

**Title:** Prospective randomized study comparing incidence of Doppler signal flow detected radial artery occlusion post-transradial percutaneous coronary intervention between Safeguard Radial versus TR band radial compression devices using a novel air-inflation technique.

**Manuscript No:** 34335



Editor-in-chief

World Journal of Cardiology

1<sup>st</sup> August 2017

Re: Revised paper submission for consideration as Original Article in the *World Journal of Cardiology*.

Dear Professor

Thank you for taking the time to consider our manuscript no. 34335 for publication in *World Journal of Cardiology* and for supplying such feedback. We very much welcome the opportunity to resubmit a revised version of our manuscript. In order to clearly address the issues raised by the reviewers and editors, please find below commentary that has been broken down on a comment by comment basis. All modifications to the manuscript have been highlighted and are described below.

Best Wishes,

Yours sincerely

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**Reviewers' comments (Code 01593993):**

(1) The authors performed a randomized trial comparing 2 different radial compression devices using a novel air-inflation technique. A total of 107 patients were randomized to safeguard vs TR band compression devices. Radial artery occlusion rate was compared between devices at 24h and 6 weeks. Radial occlusion rate was very low at 24 h (2% vs 0%) and at 6 weeks (0% in both arms). The new technique might play a role in these results. It is not described how sample calculation was performed. Clearly with such low rate of endpoint the final sample size (86 patients) may be underpower. Please elaborate on that.

(2) Please check the actual numbers: in the abstract a total of 100 patients are randomized. In the text, it is reported a total of 107. - 16% of missing patients is too high in my view and may change the results in one way or another... This is an important limitation.

(3) To demonstrate whether it is the novel air-inflation technique responsible of such good results, the authors should compare the outcomes of any of both compression devices with this technique or with the classical technique.

**Author's comments :**

(1) This randomized clinical study acts as a pilot study in evaluating the incidence of radial artery occlusion utilizing the novel and pragmatic air-inflation technique in two conventional radial artery compression devices. We acknowledge the possible limitation of the study related to missing data as described in point (2) below.

(2) Furthermore, the 107 of patients reported were consecutive patients screened. 7 patients were excluded due to various reasons as stated in the manuscript. A total of 100 patients were found to be eligible and recruited into the study. We agree with the reviewer regarding missing data from 16 patients who had out-of-hours percutaneous coronary interventions and have already acknowledged this as one of our limitations.



(3) We also agree with the reviewer that comparing this novel air-inflation technique using any of these devices versus with conventional air-inflation technique would be helpful in confirming our observations. This needs further investigation in a separate prospective study.



**Reviewers' comments (Code 02636166)** : Dear Editor: In general, the paper is well written. There is only concern regarding statistical power in this study?

**Author's comments** : This randomized clinical study acts as a pilot study in evaluating the incidence of radial artery occlusion utilizing the novel and pragmatic air-inflation technique in two conventional radial artery compression devices. While the low incidence of radial artery occlusion observed in our study is interesting, and may in part be attributed to the novel air-inflation technique, we have also acknowledged missing data as one of the limitations of this study and that further separate larger prospective studies are required to confirm these results.



**Reviewers' comments (Code 02446706):** Table 1 is unnecessary and be omitted. It should be included in the text.

**Author's comments :** We thank the reviewer for the suggestion and we have removed Table 1. Instead, we have included the data in text. Furthermore, the other tables have been re-ordered accordingly.

### **In Methods and Methods**

now reads:

Patients gave written informed consent prior to PCI and were prospectively randomized to either Safeguard Radial or TR band compression device via a pre-specified 1:1 automated randomization.

Exclusion criteria were patients less than 18 years old, pregnancy, inability to consent, inability to attend follow-up clinic and difficult radial access requiring femoral access.



**Reviewers' comments (Code 00227375):** This is an interesting manuscript about the comparison of post-PCI radial artery occlusion (RAO) incidence between two conventional radial artery compression devices using a novel air-inflation technique, Safeguard Radial and TR band. The authors demonstrated that there were no significant differences between two devices, and that only one patient in the Safeguard Radial group developed RAO at 24hours. This manuscript is nicely structured. However, I have several comments about this manuscript. Please consider the following comments. (Comments)

(1) Table 2 and Table 3 As for the indication (Table 2), number of target vessels (Table 3), and target vessels (Table 3), the authors should describe “p-value”.

(2) Table 4 The authors probably make a mistake. I think, as for hematoma, a p-value is not 0.70, but 0.078. So, the incidences of hematoma in the Safeguard Radial group tended to be higher than those in the TR band group. The authors should make mention of these matters in the results and/or discussion.

**Author's comments :**

(1) As suggested by the reviewer, we have included p values for Table 2 Indication and Table 3 Number or target vessels an. Table 1 has been excluded and written in methods section in text as per advise of a previous reviewer and Tables have been re-ordered accordingly.

