



Complications of Cryoballoon Ablation



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COI Disclosure

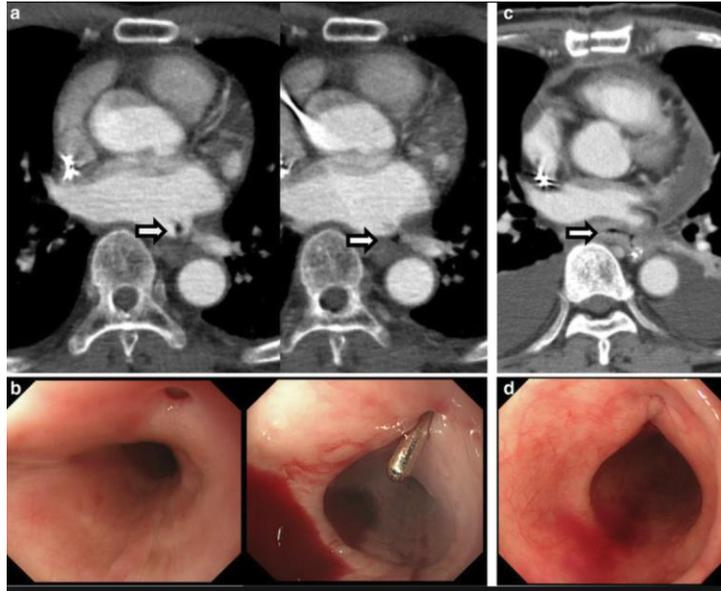
Pil-Sung Yang

The authors have no financial conflicts of interest
to disclose concerning the presentation

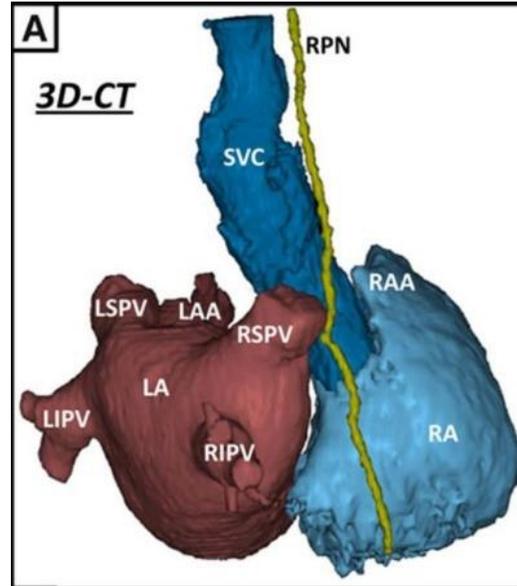


Complications of AF ablation

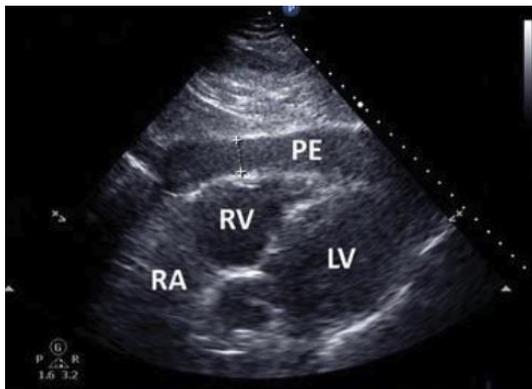
Atrioesophageal (AE) fistula



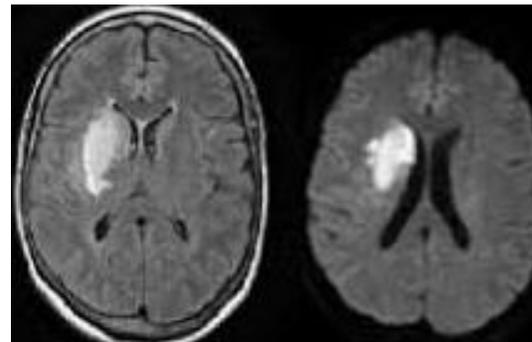
Phrenic nerve injury



Pericardial effusion / Tamponade



Peri-procedural Stroke



Type of complication

- Death
- Atrioesophageal fistula
- Pulmonary vein stenosis*
- Vascular complications†
 - Arteriovenous fistula
 - Femoral pseudoaneurysm
- Stroke/TIA‡
 - Stroke
 - TIA
- Tamponade
- Pericardial effusion
- Phrenic nerve injury
- Diaphragmatic paralysis
- DVT/PE
- Pneumothorax
- Hemothorax
- Sepsis, abscesses, or endocarditis
- Valve damage



