Performance of Two Tools for Pulmonary Vein Occlusion Assessment with a Novel Navigation System in Cryoballoon Ablation Procedure

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September 6, 2022

Abstract

Background Optimal occlusion of pulmonary vein (PV) is essential for atrial fibrillation (AF) cryoballoon ablation (CBA). The aim of the study was to investigate the performance of two different tools for the assessment of PV occlusion with a novel navigation system in CBA procedure. **Methods** In consecutive patients with paroxysmal AF who underwent CBA procedure with the guidance of the novel 3-dimentional mapping system, the baseline tool, injection tool and pulmonary venography were all employed to assess the degree of PV occlusion, and the corresponding cryoablation parameters were recorded. **Results** In 23 patients (mean age 60.0 + 13.9 years, 56.5% male), a total of 149 attempts of occlusion and 122 cryoablations in 92 PVs were performed. Using pulmonary venography as the gold standard, the overall sensitivity, specificity of the baseline tool was 96.7% (95% CI 90.0% - 99.1%), and 40.5% (95% CI 26.0% - 56.7%), respectively, while the corresponding value of the injection tool was 69.6% (95% CI 59.7% - 78.1%), and 100.0% (95% CI 90.6% - 100.0%), respectively. Cryoablation with optimal occlusion showed lower nadir temperature (baseline tool: -44.3 + 8.4 vs -35.1 + 6.5 , $p < 0.001$; injection tool: -46.7 + 6.4 vs -38.3 + 9.2 , $p < 0.001$) and longer total thaw time (baseline tool: 53.3 + 17.0 s vs 38.2 + 14.9 s, $p = 0.003$; injection tool: 58.5 + 15.5 s vs 41.7 + 15.2 s, $p < 0.001$) compared with those without. **Conclusions** Both tools were able to accurately assess the degree of PV occlusion and predict the acute cryoablation effect, with the baseline tool being more sensitive and the injection tool more specific.

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Short title: Tools for PV Occlusion Assessment

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Conclusions Both tools were able to accurately assess the degree of PV occlusion and predict the acute cryoablation effect, with the baseline tool being more sensitive and the injection tool more specific.

Key words : atrial fibrillation, cryoballoon, catheter ablation, pulmonary vein occlusion, 3-dimensional mapping

Introduction

During the past decades, catheter ablation has been an established curative treatment for atrial fibrillation (AF), with pulmonary vein isolation (PVI) as its cornerstone[1, 2]. Cryoballoon ablation (CBA) is a promising tool for achieving PVI, and its safety and efficacy have been extensively investigated[3-6]. In CBA procedure, optimal occlusion of the inflated balloon to each pulmonary vein (PV) antrum is essential for achieving adequate tissue lesions and durable PVI. To date, PV occlusion is assessed by contrast medium injection through the central lumen of the cryoballoon (CB), which increases contrast dose and radiation exposure.

The KODEX-EPD system (EPD Solutions, a Philips Company) is a novel 3-dimentional navigation system[7, 8], which was shown to be feasible to reconstruct high-resolution left atrial (LA) images, and to facilitate CBA procedure[9]. In addition, the occlusion verification software integrated in the system has recently been demonstrated to provide accurate and real-time information of occlusion degree of CB[10, 11], thus significantly reduce contrast use and radiation exposure in CBA procedure[12]. In the latest version of this system, there are two tools, the baseline tool and the injection tool, available to facilitate the process of occlusion assessment. However, the accuracy of the two tools has not been systematically evaluated.

The purpose of the present study was to investigate the performance of the two different tools for PV occlusion assessment with KODEX-EPD mapping system in CBA procedure for AF.

Methods

Study population

Consecutive patients with paroxysmal AF who underwent the initial PVI procedure with CBA in our center between December 2021 and June 2022 were prospectively enrolled. Patients with previous ablation history, significant valvular abnormalities, and intracardiac thrombus were excluded from the study. The baseline characteristics were prospectively collected. The procedural data were prospectively collected and retrospectively analyzed. The study was approved by the institutional review board, and all participants gave written informed consent. This study complies with the Declaration of Helsinki. The study was reviewed and approved by the ethics committee of Fuwai Yunnan Cardiovascular Hospital.

