

**PHILIPS**

**Bridge**

Occlusion balloon

# A path to better outcomes in lead extraction

**88.2%**

of patients survived when the endovascular balloon was properly utilized

**56.9%**

of patients survived when the device was not used, or was used improperly

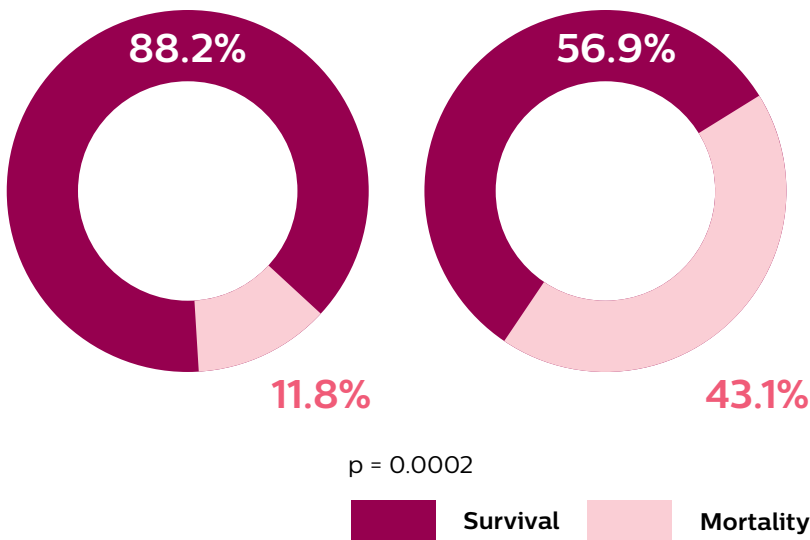
116 confirmed SVC events

**51 balloons used**

SVC tear survival **with Bridge**  
45/51 patients discharged alive

**65 without balloon**

SVC tear survival **without Bridge**  
37/65 patients discharged alive



*“When properly used, the novel device has lifesaving potential”*

– Roger Carrillo, MD

SVC tears during lead extraction are very rare, occurring in less than 0.5% of procedures. When they do occur, mortality rates average 50%, dissuading physicians from providing a potentially life-saving procedure that can add longer, improved quality of life to indicated patients.<sup>1</sup>

The Philips Bridge occlusion balloon was designed to provide hemostasis in the event of an SVC tear, allowing time for surgical repair and increasing survivability. A new study compares patient outcomes following an SVC tear when Bridge was and was not used, or was used improperly.

#### Study design<sup>1</sup>:

- Searched MAUDE database for adverse events
- Reports from July 1, 2016 to July 31, 2018 were reviewed to analyze SVC tears
- Extracting physicians were contacted for case details
- Cases were assigned according to proper use of the balloon. Non-SVC, unconfirmed SVC tears and cases with no surgical repair attempted were excluded.

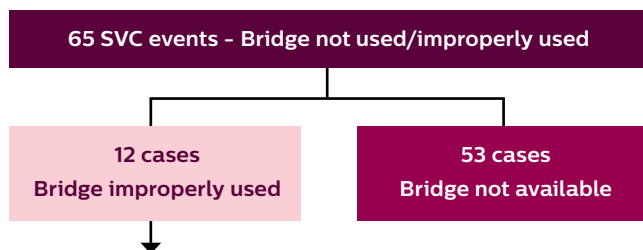
#### Results:

Of the 116 confirmed SVC events:

- 88.2% of patients (45/51) survived when Bridge was properly used
- 56.9% of patients 37/65 survived when Bridge was not used, or was used improperly
- All 45 patients rescued with the Bridge balloon were discharged without neurologic defects, and several repairs were made without the need for cardiopulmonary bypass
- Proper Bridge use significantly increased the likelihood of survival (p=0.0002)

**Key cases from the study provide valuable insight into proper use of the Bridge endovascular balloon that can lead to better, more consistent outcomes**

**Important lessons: balloon use group<sup>1</sup>**



**Guidewire removal**

- 4 cases: Guidewire was inappropriately removed prior to balloon deployment, preventing stability
- Guidewire must remain in vein throughout case and during balloon deployment

**Inappropriate sheath placement**

- 2 cases: Unable to replace 6F sheath with 12F sheath during resuscitation
- Start the case with a 12F sheath

**No contrast media used**

- 2 cases: No contrast used in syringe
- 60cc syringe should have 48cc of saline and 12cc of contrast (80/20 mix)

**Withholding deployment when indicated**

- 4 cases: Balloon not deployed when cardiac tamponade was present
- Deploy Bridge in the case of either cardiac tamponade or hemothorax

**Bridge to teamwork**

According to the study, extractors reported that incorporating the balloon rescue device into daily practice created an opportunity to improve protocols and open lines of communication among extractors, cardiac surgeons and the medical team, thus helping to ensure careful planning for intraoperative complications.

**Considerations for high-risk cases**

The study led the researchers to theorize that high-risk patients may benefit from prophylactic placement of an endovascular balloon in the inferior vena cava to facilitate rapid deployment.

While predicting operative complications and morbidity is difficult, the study revealed patient population trends consistent with other reports relative to what is considered high-risk for perforations in lead extraction.

For example:

- Most patients (54.3%) experiencing SVC tears in this study were female.
- The majority of SVC tears (52.6%) occurred in patients with ICDs and those with older leads (10.1 years).

Best practice protocol states Bridge prophylaxis **should be considered** for physician preference, high-risk patients, new physicians practicing lead extraction, low-volume operators, and an intraprocedural increase in the perceived risk.

**88.2% survival in the balloon cohort**

Characteristic	All SVC lacerations (n=116)	Balloon group (n=51)	No balloon or improper usage group (n=65)	p-value
Age, years	63.0 (± 14.4)	61.6 (± 15.1)	64.2 (± 13.9)	0.338
Gender, female	63 (54.3)	29 (56.9)	34 (52.3)	0.582
Device type	61 (52.6) ICD 48 (41.4) PPM 7 (6.0) CRTD	27 (53.0) ICD 22 (43.1) PPM 2 (3.9) CRTD	34 (52.3) ICD 26 (40.0) PPM 5 (7.7) CRTD	0.946 0.734 0.397
Indication for extraction	47 (40.5) Infectious 69 (59.5) Non-infectious	19 (37.3) Infectious 32 (62.7) Non-infectious	28 (43.1) Infectious 37 (56.9) Non-infectious	0.526
Extraction tools	105 (90.5) Laser sheaths 11 (9.5) Mechanical sheath	44 (86.3) Laser sheaths 7 (13.7) Mechanical sheath	61 (93.8) Laser sheaths 4 (6.2) Mechanical sheath	0.167
Lead dwell time, years	10.1 (± 4.8)	10.8 (± 4.3)	9.5 (± 5.0)	0.160
<b>Discharged alive</b>	<b>82 (70.7)</b>	<b>45 (88.2)</b>	<b>37 (56.9)</b>	<b>0.0002</b>

1. Ryan Azarrafiy, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circulation EP, August 2019.

