Pocket complications after cardiac implantable device implantation and replacement: clinical risk factors and influence of the perioperative antithrombotic management.

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Topic(s):
Device Complications and Lead Extraction

Citation:

Introduction
Pocket hematoma is a common complication of cardiac implantable device (CID) procedure; it is associated with an increased risk of infection and it may require surgical intervention or lead to lengthier hospital stays. The perioperative management of anticoagulation (AC) and antiplatelet (AP) therapy has an important role in hematoma formation. The number of CID procedures is in continuous rise and often patients presents important comorbidities and frailty. The best strategy to reduce this complication is still a matter of debate.

Purpose
The aim of the study was to research the clinical factors associated with pocket hematoma formation after CID implantation or replacement and to identify the best perioperative AC/AP management.

Methods
We performed a retrospective analysis of patients who underwent to CID implantation or replacement from 2014 to 2016 in our university hospital. Information about clinical status, AC/AP therapies and perioperative management were collected.

Pocket hematoma was defined as any large effusion in the pocket leading to swelling and causing pain. Local ecchymosis without swelling were excluded.

Results
The study included 487 patients (68.8% male, mean age 73.9 ±13.9 years). Atrial fibrillation was present in 166/487 patients (34.1%), a severe impaired renal function in 23/487 (4.7%), and diabetes in 117/487 (24.0%). A mechanical valve was present in 23/487 (4.7%), while 10/487 (24.2%) had a left ventricular ejection fraction (LVEF) <35%. Transcatheter aortic valve (TAVI) was implanted during hospitalization in 10/487 (2.1%), and 20/487 (4.1%) were admitted for myocardial infarction (MI).

Among our population, 206/487 patients (42.3%) were on AC therapy at implantation: 111/487 (22.8%) bridged with low molecular weight heparin (LMWH); 68/487 (14.0%) on ongoing warfarin, 27/487 (5.5%) on direct oral AC (DOAC); 57/487 (11.7%) on AC and single AP therapy, and 12/487 (2.5%) on AC and dual AP therapy.

A pocket hematoma occurred in 23/487 patients (4.7%), and in 11 cases a surgical revision was necessary.

Hematoma was mainly observed after ICD implantation (p 0.001). Pocket hematoma were more frequent in patients on AC therapy (7.8% on AC vs 2.5% without AC, p 0.007). Among AC therapies, LMWH was significantly associated with hematoma (no AC therapy 2.5%; ongoing DOACs 3.4%; ongoing warfarin 4.4%; LMWH 10.8%, p=0.006).

The clinical risk factors for pocket complications resulted mechanical valve prosthesis (26.1% vs 3.7%, p
Conclusion
LMWH was associated with high rate of pocket hematoma. The better perioperative strategy results in ongoing warfarin or ongoing DOAC. Patients at higher risk of developing pocket hematoma are those with low LVEF undergoing ICD implantation, those with mechanical valve prosthesis, and those admitted for MI.