

Left Atrial Appendage Isolation

ACC– Indiana Annual Symposium
October 2014

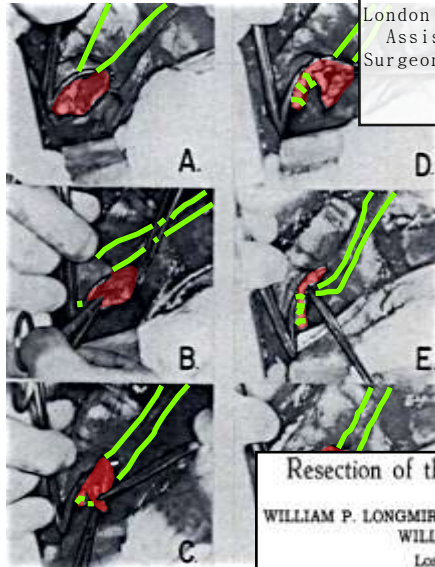
LAA as etiology for embolic events

- ▶ The majority of LA clot seen in patients with AF is localized to the appendage (up to 90%)
- ▶ Coumadin therapy is associated with >50% reduction in CVA among patients with Afib
- ▶ Observational data from surgical Cox–MAZE procedures originally published in 1991: risk of stroke is low after surgical ligation
- ▶ Randomized data from PROTECT–AF suggesting WATCHMAN device non–inferiority to warfarin with significantly less hemorrhagic stroke
- ▶ No randomized data for any other approved device or surgical technique

History of Suture Closure

1947 → 1949 → 1955 → 1985 → 2000 → 2011

Resection of the Left Auricular Appendix
 A Prophylaxis for Recurrent Arterial Emboli
 JOHN L. MADDEN, M.D.
 Department of Surgery, Long Island College of Medicine, Kings County Hospital, Brooklyn



SYSTEMIC EMBOLISM AND LEFT AURICULAR THROMBOSIS IN RELATION TO MITRAL VALVOTOMY
 BY
 AND
 J. R. BELCHER, M.S., F.R.C.S. Surgeon,
 London Chest Hospital;
 Assistant Thoracic Surgeon, the Middlesex Hospital

USE OF THE SURGICAL STAPLER TO OBLITERATE THE LEFT ATRIAL APPENDAGE
 Laurence H. Coffin, M.D., F.A.C.S., Burlington, VT



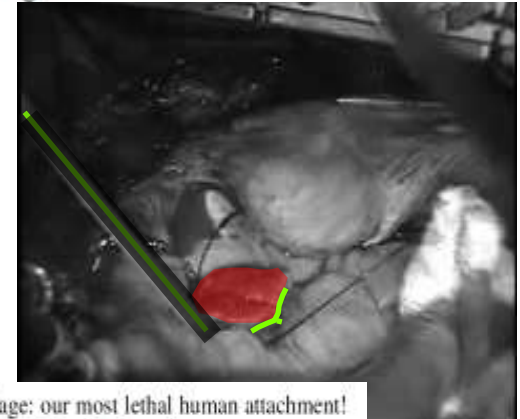
Ligation of the Left Atrial Appendage Using an Automatic Stapler
 VJ DiSesa, S Tam, LH Cohn
 Division of Cardiac Surgery, Brigham & Women's Hospital, Boston, MA

THE SURGICAL TREATMENT OF ATRIAL FIBRILLATION
 IV. SURGICAL TECHNIQUE
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 St. Louis, Mo.
 From the Division of Cardiothoracic Surgery, Department of Surgery, Washington University School of Medicine, Barnes Hospital, St. Louis, Mo.
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Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients with Atrial Fibrillation
 JL Blackhear, MD, JA Odeh, FRC(CV)†
 Division of Cardiovascular Diseases, Mayo Clinic Jacksonville, FL & Mayo Clinic, Rochester, MN



ACC/AHA/ESC PRACTICE GUIDELINES—FULL TEXT
ACC/AHA/ESC Guidelines for the Management of Patients With Atrial Fibrillation



The left atrial appendage: our most lethal human attachment!
 Surgical implications[†]
 W. Dudley Johnson^{1,2*}, A.K. Ganjoo³, Christopher D. Stone⁴, Ramahalli C. Srivivas⁵, Mary Howard^{1,6}

