Alcohol septal ablation
(Percutaneous transluminal septal myocardial ablation)

Background

Alcohol septal ablation, also commonly called percutaneous transluminal septal myocardial ablation, is a surgical alternative for treating hypertrophic obstructive cardiomyopathy (HOCM), according to the Web site of New York-Presbyterian Hospital, the joint university hospital for Cornell and Columbia Universities.

Patients who suffer from HOCM (also known as hypertrophic cardiomyopathy, or HCM) have unusually thick walls in their left ventricle, the heart’s main pumping chamber. The thickening of the left ventricle wall can interfere with the mitral valve and block the flow of blood. The decrease in blood flow can cause an increase in pressure in the heart, which makes the ventricle work harder, in turn making the wall even thicker. According to the hospital’s Web site, symptoms of HOCM can include chest pain, shortness of breath, palpitations, sudden fainting, and in some cases, death.

Alcohol septal ablation helps alleviate obstruction and improves blood flow out of the heart. It can also improve mitral valve function. According to New York-Presbyterian’s Web site, during alcohol septal ablation, a balloon catheter is inserted through the groin and led to the heart. With echocardiographic and/or fluoroscopic guidance, the catheter is led to the small artery that supplies the interventricular septum. A small amount of pure alcohol is introduced into the vessel resulting in carefully controlled myocardial infarction, which causes damage to the portion of the abnormally thick septum. A thinner wall of scar tissue that reduces the obstruction and improves the overall function of the heart replaces the septum. Many patients feel immediate improvement of their symptoms; the majority continue to improve over many months, according to New York-Presbyterian.

Alcohol septal ablation, a noninvasive nonsurgical treatment, was developed as an alternative to surgery for patients with HOCM. The surgical treatment is called left ventricular myotomy, myectomy, or Morrow’s procedure. Patients who are poor candidates for invasive surgery make good candidates for alcohol septal ablation.

Interventional cardiologists typically perform alcohol septal ablation. These physicians have completed a residency in internal medicine lasting three years, a general cardiology fellowship also lasting three years, and a one-year fellowship in interventional cardiology.
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Involved specialties

Interventional cardiologists

Positions of societies and academies

ACC

The American College of Cardiology’s (ACC) Clinical Expert Consensus Document on Hypertrophic Cardiomyopathy, jointly published with the European Society of Cardiology, states that the learning curve for expertise in the alcohol septal ablation technique is steep due in part to the relatively small number of eligible HCM patients. In particular, selection of the optimal septal perforator branch is challenging. Therefore, ablation should not be regarded as a routine technique to be employed by any expert interventional cardiologist. The ACC advises that alcohol ablation be confined to healthcare facilities with substantial and specific experience with HOCM and the procedure to ensure proper patient selection, the lowest possible rates of morbidity and mortality, and the greatest likelihood of achieving benefits.

Additionally, the ACC publishes the American College of Cardiology Foundation/American Heart Association/Society for Cardiac Angiography and Interventions Update of the Clinical Competence Statement on Cardiac Interventional Procedures. This document states that alcohol septal ablation is a percutaneous noncoronary intervention, and interventional cardiologists who perform it must acquire a set of skills and knowledge specific to percutaneous noncoronary intervention during their training. It also recommends that physicians who perform this procedure should have extensive knowledge of the outcomes, limitations, and complications of medical therapy, dual chamber pacing and surgical myectomy, and alcohol septal ablation.

With regard to all cardiac interventional procedures, including alcohol septal ablation, the document states that, “although there are currently no data regarding the minimum number of procedures required for training and for credentialing, a minimum number of 10 procedures seems to be appropriate.”

SCAI

The SCAI promotes invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care.
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The SCAI is the primary professional association for invasive and interventional cardiologists.

Aside from the SCAI’s participation in the joint statement, *American College of Cardiology Foundation/American Heart Association/Society for Cardiac Angiography and Interventions Update of the Clinical Competence Statement on Cardiac Interventional Procedures*, the society does not publish other competency, education, or privilege delineation guidelines regarding alcohol septal ablation.

Positions of other interested parties

The American Board of Internal Medicine (ABIM) offers certification in internal medicine as well as interventional cardiology, both of which interventional cardiologists must complete in the course of their postgraduate training.

