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Long-Term Outcomes of Prophylactic Placement of an Endovascular Balloon in the Vena Cava for High-Risk Transvenous Lead Extractions

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3 **Short Title:** Long-term Outcomes in Prophylactic Balloon Placement

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Abstract:

Background: Many clinicians utilize the strategy of prophylactically placing an endovascular balloon prior to transvenous lead extraction, yet there is no data regarding this practice.

Objective: This study assesses long-term outcomes of prophylactic placement of an endovascular balloon in the venae cavae of patients during transvenous lead extraction.

Methods: From April 2016 to March 2017, data was prospectively collected at two international cardiovascular centers on patients who had the balloon prophylactically placed in the venae cavae. Patients were monitored for a minimum of 3 months to capture any associated adverse events.

Results: Twenty-one patients had the balloon prophylactically placed in the venae cavae during lead extraction. The majority were male (76%), mean age was 57.6 ± 18.7 years, and mean BMI was 26.1 ± 4.4. Mean lead dwell time was 11.2 ± 8.3 years, with an average of 2.2 ± 1.1 leads per case, and most indications for extraction were non-infectious (62%). Two minor complications (10%, pocket hematomas) and 1 major complication (5%, cardiac tamponade) occurred during the procedure. All cases (100%) were procedural successes, and all patients (100%) were discharged alive. On follow-up (6.8 ± 3.7 months), all patients were alive and reported no adverse events related to prophylactic balloon placement, such as pulmonary emboli or deep venous thrombi.

Conclusion: During the study period, we observed no acute or long-term adverse outcomes
associated with prophylactic placement of an endovascular balloon in the venae cavae of patients undergoing transvenous lead extraction.
Introduction

A superior vena cava (SVC) tear is the most lethal and challenging complication that can occur during transvenous lead extraction. As infected or malfunctioning cardiac device leads are extracted from a patient, sudden hemodynamic collapse would necessitate an urgent sternotomy to surgically repair what may likely be an SVC laceration. While this complication is quite rare, occurring in only 0.5% of cases, it has disastrous effects on both patient outcomes and fears regarding lead extraction. Moreover, as both the implantation and extraction of cardiac implantable electronic devices have increased over the past several years, the total number of patients experiencing this catastrophic complication has increased as well. Therefore, the availability of rescue tools and the identification of high-risk patients are paramount to patient safety and provider readiness for this rare, yet critical, complication of transvenous lead extraction.

Early clinical data have shown that a novel, endovascular balloon (Bridge™, Spectranetics Corporation, Colorado Springs, CO) may reduce mortality associated with SVC tears during transvenous lead extractions. In the event of sudden hemodynamic collapse during lead extraction, this balloon may be quickly positioned in the SVC and deployed to provide hemostasis and hemodynamic stability, facilitating a more controlled surgical repair. As early data regarding the balloon’s utility have been positive, new questions have also emerged regarding when the balloon should be available and utilized. In a 2015 Mayo Clinic study, Fu and colleagues developed a risk stratification schema to identify which patients are at highest risk for complications, including, but not limited to, patients with low body mass index (BMI) and older leads. Consequently, with the development of the endovascular balloon to treat SVC
tears, some providers describe prophylactically placing the device in the superior or inferior vena cava (IVC) of these high-risk patients. This practice has raised concerns regarding thrombosis and potential adverse effects to the patient, such as pulmonary embolism. While there is preliminary information on the acute usage of the balloon, there is a paucity of data on the long-term effects of prophylactic balloon placement.

Thus, this study assesses long-term outcomes of prophylactic placement of an endovascular balloon in the venae cavae of patients during transvenous lead extraction.

**Methods**

**Description of balloon and the prophylactic placement strategy**

The endovascular balloon received United States Food and Drug Administration (FDA) approval in February 2016 and Conformité Européene (CE) mark approval in May 2016. The device is a compliant, low-pressure polyurethane balloon designed to provide temporary hemostasis in the SVC in the event of an endovascular tear. It is 80 mm in length, 20 mm in diameter, and has a recommended inflation volume of 60 cc.

