Compliant endovascular balloon reduces the lethality of superior vena cava tears during transvenous lead extractions

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BACKGROUND Superior vena cava (SVC) lacerations have been identified as the most lethal complication encountered during cardiac implantable electronic device lead extraction. The case fatality rate of these events approximates 50% due to rapid exsanguination. A novel, compliant balloon specifically designed for use in the SVC may provide hemostasis in the event of endovascular perforation. By temporarily occluding the compromised vessel, the endovascular balloon should delay hemodynamic collapse, provide a more controlled surgical field for repair, and thereby reduce the mortality of SVC tears complicating transvenous lead extraction.

OBJECTIVE To assess the early impact of the compliant endovascular balloon on the management of SVC tears and survival outcomes.

METHODS We searched a publicly available, United States Food and Drug Administration–maintained database for adverse events from 1 manufacturer of lead extraction tools. Reports from July 1, 2016, to December 31, 2016 were reviewed by 2 physicians to identify instances of SVC tears. Extracting physicians were contacted for further case details. Confirmed SVC tears were analyzed for patient demographics, repair strategies, and index hospitalization mortality.

RESULTS Of the complications reported, 35 cases of surgically confirmed SVC tears were identified. One hundred percent of patients (9/9) were discharged alive when the endovascular balloon was properly utilized, compared to 50% of patients (13/26) when the device was not used ($P = .0131$). Differences between all other variables analyzed were statistically insignificant.

CONCLUSION During the study period, we observed a reduction in mortality in patients who suffered SVC tears while undergoing lead extraction when treatment included an endovascular balloon.

KEYWORDS Lead extraction; Cardiac device; Repair; Superior vena cava; Laceration; Tear; Endovascular; Balloon

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Introduction

Complications in lead extraction are an infrequent occurrence, yet their onset is sudden and often lethal. Every year, hundreds of thousands of cardiac implantable electronic devices are implanted in the United States alone, successfully treating cardiac arrhythmias.[1] Yet with increasing rates of implantation, the number of devices requiring removal due to infection or malfunction has also increased.[2] Over the past decade, lead extraction has proven to be a safe and effective procedure with a major complication rate lower than 2%.[3] Unfortunately, the lethality of these complications remains high, as patients undergoing lead extraction are at risk for endovascular perforation, which can lead to rapid hemodynamic collapse. Although a tear can occur anywhere along the path of extraction tools, the superior vena cava (SVC) has been identified as the most concerning site of vascular laceration, as it has been associated with a greater than 50% mortality rate.[4] For as long as lead extractions have been performed, SVC tears have been a feared complication for operators. Patient outcomes are dependent on the rapid performance of a thoracotomy and initiation of cardiopulmonary bypass. In the lead extraction population, resuscitation is made even more difficult by the prevalence of comorbidities such as low ejection fraction and sepsis. Historically, the majority of these rescue attempts have been unsuccessful.[4]

The introduction of a new endovascular balloon (Bridge; Spectranetics, Colorado Springs, CO) has shown early

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promise in managing SVC tears during lead extractions. The endovascular balloon is a novel device designed to provide temporary occlusion of the SVC in the event of an endovascular tear, thereby limiting blood loss and providing the extraction team additional time for a surgical repair in a more controlled field.[5] In the summer of 2016, the endovascular balloon successfully rescued 4 consecutive patients with SVC tears during lead extraction.[6] Since then, usage of the endovascular balloon during lead extractions has increased, necessitating further assessment of its impact.

This manuscript presents the first data assessing the efficacy of the endovascular balloon, comparing the mortality of SVC tears that were managed with balloon occlusion with cases during the same time period in which the balloon was not utilized.