To become certified in the subspecialty of interventional cardiology, physicians must have:

➤ Attained certification in internal medicine by the ABIM
➤ Maintained a current underlying certificate in cardiovascular disease by the ABIM
➤ Satisfactorily completed the requisite graduate medical education fellowship training
➤ Demonstrated clinical competence in the care of patients
➤ Met the licensure and procedural requirements
➤ Passed the ABIM’s certification exam in interventional cardiology

To be admitted to an examination, candidates must have completed the required training in the subspecialty, including vacation time, by October 31 of the year of examination. Candidates for certification in the subspecialties must meet the board’s requirements for duration of training as well as minimum duration of full-time clinical training. Clinical training requirements may be met by aggregating full-time clinical training that occurs throughout the entire fellowship training period; clinical training need not be completed in successive months. Time spent in continuity outpatient clinic, during nonclinical training, is in addition to the requirement for full-time clinical training.

Training requires 12 months of satisfactory clinical fellowship training in interventional cardiology in addition to the required three years of cardiovascular disease training. Interventional cardiology training taken after July 1, 2002, must be accredited by the ACGME. Interventional cardiology training undertaken
prior to July 1, 2002, must be conducted within an accredited cardiovascular disease fellowship program.

Beginning with the November 2000 examination, candidates who have been out of formal training for three or more years as of June 30 of the year of examination must document post-training performance as primary operator of at least 150 therapeutic interventional cardiac procedures in the two years prior to application for examination.

During training in interventional cardiology, the fellow must have performed at least 250 therapeutic interventional cardiac procedures, documented in a case list and attested to by the training program director. In addition, the training program director must judge the clinical skill, judgment, and technical expertise of the fellow as satisfactory.

To receive credit for performance of a therapeutic interventional cardiac procedure in the training pathway, a fellow must meet the following criteria:

➤ Participate in procedural planning, including indications for the procedure and the selection of appropriate procedures or instruments.
➤ Perform critical technical manipulations of the case. (Regardless of how many manipulations are performed in any one case, each case may count as only one procedure.)
➤ Be substantially involved in postprocedural management of the case.
➤ Be supervised by the faculty member responsible for the procedure. (Only one fellow can receive credit for each case even if others were present.)
➤ Program directors will be asked to attest to the performance of at least 250 therapeutic interventional cardiac procedures for each candidate who received training in their program.

*AOBIM* The American Osteopathic Association (AOA) is a member association representing more than 61,000 osteopathic physicians (DO). The AOA serves as the primary certifying body for DOs and is the accrediting agency for all osteopathic medical colleges and healthcare facilities. The AOA’s mission is to “advance the philosophy and practice of osteopathic medicine by promoting excellence in education, research, and the delivery of quality, cost-effective healthcare within a distinct, unified profession.”
The AOA-affiliated American Osteopathic Board of Internal Medicine (AOBIM) grants certification in interventional cardiology to physicians who qualify. To be eligible to be examined in this subspecialty field, an applicant must:

➤ Have successfully completed the subspecialty examination in interventional cardiology.
➤ Be certified in cardiology by the AOBIM.
➤ Have satisfactorily completed 12 months of an AOA-approved training program in interventional cardiology. This training must follow 36 months of training in cardiology and must occur in 1997 or later. During this training period, the individual must have participated in a total case volume of a minimum of 300 cardiac interventional procedures and serve as the primary operator in a minimum of 200 of these cases.

ACGME

In its Program Requirements for Fellowship Education in Interventional Cardiology, the ACGME states that fellowships in interventional cardiology must be one year in length. The subspecialty educational program in interventional cardiology must function as an integral component of an accredited subspecialty fellowship in cardiovascular disease (cardiology). All applicants entering interventional cardiology must have completed a cardiovascular disease program accredited by the ACGME.

Fellows must have formal instruction, clinical experience, and must demonstrate competence in the prevention, evaluation, and management of both inpatients and outpatients for the following:

➤ Chronic ischemic heart disease
➤ Acute ischemic syndromes
➤ Valvular and structural heart disease
➤ Bleeding disorders or complications associated with percutaneous intervention or drugs, including but not limited to bleeding after thrombolytic usage, direct or indirect thrombin inhibitor usage, glycoprotein IIb/IIIa inhibitor usage, and thienopyridine or other antiplatelet usage
➤ Use and limitations of intra-aortic balloon counterpulsation and other hemodynamic support devices (as available)
➤ Consultation and informed consent
➤ Care of patients in the cardiac care unit, emergency department, or other intensive care settings
➤ Care of patients before and after interventional procedures
➤ Outpatient follow-up of patients treated with drugs, interventional procedures, devices, or surgery
➤ Use of antiarrhythmic drugs, including knowledge of pharmacokinetics and pharmacodynamics related to acute ischemic events occurring during and after interventional cardiac procedures
➤ Use of thrombolytic and antithrombolytic, antiplatelet, and antithrombin agents
➤ Use of vasoactive agents for epicardial and microvascular spasm

