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Short and long-term outcomes of alcohol septal ablation with the trans-radial versus the trans-femoral approach
A single center-experience

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ABSTRACT

Background: Although the trans-radial approach (TR) has been applied to various subsets of patients in percutaneous coronary intervention, the feasibility, efficacy, acute procedural and long-term outcomes of TR versus trans-femoral approach (TF) for alcohol septal ablation (ASA) have not yet been determined.
Objectives: The aim of this study was to compare the short and long-term outcomes of ASA with the TR approach compared to the TF approach.
Methods: We retrospectively analyzed 240 patients who underwent an ASA procedure at our institution from November 1999 to November 2015. The TR approach was performed in 172 cases and the TF approach in the remaining 68 cases.
Results: The use of TR approach progressively increased from 62% in 1999–2005 to 91% in 2011–2015 ($p = 0.0001$). The TF and TR group had similar age, baseline NYHA class (NYHA 3 or 4) and mean left ventricular outflow tract peak gradient before ASA. Total contrast used (TR: 73.2 ± 47.2 ml; TF: 88.7 ± 49.3 ml, $p = 0.11$), total radiation Air kerma area product (TR: 43.7 ± 48.0 Gy cm^{-2}; TF: 55.9 ± 48.2 Gy cm^{-2}; $p = 0.39$) and peak left ventricular outflow tract gradient immediately after ASA (TR: 19.1 ± 19.6 mmHg; TF: 20.4 ± 18.0 mmHg, $p = 0.63$) were similar in both groups.
Procedural success was 91.9% and 91.2% in the TR and TF groups, respectively ($p = 0.53$). At 30 days, there was 2 intra-hospital death (1 in TF and 1 in TR), 1 major stroke in the TF group and 1 coronary artery dissection in the TR group. Vascular complications were less frequent in the TR group (0.58% vs. 7.3%; $p = 0.002$). The mean length of follow-up was 4.56 ± 4.34 years (IQR 0.69–8.2; median 2.92 years; maximum: 15.5 years). By Kaplan–Meier estimate, the observed survival in the overall cohort was comparable to the expected survival for a sex and age-matched comparable general French population at 10 years (86.9 vs. 83.6%, $p = 0.88$). Survival was similar between the TR and TF group (92.1% vs. 89.7% at 6 years, respectively; $p = 0.71$).
Conclusions: Alcohol septal ablation from the radial approach can be performed with similar acute and long-term success, but with lower vascular complications compared to the femoral approach.

1. Introduction

Alcohol septal ablation (ASA) has become a common procedure to reduce left ventricular outflow tract gradient in patients with hypertrophic obstructive cardiomyopathy (HOCM) refractory to maximal medical therapy [1–8]. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) guidelines recommend ASA over surgical myomectomy mainly in patients considered high risk for surgery, particularly in the elderly [9], while the ESC guidelines [10] recommend the use of septal reduction therapy in symptomatic patients with an LVOT gradient > 50 mmHg provided that the septal reduction therapy is performed by experienced operators working as a part of a multidisciplinary team expert in the management of HOCM.

According to the standard practice of the majority of centers and operators, ASA is attempted traditionally using the trans-femoral approach (TF). Yet, the trans-radial approach (TR) is a valuable alternative to the

Abbreviations: ASA, alcohol septal ablation; TR, trans-radial; TF, trans-femoral; NYHA, New York Heart Association; HOCM, hypertrophic obstructive cardiomyopathy.

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TF approach and has been shown to reduce access-site bleeding and vascular complications [11,12] and is possibly associated with better clinical outcomes in patients undergoing angioplasty. [13,14] Early ambulation, lower patient discomfort, also makes TR an attractive alternative to the TF approach [15]. For such reasons, the TR approach is now used not only in routine coronary procedures, but also in complex percutaneous coronary interventions, chronic total occlusion interventions and peripheral interventions [16–20]. However, the efficacy, feasibility, short and long-term procedural outcomes of the TR compared to the TF approach for ASA has not been determined. In this study, we compare procedural outcomes of patients undergoing ASA by either the TR approach or the TF approach.

2. Methods

2.1. Study cohort

All consecutive patients that underwent ASA at our center between November 1999 and October 2015 were prospectively included in a dedicated database. Patients were selected for ASA if they had severe symptoms (NYHA class >II or disabling syncope) despite adequate medical therapy, in combination with a maximal resting gradient >30 mmHg and/or provocable gradient >50 mmHg. Patients with septal thickness >30 mm, septal thickness <15 mm and abnormal mitral valve morphology were excluded and underwent myomectomy.

All therapeutic options (myomectomy vs. ASA) were discussed with each patient and a decision was made after careful explanation of the risks and potential benefits and the institutional experience. The final decision regarding the choice of septal reduction therapy was done after detailed multidisciplinary evaluation and a consensus of all physicians involved in the management of HOCM patients within our institution.

