Alcohol Septal Ablation in Hypertrophic Obstructive Cardiomyopathy

The Need for a Registry

William H. Spencer III, MD; Robert Roberts, MD

Family hypertrophic cardiomyopathy is a genetic disease with an autosomal-dominant inheritance. Patients with this illness are prone to sudden death, angina, syncope, and heart failure. A subset of patients with familial hypertrophic cardiomyopathy have left ventricular outflow tract obstruction (or hypertrophic obstructive cardiomyopathy [HOCM]) at rest or HOCM that can be induced with the Valsalva maneuver or with dobutamine, isoproterenol infusion, or amyl nitrite inhalation. Patients with significant obstruction have systolic anterior motion of the mitral valve associated with the outflow obstruction, which leads to mitral regurgitation. In association with the hemodynamic burden caused by left ventricular outflow tract obstruction, other abnormalities also contribute to the disabling symptoms. These include impaired left ventricular diastolic and systolic dysfunction, myocardial ischemia, and arrhythmias. In some variant patterns, the level of obstruction may be in the mid-left ventricular cavity rather than subaortic. In addition, midventricular obstruction may be associated with subaortic obstruction. With all these abnormalities of ventricular function, the disease is frequently disabling and progressive.

Numerous treatment options have been suggested for HOCM. The primary aim of medical therapy is relief of left ventricular outflow tract obstruction; this is often done using medications such as β-blockers, calcium channel blockers (especially verapamil), and disopyramide. Medical therapy benefits many patients and allows them to lead acceptable, productive lives. Frequently, however, high doses of medication produce side effects that resemble the symptoms of the illness. These side effects may lead to impaired ventricular function and thinning of the walls, with progressive heart failure.

In most individuals, hypertrophy is localized initially to the septum. Finally, concerns about patient selection have been expressed because ethanol septal ablation in HOCM is easily performed, in contrast to left ventricular myotomy-myomectomy; thus, a more easily performed procedure might lead to the selection of patients who are less symptomatic and to injudicious, widespread use of the procedure. Also, it is possible that provocative maneuvers may artificially produce a subaortic gradient and lead to an unwarranted procedure.

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From the Section of Cardiology, Department of Medicine, Baylor College of Medicine, Houston, Tex.

Correspondence to Robert Roberts, MD, Section of Cardiology, Baylor College of Medicine, 6550 Fannin, MS SM677, Houston, TX 77030. E-mail roberts@bcm.tmc.edu

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pressure increases, concentric hypertrophy develops as a compensatory response.\textsuperscript{19–21} Secondary ventricular hypertrophy is almost always associated with fibrosis, which ultimately leads to progressive heart failure and ventricular arrhythmias.\textsuperscript{22,23} Overwhelming evidence shows that increased ventricular pressure is a very potent stimulus to cardiac growth and hypertrophy.\textsuperscript{21} Furthermore, suggestive evidence indicates that increased fibrous tissue is the culprit substrate responsible for arrhythmias and sudden death.\textsuperscript{21} Thus, it is also possible that the relief of obstruction early in the course of HOCM may prevent or attenuate the development of hypertrophy and fibrosis and their subsequent complications, including sudden death. However, to perform this procedure in the asymptomatic individual with minimal obstruction would require adequate objective evidence of its safety and long-term benefit.

Because the application of ethanol septal ablation in HOCM has been limited to only a few centers worldwide, a multicenter registry has been suggested. In North America, the majority of cases by far have been done by 1 center.\textsuperscript{15,16} Familial hypertrophy has a relatively low prevalence and, because HOCM occurs in only \approx \!30\% of those with the disease, it is unlikely that any 1 center could recruit an adequate number of patients to determine the safety and efficacy of this procedure. The proposed registry would involve multiple sites in multiple countries and use a standardized protocol, which would include strict selection criteria and a standardized battery of tests that would be interpreted before the procedure by a central core facility to ensure a homogeneous patient population to be treated. The essential technical aspects of the procedure would also be established and followed at each site. A website for reporting patient characteristics and results via the Internet plus a centralized core echocardiographic and genetic facility will be established.

The primary aim of the registry would be to ascertain the percentage of individuals in whom the outflow gradient is reduced by 80\% from baseline compared with 3 months and 1 and 2 years after the procedure. Other objectives of this registry would be to determine the incidence of complications immediately after the procedure, the effect of reducing outflow tract gradient on ventricular function at 3 months and 1 and 2 years after the procedure, and to determine the effect of the procedure on the severity of angina, dyspnea, and exercise capacity at 3 months and 1 and 2 years after the procedure. Symptomatic bradyarrhythmias and tachyarrhythmias and sudden death will be reported to the registry via the website for 2 years. In addition, the registry would determine whether the relief of outflow tract obstruction is associated with progression, lack of progression, or regression of hypertrophy. By establishing standardized selection criteria and treatment protocols, the registry would establish the short- and long-term efficacy and safety of alcohol septal ablation over a 2-year period.

**References**


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