In patients deemed high-risk, providers describe several steps taken prior to the initiation of lead extraction. First, a 12F introducer sheath is placed in the right femoral vein and secured at the insertion site with sutures. Second, a 0.035-inch stiff guidewire is advanced through the introducer sheath optimally to the right internal jugular vein or right subclavian vein (Figure 1). Third, the endovascular balloon is prophylactically advanced through the introducer sheath, over the stiff guidewire, and positioned in the superior vena cava (Figure 2). In the fourth step (‘inflation’), the balloon is slowly expanded in the SVC with an 80/20 saline/contrast mixture.
under fluoroscopy to determine the volume required to fully occlude the vessel (Figure 3). The SVC occlusion can also be confirmed by injecting a contrast medium through a 5F pigtail catheter introduced via the femoral vein (Figure 4). In the fifth and last step prior to lead extraction (‘placement’), the balloon is deflated and either retained in the SVC or withdrawn into the IVC. In the event of sudden patient hypotension, which may indicate a tear in the SVC, the balloon can be quickly repositioned at the SVC and deployed in a matter of seconds.

**Data collection**

At two tertiary cardiovascular referral centers in the United States and Germany, clinical data was prospectively gathered for all patients who had the endovascular balloon prophylactically placed in the SVC or IVC prior to transvenous lead extraction. Study enrollment began in April 2016 and concluded in March 2017. The study was conducted with institutional review board (IRB) approval at both institutions, and study participants provided their informed consent. All cases were performed in either an operating room or a hybrid suite under general anesthesia with the aid of fluoroscopy, transesophageal echocardiography, and intra-arterial blood pressure monitoring. Patient demographics and procedural data were collected during the index hospitalization, including but not limited to: age, sex, implanted device type, indication for extraction, extraction tools, dwell time of the oldest lead, location of prophylactic placement, laser time use, post-procedural balloon integrity, and survival at discharge. We collected procedural success rate in addition to major and minor complications as defined by the 2009 Heart Rhythm Society (HRS) expert consensus

Subsequently, patients were monitored for a minimum of three months to capture any long-term effects of this strategy. These include all-cause mortality, hospitalizations, and adverse
events related to prophylactic balloon placement such as pain or presence of an arteriovenous fistula at the site of balloon insertion, deep vein thrombosis, or more distal complications such as pulmonary emboli.

**Patient selection**

Our two high-volume lead extraction centers perform a combined 220 lead extraction cases per year and had similar criteria for identifying high-risk patients. Patients were classified as high-risk and considered for prophylactic balloon placement if they had any of the following characteristics: female sex, low BMI, leads older than 6 years, dual-coil implantable cardiac defibrillator (ICD) leads, or currently prescribed steroid therapy. In addition to the above criteria, the institutions also selected patients for prophylactic balloon placement when computed tomography (CT) or venography revealed aggressive calcified adhesions, extracardiac leads, or venous occlusions.

**Inclusion and exclusion criteria**

For a case to be included in this study, the following steps must have been conducted: the endovascular balloon should have been introduced in the femoral vein, inflated in the SVC for approximately 30 seconds, deflated, and then positioned in either the SVC or IVC prior to transvenous lead extraction. The balloon must also have been retained within either of these vessels throughout the duration of the procedure.

**Statistical analysis**

Summary statistics for both acute and long-term follow-up data were generated using
Results

During the study period, 21 patients had the endovascular balloon prophylactically placed prior to transvenous lead extraction. Among all patients, the majority were male (76%), mean age was 57.6 ± 18.7 years, and mean BMI was 26.1 ± 4.4 (Table 1. Demographics). Extracted devices consisted of 8 pacemakers (38%), 7 ICDs (33%), and 6 cardiac resynchronization therapy defibrillators (29%), with an average of 2.2 ± 1.1 leads per case and a mean lead dwell time of 11.2 ± 8.3 years. Eight cases (38%) necessitated the extraction of previously abandoned leads and 2 cases (10%) had leads that appeared extracardiac in gated CT imaging. Laser sheaths were used in all cases, 9 of which (43%) required the use of both mechanical and laser extraction tools (Table 2. Device and Procedural Data). The balloon was prophylactically placed in the IVC in 11 cases (52%) and retained in the SVC in 10 cases (48%) for the duration of lead extraction. Post-procedural examination in all 21 cases revealed that the prophylactically placed balloon was functional and remained undamaged. Two minor complications (10%, pocket hematomas) and 1 major complication (5%, cardiac tamponade requiring surgical intervention) occurred during the procedure. A procedural success rate of 100% was achieved and all patients were discharged alive.

