Comparing Rates of Atrioesophageal Fistula with Contact Force-Sensing and Non-Contact Force-Sensing Catheters: Analysis of Post-Market Safety Surveillance Data

OBJECTIVE

To determine the incidence of atrioesophageal fistula (AEF) associated with the use of contact force sensing and non-contact force-sensing catheters.

METHODOLOGY

RETROSPECTIVE DATA ANALYSIS
January 2014 to December 2017

Atrioesophageal fistula events calculated from Biosense Webster Inc.'s complaint database

Proprietary device sales data were used as proxy for the total number of procedures to calculate incidence rates

OUTCOMES

INCIDENCE OF AEF EVENTS

PARAMETERS ASSOCIATED WITH AEF EVENTS

RESULTS

INCIDENCE OF ATRIOESOPHAGEAL 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® non-contact force family of catheters	0.005 (0.003)

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

Contact force and non-contact force catheters have **comparably low incidence of atrioesophageal fistula events**, even when **contact force-sensing catheters** were **used 2 to 5 times more frequently** in left-atrial procedures.

LEFT ATRIUM POSTERIOR WALL ABLATION PARAMETERS FOR 7 ATRIOESOPHAGEAL FISTULA CASES VOLUNTARILY PROVIDED BY PHYSICIANS

Posterior Wall Ablation Parameter	Mean (SD)
Power Maximum, W VisiTags >25 W, %	43 (2) **95 (9)**
Contact force Maximum contact force when >25 W, g VisiTags 10–20 g, % VisiTags 20–30 g, % VisiTags 30–40 g, %	**47 (10)** 41 (15) 24 (12) 9 (6)
Duration Total time, min Maximum tag duration, s VisiTags >20 s, %	9 (4) 35 (7) **35 (34)**

High power, high force, and **long radiofrequency duration** were delivered on the posterior wall of the left atrium in the **7 cases of physician-reported AEF events.**

CONCLUSION

Contact force and non-contact force catheters were found to have **similarly low atrioesophageal fistula incidences**, even though **contact force catheters were used more frequently** for left atrium procedures.

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.

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