Abstract

Interaction Testing Between Barostim Neo Device and ASSURE Wearable Cardiac Defibrillator

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BACKGROUND

Heart failure patients treated with baroflex activation therapy (BAT) remain at risk for sudden cardiac death (SCA). A wearable cardioverter defibrillator (WCD) can provide temporary protection from SCD but potential interactions between the two systems have not been characterized. Evaluation of compatibility is essential to ensure patient safety and optimal therapeutic performance. The objective of this study is to evaluate potential electrical, functional, and clinical interactions during concurrent use of BAT and a WCD, with emphasis on device compatibility, rhythm sensing integrity, and therapy-related signal interpretation.

METHODS

Patients with Barostim™ NEO2 devices and concomitant implantable defibrillators were enrolled for interaction testing. An ASSURE® Wearable ECG (using the same detection algorithm as the ASSURE WCD) was placed on each patient to avoid any risk of shock delivery. Barostim output changes were recorded and ECG sensing and rhythm detection decisions were visually monitored via the ASSURE system tablet programmer. A stored ECG episode at each output was recorded for further review. Barostim NEO2 delivers electrical pulses typically programmed to a frequency of 40-50 pulses per second, with a current of 3-11mA, and a pulse width of 65-125µS. All parameters on the Barostim NEO2 were restored to their original settings at the conclusion of the study.

RESULTS

Five patients were enrolled in testing (4 male, 1 female; 4 with ischemic cardiomyopathy and 1 with non-ischemic cardiomyopathy). No electrical interaction with functional or clinical impact was observed between the two devices across all Barostim output settings, including the maximum output of 11 mA. Although Barostim pulses produced visibile high-frequency artifacts on surface ECG recordings, ASSURE system detection filters preserved accurate rhythm sensing without inappropriate detection or misclassification (Figure 1).

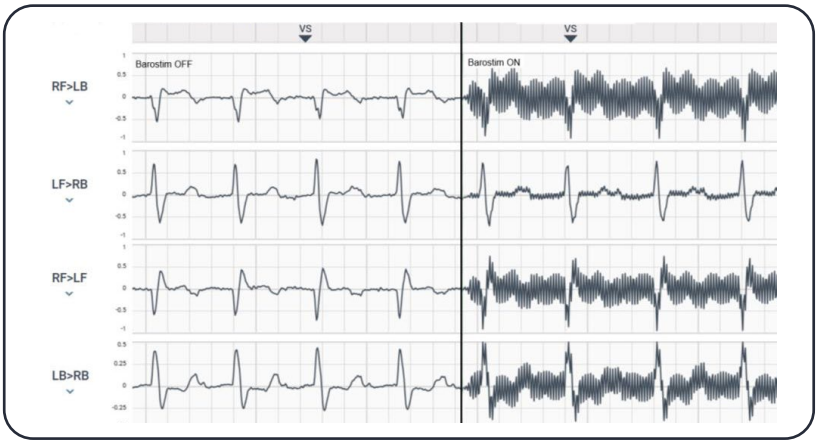


Figure 1: Example section of a manually triggered ASSURE system stored 4-lead ECG episode demonstrating the visual difference between Barostim OFF and ON. Display filtering preserves visualization of the Barostim pulses, whereas algorithm filtering removes these pulses, enabling accurate sensing as indicated by the ASSURE Detection Algorithm normal sense marker (VS).

CONCLUSIONS

In this cohort of patients with concomitant BAT and WCD use, no adverse device interactions were identified at tested settings. Nonetheless, individualized verification of sensing integrity during WCD fitting remains advisable. Concurrent use may be clinically valuable for patients who are receiving guideline directed medical therapy, BAT, and WCD protection while awaiting LVEF improvement prior to decision regarding ICD implantation.

Affiliations and References

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Disclosures

Pamela Breske and Korine Haynes: Employees and stockholders of Kestra Medical Technologies, Inc.

ASM 2026
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MKT-00223-02_A