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RANDOMIZED TRIAL

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Ankaferd blood stopper as a new strategy to avoid early complications after transradial procedures: A randomized clinical trial

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Background: We planned a three arm randomized study to evaluate the safety and efficacy of a new blood stopper, Ankaferd blood stopper (ABS) along with short-time compression, compared to either short-time compression with conventional sterile gauzes (CSG) or with a TR band after transradial (TRA) procedures.

Methods: The Ankaferd blood stopper as a new strategy to avoid early complications. After transradial procedures (ABS transradial) trial is designed in a prospective, randomized, placebo-controlled fashion and registered with http://clinicaltrials.gov (NCT02982733). Six hundred and thirty patients were randomized into three arms in a 1:1:1 fashion corresponding to three different strategies of patent hemostasis techniques after diagnostic or interventional catheterization.

Results: One (0.49%) patient in the CSG group and one patient (0.48%) in the TR Band group developed RAO at the end of the hemostasis, compared with 0 (0%) in the ABS group. At 30 days follow-up none of the groups had any patients with RAO. As a secondary end-points the difference was not statistically significant regarding hematoma among the three groups ($P = 0.70$). Bleeding during deflation of the TR Band or removal of the elastic bandage occurred in 55 patients (26.96%) in the CSG group and in 56 (27.31%) patients in the TR Band group compared to 19 patients (9.40%) in the ABS group ($P < 0.001$).

Conclusion: Ankaferd blood stopper is a promising device for use in patent hemostasis, with no evidence on RAO at short-term or long term and with reduced risk of re-bleeding at the end of hemostasis.

KEYWORDS
Ankaferd, patent hemostasis, radial artery occlusion

1 | INTRODUCTION

The most frequent complication of transradial catheterization (TRA) is radial artery occlusion (RAO). Estimated to occur in 5-10% of cases, it limits future utility of the radial artery as an access site for angiographic and therapeutic procedures.[1,2] The following factors have been identified as independent predictors in the majority of studies: the diameter of the sheath and its relationship to the size of the radial artery, postprocedure compression time, and the presence of anterograde flow in the artery during hemostasis.[3–6]

Patent hemostasis seems to be the most important parameter to decrease the risk of RAO[7] and with patent hemostasis the incidence of RAO may even be independent of heparin administration.[8] Frequent access site evaluation and application of the shortest duration of

compression needed to achieve hemostasis may presumably also be of help in reducing the occurrence of RAO. The RAO rate with patent hemostasis achieved by TR Band (Terumo medical) is around 5% with the band left in place for 2 h.[7]

In 2008, Goker et al introduced Ankaferd blood stopper (ABS) as a new hemostatic drug.[9] This drug is composed of a standardized mixture of the plants Thymus vulgaris, Glycyrrhiza glabra, Vitis vinifera, Alpina officinarum, and Urtica dioica. It is used in hospitals and ambulances in Turkey to stop bleeding occurring from external bodily injuries and operations. Ankaferd is the first Turkish medical product officially accredited by the Turkish Ministry of Health. Recently, ABS has been shown to produce local hemostasis by acting topically after major arterial vessel injury.[10,11] Reducing the compression time during patent hemostasis by facilitating hemostasis may decrease RAO. To test this hypothesis, we planned a three arm randomized study to evaluate the safety and efficacy of ABS in adjunct to short-time compression, compared to either short-time compression with conventional sterile gauzes (CSG) or with a TR band after transradial procedures.

