# Standardized Alcohol Ablation Procedure for hypertrophic obstructive cardiomyopathy and Tumor

**Patent Application Publication**


## ABSTRACT

**Varieties of Alcohol ablation method is performed worldwide and varied according to institution to institution and hospital to hospital. No certain method is followed for diagnosis of HOCM, tissue ablation and tumor. The current method represent sudden loss of life, finish AV prevent and dangerous tachyarrhytmias, lack of accuracy in targeting the specified area can cause obstruction, lack of ability to handle additional cardiac lesions, right bundle-branch block, complete heart block (that requires permanent pacemaker) and Serious ventricular arrhythmias due to inaccuracy of operation and precise determination of tissue, poor imaging of current technology, conventional catheter system, and various amount of dosing indication. In this present invention next generation advance level of technology and precise pinpoint specification is demonstrated to eradicate the same problems. In this present invention 3D imaging technology, robotic assisted PCI system, 3D catheter system, low dose indication and superior manipulation is followed. This present invention is suitable for another type of ablation like microspheres and glue for whom alcohol ablation is contraindicated. This method is robust, accurate and validated.**




Fig- 1/4

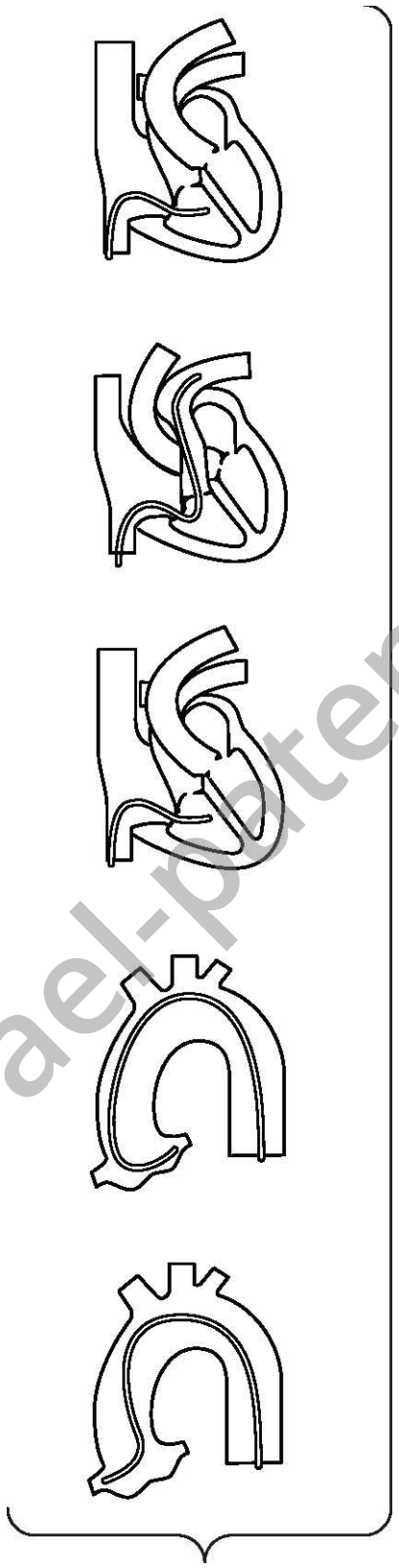

Fig-1: Open end, 6 side holes, 100 cm Multipurpose diagnostic catheters position in heart

