Peer Review File

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Reviewer A

I read the manuscript entitled "A Real-World study evaluating the safety and utility of a two-row stapler reload on pulmonary vasculature " carefully, and I found significant information and conclusions that could spark an in-depth evaluation of this fascinating topic.

The paper is well written, it covers many significant aspects, and the study is sufficiently argumentative.
Nevertheless, I think the discussion section could be ameliorated by adding some comments, considering that we often switch intraoperatively between the proper devices to approach pulmonary vessels:
Comment 1: The type: the arterial or venous vessel can determine the ligation strategy/method and, regarding this particular topic, in choosing between three or two stapling lines of auto suturing.
Reply 1: Thank you for your comment. We have added a paragraph to the discussion to clarify this point.
Change in text: Paragraph added to the Key Findings section (Page 15, Line 307-316)

2) the diameter: the segmental pulmonary artery should be considered, in theory, a better target for an 8 mm two-row stapler compared to a Boyden brach, for example. On the contrary, juxtaposing only two rows of titanium clips can determine a leak on the vessel edge.
Reply 2: We appreciate the author's suggestion of utilizing the Boyden classification for segmental anatomy and we concede that the two-row stapler is likely most beneficial for these segmental arteries and veins however given that this is a real-world observational study, the vessel for ligation was not stipulated and we regret that we did not collect data with respect to vessel diameter. we pointed out in our "Implications and Actions Needed" section.
Change in text: We added this point to our "Safety and Utility" section (page 16, line 341-343) and "Implications and Actions Needed" section (page 19, line 396-398)

3) the thickness: Covidien proposes two different colours of 8 mm two-row reloads, a thin and an ultra-thin, for vascular stapling, depending on the situation. Is it a positive addition, considering that other brands (e.g., J & J) offer only one type of 8 mm vascular reloads, ensuring it will work correctly in all cases?
Reply 3: Thank you for your comment. Although all SDR reloads have unrestricted vascular indication, we did not collect information around the reload type used on pulmonary vasculature as the reload selected for each firing was at the discretion of the surgeon. within the manuscript to call attention to this.
Change in text: We recognize that we did not collect this information within our study and have added language to our Hemostatic Intervention section (page 8, Line 152-153) and Implications and Actions Needed (page 19, line 396-398)

Reviewer B

It has been a pleasure to review this study regarding novel small-diameter reloads.
This is a well-written article on a novel device that can affect the clinical outcomes of current and future minimally invasive surgeries.
A sufficient amount of informative data is also provided, but if there were data according to the depth of the stapler (White load or Grey load) it would have been more informative in deciding the appropriate type of loads for thick and thin vasculature.
Reply 1: Thank you for calling attention to this point. All SDR reloads have unrestricted vascular indication; as a result, we did not collect information around the reload type used pulmonary vasculature as the reload selected for each firing was at the discretion of the surgeon based on comfortable compression as described in the device IFU.
Changes to text: We recognize that we did not collect this information within our study and have added language to our Hemostatic Intervention section (page 8, Line 152-153) and Implications and Actions Needed section (page 19, line 396-398)

Reviewer C

The reviewer is honored to review an article about the real-world analysis of two-row staplers in terms of their usefulness and safety. This study is clinically interesting, but there are many points to be clarified, as follows:

1) COI should be clarified between the commercial company and the authors.
Reply 1: Thank you for your comment; official disclosure forms will be published with the paper. Please refer to lines 424-428 for the COI.
Changes to text: Not applicable

2) In the methods section, seven US hospitals (Line 81) and six of the sites (Line 92) seemed incompatible. Please check this discrepancy.
Reply 2: Thank you for raising this question. Six out of seven sites decided that written informed consent was not necessary and applied for, and obtained, a waiver of written informed consent from their IRB. One site elected to obtain IRB approval and went through a consent process.
Changes to text: This point of a waiver of written informed consent was clarified in the Study Design section (page 7, line 132-138)

3) This study contained 120 subjects in 7 hospitals in the US for 22 months, which meant approximately one patient per month in a single institution was enrolled in this study. Considering the number of the lung surgeries performed in these hospitals, this number of enrollments seemed too small. This point should be explained.
Reply 3: Thank you for your question. Although the enrollment duration spanned from August 2021 to May 2023, not all seven hospitals were enrolling at the start of the study. Site activation was staggered over the study period; once sites were activated, PIs began enrolling subjects.

