STS/EACTS Latin America Cardiovascular Surgery Conference November 15-17, 2018 Hilton Cartagena | Cartagena, Colombia The Society of Thoracic Surgeons EACTS

The Left Atrial Appendage – Should it be **Closed in every Open Cardiac Surgical Case**

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Disclosures

- Founding Member HRT- Equity interest
- None regarding this presentation

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Surgical LAAO – Overview

- Success and methods
- Role in stroke prevention
- Current trials
- Guidelines

LAA exclusion - successful

- No spontaneous echo contrast
- No demonstrable flow on TEE
- Residual stump < 1cm

st E

Endo-Cardial ligation during mitral surgery

- 36% had spontaneous echo contrast
- 22% thromboembolic event

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Surgical Left Atrial Appendage Ligation Is Frequently Incomplete: A Transesophageal Echocardiographic Study Edward S. Katz, MD, FACC, Theofanis Tsiamtsiouris, MD, Robert M. Applebaum, MD, FACC, Arthur Schwartzbard, MD, FACC, Paul A. Tunick, MD, FACC, Itzhak Kronzon, MD, FACC New York, New York

Vol. 36, No. 2, 2000 ISSN 0735-1097/00/\$20.00 PII S0735-1097(00)00765-8

LAAOS

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 and Stuart J. Connolly, MD^a Toronto and Hamilton, Ontario, Canada, and Frankfurt, Germany

LAAOS

- Suture ligation vs stapler
- 20% appendage tears
- Suture ligation- 45% successful
- Staple exclusion 72% successful
- Learning curve of 4 cases success rate increased to 87%
- 2.6% pts had periprocedural stroke

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ccess rate increased to 87% stroke

Cleveland Clinic Retrospective TEE study

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Success of Surgical Left Atrial Appendage Closure

Assessment by Transesophageal Echocardiography

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Vol. 52, No. 11, 2008 ISSN 0735-1097/08/\$34.00 doi:10.1016/j.jacc.2008.03.067

Cardiac Surgery

Cleveland Clinic Retrospective TEE study

- 40% successful closure
- Excision>Suture Ligation>Staple exclusion
- If LAA is left intact suture and staple gradually cut through overtime
- Surgical excision no thormbi in incomplete exclusion

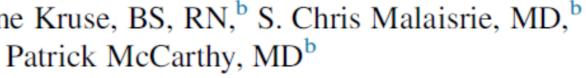
Comparison - LAA elimination techniques

ACQUIRED: ARRHYTHMIAS

A randomized, prospective pilot comparison of 3 atrial appendage elimination techniques: Internal ligation, stapled excision, and surgical excision

Richard Lee, MD, MBA,^a Patricia Vassallo, MD,^b Jane Kruse, BS, RN,^b S. Chris Malaisrie, MD,^b Vera Rigolin, MD,^b Adin-Cristian Andrei, PhD,^b and Patrick McCarthy, MD^b

Conclusions: LAA elimination is often incomplete and goes undetected. If the LAA is eliminated at the time of surgery, then TEE should be used intraoperatively to assess effectiveness and reintervention performed if warranted. Late assessment for completeness of closure should be considered before cessation of anticoagulation until more effective LAA techniques can be developed. (J Thorac Cardiovasc Surg 2016;152:1075-80)



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EDITORIAL COMMENTARY

The left atrial appendage: Won't get fooled again

Marc Gillinov, MD

From the Department of Thoracic and Cardiovascular Surgery, The Cleveland Clinic, Cleveland, Ohio.
Disclosures: Author has nothing to disclose with regard to commercial support.
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http://dx.doi.org/10.1016/j.jtcvs.2016.06.032

We have been fooling ourselves. Every time we complete an operation and dictate the words, "The left atrial appendage (LAA) was excised (or excluded) with suture (or a stapler)," we do so with confidence, certain that in our hands the LAA has been managed successfully. In their randomized, prospective pilot comparison of 3 atrial appendage elimination techniques appearing in this issue of the *Journal*, however, Lee and colleagues,¹ a group of expert surgeons, demonstrate that our confidence is misplaced. Standard surgical management of the LAA is unsuccessful in the majority of cases.