At the end of the follow-up period (6.8 ± 3.7 months), all patients were alive and reported no adverse events related to prophylactic balloon placement. No patients experienced or developed pain at the site of balloon insertion, arteriovenous fistulas, deep vein thrombi or pulmonary emboli during the follow-up period. All subsequent hospitalizations were unrelated to

JMP Pro 13 (SAS Institute, Cary, NC).
prophylactic balloon placement and attributed to the patients’ underlying disease. These 6 (29%) hospitalizations included elective ICD re-implantation, lead revision, hematoma drainage, cardioversion, and heart failure (Table 3. Follow-up Data). For all cases, there were no signs of neurological deficits during the index hospitalization or at the minimum 3-month follow-up period.

**Discussion**

The novel endovascular balloon was designed as a rapid response to exsanguination from the superior vena cava. Swine models demonstrate the balloon can be deployed in under 2 minutes and stop up to 90% of blood loss.\(^8\) Comparative analysis of early clinical data showed that patients were more likely to survive this catastrophic complication when the endovascular balloon was properly utilized.\(^4\)

However, the concept behind prophylactic placement is that an endovascular balloon already situated within or near the target vessel can be deployed much more promptly than one that is yet to be advanced over a stiff guidewire.\(^6\) Clancy and colleagues demonstrated in a swine model that every second counts; a mere 2-cm tear along the SVC can rapidly hemorrhage at a rate of 500 cc per minute, leading to complete exsanguination in under 10 minutes.\(^8\) In pre-procedural measurements conducted at our high-volume centers, the prophylactic placement strategy considerably reduced deployment times to under 15 seconds. This spared approximately 90 seconds in deployment time as compared to a balloon that was available on the instrument table, a difference which may prevent 750 cc of blood loss during a true complication. Thus, in an emergent situation, a prophylactically placed balloon may swiftly occlude the SVC and
provide hemostasis without delay, preventing critical complications such as cardiac tamponade or hemothorax from progressing. Although this strategy has been described by several providers utilizing an endovascular balloon during transvenous lead extraction, questions remain about which patients would benefit most from having a balloon ready within the venae cavae.

There have been several attempts to stratify patients into risk categories for transvenous lead extraction, efforts that may help identify patients who are at high-risk for endovascular perforation and may be considered for prophylactic balloon placement. The 2009 HRS expert consensus listed implant duration of the oldest lead, female gender, ICD lead removal, and the use of powered tools as predictors of major complications. Moreover, in 2015, Fu and colleagues at the Mayo Clinic classified patients as high-risk if they had a BMI of less than 25, had pacemaker leads older than 10 years, or ICD leads older than 5 years. Bontempi and colleagues describe the number of extracted leads, years since implant, the presence of active fixation leads, and the presence of dual-coil, ICD leads as additional predictors of extraction difficulty. Furthermore, low-volume extraction centers are associated with a greater risk for complications and have been defined by the 2017 ELECTRa registry as centers that perform less than 30 extractions per year. These data suggest that in addition to patient and lead characteristics, an extractor’s experience plays a significant role in determining the risk of a procedure. While prophylactic placement of an endovascular balloon is a clinical judgment made by the extracting physician, these different risk classifications can be useful for centers to develop a scheme on which patients would benefit most from this practice. Ultimately, having a balloon available in the room and a team competent in proper usage of the device may be more beneficial to rescue protocols than stratifying risk for prophylactic placement.

As the awareness and use of prophylactic placement has grown, some lead extractors
have expressed reasonable hesitation in adopting such a practice in the absence of data attesting to its safety. Preclinical regulatory data may ease some of these concerns, specifically regarding the thrombotic risk of the balloon in the venae cavae. In accordance to FDA submission requirements, the manufacturer of the endovascular balloon conducted a series of studies to present preclinical safety data for premarket approval in 2015. In one such study (American Preclinical Services, Minneapolis, MN, 2015), histopathological examination of swine vasculature was performed after the balloon was deployed for 45 minutes following an SVC tear. In 1 of 15 examined sections, clinically insignificant microthrombi measuring 10µm in diameter were found attached to the luminal surface and were not determined to pose a safety risk; no signs of thromboembolism were found in the heart or lungs upon gross necropsy evaluation. In a separate study, in-vitro evaluations (Nelson Laboratories, Salt Lake City, UT, 2015) seemed to corroborate the notion that the balloon does not pose a clinically significant thrombogenic risk. Partial Thromboplastin Time testing in this study categorized the endovascular balloon material as a “minimal activator of the intrinsic coagulation pathway,” scoring better than the legally marketed device used as a control in the assay. Such biocompatibility tests are common and standard protocol in the industry to evaluate the thrombogenic index of biomedical materials. Despite these promising preclinical data, there are understandable limitations to generalizing from animal and in-vitro models as no studies have been conducted to specifically assess the thrombogenicity of the deflated balloon in the venae cavae.

