

**Compliant Endovascular Balloon Demonstrates Continued  
Efficacy in Reducing the Lethality of Superior Vena Cava Tears  
During Transvenous Lead Extractions**

*Roger G. Carrillo, MD, MBA, FHRS  
Darren C. Tsang, BS, Ryan Azarrafiy, BA*

# Disclosures

- Roger G. Carrillo has served as a consultant to Spectranetics and Sensormatic; has received a research grant from St. Jude Medical; and has served on the Speakers Bureau for Medtronic, St. Jude Medical, and the Sorin Group
- Darren C. Tsang and Ryan Azarrafiy have no disclosures.
- Project Funding: None



Overview

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Results

Discussion

Conclusion



**Overview**

**Methods**

**Results**

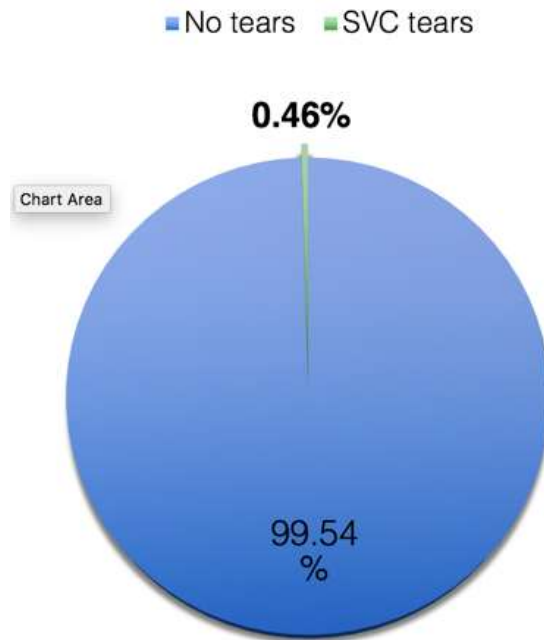
**Discussion**

**Conclusion**

# Incidence

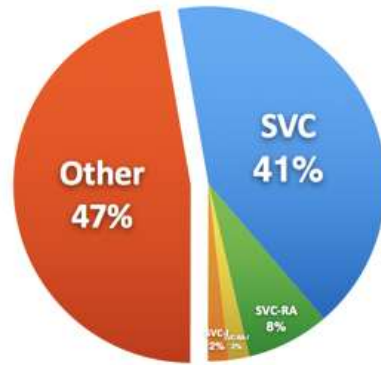
- **15,000 - 20,000**  
USA lead  
extraction

Brunner MP, Cronin EM, Wazni O, Baranowski B, Saliba WI, Sabik JF, et al. *Outcomes of patients requiring emergent surgical or endovascular intervention for catastrophic complications during transvenous lead extraction.* Heart rhythm : the official journal of the Heart Rhythm Society. 2014;11(3):419-25.

