# **VASOSTAT** versus TR BAND following RADIAL ARTERY **ACCESS FOR** CATHETERIZATION **PROCEDURES**

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### BACKGROUND

Radial access is growing rapidly worldwide. VasoStat (VS) is a radial compression device (RCD) that provides focused pressure over the puncture site. We compared time to hemostasis, clinical outcomes and patient experiences with VS versus balloon compression with Terumo TR Band (TR) in a randomized, prospective trial of subjects undergoing radial access for coronary and endovascular procedures with same-day discharge.

### **METHODS**

40 patients (Pts) with no prior radial access were randomized before procedures to VS (N=20) or TR (N=20). All Pts had ultrasound (US)guided access, 5 or 6 Fr sheaths, and heparin with vasodilators via the sheath. Pts demographics, heparin and antiplatelet therapy, number of RCD manipulations, and access site complications were recorded. Removal of RCDs was begun 1 hour after diagnostic angiograms, and 2 hours after interventional procedures. Pts completed satisfaction surveys and pain scoring scale assessment following RCD use. Hand perfusion index (PI) was measured before radial access, during RCD use, following RCD removal, and after 30 days. Radial US imaging was also performed after 30 days. Fisher's exact test and exact Wilcoxon twosample test were performed between groups using SAS software 9.4.

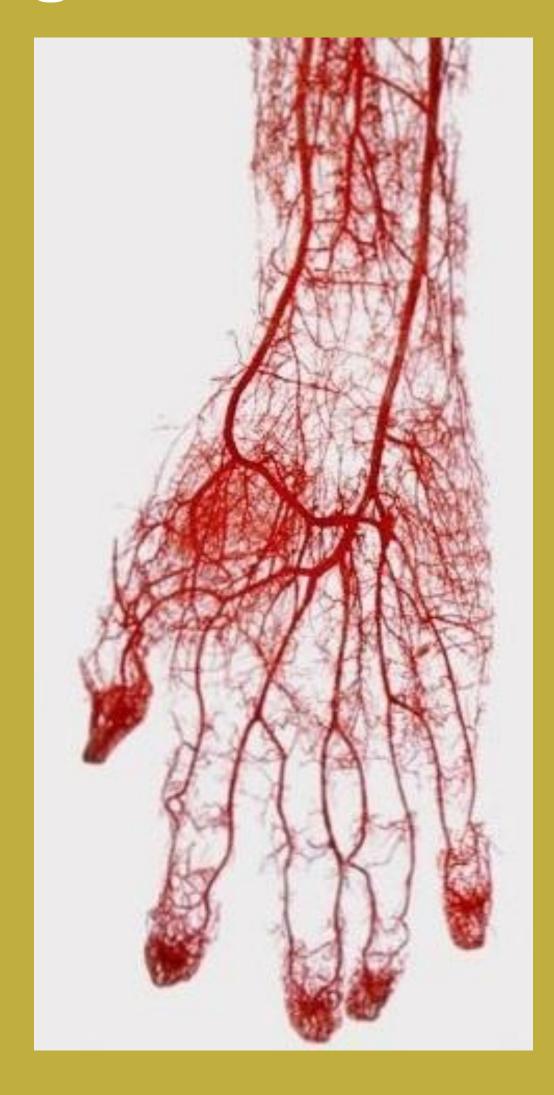
# RESULTS

Age, vascular disease, diabetes, hypertension, hyperlipidemia, kidney disease, and smoking status were similar between the two groups. More women received VS than TR (67% vs. 43%, p=0.13). Heparin dose was similar (p=0.051). Time to hemostasis was 49 minutes shorter with VS (p=0.005). RCD manipulations were lower using VS (p=0.02). Bruising was rare but less common with VS (p=0.35), and unrelated to sheath size, heparin or antiplatelet drugs. Pts reported less discomfort with VS (p=0.16). Change from baseline PI was similar at all time points. After 30 days, US detected no radial occlusions and similar radial systolic velocities (57 cm/s with VS vs. 50 cm/s with TR, p=0.85).

# CONCLUSION

When compared to use of TR, VS resulted in significantly shorter times to hemostasis and required fewer device manipulations following radial access. Bruising, patient comfort, hand PI measurements and overall clinical outcomes were similar, with no radial artery occlusions detected.