Previous data about complications, RFCA / Germany

Table I Incidence of procedure related complications, stratified by patient group

Complications, n (%)	Cryoablation Group 1 (n = 5608), n (95% CI) (%)	PV isolation Group 2 (n = 3167), n (95% CI) (%)	LA ablation Group 3 (n = 8336), n (95% CI) (%)	LA + RA ablation Group 4 (n = 2403), n (95% CI) (%)
In-hospital death*	8 (3–17) (0.1)	0 (0–5) (0.0)	7 (3–16) (0.1)	3 (0–10) (0.1)
Stroke*	27 (18–40) (0.5)	17 (10–28) (0.5)	48 (35–65) (0.6)	15 (8–26) (0.6)
Pneumonia*	30 (20–44) (0.5)	23 (14–36) (0.7)	88 (71–109) (1.1)	25 (16–38) (1.0)
Phrenic nerve injury*	21 (13–33) (0.4)	n.a.	n.a.	n.a.
Cardiac arrest*	13 (7–23) (0.2)	3 (0–10) (0.1)	17 (10–28) (0.2)	7 (3–16) (0.3)
AV Block III°*	11 (5–21) (0.2)	9 (4–18) (0.3)	29 (19–43) (0.3)	8 (3–17) (0.3)
Pericardial effusion	167 (143–195) (3.0)	100 (81–122) (3.2)	305 (272–341) (3.7)	98 (80–120) (4.1)
Pericardial drainage*	42 (29–55) (0.7)	26 (16–36) (0.8)	113 (92–134) (1.4)	20 (11–29) (0.8)
Access site complications	411 (373–452) (7.3)	219 (192–250) (6.9)	655 (607–706) (7.9)	149 (127–175) (6.2)
Vascular intervention /surgery*	15 (7–23) (0.3)	15 (7–23) (0.5)	97 (78–116) (1.2)	12 (5–19) (0.5)
Transfusion*	48 (34–62) (0.9)	40 (28–52) (1.3)	203 (175–231) (2.4)	35 (23–47) (1.5)
Total, overall	688 (637–739) (12.3)	371 (333–409) (11.7)	1149 (1083–1215) (13.8)	305 (271–339) (12.7)
Total, major	215 (186–244) (3.8)	133 (110–156) (4.2)	602 (554–650) (7.2)	125 (103–147) (5.2)

About 0.5%

About 3.5%

About 5.5%



Previous data about complications, RFCA / USA

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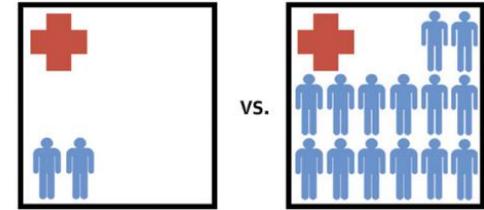
Risk of Mortality Following Catheter Ablation of Atrial Fibrillation



Edward P. Cheng, MD, PhD,^a Christopher F. Liu, MD,^a Ilhwan Yeo, MD,^b Steven M. Markowitz, MD,^a
 George Thomas, MD,^a James E. Ip, MD,^a Luke K. Kim, MD,^a Bruce B. Lerman, MD,^a Jim W. Cheung, MD^a

