Original Article

Catheter-associated meatal pressure injuries (CAMPI) in patients with long-term urethral catheters—a cross-sectional study of 200 patients

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Background: Indwelling urethral catheters (IDC) are ubiquitous to healthcare settings, and are associated with many familiar risks like haematuria, infections, bladder spasms and stones. However, a less known complication is catheter-associated meatal pressure injury (CAMPI), especially in those with long-term IDCs. The objective of this study was to explore the prevalence, associated features and management of CAMPI in adults with a long-term IDC.

Methods: A cross-sectional multi-centre study was undertaken of 200 adults with a long-term IDC across regional south-west Queensland, Australia between June 2019 to June 2021. The prevalence of CAMPI was determined by clinical examination, voluntary surveys completed by participants and documentation in medical records. Key IDC statistics included total duration of IDC, location of IDC changes, IDC size, type and fixation.

Results: Out of 200 adults with a long-term IDC, 9% (18/200) had a CAMPI. There was a higher prevalence of male CAMPI (17/169, 10%) compared to female CAMPI (1/31, 3%). The median time to identification of a CAMPI after initial IDC insertion was 12 weeks (2–136 weeks), but occurred as soon as 2 weeks. CAMPI formation was associated with IDC changes in the community, impaired mobility and congestive cardiac failure (CCF). CAMPI were mostly treated by conservative means given the frailty of the population.

Conclusions: Poor mobility, community-managed IDCs, and CCF were all found to have statistically significant associations with the development of CAMPI. CAMPI represents an important and underserved iatrogenic complication within urology practice, and greater awareness is needed to prevent it in vulnerable patients with long-term IDCs.

Keywords: Urology; urological surgical procedures; urinary catheter; complications; community health services

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Introduction

Indwelling urethral catheters (IDCs) are ubiquitous in healthcare settings and are primarily used to drain the bladder for short, limited durations during critical illness or post-operative recovery. While long-term IDCs should be avoided, they can be of therapeutic benefit in highly selected patient populations for whom intermittent catheterization, self-catheterization and surgical intervention are deemed impossible or too risky. Indications include chronic urinary retention, the promotion of healing of open sacral and perineal wounds, or enhancing comfort during end-of-life care (1).

But, as with all invasive interventions, IDCs are not without risks. Well documented acute complications include catheter-associated urinary tract infections (CAUTIs), urethral trauma, bladder spasms, hematuria and even anaphylaxis (2-5). In the long term, IDCs can lead to strictures, recurrent UTIs, traumatic IDC changes, urothelial malignancies and stones (6). Another important, but often underestimated complication is catheter-associated meatal pressure injury (CAMPI).

Mucosal membrane pressure injuries refer to injuries caused by prolonged pressure and shear forces on the moist membranes that line the respiratory, gastrointestinal, and genitourinary tracts and are typically iatrogenic—caused by medical devices (7). CAMPI occur when an IDC erodes the urethra and surrounding soft tissue, leading to complete cleavage of the penis in the most severe cases. This therefore represents significant morbidity and loss of quality of life.

Internationally, research on the prevalence, risk factors, management, and prevention of CAMPI is scarce. Existing literature on this topic primarily consists of isolated case reports (8-15) and small case series (16-27). Contemporaneous research includes a prospective study by Shenhar *et al.* from Israel investigating the prevalence of CAMPI in an acute hospital setting in which the occurrence rate was 22.4% and the median duration of the IDC was 5.5 days (28).

The aim of this study was to investigate the prevalence of CAMPI in adults with long-term IDCs—the population most at risk—while simultaneously examining its associated risk factors and management strategies. We present this article in accordance with the STROBE reporting checklist (available at https://tau.amegroups.com/article/view/10.21037/tau-23-445/rc).

Highlight box

Key findings

- The study found significant associations between the development of catheter-associated meatal pressure injury (CAMPI) and poor mobility, community-managed Indwelling urethral catheters (IDCs), and congestive cardiac failure (CCF).
- CAMPI typically manifests within an average of 18 weeks after IDC insertion, but can occur as early as 2 weeks post-insertion.

What is known and what is new?

- CAMPI is an underserved urological issue that requires greater awareness, especially in patients with long-term IDCs.
- This study identified specific risk factors associated with CAMPI development, such as poor mobility, community-managed IDCs, and CCF.

What is the implication, and what should change now?