CBA procedure

All the procedures were conducted in local anesthesia with mild sedation. After access to the LA with the Brockenborough needle and an 8.5-French Swartz sheath (SL1; St. Jude Medical, MN), a 28-mm CB catheter (Arctic Front Advance; Medtronic Inc., MN) was introduced into the LA via a 12F steerable sheath (FlexCath; Medtronic Inc.). Mapping of the LA and PVs was performed with a circular mapping catheter (Achieve; Medtronic Inc.). The LA was reconstructed using the mapping catheter with the guidance of the 3-dimentional navigation system (KODEX-EPD Navigation system, version 1.4.8a). The technical characteristics of KODEX-EPD system have been described elsewhere[7, 8].

Before delivering cryoablation, the Achieve catheter was positioned as proximal as possible in PV ostium to record PV potential. Then, the CB was inflated and advanced against the PV ostium. Baseline tool, injection tool and pulmonary venography were performed to assess the occlusion degree. (Figure 1)

The cryoablation strategy was 180 s in each PV with the following sequence: left superior PV (LSPV), left inferior PV (LIPV), right superior PV (RSPV), and right inferior PV (RIPV). To avoid phrenic nerve injury (PNI), all cryoapplicants for right PVs were performed while pacing at low output (4.0 mA and 1.0 ms duration) and clinical monitoring phrenic nerve function with tactile feedback. The nadir temperature and total thaw time of each freeze cycle were collected. Time to PVI (TTI) was also recorded if PV potential was visible during the cryoapplicants.

Occlusion assessment tools

A stepwise protocol was employed to evaluate the performance of the baseline and injection tools for the assessment of PV occlusion. (Figure 1) In occlusion assessment step 1, the baseline tool was employed and resulted in 3 outcomes: 1) 3 points: the occlusion wheel showed all green; 2) 2 points: the occlusion wheel showed 1/4 red; 3) 1 point: the occlusion wheel showed $>$ 1/4 red. If$>$ 2 points were acquired in the baseline tool, then come to the next step, otherwise the CB should be adjusted to achieve a better contact and reassessed with the baseline tool until$>$ 2 points were obtained.

Occlusion assessment step 2 (the injection tool) and step 3 (pulmonary venography) were performed simultaneously, with 4ml of contrast medium injected through the central lumen of CB. The injection tool resulted in 2 outcomes: 1) 1 point: the last quarter of the injection curve remained in the upper half; 2) 0 point: the last quarter of the injection curve fell into the lower half. Pulmonary venography resulted in 4 outcomes as previously reported[11, 13]: 1) grade IV: complete occlusion; 2) grade III: minimal leak; 3) grade II: moderate leak; 4) grade I: severe leak. If $>$ grade III was achieved, cryoapplicants could be delivered, otherwise the operator should seek to readjust the CB and perform these steps again, or employ the "pull-down" technique or segmental cryoablation.

Statistical analysis

Continuous variables were described as the mean + SD for normally distributed data and median (25%

to 75% quartile) for non-normally distributed data, and comparisons between groups were performed with Student t test. Categorical variables were described as counts and compared by chi-square analysis. Using the pulmonary venography as the gold standard, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated including the 95 % confidence interval (CI) based on a binomial distribution. The receiver operating characteristic (ROC) curve was delineated and area under curve (AUC) was calculated to determine the diagnostic ability of both tools. Spearman correlation was conducted to investigate the relationship between occlusion degree and corresponding cryoablation parameters.

All tests were 2-tailed, and a statistical significance was established at $P < 0.05$. All analyses were performed using SPSS software (version 22.0; SPSS, Inc., Chicago).

Results

Baseline characteristics of the study population

A total of 23 patients with paroxysmal AF were included in the study. Mean age was 60.0 + 13.9 years, and 13 (56.5%) were male. The median CHA_2DS_2-VASc score was 2.0 (0.5 – 3.0). Table 1 shows the baseline characteristics of the study population.

Procedural data

In 23 procedures, mean procedural time was 102.7 + 25.3 min, and mean left atrial dwelling time was 78.8 + 19.8 min. Mean radiation time was 25.3 + 8.4 min, median radiation dose was 33.0 (8.9, 55.3) mGy, and median dose area product (DAP) was 5.2 (4.7, 10.0) Gy*cm^2. All of the PVs achieved bidirectional block when rechecked at the end of the procedure. One temporary PNI occurred during cryoablation of RSPV and spontaneously resolved upon cessation of cryoablation. No major complication was observed during the peri-procedural period.