2 | METHODS AND ANALYSIS

The Ankaferd blood stopper as a New Strategy to Avoid Early Complication After Transradial Procedures (ABS Transradial) trial is designed in a prospective, randomized controlled fashion and registered with http://clinicaltrials.gov (NCT02982733). All consecutive patients undergoing transradial diagnostic or interventional procedures between November 2016 and October 2017 at the catheterization laboratory of Acibadem University Kocaeli Hospital were considered to be enrolled in the study. The exclusion criteria were sheath diameter different form 6F, age <18 years, abnormal Barbeau's test[12] before puncture and failure to provide written informed consent. The patients were randomized into three arms corresponding to three different strategies of patent hemostasis techniques after diagnostic or interventional catheterization. Randomization was done using a block design in order to ensure that the same number of patients would be assigned to each group. All procedures were performed by two interventional cardiologists at a single center. The protocol was approved by the institutional review board and written informed consent was provided by all patients.

After sterile preparation and injection of 2% prilocaine at the puncture site, a 20-gauge open bore needle was used to enter the radial artery 1-1.5 cm proximal to the radial styloid process. Observing a pulsatile flow, a 0.025″ straight guidewire was advanced. The needle was removed and a 6F short (7 cm) hydrophilic sheath (Radiofocus Introducer II, Terumo, Tokyo, Japan) was introduced over the guidewire. After sheath insertion, vasodilator (200 μg nitroglycerin) was given and subsequently 5000 IU of unfractionated heparin diluted in a 10-mL syringe was injected into the aortic arch. Radial artery angiogram was obtained just after sheath insertion in order to measure the radial artery diameter angiographically. After radial arteriography, off-line quantitative analysis was used to determine radial artery diameter. Diagnostic angiography was performed using diagnostic standard 6F Judkins catheters. Additional 5000 IU of unfractionated heparin was administered in case of an ad hoc interventional procedure. The unfractionated heparin dose given in elective interventional procedures was 10 000 IU. Before the radial sheath was removed at the end of the procedure, patients were allocated into one of the following hemostasis groups. ABS group: the compression of radial artery was obtained with ABS hemostatic pad applied directly on the skin with a folded gauze over the pad. All the dressing was then wrapped with an elastic bandage so that patent hemostasis is maintained. The patent hemostasis of the radial artery was assessed using reverse Barbeau's test as previously defined.[7] If there was no radial artery patency the elastic bandage was loosened till plethysmographic signal confirming radial artery patency. If radial artery patency could be maintained and hemostasis was achieved, this dressing with a wrapped elastic bandage was left in place for 30 min after angiography and 60 min after interventional procedures. After this period, all the dressing was removed and a clean thin dressing which was secured with a Tegaderm adhesive bandage left in place for more 90 min. This dressing was also the final dressing before it was removed at the 24 h first visit. If there is bleeding after the dressing removal, a direct manual compression of the radial artery was adopted as the final strategy to stop the bleeding. However, even during this compression careful attention was taken for the maintenance of patent hemostasis. CSG group: hemostasis was obtained by direct compression of the radial artery with a folded conventional sterile gauze wrapped with an elastic bandage and maintained for 30 min after angiography and 60 min after interventional procedures as soon as patent hemostasis was achieved. The closure technique of CSG, which is also the control group, is the same of ABS group without the tested ABS pad. TR Band group: conventional patent hemostasis technique consisting of TR Band (Terumo, Tokyo, Japan) which was applied at the access site and then inflated at the minimal volume (cc) of air that required to maintain patency with no bleeding. This volume of air was recorded. Patent hemostasis was verified by using reverse Barbeau's test.[7] The TR Band was removed after 2 h for both diagnostic and interventional procedures. If bleeding was observed after the removal of TR Band, manual compression with careful attention of patent hemostasis was adopted as the final strategy to stop the bleeding. Hemostasis was always obtained in the catheterization laboratory in all of the patients by the attending nurse before returning the patient to the ward. All the patients who underwent angiography were discharged at the end of 120 min while overnight admission was applied for the ones that underwent interventional procedures.

