

ANSWER TO THE EDITOR & REVIEWERS



January, 2015

Dear Editor,

thank you for your feedback on our paper and for providing us with the reviewer's comments and your editorial suggestions. Please find below our detailed response to all points raised.

Furthermore, please find enclosed the edited manuscript in Word format (file name: 14878-review.doc).

Title of the editorial: Percutaneous pulmonary and tricuspid valve implantations - An update

Author: Robert Wagner, Ingo Daehnert, Philipp C. Lurz

Name of Journal: *World Journal of Cardiology*

ESPS Manuscript NO: 14878

The manuscript has been improved according to the suggestions of the editor and the reviewers:

Response to the editorial office:

1 "A short running title of less than 6 words should be provided"

We have now included a short running title.

2 "Please offer the postcode"

The postal code is now offered.

3 "A conflict-of-interest statement is required for all article and study types"

The conflict-of-interest statement was moved to the desired position of the revised manuscript.

4 "Please write a summary of less than 100 words to outline the most innovative and important arguments and core contents in your paper to attract readers"

A short summary so called 'core tip' is now provided in the manuscript.

5 "Please put the reference numbers in square brackets in superscript before the end. Please check across the text."

Format of the reference numbers has been updated.

6 "Please add PubMed citation numbers and DOI citation to the reference list and list all authors. Please provide PubMed citation numbers for the reference list...."

Response to the reviewers:

Reviewer: 1206034

- **“Major comments on PPVI”**

1 First of all, in the Background and Clinical Indication section, actual indication of PPVI is not clearly mentioned. Authors should add which patients are generally considered to be good candidates for PPVI. For instance, patients who required re-do operation following surgical pulmonary valve replacement? Can patients with congenital heart disease and right ventricular overload also be candidates for primary PPVI?

For clarification, we have altered the manuscript by adding a table (Table 1) that discusses and summarizes clinical indications and morphologic requirements for PPVI. We agree with the reviewer that PPVI in patients with native or patch-extended RVOT's of major interest and appears appealing. However, as this would be “off-label use” of PPVI beyond the recommendations of the ESC task force (Baumgartner et al. 2010) and the AHA writing committee (Feldes et al. 2011), we preferred to discuss this issue in the “EXTENDED INDICATIONS & FUTURE DIRECTIONS” section ((Page 15, section “Percutaneous Pulmonary Valve Implantation”, paragraph “EXTENDED INDICATIONS & FUTURE DIRECTIONS”).

2 It is conceivable that PPVI has a potential to avoid or to delay open-heart surgery for prosthetic valve dysfunction. Actually, as described in this manuscript, a marked learning curve in outcome following PPVI has been reported. It is of great interest to know how the outcomes related to this procedure (success rate, occurrence of any complication, incidence of re-intervention) are. Please consider to add these data.

We thank the reviewer for this comment and fully agree that reporting on outcome following PPVI is of high interest to the readers of this editorial manuscript. Therefore, we had presented data regarding success and complication rates in our initial submission (Page 11, section “Percutaneous Pulmonary Valve Implantation”, paragraph “Results”). Furthermore, comprehensive data from different trials and recently published registry data by Nordmeyer et al. reporting on follow-up data (“one-year freedom for all case events”, “freedom from valve dysfunction or re-intervention”) had been part of the manuscript (Page 13, section “Percutaneous Pulmonary Valve Implantation”, paragraph “Follow Up”). We believe that a more detailed description of the different trials of Melody® or Sapien® valve implants in pulmonary position might be beyond the scope of the review but are more than happy to reconsider if the editorial board feels strongly about this point.

3 Regarding devices currently used for PPVI, differences in features and other comparative data of those two devices should be presented as a Table. It makes readers to understand differences between those two more easily.

According to the reviewers suggestion, we have added a table as recommended (Table 3).

4 Inclusion and exclusion criteria of percutaneous pulmonary valve replacement which are now described in the text body (page 5, line 6) should also be considered to be presented as a Table.

The authors addressed this comment by adding table (Table 1 in the revised manuscript).

