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ORIGINAL ARTICLE

Comparison between two protocols for deflation of the TR band following coronary procedures via the radial route

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Abstract

Aim: **Coronary interventions are increasingly being performed via the radial rather than femoral route because of the lower complication rate. Compression devices such as the TR band are used to achieve hemostasis after the procedure. At present, there are no clear protocols for the deflation of the band. In this study we compared two protocols (early deflation with increased intervals vs. late deflation with smaller intervals) in terms of total time to band removal and complications, and patient and staff satisfaction.**

Methods: **All patients who underwent a transradial coronary procedure and had a TR band fitted were enrolled into the study. The TR band was applied using the patent hemostasis method (2 ml air pushed in after the radial pulse appears on pulse oximetry after full occlusion with 16 ml air). Patients were randomly assigned to either protocol. Protocol 1 involved removal of 2 ml of air starting 1 hour after the sheath removal and then removal of 2 ml every 30 minutes until the band came off. Protocol 2 involved removal of 4 ml of air 2 hours after the sheath removal and then further 4 ml of air every 15 minutes until the band came off. Patient and staff satisfaction was measured with a visual analogue scale.**

Results: **A total of 174 patients were recruited (mean age, 60 ± 11 years; 127 male, 47 female). The baseline characteristics including total heparin dose and type of procedure, in the two arms were the same. Protocol 2 ($n = 84$) was associated with a significantly lower time to TR band removal as compared to protocol 1 ($n = 90$; 201 ± 43 min vs. 274 ± 54 min; $p < 0.001$). There was no difference in complications such as bleeding or hematoma formation between the two groups. Patient satisfaction was the same between the two groups. However, the staff preferred protocol 1 ($p = 0.01$).**

Conclusion: **A protocol of delayed initiation of TR band deflation followed by quick deflations is associated with a lower time to band removal with no increase in bleeding complications or patient satisfaction. However, the staff preferred longer intervals between deflations.**

Keywords: Coronary intervention, Radial artery, TR band

1. Introduction

Coronary angiography with or without percutaneous coronary intervention is the mainstay of management of patients with coronary artery disease [1]. There are two main access routes—the femoral or radial artery approach. Traditionally, the femoral artery was the main route of access; however, over the past decade, the radial artery has been replacing the femoral artery as the preferred route despite this being slightly more technically challenging and having a steeper learning curve [2]. Indeed, in 2015 in the UK, 80% of coronary procedures were performed via the radial route [3]. The radial approach is associated with a lower bleeding risk and allows immediate mobilization of the patient after the procedure and thereby significantly reducing the

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length of hospital stay [4]. It has therefore been shown to be more cost-efficient [5] and associated with better outcomes especially in acute coronary syndromes (ACS) [6] as compared to femoral access. At our institution, the radial artery is the primary access route for all cases.

There are many methods that can be used to obtain hemostasis of the radial artery after sheath removal [7]. These include manual pressure and a pressure bandage, or compression bands such as the TR band (Terumo Inc., Tokyo, Japan), the RADstat (Merit Medical Systems, South Jordan, UT, USA), helix device (Vascular Perspectives, London, UK), etc. One of the complications of using the radial route is the potential for radial artery occlusion, which would limit repeated use of this route [8]. The patent hemostasis method, where hemostasis is achieved whilst at the same time, maintaining the patency of the radial artery has been shown to reduce the risk of radial artery occlusion [9]. The use of compression bands helps us to be sure that we are using patent hemostasis.

At our center we use the TR band to achieve hemostasis after sheath removal. This device involves the inflation of a small balloon that compresses the artery. This balloon is then deflated over time. Despite the TR band being widely used, there are no standardized protocols available for the safe deflation of the band and different institutions use different locally generated protocols [10].

