Utilization of a Potassium Ferrate (K_2FeO_4) Hemostatic Disc (StatSeal™) to Accelerate Time to Hemostasis in Transradial Cardiac Procedures (TRA)

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BACKGROUND: TRA for cardiac catheterization is steadily increasing and is our preferred approach for diagnostic and interventional procedures, with same day PCI becoming more frequent.
Reimbursement pressures drive searches for cost savings. With TRA, conventional hemostasis management requires 2 - 3 hours of Band In Place time (BIP), delaying discharge for most patients. Duration of HB time has also been related to RAO. Shortening time to hemostasis (TTH) should lead to shorter LOS, reduced costs and improved patient satisfaction, and puts access site management under supervision of experienced CCL personnel. Results from our initial use of a novel hemostatic disc (StatSeal Advanced) to reduce TTH are reported.

DEVICE DESCRIPTION:
StatSeal Advanced (SSA) is a rigid disc formed by the compression of Potassium Ferrate (K_2FeO_4) powder. It is placed under the hemostasis balloon during radial artery compression. (Fig. 1, 2)

Fig. 1

Fig. 2

Fig. 3

When in contact with blood, SSA immediately reacts as a desiccant, causing agglomeration of byproducts within the sheath tract and at the puncture site. (Fig 3) This action immediately & effectively 'seals' the access tract and puncture site, facilitating accelerated time to hemostasis.

METHODS:
- 51 TRA Pts. (using a 6F Glidesheath) were treated with TR band (HB) and SSA.
- All Pts. anticoagulated w/ Heparin or Enoxaprin. IIb/IIIa inhibitors not used.
- Success defined as application per protocol w/o hemorrhage/ hematoma or other vascular complication.
- Time to HB deflation & removal measured.

StatSeal Advanced Procedure - Data Summary

		PCI	Dx	Total
N		15	36	51
Sex	M	11	22	33
	F	3	14	17
	nr	1		1
Age in Years	mean	62.3	61.6	61.8
	range	38 - 80	31 - 84	31- 84
Time (minutes) to first deflation	mean	22.42	21.63	21.9
	range	20 - 25	15 - 30	15 - 30
Time (minutes) to full deflation	mean	44.3	44.72	44.63
	range	40 - 50	30 - 57	30 - 57
Hematoma (Class I)		0	1 (1.9%)	1 (1.9%)
Hematoma (major)		0	0	0
RAO		0	0	0

StatSeal Advanced PROTOCOL:
- SSA applied to access site during HB positioning. inflated with 8cc air.
- At 20 minutes, 3cc removed from HB.
- Full deflation following another 20 minutes.
- Site is observed for 10'.
- HB removed.
- SSA remnant stays in place for 24 hours. (see Fig 2)

RESULTS:
- SSA placed on all pts. per protocol.
- Hemostasis achieve in 51/51 (100%).
- Mean time to 1st deflation 21.9 min (15 – 30).
- Meant time to full deflation: 40.3 min (30 – 57).
- One (1) pt. with Class I hematoma; txd with re-inflation for 15'.
- TTH managed by CCL personnel in 100% of patients.
- All Pts discharged @ 4 – 6 hours per current SOP for same day PCI.
- No evidence of RAO @ discharge.

CONCLUSIONS:
- SSA is simple to use, safe & effective in achieving rapid HB deflation despite anticoagulation.
- No apparent increase in complications observed
- No evidence of acute RAO observed.
- Pt. satisfaction improved 2° shorter band time.
- Additional studies ae warranted to explore earlier discharge, cost savings, & RAO risks, compared to standard HB application.

DISCUSSION:
There are several major potential advantages to incorporating SSA in to a radial hemostasis management protocol. Those include:
- Reduced severity of complications w/ hemostasis management supervised by CCL staff.
- Decreased LOS – earlier discharge, perhaps by 1 – 2 hours.
- Improved throughput / staff productivity while decreasing costs.
- Discharge delays could be avoided.

The author gratefully acknowledges the assistance of Tifton Fordham, RN and Rudy Davis, BS, MBA, in preparation of this poster. *StatSeal Advanced is a trademark of Biolife, LLC. TR Band is a registered trademark of Terumo Medical. Photos & graphic courtesy of Biolife, LLC*