Fellows must have formal instruction, clinical experience, and must demonstrate competence in the performance of the following technical skills:
➤ Coronary arteriograms.
➤ Ventriculography.
➤ Hemodynamic measurements.
➤ Intravascular ultrasound.
➤ Doppler flow, intracoronary pressure measurement and monitoring, and coronary flow reserve.
➤ Coronary interventions, including femoral and brachial/radial cannulation of normal and abnormally located coronary ostia and application and usage of balloon angioplasty, stents, and other commonly used interventional devices. (Each fellow must perform a minimum of 250 coronary interventions, a single coronary intervention being defined as all coronary interventions performed during one hospitalization.)
➤ Management of mechanical complications of percutaneous intervention, including but not limited to coronary dissection, thrombosis, spasm, perforation, “slow reflow,” cardiogenic shock, left main trunk dissection, cardiac tamponade including pericardiocentesis, peripheral vessel occlusion, and retained components, and pseudoaneurysm.

In regard to formal instruction, the training program must provide formal instruction for the fellows to acquire knowledge of the following content areas:
➤ The role of platelets and the clotting cascade in response to vascular injury
➤ Pathophysiology of restenosis
➤ The role and limitations of established and emerging therapy for treatment of restenosis
➤ Physiology of coronary flow and detection of flow-limiting conditions
➤ Detailed coronary anatomy
Radiation physics, biology, and safety related to the use of x-ray imaging equipment

The role of randomized clinical trials and registry experiences in clinical decision-making

The clinical importance of complete versus incomplete revascularization in a wide variety of clinical and anatomic situations

Strengths and limitations, both short- and long-term, of percutaneous versus surgical and medical therapy for a wide variety of clinical and anatomic situations related to cardiovascular disease

Strengths and limitations, both short- and long-term, of differing percutaneous approaches for a wide variety of anatomic situations related to cardiovascular disease

The role of emergency coronary bypass surgery in the management of complications of percutaneous intervention

Strengths and weaknesses of mechanical versus lytic approach for patients with acute myocardial infarction

The use of pharmacologic agents appropriate in the post-intervention management of patients

Strengths and limitations of both noninvasive and invasive coronary evaluation during the recovery phase after acute myocardial infarction

Understanding the clinical utility and limitations of the treatment of valvular and structural heart disease

The assessment of plaque composition and response to intervention

Srihari S. Naidu, MD, FACC, FAHA, FSCAI, is the director of the Cardiac Catheterization Laboratory, interventional cardiology fellowship program, and Hypertrophic Cardiomyopathy Center at Winthrop University Hospital in Mineola, NY. Naidu is also an assistant professor of medicine at SUNY–Stony Brook School of Medicine.

According to Naidu, interventional cardiologists perform alcohol septal ablation. These physicians have become board certified in internal medicine, cardiology, and interventional cardiology. The latter requires an additional one-year training after three years of internal medicine and three years of general cardiology fellowship, for a total postgraduate training period of seven years.

There are two major factors to consider when determining competency for alcohol septal ablation privileges, says Naidu. The first is the overall technical difficulty of the procedure.
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The second is that HOCM is a rare condition, and few cases require treatment with alcohol septal ablation (the majority of patients with HOCM undergo septal myectomy surgery). As a result, alcohol septal ablation is typically not taught in the vast majority of interventional cardiology fellowships. In fact, Naidu estimates that only about 5% of fellowships in interventional cardiology adequately address alcohol septal ablation.

“Most interventional cardiologists do not train in this procedure,” Naidu says.

Although many of the physicians who specialize in this procedure did complete a fellowship that covers alcohol septal ablation, others must learn the procedure through a proctoring program. This is not always easily done, says Naidu, who estimates that only about 10 doctors in the United States perform the number of cases needed on a regular basis in order to proctor other physicians.

Naidu proctors other physicians on the condition that the physician is committed to all aspects of patient care—including postprocedure care—and can demonstrate that he or she has enough opportunities to perform alcohol septal ablation to stay competent once the procedure is learned. Naidu says he performs about 10 per year.

Because the procedure is rare and not always taught within the framework of a fellowship, Naidu says physicians recently out of training must be able to provide proof from the director of their training program stating that the physician is competent in performing alcohol septal ablation.

There is some disagreement between the utility of alcohol septal ablation versus septal myectomy surgery. “Right now, it’s debatable which is better,” Naidu says.