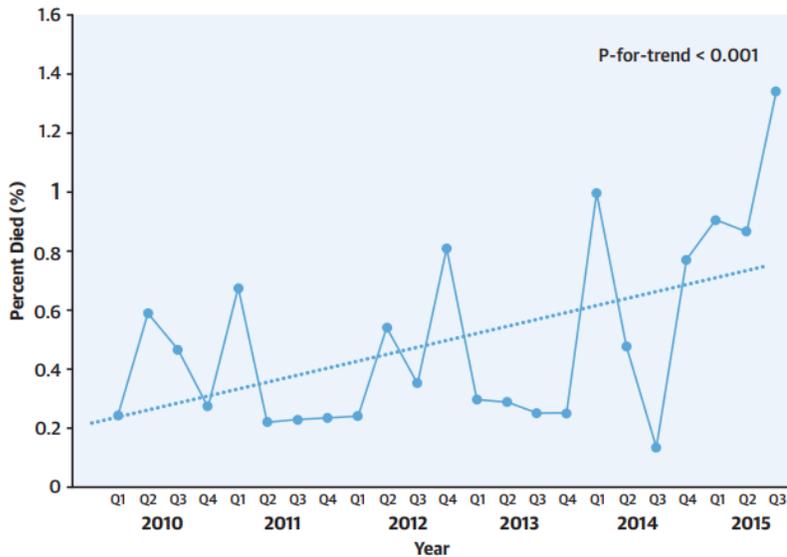
JACC, 2019, 74 (18) 2254-2264.

Low AF Ablation Hospital Volume

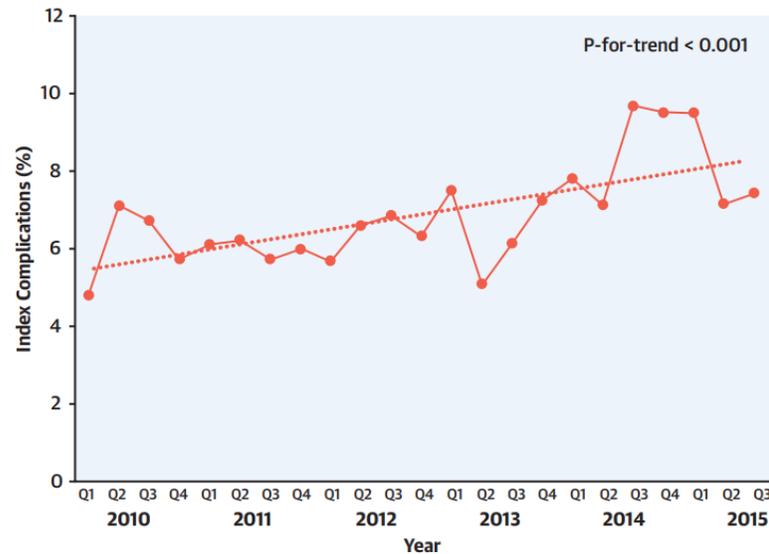


aOR 2.35; p = 0.003

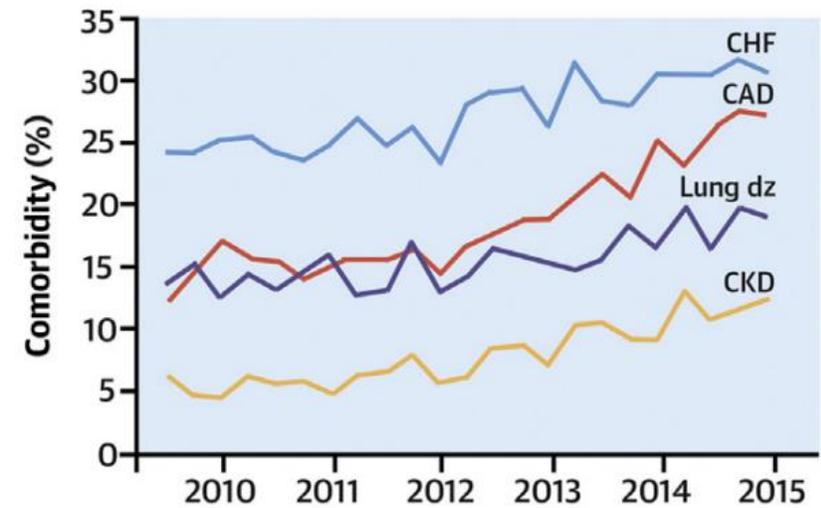
Early mortality after AF RFCA



Procedural complications for AF RFCA



Comorbidities



Previous data about complications, RFCA / Korea

Data from Severance Hospital

	Overall (n=222)
Procedure time (min)	184.0±37.2
Ablation time (sec)	4722.3±936.2
Fluoroscopy time (min)	34.8±12.3
Major complications	5 (2.3)
Cardiac tamponade	4 (1.8)
AE fistula	1 (0.5)
Stroke or TIA	0 (0)
Minor vascular complications	7 (3.2)
Femoral AV fistula	3 (1.4)
Femoral pseudoaneurysm	0 (0)
Thigh hematoma	4 (1.8)