Performance of the occlusion tools

Totally, 149 attempts of occlusion in 92 PVs were recorded and analyzed. Figure 2 shows the occlusion assessment results of different PVs when using the baseline, injection, and pulmonary venography as verification tools. Among PVs, optimal occlusion could be frequently achieved in LSPV and RSPV, whereas moderate to severe leak was commonly detected in LIPV and RIPV.

Using pulmonary venography as the gold standard, the overall sensitivity, specificity, PPV, NPV of the baseline tool was 96.7% (95% CI 90.0% - 99.1%), 40.5% (95% CI 26.0% - 56.7%), 77.9% (95% CI 68.9% - 84.9%), and 85.0% (95% CI 61.1% - 96.0%), respectively, while the corresponding value of the injection tool was 69.6% (95% CI 59.7% - 78.1%), 100.0% (95% CI 90.6% - 100.0%), 100.0% (95% CI 93.6% - 100.0%), and 60.3% (95% CI 48.5% - 70.0%), respectively. As shown in ROC curves, the AUC of the baseline and injection tool was 0.693 (95% CI 58.8% - 79.8%) and 0.848 (78.8% - 90.8%), respectively (Figure 3). Furthermore, the sensitivity, specificity, PPV, NPV of the 2 tools for different PVs were listed in table 2.

Cryoablation parameters

A total of 122 cryoablations in all the PVs were applied, in which TTI was recorded in 60 (49.2%) PVs (LSPV, 25/31; LIPV, 13/28; RSPV, 13/35; RIPV, 9/28). According to the baseline tool, the mean nadir temperature was -44.3 + 8.4 and -35.1 + 6.5 in PVs with and without optimal occlusion ($P < 0.001$), while the total thaw time was 53.3 + 17.0 s and 38.2 + 14.9 s in both groups ($P = 0.003$). When using the injection tool, the mean nadir temperature was -46.7 + 6.4 and -38.3 + 9.2 in PVs with and without optimal occlusion ($P < 0.001$), while the total thaw time was 58.5 + 15.5 s and 41.7 + 15.2 s in both groups ($P < 0.001$) (Figure 4). Table 3 shows the correlation between PV occlusion and cryoablation parameters.

Discussion

To the best of our knowledge, the present study is the first to investigate the performance of both the baseline and injection tool in assessing PV occlusion with the latest version of KODEX-EPD system. The major findings of the present study are: i) both tools were able to accurately assess the degree of PV occlusion in

CBA procedure; ii) both tools could predict the acute cryoablation effect; iii) baseline tool showed a higher sensitivity, while injection tool showed a higher specificity.

KODEX-EPD for CBA procedure

KODEX-EPD system is a novel dielectric-based 3-dimentional mapping system. Since its first clinical use, it has been evolved in various electrophysiological procedures including CBA procedure[7, 8, 10, 14, 15]. Currently, CBA procedures are performed with the guidance of fluoroscopy in most centers, which is associated with potential harm of excessive radiation exposure. Moreover, the fluoroscopic navigation limits the further application of CBA technique. The KODEX-EPD system can provide real-time high-resolution LA images, which largely facilitates the catheter manipulation and PV occlusion verification in CBA procedure[9]. Furthermore, it could accurately detect various leak around the inflated balloon[11], which could avoid frequent angiography. A recent study showed that the guidance of KODEX-EPD could effectively reduce the radiation exposure as well as contrast dye use[12]. The median radiation time of the present study was 25.3 min, which is longer than previous reports[12]. The reasons may be: i) frequent pulmonary venography to verify PV occlusion in our study; ii) the impact of learning curve because these data were collected as soon as the KODEX–EPD system became available in our center.

Occlusion assessment tools

Optimal occlusion of PV is a prerequisite of successful PVI. Hence, the PV occlusion assessment is of crucial value in CBA procedure. Currently, pulmonary venography is regarded as the standard criterion, although various alternatives have been proposed to reduce contrast or fluoroscopy use, such as intracardiac echocardiography (ICE)[16], transesophageal echocardiography (TEE)[17, 18], and change of the pressure waveform recorded at the CB tip during occlusion[19, 20].

Also, KODEX-EPD system is equipped with various tools for occlusion assessment[11, 21-23]. Cauti FM et al[11] demonstrated high accuracy of the integrated occlusion verification tool (the same technique as baseline tool in our study) in version 1.4.5 and 1.4.6. The novel injection-based workflow, available since 1.4.7 software version, uses contrast medium as a dielectric insulator and measures dielectric changes across the electrodes of the circular mapping catheter, which is expected to have a higher accuracy compared with the baseline tool, especially for detection of smaller leaks. These two tools for detecting occlusion can be used together or independently. In the present study, both tools were tested in 23 patients receiving CBA. We found that baseline tool showed a higher overall sensitivity, while injection tool showed a higher overall specificity. This finding indicates that baseline tool may serve as a real-time assessment tool, while injection tool may serve as a final confirmation tool for PV occlusion.