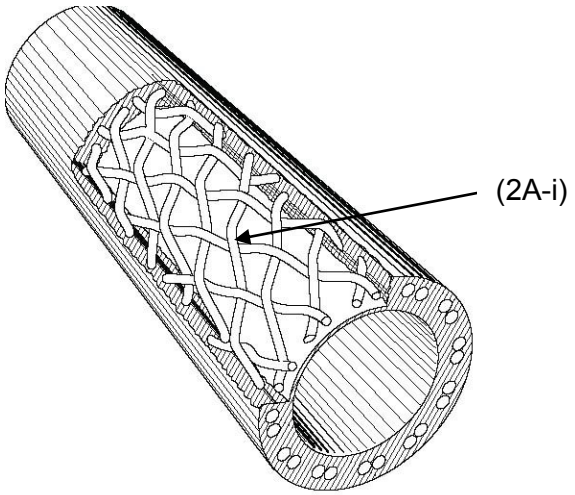


Fig-2A: Catheter composition- Wire braided body, the braided catheter construction allows for precise torque control and enhanced pushability (2A-i).

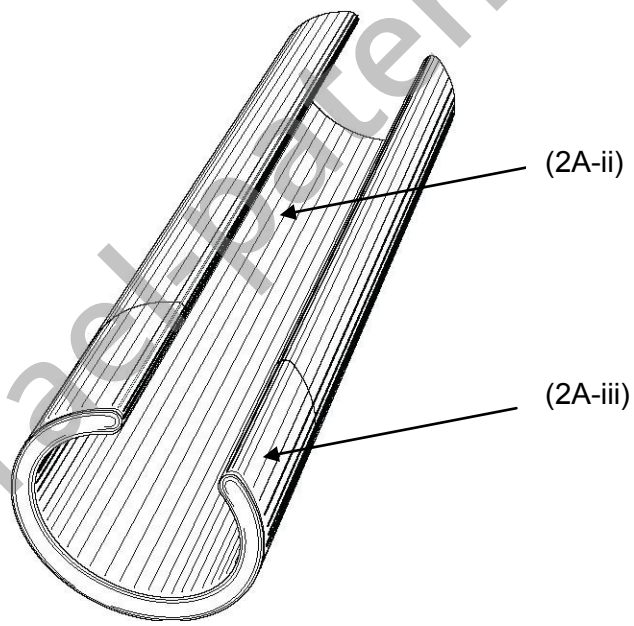


Fig-2B: Catheter composition - Large inner lumen: thin wall technology allows for larger inner lumen diameter facilitating easy injections and higher flow rates (2A-ii); Radioopaque tip: improves visibility to help reduce the risk of vascular damage upon entering tortuous or fragile vessels (2A-iii).