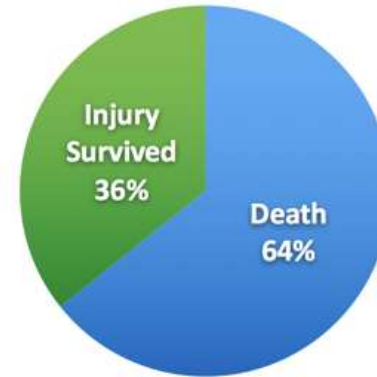


# Tears in the SVC pose a disproportionate risk to patients

Location of Adverse Events



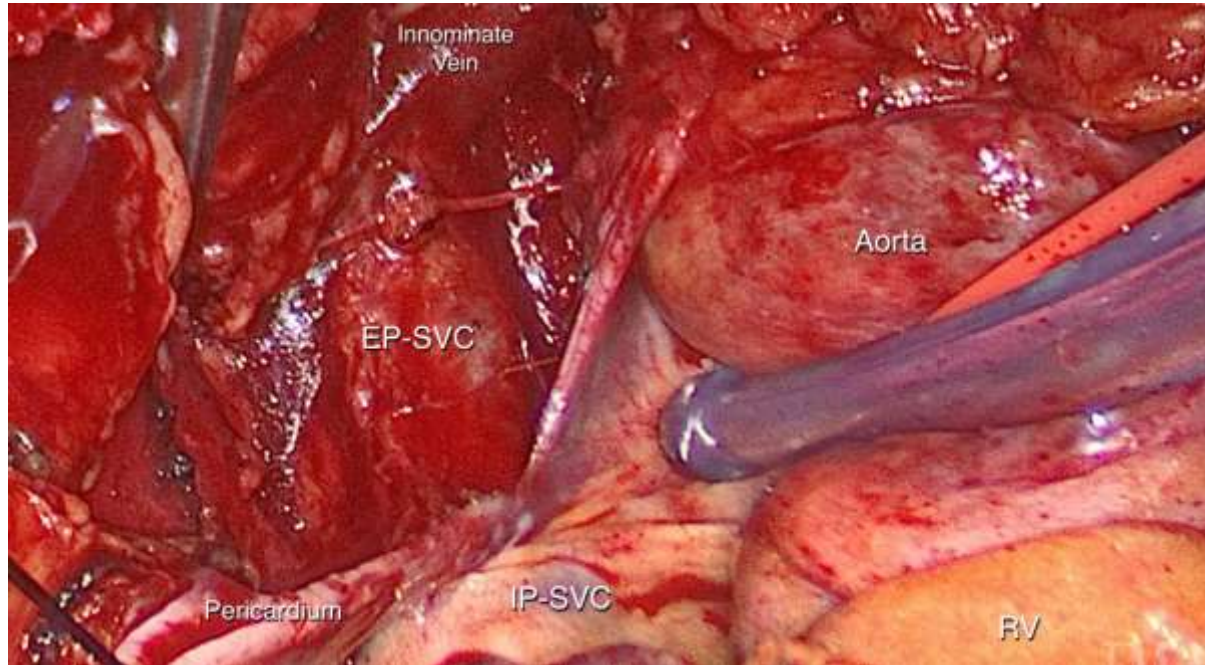
Outcomes from SVC Tears



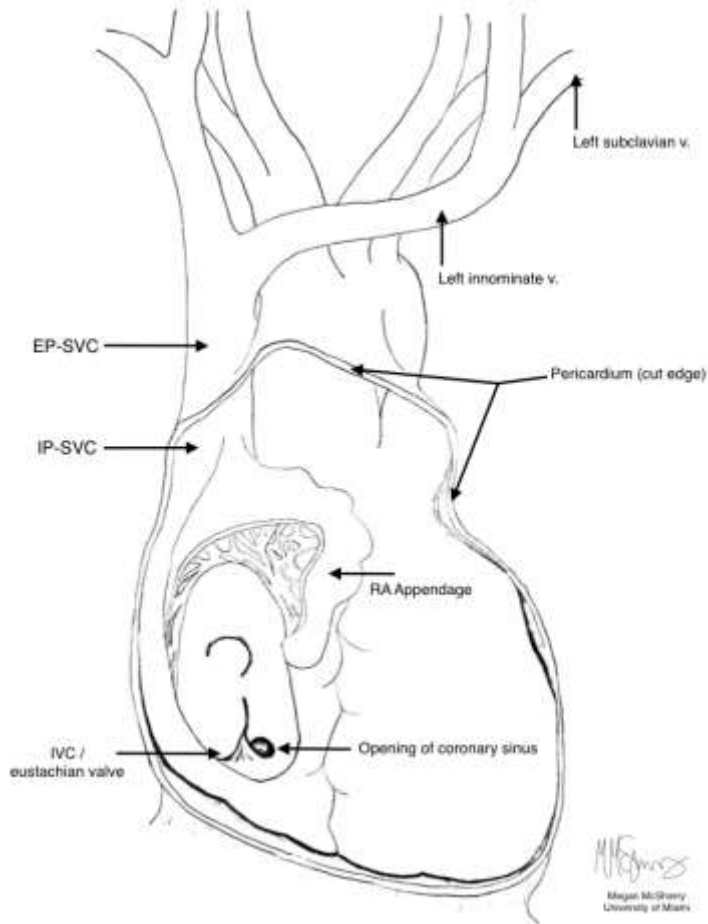
Hauser R, Katsiyannis W, Gornick C, et al: *Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction*. *Europace* 2010;12(3):395–401.