The primary endpoint of the study was radial artery occlusion immediately post-hemostasis, 24 h later and at 30-day. The patients were evaluated for the presence of bleeding during deflation process of the TR Band or removal of the compression dressings by the nurses. Radial artery patency and/or hematoma were assessed at 24 h and 30 days after the procedure by the same ward nursing staff who cared with the patient's initial hemostasis. A pain assessment tool from 0 to 10 scale was used to understand the presence and severity of any pain regarding the access site at 24 h. Radial artery patency was assessed

using reverse Barbeau's test as previously defined.[7] A pulse oximeter sensor was placed over the index finger and both radial and ulnar arteries were compressed to observe a loss of the plethysmographic signal. After the signal disappeared, the radial artery was released and the presence of the signal was assessed. Return of the signal indicated radial artery patency and the absence of return of the signal indicated RAO. All findings of occlusion were confirmed ultrasonographically by another investigator. Local hematomas were graded according to a specific scale[13] and hematomas larger than ≥5 cm were considered significant at 24 h after the procedure.

2.1 | Data collection

All findings, including clinical and laboratory data, were documented in the subjects medical record.

2.2 | Statistical analysis

Quantitative variables were presented as means (±standard deviation), and categorical variables were indicated as the absolute number (percentage). Data were tested for normal distribution using the Kolmogorov-Smirnov test. Comparison of the three groups was performed using analysis of variance (ANOVA). Categorical variables were compared using a Pearson Chi Square test, or with Fisher exact test. A two-tailed *P*-value of <0.05 was considered significant. Binary logistic regression analysis was used to evaluate independent association between bleeding after device removal and clinical parameters. The effects of different variables on bleeding after device removal or during deflation of the TR Band were calculated in univariate analysis for each. The variables for which the unadjusted *P*-value was <0.005 in logistic regression analysis were identified as potential risk markers and included in the full model. All statistical studies were carried out with SPSS program (version 21,0, SPSS, Chicago, IL).

2.3 | Ethical considerations

The study was performed in agreement with the Declaration of Helsinki and is approved by the ethics committee of Acibadem University (Sayı:ATADEK 2016-17/4). The study was funded by Arter Medical Equipment Company.

3 | RESULTS

Out of 1000 screened patients, a total of 630 patients were randomized in a 1:1:1 fashion. Eight patients were lost to follow-up in ABS group, six patients in CSG group and five patients in TR Band group (Figure 1). None of the lost follow-up patients showed any signs of RAO immediately post-hemostasis.

Besides diagnostic coronary angiography (*n* = 348), our final analyzed study population comprised of patients who were excluded in the main RAO studies such as peripheral angiography (*n* = 20),

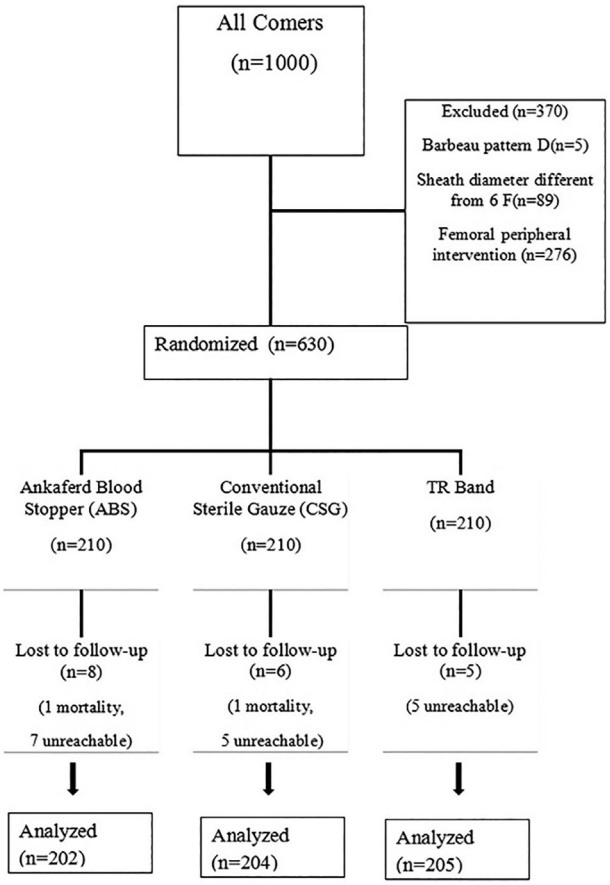

FIGURE 1 The ABS transradial (the Ankaferd blood stopper as a new strategy to avoid early complication after transradial procedures) trial randomized 630 patients. All comers to our catheterization laboratory between November 2016 and October 2017 were assessed for eligibility