**Table 2 (now Table 1)**

now reads:

Variables	Safeguard Radial N=42	TR band n=42	p value
Indication			
Elective	18	16	0.88
UA	6	8	0.90
NSTEMI	13	8	0.70
STEMI	5	10	0.60



**Table 3 (now Table 2)**

now reads:

Variables	Safeguard Radial	TR band	p value
	N=42	n=42	
Number of target vessels			
treated with PCI			
1	39	39	1.00
2	3	3	1.00
≥3	0	0	1.00
Target vessels			
LM	1	0	0.98
LAD/Diagonal	19	22	0.87
LCx/OM	7	7	0.96
RCA	18	12	0.64
IM	0	2	0.77
VG	0	2	0.77

(2) The authors thank the reviewer for pointing the mistake in p value 0.07 and this has been amended.

The results remain non-significant and therefore, discussion remains the same.

**Table 4 (now Table 3)**

now reads:



Variables	Safeguard Radial	TR band	p value
	N=42	n=42	
Hematoma	7%	0%	0.07



**Reviewers' comments (Code 00259340):** The authors present here a Prospective randomized study comparing the incidence of radial artery occlusion post-transradial percutaneous coronary intervention between two radial compression devices using a novel air-inflation technique, with about 100 patients. The manuscript is well written and the main limitations acknowledged in the paper. The overall interest is mainly limited due to the restricted field of study. However, the final result is pretty correct.

(1) As minor suggestions - State the type of p (two tail?) –

(2) A pair of pictures with the devices would probably be a good idea for the reader.

(3) Discussion. Are these devices better than manual compression?

(4) What about costs? Elaborate. To sum up, my feeling here is this is a nice little trial that, if slightly improved, could be acceptable for publication.

**Author's comments:**

(1) We thank the reviewer for the suggestion.

**Materials and methods (under subsection Statistics)**

now reads:

p <0.05 was considered significant (two-tailed significance)

(2) We agree with the reviewer's suggestions and we have amended the methods section and included images of both devices, labeled as Image 1 and 2.



**Materials and methods (under subsection Radial sheath removal and hemostatic compression technique)**

now reads:

Patients were randomized to either TR band (Terumo Interventional Systems) or Safeguard Radial (Merit Medical) hemostatic compression device groups (Image 1 and 2).

**Image 1. TR band compression device**



**Image 2. Safeguard Radial compression device**



(3) We thank the reviewer for the comments and agree that while it is widely acknowledged globally that radial artery occlusion is the ‘Achilles heel’ of transradial catheterization, few, if any data, are currently available in the literature to support the superior use of either technique of compression (by



manual compression versus compression devices. However, anecdotally, it is believed that transradial compression devices provide several benefits including the capability of employing defined consistent pressure to enable patent hemostasis, provide clear visual assessment of puncture site, improve patient comfort and ease of device application, contribute to quicker ambulation, reduce staff time and reduce operator fatigue when longer periods of compressions are required.

(4) Our study did not aim to seek cost-effectiveness of either device. However, the costs of both devices are comparable. Further larger studies are required to evaluate the costs saved due to reduced radial artery occlusion complications, reduction of staff, quicker ambulation and possibly less complications due to reduction of operator fatigue when longer periods of compression are needed.



**Editor's comments:**

- (1) Please add zip code and detailed address.
- (2) Please provide the AIM of this study. No more than 30 words.
- (3) Please provide this section according to the guideline and format attached

**COMMENTS**

*Background*

*Research frontiers*

*Innovations and breakthroughs*

*Applications*

*Terminology*

**Author's comments:** We thank the Editor for the suggestions and we have amended accordingly.

- (1) At the title page, details now read as:

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- (2) Abstract now reads as:

**Introduction:**

Radial artery occlusion (RAO) remains a significant vascular complication post-compression device application in an era of increasing transradial percutaneous coronary intervention (PCI) use.

**Aim:**

We aimed to compare post-PCI RAO incidence between two conventional radial artery compression devices using a novel air-inflation technique.



(3) After the Conclusion, COMMENTS now reads as:

## **COMMENTS**

### *Background*

Radial artery occlusion is a rare but significant complication post-transradial percutaneous coronary intervention, which is increasing in its use, globally. Therefore, better radial artery compression techniques are required to reduce such complication.

### *Research frontiers*

Conventional radial artery compression devices by varying air-inflation techniques have shown different results in reducing the incidence of radial artery occlusion post-percutaneous coronary intervention. These suggest that novel air-inflation techniques using such devices may yield better results in reducing incidence of radial artery occlusion.

### *Innovations and breakthroughs*

We have shown a much lower short-term incidence of post-percutaneous coronary intervention radial artery occlusion, compared to current literature, using a novel and pragmatic air-inflation technique in two conventional radial compression devices, Safeguard Radial and TR band.

### *Applications*

This pilot study's methods and results of this study could be used in a larger prospective study aiming to the impact of this novel air-inflation technique with two conventional radial compression devices in different settings of transradial percutaneous coronary intervention.

### *Terminology*

Radial artery occlusion is a rare but significant complication of transradial percutaneous coronary intervention. Novel and pragmatic radial compression techniques are required to reduce the incidence of such complication.