrates that the anchoring balloon is mistakenly inflated in the urethra in approximately 10% of patients among junior doctors. Therefore, a safer urethral catheter system in conjunction with supervised training may be necessary to eradicate the risk of unnecessary urethral trauma during UC.

Our clinical trial also demonstrates that incorporation of a novel safety-valve device eliminates the potential for catheter balloon inflation related injuries to the urethra. We found that the safety-valve facilitates successful inflation of the urinary catheter's anchoring balloon in the bladder as evidenced by successful UC of all patients. Similar significant technological advances have been recently described and advocated in urinary catheter device design. Wagner *et al.* introduced the concept of a vision-guided urinary catheter as an auxiliary device for nursing personnel in cases of difficult catheterisation[9]. Azar *et al.* trialled a recently developed atraumatic urinary catheter in an animal model[10]. The authors assessed their device by forcibly extracting catheters with the balloon still inflated and found no evidence of urethral trauma in 10/14 male rabbits. Wu *et al.* emphasised that urethral resistance pressure, intravesical pressure and catheter inflation forces (Newtons) are parameters that should be developed for designing an atraumatic urinary catheter. The safety device outlined in this present study allows fluid to decant through an activated safety valve

at a threshold pressure that can be tailored to specific balloon inflation pressures (e.g. 150kPa) thereby eliminating the potential for urethral trauma[11]. This offers an advantage over emerging technology as it eliminates the need for vision-guidance using scientifically derived and clinically evaluated pressure differentials and flow resistance. This technology therefore offers an effective and dependable solution to a preventable iatrogenic injury. Our findings are clinically relevant as millions of urinary catheters are inserted annually and iatrogenic urethral injuries are a potentially preventable source of injury in patients[12]. Iatrogenic complications from UC are associated with medicolegal implications, financial penalties, longer inpatient stays and long-term urethral stricture disease. In addition to short-term and long-term iatrogenic morbidity and monetary loss, urethral injuries lead to an increased burden on urological resources, inpatient beds and skill use[1].

Globally, the most commonly used urethral catheter was devised by Foley in 1929 and its design was patented in 1936[13]. Since then no significant alteration has occurred for improving the safety design of urethral catheters[13]. The modern Foley catheter is coated with a silicone elastomer to reduce the potential for latex toxicity associated with the original device[8]. Catheter research is primarily aimed at decreasing the incidence of urinary tract infections by coating antiseptic or antimicrobial agents over the catheter. 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[13]. Recently, the incidence, cost, complications and clinical outcomes of iatrogenic urethral catheterisation injuries was prospectively monitored across 2 tertiary referral teaching hospitals and the incidence of significant urethral trauma was 6.7 patients per 1,000 patients catheterised[1]. Furthermore, 81% of patients with urethral trauma sustained a Clavien-Dindo complication grade ≥2. The cost of managing these inpatient complications was €335,377 or €60 per inpatient catheterised over a 6-month

period[1]. To decrease or eliminate the risk of urethral injury or rupture during UC, urologists must be willing to support safer urethral catheter design modifications such as the technology outlined in this study. One recent study of 130 junior doctors found that 90% would be interested in a safety mechanism for preventing urethral trauma and 71% felt that such a mechanism should be mandatory when catheterising male patients[14]. Similarly, we noted that 100% of respondents to our questionnaire believed that a safety mechanism for preventing urethral trauma during UC should be compulsory when catheterising male patients.

5.0 Conclusion

A clinical trial of a novel safety-valve device intended to prevent anchoring balloon inflation in the urethra was piloted, using appropriate pressure differentials. No urethral injuries due to traumatic catheterisation were recorded. This technology therefore offers an effective and dependable solution to a preventable iatrogenic urethral injury.