peripheral intervention (*n* = 4), elective percutaneous coronary intervention (PCI) (*n* = 39), and ad hoc PCI (*n* = 200). Otherwise excluded in other studies, patients with previous ipsilateral radial artery puncture (*n* = 118), warfarin therapy (18), new oral anticoagulant (NOAC) therapy (*n* = 8) were also taken part in our final analyzed study population.

Baseline data for the three groups is presented in Table 1. Baseline characteristics were similar in both groups. No significant difference was observed in height, weight, antiplatelet, and anticoagulant treatment between the groups ($P > 0.05$).

Clinical and procedural characteristics such as acute coronary syndrome, previous radial puncture, radial artery anomaly, radial artery diameter, procedural time were not different among the groups (Table 2). While the need for manual compression was less in the ABS group ($P < 0.001$), the ABS group and CSG group experienced more pain compared to the TR Band group after the first 24 h ($P = 0.001$).

Results of outcome measures are shown in Table 3. One (0.49%) patient in the control group and one patient (0.48%) in the TR Band group developed RAO at the end of the hemostasis, compared with 0 (0%) in the ABS group. This statistically unratable result regarding RAO repeated itself at the 24 h follow-up. At 30 days follow-up none of the

TABLE 1 Baseline characteristics of the patient groups

N = 611 patients; *n*, (%)	Ankaferd blood stopper (*n* = 202)	Conventional sterile gauze (*n* = 204)	Transradial band (*n* = 205)	*P*-value
Age (years)	62.51 ± 10.04	61.63 ± 10.84	61.54 ± 10.81	0.55
Sex (males)	129 (63.86)	141 (69.11)	141 (68.78)	0.45
Height (cm)	168.47 ± 8.23	168.55 ± 8.18	168.93 ± 8.33	0.83
Weight (kg)	82.20 ± 14.44	83.03 ± 14.23	81.76 ± 12.88	0.63
Body mass index (kg/m^2)	28.95 ± 4.63	29.28 ± 4.54	28.70 ± 4.42	0.54
Smoking	51 (25.24)	54 (26.47)	56 (27.31)	0.89
Diabetes mellitus	80 (39.60)	71 (34.80)	77 (37.56)	0.60
Hypertension	127 (62.87)	123 (60.29)	131 (63.90)	0.74
Chronic renal failure	11 (5.44)	4 (1.96)	8 (3.90)	0.07
Previous CABG[a]	24 (11.88)	19 (9.31)	28 (13.65)	0.38
Previous myocardial infarction	12 (5.94)	7 (3.43)	14 (6.82)	0.28
Peripheral arterial disease	19 (9.40)	12 (5.88)	18 (8.78)	0.05
Chronic p2y12 inhibitor therapy	3 (1.48)	5 (2.45)	4 (1.95)	0.40
Chronic aspirin therapy	105 (51.98)	111 (54.41)	120 (58.53)	0.05
Chronic clopidogrel therapy	46 (22.77)	35 (17.15)	48 (23.41)	0.46
Chronic warfarin therapy	6 (2.97)	6 (2.94)	6 (2.92)	1.00
Chronic new oral anticoagulant therapy	5 (2.47)	1 (0.49)	2 (0.97)	0.24

[a]Coronary artery by-pass surgery.

groups comprised any patients with RAO. The difference was not statistically significant regarding hematoma among the three groups ($P = 0.70$).