Methods

Description of balloon and instructions for usage

The endovascular balloon received United States Food and Drug Administration (FDA) approval in February 2016. The device is a compliant, low-pressure plastic balloon designed to provide hemostasis in the SVC in the event of an endovascular tear (Figure 1). It is 80 mm in length and 20 mm in diameter and has a maximum inflation volume of 60 cc.[5]

Three steps are taken prior to the initiation of lead extraction. A 0.035-inch stiff guidewire is advanced from the femoral vein optimally to the right internal jugular vein. Second, a 12F introducer sheath is advanced over the stiff guidewire and secured at the insertion site to enable rapid deployment of the endovascular balloon in the event of a tear. Finally, the team should also prepare a sterile 60 cc Luer Lock syringe with a stopcock and a mixture of 48 cc saline and 12 cc contrast media. In the event of sudden patient hypotension, which may be indicative of an SVC tear, the balloon should be quickly advanced through the introducer sheath and over the stiff guidewire, positioned at the SVC, connected to the Luer Lock syringe, and fully inflated.

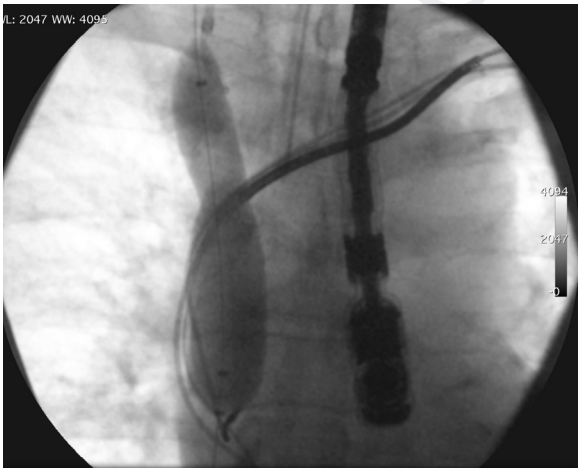

Figure 1 Fluoroscopic image of inflated endovascular balloon in the superior vena cava.

Data collection

In this study, all reported complications from a single lead extraction tool manufacturer from July 1, 2016, to December 31, 2016 were identified using the Manufacturer and User Facility Device Experience (MAUDE) database, an FDA-regulated registry of adverse events related to medical devices. The FDA requires device manufacturers, including the sole manufacturer of laser lead extraction tools and the endovascular balloon, to publicly report adverse events within this system. Two physicians independently reviewed the MAUDE database to classify events as SVC tears or non-SVC tears and record survival outcomes. Following these classifications, a standard form was generated to collect demographic data relevant to lead extraction. If this information was unavailable on MAUDE, we requested additional information from the manufacturer and directly contacted extracting physicians to gather the most accurate case data. Cases were subsequently stratified into 2 cohorts: tears in which an endovascular balloon was used according to manufacturer guidelines and tears in which an endovascular balloon was either not used or improperly used.

Inclusion and exclusion criteria

For a case to be classified as an SVC event, tears must be surgically confirmed by sternotomy or autopsy. We defined the SVC as the vessel between the innominate vein and the right atrium. All tears of the SVC, including those at the SVC/right atrial and innominate/SVC junctions were also classified as SVC events. All unconfirmed SVC tears, even those suspected, were excluded from this study. If the lacerations involved only the right atrium, right ventricle, innominate vein, or subclavian vein, they were not considered SVC events.

Another criterion for inclusion was an attempt to surgically repair either on or off cardiopulmonary bypass. Therefore, patients who underwent median sternotomy without an attempt for repair were excluded. This included a patient with an advance directive to avoid prolonged artificial life support.

Definitions

Patients were assigned to the "balloon use" cohort under 2 conditions: if a stiff guidewire was pre-positioned from the right femoral vein to either the right internal jugular or right subclavian vein prior to extraction, and, subsequently, if this wire remained within the vein during balloon deployment. Patients were assigned to the "no use/improper use" cohort if either the balloon was not used entirely or a stiff guidewire was not in the vein during balloon deployment.

Statistical analysis

All cases that met study criteria were analyzed for age, sex, implanted device type, indication for extraction, extraction tools, dwell time of the oldest lead, balloon deployment, and survival at discharge. Statistical analyses were performed using JMP Pro 13 (SAS Institute, Cary, NC). Continuous variables were analyzed using a *t* test and categorical variables