- An interprofessional approach is needed to manage CAMPI risk factors and promote wound healing.
- Changes should include counseling patients about CAMPI risks at the time of IDC insertion, early escalation to specialist urology support if CAMPI is detected, and developing resources to educate patients, caregivers, and medical officers.

Methods

Study design and population

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). We conducted a cross-sectional observational study with ethics approved by the Darling Downs Health Human Research Ethics Committee (No. HREA/2020/QTDD/62452). The study was registered with the Australia and New Zealand Clinical Trials Registry (No. ACTRN12620000626965). Written consent was obtained from individual patients for the publication of de-identified clinical photographs in this paper.

The study was carried out in two major health services in south-west Queensland: West Morton and Darling Downs Health Services. These healthcare facilities collectively cover an extensive area of 99,000 square kilometers and serve a population of over 590,000 individuals residing in regional, rural, and remote areas.

Participants were recruited from the urology outpatient clinics, trial of void clinics, urology nurse practitioner clinics, and inpatient consultations. All eligible patients who had long-term IDCs in place for at least 4 weeks between June 2019 and June 2021 and were 18 years of age or older were included consecutively in the study, with the aim of including 197 patients based on sample size calculations.

Data collection

Participants were invited to voluntarily complete a survey

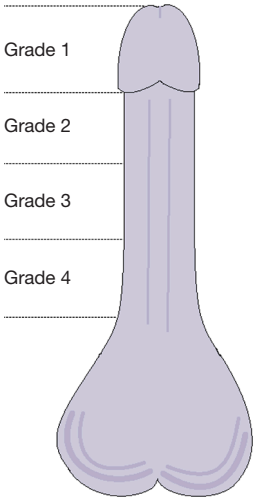

Figure 1 Catheter-associated meatal pressure injury grading system—male.

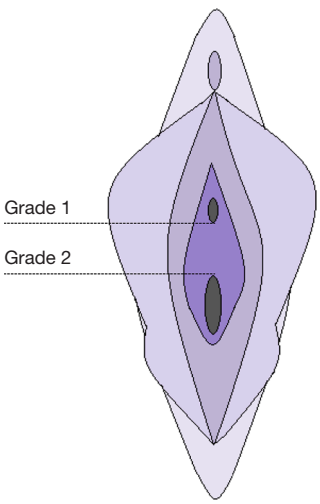

Figure 2 Catheter-associated meatal pressure injury grading system—female.

(Figure S1) regarding their experiences with an IDC. Additionally, the researchers analyzed participants' medical records to gather information about IDC management, demographics and comorbidities. Our team of investigators, including medical and nursing staff, assessed the CAMPI grade by physical examination at the time of inclusion.

The IDC data encompassed details such as the date of initial insertion, size, type and fixation of the IDC, total duration of IDC usage, and location of documented changes. Proper fixation was defined as the IDC being fixed to the upper thigh or abdomen without tension or bowstring effect on the meatus. Urological data included any urology procedures conducted in the previous 12 months, presence of urinary incontinence, UTIs within the past 6 months, and diagnoses of prostatomegaly, urethral stricture disease, or neurogenic bladder.

Basic demographic information consisted of age, gender, body mass index (BMI), and mobility status. Comorbidity data included the prevalence of spinal cord injury, smoking status, hypertension, atrial fibrillation, ischemic heart disease, congestive heart failure, asthma, chronic obstructive pulmonary disease, chronic kidney disease (stage 2 or worse), diabetes, cerebrovascular event, dementia, autoimmune conditions, malignancy (both historical and active, categorized as prostate, bladder or other), and any admission(s) to the intensive care unit (ICU) within the previous 12 months. All patients with spinal cord injuries were included with the neurogenic bladder data.

Statistical analysis

Differences in demographic features and comorbidities between adults with CAMPI and those without CAMPI were analyzed using *t*-tests and Fisher's exact tests as appropriate. Statistically significant results were defined as those with a P value ≤ 0.05.

Male CAMPI grading system

We adapted Smith's (29) and Browne's (30) classification of hypospadias, Shenhar's (28) stratification of CAMPI in their study, as well as Becker's proposed grading score (31) into a system that would be easily translatable and reportable for future use in a community setting. Specifically, male CAMPI was divided into four grades (*Figure 1*) wherein each grade is defined by the most proximal anatomical extent of the pressure injury:

- Grade 1: erosion of the meatus, confined within the glans.
- Grade 2: erosion to distal 1/3 of penile shaft.
- Grade 3: erosion to middle 1/3 of penile shaft.
- Grade 4: erosion to proximal 1/3 of penile shaft/penoscrotal junction.

