

# Pocket related complications following cardiac rhythm device implantation in patients receiving anticoagulation or dual antiplatelet therapy: Prospective Evaluation of different preventive strategies

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**Background:** Pocket hematoma is a common complication after cardiac rhythm device implantation (CRDI) in patients receiving anticoagulation or dual antiplatelet therapy (DAPT). We sought to assess the safety and effectiveness of a vacuum drainage system (VDS) or a hemostatic gelatine sponge (HGS) compared to standard of care (UC - compression, electrocautery, untreated cotton pledgets).

**Methods:** We conducted a prospective randomized study and enrolled all patients admitted for CRDI receiving anticoagulation or DAPT. Participants received VDS, HGS, or UC following CRDI. The primary endpoint was a composite of hematoma needing evacuation, and pocket infection.

**Results:** We included 250 patients (mean age  $72 \pm 6$  years). 80 (32%) were female. 82 patients (31%) received VDS, 87 (35%) HGS, and 81 (31%) UC; 112 patients (45%) were treated with anticoagulation, 110 (44%) received DAPT, and 28 (11%) both. The primary endpoint occurred in 0/82 patients from the VDS group, 2/87 from the HGS group, and 2/81 of the UC group, respectively (0% versus 2% versus 2.3%;  $p=0.4$ ). Use of HGS was associated with a higher incidence of minor pocket hematoma compared to UC (17.2% versus 7.4%;  $p=0.06$ ). The rate of pocket infections was low: 1/250 (0.4%). Postoperative Immunoglobulin E levels were  $106 \pm 219$  IU/ml (VDS),  $119 \pm 498$  IU/ml (HGS), and  $181 \pm 488$  (UC), respectively. Postoperative increase of C-reactive protein was VDS:  $\Delta 16 \pm 25$  mg/l versus HGS:  $\Delta 28 \pm 28$  mg/l, versus UC:  $\Delta 12 \pm 14$  mg/l;  $p < 0.001$  [HGS versus UC].

	UC (81 pts)	VDS (82 pts)	HGS (87 pts)	p-value
Anticoagulation [n (%)]	35 (43)	36 (44)	41 (47)	0.8
Coumadin therapy	20 (25)	20 (24)	29 (33)	0.3
Subcutaneous LWMH	8 (10)	9 (11)	7 (8)	0.8
Intravenous UFH	7 (8)	7 (9)	5 (6)	0.8
Dual antiplatelet therapy [n (%)]	34 (42)	41 (50)	35 (40)	0.3
Anticoagulation + DAPT [n (%)]	12 (15)	5 (6)	11 (13)	0.2
Coumadin therapy + DAPT	5 (6)	0	5 (6)	0.08
Subcutaneous LWMH + DAPT	3 (4)	2 (2)	3 (4)	0.7
Intravenous UFH + DAPT	4 (5)	3 (4)	3 (4)	0.9

Table 1: Type of anticoagulation in the study groups

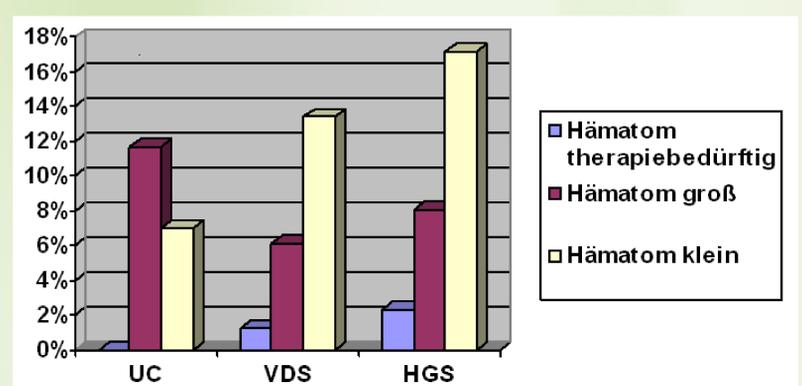


Figure 1: Amount of hematoma formation in the study groups

**Conclusions:** Effectiveness of VDS, HGS and UC was comparable regarding the frequency of clinically relevant pocket hematomas. The observed rate of pocket infections was low. HGS seems to have the highest inflammatory potential.