Výsledky 5letého sledování souboru pacientů s katetrizační exklusí ouška levé síně systémem Lariat

Hála P, Dujka L, Janotka M, Lekešová V, Mráz T, Petrů J, Prokopová M, Šedivá L, Škoda J, Neužil P

Kardiologické oddělení
Nemocnice Na Homolce
Praha

Výsledky 5l souboru pacient ouška le

Autoři nemají konflikt zájmů

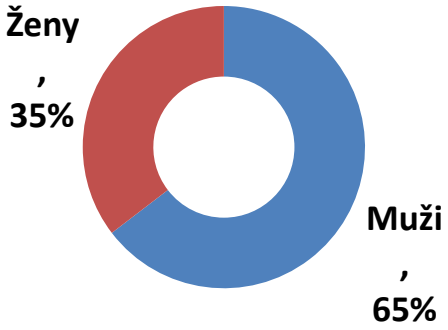
Hála P, Dujka L, Janotka M, Lekešová V, Mráz T, Petrů J, Prokopová M, Šedivá L, Škoda J, Neužil P

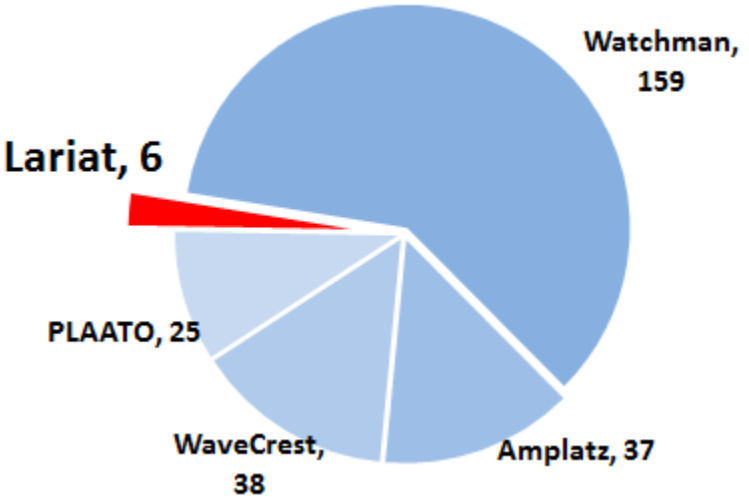
Kardiologické oddělení
Nemocnice Na Homolce
Praha

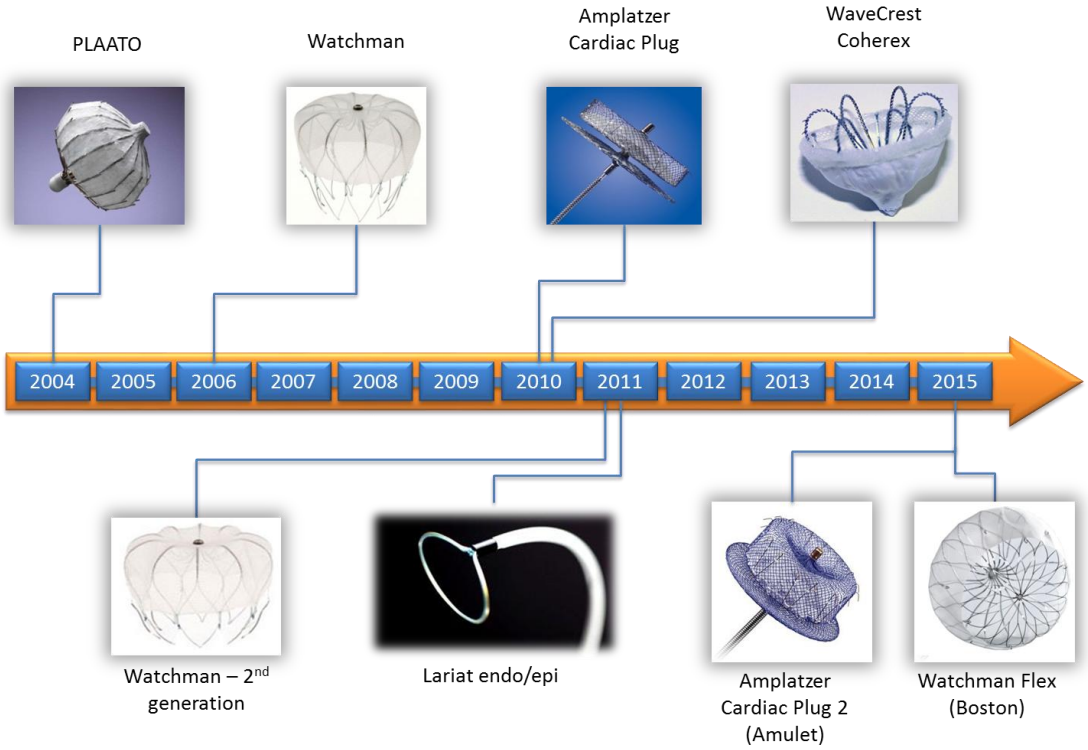
Způsoby eliminace ouška levé síně v NNH

celkový počet implantací = 263
8 různých okluderů

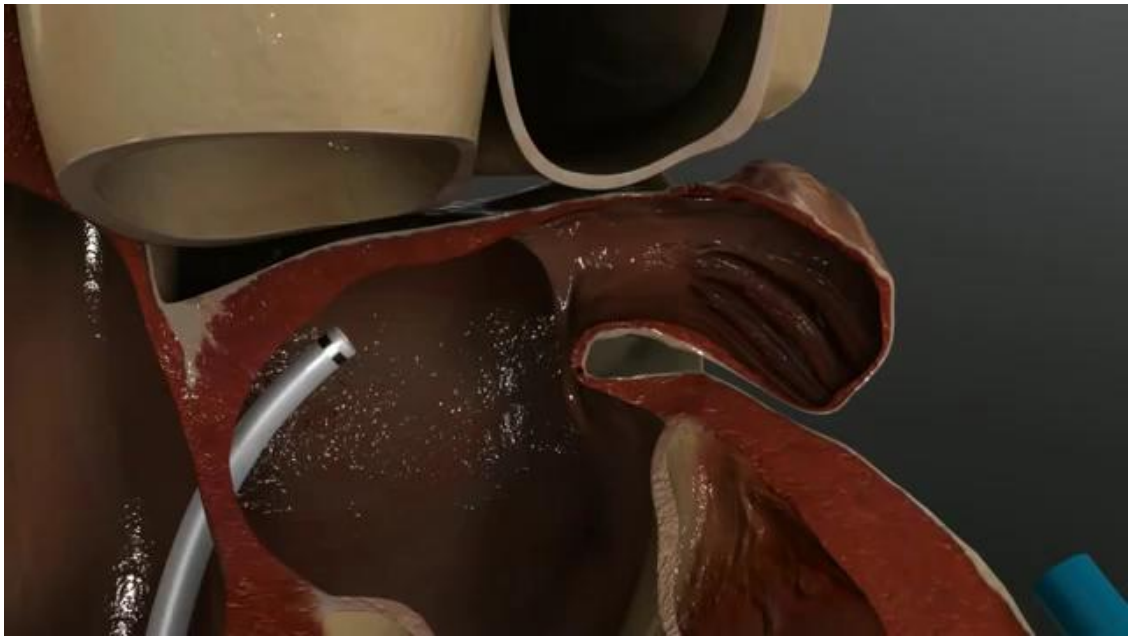
Systém Lariat = 6 pacientů ~ 2%
v letech 2011-2012





