

Peer Review File

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Reviewer A

***Comment 1:** The authors have successfully implemented a simple cost saving maneuver that appears to shorten operative time during PCNL without compromising outcomes. While I have never personally utilized this technique it intuitively makes sense. There are obviously many alternatives using available products (Cook Medical - Lieberman Sheath Introducer, Boston Scientific - 8/10 dilator/sheath set, etc.) to the dilemma proposed with their one-shot technique. I am surprised to see this is not significantly more bleeding in the group of patients with the one-shot technique because of the placement of the sheath twice. If the standard at this practice while performing ECIRS is to use a retrograde ureteral access sheath then it makes sense to use the proposed double lumen version in order to prevent opening additional products.*

I would like to see a more formal cost saving analysis presented in a table format because I believe this is the true value of the research. I believe the OR time analysis is likely from user comfort.

Interesting idea and well implemented.

Response 1: Thank you for pointing out this issue. We have added the table for cost comparison (Table 4). When we use both a commercial base dilator and a dual-lumen catheter, the maximal cost of each is found to be 870 US dollars (using a Navigator) and 1010 US dollars (using a Flexor), while in the i-UAS group, it entails only the access sheath cost (410 US dollars). Accordingly, we have added the following information to the text (page 18, lines 178-179):

“When we use both a commercial base dilator and a dual-lumen catheter, the maximal total cost is found to be 870 US dollars (when using a Navigator™) and 1010 US dollars (when using a Flexor™), respectively (Table 4).”

Reviewer B

This study examined the usefulness of the 10-12 Fr inner tube of the ureteral access sheath (iUAS) as a substitute for dual-lumen catheters and dilators in endoscopic combined intrarenal surgery (ECIRS). The authors retrospectively compared the two procedures; one was to insert a safety guidewire (GW) via the iUAS (2018-2020), and the other was to insert a safety GW after the 17 Fr metal tract was created (2016-2018). Patient selection was based on the year of the process. Although they focused on the efficacy of the iUAS, the main outcome came from the comparison of the application of dual-lumen catheters. They found there is no difference in safety, but operative time was shorter when they use iUAS.

I agree that the application of iUAS as a dual-lumen catheter is an interesting and useful tip. However, the main finding was that the use of a dual-lumen catheter was not associated with safety, which seems to have small clinical significance and novelty.

Comment 1: *I want to confirm that dual-lumen catheter was not used for all patients in the one-step dilation group or not. I wonder why commercially available dual-lumen catheter was not utilized when the author believes the placement of safety GW before tract dilation is important. This point should be described in the manuscript.*

Response 1: Thank you for this comment. Considering the extra cost, we never used a dual-lumen catheter for any of the patients in the one-shot group. In the one-shot group, we inserted two guidewires through the percutaneous metal outer sheath (17.5 Fr) once we created the renal access; further, we removed the metal sheath leaving the two guidewires and reinserted the metal sheath using one guidewire while the other guidewire was left at the outside of the metal sheath as a safety-wire (Figure 2). However, our additional analysis (please see Response #2) demonstrated that using i-UAS as a dilator and a dual-lumen catheter was associated with a lower chance of tract troubles as well as shorter operative time. These results imply that we should preferably use a dilator and/or dual-lumen tubes for the creation of the nephrostomy tract.

Comment 2: *To improve safety outcomes by a single, small change in surgical procedures is difficult. I think the placement of safety GW reduces the risk of loss of tract or inner tract dislocation. Is there any information on surgical troubles during tract creation from surgical records?*

Response 2: Thank you for the comment. We collected the data for the tract creation troubles (including tract loss and injuries of the pelvis during tract creation) and performed univariate and multivariate analyses (we have added the results obtained in Tables 2 and 3). In multivariate analysis, the use of i-UAS was found to be a strong factor associated with reduced tract troubles.

Accordingly, we have added the following information in the revised manuscript:

(page 6, line 43) “as well as fewer tract creation troubles”

(page 10, line 83) “tract creation troubles (including tract loss and pelvic injuries during tract creation)”

(page 13, line 128) “tract creation troubles (p = 0.05)”

(page 14, lines 133) “However, the use of i-UAS was a strong factor for a shorter operative time and reduced tract creation troubles.”

(page 15, line 145) “reduced tract creation troubles and”

(page 16, lines 163-164); “but was associated with a lower chance of tract creation

troubles.”

Comment 3: *The authors mentioned the cost-effectiveness in the Discussion. The comparison should be for the cost of the commercial dual-lumen catheter (plus 10-12Fr dilator).*

Response 3: Thank you for pointing out this issue. We have added the table for cost comparison (Table 4). When we use both a commercial base dilator and a dual-lumen catheter, the maximal cost of each is found to be 870 US dollars (using a Navigator) and 1010 US dollars (using a Flexor), while in the i-UAS group, it entails only the access sheath cost (410 US dollars). Accordingly, we have added the following information to the text (page 18, lines 178-179):

“When we use both a commercial base dilator and a dual-lumen catheter, the maximal total cost is found to be 870 US dollars (when using a Navigator™) and 1010 US dollars (when using a Flexor™), respectively (Table 4).”