Thoracoscopic Extracardiac Obliteration of the Left Atrial Appendage for Stroke Risk Reduction in Atrial Fibrillation
 Joseph L. Blackhear, MD,* W. Dudley Johnson, MD,† John A. Odell, MD,* Vickie S. Baker, RN,* Mary Howard, RN,† Lesly Pearce, MS,‡ Christopher Stone, MD,† Douglas L. Packer, MD,§ Harrell V. Schaff, MD§
 Jacksonville, Florida; Milwaukee, Wisconsin; Miami, North Dakota; and Rochester, Minnesota

Resection of the Auricular Appendages^{*}
 WILLIAM P. LONGMIRE, JR., M.D. JOHN M. BEAL, M.D. and
 WILLIAM H. LEAKE, M.D.
 Los Angeles, California



Amputation of the Canine Atrial Appendages
 Hellerstein, HK

The Closed Heart MAZE: A Nonbypass Surgical Technique
 Richard Lee, MD, Takashi Nitta, MD, Richard B. Schuessler, PhD,
 David C. Johnson, MD, John P. Boineau, MD, and James L. Cox, MD
 Division of Cardiothoracic Surgery, Washington University School of Medicine, St. Louis, Missouri

Current LAA recommendations

- ▶ Cardiac surgery guidelines recommend LAA ligation in patients at high risk for stroke and/or Afib
- ▶ ACC/AHA/HRS guidelines allow for consideration of LAA ligation at the time of cardiac surgery (IIb, LOE C)
- ▶ 2014 ACC/AHA/HRS Afib guideline update makes no formal recommendation for device-based therapies

WATCHMAN device

- ▶ Data from PROTECT-AF and suggested non-inferiority to warfarin for prevention of CVA
- ▶ Randomized PREVAIL trial showed improved safety but did not meet non-inferiority endpoint due to low risk in the warfarin group
- ▶ Ongoing implants in the Continued Access Registry suggest improving safety with experience
- ▶ Final FDA approval pending

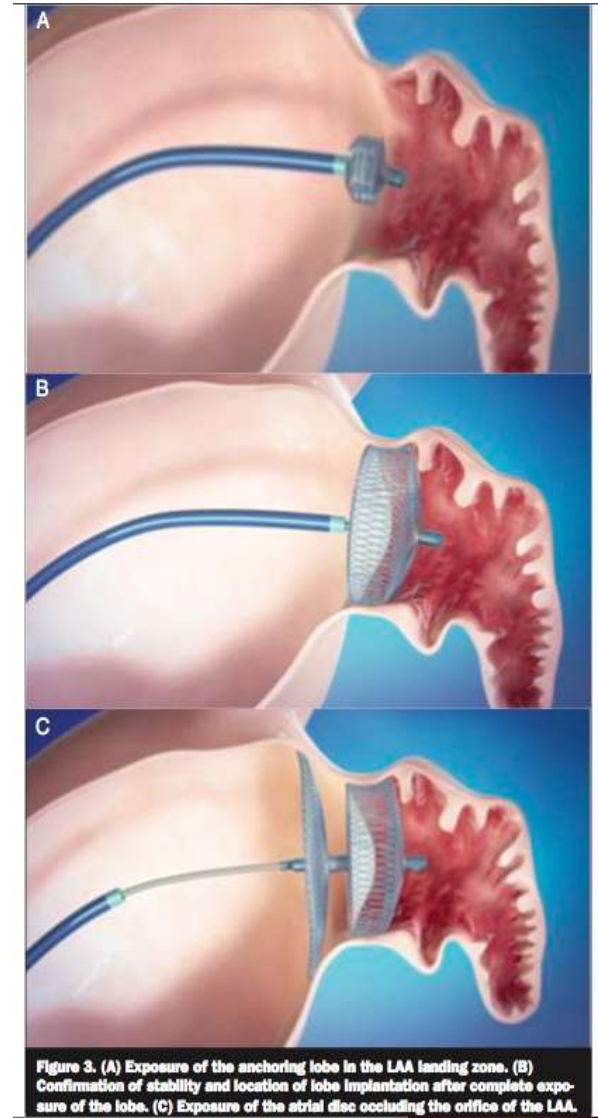


PROTECT-AF Results

	Watchman (n= 463)	Warfarin (n=244)
Ischemic Stroke	3.0	4.9
CV/Unexplained death	0.7	2.7
Hemorrhagic Stroke	0.1	1.6
Mortality	3.0	4.8
Primary Safety Endpoint	7.4	4.4

