HotBalloon Ablation Experience in Japan

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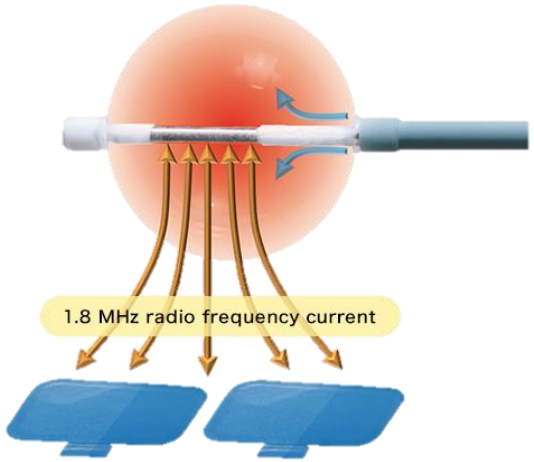
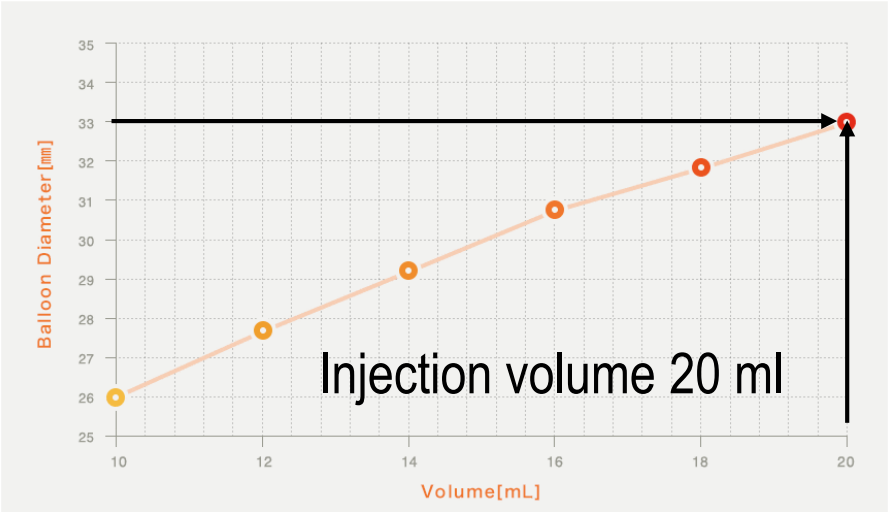
Disclosure

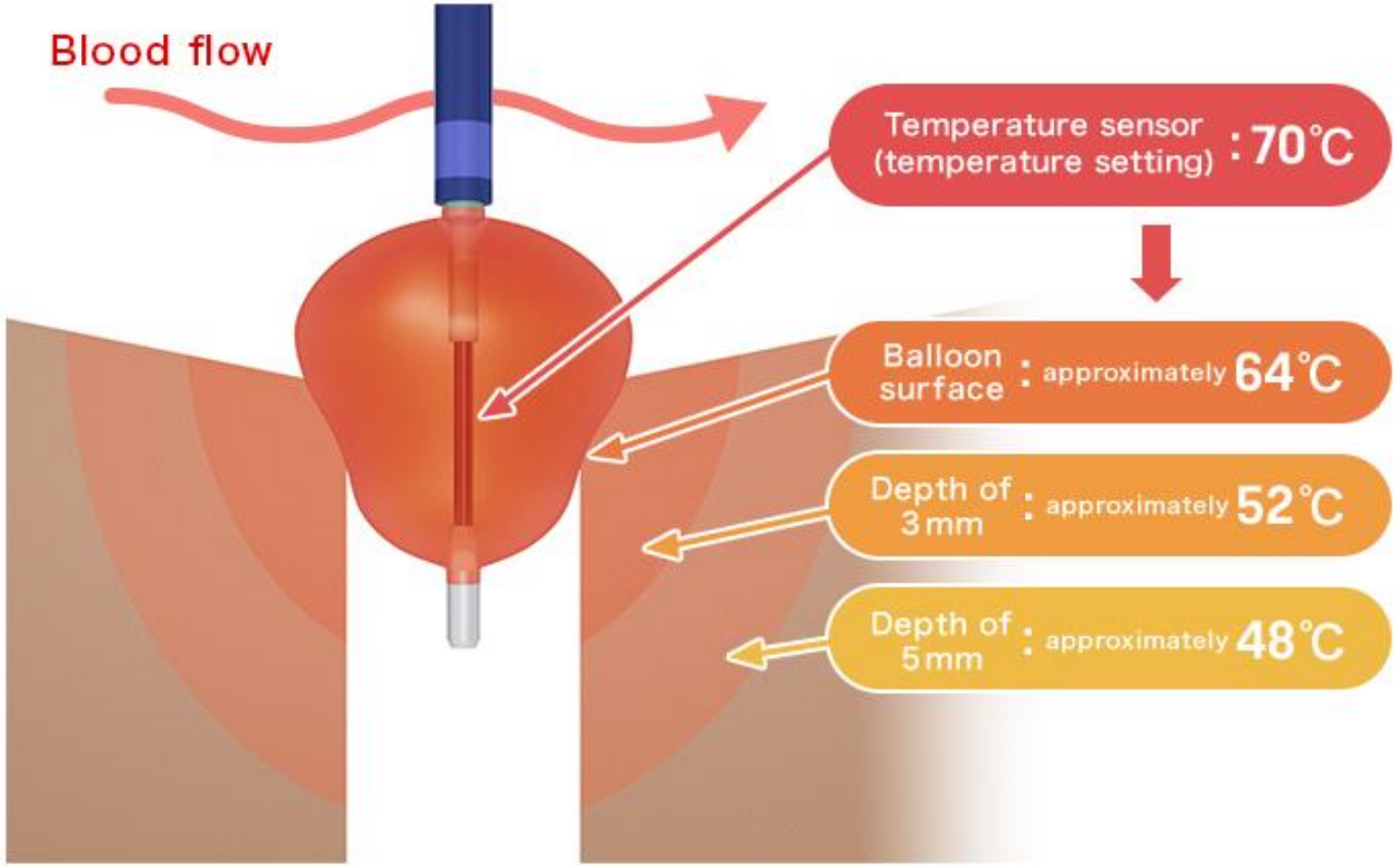
Relationships with commercial interests:

- Consulting Fees: Toray Industries

Principle of the Radiofrequency HotBalloon System







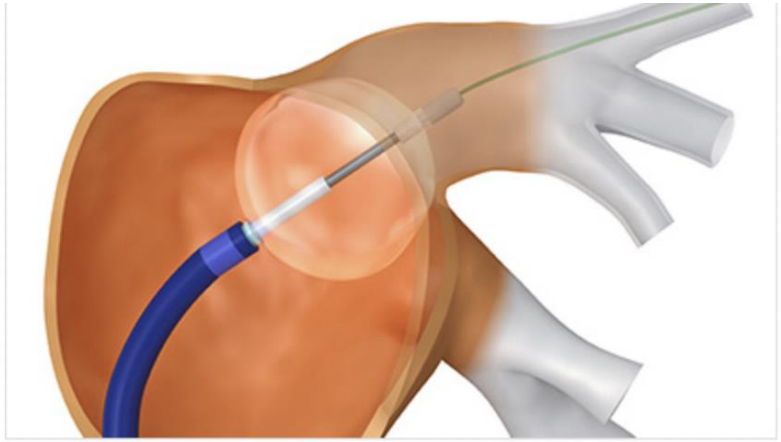
Balloon injection volume 10ml

≒ balloon diameter of 26mm

time dependent lesion formation with conductive heating

KHRS 2023

Radiofrequency HotBalloon System 1st generation



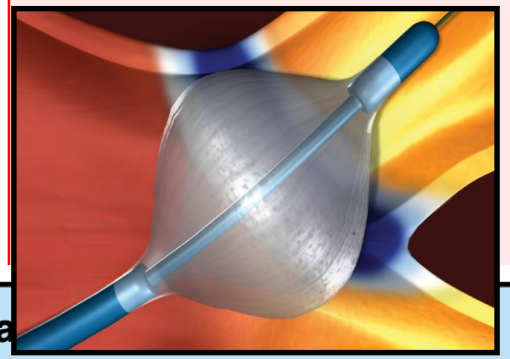
temperature controlled ablation

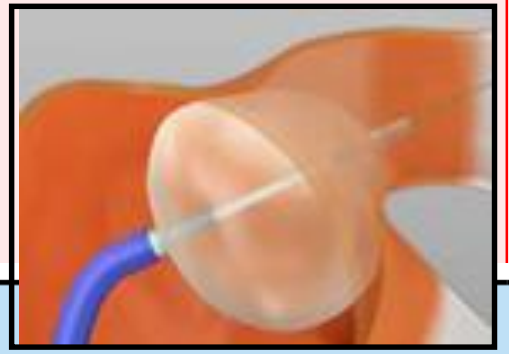
Agitation pump

Power : automatically adjusted to achieve the target balloon central temperature

Temperature: maximum 73℃ (1st generation: balloon central temperature monitoring)

Balloon Based Ablation





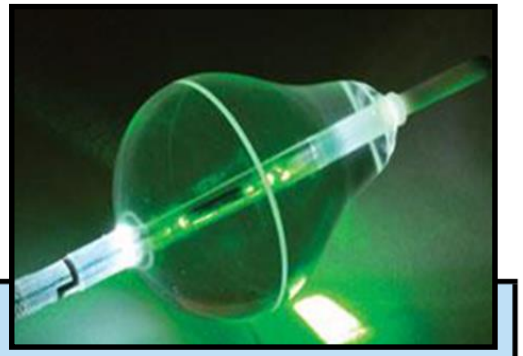


Table 65. Characteristics of Balloon Devices Availa	Cryoballoon	RF hot balloon	Laser balloon
Company	Medtronic	Toray	CardioFocus
Balloon size (diameter)	Fixed (28 or 23 mm)	Variable (max. 33 mm)	Variable #
Shaft size (Fr)	10.5	12	12
One-shot device	Yes	Yes	No
Use of guidewire for balloon placement	Yes	Yes	No
Recording of PV electrogram during ablation	Possible	Not possible	Not possible
Facility to emit gas	Necessary	Not necessary	Not necessary

