MOŽNOSTI CHIRURGICKÉ EXKLUZE OUŠKA LEVÉ SÍNĚ

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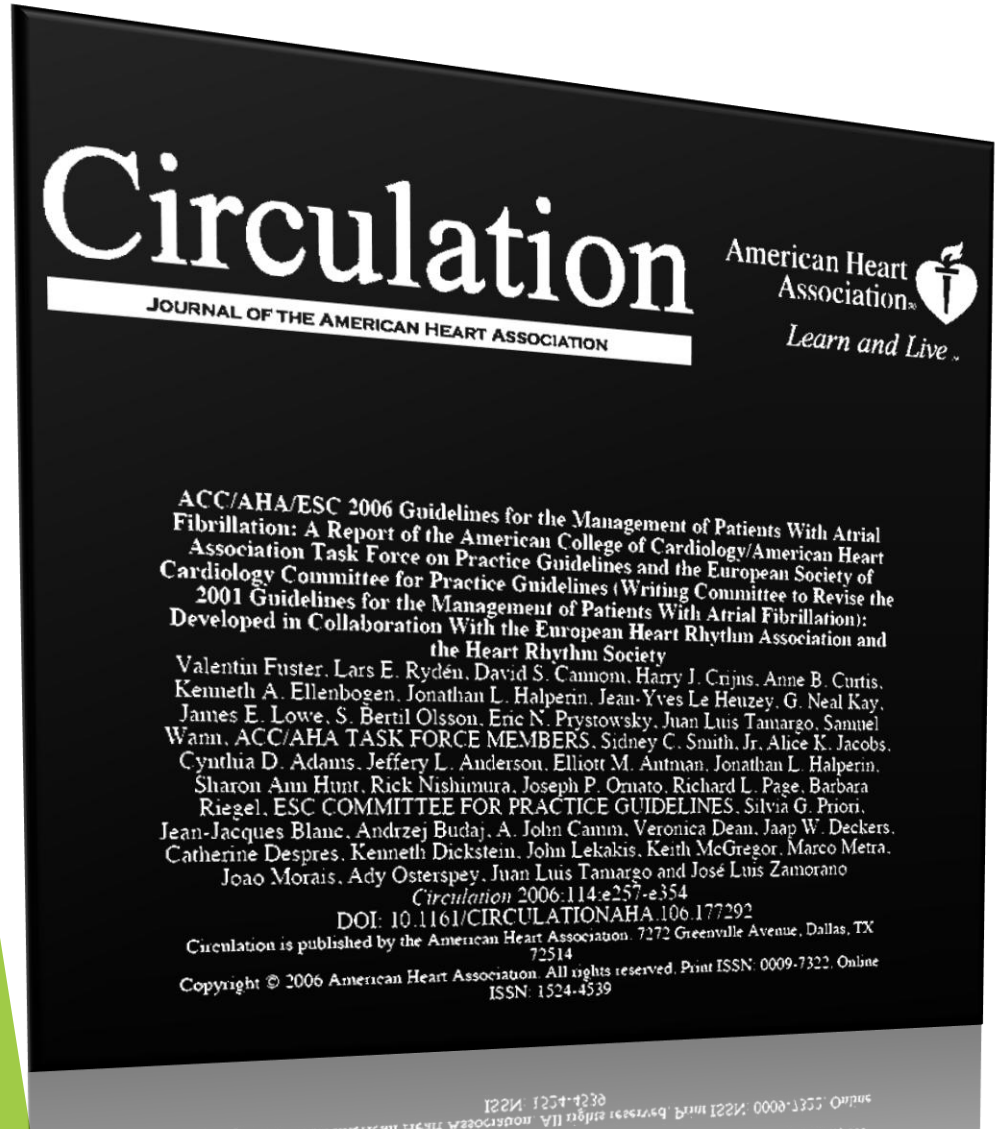
Ground for focusing on LAA during AF

- *2012 focused update of the ESC Guidelines for the management of atrial fibrillation. Eur Heart J 2012, 33, 2719-2747*
- **Risk of stroke is 5 x bigger in patients with AF than with SR** - *Blackshear et al.: Ann Thorac Surg, 1996, 61, 755-9*
- **90% patients with nonvalvular AF have thrombi in LAA** - *Blackshear et al.: Ann Thorac Surg, 1996, 61, 755-9*
- **LAA is a potential electrical substrate of AF** - *Shirani J et al.: Cardiovasc Patol 2000, 9, 95-101*

The AHA/ACC/ECS Guidelines for the Management of Patients with Atrial Fibrillation



"Because the LAA is the site of 95% of detected thrombi, this structure should be removed from circulation when possible during cardiac surgery in patients at risk of developing postoperative AF."

What about the 3 million patients who *already have* atrial fibrillation???