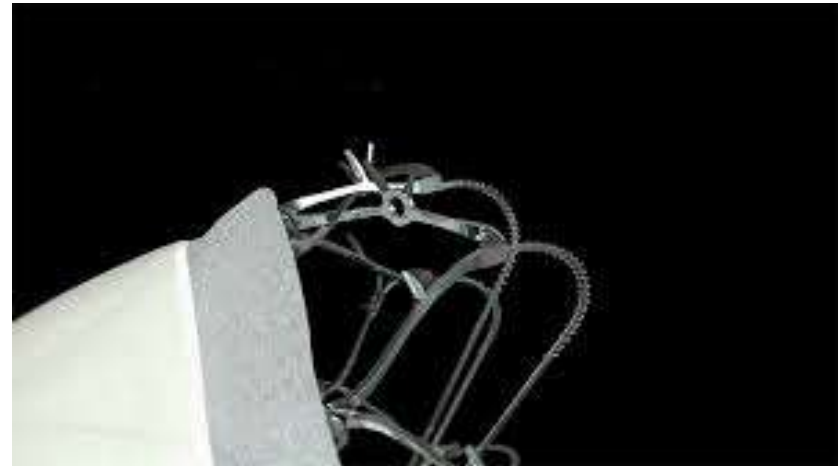
Amplatzer Cardiac Plug (ACP)

- ▶ Transeptal delivery over a large sheath with direct insertion into the LAA
- ▶ Flexible, braided nitinol mesh delivered transeptal with 9–13F sheath
- ▶ Long term risk of device erosion and short term risk of perforation not well defined
- ▶ Clinical trials underway



Coherex WaveCrest Occluder

- ▶ Transeptal delivery over a large sheath with direct insertion into the LAA
- ▶ CE Mark Approval
- ▶ Clinical trials underway
- ▶ More gripping barbs than other devices, possibly better visualization

