



Highlights from:

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Radiofrequency Perforation and Conventional Needle Percutaneous Transseptal Left Heart Access: Pathological Features

INTRODUCTION

- ▶ This study compared the nature and extent of tissue injury and subsequent healing response to perforating radiofrequency (RF) energy compared with mechanical needle puncture.

METHODS

- ▶ Transseptal puncture was performed on piglets using either RF energy (Baylis Medical*) or a conventional mechanical needle, and were sacrificed at one hour (acute response) or one month (chronic response).
- ▶ Intentional RF perforation of the aortic root was performed on separate animals, representing a complication of any percutaneous transseptal access, which were sacrificed at one month.
- ▶ Gross and histopathological analyses were performed on harvested tissues.

RESULTS

Acute findings

- ▶ Gross RF lesions were similar to needle puncture characterized by subendocardial hemorrhage in the tissue margins with limited extension into the adjacent pericardial and pleural spaces, consistent with mechanical trauma due to sheath and dilator insertion.
- ▶ Mechanical needle injury pattern comprised of a mural thrombus surrounding the newly-created lumen, areas of hemorrhage and tissue edema consistent with acute inflammatory response, and focal contraction band necrosis in the adjacent myocardium.
- ▶ RF injury pattern consisted of minimal mural thrombus, thermal injury zone in the myocardium adjacent to the neolumen, and a halo of contraction band necrosis. This wound response fell short of classic coagulative necrosis characteristic of ablative RF.

Chronic findings

- ▶ A residual lumen was found in two of three animals at one month after mechanical needle puncture. Only one animal had a circumferential collagenous scar surrounding a region of residual granulomatous inflammation.
- ▶ A residual lumen was found in only one of three animals following RF puncture. All animals had well-developed circular scarring with homogenous fibrosis, neovascularization, and minimal residual inflammation.
- ▶ In the aortic perforation cases, dense collagen scar formation was observed with no residual patent defect or inflammation.

DISCUSSION AND CONCLUSIONS

- ▶ Similar extent of acute atrial tissue injury between RF and mechanical needle puncture, with well-developed healing at one month.
- ▶ All animals survived intentional aortic perforation, with healing and no evidence of inflammation at one month.
- ▶ Findings support the safety and clinical utility of RF energy for interatrial septal tissue puncture.

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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