curvo™

www.curvolabs.com

PROCEDURE BASICS

Electrophysiology (EP)

Electrophysiology (EP) studies and ablations are a mainstay of hospital's EP lab, and the source of much inpatient revenue. The purpose of an EP procedure is to "map" the electrical system of the heart and, if possible, to correct anomalies in the heart's electrical system. The physiology of the heart contains electrical pathways that generate signals to the chambers to the heart to pump on a precise basis. Occasionally, the circuitry is compromised or damaged which causes the heart to beat irregularly.

The most common problem is atrial fibrillation which causes the upper chambers of the heart not to beat in synchrony with the lower chambers of the heart. Uncorrected, this can lead to serious problems including stroke or death.

A common approach to fixing the circuitry is to "ablate" or zap the offending node causing the irregularity. Biosense Webster and Abbott St. Jude employ an electrical adjustment through an ablation catheter (RF ablation) while Medtronic uses cryoablation to accomplish the same function.

Dexur estimates that there were 35,000 cases assigned to MS-DRG 274, the payment category for inpatient intracardiac procedures which includes ablations as well as mappings. Hospital outpatient payment and inpatient payments were about the same, $21,000, while the physician payment for a complete ablation with mapping studies was about $1,100. There are an estimated 800 facilities that perform some types of EP studies in US hospitals.

Some estimates indicate that the pulmonary veins around the heart are the source of up to 94% of atrial fibrillations. The most a common ablation procedure is pulmonary vein isolation (PVI) in which a series of burns around each of the four pulmonary veins is performed during an ablation procedure.

In order to complete this procedure, a number of catheters are threaded into a vein from the groin to the heart, each with different purposes: the ultrasound catheter (ICE or intracardiac echocardiography) provides visualization of the heart structures during the procedure. Ultrasound has allowed ablation procedures to avoid using X-Rays or flouroscopy, thus reducing radiation exposure to the patient and the physicians.

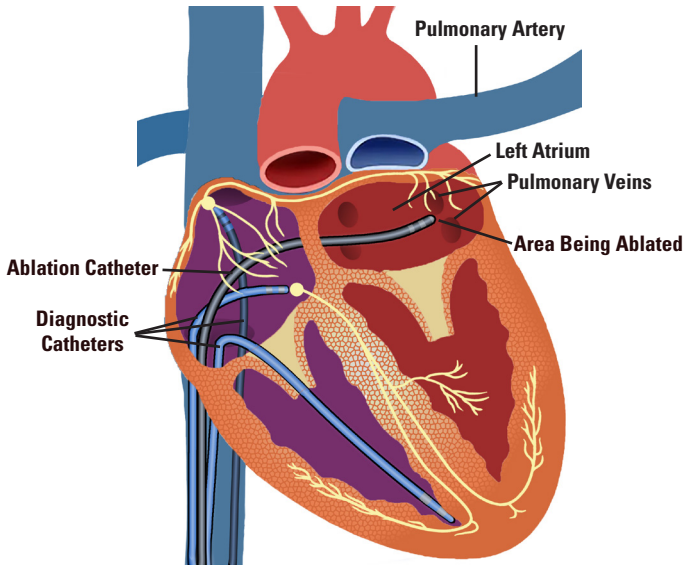
Other catheters include those which can both provide general location information, and mapping catheters which create a 3D image of the inside of the heart. Other supplies for the proce-

Key Statistics on Coronary Ablation

Factor	Location	Estimate
Procedures		
Coronary Ablations	Inpatient Procedures	70,000
	Outpatient Procedures	160,000
Medicare Reimbursement		
Facility		
Inpatient Perc Intracardiac Proc (MS-DRG 274)		$20,563
Outpatient Level 3 EP Proc (APC 5123)		$21,464
Physician		
Ablation (CPT 93656)		$1,145
Intracardiac Ultrasound (CPT 93662)		$115
Cardiac Mapping (CPT 93613)		$302
Facilities Performing Ablations		**app. 800**

Sources: Medicare inpatient, outpatient, and physician 2021 payment schedules, Dexur.com procedure estimates, and industry sources.

