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Take the Lead: Best Practices in Lead Management

National Highlights & Current Trends

Image Guided Therapy | Lead Management

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Disclaimer

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Bridge occlusion balloon

Ralph Augostini, MD & Raul Weiss, MD | The Ohio State University, OH

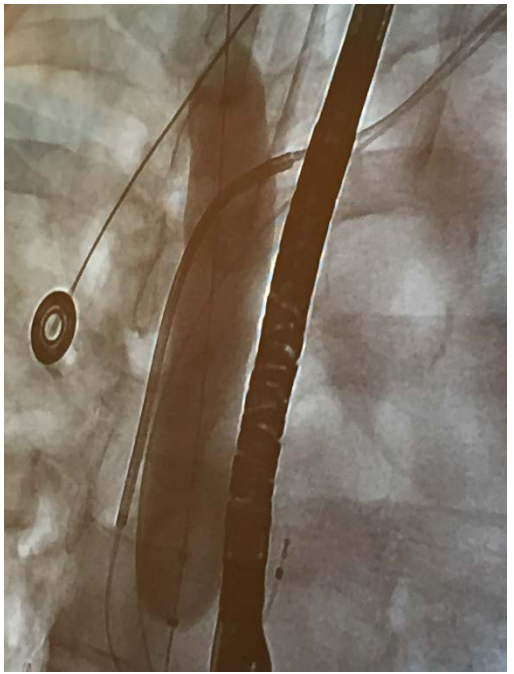
Protocol

- ✓ Bridge prophylaxis for high-risk patients (chart on right)
- ✓ Incorporate Bridge into pre-case time-outs

Risk Stratification for Bridge Prophylaxis	
Pacing lead	**> 5 years old**
Dual coil ICD lead	**> 3 years old**
Single coil ICD lead	**> 4 years old**

Rationale

- ✓ *"When an SVC tear happens, every moment really counts. Forget about the cost and just get the balloon up. You can't put a price on a life."*
- ✓ *"I want to look the family in the eye and say I did everything I could. Without prophylactic placement of Bridge, you can't say that."*
- ✓ *"The reluctance to refer is because of a small number of catastrophic events. If you have a tool that can support survival, then more patients with lead issues can be treated appropriately. Why wouldn't you make the potential for surviving a catastrophic event even better?"*



***"At our institution Bridge is standard of care**. Everyone knows that if we start a high-risk procedure, we are going to prophylactically use Bridge. It is a mandatory step."* **- Dr. Weiss**

For more information, see D051098-00 Ohio State Bridge Experience

Surgical Partnership

David Riggio, MD | HonorHealth Scottsdale, AZ

Current Set-Up

- ✓ **Surgeon & perfusionist are compensated a flat amount** (by the hospital) for each lead extraction. The additional compensation is built into their contracts.
- ✓ Dr. Riggio ensures **patient prep is complete before surgeon arrives** to optimize surgeon's time.
- ✓ During extraction, surgeon is either rounding, seeing patients, or in the room. Surgeon is always immediately available. Perfusion is set up and available before each procedure.
- ✓ Scheduler has a checklist to support smooth coordination for extractions, including: perfusionist, cath lab staff, EP staff, surgical staff, patient labs and blood type, etc.

"My back-up surgeons understand that we all have to work together in the long run in order to optimize patient care and our practices."

- Dr. Riggio

How Partnership was Set-Up

- ✓ **Extractor & EP group wanted to be a Center of Excellence for EP procedures**, and asked hospital to support their safety and efficacy needs.
- ✓ Extraction is an important component of treating a wide array of patients, both within the hospital system and for receiving referrals. **All EP cases can be performed at their institution instead of somewhere else** (implants, upgrades, ablations, Watchman implants, etc.).
- ✓ For these reasons, Dr. Riggio was able to secure hospital administration support for compensating the CV surgeon and perfusionist.