The protocols generally involve either early initiation of deflation with longer intervals or later initial deflation followed by shorter intervals of deflation thereafter. The official protocol by Terumo (the manufacturers of the device) suggests that deflation should commence after 1 hour if 50 units/kg or less of heparin was given or after 2 hours if a higher dose of heparin was given. After this, 3–5 ml of air should be removed every 10–15 minutes [11].

At our institution, all patients are given a minimum of 70 units/kg of heparin. We hypothesized that standard protocol of early initiation of deflation of air (within an hour) but with longer intervals of deflation would be inferior to the modified protocol that involves a delayed initiation but shorter intervals. Recently, there have been trials which show that an accelerated protocol that starts almost 30 minutes after the sheath removal is safe without an increase in bleeding complications [12,13] but with overall longer time to removal. However, other groups have demonstrated increased bleeding with these accelerated protocols [13,14] and suggested the delayed protocol.

The aim of our study therefore was to compare this modified protocol of early initiation of deflation of the TR band with the standard protocol of delayed initiation of the band and compare the total time taken for band removal and assess the safety and complications such as bleeding between the two protocols. We also sought to see which protocol would be preferred by patients and staff.

Abbreviation

CCU Coronary care unit

2. Methods

All patients older than 18 years who were admitted in the coronary care unit (CCU) or general cardiology ward, underwent a transradial coronary procedure, and had a TR band fitted after sheath removal were enrolled into the study. Recruitment started in January 2018 and continued until August 2018. However, we excluded patients who had a radial procedure via the radial artery studied as we felt that radial artery damage caused by a previous procedure might affect the bleeding and complication rate.

Patients were included irrespective of the procedure (diagnostic coronary angiography or percutaneous coronary intervention), or indications (stable coronary artery disease or acute coronary syndrome). We excluded patients who had the TR band accidentally removed prematurely or because of bleeding or hematoma prior to deflation, and those who did not gave consent.

The TR band was applied using the patent hemostasis method, which has been described previously [15]. In short, the TR band is inflated with 16 ml of air and a pulse oximetry is applied on the thumb of the hand where the procedure was performed. The ulnar artery is occluded until the pulse waveform disappears on the pulse oximetry monitor. Then, 2 ml of air is removed sequentially from the TR band while the ulnar artery is still occluded until a pulse waveform appears on pulse oximetry. Finally, 2 ml of air is pushed back in to the TR band and left in place until deflation starts as per the selected protocol. Patients were randomly assigned to one of two protocols. Randomization was done manually with all the printed protocols folded unmarked and mixed together in a box. A printed sheet was picked at random from the box for each patient. It was not possible to identify the protocol prior to picking from the box.

Protocol 1 involved removal of 2 ml of air starting 1 hour after the sheath removal and then removal of 2 ml every 30 minutes until the band came off.

Journal of the Saudi Heart Association
2020;32:52–56

Protocol 2 involved removal of 4 ml of air 2 hours after the sheath removal and then further 4 ml of air every 15 minutes until the band came off. If bleeding was observed, 2 ml of air was further injected into the sheath. The patients were sent from the catheter laboratory back to the ward with a printed protocol explaining the protocol and with the expected time of each deflation clearly mentioned. Informed consent was obtained from all patients prior to enrolling in the study. No further wrist immobilizers were used along with the TR band. At the time of band removal, all patients had their radial artery palpated to look for any immediate occlusion.

Patient comfort and staff satisfaction was performed using a visual analogue scale. Patients were asked to fill the scale at the end of sheath removal. This was on a scale of 1–10, where 1 was extremely comfortable and 10 was extremely uncomfortable. With regard to staff satisfaction, it could not be done for each patient as there were multiple nurses involved in the care of a particular patient and across each shift. Therefore, at the end of the study, the nurses involved were asked to fill the visual analogue scale to rate their experience with each protocol. They had to rate on a scale of 1 to 10 the ease of each protocol, in which 1 was extremely easy and 10 was extremely difficult. We had only included nurses who had used both protocols on at least 10 patients to fill in this survey.