As shown in Table 3, bleeding during deflation of the TR Band or removal of the elastic bandage occurred in 55 patients (26.96%) in the CSG group and in 56 (27.31%) patients in the TR Band group compared to 19 patients (9.40%) in the ABS group ($P < 0.001$). Major complications such as AV fistula, evidence of ischemia or major bleeding which may necessitate intervention or transfusion were not observed in any of the groups. However, in the TR Band group the only RAO was associated with a pseudoaneurysm, which was treated with local compression under Doppler-ultrasound guidance. At 1-month follow-up, this patient showed neither RAO nor pseudoaneurysm signs which was confirmed by Doppler.

Logistic regression analysis was performed on all variables for the bleeding complication (Table 4). Age, weight, height, chronic clopidogrel therapy, heparin dose were included into the multivariate logistic regression model because of their unadjusted *P* values were <0.05. Heparin dose (OR: 3.120 95% CI: 2.052-4.743, $P < 0.001$), height (OR: 1.034 95% CI: 1.006-1.063, $P = 0.019$), weight (OR: 1.021 95% CI: 1.004-1.039, $P = 0.018$), and chronic clopidogrel therapy (OR: 1.615 95% CI: 1.009-2.586, $P = 0.046$) were found as the independent predictors of bleeding.

4 | DISCUSSION

The main result of our study is that with patent hemostasis by using ABS it is possible to totally avoid RAO and ABS is very effective in preventing bleeding complications at the end of patent hemostasis.

Despite conventional patent hemostasis with dedicated devices such as TR Band, the contemporary "real-world" incidence of RAO reported from institutions with expertise in performing TRA continues to reach 10%.[14] Knowing that reducing the duration of compression from 6 to 2 h, reduces the incidence of RAO,[15] we tested the hypothesis reducing the compression time even further with the help of ABS which might cause even less RAO rates. Interestingly, none of our study patients had RAO at 30-day follow-up. One of the lowest RAO achieved at 30-day was revealed in the PROPHET-II Trial with a 3% RAO using conventional patent hemostasis with TR Band and a 0.9% RAO rate in the group of simultaneous ipsilateral ulnar artery transient compression.[16] Recently, Koutouzis et al defined ipsilateral ulnar artery transient compression for facilitating radial artery patent hemostasis as the ULTRA method which reached a 0% RAO rate at the end of the patent hemostasis.[17] The conventional TR Band scored a 5% RAO whereas the RAO rate was %13.9 at the end of hemostasis in the PROPHET-II study. In our study the ABS group showed no RAO while the other groups had one patient with RAO in each group. In terms of RAO all groups in our study showed excellent results as similar as to those with the ULTRA method. It is hard to explain our %0 RAO rate at 30-day, because all of our study population underwent procedures with 6F sheaths and 118 patients had at least their second procedure at the same radial artery which both factors are known to increase the RAO rate.[18,19] Our low RAO rates in all groups need explanation. First, patent hemostasis was achieved in

