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Periprocedural Complications and Long-Term Outcome After Alcohol Septal Ablation Versus Surgical Myectomy in Hypertrophic Obstructive Cardiomyopathy

A Single-Center Experience

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CME Objective for This Article: At the completion of this article, the learner should be able to: 1) describe the alcohol septal ablation procedure and its potential complications; and 2) describe the myectomy procedure and its potential complications.

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Periprocedural Complications and Long-Term Outcome After Alcohol Septal Ablation Versus Surgical Myectomy in Hypertrophic Obstructive Cardiomyopathy

A Single-Center Experience

ABSTRACT

OBJECTIVES This study compared alcohol septal ablation (ASA) and surgical myectomy for periprocedural complications and long-term clinical outcome in patients with symptomatic hypertrophic obstructive cardiomyopathy.

BACKGROUND Debate remains whether ASA is equally effective and safe compared with myectomy.

METHODS All procedures performed between 1981 and 2010 were evaluated for periprocedural complications and long-term clinical outcome. The primary endpoint was all-cause mortality; secondary endpoints consisted of annual cardiac mortality, New York Heart Association functional class, rehospitalization for heart failure, reintervention, cerebrovascular accident, and myocardial infarction.

RESULTS A total of 161 patients after ASA and 102 patients after myectomy were compared during a maximal follow-up period of 11 years. The periprocedural (30-day) complication frequency after ASA was lower compared with myectomy (14% vs. 27%, $p = 0.006$), and median duration of in-hospital stay was shorter (5 days [interquartle range (IQR): 4 to 6 days] vs. 9 days [IQR: 6 to 12 days], $p < 0.001$). After ASA, provoked gradients were higher compared with myectomy (19 [IQR: 10 to 42] vs. 10 [IQR: 7 to 13], $p < 0.001$). After multivariate analysis, age (per 5 years) (hazard ratio: 1.34 [95% confidence interval: 1.08 to 1.65], $p = 0.007$) was the only independent predictor for all-cause mortality. Annual cardiac mortality after ASA and myectomy was comparable (0.7% vs. 1.4%, $p = 0.15$). During follow-up, no significant differences were found in symptomatic status, rehospitalization for heart failure, reintervention, cerebrovascular accident, or myocardial infarction between both groups.

CONCLUSIONS Survival and clinical outcome were good and comparable after ASA and myectomy. More periprocedural complications and longer duration of hospital stay after myectomy were offset by higher gradients after ASA.
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Obstruction of flow in the left ventricular outflow tract (LVOT) is found in ~70% of patients with hypertrophic cardiomyopathy, referred to as hypertrophic obstructive cardiomyopathy (1). Although medical treatment can provide relief of symptoms, a sizable subset of patients with hypertrophic obstructive cardiomyopathy remains symptomatic, and in these subjects, invasive treatment (i.e., septum reduction) is an established treatment option (2,3). Both alcohol septal ablation (ASA) and surgical myectomy have proved to be effective methods for relief of symptoms (4-6). In recent studies, ASA is associated with excellent survival, comparable to survival in an age- and sex-matched population (7,8). Because ASA is also a less invasive treatment than myectomy, it may thus be a preferred treatment. On the other hand, previous studies have also reported a greater need for pacemaker implantation and a higher rate of reinterventions after ASA compared with myectomy (3,4), and in a single-center study, a warning was given that ASA may in fact increase cardiac mortality (9). We report our experience in a comprehensive study of both procedures including periprocedural complications, survival, cardiac survival, long-term symptomatic status, and clinical outcome.

SEE PAGE 1235

METHODS

STUDY DESIGN AND PATIENT POPULATION. All patients who underwent either ASA or a surgical myectomy at the St. Antonius Hospital, Nieuwegein, the Netherlands, between January 1981 and January 2010 were included. ASA was carried out from January 2000 onward. For patients to be selected for septum reduction (either ASA or myectomy), they had to have severe symptoms (New York Heart Association [NYHA] functional class ≥3) despite optimal medical therapy, in combination with a resting gradient of 30 mm Hg and/or a provocable gradient ≥50 mm Hg. Patients with concomitant (sub)valvular disease, coronary artery disease, or other conditions that warranted surgery underwent myectomy. Patients who were eligible for both options were informed about the known risks and benefits of both ASA and surgical myectomy and were offered the choice between these procedures. We performed a retrospective analysis of all baseline characteristics and periprocedural complications. Long-term survival and clinical outcome were investigated using a questionnaire and hospital records. The study conformed to principles defined in the Declaration of Helsinki. Local institutional review board approval was obtained.

