Recurrent Stroke under Anticoagulation in Mild MS & AF

- Minimal maze operation and LAA excision or exclusion-

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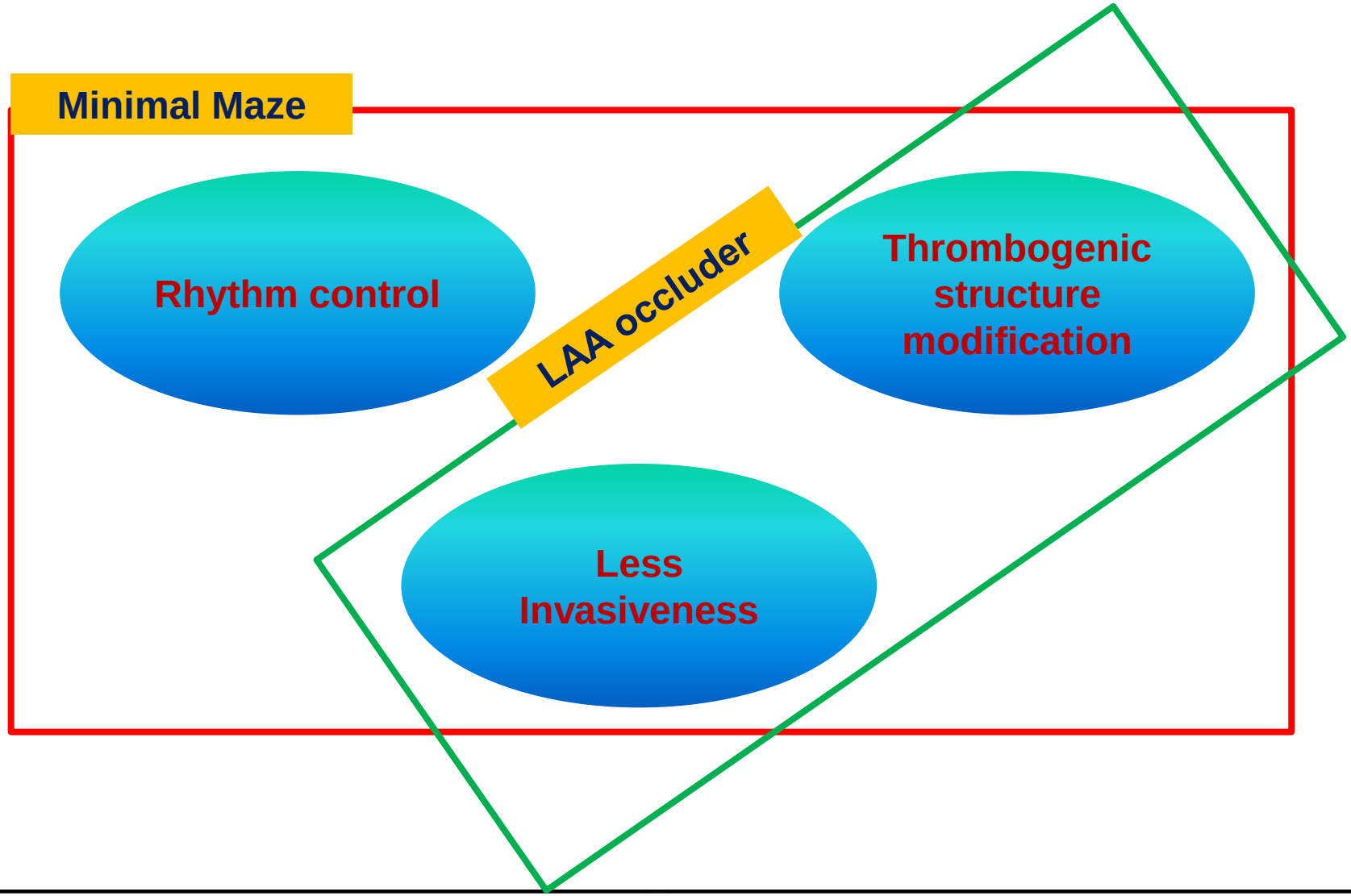
University of Yonsei, College of Medicine

Issue focus

- **Procedural Result (completeness)**
  - Surgery vs. Intervention
  - Rhythm care or not (Only prevention stroke?)
- **Disease understanding**
  - Valvular heart disease combined case
  - Disease progression
  - Operation possibility

Mini-maze LAAE vs. LAA occluder



Issue 1

Valve combined case

Natural course of Mitral Stenosis

Progression of degenerative mitral stenosis: insights from a cohort of 254 patients.

Tyagi G, Dang P, Pasca I, Patel R, Pai RG.

- Follow up period : 2.6 ± 2.2 years
- Mean gradient : ↑ 0.8 ± 2.4 mmHg (0-15 mmHg)/yr
- The rate of progression was faster
  - Lesser degrees of stenosis (p = 0.01)
  - Low serum albumen levels (p = 0.04)
  - Lack of beta-blockers (p = 0.01)
  - DM

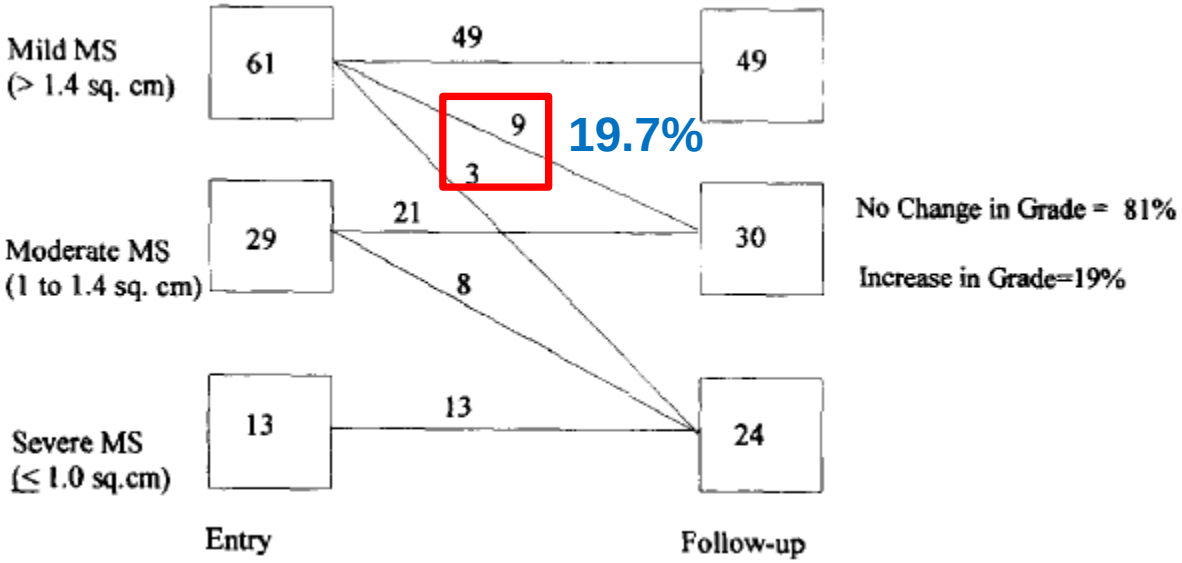
J Heart Valve Dis. 2014 Nov;23(6):707-12.

Doppler Echocardiographic Assessment of Long-Term Progression of Mitral Stenosis in 103 Patients: Valve Area and Right Heart Disease

ALEX SAGIE, MD, NELMACY FREITAS, MD, LUIS R. PADIAL, MD, MARCIA LEAVITT, ELEANOR MORRIS, RDCS, ARTHUR E. WEYMAN, MD, FACC, ROBERT A. LEVINE, MD, FACC

Boston, Massachusetts

- 103 patients (mean age 61 years, F: 74%)
- Follc to 11)
- Mea
- 35 p)n)



J Am Coll Cardiol 1996;28:472-9

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Bulletin of the World Health Organization

Bull World Health Organ. 1981; 59(2): 285–294. PMCID: PMC2396050

The community control of rheumatic fever and rheumatic heart disease: report of a WHO international cooperative project

T. Strasser, N. Dondog, A. El Kholy, R. Gharagozloo, V. V. Kalbian, O. Ogunbi, S. Padmavati, K. Stuart, E. Dowd, and A. Bekessy

- In developing countries, on the other hand, MS progresses much more rapidly, and may lead to symptoms in younger patients, typically in young adults, or in the teenage years

Rheumatic case !!

Question

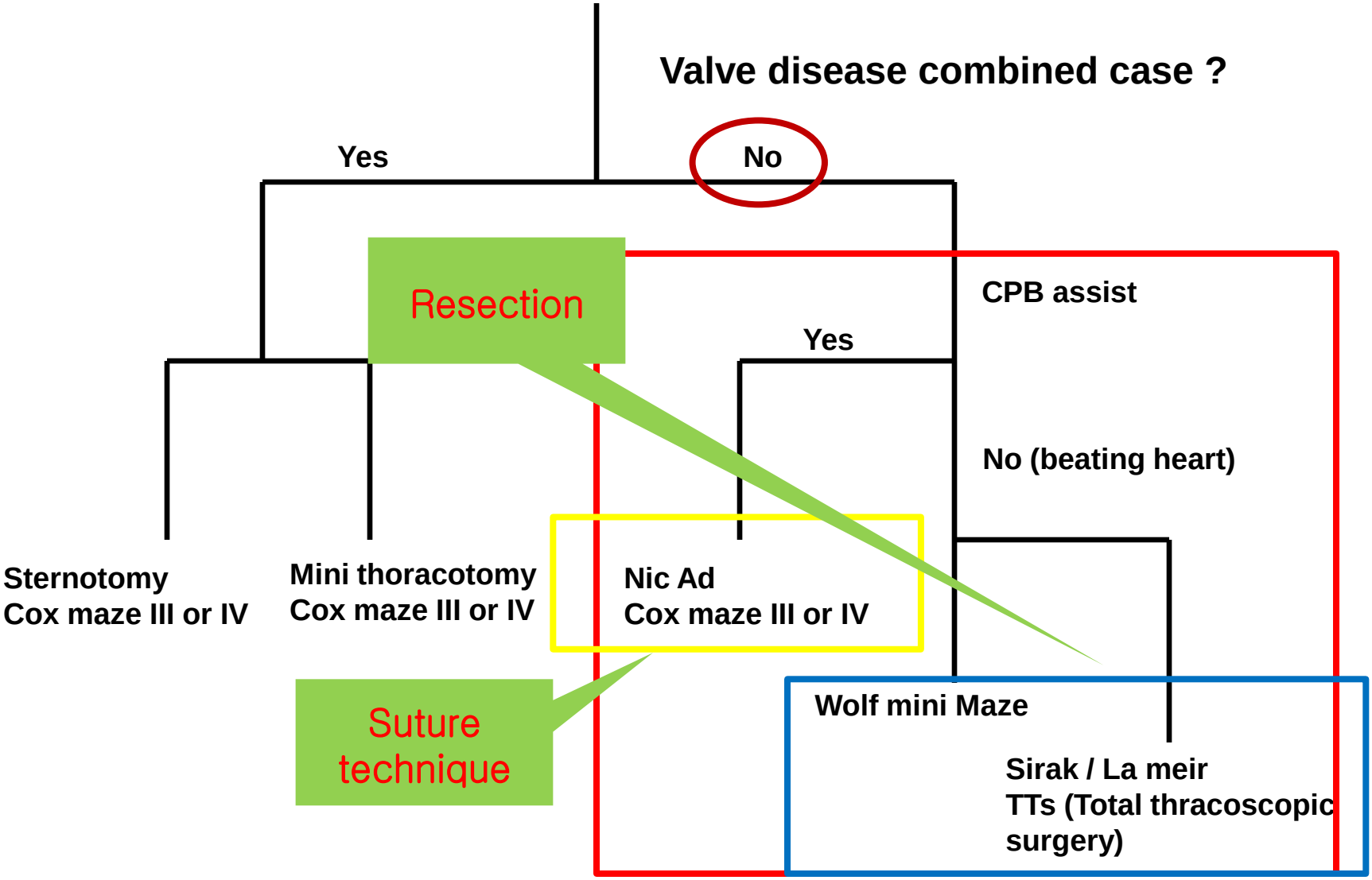
- **We have to consider open cardiac surgery for mitral valve within 5-6 years after LAA procedure.**

- **At time of reoperation, which procedure is more favorable to operator and patients?**