Thus, early clinical data on the long-term effects of prophylactic balloon placement are critical to elucidating the feasibility of this practice. In our two centers, we monitored 21 patients for a minimum of 3 months to capture any adverse events following prophylactic placement. We assessed for deep venous thrombi and pulmonary emboli; none of the patients reported any of
these clinical conditions throughout the duration of the study. Hence, we have not observed any
evidence of clinical thromboembolic events that could be associated with prophylactic balloon
placement.

Vascular complications at access sites are another common concern for catheter-based
procedures such as insertion of an endovascular balloon. These could be minimized with
increased volume and experience of personnel performing the percutaneous venipuncture. The
use of vascular ultrasound is recommended to further decrease risk of vascular access
complications. Although venous sheath insertions are used in both prophylactic and emergency
balloon deployment, their complications are a possibility in both clinical situations. Throughout
the follow-up period of our study, we documented any issues related to femoral vascular access.
No patient reported pain at the site of balloon insertion nor presence of arteriovenous fistulas,
and physical examinations revealed complete recovery at sites of access. Alongside preclinical
data, our early clinical experience may inform providers on the use of the prophylactic strategy
and offer insight regarding its safety.

While not a central component of our study, our centers chose to inflate and deflate the
balloon in the SVC prior to the extraction. There are several possible advantages to this practice.
One advantage is that this could aid extractors in predetermining the volume of saline/contrast
mixture required to fully occlude the vessel. This practice also allows extraction teams to
document the optimal position of the device in the SVC in a non-emergent setting, thereby
reducing perioperative uncertainty. Moreover, extractors have an opportunity to assess the
patency, size, and shape of the SVC, factors that may help in both planning the procedure and
improving response times to complications. Above all, the time needed for balloon deployment
decreases with increased proficiency, familiarity, and level of experience with the device.
Inflating and deflating the balloon prior to the procedure is an opportunity for extraction teams to practice balloon deployment under optimal conditions, allowing team members to become well-versed in the device and its usage in a controlled setting. Altogether, this practice may help lead extractors better prepare for complications by offering additional insight into a patient’s SVC anatomy and fostering greater proficiency in deploying the rescue device.

Lastly, it is interesting to note that our two centers prophylactically placed the balloon in different locations. While one center chose to withdraw the balloon into the IVC after deflation and prior to lead extraction, the other preferred to leave the deflated balloon in the SVC. Regardless of differences in institutional preferences, prophylactic placement did not preclude either center from achieving success in these high-risk patients. Our centers were able to use a combination of laser and mechanical extraction tools, while employing both subclavian and femoral approaches, without compromising the integrity of the endovascular balloon in the venae cavae. Overall, our most recent follow-up data show that for our study cohort, the prophylactic placement of an endovascular balloon in the SVC and IVC was feasible and has not been associated with any acute or long-term adverse outcomes.

Study limitations

Due to the novelty of the endovascular balloon and the dependency of prophylactic placement on the physician’s clinical judgment, this study is inherently limited by a small sample size. The observations were nonrandomized, so the study sample was dependent upon the number of high-risk patients who presented at our referral centers during the selected time frame. Moreover, the facilities were high-volume centers for lead extraction, which may have reduced the risk associated with this procedure. Therefore, our study does not necessarily reflect the
outcomes and the level of risk that may be encountered at a low-volume center. The study is
further limited by the varying definitions in the literature for what constitutes a high-risk lead
extraction. This is because even the absence of high-risk indicators does not preclude the
possibility of an SVC tear, complicating which patients should be selected for prophylactic
placement. Additional studies that continue to assess the long-term effects of prophylactic
balloon placement are necessary to better understand the risks or benefits of this strategy.