Marc Gillinov, MD

Central Message

With standard surgical techniques, left atrial appendage excision and exclusion are unsuccessful more than half the time.

See Article page 1075.

LAAO- surgical devices



• AtriClip

- External clip
- Sustained compression
- tissue growth
- Tigerpaw
 - Easier to apply
 - Recalled due to tears

AtriClip – Short term results



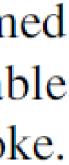
Acquired Cardiovascular Disease

Exclusion of the left atrial appendage with a novel device: Early results of a multicenter trial

Gorav Ailawadi, MD,^a Marc W. Gerdisch, MD,^b Richard L. Harvey, MD,^c Robert L. Hooker, MD,^d Ralph J. Damiano, Jr, MD,^e Thomas Salamon, MD,^f and Michael J. Mack, MD^g

Conclusions: In this small study, safe and atraumatic exclusion of the left atrial appendage can be performed during open cardiac surgery with the AtriClip device with greater than 95% success and appears to be durable in the short term by imaging. Long-term studies are needed to evaluate the efficacy in the prevention of stroke. (J Thorac Cardiovasc Surg 2011;142:1002-9)

Ailawadi et al



AtriClip- long term results

- 3.5+/-0.5 years
- Stable clip, no recurrence and no thrombi

European Journal of Cardio-Thoracic Surgery 45 (2014) 126-131 doi:10.1093/ejcts/ezt204 Advance Access publication 8 May 2013

Safe, effective and durable epicardial left atrial appendage clip occlusion in patients with atrial fibrillation undergoing cardiac surgery: first long-term results from a prospective device trial

Maximilian Y. Emmert^a, Gilbert Puippe^b, Stephan Baumüller^b, Hatem Alkadhi^b, Ulf Landmesser^c, Andre Plass^a, Dominique Bettex^d, Jacques Scherman^a, Jürg Grünenfelder^a, Michele Genoni^e, Volkmar Falk^a and Sacha P. Salzberg^{a,*}

^a Clinic for Cardiovascular Surgery, University Hospital Zurich, Zurich, Switzerland b Institute of Diagnastic and Interventional Dadialamy University Heavital Zurich Zurich Cultrarland

ORIGINAL ARTICLE

AtriClip- Minimally invasive

JACC: CLINICAL ELECTROPHYSIOLOGY © 2017 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER

CONSIDERATIONS IN LA APPENDAGE CLOSURE

Angiographic Efficacy of the Atriclip Left Atrial Appendage Exclusion **Device Placed by Minimally Invasive** Thoracoscopic Approach

Christopher R. Ellis, MD,^a Sam G. Aznaurov, MD,^a Neel J. Patel, MD,^a Jennifer R. Williams, MD,^a Kim Lori Sandler, MD,^a Steven J. Hoff, MD,^b Stephen K. Ball, MD,^a S. Patrick Whalen, MD,^c John Jeffrey Carr, MD^a

VOL. 3, NO. 12, 2017 ISSN 2405-500X/\$36.00 http://dx.doi.org/10.1016/j.jacep.2017.03.008



AtriClip – Minimally invasive

RESULTS Complete LAA closure (defined by complete exclusion of the LAA with no exposed trabeculations, and clip within 1 cm from the left circumflex artery) was found in 61 of 65 subjects (93.9%). Four cases had incomplete closure (6.2%). Two clips were placed too distally, leaving a large stump with exposed trabeculae. Two clips failed to address a secondary LAA lobe. No major complications were associated with TT placement of the Atriclip. Follow-up over 183 patient-years revealed 1 stroke in a patient with complete LAA closure and no thrombus (hypertensive cerebrovascular accident).

CONCLUSIONS Angiographic LAA closure efficacy with a TT-placed Atriclip is high (93.9%). The clinical significance of a remnant stump is unknown. Confirmation of complete LAA occlusion should be made before cessation of systemic anticoagulation. (J Am Coll Cardiol EP 2017;3:1356-65) © 2017 by the American College of Cardiology Foundation.

