Biosense Webster
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Focus on Safety in Atrial Fibrillation Ablation

The articles in this email may consist of clinical trials and observational studies as well as economic analyses. Access to these articles and to additional clinical articles with similar results are provided through the emebedded links. Membership to individual sites may be required in order to access the material.

Comparison of Atrioesophageal Fistula Rates Between Contact Force-Sensing and Non-Contact Force-Sensing Catheters

Calkins H, Natale A, Gomez T, Etlin A, Bishara M. Comparing rates of atrioesophageal fistula with contact force-sensing and non-contact force-sensing catheters: analysis of post-market safety surveillance data. *J Interv Card Electrophysiol.* 2019 Nov 22. doi: 10.1007/s10840-019-00653-5. [Epub ahead of print]

OBJECTIVE

- To assess the incidence of atrioesophageal fistula associated with contact force-sensing and noncontact force-sensing catheters

METHOD

- Retrospective analysis of the number of atrioesophageal fistula events from 2014–2017 calculated from Biosense Webster Inc.'s complaint database
- Sales data used as proxy for total number of procedures

RESULTS

- Contact force and noncontact force catheters have comparably low incidence of atrioesophageal fistula events, even when contact force-sensing catheters were used two-to-five times more frequently in left-sided procedures
- High power, high force, and long radiofrequency duration were delivered on the posterior wall of the left atrium in all 7 reported atrioesophageal fistula events

Incidence of atrioesphageal fistula (AEF) Jan. 2014 – Dec. 2017

Catheter type	Incidence of AEF % of sales (SD)
THERMOCOOL SMARTTOUCH® contact force family of catheters	0.006 (0.003)
THERMOCOOL® noncontact force family of catheters	0.005 (0.003)

P=0.69 (Two-tailed Mann-Whitney U test)

KEY TAKEAWAYS

- Contact force and non-contact force catheters have a similar incidence of atrioesophageal fistula, even though contact force catheters were used more frequently for left atrial procedures

ARTICLE WITH SIMILAR RESULTS

Macle L, Frame D, Gache LM, Monir G, Pollak SJ, Boo LM. Atrial fibrillation ablation with a spring sensor-irrigated contact force-sensing catheter compared with other ablation catheters: systematic literature review and meta-analysis. *BMJ Open* 2019; 9:e023775.

Predictors of Cardiac Perforation with Catheter Ablation of Atrial Fibrillation

Friedman DJ, Pokorney SD, Ghanem A, et al. Predictors of cardiac perforation with catheter ablation of atrial fibrillation. *JACC Clin Electrophysiol.* 2020 In press.

OBJECTIVE

- To identify factors associated with the risk of cardiac perforation for atrial fibrillation ablation in contemporary clinical practice

METHOD

- Retrospective analysis of Medicare beneficiaries who underwent atrial fibrillation ablation between July 1, 2013 and December 31, 2017
- Logistic regression models were used to assess predictors of cardiac perforation

RESULTS

- The rate of cardiac perforation declined from 0.67% in 2013 to 0.52% in 2017
- **Cardiac perforation rate is low and occurred in 0.61% (623/102,389) of patients within 30 days of index ablation procedure**
- Female sex, obesity, and non-use of intracardiac echocardiography (ICE) are associated with increased risk for perforation, while cardiac surgery is associated with decreased risk of perforation

Factors Associated with Cardiac Perforation

4.9x
Increased odds when ICE was not used

1.4x
Increased odds for female sex

1.4x
Increased odds for obesity

KEY TAKEAWAYS

- Cardiac perforation is a rare complication of atrial fibrillation ablation and incidence has decreased over time
- Use of intracardiac echocardiography (ICE), a modifiable factor, is one of the strongest predictors of lowering risk of cardiac perforation today.

ARTICLE WITH SIMILAR RESULTS

Goya M, Frame D, Gache L, et al. The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: meta-analysis of efficiency, effectiveness, and safety outcomes. *J Cardiovasc Electrophysiol.* 2020;31(3):664-673.

FORWARD TO A FRIEND

In the US, 4mm Catheters (NAVISTAR® Catheter, CELSIUS® Catheter, EZ STEER® Catheter (NAV and Non-NAV) have a "General Indication" for creation of endocardial lesions in patients 4 years of age and older. This "General Indication" includes treatment of Ventricular Tachycardia.

THERMOCOOL® Navigation Catheters are indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with CARTO® 3 Systems (excluding NAVISTAR® RMT THERMOCOOL® Catheter).

Bertaglia E, Bella PD, Tondo C, Proclemer A, Bottoni N, De Ponti R, et al. Image integration increases efficacy of paroxysmal atrial fibrillation catheter ablation: results from the CARTOMERGE® Module Italian Registry. Europace 2009;11:1004-1010.

THERMOCOOL® Navigation Catheters are indicated for the treatment of recurrent drug/device refractory sustained monomorphic ventricular tachycardia (VT) due to prior myocardial infarction (MI) in adults

The NAVISTAR® THERMOCOOL® and EZ STEER® THERMOCOOL® NAV Catheters are FDA approved for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation, when used with compatible three-dimensional electroanatomic mapping systems.

In the US, Biosense Webster THERMOCOOL® Non-Navigational Catheters are indicated for the treatment of Type I Atrial Flutter in patients 18 years of age or older.

Always verify catheter tip location using fluoroscopy or IC signals and consult the CARTO® 3 System User Guide regarding recommendations for fluoroscopy use. Pellegrino, P.L., Brunetti, N.D., Gravina, D., Sacchetta, D., De Sanctis, V., Panigada, S., Di Biase, L., Di Biase, M., and Mantica, M. (2013). Nonfluoroscopic mapping reduces radiation exposure in ablation of atrial fibrillation. Journal of cardiovascular medicine 14, 528-533. Earley, M.J., Showkathali, R., Alzetani, M., Kistler, P.M., Gupta, D., Abrams, D.J., Horrocks, J.A., Harris, S.J., Sporton, S.C., and Schilling, R.J. (2006). Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial. Eur Heart J 27, 1223-1229

Caution: US law restricts this device to sale by or on the order of a physician. Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.