

Clinical Efficacy of SoftSeal-STF Hemostatic Pad with Short Hold Time Compared to Traditional Manual Compression After Transfemoral Catheterization

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BACKGROUND

- Access site complications after angiography and percutaneous coronary intervention (PCI) affect mortality, morbidity, length of stay and overall cost.
- Several studies and meta-analysis have associated vascular closure devices (VCDs) with increased rates of access site complications when compared to manual compression.
- Thus, there is a lack of consensus regarding whether traditional manual compression or VCDs is superior regarding achieving hemostasis while mitigating complications.
- The SoftSeal-STF Hemostatic Pad is a novel product to achieve hemostasis.

HYPOTHESIS

- Using the SoftSeal-STF Hemostatic Pad with a short hold time is equivalent to traditional manual compression after transfemoral catheterization.

METHODS

- Prospective analysis of consecutive patients undergoing femoral cardiac catheterization with and without PCI was conducted.
- Patients were divided into 2 groups: those with the SoftSeal-STF Hemostatic Pad and short hold time, and those with traditional manual compression (assumption of 20 minutes of manual compression).

Table 1: SoftSeal-STF Hemostatic Pad Hold Time

PROCEDURE	ACT		
	< 170	170 TO 220	> 220
TFA (trans femoral access)	1 MINUTE / Fr	2 MIN / Fr	NOT RECOMMENDED

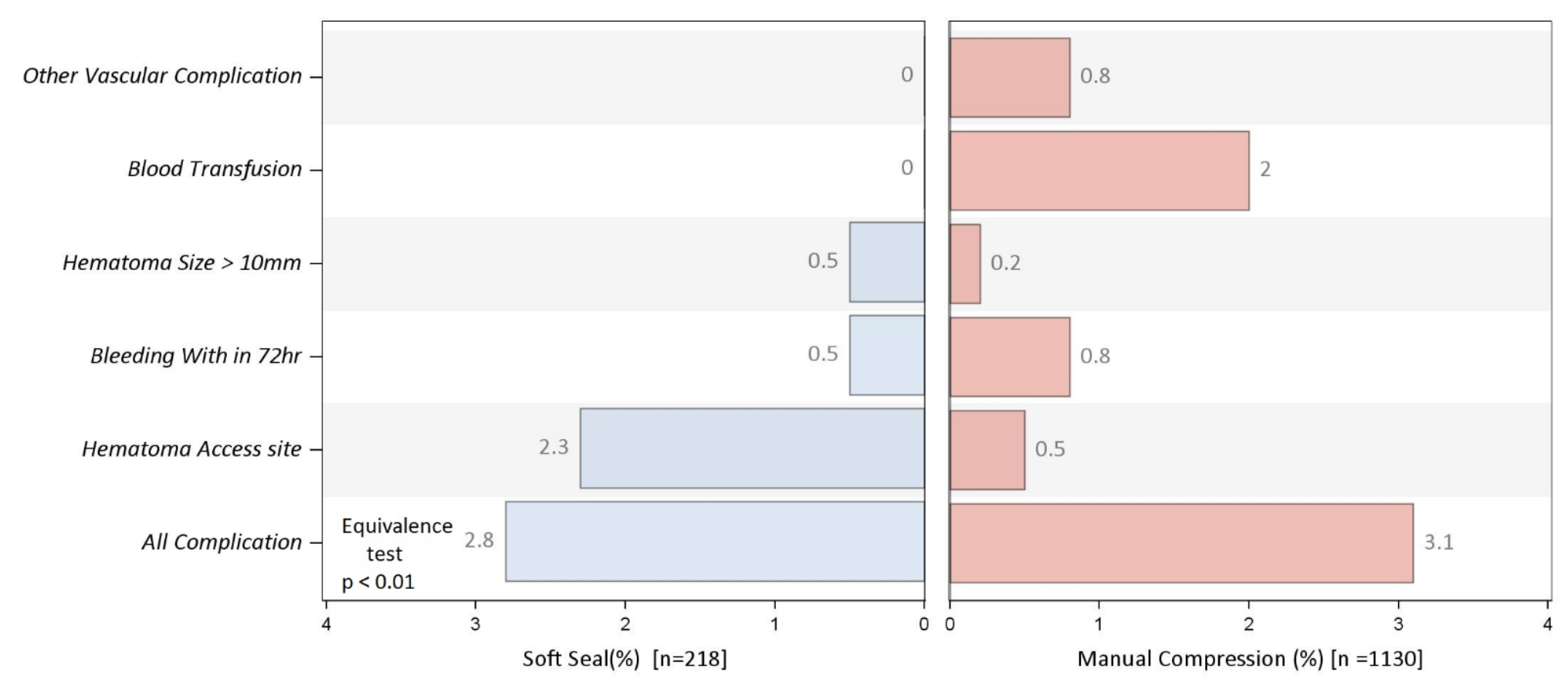
- Groups underwent 1:1 propensity matching for bleeding risk score and type of anticoagulant used.
- Total of 1,348 patients were included in the propensity match analysis.
- Statistical analysis was performed for equivalence.

RESULTS

Table 2: Access Site Complications

Complications	Overall (1348)		Soft Seal (218)		Manual Compression (1130)	
	n	%	n	%	n	%
Hematoma Access Site	11	0.8%	5	2.3%	6	0.5%
Bleed Within 72 hours	10	0.7%	1	0.5%	9	0.8%
Hematoma Size > 10mm	3	0.2%	1	0.5%	2	0.2%
Blood Transfusion	23	1.7%	0	0.0%	23	2.0%
Other Vascular Complication	9	0.7%	0	0.0%	9	0.8%

Graph 1: Access Site Complications



RESULTS

Table 3: Hold Time Analysis (in minutes)

Mean (SD)	95% CI	P-value
7.79 (3.38)	(7.34, 8.25)	<0.001

(Assuming 20 minutes of traditional manual hold)

DISCUSSION

Hemostasis without complication occurred in 97.2% of the SoftSeal-STF Hemostatic pad group and 96.9% of the traditional manual compression group, proportion difference with 95% CI is 0.35% (-2.14%, 2.83), significant for equivalence (p<0.0001) using a 5% margin.

CONCLUSION

Clinical efficacy of the SoftSeal-STF Hemostatic Pad with significantly shorter hold times is equivalent to traditional manual compression.

DISCLOSURES

The authors have no disclosures.