PROCEDURE. ASA was performed as described in detail previously (10). In short, with the aid of a flexible coronary guidewire, a coronary balloon was placed in the most proximal septal perforator branch. Myocardial contrast echocardiography was used for further guidance. Only when the region of contrast in the septum was judged satisfactory and adjacent to the area of septal contact of the anterior mitral valve leaflet, 0.5 to 3 ml of concentrated ethanol was slowly injected through the inflated balloon catheter. The balloon was left inflated for 10 min to prevent retrograde spill of ethanol. Invasive gradients in the LVOT were measured continuously during the procedure using a 6-F pigtail catheter inserted in the left ventricle. For testing of a provocable gradient, the Valsalva maneuver and extrasystolic beats were used. When the gradient in the LVOT remained ≥30 mm Hg after the first ablation (either at rest or after provocation), the procedure was repeated in 1 or 2 more accessible septal branches. During the procedure, all patients received a temporary transvenous pacemaker. If an atrioventricular block remained >48 h after the procedure, a definitive pacemaker was implanted.

Myectomy was performed as described previously (11). Perioperative transesophageal echocardiography and visual inspection by the surgeon were performed to determine the extension of the myectomy and any (sub)valvular abnormalities. When necessary, surgery was combined with coronary artery bypass grafting (CABG).

FOLLOW-UP. The degree of LVOT obstruction before intervention was measured using transthoracic echocardiography. Determination of the gradient directly after surgical myectomy was performed intraoperatively using transesophageal echocardiography. The gradient post-ASA was determined invasively immediately after the procedure. For follow-up, the last available report of an echocardiogram was used for determination of left ventricular ejection fraction and the gradient in the LVOT. A questionnaire was sent to all patients still alive in December 2010. In this questionnaire, patients were asked about their symptomatic status, NYHA functional class status (1 to 4), chest pain, and syncope. Clinical events (readmittance for heart failure, a repeat intervention with ASA or surgical myectomy, and appropriate implantable cardioverter-defibrillator [ICD] shocks) were captured any time after the procedure using hospital records and questionnaires. Inquiry by telephone was used to complete data when necessary. Civil registries were used to determine whether patients were still alive. The cause of death was obtained from hospital and general practitioner records.

ABBREVIATIONS AND ACRONYMS

ASA = alcohol septal ablation

CABG = coronary artery bypass grafting

CVA = cerebrovascular accident

ICD = implantable cardioverter-defibrillator

LVOT = left ventricular outflow tract

NYHA = New York Heart Association

SCD = sudden cardiac death

VT = ventricular tachycardia

STUDY ENDPOINTS. The primary endpoint was all-cause mortality and was determined during a maximal follow-up period of 11 years after both procedures. Secondary endpoints consisted of annual cardiac death rate, NYHA functional class at late follow-up, rehospitalization due to heart failure, reintervention, cerebrovascular accident (CVA), and myocardial infarction and were determined during the entire follow-up period (average, 9.1 [interquartile range (IQR): 3.3 to 13.5] years after myectomy and 5.1 [IQR: 2.9 to 7.5] years after ASA). Cardiac death consisted of death due to heart failure and or sudden cardiac death (SCD). To prevent underestimation of cardiac death, deaths of unknown cause were also considered as cardiac death. Patients with an ICD were investigated for appropriate ICD shocks. Complications were considered periprocedural when occurring during the intervention or in the first 30 days after the intervention.

STATISTICAL ANALYSIS. Data are given as mean ± SD when normally distributed, as median and interquartile range for skewed distributions, and as frequencies and percentages for categorical variables. The Student *t* test (2-paired) and Mann-Whitney *U* test were used to compare variables between groups, where appropriate. The Fisher exact test was used for comparison of categorical variables. Cox proportional

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 11, 2014
NOVEMBER 2014:1227-34

hazard analysis was carried out for the first occurrence of all-cause mortality. All baseline variables listed in Table 1 were considered in the multivariate models when a p value <0.1 was obtained on univariate analysis. In a second analysis, type of treatment (myectomy or ASA) was forced into the multivariate model to evaluate the multivariate effect on outcome. Due to the difference in follow-up duration, cardiac mortality and clinical events were compared on an annual basis. All-cause mortality was also compared during a maximal follow-up duration of 11 years after both procedures. All reported probability values are 2 tailed, and a p value <0.05 was considered statistically significant. Statistical analyses were performed using STATA version 11.0 (StataCorp, College Station, Texas).

