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# Assessment of the Micra™ leadless pacemaker system in patients after TAVI (MITAVI) – a case-control study

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## BACKGROUND

The incidence of newly developed AV conduction disturbances is higher after transfemoral aortic valve implantation (TAVI) than after conventional surgical valve replacement. Radial forces exerted by the TAVI help to secure the valve prosthesis in the left ventricular outflow tract but also compress adjacent AV conduction tissue. Patients with permanent atrial fibrillation or with an anticipated low rate of ventricular pacing (back-up pacing only) are eligible for single chamber pacing with a leadless cardiac pacemaker (LCP). As conventional single chamber pacemakers have been the systems of choice in TAVI patients up to now, data about safety and performance of LCPs in this setting are still scarce. Several considerations have to be taken into account in TAVI patients: Implantation itself may be more challenging as the access site in the right groin has previously been used for the TAVI implantation. Moreover, severe left ventricular hypertrophy and distorted geometry of the left ventricular outflow tract by the TAVI prosthesis may complicate the LCP implantation into the right ventricle or impair proper LCP function (pacing threshold, impedance, sensing). Oral anticoagulation therapy in TAVI patients with atrial fibrillation combined with mandatory antiplatelet therapy in the weeks after TAVI may put patients at higher risk for access site bleedings. The aim of this investigation was to systematically assess safety and performance of LCP after TAVI.

## METHODS

In this single center, retrospective case-control study patients who had received a Micra™ LCP within 4 weeks after TAVI (group 1 = G1) due to a new onset AV conduction disturbance were compared with sex and age matched (± 2.5 years) controls who had received an LCP, but no TAVI (group 2 = G2). Device parameters (R wave sensing, pacing threshold, impedance, battery life) as well as serious adverse device effects (SADEs) were compared between the groups at implant and until 12 months thereafter. Furthermore, baseline characteristics, implant complications, procedure and fluoroscopy times were assessed in both groups. Continuous variables are described as median and interquartile range. An unpaired Mann-Whitney U-test or a Chi2 test were applied to compare baseline characteristics, as appropriate. Device parameter changes between different time points were evaluated using a mixed effects linear regression model.

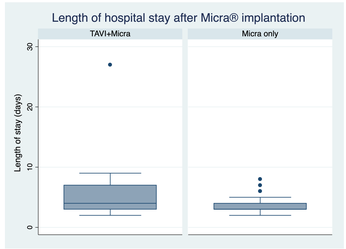


Figure 3: Length of hospital stay in days after pacemaker implantation.

## RESULTS

Thirty-one patients received an LCP after a median of 5 days after TAVI implantation (indications complete AV block [n=6], afib with slow conduction [n=6] and SR with intermittent AV block [n=19]). LCP implant time was longer in G1 as compared with G2 (G1: 45 [30-55] min., G2: 30 [20-45] min., p=0.003, see Figure 1). The same trend could be found for fluoroscopy time (G1: 7 [4-11] min., G2: 5 [4-8] min., p=0.052, see Figure 2). 32% of patients in G1 were on oral anticoagulation vs. 65% in G2 (p=0.203). Bridging regimens and the rate of suspension for LCP implantation were not different between groups. Subjects in G1 were more often on a concomitant antiplatelet therapy (G1: 100%, G2: 16%, p<0.001). Overall, only one complication occurred in G1 which was not related to the LCP implant procedure (death due to myocardial infarction during the index stay after LCP implantation, p=0.492 for inter-group difference). Baseline device parameters as well as length of stay after LCP implantation (see Figure 3) did not significantly differ between both groups. During 12 months of follow-up, the ventricular pacing rate was persistently higher in G2 (3 months: G1: 1.2 [0.3-7.3]%, G2: 44.9 [14.8-84.0]%, p<0.001; 12 months: G1: 1.0 [0.2-5.8]%, G2: 69.9 [25.1-90.2]%, p<0.001). R wave sensing significantly increased in both groups over time (0.24 mV per month on average for G1 and G2, p=0.952 for inter-group difference), whereas the pacing threshold remained stable (p=0.791 for inter-group difference). No SADEs were identified.

## CONCLUSION

Micra™ LCP implantation for treatment of AV conduction disturbances after a TAVI procedure is safe but associated with slightly longer procedure durations. Immediate implantation complication rate as well as device baseline parameters were not different as compared with matched patients who received a Micra™ LCP without a prior TAVI procedure. During a 12-month follow-up period, pacing thresholds remained stable and R wave sensing increased in a similar fashion in both groups.

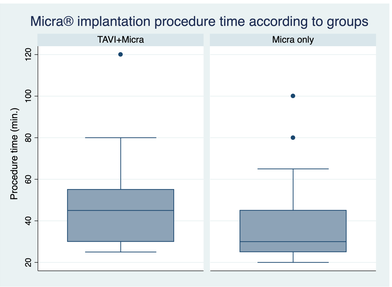


Figure 1: Procedure time in minutes for Micra™ LPM implantations according to group.

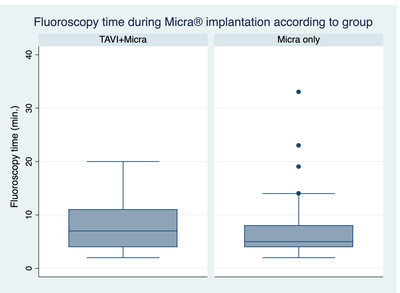


Figure 2: Fluoroscopy time in minutes for Micra™ LPM implantations according to group.

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