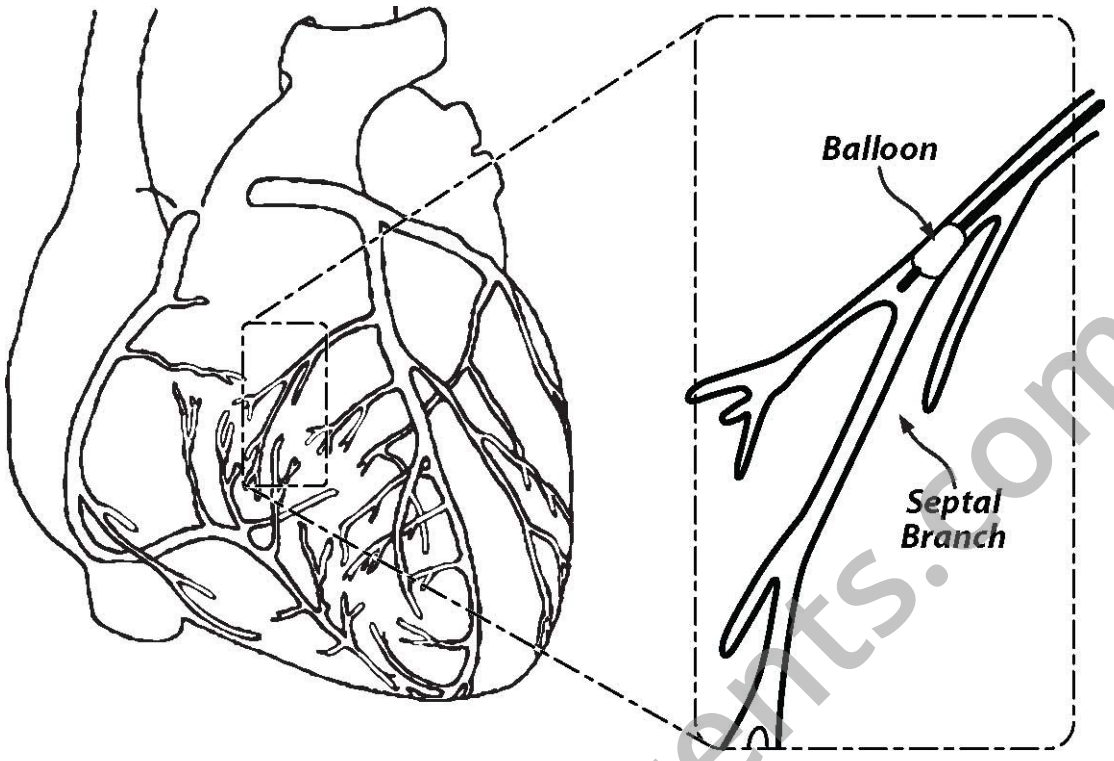


Fig 3: Catheter position during alcohol ablation

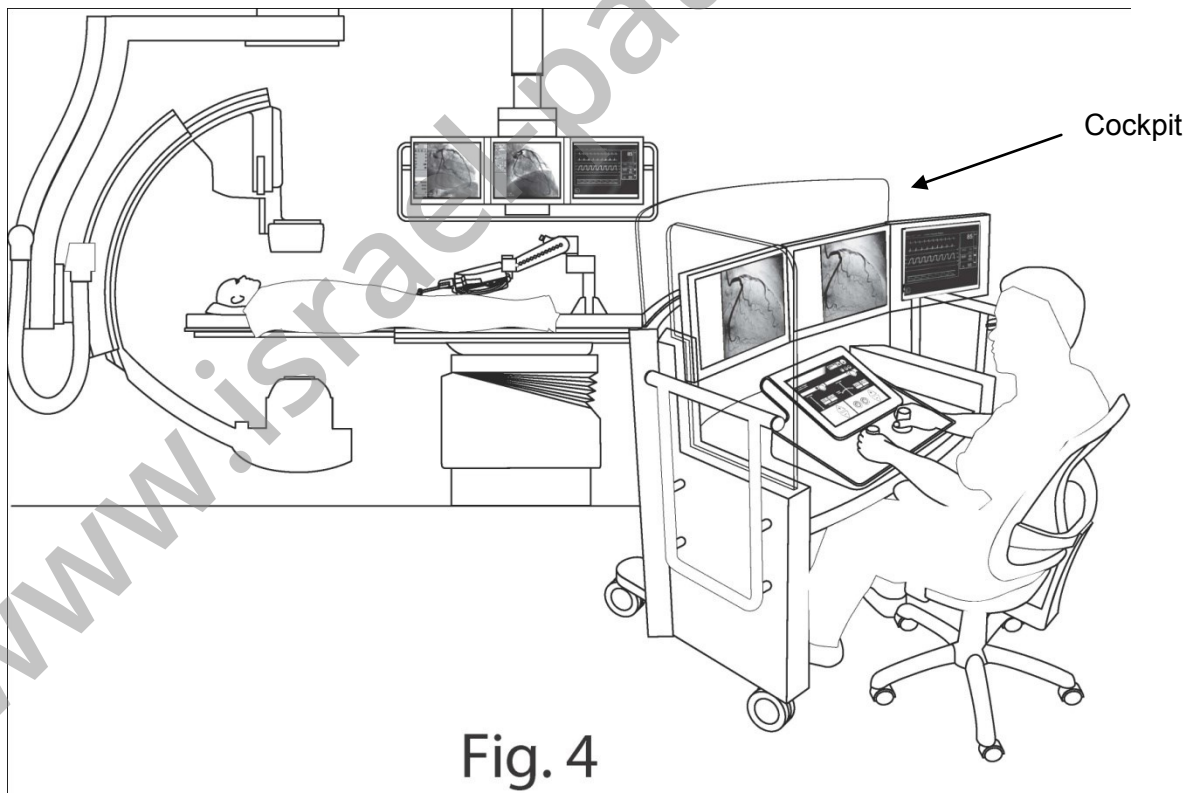


Fig. 4

**Fig.4:** Robotic assisted PCI system.

## Cross references to related applications:

[0001] The present application claims the benefit of safe and effective procedure of alcohol ablation procedure of U.S. patent application publication no. US 2008/0045890 A1 (Sewerd et al, Feb 21, 2008) for hypertrophic obstructive cardiomyopathy, abnormal growing tissues and Tumor.

## Background of the Invention

### Field of the Invention

[0002] Alcohol ablation technique is used worldwide for more than 20 years in many hospitals, clinics and research institutions. More than 800-1700 various types of procedures are available among the practitioners but no standard established method is claim for successful treatment. No optimized guideline does create till 2012. The patient suffering from hypertrophic obstructive cardiomyopathy (HOCM) is the main target for such alcohol ablation. The condition is caused by a thickening of the muscle wall between the left and right ventricles of the heart. The septalmyectomy is the only gold standard surgery to cure this condition which has very little surgical accuracy, patient safety and longtime operation. Surgical resection of the excess material requires the administration of a general aesthetic and a long recovery time, while the alcohol ablation method is done without general anesthesia, and patients recover much more quickly.

[0003] Alcohol septal ablation is necessary when the HOCM patient cannot tolerate open heart surgery. It is alternative medical therapy to surgical myectomy for the treatment of LVOT (left ventricular outflow tract) obstruction.

