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Effectiveness of the TopClosure® 3S System in Prevention of Hematoma Formation Following Implantation of Cardiovascular Electronic Devices in Patients Prone to Bleeding

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Background:

Cardiovascular implantable electronic devices (CIEDs) are frequently inserted while patients are on anticoagulant or anti-aggregant therapy. As a result, the probability for hematoma formation and its consequences is higher.

Objective:

To evaluate the effectiveness of TopClosure® 3S System in preventing local hematoma formation following implantation of CIEDs in patients prone to bleeding complications due to anticoagulant or potent anti-aggregant treatment.

Methods:

During 10-11/2012 we identified 20 patients prone to bleeding among our patients requiring CIED implantation. Patients were assigned alternately to TopClosure® 3S therapy, or to usual pressure dressings, the latter served as the control group. Ten days following surgery, wound dressings were removed and an independent surgeon evaluated healing stage prior to staple removal. Therapy outcome was assessed by permission to extract staples, need to continue antibiotics, or requiring further TopClosure® application.

Results:

Only one patient of the treatment group required additional antibiotic therapy and TopClosure® application (10%) compared to 6 patients in the control group (60%), who required additional antibiotic administration, deferral of staple removal, or further pressure dressing application. Conclusions: The use of the TopClosure®, following CIED implantation in cardiac patients on active anticoagulant and/or intense anti-aggregant therapy, proved in this ongoing study to be safe and efficacious.