TABLE 2 Clinical and procedural characteristics of the patient groups

Patients; *n*, (%)	Ankaferd blood stopper (*n* = 202)	Conventional sterile gauze (*n* = 204)	Transradial band (*n* = 205)	*P*-value
Asymptomatic	67 (33.16)	74 (36.27)	67 (32.68)	0.53
Stable angina pectoris	103 (50.99)	108 (52.94)	112 (54.63)	0.62
Acute coronary syndrome	22 (10.89)	16 (7.84)	17 (8.29)	0.12
Peripheral Procedure	10 (4.95)	6 (2.94)	9 (4.39)	0.10
Previous ipsilateral radial puncture	46 (22.77)	33 (16.17)	39 (19.02)	0.24
Percutaneous coronary intervention	80 (39.60)	80 (39.21)	80 (39.02)	0.99
Right radial approach	167 (82.67)	180 (88.23)	171 (83.41)	0.64
Radial anomaly on angiography	24 (11.88)	13 (6.37)	21 (10.24)	0.15
Radial artery diameter (mm)	2.02 ± 0.31	2.11 ± 0.35	2.10 ± 0.30	0.06
Radial artery spasm	33 (16.33)	25 (12.25)	35 (17.07)	0.05
Volume of Contrast (mL)	109.7 ± 75.71	103.2 ± 66.29	108.5 ± 77.45	0.63
Presence of loading dose of clopidogrel	75 (37.12)	83 (40.68)	83 (40.48)	0.32
Tirofiban usage	7 (3.46)	5 (2.45)	6 (2.92)	0.24
Procedural time (min)	20.11 ± 20.61	18.23 ± 17.73	18.50 ± 18.98	0.55
Unsuccessful patent hemostasis	2 (0.99)	1 (0.49)	0 (0)	0.36
Manual compression after device removal	**19 (9.40)**	**54 (26.47)**	**54 (26.34)**	**<0.001**
Total nursing time after procedure (min)	2.64 ± 1.41	2.70 ± 1.62	2.59 ± 1.34	0.43
SBP before sheath removal	151.80 ± 26.54	147.09 ± 24.48	148.09 ± 25.29	0.14
DBP before sheath removal	86.27 ± 15.13	83.81 ± 14.37	83.08 ± 12.92	0.06

SBP, systolic blood pressure; DBP, diastolic blood pressure.
Bold values indicate significant values at $P < 0.05$.

99.5% of our study patients and even during manual compression due to rebound bleeding which may eventually lead to revengeful pressure and RAO. Second, the interventions were performed by two radial operators who are experienced. Additionally, the nursing team handling the patients was also familiar with this method for a long period. Third, patients under NOAC (*n* = 8) and warfarin therapy (*n* = 18) alongside with 239 patients getting additional 5000 U of heparin (PCI + adhoc PCI) were not excluded from the study which may have decreased the RAO further down to 0.32% for all the study population at the end of the hemostasis. Finally, trying to relate the very low RAO rate (0.48%) to any reason in our conventional TR Band group, the study from Dangoisse et al was very enlightening.[20] In this paper, they reached a 0.6% RAO rate at 24 h when their used only 10 cc volume of air for the TR Band patent hemostasis. Likewise, the average volume of air used in our TR Band group was 10.5 cc.

In accordance with our 0% RAO rate in the ABS group, another hemostatic pad named as the QuickClot indicated no RAO occurrence at 24 h.[21] However, the rebound bleeding rate (20%) was two times greater than our bleeding rate with ABS (9.40%) after the removal of the closure dressings. In a very recent pilot study with totally 30 patients included, successful hemostasis was achieved in 100% of patients with both the 30- and 60-min compression groups (in which the compression time was increased two- to fourfold compared to the first QuickClot study) using the QuikClot pad with no RAO.[22] Hemostasis failure occurred in 50% of patients when the TR Band was initially weaned at the protocol-driven time.[22] In our conventional patent hemostasis with TR Band hemostasis failure was 27.31%, and

TABLE 3 Outcome measures

Patients; *n*, (%)	Ankaferd blood stopper (*n* = 202)	Conventional sterile gauze (*n* = 204)	Transradial band (*n* = 205)	*P*-value
RAO at the end of hemostasis	0 (0)	1 (0.49)	1 (048)	0.36
RAO at 24 h follow-up	0 (0)	1 (0.49)	1 (0.48)	0.63
RAO at 30-day follow-up	0 (0)	0 (0)	0 (0)	1.00
Hematoma	4 (1.98)	3 (1.47)	2 (0.97)	0.70
Bleeding after device removal	**19 (9.40)**	**55 (26.96)**	**56 (27.31)**	**<0.001**

RAO, radial artery occlusion.
Bold values indicate significant values at $P < 0.05$.