Yonsei Med J 2019 Apr;60(4):360-367

Major complications (stroke, tamponade, AE fistula): **about 2.3%**

Data from Health Insurance Review and Assessment (HIRA)

	Male (n=2,821)	Female (n=1,029)	Total (n=3,850)
Stroke, n(%)	12 (0.4)	6 (0.6)	18 (0.5)
Blood transfusion, n(%)	89 (3.2)	96 (9.3)*	185 (4.8)
Pericardiocentesis, n(%)	77 (2.7)	28 (2.7)	105 (2.7)
Creation of pericardial window	1	0	1
Cardiopulmonary resuscitation, n(%)	4 (0.1)	2 (0.2)	6 (0.2)
Death during admission	2	1	3
Any of the above outcomes, n(%)	138 (4.9)	112 (10.9)*	250 (6.5)

International Journal of Arrhythmia 2018;19(1):14-21

Major complications (stroke, tamponade, arrest): **about 3.4%**



Previous data about complications, RFCA / Korea

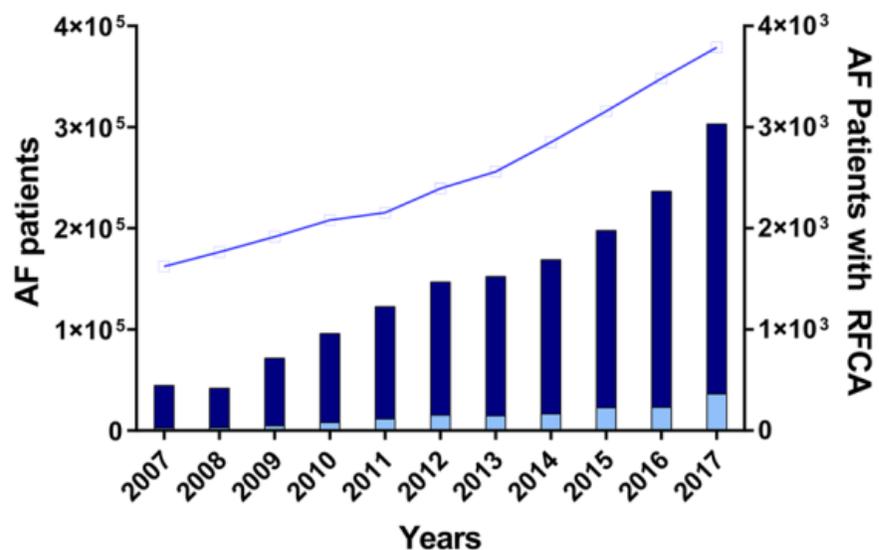
ORIGINAL ARTICLES

WILEY

Temporal trends of catheter ablation for patients with atrial fibrillation: A Korean nationwide population-based study

Euijae Lee MD¹ | So-Ryoung Lee MD¹ | Eue-Keun Choi MD, PhD¹ |
 Kyung-Do Han PhD² | Myung-Jin Cha MD¹ | Gregory Y.H. Lip MD^{1,3,4} |
 Seil Oh MD, PhD¹

