Transradial approach and subclavian wired temporary pacemaker to increase safety of alcohol septal ablation for treatment of obstructive hypertrophic cardiomyopathy: The TRASA trial

Réduction des complications de l’alcoolisation septale des cardiomyopathies obstructives par approche trans-radiale et stimulation externe par sonde vissée sous-clavière : étude TRASA

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Received 4 February 2011; received in revised form 30 April 2011; accepted 3 May 2011
Available online 27 August 2011

KEYWORDS
Hypertrophic obstructive cardiomyopathy; Interventional cardiology; Alcohol septal ablation

Summary
Background. — Alcohol septal ablation (ASA) is a therapeutic catheter-based option and an alternative to surgical myectomy in the treatment of patients with hypertrophic obstructive cardiomyopathy. Although the safety of the ASA procedure has been consistently improved, a temporary transvenous pacemaker is recommended for at least 48 h postprocedure, with several drawbacks, including the risk of cardiac perforation and infection, and the absence of any fixation mechanism. In addition, femoral artery catheterization has resulted in a concomitant increase in bleedings and iatrogenic femoral artery injuries.

Abbreviations: ASA, alcohol septal ablation; AV, atrioventricular; BBB, bundle branch block; HOCM, hypertrophic obstructive cardiomyopathy.
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doi:10.1016/j.acvd.2011.05.006
Aims. — To evaluate and validate the feasibility of less invasive management of ASA using the transradial approach and a subclavian wired temporary pacemaker.

Methods. — To avoid transfemoral temporary pacing, we used a subclavian bipolar active-fixation permanent pacing lead, stitched to the skin and connected to a desterilized recuperation pacemaker. The day before discharge, if there was no high-degree atrioventricular block, the pacemaker lead was removed. In all patients, we used the right radial access and the left main was cannulated with a 6F Judkins left 3.5 guiding catheter.

Results. — Thirty consecutive patients were prospectively and successfully included in our study. No complication was observed during the hospital stay, neither access-site nor stimulation-lead related.

Conclusions. — Our study shows the feasibility and safety of a transradial approach and a subclavian wired temporary pacemaker. The reduction in periprocedural complications offered by this strategy reflects the less invasive nature of ASA, without increasing the cost and complexity of the procedure.

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**Background**

ASA is a therapeutic catheter-based option and an alternative to surgical myectomy in the treatment of patients with HOCM [1,2]. Both techniques currently appear to provide equivalent results in mortality, and in subjective and objective measurements of performance in symptomatic HOCM patients [3—5]. The total number of ASAs performed largely outnumbers surgical septal reduction. However, the procedural complication rate probably still exceeds that of myectomy, especially related to AV conduction problems [3], transient pacing and femoral access site. The safety of the ASA procedure has been consistently improved, using myocardial contrast echocardiography to improve localization of the targeted septal branch, with smaller volumes of alcohol injected at a slower rate [6—8]. Onset of delayed complete heart block may occur up to several days after an uncomplicated ASA procedure [9,10]. Therefore, a temporary transvenous pacemaker is recommended for at least 48 hours postprocedure, and telemetric monitoring for 5 to 8 days is recommended by some groups [9]. Transfemoral temporary pacing catheters have several drawbacks, including the risk of cardiac perforation and infection, and the absence of any fixation mechanism. In addition, femoral artery catheterization has resulted in a concomitant increase in bleedings and iatrogenic femoral artery injuries. The aim of the present study was to evaluate and validate the feasibility of less invasive management of ASA using the transradial approach and a subclavian wired temporary pacemaker.
Methods

Patients

Consecutive patients with symptomatic HOCM despite optimal medical treatment (New York Heart Association functional class III to IV) were prospectively included in our study. All subjects demonstrated a dynamic left ventricular outflow tract gradient of at least 50 mmHg at rest or on provocation and a septal thickness >18 mm. Patients with a negative Allen’s test or specific contraindication for radial access were excluded. Our institutional review committee approved the study and all patients gave written informed consent.

Subclavian external temporary pacing

To avoid transfemoral temporary pacing, we performed a safer approach the day before ASA. Using a subclavian 7Fr peel-away introducer sheath, a bipolar active-fixation permanent pacing lead was positioned in the right ventricle under fluoroscopy guidance, with the tip screwed into the apical septum (Fig. 1). Taking into account the potential complications of subclavian way (infection, haemopneumothorax and bleeding), lead insertion was performed only by skilled personnel, under stringent aseptic technique in the electrophysiology lab. The lead was stitched to the skin using the anchoring sleeve, then connected to a VVI permanent pacemaker that had been preprogrammed in bipolar mode for stimulation and detection (rate 60 beats/minute, output 5 V). This was secured to the skin with an occlusive sticking (Fig. 1). We used a desterilized recuperation pacemaker for cost-effectiveness.

