Cardiac Tamponade From Permanent Pacemaker Implantation
Is the Pressure Building?*

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Cardiac perforation is one of the most feared complications of transvenous pacemaker lead implantation because of the potential for significant morbidity and mortality (1). It is important to understand the prevalence of such a severe complication and the characteristics that may help predict those patients who may be at higher risk for the complication, because this information could help elucidate mechanisms of tamponade as well as provide warning signs for the implanting physician. Previously published reports on the subject have estimated the prevalence of cardiac perforation from permanent pacemaker systems to be 0.1% to 0.8% (2–4), but these studies were small, and more contemporary pacemaker and lead systems have not been evaluated.

In this issue of the JACC: Clinical Electrophysiology, Moazzami et al. (5) report their findings after analyzing National Inpatient Sample data from 922,549 patients in the United States implanted with permanent pacemaker devices between 2008 and 2012. The authors found that the incidence rate of cardiac tamponade increased from 0.26% to 0.35% (p < 0.0001) over the 4-year study timeframe, as did the rate of in-hospital mortality in patients who developed tamponade. Overall, female sex (odds ratio [OR]: 1.23; 95% confidence interval [CI]: 1.04 to 1.54; p = 0.011), implantation of dual-chamber pacemakers (OR: 1.68; 95% CI: 1.17 to 2.41; p < 0.004), and chronic liver disease (OR: 3.18; 95% CI: 1.92 to 5.64; p < 0.001) predicted a greater odds of cardiac tamponade, whereas hypertension (OR: 0.71; 95% CI: 0.45 to 0.94; p = 0.021) and atrial fibrillation (OR: 0.78; 95% CI: 0.61 to 0.96; p = 0.002) were associated with a lower odds of tamponade.

The study has several strengths that are worth highlighting. Although previous studies have evaluated the prevalence and predictors of cardiac perforation in an implantable cardioverter-defibrillator population (6), and small studies have suggested characteristics associated with tamponade in a pacemaker population (2–4), no contemporary large-scale study to date has been performed to properly address the study question. Most important, as the largest study of its kind, ample power was available to evaluate patient characteristics that were associated with cardiac tamponade. Moazzami et al. (5) were quite comprehensive in their evaluation by querying several patient and device-level characteristics that could have been associated with cardiac tamponade. As a result, they were able to identify 5 predictors of higher or lower cardiac tamponade risk, many of which are congruent with previous studies or have biological plausibility. Although female sex had been anecdotally associated with increased risk of cardiac perforation (7), this had been more recently confirmed in a defibrillator implantation population (6) and would be expected in a transvenous pacemaker population for the same reasons. Implantation of additional leads increasing the risk of cardiac tamponade seems intuitive, but the association of chronic liver disease with cardiac tamponade seems more novel and may be related to the potential for

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bleeding due to coagulopathy, systemic tissue characteristics from liver disease, or anatomic considerations from hepatomegaly. The protective association of atrial fibrillation with cardiac tamponade may be related to implantation of fewer atrial leads in permanent atrial fibrillation or atrial enlargement from the arrhythmia or atrial fibrosis, whereas that of hypertension may be related to hypertrophy of the cardiac chambers. With this knowledge regarding predictors of cardiac tamponade, implanters may be able to alter implant technique or have additional backup available for patients at highest risk.

Such large numbers of pacemaker procedures evaluated by Moazzami et al. (5) also allowed for power to evaluate trends in the prevalence of the complication across more recent years of implantation. This study likely provides the largest body of evidence to date in contemporary practice that rates of cardiac tamponade after pacemaker implantation, although still low, may be increasing throughout the study timeframe of 2008 to 2012. The trend of increase was gradual, which lends credence to a true signal. In-hospital mortality also tracked with increased cardiac tamponade rates. These findings sound an alarm to implanting physicians, as we must not remain complacent in reducing the risk of a serious complication, even in a routine procedure.

Although the methodology of the study overall appears to be sound, several details of the study should draw caution. First, it is possible that undercoding for cardiac tamponade in the earlier years of the study or better coding in the later years could have artificially made cardiac tamponade appear more prevalent in recent years. Second, a true increase in prevalence of cardiac tamponade may itself be a marker of frailer patients being implanted with permanent pacemakers, as alluded to in previous studies (8), and not necessarily worsening of technique. Third, because of the nature of the National Inpatient Sample, specific lead and device characteristics (e.g., size and type of leads implanted) were not able to be collected, and their relative contribution to the risk of cardiac tamponade remains understudied in this population.

Contemporary medical and technological advances may carry importance regarding the risk of cardiac tamponade after pacemaker implantation that should inform future studies. First, alternative lead locations for ventricular pacing other than the right ventricular apex, such as a septal or His bundle location, may improve on the risk of perforation and should be investigated (9). Second, the advent of leadless pacemakers implanted without a pulse generator may change the overall risk of cardiac perforation, with early studies indicating a potential for higher cardiac tamponade risk. Adoption of this new technology should carry with it careful consideration of potential risks (10). Third, although warfarin has been prescribed for decades, and recent data have suggested uninterrupted therapy is safe during pacemaker implantation (11), the increased use of non–vitamin K antagonist oral anticoagulants and their reversal agents brings a new issue of uninterrupted versus interrupted therapy around pacemaker implantation with these agents. Additionally, the need for bridging therapy in patients with interrupted oral anticoagulation continues to be an area of full unknown risk. Fourth, the issue of specific training in cardiac electrophysiology as well as operator volume related to pacemaker implantation may be an area that requires further study, as previous studies evaluating complications from implantable cardioverter-defibrillator implantation have shown subspecialty training and volume to be important predictors of safer procedures (12,13).

In conclusion, Moazzami et al. (5) provide a valuable contribution to the published data regarding the modern-day prevalence of cardiac tamponade after pacemaker implantation and patient characteristics that may help predict the complication in general. The study provides strong evidence that rates of cardiac tamponade remain low, but it also highlights a trend of increase of the complication that should call attention to vigilance in preventing further rise. Future studies will be important to determine device and procedural characteristics that may influence the risk of cardiac tamponade from these procedures as well as techniques to mitigate these risks, particularly in high-risk populations. In the mean time, pacemaker implanters should be aware that based on information gleaned from this study in a time period when the prevalence of a significant complication appears to be increasing, the pressure may be building.

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