Comparing the Safety and Effectiveness of Dedicated Radiofrequency Transseptal Wires to Electrified Metal Guidewires

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Abstract

Application of electrocautery to a metal guidewire can be used to perform transseptal puncture (TSP). Dedicated radiofrequency guidewires (RF) may represent a better alternative. This study compares safety and effectiveness of electrified guidewires to a dedicated RF wire. TSP was performed on porcine hearts using an electrified 0.014" or 0.032" guidewire under various power settings compared to TSP using a dedicated RF wire with 5W power. The primary endpoint was the number of attempts required to achieve TSP. Secondary endpoints included the rate of TSP failure, TSP consistency, effect of the distance between tip of the guidewire and the tip of the dilator, and effect of RF power output level. Qualitative secondary endpoints included tissue puncture defect appearance, thermal damage to the TSP guidewire or dilator, and tissue temperature using thermal imaging. The RF wire required 1.10 ± 0.47 attempts to cross the septum. The 0.014" electrified guidewire required 2.17 ± 2.36 attempts (2.0x higher than the RF wire; $p<0.01$), and the 0.032" electrified guidewire required 3.90 ± 2.93 attempts (3.5x higher than the RF wire; $p<0.01$). Electrified guidewires had a higher rate of TSP failure, larger defects, more tissue charring, higher temperatures, and greater tissue heating. Fewer RF applications were required to achieve TSP using a dedicated RF wire compared to an electrified guidewire. Smaller defects and lower tissue temperatures were also observed using the RF wire. Electrified guidewires required greater energy delivery and were associated with equipment damage and tissue charring.

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Abstract

Background

Application of electrocautery to a metal guidewire is used by some operators to perform transseptal puncture (TSP). Commercially available dedicated radiofrequency guidewires (RF) may represent a better alternative. This study compares safety and effectiveness of electrified guidewires to a dedicated RF wire.

Methods

TSP was performed on freshly excised porcine hearts using an electrified 0.014" or 0.032" guidewire under various power settings compared to TSP using a dedicated RF wire with 5W power (0.035" VersaCross RF System, Baylis Medical, Montreal, Canada). The primary endpoint was the number of attempts required to achieve TSP. Secondary endpoints included the rate of TSP failure, TSP consistency, effect of the distance between tip of the guidewire and the tip of the dilator, and effect of RF power output level. Qualitative secondary endpoints included tissue puncture defect appearance, thermal damage to the TSP guidewire or dilator, and tissue temperature using thermal imaging.

Results

The RF wire required on average 1.10 ± 0.47 attempts to cross the septum. The 0.014" electrified guidewire required an overall mean of 2.17 ± 2.36 attempts (2.0 times as many as the RF wire; $p<0.01$), and the 0.032" electrified guidewire required an overall mean of 3.90 ± 2.93 attempts (3.5 times as many as the RF wire; $p<0.01$). Electrified guidewires had a higher rate of TSP failure, and caused larger defects and more tissue charring than the RF wire. Thermal analysis showed higher temperatures and a larger area of tissue heating with electrified guidewires than the RF wire.

Conclusion

Fewer RF applications were required to achieve TSP using a dedicated RF wire compared to an electrified guidewire. Smaller defects and lower tissue temperatures were also observed using the RF wire. Electrified guidewires required greater energy delivery and were associated with equipment damage and tissue charring, which may present a risk of thrombus, thermal injury or scarring.

KEYWORDS

transseptal puncture, RF puncture, interatrial septum, atrial septal defect, diathermy, electrosurgery, RF wire

Disclosures

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Introduction

Transseptal puncture (TSP) is commonly performed using radiofrequency (RF) or mechanical needles to obtain left atrial (LA) access during procedures to treat heart rhythm disorders and structural heart disease.[1] Challenging TSP can occur due to anatomic variability, as well as in patients with a history of multiple ablations or congenital heart disease (CHD).[2, 3] Performing TSP on fibrotic or aneurysmal septa using traditional mechanical needles can lead to lower success rates and a higher risk of injury.[4] In comparison, dedicated radiofrequency (RF) transseptal needles have been shown to improve the rate of successful left atrial cannulation, as well as reduce procedure time[5] and complications such as cardiac tamponade[5] and plastic particle embolization[6] even in cases of challenging anatomy.[4, 7, 8]