[0004] There is no standard universal procedure of alcohol ablation worldwide. The technique of alcohol septal ablation varies from institution to institution. The varied techniques may contribute to differences in the risk of sudden death after the procedure. Some centers perform an alcohol septal ablation by selecting multiple septal branches and using 2 to 5 mL of alcohol. Others perform the procedure by selecting smaller branches of a septal perforator artery and infusing <1.5 mL of alcohol. [1] [2] [3] [4] [5] [6] [7] [8]

1 Josef Veselka, Alcohol septal ablation for hypertrophic obstructive cardiomyopathy: focus on safety, SWISS Med Wkly 2007;137:657–659
2 Alcohol septal ablation procedures, London's Royal Brompton Hospital, 1994
3 Alcohol Septal Ablation, Harris County Hospital District, by Ian Kenney, May 15, 2010
4 Hyprertrophic Obstructive Cardiomyopathy, North Carolina Medical Journal
5 The State of Queensland (Queensland Health), 2011
6 Alcohol Septal Ablation, Salpizio Cardiovascular Center, University of California, San Diego
7 Alcohol Septal Ablation, Heidelberg Medical Consultancy and Health Tourism Pvt Ltd,13 Jul 2010
8 Alcohol ablation of the septum, by Dr. Sherrid, St. Luke's Hospital, 2009

[0005] Better knowledge on the pathophysiology of the obstruction, identification of right candidates, Technological advances to the diagnostic tools like cardiac magnetic resonance imaging, computed tomography, transesophageal echocardiography, and echocardiography are highly useful for precise determining of obstruction and defining the treatment strategy can provide the safe, effective and technique of ASA without complications. Transesophageal echocardiography may be necessary when the quality of the image is poor while in most cases transthoracic echocardiography serves for the guidance of ASA. The more accurate intravascular ultrasound probes needed to develop in this context. ASA is performed using coils, spheres, and Teflon stents but now these techniques are not usable due to the lack of efficacy. [9]