There are advantages and disadvantages to both treatments. One advantage is that alcohol septal ablation is considered less risky than surgery due to its minimally invasive nature, with a shorter hospital stay and associated morbidity. However, the chance that the patient will require a pacemaker is greater than it is with patients who undergo septal myectomy surgery. And, unlike septal myectomy, alcohol septal ablation is a newer procedure in which long-term efficacy and safety data are not yet available. According to Naidu, there is less than a 1% procedural
complication rate with alcohol septal ablation. In addition, patients do not need general anesthesia for the procedure.

Many medical facilities specialize in either septal myectomy or alcohol septal ablation based on local expertise. As a result, many patients who need to undergo an alcohol septal ablation procedure may need to travel to a facility that performs the procedure, sometimes across state lines.

According to Naidu, physicians should perform at least five alcohol septal ablations within a 12-month period to attain competency, either in a training program or proctored setting. Physicians should then perform at least five per year to remain competent in the procedure.

Naidu says the ACC and the AHA are expected to jointly issue standards sometime in the first half of 2010. “At present, there’s very little out there,” he says.

Christopher D. Nielsen, MD, is an associate professor of medicine at the Medical University of South Carolina (MUSC) in Charleston. Nielsen serves as director of MUSC’s Adult Cardiac Catheterization laboratories and director of the organization’s interventional cardiology fellowship program.

According to Nielsen, interventional cardiologists perform alcohol septal ablation. These physicians have completed an internal medicine residency, a general cardiology fellowship, and an extra year (sometimes two) of interventional cardiology training.

Nielsen says most medical institutions do not perform alcohol septal ablation, and the institutions that do perform the procedure only have a few cases. As a result, few fellows learn the procedure in a fellowship setting. “Less than 10% of interventional fellows completing training are competent to perform this procedure,” Nielsen says.

On the other hand, there are institutions and centers that offer proctoring. Nielsen says that he and William Spencer, another interventional cardiologist at MUSC who specializes in alcohol septal ablation, proctor other physicians in the procedure. Proctoring is usually done by traveling to the trainee’s institution where a couple of cases have been arranged, and the trainee performs the procedure under the guidance of the proctor.

Medical University of South Carolina
Charleston, SC
Nielsen notes that there are few established clinical guidelines regarding the procedure specifically, but that other guidelines are applicable. “This procedure has been viewed as a type of angioplasty, and many have felt that privileges are covered under standard angioplasty privileges,” he says. “However, many have lobbied for formal credentialing recommendations, and I believe that the ACC is going to review this soon.”

Nielsen says that at MUSC, it is recommended that a physician perform at least 10 procedures during fellowship training. For experienced certified interventionalists, a minimum of three proctored procedures is recommended. Physicians must perform at least three procedures yearly to maintain privileges, but more would be desirable. There are no universally agreed-upon guidelines for this yet.

Nielsen says the treatment of HOCM requires a team approach. In addition to a competent interventional cardiologist to perform the procedure, it requires physicians who are interested in and well trained in evaluation and treatment of HOCM to decide whether the patient is best treated medically, or with alcohol septal ablation, or with surgical myectomy. According to Nielsen, excellent echocardiography support is important for accurate preprocedure diagnosis and assessment, intra-procedure guidance, and follow-up after the procedure. There needs to be excellent critical care unit support by trained staff members who know how to monitor patients who have undergone alcohol septal ablation procedures (they often require temporary pacemakers) and to assess these patients for complications.

When performed properly, Nielsen says most patients respond to the procedure very well. However, if performed improperly (e.g., the procedure results in a larger-than-expected infarction or an infarction remote from the intended area), the consequences to the patient may be severe.

Nielsen says that MUSC historically has performed about 75 procedures per year, but that number has decreased to about 30–40 procedures in the past few years. “Our volume has decreased because there was a pent-up demand for the procedure when it first came out, and now we are just seeing the new cases,” he says. “There are now also more cardiologists performing the procedure around the country. I have personally performed over 150 of these procedures, and over the past two years, I have performed about 15 per year.”
The Joint Commission

The Joint Commission has no formal position concerning the delineation of privileges for alcohol septal ablation. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the rationale for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission says the information review and analysis process is clearly defined. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.
### CRC draft criteria

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

<table>
<thead>
<tr>
<th>Minimum threshold criteria for requesting clinical privileges in alcohol septal ablation</th>
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<tr>
<td><strong>Basic education:</strong> MD or DO</td>
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<tr>
<td><strong>Minimum formal training:</strong> Successful completion of an ACGME- or AOA-accredited fellowship in interventional cardiology. If alcohol septal ablation training was not included in the fellowship program, the applicant must have completed training with an experienced alcohol septal ablation team that included proctoring for initial procedures.</td>
</tr>
<tr>
<td><strong>Required previous experience:</strong> Demonstrated current competence and evidence of the performance of at least six alcohol septal ablation cases annually over the reappointment cycle.</td>
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</table>

### References

A letter of reference must come from the director of the applicant’s alcohol septal ablation training program. Alternatively, a letter of reference regarding competence should come from the chief of interventional cardiology at the institution where the applicant most recently practiced.

### Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully performed at least six alcohol septal ablation cases annually over the reappointment cycle based on the results of ongoing professional practice evaluation and outcomes.

In addition, continuing education related to alcohol septal ablation should be required.

### For more information

For more information regarding this procedure, contact:

Accreditation Council for Graduate Medical Education  
515 North State Street, Suite 2000  
Chicago, IL 60654  
Telephone: 312/755-5000  
Fax: 312/755-7498  
Web site: [www.acgme.org](http://www.acgme.org)
Alcohol septal ablation (Percutaneous transluminal septal myocardial ablation)  

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American Board of Internal Medicine  
510 Walnut Street, Suite 1700  
Philadelphia, PA 19106  
Telephone: 800/441-2246  
Fax: 215/446-3590  
Web site: www.abim.org

American College of Cardiology  
Heart House  
2400 North Street NW  
Washington, DC 20037  
Telephone: 202/375-6000  
Fax: 202/375-7000  
Web site: www.acc.org

American Osteopathic Association  
142 East Ontario Street  
Chicago, IL 60611  
Telephone: 800/621-1773  
Fax: 312/202-8200  
Web site: www.osteopathic.org

American Osteopathic Board of Internal Medicine  
1111 W 17th Street  
Tulsa, OK 74107-1898  
Telephone: 918/561-1267  
**Note:** Information on AOBIM can be found on the American College of Osteopathic Internists.  
Web site: www.acoi.org

Medical University of South Carolina  
Division of Cardiology  
135 Rutledge Avenue, Suite 1201  
P.O. Box 250592  
Charleston, SC 29425  
Telephone: 843/792-0680  
Fax: 843/792-7771  
Web site: www.muschealth.com

Society for Cardiovascular Angiography and Interventions  
2400 N Street, NW, Suite 500  
Washington, DC 20037-1153  
Telephone: 202/741-9854; 800/992-7224  
Fax: 202/375-6837  
Web site: www.scai.org
Alcohol septal ablation (Percutaneous transluminal septal myocardial ablation)

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The Joint Commission
One Renaissance Boulevard
Oakbrook Terrace, IL 60181
Telephone: 630/792-5000
Fax: 630/792-5005
Web site: www.jointcommission.org

Winthrop University Hospital
Hypertrophic Cardiomyopathy Center
120 Mineola Boulevard, Suite 500
Mineola, NY 11501
Telephone: 516/663-9696
Fax: 516/663-9535
Web site: www.winthrop.org
Privilege request form
Alcohol septal ablation
(Percutaneous transluminal septal myocardial ablation)

To be eligible to request clinical privileges in alcohol septal ablation, an applicant must meet the following minimum threshold criteria:

➤ Basic education: MD or DO

➤ Minimum formal training: Successful completion of an ACGME- or AOA-accredited fellowship in interventional cardiology. If alcohol septal ablation training was not included in the fellowship program, the applicant must have completed training with an experienced alcohol septal ablation team that included proctoring for initial procedures.

➤ Required previous experience: Demonstrated current competence and evidence of the performance of at least six alcohol septal ablation cases annually over the reappointment cycle.

➤ References: A letter of reference must come from the director of the applicant’s alcohol septal ablation training program. Alternatively, a letter of reference regarding competence should come from the chief of interventional cardiology at the institution where the applicant most recently practiced.

➤ Reappointment: Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms. Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully performed at least six alcohol septal ablation cases annually over the reappointment cycle based on the results of ongoing professional practice evaluation and outcomes. In addition, continuing education related to alcohol septal ablation should be required.

I understand that by making this request, I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ______________________________________________________

Typed or printed name: _____________________________________________________

Date: _____________________________________________________________________
Alcohol septal ablation (Percutaneous transluminal septal myocardial ablation)

The information contained in this document is general. It has been designed and is intended for use by hospitals and their credentials committees in developing their own local approaches and policies for various credentialing issues. This information, including the materials, opinions, and draft criteria set forth herein, should not be adopted for use without careful consideration, discussion, additional research by physicians and counsel in local settings, and adaptation to local needs. The Credentialing Resource Center does not provide legal or clinical advice; for such advice, the counsel of competent individuals in these fields must be obtained.

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