

## A local gentamicin-collagen sponge reduces cardiovascular implantable electronic device infections and pocket hematoma

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**Background:** Implantation or replacement of cardiovascular implantable electronic device (CIED) may be associated with complications such as pocket hematoma and infections.

**Purpose:** The aim of this study is to determine whether a lyophilized collagen impact impregnated with the aminoglycoside antibiotic gentamicin, applied according to the size of pocket into the surgical wound during implantation or replacement, reduces major CIED infections and pocket hematoma 12 months after the surgical intervention.

**Methods:** We conducted a retrospective study including 1189 patients (mean age  $77.45 \pm 9.83$  y.o.), who underwent implantation or replacement of CIED in our center between June 2007 and November 2018. We compared 475 patients treated with the local gentamicin-collagen sponge (group I) with 714 patients who did not receive it (group II). The primary endpoints were the reduction of infectious complications and pocket hematoma through 12 months of follow-up post procedure.

**Results:** Complications occurred in 127 of 1189 patients (10.68%): 102 of 1189 patients (8.58%) developed pocket hematoma, 20 of 1189 patients (1.68%) infectious events and 5 of 1189 patients (0.42%) both. Specifically, the rate of complications was lower in group I: pocket hematoma 0.63% vs 13.86% ( $p < 0.001$ ), infections 0.21% vs 2.6% ( $p = 0.02$ ), both 0% vs 0.7% ( $p = 0.17$ ). The study also shows a statistically significant major incidence of infectious complications in subjects undergoing implantation or replace-

ment of ICD, compared to subjects undergoing implantation or replacement of PPM (5.59% vs 1.5%;  $p < 0.05$ ).

Regarding the type of intervention and the incidence of complications within the subgroups, was demonstrated a statistically significant reduction in the incidence of infections in de novo implant-group I subgroup compared to de novo implant-group II subgroup (0.5% vs 3.5%;  $p < 0.05$ ); a statistically significant reduction in the incidence of infectious complications was also observed in replacement-group I subgroup (0%) compared to replacement-group II subgroup (0% vs 1.4%;  $p < 0.05$ ). Similar results were demonstrated for the incidence of pocket hematoma, with a statistically significant reduction in de novo implant-group I subgroup compared to de novo implant-group II subgroup (0.5% vs 14.13%;  $p < 0.05$ ) and in replacement-group I subgroup compared to replacement-group II subgroup (1.4% vs 12.5%;  $p < 0.05$ ).

The association between therapy and development of hematoma was not statistically significant. The association between comorbidities and infectious complications in both groups was always statistically significant.

**Conclusion:** The local gentamicin-collagen sponge is a medical device which can be used in addition to local hemostasis and prophylactic doses of systemic antibiotics, with the aim of reducing infective complications and pocket hematoma after permanent CIED implantation or replacement.