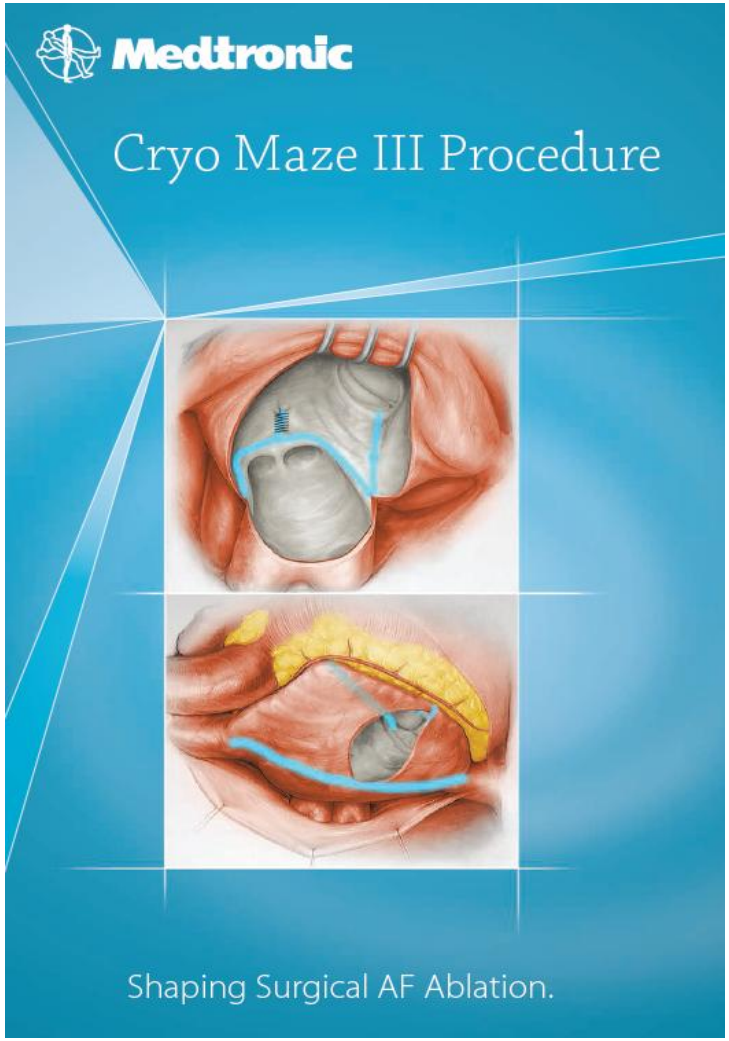
Issue 2

Brief surgical categories

Maze procedures for AF



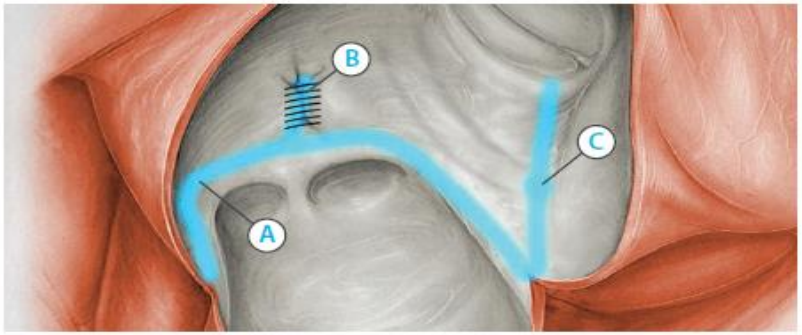
Modified Cox-Maze III

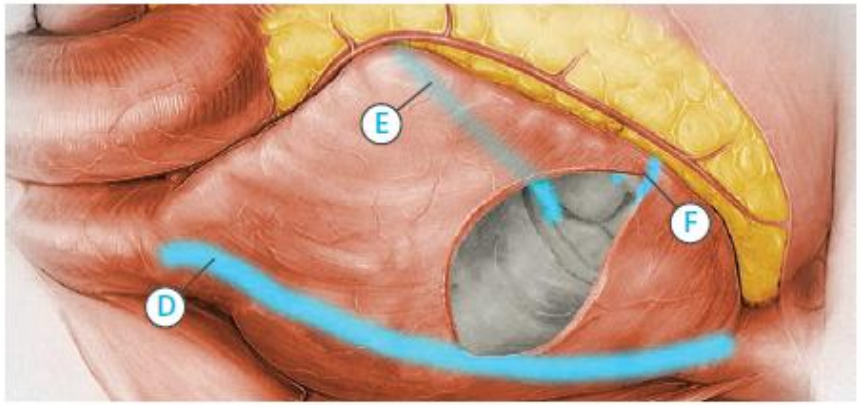


Designed for easy access.

The unique malleability of the Cardioblate® CryoFlex™ probe delivers argon-powered cyroablation for reproducible, transmural lesions. The probe tip can be reshaped by hand to create complete Maze III sets with a single probe.

Lesions of the Cryo Maze III Procedure





(A) Pulmonary Vein Isolation

Pulmonary vein isolation (PVI) prevents triggers in and around the pulmonary vein (PV) orifices from inducing atrial fibrillation.

Limitations of PVI alone—In a 293-patient study of paroxysmal patients

- 68% had triggers located exclusively within the PVs.
- 20% had triggers both within and outside of the PVs.
- 12% had exclusively non-PV triggers.

Therefore, pulmonary vein isolation alone will have limited success.[13]

Box versus pairs—A clinical study by Damiano et al, demonstrated that a box lesion around all four PVs is associated with a lower failure rate and lower use of postop AARx than isolation of the PVs in pairs.[14]

(B) Left Atrial Appendage Lesion

The left atrial appendage (LAA) lesion prevents reentrant circuits around the base of the left atrial appendage.[15]

(C) Mitral Line and Coronary Sinus Lesion

The mitral line and coronary sinus (CS) lesion stop left atrial isthmus-dependent flutter.

Benefit of the mitral-CS lesion—Success of left-sided procedures increases by 10% to 20% when the mitral line and coronary sinus lesions are included to block conduction across the left atrial isthmus.[7]

Importance of ablating the coronary sinus—The coronary sinus itself can conduct cardiac signals.[16] Up to 20% of Maze III patients will have atrial fibrillation recurrences, if both the mitral line and the CS lesion are not performed. "The only sure way to interrupt conduction along the coronary sinus is to cryoablate it."[17]

(D) Intercaval Lesion

The intercaval lesion from the superior vena cava (SVC) to the inferior vena cava (IVC) prevents macro-reentrant circuits from forming around the orifices of the superior and/or inferior vena cava.[18]

(E) Counter Lesion

The counter lesion prevents macro-reentrant circuits from forming around the base of the right atrial appendage.

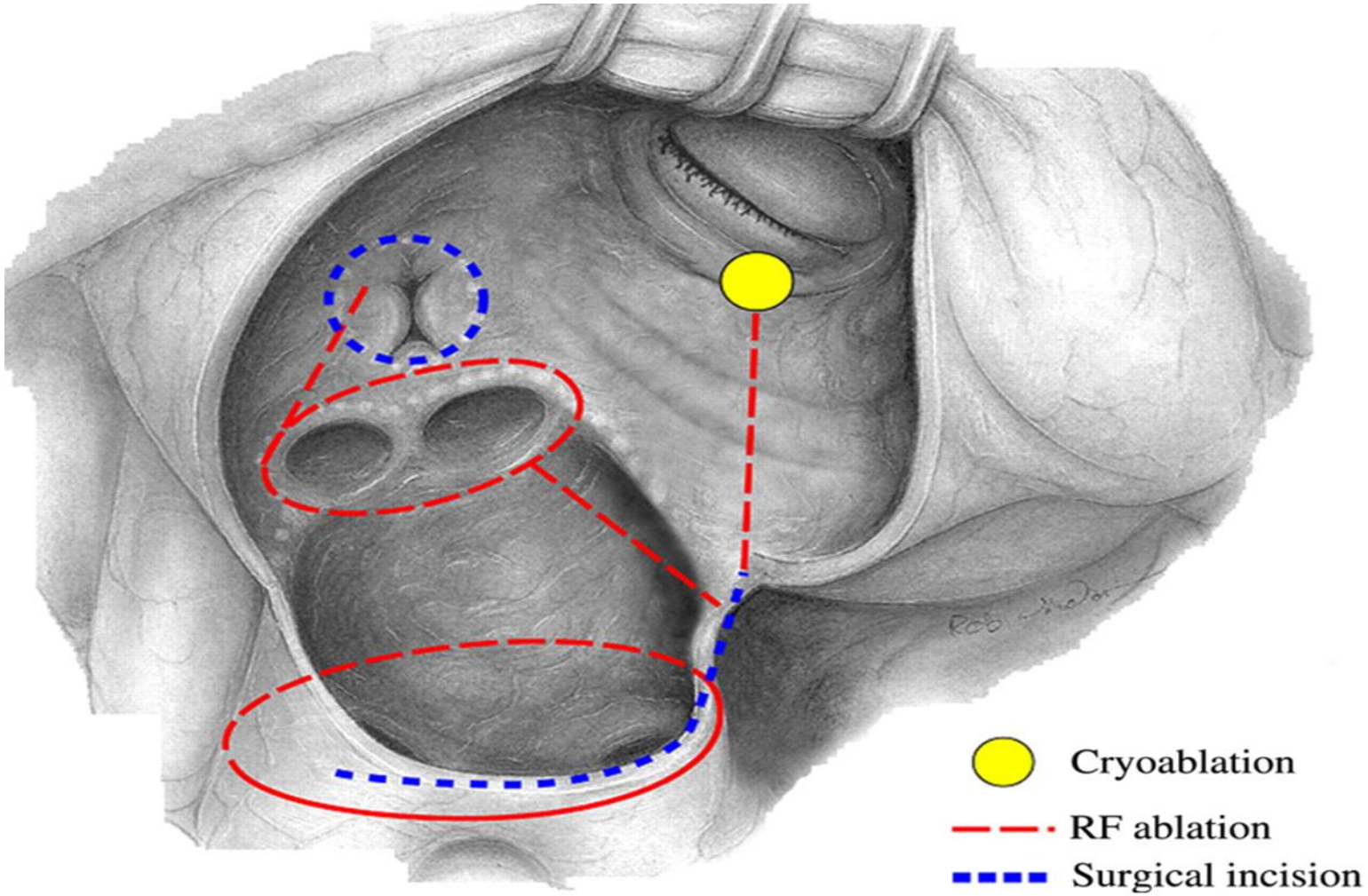
Dome lesion—For enlarged atria, this lesion can be extended across the top of the right atrial appendage onto the right atrial lateral wall toward the "T" lesion (leaving a 2-3cm gap).[19]

(F) "T" Lesion

Combined with the intercaval line and the counter lesion, the "T" lesion prevents both typical (isthmus-dependent) right atrial flutter and other macroreentrant atrial fibrillation.

"T" lesion versus "flutter line"—Although in some procedures, the "T" lesion and intercaval line are sometimes replaced by a cavotricuspid isthmus lesion, also known as a "flutter line"—the flutter line does not reduce the area of the RA to prevent it from sustaining reentrant atrial fibrillation.[18]

Cox-Maze IV

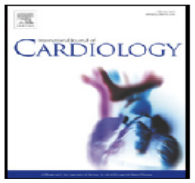


Issue 3

Result of Surgical therapy

Table 4
Minimally-invasive surgery for atrial fibrillation: morbidity.

Morbidity	N = 842	
Surgical complications	27	3.20%
Conversions	14	1.70%



ABSTRACT

Background: In this paper we present a systematic literature overview and analysis of the first results and progress made with minimally-invasive surgery using RF energy in the treatment of AF. The minimally-invasive treatment for atrial fibrillation (AF) tries to combine the success rate of surgical treatment with a less invasive approach to surgery. It has the additional potential advantage of ganglion plexus (GP) ablation and left atrial appendage exclusion. Furthermore, additional left atrial ablation lines (ALAL) can be created in non-paroxysmal AF patients.

Methods: For the search query multiple databases were used. Exclusion and inclusion criteria were applied to select the publications to be screened. All remaining articles were critically appraised and only relevant and valid articles were included in our results.

Results: Twenty-three studies were included. In 15 studies GPs around the pulmonary veins were ablated. In four studies ALAL were performed. Single procedure success rate was 69% (95% CI, range 58%–78%) without antiarrhythmic drugs (AAD) and 79% (95% CI, range 71%–85%) with AAD at one year follow-up. Mortality was 0.4%, and various complications were reported (3.2% surgical, 3.2% post-surgical, 2.6% cardiac, 2.1% pulmonary, 1.7% other).

Conclusions: Twenty-three studies of minimally-invasive surgery for AF have been reviewed with success rates between that of the standard maze procedure and catheter ablation. These first combined results show promise; however, minimally-invasive surgery is still evolving, for instance by the recent inclusion of electrophysiological endpoints. Furthermore, the type of ALAL and the additional value of GP ablation have to be elucidated.