[0006] The modification of current technology reduce the complications in ASA. These alterations include the use of new electrophysiology catheters with active fixation elements that reduce the risk of perforation related to the manipulation of the temporary pacemaker, or the use of jugular or subclavian venous access, facilitating patient mobility. Radial artery access reduces vascular complications and it requires optimum french (F) high flow guiding catheter. This facilitates adequate contrast flow in order to maintain good visibility of the small-caliber septal branches, which usually requires 7-Fr catheters. [10]

[0007] It is reasonable for alcohol septal ablation (and surgical myectomy) to target a distinct pathophysiology of dynamic outflow tract obstruction refractory to medical therapy, as opposed to any particular disease, namely HCM. Alcohol septal ablation perhaps need not be limited to asymmetric hypertrophy, but rather to cases in which a high degree of success can be predicted based on precise determinations of the location of the obstruction and the likelihood that available septal perforators subtend the offending myocardium, as guided by myocardial contrast echocardiography. Recognition of this pathophysiology, as opposed to the HCM disease state, should trigger a change in management from one that targets afterload reduction and congestion (as in the traditional treatment for hypertension-related hypertrophy and diastolic dysfunction) to one that targets the outflow tract obstruction itself with hydration, negative inotropic agents, avoidance of pure afterload-reducing medications and septal reduction therapy, when appropriate.



9 Alcohol Septal Ablation, Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia, by Lorraine Robertson, RN, BSCN CCN(C), Educator, Heart Health & Emergency

10 George Latsios, Substitution of ethanol with specially designed microspheres in a TASH procedure, EuroIntervention 2011;6:889-892.

## Brief summary of the Invention

[0007] The present invention provides systematic improved technology and a sequential procedure for ablating the abnormally growing tissue in HOCM patient and tumor. The present method comprises multidisciplinary item for ablating the tissue. This system includes Second-generation real-time 3D echocardiography, [11] [12] 7F high flow catheter,[13] [14] low dosing ethanol, local anesthetic, and Robotic assisted PCI[15].

[0008] Current methods utilized for alcohol ablation are described in the website of livestrong, The State of Queensland (Queensland Health), 2011; Salpizio Cardiovascular Center, University of California, San Diego; Heidelberg Medical Consultancy and Health Tourism Pvt Ltd,13 Jul 2010; Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia; St. Luke's Hospital, 2009; HeartPlace Cardiac Specialties Cardiovascular Coronary Angiography Angioplasty Dallas Texas; Barnes-Jewish Hospital, Loyola University Health System, Jackson Memorial Hospital, University of Ottawa Heart Institute, New Mexico Heart Institute, UNC Invasive Cardiology Services, University of Florida and Shands Academic Health Centre, MedStar Heart Institute, Washington, John R. Leyendecker, M.D. and Gerald D. Dodd III, M.D., Semin Liver Dis. 2001, 21(2); John Hopkings Medical Centre, Everyday Health Media, LLC; Sherif F. Nagueh, MD, J Am CollCardiol. 2011;58(22):2322-2328. doi:10.1016/j.jacc.2011.06.073; C. Cappelli, QJM: An International Journal of Medicine Volume 101, Issue 8 Pp. 657-662, 2008;

[0009] The advantage of the present invention is that the every step is precise and specific. The procedure is performed according to pinpoint specification. The materials are advanced and next generation graded. This procedure also is suitable to eradicate the liver tumor, thyroid tumor, kidney tumor.

## Detailed description of the drawings

[0010] Fig. 1 shows the precise location of the 3D catheter navigated by joystick controller.



11 3D Catheter integrate real-time intracardiac echocardiography (ICE), Biosense webstar company
12 Roberto M. Lang et al, EAE/ASE Recommendations for Image Acquisition and Display Using Three-Dimensional Echocardiography, J Am Soc Echocardiogr 2012;25:3-46.
13 ALI OTO et al, Cyanoacrylate for Septal Ablation in Hypertrophic Cardiomyopathy, Journal of Interventional Cardiology, Vol. 24, No. 1, 2011
14 Cordis percutaneous entry and guidance of angiographic catheters, August 2010
15 CorPath 200 Robotic-assisted PCI System

[0011] Fig. 2A shows the Wire braided body of catheter allows for precise torque control and enhanced pushability.