When compared to use of a TR Band, VasoStat resulted in significantly shorter times to hemostasis and required fewer device manipulations following radial access.





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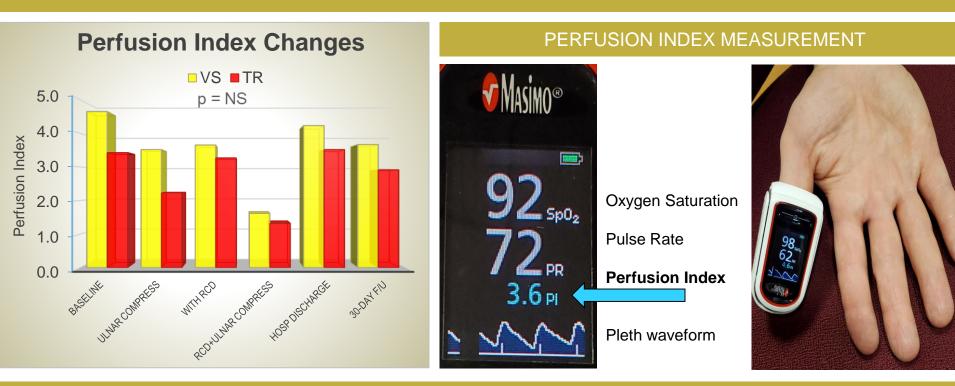
### DISCUSSION

- > Hand perfusion index changes from baseline demonstrated no superiority of one RCD over the other.
- > "Best practices" using US guidance for access, hydrophilic sheaths, radial cocktail infusion via the sheath, and patent hemostasis during radial compression, reduces the incidence of radial artery thrombosis<sup>1</sup>; 0% was seen in this study using 30-day followup duplex US.
- > VS reduced time to hemostasis, by more than 1 hour for interventional cases as compared to TR, thereby allowing earlier hospital departure when same-day discharge was planned.
- > Same-day discharge for elective PCI and Endo interventions following radial access may become the new paradigm of care<sup>(2,3)</sup>, with reduced bleeding complications, improved patient quality of life and nursing satisfaction, and reduced costs which could potentially exceed \$5,000 per case.

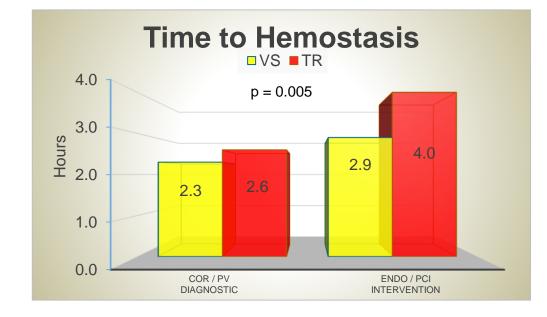
- Minor RL, Maley T, Jenkins D. Same-Day Discharge following Transradial Access for Elective Percutaneous Coronary Intervention: Experience with 51 Community Hospital in Montana. Presented at the ACC Rockies Chapter Annual Meeting, Park City, Utah, August 3, 2019.

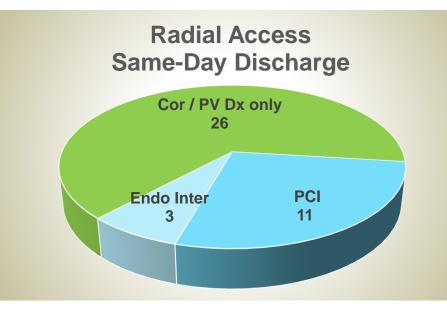
  Minor RL, Maley T, Jenkins D. Transradial Access for Endovascular Interventions with Same-Day Discharge: Feasibility and Safety in a Community Hospital.

## PERFUSION INDEX MEASURES CHANGES IN HAND BLOOD FLOW



# RADIAL HEMOSTASIS & SAME-DAY DISCHARGE





# RADIAL COMPRESSION DEVICE (RCD)



## **DISCLOSURE INFORMATION**

- R. Minor: Medtronic Vascular: Advisory Board.
- T. Maley: Nothing to disclose.
- D. Jenkins: Nothing to disclose.
- YH Li: Nothing to disclose.