RESULTS

A total of 161 patients underwent ASA and 102 patients underwent myectomy. Baseline characteristics of the 2 treatment groups are shown in Table 1. Angina pectoris and coronary artery disease were more common in patients who underwent myectomy. Also, revascularization by combining CABG with myectomy was more common than revascularization by combining percutaneous coronary intervention with ASA. Septal and posterior wall diameters were slightly larger in the ASA patients. Other baseline characteristics were comparable.

TABLE 1 Baseline Characteristics

Parameter	Myectomy (n = 102)	ASA (n = 161)	p Value
Age, yrs	56 ± 16	59 ± 14	0.09
Male	46 (47)	53 (85)	0.31
NYHA functional class (I/II/III or IV), %	5/19/76	1/19/80	0.12
Angina (CCS)	2.3 ± 0.6	2.0 ± 0.5	0.002
Syncope	20 (20)	18 (29)	0.74
LVH >30 mm	5.9 (6)	5.6 (9)	0.999
VT on Holter monitoring	1 (1)	6 (10)	0.17
Beta-blocker or calcium channel blocker	88 (90)	80 (129)	0.16
Medical history			
Previous CVA	2.0 (2)	1.2 (2)	0.999
Previous AF	21 (21)	15 (24)	0.67
Coronary artery disease	17 (17)	5 (8)	0.004
ICD	2.9 (3)	2.5 (4)	0.999
Appropriate shock	1.0 (1)	0.6 (1)	0.999
Pacemaker	1.0 (1)	4.3 (7)	0.16
Family history of SCD	11 (11)	9 (14)	0.66
Family history of HCM	23 (23)	19 (31)	0.53
Echocardiogram			
Septal thickness, mm	20 (17-24)	21 (19-24)	0.03
Posterior wall thickness, mm	14 ± 3	15 ± 4	0.01
Degree of MI	2.0 ± 1.1	1.6 ± 1.0	0.38
Gradient baseline, mm Hg	50 (25-75)	32 (18-75)	0.088
Gradient after provocation, mm Hg	95 (70-120)	101 (69-150)	0.31
Additional intervention			
Myectomy + CABG	18 (18)	–	–
ASA + PCI	–	2.5 (4)	–

Values are mean ± SD, % (n), or median (interquartile range) for skewed distributions.
ASA = alcohol septal ablation; AF = atrial fibrillation; CABG = coronary artery bypass grafting; CCS = Canadian Cardiovascular Society; CVA = cerebrovascular accident; HCM = hypertrophic cardiomyopathy; ICD = implantable cardioverter-defibrillator; LVH = left ventricular hypertrophy; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SCD = sudden cardiac death; VT = ventricular tachycardia.

PERIPROCEDURAL COMPLICATIONS. Periprocedural severe complications (death, CVA, and ventricular tachycardia (VT)/ventricular fibrillation) after ASA and myectomy were not significantly different (Table 2). One patient in the ASA group died because of spill of alcohol, and a second patient died because of tamponade caused by a pacemaker lead perforation. Two patients died of refractory cardiogenic shock after myectomy. In the first patient, no cause of the cardiogenic shock was identified; in the second patient, the cause was right ventricular infarction. Two other patients who underwent myectomy had a disabling CVA. A repeat thoracotomy was necessary in 11 patients, in 7 because of excessive bleeding, 2 underwent an additional myectomy because of a significant residual gradient, 1 had an aneurysm of the aortic sinus needing repair, and in 1 a ventricular septal rupture occurred that was repaired with a patch. After ASA, closure of a ventricular septal rupture was also performed but at a later stage, and this was combined with a myectomy. All repeat thoracotomies were performed successfully and were not associated with a worse long-term outcome. Other periprocedural complications were comparable between ASA and myectomy (Table 2). The total periprocedural complication frequency was lower in the ASA group compared with the myectomy group (14% [22 of 161] vs. 28% [29 of 102], p = 0.004). When comparing ASA and myectomy in the same time period of 2000 to 2010, 77% (161 of 209) of patients underwent ASA. In this time period, ASA patients also had a lower periprocedural complication frequency than the myectomy patients (14% [22 of 161] vs. 38 % [18 of 48], p < 0.001). Patients after ASA also had a lower complication frequency compared with patients after myectomy without CABG (14% [22 of 161] vs. 29% [24 of 84], p = 0.006). Complication frequency of patients undergoing surgical myectomy with CABG was comparable to that of patients undergoing myectomy without CABG (28% [5 of 18] vs. 29% [24 of 84], p = 1.0).