Notably, the discrepancies between both tools were not uncommon. Our findings indicated that different tools might be suitable in different PVs. For example, the baseline tool was more effective in LSPV and RSPV. The reasons were: i) most attempts of LSPV and RSPV could achieve optimal occlusion in both tools as well as in pulmonary venography; ii) in cryoablation of RSPV, minimal leak was encouraged, also known as "proximal-seal" technique[24], to reduce the risk of PNI, whereas the pursuit of complete occlusion with the injection tool might lead to overfreezing and increase the risk of PNI. In contrast, complete occlusion in inferior PVs with the injection tool was associated with lower nadir temperature and longer thaw time, which might result in more durable PVI.

Limitation

Firstly, the sample size of the present study is relatively small. Thus, the generalization of these conclusions needs to be further tested in larger cohorts. Secondly, we did not include TTI into statistical analysis because of the low TTI recording rate in the study. Finally, our data were collected with version 1.4.8a of the KODEX-EPD system. With the revolution of the system, more maneuvers will be clinically available to facilitate the CBA procedure in the near future.

Conclusions

In conclusion, both tools were able to accurately assess the degree of PV occlusion and predict the acute cryoablation effect, with the baseline tool being more sensitive and the injection tool more specific.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgement

This study was supported by Fuwai Yunnan Cardiovascular Hospital, Yunnan Provincial Cardiovascular Disease Clinical Medical Center Project (No. FZX2019-06-01). The authors sincerely thank Xue Du M.D. Ph.D. for the preparation of the manuscript.

Data availability statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Author contributions

Study concept and design: Qiao Y, and Niu GD. Analysis and interpretation of data: Qiao Y, Zhao Z, Fu MP, Cai X, Guo YL, Liu K, and Guo JR. Drafting of the manuscript: Qiao Y and Niu GD. Critical revision of the manuscript for important intellectual content: Qiao Y, Guo T, and Niu GD. Statistical analysis: Qiao Y. Approval of the article: Qiao Y, Zhao Z, Fu MP, Cai X, Guo YL, Liu K, Guo JR, Guo T, and Niu GD.

References

1. Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomstrom-Lundqvist C, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Eur Heart J. 2021;42(5):373-498.

2. Calkins H, Hindricks G, Cappato R, Kim YH, Saad EB, Aguinaga L, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Europace. 2018;20(1):e1-e160.

3. Packer DL, Kowal RC, Wheelan KR, Irwin JM, Champagne J, Guerra PG, et al. Cryoballoon ablation of pulmonary veins for paroxysmal atrial fibrillation: first results of the North American Arctic Front (STOP AF) pivotal trial. J Am Coll Cardiol. 2013;61(16):1713-1723.

4. Kuck KH, Brugada J, Furnkranz A, Metzner A, Ouyang F, Chun KR, et al. Cryoballoon or Radiofrequency Ablation for Paroxysmal Atrial Fibrillation. N Engl J Med. 2016;374(23):2235-2245.

5. Chun KR, Stich M, Furnkranz A, Bordignon S, Perrotta L, Dugo D, et al. Individualized cryoballoon energy pulmonary vein isolation guided by real-time pulmonary vein recordings, the randomized ICE-T trial. Heart Rhythm. 2017;14(4):495-500.

6. Ferrero-de-Loma-Osorio A, Garcia-Fernandez A, Castillo-Castillo J, Izquierdo-de-Francisco M, Ibanez-Criado A, Moreno-Arribas J, et al. Time-to-Effect-Based Dosing Strategy for Cryoballoon Ablation in Patients With Paroxysmal Atrial Fibrillation: Results of the plusONE Multicenter Randomized Controlled Noninferiority Trial. Circ Arrhythm Electrophysiol. 2017;10(12).

7. Maurer T, Mathew S, Schluter M, Lemes C, Riedl J, Inaba O, et al. High-Resolution Imaging of LA Anatomy Using a Novel Wide-Band Dielectric Mapping System: First Clinical Experience. JACC Clin Electrophysiol. 2019;5(11):1344-1354.

