

## Peer Review File

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### Reviewer A

This is a very interesting study concerning an under-addressed but very common problem in urology. I think rephrasing the Materials and methods would significantly improve the article. Please find my comments below.

#### Abstract

- It is stated that the study is prospective while it is a cross-sectional study as stated in the Materials and Methods.
  - Reply: thank you, we agree
  - Change in text: removed prospective. (Page3/line19)

#### Main body

##### Introduction

- “long-term or permanent IDCs are of therapeutic benefit in urinary retention refractory to medical or surgical interventions”. I think you should change this sentence, as IDC should not be a long-term therapy, as its risks/benefit ratio is worse than self-catheterization +/- urinary diversion. (<https://uroweb.org/guidelines/neuro-urology/chapter/the-guideline-point-3.4.2.5.1>).
  - Reply: we agree. We should clarify that long term/permanent IDCs are only of benefit in very specific situations where self-catheterisation and urinary diversion are impossible due to anaesthetic/patient concerns
  - Change in text: page4/line19-23
- “Our data is representative of rural and regional Queensland, Australia, but can be extrapolated to inform metropolitan and international cohorts.” I would rather place this point in the discussion.
  - Change in text: moved to Page16/line19

##### Materials and methods

- I feel the 3 first paragraphs of the Materials and methods need rephrasing. Several items are stated twice (e.g., 4 weeks for long-term catheter at lines 13 and 23, age > 18 years, informed consent).

- Reply: We agree, there is repetition
- Changes in text: rewritten these paragraphs to read better. (Page 6/line5-21)

I don't understand why the 2 major hospitals first cited (West Morton Hospital and Health Service, and Darling Downs Hospital and 16 Health Service) differ from the 2 cited in the paragraph below (e two major public hospitals 22 involved, namely Toowoomba Hospital and Ipswich Hospital). Are they the same? Were the patients recruited in one place and then followed in another hospital? Could you clarify this?

- Reply: We agree. The way we have explained this is confusing, especially to an audience not local to Australia. The health services are Darling Downs and West Morton. These include major hospitals (Toowoomba and Ipswich), as well as outpatient clinics, nurse clinics etc.
- Change in text: For ease of understanding, we have only included the names of the broader health services. see page 6/line9

- You may replace "Appendix 1" with "Doc S1" if you want to place the study chart as supplementary documentation.

- Reply: we agree
- Change in text: Changed to Doc S1. Page6/line21

- How did you determine the number of patients that you wanted to include in your study? Did you include all the patients you were able to recruit between June 19 and June 21? Did you make power calculations or was it arbitrary? Were the patients recruited consecutively?

- Reply: We did not know the number of people with long term IDCs in our health services. Limited literature made estimating prevalence of CAMPI in the long-term IDC population difficult also, but 15% was a reasonable estimate. With a confidence interval of 95%, a margin of error of 5% and an estimated CAMPI prevalence of 15%, we would need 197 patients according to sample size calculations. We included all patients that we were able to recruit, and they were recruited consecutively.
- Change in text: Page6/line18

- How did you define chronic kidney disease?

- Reply: CKD was defined as stage 2 or worse
- Change in text: Page7/line15

- Concerning Cancer, did you report it for all patients who have a history of cancer or

for those who have an active neoplasia? You may want to separate bladder cancer, prostate cancer, and other malignancies if you have the data.

- Reply: we included both historical and active. We have the data for cancer type and can include this in the body
  - Change in text: Page 7/line16, and page10/line4
- The CAMPI grading system is interesting. However, could you specify how you assessed CAMPI in this study? Did you have one or several investigators who checked patients' CAMPIs at the time of inclusion? Were the patients asked to self-report their CAMPI? Was it exclusively based on the medical records?
- Reply: Our team of investigators, including medical and nursing staff, assessed the CAMPI grade at the time of inclusion by physical examination. Patients did not self-report CAMPI grade, but did report on their experience of the IDC.
  - Change in text: Page7/line1

