# Applying Runthrough Guidewire To Transseptal Puncture Without Iodinated Contrast Agent

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# Abstract

**Aims**: Conventional transseptal puncture(TSP) relies on fluoroscopy and iodinated contrast agent to distinctly position the transseptal needle at the left atrium, however, there exists great challenges in clinic in patients with contrast hypersensitivity or allergy-like reactionsin the procedure. This study aimed to evaluate a novel approach to TSP assisted by Runthrough guidewire and fluoroscopy without use of iodinated contrast agent.

**Methods:** Sixty patients with paroxysmal atrial fibrillation undergone radiofrequency catheter ablation were enrolled from February 2021 to October 2021, and randomised to routine TSP group and Runthrough guidewire assisted group. The two groups were compared regarding the total operative time, length of fluoroscopy exposure, difference of radiation dose in X-ray, and the safety was evaluated in the patients undergone TSP without iodinated contrast agent.

**Results:** There were no differences in baseline demographics or clinical characteristics between the two groups**.** Although the total procedure time[(1.98±0.29) min *vs.*(2.11±0.14) min, $P$<0.04],length of fluoroscopic exposure [(1.83±0.30) *vs.*(1.98±0.14), $P$<0.19] and radiation dose in X-ray[(27.83±3.21) uGym$^2$ *vs.*(29.13±1.57) uGym$^2$, $P$<0.30] were somewhat statistically different between groups, yet the difference was insignificant. No complications, including pericardial tamponade and aortic perforation, occurred in all patients.

**Conclusion:** Iodine-free TSP under the guidance of Runthrough guidewire and fluoroscopy can be a simple, safe, economical and effective approach to TSP, and may be reproduced as a novel option for TSP in patients with contrast hypersensitivity or allergy-like reactions.


# Introduction

Transseptal puncture(TSP), first created by Professor Ross and Morrow early in 1958[1], was initially applied to left heart catheterization and measurement of the left atrial pressure. This technology has gained wider access to cardiac interventional procedures, especially radiofrequency catheter ablation of atrial fibrillation and percutaneous left atrial appendage occlusion as the progress of percutaneous coronary intervention[2], and so far has become one of the essential clinical skills of a physician in management of arrhythmia. TSP can be a relatively safer procedure, yet the complications associated with it, such as acute pericardial tamponade, is in the neighbourhood of 0.74%-0.79% even in the best hands[3], which suggests that TSP still represents a procedure with high risks, and even life-threatening due to the inevitable serious complications being present objectively. Conventional TSP relies on fluoroscopy and iodinated contrast agent to clearly indicate the transseptal needle at the left atrium, however, there exists great challenges in clinic in patients with contrast hypersensitivity or allergy-like reactionsin the procedure. Luckily, many novel atrial septal punctures have been introduced with continual creation of relevant auxiliary technologies, including transesophageal echocardiography(TEE), intracardiac echocardiography(ICE) and TSP guided by electroanatomic mapping (EAM) [4, 5].

Nonetheless, these technologies require cooperation of multidiscipline(for instance, uninterrupted anesthesia during the procedure, assistance of esophageal ultrasound by a professional provider, etc.), and are involved in other issues such as patient's tolerance in procedure, which leads to significantly added medical expense and longer learning curve as well as difficulty in wider clinical recommendation. Therefore, this study was designed to explore a methodology for TSP assisted by Runthrough guidewire and fluoroscopy without use of iodinated contrast agent.

# Methods

### Patient data

Sixty patients with paroxysmal atrial fibrillation undergone radiofrequency ablation in the First Affiliated Hospital of Wannan Medical College, Anhui, China, were consecutively included from February to October of 2021, and randomly allocated to conventional TSP group and Runthrough guidewire assisted group (Figure 1). All patients underwent esophageal ultrasound or computed tomography angiography (CTA)of the left atria to exclude thrombosis at left atrial appendage, and oral warfarin or a new anticoagulant for three to four weeks before operation. Fasting started about 4 to 6 hours prior to the procedure. Written informed consent was obtained from all patients. Exclusion criteria were as follows: 1)history of catheter ablation for atrial fibrillation in the past 6 months; 2)left ventricular ejection fraction<0.35; 3) New York Heart Association (NYHA) cardiac function III or IV; and 4) patent foramen ovale(PFO) confirmed by TEE.