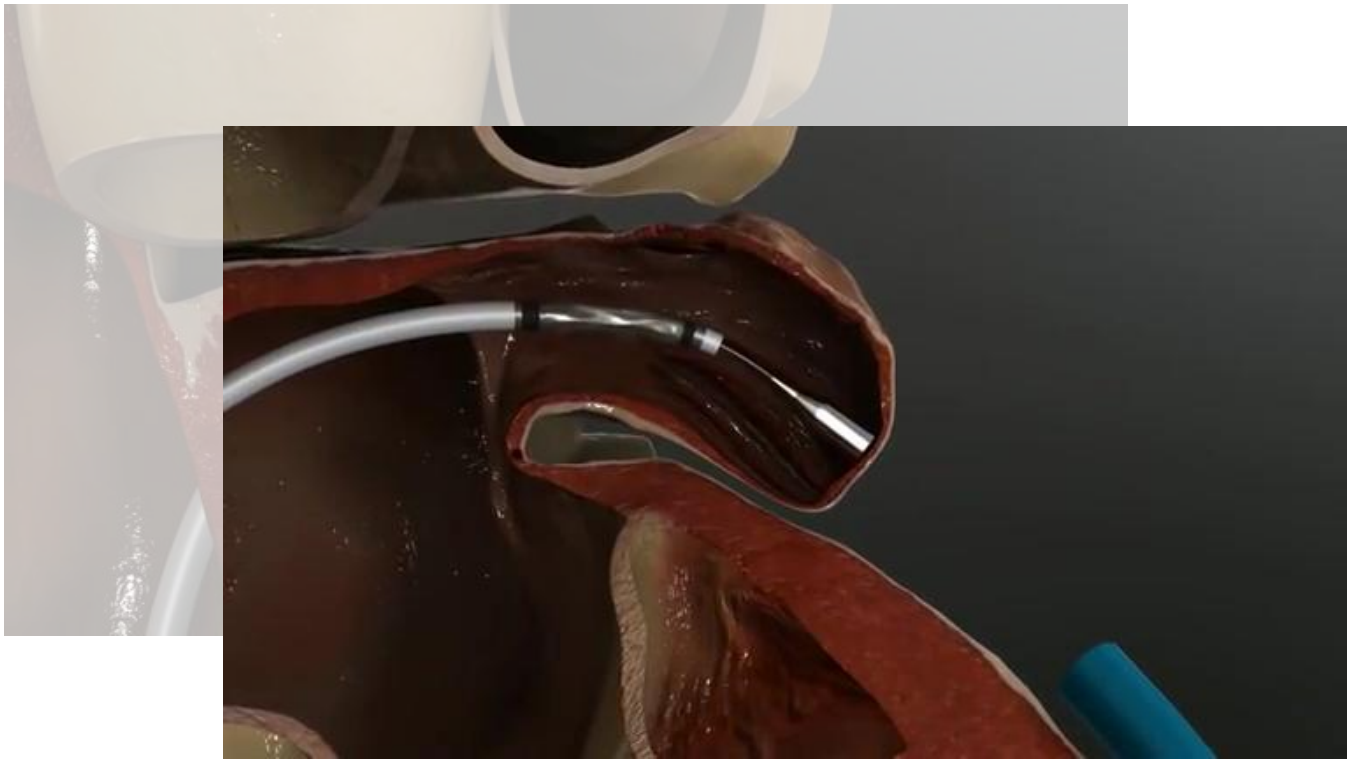


Epikardiální okluse ouška levé síně - Lariat



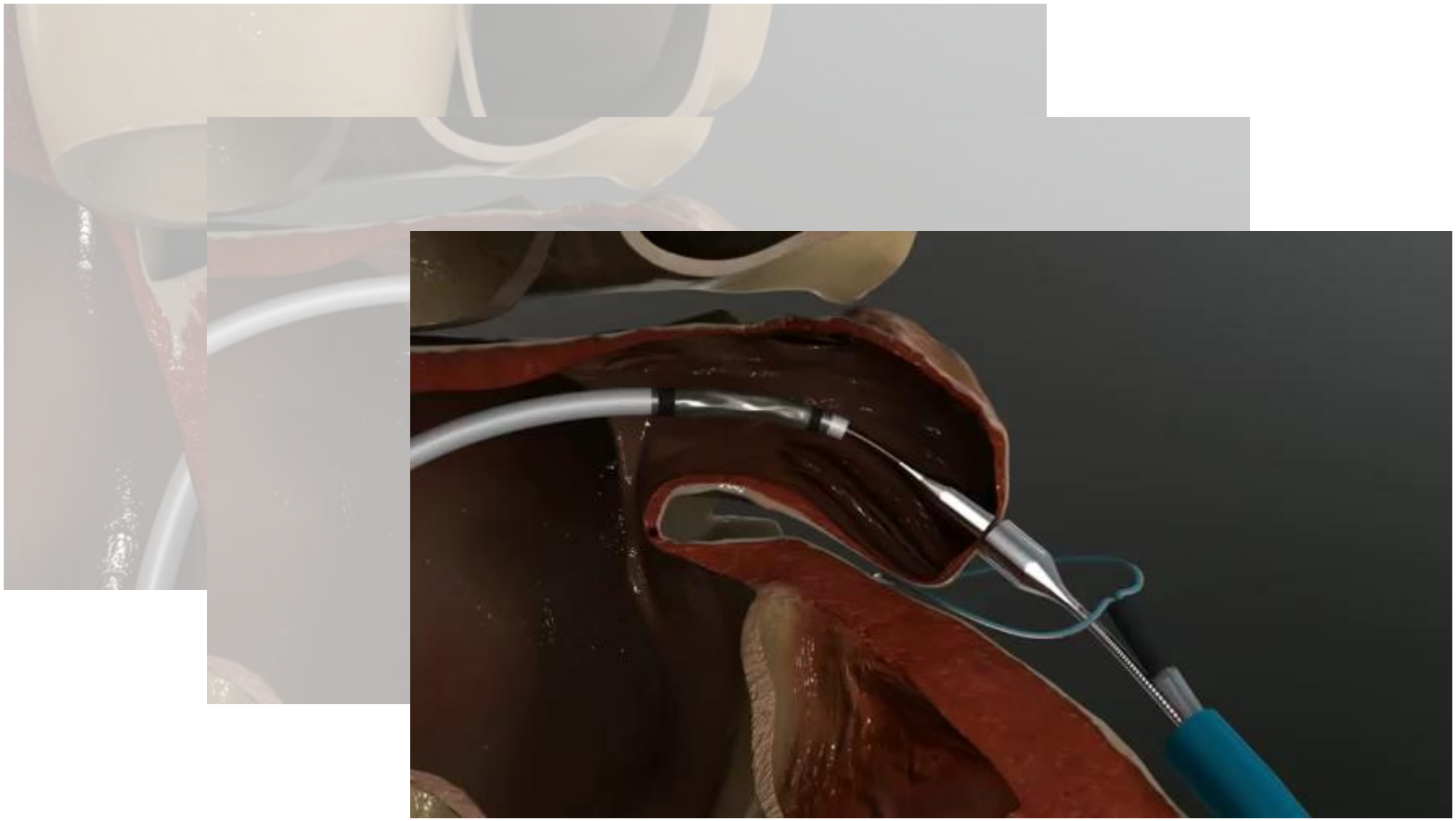
Transseptální zavedení katetru s magnetickým koncem do LAA