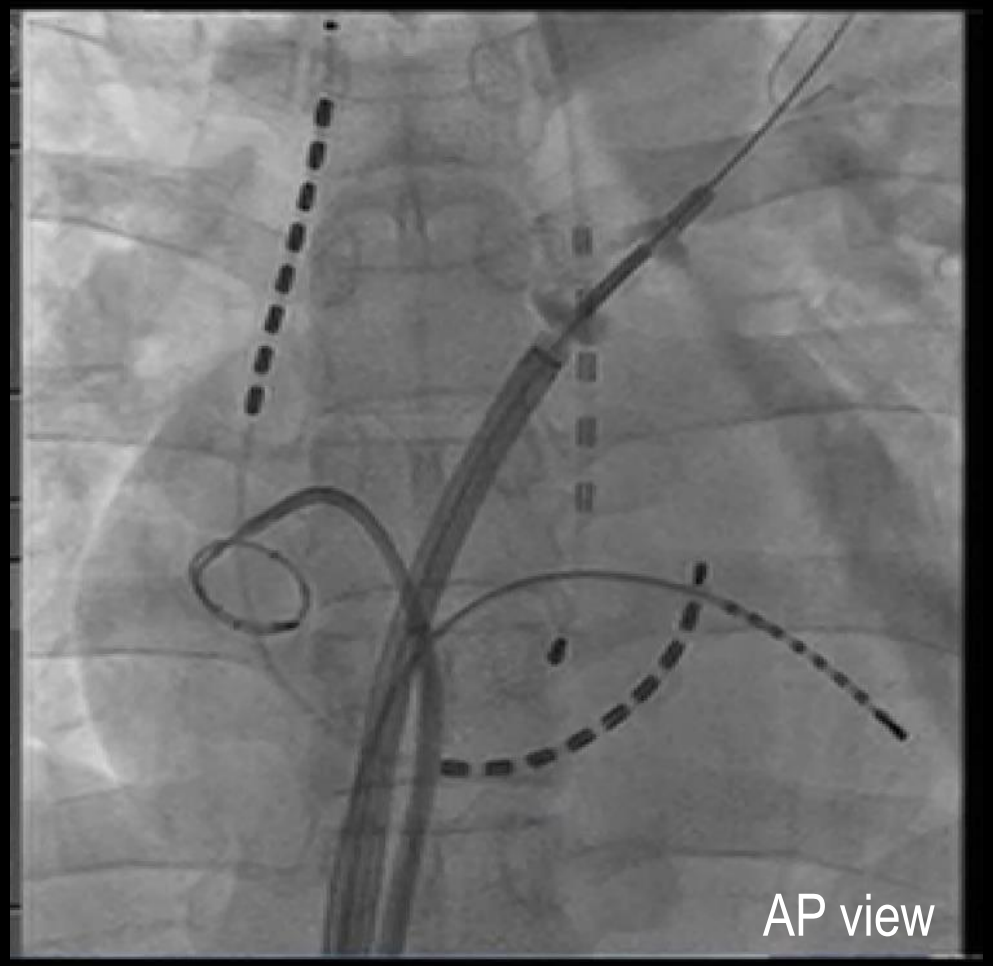
Single-shot device

max. 41mm

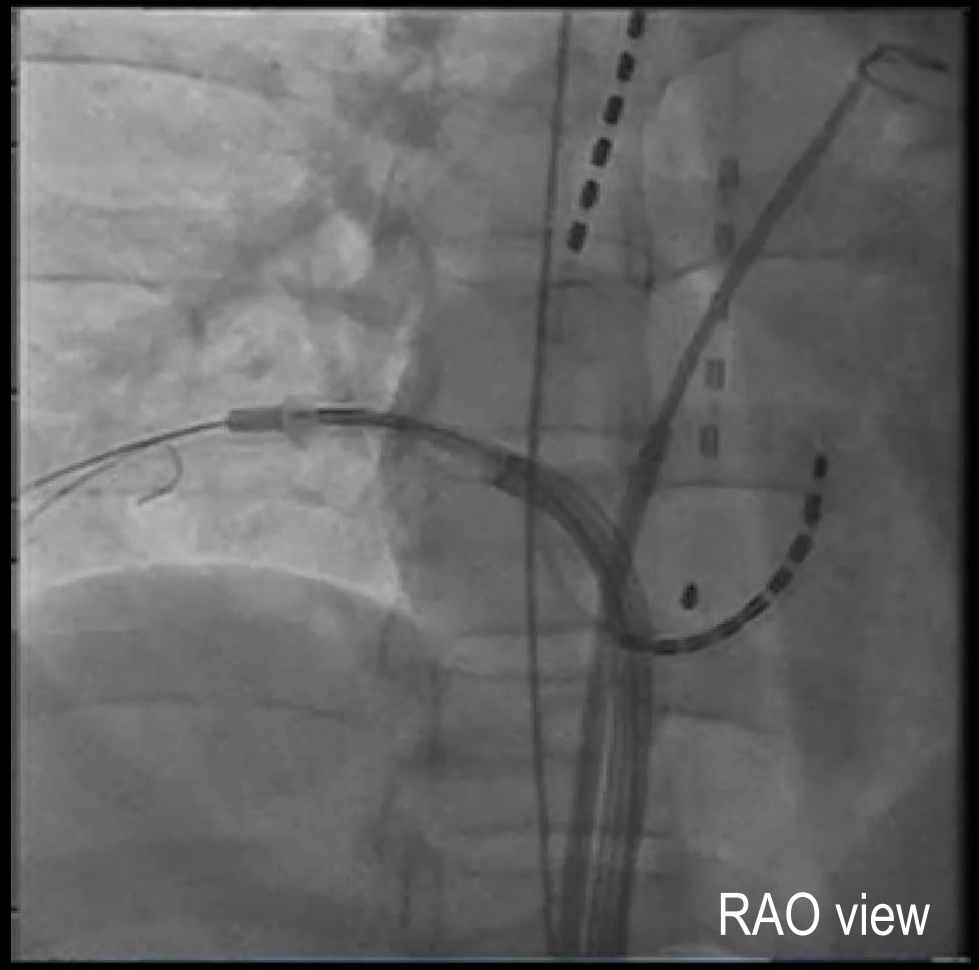
Circ J 2021; 85: 1692–1700

"Single-shot-device" with size-adjustable high-compliant balloon

LSPV



RIPV



1. coaxial position 2. keeping forward pressure 3. PV occlusion (deformation of the balloon)

Unique Features of Radiofrequency HotBalloon (1st Gen)

Size-adjustable (26 – 33mm)

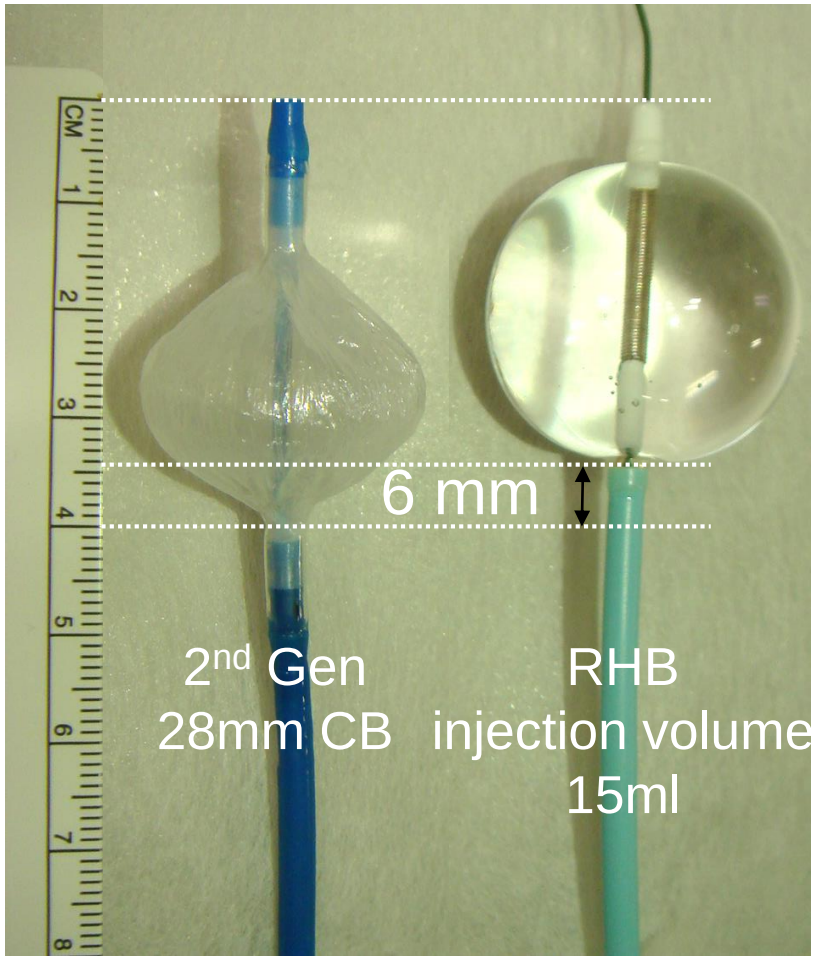
- ✓ suitable for larger PV ostia
- ✓ larger isolation area
- ✓ avoids phrenic nerve palsy

High-compliant balloon

- ✓ suitable for variable PV anatomy

Short tip-balloon distance

- ✓ easy to manipulate in the small left atrium

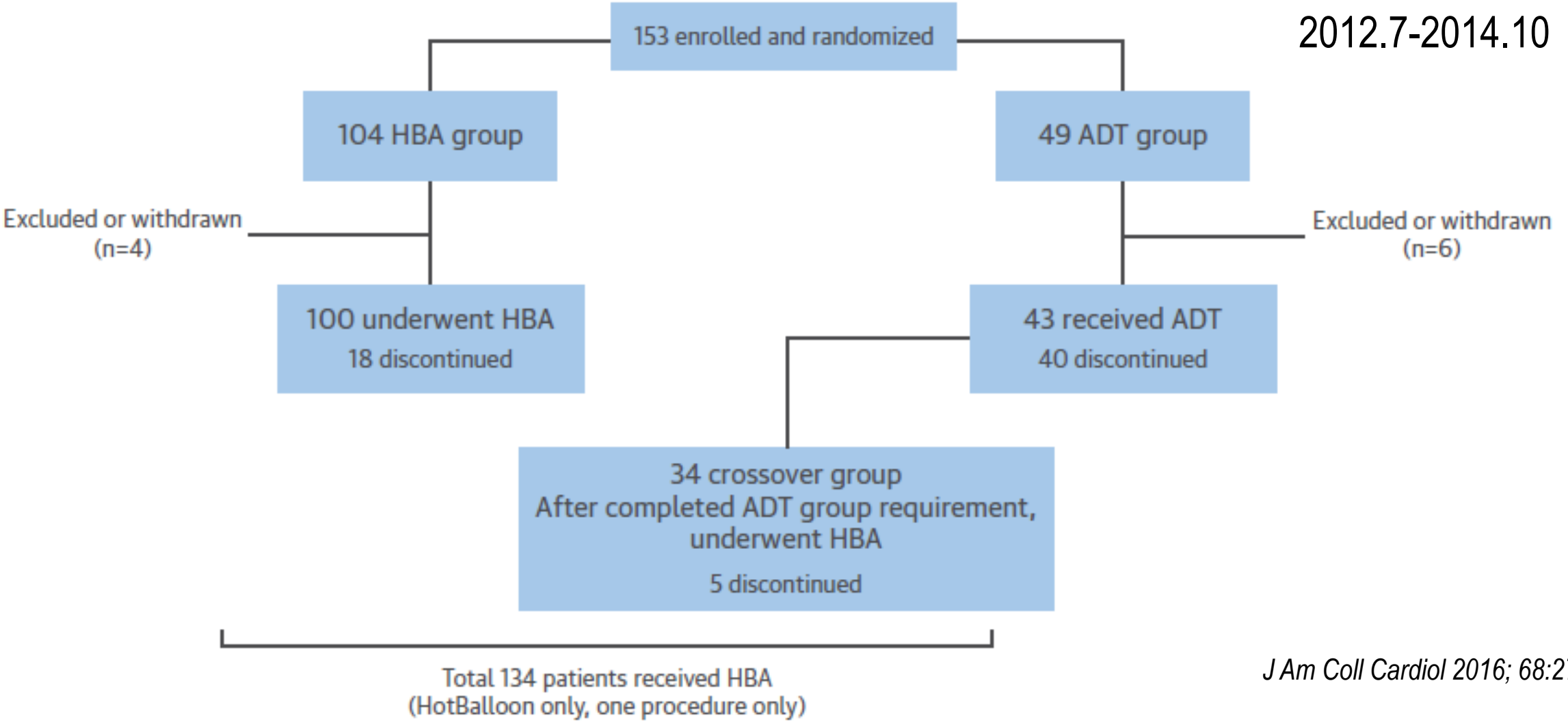


J Interv Card Electrophysiol. 2021;62:21-30.