### Qualification of the physicians

Physicians participated in current study were those who had many years of clinic practice in interventional management of arrhythmia, and performed TSP in over 150 patients on average per year. Additionally, all providers were totally competent at estimating and managing the complications associated with therapeutic catheterization.

### TSP procedure

### Conventional TSP procedure with iodinated contrast agent

A 10-pole electrode catheter (Biosense-Webster Inc., Diamond Bar,CA, USA)was initially positioned at the coronary sinus (CS)via left subclavian vein or left femoral vein. Transseptal sheath with its dilator (SL1;size: 8.5F; Synaptic Medical Technology Co., Ltd. Beijing, China) was delivered into the superior vena cava through right femoral vein assisted by a long J-tipped guidewire(0.032 inch×180 cm; Synaptic Medical Technology Co., Ltd. Beijing, China), which was then replaced by a transseptal needle (Synaptic Medical Technology Co., Ltd. Beijing, China). Under the fluoroscopy by postero-anterior(PA) projection, the puncture assembly(including sheath–dilator and the transseptal needle)were then carefully withdrawn against the patient's foot while observing the motions of catheter tip at fluoroscopy until two falls occurred, which indicated successful descent of the assembly from the superior vena cava and into the fossa ovalis.Next, the puncture assembly were gently adjusted at the right anterior oblique

fluoroscopic(RAO) 30-45° projection. Once the right puncture location was decided, the transseptal needle was pushed through the fossa ovalis into left atrium. TSP was directly performed in patients undergoing conventional procedure after injecting 2-3ml of iodinated contrast agent via the transseptal needle. After confirming access to the left atrium, the transseptal needle was fixed, and the transseptal sheath with its dilator was advanced into the left atrium. The long J-tipped guidewire was introduced after withdrawal of the transseptal needle, and confirmed to be in place in the left superior pulmonary vein at PA projection and the left anterior oblique (LAO) projection (30-45°). Finally, the transseptal sheath with its dilator was introduced into left atrium under the protection of the guidewire.

### TSP procedure assisted by Runthrough guidewire

After transseptal needle tip reaching left atrium through the fossa ovalis, a Runthrough guidewire(0.014 inch×180 cm, Terumo Corporation, Japan) was introduced and positioned without use of iodinated contrast agent. The Runthrough guidewire was driven into the left superior pulmonary vein by the same position(PA and LAO projection) as conventional TSP procedure. Upon confirming that the distal tip of the Runthrough guidewire was exposed into the left superior pulmonary vein and by the outside of the contour of the heart under fluoroscopy, the Runthrough guidewire was secured, and the transseptal needle and the transseptal sheath with its dilator were introduced into the left atrium under the protection of the guidewire (Figure 2). Then the Runthrough guidewire, the transseptal needle and the dilator were drawn out after the transseptal sheath was positioned and maintained in the left atrium.

The blood was drained through the sheath, and heparin was administrated immediately in dose of 80–100 U/kg. All patients received only one TSP and circumferential pulmonary vein isolation (CPVI) by Carto 3 system(Biosense-Webster Inc., Diamond Bar,CA, USA).

### Imaging system and radiation dose measurement

Fluoroscopic imaging was performed using Simens single-plane pulsed system (SIEMENS Artis Zee Ceiling, Siemens Medical Systems NA.) at 6 frames/s, The total puncture time was defined as the time from withdrawal of the puncture assembly from superior vena cava to successfully positioning the transseptal sheath at the left atrium. The radiation dosage was measured by dose per unit area (uGym$^2$), and the radiation length during puncture was recorded for each patient.

### Study endpoint

The endpoints in current study consisted of: ① TSP duration(the time from retracting the puncture assembly from the superior vena cava to the transseptal sheath retained in the left atrium); ②radiation time(total fluoroscopy length during TSP); ③ radiation dose(the radiation dose automatically recorded by X-ray device during TSP) (uGym$^2$); and④ complications(adverse events involved in TSP, including cardiac tamponade and aortic perforation).

### Statistical analysis

All statistical data were analysed with software SPSS version 22.0(Inc. Chicago, IL). Measurement data were expressed as$\bar{x}$±S, and compared between groups using *t*-test. The counting data was presented as percentage, and compared between groups using $\chi^2$ test. *P* value < 0.05 was accepted as statistical significance.