SURVIVAL AND APPROPRIATE ICD SHOCKS. Follow-up was completed in 99% (261 of 263) of the study population. Two patients were lost to follow-up due to a

TABLE 2 Periprocedural Complications (30 Days)

	Myectomy (n = 102)	ASA (n = 161)	p Value
Periprocedural death	2.0 (2)	1.2 (2)	0.56
Ventricular fibrillation/sustained VT	0	2.5 (4)	0.16
CVA	2 (2)	0	0.15
Dissection LAD	0	0.6 (1)	1.0
Pneumothorax	2 (2)	0.6 (1)	0.56
Mediastinitis	2 (2)	0	0.15
Pacemaker infection	0	1.2 (2)	0.52
Pacemaker implantation	9 (9)	7 (11)	0.64
Tamponade	8.8 (9)	1.2 (2)	0.004
Urgent repeat thoracotomy	11.4 (11)	0	< 0.001
All complications (1 per patient)	28 (29)	14 (22)	0.004
Length of hospital stay, days	9 (6-12)	5 (4-6)	<0.001

Values are % (number) and median (interquartile range) for skewed distributions. LAD = left anterior descending artery; other abbreviations as in Table 1.

TABLE 3 Clinical Outcome

	Myectomy (n = 102)	ASA (n = 159)	p Value
Follow-up duration, yrs	9.1 (3.3-13.5)	5.1 (2.9-7.5)	<0.0001
All-cause death, annual	2.2 (21)	1.5 (13)	0.25
Cardiac death, annual	1.4 (13)	0.7 (6)	0.15
Noncardiac death, annual	0.8 (8)	0.8 (7)	0.91
NYHA functional class (I/II/III or IV), %	52/30/18	53/31/16	0.89
Angina status (CCS)	0.5 ± 0.9	0.7 ± 1.0	0.14
Syncope	2.0 (2)	8.2 (13)	0.053
Rehospitalization for heart failure, annual	0.6 (6)	0.3 (3)	0.40
MI, annual	0.2 (2)	0.1 (1)	0.66
CVA, annual	0.5 (5)	0.3 (3)	0.57
ICD implantation	1 (1)	3 (5)	0.41
Appropriate ICD shock	(0)	(0)	-
Reintervention	1 (1)	6.3 (10)	0.055
Repeat ASA	-	3.8 (6)	0.08
Repeat myectomy	1 (1)	2.5 (4)	0.65
Post-procedural gradient, mm Hg	12 (8-20)	10 (0-20)	< 0.001
Echocardiogram (late follow-up)			
Gradient baseline, mm Hg	9 (4-10)	10 (7-19)	0.003
Gradient after provocation, mm Hg	10 (7-13)	19 (10-42)	< 0.001
Ejection fraction %	61 ± 11	63 ± 8	0.26

Values are median (interquartile range) for skewed distributions, an annual percentage (total numbers during total follow-up period), or mean ± SD. Abbreviations as in Table 1.

foreign address. During the maximal follow-up duration of 11 years, all-cause mortality after ASA and myectomy was comparable (Table 3, Figure 1), and after multivariate analysis, only age at baseline was an independent predictor (Table 4). After type of procedure was forced into a second multivariate analysis, ASA versus myectomy was also not associated with death (hazard ratio: 1.20 [95% confidence interval: 0.49 to 2.94], p = 0.69). The median follow-up duration was 9.1 years (IQR: 3.3 to 13.5 years) after myectomy and 5.1 years (IQR: 2.9 to 7.5 years) after ASA. After myectomy, 2 deaths were due to heart failure, 2 patients had SCD, and in 9 patients, the cause of death was unknown. After ASA, 3 deaths were due to heart failure, and in 3 patients, the cause of death could not be determined. Even when the deaths of unknown causes were considered to be cardiac deaths, the annual occurrence of cardiac death after ASA and myectomy was comparable (Table 3). In total, 7 ICDs were implanted before the procedure (myectomy, n = 3; ASA, n = 4), and a total of 6 ICDs were implanted after the procedure (myectomy, n = 1; ASA, n = 5) (Tables 1 and 2). No appropriate ICD shocks were observed during the entire follow-up period in any of the patients with ICDs.