CHA_2DS_2-VASc

- European Heart Rhythm Association, European Association for Cardiothoracic Surgery. Camm et al.: Guidelines for managment of atrial fibrillation. Eur Heart J 2010
- Lip GY et al.: Identifying patients at high risk for stroke despite anticoagulation. Stroke 2010

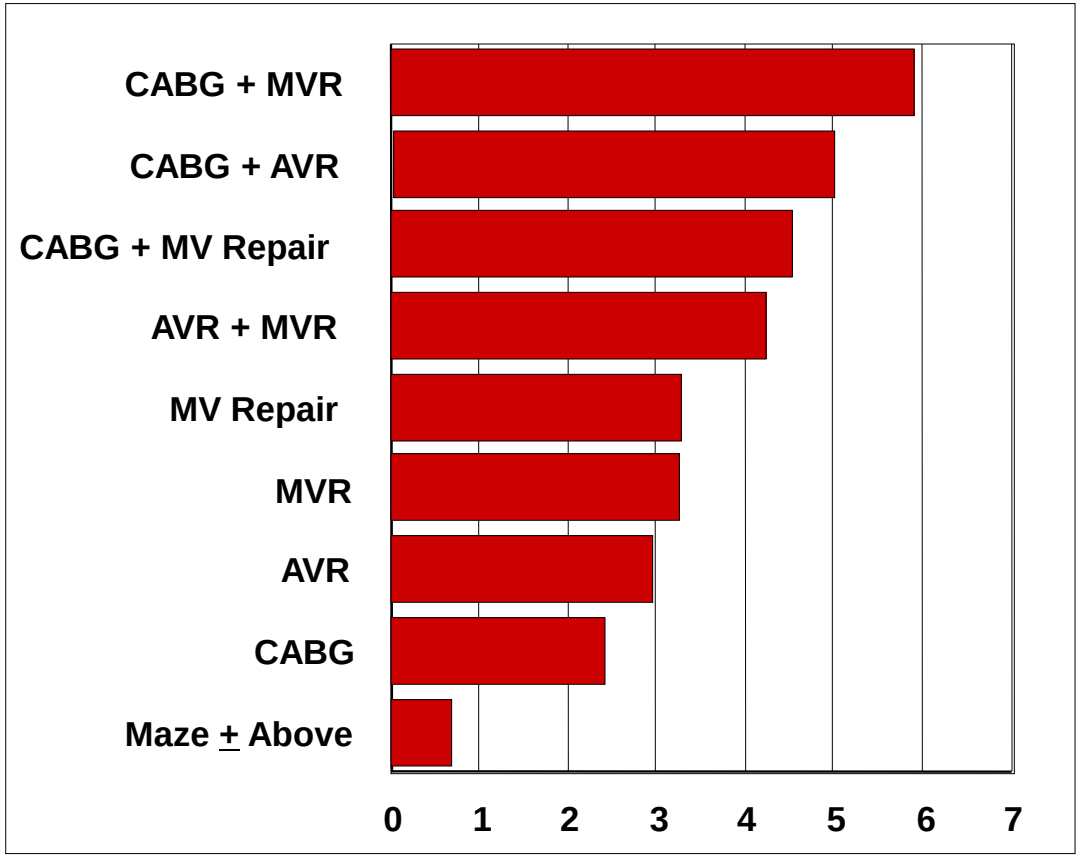
CHA_2DS_2 -VASc	Risk of stroke per year
1	1,3%
3	3,2%
6	9,8%
9	15,2%

AF and permanent anticoagulation
HAS-BLED score

- 14-44 % pts are contraindicated for permanent anticoagulation (Warfarin) *Brown MT, Bussel JK: Mayo Clinic Proc 2011, 86, 304-14*
- *Horskotte D et al.: Improvement of oral anticoagulation therapy by INR Self-management. J Heart Valve Disease 2004, 13, 335-338*
- **A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: the Euro Heart Survey.** *Pisters R et al: Department of Cardiology, Maastricht University Medical Centre, Maastricht*

