

Ventricular tachyarrhythmias in patients with Micra™ leadless cardiac pacemakers - a safety study with implantable loop recorders

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Introduction:

Several studies have demonstrated high implantation success rates and low device-related complication rates with stable pacing thresholds and sensing values for Micra™ leadless cardiac pacemakers (LCP). However, malignant ventricular tachyarrhythmias caused by suspected pro-arrhythmogenic effects of LCP leading to life-threatening critical conditions were recently described in case reports.

Methods:

The aim of this single-center study was to investigate the incidence of ventricular tachyarrhythmias in patients with Micra™ LCP during the index stay and after hospital discharge with implantable loop recorders (ILR).

Results:

No sustained ventricular tachyarrhythmias occurred in 283 patients with Micra™ LCP during the index stay after implantation. Eleven of these patients were monitored with an ILR over a median follow up duration of 22.9 months (IQR 5.7 – 31.5 months) (Table 1). ILR interrogations revealed no ventricular tachyarrhythmias (nsVT: n = 0, VT: n = 0, VF: n = 0) (Table 2). Pacing thresholds and sensing values of the LCP remained stable, whereas battery capacity and electrode impedance declined over time (Figure 1). The ILR did not detect any malfunctions of the LCP (asystole > 3 seconds: n = 0, bradycardia < 40/min: n = 0). No serious adverse events (syncope, stroke, pericardial effusion) occurred during the follow-up period.

ID	Age [years]	Sex	CAD	Hypertension	Diabetes	CKD	TAVR	Rhythm at implantation	EF [%]	ILR indication	ILR to LCP [months]	LCP indication	LCP position	Follow-up after LCP implantation [months]
#1	83	male	yes	yes	yes	no	yes	SR	60	AVB I and LBBB post TAVR	2.9	AVB III and pauses of 7 sec.	septal	33.1
#2	75	male	yes	yes	yes	yes	no	SR	60	recurrent syncope	3.0	paroxysmal AF and bradycardia < 30/min	septal	33.3
#3	36	male	no	no	no	no	no	SR	60	Lyme Carditis with intermittent AVB III	3.0	AVB III and pauses of 10 sec.	septal	23.7
#4	33	male	no	no	no	no	no	SR	65	syncope, suspected epilepsy	3.7	SSS and pauses of 4.8 sec.	apical	23.6
#5	81	female	yes	yes	no	no	yes	SR	65	AVB I and LBBB post TAVR	6.4	SSS with sinus arrest and pauses of 3 sec.	septal	22.6
#6	76	male	yes	yes	no	no	yes	SR	65	LAH and RBBB post TAVR	13.7	AVB III and pauses of 5 sec.	septal	22.4
#7	76	male	no	yes	no	yes	no	AF	65	recurrent syncope	7.4	SSS and pauses of 6.5 sec.	septal	7.9
#8	82	male	yes	yes	yes	yes	yes	SR	60	AVB I post TAVR	3.2	AVB III and pauses of 4 sec.	septal	29.0
#9	81	male	no	yes	no	no	no	AF	65	recurrent syncope	0.2	AF and pauses of 9 sec.	septal	15.2
#10	42	male	no	no	no	no	no	SR	60	presyncope	37.9	AVB III and pauses of 8 sec.	septal	8.6
#11	79	female	no	yes	yes	no	yes	SR	60	Post TAVR	51.4	Intermittent AVB III	septal	6.9

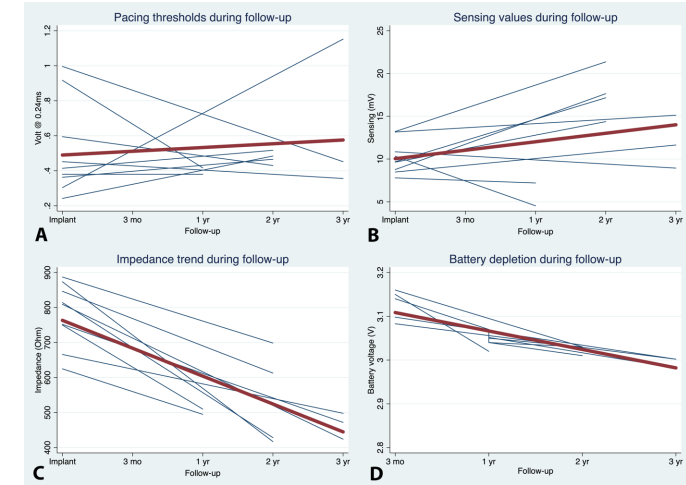


Figure 1

ID	nsVT	VT	VF	Asystole	Bradycardias (HR < 40/min)	AF burden [%]
#1	0	0	0	0	0	0
#2	0	0	0	0	0	4.8
#3	0	0	0	0	0	0
#4	0	0	0	0	0	0
#5	0	0	0	0	0	0
#6	0	0	0	0	0	0
#7	0	0	0	0	0	39.6
#8	0	0	0	0	0	0
#9	0	0	0	0	0	100
#10	0	0	0	0	0	0
#11	0	0	0	0	0	0

Table 1

Table 2

Conclusions:

In this single-center study no episodes of ventricular tachyarrhythmias were detected in patients with Micra™ LCP during the index stay after implantation and after hospital discharge by ILR. Further large-scale prospective studies are warranted to exclude pro-arrhythmogenic effects of LCP.