LAAO- prevention of stroke in Afib

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY © 2015 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION PUBLISHED BY ELSEVIER INC.

Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation

A Patient-Level Meta-Analysis

David R. Holmes, JR, MD,* Shephal K. Doshi, MD,† Saibal Kar, MD,‡ Matthew J. Price, MD,§ Jose M. Sanchez, MD,∥ Horst Sievert, MD,¶ Miguel Valderrabano, MD,# Vivek Y. Reddy, MD**

VOL. 65, NO. 24, 2015 ISSN 0735-1097/\$36.00 http://dx.doi.org/10.1016/j.jacc.2015.04.025

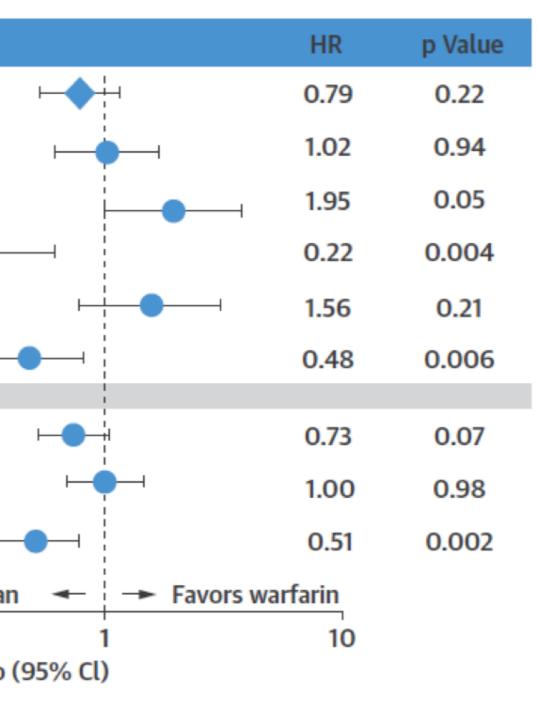


LAAO- prevention of stroke in Afib

FIGURE 2 PROTECT AF/PREVAIL Combined: Meta-Analysis Shows Comparable **Primary Efficacy Results to Warfarin**

Efficacy

All stroke or SE	
Ischemic stroke or SE	
Hemorrhagic stroke	⊢
Ischemic stroke or SE >7	days
CV/unexplained death	⊢
All-cause death	
Major bleed, all	
Major bleeding, non procedure-rela	ated ⊢
	Favors Watchma
0.01	0.1
	Hazard Ratio



NOAC vs Warfarin

Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials

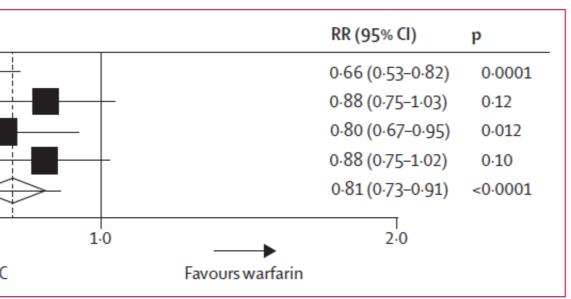
Christian T Ruff, Robert P Giugliano, Eugene Braunwald, Elaine B Hoffman, Naveen Deenadayalu, Michael D Ezekowitz, A John Camm, Jeffrey I Weitz, Basil S Lewis, Alexander Parkhomenko, Takeshi Yamashita, Elliott M Antman

Summary

Background Four new oral anticoagulants compare favourably with warfarin for stroke prevention in patients Lancet 2014; 383: 955-62

	NOAC (event	s) Warfarin (events)	
RE-LY ⁵ *	134/6076	199/6022 -	
ROCKET AF ⁶ †	269/7081	306/7090	
ARISTOTLE ⁷ ‡	212/9120	265/9081	
ENGAGE AF-TIMI 488§	296/7035	337/7036	_
Combined (random)	911/29312	1107/29229	\prec
		0.5	4
			Favours NOAC