LA: left atrium, LAA: left atrial appendage, PV: pulmonary vein, TIA: transient ischemic attack.

Minimal invasive surgery for atrial fibrillation: an updated review

Mark La Meir[1†], Sandro Gelsomino[1,2*†], Fabiana Lucà[1,2], Laurent Pison[1], Andrea Colella[2], Roberto Lorusso[3], Elena Crudeli[2], Gian Franco Gensini[2], Harry G. Crijns[1], and Jos Maessen[1]

[1]Department of Cardiothoracic Surgery and Cardiology, Academic Hospital Maastricht and Cardiovascular Research Institute Maastricht, Maastricht, The Netherlands; [2]Department of Heart and Vessels, Careggi Hospital, Via Delle Oblate 1, 50134, Florence, Italy; and [3]Civic Hospital, Brescia, Italy

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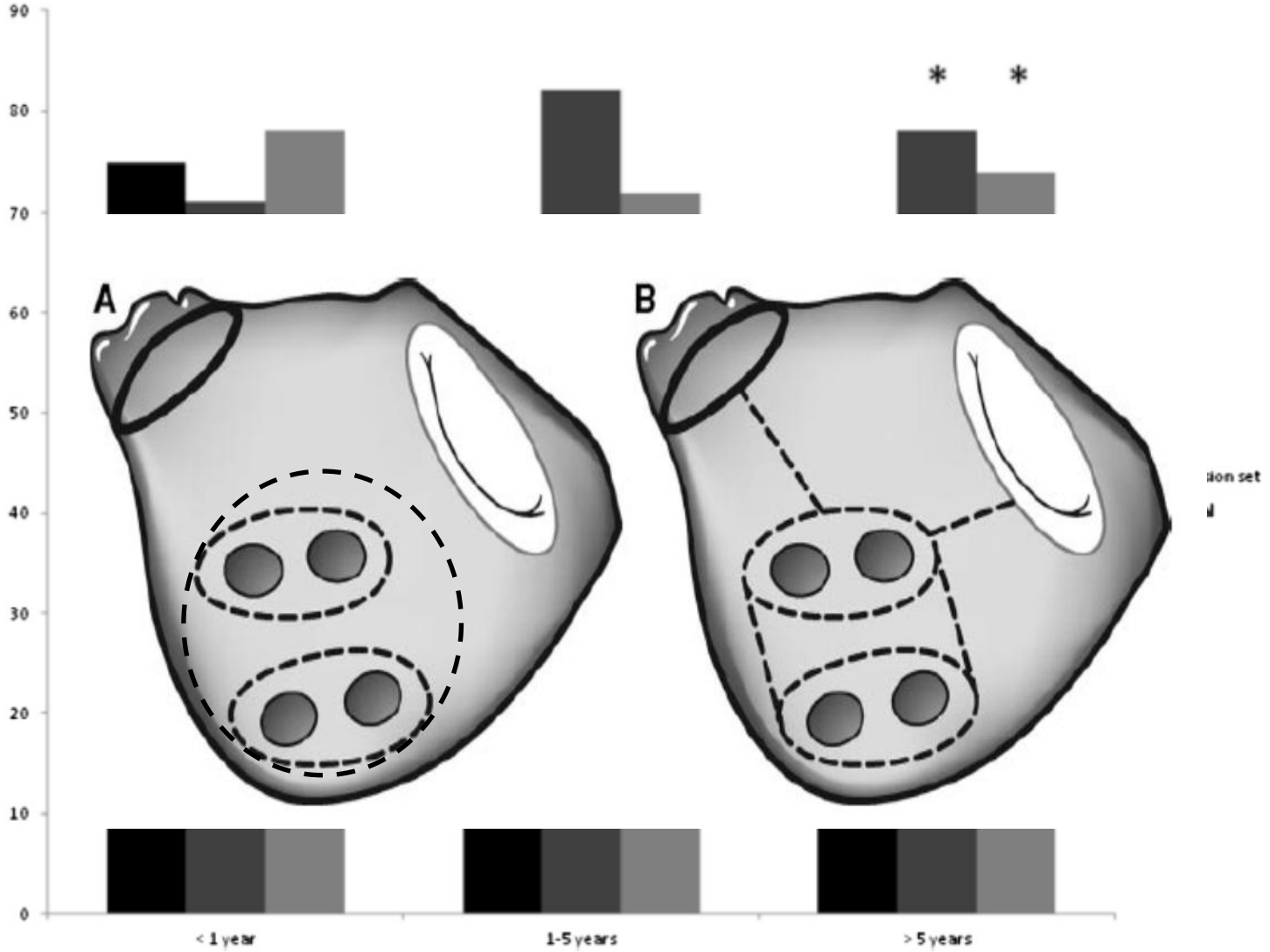
Conclusions

Minimally invasive surgical ablation of SA-AF achieved satisfactory 1-year results when the bipolar radiofrequency was employed as energy source with AAD-free success rate comparable to PCA. The success rate in paroxysmal was even higher than in PCA. In persistent and LSP, results were improved by additional LA ablation lines. In contrast, GP ablation and LAA removal seem not to influence the recurrence of AF and the occurrence of post-operative thromboembolic events. Nevertheless, the relatively high complication rate reported suggests that such techniques require further refinement. Finally, the preliminary results of the hybrid approach are promising but they need to be confirmed.

Europace (2013) 15, 170–182

Surgical ablation for atrial fibrillation for two decades: Are the results of new techniques equivalent to the Cox maze III procedure?

John M. [illegible] MD,
Joseph A [illegible] nd
Hartzell [illegible]



J Thorac Cardiovasc Surg 2014;147:1478-87

A minimally invasive Cox maze IV procedure is as effective as sternotomy while decreasing major morbidity and hospital stay

Christopher P. Lawrance, MD, Matthew C. Henn, MD, Jacob R. Miller, MD, Laurie A. Sinn, RN, BSN, Richard B. Schuessler, PhD, Hersh S. Maniar, MD, and Ralph J. Damiano, Jr, MD

- 356 retrospectively reviewed
- January 2002 to February 2014
- RMT=104 vs. ST =252

Conclusions: The Cox maze IV procedure performed through a right minithoracotomy is as effective as sternotomy in the treatment of atrial fibrillation. This approach was associated with fewer complications, decreased mortality and decreased length of stay in the intensive care unit and hospital length of stay. (J Thorac

years)

J Thorac Cardiovasc Surg 2014;148:955-62

Minimally Invasive Stand-Alone Cox-Maze Procedure for Patients With Nonparoxysmal Atrial Fibrillation

Niv Ad, MD, Linda Henry, PhD, Ted Friehling, MD, Marc Wish, MD, and Sari D. Holmes, PhD

Inova Heart and Vascular Institute, Falls Church, Virginia

- 104 stand-alone Cox-Maze procedures for non-PAF
- Right mini- thoracotomy (6 cm)
- Mean age (years): 55.9 ± 9.0
- 78% : long-standing persistent AF

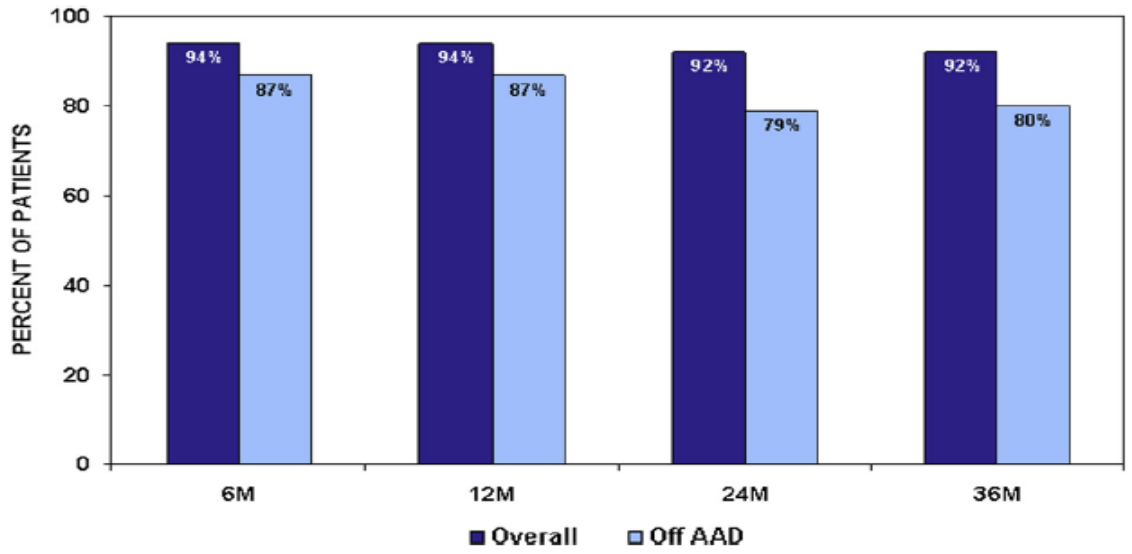
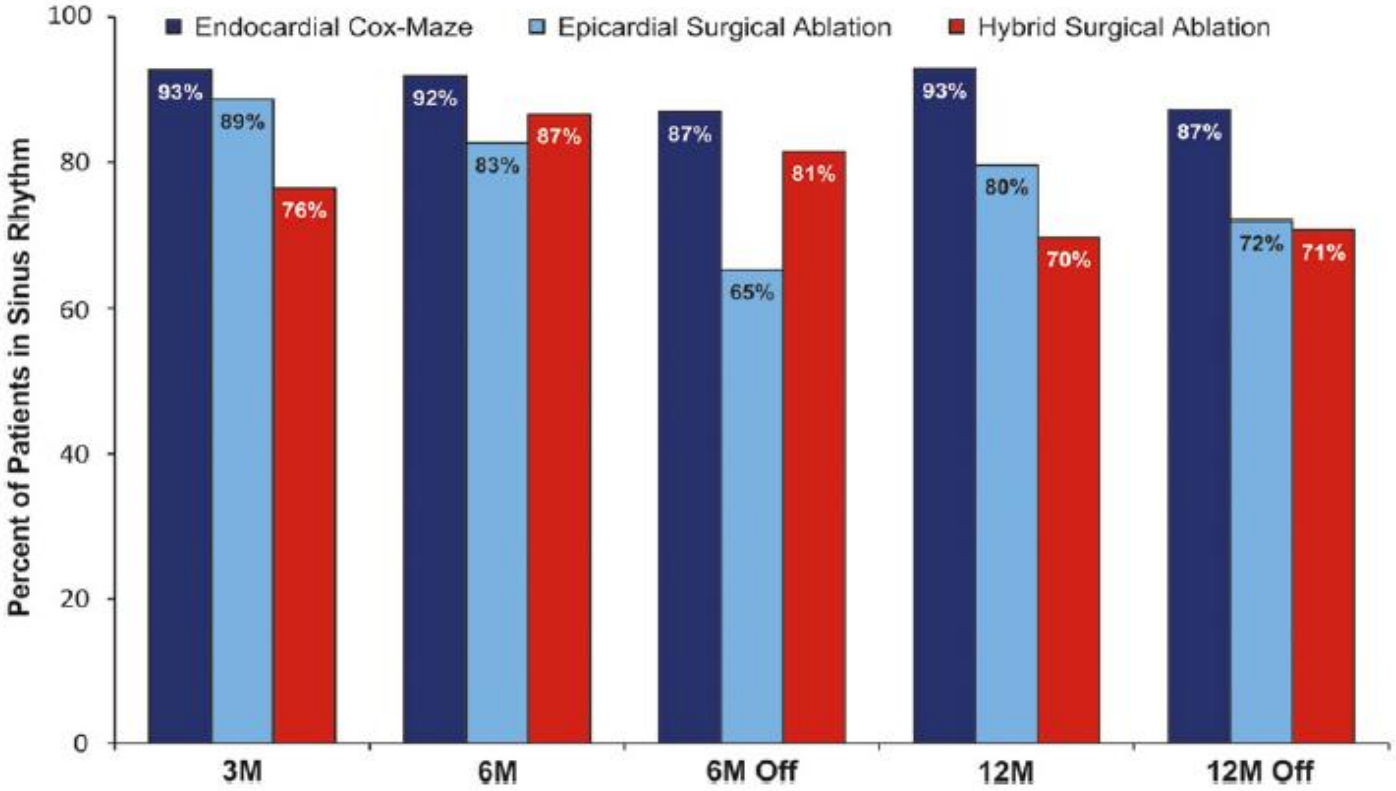


Fig 2. Return to sinus rhythm and sinus rhythm off antiarrhythmic drugs (AAD) is shown at 6, 12, 24, and 36 months after the Cox-Maze procedure.