# Results

The baseline demographics and clinical characteristics of the 60 patients were tabulated in Table 1. No differences were shown between the two group pertinent to mean age[(60.93±10.08) years *vs.* (62.10±9.64), *P*>0.05)], genders(17(56.67%) *vs.* 13(43.33%),*P*>0.05), CHA2DS2-VASc score (1.97±1.33 *vs.* 2.00±1.53, *P*>0.05), HASBLED score(0.57±0.50*vs.*0.50±0.51, P>0.05),body mass index(BMI) (24.88±2.94 *vs.* 23.46±2.64, *P*>0.05), left atrial diameter (39.87±5.59 *vs.* 38.90±5.49, *P*>0.05), and left ventricular ejection fraction(62.27±5.91 *vs.*62.67±3.74, *P*>0.05).Left atrium access was completely and successfully achieved in both groups of patients. Although the total procedure time[(1.98±0.29) min *vs.* (2.11±0.14) min, *P*<0.04], length of fluoroscopic exposure [(1.83±0.30) *vs.*(1.98±0.14), *P*<0.19] and radiation dose in X-ray[(27.83±3.21) uGym$^2$ *vs.* (29.13±1.57) uGym$^2$, *P*<0.30]were statistically different between the two groups, yet the difference was insignificant (Table 2).

Table 1
Baseline demographics and clinical characteristics for patients in both groups

| | **Conventional TSP group (*n*=30)** | **Runthrough guidewire assisted group (*n*=30)** | ***P* value** |
|---|---|---|---|
| Age (years) | 60.93±10.08 | 62.10±9.64 | >0.05 |
| Male, n (%) | 17(56.67%) | 13(43.33%) | >0.05 |
| $CHA_2DS_2$-VAScscore | 1.97±1.33 | 2.00±1.53 | >0.05 |
| HASBLED score | 0.57±0.50 | 0.50±0.51 | >0.05 |
| BMI, kg/m2 | 24.88±2.94 | 23.46±2.64 | >0.05 |
| LAD, mm | 39.87±5.59 | 38.90±5.49 | >0.05 |
| LVEF, % | 62.27±5.91 | 62.67±3.74 | >0.05 |
| Comorbidity,n (%) | | | >0.05 |
| Hypertension | 16(53.33%) | 19(63.33%) | |
| Diabetes | 4(13.33%) | 2(6.67%) | |
| CAD | 8(26.67%) | 7(23.33%) | |
| BMI:body mass index; LAD: left atrial diameter; LVEF: left ventricular ejection fraction; CAD: coronary artery disease | | | |

Table 2
Comparison of the procedure results between the two groups

| | Total procedure time (min) | Fluoroscopic time (min) | Radiation dose (uGym$^2$) |
|---|---|---|---|
| Conventional TSP group (*n* =30) | 1.98±0.29 | 1.83±0.30 | 27.83±3.21 |
| Runthrough guidewire assisted group(*n* =30) | 2.11±0.14 | 1.98±0.14 | 29.13±1.57 |
| *t* | -2.15 | -2.49 | -2.28 |
| *P value* | 0.04 | 0.19 | 0.30 |

In patients undergone TSP assisted by Runthrough guidewire, failure occurred in 6 patients because of the Runthrough guidewire being not enough facilitate the transseptal sheath to completely pass through the fossa ovalis that the dilator tip was lodged in the left surface atrium of fossa ovalis, for which we managed by retreating the transseptal needle and Runthrough guidewire that was replaced by J-tipped guidewire, and then advanced the J-tipped guidewire into the left superior pulmonary vein, Eventually, the transseptal sheath successfully gained access to the left atrium.

No major complications (e.g., cardiacperforation, aortic perforation) occurred in either group, and all patients underwent successful CPVI.

# Discussion

TSP technology was described early in 1950s, and currently widely used in catheter ablationof arrhythmia, percutaneous left atrial appendage occlusion, treatment of mitral valve conditions, or transcatheter aortic valve replacement(TAVR) as progressive development of cardiac interventions[6, 7]. Current TSP primarily involve puncture guided by X-ray or ultrasound (including TEE and ICE) and transseptal puncture guided by electroanatomic mapping (EAM) [8]. At present, TSP assisted by fluoroscopy still remains most widely used in clinic. However, iodinated contrast agent is absolutely essential in the TSP, no matter whether the procedure is performed by traditional RAO at 45° projection or modified transseptal puncture by view of RAO 45°[9], therefore, allergy to iodinated contrast agent has been frequently reported in patients undergone TSP [10].For instance, Li *et al*[11] reported that the incidence of allergic reaction to iodinated contrast agent was 0.4% in Chinese population. This adverse event not only narrows the patients with indications to undergo routine TSP, but also potentially jeopardises the patients' lives. In addition, post contrast acute kidney injury has been reported as one of the common complications from iodine, accounting for 11% of the cases of all hospital-acquired renal insufficiency[12]. Although the dose capable of inducing clinical adverse effects by using iodinated contrast agent during TSP is far lower than the dosage proposed in the *Consensus of Chinese Experts on Prevention of Adverse Reactions Related to Iodinated Contrast Agents in Interventional Diagnosis and Treatment of Arterial Cardiovascular Diseases*(2021) [13], yet special concerns should be given to whether the renal function