J Cardiovasc Electrophysiol. 2020;31:2616–2625



— Patients with AF ■ AF RFCA patient ■ Redo patient

	2007–2010	2011–2014	2015–2017
Number of AF RFCA patients	2563	5928	7388
Hemorrhage requiring transfusion	183 (7.14)	288 (4.86)	250 (3.38)
Cardiac tamponade	123 (4.80)	174 (2.94)	179 (2.42)
Bleeding complications ^a	242 (9.44)	377 (6.36)	364 (4.93)
Major vascular complications ^b	14 (0.55)	59 (1.00)	39 (0.53)
Pneumonia	28 (1.09)	92 (1.55)	121 (1.64)
Pericarditis	18 (0.7)	9 (0.15)	15 (0.2)
Esophageal injury	0 (0)	5 (0.08)	13 (0.18)
Sepsis	5 (0.2)	6 (0.1)	22 (0.3)
Pneumothorax	4 (0.16)	3 (0.05)	7 (0.09)
Ischemic stroke	3 (0.12)	8 (0.13)	7 (0.09)
Intracranial hemorrhage	1 (0.04)	2 (0.03)	3 (0.04)
Infective endocarditis	2 (0.08)	3 (0.05)	3 (0.04)
Heart failure aggravation	3 (0.12)	6 (0.1)	22 (0.3)
Cardiopulmonary resuscitation	11 (0.43)	15 (0.25)	16 (0.22)
All-cause death	4 (0.16)	10 (0.17)	6 (0.08)
Total patients	304 (11.86)	515 (8.69)	555 (7.51)



Previous data about complications, RFCA / Korea

RESEARCH

Open Access

Catheter ablation of atrial fibrillation in Korea: results from the Korean Heart Rhythm Society Ablation Registry for Atrial Fibrillation (KARA)



Euijae Lee^{1†}, Hyoung-Seob Park^{2†}, Seongwook Han², Gi-Byung Nam³, Jong-Il Choi⁴, Hui-Nam Pak⁵, Il-Young Oh⁶, Dong-Gu Shin⁷, Young Keun On⁸, Sang Weon Park¹, Young-Hoon Kim⁴ and Seil Oh^{9*} on behalf of the KARA investigators

Int J Arrhythm (2021) 22:20

- ✓ 37개 center
- ✓ 총 2,402 환자
- ✓ First ablation: 88.8%
- ✓ Procedure date: 2017년 9월 ~ 2019년 12월

Variables

Total (N = 2402)

No complication	2348 (97.8%)
Any complication	54 (2.2%)
Cardiac tamponade ¹	15 (0.6%)
Pericardial effusion	6 (0.2%)
Pericarditis	3 (0.1%)
Access site complications ²	11 (0.5%)
Phrenic nerve palsy	5 (0.2%)
Cerebrovascular accidents ³	5 (0.2%)
Others ⁴	9 (0.4%)
Mode of treatment	54
Conservative management	32 (59.3%)
Interventional management	22 (40.7%)

Any complications: **2.2%**



Previous data about complications, Cryo / Korea

Cryoballoon Catheter Ablation in Korean Patients With Paroxysmal and Persistent Atrial Fibrillation: One Year Outcome From the Cryo Global Registry

Hong Euy Lim , MD, PhD¹, Il-Young Oh , MD, PhD², Fred J Kueffer, MS³, Kelly Anna van Bragt , PhD³, and Young Keun On , MD, PhD, FHRS⁴

Korean Circ J. 2022 52(10):755-767

- ✓ 3개 center
- ✓ 총 299 환자
- ✓ Procedure date: 2019년 4월 ~ 2020년 05월

Adverse events	Korea cohort (n = 299)
Serious* device- or procedure-related adverse events	2 (2, 0.7)
Incision site hematoma	1 (1, 0.3)
Vascular pseudoaneurysm	1 (1, 0.3)
Non-serious procedure-related adverse events	5 (5, 1.7)
Phrenic nerve injury	3 (3, 1.0)
Urinary retention	1 (1, 0.3)
Haemoptysis	1 (1, 0.3)
Non-procedure-related serious* adverse events	55 (45, 15.1)
Arrhythmia supraventricular	6 (6, 2.0)
Atrial fibrillation	32 (29, 9.7)
Atrial flutter	5 (5, 1.7)
Cholecystitis acute	1 (1, 0.3)
Coronary artery disease	1 (1, 0.3)
Gastritis	1 (1, 0.3)
Hashimoto's encephalopathy	1 (1, 0.3)
Hypertrophic cardiomyopathy	1 (1, 0.3)
Inguinal hernia	1 (1, 0.3)
Pneumonia	2 (2, 0.7)
Sinus node dysfunction	3 (3, 1.0)
Thermal burn	1 (1, 0.3)

