Peer Review File

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Reviewer A

Comment 1: There are previously published articles with the same study design and conclusions. Nakamura and colleagues, and the Spanish TAVI registry have similar are some of the examples. Good statistics with IPW, but it doesn't bring nothing new to what is already known.

Reply 1: Thank you for your comments. As you mentioned, Nakamura and colleagues, and the Spanish TAVI registry have already reported the outcomes after TAVI with similar study design. However, there were only a few studies that analyzed vascular access site complications between open puncture and percutaneous puncture using propensity score matching and risk factors of access site vascular complications in TF-TAVI. Our study revealed that open puncture had a significantly lower rate of access site complications after IPW and showed the risk factors for access site vascular complications with a more clear cut-off value than other studies. We believe that our findings are useful to help prevent access site vascular complications in TF-TAVI.

Changes in the text: No changes.

Reviewer B

There are some important conclusions to extract from this manuscript, such as risk factors for choosing one given vascular access. However, the manuscript will benefit from some clarifications.

Comment 1: The manuscript would benefit from an English proofreading.

Reply 1: Thank you for your helpful comment. The manuscript has undergone revision and language editing by a native English speaker again.

Changes in the text: The manuscript has undergone English language editing.

Comment 2: Both approaches had a high complication rate when sheath / CFA diameter ratio ≥ 0.9. As sheath/CFA diameter was lower in the PP group, this might have

explained the higher rate of complications. Might the authors conclude that when sheath/CFA diameter > 0.9 they recommend open access?

Reply 2: We appreciate your useful comments. As you mentioned, the PP group had a lower sheath/CFA diameter ratio than the OP group before propensity score matching. However, we analyzed the vascular access site complications after propensity score matching using IPW, which showed no significant difference in sheath/CFA diameter ratio between the OP and PP groups. Therefore, we consider that sheath/CFA diameter ratio did not affect the outcomes. Moreover, when sheath/CFA diameter ratio ≥0.9, both groups had higher rates of vascular access site complications. Therefore, in such cases, we should consider alternative approaches, such as trans-subclavian, direct aortic, or transapical approaches to prevent access site vascular complications.

Changes in the text: We have added the following text to the conclusion of the Abstract: 'The other approaches may be reconsidered when sheath/CFA diameter ratio ≥0.9.' Moreover, we have added the following text to the Discussion and Conclusion sections of main text: 'Therefore, when performing TF-TAVI, alternative approaches such as the trans-subclavian, direct aortic, or transapical approaches should be considered when the sheath/CFA diameter ratio is high'in the Discussion section, page 20, line 4 to 6, and 'When such a ratio is encountered, other TAVI approaches should be considered. Preoperative assessment using CT angiography is useful for preventing vascular access site complications', page 23, line 6 to 7.

Comment 3: This study constitutes a non randomized retrospective study, as the authors properly stated in the limitations. However, this might have a selection bias. Patients were precisely categorized in one of both groups depending on characteristics that were ultimately regarded as risk factors for complications.

Reply 3: We appreciate your helpful comments. As you mentioned, patients may be precisely categorized in one of both groups depending on characteristics that were ultimately regarded as risk factors for complications. Moreover, inherent factors may have affected the outcomes. However, we analyzed the data using propensity score matching and IPW which adjusted for confounding factors. Accordingly, we have made changes in the Limitations of the Discussion section.

Changes in the text: We have added the following text to the Limitation of Discussion section, page 22, line 9 to 12, 'Patients may have been selected to undergo the OP or PP

approach based on characteristics that were regarded as risk factors for complications, including CT angiography findings. Moreover, other inherent factors may have affected outcomes. However, the data was analyzed using IPW, which adjusted for confounding factors'

Comment 4: In terms of the patients, Are these 411 patients consecutive patients? Why among 411 patients TAVI was only performed in 351? The manuscript will benefit from an explanation.

Reply 4: Thank you for your helpful comments. We are sorry for the insufficient explanation. Among 411 patients, TF-TAVI was performed in 351 patients; 41 underwent the transapical approach, two the direct aortic approach, and 17 the trans-subclavian approach.

