

Radial hemostasis is facilitated with a potassium ferrate hemostatic patch (Statseal): the randomized controlled Statseal with TR Band Assessment Trial (STAT)

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BACKGROUND

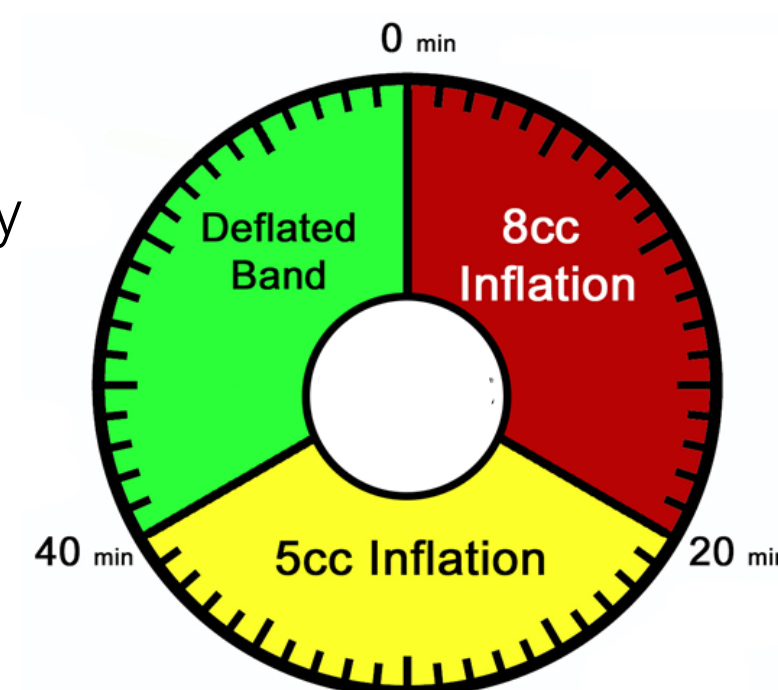
- Transradial route is the preferred access site for cardiac catheterization
 - Reduced bleeding and complications, improved patient comfort
 - Improved throughput and same-day discharge
- Hemostasis most frequently achieved with an air-bladder bracelet (TR Band, Terumo)
- No standardized protocol for TR band deflation
 - Typically 2 hours diagnostic, up to 4 hours PCI

STUDY DESIGN

- Randomized, open label controlled trial
- Primary endpoint:
 - Time to full TR band deflation with initial successful hemostasis
 - >95% power for detecting 60 min difference
- Secondary endpoints:
 - Radial artery occlusion and Radial artery patency (by plethysmography)
 - Hematoma formation
 - Time to discharge for outpatients