[0012] Fig. 2B shows thin wall technology of Catheter having Radioopaque tip that allows for larger inner lumen diameter facilitating easy injections and higher flow rates and improves visibility to help reduce the risk of vascular damage upon entering tortuous or fragile vessels. This design provides the same inner lumen diameter from hub to tip which eliminates contrast jetting and allows for smoother flow and catheter stability.

[0013] Fig. 3 shows the Catheter position precisely during alcohol ablation.

[0014] Fig.4 shows the Robotic assisted PCI system having cockpit, discrete control, compatible with enhance visualization, and safety from radiation.

**Detailed Description of the Invention**

[0015] The present invention provides methods and systems for ablating tissues, typically in patients with Hypertrophic obstractivecardiomayopathy (HOCM) and patients with the collateral formation to the right coronary artery in whom ASA is contraindicated.. In other cases, patients who have hyperproliferative tumors, benign prostatic hyperplasia, or other disorders that may require ablation of tissues may also be candidates for receiving treatment according to the present invention in order to reduce the size or presence of certain tissues in the body.

[0016] The present invention will preferably utilize next generation advance graded devices and methods for intravascular approach and transvascular or transventricular injection of the ablating agent of alcohol (specially ultra-low dose100% ethanol) or Microspheres or glue (cyanoacrylate). The following description provides several representatives embodiments of gold standard diagnostic catheters with specially designed of large inner lumen and thin wall technology allows for larger inner lumen diameter, facilitating easy injections and higher flow rates which is suitable for delivery of the ablating agents into the desired location of the heart, vessels and tissues. After delivery of the ablating agent the catheter is removed without damaging the heart or any tissue and vessels by the tip of the catheter. The radiopaque tip of the catheter has improved visibility to help reduce the risk of vascular damage upon entering tortuous or fragile vessels. Wire Braided Body construction of the catheter allows for precise torque control and enhanced pushability. This specially designed catheter provides the same inner lumen diameter from hub to tip, which eliminates contrast jetting and allows for smoother flow and improved catheter stability.

[0017] The present invention of the embodiment provides robotic assisted PCI system to keep the physician radiation free operation. This system demonstrated the safety and efficacy of the precise ablation using catheter. It enables the placement of coronary guidewires and balloon/stent devices from the safety of a radiation-protected, Interventional Cockpit. Robotic precision extends dexterity with 1mm discrete movements.

[0018] The present invention of the embodiment provides Second-generation real-time 3D echocardiography which gives more clear complete visualization and comprehensive assessment of cardiac morphology and pathomorphology. The 3d image of the heart helps to manipulate the heart structure, vessels and tissue location accurate way.

[0019] The present invention of the embodiment provides step by step pinpoint specific procedure with specification. Before the procedure patient information will need to collect that is any bleeding problem, taking of coumadin or other blood thinning medication, allergy to iodine, alteration of insulin or pill regimen of diabetic patient, patients with a history of kidney problems, having normal meal the evening before procedure, prohibition from eat, drink or chew anything after 12 midnight, use of any medications allowed. During the procedure, an IV (intravenous line) will insert in arm administers sedatives, medications, and fluids. The catheter insertion site will be cleansed with an antiseptic soap and shaved and numbed with a local anesthetic. A tiny incision will be made in the skin. Doctor guides a thin, flexible wire in blood vessel to heart. Doctor will insert a 7F high flow specially designed catheter through a sheath, slides it over the guide wire, and guides it into coronary arteries using robotic assisted PCI system from a remote place. Once the catheter reaches to heart, a liquid dye (contrast fluid) is injected; doctor can view heart and arteries on a special screen called an angiogram. The patient may be asked to hold breath for five to ten seconds while some of the photos of heart are taken, and patient may also be asked to cough a few times after the dye has been injected. A balloon catheter is inserted into artery and inflated. When the artery in question is located, a tiny amount of pure alcohol is injected through the catheter. The alcohol kills the cells on contact, causing a "mini" heart attack. The septum gradually shrinks back to a more normal size and widens the passage for normal blood flow. After the procedure doctor removes the catheter. The patient will be admitted to the hospital for three to five days for monitoring. Patient may experience some minor chest discomfort. Bruising around the catheter insertion site may develop. Patient will begin to feel better almost immediately. Patient drink lots of fluids. Chest pain or swelling occurs around the insertion site rarely occur after the ablation. Patients may resume normal activities after two days. Follow-up appointments will be necessary including echocardiograms to evaluate the healing of patient septum.