※real time PV potential monitoring: available with 2nd Gen RHB

Radiofrequency HotBalloon: Randomized controlled trial

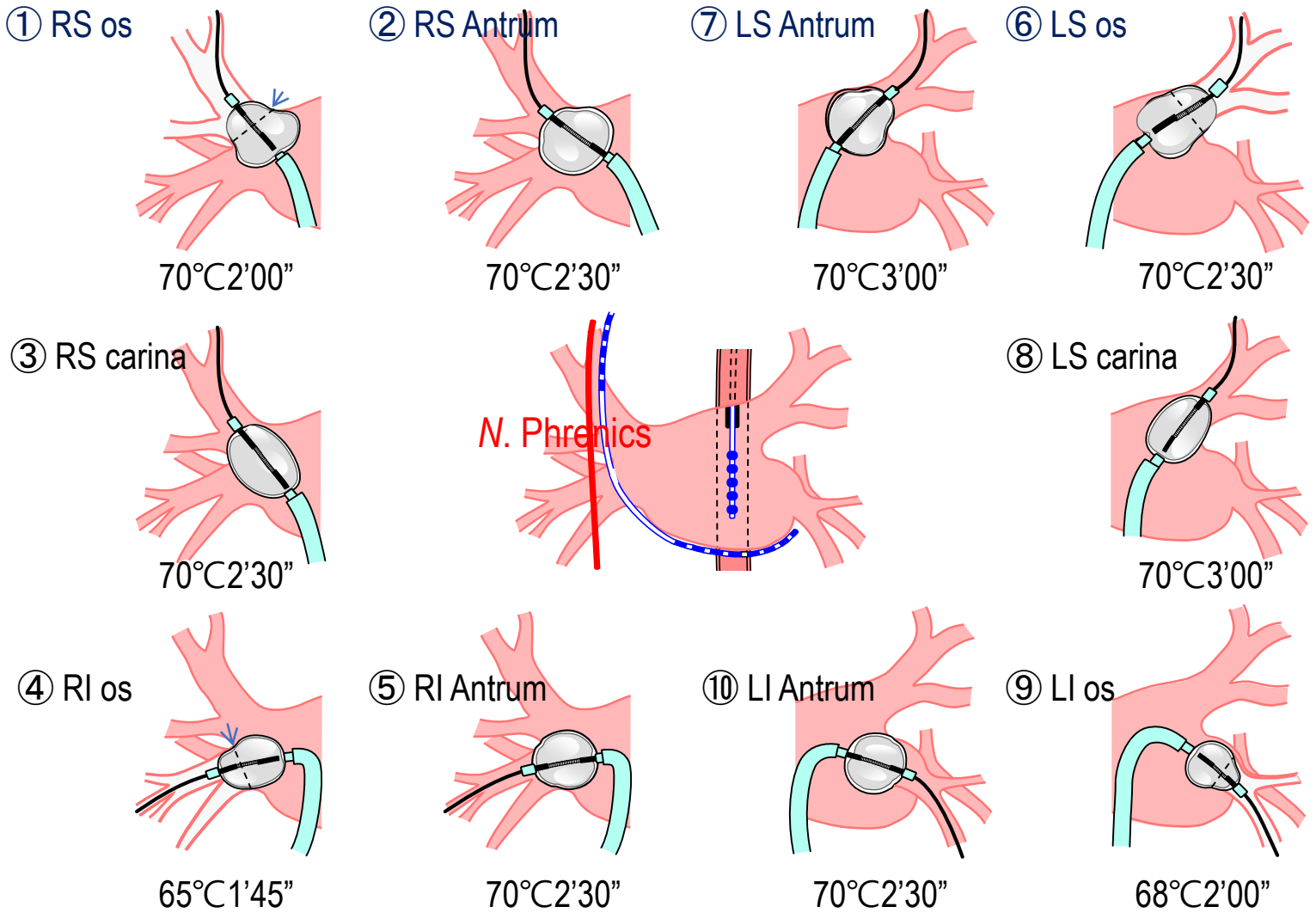
2012.7-2014.10



J Am Coll Cardiol 2016; 68:2747

17 sites (Japan), first balloon based PVI in Japan

Ablation Protocol (clinical trial)



- ✓ 10 ablation sites (PV ostium, antrum, carina)
- ✓ PV isolation rate (per PV) 98%
- ✓ Complications
  - severe PV stenosis (>70%, 5.2%*)
  - phrenic nerve injury (3.7%*)

• result from the clinical trial

TABLE 2 Procedural Characteristics

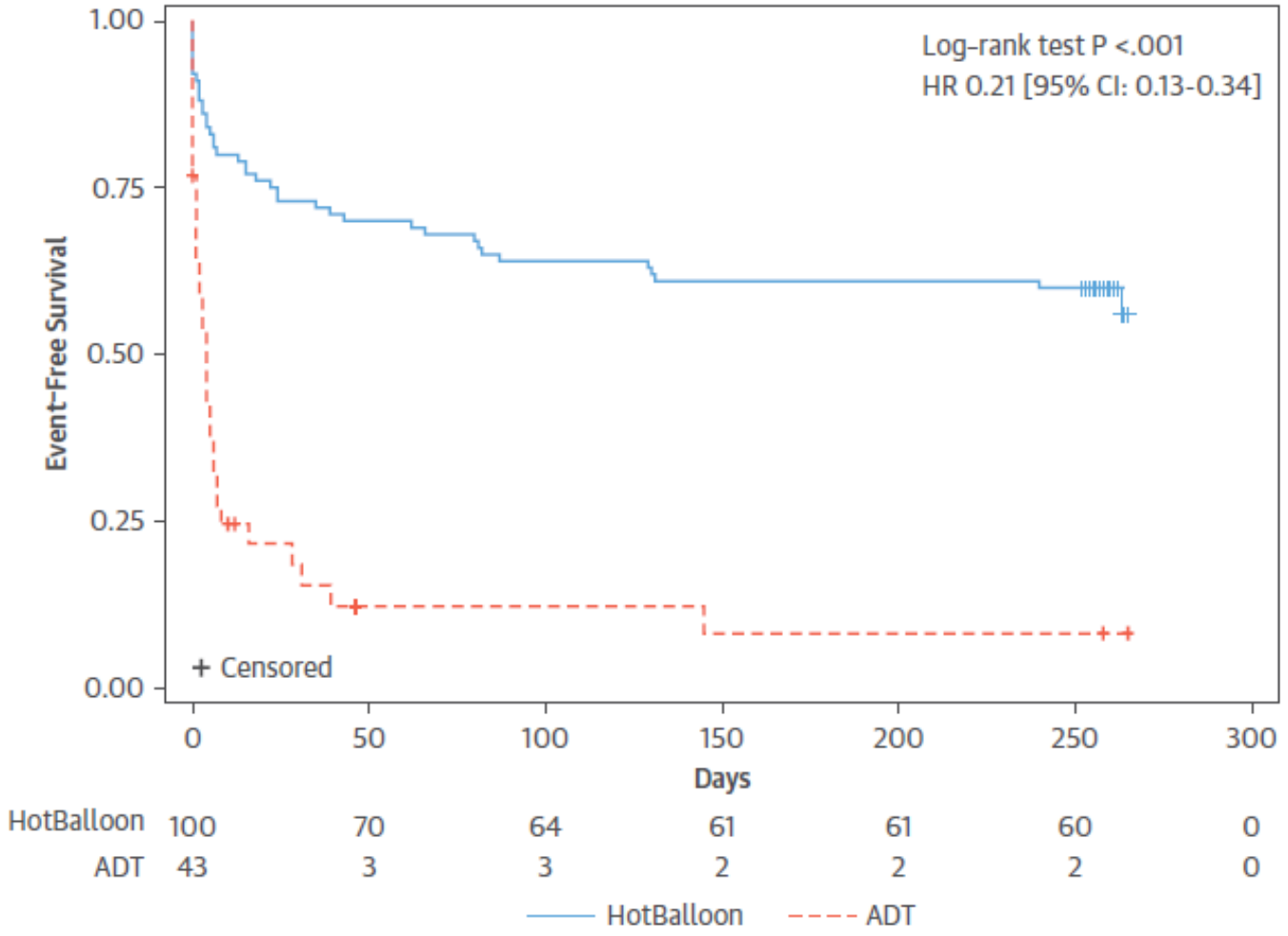
	HBA (n = 100)	HBA and Crossover (n = 134)
Volume in the balloon per PV, ml		
Right superior	9.5 ± 1.6	9.7 ± 1.7
Right inferior	7.9 ± 1.8	8.1 ± 1.9
Left superior	10.1 ± 2.0	10.2 ± 1.9
Left inferior	8.8 ± 1.6	8.9 ± 1.6

Balloon injection volume 10ml

≒ balloon diameter of 26mm

J Am Coll Cardiol 2016; 68:2747

Sinus Rhythm Maintenance



J Am Coll Cardiol 2016; 68:2747

Severe PV stenosis (5.2%) and phrenic nerve palsy (3.7%) is a highly concerned.