METHODS

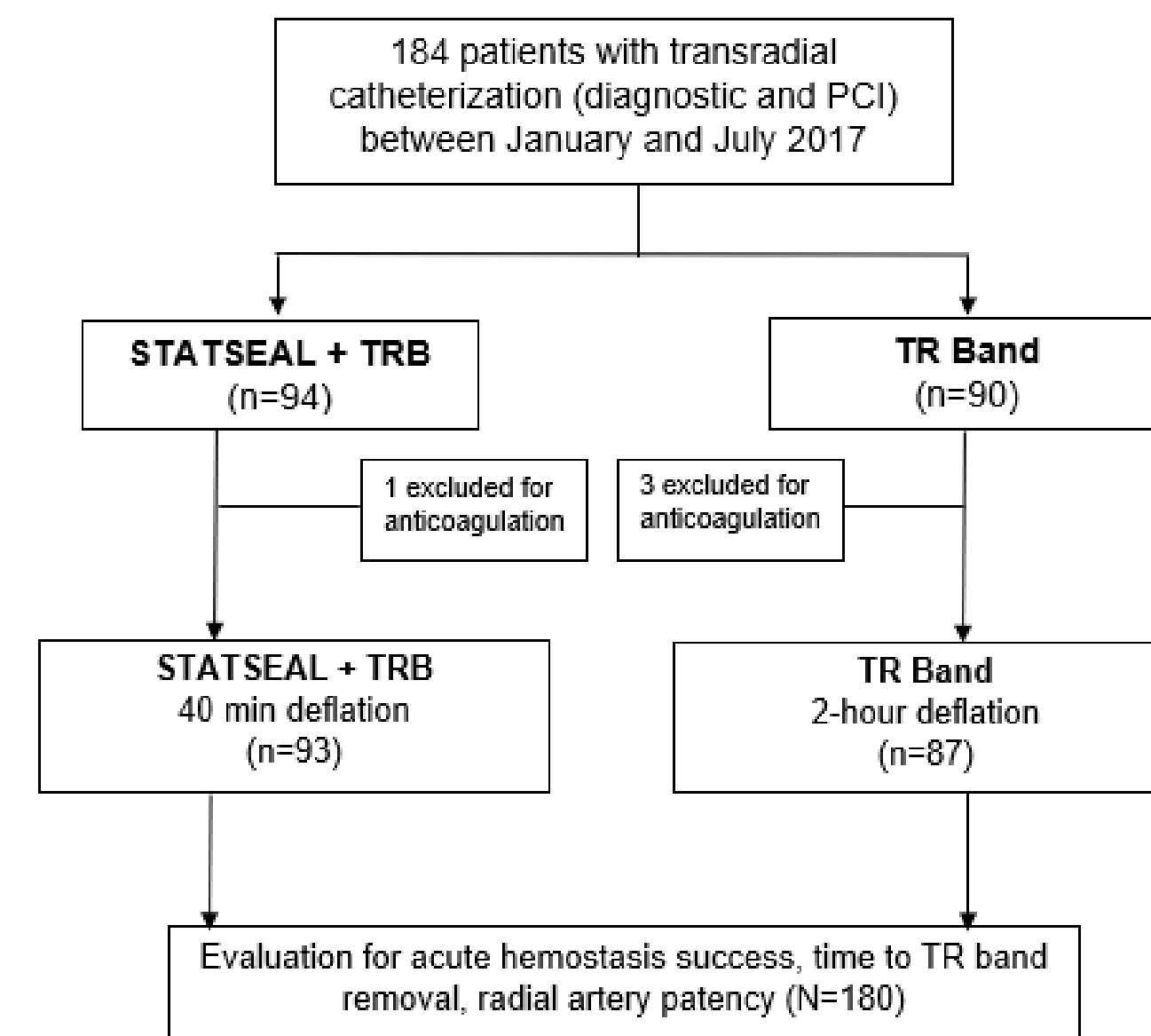
- Minimum of 5,000 units of UFH or therapeutic bivalirudin
- Patent hemostasis and RAO measured by plethysmography
- StatSeal protocol:
 - Initial 8 cc inflation (occlusive pressure) x 20 min
 - Deflate to 5 cc (patent hemostasis) x 20 min
 - Deflate completely @ 40 min, remove TR band @ 60
 - StatSeal left on x 24 hours



REFERENCES

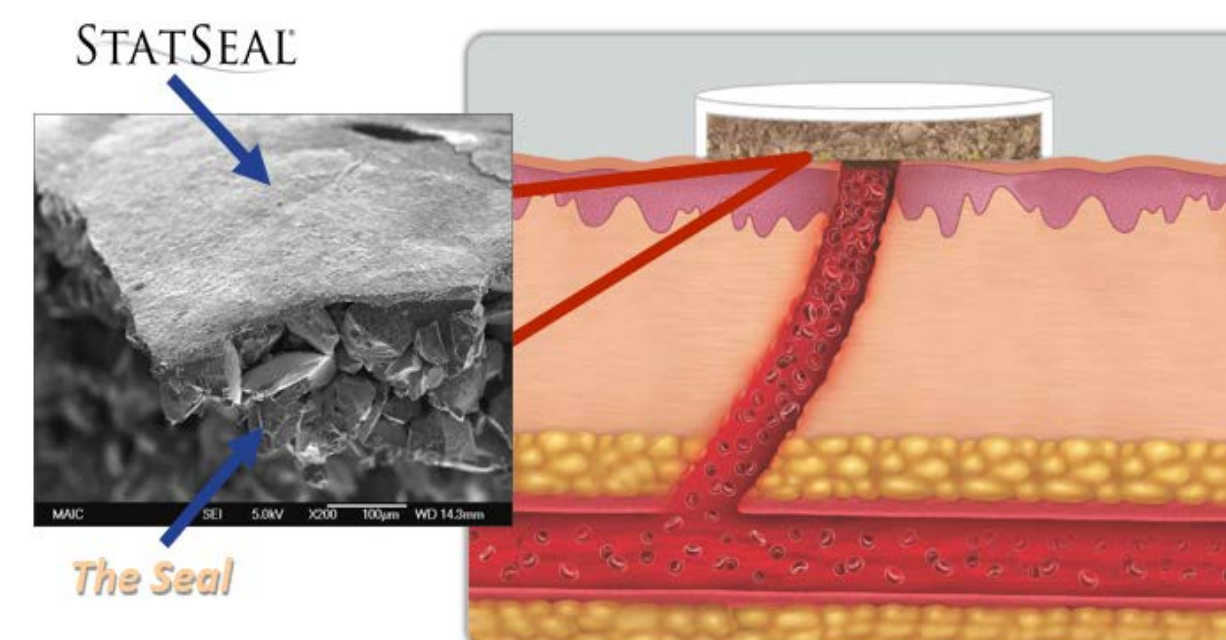
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STUDY FLOW