## Results

- Line 1: I wouldn't say it is a cohort as it is a cross-sectional study.
  - Reply: We agree
  - Change in text: Page 8/line 20
- Line 11: You should choose between using mean (standard deviation) or median (interquartile range) in the article and tables. Getting a raw value of an interquartile range without the median is not helpful. I think median + Q1-Q3 and/or range is better as we cannot assume that the data follow a normal law.
  - Reply: Yes, we agree. We have opted for mean and standard deviation
  - Changes in text: page9/line10. Also adjusted table.
- How many weeks were between the changes? Was it associated with a higher risk of CAMPI?
  - Reply: We understand this point, and have considered it also. Though we have this data, we did not include it in the study given that there was an unacceptable amount of variation in each individual patient's time between changed. For example, many patients had IDC changed between 2-6 weeks, over years. This is not definitive enough for us to make any valid conclusion. Furthermore, given that the total duration of IDCs ranged from just 4 weeks to many years, the number of changes in many patients was too few or too variable for reporting.
  - Changes in text. Nil
- P10 line 7: Concerning cancer, cf to the comment I made in materials and methods.

- Data is separated on Page 7/line16, and page10/line4
- P10 paragraph 2: You could use the median – Q1-Q3 if you want to avoid the outlier problem.
  - Change in text: page 10/line10
- The SPC abbreviation should be explained at line 16 instead of line 20, p11.
  - Reply: we agree
  - Change in text: page11/line13
- Are SCI patients included in the larger neurogenic bladder group?
  - Reply: yes, all patients with SCI were part of the neurogenic bladder group
  - Change in text: Page7/line18

#### Table 1:

- Why did you not perform all the statistical analyses (e.g., mean duration of IDC)?
  - Reply: We have uploaded an incorrect version of the table which accounts for missing statistical analyses and results. We have corrected this,
  - Changes: Table has been corrected.
- Could you add the standard deviation to the means in the table?
  - Reply: Yes, this can be included
  - Changes in text: Table updated with standard deviation
- Why did you put the range of IDC size for non-CAMPI and not for CAMPI?
  - Reply: This was an error
  - Changes in text: We have updated the table appropriately.
- Only a suggestion, but you may want to split your Table 1 into 2 separate tables. 1 with basic demographic data and 1 with more catheter-related data (size, duration, coating, who made the changes...).
  - Reply: Yes, can do.
  - Change: We have split table 1 into 2 parts. We have removed table 2 from the submission as it does not contribute high yield information.

#### Discussion

- Can you compare the prevalence of CAMPI to previous studies?
  - Reply: Yes, we can do this. There is limited data, with Shenhar et al being the only other study to the best of our knowledge looking at the prevalence. Comparison is difficult because of study design, but serves to highlight the need

for more research.

- Changes in text: Page12/line15
  
- “Furthermore, we speculated that IDCs that were not appropriately fixed would cause greater CAMPI rates...”. Could you place the related data in the Results part? Also, you add fixation in the guideline stated below this part. As you didn’t find any difference, can you cite the paper that found a significant result concerning this point?
  - Reply: Yes, we have included the CAMPI and non CAMPI fixation results. We have also discussed these, and included a reference as to why we recommend proper fixation despite our results
  - Change in text: Page11/line1. Page15/line10. Page16/line12
  
- Concerning the prevention of CAMPI, you could discuss the possibility of performing self-catheterization instead of IDC. Do you know if some patients were capable of learning self-catheterization and finally had IDC? Also, long-term IDC should be reserved for palliative patients (cf. European guidelines above), and you could mention that re-assessment of the indication and potential alternatives should occur if the IDC duration is longer than expected (for example, > 4 weeks).
  - Reply: this is a good point and is an important inclusion in our study. We have expounded our discussion on management options for better education for the reader.
  - Changes in text: Page15/line22
  
- Concerning congestive cardiac failure, could you discuss the effects of the penile edema on the tissues, similar to the relation between lower limb edema and skin ulcers (<https://www.ncbi.nlm.nih.gov.ezproxy.med.nyu.edu/pmc/articles/PMC7524111/>)?
  - Reply: Yes, this is a good idea and can be added to this discussion
  - Changes in text: We have referred to this study and hypothesized that similar skin changes to the lower limb could happen in the penis in CCF leading to CAMPI. See Page13/Line22
  