Epikardiální okluse ouška levé síně - Lariat



Spojení s magnetickým katetrem zavedeným v perikardu

Epikardiální okluse ouška levé síně - Lariat

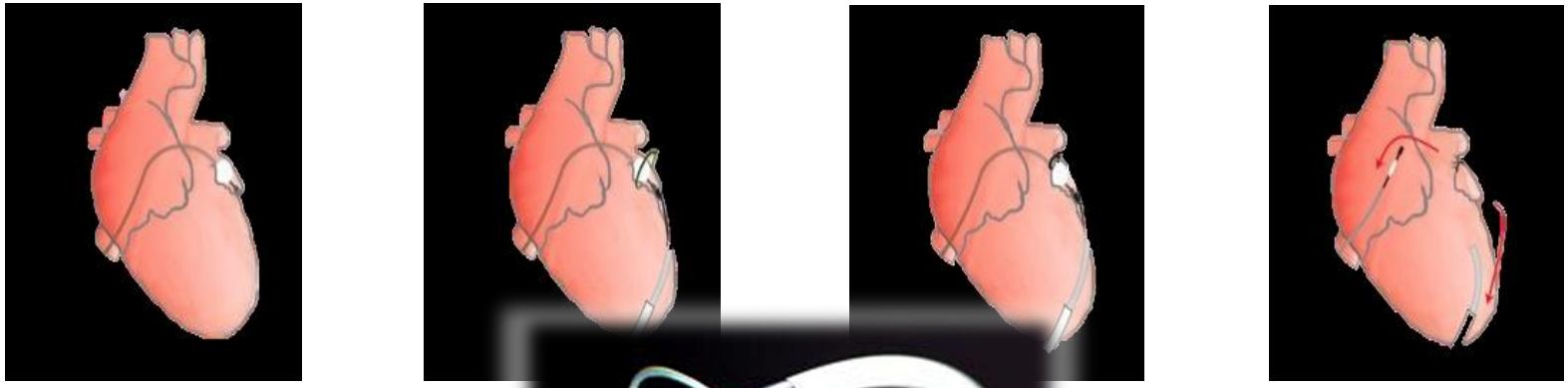


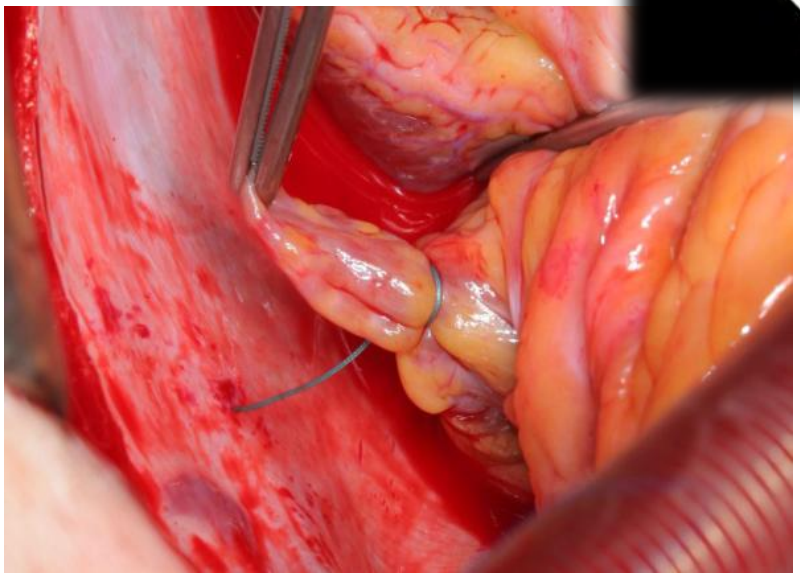
Převlečení smyčky přes ouško levé síně

Epikardiální okluse ouška levé síně - Lariat

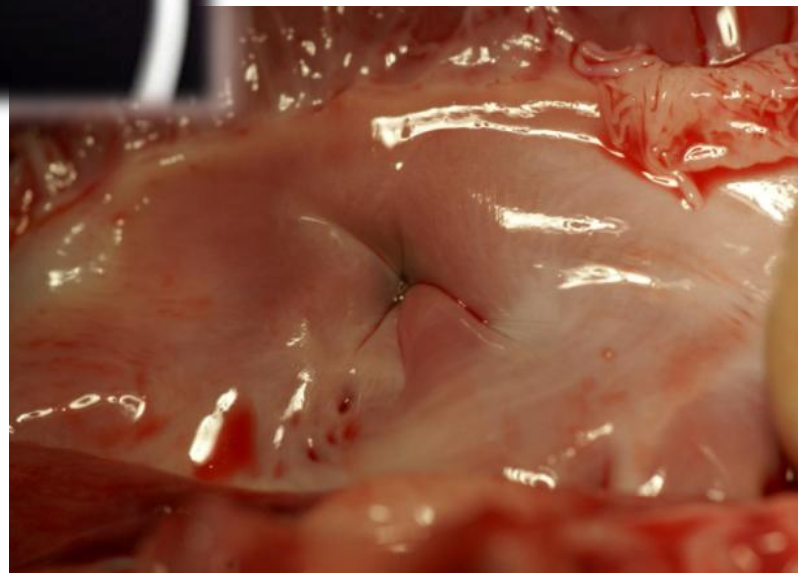
Utažení smyčky okolo baze ouška a odstranění zaváděcích katetrů

