Clinical impact of capsulectomy during cardiac implantable electronic device generator replacement

: A prospective randomized trial

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COI Disclosure

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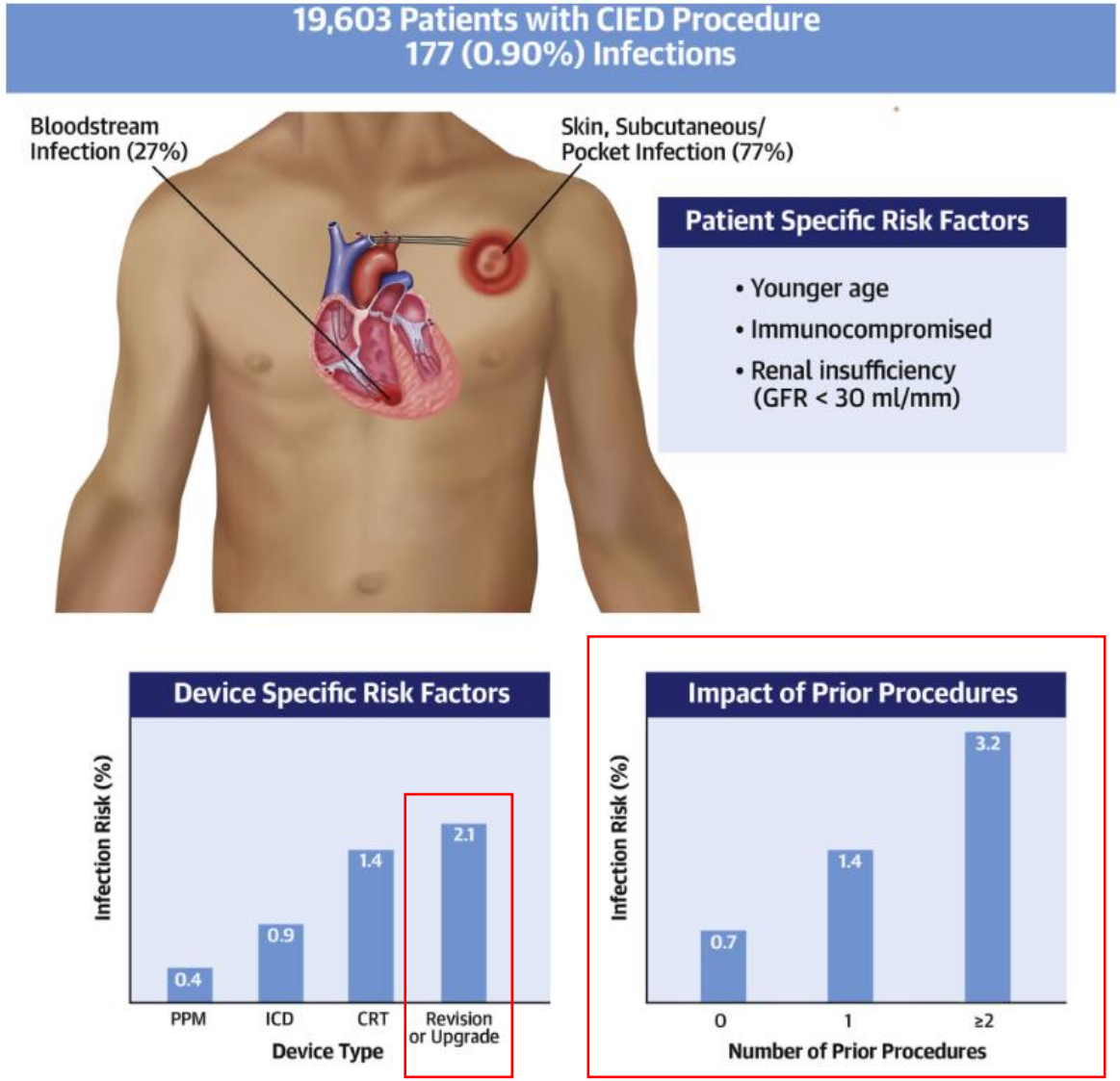
The authors have no financial conflicts of interest to disclose concerning the presentation