would be changed in the aged patients and those with primary renal insufficiency or diabetes mellitus following TSP. Either TEE or ICE applied to assisting TSP can make free use of iodinated contrast agent and improve the safety and successful rate, whereas clinical application of the ultrasonic device is greatly limited, because it requires cooperation of qualified professionals, which will further increase the medial cost as well as difficulty of procedure.

TSP assisted by Runthrough guidewire can avert from iodinated contrast agent in routine procedure. The diameter and the length, measured by 0.014 inch× 180 cm, can ensure safe and smooth advancing of the intra-needle through the atrial septum. The key advantages of this technique lie in: 1)by the property that Runthrough guidewire can pass through the trasseptal needle core, and then gain access to the left atrium when the TS needle breaks through the atrial septum without angiography by iodinated contrast agent. The TS needle and transseptal sheath can be pushed into the left atrium via the left superior pulmonary vein assisted by Runthrough guidewire; and 2) designed to be an all-in-one workhorse wire with a fine diameter, soft, atraumatic and low tip, possessing better maneuverability and higher safe operation in the left atrium. The disadvantage rests with the difficulty in feeding transseptal sheath in certain cases due to insufficient supporting force of the guidewire. However, this can be managed by enough advancing the Runthrough guidewire into the distal end of the left superior pulmonary vein in TSP, and as necessary, the transspetal needle together with the guidewire can be withdrawn with the transseptal sheath being retained in the left atrium. Then the sheath is fed into the left superior pulmonary vein by a J-tipped guidewire. Cautions for TSP assisted by Runthrough guidewire are that the puncture assembly should be carefully advanced during puncture, and must gain access to the left atrium when the transseptal needle is totally confirmed to be in the left atrium and the guidewire is in the left superior pulmonary vein (validation of the position by LAO and PA projection). Additionally, the puncture assembly should not be heavily adjusted until the transseptal needle is retracted from the left atrium to prevent incidence of cardiac tamponade from atrial injury caused by the sharp needle tip. Although difficult TSP procedures assisted by PTCA guidewire were reported in some previous literatures[14], yet current study described the cautions and processes on the TSP under the guidance of Runthrough guidewire without use of iodinated contrast agent, and made prospective comparison with conventional TSP.

Based on corresponding clinical practice, this study confirms that TSP assisted by Runthrough guidewire without iodinated contrast agent is safe, economical and effective for electrophysiologists with rich experience in TSP, and the procedure can be completed within 2-3 minutes. Although there was difference in total operative time, duration of fluoroscopy and radiation dose between TSP with iodinated contrast agent and that assisted by Runthrough guidewire, yet the difference remained insignificant. The major reasons are: 1)the physicians are not that skilled at this new technique; 2)failure of advancing the transseptal sheath in some cases in procedure due to insufficient sustenance of the Runthrough guidewire that had to be replaced by J-tipped guidewire, which resulted in added total procedure time, prolonged fluoroscopy and increased radiation dose. Nevertheless, the increased operative time and fluoroscopy dose are still within the tolerance limits in terms of the whole operation. Therefore, this

technique can be a novel alternative for TSP assisted by TEE or ICE in patients with contrast hypersensitivity or allergy-like reactions undergoing TSP, and also be extended to interventional therapy of structural heart conditions (such as TAVR, percutaneous mitral valve replacement, etc.). It should be noted that this technique, though simple and easy in procedure, is not necessarily applied to all patients. In certain intricate cases (such as atrial septal aneurysm, abnormal cardiac anatomy, etc.),TSP under the guidance of TEE or ICE remains prerequisite, because either of the procedure can ensure safety.

