



Highlights from:

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Winkle et al., Journal of Interventional Cardiac Electrophysiology (JICE), Mar 2013 DOI: 10.1007/s10840-013-9782-x

Physician-controlled costs: The choice of equipment used for atrial fibrillation ablation

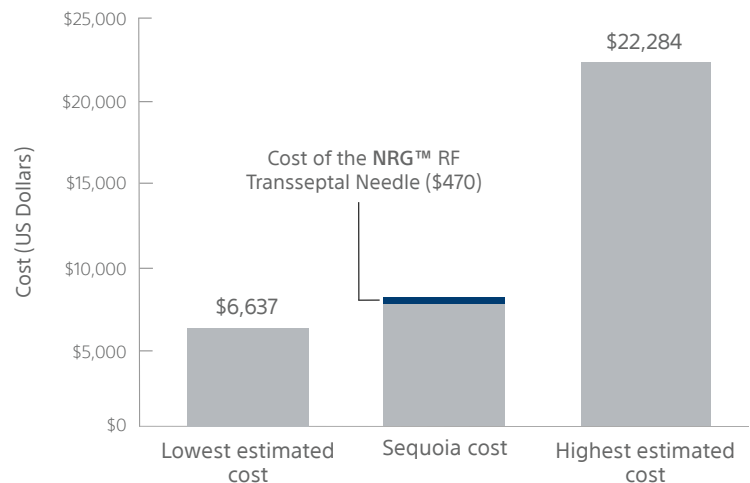
INTRODUCTION

- ▶ This study evaluated the cost-per-procedure used to perform an atrial fibrillation ablation procedure.

RESULTS AND DISCUSSION

- ▶ The lowest estimated cost-per-procedure was \$6,637 and the highest estimated cost-per-procedure was \$22,284.
- ▶ Sequoia Hospital follows a low cost-per-procedure equipment scenario of \$7,968, as they have found little scientific evidence to suggest that most of the higher valued equipment is safer or more efficacious.
- ▶ Sequoia Hospital, however, routinely uses three higher valued devices:
 - The **NRG™** Radiofrequency (RF) Transseptal Needle (Baylis Medical®)
 - Bi-directional irrigated RF ablation catheter
 - Variable diameter circular catheter to verify pulmonary vein isolation
- ▶ The authors routinely use the **NRG™** RF Transseptal Needle, which was shown to be safer with fewer tamponades, and which allows for greater efficacy and faster septal crossing compared to the mechanical transseptal needle.¹

Cost-per-procedure



* A wholly-owned subsidiary of Boston Scientific Corporation.

¹ Winkle, R.A., et al., The use of a radiofrequency needle improves the safety and efficacy of transseptal puncture for atrial fibrillation ablation. Heart Rhythm, 2011. 9(8): p. 1411-5. DOI: 10.1016/j.hrthm.2011.04.032

Brief Summary | **NRG™** Transseptal Needle

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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