TABLE 4 Logistic regression analysis for bleeding after device removal

Variable	Univariate analysis OR (95% CI)	*P*	Multivariate analysis OR (95% CI)	*P*
Sex (male)	1.438 (0.963-2.149	0.076		
Age (years)	**0.973 (0.955-0.992)**	**0.006**[a]	0.989 (0.969-1.010)	0.308
Height (cm)	**1.041 (1.017-1.066)**	**0.001**[a]	**1.034 (1.006-1.063)**	**0.019**
Weight (kg)	**1.028 (1.013-1.044)**	**<0.001**[a]	**1.021 (1.004-1.039)**	**0.018**
Body mass index (kg/m^2)	1.043 (0.998-1.091)	0.061		
Diabetes mellitus	1.022 (0.684-1.526)	0.917		
Hypertension	1.003 (0.672-1.496)	0.990		
Radial artery diameter (cm)	1.643 (0.927-2.910)	0.089		
Chronic clopidogrel therapy	**1.952 (1.291-3.047)**	**0.003**[a]	**1.615 (1.009-2.586)**	**0.046**
Heparin dose (IU)	**2.954 (1.983-4.400)**	**<0.001**[a]	**3.120 (2.052-4.743)**	**<0.001**
Presence of loading dose of clopidogrel	1.054 (0949-1.170)	0.324		
Chronic aspirin therapy	1.169 (0.790-1.729)	0.435		
Chronic warfarin therapy	1.363 (0.388-4.780)	0.629		
Systolic blood pressure before sheath removal	0.996 (0.988-1.003)	0.280		
Diastolic blood pressure before sheath removal	1.002 (0.989-1.016)	0.750		

OR, odds ratio.
Bold values indicate significant values at $P < 0.05$.
[a]Parameters included into multivariate logistic regression model.

the ABS group had approximately three times less bleeding rate (9.40%, $P < 0,001$) compared to the other two groups. Since re-bleeding/compression regarded as a manageable issue and its incidence ranges from 1% to 18.4%[20,23,24] with conventional patent hemostasis, 9.40% re-bleeding with ABS seems highly acceptable considering the 0% RAO rate achieved in short and long term. Besides, knowing the predictors of bleeding we may have the chance to further decrease the re-bleeding rate with ABS by simply increasing the compression time a bit in this risky population.

5 | LIMITATIONS

All procedures in our study were performed by experienced operators and patent hemostasis was achieved by a experienced nursing team. Therefore, the observed results may not be applicable to less experienced centers. Second, this trial has originated from one center, with only two operators. Third, needed sample size was not assessed before trial, but the recruited subjects were at least outnumbering the similar studies.[21,22] Fourth, we have somewhat modified the conventional patent hemostasis with the TR Band which was inflated at the minimal volume of air required for patent hemostasis and rebound bleeding was treated with manual compression under the guidance of patent hemostasis instead of adding 2 cc volume of air and prolonging the TR Band hemostasis. This should be acknowledged as a possible factor that could influence the results. Fifth, we used 6F sheaths in all patients instead of 5F because possible need for ad hoc angioplasty and it may be a limiting factor when considering that the sheath size is an important parameter for RAO.[3] Sixth, activated clotting time (ACT) levels were not checked for each of the two groups but re-bleeding may be correlated with the ACT level reached during transradial interventions. Measurement of ACT could have provided an additional and objective proof for the cause re-bleeding/compression in the groups. Finally, although Doppler ultrasonography (which was used in two patients to confirm RAO) provides more definite evidence for RAO, reverse Barbeau's test is also effective and was used in many studies in the evaluation of radial artery patency,[7,8,15] so we do not consider assessment of RAO with this method as a major confounder.

6 | CONCLUSION

ABS is promising for use in patent hemostasis during TRA, with no incidence of short-term or long-term RAO and with remarkable reduced risk of re-bleeding at the end of hemostasis.

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