LAAO in pts with Afib

European Journal of Cardio-Thoracic Surgery 47 (2015) 847-854 doi:10.1093/ejcts/ezu291 Advance Access publication 26 July 2014

Cite this article as: Tsai Y-C, Phan K, Munkholm-Larsen S, Tian DH, La Meir M, Yan TD. Surgical left atrial appendage occlusion during cardiac surgery for patients with atrial fibrillation: a meta-analysis. Eur J Cardiothorac Surg 2015;47:847–54.

Surgical left atrial appendage occlusion during cardiac surgery for patients with atrial fibrillation: a meta-analysis

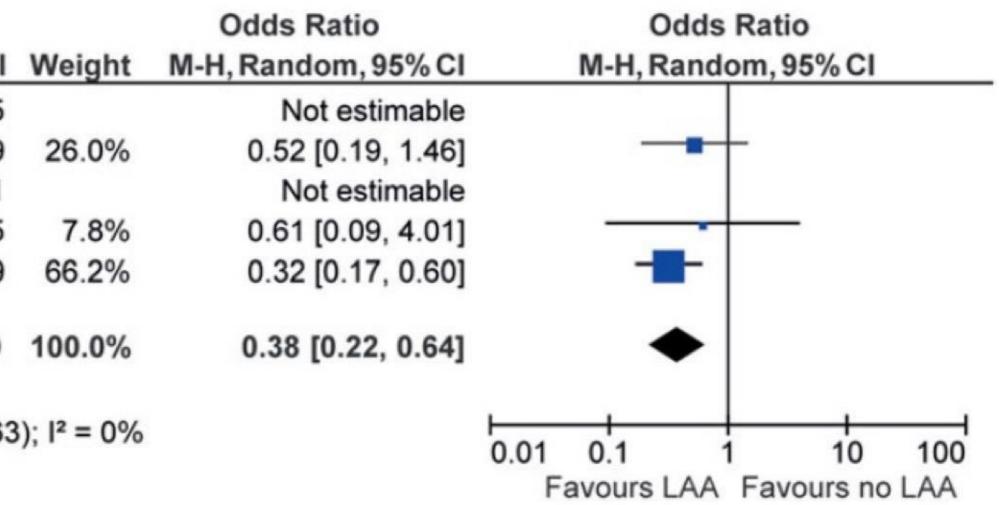
Yi-Chin Tsai^{a,†}, Kevin Phan^{b,c,†}, Stine Munkholm-Larsen^{c,d}, David H. Tian^b, Mark La Meir^{e,f} and Tristan D. Yan^{b,g,*}

ORIGINAL ARTICLE

LAAO in pts with Afib

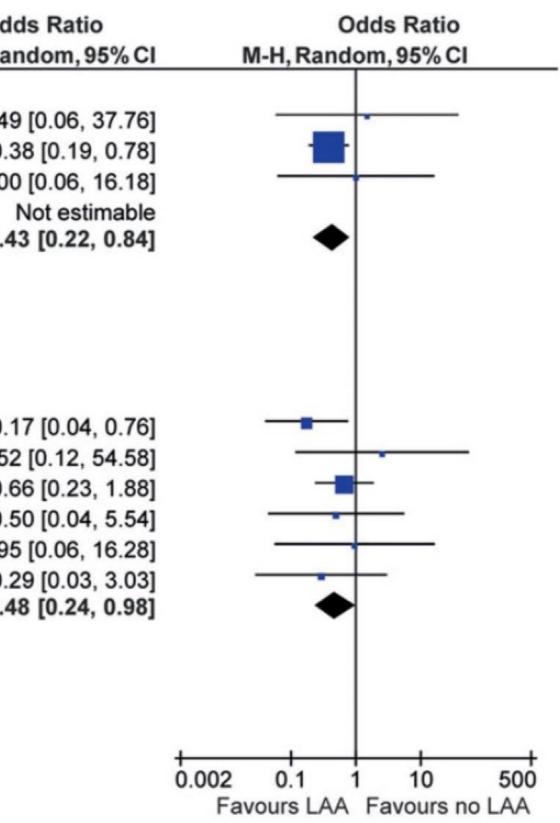
	LAA		no LAA	
Study or Subgroup	Events	Total	Events	Total
Healey	0	52	0	25
Lee	6	119	11	119
Nagpal	0	22	0	21
Whitlock	2	26	3	25
Zapolanski	12	808	44	969
Total (95% CI)		1027		1159
Total events	20		58	
Heterogeneity: Tau ² = Test for overall effect:				9 = 0.63