Changes to text: The staggered site activation was clarified in the Study Design section (page 6, line. 120-122)

4) The most important point of this study was the safety of this two-row stapler. In this regard, three cases in which clinically necessary hemostatic intervention was required should be explained in more details. For example, schema of the situation of the bleeding or its surgical picture should be provided in each case.
Reply 4: Thank you for bringing this to our attention. We have added additional language within the manuscript for clarity. Photographs were not taken per our methodology. practice. Given the minimal nature of the bleeding, we do not feel that diagrams would be of any benefit.
Changes to text: We have added a sentence to the Hemostatic Intervention section to clarify that surgeons were asked to not deviate from their typical practice, (page 8, Line 152-153) and more details surrounding the AEs in the Safety and Utility section (page 14, line 285-288)

5) In Table 2, what does "conventional thoracoscopic" mean? Multi-portal VATS?
Reply 5: Thank you for your question. We have adjusted nomenclature within Table 2 accordingly: Open thoracotomy, thoracoscopic, robotic assisted.
Changes to text: Updated Table 2 with adjusted nomenclature

6) In Table 2, there are so many different surgical procedures in this study. In lung transplant, did the authors use this stapler for PH patients? The reviewer would say the value of the pulmonary arterial pressure would affect the adverse bleeding events. Please explain this point.
Reply 6: Yes, thank you for this question. The authors performing lung transplants did use the stapler in patients with different levels of PH. Nevertheless, the lung transplant pneumonectomy was performed after the institution of central CPB or VA ECMO.
Changes to text: This point was addressed with an additional sentence in the Key Findings section (page 15, line 315-316)

7) Who performed the surgical procedures in this study? This point would also be clarified in this study because the authors stated that no subjects experienced AEs directly related to the study device alone (Line 215-6 and Table 9). In Table 9 they also described that adverse events which related to both the device and the procedure were seen in 3 out of 44 events.
Reply 7: The surgical procedures were performed by authors SK, DS, CS, and PS as noted on page 1, lines 24-26 in the author contributions for points 3 (Provision of study materials or subjects) and 4 (Collection and assembly of data).
Changes to text: Additional PIs were listed in the Acknowledgements section of the manuscript (page 20, line 411-412). Additional language was added to the Safety and Utility section to clarify device-related only adverse events and both device and procedure related adverse events. (page 13, line 274-275)

Reviewer D

Comments

1. Why were two cases of esophagectomy included? Generally, it was not necessary to divide the pulmonary artery or vein in esophagectomy.

Reply 1: Thank you for your question. In these specific esophagectomy cases, pulmonary arteries were transected with the subject device which qualified them to be included. While this may not be typical in esophagectomy cases, it was confirmed by the operating surgeon that pulmonary arteries were transected with the subject device during these two cases; they were combined lung and esophageal cases.

Changes in text: Footnote to Table 2

2. Previously, a small cases series on SDR was reported (Pulmonary artery division using Signia Small Diameter Reload: an initial experience. International Journal of Surgery and Medicine: 7(5): 10-12, 2021). According to this report, the diameter of divided arteries was described. The diameter of the vessels may influence the outcome. What was the diameter of the vessels in your data?

Reply 2: Thank you for your attention to this detail. Both white and gray reloads are indicated for vasculature and the reload chosen for use is at the discretion of the surgeon. As a real-world observational study, we did not collect vessel type or diameters data; this point was added to the paper. It is not standard practice for surgeons to measure vessel diameters prior to firing a vascular reload. It is clear preference for stapling compared to other alternatives, based on surgeon preference and comfort level. We agree that this data would be helpful in the ongoing education of surgeons and will consider this endpoint for future studies.

Changes in text: We recognize that we did not collect this information within our study and have added language to our Hemostatic Intervention section (page 8, Line 152-153) and Implications and Actions Needed section (page 19, line 396-398)

3. SDR has three types of cartridges according to the length and the thickness. Do you have data on the cartridge type used?