TREATMENT EFFECT. Questionnaires for symptomatic status were completed in 96% (220 of 229) of patients still alive at follow-up. No differences were found between myectomy and ASA patients for symptomatic status, rehospitalization for heart failure, CVA, and myocardial infarction at follow-up (Table 3). Echocardiograms at late follow-up were retrieved for 92% (241 of 263) of patients with an average interval after the procedure of 3.9 ± 4.7 years. Baseline and provoked gradients in the LVOT at late follow-up were higher for patients after ASA (Table 3). A total of 10 reinterventions because of both a significant residual/recurrent gradient and symptoms were performed after ASA; 6 by means of ASA and 4 with surgical myectomy, whereas a second procedure (i.e., ASA) was performed in the myectomy group (6.3% vs. 1.0%, p = 0.055) (Table 3).

DISCUSSION

The main finding of the study is that long-term survival in our single-center study was comparable after ASA and myectomy. In addition, we found that long-term symptomatic improvement after both procedures was comparable as well as the occurrence of cardiac death, CVA, myocardial infarction, and rehospitalization for heart failure. However, ASA was associated with a lower frequency of periprocedural complications and a shorter duration of hospital stay compared with myectomy.

PERIPROCEDURAL COMPLICATIONS. Severe periprocedural complications (death, CVA, and VT/ventricular

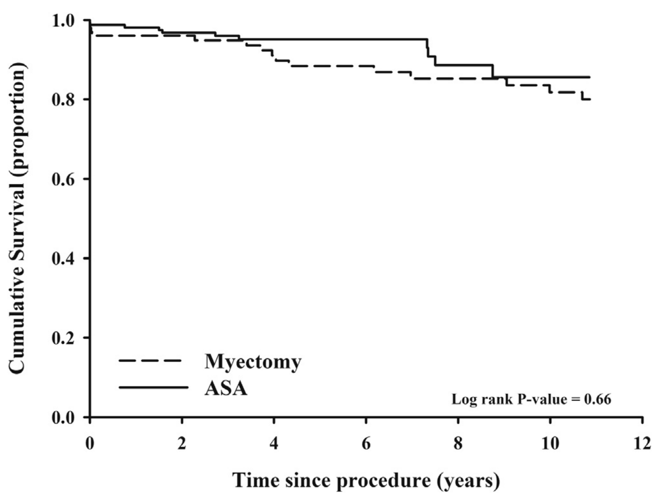

FIGURE 1 Survival After ASA Versus Myectomy

Cumulative survival after alcohol septal ablation (ASA) and myectomy using Cox proportional hazard analysis.

fibrillation) were comparable between both treatments (**Table 2**) and largely comparable to previous studies (7,12,13). Regarding the need for pacemaker implantation, the results after myectomy and ASA were also comparable, which is somewhat at variance with data reported in the literature, including in meta-analyses, generally showing a greater need for pacemaker implantation after ASA (4,5). Importantly, in these meta-analyses, age at baseline was higher for ASA, which may have confounded the association between ASA patients and the need for pacemaker implantation, whereas in the present study, age at baseline was comparable for ASA and myectomy. Another explanation for the comparable rate of pacemaker implantation in the present study may be the periprocedural use of myocardial contrast echocardiography or the judicious use of alcohol in the present study (14,15).

The total frequency of periprocedural complications in the present study was, however, lower for patients undergoing ASA compared with myectomy, and this has not been reported previously. Also after correction for the time period and after exclusion of myectomy combined with CABG, the frequency of complications remained lower after ASA. The difference in complication frequency was mainly due to a need for repeat thoracotomy after myectomy (because of bleeding, tamponade, repair of an aneurysm of the aortic sinus, and the need for a second myectomy). These complications and the longer hospital stay after myectomy reflect the more invasive nature of myectomy. Nevertheless, all periprocedural complications were treated successfully and were not associated with a worse long-term outcome.

