



Review

Iatrogenic atrial septal defect following transeptal cardiac interventions

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ABSTRACT

In the Era of expanding use of transeptal structural heart disease interventions and catheter ablation techniques for atrial fibrillation, there is increasing interest in the iatrogenic atrial septal defect (iASD) often associated with these procedures. The purpose of this review is to summarize the current evidence on the incidence and clinical impact of iASD, to identify possible predictors of persistent iASD, and to propose a standardized method for the detection, follow up and management of iASD.

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1. Introduction

The number of left atrial transcatheter procedures performed via a transeptal (TS) approach has grown exponentially over the last two decades [1]. Persistent iatrogenic atrial septal defect (iASD) is a known potential complication of electrophysiological and structural interventional procedures involving puncture and dilatation of the inter-atrial septum with an incidence of 0–50% [2–13]. Most of the published studies on iASD are inconclusive with regard to the clinical significance of the iASD. However, a recent study by Schueler et al. revealed that persistent iASD in patients who underwent transcatheter mitral valve repair (TMVR) was associated with worsening heart failure symptoms, pulmonary hypertension, and excess mortality [10]. In addition, an increasing number of case reports of deleterious effects of iASD including acute hypoxemia, heart failure and systemic embolization have recently been published [14–24].

The purpose of this paper is to:

- (1) Review the current evidence on the incidence and clinical impact of iASD after interventional structural and electrophysiological heart interventions.
- (2) Identify possible predictors of persistent iASD.
- (3) Propose a standardized method for the detection, follow up and management of iASD.

2. Methods

We reviewed existing reports of iASD associated with percutaneous TS procedures. A PubMed literature search for “iatrogenic atrial septal defect” was performed on November 13th, 2015, and returned 139 references. Studies/case series were eligible to be included in this systematic review if they: (1) prospectively enrolled more than 10 patients (2) utilized transesophageal echocardiogram (TEE) as a method of iASD detection and (3) reported at least 6-months follow-up. Studies meeting the inclusion criteria were used to calculate the incidence of persistent iASD after interventional and electrophysiological procedures via a TS approach. Comparison of the mean incidence of iASD between different procedures was performed using a Chi Square test. References for available articles were also manually screened to identify other reported series. In order to provide a comprehensive review, studies on iASD that did not meet the inclusion criteria (retrospective studies and studies examining the incidence of iASD with means other than TEE) were also reviewed and summarized separately.

3. Results

A total of 139 studies were screened for eligibility. Of those, eight studies including 460 patients met the inclusion criteria (Table 1). These studies aimed at investigating the incidence of iASD in patients who underwent one or more of the following procedures via a TS route: radiofrequency (RF) or cryoballoon ablation (CB) of atrial fibrillation, percutaneous balloon mitral valvuloplasty (PBMV), left atrial appendage (LAA) closure, and transcatheter mitral valve repair (TMVR). We did not find any study investigating iASD after paravalvular leak (PVL) closure, percutaneous left ventricular assist device (pLVAD)

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Table 1

A Summary of prospective studies examining the incidence and clinical impact of iASD by transesophageal echocardiography.

Study	Procedure	Sheath Size (Fr)	iASD Incidence	Follow up (months)	Diameter (mm)	Echo parameters	Clinical events
Riling (2008)	PVI RF	8(x2) Ψ	1/31 (3.2%)	12	<3	NR	None
Hammerstingl (2006)	PVI RF	8(x2) Ψ	0/15 (0%)	9	0	NR	NR
Rilling (2010)	PVI CB	8&12*	8/40 (20%)	6	<3	NR	None
Hammerstingl (2006)	PVI RF	8&7*	8/27 (29.6%)	9	4	NR	NR
Singh (2011)	LAA closure	12	14/253 (7%)	12	<3 (50%)	NR	No Δ in stroke
Chan (2011)	PVI CB	12	4/13 (4.6%)	9	4.6	NR	None
Yoshida (1989)	PBMV	14	3/15 (20%)	6	1.1	NR	None
Schueler (2015)	TMVR	22	33/66 (50%)	6	4.3 \times 3.8	\uparrow RVSP, RAD, & RVD	\uparrow Death, HF

Fr; french, TS; transseptal puncture, iASD; iatrogenic atrial septal defect, PVI; pulmonary vein isolation, RF; radiofrequency, CB; cryoballoon, RAD; right atrial diameter, LAA; left atrial appendage, PBMV; Percutaneous balloon mitral valvuloplasty, TMVR; transcatheter mitral valve repair, NR; not reported, RVSP; right ventricular systolic pressure, RVD; right ventricular diameter, No Δ ; no difference, HF; heart failure, *; single TS, Ψ , double TS.

placement, and pulmonary vein stenting or transseptal mitral valve in valve (VinV) implantation.