8. Romanov A, Dichterman E, Schwartz Y, Ibragimov Z, Ben-David Y, Rodriguez H, et al. High-resolution, real-time, and nonfluoroscopic 3-dimensional cardiac imaging and catheter navigation in humans using a novel dielectric-based system. Heart Rhythm. 2019;16(12):1883-1889.

9. Rottner L, Nodorp M, Jessica W, Schleberger R, Sinning C, Lemoine M, et al. High anatomical accuracy of a novel high-resolution wide-band dielectric imaging system in cryoballoon-based ablation. Pacing Clin Electrophysiol. 2021;44(9):1504-1515.

10. Cauti FM, Rossi P, Polselli M, Iaia L, Giannitti CM, Bianchi S. Occlusion tool software for pulmonary vein occlusion verification in atrial fibrillation cryoballoon ablation to avoid the use of contrast injection. HeartRhythm Case Rep. 2020;6(8):516-519.

11. Cauti FM, Solimene F, Stabile G, Polselli M, Schillaci V, Arestia A, et al. Occlusion tool software for pulmonary vein occlusion verification in atrial fibrillation cryoballoon ablation. Pacing Clin Electrophysiol. 2021;44(1):63-70.

12. Schillaci V, Stabile G, Arestia A, Shopova G, Agresta A, Poggi S, et al. Fluoroscopy and contrast media use in cryoballoon ablation of atrial fibrillation using a novel imaging system. Heart Vessels. 2022;37(1):115-120.

13. Neumann T, Vogt J, Schumacher B, Dorszewski A, Kuniss M, Neuser H, et al. Circumferential pulmonary vein isolation with the cryoballoon technique results from a prospective 3-center study. J Am Coll Cardiol. 2008;52(4):273-278.

14. Hua W, Hu YR, Gu M, Cai C, Chen XH, Niu HX, et al. A feasible approach for His bundle pacing using a novel mapping system in patients receiving pacemaker therapy. HeartRhythm Case Rep. 2019;5(8):433-435.

15. Scara A, Sciarra L, Bressi E, De Ruvo E, Grieco D, Borrelli A, et al. Cardiac resynchronization therapy guided by the new KODEX-EPD imaging system. J Arrhythm. 2021;37(5):1383-1387.

16. Yorgun H, Canpolat U, Oksul M, Sener YZ, Ates AH, Crijns H, et al. Long-term outcomes of cryoballoon-based left atrial appendage isolation in addition to pulmonary vein isolation in persistent atrial fibrillation. Europace. 2019;21(11):1653-1662.

17. Siklody CH, Minners J, Allgeier M, Allgeier HJ, Jander N, Weber R, et al. Cryoballoon pulmonary vein isolation guided by transesophageal echocardiography: novel aspects on an emerging ablation technique. J Cardiovasc Electrophysiol. 2009;20(11):1197-1202.

18. Ottaviano L, Chierchia GB, Bregasi A, Bruno N, Antonelli A, Alsheraei AT, et al. Cryoballoon ablation for atrial fibrillation guided by real-time three-dimensional transoesophageal echocardiography: a feasibility study. Europace. 2013;15(7):944-950.

19. Siklody CH, Minners J, Allgeier M, Allgeier HJ, Jander N, Keyl C, et al. Pressure-guided cryoballoon isolation of the pulmonary veins for the treatment of paroxysmal atrial fibrillation. J Cardiovasc Electrophysiol. 2010;21(2):120-125.

20. Safavi-Naeini P, Shanoon F, Nazeri A, Rasekh A, Saeed M, Razavi M, et al. Cryoballoon pressure waveform change during balloon inflation is not a reliable predictor of adequate pulmonary vein occlusion. Pacing Clin Electrophysiol. 2014;37(12):1702-1707.

21. Rottner L, Moser F, Weimann J, Moser J, Schleberger R, Lemoine M, et al. Accuracy and Acute Efficacy of the Novel Injection-Based Occlusion Algorithm in Cryoballoon Pulmonary Vein Isolation Guided by Dielectric Imaging. Circ Arrhythm Electrophysiol. 2022;15(2):e010174.

22. Rillig A, Rottner L, Nodorp M, Lin T, Weimann J, Munkler P, et al. Novel Wide-Band Dielectric Imaging System and Occlusion Tool to Guide Cryoballoon-Based Pulmonary Vein Isolation: Feasibility and First Insights. Circ Arrhythm Electrophysiol. 2020;13(12):e009219.