6.0 References

1. Davis NF, Quinlan MR, Bhatt NR, Browne C, MacCraith E, Manecksha R, Walsh MT, Thornhill JA, Mulvin D.Incidence, Cost, Complications and Clinical Outcomes of Iatrogenic Urethral Catheterization Injuries: A Prospective Multi-Institutional Study. J Urol. 2016 Nov;196(5):1473-1477.
2. Sullivan JF, Forde JC, Thomas a Z, Creagh T a. Avoidable iatrogenic complications of male urethral catheterisation and inadequate intern training: A 4-year follow-up post implementation of an intern training programme. Surgeon. 2014;2–5.
3. Thomas AZ, Giri SK, Meagher D, Creagh T. Avoidable iatrogenic complications of urethral catheterization and inadequate intern training in a tertiary-care teaching hospital. BJU Int. 2009;104:1109–12.
4. Kashefi C, Messer K, Barden R, Sexton C, Parsons JK. Incidence and Prevention of Iatrogenic Urethral Injuries. J Urol. 2008;179(June):2254–8.
5. Simhan J. Reducing iatrogenic urethral trauma. J Urol [Internet]. American Urological Association Education and Research, Inc.; 2015;194(4):871–2.
6. Davis NF, Mooney RO, Cunnane CV, Cunnane EM, Thornhill JA, Walsh MT. Preventing Urethral Trauma from 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 Oct;194(4):1138-45
7. Davis NF, Cunnane EM, Mooney RC, Manecksha RP, Thornhill JA, Walsh MT. Quantification of User and Manufacturer Variabilities in Urinary Catheter Anchoring Balloon Inflation and Mitigation of Variability by Flow Resistance. Urology. 2017 Apr;102:258-263
8. Bhatt NR, Davis NF, Quinlan MR, Flynn RJ, McDermott TED, Manecksha RP, et al.

A prospective audit on the effect of training and educational workshops on the incidence of urethral catheterization injuries. Can Urol Assoc J. 2017;11(7):E302–6.

9. Wagner KR, Bird ET, Coffield KS. Urinary Catheterization: a Paradigm Shift in Difficult Urinary Catheterization. Current Urology Reports. 2016. Nov;17(11):82
10. Azar R, Shadpour P. *In Vivo* Trial of a Novel Atraumatic Urinary Catheter Design for Prevention of Catheter-Induced Trauma. J Endourol. 2016;30(7):822–7.
11. Wu AK, Blaschko SD, Garcia M, McAninch JW, Aaronson DS. Safer urethral catheters: How study of catheter balloon pressure and force can guide design. BJU Int. 2012;109:1110–4.
12. Manalo M, Lapitan MCM, Buckley BS. Medical interns' knowledge and training regarding urethral catheter insertion and insertion-related urethral injury in male patients. BMC Medical Education. 2011. p. 73.
13. Feneley RCL, Hopley IB, Wells PNT. Urinary catheters: history, current status, adverse events and research agenda. J Med Eng Technol. 2015;39(8):459–70.
14. Davis NF, Mooney ROC, O'Brien MF, Walsh MT. Attitudes among junior doctors towards improving the transurethral catheterisation process. Ir J Med Sci 2015; Jun;184(2):365-7. .

Figure legend:

Figure 1: Urinary-catheter 'safety-valve' for preventing balloon related urethral injuries during UC

Legend: The safety-valve attaches distally to an existing commercial syringe and proximally to any commercial urinary catheter (A). If the catheter's anchoring balloon is inflated in the urethra, the safety valve is activated thereby preventing inflation of the balloon in the incorrect position and limiting the potential for urethral trauma. The flow restrictor prevents rapid inflation of the anchoring balloon which can bypass the safety valve (B). The valve remains inactivated when the balloon is in the bladder. This means that the anchoring balloon can only be inflated when positioned correctly in the bladder.

Table 1: Questionnaire design and attitudes of respondents towards the urinary catheter safety-valve device.

Question	Yes (%)	No (%)
Do you feel confident inserting a transurethral catheter independently?	30 (97)	1 (3)
Have you ever inflated the catheter's anchoring balloon in the urethra instead of the bladder in a male patient?	3 (10)	28 (90)
Would a safety mechanism that prevents urethral trauma from trans-urethral catheterisation interest you?	27 (87)	4 (13)
Did you find the safety-valve user friendly?	26 (84)	5 (16)
Do you think a safety mechanism that prevents urethral trauma during catheterisation should be compulsory?	31 (100)	0 (0)
Would you use this safety device again during urethral catheterisation?	31 (100)	0 (0)