Any procedure-related complications: **2.3%**

Serious procedure-related complications: **0.7%**



Korea Cryoballoon Ablation Registry

Clinical outcomes in patients with atrial fibrillation who received cryoballoon ablation
– a multicenter retrospective cohort study –

참여 기관	연구책임자	환자 수
강북삼성병원	이성호	82
건국대학교병원	권창희	100
분당서울대학교병원	오일영	657
분당차병원	양필성	50
삼성서울병원	김주연	200
서울대학교병원	이소령	262
서울아산병원	차명진	296
고려대학교안암병원	심재민	100
이화대학교목동병원	박준범	66
충남대학교병원	김준형	6
한림대학교성심병원	임홍의	818
해운대백병원	김기훈	52

✓ 12개 center

✓ 총 2,689 환자

✓ First ablation: 2,678명 (99.6%)

✓ Procedure date: 2018년 5월 ~ 2022년 6월



Results (1)

	Overall (N=2689)
Age	62.0 ± 10.1
Sex (male)	76.0%
AF duration (days)	1122.6 ± 1175.4
Persistent AF	55.8%
BMI	25.7 ± 3.4
CHA2DS2 VASc score	2.1 ± 1.5
HF	23.6%
HTN	59.0%
DM	21.9%
Previsous stroke or TIA	11.8%
Previous MI	1.3%
CAD	8.7%
PAOD	0.5%
eGFR	81.7 ± 18.8
CKD/ESRD	17.1%
Mitral Stenosis or MVR	1.0%
Sick sinus syndrome	5.4%
HCMP	2.2%
ICD/PM implantation	4.2%

	Overall (N=2689)
Medications	
OAC	
- apixaban	27.2%
- dabigatran	9.5%
- edoxaban	33.8%
- rivaroxaban	19.0%
- warfarin	9.8%
- unknown	0.8%
NOAC reduced dose	17.6%
OAC skip for ablation	30.5%
Antiplatelet	3.5%
Procedural characteristics	
Redo ablation	0.2%
use of ICE	91.2%
CTI ablation	21.4%
Echocardiographic parameter	
LA volume index	50.2 ± 19.0
LVEF (%)	58.8 ± 8.6
E of e'	9.6 ± 3.9



Results (2)

Complication	Case N.	Event N.	%
Any complication	2689	123	4.6%
<u>Major complication</u>	<u>2689</u>	<u>12</u>	<u>0.4%</u>
Cardiac tamponade	2689	8	0.25%
Pericardial effusion	2689	22	0.8%
Access site complications	2689	26	1.0%
Phrenic nerve palsy	2689	52	1.9%
Transient palsy: 51 cases/ Permanent palsy: 1 case			
Cerebrovascular accidents	2689	3	0.1%
AE fistula	2689	0	0.00%
Hemoptysis	2689	11	0.4%
Gastroparesis	2689	7	0.3%
PV stenosis	2689	1	<0.1%
Complete AV block	2689	1	<0.1%
In hospital cardiac surgery	2689	2	<0.1%
In hospital acute MI	2689	1	<0.1%
In hospital death	2689	1	<0.1%



Results (3)

	Patients without complication (N=2566)	Patients with complication (N=123)	p value
Age	61.9 ± 10.1	62.9 ± 10.6	0.281
Sex (male)	76.1%	73.6%	0.596
AF duration (days)	1128.3 ± 1186.1	1016.0 ± 949.6	0.213
Persistent AF	55.7%	57.0%	0.851
BMI	25.7 ± 3.4	24.6 ± 3.3	<0.001
CHA2DS2 VASc score	2.1 ± 1.5	2.5 ± 1.8	0.025
HF	22.9%	35.5%	0.002
HTN	58.6%	66.1%	0.122
DM	21.8%	23.1%	0.812
Previsous stroke or TIA	11.8%	12.4%	0.944
Previous MI	1.1%	5.0%	0.001
CAD	8.7%	9.9%	0.758
PAOD	0.6%	0.0%	0.842
eGFR	82.0 ± 18.3	77.3 ± 25.2	0.043
CKD	14.0%	20.7%	0.057
ESRD	2.6%	7.4%	0.004
Mitral Stenosis or MVR	0.9%	2.5%	0.201
Sick sinus syndrome	5.5%	4.1%	0.673
HCMP	2.2%	3.3%	0.603
ICD/PM implantation	24.2%	6.7%	0.705