While application of electrocautery to the proximal end of a mechanical transseptal needle has been used to facilitate catheterization of difficult septa, electrosurgical parameters have not been clearly defined or optimized for TSP, and there is variability between operators in power settings (20-50W), RF application times (up to 11s) and the number of energy applications required.[9-14] More importantly, electrifying a hollow needle can cause coring of cardiac tissue, presenting a risk of systemic embolization.[15]Use of electrocautery with standard metal guidewires has been proposed as an alternative to perform TSP;[16] however, the safety and effectiveness of this approach is unknown. Standard guidewires are not optimized for electrosurgical use and have been associated with several complications during laparoscopic procedures including guidewire fracture,[17, 18] stripping of the guidewire coating,[19] as well as electrical[20] and thermal injury[21-25]to patients. Recently, a dedicated RF transseptal wire (VersaCross Transseptal Solution, Baylis Medical, Montreal, Canada) has been shown to be safe and effective at both performing TSP and reducing device exchanges to improve procedural efficiency.[26, 27] The objective of this study was to compare the safety and effectiveness of electrified guidewires (EG) to a dedicated RF transseptal wire in an ex vivo porcine TSP model.

Methods

Experimental Model

An ex vivo porcine model was developed using hearts harvested the same day from swine weighing approximately 100kg. Punctures were performed on the interatrial septum using the dedicated RF wire and corresponding generator (RFP-100A, Baylis Medical), or by connecting a 0.014" coronary guidewire (Asta-to, Asahi Intecc, Aichi, Japan or BMW, Abbott Vascular, Abbott Park, IL) or a standard 0.032" guidewire (Paragon, Integer, Plano, TX) to an electrosurgical generator (ValleyLab, Medtronic, Boulder, CO). Several power settings (20W, 35W and 50W in cut mode) were used in each experiment utilizing electrified guidewires. RF power was manually applied to the proximal end of the guidewire for approximately 2 seconds using an electrocautery pen to represent common clinical use,[9, 11, 28] while a predefined 1 second pulse mode setting (approximately 5W) was delivered through the dedicated RF wire (Figure 1). The primary endpoint was the number of RF applications required for TSP. Secondary endpoints included TSP failure rate, TSP consistency, effect of RF power output level, and effect of distance between the tip of the guidewire and the tip of the dilator. Additional qualitative secondary endpoints included tissue puncture collateral damage (e.g. tissue charring, defect size, puncture morphology homogeneity), damage to the TSP guidewire or dilator (e.g. melting, charring and deformation) and the area of tissue heating and peak temperature measured using thermal imaging (FLIR E60, FLIR Systems, Austin, TX).

Atrial Septal Puncture

Interatrial septa isolated from 36 porcine hearts were immersed in a room temperature bath of 0.9% sodium chloride solution and positioned on a cork sample holder to normalize force applied during puncture (Figure 2A). RF energy was delivered using the RF wire and electrified guidewires under each power setting. Additional energy applications were delivered until the tip of the wire perforated the septum, or up to a maximum of 8 attempts. Failure to puncture was defined as the inability to perforate the septum after 8 RF applications. To model a range of conditions in clinical practice, multiple distances from the distal wire to the dilator tip were tested; 1mm (i.e. underexposure of wire tip), 3mm (i.e. ideal wire tip exposure) and 5mm (i.e. over-exposure of wire). The number of RF applications required to perforate the septum was recorded for each treatment condition. Each treatment condition was repeated at least six times. Inspection of puncture sites was performed immediately post-puncture under 30-50X magnification using an optical microscope (VHX-5000, Keyence, Osaka, Japan) to confirm TSP success and qualitatively assess the defect site.