Female CAMPI grading system

Since the female urethra is shorter and surrounded by vulval tissues, we devised a simpler grading system for female CAMPI (*Figure 2*):

Figure 3 Examples of catheter-associated meatal pressure injury grades.

- ❖ Grade 1: erosion localized to the urethral orifice.
- ❖ Grade 2: erosion extending into the urethra and/or vulval tissues.

Results

A total of 200 adults with long-term IDCs, comprised of 169 males (84.5%) and 31 females (15.5%) were included in this study. Overall, eighteen participants had a CAMPI thereby affording an overall prevalence of 9%. CAMPI was more prevalent among males (17/169, 10%) compared to females (1/31, 3%). The single female case involved erosion localized to the urethral orifice (Grade 1). In the male CAMPI cases, Grade 1 was most common (14/17, 82%) followed by Grade 3 (2/17, 12%) and Grade 2 (1/17, 6%). There were no Grade 4 CAMPIs. Real-life examples of male CAMPI grades are presented in *Figure 3*.

Demographic features of CAMPI

An overview of demographic, comorbidity and IDC data for all adults with a long-term IDC is presented in *Table 1*. The mean age of all participants was 72 years with a standard deviation of 13.4. There was no significant difference in the mean age of adults with a CAMPI compared to those without a CAMPI (78±8.8 *vs.* 73±10.2 respectively). Similarly, the average BMI of participants with a CAMPI was similar to those without a CAMPI (25±6.0 *vs.* 26±6.7, respectively).

A significantly higher proportion of adults with CAMPI had decreased functional status defined as being bed bound or requiring a mobility aid (72% *vs.* 36%, P<0.01).

Participants with CAMPI also had higher rates of ICU admissions, UTIs and prostatomegaly, however none of these attributes were found to be statistically significant (*Table 1*).

Co-morbidity associations of CAMPI

Hypertension, diabetes and chronic kidney disease were the most common comorbidities across the entire cohort. However, congestive cardiac failure (CCF) was the only comorbidity with a statistically significant association with CAMPI (28% *vs.* 9%, P=0.02).

There was no significant difference in the prevalence of spinal cord injuries between participants with CAMPI and those without CAMPI (6% *vs.* 3%, P=0.51). There were higher rates of malignancy in adults with CAMPI, but this was not statistically significant (50% *vs.* 35%, P=0.19). The most common type of malignancy in both groups was prostate cancer (89% *vs.* 65%). Bladder cancer was rare in both groups (2% *vs.* 0%).

Catheter-associated features of CAMPI

Across the cohort, the total duration of an IDC ranged from 4 weeks to 13 years. Overall, the mean IDC duration in patients without CAMPI was 38 weeks, whereas the mean IDC duration in patients with CAMPI was 52 weeks. There was no statistical difference in these values. The median time between insertion of IDC to detection of CAMPI was 12 weeks, with a range of 2–136 weeks.

The size of IDCs ranged from 12 to 22 French (Fr), with the average (both mean and median) IDC size being

Table 1 Overview of demographic, comorbidity and IDC data for adults with a long-term IDC

Variable	Non-CAMPI (n=182)	CAMPI (n=18)	P value
Demographic features			
Male, n [%]	152 [84]	17 [94]	0.22
Female, n [%]	30 [16]	1 [6]	
Age, year (mean ± SD)	73±10.2	78±8.8	0.06
BMI, kg/m^2 (mean ± SD)	26±6.7	25±6.0	0.70
Mobility, n [%]			
Independent	117 [64]	5 [28]	<0.01
Four-wheel-walker	43 [24]	9 [50]	
Wheelchair	18 [10]	2 [11]	
Bed bound	3 [2]	1 [6]	
Walking stick	1 [1]	1 [6]	
Residence, n [%]			
Home	159 [87]	15 [83]	0.74
High care nursing home	4 [2]	0	
Residential aged care facility	18 [10]	3 [17]	
Supported accommodation	1 [1]	0	
Comorbidity features, n [%]			
Urological procedures in past 12 months	101 [55]	6 [33]	0.07
ICU admissions in past 12 months	12 [7]	3 [17]	0.12
Urinary incontinence	27 [15]	1 [6]	0.27
UTI in past 6 months	62 [34]	9 [50]	0.17
Prostatomegaly	95 [52]	11 [61]	0.47
Urethral stricture	19 [10]	1 [6]	0.50
Neurogenic bladder	47 [26]	4 [22]	0.74
Spinal cord injury	5 [3]	1 [6]	0.51
Smoking			
No	124 [68]	14 [78]	0.47
Yes	20 [11]	1 [6]	
Ex-smoker*	38 [21]	3 [17]	
Hypertension	104 [57]	14 [78]	0.09
Atrial fibrillation	25 [14]	4 [22]	0.33
Ischaemic heart disease	40 [22]	6 [33]	0.27
Congestive cardiac failure	17 [9]	5 [28]	0.02
Asthma	9 [5]	2 [11]	0.27
Chronic obstructive pulmonary disease	32 [18]	3 [17]	0.92

