Transitioning from EP Diagnostic to Therapeutics: What are the Essential Considerations?

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When hospitals make the decision to expand the cath lab to perform electrophysiology (EP) procedures, it is important to look into the impact it will have on the total cardiology program. Traditionally, hospitals have looked to recognized medical specialist societies to provide insight and direction regarding clinical policy and process. This is no different for EP procedures, which have been routinely conducted in the cardiac catheterization lab setting. When looking for guidance and/or recommendations for EP catheter ablation treatment, the North American Society of Pacing and Electrophysiology (NASPE) and American College of Cardiology (ACC) offer policy statements.

Catheter ablation is one procedure which has transformed the field of electrophysiology. Catheter ablation destroys atypical heart tissue which is responsible for abnormally fast heart rates. Previously, the treatment for many tachycardiac arrhythmias required extensive open-heart surgery. Catheter ablation, through the use of radiofrequency ablation, has, in many instances, made surgery and long-term drug therapy no longer necessary. Therefore, "the number of reported ablation procedures performed annually in the United States has increased from 450 in 1989 to? 15,000 annually.[1] This increase in demand has made the addition of EP services at many hospitals very attractive.

When a hospital is considering expanding cardiology services to include EP and catheter ablation treatment, an assessment of existing clinical services is in order. One of the first questions to address is whether the hospital already has an established open-heart surgery program. While there are no defined regulations that require the "on site" availability of open-heart surgery services when performing catheter ablations, it appears to be an accepted medical practice.

As previously stated, two recognized organizations that provide electrophysiology clinical competency recommendations are the ACC and NASPE. However, the ACC defers to NASPE for specific guidelines. NASPE produces clinical competency recommendations for EP services. Recommended guidelines state "Comprehensive catheter ablation programs require a fully equipped invasive electrophysiological laboratory and ready access to surgical support and facilities. It was felt that full cardiac surgical support was desirable; nevertheless, at minimum, facilities performing ablation should have thoracic surgical backup."[2] The guidelines are not specific regarding the need to have open-heart surgery available "on site," leaving this open for interpretation.

However, what the NASPE policy statement on catheter ablation, as published in PACE, does present, are equipment and clinical process recommendations. Cine or digital imaging, and hemodynamic monitoring and recording of, at the very least, arterial pressures and O_2 saturation are recommended. Standard cath lab radiation exposure precautions must be maintained, especially in extended ablative procedures.

Equipment required for ablations includes an external defibrillator with non-invasive pacing, a radiofrequency current generator with temperature and impedance monitoring capability and a power output of at least 50 Watts. Other desirable equipment includes mapping equipment, and recording equipment capable of monitoring a minimum of three surface leads and at least four intra-cardiac leads concurrently. Hard copies of these recordings also need to be available for cardiologists' immediate review.

Airway maintenance equipment, such as oxygen, suction and general anesthesia should be available. If your lab is doing pediatric cases, general anesthesia is mandatory.

Staff in cardiac cath/EP labs can differ from hospital to hospital. Members of the EP team for ablation procedures generally will be similar to that of the cath lab. In addition to cath lab training, the EP staff requires experience and ongoing specialization with EP procedures. Ideally, if volume allows, there should be staff dedicated to the EP lab.

Staffing for ablations should consist of at least three team members in addition to the attending physician. It is "recommended that staff utilized for ablative procedures have experience with at least 30 catheter ablations before working independently in the EP lab, and that they continue to assist on 30 cases per year."[3] The number of physicians involved in the case, their experience, and the difficulty of the case can change the staff composition to include more or less personnel.