23. Rottner L, Sinning C, Reissmann B, Schleberger R, Dinshaw L, Munkler P, et al. Wide-Band Dielectric Imaging and the Novel Cryoballoon-Occlusion Tool to Guide Cryoballoon-Based Pulmonary Vein Isolation. Circ Arrhythm Electrophysiol. 2020;13(8):e008507.

24. Su W, Kowal R, Kowalski M, Metzner A, Svinarich JT, Wheelan K, et al. Best practice guide for cryoballoon ablation in atrial fibrillation: The compilation experience of more than 3000 procedures. Heart Rhythm. 2015;12(7):1658-1666.

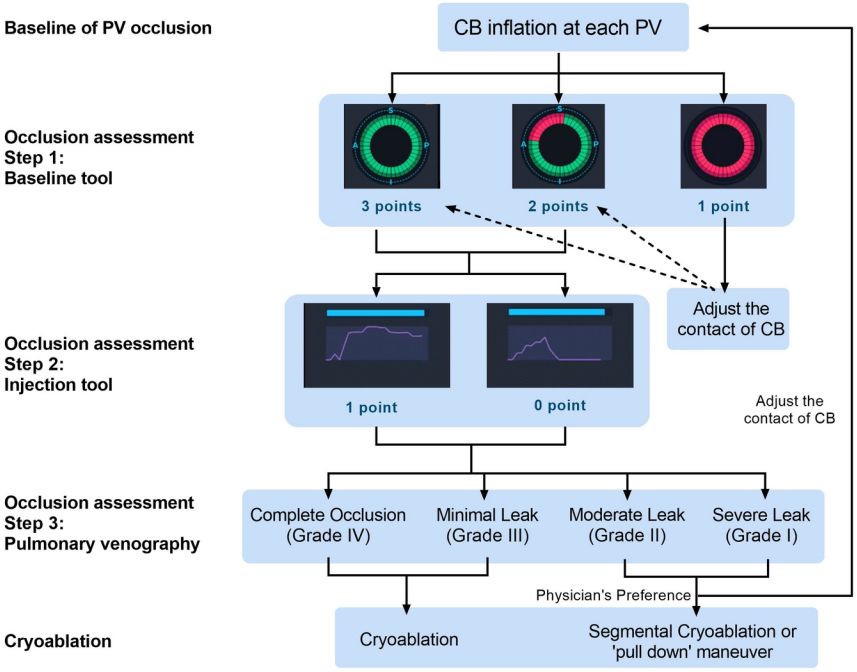
Figure legends

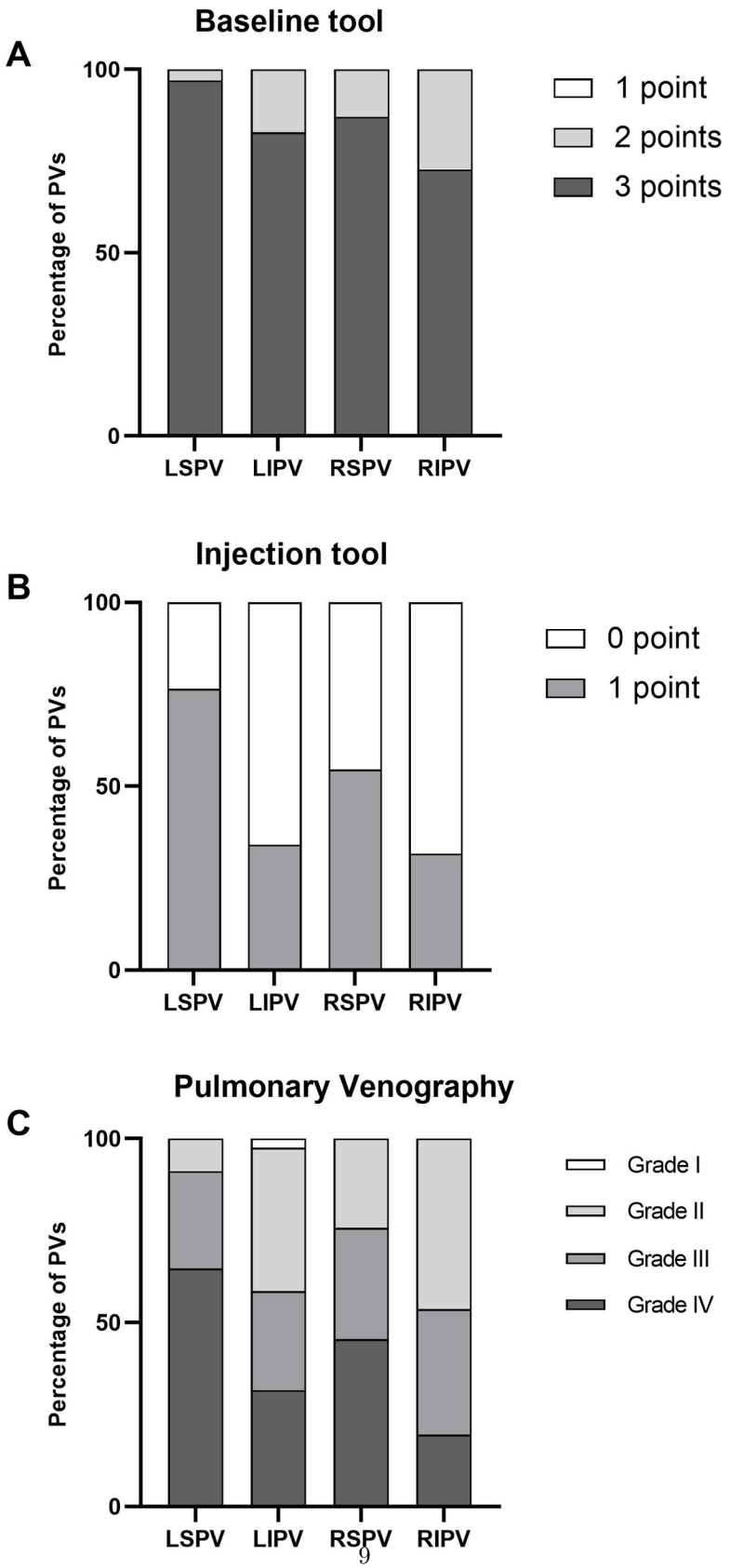
Figure 1 Flow chart of the study design. CB, cryoballoon; PV, pulmonary vein.