# Human anatomy of SVC



# Anatomy of the SVC



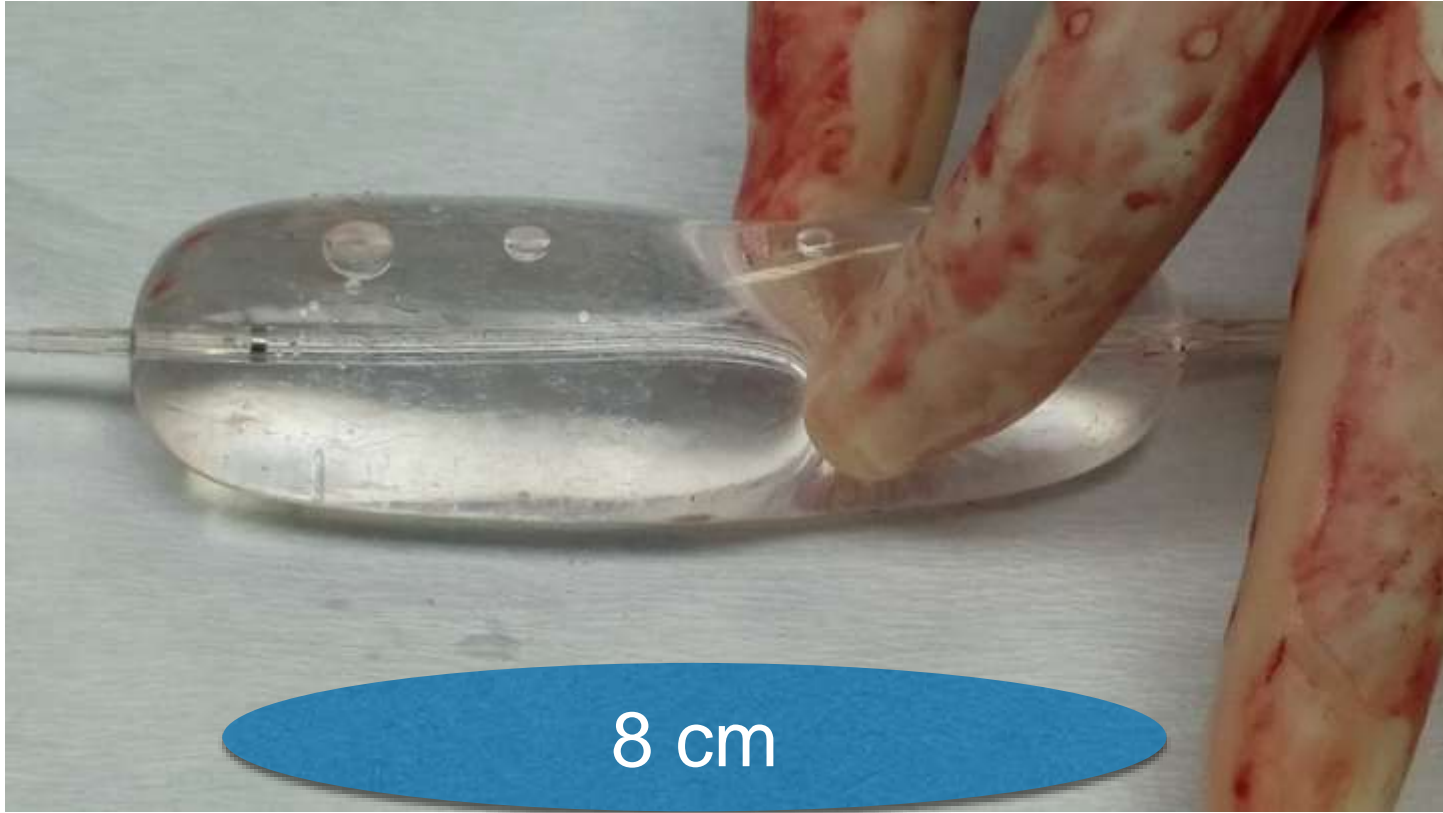
- The pericardium extends above the right atrium and covers about 30-40% of the SVC.
- An SVC tear on the lower 1/2 of the vessel could result in a pericardial **tamponade**