HAS-BLED score	Risk of major bleeding per year
1	3,4 %
4	8,9%
5	9,1%

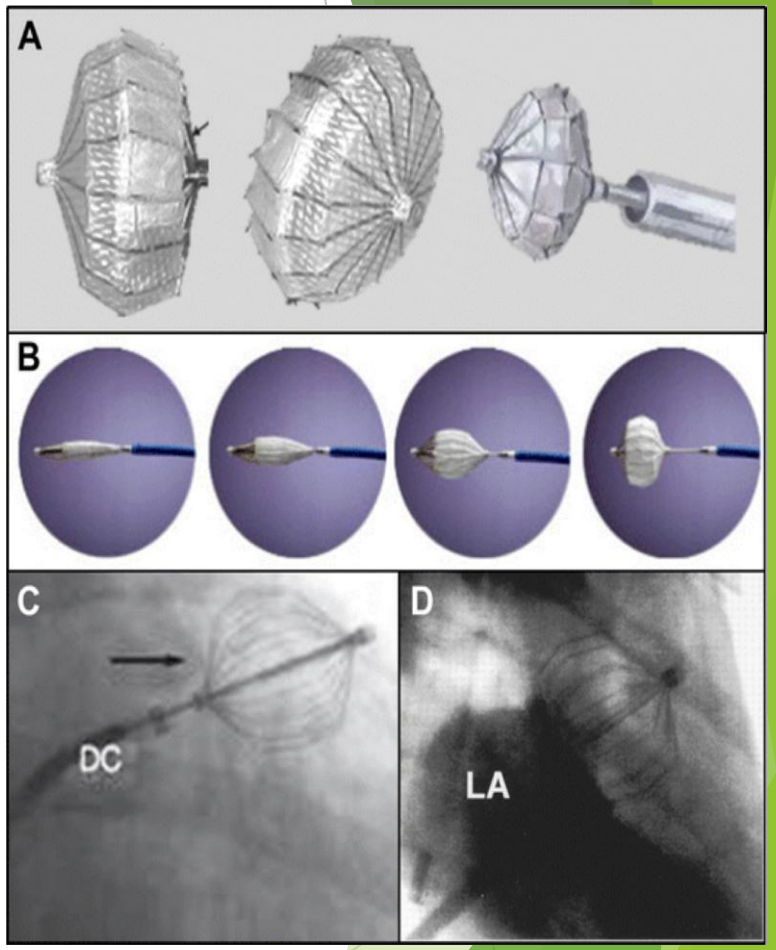
Comparative Perioperative Stroke Rate



National Adult Cardiac Surgery Database

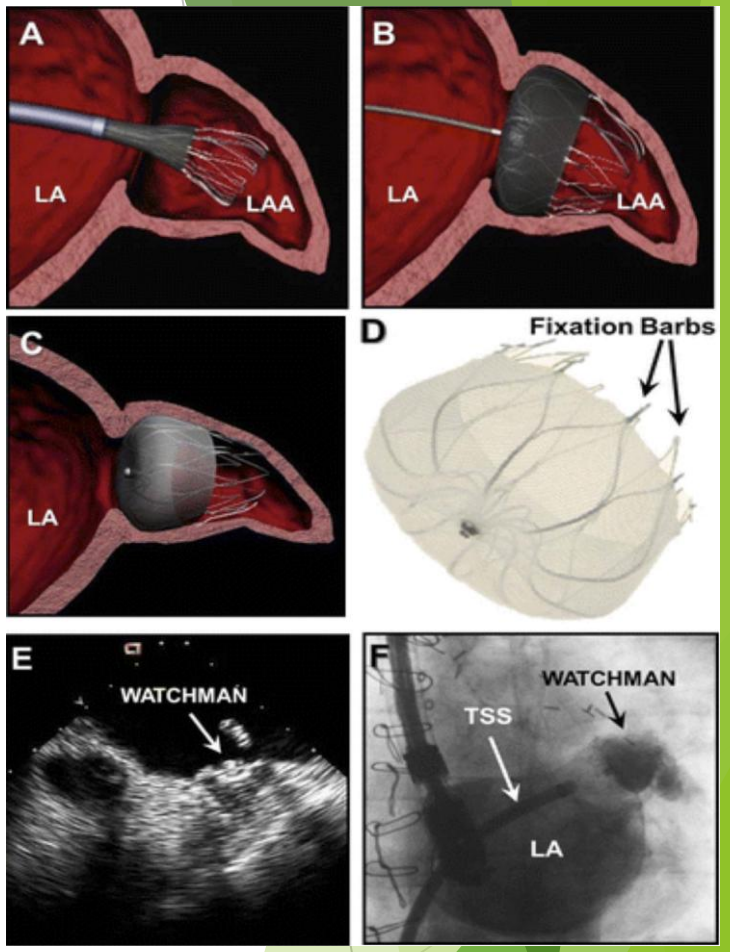
PLAATO

- Efekt okluze 90%
- Komplikace – tamponáda, CMP, emboliazce zařízení, …
- Finanční problémy – ukončení výroby