Ann Thorac Surg 2013;96:792–9

A systematic review of minimally invasive surgical treatment for atrial fibrillation: a comparison of the Cox-Maze procedure, beating-heart epicardial ablation, and the hybrid procedure on safety and efficacy†

Hyung Gon Je, Deborah J. Shuman and Niv Ad*

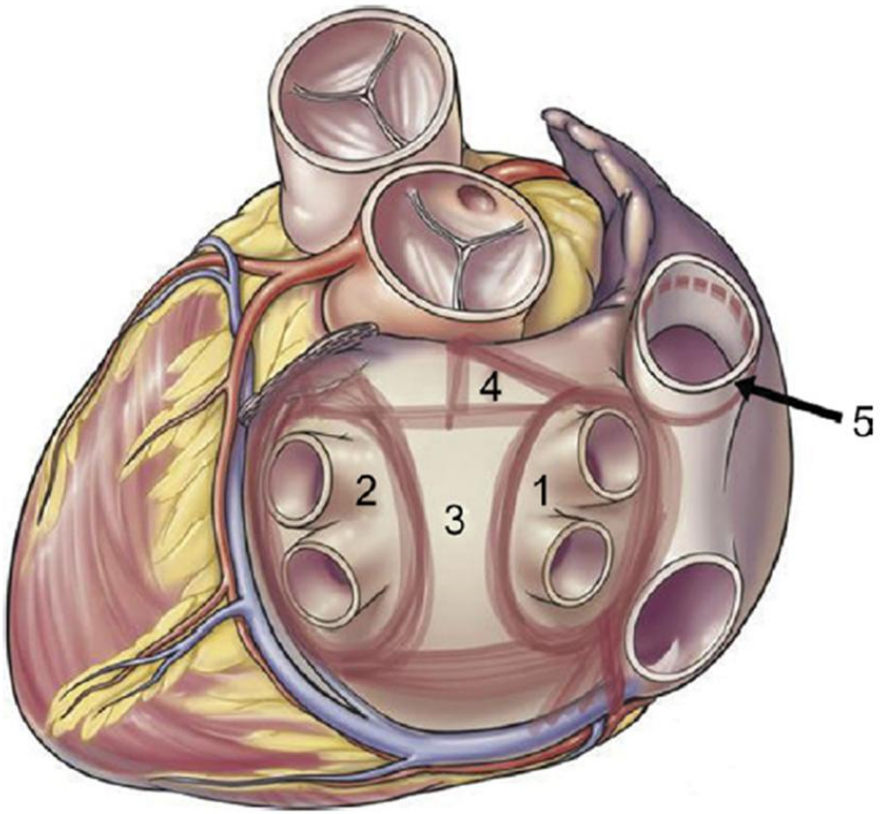


European Journal of Cardio-Thoracic Surgery 48 (2015)

Interim Results of the 5-Box Thoracoscopic Maze Procedure

John H. Sirak, MD, and David Schwartzman, MD

Division of Cardiac Surgery, Ohio State University, Columbus, Ohio; University of Pittsburgh Heart and Vascular Institute, Pittsburgh, Pennsylvania



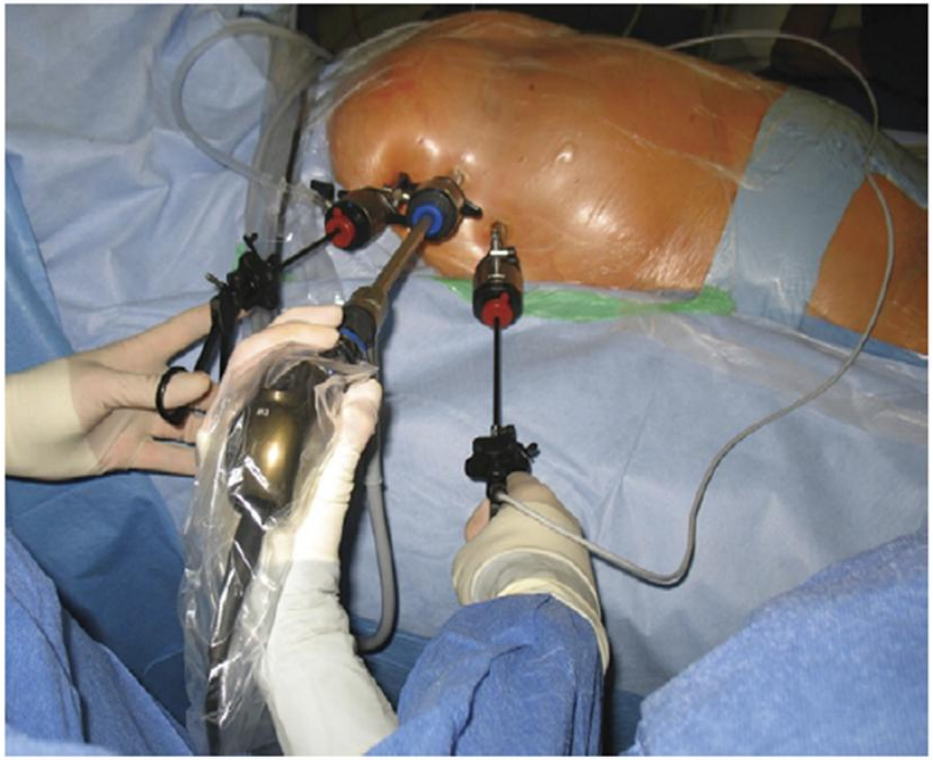
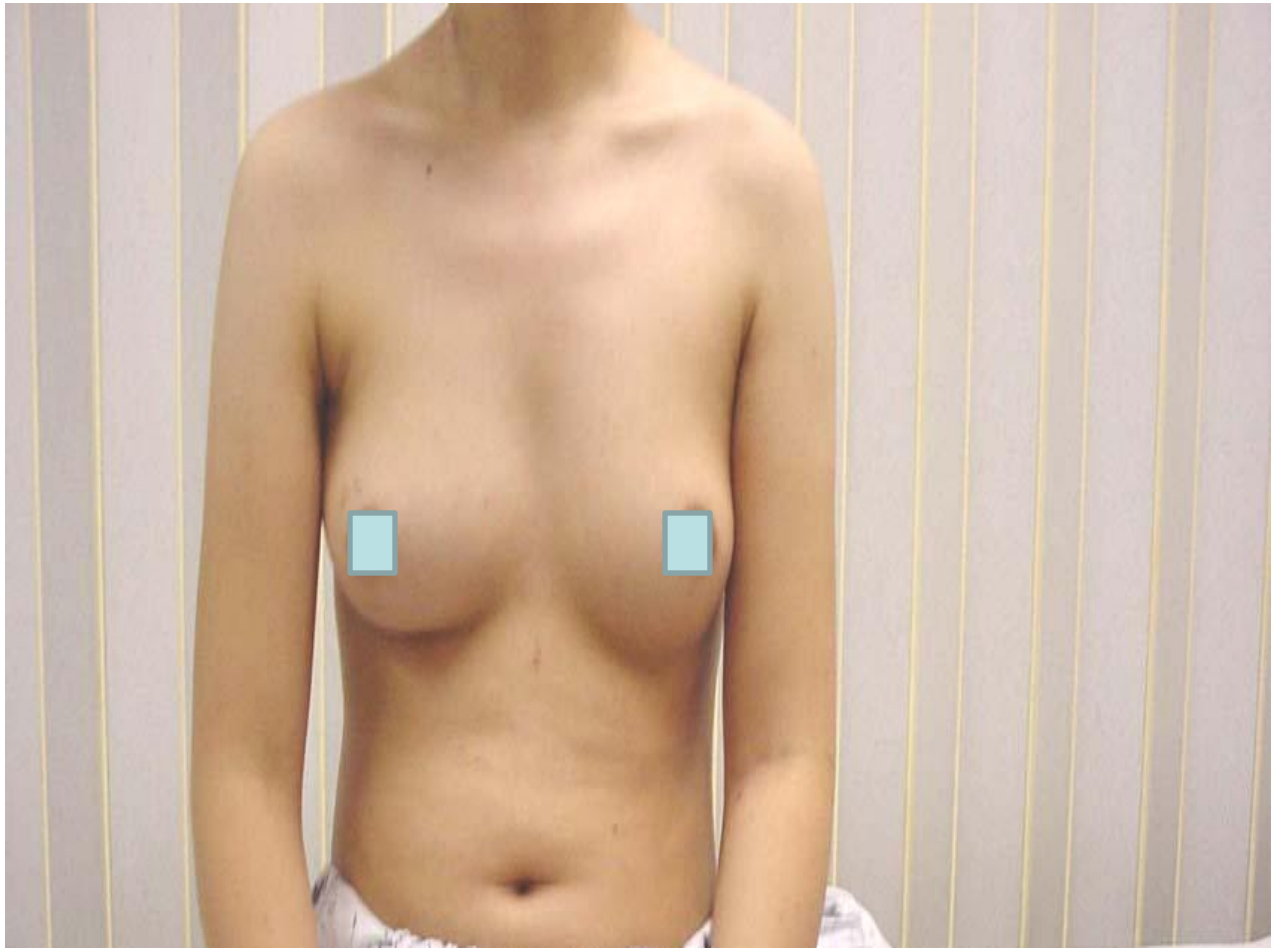


Fig 2. Port placement for thoracoscopic access on the right side of the chest.

Free

Free of AF off drugs

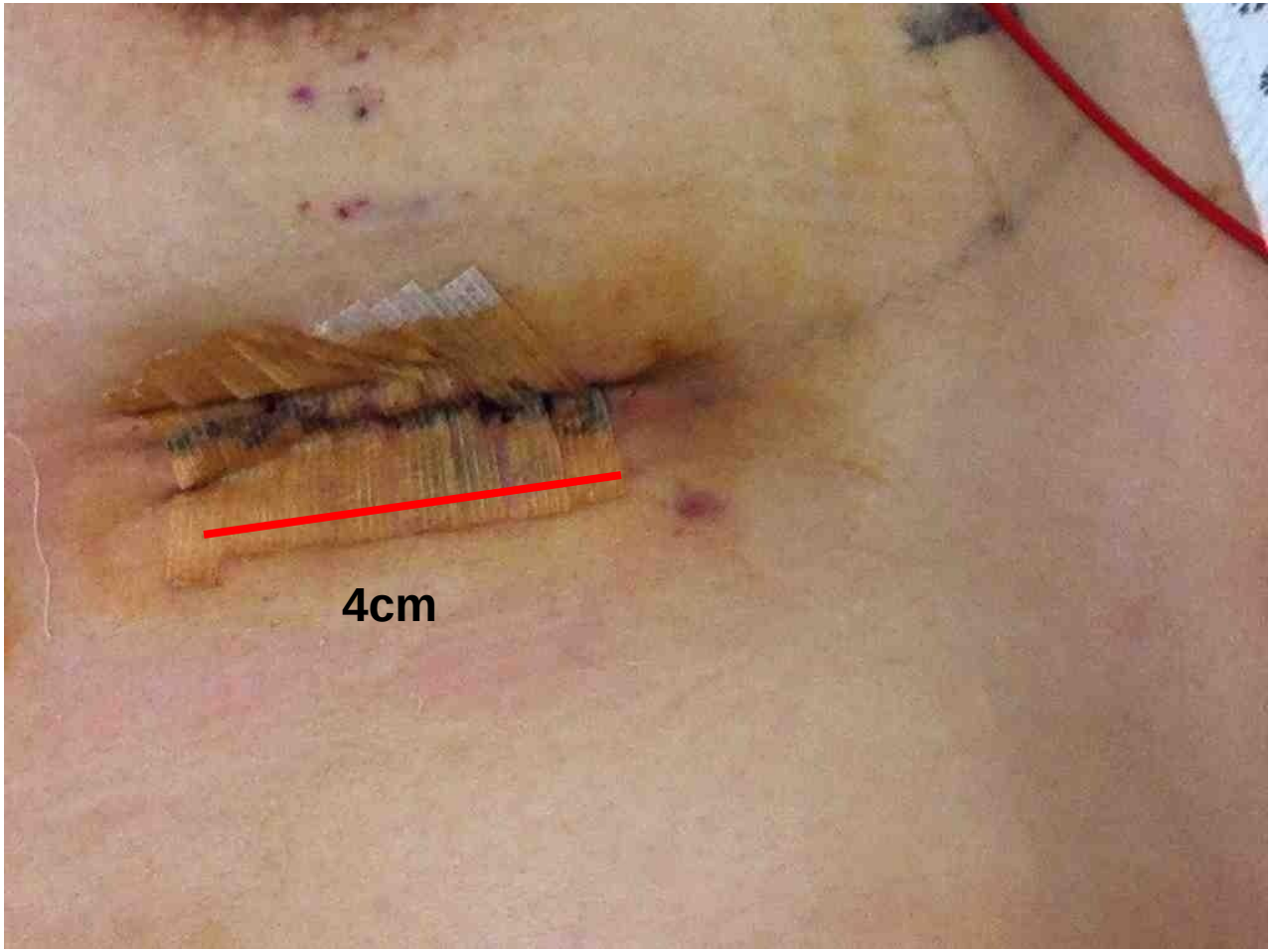
F/46 – MVP (Physio 30mm, T-resection of P2), Maze operation



Cryo-biatrial maze operation

Rt.mini-thoracotomy

Severance Wolf mini-Maze



Severance Thoracsopic maze

Issue 3

Why should we consider LAA excision or exclusion?