Epikardiální okluse ouška levé síně - Lariat

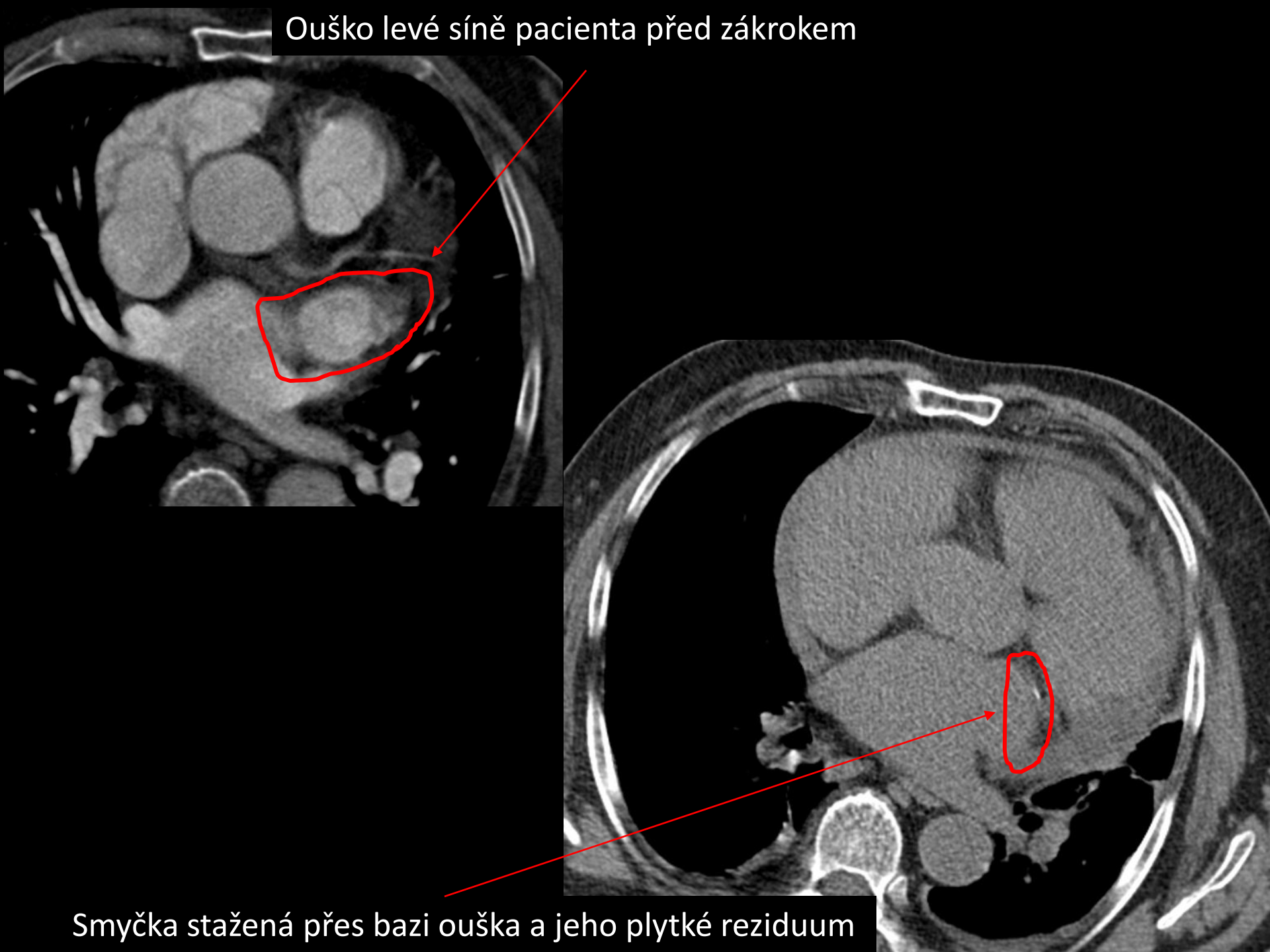




Pohled do vypreparovaného perikardu, smyčka Lariat stažena okolo baze ouška (experiment)



Pohled na endokardiální povrch levé síně, reziduum po eliminaci ouška (experiment)


Ouško levé síně pacienta před zákrokem
Smyčka stažená přes bazi ouška a jeho plytké reziduum

Heart Rhythm
Volume 12, Issue 7, July 2015, Pages 1501–1507

Endocardial (Watchman) vs epicardial (Lariat) left atrial appendage exclusion devices: Understanding the differences in the location and type of leaks and their clinical implications

Pillarisetti J, Reddy YM, Gunda S, Swarup V, Lee R, Rasekh A, Horton R, Massumi A, Cheng J, Bartus K, Badhwar N, Han F, Atkins D, Bommana S, Earnest M, Nath J, Ferrell R, Bormann S, Dawn B, Di Biase L, Mansour M, Natale A, Lakkireddy D.

Background

Prospektivní studie s 478 pacienty:

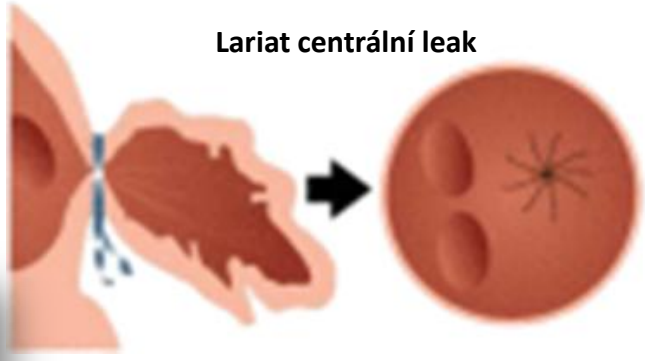
Ouška uzavřená systémem Lariat měla menší incidenci leaků, které byly současně menší, v porovnání s pacienty s implantovaným okluderem Watchman.

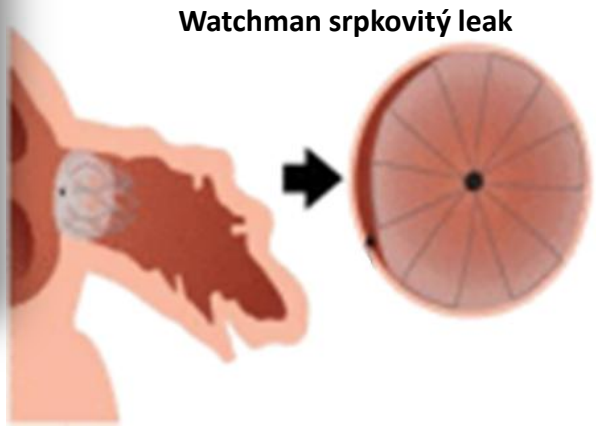
Results

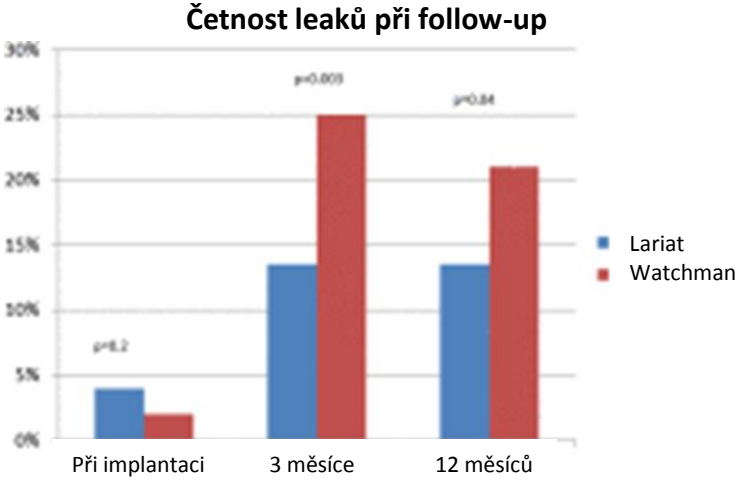
A total of 478 patients (219 with the Watchman device and 259 with the Lariat device) with successful implants were included. Patients in the Lariat group had a higher $CHADS_2$ (congestive heart failure, hypertension, age >74 years, diabetes, stroke) score and a larger left atrium and LAA. A total of 79 patients (17%) had a detectable leak at 1 year. More patients in the Watchman group had a leak compared with those in the Lariat group (46 [21%] vs 33 [14%]; *P* = .019). All the leaks were eccentric (edge effect) in the Watchman group and concentric (gunny sack effect) in the Lariat group. The size of the leak was larger in the Watchman group than in the Lariat group (3.10 ± 1.5 mm vs 2.15 ± 1.3 mm; *P* = .001). The Watchman group had 1 device embolization requiring surgery and 2 pericardial effusions requiring pericardiocentesis. In the Lariat group, 4 patients had cardiac tamponade requiring urgent surgical repair. Three patients in each group had a cerebrovascular accident and were not associated with device leaks.

