

Meta-Analysis of Radial Hemostasis Trials Using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc

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Background

Incorporating a potassium ferrate hemostatic disc (StatSeal Advanced™, Biolife, LLC) as an adjunct to a hemostasis band (HB) has been shown to reduce time to hemostasis (TTH) with low rates of radial artery occlusion (RAO). Hematoma rates however have been variable across previous trials. We aimed to perform a meta-analysis of available radial hemostasis studies that utilized a potassium ferrate disc in conjunction with a patent hemostasis technique.

The hemostatic disc consists of a compressed hydrophilic polymer and potassium ferrate powder. When in contact with blood, this immediately reacts as a desiccant, causing agglomeration of byproducts within the sheath tract and at the puncture site facilitating accelerated time to hemostasis.

Methods

We included data from 1 randomized and 2 non randomized trials for a total of 2167 patients. The meta-analysis performed was a random-effects meta-analysis. Endpoints included hematoma formation, TTH and RAO. Prior to performing the meta-analysis for each endpoint, a Cochran's Q statistic was calculated to assess homogeneity of the studies with respect to the distribution of the endpoint. For all endpoints, Cochran's Q indicated significant heterogeneity (at a 0.10 level of significance) which required use of a random effects meta-analysis (DerSimonian-Laird approach). RAO and hematoma correlation analysis was performed for age, weight, heparin dosing and gender. The Pearson correlation coefficient of time-to-hemostasis for each variable was calculated.

Results

RAO rate was 1.9% (95% CI 0.08%-6.1%). The hematoma rate was 5.9% (95% CI 0.4%-17.4%). The mean TTH was 50.7 min (SD 13.70 min). RAO was not greater in males compared with females (2.5%; 95% CI, 0.03-8.9 versus 0.7%; 95% CI, 0.2-1.4). There was no association between weight, gender, heparin dosing or age with hematoma formation. RAO was associated with age but not weight, gender or heparin dosing.

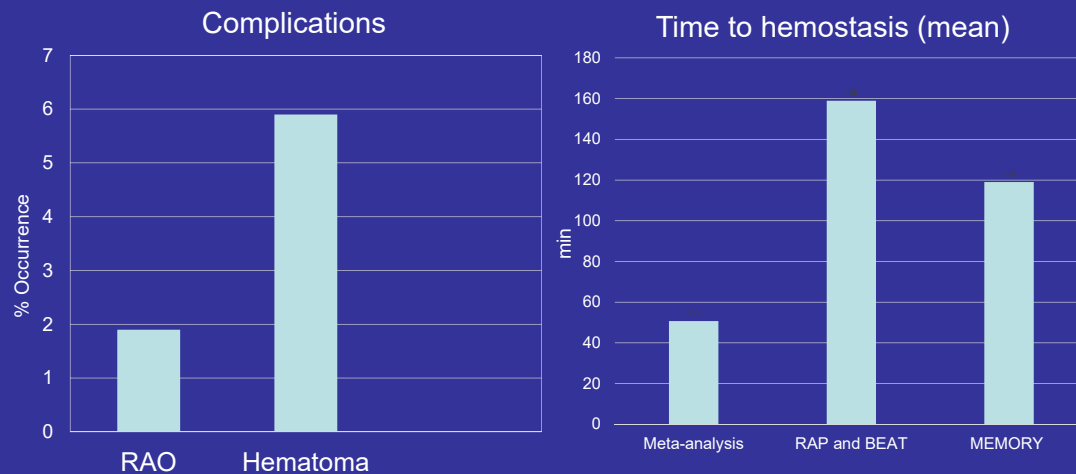
Limitations

This meta-analysis includes both observational and randomized data. The variable sample sizes from the trials also limits the strength of the conclusions.

Disclosures

Matheen Khuddus: Consultant for Medtronic and Abbott

Principal Finding: TTH, Hematoma and RAO Rate using Patent Hemostasis and a Potassium Ferrate Hemostatic Disc

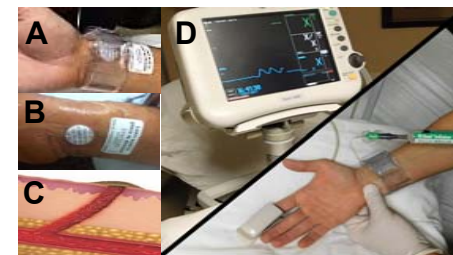


Radial artery hemostasis can be achieved rapidly with low rates of complications using patent hemostasis and a potassium ferrate hemostatic disc. Further investigation is warranted.

#RadialFirst

StatSeal Advanced is a trademark of Biolife, LLC. Photos & graphic courtesy of Biolife, LLC. The authors gratefully acknowledge the assistance of the research staff at The Cardiac and Vascular Institute Research Foundation in preparation of this poster

Tables and Figures



Baseline Clinical and Procedural Characteristics

Age, years	64.5 ± 4.31		
Male, %	56% ± 6.2%		
Heparin, units	4542 ± 1240		
Sheath, size			
4 Fr	35.6%		
5 Fr	47%		
6 Fr	12.6%		
6 Fr GSS	2.8%		
	RAO	No RAO	p-value
All Subjects	1.9% (0.08%, 6.1%)		
Heparin dose (units)	4479.5 (806.03)	4549.7 (736.37)	p=0.0566
Weight (kg)	85.62 (5.15)	87.3 (5.10)	p=0.169
Age (years)	56.0 (5.95)	64.3 (3.07)	p<0.001
Gender			
Male	2.5% (0.03%, 8.9%)		p=0.971
Female	0.7% (0.2%, 1.4%)		
	Hematoma	No Hematoma	p-value
All Subjects	5.9% (0.4%, 17.4%)		
Heparin dose (units)	4499.43 (600.38)	4565.61 (737.69)	p=0.087
Weight (kg)	83.8 (5.27)	87.6 (4.99)	p=0.245
Age (years)	67.0 (1.75)	64.1 (2.98)	p=0.355
Gender			
Male	4.9% (0.2%, 15.2%)		p=0.463
Female	7.3% (0.3%, 22.0%)		
	TTH (min)	TTH (correlation)	p-value
All Subjects	50.7 (13.70)		
Heparin dose (units)		0.096877	p=0.353
Weight (kg)		-0.039171	p=0.536
Age (years)		0.066103	p=0.002
Gender			
Male	50.5 (14.60)		p=0.863
Female	50.6 (12.34)		