Figure 3: Forest plot of the odds ratio (OR) of all-cause mortality in the left atrial occlusion (LAA) group versus non-LAA group. The estimate of the OR of each trial cor-



LAAO in pts with Afib

	LAA	surg	non-LA	A surg		Ode
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Rai
30-day						
Healey	1	52	0	25	4.4%	1.49
Kim	14	1405	17	662	89.7%	0.3
Lee	1	119	1	119	5.9%	1.00
Nagpal	0	22	0	21		
Subtotal (95% CI)		1598		827	100.0%	0.4
Total events	16		18			
Heterogeneity: Tau ² =	0.00; Chi ²	= 1.03	, df = 2 (F	P = 0.60); l ² = 0%	
Test for overall effect:	Z = 2.46 (P = 0.0	1)			
Latest follow-up						
Garcia-Fernandez	2	58	25	147	23.3%	0.1
Healey	2	52	0	25	5.4%	2.52
Kim	6	631	9	631	47.0%	0.6
Lee	1	119	2	119	8.7%	0.5
Nagpal	1	22	1	21	6.3%	0.95
Whitlock	1	26	3	25	9.3%	0.2
Subtotal (95% CI)		908		968	100.0%	0.4
Total events	13		40			
Heterogeneity: Tau ² =	0.00; Chi ²	= 3.78	, df = 5 (F	P = 0.58	3); l ² = 0%	
Test for overall effect:						
	2.01(0.0	.,			





Canadian Journal of Cardiology 29 (2013) 1443-1447

Clinical Research Left Atrial Appendage Occlusion Study II (LAAOS II)

Richard P. Whitlock, MD, PhD,^a Jessica Vincent, MSc,^a Mary Helen Blackall, BScN,^a Jack Hirsh, MD,^a Stephen Fremes, MD,^b Richard Novick, MD,^c P.J. Devereaux, MD, PhD,^a Kevin Teoh, MD,^a Andre Lamy, MD,^a Stuart J. Connolly, MD,^a Salim Yusuf, DPhil,^a Michel Carrier, MD,^d and Jeff S. Healey, MD^a

^a Population Health Research Institute, Hamilton Health Sciences/McMaster University, Hamilton, Ontario, Canada ^b Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada ^c London Health Sciences Centre, London, Ontario, Canada ^d Montreal Heart Institute, Montreal, Québec, Canada

	(
Outcome at 1 year	
Death, MI, stroke,	
non-CNS embolism,	
or major bleeding, n (%*)	
Death, n (%*)	
Stroke, n (%*)	
Non-CNS embolism, n (%*)	
Major bleeding, n (%*)	
Reoperation for bleeding, n (%)	
	_



Occlusion arm (n = 26)	No-occlusion arm (n = 25)	Relative risk (95% CI)
4 (15.4)	5 (20.0)	0.7 (0.2-2.7)
2 (7.7) 1 (3.9) 0 (0.0) 1 (3.8)	3 (12.0) 3 (12.0) 0 (0.0) 2 (8.0)	0.6 (0.1-3.4) 0.3 (0.0-3.3) 1.0 (0.0-46.8) 0.4 (0.0-4.6)
2 (8.0)	1 (3.9)	1.9 (0.2-19.9)