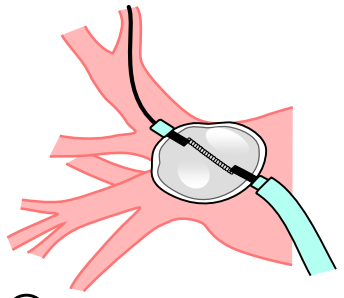
SATAKE·HotBalloon

2016.4.1. Approved for treatment PAF

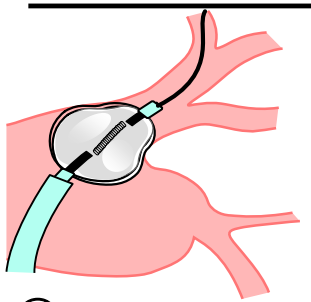
2022.5.9. Approved for treatment persistent AF

※recommendation: balloon injection volume ≥10ml

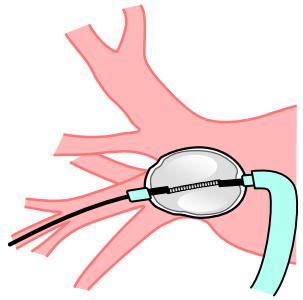
Antral PV isolation (Single-Shot Approach)



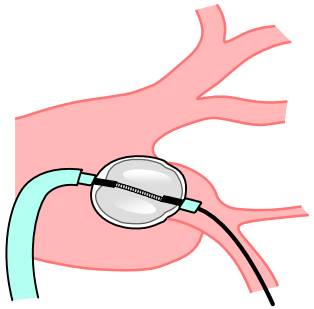
① **RSPV Antrum**
70℃ 3'30"



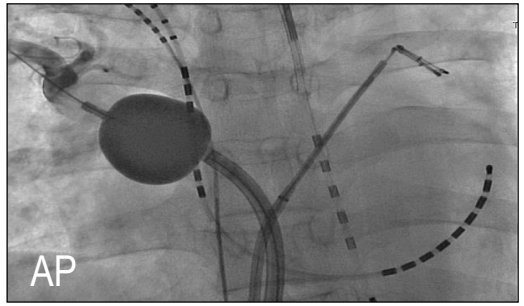
③ **LSPV Antrum**
70℃ 4'00"

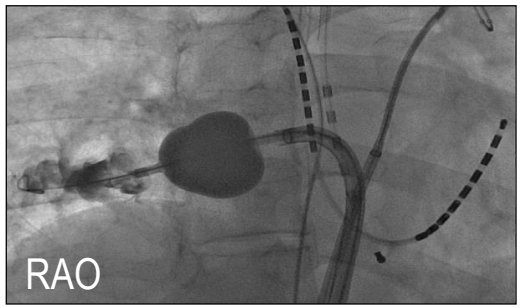


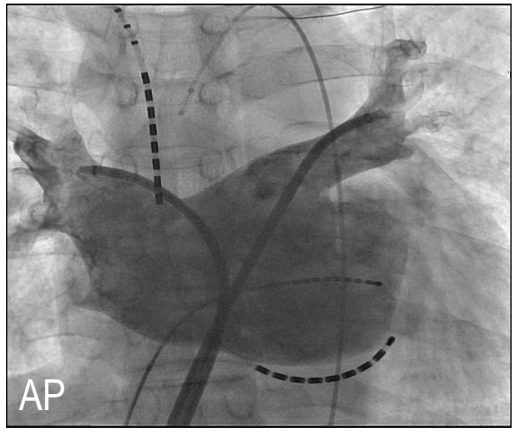
② **RIPV Antrum**
70℃ 3'00"

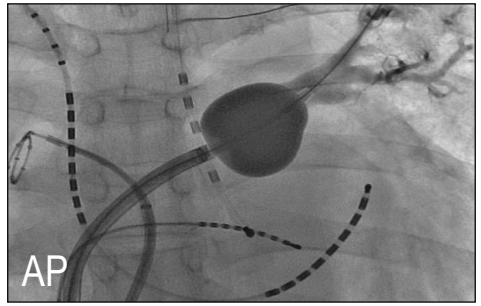


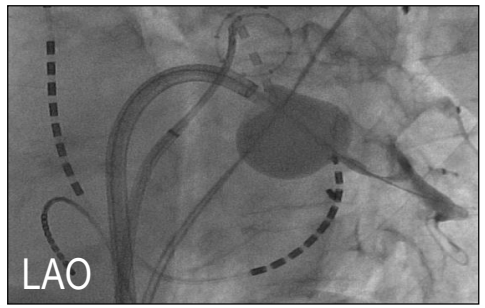
④ **LIPV Antrum**
70℃ 2'00"-2'30"



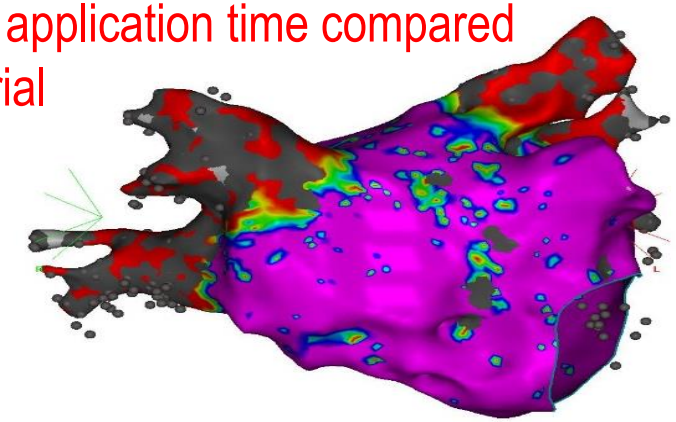


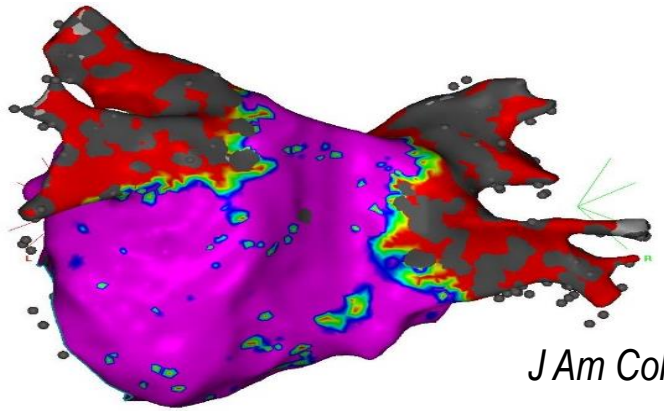






Longer energy application time compared to the clinical trial



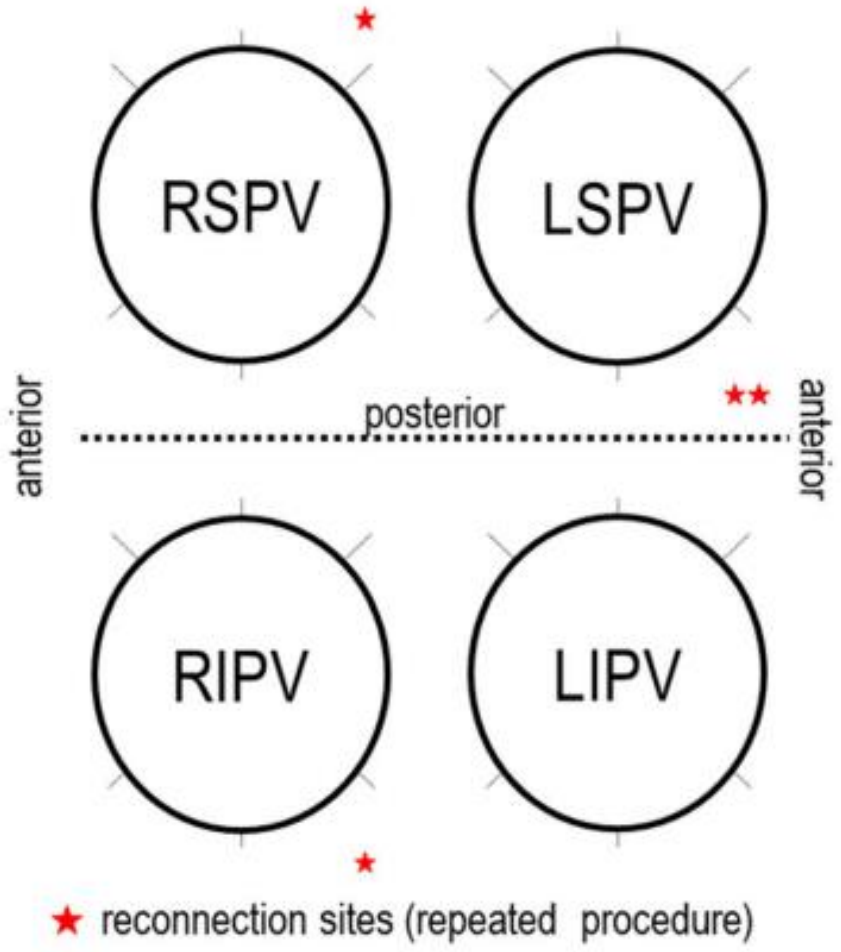


J Am Coll Cardiol EP 2019;5:354

Durability after the Radiofrequency HotBalloon ablation

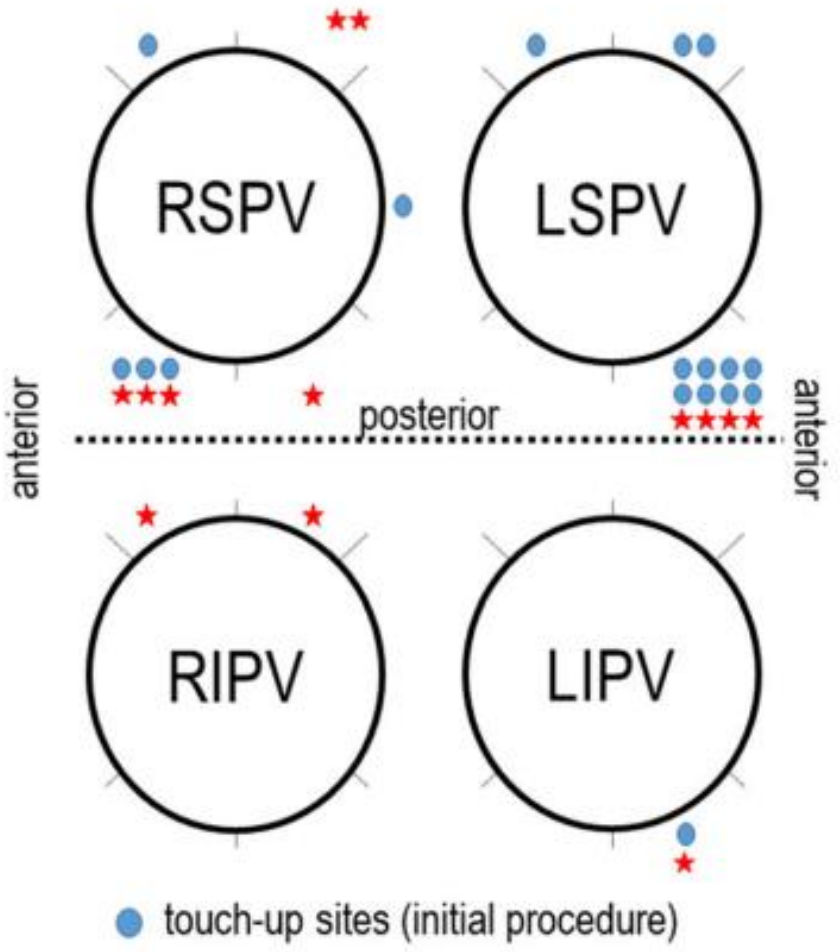
Patients without Touch-up ablation (n=11, 43 PVs)