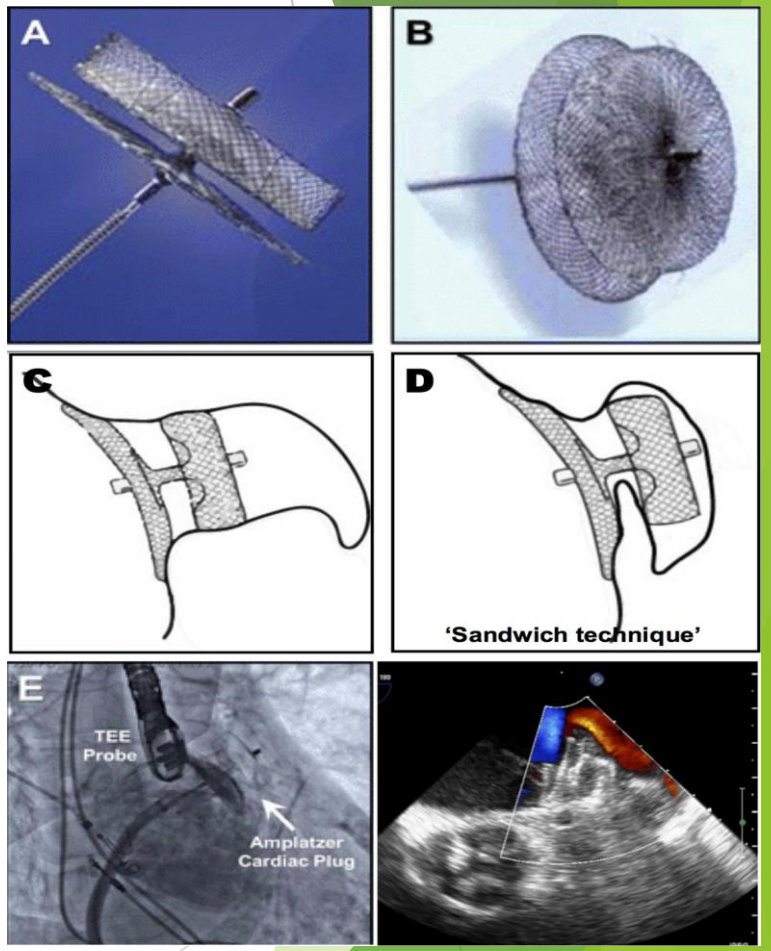
Watchman

- CE i FDA,
- 2. generace
- Vs. Warfarin noninferiorita v efektu prevence CMP, redukce krvácivých komplikací
- Komplikace ve vztahu k výkonu a nebo zařízení 8,7%
- Endoleak cca 1/3 pacientů (1. generace)



ACP (ACP AMULET)

- Primárně „nemálo“ závažných komplikací (emboliazce, CMP, trombózy, periardiální výpotky, tamponáda,…)



LARIAT

Images and Case Reports in Arrhythmia and Electrophysiology

Left Atrial Thrombus After Appendage Closure Using LARIAT

Evaldas Giedrimas, MD; Albert C. Lin, MD; Bradley P. Knight, MD

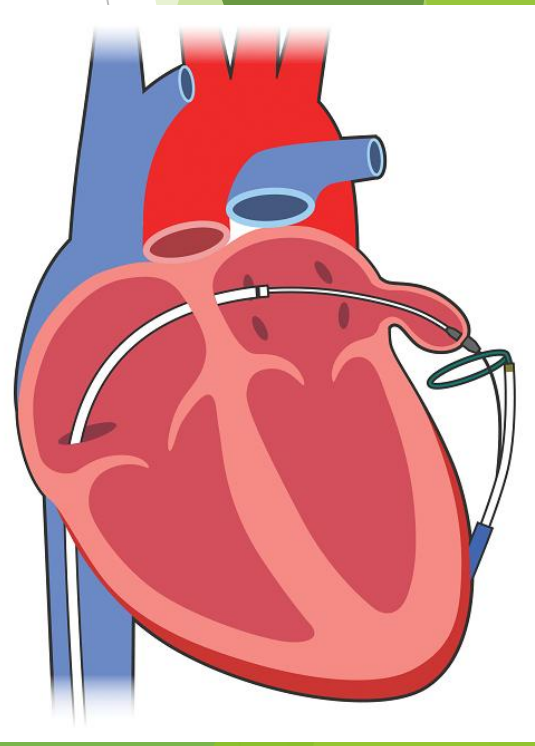
- Jediný je „epikardiální“ s výhodou elektrické izolace, ale kombinací rizik epi a transeptální punkce (poranění srdce, tamponády,…)
- Kopíruje chirurgickou ligaci, kde efekt neselktovaného souboru (s Cleveland kritérii) není více než 50-70%

Percutaneous Left Atrial Appendage Suture Ligation Using the LARIAT Device in Patients With Atrial Fibrillation

Initial Clinical Experience

Krzysztof Bartus, MD, PHD,* Frederick T. Han, MD,† Jacek Bednarek, MD, PHD,‡ Jacek Myc, MD, PHD,* Boguslaw Kapelak, MD, PHD,* Jerzy Sadowski, MD, PHD,* Jacek Lelakowski, MD, PHD,‡ Stanislaw Bartus, MD, PHD,* Steven J. Yakubov, MD,§ Randall J. Lee, MD, PHD† ¶

Krakow, Poland; San Francisco, California; and Columbus, Ohio



Obecné limitace katetrového uzávěru LAA

- Transseptální punce
- Anatomické limitace – jak ouška tak např. RCx!!!
- Bez CA není jednoduché provézt kvalitní TEE bez kterého je implantace „méně bezpečná?“ (s CA se zmenšuje rozdíl oproti chirurgické implantaci)

- Tamponáda (1-3 - ? %)
- Endoleak (~ 30% ?) – IE, trombus LS,…
- Embolizace

- LAA pod okluderem je potenciální arytmogenní ložisko

„Cleveland Clinic criterias of effectivity“
for surgical treatment of LAA

Kanderian AS, Gillinov AM, Pettersson G et al.: Success of surgical left atrial appendage closure. JACC 2008, 52, No 11, 924-9

1. *No any leaks*
2. *Pouch less than 10 mm*

Standard surgical procedures (resection, ligation or stapler) have success rate **only 0-73%** (by these criterias)

Garcia-Fernandez MA, Perez-David E, Quiles J et al.: Role of left atrial appendage obliteration in patient with mitral valve prosthesis. J Am Coll Cardiol 2003, 42, 1253-8