# Rescue Tool Concept



- Significantly reduce the rate of blood loss
- More time to determine plan of action



8 cm

WL: 2047 WW: 4095



Zoom: 145% Angle: 0  
Im: 1/56

WL: 2047 WW: 4095



Zoom: 145% Angle: 0  
Im: 1/120

WL: 2047 WW: 4095



Zoom: 145% Angle: 0  
Im: 17/57

# Objective

The goal of this study is to assess the impact of a compliant endovascular balloon on the management of SVC tears and survival outcomes after more than one year in clinical practice





Overview

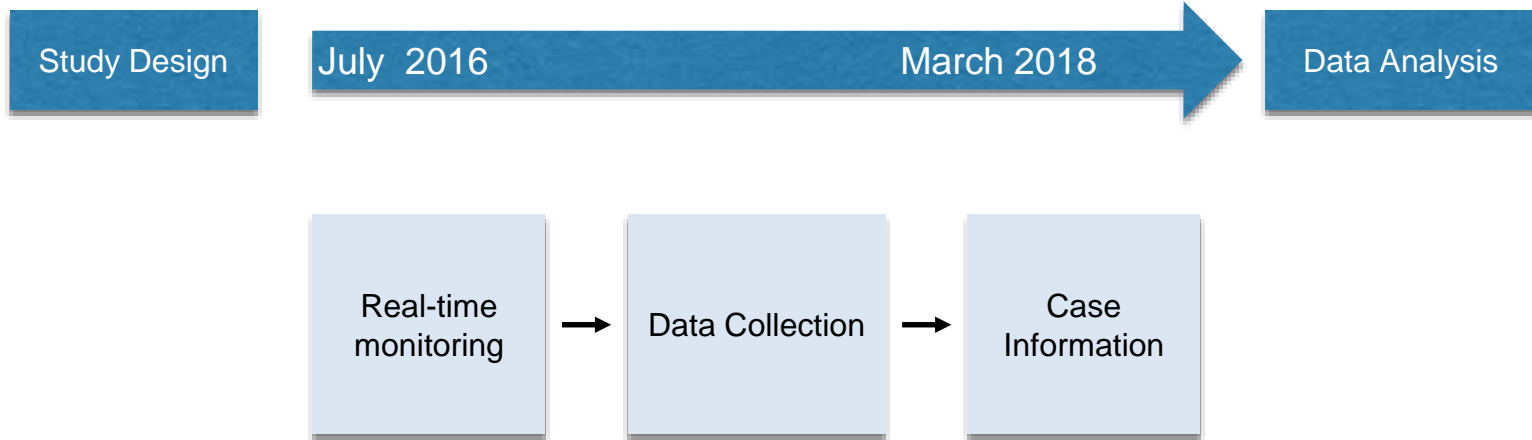
**Methods**

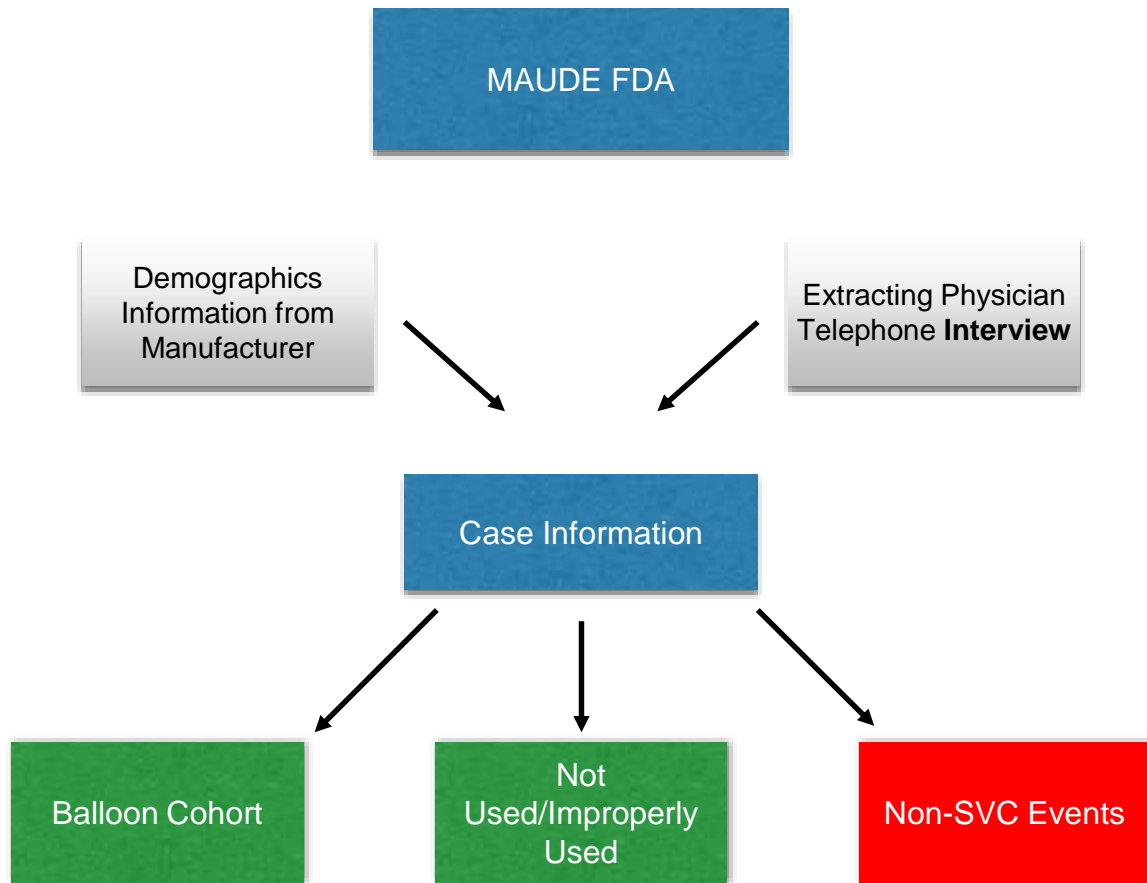
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# Study Timeline





# Inclusion and Exclusion Criteria

Included	Excluded
Surgically confirmed SVC tear by sternotomy	Unconfirmed SVC tears
Between innominate vein and right atrium	Non-SVC tears (right atrium, right ventricle, innominate vein-subclavian vein, etc.)
	Surgical repair not attempted

# Definitions

## “**Balloon Use**” Cohort:

- A stiff guidewire was prepositioned from the right femoral vein to either the right internal jugular or right subclavian vein prior to extraction
- Wire remained within the vein during balloon deployment

## “**Non-Balloon**” Cohort:

- The balloon was not used entirely or the stiff guidewire was not in the vein during balloon deployment



