

Peer Review File

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Reviewer A:

Comment 1: The authors aimed to assess the impact of various patient demographic factors on AUS and MS outcomes through a retrospective research network database. This is an interesting, well-written study on AUS and MUS outcomes and predictive factors of complications.

Reply 1: We thank the reviewer for their positive words.

Comment 2: AUS and MUS are not provided for the same patients or the same degree of incontinence so I am a little bit surprised that you studied both of them in the same time... they don't have the same complications (infection and explantation for AUS, pain and retention for MUS).

Reply 2: As multiple reviewers mention that AUS and MUS may best be studied separately, we have made the decision to remove the MUS portion of the manuscript.

Comment 3: For your information, most of the guidelines do not recommend MUS in patients with severe incontinence or who have had radiotherapy or urethra surgery past... so there is nothing new from your study.

Reviewer B:

Comment 1: Overall, it is a decent study which confirms previously published literature. The strength of this study is its size and follow-up period. Nonetheless, I have the following concerns:

Looking at Figure 1, it is unclear what is the number of patients at risk at each time point?

Reply 1: The figure is drawn directly from the TriNetX website and we do not have the ability to determine the number of patients at risk at each time point, unfortunately. However, we did edit the figure per another comment in order to make the x-axis in terms of years and not days.

Comment 2: Regarding the PSM, it is unclear how it was done methodologically, especially after looking at Tables 2-4. The way the methods are written and the tables are portrayed, it seems like PSM was performed using a UNIVARIATE logistic regression, which is worrisome. I would suggest having a statistician assist you with this, otherwise please refer to the literature by Peter C. Austin.

Reply 2: PSM is performed internally via the TriNetX website/platform. We have added more to the Methods section to better explain this (Page 4, Lines 24-27), including a web-reference to the TriNetX FAQ section.

“TriNetX has developed their own platform so that users can perform PSM directly on their website which runs logistic regression based on user-specified variables of interest to obtain a list of propensity scores and then uses 1:1 greedy nearest-neighbor propensity score matching to obtain the matched cohort(14).”

Comment 3: How was the 2015 ICD-9 to ICD-10 transition handled? Neither the methods section or Table 1 mention this.

Reply 3: Added a sentence (Page 4, lines 10-12) to clarify this based on the TriNetX FAQ section.

“Per the TriNetX website, if an HCO provided data in ICD-9-CM, a 9-to-10-CM mapping based on general equivalence mappings plus custom algorithms and curation to transform data from ICD-9-CM to ICD-10-CM was used.”

Comment 4: In page 4, line 20, when you say “analyzed each risk factor individually”, did you mean subgroup analyses or univariate analyses?

Reply 4: Edited this line to attempt to better clarify. We wanted to perform a direct comparison of each risk factor (Ie diabetes vs no diabetes), but still use the remaining risk factors to perform a PSM.

“We then performed subgroup analyses for each individual risk factor (i.e., patients with DM against patients without DM) and utilized all remaining variables for propensity score matching (PSM).” (Page 4, lines 20-22)

Comment 5: In page 5, line 18: what do you mean by “in terms of RR”? Typo maybe?

Reply 5: Reworded the sentence to better clarify. Meant that urethroplasty had the highest absolute RR value.

“A history of urethroplasty was associated with the highest RR for re-intervention and complication and RT was associated with highest RR for infection.” (Page 5, lines 20-21)

Comment 6: Limitations: how accurate and reliable is the coding in TriNet? Is this a validated database? Is there some type of quality check? what is its inter-rater reliability? If this information is not available, I would recommend highlighting all these shortcomings in the limitations.