Comment 4: *Since the inner tube of the ureteral access sheath was not made for dilation of lumbar muscle/fascia, I have a concern about the safety and strength.*

Response 4: Thank you for this comment. Although we experienced 3 tract creation troubles in the i-UAS group, there were no troubles in other cases. Therefore, we considered that using i-UAS was good enough and safe for dilation.

Comment 5: *The authors showed that Op. time was shorter in the iUAS group, but the learning curve should be highly effective. Some sensitivity analysis should be necessary. For example, comparing 2017-2018 and 2018-2019, or stratifying cases by surgeon's experience may support the author's conclusion.*

Response 5: Thank you for the comment. We added the results of the sub-analysis comparing the procedures between 2017-2018 in the one-shot group (n = 50) and 2018-2019 in the i-UAS group (n = 50) in Supplemental Table 1. Although there were no significant differences in terms of patients' demographics, the operative time was still shorter in the i-UAS group, suggesting that the learning curve might not affect the results. We have added the following information to the text (page 19, lines 192-195):
“Comparing the procedures between 2017-2018 in the one-shot group (n = 50) and 2018-2019 in the i-UAS group (n = 50), there were no significant differences in terms of patients' demographics. However, the operative time was still shorter in the i-UAS group (Supplemental Table 1), suggesting that the learning curve might not affect the results.”

Comment 6: *Table 3 was difficult to understand. is it a multivariate analysis of all*

variables? why is DM only included in multivariate analysis of postoperative pyelonephritis? I also suggest the ORR or Coefficient of age, BMI, sex, and patient position be included.

Response 6: Thank you for this comment. We included age, BMI, sex, patient position, as well as DM in the multivariate analysis, and the results showed that using i-UAS remained a strong factor that was associated with a shorter operative time. Our results indicated that older patients had a greater chance of operative injuries and male patients required longer hospitalization. Further, the modified Valdivia position contributed to lower chances of urinary injuries and postoperative pyelonephritis. Accordingly, we have added the following sentence to the text (page 14, lines 135-136):

“Our results indicated that older patients had a greater chance of operative injuries and male patients required longer hospitalization. Further, the modified Valdivia position contributed to lower chances of urinary injuries and postoperative pyelonephritis.”

Comment 7: In Table 3, the stone density and volume should be scaled (for example, every 100HU or 1000mm³) to gain readability.

Response 7: Thank you for this comment. We scaled the stone density every 100 HU and the stone volume every 1000 mm³ and performed the multivariate analysis again, with the results shown in Table 3.

Reviewer C

The authors evaluate the safety and efficacy of an inner ureteral access sheath with a double-lumen channel used in ureteroscopic lithotripsy as a dilator for the percutaneous tract in endoscopic combined intrarenal surgery (ECIRS). They concluded an inner ureteral access sheath as a dilator and a double-lumen catheter to insert a safety guidewire during ECIRS is a convenient and safe technical method for creating a nephrostomy tract that can reduce the operative time.

The reviewer generally agrees with the conclusion and it is a unique method and could be very useful in ECIRS.

However, there are several issues need to improve. The reviewer would like suggests several issues as follows;

1) Specific comments for revision

a) Minor

Comment 1: *Since it is difficult to visualize the two groups (i-UAS group and one-shot group), please provide photos or illustrations of the two surgical methods. Please consider adding one-shot group in figure 1 for comparison.*

Response 1: Thank you for this comment. We have revised the images in Figure 1

(including extracorporeal images during the procedure, fluoroscopic images, and endoscopic images) and also added images of the one-shot group in Figure 2.

Comment 2: *In one-shot group, the size of dilation was 16.5/17.5- or 16.5/19.5-Fr. On the other hand, in i-UAS group, the size of i-UAS is 10-12Fr. Is it difficult or smooth to insert a PNL tract that size is 16.5Fr?*

Response 2: Thank you for this comment. Thank you for the comment. We collected the data for the tract creation troubles (including tract loss and injuries of the pelvis during tract creation) and performed univariate and multivariate analyses (we have added the results obtained in Tables 2 and 3). In multivariate analysis, the use of i-UAS was found to be a strong factor associated with reduced tract troubles.

Accordingly, we have added the following information in the revised manuscript:

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(page 15, line 145) “reduced tract creation troubles and”

(page 16, lines 163-164); “but was associated with a lower chance of tract creation troubles.”

Although we experienced 3 tract troubles during the use of i-UAS, there was no trouble in other cases. Therefore, we considered that using i-UAS was good enough and safe for dilation.