PV durability: 91%



Patients with Touch-up ablation (n=15, 60 PV)

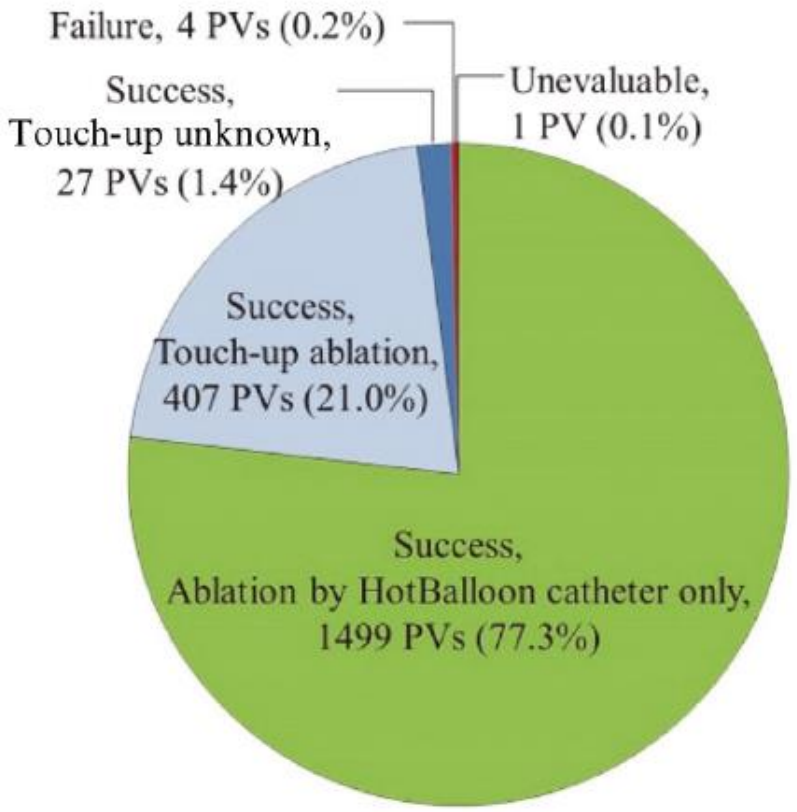
PV durability: 78%



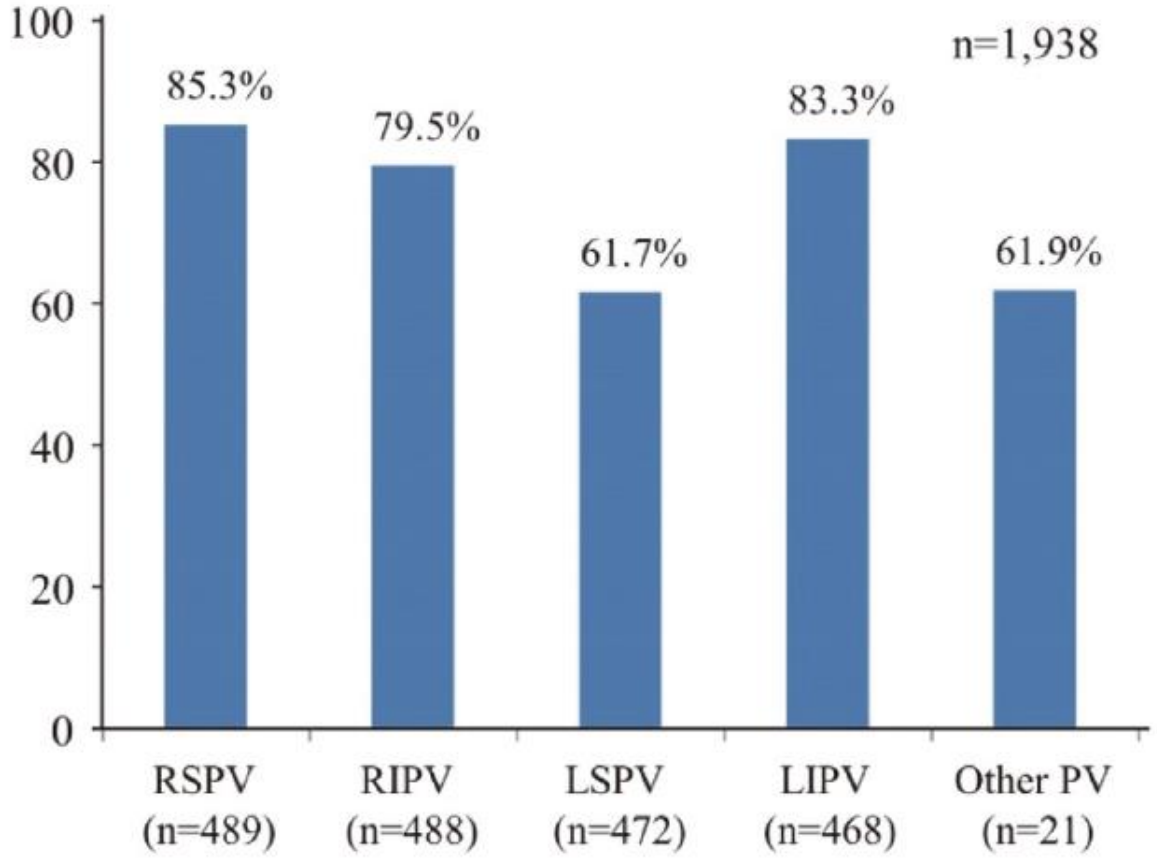
J Interv Card Electrophysiol. 2021;62:21-30.

Post Marketing Study

Enrollment period：2015.Nov - 2017.Mar
47 hospitals, 546 patients



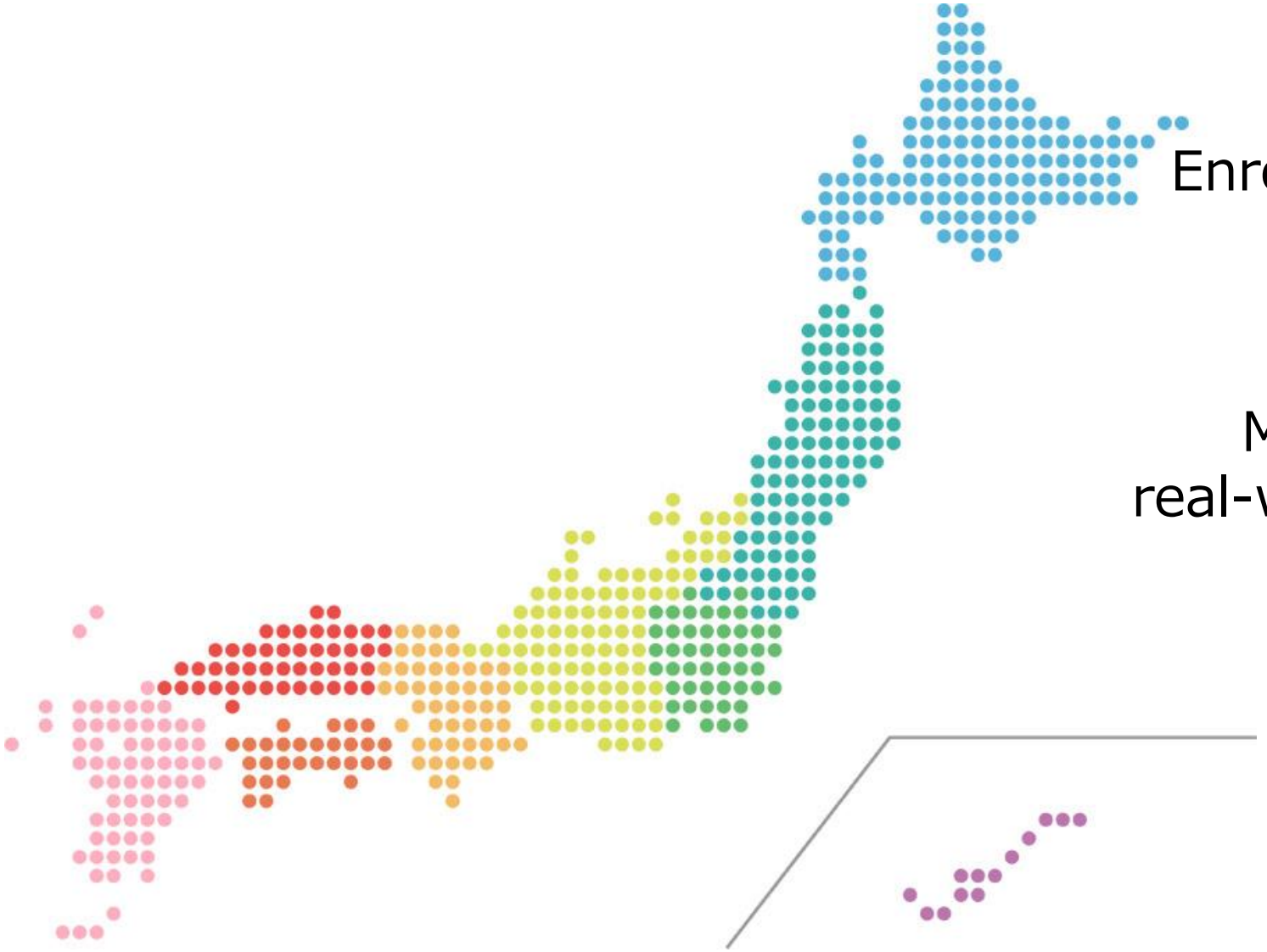
A. Acute success rate of PV isolation



B. Success rate of PV isolation using only HotBalloon catheter

Circ J 2021;85.1314

HARVEST Study



Enrollment: 2017.Sep – 2018.May

33 institutions

Multicenter registry to collect
real-world data of RHB 1st generation

All types of AF included

Circ J 2023; 87: 65–73

HARVEST Study

	paroxysmal	persistent	longstanding	P value
Number of pts	370 (60.4)	136 (22.2)	107 (17.5)	
Injection volume, ml				I
LSPV	12.1±1.7	13.2±1.8	12.8±1.6	<0.0001
LIPV	10.9±1.3	11.3±1.4	11.4±1.3	0.0009
RSPV	12.3±.20	13.6±2.5	13.9±2.6	<0.0001
RIPV	10.6±1.6	11.2±1.6	11.3±1.5	<0.0001
PV isolation rate, %				
LSPV	70.1%	61.5%	62.7%	<0.0001
LIPV	89.8%	91.2%	86.1%	0.0009
RSPV	91.0%	83.6%	80.2%	<0.0001
RIPV	91.5%	91.7%	84.1%	0.08