Rationale and design of the Left Atrial Appendage Occlusion Study (LAAOS) III

Richard Whitlock^{1,2}, Jeff Healey^{2,3}, Jessica Vincent², Kate Brady², Kevin Teoh^{1,4}, Alistair Royse⁵, Pallav Shah⁶, Yingqiang Guo⁷, Marco Alings⁸, Richard J. Folkeringa⁹, Domenico Paparella¹⁰, Andrea Colli¹¹, Steven R. Meyer¹², Jean-François Legare¹³, François Lamontagne¹⁴, Wilko Reents¹⁵, Andreas Böning¹⁶, Stuart Connolly^{2,3}

Methods: We plan to randomize 4,700 patients with AF in whom on-pump cardiac surgical procedure is planned to undergo LAA occlusion or no LAA occlusion. The primary outcome is the first occurrence of stroke or systemic arterial embolism over a mean follow-up of four years. Other outcomes include total mortality, operative safety outcomes (chest tube output in the first post-operative 24 hours, rate of post-operative re-exploration for bleeding in the first 48 hours post-surgery and 30-day mortality), re-hospitalization for heart failure, major bleed, and myocardial infarction.



LAA closure in patients without AF?

- No prospective evidence
- Can we identify high risk pts

MAYO Clinic – LAAO analysis

ORIGINAL RESEARCH ARTICLE

Impact of Left Atrial Appendage Closure During **Cardiac Surgery on the Occurrence of Early Postoperative Atrial Fibrillation, Stroke, and Mortality**

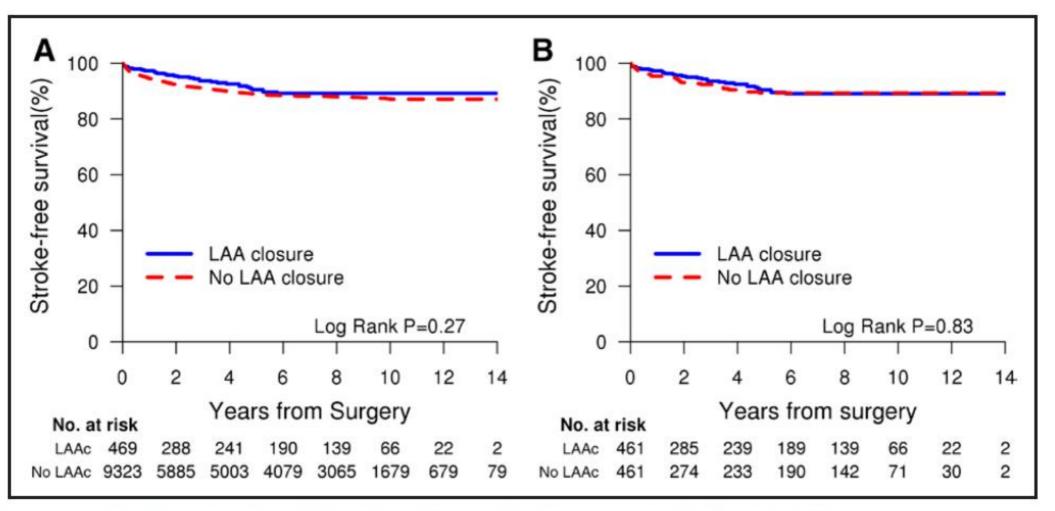
A Propensity Score–Matched Analysis of 10633 Patients

Circulation. 2017;135:366–378. DOI: 10.1161/CIRCULATIONAHA.116.021952

STS/EACTS Latin America Cardiovascular Surgery Conference 2018



MAYO Clinic – LAAO analysis



closure group.

CONCLUSIONS: After adjustment for treatment allocation bias, LAA closure during routine cardiac surgery was significantly associated with an increased risk of early POAF, but it did not influence the risk of stroke or mortality. It remains uncertain whether prophylactic exclusion of the LAA is warranted for stroke prevention during non-atrial fibrillation-related cardiac surgery.