Changes in the text: We have added the text of '(the transapical, direct aortic, and trans-subclavian approach was performed in 41, 2, and 17 patients, respectively)' in the Methods section, page 8, line 11 to12.

Comment 5: Some Baseline characteristics (CFA depths and sheath/CFA diameters) are different between groups and might influence results.

Reply 5: Thank you for the comment. As you mentioned, CFA depth and sheath/CFA diameter ratio were different between the two groups before propensity score matching. However, after matching and IPW, there were no significant differences in CFA depth and sheath/CFA diameter ratio. We consider that these factors did not affect the outcomes. We are sorry for the lack of data regarding CFA depth in Supplementary Table 1. We have added the data accordingly.

Changes in the text: We have added the data of CFA depth in Supplementary Table 1.

Comment 6: Did the 12 closure device failures that underwent surgery were excluded from the analysis? If so, state it.

Reply 6: Thank you for your comment. We analyzed the data including the 12 closure device failures.

Changes in the text: No change.

Comment 7: How do you define bleeding as a procedural complication?

Reply 7: Thank you for your question. We defined bleeding associated with vascular access site complications as contrast extravasation on intraoperative angiography or visible bleeding from the injury site. Moreover, we defined the bleeding of closure device failure as that which required surgical repair, manual compression for more than an hour, or blood transfusion.

Changes in the text: We have added the following text to the Methods section, page 9, line 3 to 6, 'Vascular closure device failure bleeding was defined as bleeding after device failure that required surgical repair, manual compression for >1 hour, or blood transfusion. Bleeding associated with vascular access site complications was defined as contrast extravasation on intraoperative angiography or visible bleeding from the injury site.'

Comment 8: Can the authors hypothesize why the EIA was more frequently affected compared to femoral artery? Might be the puncture/surgical procedure, being higher than the inguinal ligament? Not clear in the methods section and might explain why there is higher rate of bleeding.

Reply 8: Thank you for your comments. In our study, CFA complications were common in both groups, however, EIA dissection and injury also frequently occurred in the PP group. In the PP approach, we performed puncture of the CFA under ultrasonographic guidance. As you mentioned, we cannot deny that puncture sites higher than the inguinal ligament may have caused EIA complications. However, we have no data regarding this. Additionally, our study showed that the average EIA diameter was about 0.5 mm smaller than that of the CFA, which may have predisposed the EIA to injury after insertion of a large-diameter sheath.

Changes in the text: We have added the following text to the Discussion section, 'Although the PP approach was performed under ultrasonographic guidance, we cannot deny that puncture sites higher than the inguinal ligament may have caused EIA complications. Additionally, our study showed that the average EIA diameter was approximately 0.5 mm smaller than the CFA diameter; insertion of large-diameter sheaths may have caused EIA injuries as well.'

Comment 9: Which was the rationale for patients who had ventral calcification of the vessel? Did those patients undergo open procedure?

Reply 9: Thank you for your questions. We evaluated the location of calcification in CFA using preoperative CT angiography. If a patient had severe ventral calcification of the CFA, we commonly chose the open puncture approach. We have already described this information in the Methods section.

Changes in the text: No change.

Reviewer C

Very interesting and very good work. I would like to highlight a very well-structured methodology and honesty regarding the results presented.

Comment 1: Transcription error: -Line 257: operation time and transfusion rate were HIGHER with OP, not LOWER.

Reply 1: Thank you for your helpful suggestions. As you mentioned, operation time and transfusion rate are higher with OP group than PP group. We have revised the sentences.

Changes in the text: We have revised the word from lower to higher in the Discussion section, page 17, line 12.

Comment 2: In the discussion, I would emphasize more that patient selection according to patient anatomy and therefore the importance of performing a preoperative imaging study (ECHO and/or angio-CT) for open or percutaneous approach is the best strategy in the prevention of vascular complications. According to the results obtained, given the high incidence of percutaneous closure device failure, some of them with terrible outcome, and the absence of surgical wound complications, only very favorable anatomy should be selected for percutaneous cases (CFA depth < 35 mm,...).

