Radial Artery Vascular Complications and Resource Utilization in Subjects Undergoing an Angiogram / Percutaneous Coronary Intervention: The RAVE Trial

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BACKGROUND

Transradial approach (TRA) is the preferred access route for percutaneous coronary procedures. The most frequently employed method for achieving patent hemostasis after sheath removal is a radial compression device. We investigated the effects of using the SoftSeal®-STF hemostatic pad (Chitogen Inc.) in combination with various compression techniques on time to patent hemostasis and incidence of transradial access complications compared to standard of care use of a radial compression device.

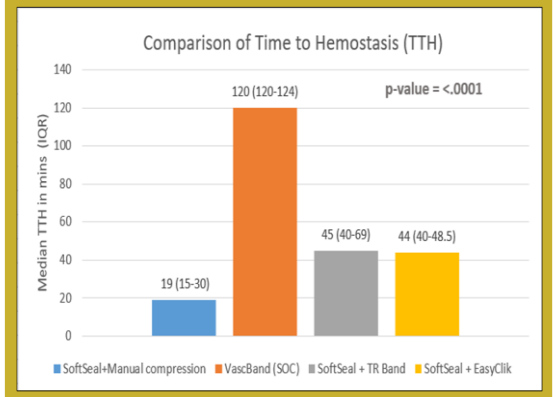
METHODS

- Prospective, single-site trial on adult patients undergoing coronary angiography and/or percutaneous coronary intervention via TRA.
- The study cohort comprised 300 patients assigned to 1 of 4 arms:

  1) SoftSeal®-STF Hemostatic Pad + manual compression
  2) VascBand Compression device applied for 2 hours - Standard of Care (SOC) practices
  3) SoftSeal®-STF Hemostatic Pad + TR Band Compression device
  4) SoftSeal®-STF Hemostatic Pad + EasyClik compression device

- Time to patent hemostasis and TRA complications were compared among the groups.

Use of the **SoftSeal®-STF hemostatic pad with vascular compression** is associated with a **significant reduction in time to hemostasis,** which may allow patients to be **discharged earlier**



Values in parenthesis represent interquartile range

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RESULTS

Table 1: Patient Baseline Characteristics

	SoftSeal N= 49	SOC, VascBand N=51	SoftSeal + TR Band N= 100	SoftSeal + EasyClik N=100	p-value
Age at procedure, mean, SD	66.8 ± 11.2	64.2 ± 9.8	64.4 ± 11.1	66.6 ± 11.1	0.3487
Female	24 (49%)	18 (35.3%)	41 (41%)	34 (34%)	0.3125
Race					
White	43 (87.8%)	43 (84.3%)	86 (86%)	88 (88%)	0.9218
African American	6 (12.2%)	7 (13.7%)	14 (14%)	11 (11%)	0.9251
Other	0	1 (2%)	0	1 (1%)	0.571
Ethnicity : Hispanic	1 (2%)	1 (2%)	5 (5%)	2 (2%)	0.5596
Smoker	10 (20.4%)	15 (29.4%)	33 (33%)	16 (16%)	0.031
Dyslipidemia	33 (67.4%)	39 (76.5%)	85 (85%)	87 (87%)	0.0177
Prior MI	4 (8.2%)	11 (21.6%)	13 (13%)	18 (18%)	0.2182
CHF	6 (12.2%)	9 (17.7%)	21 (21%)	23 (23%)	0.4478
Hypertension	40 (81.6%)	45 (88.2%)	86 (86%)	83 (83%)	0.7533
Prior PCI	7 (14.3%)	16 (31.4%)	22 (22%)	25 (25%)	0.2271
Prior CABG	0	1 (2%)	4 (4%)	5 (5%)	0.3935
Patient history of CAD	16 (32.7%)	23 (45.1%)	52 (52%)	57 (57%)	0.0375
Family History of CAD	24 (49%)	20 (39.2%)	69 (69%)	58 (58%)	0.0031
Diabetes	10 (20.4%)	25 (49%)	34 (34%)	35 (35%)	0.0285
Atrial Fibrillation	9 (18.4%)	9 (17.7%)	15 (15%)	22 (22%)	0.6467
Chronic lung disease	6 (12.2%)	4 (7.8%)	15 (15%)	18 (18%)	0.3833
Current Dialysis	0	2 (3.9%)	2 (2%)	2 (2%)	0.5806
Cerebrovascular disease	4 (8.2%)	7 (13.7%)	8 (8%)	15 (15%)	0.3584
Peripheral vascular disease	1 (2%)	3 (5.9%)	7 (7%)	8 (8%)	0.5554

Table 2: Adverse Events

	Softseal + manual compression N= 49	VascBand N=51	SoftSeal+TR Band N= 100	SoftSeal + EasyClik N=100	p-value
Event type					
Bleeding (minor)	7 (14.2%)	1 (2%)	11 (11%)	11 (11%)	0.1805
Hematoma	2 (4.1%)	0 (0%)	0 (0%))	0 (0%)	0.0762
Pseudoaneurysm	0 (0%)	1 (2%)	0 (0%)	0 (0%)	0.1794
Rash	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0.571
Others	2 (4.1%)	0 (0%)	1 (1%)	0 (0%)	0.1011
Serious Adverse Event (SAE)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	NA

CONCLUSION

Use of SoftSeal®-STF hemostatic pad in combination with compression techniques is safe and significantly reduces time to hemostasis during TRA with no difference in radial artery occlusion when compared to current standard of care. This can significantly impact resource utilization (time to same-day discharge) in a busy cardiac catheterization laboratory.

DISCLOSURE INFORMATION

Authors have nothing to disclose. Chitogen Inc. provided funding in support of this study.