LONG-TERM OUTCOME. One of the feared long-term complications after ASA is the possible predisposition for ventricular arrhythmia after the induction of a septal infarction (1). In 1 single-center study, a higher rate of ICD shocks and SCD was found after ASA compared with myectomy (9). In the present study, other recent studies, and a meta-analysis, the occurrence of SCD and appropriate ICD shocks was comparable and uncommon both after ASA and myectomy (4–8). However, it should be stressed that post-septal reduction hypertrophic cardiomyopathy patients at high risk of SCD (irrespective of the procedure) should nonetheless be considered for ICD implantation (16).

Regarding the treatment effect, long-term symptomatic results determined with a questionnaire were comparable with a sustained benefit after both interventions at long-term follow-up, which is comparable to a previous single-center study (7). We also did not find any difference in cardiovascular events during long-term follow-up. A trend was seen for more syncope after ASA, but this did not reach statistical significance. Post-procedural gradients after ASA and myectomy were measured under different circumstances using different techniques (invasive vs. transesophageal echocardiography) and therefore cannot be compared. At long-term follow-up, echocardiographic gradients were slightly higher for ASA patients compared with myectomy patients in the present study. The number of reinterventions after ASA in the present study was low (6%) compared with 8% to 9% in previous studies (7,17). In the myectomy group, only 1 reintervention was performed (1%). In

TABLE 4 Predictors of All-Cause Mortality

Parameter	Univariate		Multivariate	
	HR (95% CI)	p Value	HR (95% CI)	p Value
ASA vs. myectomy	0.84 (0.38–1.84)	0.66		
Age (per 5 yrs)	1.42 (1.18–1.71)	<0.001	1.34 (1.08–1.65)	0.007
Female	1.99 (0.90–4.41)	0.090	1.25 (0.48–3.23)	0.64
NYHA functional class (III/IV vs. I/II)	1.81 (0.62–2.28)	0.279		
Previous AF	0.89 (0.30–2.58)	0.83		
Coronary artery disease	2.96 (1.11–7.90)	0.030	2.56 (0.92–7.14)	0.072
Baseline septal thickness, mm	1.03 (0.91–1.18)	0.63		

Maximal follow-up time for both groups is 11 years.
CI = confidence interval; HR = hazard ratio; other abbreviations as in **Table 1**.

2 patients, the myectomy procedure was immediately repeated after evaluation with intraoperative transesophageal echocardiography requiring a second pump run. They were counted as complications and not as a reintervention.

STUDY LIMITATIONS. Like all previous studies comparing ASA and myectomy, this study was a nonrandomized, observational study. However, with the exception of concomitant coronary artery disease and a slight difference in the degree of left ventricular hypertrophy, all clinical characteristics in the 2 treatment groups were comparable. In particular, the average age was comparable in the 2 groups, which suggests that selection bias did not play a major role. The low prevalence of VT on Holter monitoring in myectomy patients was possibly related to missing Holter monitoring reports in these patients. Another potential limitation is the fact that myectomy was performed during a longer time period than ASA. ASA patients were therefore treated in a more modern era, which could have influenced our results. However, after statistical correction, these factors did not translate to a difference in survival between both treatment groups. Also, the difference in periprocedural complications frequency between ASA and myectomy remained after correction for the same time period. A strength of the study is the long follow-up and the completeness of the data. An extensive search of all hospital records and operation reports was performed and completed for complications in all patients. Questionnaires and, when necessary, consulting by telephone were used to obtain a more objective result of symptomatic status of the patient at late-term follow-up. Finally, unlike many other studies, a strength of the study is the fact that both periprocedural complications and long-term outcome were analyzed in a single study.

CONCLUSIONS

This study adds to the increasing body of evidence (4–8) that long-term survival, clinical outcome in terms of symptomatic status, risk of heart failure, and arrhythmic events after ASA is good and comparable to that of myectomy. Due to the comprehensiveness of the present study, in addition to advantages, some disadvantages of a more invasive surgical versus a percutaneous procedure have become clear. After ASA, the periprocedural complication frequency was lower and duration of hospital stay was shorter, reflecting its less invasive nature compared with myectomy. On the other hand, gradients after myectomy are lower at late follow-up, which could favor myectomy. Furthermore, some conditions warrant a surgical approach such as coronary septal anatomy unsuitable for ASA (18), (sub)valvular abnormalities, or multivessel coronary artery disease. Taken together, patients should be evaluated on an individual basis by a multidisciplinary team of cardiologists and surgeons. When both procedures are feasible, after providing adequate information, preference of the patient should be part of the equation to determine the best treatment option.

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