Stroke Prevention in AF

- AF increases stroke risk 5 fold
- Strokes more severe in patients with AF, with 70% chance of death or permanent disability

Seminars in Neurology. 2010;30:528–536

- AF-associated ischemic strokes generally occlude large intracranial arteries

Cerebrovascular Disease. 2010;30(4):389-95

- 91% of stroke in AF caused by thrombus formed in LAA

Cerebrovascular Disease. 2010;30(4):389-95

Stroke Prevention in AF

- Compared with non-AF patients, AF patients have poorer survival and more recurrent strokes

- Relative or absolute contraindications to anticoagulation present in up to 40% of AF patients, usually due to a history of bleeding or an elevated risk of falls and trauma.

Cardiol Res Pract. 2012; 2012: 610827

The Annals of Thoracic Surgery
Volume 61, Issue 2, February 1996, Pages 755–759

Current review

Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation

MD Joseph L. Blackshear[a, b], FRCS(Ed) John A. Odell[a, b]

Table 1. Review of Published Reports Detailing the Frequency and Site of Thrombus Location in Patients With Nonrheumatic Atrial Fibrillation

Setting	No. of Patients	Thrombus Location: LA Appendage	Thrombus Location: LA Cavity	Reference No.
TEE[a]	317	66	1	40
TEE	233	34	1	25
Autopsy	506	35	12	39
TEE	52	2	2	28
TEE	48	12	1	41
TEE and Operation	171	8	3	24
SPAF III TEE Study	359	19	1	42
TEE	272	19	0	26
TEE	60	6	0	43
Total	1,288	201	21	

15%

[a] 5% of this cohort had mitral stenosis or a prosthetic mitral valve.

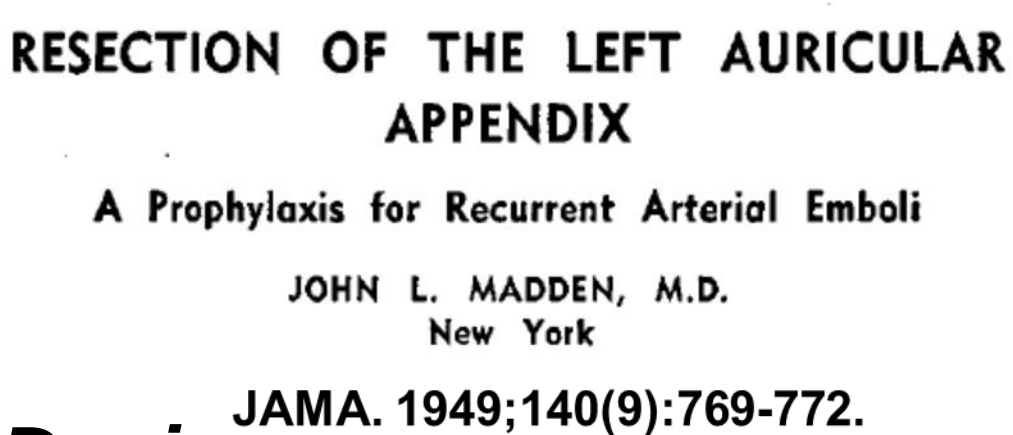
LA = left atrium; SPAF III = Stroke Prevention in Atrial Fibrillation Trial; TEE = transesophageal echocardiography.

LAA Management
What is Ideal Procedure?

- Complete (permenant) excision/exclusion
- Rapid and simple
- No bleeding risk

Surgical LAA Management

- **Suture closure**
  - **Two-layered closure**
  - **A**
- **Sta**
  - **S**
  - **B**
- ***New Devices***
  - **Safer and better**
  - **More expensive**



RESECTION OF THE LEFT AURICULAR APPENDIX

A Prophylaxis for Recurrent Arterial Emboli

JOHN L. MADDEN, M.D.
New York

JAMA. 1949;140(9):769-772.

Surgery

Left Atrial Appendage Occlusion Study (LAAOS): Results of a randomized controlled pilot study of left atrial appendage occlusion during coronary bypass surgery in patients at risk for stroke

Jeff S. Healey, MD,[a] Eugene Crystal, MD,[b] Andre Lamy, MD,[a] Kevin Teoh, MD,[a] Lloyd Semelhago, MD,[a] Stefan H. Hohnloser, MD,[c] Irene Cybulsky, MD,[a] Labib Abouzahr, MD,[a] Corey Sawchuck, MD,[a] Sandra Carroll, BSc,[a] Carlos Morillo, MD,[a] Peter Kleine, MD,[c] Victor Chu, MD,[a] Eva Lonn, MD,[a]

- 77 CABG patients randomized to LAA occlusion or control
- Problems: 9 LAA tears
- Failures: 30%

Am Heart J 2005;150:288-93

Success of Surgical Left Atrial Appendage Closure

Assessment by Transesophageal Echocardiography

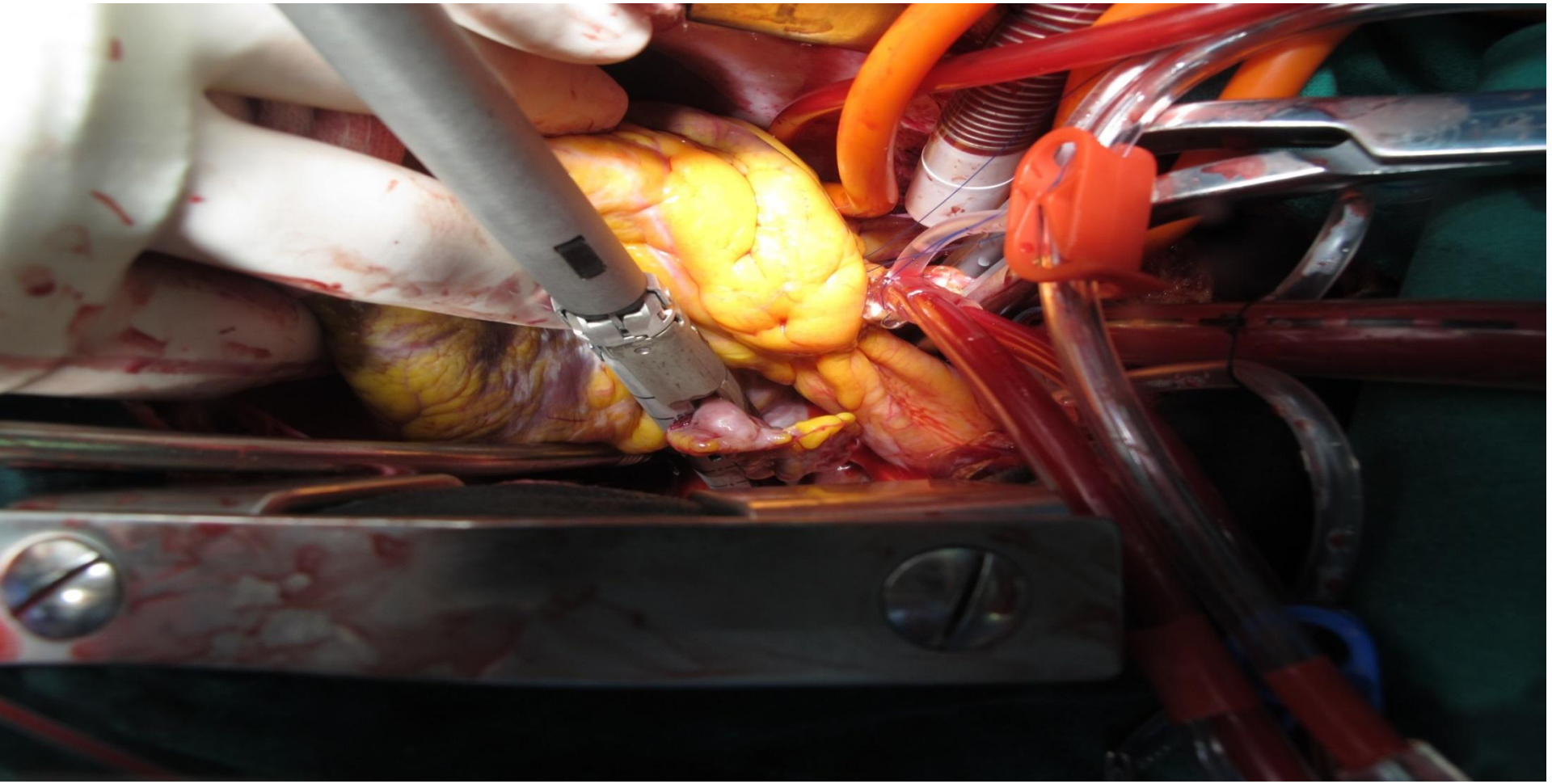
Anne S. Kanderian, MD,* A. Marc Gillinov, MD,† Gosta B. Pettersson, MD, PHD,†
Eugene Blackstone, MD,† Allan L. Klein, MD, FACC*
Cleveland, Ohio

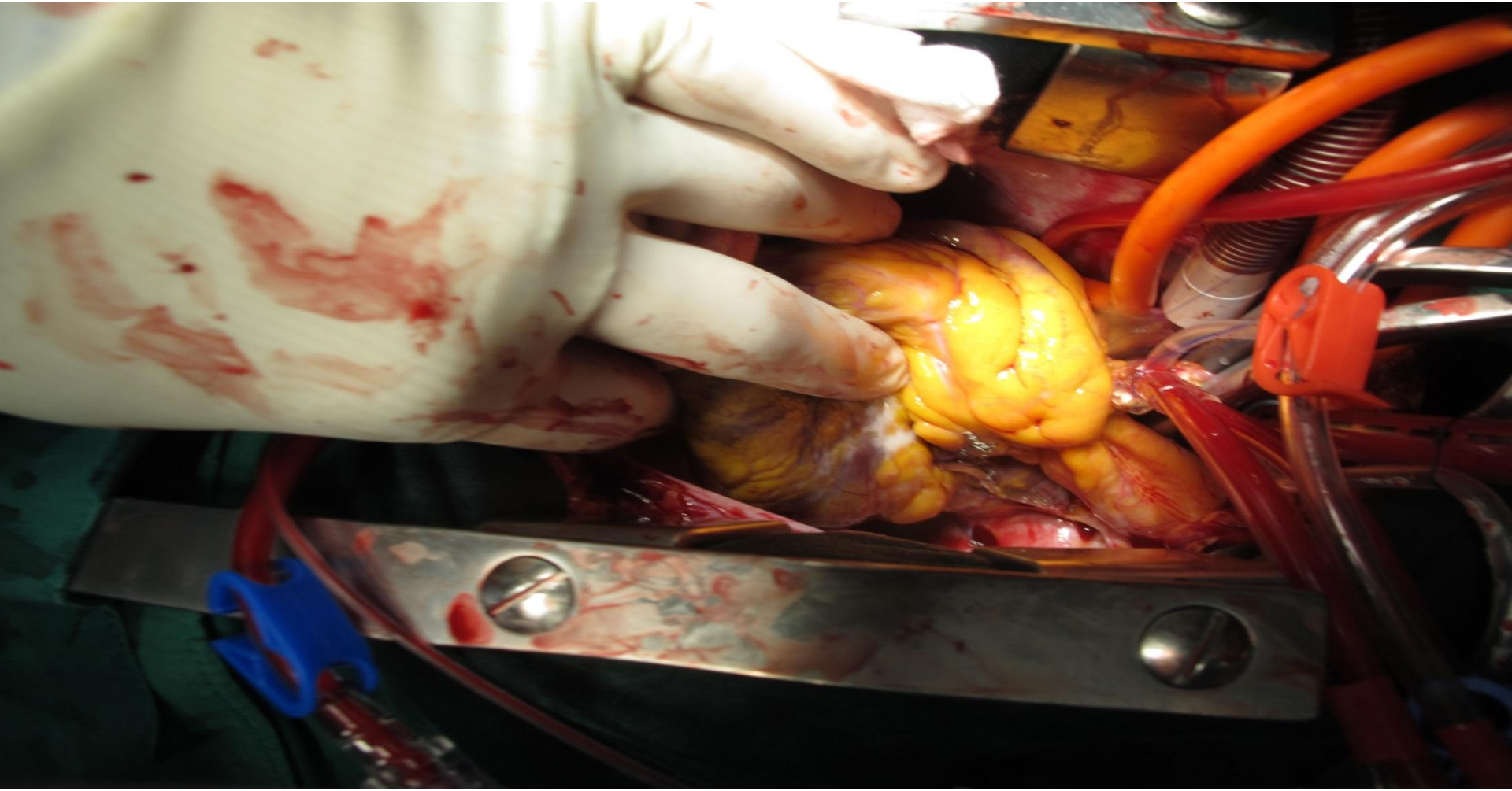
pler). Only 55 of 137 (40%) of closures were successful. Successful LAA closure occurred more often with excision (73%) than suture exclusion (23%) and stapler exclusion (0%) ($p < 0.001$). We found LAA thrombus to be present in 28 of 68 patients (41%) with unsuccessful LAA exclusion versus none with excision. At time of TEE, 6 patients with successful LAA closure (11%) and 12 with unsuccessful closure (15%) had evidence of stroke/transient ischemic attack ($p = 0.61$).