Table 1 (*continued*)

Table 1 (*continued*)

Variable	Non-CAMPI (n=182)	CAMPI (n=18)	P value
Chronic kidney disease	47 [26]	6 [33]	0.49
Diabetes (any type)	63 [35]	9 [50]	0.19
Cerebrovascular accident	30 [16]	3 [17]	0.98
Dementia	15 [8]	3 [17]	0.23
Autoimmune condition	4 [2]	0	0.52
Cancer	63 [35]	9 [50]	0.19
Prostate cancer (% in males)	41 [23]	8 [44]	0.1
Bladder cancer	4 [2]	0 [0]	>0.99
Other	18 [10]	1 [6]	–

*, ex-smoker = not smoking >12 weeks. IDC, indwelling urethral catheter; CAMPI, catheter-associated meatal pressure injury; SD, standard deviation; BMI, body mass index; ICU, intensive care unit; UTI, urinary tract infection.

Table 2 Overview of catheter data in adults with a long-term IDC

Variable	Non-CAMPI (n=182)	CAMPI (n=18)	P value
Number of patients who had IDC changes in the community, n [%]	47 [26]	9 [50]	0.03
Duration of IDC, weeks (mean ± SD)	38±73	52±41	0.42
IDC size (French)			
Median	16 [14–16]	16 [15–16]	0.15
Range	12–22	12–16	–
IDC material, n [%]			
Latex	142 [78]	12 [67]	0.49
Silicone	31 [17]	4 [22]	

IDC, indwelling urethral catheter; CAMPI, catheter-associated meatal pressure injury; SD, standard deviation.

16 Fr. All IDCs were 40 cm long. Over two-thirds of adults with a CAMPI had an IDC greater than or equal to 16 Fr (13/18, 72%). Latex IDCs were more common than silicone IDCs in both groups (78% non-CAMPI *vs.* 67% CAMPI, P=0.49). More than one-third of the CAMPI cases had a hydrogel-coated IDC *in-situ* (7/18, 39%).

The type of catheter was not documented for 6% (11/200) of the overall cohort and 11% of CAMPI cases (2/18). For the majority of these cases (8/200, 4%), the IDC was inserted and changed at a rural or remote hospital. In three cases, the IDC was inserted in either the Emergency Department (2/200, 1%) or the ward (1/200, 0.5%) of a major public hospital.

At the time of recruitment, the IDC was not appropriately secured in 21/182 (11.5%) patients of non-CAMPI and 3/18 (16.7%) of CAMPI (P=0.46) (*Table 2*).

Adults with CAMPI were more likely to have their IDC changed in the community. Specifically, 50% of CAMPI cases (9/18) had their IDC changed by community nursing services, whereas only 26% of participants (47/182) without CAMPI had their IDC changes performed in the community (P=0.03).

Management of CAMPI

The majority of the male CAMPI cases (8/18, 44%) were managed conservatively with specialist urology nursing support and catheter education. In these cases, the decision

to keep a long-term IDC in the setting of a CAMPI was due to the patient being too frail and comorbid for surgical intervention, including suprapubic catheter (SPC) insertion, and did not have the dexterity for self-catheterization. For two of these conservatively managed cases, urology-trained nurses attended residential aged care facilities to assist with regular IDC changes.

Seven male CAMPI cases (7/18, 39%) were treated with insertion of an SPC. Two men (2/18, 11%) passed a trial of void after undergoing a transurethral resection of the prostate (TURP). One man (1/18, 6%) passed a trial of void after completing an appropriate course of antibiotics for UTI and commencing androgen deprivation therapy for prostate cancer.