Overall, persistent iASD was found beyond six months after a TS intervention in 71/460 patients (15.4%). Transesophageal echo was performed prospectively at least once at six, nine and twelve months. Multiple baseline, procedural and post-procedural characteristics were investigated as possible predictors of persistent iASD, with significant heterogeneity of the tested predictors. The strongest predictor of developing a persistent iASD was the size of the sheath or guiding catheter (Fig. 1). The incidence of persistent iASD (at maximum follow up) strongly correlated with the size of the transseptal sheath/guide used: 2.2%, 6.8%, 23.1% and 50% in patients who had cannulation of the TS with sheath/guide sizing <8, 12, 14–20 (a single 14 Fr sheath, two 8 Fr or 8 Fr and 12 Fr sheaths via a single TS), and 22 French, respectively ($p < 0.001$). Left atrial (LA) pressure, right ventricular systolic pressure (RVSP), and the presence of severe mitral or tricuspid regurgitation correlated with persistent iASD [12,25]. Baseline left ventricular function, age, gender and left atrial size did not correlate with iASD persistence [4,9].

Two studies reported the impact of the iASD on echocardiographic parameters and clinical outcomes [10,12]. AT 6 months follow up after TMVR, Schuller et al. compared the rates of adverse events in patients with persistent iASD and those without persistent iASD [10]. The two groups had similar baseline characteristics, New York Heart Association functional class, severity of mitral regurgitation, and acute procedural success rates ($p > 0.05$). Patients with iASD had less decrease of RVSP (-1.6 ± 14.1 mm Hg vs. 9.3 ± 17.4 mm Hg; $p = 0.02$), more incidence of New York Heart Association functional classes $>II$ (57% vs. 30%; $p =$

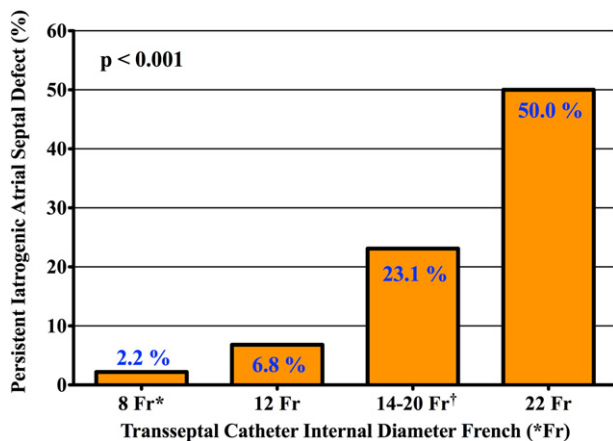


Fig. 1. The relationship between the transseptal sheath diameter and the incidence of persistent iASD. *Fr; French, †16–20 Fr refers to pulmonary vein isolation procedures performed with a single transseptal puncture with two side-to-side sheath (two 8.5 Fr or one 8.5 Fr and one 12 Fr).

0.04), higher levels of N-terminal pro-brain natriuretic peptide (6667.3 ± 7363.9 ng/dl vs. $4,835.9 \pm 6,681.7$ ng/dl; $p = 0.05$), and higher death rates during 6 months (16.6% vs. 3.3%; $p = 0.05$) compared with those who had no persistent iASD. Singh et al. examined the rates of stroke and systemic embolization in 253 patients after LAA closure with the Watchman device (Boston Scientific, Maple Grove, MN) [12]. At 12 months follow up, there was no significant difference in the incidence of stroke or systemic embolization in patients with persistent iASD versus those without persistent iASD (3.2% vs 1.5, $p = 0.42$), and no clinical evidence of right heart volume overload and pulmonary hypertension in either of the two groups.

Twelve other studies not meeting the inclusion criteria investigated iASD after various TS procedures. These studies vary significantly in the detection method (2D TTE, 3D TTE, 2D TEE, and venovenous indicator dilution curves), length of follow up and incidence of iASD. A summary of these studies is provided in Table (2).

4. Discussion

4.1. Incidence and predictors of persistent iASD

The TS puncture was developed by Ross, Braunwald and Morrow in the late 1950s to allow left heart catheterization, primarily for the evaluation of valvular heart disease [26]. This technique remained infrequently used by cardiologists until the introduction of catheter ablation of atrial fibrillation in the 1990s.

In more recent years, the emerging percutaneous transcatheter therapies of valvular and congenital heart disorders, led to a wide spread utilization and further modification of the TS puncture technique (Table 3). Yoshida et al. were the first to prospectively study the incidence of iASD after PBMV in 1989. However, the interest in iASD and its implications started to grow substantially with the increasing utilization of ablation techniques of atrial fibrillation [13]. Studies on iASD after PVI provided important insights into the effect of variable PVI techniques on the rates of persistent iASD [8,9,25]: (1) persistent iASD was more common after CB PVI ablation than after RF PVI method. Notably, the CB ablation catheter has a 12 Fr inner diameter compared with the 8–8.5 Fr inner diameter of the RF ablation catheter (2). The majority of PVI ablation cases (especially when the RF technique is utilized) require active manipulation of an ablation catheter (8.5–12 Fr) and a mapping catheter (7–8.5Fr) across the septum. This could be done with a single TS puncture with side-to-side ablation and mapping catheters or by performing two separate TS punctures. Persistent iASD was more common in patients who had PVI via a single TS puncture with two side-to-side sheaths compared with those who had PVI via two separate entries to the LA via double TS punctures (Table 1) [8,9,25]. These findings were also replicated in several other retrospective reports (Table 2) [3,6,11,27], and have raised concern among electrophysiologists regarding the non-negligible prevalence of persistent iASD

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