Results of Partnership

- ✓ **Smoother scheduling for extractions** since CV surgical team is compensated for extractions.
- ✓ **Enhancement of comradery with EP and surgical teams**, creating positive working relationships and **optimizing patient care.**

Dedicated Block/Hybrid OR Time

Robert Canby, MD | St. David's & South Austin, TX

Set-Up

- ✓ **Extraction time dedicated 2 ½ days each week** (Monday, Wednesday, Friday)
- ✓ **OR team is present during cases** (surgeon, perfusionist, nurse). Hospital agreement for one of the surgeons and the OR team to be scheduled to backup extractions, and hospital compensates surgeon for their backup time

Keys to Acquiring Set-Up

- ✓ **Asked hospital administration for block time and surgical support**
  - Included this in outline of the **infrastructure needed to support EP procedures** (including extraction) in order to be **recognized as an advanced center** for EP procedures
- ✓ Dr. Canby runs very **efficient extractions** and does not waste the surgeon/OR team's time
  - Extractions performed first thing in the morning. Patients prepped by 8am (follow same process every case) & extraction begins on-time.
  - Prepared to switch tools as needed in order to continue progression of lead removal.
  - Communicate & be respectful of time: release OR team soon after extraction is complete.
  - Bottom line: **Be efficient, be on time, be decisive.**
- ✓ High volume is key
  - Support comes with volume: cases, surgical partnership, surgical compensation, block time, etc.
  - **You need to commit to lead extraction in order to receive dedicated resources**, including block time and surgical partnership.

"The key is to commit to enough volume to command block time and resources to support your lead extractions."
- Dr. Canby

Results of Dedicated Time & Partnership

- ✓ **High volume extraction center** performing ~350 cases per year
- ✓ **Smooth workflows** for everyone involved in extractions
- ✓ **Positive working relationships**
- ✓ **Patients treated appropriately**

Infection Economics & Electronic Medical Records (EMR)

17	498	57
Live Accounts	Alerts	Cases

Numbers as of Q1 2019[1]

Key Concepts of EMR:

1. Patients with **cardiac devices + positive blood culture** should be identified for extractor consult/extraction (class I indication)[2]

2. Patients are likely being **missed within the hospital system**, which can add costs and lead to inferior clinical outcomes[3]

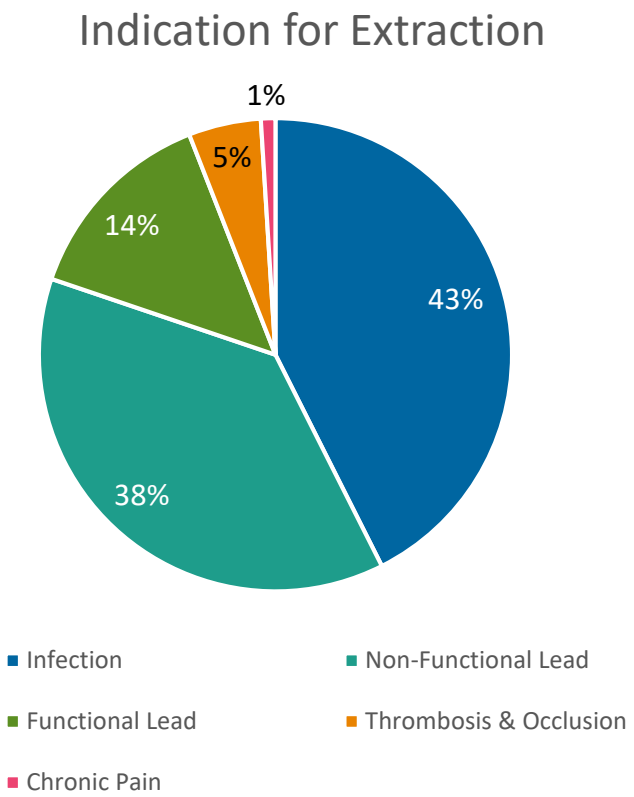
3. EMR can help make a **significant impact to the hospital and patient care for little to no cost** with an existing EMR program[4]