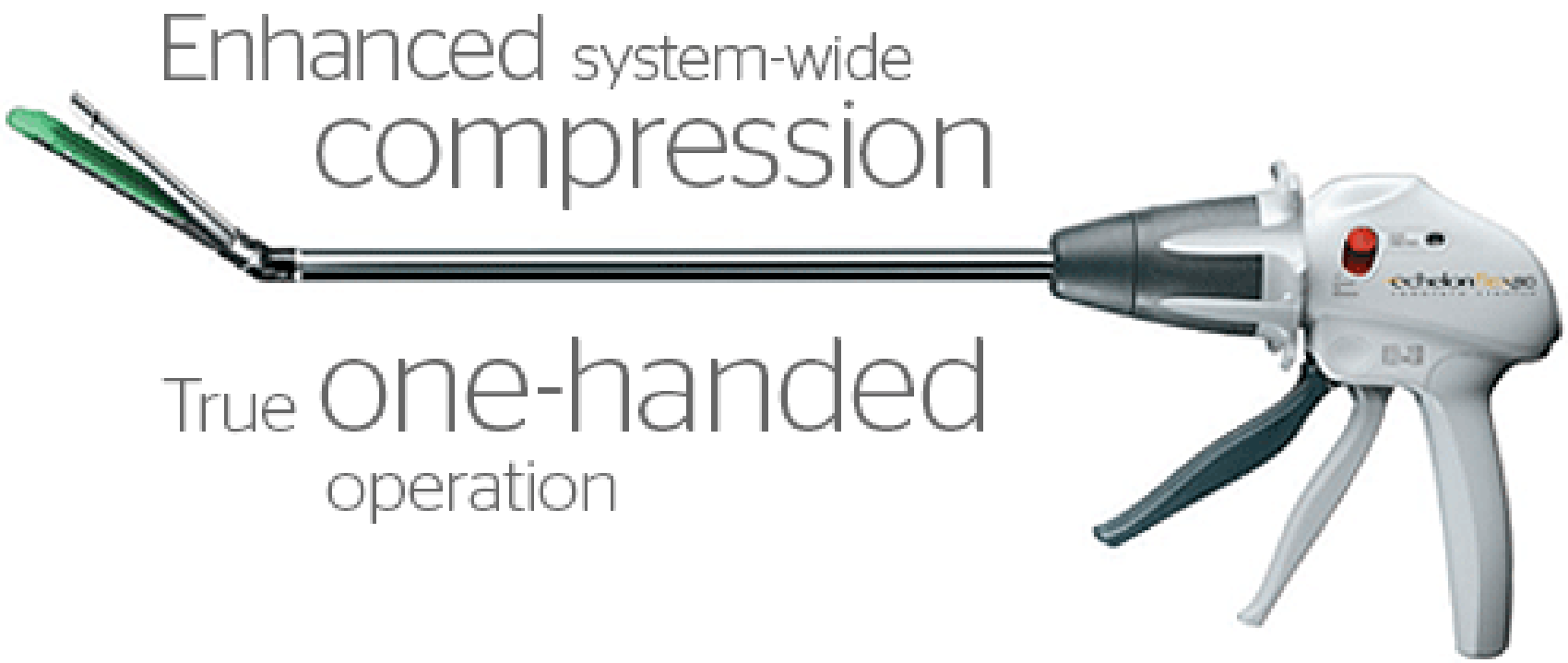
Residual leak after „occlusion“ of LAA is a bigger risk for stroke than incomplete exclusion (pouch) or dropping LAA without any care

2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design

Exkluze ouška LS:

- Není jednoznačně prokázán efekt chirurgické exkluze ouška LS ve smyslu redukce CMP či lepšího přežití. Nicméně efekt zavedené chirurgické exkluze je omezený pro její malou efektivitu. Je-li exkluze indikována, mělo by být spíše použito speciální pomůcky (např. AtriClip). IIa B

Stapler


Enhanced system-wide
compression
True one-handed
operation

Exclusion of the left atrial appendage with the TigerPaw II system: a word of caution

Guillermo Ventosa-Fernandez, Eduard Quintana, Manuel Castellá and Daniel Pereda*

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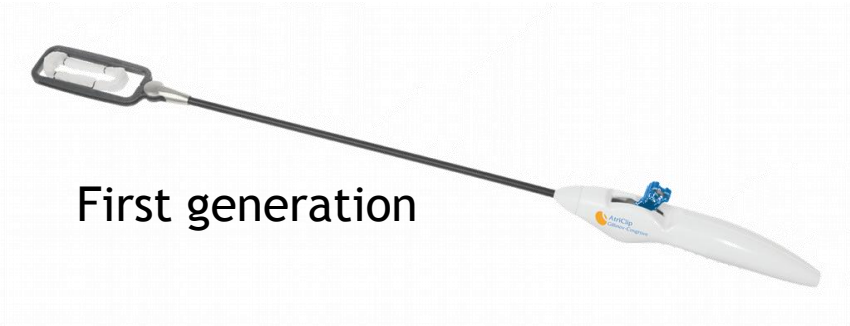
CASE REPORT – ADULT CARDIAC

Abstract
Exclusion of the left atrial appendage (LAA) may significantly reduce the incidence of stroke associated with atrial fibrillation (AF), since this is the main thrombus source. LAA closure is becoming a therapeutic target for preventing AF-related stroke, attracting much interest in recent years. Different devices are available to provide LAA exclusion during cardiac surgery. We describe herein our experience with the recently introduced TigerPaw II system for LAA exclusion, and report a high prevalence of device malfunction. Design improvements may address these issues and increase safety for new technological devices designed for surgical LAA closure.