**Conclusions**

During the study period from April 2016 to March 2017, we observed no acute or long-
term adverse outcomes associated with prophylactic placement of an endovascular balloon in the
venae cavae of patients undergoing transvenous lead extraction.
Tables

Table 1. Demographics

<table>
<thead>
<tr>
<th>Demographics (n = 21)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>57.6 ± 18.7</td>
</tr>
<tr>
<td>Male sex</td>
<td>16 (76)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>26.1 ± 4.4</td>
</tr>
<tr>
<td>Caucasian race</td>
<td>14 (66)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>7 (33)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>6 (29)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>14 (66)</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>3 (14)</td>
</tr>
<tr>
<td>Malignancy</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Prior open heart surgery</td>
<td>6 (29)</td>
</tr>
<tr>
<td>NYHA Class</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>5 (24)</td>
</tr>
<tr>
<td>II</td>
<td>10 (48)</td>
</tr>
<tr>
<td>III</td>
<td>6 (29)</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>44.0 ± 11.5</td>
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</table>

Values are given as n (%) or mean ± SD
Table 2. Device and Procedural Data

<table>
<thead>
<tr>
<th>Device and Procedural Data</th>
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<tbody>
<tr>
<td>(n = 21)</td>
<td></td>
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<tr>
<td>Pacemaker</td>
<td>8 (38)</td>
</tr>
<tr>
<td>ICD</td>
<td>7 (33)</td>
</tr>
<tr>
<td>CRT-D</td>
<td>6 (29)</td>
</tr>
<tr>
<td>Indication for extraction</td>
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<tr>
<td>Infectious</td>
<td>8 (38)</td>
</tr>
<tr>
<td>Non-infectious</td>
<td>13 (62)</td>
</tr>
<tr>
<td>Lead dwell time, years</td>
<td>11.2 ± 8.3</td>
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<tr>
<td>Leads per case</td>
<td>2.2 ± 1.1</td>
</tr>
<tr>
<td>Abandoned leads</td>
<td>8 (38)</td>
</tr>
<tr>
<td>Extracardiac leads</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Extraction tool</td>
<td></td>
</tr>
<tr>
<td>Laser sheath</td>
<td>21 (100)</td>
</tr>
<tr>
<td>Mechanical and laser sheaths</td>
<td>9 (43)</td>
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<tr>
<td>Laser time, seconds</td>
<td>68.6 ± 13.0</td>
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<tr>
<td>Approach</td>
<td></td>
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<tr>
<td>Subclavian</td>
<td>21 (100)</td>
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<tr>
<td>Subclavian + Femoral</td>
<td>4 (19)</td>
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<td>Balloon placement</td>
<td></td>
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<tr>
<td>SVC</td>
<td>10 (48)</td>
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<tr>
<td>IVC</td>
<td>11 (52)</td>
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<tr>
<td>Major complication</td>
<td></td>
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<tr>
<td>Cardiac tamponade</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Minor complication</td>
<td></td>
</tr>
<tr>
<td>Pocket hematomas</td>
<td>2 (10)</td>
</tr>
<tr>
<td>Procedural success</td>
<td>21 (100%)</td>
</tr>
<tr>
<td>Discharge survival</td>
<td>21 (100%)</td>
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</tbody>
</table>

Values are given as n (%) or mean ± SD
Table 3. Follow-up Data

<table>
<thead>
<tr>
<th>Follow-up Data (n = 21)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>3-month survival</td>
<td>21 (100)</td>
</tr>
<tr>
<td>Pain at site of insertion</td>
<td>0 (0)</td>
</tr>
<tr>
<td>AV fistula</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pulmonary embolus</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Hospitalizations</td>
<td>6 (29)</td>
</tr>
<tr>
<td>ICD re-implantation</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Lead revision</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Hematoma drainage</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Cardioversion</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

Values are given as n (%)
Figure legends

Figure 1: A) Stiff guidewire placed in the right internal jugular vein, B) Representative image demonstrates the 12F introducer sheath with a prepared endovascular balloon

Figure 2: A) The radiopaque markers of the endovascular balloon positioned in the SVC, B) The radiopaque markers of the endovascular balloon positioned in the IVC

Figure 3: Slowly and smoothly inflated endovascular balloons at the SVC level in different cases/anatomies prior to lead extraction

Figure 4: A) Venography showing a near occlusion of the SVC, B) Venography showing a complete occlusion of the SVC
References