Conduction System of Heart



curvo™

dure include transseptal needles, used to cross from the right atrium to the left, sheaths used to guide the catheters through a vein from the patient's groin to the heart, IV solutions and tubing which are used to keep the ablation catheter cool.

While the technology of these devices is impressive, the cost of a single procedure can be daunting. The ablation catheter, the most integral part of the procedure, can cost more than a hip or knee implant, at $3,000 to $4,000. Ultrasound catheters are about $2,000, and mapping catheters average about $2,000. The average disposable costs during an ablation procedure can be well over $10,000, while the hospital reimbursement is about $21,000. In other words, about half of the hospital payment is for the supplies and equipment used in the procedure.

Cost Drivers

While each procedure has to be tailored to the individual patient, and the possibility of unexpected events makes estimating time and duration difficult, a couple of metrics may be used to identify areas to improve operational efficiency such as:

• How many catheters are used in each case? Using additional catheters will not only increase costs, but may expose the patient to additional trauma, since each catheter is typically threaded through a separate sheath in the groin.

• What is the mix of catheters being used? The advanced mapping catheters provide a wealth of information to the EP physicians by painting a three-dimensional view of the heart and also record which areas have been ablated. The advanced mapping catheters are more expensive and require more extensive software and technical support. Catheters have between 4 and 22 electrodes to record heart activity in different locations. Other options for catheters include whether they are irrigated or not, steerable or not, among other features. In general, additional features will have added costs.

• Are catheters reprocessed? The FDA has cleared at least 3 companies for EP mapping and ultrasound catheter reprocessing—Sterilmed, Innovative Health, and Stryker Sustainability. The reprocessed catheters can be as much as 30% less in cost than the catheters offered by the main manufacturers—Biosense Webster, Boston Scientific, and Abbott.

• How many competing systems are being used? Most of the companies' systems are incompatible with each other, and many physicians are reluctant to work with systems they are unfamiliar with, so it is not usual for a hospital to have purchased several expensive ssytems that accomplish the same thing.

• Ratio of diagnostic vs. therapeutic procedures. Therapeutic procedures will include ablation catheters and will cost more.

EP Catheters

CRN Market Share of EP Catheters

Manufacturer	Market Share
Biosense Webster	Over 50%
Abbott	Less than 25%
Medtronic	Less than 10%
Boston Scientific	Less than 10%
Others	Less than 10%

Others includes Acutus, catheters reprocessed by Stryker Sustainability, InnovativeHealth, Sterilmed, and others.

Source: Curvo Labs, 2020 data. Represents purchases from 164 hospitals between January 1, 2020 and December 31, 2020

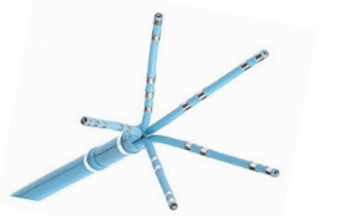
Electrophysiology Supplies and Equipment

Product	Sample Product	Cost/Unit
Ablation Catheters		
RF (radio-frequency)	Thermacool	$3,000
Cryoablation	Arctic Front	$4,000
Diagnostic Catheters		
Ultrasound	AcuNav	$2,000
Mapping	Pentaray, TactiCath	$1,700
Other	Webster	$500
Transseptal Needle System	BRK Transeptal Needle	$200
Accessories		
Sheaths	Visigo	$1,000
Patch	Carto 3	$350
Equipment		
Cables	Carto 3 Cable	$400

Note: Excludes capital equipment for ablation generators, mapping systems, software, service agreements, ultrasound systems

Source: Curvo Labs estimates

Electrophysiology Supplies and Equipment



Pentaray Mapping Catheter, Biosense Webster

Arctic Front Cryoablation Catheter, Medtronic

Flexability RF Ablation Catheter, Abbott

Lasso Mapping Catheter, Biosense Webster

Soundstar Intracoronary Echocardiographic (ICE) Ultrasound Catheter, Biosense Webster