Circ J 2023; 87: 65 – 73

Superior PVs: larger injection volume, lower isolation rate
Inferior PVs : lower injection volume, higher isolation rate

Complications (Post Marketing Study/HARVEST Study)

Post Marketing study

	N = 530
Stroke	2 (0.4%)
Cardiac tamponade	5 (0.9%)
Pericardial effusion	4 (0.8%)
AV fistula	2 (0.4%)
Aspiration pneumonia	3 (0.6%)
Hemoptysis	2 (0.4%)

Circ J 2021;85.1314

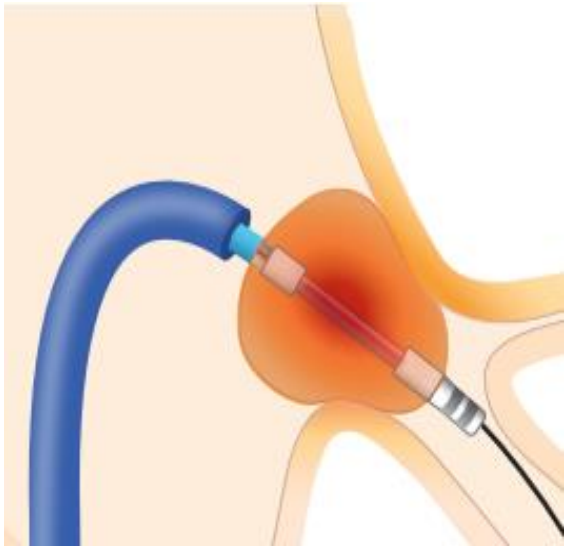
HARVEST Study

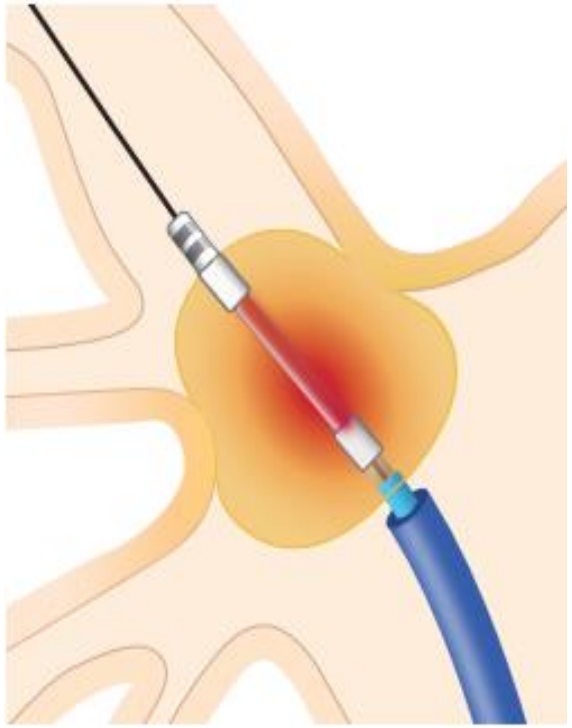
	N = 613
Stroke	1 (0.2%)
Cardiac tamponade	4 (0.7%)
Pseudo-aneurysm	2 (0.3%)
Hematoma	2 (0.3%)
Aspiration pneumonia	3 (0.5%)
Phrenic nerve palsy	6 (1.0%)
Esophageal fistula	1 (0.2%)
PV stenosis (>70%)	5 (1.7%)