Table 2: Demographics of patients that underwent UC with the safety-valve device

Demographic	**Number (n)**
Age (years)	76 ±12
ASA grade	3 ±1.4
Number of times safety-valve activated	7
Indication for urethral catheterisation (n)	
Urinary retention	25
Monitoring of urine output	68
Long-term indwelling catheter	7

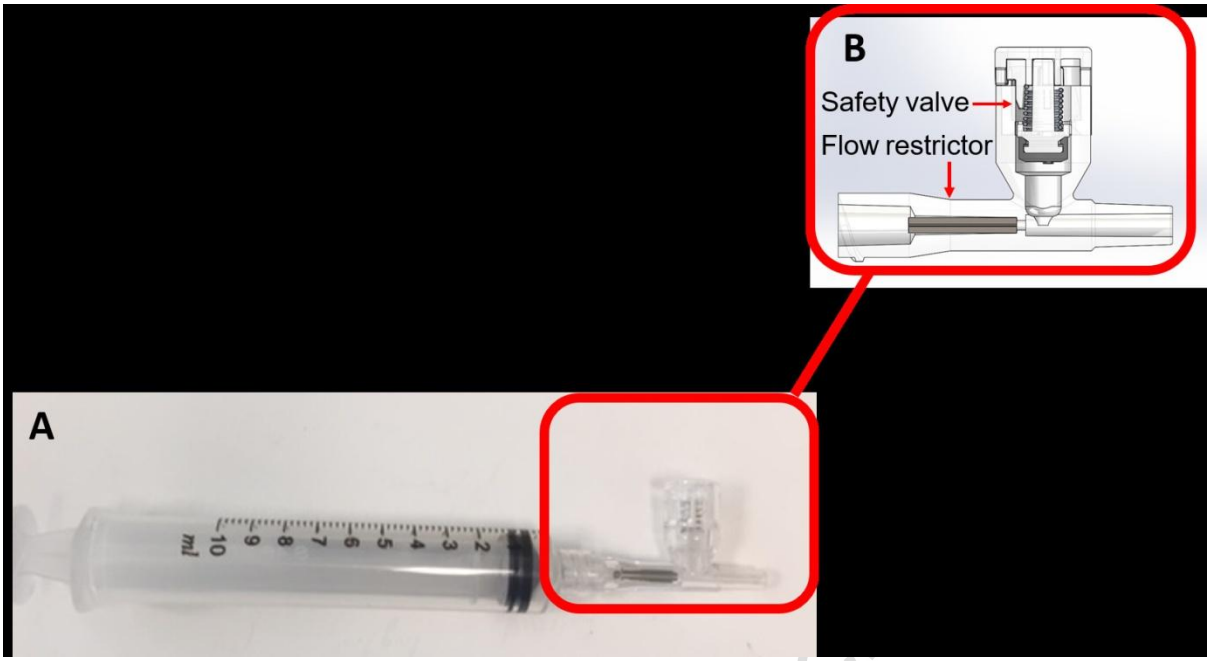
Table 3: Details of patients in whom the safety-valve activated indicating a misplaced urinary catheter anchoring balloon.

Legend: Three patients had a history of prostatic enlargement and 4 patients had no previous urological history. In 3 cases the intern documented difficulty with the catheterisation. These 3 patients had a known history of BPH indicating technical difficulties. In 4 cases the safety-valve activated in patients with no known urological history indicating a lack of experience of the intern.

*BPH: benign prostatic hyperplasia, UC: urethral catheterisation

Patient number	Age	Details of UC and safety-valve activation
1	74	Known history of BPH Patient required UC for output monitoring post orthopaedic surgery Intern documented difficulty passing catheter
2	68	Known history of BPH Patient required UC for PVR >400ml Intern documented difficulty passing catheter
3	78	No past urological history Patient required UC for PVR >400ml post inguinal hernia surgery No difficulty documented with catheterisation
4	75	No past urological history Patient required UC for urinary output monitoring post colorectal surgery No difficulty documented with catheterisation
5	72	Known history of BPH Patient required UC for PVR >400ml

		Intern documented difficulty passing catheter
6	75	No past urological history Patient required UC for output monitoring post orthopaedic surgery No difficulty documented with catheterisation
7	69	No past urological history Patient required UC for urinary output monitoring post colorectal surgery No difficulty documented with catheterisation



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