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Whom to further monitor in remote monitoring?

Editorial Comment on: "Rate and predictors of electrical failure in non-recalled defibrillator leads"

Implantable cardiac defibrillator (ICD) is a well-established therapy for primary and secondary prevention of sudden cardiac death [1,2]. ICD lead failure is one of the most feared device-related complications as it could result in inappropriate shocks, inhibition of pacing or even death. Prediction or at least early recognition of electrical lead failure is critical to prevent unpredictable and unforeseen outcomes. Certain ICD leads such as the Sprint Fidelis (Medtronic, Minneapolis, MN) and Riata (St. Jude Medical, Sylmar CA) leads, have been identified as prone to failure and hence were recalled by the US Food and Drug Administration. Patients with recalled leads require specific management and follow-up in addition to remote monitoring [3]. How about patients with non-recalled ICD leads? Could we identify those at risk for lead failure? Unfortunately, data concerning the rate and clinical predictors of non-recalled electrical lead failure remain sparse.

The study by Khattak et al. evaluates the electrical failure rate and predictors in non-recalled defibrillator leads [4]. Medical records data were used for identification of consecutive patients who had undergone ICD implantation with non-recalled ICD leads at the University of Pittsburgh Medical Center between 2002 and 2014. The study cohort consisted of 2410 patients who were followed, over an average duration of 3.9 years, to the endpoint of death, or electrical lead malfunction resulting in lead extraction or replacement with a new ICD lead. During follow-up; 53% of the study patients died (from any cause) with functional ICD leads in situ, 3.5% had their leads extracted for infection or heart transplantation, and 2.3% had an electrical lead failure. The annual failure rate of those non-recalled leads was 0.6%.

The clinical characteristics of patients who developed electrical lead failure were analyzed in comparison to those who had no lead dysfunction. Body mass index (BMI), functional status, creatinine level, QRS complex width, number of implanted leads and the presence of ischemic cardiomyopathy were identified as significant predictors for lead failure, in univariate analysis, among other characteristics.

In a multivariate analysis model, however, only a lower BMI, the presence of non-ischemic cardiomyopathy, and a better functional status independently predicted electrical lead failure.

The authors should be complimented for methodically investigating the rate and predictors of failure in non-recalled ICD leads. The results highlight clinical variables which are independent predictors of lead failure. The study included consecutive patients at a large center with different operators which would help to avoid selection bias of patients, implant techniques and underreporting of ICD lead failure.

1. Should we monitor patients with low BMI or highly active patients closely for lead failure?

At the first glimpse, an annual lead failure rate of 0.6% over the follow-up period may seem relatively low in comparison with the failure rate of the recalled leads. Nevertheless, the yearly risk of ICD lead failure over long term follow-up would be expected to rise progressively. For instance, and learning from the recalled leads, initial reports had suggested that the failure rate of Sprint Fidelis lead is somewhat low (<2% yearly). However, contemporary evidence showed that lead failure rate was increasing over the years. The failure rate of this recalled lead reached up to 4.5% per year in long-term follow-up [5]. Given the aging population of our cardiac patients and the increasing dwell-time of leads, the failure rate of non-recall leads would be expected to increase as well. Highly functional patients, as well as patients with low BMI, appear to be at a higher risk for lead failure irrespective of other clinical or device system characteristics. If we decide not to closely follow-up those particular patients at increased risk; we should, at minimum, consider these clinical risk predictors and acknowledge them at the time of device selection and follow-up planning.

2. Higher lead failure rate in non-ischemic cardiomyopathy patients: can it be a reason to shy away from transvenous ICD in this patient population?

In this study [4], the presence of non-ischemic cardiomyopathy was found to be an independent predictor of higher ICD lead failure rate. To some extent, this is explained by the potential survival bias as patients with non-ischemic cardiomyopathy have a better survival rate than ischemic cardiomyopathy patients. The longer a lead survives with a patient, the more likely it is to be exposed to mechanical stress and electrical dysfunction more so in an active patient. In the context of unmeasured confounders, it would be tough to justify closer monitoring of this patient population across the board. Nonetheless, this should be at least discussed with the patient as a part of shared decision making, at the time of device selection especially with the advent of subcutaneous defibrillators.

These findings do alert us specifically in the daily rigors and "noise" of contemporary device clinics to think about highly active patients, may be even consider physical maneuvers to elicit any change in lead parameters and function, to identify the impending lead failure.

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