Operators performing the ASA procedure were proficient in both femoral and radial access and the decision to move to radial approach due to the accumulation of data in favor of the radial approach. Patients were excluded from TR approach if they were known to have the following conditions: Raynaud's disease, symptoms of upper limb claudication, absent pulses (in setting of PVD and possible supra-aortic disease). The Allen's test was not routinely performed, as it has not been shown to reduce trans-radial complication rates [21].

This paper complies with the Declaration of Helsinki and the locally appointed ethics committee has approved the research protocol. Informed consent has been obtained from each subject.

2.2. Procedure description

In all patients, diagnostic coronary angiography was performed to exclude significant coronary artery disease and analyze in detail the septal arteries anatomy. For the radial procedures, the patient's right or left arm was supported using a dedicated radial access support system. The right radial was the default access for all operators unless the artery was small or occluded, in which the left radial was chosen. In the TR group, the radial artery was catheterized with a dedicated arterial puncture kit (with plastic cannula and hydrophilic wire) and a short hydrophilic sheath (Radifocus, Terumo, Japan) [22]. Procedures were performed using a 5F or 6F left guiding catheter or a 6.5F dedicated sheathless catheter (Eucath, ASAHI, Intecc). We administered per protocol a radial cocktail consisting of: 200 μg of Nitroglycerin, 5 mg of Diltiazem and 5000 Units of heparin.

In the TF group, right or left femoral artery was catheterized by the modified Seldinger technique and a 6F left guiding catheter was used. Prophylactic temporary pacing catheter was inserted before the procedure via the femoral vein.

ASA was always performed with the assistance of myocardial contrast echocardiography or agitated contrast to identify the septal region irrigated by the selected septal branch. The presupposed septal branch responsible for basal obstruction was wired and a short (6 to 8 mm) coaxial balloon (1.5 to 2.5 mm) was inflated at the origin of the septal branch. If contrast enhancement of the papillary muscles or free wall was observed, another septal or sub-septal branch was selected. When enhancement of the basal septum was detected, 1 to 3 ml of 96% desiccated concentrated ethanol was slowly injected through the balloon catheter shaft (1 ml for each 1 mm increment of septal branch diameter at a rate of 1 ml/min). If the left ventricular outflow tract gradient remained >30–50 mmHg on echocardiography and the septal enhancement was not anatomically optimal, another septal branch was explored. If results were satisfactory (peak gradient decrease >50%), the balloon was deflated, and coronary angiography was repeated to confirm no reflow in the treated septal branch. Hemostasis of the radial artery was obtained with the TR band (Terumo, Japan) and femoral hemostasis was obtained with a suture-based device (ProGlide, Abbott Vascular, US), a collagen plug-based devices (AngioSeal, or FemoSeal, St Jude Medical, US) or manual compression depending on operator preference. Patients were observed in the cardiac care unit for at least 72 h and a permanent pacemaker was implanted if atrio-ventricular block persisted for more than 48 to 72 h. Blood was collected with troponin and CK-MB levels measured in the first 2 days after ASA. On the medical ward, patients remained on continuous cardiac telemetry until discharge at day 5.

2.3. Endpoints and definitions

In this study, we aimed to determine the efficacy, feasibility, short and long-term procedural outcomes of the TR approach vs. the TF approach after ASA. Procedural success was defined as >50% decrease in peak gradient. Cardiovascular death was defined as death related to any cardiovascular disease. Death within 30 days after ASA was considered ASA related. Sudden cardiac death was defined as unexpected death with or without documented ventricular fibrillation within 1 h after a witnessed collapse, in patients who previously were in stable clinical condition, or nocturnal death with no antecedent history of worsening symptoms.

Vascular complications were defined as any of the following: vessel perforation, pseudo-aneurysm, arterial dissection, compartment syndrome, retroperitoneal hematoma, hematoma >5 cm, need for red blood cell transfusion, hemoglobin drop >3 g/dl or any event that required a vascular intervention. Arrhythmic events were defined as: high-grade heart block leading to permanent pacemaker implantation, ventricular tachycardia, ventricular fibrillation and ICD implantation. Coronary complications were defined as: coronary dissection, coronary perforation, and alcohol displacement.

2.4. Clinical follow-up

All patients were followed at 30 days after discharge and had routine follow-up every 6- to 12 months according to physician preference. Patients who had persistent self-limiting symptoms with residual gradient were considered for further septal reduction therapy. We considered first repeat ASA targeting another septal if technically safe and feasible. Otherwise, patients were referred for cardiac myomectomy. Clinical outcomes were collected using hospital records and referring physician's records. When data was missing from the records, patients were also contacted by telephone to determine cardiovascular symptoms, potential complications related to septal ablation and need for additional procedures including further septal reduction therapy (i.e., surgical myectomy, repeat septal ablation), pacemaker or defibrillator implantation.

2.5. Statistical analysis

Categorical variables were compared using Fisher's exact test. Continuous variables are reported as mean ± standard deviation and