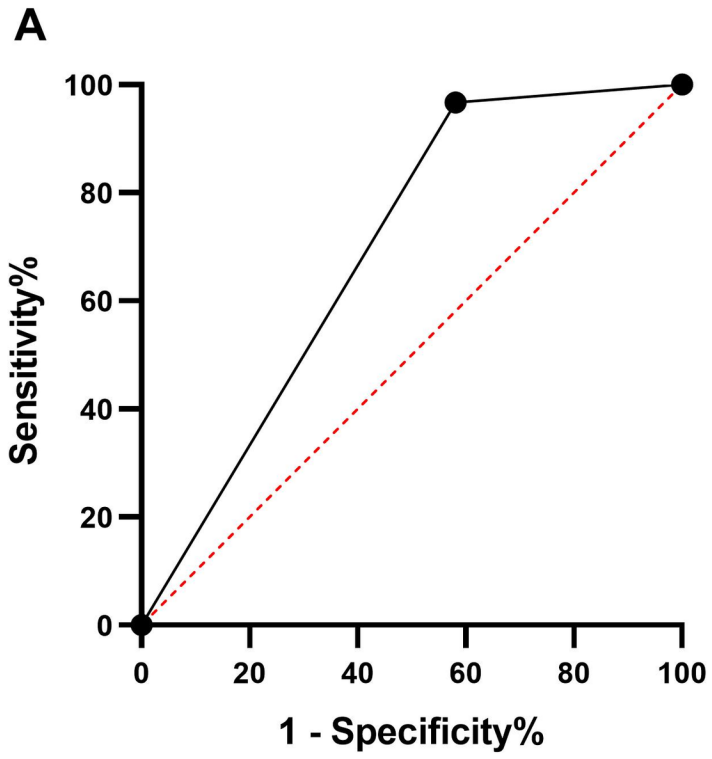
Figure 2 Occlusion assessment results of different pulmonary veins using the baseline tool (A), injection tool (B), and pulmonary venography (C) as verification standards. LSPV, left superior pulmonary vein; LIPV, left inferior pulmonary vein; RSPV, right superior pulmonary vein; RIPV, right inferior pulmonary vein.