Results (4)

	Patients without complication (N=2566)	Patients with complication (N=123)	p value
Procedural characteristics			
Redo ablation	0.2%	0.0%	0.999
use of ICE	91.0%	95.0%	0.17
CTI ablation	21.3%	24.8%	0.418
Echocardiographic parameter			
LA volume index	50.2 ± 19.0	51.9 ± 17.8	0.356
LVEF (%)	58.9 ± 8.5	58.3 ± 10.0	0.563
E of e'	9.5 ± 3.8	10.8 ± 5.4	0.11
Medications			
OAC			
- apixaban	26.9%	31.4%	-
- dabigatran	9.8%	4.1%	
- edoxaban	33.8%	33.1%	
- rivaroxaban	19.2%	15.7%	
- warfarin	9.5%	14.9%	
- unknown	0.8%	0.8%	
NOAC reduced dose	17.9%	13.2%	
OAC skip for ablation	31.0%	20.7%	0.054
Antiplatelet	3.3%	8.3%	0.013



Conclusion

In Korea Cryoballoon registry

- Major complication rate: 0.4%
- Cardiac tamponade: 0.25%
- No AE fistula
- Phrenic nerve palsy: 1.9%, but almost cases are transient palsy
- Permanent palsy: 1 case

Safe procedure!



Thank you for your attention.

Fire and ICE study

End Point	Radiofrequency Group (N=376)	Cryoballoon Group (N=374)	P Value*
	<i>no. of patients (%)</i>		
Primary safety end point†	51 (12.8)‡	40 (10.2)‡	
Death from any cause§	0	2 (0.5)¶	0.50
Stroke or TIA from any cause§	2 (0.5)	2 (0.5)	1.00
Atrial arrhythmia	13 (3.5)	8 (2.1)	0.38
Atrial flutter or atrial tachycardia	10 (2.7)	3 (0.8)	0.09
Non-arrhythmia-related serious adverse events§	36 (9.6)	28 (7.5)	0.36
Groin-site complication**	16 (4.3)	7 (1.9)	0.09
Unresolved phrenic nerve injury††			
At discharge	0	10 (2.7)	0.001
At 3 months	0	2 (0.5)	0.25
At >12 months	0	1 (0.3)	0.50
Cardiac tamponade or pericardial effusion	5 (1.3)	1 (0.3)	0.22
Pulmonary or bronchial complication	4 (1.1)	2 (0.5)	0.69
Transient neurologic complication	3 (0.8)	1 (0.3)	0.62

N Engl J Med 2016; 374:2235-2245



EARLY-AF trial

Event	Ablation Group (N = 154)	Antiarrhythmic Drug Group (N = 149)
Any serious adverse event related to the trial regimen — no. of patients (%)*	5 (3.2)	6 (4.0)
Any safety end-point event — no.		
Patients	14	24
Events	15	27
Death — no.	0	0
Cardiac event — no.		
Pericardial effusion for which drainage was warranted or tamponade	0	1†
Pericardial effusion for which drainage was not warranted	0	0
Pericarditis	0	0
Exacerbation of heart failure	0	1
Syncope	1	2
Wide-complex tachycardia or proarrhythmic event	0	2
Bradycardia or atrioventricular block for which pacemaker insertion was warranted	2	2
Acute coronary syndrome	0	2
Neurologic event — no.		
Stroke	0	0
Transient ischemic attack	0	1
Vascular event — no.		
Arteriovenous fistula	0	0
Hematoma for which intervention was warranted	0	0
Hematoma for which intervention was not warranted	1	0
Pseudoaneurysm for which intervention was warranted	0	0
Deep-vein thrombosis	1	0
Pulmonary event — no.		
Persistent phrenic-nerve palsy	3‡	0
Pneumonia	1	0
Self-limited hemoptysis	1	1
Gastrointestinal event — no.		
Esophageal injury or perforation	0	0
Gastrointestinal upset such as indigestion or diarrhea	2	1

N Engl J Med 2021; 384:305-315