AtriClip (AtriCure)

The AtriClip - LAA clip system (*Atricure, West Chester, OH, USA*) - is a self-closing external LAA occluder. It is available in 4 sizes, from 35 mm to 50 mm in 5 mm steps. It consists of a nitinol skeleton with a titanium contact plane, covered with Dacron polyester fabric. The parallel compression planes symmetrically exert a pressure of 2–8 psi on the entire contact area.

- Articulation of Head to Shaft
- Malleable Shaft
- Remote Suture
- Universal Application



First generation

Second generation

AtriClip

- Salzberg SP, Gillinov AM, Anyanvu A et al.: Surgical left atrial appendage occlusion: evaluation of novel device with magnetic resonance imaging. Eur J Cardiothorac Surg 2008, 34, 766-70
- Emmert MY, Puippe G, Bamuller S et al.: Safe, effective and durable epicardial left atrial appendage clip occlusion in patient with atrial fibrillation undergoing cardiac surgery . Eur J Cardiothorac Surg, 2013
- Ailawadi G, Gerdisch MW, Harvey RL et al.: Exclusion of the left atrial appendage with a novel device: early results of a multicenter trial. J Thoracic Cardiovasc Surg 2011, 142(5),1002-9
- Ad N, Massimiano PS et al.: New approach to exclude the left atrial appendage during MICS. Innovations 2015,10,323-327
- Mokracek A, Kurfirst V, Bulava A, Hanis J, Tesarik R, Pesl L: Thoracoscopic occlusion of the left atrial appendage: early results. Innovations 2015;10:179-182

1. Stability
2. No migration
3. No leaks
4. **Electrical isolation**

České Budějovice AtriClip prvních 100 pts

18.7.2012 – 11.9.2015 **100pts**

CHA_2DS_2 VASc (Ø)	2,47 (0-6)
EuroScore (Ø)	4,09 (1,5-15)
Follow up	1873 (Ø 18,5) M

EndoMAZE	60
MAZE + klip	79
KCH výkon + klip	16
Pouze klip	5

České Budějovice AtriClip prvních 100 pts

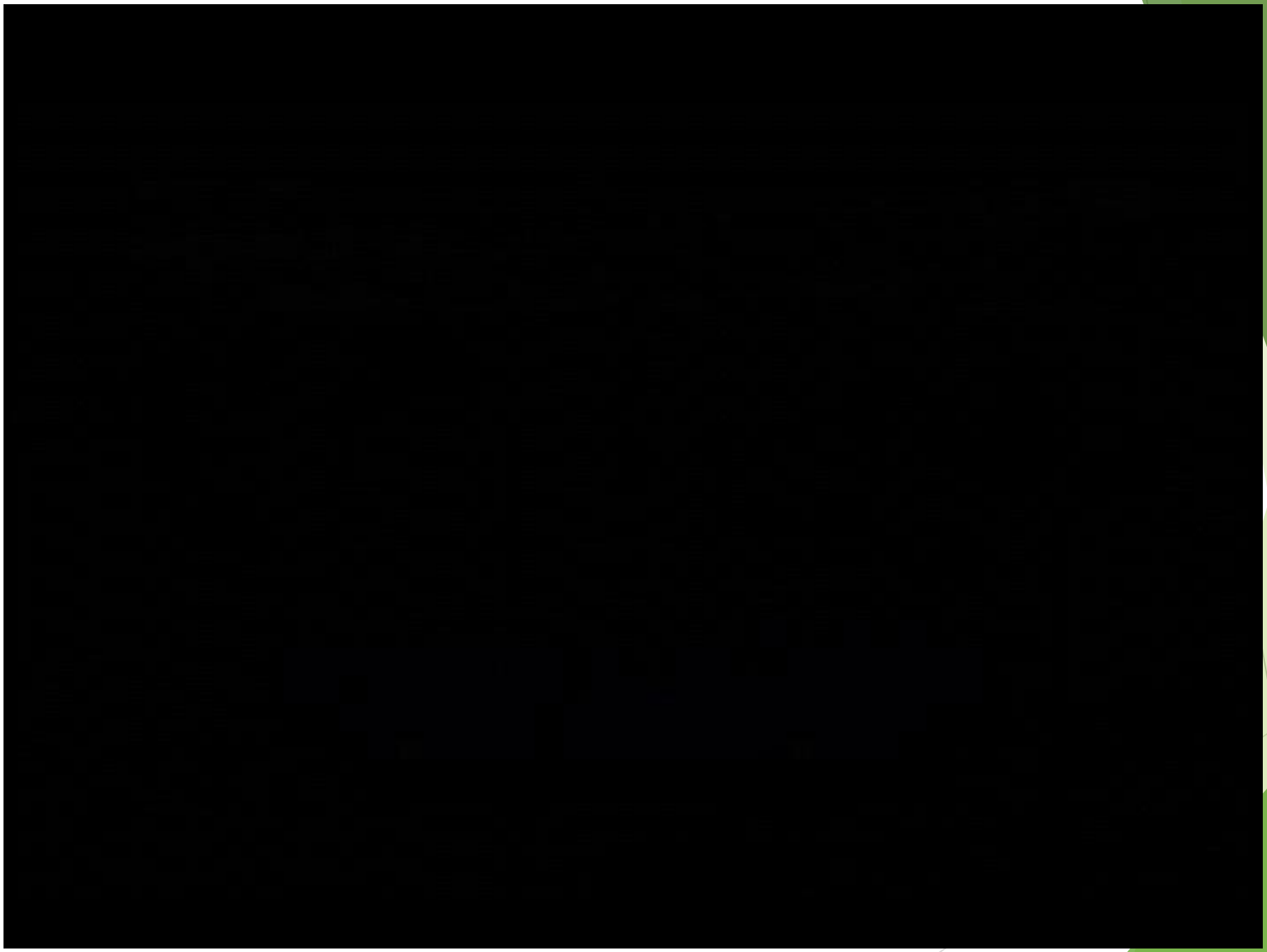
	periprocedurální	Follow up
TIA	1	
TIA		3x (z toho 1 steal)
CMP		1
krvácení		1 (GIT – trombex)

