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Comparison of Transseptal Puncture Using a Dedicated RF Wire Versus a Mechanical Needle With and Without Electrification in an Animal Model

HIGHLIGHTS

- In an ex vivo study, mechanical puncture using the FlexCath Cross™ (formerly known as AcQCross™)* Transseptal Solution (FC) required more force and device advancement than purpose-built radiofrequency (RF) puncture with the VersaCross™ RF Transseptal Solution (VC).
- VC (~10 W) achieved 100% transseptal puncture (TSP) success.
- FC required more power (30 W) to achieve 91% TSP success, and was associated with tissue charring, larger septal defects, and tissue coring in 57% of punctures.

INTRODUCTION

- The application of electrocautery to needles and guidewires for TSP as an alternative to dedicated RF systems may be associated with increased safety risks, such as tissue coring and thermal damage.
- This study compared the safety and efficacy of two commercially available transseptal systems:
  - **VersaCross™ RF Transseptal Solution (Boston Scientific):** An RF wire with a discrete, rounded electrode powered by the dedicated RFP-100A™ RF Puncture Generator†
  - **FlexCath Cross™ Transseptal Solution (Medtronic)*:** An open-ended, deployable mechanical needle powered by a standard electrosurgical generator.

METHODS

- **In vivo experiments:** RF puncture was performed on live swine with intracardiac echocardiography and fluoroscopy guidance, and evaluated for possible tissue cores.
- **Ex vivo experiments:** Punctures were performed on freshly excised swine septa (Table 1) in 100% egg white solution, which has similar electrical conductivity as human blood.
  - Mechanical force and device displacement were measured using an Instron mechanical tester (Instron).
  - Qualitative assessment of defect size and tissue charring was performed post-puncture using an optical microscope.
  - Tissue coring was confirmed using Masson's trichrome staining and blinded pathology analysis.

Transseptal Device	Puncture Method
VersaCross RF Transseptal Solution	RF: 1 s constant mode (~10 W)
FlexCath Cross Transseptal Solution*	Mechanical force RF: 10 W (up to 5 attempts) 20 W, 30 W (up to 2 attempts each)

Table 1. TSP settings for ex vivo experiments.

RESULTS

Efficacy

- VC achieved 100% TSP success with ~10 W power and required only 1.0 ± 0.0 attempts (Figure 1A).
- FC required a greater amount of power (30 W) and 1.53 ± 0.51 attempts to achieve 91% puncture success (FC failed to puncture at 10 W and 20 W) (Figure 1A).

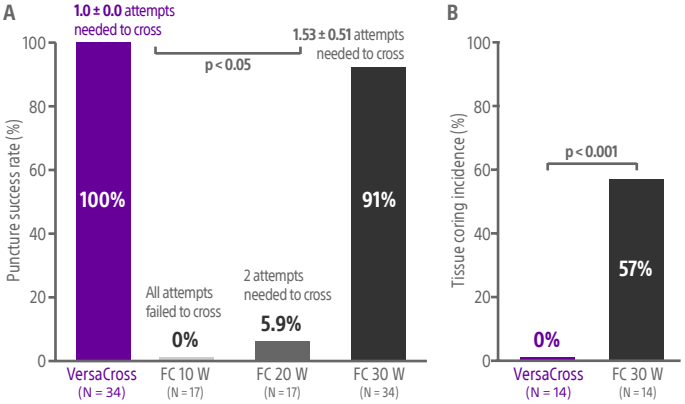

Figure 1. Compared to the FlexCath Cross (FC) system, (A) the VersaCross system required fewer puncture attempts and less power to achieve transseptal puncture, and (B) had zero incidence of tissue coring.

Safety

- In vivo TSP in swine using FC at 30 W resulted in multiple particulates that may have included tissue cores.
- Mechanical puncture with the FC needle required 6x more force and 8 mm more device advancement compared to RF puncture using VC ($p < 0.05$).
- FC needle punctures with 30 W of energy were associated with more tissue charring and larger defects.
- Tissue cores (0.5 – 3.2 mm) were observed in 57% of successful punctures using electrified FC needles (Figure 1B).

DISCUSSION AND CONCLUSIONS

- Excessive force and displacement using a sharp-tipped mechanical needle risks unintended puncture and injury.
- For energy-assisted TSP, electrode current density at the tissue interface and RF generator energy waveform impact TSP efficacy and safety.
  - 100% TSP success was achieved with 1 energy application using the purpose-built VersaCross system.
  - The open-ended FlexCath Cross needle required higher power and multiple energy applications for RF TSP, and was associated with tissue coring.
- These findings corroborate previous studies showing purpose-built RF devices improve TSP consistency and reliability in patients with varying anatomies[1,2], and have lower risk of thermal damage and tissue coring vs. non-dedicated devices.[3,4]

* This study was performed using the AcQCross™ Transseptal Access System, which is now rebranded as the FlexCath Cross™ Transseptal Solution, Medtronic.
† Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

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