Tissue Thermal Imaging

Approximately 6 cm of ventricular myocardium was isolated from the apex of porcine hearts and partially immersed in a room temperature saline bath (Figure 2B). Temperature was recorded using a thermal camera as RF was applied through each of the wires. The color scale was normalized with respect to room temperature as the baseline (black).

Statistical analysis

The number of energy applications required to successfully puncture the septal tissue for each treatment condition was assessed as a mean with standard deviation (95% confidence interval). The paired *t*- test was used to compare the number of applications. Levene's test was used to assess the homogeneity of variances. A probability value of <0.05 was used to determine statistical significance. Analyses were performed using Excel software (Microsoft Office 10, Microsoft, Seattle, USA).

Results

Tissue Puncture Effectiveness

The RF wire required on average 1.10 $\pm$ 0.47 attempts to cross the septum. The 0.014" electrified guidewire required an overall mean of 2.17 $\pm$ 2.36 attempts (2.0 times as many as the RF wire; $p<0.01$), and the 0.032" electrified guidewire required an overall mean of 3.90 $\pm$ 2.93 attempts (3.5 times as many as the RF wire; $p<0.01$, Figure 3A). Across power output levels, the 0.014" electrified guidewire required a range of 1.2-2.6 times as many applications as the RF wire, and the 0.032" electrified guidewire required 3.4-4.1 times as many attempts as the RF wire to perforate the septum (Figure 3B). The number of RF applications was significantly more consistent for the RF wire than both 0.014" and 0.032" electrified guidewires ($p<0.001$, Figure 3B). Increase in the power applied to electrified guidewires, from 20W to 50W, did not significantly improve the consistency in TSP success. Across all power settings, the 0.014" and 0.032" electrified guidewires failed to puncture the septum in 6% and 19% of tissues, respectively. The RF wire did not fail to perforate any of the tissue specimens.

While the dilator-wire tip distance had no measurable effect on the rate of successful puncture using the RF wire, an increase in distance from 1mm to 5mm reduced TSP effectiveness for both 0.014" and 0.032" electrified guidewires (Figure 3C). At 1mm dilator-wire tip distance, all wires perforated the septum on the first attempt. However, increasing the distance to 3mm and 5mm required more RF attempts and introduced variability in the TSP effectiveness, especially for electrified guidewire. At the maximum dilator-wire tip distance tested (5mm), the 0.014" electrified guidewire required 5.8 $\pm$ 3.4 attempts for TSP and failed to puncture in 40% of the septa after 8 attempts, while the 0.032" electrified guidewire failed to puncture in all septa after 8 attempts (Figure 3C).

Tissue Puncture Site Comparison

There were visually larger defects with a greater amount of tissue charring, and non-homogeneous morphology at puncture sites made by 0.014" and 0.032" electrified guidewires compared to the RF wire (Figure 4). These qualitative differences between electrified guidewires and RF wire septal defects were observed at all power settings and dilator-wire tip distances. Within electrified guidewire groups, the size of puncture defects appeared larger, and more charring was observed with increasing power.

Guidewire and Dilator Damage

Qualitative inspection of wires and dilators before and after TSP revealed varying levels of equipment damage with use of electrified guidewire (Figure 5). Shorter dilator-wire tip distances led to visually greater wire and dilator damage. While positioning the wire tip 1mm from the dilator improved the TSP effectiveness of electrified guidewire (Figure 3B), this created significant equipment damage including melting of 0.014" electrified guidewire, deformation and charring of 0.32" electrified guidewire, as well as melting and charring of the respective dilators (Figure 5). Using moderate dilator-wire tip distance (3mm), increasing the power applied to electrified guidewire increased the level of equipment damage (Supplementary Figure 1). In comparison, there was no sign of charring, melting or deformation using the dedicated RF wire at all dilator-wire tip distances (Supplementary Figure 1).