Conclusion

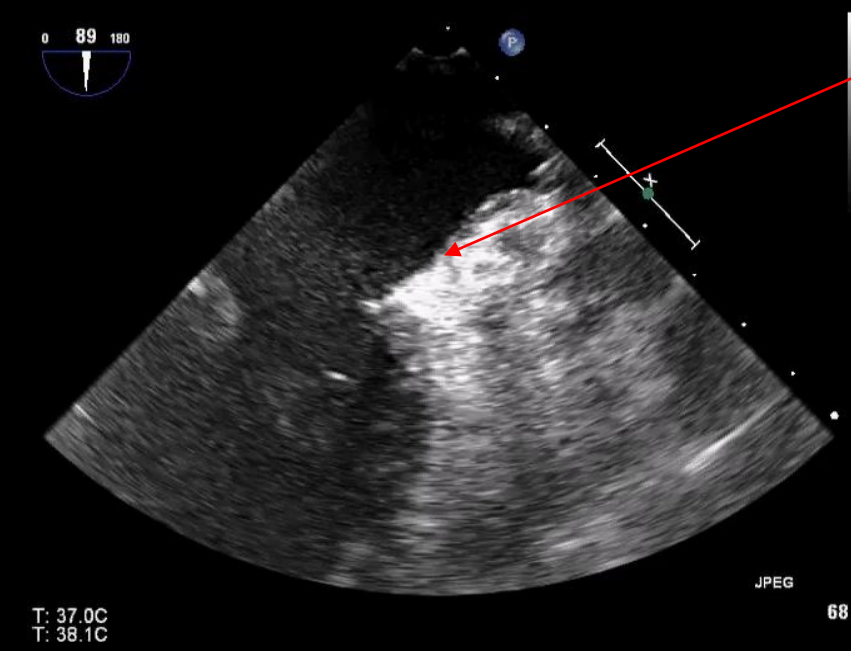
The Lariat device is associated with a lower rate of leaks at 1 year as compared with the Watchman device, with no difference in rates of cerebrovascular accident. There was no correlation between the presence of residual leak and the occurrence of cerebrovascular accident.

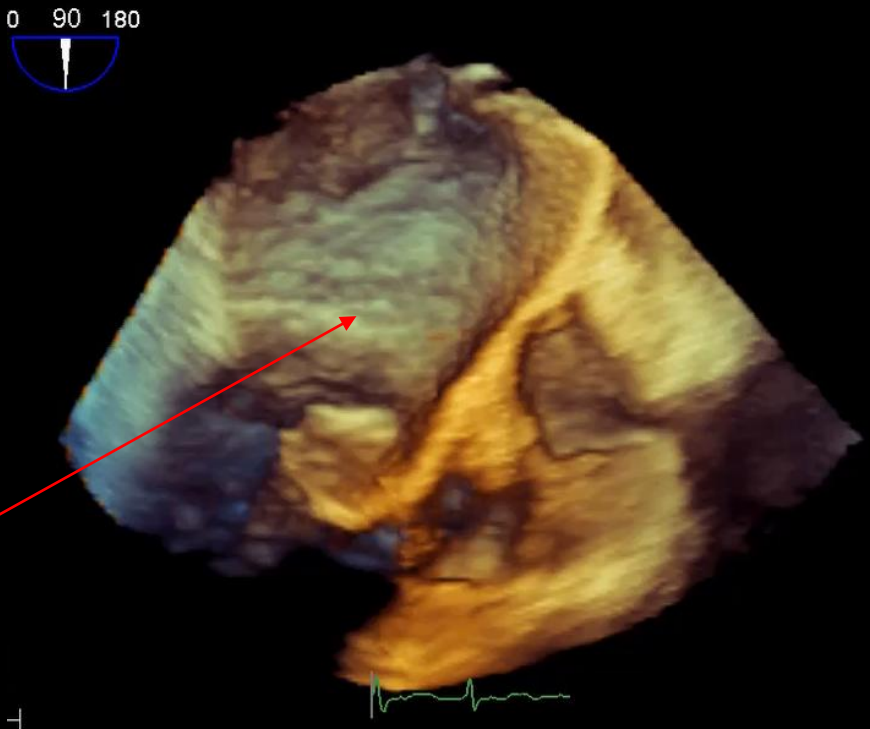






Zcela chybějící dutina ouška po zákroku





Plytké reziduum po uzavření ouška

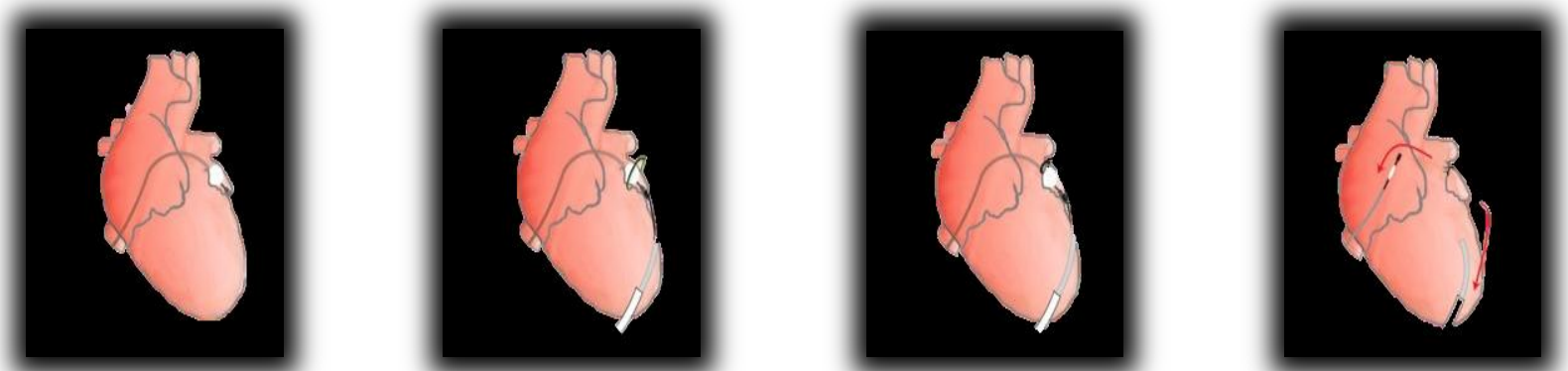
Lariat – epikardiální okluse ouška levé síně

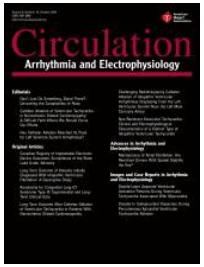
Výhody

- absence cizorodého materiálu v krevním řečišti
- menší incidence leaků
- odpadá nutnost epitelizace
- není nutná antitrombotická léčba
- eliminuje arytmogenicitu ouška

Nevýhody

- celková anestezie a jícnová echokardiografie
- rizika epikardiální přístup – perforace, perikarditis
- zdlouhavost procedury
- není vhodná pro každou morfologii ouška
- větší dávka RTG
- zatím malá zkušenost





Left Atrial Appendage Electrical Isolation and Concomitant Device Occlusion to Treat Persistent Atrial Fibrillation

Sandeep Panikker, Julian W.E. Jarman, Renu Virmani, Robert Kutys, Shouvik Haldar, Eric Lim, Charles Butcher, Habib Khan, Lilian Mantziari, Edward Nicol, John P. Foran, Vias Markides and Tom Wong

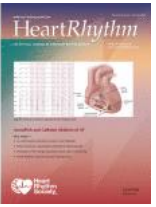
http://dx.doi.org/10.1161/CIRCEP.115.003710
Circulation: Arrhythmia and Electrophysiology. 2016;9:e003710
Originally published July 12, 2016

Background—Left atrial appendage (LAA) electric isolation is reported to improve persistent atrial fibrillation (AF) ablation outcomes. However, loss of LAA mechanical function may increase thromboembolic risk. Concomitant LAA electric isolation and occlusion as part of conventional AF ablation has never been tested in humans. We therefore evaluated the feasibility, safety, and efficacy of LAA electric isolation and occlusion in patients undergoing long-standing persistent AF ablation.