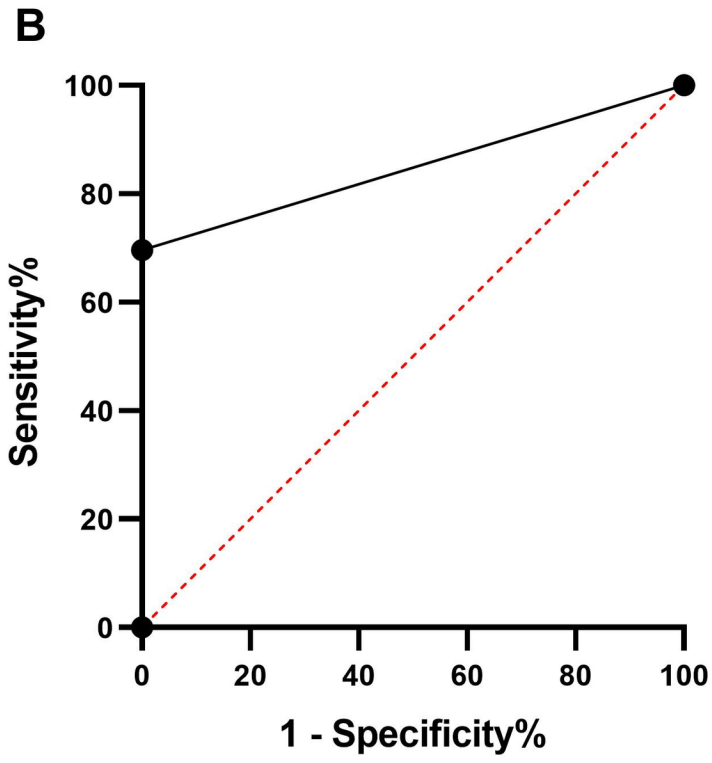
Figure 3 Receiver operating characteristic curves showing occlusion assessment value of the baseline (A) and injection tool (B).

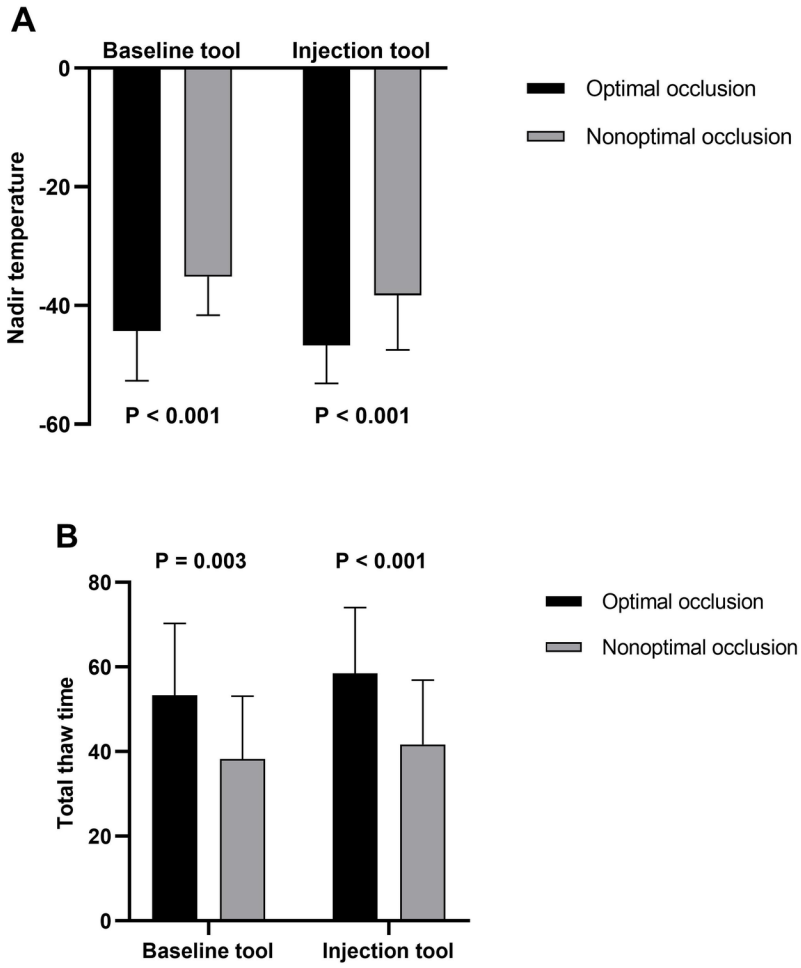
Figure 4 Nadir temperature (A) and total thaw time (B) in pulmonary veins with and without optimal occlusion using the baseline and injection tool. Optimal occlusion refers to 3 points in the baseline tool or 1 point in the injection tool; nonoptimal occlusion refers to< 2 points in the baseline tool or 0 point in the injection tool.











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