CLINICAL EVIDENCE FOR ROBOTICS IN EP

DATA TRANSPARENCY

Because safety and better outcomes for patients are your first priorities

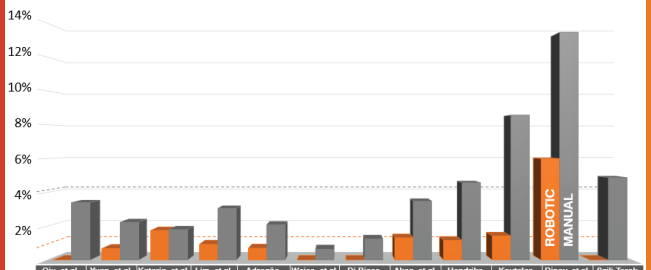
ROBOTIC VS. MANUAL

>50 PATIENTS

2012-2020

We believe data should be presented clearly and comprehensively. That's why we present data from all known publications describing robotic vs. manual cardiac catheter ablations in head-to-head comparisons with greater than 50 patients since 2012.

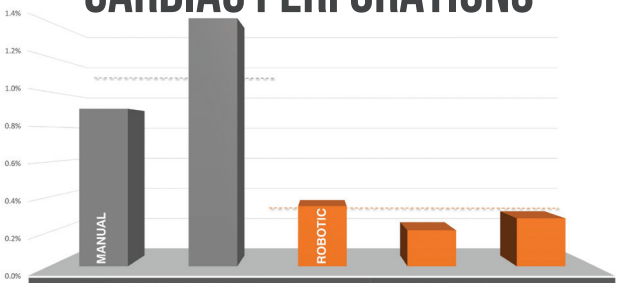
MAJOR ADVERSE EVENTS



	Qiu, et al. 2018	Yuan, et al. 2017	Kataria, et al. 2017	Lim, et al. 2017	Adragão, et al. 2016	Weiss, et al. 2016	Di Biase, et al. 2015	Akca, et al. 2015	Hendriks, et al. 2015	Koutalas, et al. 2015	Dinov, et al. 2012	Szili-Torok, et al. 2012
n=152	214	336	443	574	627	218	1,517	239	140	102	113	
PVC	AF	AF	AF	AF	AF	VT	AF, SVT, VT	VT	AF	VT	VT	

Major adverse event rates comparing robotic (orange) vs. manual navigation (gray) in head-to-head publications of >50 patients from 2012-2019. Studies which did not report data for major adverse events or reported no major adverse events in either group were excluded.
AF=Atrial Fibrillation, PVC=Premature Ventricular Contraction, SVT=Supraventricular Tachycardia, VT=Ventricular Tachycardia

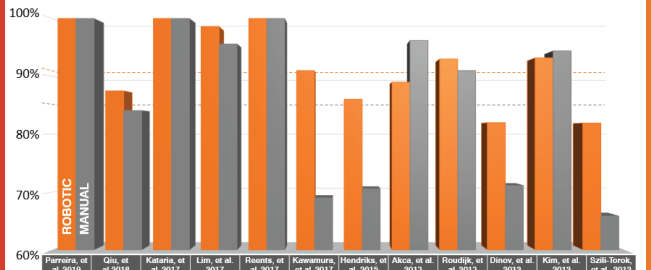
CARDIAC PERFORATIONS



SAFER[18] German Registry	RMN Published Controlled Studies[6, 8, 10, 11, 14, 16, 19-25]		RMN Published Observational Studies[26-49]	FDA MAUDE Database[50]
2010 – 2017	2003 – 2017		2003 – 2017	2010 – 2018
n= 21,141	1,434	1,831	2,851	17,940

Rate of cardiac perforations with manual navigation (gray) vs. RMN (orange).

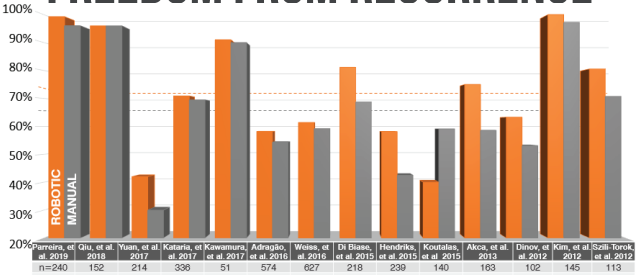
ACUTE SUCCESS



	Parreira, et al. 2019	Qiu, et al. 2018	Kataria, et al. 2017	Lim, et al. 2017	Reents, et al. 2017	Kawamura, et al. 2017	Hendriks, et al. 2015	Akca, et al. 2013	Roudijk, et al. 2013	Dinov, et al. 2012	Kim, et al. 2012	Szili-Torok, et al. 2012
n=240	152	336	443	218	51	239	163	82	102	145	113	
SVT	PVC	AF	AF	SVT	VT	VT	AF, SVT, VT	SVT	VT	AP	VT	

Acute success rates comparing robotic (orange) vs. manual navigation (gray) in head-to-head publications of >50 patients from 2012-2019. Studies which did not report acute success data were excluded. *AF=Atrial Fibrillation, AP= Accessory Pathway-Mediated Tachycardia, PVC=Premature Ventricular Contraction, SVT=Supraventricular Tachycardia, VT=Ventricular Tachycardia*