Percutaneous transluminal septal myocardial ablation

In all patients, we used right radial access and the left main was cannulated with a 6F Judkins left 3.5 guiding catheter. After identification of the septal branches of the left anterior descending coronary artery, a 1.5—2.5 × 10 mm balloon was introduced over a 0.014 inch guidewire and positioned into the first septal branch. If the position of the balloon was considered satisfactory, the guidewire was removed and the balloon inflated. Subsequently, 1 mL of echocontrast agent (Levovist, Schering AG, Berlin, Germany) was injected through the balloon catheter shaft. With echocardiography, the myocardial territory supplied by this septal branch was identified and retrograde spill of contrast into the left anterior descending coronary artery or the right ventricle was excluded. If satisfying images were obtained, 1 mL of concentrated ethanol (at a rate of 0.5 mL/30 sec) was injected through the balloon catheter shaft under close echocardiogram surveillance. After 5 min, the balloon was deflated and coronary angiography was repeated to confirm septal occlusion and the integrity of the left anterior descending coronary artery (Fig. 2). A second perforator artery was cannulated and ablated if gradient reduction <50% was not achieved after the first septal ablation.

After the procedure, patients were observed for 2 days in the intensive care unit and 6 days on the cardiology ward.
Radial access and our original temporary pacing method allowed rapid ambulation. The day before discharge, if there was no high-degree AV block, the pacemaker lead was removed.

**Statistical analysis**

Statistical analysis was performed using Graphpad Prism software (version 4.00; Graphpad Software, Inc., San Diego, CA, USA). Continuous variables are expressed as means ± standard deviations and categorical variables as frequencies and percentages.

**Results**

Thirty consecutive patients were prospectively included in our study. Among the 30 patients who underwent ASA, the mean age was 64.6 years and 68% were women. The baseline characteristics are presented in Table 1. All of the procedures were successful, with radial access and subclavian temporary pacing using an active-fixation lead. The average gradient was 84.2 ± 29.4 mmHg at the start of the procedure and 18.7 ± 16 mmHg at its completion. Overall, 12 of 30 patients (40%) developed right BBB, none developed left BBB and six (20%) developed complete AV block, requiring a permanent pacemaker implantation in four cases (13.3%). Without our approach allowing safer and prolonged temporary pacing, the other two patients would probably have had definitive implantation for a finally transient AV block. Patients who experienced definitive complete AV block differed from patients without complete heart block in terms of QRS duration (116 ms vs 95 ms) and pre-existing left BBB (50% vs 8%). Sex, age and amount of ethanol were not different in these subgroups. No complication was observed during the hospital stay, neither access-site nor stimulation-lead related (Table 2). At 6-month follow-up, all of the patients who underwent implantation of a permanent pacemaker remained pacemaker dependent.

<table>
<thead>
<tr>
<th><strong>Table 1</strong> Patient characteristics (n = 30).</th>
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<td><strong>Women (%)</strong></td>
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<td><strong>Age at procedure (years)</strong></td>
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<tr>
<td><strong>BMI</strong></td>
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<tr>
<td><strong>Resting systolic blood pressure (mmHg)</strong></td>
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<tr>
<td><strong>Family history of HOCM (%)</strong></td>
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<td><strong>Family history of sudden death caused (%)</strong></td>
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**Symptoms**
- Dyspnoea NYHA class 3.1 ± 0.2
- Angina (%) 22
- Palpitations (%) 57
- Presyncope-syncope (%) 43
- BNP (pg/mL) 811 ± 250

**Medications at procedure**
- Beta-blocker (%) 86
- ACE inhibitor (%) 21
- Calcium channel blocker (%) 36
- Amiodarone (%) 7
- Oral anticoagulation (%) 21
- Aspirin (%) 21

**Preprocedure heart rhythm**
- QRS (ms) 98 ± 10
- Left bundle branch block (%) 7
- Normal sinus rhythm (%) 100

**Preprocedural echocardiogram**
- LVOT gradient at rest, G(max) (mmHg) 89 ± 40
- Septal thickness (mm) 22 ± 6
- Pulmonary artery mean pressure (mmHg) 35 ± 12
- Left ventricular ejection fraction (%) 70 ± 4

<table>
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<tr>
<th><strong>Table 2</strong> Procedural results (n = 30).</th>
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<tr>
<td><strong>Number of septal arteries Injected</strong></td>
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<tr>
<td><strong>Volume of ethanol injected (mL)</strong></td>
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<tr>
<td><strong>Change in LVOT gradient (mmHg)</strong></td>
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<tr>
<td>Baseline</td>
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<tr>
<td>Postablation</td>
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<tr>
<td><strong>Troponin peak (ng/mL)</strong></td>
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<td><strong>QRS (ms)</strong></td>
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**Complications**
- Right bundle branch block postablation (%) 50
- New permanent pacemaker dependency (%) 13

Values are mean ± standard deviation for quantitative variables and n (%) for qualitative variables. ACE: angiotensin-converting enzyme; BMI: body mass index; BNP: brain-type natriuretic peptide; HOCM: hypertrophic obstructive cardiomyopathy; LVOT: left ventricular outflow tract; NYHA: New York Heart Association.