Circ J 2023; 87: 65 – 73

RHB 1st generation = balloon central temperature controlled ablation

※Balloon central temperature is constant
regardless of balloon size





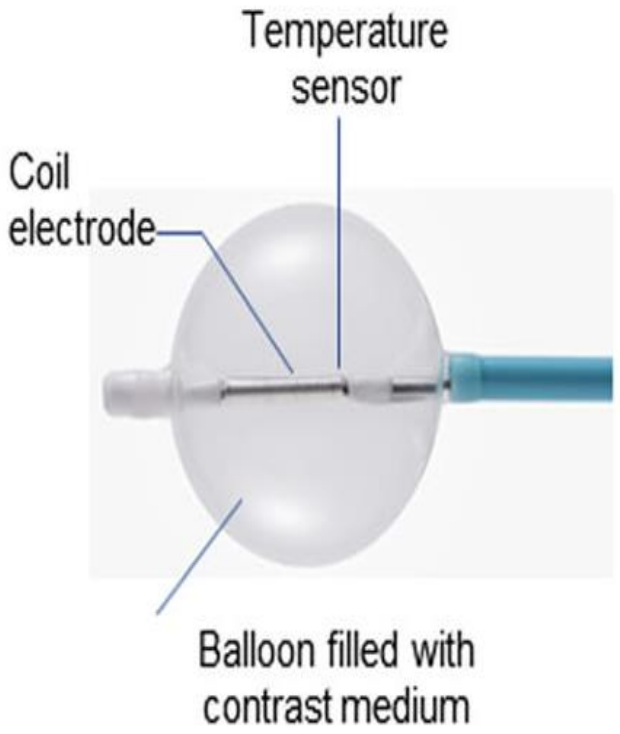
Balloon size　small ⟷ large

Balloon surface temperature　high → low

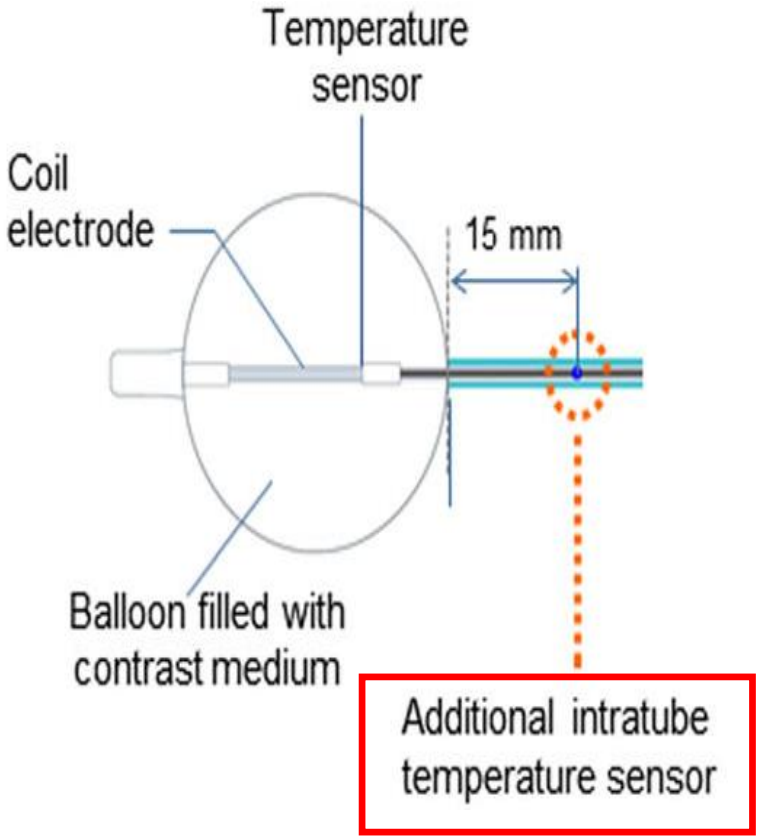
efficacy ↑　　efficacy ↓

collateral injury ↑　　collateral injury ↓

RHB 2nd generation: balloon surface temperature monitoring

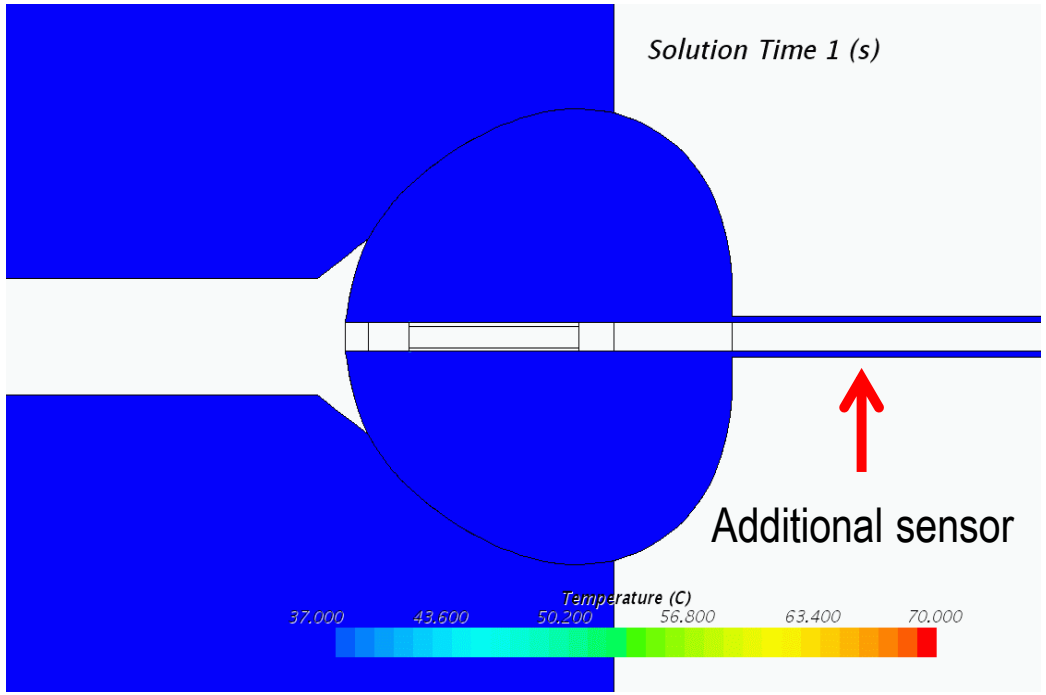


RHB 1st generation



RHB 2nd generation

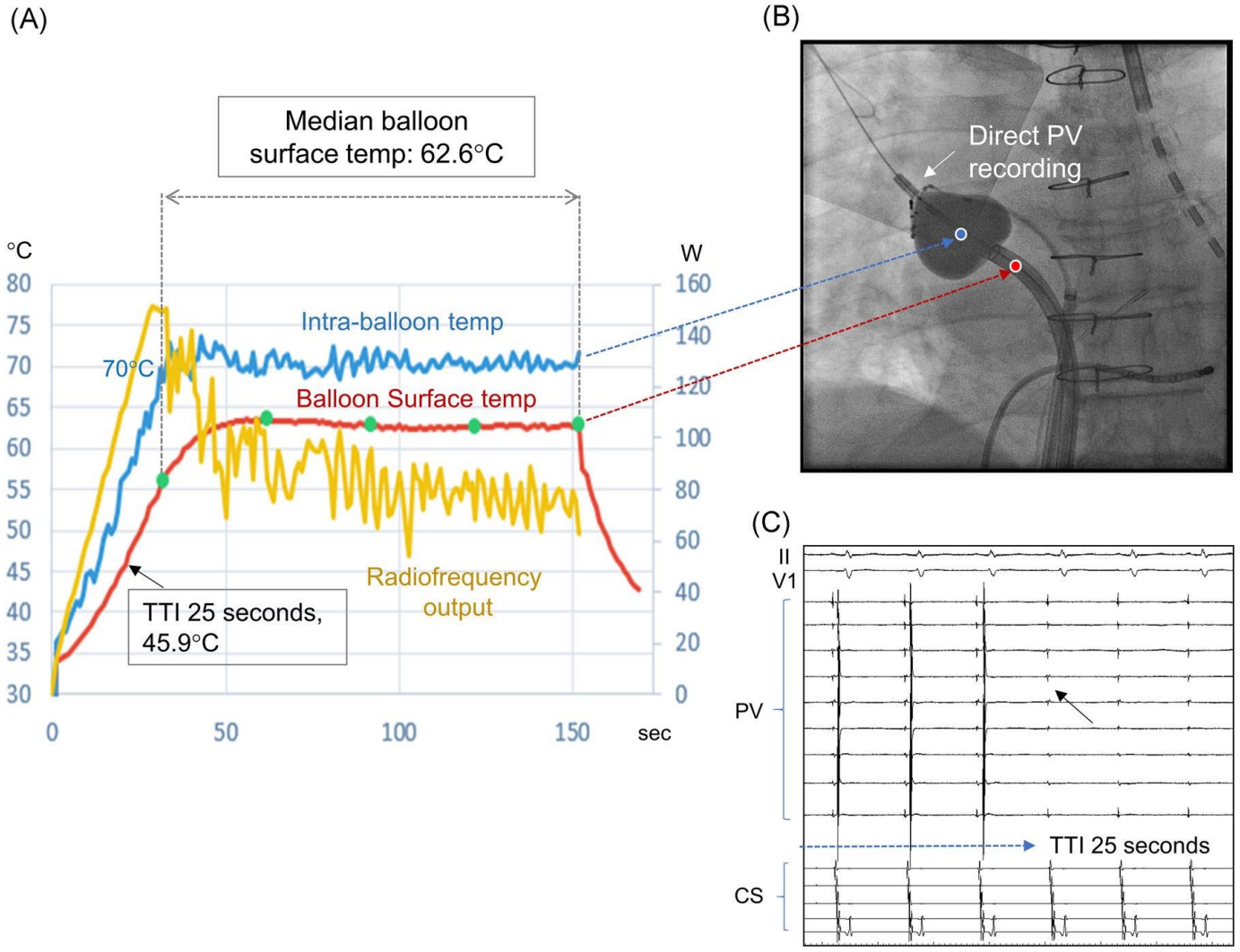
Computer Aided Engineering

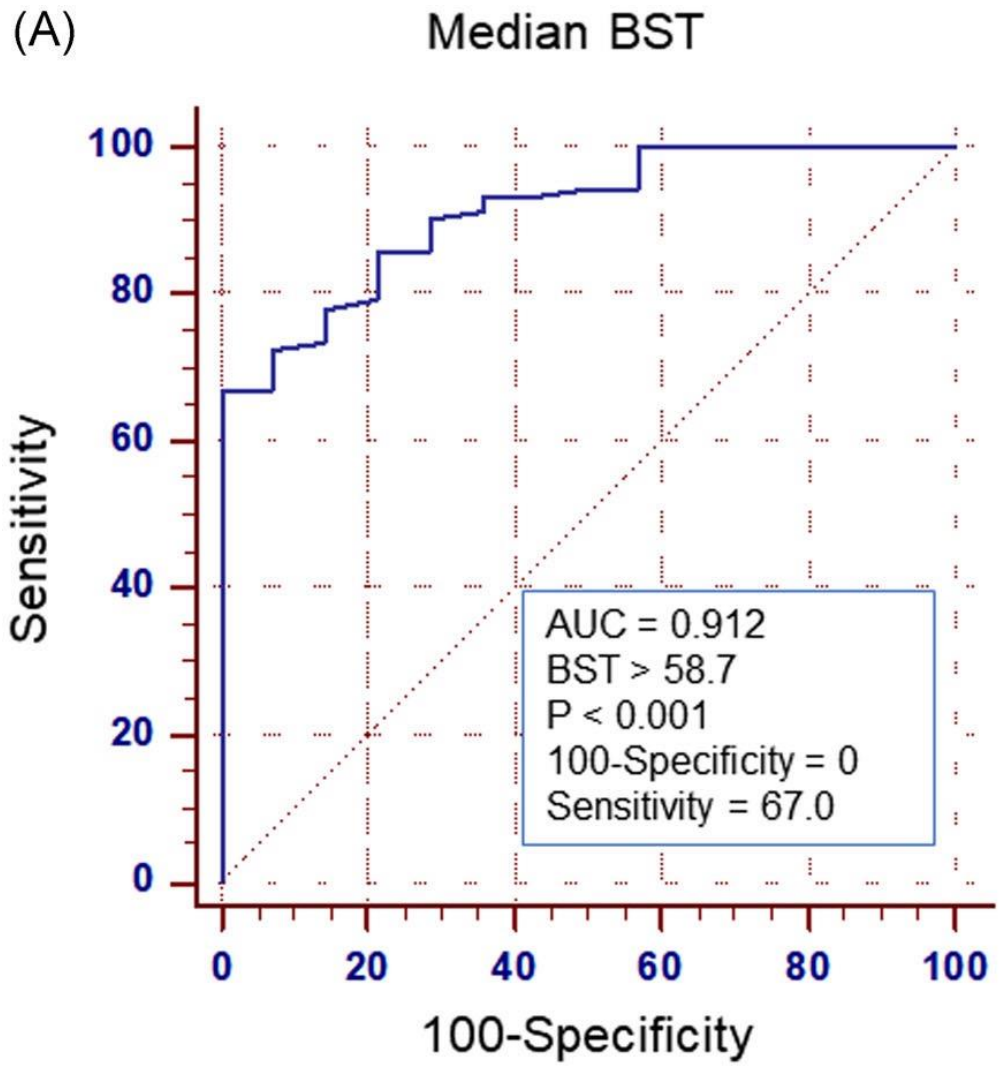


Catheter shaft temperature is identical to balloon surface temperature

J Cardiovasc Electrophysiol. 2021;32:2625-2635.
J Med Eng Technol. 2022;46:687-692.

Balloon Surface Temperature Monitoring (RHB 2nd generation)

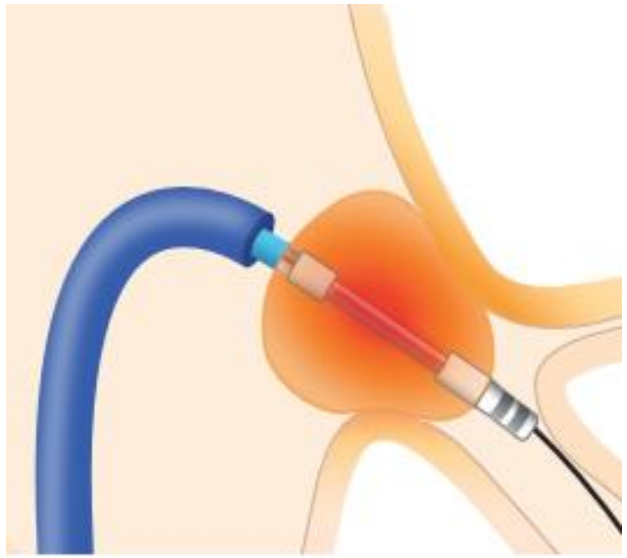


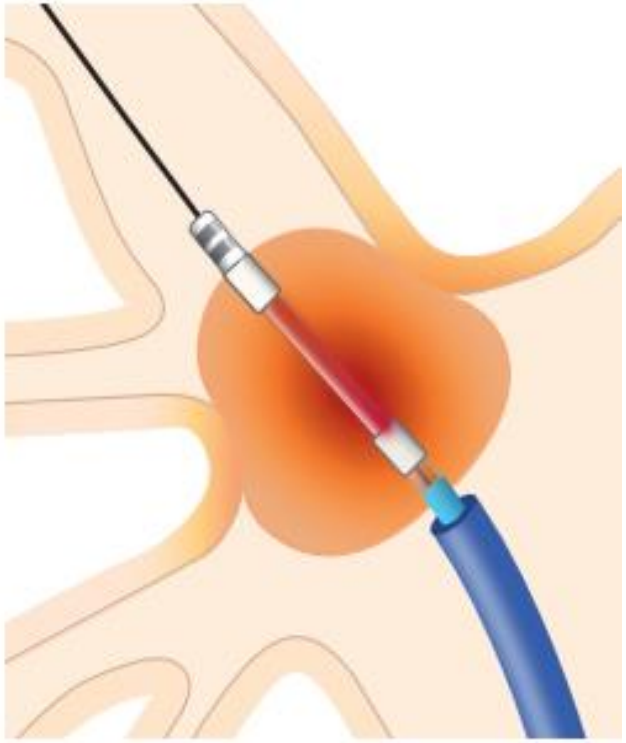


J Cardiovasc Electrophysiol. 2021;32:2625-2635.

The best median balloon surface temperature cutoff value for acute success: >58.7° C