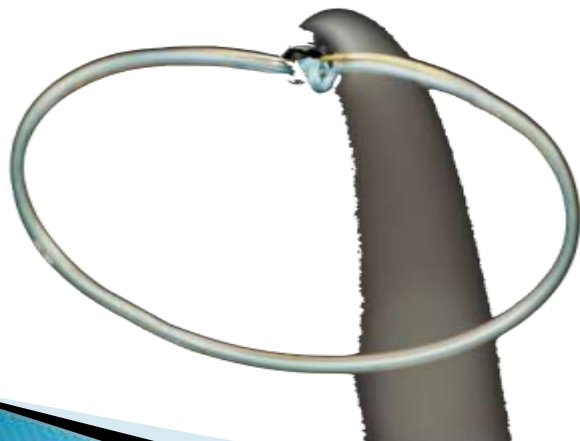


LARIATTM suture delivery device



40mm pre-tied, “0” polyester suture loop mounted on collapsible snare

Magnetic wire system requires trans-septal and pericardial access



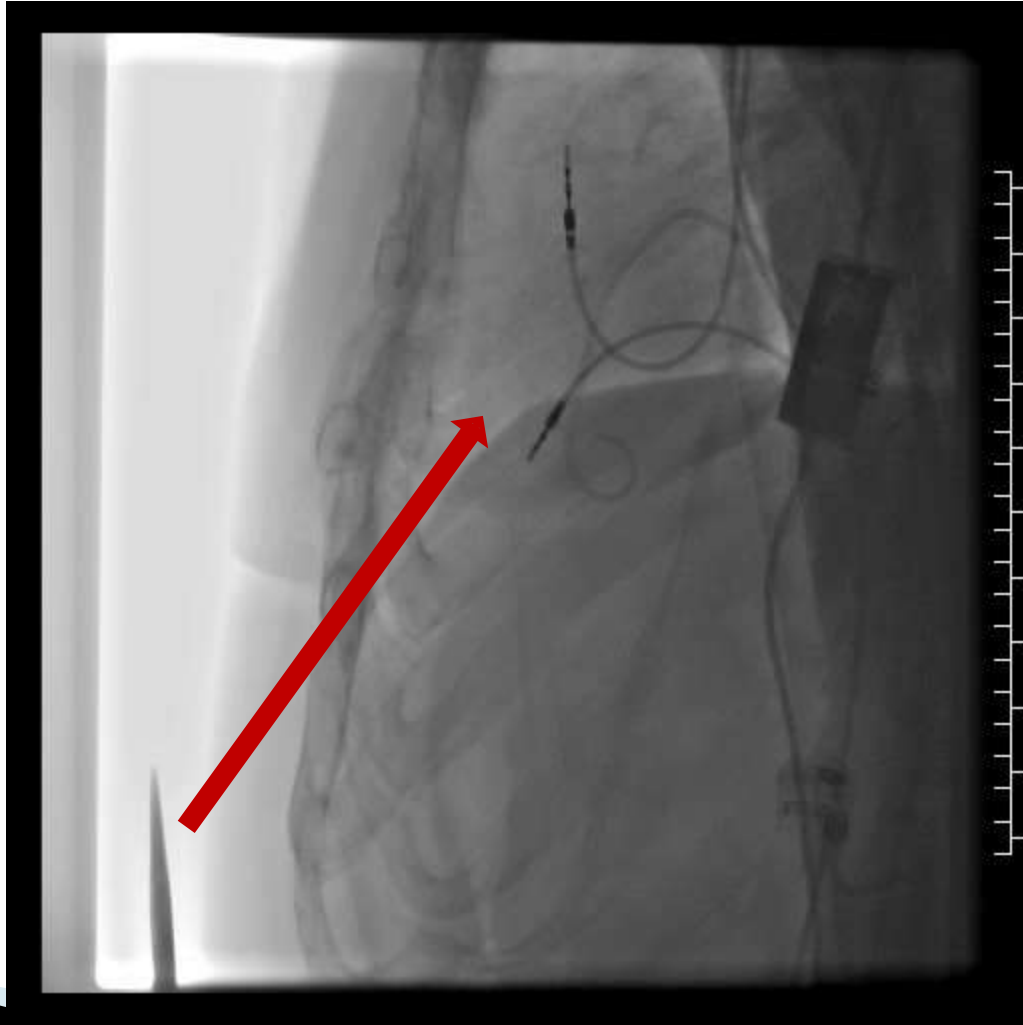
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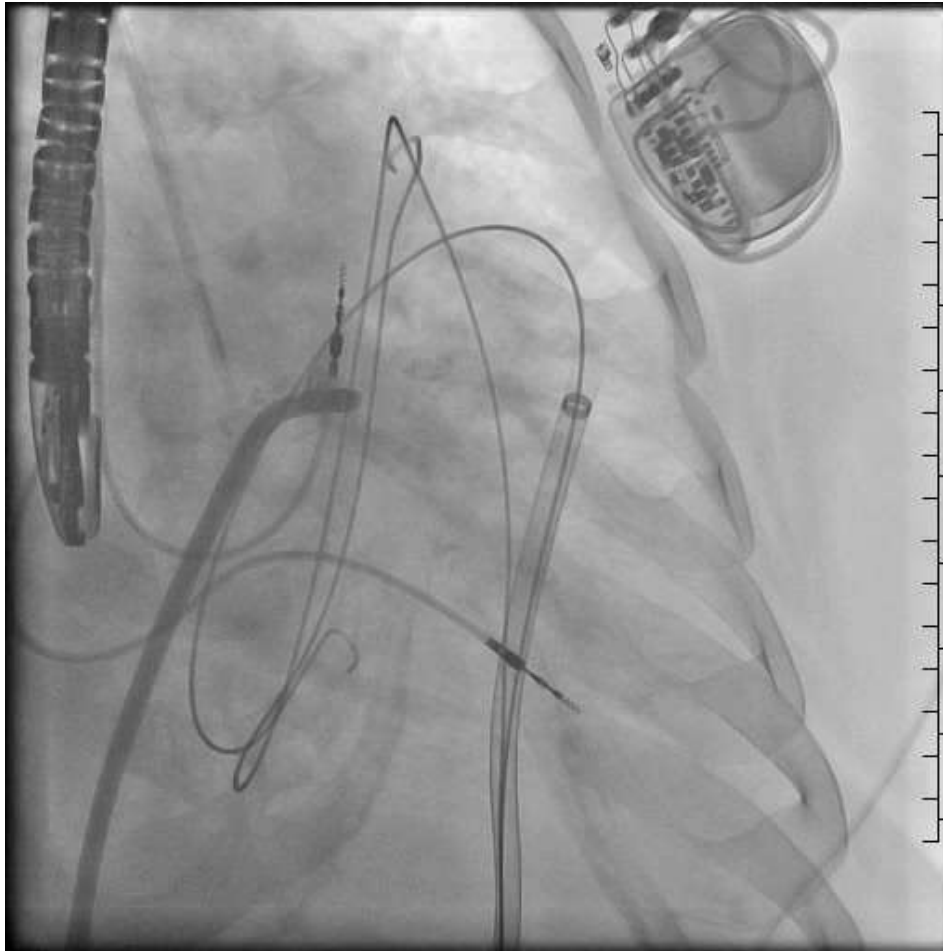
LARIAT system for LAA closure