CIED infection

- Occurring in about 1%/year of CIED patients
- Overall mortality 13.7% following infection
- Generator replacement ↑ risk of infection



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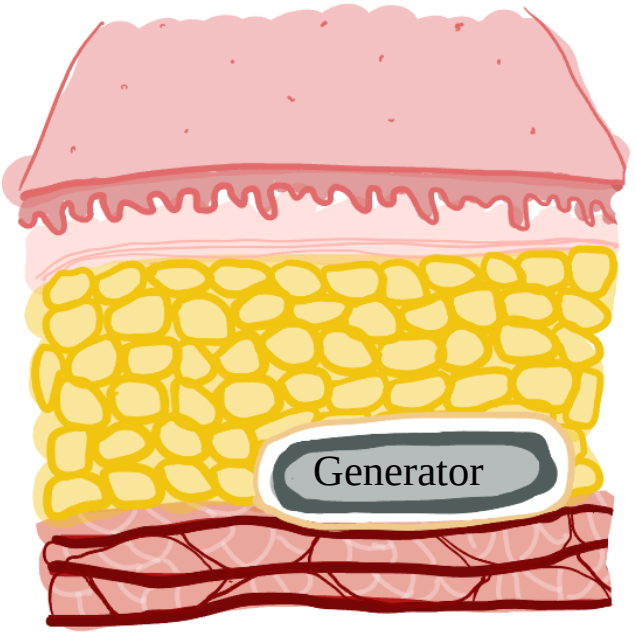
Capsule surrounding CIED generator

- Fibrotic tissue
- Hypo- / Avascular
- Chronic inflammation
- Bacterial colonization



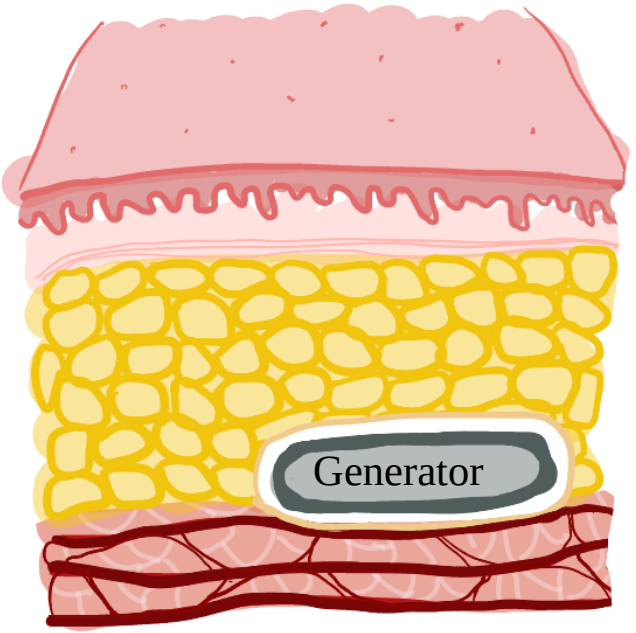
Can often be a source of infection

Capsule surrounding CIED generator

Preserve ?

Resect ?