The single female CAMPI case occurred in the setting of a protracted 9-month long hospital admission. The IDC was initially inserted following repair of an anterior bladder injury during an emergency laparotomy with small bowel resection. This patient subsequently underwent three further re-look laparotomies for ischemic bowel. In the setting of complex abdominal surgery and deconditioning, the patient was not a suitable candidate for SPC insertion. Consequently, a 14-Fr Bard Lubrisil IDC remained *in-situ* for 36 weeks (9 months). This IDC was regularly changed by the Urology team every 4–6 weeks, and the time from IDC insertion to CAMPI detection was 6 months.

Discussion

Prevalence

The prevalence of CAMPI within this cohort accounted for 9% (18 out of 200) of participants. CAMPI were more prevalent among males, affecting 10% (17 out of 169) of male participants compared to 3% (1 out of 31) of female participants. However, it should be noted that these prevalence rates could be influenced by selection bias since the study specifically targeted and recruited individuals from Urology services, which typically cater to older male adults. To the best of our knowledge, Shenhar *et al.* have completed the only other study investigating the prevalence of CAMPI, but differences in study design make comparison limited. Shenhar *et al.* included hospitalized men in a single center with a median IDC duration of 5.5 days (28). They concluded a prevalence of 22.4%, notably higher than our study (9%) of patients with long-term IDCs in place for greater than 4 weeks. Explanations of this disparity include differences in grading, and different patient populations. Shenhar classified a grade 1 CAMPI as "intact skin and mucosa with non-blanchable erythema" whereas we defined it as "Erosion of the meatus, confined within the glans". These systems come with the inherent bias of over- and under-reporting based on a clinician's examination. Their acutely unwell cohort in hospital were also potentially prone to pressure injuries. It is clear however that our current information base about CAMPI is sparse with need for literature, education and standardization to better understand, prevent, refer and treat CAMPI. This is highlighted by Becker *et al.* who stated that CAMPI are "virtually unknown to a high number of medical staff" with referrals to Urology services including descriptions like "broken urethra" and "cleft of the penis" (31).

Mobility

Among the cohort, adults who were bed-bound or relied on mobility aids exhibited higher rates of CAMPI. Previous studies have reported a correlation between neurological disorders and an increased risk of urethral injury (1,9,10,12,16,19-22). Specifically, patients with reduced penile sensation, neurological diseases, spinal cord injuries, and neurogenic bladder dysfunction have shown a higher likelihood of developing CAMPI. While in our study, the presence of a spinal cord injury did not demonstrate a statistically significant association with CAMPI, this is possibly due to the low prevalence of such injuries within our cohort (3%, 6/200). The higher risk to immobile patients is a major finding in this study and specifying further investigation to this subset population could be important in increasing the awareness of this problem.

CCF

CCF was found to be associated with the formation of CAMPI in this study. CCF has a significant association with ulcers elsewhere, especially the lower limbs (32,33). In chronic lower limb oedema resulting from CCF the skin undergoes a process of liquid transudation and epithelial maceration making it fragile and prone to inflammation, injury and ulceration. Additionally, the accumulation of fluid in the tissues can impair the delivery of oxygen and nutrients to the skin, further compromising its integrity (32,33). These skin changes could extend to penile tissue contributing to the formation of CAMPI in patients with CCF. Furthermore, patients with CCF may have mobility limitations due to decreased exercise tolerance and lower

limb oedema which serve as additional risk factors for mucosal pressure injuries in general.

Community IDC changes

This study also identified an association between IDC changes performed by community nursing services and the formation of CAMPI. Half of all CAMPI cases involved IDC changes conducted by community nursing services. Patients who undergo IDC changes in community settings, especially in health services with limited resources, might experience longer intervals between changes, leading to less frequent monitoring and delayed detection of IDC complications. An additional hypothesis is that without specialist support readily available in the community, delays in identification and referral to urology services may occur.

IDC material and fixation

Some of our hypotheses about associations to CAMPI were not shown to be significant within our dataset. We posited a correlation between CAMPI and specific IDC materials, like latex, as well as improper IDC fixation.

By minimizing urethral irritation and inflammation, specialized IDC materials can theoretically mitigate the degradation of the mucosa and protect against CAMPI. Limited evidence suggests that silicone causes less histological evidence of urethral inflammation than both latex and hydrogel (34). Furthermore, Lam showed that IDCs coated in antimicrobials may reduce both the presence of bacteriuria, and clinical UTIs. This too could contribute to less urethral inflammation and protect against CAMPI (35). However, whether this translates to clinical practice is yet to be clarified. Our cohort included a varied selection of IDCs made from latex and silicone, both with and without hydrogel coating, and no statistical significance between these and CAMPI formation was found.