Figure 1. Kaplan-Meier analysis showing freedom from ischemic stroke in LAA closure group versus no LAA



Chua et al

Clinical utility of CHADS₂ and CHA₂DS₂-VASc scoring systems for predicting postoperative atrial fibrillation after cardiac surgery

Su-Kiat Chua, MD,^{a,b,c} Kou-Gi Shyu, MD, PhD,^{a,b} Ming-Jen Lu, MD,^d Li-Ming Lien, MD, PhD,^e Chia-Hsun Lin, MD,^d Hung-Hsing Chao, MD, PhD,^d and Huey-Ming Lo, MD^{b,f}

Methods: A total of 277 consecutive patients who underwent cardiac surgery were prospectively included in this risk stratification study. We calculated the CHADS₂ and CHA₂DS₂-VASc scores from the data collected. The primary end point was the development of postoperative atrial fibrillation within 30 days after cardiac surgery.

atrial fibrillation rates at a cutoff value of 2 (12% vs 32%; P = .01).

Conclusions: CHADS₂ and CHA₂DS₂-VASc scores were predictive of postoperative atrial fibrillation after cardiac surgery and may be helpful for identifying high-risk patients. (J Thorac Cardiovasc Surg 2013;146:919-26)

Louis in notionto without AE9

Perioperative Management

Results: Eighty-four (30%) of the patients had postoperative atrial fibrillation at a median of 2 days (range, 0-27 days) after cardiac surgery. The CHADS₂ and CHA₂DS₂-VASc scores were significant predictors of postoperative atrial fibrillation in separate multivariate regression analyses. The Kaplan-Meier analysis obtained a higher postoperative atrial fibrillation rate when based on the CHADS₂ and CHA₂DS₂-VASc scores of at least 2 than when based on scores less than 2 (both log rank, $P \le .001$). In addition, the CHA₂DS₂-VASc scores could be used to further stratify the patients with CHADS₂ scores of 0 or 1 into 2 groups with different postoperative

ATLAS - Study

- No documented history of Afib
- CHA2DS2-VASc ≥ 2
- HASBLED >3
- AtriClip exclusion
- CVA and survival
- Healthcare resources
- 2000 pts through 40 sites

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Guidelines

Table I Professional society guideline recommendations for left atrial appendage occlusion

Guideline

American Heart Association/American College of Cardiology²² European Society of Cardiology²³

Recommendation

Surgical excision of the LAA cardiac surgery

Surgical excision of the LAA cardiac surgery or thora

Percutaneous LAA closure stroke and contraindicat

	Grade	Level of evide
A may be considered in patients undergoing	IIB	С
A may be considered in patients undergoing acoscopic AF surgery	IIB	В
e may be considered in patients with a high risk of tions to long-term oral anticoagulation	IIB	В



The Society of Thoracic Surgeons 2017 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation

Vinay Badhwar, MD, J. Scott Rankin, MD, Ralph J. Damiano, Jr, MD, A. Marc Gillinov, MD, Faisal G. Bakaeen, MD, James R. Edgerton, MD, Jonathan M. Philpott, MD, Patrick M. McCarthy, MD, Steven F. Bolling, MD, Harold G. Roberts, MD, Vinod H. Thourani, MD, Rakesh M. Suri, MD, DPhil, Richard J. Shemin, MD, Scott Firestone, MS, Niv Ad, MD

Recommendations

It is reasonable to perform LA appendage excision or exclusion in conjunction with surgical ablation for AF for longitudinal thromboembolic morbidity prevention. (Class IIA, Level C limited data)

At the time of concomitant cardiac operations in patients with AF, it is reasonable to surgically manage the LA appendage for longitudinal thromboembolic morbidity prevention (Class IIA, Level C expert opinion). Multidisciplinary heart team assessment, treatment planning, and long-term follow-up can be useful and beneficial to optimize outcomes of surgical ablation for

AF. (Class IIA, Level C expert opinion).

(CrossMark

Conclusions

- No LAAO should not be routinely performed in all cases LAAO – should be done in Pts with afib
- AtriClip is most optimal device
- Intraop Echo confirmation is of paramount importance

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THANK YOU







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