FREEDOM FROM RECURRENCE



	Parreira, et al. 2019	Qiu, et al. 2018	Yuan, et al. 2017	Kataria, et al. 2017	Kawamura, et al. 2017	Adragão, et al. 2016	Weiss, et al. 2016	Di Biase, et al. 2015	Hendriks, et al. 2015	Koutalas, et al. 2015	Akca, et al. 2013	Dinov, et al. 2012	Kim, et al. 2012	Szili-Torok, et al. 2012
n=240	152	214	336	51	574	627	218	239	140	163	102	145	113	
SVT	PVC	AF	AF	VT	AF	AF	VT	VT	AF	AF, SVT, VT	VT	AP	VT	
1.4 Years	2.2	3.5	2.2	2.1	2.6	1.0	1.3	2.1	2.4	1.6	1.1	1.8	1.7	

Freedom from recurrence rates comparing robotic (orange) vs. manual navigation (gray) in head-to-head publications of >50 patients from 2012-2019 with follow-up greater than or equal to one year. Studies which reported follow-up of less than one year or did not report freedom from recurrence data were excluded. *AF=Atrial Fibrillation, AP= Accessory Pathway-Mediated Tachycardia, PVC=Premature Ventricular Contraction, SVT=Supraventricular Tachycardia, VT=Ventricular Tachycardia*

Stereotaxis robotic technology has been described in more than 400 scientific publications. Review the above data in detail and discover the full, searchable database of publications at www.RoboticEP.com/clinical-data

STEREOTAXIS™

KEY CLINICAL EVIDENCE FOR ROBOTICS IN EP

ATRIAL FIBRILLATION

- Ghadban R et al. ,2020. "Radiofrequency atrial fibrillation with irrigated tip catheter using remote magnetic navigation compared with conventional manual method." *Journal of Interventional Cardiac Electrophysiology* 95-102.
  - MAN & RMN are comparible in terms of AF Ablation success rates
  - RMN has lower complication rates and fluoroscopy times, but longer procedural times.

- Noten AME et al. 2019. "Robotic Navigation Shows Superior Improvement in Efficiency for Atrial Fibrillation Ablation." *Journal of Atrial Fibrillation*
  - RMN showed greater generational improvement in procedure times compared to CRYO and MCN

- Luo Q et al. "Utilization of steerable sheath improves the efficiency of atrial fibrillation ablation guided by robotic magnetic navigation compared with fixed-curve sheath." *Clin Cardiol*. 2022 Feb 23. doi: 10.1002/clc.23801. Epub ahead of print. PMID: 35195273.
  - Steerable sheaths reduce procedure times versus fixed sheaths: 90.4 ± 20.7 versus 111.9 ± 25.2 min, $p < .001$
  - Utilization of steerable sheath technology can improve the efficiency of AF ablation guided by RMN, primarily by reducing the total procedure and RF delivery times without compromising safety. Procedure time 111.9 ± 25.2 vs. 90.4 ± 20.7 min, $p < .001$

VENTRICULAR ARRHYTHMIAS

- Blandino A, et al. "Outcomes of manual versus remote magnetic navigation for catheter ablation of ventricular tachycardia: a systematic review and updated meta-analysis". *Pacing Clin Electrophysiol.* 2021 Jun;44(6):1102-1114. doi: 10.1111/pace.14231. Epub 2021 Apr 24. PMID: 33825206.
  - RMN was superior to MAN guided CF ablations in terms of acute success, complications, and fluoro times

- Hendriks et al. "Safety & Clnical Outcome of Catheter Ablation of Ventricular Arrhythmias Using Contact Force Sensing, Consecutive Case Series" *J Cardiovasc Electrophysiol.* 2015 Jul
  - RMN was superior with regard to acute success, reduction of major complications, and recurrence rate.

SVT & CONGENITAL

- Roy K et al. 2016 "RMN for catheter ablation in patients with CHD: A Review" *Journal of Cardiovascular Electrophyisology*. Vol 6
  - Editorial on advantages of RMN in the setting of ACHD

- Noten AME et al. 2021. "RMN shows superior long-term outcomes in pediatric atrioventricular (nodal) tachycardia ablation compared to manual radiofrequency and cryoablation" *International Journal of Cardiology Heart and Vascular*. Vol 3
  - RMN had significantly lower recurrence rates compared to MAN and CRYO at mean follow-up of 5.5 ± 2.9 years (AVRT: 4.3% versus 15.6% versus 54.5%, $P < 0.001$; AVNRT: 7.7% versus 8.3% versus 35.7%, $p= 0.008$; for RMN versus MAN versus CRYO respectively).

CLINICAL SCIENCE

- Bhaskaran A et al. "Magnetic guidance versus manual control: comparison of radiofrequency lesion dimensions and evaluation of the effect of heart wall motion in a myocardial phantom." *J Interv Card Electrophysiol.* 2015;44(1):1-8.
  - In vitro simulations show that robotic catheters are more stable on simulated wall motion, leading to more focal lesions

- Bun S-S et al. 2017. "Radiofrequency catheter ablation of atrial fibrillation: Electrical modification suggesting transmurality is faster achieved with remote magnetic catheter in comparison with contact force use." *Journal of Cardiovascular Electrophysiology* 1-9.
  - Faster EGM modification is achieved with RMN due to increased catheter stability

- Luo Q et al. "Utilization of steerable sheath improves the efficiency of atrial fibrillation ablation guided by robotic magnetic navigation compared with fixed-curve sheath." *Clin Cardiol*. 2022 Feb 23. doi: 10.1002/clc.23801. Epub ahead of print. PMID: 35195273.
  - Signal energy attenuation and impedance drop were evaluated as lesion dimension surrogates and signal fragmentation and shrinkage were estimated as lesion quality surrogates.
  - RMN creates more homogeneous lesion sets. MCN lesions are larger but less homogeneous relative to RMN.

STEREOTAXIS™