- **“Minor comments”**

We apologize for the typing mistakes that all were corrected as suggested. The term „TPV“ was eliminated due to overlapping with the previously used term of „PPVI“.

- **“Major comments on PTVI”**

1 At present, PTVI is just on the preliminary stage and has only limited clinical availability because specific devices for PTVI are approved. In addition, limited data which mainly consist of case series of PTVI with valve-in-valve technique for prosthetic tricuspid valve dysfunction are now available. Thus, descriptions regarding patient selection should be limited and interpreted with caution since patient selection can't be determined from such limited clinical data. At least, authors should describe patient selection with caution.

For clarification, we have altered the manuscript as follows: Page 18, section “Percutaneous Tricuspid Valve Implantation”, paragraph “PATIENT SELECTION CRITERIA (IN SELECTED SERIES)” :

...“After all, patient selection criteria for percutaneous tricuspid valve replacement are yet based on (very) limited data.”.....

2 Authors indicated that the level of indication was raised to Class I and IIa for the most situations functional tricuspid regurgitation with reference #61. We believe that this article (reference #61) only describes indications for “surgical” valve repair or replacement for tricuspid regurgitation and nothing regarding percutaneous tricuspid valve replacement.

We feel very sorry, but the reviewer's remark regarding reference #61 is not clear to the authors as only reference #59 relates to ...“The level of indication...for...functional tricuspid regurgitation”. We assume the reviewer comments on indications of surgical valve repair or replacement are related to the reference: Vahanian A, Iung B. The new ESC/EACTS guidelines on the management of valvular heart disease. Archives of cardiovascular diseases. Oct 2012;105(10):465-467.

We agree with the reviewer that Vahanian et al. (manuscript reference #59) reports on indications for the surgical approach which cannot be simply adopted for the percutaneous approach. Under consideration of the yet limited data regarding patient selection criteria for percutaneous tricuspid valve replacement the authors pointed out that: ...“Principally, if a percutaneous approach seems to be an option of treatment in clinical practice, the clinical indication for “Valve-in-Valve” implantation should be based on the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) or the American College of cardiology/American Heart Association guidelines for tricuspid valve surgery. The percutaneous

approach should be reserved particularly for those cases considered to be high-risk cases for conventional surgery..."

For percutaneous procedures for tricuspid valve disease, balloon tricuspid commissurotomy in patients with isolated, symptomatic severe tricuspid stenosis without tricuspid regurgitation is indicated as Class IIb (Level of evidence: C). If this is true, authors should revise descriptions related this.

The reviewer is right to point out that balloon tricuspid commissurotomy is an option in isolated severe tricuspid stenosis. Nevertheless, the presented manuscript is intended to focus and update on percutaneous (pulmonary and tricuspid) valve implantation procedures as indicated by the manuscript title. Therefore, we again believe that discussing balloon tricuspid valvuloplasty is beyond the scope of this paper

Reviewer: 1198134

1 Authors needs make effort to revise the scientific writing of this manuscript.

The reviewer's suggestion to "make effort to revise the scientific writing..." was carefully adopted into the revision of the manuscript.

2 The "labelling in figure 2, 5 and 6 should be corrected and unified"

We apologize for the labeling issue. All figures were updated and unified in labeling as suggested.

3 In Table 1, how to get the p value=0.001 in different trails?

The table's legend was corrected. Corrected p value(s) are now provided.

4 The section of references should be carefully revised.

The suggestion to revise the references was carefully adopted according to the editorial recommendations (see response to the editorial office comments to authors).

Reviewer: 2575809

We thank the reviewer for rating the manuscript as "an excellent review article, very updated in percutaneous pulmonary and tricuspid valve replacement techniques...."

The suggestion to "check references and insert them as indicated by the instructions to authors..." was carefully adopted.

Reviewer: 00214291

We thank the reviewer for rating the manuscript as a "very interesting overview".

We would be pleased if our revised manuscript could be now accepted for publication in World Journal of Cardiology.

Sincerely yours,

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