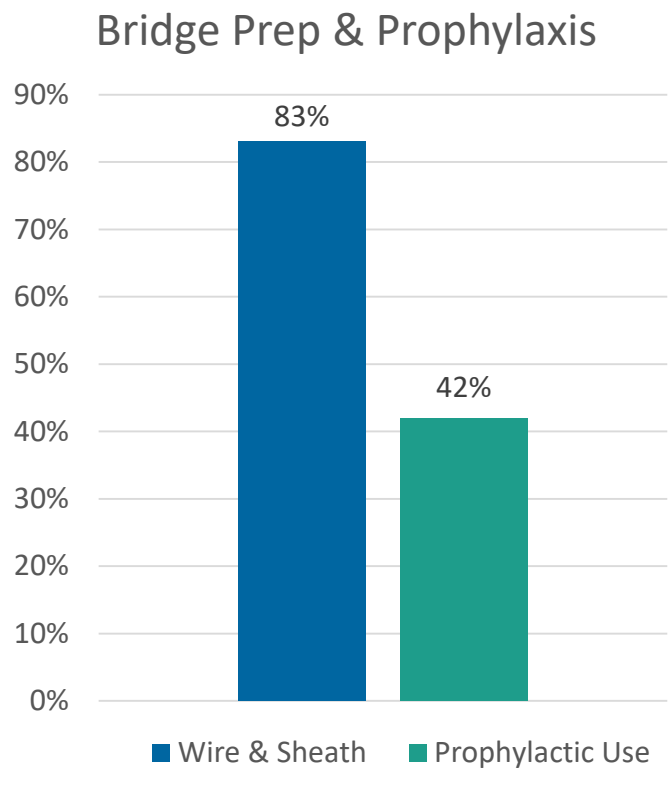
Image courtesy of Arnold Giedrimas, MD

Case of patient with recurring infection, finally treated appropriately after EMR was implemented.
Over 10 months there were **9 hospital visits** or admissions for infection totaling **>$400,000 in direct hospital cost**[4]

For more information, see D045671-00 Using EMR to Fight CIED Infection - Committee Deck

National Case Log Trends[5]





Numbers as of Q2 2019

Important Safety Information

Indications for Use
The Bridge Occlusion Balloon Catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Any use for procedures other than those indicated in these instructions is not recommended
Contraindications
None Known
Warnings
Lead extraction should be performed at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. It is strongly suggested that the recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) be followed for best results.
Prior to initiating the lead extraction procedure, a Bridge Occlusion Balloon Catheter compatible guidewire should be placed through a venous access site and across the length of the superior vena cava. Attempting to place a compatible guidewire after a venous tear occurs may:

- result in an inability to traverse the superior vena cava with the guidewire
- result in the guidewire exiting the vasculature at the tear site
- result in an inability to place the Bridge Occlusion Balloon Catheter
- delay or prevent the ability to achieve occlusion

Do not position the Bridge Occlusion Balloon Catheter in a manner that would obstruct the right atrium. Obstruction of the atrium could lead to arrhythmias and/or hemodynamic compromise. Failure to observe recommended inflation techniques may result in the formation of contrast crystals which could prevent deflation.
Do not over-inflate the Bridge Occlusion Balloon Catheter after fully occluding the vessel. Over inflation may result in damage to the vessel, rupture of the balloon, or introduction of air emboli.
Do not exceed the Maximum Inflation Volume. Over inflation may result in damage to the vessel, rupture of the balloon, or introduction of air emboli.
Occlusion of the superior vena cava beyond 30 minutes is not recommended as this may increase the risk of adverse physiologic or neurologic complications.
Do not resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.
Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties
Refer to the IFU for additional information.

References

1. Philips data on file. EMR tracking document, 2019.
2. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
3. Sohail, M Rizwan, et al. Incidence, Treatment Intensity, and Incremental Annual Expenditures for Patients Experiencing a Cardiac Implantable Electronic Device Infection: Evidence From a Large US Payer Database 1-Year Post Implantation. Circ Arrhythm Electrophysiol. 2016; 9(8).
4. Southcoast and Yale case studies. D039963-00 & D041246-00. Philips Data on file, 2018.
5. Philips data on file. Case log book, 2019.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