Reply 6: We did mention that using a large registry for studies such as this

includes inherent limitations, but the Reviewer brings up good specific suggestions. Per communication with the TriNetX team, we were told “TriNetX maps the data to a standard and controlled master terminology then is transformed into a proprietary data schema. This transformation process includes an extensive data quality assessment that includes ‘data cleaning’ that rejects records that don’t meet the TriNetX quality standards.” We have reflected this within the manuscript:

“The data within TriNetX reflects how the information is received from the HCOs, and like all registry studies, degrees of assumptions must be made regarding the quality, reliability and accuracy of this, and any, large, de-identified data set. Per email communications with TriNetX support, once HCO data are transformed into the TriNetX proprietary data schema the data undergoes extensive data quality assessment that includes rejection of record that do not meet their quality standards.”
(Page 9, lines 8-13)

Reviewer C:

Comment 1: In this article the authors present a review of patients included in a database (TriNetX) in whom artificial urinary sphincter has been used as a treatment for stress urinary incontinence in men over the last 20 years.

It is a well-written manuscript, although it has several aspects to improve before it can be published:

Reply 1: We appreciate the feedback.

Comment 2: The limitations of the study are very relevant and reduce the applicability and extrapolation of the study results. The absence of specific surgical details such as approach taken (i.e. transcorporeal vs. penoscrotal vs. perineal) or AUS cuff size selected leads to a large bias in determining the causes of complications and re-interventions. In addition, not knowing the cause of reoperation leads to a large information gap.

Reply 2: We agree this is a limitation of using a registry such as TriNetX...

Comment 3: Despite this, the article is of statistical value at a descriptive level, with more than 4000 patients included, but the discussion and conclusions should be modified due to these important biases.

Reply 3: And we have expanded on the strengths and limitations in the discussion and conclusion sections:

“Further, our analyses were limited to generic ICD/CPT codes and we were unable to better assess specific surgical details such as approach taken (i.e transcorporeal vs penoscrotal vs perineal) or AUS cuff size selected. Likewise, we were unable to

identify the specific etiology for the need of device re-intervention, which can have notable clinical differences if the revision was for a migrated scrotal pump versus an eroded pump, for example. There also may be an overlap between a device complication and an infection, such as if the device erodes. One surgeon may describe this as an infection, another may describe as a complication, and a third may describe as both, without an ability to distinguish between these scenarios based on the data in TriNetX. These factors may limit the applicability of our results. However, despite these limitations, we were able to provide the largest, and longest series of AUS patients, to our knowledge, and these strengths should be considered in light of the aforementioned limitations.” (Page 8, Lines 17-27)

Comment 4: The units of the Kaplan-Meyer curve should be in years, not days, as this makes the figure difficult to read.

Reply 4: We have changed the figure per suggestion

Comment 5: Table 1 should be deleted as it does not contribute relevant information to the manuscript.

Reply 5: We will move the table to be a supplemental table, as we believe that this information could be something some readers may be interested in.

Reviewer D:

Comment: The authors present an analysis of a registry database to analyze AUS reinterventions, complications, and infection.

This is a very well-written paper and contains the largest patient group reported so far. It would be interesting to know the erosion rate but likely this is not feasible given the database. The authors could consider speaking about infection/erosion as there is a wide overlap. The authors could also consider to omit the male sling part. It doesn't really contribute and may be better addressed with a separate paper. In this regard, it would be interesting to stratify sling outcomes by type (e.g. AdVance) and subtype (i.e. prior to XP and with XP).

Reply: We appreciate the Reviewer's feedback and agree it would be interesting to know erosion rate, etc, but this is not feasible. We have added an extended discussion to our limitations paragraph about this particular topic.

After reflection, and taking into account the feedback within, we will omit the male sling portion of our manuscript and appreciate the Reviewer's suggestions to stratify sling outcomes by type. We won't be able to evaluate specific sling types and subtypes directly within TriNetX but stratifying by year prior/after XP release, may closely enough approximate this analysis, and we appreciate the

Reviewer’s suggestion for an interesting study idea.

“Likewise, we were unable to identify the specific etiology for the need of device re-intervention, which can have notable clinical differences if the revision was for a migrated scrotal pump versus an eroded pump, for example. There also may be an overlap between a device complication and an infection, such as if the device erodes. One surgeon may describe this as an infection, another may describe as a complication, and a third may describe as both, without an ability to distinguish between these scenarios based on the data in TriNetX. These factors may limit the applicability of our results.” (Page 8, Lines 19-25)