STATSEAL

- Topical hemostatic patch, adjunct to compression
- Hydrophilic polymer dehydrates and concentrates blood solids
- Potassium ferrate agglomerates the solids and proteins beneath seal



PROCEDURAL CHARACTERISTICS

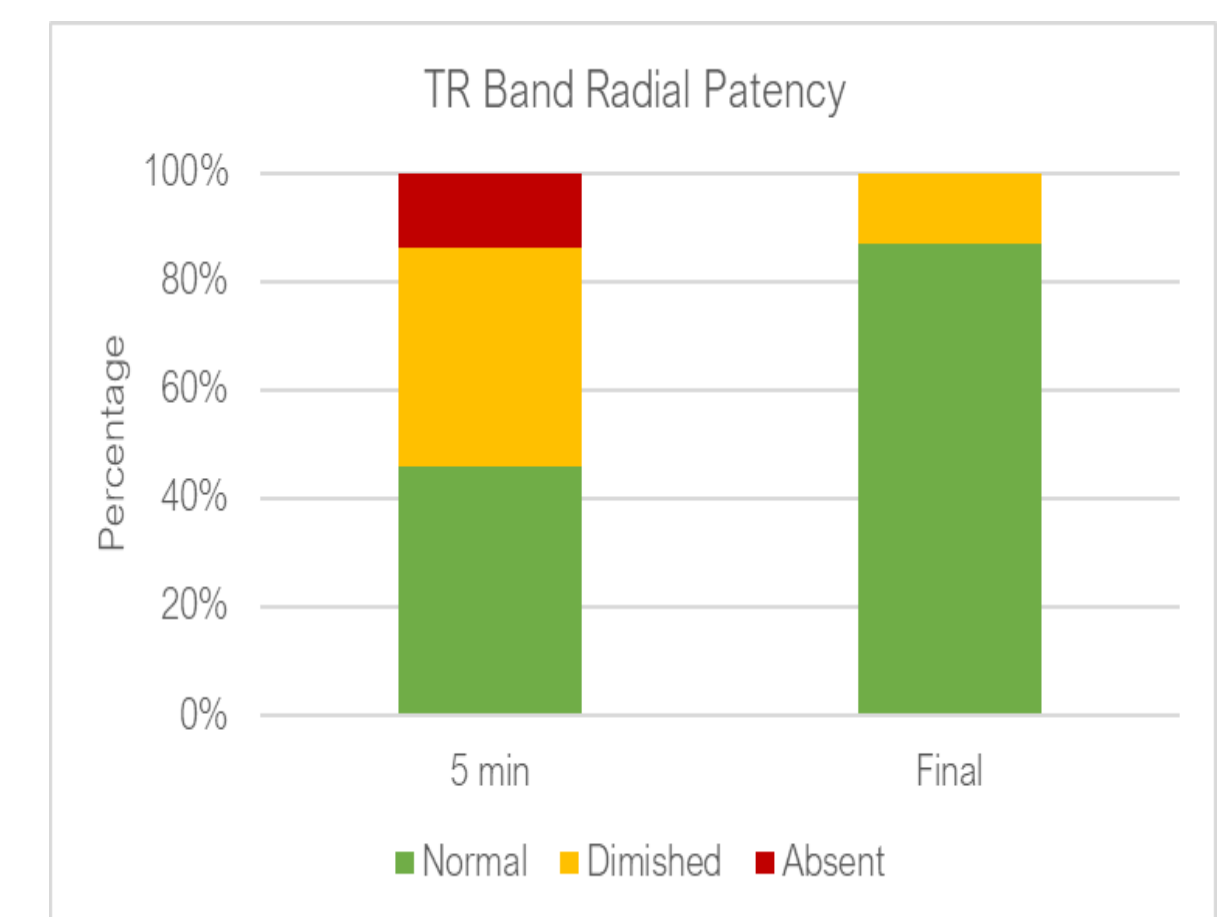
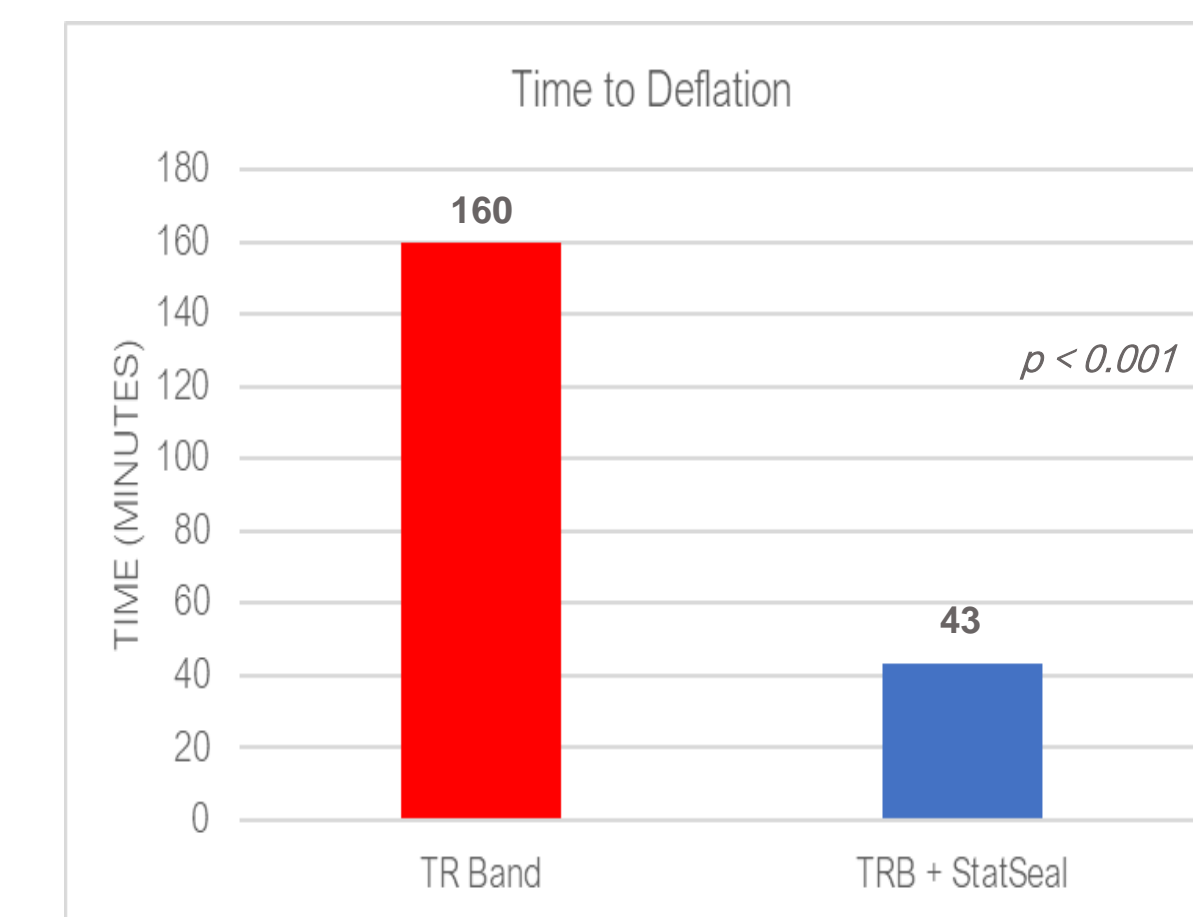
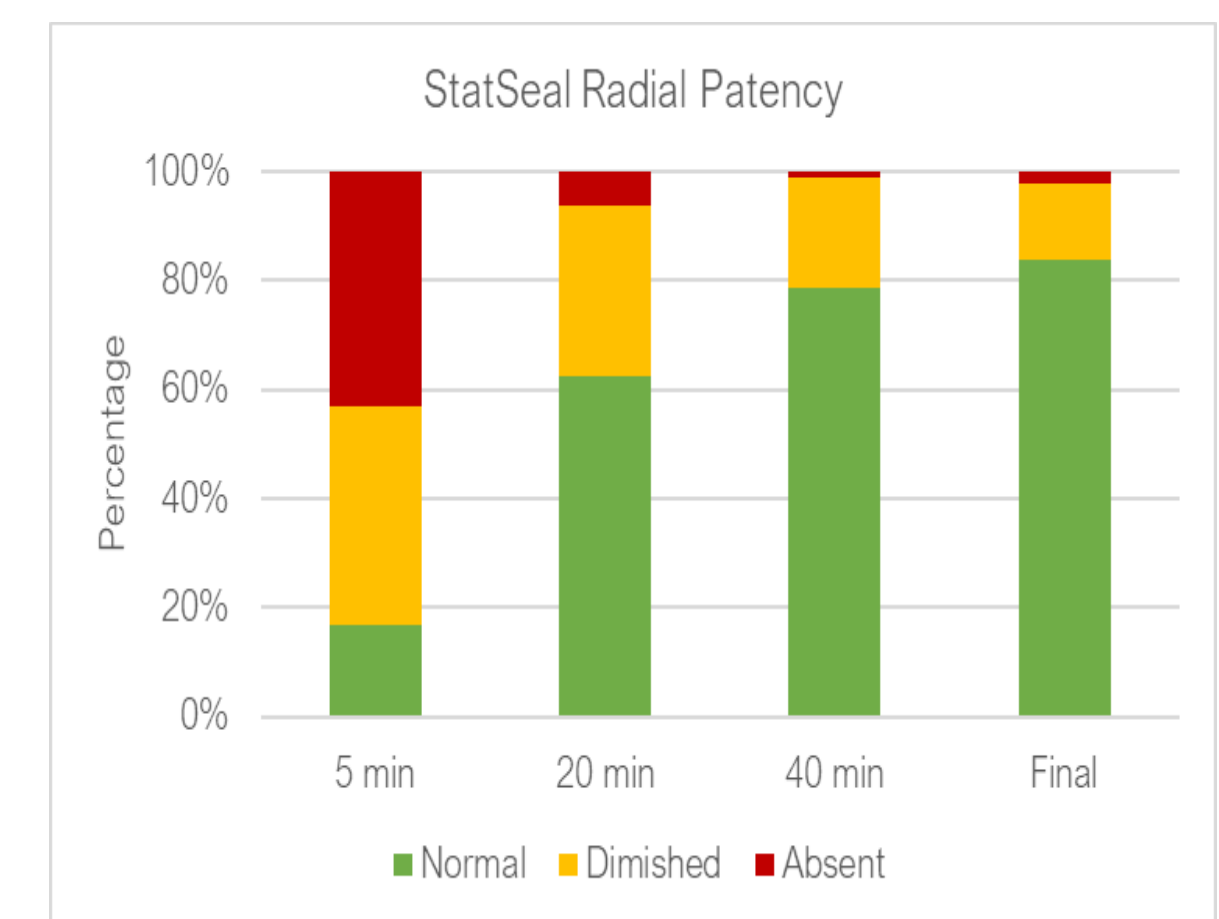
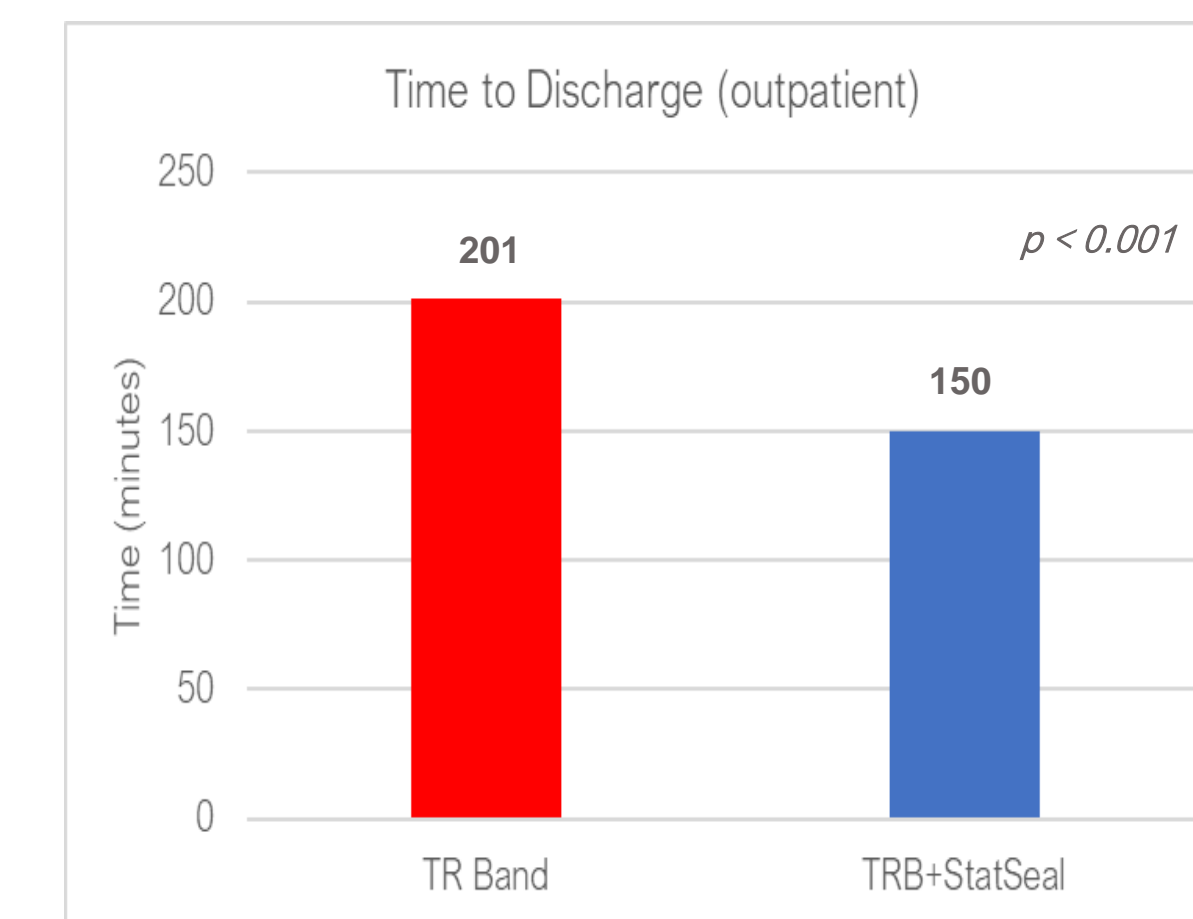