Conclusion  
Discussion

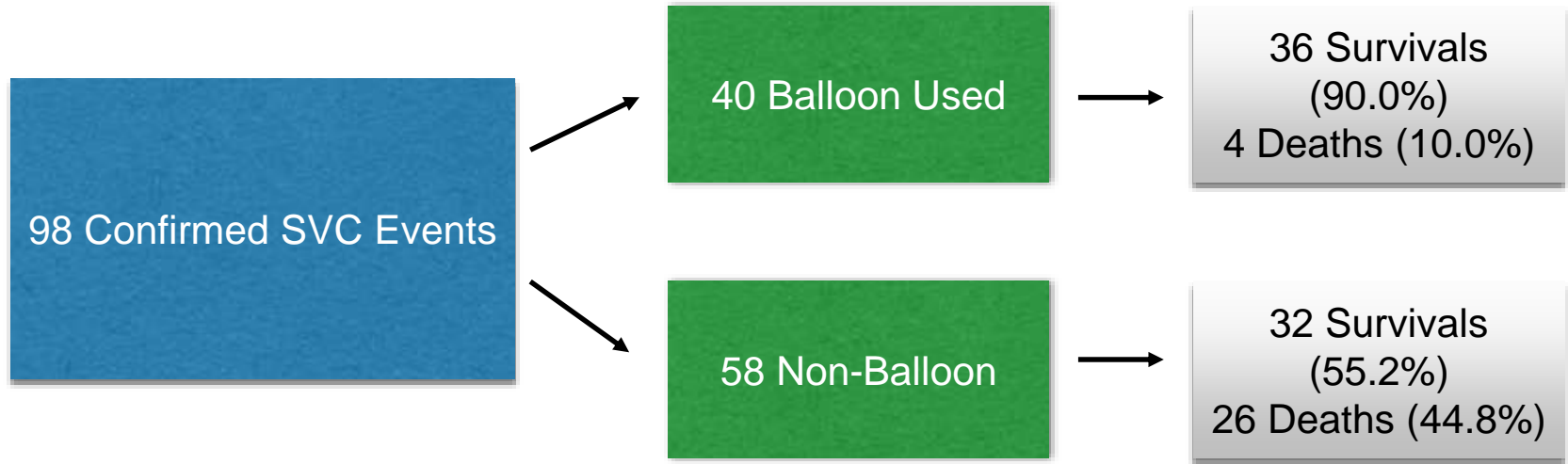
**Results**

Methods

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# July 2016 to March 2018



$P=0.0002$

89 Non-SVC Events

Characteristic	All SVC Lacerations (n = 98)	Balloon Cohort (n=40)	No Balloon or Improper Usage Cohort (n=58)	p-value
Age, Years	61.6 (± 13.9)	59.1 (± 13.4)	63.3 (± 14.1)	0.158
Gender, Female	50 (52.0)	21 (53.9)	29 (50.9)	0.775
Device Type	50 (52.6) ICD 39 (41.1) PPM 6 (6.3) CRTD	21 (53.9) ICD 17 (44.7) PPM 1 (2.6) CRTD	29 (51.8) ICD 22 (39.3) PPM 5 (8.9) CRTD	0.843 0.675 0.210
Indication for Extraction	37 (38.1) Infectious 60 (61.9) Non-infectious	12 (30.0) Infectious 28 (70.0) Non-infectious	25 (43.9) Infectious 32 (56.1) Non-infectious	0.166
Extraction Tools	91 (92.9) Laser Sheaths 7 (7.1) Mechanical Sheath	37 (92.5) Laser Sheaths 3 (7.5) Mechanical Sheath	54 (93.1) Laser Sheaths 4 (6.9) Mechanical Sheath	0.803
Lead Dwell Time, Years	10.1 (± 4.9)	10.6 (± 4.6)	9.7 (± 5.0)	0.381
Discharged Alive	68 (69.4)	36 (90.0)	32 (55.2)	<b>0.0002</b>



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# The Data

1. The **lethality** of superior vena cava injuries observed was consistent with the existing literature, approximating 45% (Non-Balloon Cohort).
2. SVC tears occurred in populations identified as having a **higher risk** for complications, including patients of female sex (52.1%), with ICDs (52.6%), and older leads (10.1 years).
3. Balloon use significantly increased the likelihood of **survival** during the study period ( $p=0.0002$ ).

# Study Limitations

- Sample size due to the rare occurrence of major complications during lead extraction
- Study assumes compliance with federal reporting regulations

# Summary of Recommendations

Bridge to Surgery

2017 2018

Best Practice Protocol Derived From Early Clinical Experience with the Bridge Occlusion Balloon:  
Consensus Statement from the Miami Eleventh Annual Lead Management Symposium

Wilkoff BL, Kennergren C, Love CJ, Kutalek SP, Epstein LM, Carrillo R (2017). *Bridge to surgery: Best practice protocol derived from early clinical experience with the Bridge Occlusion Balloon. Federated Agreement from the Eleventh Annual Lead Management Symposium*, Heart Rhythm, 14(10), 1574-1578, doi: 10.1016/j.hrthm.2017.07.008.