Tissue Puncture Thermal Impact

During RF application, heat distribution was visually larger in the case of electrified guidewires compared to the RF wire by thermal imaging (Figure 6). Peak temperature at the core of the heated area exceeded 100°C using electrified guidewires compared to approximately 30°C using the RF wire, indicating a greater temperature increase relative to baseline (room temperature). The larger heating area and higher peak temperature at the core were observed at all power settings when electrified guidewires were used relative to the RF wire.

Discussion

Tissue puncture using RF energy relies on transfer of alternating current to the target tissue to generate localized heating and tissue vaporization. Successful crossing requires focal delivery of current. The current density (rate of charge transfer per unit area) is dependent on the amount of delivered power and electrode size. Off-label application of electrocautery to metal guidewires during atrial septal puncture may lead to unintended damage to the dilator or guidewire itself with potential adverse clinical consequences. Firstly, electrified guidewires have an active electrode that is dependent on manual exposure of the wire from dilator (i.e. dilator-wire tip distance), which introduces uncertainty in the exact current density and, therefore, TSP effectiveness and consistency between cases. This may explain why more power was needed in the present study when using electrified guidewires compared to a dedicated RF wire. Additionally, electrified guidewires are typically coated with fluoropolymers and epoxy based hydrophilic coatings (such as polytetrafluoroethylene) for lubricity and electrical insulation, which has been suggested to be a source of current leakage along the entire length of the wire.[29, 30] This not only impacts the effective current density and TSP effectiveness, but also poses electrosurgical safety risks for patients[31-33] that can, otherwise, be mitigated by minimizing power[34, 35] and using dedicated insulated tools.[36, 37]

The present study compared the safety and effectiveness of a dedicated RF wire to electrified guidewires using a range of power settings and dilator-wire tip distances. The RF wire with pre-set average power of 5W demonstrated 100% success at TSP. While higher power with electrified guidewires was expected to correlate with increased current density and tissue vaporization, electrified guidewires had lower effectiveness and greater variability in TSP success between samples than the dedicated RF wire. Increasing the power applied to electrified guidewires from 20W to 50W did not translate into a substantial improvement on TSP effectiveness, suggesting the current leakage along the length of the guidewire may reduce the effectiveness of RF delivery. The distance between the dilator and wire tip did not significantly impact TSP using the dedicated RF wire, but appeared to have an inverse effect on TSP success using electrified guidewires. However, a small dilator-wire tip length also correlated with damage to both the wire and dilator tip, presenting a risk of particle liberation and embolization. At the maximum dilator-wire distance tested (5mm), the 0.014" electrified guidewires required significantly more RF applications than the RF wire, and the 0.032" guidewires failed to perforate the septum. The discrete active electrode and insulated shaft of the dedicated RF wire may explain why TSP effectiveness was not sensitive to the distance between the dilator and wire, and why no damage was observed on the RF wire or its dedicated dilator.

Perforation of the atrial septum using a dedicated RF system has been previously shown to create a similar extent of tissue injury and healing as mechanical needle puncture.[38] In the present study, electrified guidewires under all conditions led to larger tissue defects, evidence of tissue charring, and irregular morphology compared to the purpose-built RF system, suggesting a greater extent of tissue injury. Tissue charring has been correlated with thermal injury, destructive degeneration with amorphous or necrotic tissue,[21, 39] and thrombus formation.[40] Disruption of collagen and fibrous structures impact tissue elasticity[21] and may present a risk of tearing or persistent atrial septal defects.[41]

The use of higher power presents greater risks of electrosurgical injury[34, 35, 42] and thermal damage,[43] as well as thrombus[44] and coagulum formation.[14, 45]{Gowda, 2017 #17} Localized temperature measurements demonstrated higher core temperature and a visually larger area of tissue heating with use of electrified guidewires, as compared to the dedicated RF wire, which is consistent with the observed larger puncture defects, tissue charring and equipment deformation.

Overall findings suggest electrified guidewires create larger defects and are more sensitive to the distance between the tip of the wire and the tip of the dilator, which may be difficult to assess and control precisely in a clinical setting, thereby, causing uncertainty in TSP success and inconsistency between cases. Although the RF wire has a larger shaft diameter (0.035") compared to the electrified guidewires used in this study (0.014" and 0.032"), the size of septal defects appeared to be smaller.