The team should consist of a scrub person, a circulating nurse and a cardiovascular technician (CVT) monitoring person. Normal cath lab responsibilities for these positions remain the same with the exception of the CVT monitoring person. Ideally, the staff member monitoring the case will be CVT certified and have familiarity with ablative procedures. Additional responsibilities charged to the CVT monitoring person, besides observing the patient and recording and documenting clinical information, will be operating the radiofrequency generator used during the ablation. The monitoring staff person will turn the equipment on and off and feed information to the physician throughout the case. It is vital to have excellent communication between the CVT monitoring person and the physician. While operation of the equipment on is not difficult, it requires intense concentration. It is vitally important not to activate the ablator until instructed by the physician. The ablator permanently destroys viable cells. This can be especially significant in AV ablations, where ablating the inappropriate area can place the patient into permanent heart block requiring a pacemaker. Unlike cardiac catheterization procedures, the CVT staff member monitoring the case needs to be informing the physician every few seconds of the measured value and the length of time the machine has been operating. The information the physician needs to be aware of includes: the power or temperature, impedance, and the length of time the generator is active. Any changes in these values need to be reported immediately. "If the catheter loses contact with the myocardium, blood around the catheter tip may become superheated and boil."[4] For this reason, the CVT monitoring person needs to be prepared to turn the ablator off immediately by keeping his/her finger on or in close proximity to the power button. If discontinued early, the ablator can always be reactivated, but if left on too long, the damage becomes permanent.

Having an experienced staff on board is just one piece of the puzzle. Electrophysiology labs performing ablations should maintain a high volume for proficiency. The NASPE Policy Statement provides information on the success of ablation procedures as related to volume.

Today, most institutions do not require board certification in Clinical Competency in Electrophysiology (CCEP) as a credentialing requirement. However, CCEP recommends applicants should have met board requirements as described on the AHA journal Circulation website.[5] Respondents to the CCEP Training Program Directors' Survey uniformly indicated that two years were required to achieve training in all aspects (diagnostic and therapeutic) of CCEP.[1] Additionally, there is general consensus among EP practitioners that one year of specialized training in EP is needed to gain the knowledge and technical skills necessary to become proficient in EP. In addition to general cardiology fellowship training, the Clinical Competency Electrophysiology Training Program Directors' Survey[1] indicates that a minimum of 90 cases are required to acquire clinical competency in ablation. Furthermore, the NASPE Ad Hoc Committee[1] on catheter ablation recommends that a physician be the primary operator on >= 30 procedures, including 15 accessory pathway ablations.

Not surprisingly, the majority of EP physicians are located at high-volume academic centers. According to the NASPE website,[6] the state of California has the most EP physicians at 161, while Wyoming has only one. More rural areas suffer a dearth of these specialists, and patients must often rely on referrals from their cardiologists to be evaluated at tertiary centers. The wait time to see these highly demanded specialized EP cardiologists can be two months or more. The Cardiovascular Roundtable[7] notes that while the number of electrophysiologists has doubled between 1996 and 2001, the number of patients receiving EP therapy remains small due to an EP physician workforce being unable to meet the demand.

In conclusion, hospitals must consider a number of clinical issues when deliberating the feasibility of implementing a full-service EP program. Having open-heart surgery back-up on site is one of the most important considerations and must be carefully thought-out. Offering open-heart surgery can be a very expensive proposition, and often there are regulatory challenges and barriers to entry. Twenty-five states require hospitals to file Certificate of Need (CON) applications for acute care services. Each of these states has established a specific criterion for the clinical and/or financial threshold that would trigger the need to file the CON application, but all require an application for open-heart surgery at this time.

States also have established Department of Health Regulations that vary within each jurisdiction. Some states require hospitals to make notification of new services, and others will review services on inspection tours.

Gathering information from clinical resources, developing financial projections, and researching state-specific regulations regarding EP and open-heart surgery are all essential elements of a thorough due diligence. Preparation and presentation of all available information to the stakeholders — including hospital administration and medical staff — will set the stage for a well thought-out decision that will meet patients' needs with a successful, high-quality EP program.

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1. Tracey CM, Masood A, DiMarco JP, et al. American College of Cardiology/American Heart Association clinical competency statement on invasive electrophysiology studies, catheter ablation, and cardioversion. Circulation 2000;102:2309–2320.
2. Scheinman MM. NASPE survey on catheter ablation. Pacing Clin Electrophysiol 1995;18:1474–1478.
3. Scheinman M, Calkins H, Gillette P, et al. NASPE Policy Statement on catheter ablation: Personnel, policy, procedures, and therapeutic recommendations. PACE 2003;26:789–799.
4. http://www.theeplab.com
5. http://circ.ahajournals.org/cgi/content/full/102/18/2309
6. http://www.naspe.org
7. Cardiovascular Roundtable, 2004 sessions.

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