

Evaluation of surgical electromagnetic interference in leadless pacemakers



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Introduction

The number of patients receiving the Micra single-chamber transcatheter pacing system (Medtronic, Minneapolis, MN) has been increasing since The Food and Drug Administration (FDA) approval in 2016. These patients are now presenting for procedures requiring electrosurgery. Electrosurgery can potentially cause oversensing of electromagnetic interference (EMI), pacing inhibition, and device reset. The Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) consensus statement on perioperative management of devices does not yet address patients with leadless pacemakers.¹ Mickus and colleagues² report 1 patient who had 2 head/neck surgeries with no perioperative reprogramming and no pacing inhibition noted. Beyond this there is limited published data on surgical EMI in patients with Micra leadless pacemakers.

The objective of this case series is to evaluate for evidence of oversensing of EMI or device reset in subjects who required a surgical procedure with electrosurgery or biopsy with an implanted Micra leadless pacemaker.

Case report

Methods

This case series was approved by Edward Elmhurst Health Institutional Review Board (Clinicaltrials.gov registration number NCT03508128). All adult patients with Micra leadless pacemakers implanted at Edward-Elmhurst from May 2016 to March 2018 who then required a procedure with electrosurgery or biopsy were enrolled. Age, sex, indication for Micra leadless pacemaker, pacemaker dependence, and perioperative procedure data were collected. Postoperative interrogations were obtained from either hospital or next

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KEY TEACHING POINTS

- The number of patients receiving the Micra single-chamber transcatheter pacing system has been increasing since The Food and Drug Administration approval in 2016. These patients are now presenting for procedures requiring electrosurgery.
- Given the small size of the Micra leadless pacemaker, there is no hall sensor that would trigger mode change to asynchronous VOO pacing in the presence of a magnet. It will be important to determine risk of oversensing electromagnetic interference (EMI) for surgical procedures to determine who, if any, will require reprogramming.
- There was no evidence of oversensing of EMI or device reset in Micra leadless pacemakers during electrosurgery or biopsy in this small case series. Reprogramming asynchronous VOO may not be necessary for surgery.

scheduled remote/office visits. All postprocedure device interrogations were reviewed to determine evidence of oversensing from EMI or device reset. There are no high-rate episode logs or details in Micra leadless pacemakers. Heart rate histograms were reviewed for sensed ventricular beats > 200 beats per minute (bpm) that could also be suggestive of EMI.

Sensing integrity counters (SIC) were used to identify nonphysiologic short V-V intervals that could be suggestive of EMI. The SIC is a counter within Medtronic devices that detects senses occurring at cycle lengths < 140 ms. For traditional cardiac systems, SIC is a diagnostic counter included as part of the lead integrity alert algorithm intended to uncover nonphysiological senses from lead failure, but it has also uncovered non-lead system failure events, including EMI.³ Although Micra is not a lead, nor does it have the lead integrity algorithm available, it does have the SIC diagnostic, which may assist in uncovering nonphysiological sensed events such as EMI.

Table 1 Procedures and outcomes

Procedure	Type of electrosurgery or biopsy	Mode	Sensitivity	SIC	Heart rate > 200 bpm*	Device reset	Reported pacing inhibition
Hysterectomy, salpingectomy, and repair of enterocele	Monopolar	VVIR	2.0 mV	SIC 0	No	No	No
Foot ulcer debridement and toe amputation	Monopolar	VVI	2.0 mV	SIC 0	No	No	No
Neck exploration and mediastinal drainage	Monopolar	VVI	2.0 mV	SIC 0	No	No	No
Cystoscopy, bladder biopsy, and fulguration	Fulguration and biopsy	VVI	1.5 mV	SIC 0	No	No	No
EGD with biopsy	Biopsy	VVI	1.5 mV	SIC 0	No	No	No
Exploratory laparotomy and colon resection	Monopolar	VVI	1.5 mV	SIC 0	No	No	No
Repair hip fracture	Monopolar	VVI	2.0 mV	SIC 0	No	No	No

EGD = esophagogastroduodenoscopy; SIC = sensing integrity counter.
*On heart rate histogram.

Postprocedure programmed parameters were reviewed for evidence of device reset. Device reset for Micra leadless pacemakers is VVI 65 bpm with programmed sensitivity of 2.80 mV and programmed amplitude of 3.5 V at 0.24 ms. Anesthesia, surgical, and nursing records were reviewed for any documentation of pacing inhibition.

Results

Results are summarized in [Table 1](#). There were 6 subjects who had 7 procedures. Mean age was 79 years and 3 of 6 subjects (50%) were male. Only 1 subject (17%) was pacemaker dependent. Five of the 6 (83%) had an indication of atrioventricular block with atrial fibrillation and 1 subject had an indication of atrioventricular block in the absence of atrial fibrillation.

All subjects had routine monitoring during their procedures in the presence of an anesthesiologist. Electrosurgical return pad “grounding pad” location was per routine. Five subjects had surgery requiring monopolar electrosurgery, 1 subject had bladder fulguration, and 1 had esophagogastroduodenoscopy with biopsy. No subjects had histograms with high ventricular rates > 200 bpm and all SIC were 0. There was no reported pacing inhibition. No subjects had device reset.

Discussion

It will be important to determine the risk of oversensing EMI for surgical procedures to determine which patients, if any, will be at risk and may require preoperative reprogramming to asynchronous pacing. Given the small size of the Micra leadless pacemaker, there is no hall sensor, which would trigger mode change to asynchronous VOO pacing in the presence of a magnet. Medtronic recommends that if pacing inhibition is of concern, perioperative asynchronous programming can be considered. In this series there was only 1 subject who was pacemaker dependent and no pacing inhibition was reported on chart review in any subject, but clearly more subjects will need to be evaluated.

Although this is a small case series, it is encouraging that there is no evidence of EMI in neck, abdominal, and lower

extremity procedures. There is a possibility that very short episodes of oversensing were not stored, but this would likely be of no clinical significance. We were only able to evaluate heart rate histograms, as there are no stored episode details or logs in Micra leadless pacemakers. Although Medtronic’s recommendation for minimizing risk of surgical EMI is consistent with transvenous devices, the clinician workflow and true risk of EMI in leadless pacemakers still needs to be determined.

Conclusion

The number of patients receiving the Micra single-chamber transcatheter pacing system has been increasing since FDA approval in 2016. These patients are now presenting for procedures requiring electrosurgery. We evaluated 6 subjects with Micra leadless pacemakers who underwent 7 procedures involving surgery or esophagogastroduodenoscopy and found no evidence of oversensing of EMI or device reset. Reprogramming to asynchronous pacing may not be necessary for surgery. A larger multicenter study with intraoperative evaluation of pacing inhibition is warranted.

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