Characteristic	TR Band N=87	TRB + StatSeal N=93	P-value
Diagnostic Procedure	65 (75%)	64 (68%)	0.41
6F Sheath	44 (51%)	47 (51%)	1.0
Single wall technique	55 (63%)	60 (65%)	0.88
Number of forward attempts	2.74 ¶ 2.7	2.87 ¶ 3.04	0.75
Aspirin	65 (76%)	74 (80%)	0.44
Heparin dose	6071 ¶ 2250	6230 ¶ 2136	0.64
Bivalirudin	7 (8%)	4 (4.3%)	0.36
P2Y12 Inhibitor	29 (33%)	32 (34%)	1.0
GPIIb/IIIa	0	2 (2%)	0.50
Peak ACT	248 ¶ 115	241 ¶ 80	0.66
Last SBP	135 ¶ 25	134 ¶ 24	0.70

Values are Mean ± SD, or N (%)

CLINICAL OUTCOMES

Outcome	TR Band N=87	TRB + StatSeal N=93	P-value
Any Hematoma	9 (10.3%)	16 (17.2%)	0.20
Class I (< 5cm)	8	12	0.48
Class II (5-10 cm)	1	4	0.37
Radial Artery Occlusion	0	2	0.50

OUTCOME



Final patency compared with StatSeal
p= 0.53

SUMMARY

- In this multicenter randomized controlled trial, a rapid TR band deflation protocol with StatSeal reduces compression time and time to discharge following transradial catheterization.
- Following initial occlusive pressure, there was no difference in radial patency upon TR band removal.
- The frequency of hematomas was numerically but not statistically higher with Statseal