Study Limitations

This benchtop model was designed to simulate TSP in clinical practice while allowing a direct measurement of TSP effectiveness and examination of tissue defects using ex vivo swine tissues. However, it did not account for factors such as blood flow and body temperature, which may affect tissue quality, heat dissipation and puncture site response. Application of diathermy to guidewires in this study was manually approximated to 2 seconds to mimic typical clinical use. This may have resulted in greater energy delivery than the 1 second output used with the dedicated radiofrequency wire. Histological examination of punctured tissues was not performed. Further in vivo studies are needed to confirm the observations from the present model as well as assess cost implications. A prior study comparing a dedicated RF needle system with a mechanical needle for TSP found that the overall cost of performing a TSP was lower with the RF needle despite higher equipment costs.[46]

Conclusion

A dedicated RF wire had greater success and consistency in achieving TSP compared to electrified metal guidewires, which required higher power, were more dependent on the distance between the wire tip and dilator tip, and required more RF applications to perforate tissues. Use of electrified guidewires for TSP was associated with damage to the guidewire and dilator and may present electrosurgical hazards, as well as risks of thrombus, thermal injury, and tissue scarring. Further studies are needed to identify the clinical implications of these findings and assess cost considerations related to routine use of dedicated RF wires for TSP.

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Figures

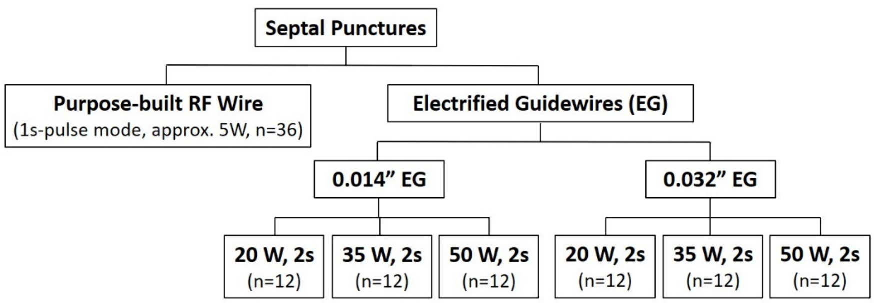


Figure 1. Transseptal puncture was performed using a dedicated RF wire or different electrified guidewires under various power settings.

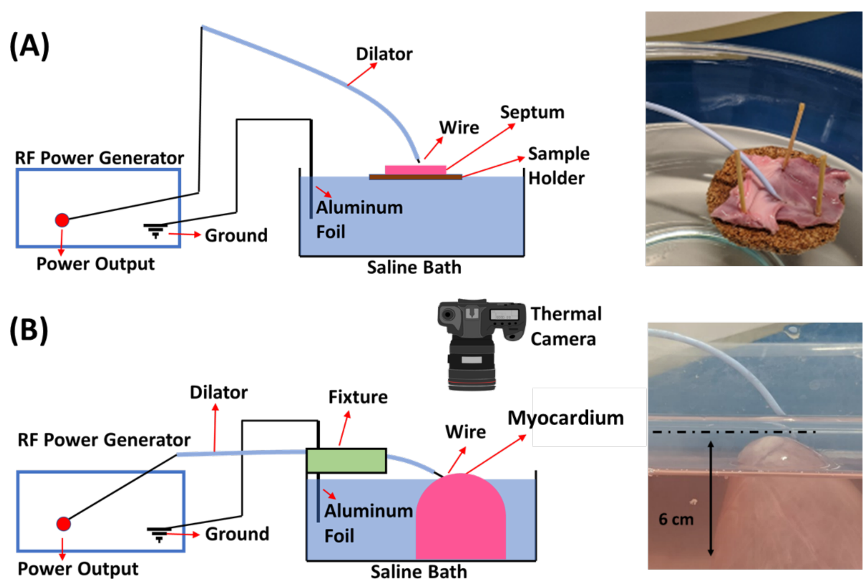


Figure 2. (A) Ex vivo septa were fixed onto a cork sample holder in a saline bath to perform transseptal puncture and to ensure consistent force application between experiments. (B) A thermal camera was placed above the myocardium that was immersed in a saline bath to capture the heat profile during RF delivery.