Conclusions There is a high occurrence of unsuccessful surgical LAA closure. Of the various techniques, excision appears to be the most successful. (J Am Coll Cardiol 2008;52:924–9) © 2008 by the American College of Cardiology Foundation

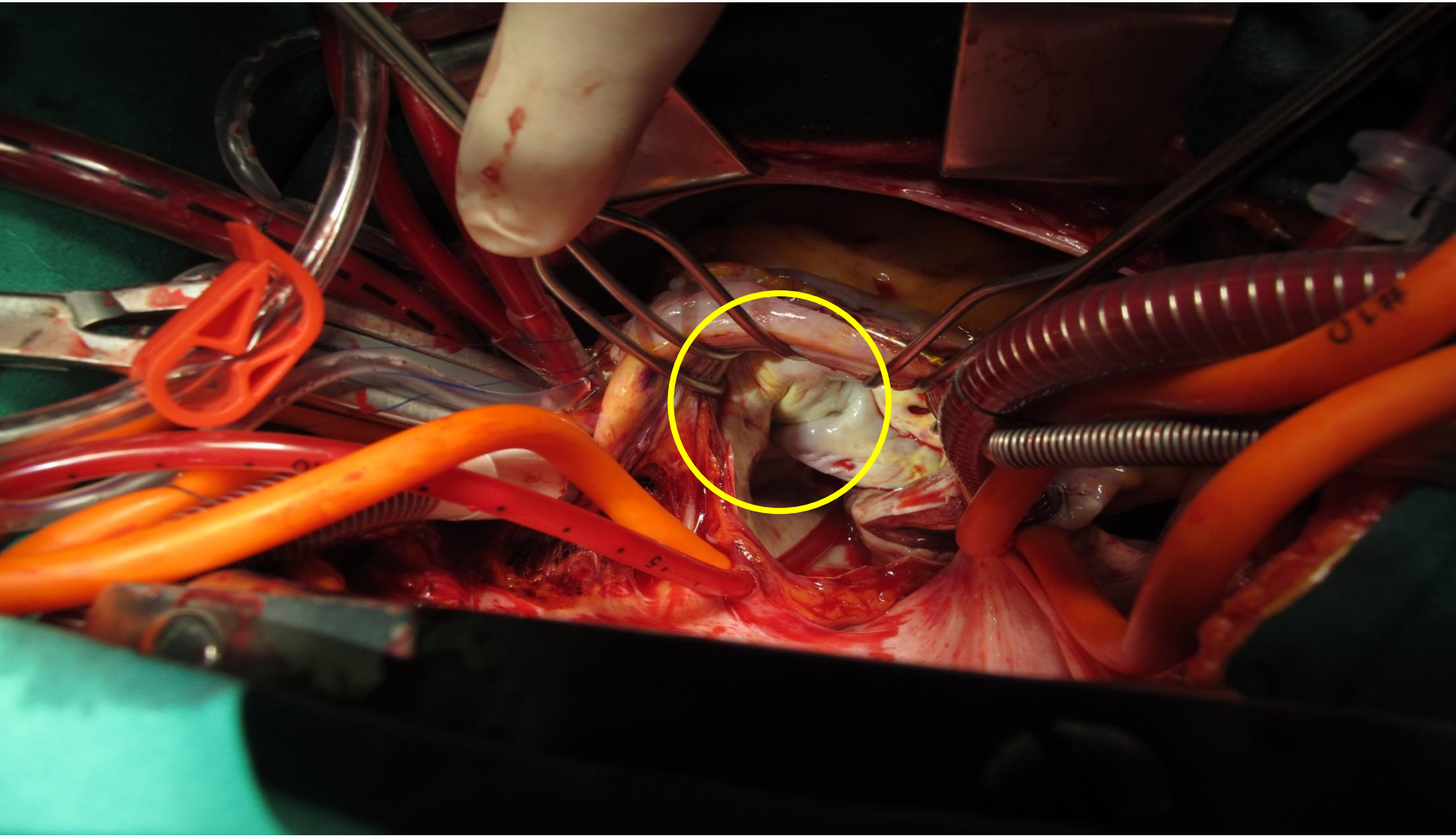
Recently this is not adjustable to real surgical field …

LAA excision by Endo-GIA (autosuture)





Clear inside (No residual stalk)



Recent evolving techniques

Device-Based Epicardial LAA Management

NEW TECHNOLOGY

Prospective Clinical Study of a Novel Left Atrial Appendage Occlusion Device

A. David Slater, MD, Antone J. Tatooles, MD, Arthur Coffey, MD, Patroklos S. Pappas, MD, Michael Bresticker, MD, Kevin Greason, MD, and Mark S. Slaughter, MD

Division of Thoracic and Cardiovascular Surgery, University of Louisville, Louisville, Kentucky; Advocate Christ Hospital and Medical Center, Oak Lawn, Illinois; Clarian Health Partners/Methodist Hospital, Indianapolis, Indiana; and Mayo Clinic/St. Mary's Hospital, Rochester, Minnesota

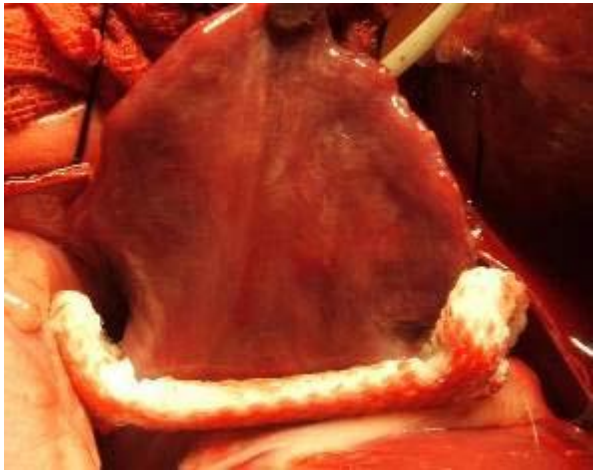
- 60 patient prospective trial
- 1 LAA tear (suture repair)
- 1 Device malfunction
- 90% Success
- 90 day follow-up
- Failure = Residual cavity (6 mm)

2015-04 Recall in market

- 4154 TigerPaw II devices currently in distribution have been recalled. All hospital stock is to be removed, quarantined, and returned to the company….

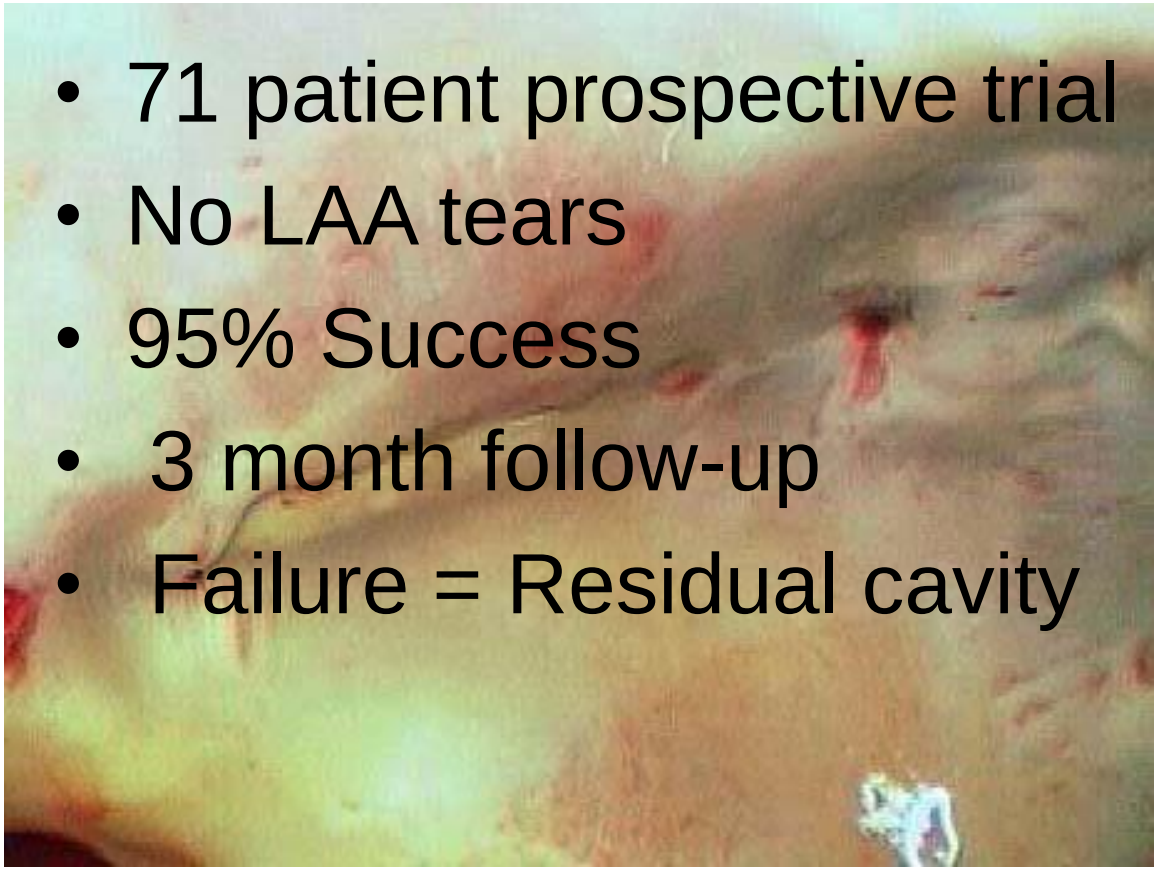
- Reports the device could cause tearing of the left atrial wall and bleeding, which the FDA says may or may not be caused by incomplete closure of the system's fastener.

AtriClip

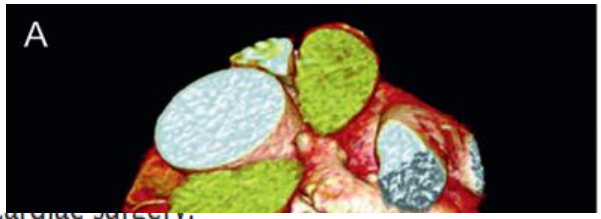


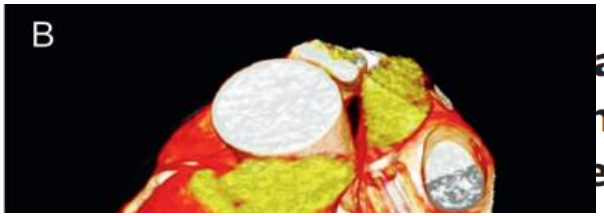
- **Parallel clamp design**
  - **Occludes LAA**
  - **Uniform clamping pressure**
  - **Cloth covering**

Endocardial View: 5 Months



Courtesy of Dr. Marc Gerdisch





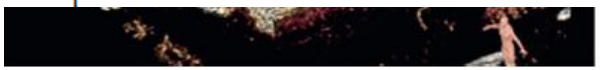
al appendage clip
ndergoing cardiac
ective device trial

cardiac surgery.