**Discussion**

The results of the present study suggest the validation of a potentially safer way to conduct ASA in patients with HOCM, reducing complications and the need for permanent pacemaker implantation. Over a number of decades, ASA has emerged as a potentially less invasive, alternative mode of treatment of HOCM [1,3,5]. However, the procedural complication rate exceeds that of myectomy, which remains the ‘gold standard’ therapy in centres with skilled cardiac surgeons [11]. In-hospital complications of ASA include complete AV block, tamponade, sustained ventricular arrhythmias, left anterior descending coronary artery dissection, remote infarction, pulmonary embolism, stroke, mitral regurgitation, ventricular septal defects and groin haematoma or femoral artery injuries. In-hospital mortality ranges from 0 to 4% and at experienced centres, mortality is in a lower range even in high-risk patients [7]. No impairments in short- or long-term survival were noted in recent meta-analyses [3,5]. Our study demonstrated the feasibility and safety of less invasive management of ASA using the transradial approach and a subclavian wired temporary.
pacemaker. This option may be useful for reducing the complication rate of the procedure.

Value of screwed pacemaker leads

The occurrence of pacemaker dependency is not rare after ASA, even when low amounts of ethanol are used under echocardiography guidance [3]. The pacemaker implantation rate in experienced centres remains at around 10% [9]. However, complete AV block may be a transient phenomenon occurring in almost 20% of cases [12], while a few patients might develop complete AV block up to 7 days after ASA [10]. Therefore, a watchful waiting strategy with a temporary pacemaker after ASA seems to be a reasonable approach to lower the rate of definitive implantation and to avoid adverse events related to delayed AV block. Patients with early or delayed complete AV block usually receive a permanent pacemaker. However, there is also a significant recovery in echocardiogram variables of cardiac conduction with time, resulting in a low pacing requirement for many patients who received early permanent pacemakers [7]. These data suggest a prolonged period for temporary pacing to avoid some unjustified implantations. However, several complications may occur with long-term temporary transfemoral pacing, including tamponade, subcutaneous displacement because of the absence of any fixation mechanism, infection or ventricular arrhythmias [13,14]. The requirement for transfemoral temporary pacing support with these potential problems and prolongation of the immobilization of the elderly patient greatly lowers our threshold for an early permanent pacemaker. The use of an active-fixation electrode with an external pacemaker is probably of value in this context. The active-fixation lead can be easily positioned by the subclavian route and connected to a generator with a high output in bipolar mode, secured to the skin. Although myocardial perforation using permanent pacing leads has been reported after pacemaker implantation [15], this is very rare. Moreover, it allows rapid ambulation, early discharge from the intensive care unit and a reduction in infection and thromboembolic risks. The increased cost of the electrode is easily offset by the reductions in complications and the duration of the stay in the intensive care unit, and potential avoidance of proton-pump inhibitors.

Value of radial access

The transradial approach for coronary intervention was first introduced by Kiemeneij et al. [16] and its benefits have subsequently been clearly demonstrated in several studies from different centres [17]. Radial access reduced the risk of major bleeding and the length of hospital stay after coronary intervention compared with femoral access. This reduction in major bleeding corresponded to a trend for reduction in ischaemic events with radial access. In multiple studies, major bleeding events have been shown to be independently associated with a marked increased risk of death and ischaemic events in patients undergoing percutaneous coronary intervention and those with acute coronary syndromes [18,19]. In our small population, procedural success was elevated (100%) and access site bleeding complications were virtually eliminated, even in the 21.4% patients with oral anticoagulation. On top of the bleeding hazard reduction, the transradial approach and a subclavian wired temporary pacemaker allow safe and rapid ambulation. The ability to rapidly ambulate patients is a significant benefit of the transradial approach, comfortable for the patient and lowering the thromboembolic risk [20]. In the present study, the length of stay in the intensive care unit and the total length of hospital stay were shortened with this strategy compared with other studies and registries of ASA in HOCM.

There is a substantial economic benefit with the transradial approach, which can be demonstrated with either evaluation of hospital costs or total hospital charge [20,21]. Procedural morbidity is less and patients overwhelmingly prefer the transradial over the femoral approach.

Conclusions

Although surgical myectomy continues to be the ‘gold-standard’ treatment for refractory HOCM, ASA has emerged to be an attractive alternative, offering interesting results in terms of mortality benefit and functional improvement. In many centres, the frequency of surgical myectomy has been largely reduced in favour of performing ASA as the definitive treatment strategy. However, this technique carries with it a certain number of specific complications—in particular, a higher level of AV conduction problems and the risks of the transfemoral route. Our study shows the feasibility and safety of a transradial approach and a subclavian wired temporary pacemaker. The reduction of periprocedural complications offered by this strategy reflects the less invasive approach of ASA, without increasing the cost and complexity of the procedure.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References


