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Identifying the predictors of hematoma after device implantation: Closing in on the suspects with an aim to prevent the menace?

Implantation of various cardiac implantable electronic devices (CIED) is becoming increasingly common day by day. At the same time, the recipient patient population, especially that of implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT-P and CRT-D) devices, is also getting older with greater co-morbidities, including atrial fibrillation. As a result, various procedure related complications are now being frequently encountered in clinical practice. Pocket hematoma is once such common, but often neglected, complication of the implant procedure that not only is discomforting to the patient, but may also result in prolonged hospital stay, reoperation and higher healthcare costs in the short-term. Even more importantly, hematoma formation is a perfect example of how a seemingly minor complication can result in a disastrous late consequence, i.e. pocket infection in this case. The recently published BRUISE CONTROL INFECTION Study, just like many other previous studies [1], showed that clinically significant hematoma formation after a device implant was the only independent predictor of the risk of infection at 1-year follow-up [2].

Sridhar et al. should be complemented for analysing one of the largest databases of ICD and CRT-D recipients and presenting the data on the incidence, predictors and short-term in-hospital outcomes of pocket hematoma [3]. It is reassuring to know that the incidence of hematoma after these implants (2.6%) is not alarmingly high and comparable to many similar studies [4] although, the incidence is quite variable in the literature due to absence of a standard definition of diagnosis of hematoma. However, the actual incidence of hematoma in clinical practice is likely to be much higher for a number of reasons. Firstly, the study by Sridhar et al. included only de novo implants and excluded patients with upgradations, revisions and replacements where the risk of hematoma is usually higher [5]. Secondly, the study included only the patients in which the hematoma developed during hospital stay, though in practice, hematoma is frequently recognised much later after discharge from hospital and is managed in outpatient setting or requires readmission for pocket revision or evacuation. Thirdly, many of the times an apparently non-significant hematoma may not be reported at all especially since specific International Classification of Diseases coding for the same does not exist as stated by the authors themselves.

A number of steps need to be followed in order to ensure prevention of occurrence of a serious complication. These include –

1. Estimation of incidence of complication.
2. Identification of predictors of the complication, i.e., the high-risk patients.
3. Measures to prevent the complication in all patients but more emphatically in those with higher risk as identified in step 2.
4. Discovering and studying the newer active measures to reduce in the risk of a complication in high risk patients.
5. Recommending routine use of the measures found effective in step 4 in high risk patients.

Hence, determining the incidence and identification of predictors of hematoma after ICD or CRT-D implant are essential initial steps to reduce the occurrence of this complication.

Sridhar et al. in their retrospective analysis of more than 85000 patients found that higher age, congestive heart failure, coagulopathy and renal dysfunction had a higher incidence of hematoma formation after primary or de novo ICD or CRT-D implantation [3]. This is in general in line with the other published data in the literature [4,6]. However, a few important variables like presence of atrial fibrillation and use of anti-platelets or oral anticoagulants that predispose to hematoma occurrence were not studied individually and possibly clubbed under the heading coagulopathy by Sridhar et al. Information on the perioperative management of anticoagulation in these patients particularly bridging with low molecular weight or unfractionated heparin that has been associated with high risk of hematoma in various studies would have been extremely desirable. The authors have also not defined clearly what they meant by coagulopathy. Moreover, as the authors mentioned themselves, the study had all the limitations of retrospective design. Nonetheless, the clinically identified independent predictors of risk help us in focusing our preventive measures more emphatically in these patients in clinical practice.

Interestingly, the incidence of hematoma was similar during ICD and CRT-D implant indicating that the length of the procedure is not likely to affect the occurrence of hematoma though, it may have an influence on the risk of infection.

The authors in their study also looked at the short term impact of hematoma formation and found that it increased the length of hospital stay and the cost of hospitalization [3]. Though, there was no significant increase in in-hospital mortality in their study but the actual impact on mortality can only be assessed over

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long-term taking into account risk of infection attributed by hematoma formation. The present study also did not look into the risk of reoperation for evacuation of hematoma that itself can increase the risk of infection and perhaps long-term mortality.

The presence of atrial fibrillation requiring oral anticoagulation, some other indication for oral anticoagulation (e.g., prosthetic heart valve) and use of antiplatelet especially dual antiplatelet therapy for acute coronary syndrome or coronary stent have been known to increase the risk of hematoma formation after device implantation. Though, it has been believed for many years that temporary withholding the oral anticoagulant (especially warfarin) and bridging with unfractionated or low molecular heparin can be used as a strategy for surgical procedures including device implantation; multiple studies in last few years have indicated that the bridging strategy is associated with the worst clinical outcome and high incidence of hematoma formation [4,7,8]. Recent recommendations including the 2016 ESC guidelines on atrial fibrillation [9] suggest that most procedures including device implantations should be performed on therapeutic anticoagulation to achieve the best balance in reducing stroke risk and avoiding hematoma formation. The data on whether a similar strategy of uninterrupted anticoagulation with novel anticoagulants can be recommended is limited but the results of the ongoing BRUISE CONTROL -2 study [10] should answer that question.

The findings of this large retrospective study confirm that the risk of hematoma formation after ICD or CRT-D implantation is not very high; and is more likely in presence of advanced age, heart failure, and renal dysfunction, and with knowledge from other studies in atrial fibrillation, with use of oral anticoagulation or antiplatelet agents and bridging strategy.

Having known the “suspects”, it is prudent to take adequate measures to prevent its occurrence! Apart from performing the procedure on uninterrupted warfarin (and perhaps uninterrupted use of newer oral anticoagulants); more active measures such as judicious use of electrocautery, intrapocket administration of prohemostatic agents (e.g., tranexamic acid [11], fibrin sealant [12]) and application of pressure dressings have often been used in clinical practice. These measures need to be standardized and evaluated in randomized studies to ascertain whether they actually reduce the risk of formation of hematoma before they can be recommended routinely to the “suspects” undergoing implant procedures to reduce the “menace” of post-procedure hematoma.

Conflicts of interest

None.

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