- Could you discuss the expected impact of the theoretically more protective IDC materials, and add a reference?
  - Reply: Yes, we can include the theoretical benefits of silicone and antimicrobial coating on urethral inflammation.
  - Change in text: page14/line22

**Reviewer B**

The authors appear to have missed the basic problem for the occurrence of catheter-associated urethral trauma. Trauma occurs when the catheter is pulled. This happens when the tubing attached to the catheter is not anchored to the thigh and the weight of the leg bag pulls the catheter. Trauma can occur when there is a bow string effect. If the Foley catheter is fixed the thigh, the catheter is pulled during movements of the ipsilateral thigh e.g., turning the patient or abducting the thigh or flexing the thigh. Trauma also occurs when a short length catheter is used especially in male patients e.g., using a female catheter in a male patient.

As the authors did not look for (1) whether the catheter was anchored to the thigh or not (2) whether the tubing attached to the catheter was anchored to the thigh or not (3) whether the leg bag was anchored either to the bed or to the legs (4) the length of the Foley catheter (5) whether there was bow string effect especially when the thigh was abducted or when the thigh was flexed.

The study has a fundamental flaw. If I study many irrelevant variables, the statistical test may show correlation with some factor. But the clinical significance of such a correlation is very little. If the authors wish I shall be happy to send relevant publications on this subject. Furthermore, the authors did not discuss the importance of catheter care in the management. I wish the authors had spoken with doctors and nurses who have hands-on experience; those who are working on the wards while planning this study.

- Reply: We appreciate your feedback. We agree that the mechanism you described is a key factor in catheter-associated urethral trauma, and would add that long term pressure without acute trauma is also a cause. We have included our data to address some of the issues listed, but do not have all this information. We have included it in our discussion. Our study used male-length Foley catheters exclusively. We identified congestive CCF and immobility as significant risk factors for CAMPI, and these have also been found as significant risks in the development of ulcers and pressure injuries elsewhere. We therefore respectfully disagree that these are irrelevant. Our discussion about management was rudimentary, and we have developed this further as suggested. Finally, all members involved in this study are specialist urology medical and nursing staff working with IDCs daily. While we admit this study is not perfectly designed, we do think it does offer important insights and continues the discussion about this important topic.
- Changes in text: Page16/line6, Page15/line9,

**Reviewer C**

Nice short study that highlights a seemingly under reported issue and makes recommendations about how it could be better managed. I have attached an annotated pdf file and my comments contained within.

In response to the pdf supplied, we have

1. updated the references for the introduction as requested
2. Clarified the references to urethral trauma, as these were incorrect, as requested.
3. Included ethics approval number as suggested
4. Removed the word “between” as requested
5. Removed the sentence “interestingly, the majority of the cohort, both with and without CAMPI, resided in their own home (83% vs 87%, respectively)” as requested
6. Removed the word “interestingly” in the “comorbidity associations of CAMPI” section
7. Removed the word “relatively” in the discussion on prevalence
8. Removed “Excluding the single outlier in the dataset and considering the limitations of a cross-sectional study, the findings indicate that CAMPI is typically detected approximately 18 weeks after IDC insertion” as this is erroneous.
9. Properly annotated the figures

## **Reviewer D**

The authors present a prospective multi-center cross sectional study investigating the impact of catheter associated meatal pressure injury (CAMPI) via both survey and evaluation of the medical record. They found that poor mobility, community managed catheters, and congestive heart failure were associated with the development of CAMPI with average of 18 weeks after catheter insertion to diagnosis. The authors also developed a grading system for male and female CAMPI based on prior studies that may become of some clinical benefit.

Limitations of this study include the low number of female participants (31) with only one female patient with CAMPI. Also limited in this study was the number of patients with SCI, who historically have had higher rates of urethral injury from long term catheter use.

Finally, the survey nature of this cross-sectional study creates natural limitations, which

the authors have addressed.

Overall, the article is well written. It provides new data in an area with limited prior literature. The authors have overall addressed limitations.

- Reply: Thank you for this review
- No Changes required