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Morbidity and mortality in patients precluded for transvenous pacemaker implantation: Experience with the Micra transcatheter pacemaker

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Topic(s):
Device Complications and Lead Extraction

Citation:

Funding Acknowledgements:
Supported by Medtronic

Background: The Micra transcatheter pacemaker has proven to be a safe and effective alternative to transvenous pacemakers (TVPs). However, the safety profile after Micra implantation in patients deemed poor candidates for TVPs is poorly understood.

Purpose: To evaluate the safety and all-cause mortality outcomes in Micra recipients stratified by whether or not they were precluded for therapy with TVP.

Methods: Micra patients from the Micra Transcatheter Pacing (IDE) Study, Continued Access (CA) study, and Post-Approval Registry (PAR) were divided into groups based upon whether or not the implanting physician considered the patient to be precluded from receiving a transvenous pacing system. All-cause mortality was compared between the Micra patient groups and patients receiving a single-chamber transvenous pacing system (SC-TVP) since 2010 from the Medtronic product surveillance registry using univariate and multivariate Cox models.

Results: Among 2,819 patients who underwent a Micra implant attempt, the overall major complication rate through 24 months was 3.5%. In these patients, 548 were deemed precluded from TVP implantation. Prior device infection or bacteremia (38.9%), venous access issues (36.1%) and thrombosis (10.2%) were amongst the most common causes of preclusion for TVP implantation. These patients were younger (71.7 vs. 76.7 years), more frequently on hemodialysis (26.3% vs. 2.5%), and more often had a prior CIED implanted (38.4% vs. 4.4%) than non-precluded patients. Over an average follow-up of 13.5±11.1 months, all-cause mortality was significantly higher in precluded Micra patients compared with SC-TVP patients (HR: 2.16, 95% CI: 1.54-3.2, P<0.001) (Figure 1). However, there was no significant difference in all-cause mortality when comparing non-precluded Micra patients and SC-TVP patients (HR:1.12, 95% CI: 0.86-1.44, P=0.401). Acute all-cause death (within 1 month) among Micra patients was 2.74% and 1.32% in the precluded and not precluded TVP groups, respectively. The procedure-related death rate was 0.55% for the TVP precluded group and 0.13% for the not precluded group (P=0.092). The major complication rate through 24-months was similar between the two Micra groups (4.0% vs 3.4%, P=0.630).

Conclusion: The overall safety profile of Micra remains is in line with previously reported data. All-cause mortality risk (both acute and long term) appears to be higher in patients who were precluded from receiving TVP.
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Acute all-cause death (within 1 month) among Micra patients was 2.74% and 1.32% in the precluded and non-precluded TVP groups, respectively. The procedure-related death rate was 0.55% for the TVP precluded group and 0.13% for the not precluded group (P=0.092). The major complication rate through 24-months was similar between the two Micra groups (4.0% vs 3.4%, P=0.630).

Conclusion: The overall safety profile of Micra remains in line with previously reported data. All-cause mortality risk (both acute and long term) appears to be higher in patients who were precluded from receiving TVP.

Univariate Analysis

HR Precluded vs SC IPG: 2.26, 95% CI: 1.69 - 3.03, P<0.001
HR Not Precluded vs SC IPG: 0.89, 95% CI: 0.70 - 1.14, P= 0.356

Multivariable Analysis

HR Precluded vs SC IPG: 2.18, 95% CI: 1.57 - 3.04, P<0.001
HR Not Precluded vs SC IPG: 1.13, 95% CI: 0.87 - 1.45, P=0.364

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The figure shows the death rate for any cause over time for three groups: Micra precluded, Micra not precluded, and Single Chamber IPG. The death rates are marked at 0%, 20%, 40%, 60%, 80%, and 100% of the x-axis. The y-axis represents the percentage of patients who died. The x-axis represents the number of months from implantation. The graph also includes a table showing the number at risk for each group at different time points.