Methods and Results—Patients with long-standing persistent AF (age, 68±7 years; left atrium diameter, 46±3 mm; and AF duration, 25±15 months) underwent AF ablation, LAA electric isolation, and occlusion. Outcomes were compared with a balanced (1:2 ratio) control group who had AF ablation alone. Among 22 patients who underwent ablation, LAA electric isolation was possible in 20. Intraprocedural LAA reconnection occurred in 17 of 20 (85%) patients, predominantly at anterior and superior locations. All were reisolated. LAA occlusion was successful in all 20 patients. There were no major periprocedural complications. Imaging at 45 days and 9 months confirmed satisfactory device position and excluded pericardial effusion. One of twenty (5%) patients had a gap of ≥5 mm requiring anticoagulation. Nineteen of twenty (95%) patients stopped warfarin at 3 months. Without antiarrhythmic drugs, freedom from AF at 12 months after a single procedure was significantly higher in the study group (19/20, 95%) than in the control group (25/40, 63%), *P*=0.036. Freedom from atrial arrhythmias was demonstrated in 12 of 20 (60%) and 18 of 20 (90%) patients after 1 and ≤2 procedures (mean, 1.3), respectively.

Conclusions—Persistent AF ablation, LAA electric isolation, and mechanical occlusion can be performed concomitantly. This technique may improve the success of persistent AF ablation while obviating the need for chronic anticoagulation.

Heart Rhythm
Volume 12, Issue 1, January 2015, Pages 52–59



Impact of left atrial appendage exclusion using an epicardial ligation system (LARIAT) on atrial fibrillation burden in patients with cardiac implantable electronic devices

Afzal MR, Kanmanthareddy A, Earnest M, Reddy M, Atkins D, Bommana S, Bartus K, Rasekh A, Han F, Badhwar N, Cheng J, Dibiase L, Ellis CR, Dawn B, Natale A, Lee RJ, Lakkireddy D.

Background

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U pacientů (Fibrilace síní + kardiostimulátor) dojde po uzávěru ouška systémem Lariat ke snížení AF burden. Znatelné zejména u neparoxysmálních forem arytmie.

Methods

A total of 50 patients with AF and cardiac implantable electronic devices who underwent successful LAA exclusion were enrolled in this prospective observational study. AF burden before LAA exclusion (baseline) and 3 and 12 months after exclusion was assessed by device interrogation.

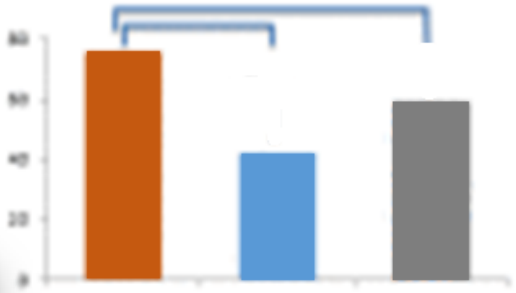
Results

AF burden at 3-month follow-up (42% ± 34%) was significantly lower compared to baseline (76% ± 33%, $P < .0001$). The reduction in AF burden was sustained at 12 months (59% ± 26%, $P < .001$). Subgroup analysis revealed that AF burden at 3-month follow-up was similarly reduced in both paroxysmal AF (n = 19) and nonparoxysmal AF (n = 31). However, there was no reduction in AF burden in patients with paroxysmal AF at 12 months. AF burden in patients with known AF triggers in the LAA (n = 9) was significantly reduced at 3 months (52% ± 35%) and 12 months (42% ± 19%) compared to respective baseline (84 ± 31%, $P < .0001$).

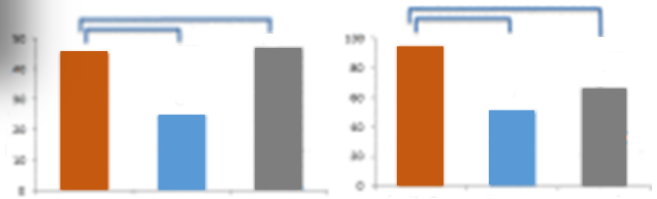
Conclusion

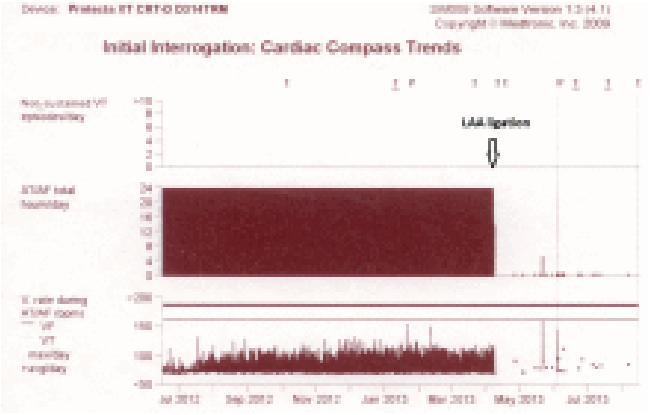
LAA exclusion appears to reduce AF burden. The presence of AF triggers in the LAA appears to be the strongest predictor of AF reduction. The study underscores the role of the LAA in arrhythmogenesis for AF and highlights the complementary role of LAA exclusion in restoration of normal sinus rhythm.

Snížení AF burden po Lariat ligaci ouška
50 pacientů



parox FiS **non-parox FiS**





Percutaneous alternative to the Maze procedure for the treatment of persistent or long-standing persistent atrial fibrillation (aMAZE trial): Rationale and design

Randall J. Lee, MD, PhD,[a] Dhanunjaya Lakkireddy, MD,[b] Suneet Mittal, MD,[c,d] Christopher Ellis, MD,[e] Jason T. Connor, PhD,[f,g] Benjamin R. Saville, PhD,[f,h] and David Wilber, MD[i] *San Francisco, CA; Kansas City, KS; New York, NY; Ridgewood, NJ; Nashville, TN; Austin, TX; Orlando, FL; and Chicago, IL*

Background Pulmonary vein antrum isolation (PVI) as a treatment of paroxysmal atrial fibrillation (AF) is associated with a high rate of success; however, outcomes for treating persistent and long-standing persistent AF with PVI alone are substantially lower and often require multiple procedures to maintain long-term freedom from atrial arrhythmias. Foci and/or substrate outside the pulmonary veins, particularly in the left atrial appendage (LAA), has been identified as a key mechanism in the maintenance of persistent AF and long-standing persistent AF.

Objective The goals of the study are to evaluate the safety and effectiveness of the LARIAT System to percutaneously isolate and ligate the LAA and to determine if LAA ligation as adjunctive therapy to PVI improves maintenance of sinus rhythm in patients with persistent and long-standing persistent AF.

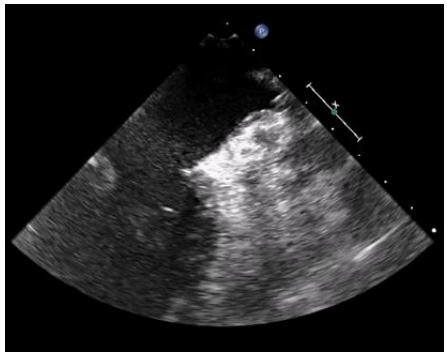
Study Design The trial is a prospective, multicenter, randomized controlled study. The trial design incorporates a Bayesian adaptive design that will randomize a maximum of 600 patients with persistent or long-standing persistent AF to LAA ligation and PVI vs PVI alone in a 2:1 randomization. The primary end points include 30-day safety of the LARIAT procedure and freedom from documented AF, atrial flutter, or atrial tachycardia of more than 30 seconds at 12 months after the PVI off antiarrhythmic drugs. Key secondary outcomes include a composite of cardiovascular death and stroke, as well as quality of life.