RHB 2nd generation = balloon surface temperature controlled ablation





Balloon size small ⟷ large

Balloon surface temperature

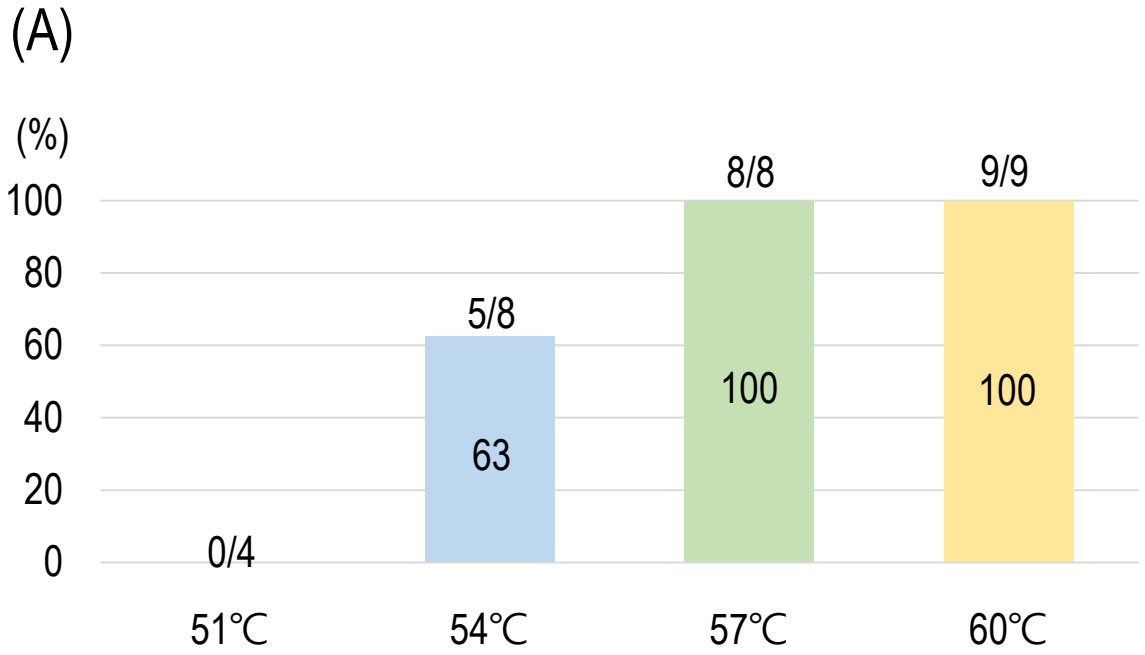
Target balloon surface temperature

collateral injury ↓

efficacy ↑

Optimal balloon surface temperature with RHB 2nd Generation

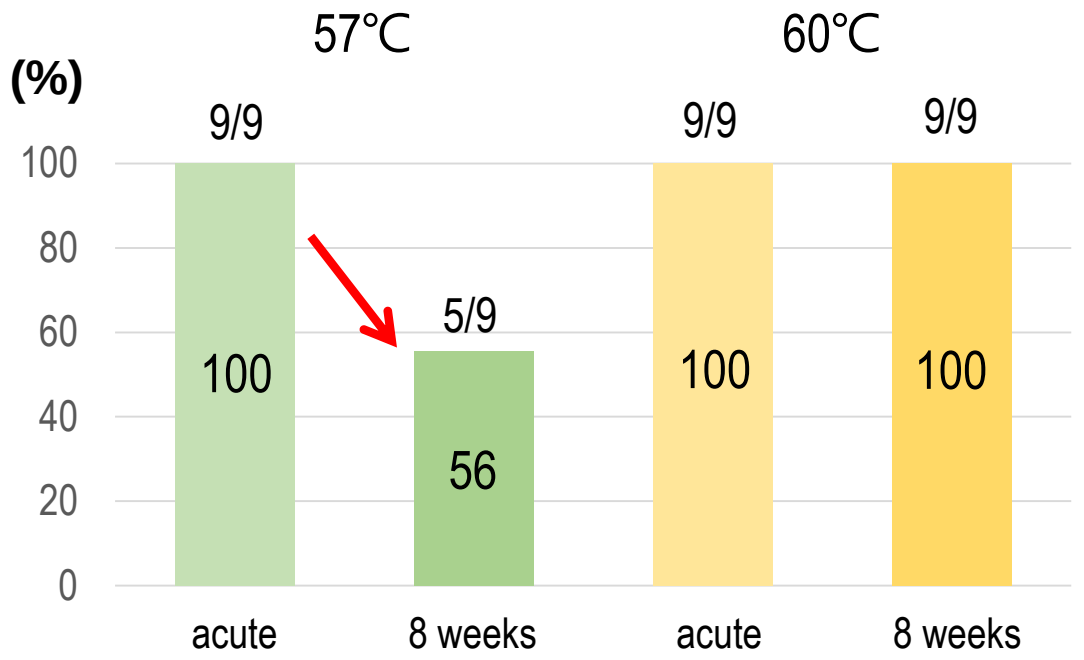
Acute target vein isolation

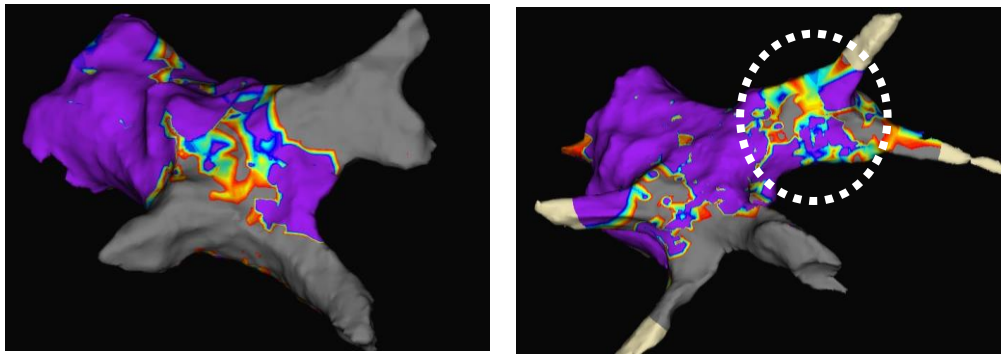


Balloon surface temperature

No collateral injury or severe PV stenosis after energy application with balloon surface temperature of 60 ℃

Lesion durability at 8 weeks

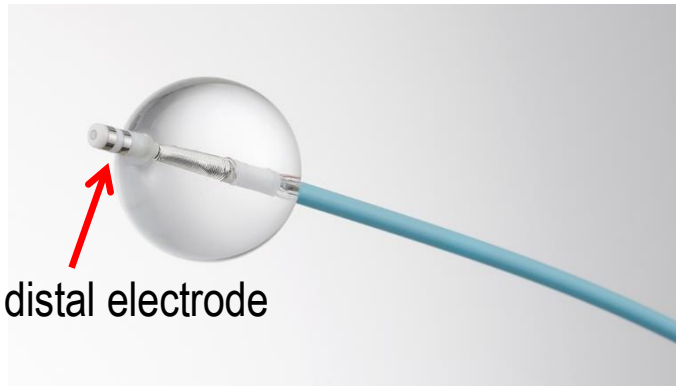


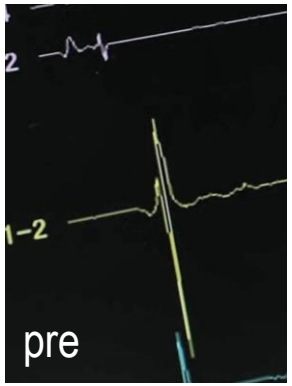


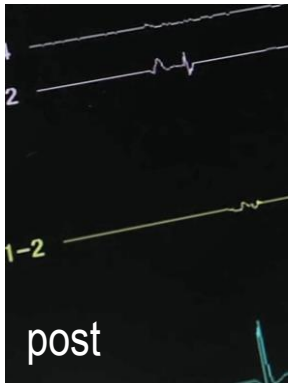
Reconnection at 8 weeks

In preparation

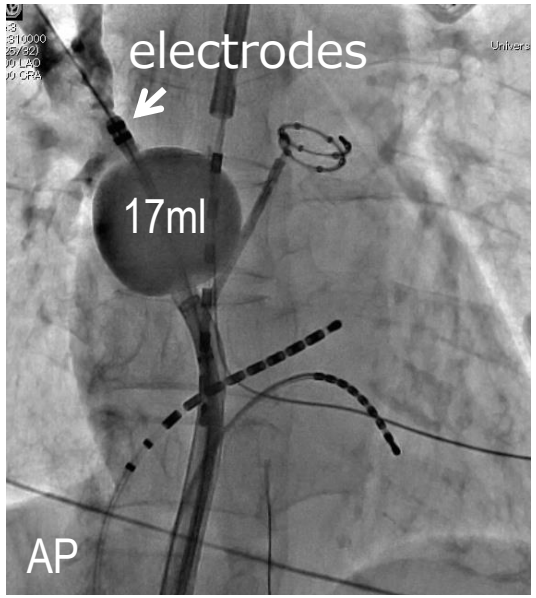
RHB 2nd generation = real-time PV potential monitoring

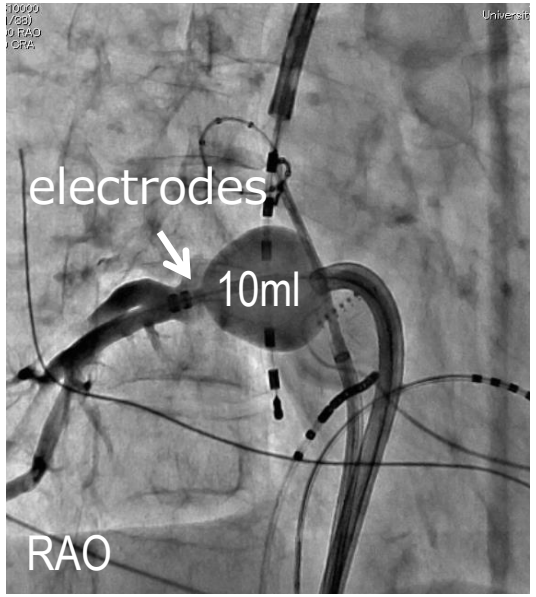


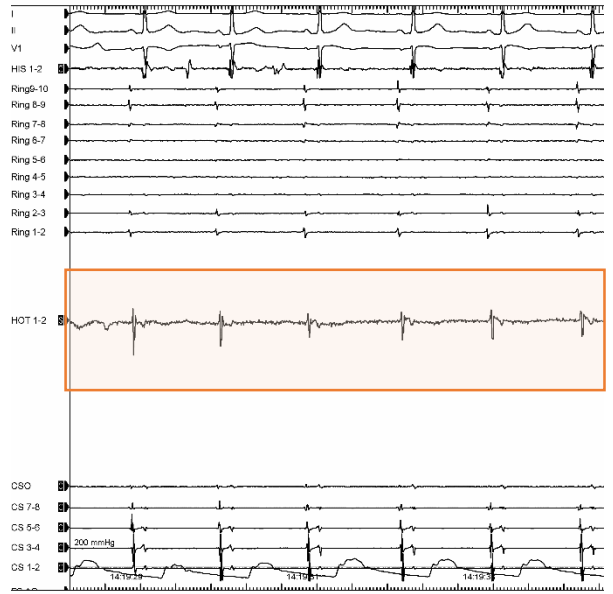




- Real-time PV potential monitoring available (depends of PV anatomy)
- Helps to establish an optimal energy application protocol.







Perspectives of RHB 2nd Generation

	Cryoballoon	Hot Balloon (1st Gen)	Hot Balloon (2nd Gen)
Energy Source	N2O	Radiofrequency Current	
Balloon Compliant	X	○	
Balloon size	23, 28mm	25-33mm (size adjustable)	
Balloon Surface Temperature	-80℃	unknown	○
Real time PV potential monitoring	○	X	○
Energy application time	180 seconds	180-240 seconds (protocol not established)	
Acute success rate	◎	△	○
Lesion Durability	○	○	○

※2nd Gen Hot-balloon (2 models): Either balloon surface temperature monitoring nor real time PV potential recording is available

HARVEST-2 Registry (on going)

Prospective multicenter registry to evaluate efficacy and safety of the RHB 2nd generation.

Conclusions

- ✓ Size adjustable radiofrequency hot-balloon catheter is a feasible option for patients with various PV anatomy.
- ✓ Durability of the lesion was high after radiofrequency HotBalloon ablation.
- ✓ 2nd generation HotBalloon system capable of balloon surface temperature and real time PV potential monitoring would provide more insights to establish an optimal ablation protocol.
- ✓ Balloon surface temperature controlled ablation is expected to improve an outcome and reduce complication using the 2nd generation HotBalloon system.