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

Fadi J. Sawayaa, Yves Louvarda, Marco Spazianoa, Marie-Claude Moricea, Fouad Haguea, Carlos El-Khourya,
Andrew Roya, Philippe Garota, Thomas Hovassea, Hakim Benamera, Thierry Unterseeha, Bernard Chevalier a,
Stéphane Champagnea, Jean-François Piecha, Didier Blanchardb, Bertrand Cormiera, Thierry Lefèvre a,*

a Department of Cardiology, Ramsay Générale de Santé, Institut Cardiovasculaire Paris-Sud—Hôpital Privé Jacques Cartier, Massy, France
b Publique-Hôpitaux de Paris, Hôpital Européen Georges Pompidou, Paris, France

abstract

Article history:
Received 7 May 2016
Received in revised form 16 June 2016
Accepted 22 June 2016
Available online 25 June 2016

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.

© 2016 Elsevier Ireland Ltd. All rights reserved.

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
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 am- 
bulation, lower patient discomfort, also makes TR an attractive alterna-
tive to the TF approach [15]. For such reasons, the TR approach is now 
used not only in routine coronary procedures, but also in complex per-
cutaneous 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 ap-
proach 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 >1 or disabling syncope) despite adequate medical therapy, in combination with a maximal resting gradient >30 mmHg and/or provocative 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 physi-
cians 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. In-
formed 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 proto-
col a radial cocktail consisting of: 200 μg of Nitroglycerin, 5 mg of Dilti-
azem 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 con-
trast 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) co-
axial 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% desic-
cated 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 enhance-
ment was not anatomically optimal, another septal branch was ex-
plored. If results were satisfactory (peak gradient decrease >50%), the 
balloon was deflated, and coronary angiography was repeated to con-
firm no reflow in the treated septal branch. Hemostasis of the radial ar-
tery 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 tro-
ponin 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 ap-
proach 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 consid-
ered 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 syn-
drome, retroperitoneal hematoma, hematoma >5 cm, need for red 
blood cell transfusion, hemoglobin drop >3 g/dl or any event that re-
quired 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 gradi-
ent were considered for further septal reduction therapy. We consid-
ered 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