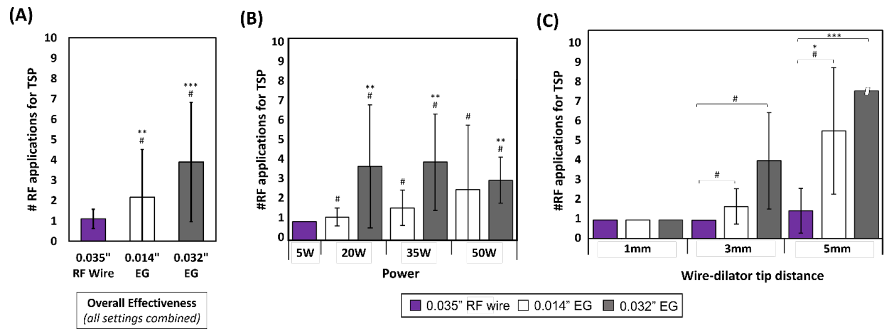


Figure 3. (A) Overall effectiveness of RF wire compared to electrified guidewires (EG) (B) 0.032" EG requires significantly more RF applications and both EGs have more variability between tissue samples than the dedicated RF wire. (C) TSP using the RF wire was 100% successful regardless of the distance between the wire tip and dilator tip, whereas effectiveness of EG declined with distance. Data reported as mean attempts to perforate each sample, up to 8 RF applications (Significance shown for electrified guidewires vs. RF wire. *p<0.05, **p<0.01, ***p<0.0001 for means between each group; #p $<$ 0.0001 for sample variance within each group).