- ▶ FDA approved for “soft tissue closure”
- ▶ Not proven for stroke prevention in randomized clinical studies
- ▶ Over 1000 implants in the USA and more in Europe
- ▶ Reimbursement by Medicare and private insurance usually on appeal only
- ▶ Currently utilized only in patients with no other option for stroke prevention

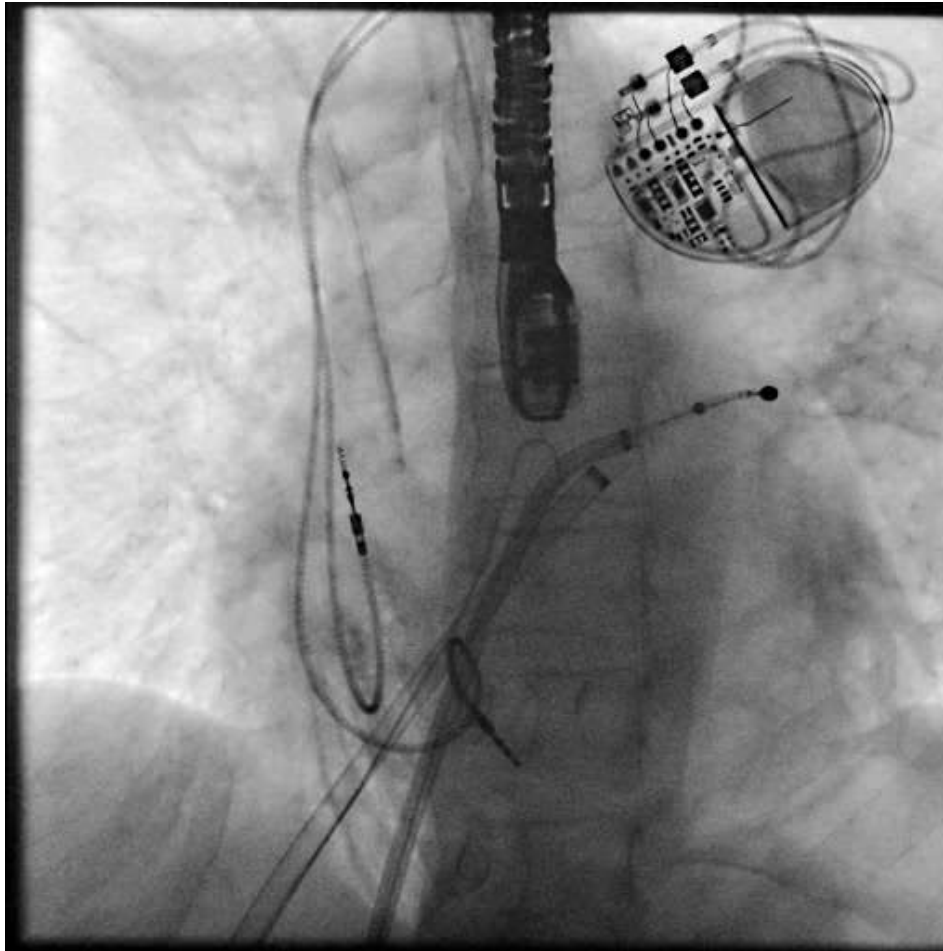
Pericardial Access



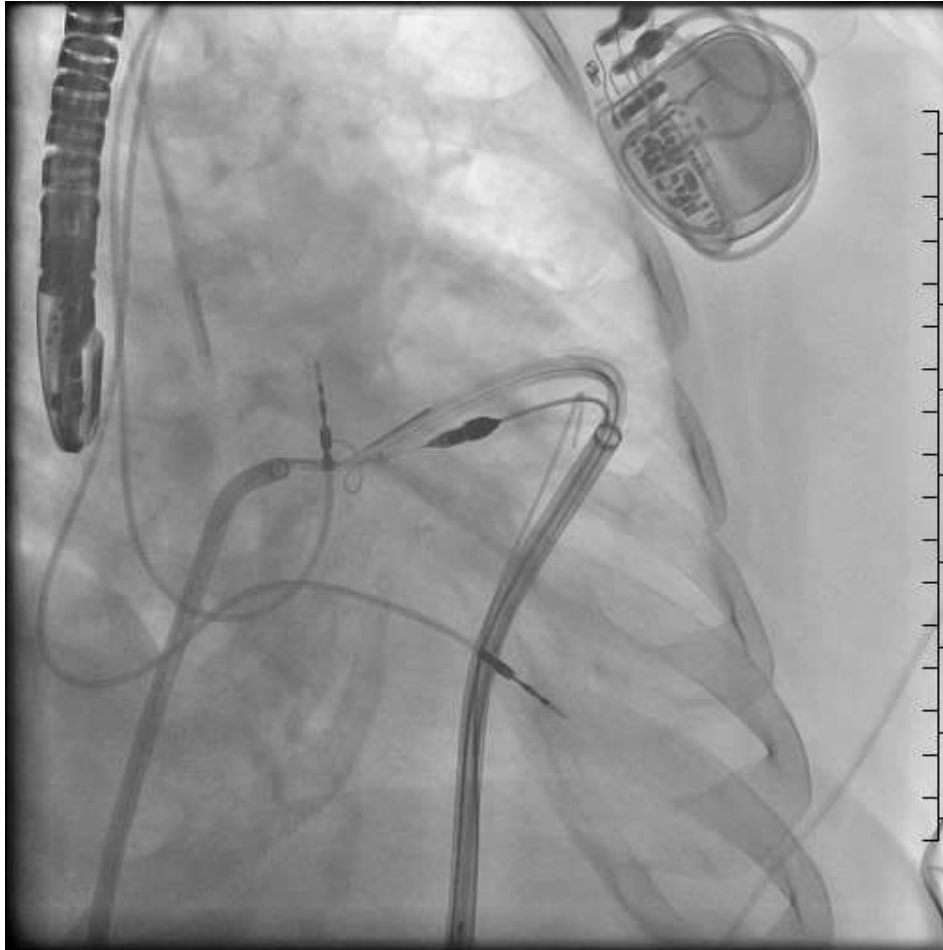