Our previous observations had shown that with our existing protocol the mean time to band removal was about 275 ± 30 minutes. The sample size calculated to find a difference of at least 15 minutes with an alpha error of 0.05 and power of 90%, was 168.

Ethics approval was obtained from the hospital ethics committee, and the study was performed according to the guidelines of the Declaration of Helsinki. The study has been registered at clinicaltrials.org (identifier number NCT03380065). All statistical calculations were performed using SPSS version 22 (SPSS Inc., Chicago, IL, USA). Student *t* test was used for normally distributed data and Mann–Whitney *U* test was used for nonnormally distributed data. Chi-square test was used for categorical values. A p value <0.05 was considered significant.

3. Results

A total of 200 patients were recruited into the study. The 26 patients who had incompletely filled their forms were excluded from the analysis. None of the patients approached had refused consent. The data from 174 patients were analyzed. The mean age of the patients was 60 ± 12 years, of whom 72% were male. The baseline characteristics in the two arms were the same (Table 1). All patients had received a minimum of 70 units/kg of heparin along with a loading dose of clopidogrel (600 mg) and aspirin (300 mg) as is standard protocol in our institution for patients undergoing coronary angiography with a view to proceeding for angioplasty if required. There was no difference in the number of patients receiving any glycoprotein IIb/IIIa inhibitors in the two groups. There was no difference in the time interval from the last heparin dose to sheath removal and application of the TR band in each group. At the time of band removal, all patients in the study had their radial arteries palpable. However, we did not perform Doppler studies to confirm patency.

Table 2 shows the results obtained. Protocol 2 (n = 84) was associated with a significantly lower time to band removal as compared to protocol 1 (n = 90; 201 ± 43 min vs. 274 ± 54 min; $p < 0.001$). There was no difference in bleeding or hematoma formation (17% vs. 24%; $p = 0.2$) between the two groups. All the bleeding episodes were very mild oozing, which stopped on increasing the air. None of the bleeding complications required transfusions. All the hematomas were small (<1 cm). There was no difference in the number of re-inflations of the

Table 1. Baseline characteristics of the patients.

	Protocol 1 (n = 90)	Protocol 2 (n = 84)	p
Age (y)	60 ± 11	60 ± 12	0.9
Sex (M:F)	65:25	62:22	0.54
Procedure performed			
CAG only	47	41	0.38
CAG + PCI	31	36	
PCI only	12	7	
Total heparin dose (units)	5416 ± 1520	5565 ± 1740	0.12
Interval from last heparin dose to sheath removal (min)	20 (10–40)	20 (10–40)	0.99
Additional glycoprotein IIb/IIIa inhibitors	4	6	0.9

Data are presented mean ± standard deviation or n. Analysis was done using Student t test or Chi-square test as appropriate.
CAG = coronary angiography; F = female; M = male; PCI = percutaneous coronary intervention.

Table 2. Results of the study.

	Protocol 1 ($n = 90$)	Protocol 2 ($n = 84$)	p
Delay in deflation from expected time (min)	28 (0–115)	15 (0–74)	0.28
Total time for band removal (min)	274 ± 54	201 ± 43	<0.001
Interval between last dose of heparin and sheath removal (min)	20 (10–40)	20 (10–40)	0.99
Number of re-inflations			
0	74	63	
1	14	15	0.2
2	2	3	
3	0	3	
Complications			
Nil	73	63	
Bleeding	14	21	0.24
Hematoma	1	0	
Bleeding and Hematoma	1	0	
Staff satisfaction score (n = 45)	2 (2–4)	4 (4–6)	0.01
Patient comfort score	0 (0–2)	2 (0–2)	0.2

Data are presented as mean ± standard deviation or median (interquartile range). Analysis was done by Mann–Whitney *U* test, Student *t* test, or chi-square test as appropriate.
CCU = coronary care unit.

band because of bleeding in both groups (17% vs. 25%; $p = 0.2$). There was no significant delay with regard to the actual time of air removal versus the expected time of air removal for each group, although numerically protocol 1 had a median delay of 28 minutes [interquartile range (IQR), 0–115] as compared to protocol 2, which had a median delay of 15 minutes (IQR, 0–76 min).