Conclusion The aMAZE trial will determine if LAA ligation as adjunctive therapy to PVI increases the efficacy of maintaining sinus rhythm in patients with persistent and long-standing persistent AF. (Am Heart J 2015;170:1184-94.)

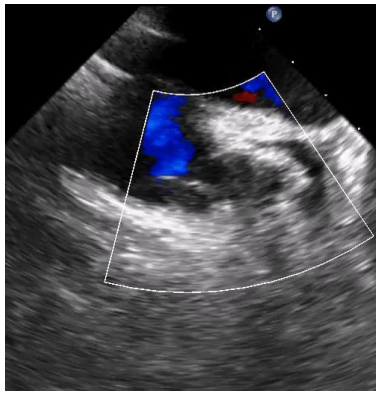
Okluse ouška systémem Lariat

Celkově 6 pacientů v letech 2011-2012

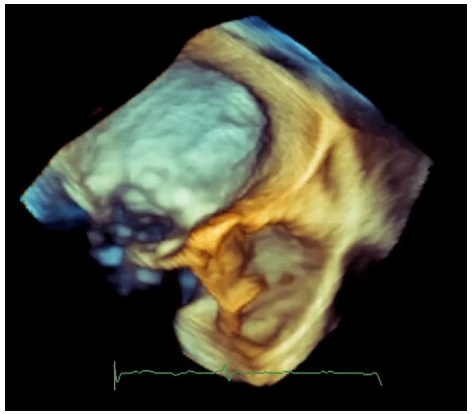
#	typ FiS		Důvod okluse ouška	věk OLAA	CHADSVASc	HASBLED	Bezprostřední antitrombotická léčba	Převedení na ASA	leak na konci výkonu [mm]	leak 1. den po výkonu [mm]
1	perm	♂	FiS, recidivující iCMP, pády	73	4	3	DAPT	16M	0	2.5
2	perm	♀	kolísavé INR	72	3	2	DAPT	6M	0	0
3	perm	♂	iCMP embolizační	80	5	2	warfarin + LMWH	1M	0	0
4	perm	♂	hematurie na warfarinu	84	4	2	Pradaxa	1W	0	0
5	persist	♂	kolísavé INR, opakované RFA FiS/AT	60	2	1	DAPT	2M	2	2
6	parox	♀	kolísavé INR	71	5	1	LMWH	1M	0	0
				Ø 73	Ø 3.8	Ø 1.8				



Zcela chybějící dutina ouška po zákroku



Reziduální leak po zákroku

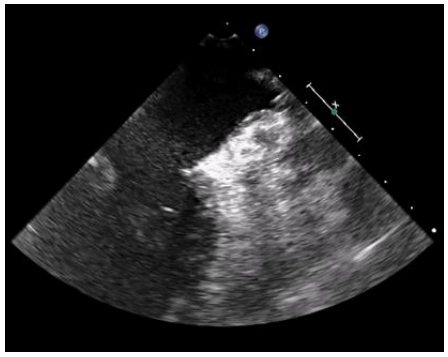


Chybějící dutina ouška po 5 letech

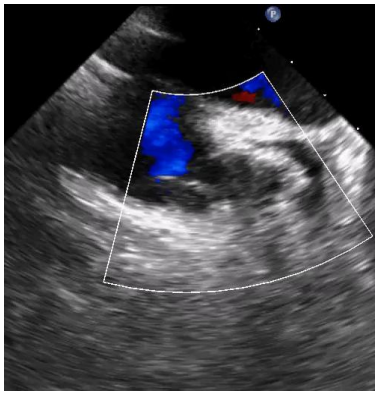
Výsledky po 5letech sledování

#	typ FiS		věk	Rytmus	Celková doba sledování [roky]	Leak 1 den po implantaci	Leak na konci sledování	CMP	Krvácení	ASD na konci sledování	Komplikace Poznámka
1	perm	♂	73		4.9	2.5	2.5	0	0	0	zemřel - tumor moč. měchýře
2	perm	♀	72	FiS	5.4	0	0	0	0	PFO	přechodně trombus
3	perm	♂	80	FiS	4.0	0	0	0	0	0	-
4	perm	♂	84		1.6	0	0	0	z dásní	0	zemřel – sarkom
5	persist	♂	60	FiS	5.4	2	3	0	0	PFO	efuse perikardu
6	parox	♀	71	SR	5.5	0	0	0	0	0	
			Ø 73		27 pacientoroků						

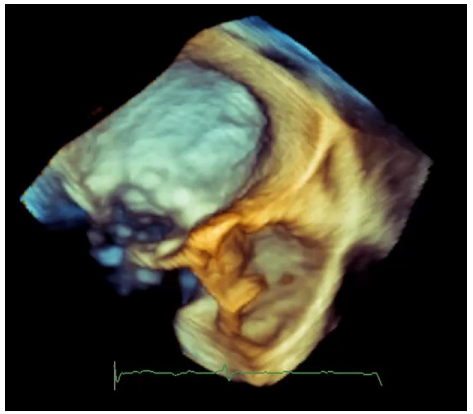
27 pacientoroků



Zcela chybějící dutina ouška po zákroku



Reziduální leak po zákroku

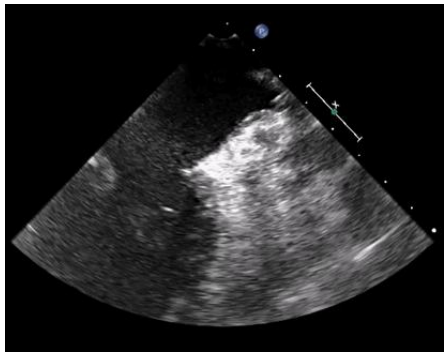


Chybějící dutina ouška po 5 letech

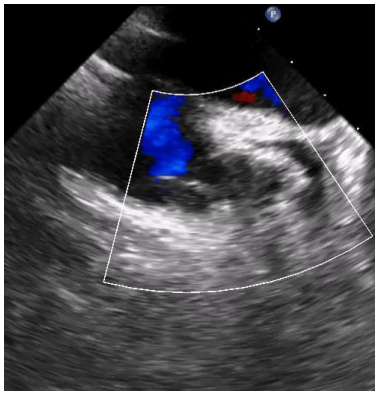
Výsledky po 5letech sledování

#	typ FiS		věk	Rytmus	Celková doba sledování [roky]	Leak 1 den po implantaci	Leak na konci sledování	CMP	Krvácení	ASD na konci sledování	Komplikace Poznámka
1	perm	♂	73		4.9	2.5	2.5	0	0	0	zemřel - tumor moč. měchýře
2	perm	♀	72	FiS	5.4	0	0	0	0	PFO	přechodně trombus
3	perm	♂	80	FiS	4.0	0	0	0	0	0	-
4	perm	♂	84		1.6	0	0	0	z dásní	0	zemřel – sarkom
5	persist	♂	60	FiS	5.4	2	3	0	0	PFO	efuse perikardu
6	parox	♀	71	SR	5.5	0	0	0	0	0	
			Ø 73		27 pacientoroků						