Addressing lifestyle causes is central to maintaining a healthy cardiovascular system. Patients are encouraged to eat a healthy diet, Exercise, Lose weight, Quit smoking.

[0020] The present invention of the embodiments provides the necessary operational steps that the patients underwent coronary 3D echocardiography and temporary pacemaker was placed in the apex of the right ventricle except those who already have a permanent pacemaker in place for HOCM. But in other case the catheter is placed close to the peripheral margin of the tumor and pacemaker is not required. A multipurpose catheter was advanced into the apex of the left ventricle to measure the pressure gradient between guiding catheter in the aorta and multipurpose catheter in the apex of the left ventricle (PG start). A 7 Fr guiding catheter was then engaged in the left main coronary artery. A slightly oversized over-the-wire balloon catheter of 1.5-2.5 mm in diameter was introduced over a coronary wire into the first septal perforator and inflated. A contrast medium was injected through the central balloon lumen to ensure that balloon inflation prevented spillage into the left anterior descending artery. Contrast myocardial 3D echocardiography (concentration, 300 mg/ml) was done to delineate the area to be infarcted. Ethanol (100%) was injected very slowly per fractions (0.5-1 ml/1 min) and finally 2 ml of saline or 1% Lidocaine were used to perform a careful flush of the central balloon lumen. The balloon catheter was left in place at least 5 min after the last ethanol injection. The measurement of the final peak-to-peak pressure gradient (PG end) was done by guiding and multipurpose catheters. Finally, the echocardiography was carried out to confirm the patency of the left anterior descending artery and occlusion of the target branch. If a single large first septal branch was not found or the reduction of pressure gradient was insufficient (< 50%), a second septal branch was ablated. The maximal amount of alcohol injected will 3 ml. When LVOTPG decreased sufficiently or complete heart block developed, the procedure was stopped at lower dose. The total volume of alcohol was based on relief of LVOTPG and development of conduction abnormalities during injection. When LVOTPG was abolished at lower dose than 3 ml or complete heart block developed, the procedure was stopped at lower dose than 3 ml of alcohol. Patients were observed in the intensive care unit for at least 24 hr; the pacemaker lead was then removed if there was no episode of high-degree atrioventricular block. Blood was withdrawn for MB fraction of creatine kinase (CK-MB) at 6-hr intervals for 2 days.

What is claimed is:

1. A method for treating a patient, said method comprising operation procedure of alcohol ablation technology that also can suffice for glue or microspheres ablation to whom alcohol septal ablation is contraindicated,