# Summary of Recommendations

- 1) **Guide wire:** **All** patients should have a stiff 0.035” guide wire deployed from either femoral vein through the SVC preferable to the **right internal jugular, right subclavian or innominate vein** prior to every lead extraction procedure
- 2) **Introducer Sheath:** **All** patients should have ~~either a 6F peel-away or~~ **12F femoral vein** introducer sheath inserted for introduction of the stiff 0.035” guide wire prior to every lead extraction procedure

# Summary of Recommendations

- **3) Immediate Deployment:** The Bridge occlusion balloon and pre-filled inflation syringe must be ready for deployment, without delay, as soon as a tear in the SVC is suspected
- **4) Tamponade and Hemothorax:** The Bridge occlusion balloon should be immediately deployed when there is evidence of either cardiac tamponade or hemothorax. Intra-pericardial SVC tears may cause cardiac tamponade

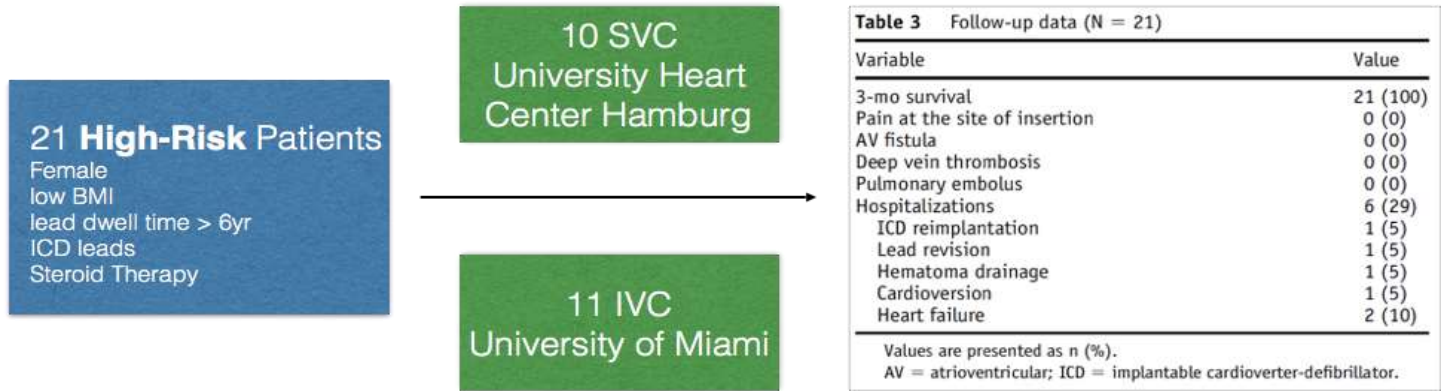
# Summary of Recommendations

- 5) **Bridge Familiarity:** All team member that are part of extraction cases should be familiar with the Bridge occlusion balloon and the deployment workflow
- 6) **Bridge Competence:** Extracting physicians should become competent and comfortable in deployment and inflation of the Bridge occlusion ballot in non-emergent settings
- 7) **Bridge Prophylaxis:** Prophylactic placement of the Bridge occlusion balloon ~~may be considered~~ **is recommended** for reasons including but not limited to, procedures and patients deemed **high risk**, **new physician** practicing lead extraction, **low volume** operators and **intra-procedural** increase in the perceived risk

# Long-term outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions

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Darren C. Tsang, Ryan Azarrafiy, Simon Pecha, Hermann Reichenspurner, Roger G. Carrillo, Samer Hakmi. *Long Term Outcomes of prophylactic placement of an endovascular balloon in the vena cava for high-risk transvenous lead extractions.* Heart Rhythm. 2017. ISSN 1547-5271, <http://dx.doi.org/10.1016/j.hrthm.2017.08.003>

**No acute or long-term effects associated** with prophylactic placement strategy

- A simple change in workflow and a well-rehearsed team can make a difference in patient safety
- Our institution had one superior vena cava tear last year
- An organized team response led to a successful outcome

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# Conclusion

- During the period from July 2016 through March 2018, patients undergoing lead extraction were **more likely to survive** superior vena cava tears when treatment included an endovascular balloon.
- When properly used, the novel device has lifesaving potential



**Darren Tsang  
Thomas Boyle  
Ryan Azarrafiy**





Thank You