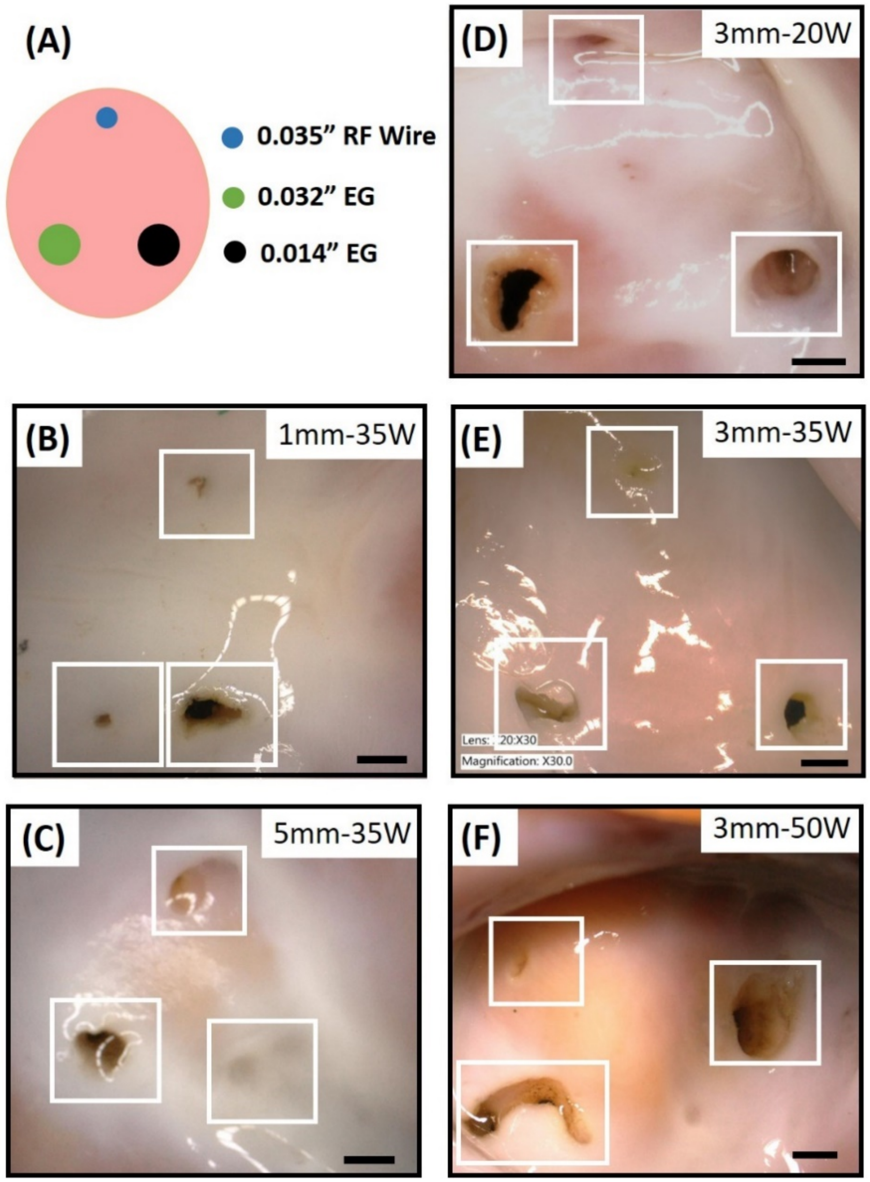


Figure 4. (A) Schematic layout showing multiple punctures made on the same septum using each wire under different dilator-wire tip distances and EG power settings, respectively: (B) 1mm and 35W, (C) 3mm and 20W, (D) 3 mm and 35W, (E) 3mm and 50W, and (F) 5mm and 35W. The dedicated wire in all experiments delivered a preset power of 5W. (Scale bar is 1mm.)

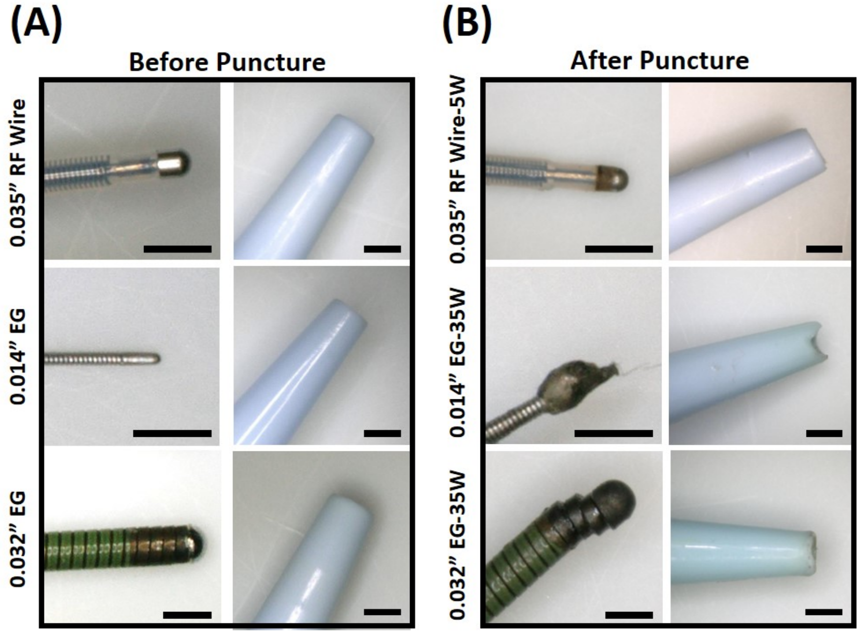


Figure 5. Representative images of the dedicated RF wire system, electrified guidewires (EG) and respective dilators using an optical microscope (A) before transseptal puncture and (B) after transseptal puncture. The dedicated RF wire system showed no damage. In both 0.014" and 0.032" EG setups, the metal wire tip was melted and/or deformed, and the respective dilator showed signs of melting and charring. Images show representative devices at moderate power levels and 1mm distance between the dilator tip and wire tip, corresponding to the highest EG transseptal puncture effectiveness. (Scale bar is 1mm.)