Reply 2: We appreciate your useful comments. As you mentioned, CT angiography and ultrasonography are very useful to reduce the rate of vascular access site complications in TAVI. Our study revealed that the CFA depth and sheath/CFA diameter ratio were independent risk factors for vascular access site complications. The two risk factors are assessed using CT angiography, which should be performed before the procedure to

prevent vascular access site complications. We have revised the Discussion section accordingly.

Changes in the text: We have added the following text to the Discussion and Conclusion section, ‘Both risk factors can be assessed using CT angiography, which illustrates its importance when assessing patients before performing TF-TAVI.’ to the Discussion section, from page17, line 18 to page 18, line 1, and ‘When such a ratio is encountered, other TAVI approaches should be considered. Preoperative assessment using CT angiography is useful for preventing vascular access site complications.’ to the Conclusion section, page 23, line 6 to 7.

Comment 3: Given the high risk of complications in patients with a sheath/CFA ratio in both open and percutaneous access for transfemoral TAVI, it would be interesting to discuss which alternative surgical accesses would be considered more appropriate in this subgroup of patients (subclavicular access, carotid access, transaortic access, transapical access,...) and how would you choose among them. In general, very good and systematic work, with revealing results despite its clear limitations typical of retrospective studies.

Reply 3: Thank you for your useful comments. Our study revealed that sheath/CFA ratio ≥0.9 was significantly associated with vascular access site complications. This finding suggested that alternative approaches such as trans-subclavian, direct aortic, or transapical approaches should be considered in such cases to prevent vascular access site complications. Moreover, we chose the approach in individual patients at a joint conference between cardiologists and cardiovascular surgeons based on patient characteristics and preoperative CT angiography findings.

Changes in the text: We have added the following text to the conclusion of the Abstract, ‘When the sheath/CFA diameter ratio is ≥0.9, approaches other than the TF approach should be considered.’ Moreover, we have added the following text to the Discussion and Conclusion section of main text, ‘Therefore, when performing TF-TAVI, alternative approaches such as the trans-subclavian, direct aortic, or transapical approaches should be considered when the sheath/CFA diameter ratio is high.’in the Discussion section, page 20, line 4 to 6, and ‘When such a ratio is encountered, other TAVI approaches should be considered.’ after the sentence of Sheath/CFA dimeter ratio ≥0.9 was significantly associated with vascular access site complications with both approaches, page 23, line 6.

Reviewer D

Comment 1: In high volume centers OP guided TF-TAVI is not performed after CT images reconstruction and assessment of iliofemoral calcification or tortuosity. I disagree with operative selection of puncture site in TF-TAVI.

Reply 1: Thank you for your comment. However, many studies have recommended preoperative vascular access site assessment using CT angiography to choose the approach in patients undergone TAVI. Moreover, our data showed the risk factors for vascular access site complications based on CT angiography findings. Therefore, we believe that it is important to evaluate the access site vessels using CT angiography before the procedure to prevent vascular access site complications.

Changes in the text: No change.

Comment 2: With technical improvement and better vascular closure devices vascular complication and mortality is significantly reduced.

Reply 2: Thank you for your comment. As you mentioned, good vascular closure devices and technical improvement may reduce the incidence of vascular complications. We also have been using the Perclose ProGlide closure device, which can obtain good hemostasis at the puncture site. However, some patients still developed vascular access site complications. Our study showed that depth of CFA and sheath/CFA diameter ratio were significantly associated with vascular access site complications. This suggests that it is difficult to reduce vascular complications with technical improvements and/or use of a vascular closure device.

Changes in the text: No change.

Comment 3: By using calcification-tortuosity score or VARC and avoiding puncture plaque at the arterial site, complication and the need for surgery pre and post TF-TAVI can be avoided.

Reply 3: Thank you for your helpful comment. As you mentioned, we may decrease vascular access site complications by using calcification-tortuosity score or VARC and avoiding puncture plaque at the arterial stie. However, our data showed that CFA depth and sheath/CFA diameter ratio were independent risk factors for vascular access site

complications. We believe that it is easy to identify these risk factors using preoperative CT angiography more appropriately.

Changes in the text: No change.