- Procedure time…
- Hematoma…
- Pocket revision due to lead injury…

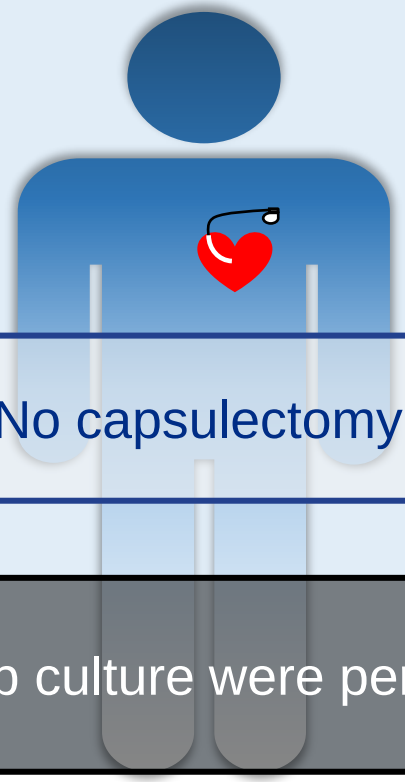


Risk of device infection

Study method

Control group

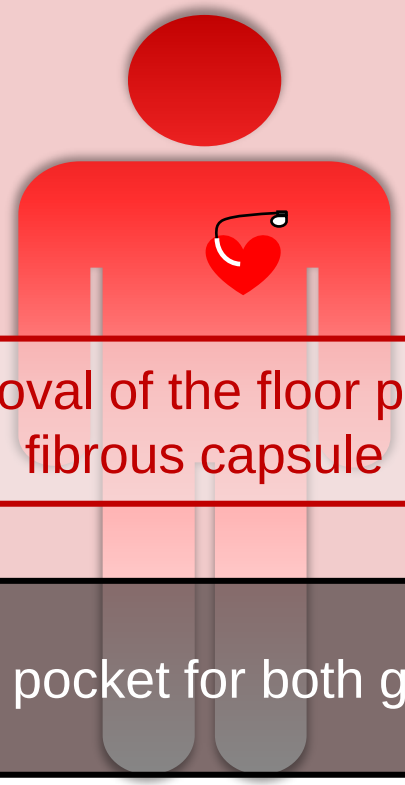
N=98



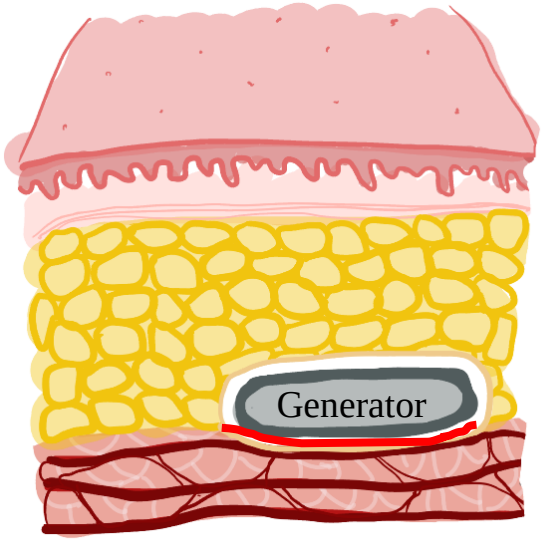
No capsulectomy

Intervention group

N=97



Removal of the floor part of fibrous capsule



Outcome

Incidence of device infection requiring pocket revision

Swab culture were performed in the pocket for both group

Prevalence of bacterial colonization in the pocket

Baseline characteristics

- Mean follow-up duration 54.3±28.9 months
- Mean age 70.2±13.6 years
- 108 (55.4%) female
- Anti-thrombotic agent more common in the intervention group, no significant difference
- Defibrillator more common in the intervention group
- 182 (93.3%) undergoing tissue swab culture

	Intervention (N=97)	Control (N=98)	p-value
Age	68.5 ± 13.2	71.9 ± 13.9	0.079
Female	58 (59.8%)	50 (51.0%)	0.276
Hypertension	51 (52.6%)	55 (56.1%)	0.724
Stroke	9 (9.3%)	12 (12.2%)	0.662
Anticoagulant	24 (24.7%)	18 (18.4%)	0.364
Antiplatelet	32 (33.0%)	28 (28.6%)	0.608
Device type			0.045
Defibrillator	33 (34.0%)	18 (18.3%)	
Pacemaker	64 (66.0%)	80 (81.6%)	
Lead revision	25 (25.8%)	29 (29.6%)	0.663
Device upgrade	5 (5.2%)	3 (3.1%)	0.707
Time since previous procedure	2782.3 ± 967.8	2940.5 ± 1344.1	0.347