Patient comfort scores were the same between the two groups. Staff satisfaction scores ($n = 45$) showed that the staff preferred protocol 1 [score 2 (2–4)] over protocol 2 [4 (4–6)] ($p = 0.01$).

4. Discussion

The TR band is probably one of the most commonly used compression devices after a coronary procedure via the radial route. However, as mentioned earlier, there are no clear protocols for weaning off the band. There are various protocols that have been reported, including accelerated protocols and standard protocols and protocols that are individualized according the medications given during the procedure, with some studies [12,13] showing that the accelerated protocols are safe with comparable bleeding complications.

Our study showed that protocol of late initiation of TR band deflation followed by frequent deflation is associated with quicker band removal as compared to early initiation with less frequent deflation. This can be explained by better hemostasis with longer compression leading to quicker removal once deflation is initiated. Previous studies have also shown complete compression for at least 90–120 minutes prior to deflation to be associated with quicker band removal [9].

Despite there being a significantly lower time to TR band removal, with protocol 2 there was no increase bleeding or hematoma formation compared to protocol 1. This could be because hemostasis is already achieved when the deflation was initiated. However, as already stated, none of the bleeding episodes were major requiring transfusions, and all were minor oozing. None of the hematomas formed were large with all being less than 1 cm in size.

There are multiple benefits of a shorter band removal time. For the patient, the quicker the band comes off, the less discomfort they have and the quicker they can be discharged. However, in our study, patient satisfaction scores were the same in both groups. Shorter band removal times are also preferred as they have been shown to be associated with a lower incidence of radial artery occlusion [16] although the use of patent hemostasis appears to negate the effect of the duration of radial artery compression.

Surprisingly, we found that patients on protocol 1 (less frequent deflations) had more delay in actual air removal with respect to the prescribed time, as compared to protocol 2 (more frequent deflations). One would had expected that if the intervals were longer the deflations would be on time. One explanation could be that staff tend to get busy with other activities and delay deflations [17]. By contrast, with frequent deflations, staff are more likely to remember and attend the patient frequently and will not be involved with other activities.

Journal of the Saudi Heart Association
2020;32:52–56

The staff preferred protocol 1 with longer intervals as it is less intensive and it gave them time to perform other jobs. However, as discussed above, this led to delayed deflations. Protocol 2 with short intervals was more intensive and hence not popular with the staff. The patients, however, did not find any difference between two protocols.

The main limitation of our study was the inaccuracies in documenting the actual time of deflations. There were incompletely and inaccurately filled forms, as a result of which we had to exclude 26 forms for this reason. Multiple staff were taking care of a particular patient through the day because of shift changes, and this may have led to some inconsistency in patient care and form filling. Some patients had left the ward for other procedures, and this might have led to some delays in deflation. These were excluded from the analysis. Two wards (general cardiology ward and CCU) were involved in the study. Both of these wards have totally different staff/patient ratio. However, our analysis showed that there was no difference in the outcomes based on the ward. Another major limitation is the fact that we did not study the long-term effects of either protocol on rates of radial artery occlusion. However, this was beyond the scope of our study.

This is a single-center experience with small number of patients. However, although we cannot generalize these results as a consequence of that, we can state that the results are very strongly positive in favor of the delayed initiation protocol. We would like to recommend that all institutions use this protocol; however, we can appreciate that, because of logistic reasons, this might not always be possible in all institutions.

5. Conclusion

Our study showed that the protocol with late initiation but frequent deflations of the TR band resulted in quicker band removal with no increase in complications. This ought to be the standard of care in centers that use TR band for hemostasis after coronary procedures via the radial route.

Conflicts of interest

The authors declare no conflict of interest.

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