METHODS: Forty patients with AF were enrolled in this prospective 'first-in-man' trial. The inclusion criterion was elective cardiac surgery in adult patients with AF for which a concomitant ablation procedure was planned. Intraoperative transoesophageal echocardiography (TEE) was used to exclude LAA thrombus at baseline and evaluate LAA perfusion after the procedure, while computed tomography (CT) was used for serial imagery workup at baseline, 3-, 12-, 24- and 36-month follow-up.

RESULTS: Early mortality was 10% due to non-device-related reasons, and thus 36 patients were included in the follow-up consisting of 1285 patient-days and mean duration of 3.5 ± 0.5 years. On CT, clips were found to be stable, showing no secondary dislocation 36 months after surgery. No intracardial thrombi were seen, none of the LAA was reperfused and in regard to LAA stump, none of the patients demonstrated a residual neck >1 cm. Apart from one unrelated transient ischaemic attack (TIA) that occurred 2 years after surgery in a patient with carotid plaque, no other strokes and/or neurological events demonstrated in any of the studied patients during follow-up.

CONCLUSION: This is the first prospective trial in which concomitant epicardial LAA occlusion using this novel epicardial LAA clip device is 100% effective, safe and durable in the long term. Closure of the LAA by epicardial clipping is applicable to all-comers regardless of LAA morphology. Minimal access epicardial LAA clip closure may become an interesting therapeutic option for patients in AF who are not amenable to anticoagulation and/or catheter closure. Further data are necessary to establish LAA occlusion as a true and viable therapy for stroke prevention.



European Journal of Cardio-Thoracic Surgery 45 (2014) 126–131

Issue 4

How about the opposite ?
Current opinion about Watchman

- The WATCHMAN device :
  - First LAA closure device
  - 2 pivotal randomized studies
  - PROTECT AF
  - PREVAIL
- PROTECT AF
- PREVAIL

specific labeling for the device if approved and to recognize the limitations of the present data (conflicting findings across trials, lack of information against patients who cannot take warfarin, and for those who are on NOACs). Following the third panel, it is anticipated that the device will be approved for marketing in the United States with limited labeling. Robust postmarketing studies would require addressing the residual concerns and the unanswered questions to find the optimal application of the WATCHMAN device in the right patient population.

Am J Cardiol 2015;115:378e384

Problems in Addition to Stroke and Bleeding After Left Atrial Appendage Closure

as an alternative for stroke prevention in patients with atrial fibrillation (AF) in whom oral anticoagulation is not possible because of contraindications about a high bleeding risk. However, according to the protocol of the WATCHMAN investigating trials, anticoagulant and antiplatelet therapies are mandatory after implantation of the device: A combination of warfarin plus aspirin 81 mg is recommended through 45 days after implantation, followed by aspirin 325 mg plus clopidogrel 75 mg through 6 months after implantation, followed by indefinite use of aspirin 325 mg. Previous studies in patients with AF showed, however, that the combination of aspirin with clopidogrel was associated with a major bleeding rate of

despite implantation of the device.

The combined therapy with warfarin and aspirin for 45 days after device implantation may even prevent complete LAA sealing and, thus, promoting leaks between the LAA wall and the device. Incomplete LAA exclusion creates a pouch with stagnant blood flow, which enhances thrombus formation. The high blood flow velocity jet at the small LAA orifice may promote embolization of thrombotic material from inside.

The LAA myocardium has a higher distensibility than the left atrial myocardium. Progressive dilation of the LAA is observed in AF, and thereby, leakage of an initially completely closed LAA may occur.[4] Because it is unknown how many

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31 March 2015

Am J Cardiol 2015;116:335e338

Procedural risk

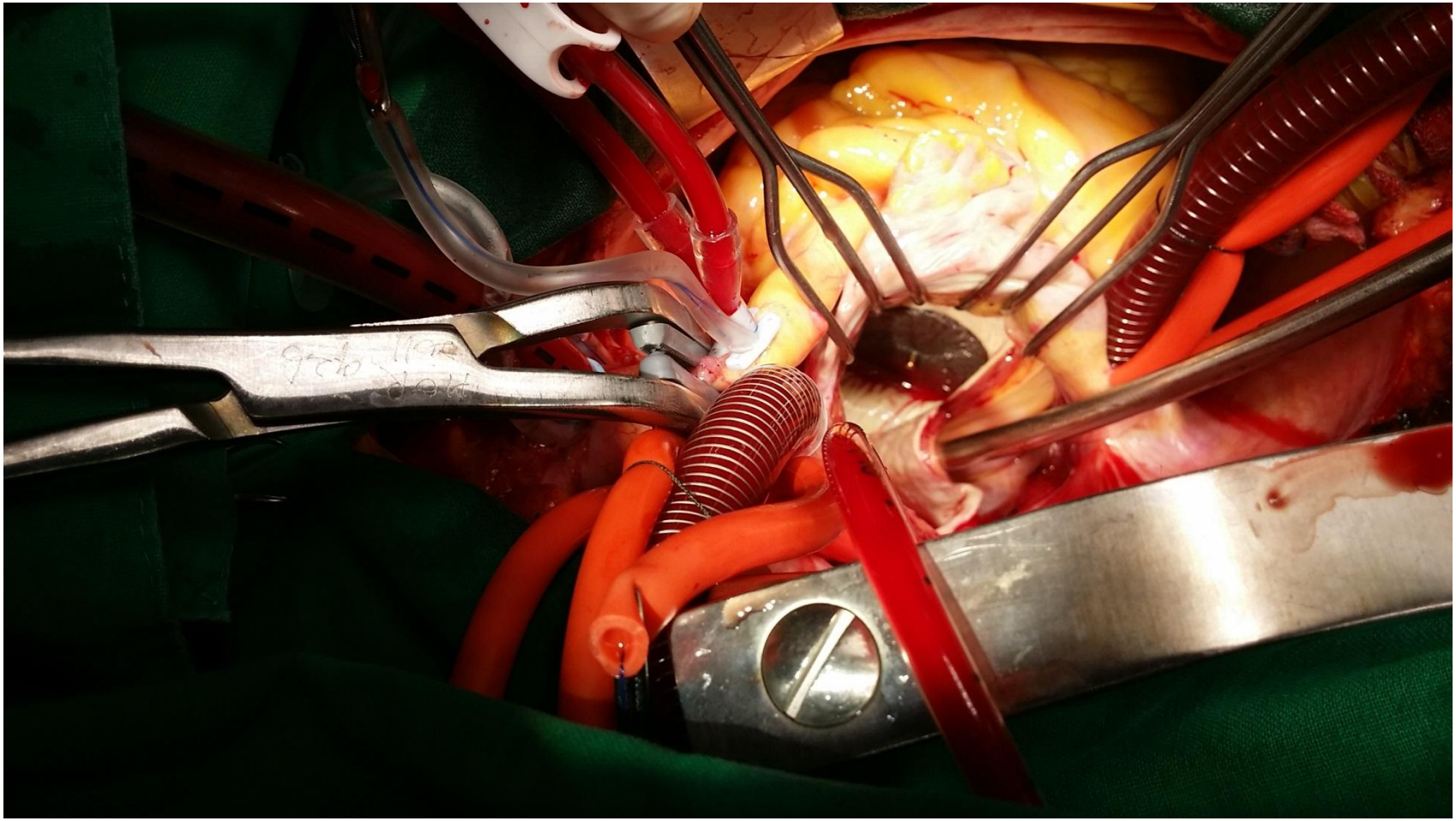
Implantation of the WATCHMAN

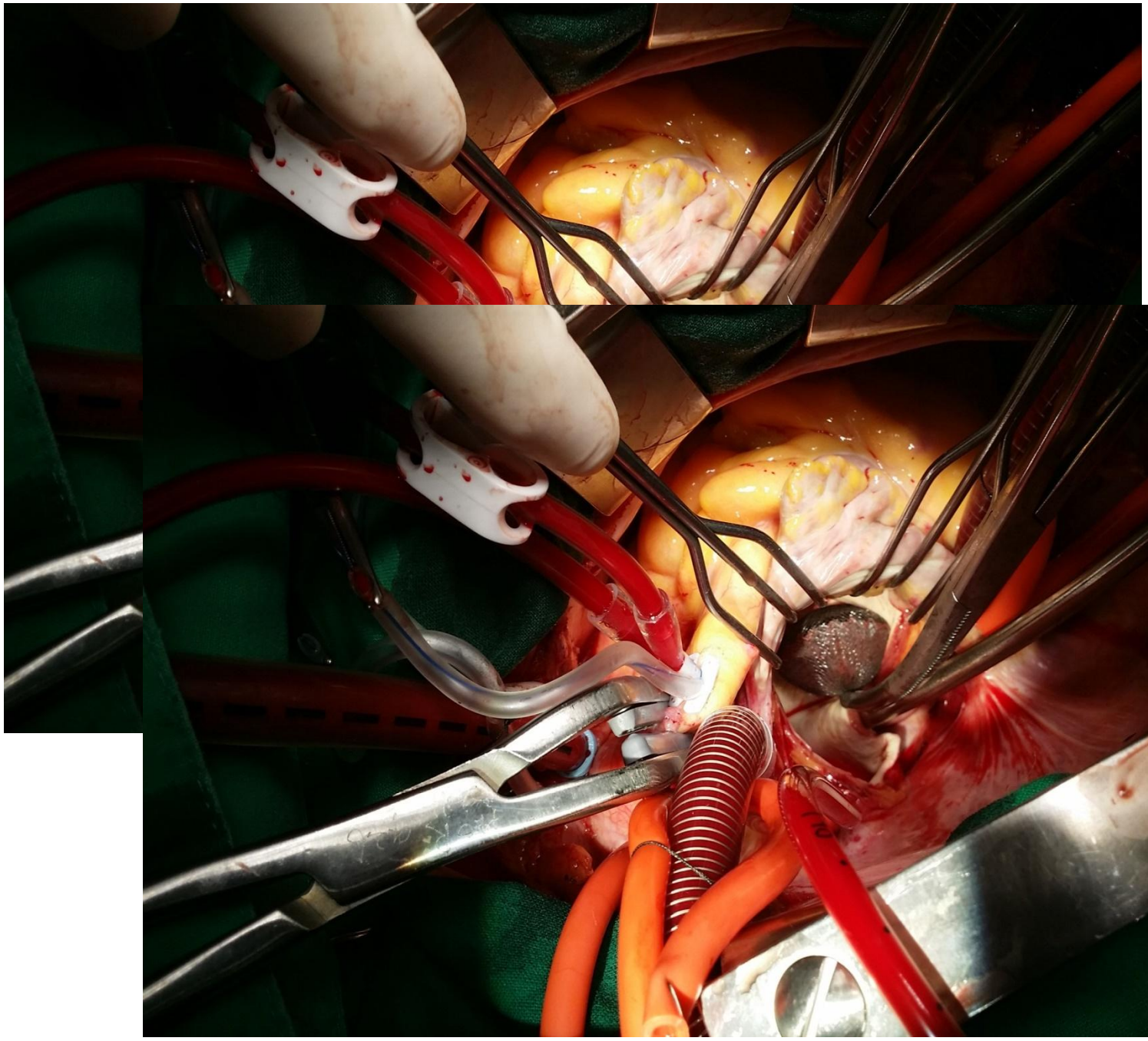
- 449 WATCHMAN implants -12.3%
  - Pericardial effusion requiring drainage or surgery in 5%
  - Acute ischemic stroke due to air or thromboembolism in 1%
  - Four (1%) required device removal due to device embolization or postimplant sepsis