# Research Limitations

There are several limitations in current study. First, relatively smaller samples have to be compensated by expanded subjects in following clinical observation in order to validate the safety and efficacy of this technique. Next, patients enrolled in this study were those with paroxysmal atrial fibrillation undergoing catheter ablation for the first time, and whose cardiac structures were relatively normal. Therefore, whether TSP assisted by Runthrough guidewire can be workable and safe needs further verifying in patients with enlarged atrium or severe lipomatous hypertrophy of the interatrial septum compared to the patients with persistent atrial fibrillation or recurrent atrial fibrillation undergoing secondary ablation.

# Conclusions

In summary, we consider that TSP assisted by Runthrough guidewire under fluoroscopy without use of iodinated contrast agent is safe, economical, easy in performance and reproducible. This technique can be used as a novel approach to TSP in patients with contrast hypersensitivity or allergy-like reactions, and is worthy of clinical recommendation.

# Declarations

### Data availability

The research data are on file and available on request from the corresponding author.

### ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Institutional Ethics Committee for Biomedical Research of the First Affiliated Hospital of Wannan MedicalCollege.The patients/participants provided their written informed consent to participate in this study.

### AUTHOR CONTRIBUTIONS

JW:drafted the manuscript. JW,PF,JL,YW,XW,and HY:performed the procedures and collected the data. HY and JW: designed this research and revised the manuscript. All authors read and approved the final version of the manuscript.