2. A method as in claim 1, wherein precise determination of tumor tissue and vessels in heart or other part of the patient's body.
3. A method as in Claim 2, wherein precise determination is conducted by the robotic assisted PCI system (Fig. 4),
4. A method as in claim 3, wherein a 3D catheter(Fig. 2A, 2B) is positioned by said system,
5. A method as in claim 4, wherein 3D catheter(Fig. 2A, 2B) is specially designed consisted with a radiopaque tip, and a 7F catheter of high flow ability,
6. A method as in claim 1, wherein 0.5 ml of 100% concentrated ethanol is administered in the ablating location (Fig. 3)
7. A method as in claim 2, wherein precise determination of the tissue location is guided by second generation 3D echocardiography system (Fig. 1),
8. A method as in claim 1, wherein a tissue ablating agent is 0.5 mL *N*-butyl cyanoacrylate was mixed with 2.5 mL of Lipiodol which yields one-sixth diluted glue (17%) cyanoacrylate or 2.5 ml of microspheres measuring 100 μm in diameter (Fig. 2A, 2B),
9. A method as in Claim 3, wherein the system allows interventional cardiologists to perform PCI in a cockpit using two joysticks (Fig. 4) to control the catheter and devices and to precisely move guidewires and balloon/stent catheters (Fig. 1).The system also has the potential to enhance the view of the angiography screen and 95% reduced radiation exposure to the physician (Fig.4).
10. A method as in Claim 3, wherein the system is composed of interventional cockpit (Fig. 4), and a bedside unit (Fig. 4). The bedside unit is composed of an articulated arm containing the robotic drive; and a single-use cassette with attached guide catheter supported with guide catheter arm and loaded balloon catheter.
11. A method as in claim 5, wherein the catheter has Large Inner Lumen, Wire Braided Body and kink-resistant shaft(Fig. 2A, 2B),
12. A method as in claim 1, wherein a 25 gauge needle catheter is used to deliver the ablating agent into the tumor or abnormal growing tissue (Fig. 3),
13. A method as in claim 1, wherein the tissue is cardiac tissue which is abnormally thickened due to hypertrophic cardiomyopathy (Fig. 3),
14. A method as in claim 1, wherein the tissue is prostate tissue affected by benign prostatic hyperplasia or liver tumor or kidney tumor or thyroid gland tumor,
15. A method for treating a patient suffering from an obstructive hypertrophic cardiomyopathy, said method comprising:
    Second generation 3D imaging device, 3D catheter needle, Robotic controlled PCI, low dose ablating agent;

Advancing of the catheter positioning from a lumen of a blood vessel to the location beyond the endothelium of the blood vessel in a target cardiac tissue region;
And injecting ethanol or a composition of ethanol and a contrast medium or a composition of ethanol or cyanoacrylate or microspheres, contrast medium and a diluent through the catheter needle into tissue at a location beyond the endothelium of the vessel,

16. A method as in claim15, wherein the blood vessel is a coronary artery(Fig. 3),
17. A method as in claim 15, wherein the blood vessel is a coronary vein(Fig. 3),
18. A method as in claim 15, wherein the target cardiac tissue region is the cardiac septum(Fig. 3),
19. A method as in claim 15, wherein the catheter needle and robotic guiding is advanced into a perivascular space beyond the outside of the endothelium,
20. A method as in claim 15, wherein the catheter needle and robotic guiding is advanced into the adventitia and/or periadventitital tissue surrounding by the blood vessel,
21. A method as in claim 15, wherein the ethanol and a contrast medium or a composition of another ablating agent cyanoacrylate or microspheres and contrast medium or diluent is injected in an amount sufficient to permeate a total tissue volume of at least 0.5 ml.
22. A method as in claim 8, wherein drinkable alcohol with minor concentration/quantity of 2-5 ml is suitable for this selected 3D catheter(Fig. 2A, 2B) and the strong alcohol damages the catheter.
23. A method as in claim 8, wherein determined alcohol for ablation procedure is <1.5 ml that is so much minor and so it does not affect the catheter.
24. A method as in claim 4, wherein 3D catheter(Fig. 2A, 2B) is a catheter with a “longitutional slot" allowing controlled alcohol or other chemicals into the tissue with precise controlled amounts, precise torque control, flexible kink-resistant shaft, flexible dilator, and sheath assembling.