Transeptal access– 8.5F SL1



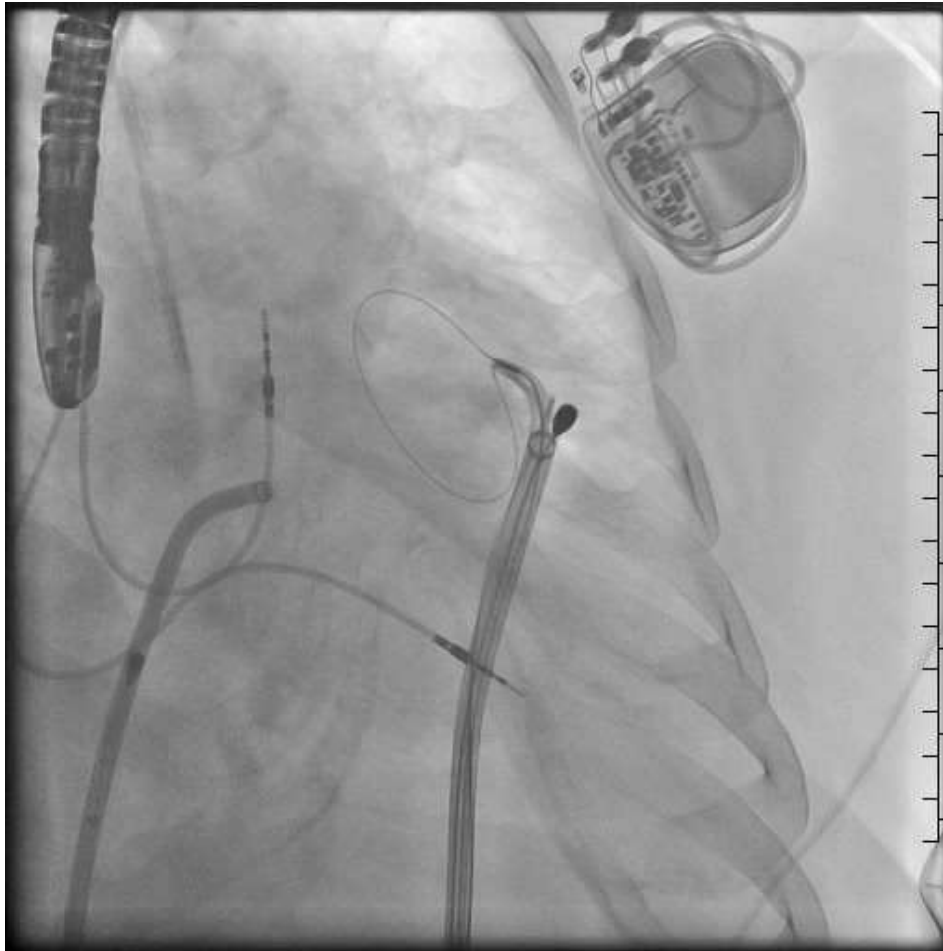
Magnetic rail



Device Delivery

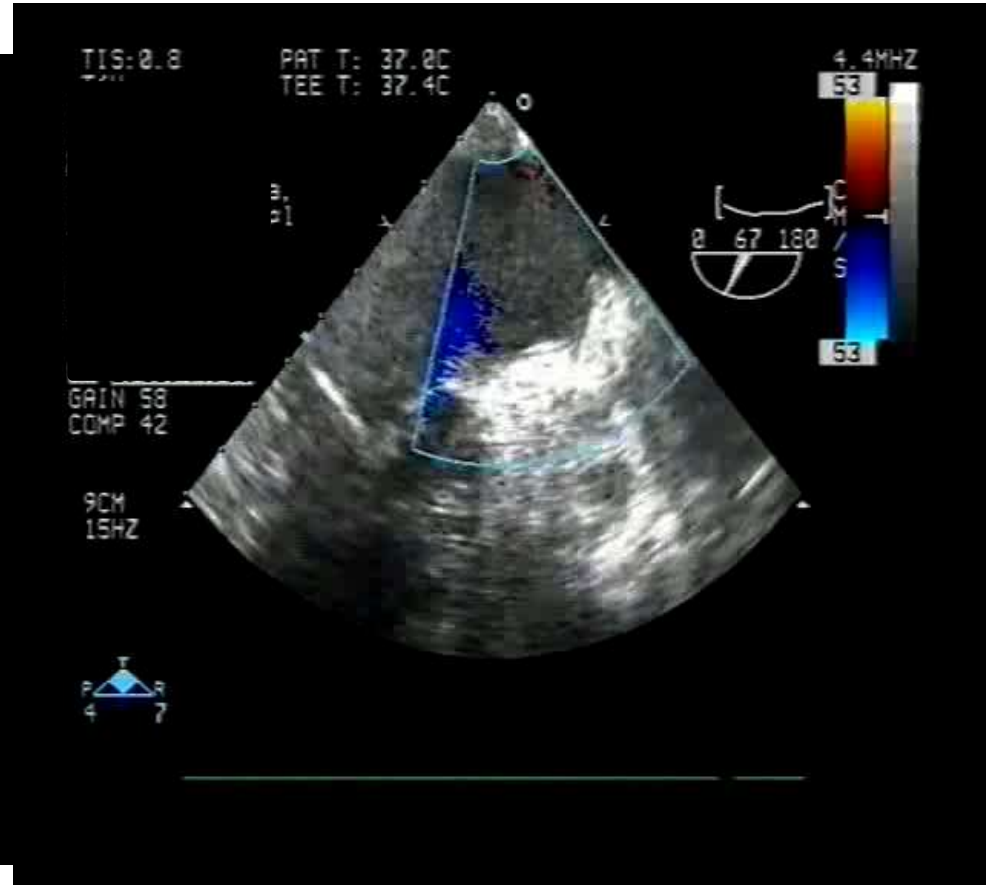
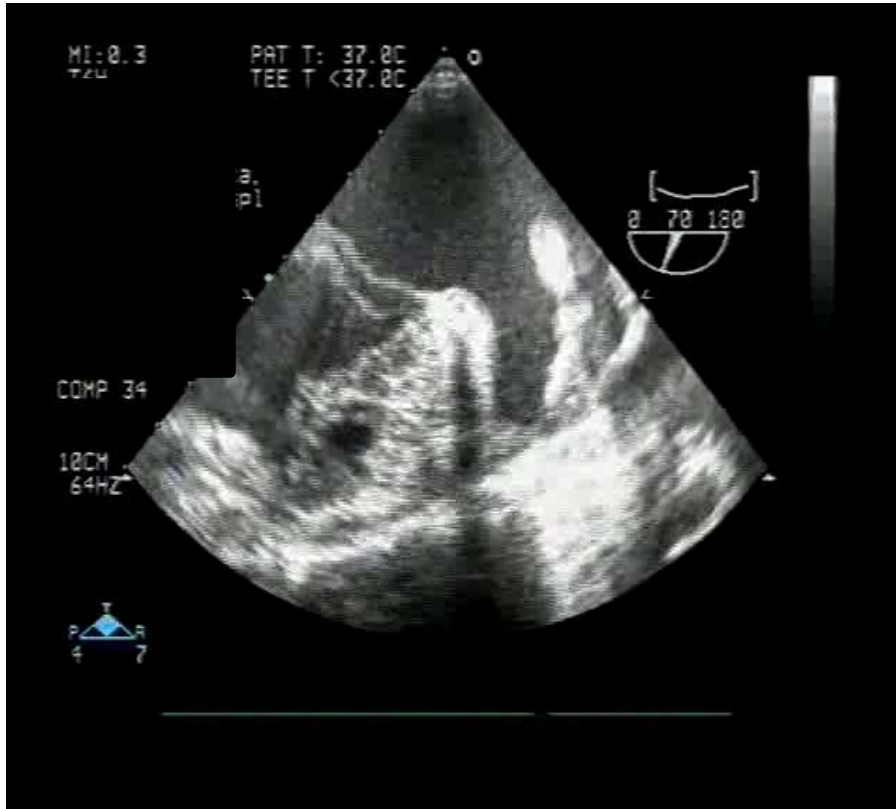