Table 1. Baseline characteristics

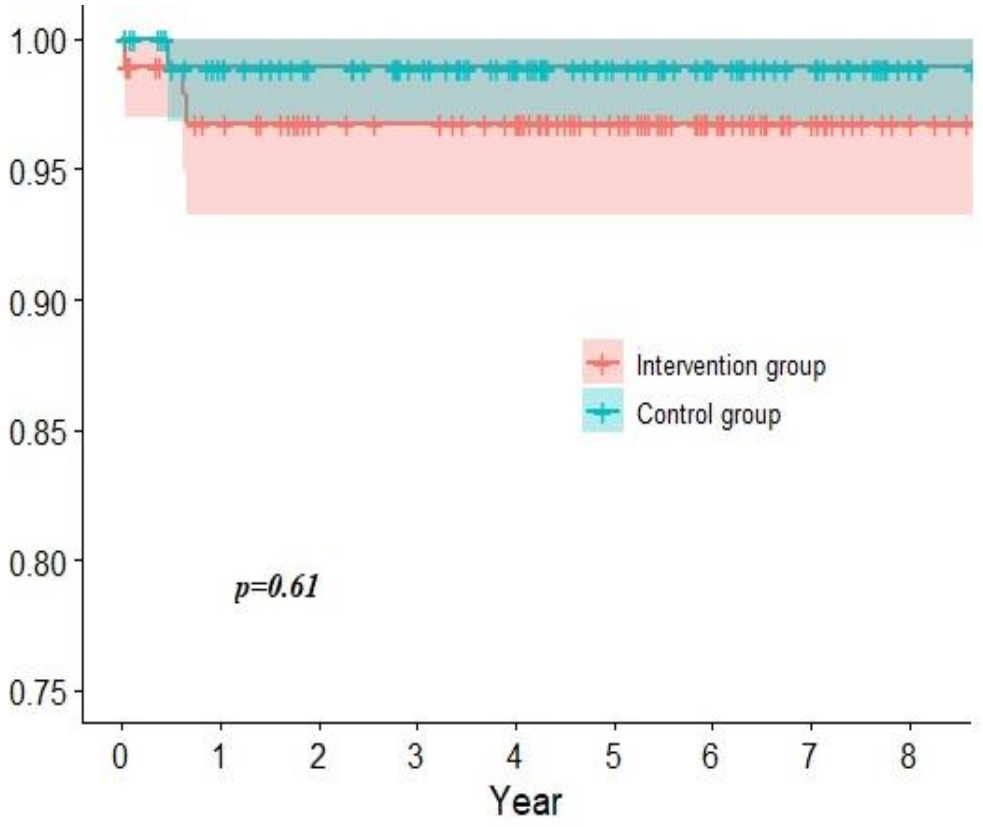
Outcomes

Table 2. Outcomes between the two groups

	Intervention (N=97)	Control (N=98)	p-value
Primary outcome			
Device infection requiring wound revision	3 (3.1%)	1 (1.0%)	0.606
Secondary outcomes			
Hematoma	3 (3.1%)	7 (7.1%)	0.338
Hematoma requiring wound revision	1 (1.0%)	0 (0.0%)	0.996