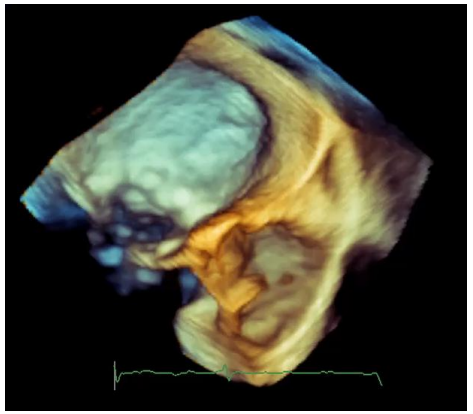
27 pacientoroků



Zcela chybějící dutina ouška po zákroku



Reziduální leak po zákroku



Chybějící dutina ouška po 5 letech

Závěry

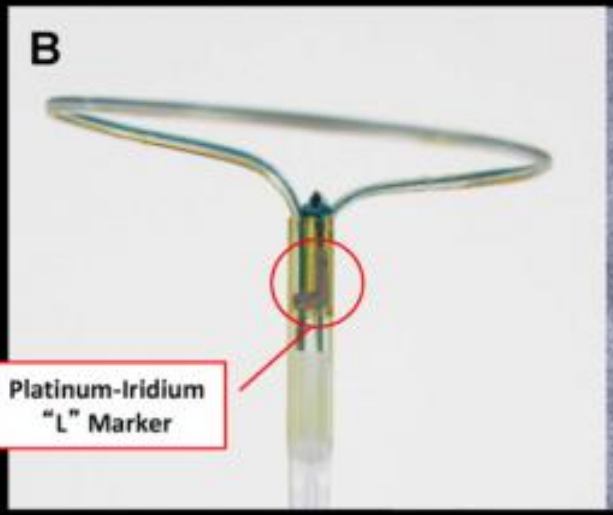
- Lariat je proveditelná alternativní metoda okluse ouška s akceptovatelnými riziky výkonu
- Výhodná pro možnost okamžitého vysazení antitrombotické léčby
- Po 5 letech sledování nedošlo ke zvětšení leaku
- Pacienti užívali monoterapii ASA, nedošlo k žádné kardioembolizační příhodě
- Nová generace Lariat+ si dává za cíl zjednodušit a zpřesnit proceduru
- Potenciálně výhodná v příznivém ovlivnění výskytu Fibrilace síní

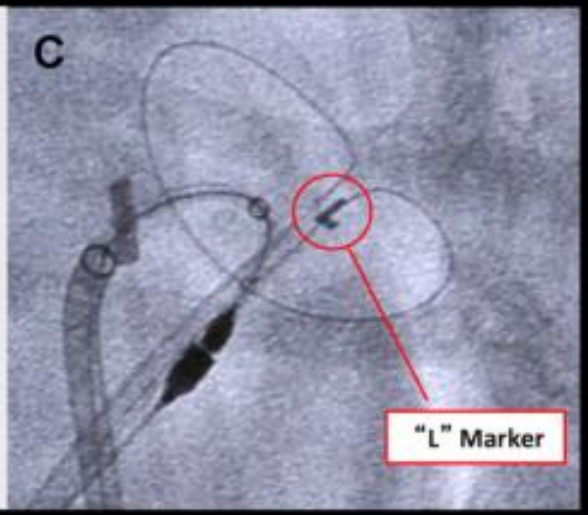
NEMOCNICE NA HOMOLCE

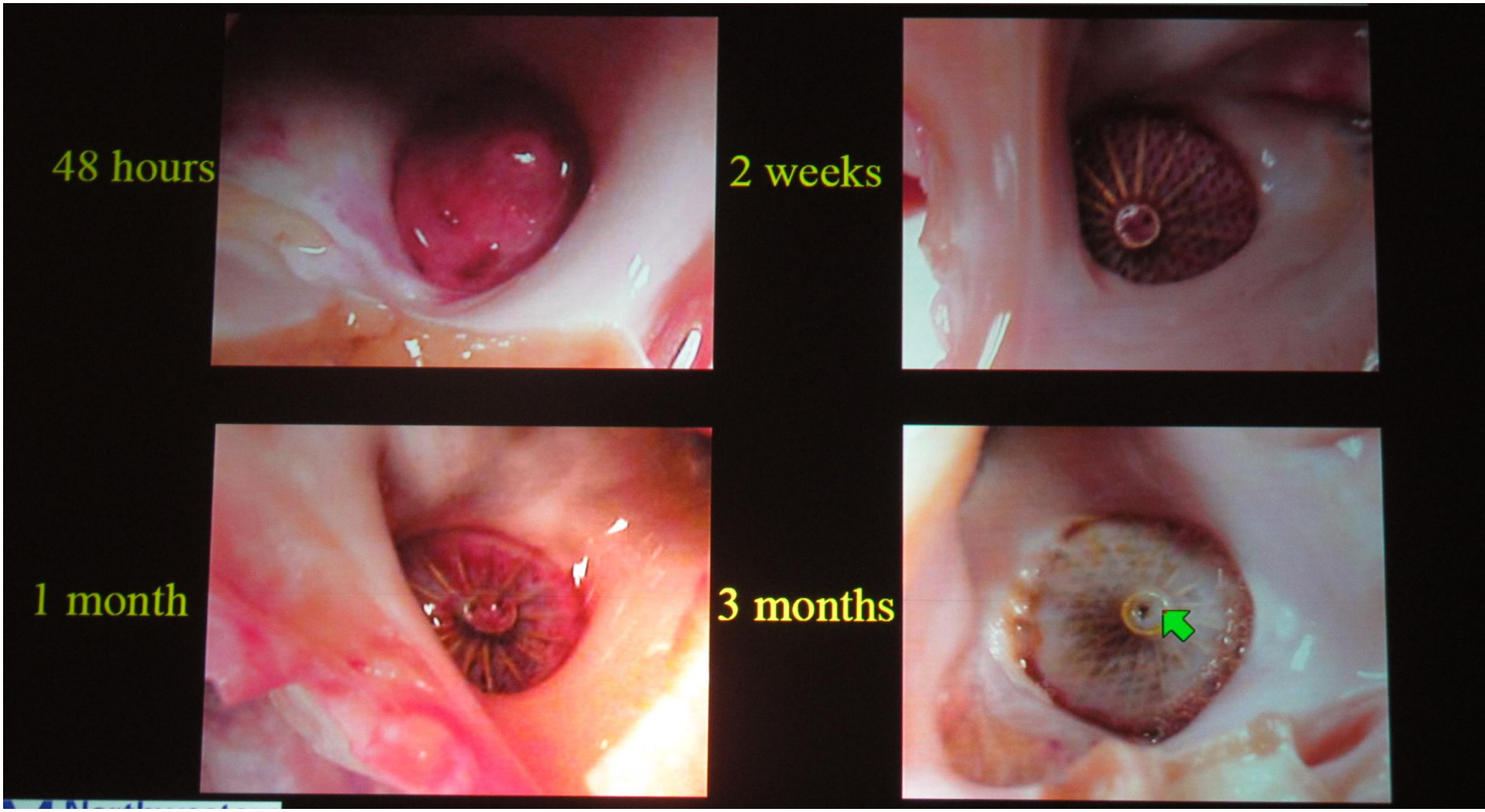
Next Generation LARIAT +

Snare width increased from 40mm to 45mm

- *Allows treatment of patients with LAAs > 40mm*






48 hours
2 weeks
1 month
3 months