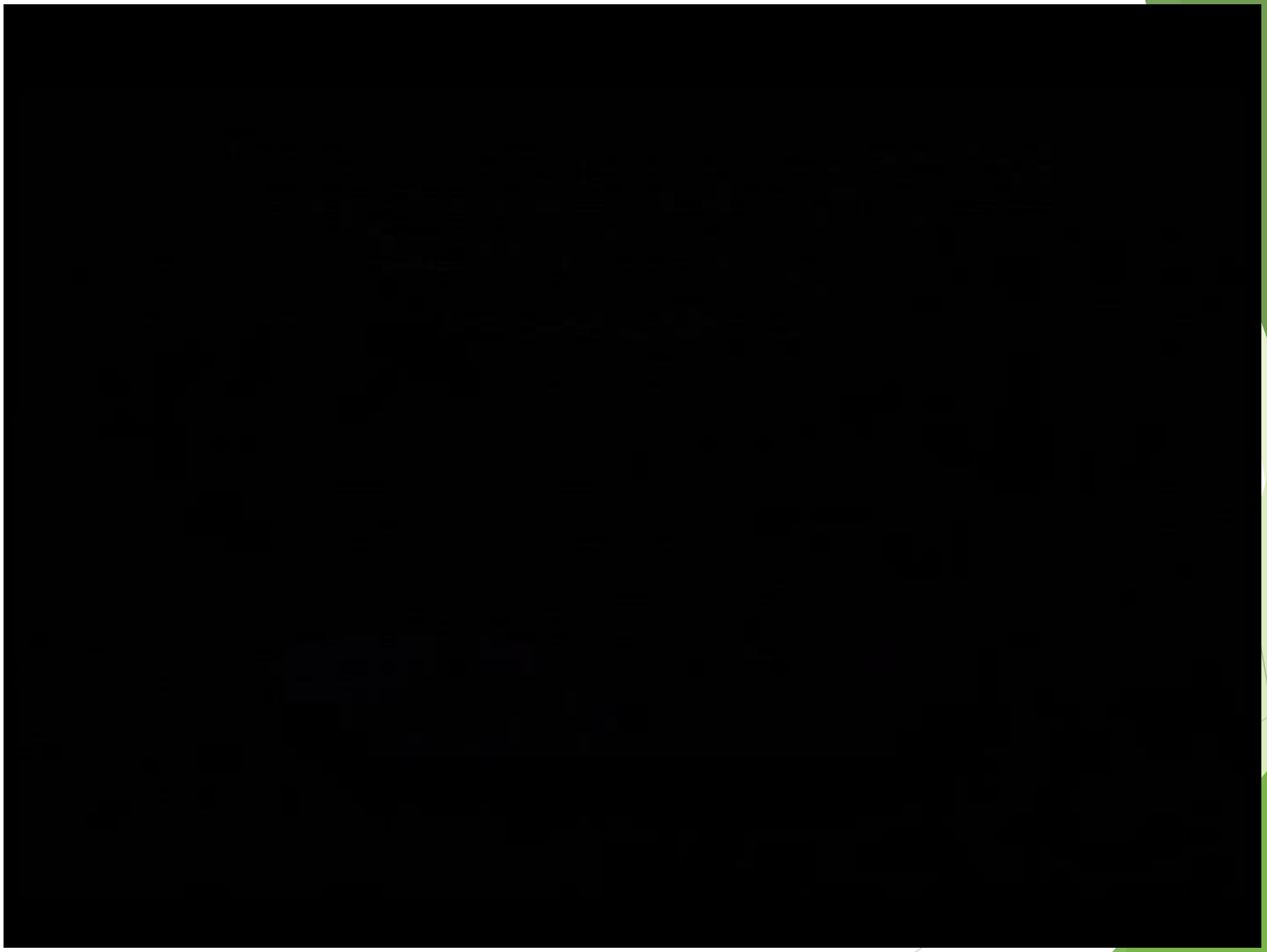
Endoleak (TTE/TEE)	**0**
Pouch ≥ 10mm	2
Částečné naložení	1