Furthermore, we speculated that IDCs that were not appropriately fixed would cause greater CAMPI rates. We reasoned that this could lead to excessive tension on the catheter due to the weight of the attached drainage system, acting as a bowstring that would erode through the urethra. While we did find this in more than 15% of CAMPI cases (3/18, all male), it was not statistically different to the non-CAMPI cohort (11.5%, 21/182). However, there is a significant margin for error with this variable in our study. Firstly, proper securement was only reported at a single snapshot at the time of recruitment, with subsequent assessments not made. Secondly, we do not know how each patient managed their IDC in the community, whether they were compliant with fixation outside of medical and nursing review, the positioning of the IDC during sleep, or whether the leg bag tubing caused any dragging of the IDC against the ventral aspect of the meatus. Admittedly, capturing this data accurately is challenging, and we therefore recommend clear documentation regarding the IDC type, size, length and fixation at every change (36).

Management and prevention

The core principle in the management of CAMPI is to make the patient IDC free. Initial assessment should therefore include a comprehensive review of the indication for the long-term IDC, and whether a trial of void is possible. If not, appropriately motivated and dexterous patients could learn self-intermittent catheterization. Because long-term IDCs are generally reserved as a palliative option, surgical intervention is often precluded in this patient cohort. However, the insertion of an SPC, or a TURP can be utilized to good effect, as was the case in our cohort. When these options are not viable, supportive management is essential with Urologist oversight and specialised urological nursing input. A multidisciplinary approach to optimise general risk factors that contribute to poor wound healing like obesity, smoking status, diabetes and nutrition, as well as specific CAMPI risk factors like CCF and mobility is also needed.

Finally, meticulous catheter care is essential and patients should be counselled on regular checks of the IDC insertion site, with cleaning of the glans and foreskin to reduce infection risk. Additionally, prevention of overfilling of the drainage system can reduce the weight and drag upon the meatus. Despite our results, we also recommend proper fixation with minimal tension upon the meatus given that Shenhar *et al.* demonstrated a statistically significant correlation with lack of catheter fixation to CAMPI in the acute setting (28).

However, the primary emphasis should be on the prevention of CAMPI in the management of long-term IDCs. We recommend counselling the patient of the risk of CAMPI at the time of the initial long-term IDC insertion, and early escalation to specialist urology support if CAMPI is detected. Therefore, promoting CAMPI awareness and developing resources to educate and equip vulnerable

patients along with their caregivers, community services, nursing homes and medical officers is essential. Our data is representative of rural and regional Queensland, Australia, but can be extrapolated to inform metropolitan and international cohorts.

Limitations

This cross-sectional study had a significant limitation in that it was unable to measure the incidence of CAMPI or establish causal relationships. The voluntary nature of the participant survey introduced the possibility of non-response bias, and participants who completed the survey may have been susceptible to recall bias. Additionally, recruiting participants who had already been referred to urology services may have introduced over-detection bias. However, by not sampling the general population, under-detection is also plausible as we have shown that the highest risk patients are those with mobility issues and are generally in long-term care facilities. Due to the cross-sectional design of this study, it was not possible to conduct long-term follow-up on the management of CAMPI. A larger and longitudinal study would be more suitable for assessing the natural progression of CAMPI and treatment outcomes. Finally, there are other mucosal pressure injuries associated with IDCs that were not explored in this study, like pressure necrosis of the urethra due to compression against the pubic bone in the wheelchair bound, and intrinsic sphincter weakness from urethral atrophy in females. Both of these warrant further consideration.

Conclusions

Poor mobility, community-managed IDCs, and CCF were all found to have statistically significant associations with the development of CAMPI. Typically, CAMPI is detected within an average of 18 weeks (or 4.5 months) after the insertion of the IDC, although it can manifest as early as 2 weeks post-insertion. CAMPI represents an important and underserved urological issue, and greater awareness is needed to prevent it in vulnerable patients with long-term IDCs.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tau.amegroups.com/article/view/10.21037/tau-23-445/rc

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tau.amegroups.com/article/view/10.21037/tau-23-445/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This cross-sectional observational study was granted ethics approval by the Darling Downs Health Human Research Ethics Committee (No. HREA/2020/QTDD/62452). The study was registered with the Australia and New Zealand Clinical Trials Registry (No. ACTRN12620000626965). Written consent was obtained from individual patients for the publication of de-identified clinical photographs in this paper.

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