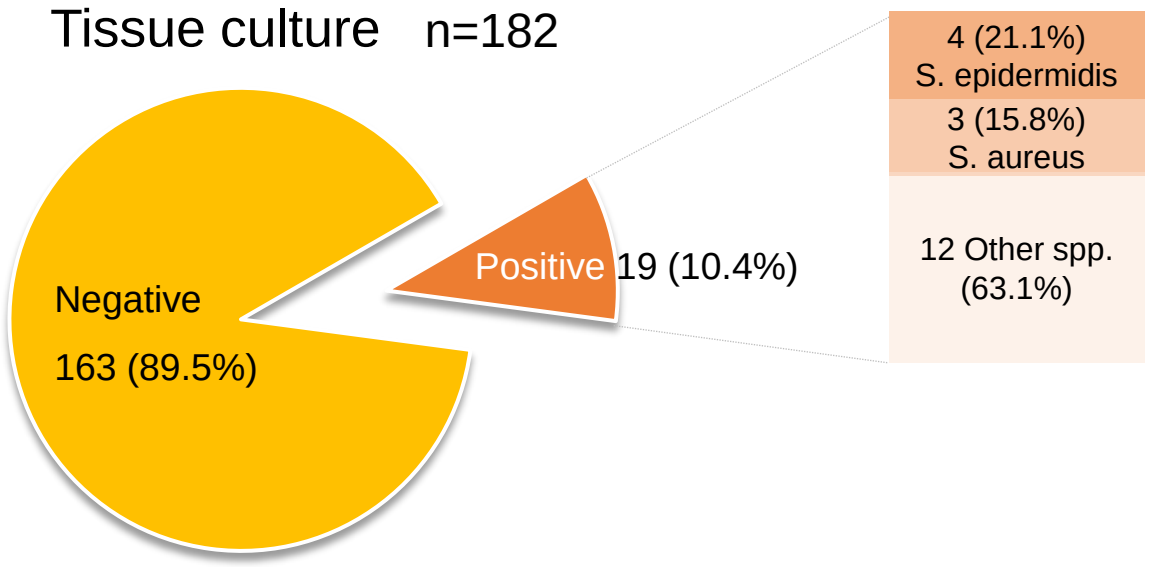
No significant differences in both group

Figure 1. Kaplan-Meier curves for primary outcome



Outcomes

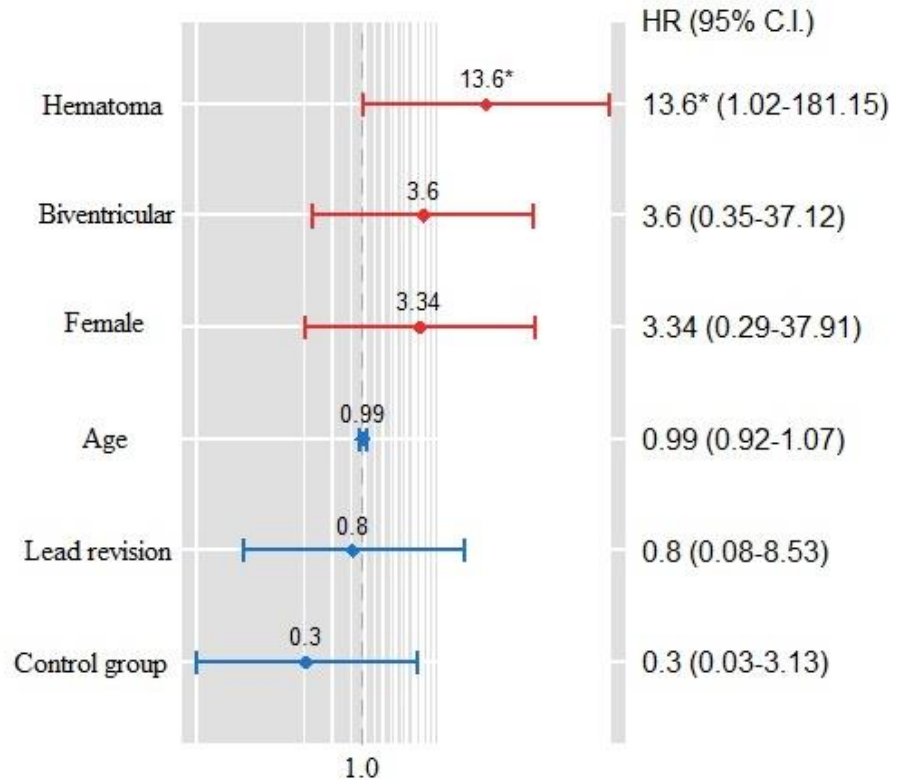
Figure 2. Outcomes of patients with swab culture



None of the 19 were found to have developed device infection during the follow-up period

Outcomes

Figure 3. Cox multivariable analysis for predicting device infection



Hematoma was the only independent factor associated with device infection

Conclusion

1. Capsulectomy during replacement of generator did not reduce the incidence of device infection.

2. There was no association between bacterial colonization in the capsule and device infection.

3. The occurrence of hematoma was the only independent risk factor associated with device infection.