Warfarin	33
NOAC	6
Nízkomolek. heparin	4
Duální antiagregace	21
ACP	36

Více než 70.000 implantací celosvětově
BEZ DOKUMENTOVANÉHO ENDOLEAKU

AtriCure data



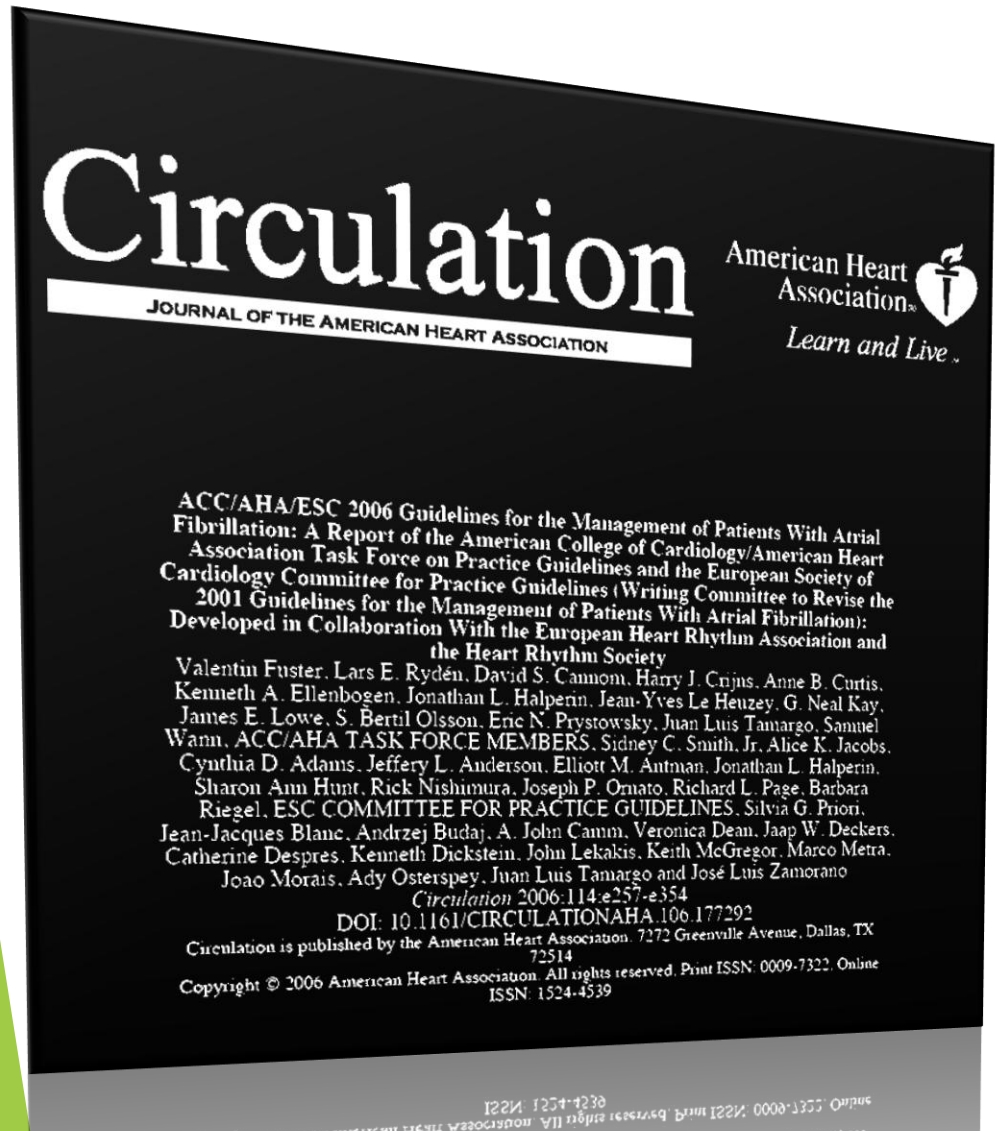


Conclusion
AtriClip

1. Quick, safe, reproducible and extremly effective metod of exclusion LAA by the hardest criterias
2. Comparative results for all surgical approaches (standard vs. minimally invasive - minitoracotomy, toracoscopy,…
3. Without heart anatomical contraindication for implantation
4. No arteficial material inside of the heart (IE, trombosis,…)
5. Electrical isolation of LAA

6. „price“– cost/effective (…1,5 - 3 years NOAC treatment….)

The AHA/ACC/ECS Guidelines for the Management of Patients with Atrial Fibrillation



Znamená to tedy, že každému nemocnému s amanézou FiS před jinou kardiochirurgickou procedurou (významný RF pooperační FiS) by se mělo uzavřít ouško LS *budeme-li mít bezpečnou a spolehlivou metodu*?

Možná ano – nutnost sběru dat

Cox (CoxMAZE IV concomitant procedure - FDA consensus):
Ouško LS by mělo být uzavřeno vždy,
když se provádí procedura pro FiS
Bez ohledu na její charakter –
budeme-li mít bezpečnou a spolehlivou metodu