<u>Sex-based differences in patients with the Micra[™] leadless</u> <u>cardiac pacemaker</u>

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Introduction

Following the tendency towards individualized therapy in all disciplines of medicine, sex-specific differences are receiving more and more attention in cardiology in general and also in the field of pacemaker therapy.

Methods

The aim of this study was to identify commonalities and differences between sexes in terms of baseline data, indication and outcome parameters of patients with the MicraTM leadless cardiac pacemaker (LCP) system. In this retrospective, single-center study, we analyzed data from all patients with LCP implantation between December 2013 and July 2020

Results

Out of 283 patients with Micra[™] LCP. 103 were female (F: 36.4%) and 180 were male (M: 63.6%). Baseline data did not differ significantly between both sexes: mean age (F: 79.7±7.7 years, M: 78.8±10.5 vears), atrial fibrillation (F: n=70, 68.0%, M: n=138, 76.2%), CHA2DS2-VASc-score (F: 4.6±1.3 including 1 point for female sex, M: 3.6±1.4). The most frequent indications were atrial fibrillation with slow conduction, third degree AV-block and sick sinus syndrome for both sexes (table 1). There were no significant differences with respect to mean implantation procedure time (F: 42.3±17.7 min, M: 44.7±19.2 min), number of deployments (F: 1.7±1.5, M: 1.8±1.9), sensing values (F: 10.6±5.0 mV, M: 10.7±4.6 mV), pacing thresholds (F: 0.49±0.3 V/0.24ms, M: 0.56±0.31 V/0.24ms) or impedance (F: 786±233 Ω, M: 767±236 Ω).

Overall, 12 complications (4.2%) were reported: 6 (2.1%) during implantation, 6 (2.1%) during the index stay after implantation. While the rate of complications did not differ significantly between both sexes (F: n=6, 5.8%, M: n=6, 3.3%, p=0.32), there were significantly more major complications (figure 1) in women (F: n=4, 3.9%, pericardiocentesis: n=2, unsuccessful LCP implantation: n=1, intraprocedural death due to severe sepsis after device extraction: n=1) compared to men (M: n= 1, 0.6%, stroke: n=1, p=0.04) as shown in figure 1. Long-term mortality (figure 2) did not significantly differ between women and men (F: n=21, 20.4%, M: n=39, 21.7%, log-rank p=0.43) over a median follow-up of 25 months (IQR 14-47 months).

<u>Conclusions</u>

Our study revealed no significant differences in baseline and procedural data between women and men receiving Micra[™] LCP therapy. However, more major complications occurred in women compared to men. Survival analysis did not demonstrate a difference in all-cause mortality.

Indication	female	male	total
Atrial fibrillation with bradycardia	33 (32%)	84 (46.7%)	117 (41.3%)
Total AV-block	32 (31.1%)	54 (30%)	86 (30.4%)
Sick sinus syndrome	22 (21.4%)	19 (10.6%)	41 (14.5%)
AV I + BBB	11 (10.7%)	13 (7.2%)	24 (8.5%)
AV II	3 (2.9%)	6 (3.3%)	9 (3.2%)
Bifascicular block	1 (1%)	4 (2.2%)	5 (1.8%)
Ablate & pace	1 (1%)	0	1 (0.4%)

Table 1– Indications for Micra™ implantation by sex

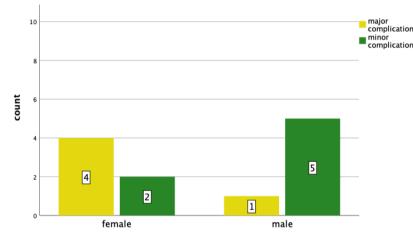


Figure 1 – Major and minor complications by sex