Reply 3: Thank you for the question. SDR is available in three configurations however data were not collected around the specific reload type used for every vascular firing as the vascular indication spans all three types of reloads. This limitation was included in our manuscript. It is the surgeon's discretion to correctly select the reload based on the thickness it compresses down to as described in the device Instructions for Use (IFU).

Changes in text: Line We added language to the Hemostatic Intervention section (page 8, Line 152-153) and Implications and Actions Needed section (page 19, line 396-398)

Reviewer E

The authors confirm the safety and discuss the utility of a two-row stapler reload, by assessing the incidence of clinically necessary intraoperative hemostatic intervention when applied to pulmonary vasculature in real-world applications. They found that the clinically necessary intraoperative hemostatic intervention rate for SDR staple lines was only 0.99%. They conclude that the SDR is an appropriate device for pulmonary vascular transection.

I have the following concerns.

Comment 1
Title page, author name and author contributions, and footnotes are insufficient. Please check the submission rules carefully. Authors should review the full text and adhere to the submission rules.
Reply 1: Thank you for bringing this to our attention. We updated the running title and title page to include more thorough corresponding author information. We updated the IRB information to include the IRB numbers in the Methods and Footnotes. None of the authors have a 16-digit ORCID, and there are no disclaimers.
Changes in text: Lines We updated the title page (page 1, line 8-9, 16-19,) IRB information in the Study Design section (page 7, line 132-136) and the Footnotes (page 21, 411-412, 435-439)

Comment 2
SDR in line 72 is used for the first time as an abbreviation in the text. Please supplement with the official name of the SDR. On the other hand, SDR in lines 131-132 is not an abbreviation used for the first time.
Reply 2: Thank you for bringing this to our attention. In the Objective, the device name was updated to spell out Small Diameter Reload (SDR). We opted to keep the full name of the device under the Device section. We also spelled out the device in the highlight box.
Changes in text: Line 67 (highlight box), 107

Comment 3
There are many tables compared to the content of the paper. For example, Tables 4 and 5 can be combined.
Reply 3: Thank you for your suggestion. We agree with your suggestion and have combined Tables 4 and 5.
Changes in text: Table 4
The contents of Table 8 should be included in the main text, so there is no need to make it into a table.
Reply 3: The content from Table 8 was described within the Results: Additional Outcomes section of the manuscript and the table was deleted.
Changes in text: Table 8 deleted, Line 266-270

Comment 4
The results of the use of SDRs for pulmonary veins and pulmonary arteries are statistically compared. Therefore, the authors should specify in the Methods section that this statistical analysis will be performed.
Reply 4: Thank you for your comment. The paper was updated to clarify statistical analysis performed on the use of SDRs for pulmonary veins and arteries.
Changes in text: Line 163-166
The analysis of bleeding event rates by Powered or Manual in Table 7 should also be specified

in the Methods section.

Reply 4: Thank you for your comment. The paper was updated to clarify statistical analysis performed on powered or manual handles.

Changes in text: Line 163-166

Comment 5

The authors describe the results separately on Likert scales 1-3 and 4,5. The authors should provide a detailed breakdown of scores 1-3. The surgical response to score 3 is particularly important in terms of surgical safety.

Surgeons should not be overconfident with staplers and should always be prepared for contingencies. Providing details of the scores would provide clinicians with useful information.

Reply 5: Thank you for your comment. Based on your comment 3, Tables 4 and 5 were combined and a breakdown of scores were added to the table for granularity.

Changes in text: Table 4 was deleted; Table 5.

Comment 6

Please detail the results of the Likert score and then perform the statistical analysis again.

Reply 6: We stratified the data into "no intervention needed" and "intervention needed" to perform the analysis. Scores 1-3 were "no intervention needed" and scores 4-5 were "clinically necessary intervention needed." Because no intervention was needed for Likert scores 1-3, we chose to include them as minimal to no risk and therefore, did our statistical analysis based on the important Likert scale scores of 4 and 5.

Changes in text: A clarifying sentence was added to the Likert Scale section (page 12, Line 238-240)

Comment 7

Table 2 Operative time, hr:mm → hr:min

Reply 7: Thank you for your attention to detail. Table 2 was updated accordingly.

Changes in text: Table 2.