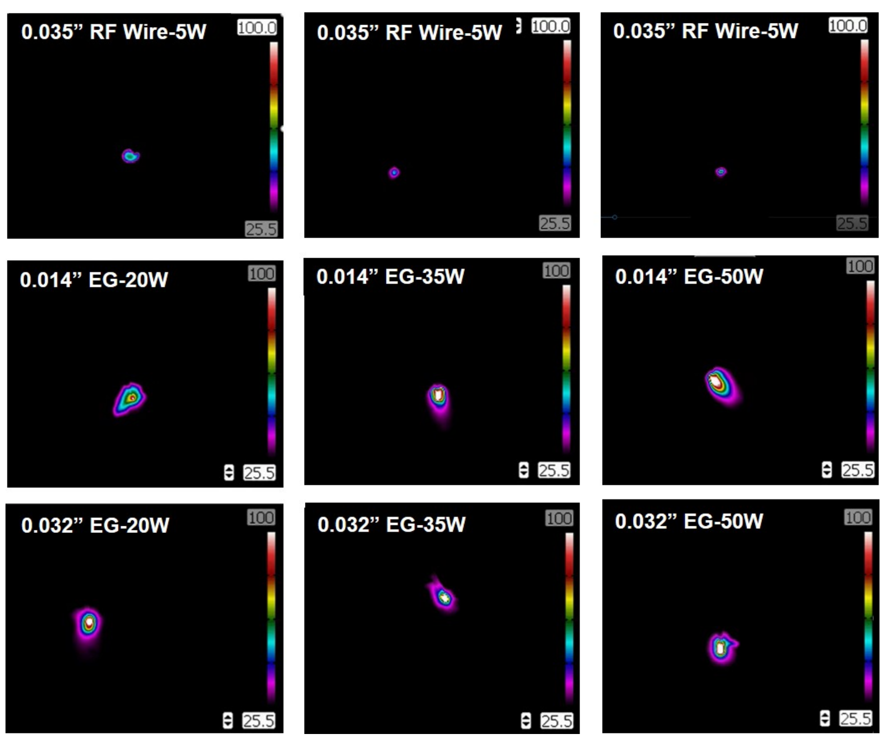
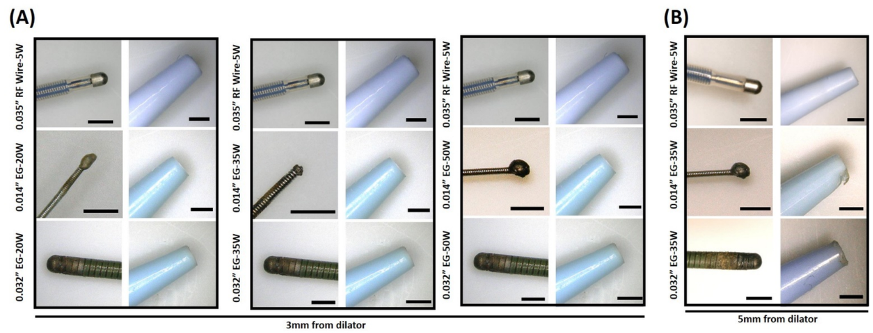


Figure 6. Thermal camera images of RF delivery using the 0.035” dedicated RF wire, 0.014” and 0.032” electrified guidewires (EG; 20, 35 and 50W delivered power). Temperature recordings were normalized to ambient room temperature (black), indicating an approximately 80°C temperature rise with electrified guidewires versus 10°C with the RF wire.



Supplementary Figure 1. Representative images of the dedicated RF wire system, electrified guidewires (EG) and respective dilators using an optical microscope at (A) 3mm dilator-wire tip distance and various power settings, or (B) 5mm dilator-wire tip distance at 35W power. The RF wire system showed no signs of damage. In both 0.014” and 0.032” EG setups, the metal wire tip was melted and/or deformed, and the respective dilator showed signs of melting and charring. (Scale bar is 1mm.)