EARLY PROCEDURE-RELATED ADVERSE EVENTS BY GENDER IN MADIT-CRT

ACC Moderated Poster Contributions
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Background: This study investigated the type and frequency of procedure-related adverse events among those enrolled in the MADIT-CRT and identified clinical predictors for gender-specific events.

Methods: 444 Females and 1,346 males were enrolled in MADIT-CRT. We compared differences in the rate of procedure-related adverse events by gender that occurred ≤ 30 days after the index procedure in the ICD and CRT therapy groups. Eight types of major adverse events were identified; defined as procedure-related complications deemed potentially life-threatening or requiring re-operation. Best subset regression analysis (P<0.10) was performed to identify baseline clinical factors associated with procedure-related adverse events that differ by gender.

Results: Women randomized to the CRT-D treatment arm received a greater reduction in the risk of heart failure or death versus those in the ICD-only arm compared to men (p<0.001). However, women were 2.25 times more likely than men to experience a major procedure-related adverse event as a result of ICD or CRT therapy (6.8% vs. 3.1%; P=0.001), including pneumothorax/ hemothorax (4% vs. 1%; P<0.001). Women were more likely to experience a major adverse event related to CRT than to ICD implantation (9.2% vs. 2.9%; P=0.010). The clinical predictors of any major event in females were smaller body mass index (BMI), elevated blood urea nitrogen, and elevated creatinine; the clinical predictors in males were elevated systolic blood pressure, current smoking, New York Heart Association (NYHA) Class II, QRS duration >150ms, history of ventricular arrhythmia, and diabetes. The predictor for pneumothorax/ hemothorax was reduced BMI for women and men.

Conclusions: Women demonstrate greater clinical benefit from CRT than men but are more likely to experience adverse procedure-related events within the first 30 days after device implantation. A smaller BMI seems to be a major factor associated with pneumothorax/hemothorax in both females and males.