Closure and Device Removal



Before

After



Post-procedure

- ▶ 24–48 hours in hospital
- ▶ Pericardial drain overnight following procedure
- ▶ Colchicine prophylaxis for pericarditis
- ▶ 30 day TEE to confirm closure and evaluate for thrombus

LARIAT exclusions

- ▶ LAA width >40 mm
- ▶ Previous cardiac surgery or pericarditis
- ▶ Position of LAA behind the pulmonary artery
- ▶ Thrombus on TEE
- ▶ Previous ASD closure with implant

Efficacy

	PLACE PLACE II Study	ACP Registry Data	WATCHMAN PROTECT AF Trial ^{II}
# Pts	89	183	463
Intent-to-Treat	85/89 (96%)	175/183 (96%)	408/463 (88%)
Acute Closure	81/85 (95%)	99.5	NA
30d Closure	81/85** (95%)	NA	NA
90d Closure	77/81** (95%)	NA	346/408 (85%)
6mos or 1 Year Closure	64/65** (98%)	98.9%	275/389** (71%)
Access Requirement	8.5F	9F-13F	14F

Lariat Initial US experience

Percutaneous Left Atrial Appendage Suture Ligation



Not Ready for Prime Time*

Nikolaos Dargatzis, MD,[†] Sascha Rolf, MD,[‡] Gerhard Hindricks, MD[†]

Effectiveness of LAA isolation vs. anticoagulation

- ▶ Randomized trials are lacking
- ▶ Patients included in studies already completed have generally been a low-risk, selected population
- ▶ “All-comers” registry data will provide important information regarding long term stroke risk and procedural complications

Antiplatelet/AC use after LAA closure

- ▶ For patients receiving suture-based closure with LARIAT procedure, common practice is ASA/Plavix for 30 days and then ASA alone
- ▶ Some patients have been treated with ASA alone or no antiplatelet agents at all, safety outcomes in this group are unknown
- ▶ Patients treated with implantable devices generally require DAPT or anticoagulation for at least 3 months but optimal strategy is not defined

Who is the best candidate?

Is there an economic argument for
LAA occlusion?

Future applications of LAA devices

- ▶ Stroke reduction for patients unable to tolerate anticoagulation
- ▶ Potential treatment in combination with improved ablation techniques for a truly “curative” afib procedure
- ▶ Alternative to anticoagulation in patients with high bleeding risk and/or desire to discontinue anticoagulation