The PROTECT AF trial, Am Heart J 2006;151:956-61

LAA occluder migration

- M /79-





CARDIOVASCULAR FLASHLIGHT

doi:10.1093/eurheartj/ehv077

Watch out for the WATCHMAN

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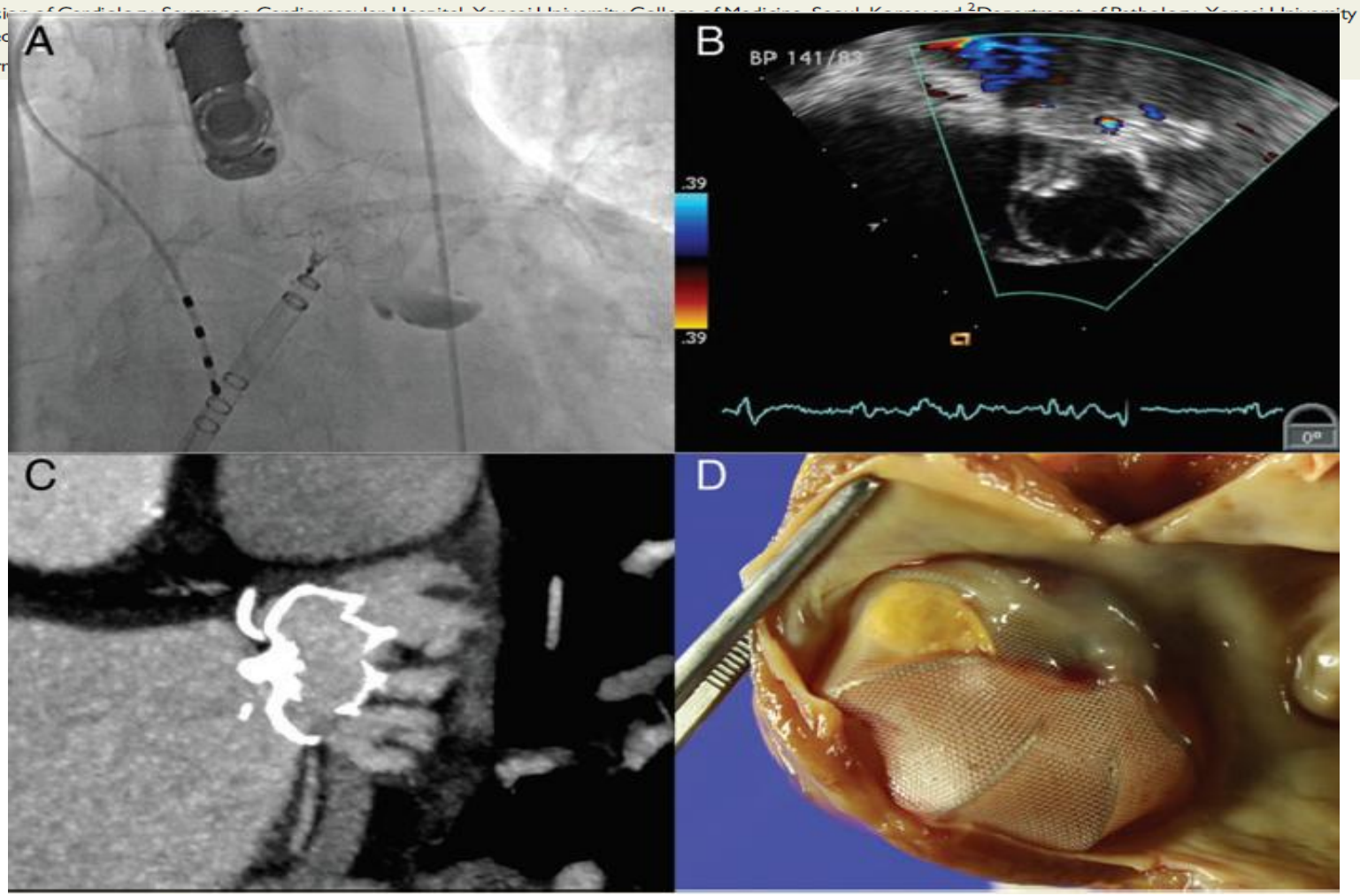
* Corr…

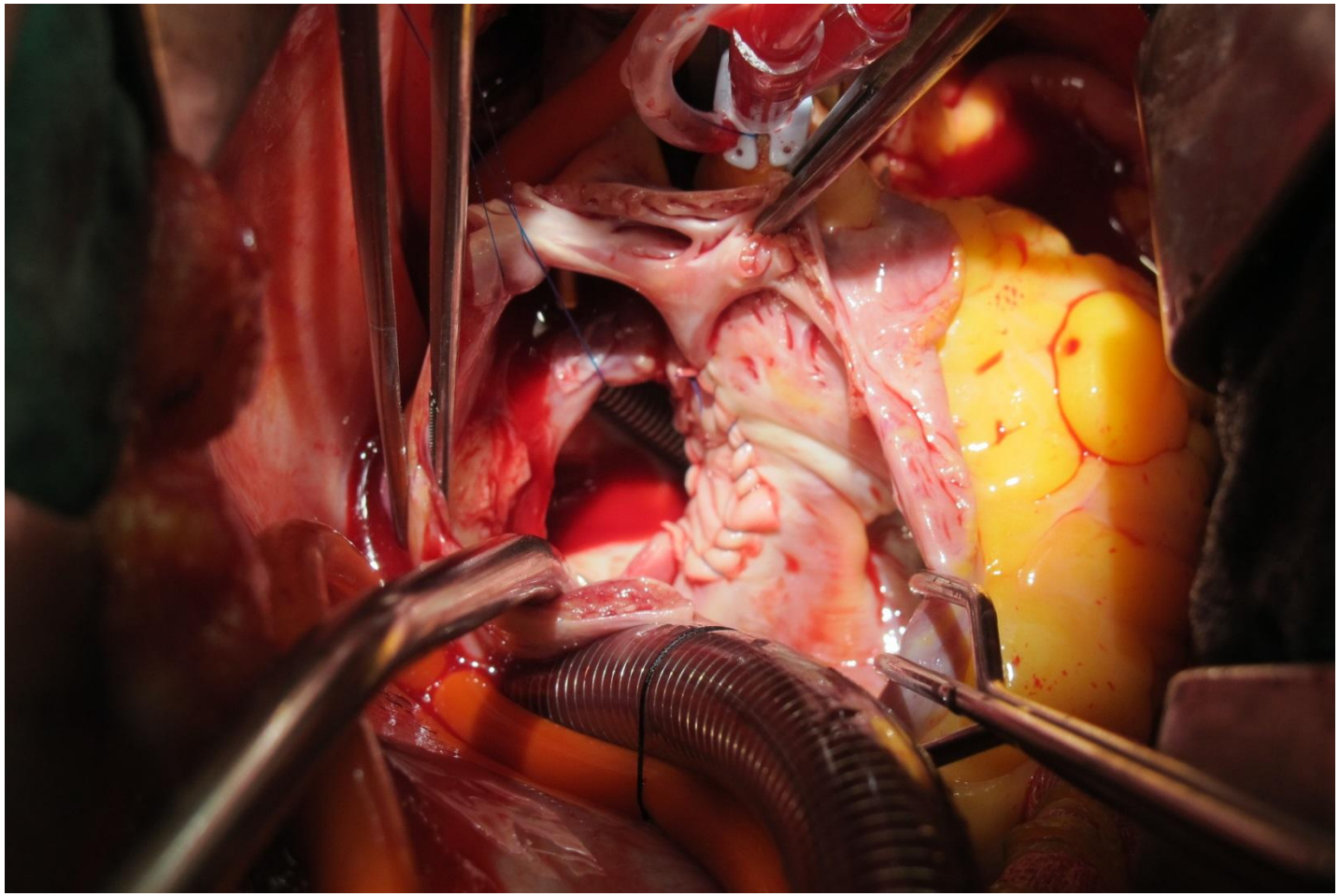


European Heart Journal Advance Access published April 1, 2015

Complete endothelialization?

No healing process

Disaster from infection



Issue 5

Patient charge

Cost comparison

	Total Cost (kw)	Device (kw)
Cryo maze operation (10 days)	9,234,258	3,524,738
RF maze operation (10 days)	9,936,779	6,502,817
LAA occlude procedure (4, 21 days)	17,733,526	9,773,587 8,834,000 780,000

Rhythm control + LAAE **Vs.** **Only LAAE**

Procedure time

	Time (hrs)
Cryo maze operation (maze + LAA exclusion)	2
RF maze operation (maze + LAA resection)	2
LAA occlude procedure (Only exclusion)	?

Summary

- **Clear, certain and complete result !**
- **Consider procedure economics !**
- **Killing two birds with one stone !**

Thank you for your attention!

When LAA must be excluded?

- LAA obliteration/exclusion when mitral valve surgery is performed …ACC/AHA guideline 2006
- patients with AF also include LAA exclusion from systemic circulation whenever possible during cardiac surgery in patients at risk of developing postoperative AF …ACC/AHA/ESC 2006 guidelines
- LAA is also occluded/excluded when Maze procedures for ablation of AF are performed…
- LAA exclusion is also indicated in patients with chronic AF who have a contraindication to chronic anticoagulation

TABLE 3 Definitions of AF: A Simplified Scheme

Term	Definition
Paroxysmal AF	• AF that terminates spontaneously or with intervention within 7 d of onset. • Episodes may recur with variable frequency.
Persistent AF	• Continuous AF that is sustained >7 d.
Long-standing persistent AF	• Continuous AF >12 mo in duration.
Permanent AF	• The term "permanent AF" is used when the patient and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm. • Acceptance of AF represents a therapeutic attitude on the part of the patient and clinician rather than an inherent pathophysiological attribute of AF. • Acceptance of AF may change as symptoms, efficacy of therapeutic interventions, and patient and clinician preferences evolve.
Nonvalvular AF	• AF in the absence of rheumatic mitral stenosis, a mechanical or bioprosthetic heart valve, or mitral valve repair.

AF indicates atrial fibrillation.

Minimally invasive surgery for atrial fibrillation

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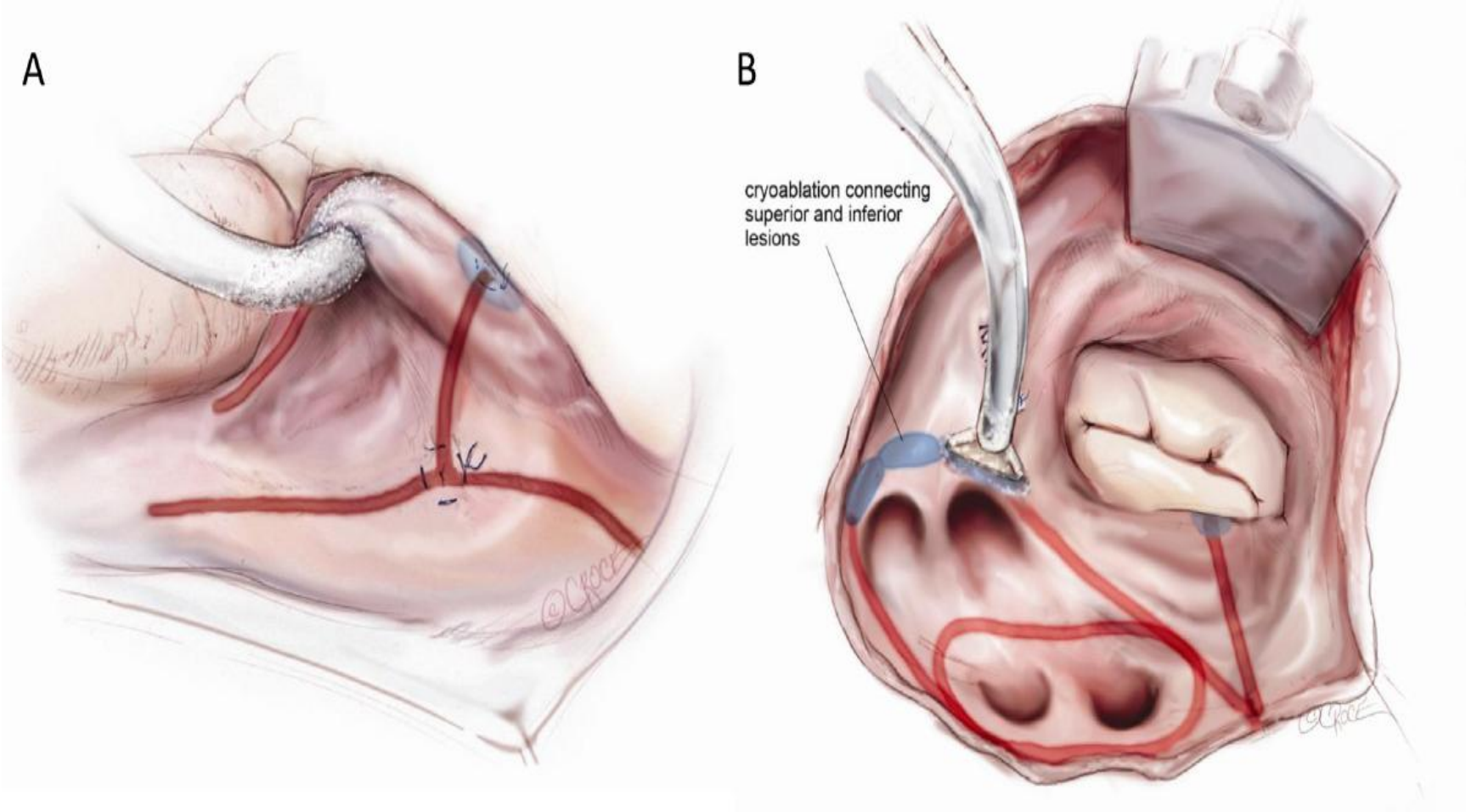

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