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# Figures

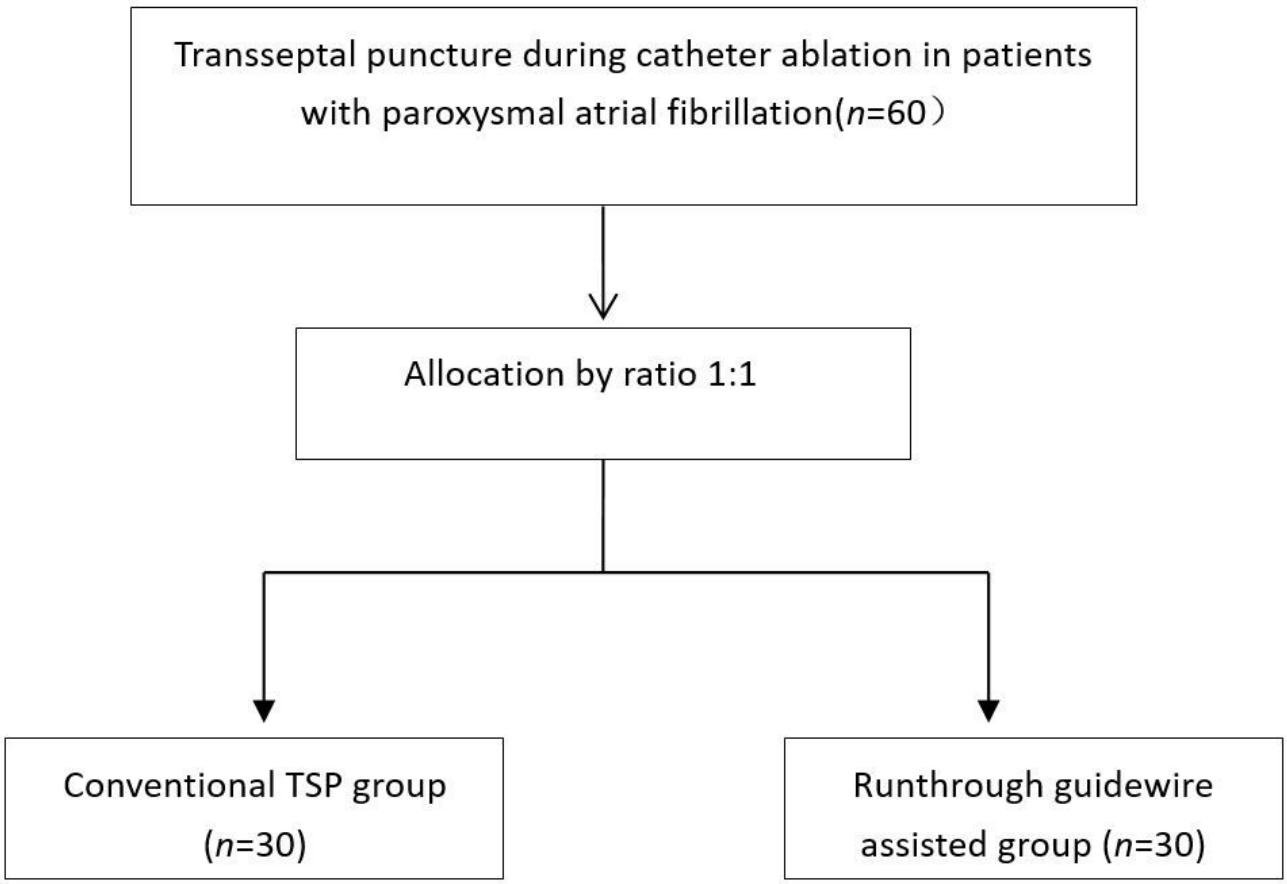
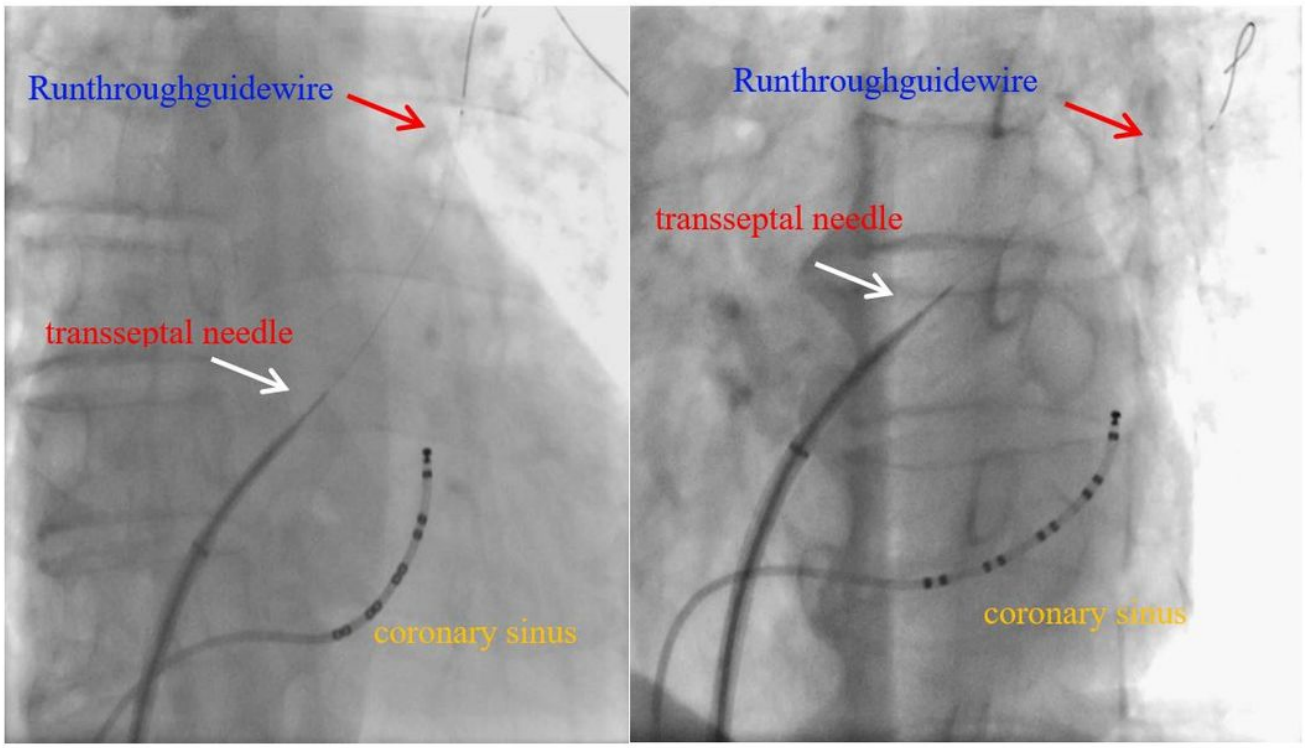



**Figure 1**

Allocation scheme for the patients enrolled in the study




## Figure 2

Left anterior oblique (LAO) and postero-anterior (PA) views in which catheters are displayed as anatomical references,with a decapolar catheter in the coronary sinus (CS) ; an 8.5F SL1 transseptal sheath and dilator (Synaptic Medical Technology) and transseptal needle (Synaptic Medical Technology) with deployment of a Runthrough guidewire(0.014 inch×180 cm, Terumo Corporation, Japan)through the transseptal needle.