Année 2020/2021

Thèse

Pour le

DOCTORAT EN MEDECINE

Diplôme d'État

par

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Né le 10 juillet 1993 à Tyre (LIBAN)

TITRE

Leadless cardiac pacing: a single center experience

Présentée et soutenue publiquement le **26 octobre 2021** date devant un jury composé de :

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SERMENT D'HIPPOCRATE

En présence des Maîtres de cette Faculté,
de mes chers condisciples
et selon la tradition d'Hippocrate,
je promets et je jure d'être fidèle aux lois de l'honneur
et de la probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuits à l'indigent,
et n'exigerai jamais un salaire au-dessus de mon travail.

Admis dans l'intérieur des maisons, mes yeux
ne verront pas ce qui s'y passe, ma langue taira
les secrets qui me seront confiés et mon état ne servira pas
à corrompre les mœurs ni à favoriser le crime.

Respectueux et reconnaissant envers mes Maîtres,
je rendrai à leurs enfants
l'instruction que j'ai reçue de leurs pères.

Que les hommes m'accordent leur estime
si je suis fidèle à mes promesses.
Que je sois couvert d'opprobre et
méprisé de mes confrères
si j'y manque.

REMERCIEMENTS

À mon maître et président de jury,
Monsieur le Professeur BABUTY,
Vous me faites l'honneur de juger ce travail.
Merci pour votre enseignement, votre disponibilité et votre bienveillance.
Merci de nous avoir transmis ce sens unique de la prise de décision.
Vous avez toute ma reconnaissance.
Soyez assuré de mon profond respect.

À mon maître et directeur de thèse,
Monsieur le Docteur CLEMENTY,
Merci de me faire l'honneur de juger ce travail.
Merci pour ta pédagogie, ta disponibilité et la confiance que tu m'as apporté.
Merci pour ta bonne humeur, ta sympathie et ta passion que tu sais si bien transmettre.
Sois assuré de ma profonde estime.

À mon maître et juge,
Monsieur le Professeur ANGOULVANT,
Vous me faites l'honneur de juger ce travail.
Merci pour votre enseignement, votre confiance et votre bienveillance.
Merci d'avoir participé à la naissance de ma passion pour la Cardiologie sur les bancs de la Faculté de Médecine.
Soyez assuré de ma profonde considération.

À mon maître et juge,
Monsieur le Docteur BISSON,
Merci de me faire l'honneur de juger ce travail.
Merci pour tes conseils, ta rigueur et ta sympathie.
Sois assuré de mon entière estime.

À mon maître et juge,
Monsieur le Docteur BODIN,
Merci de me faire l'honneur de juger ce travail.
Merci pour ta disponibilité, ta bienveillance et ta bonne humeur.
Merci pour ce grand moment qu'était ma première garde de Cardiologie.
Sois assuré de ma sincère reconnaissance.

À mon maître et juge,
Monsieur le Docteur AH-FAT,
Merci de me faire l'honneur de juger ce travail.
Merci pour ta confiance et tous tes conseils.
Merci pour ton amitié et pour tous ces fous rires.
Sois assuré de sincère reconnaissance.

A toutes les personnes que j'ai rencontré durant ces 10 dernières années, depuis mon arrivée en France. Merci d'avoir contribué à la personne que je suis et au médecin que je serai.

A Monsieur le Professeur FAUCHIER, merci pour la confiance que vous m'avez portée pendant toute la durée de mon internat.
A Madame le Professeur BERNARD ainsi qu'au Dr DION, pour ce stage d'échographie plein d'enseignements.
A Monsieur le Professeur IVANES, pour ton aide précieuse lors de ces mercredi aprèm aux boxes.
Au Dr PACOURET et au Dr DESVEAUX, pour votre expérience et votre enseignement.
Au Dr QUILLIET et au Dr SAINT ETIENNE, pour vos compétences et votre passion, vous êtes des exemples du futur coronarographiste auquel j'aspire.
Au Dr CLERC, pour votre disponibilité et votre bonne humeur à toute épreuve.
Au Dr PIERRE, pour votre pédagogie et votre motivation.

A Clémentine et Cécile, pour leur précieuse aide pendant mon premier semestre au CHU.
A Walid et Carl, les 2 grands frères libanais, pour leur confiance et leurs précieux conseils.
A Thibaut G, pour la considération que tu m'accordes et le savoir que tu m'as transmis.
A Mathias, Mathieu D, Julien, Thibaut L, Matthieu G, Iris et Jérémie, pour ces bons moments et pour les conseils que vous avez pu m'apporter.

A toute l'équipe du centre Bois Gibert qui m'a accompagné durant mes premiers pas d'interne, vous aurez toujours une place spéciale dans mon cœur.
A l'équipe de Cardiologie du CH de Chartres, en particulier au Dr Albert, Thibaud, Sandrine, Grégoire et Pierre, pour l'excellent accueil et la qualité de la formation.
A l'équipe de Réanimation du CHRO, en particulier aux Dr Boulin, François Barbier, Toufik, Mai Ann et Sophie, pour ce semestre inoubliable et cette belle expérience.
A l'équipe du Pr Montalescot pour cet InterCHU parisien, en particulier au Pr Silvain, Michel Z, Marc B, Nesrine, Niki et Androula P, et toutes les autres belles rencontres, pour votre accueil, votre enseignement et votre sympathie.

A tous les membres du personnel paramédical que j'ai rencontré durant mon internat, merci de m'avoir supporté au quotidien, merci pour votre motivation et votre soutien.
A toutes les secrétaires et en particulier à celles du CHU de Tours, merci pour votre réactivité et votre contribution précieuse à cette thèse.

<u>Un énorme merci à mes co-internes.</u>

A Alexis, pour ton soutien indéfectible et ta présence quand il le fallait, pour ton écoute et pour ton intelligence humaine.
A Vincent, Marion et Jean, pour votre amitié, pour tous ces moments inoubliables en HC, et pour tous les souvenirs qu'on a ensemble.
A Pascal le grand frère, pour ce semestre d'écho dont on se souviendra longtemps !
A Maeva, Thibault L et Hanna, pour les bons moments et pour vos précieux conseils.

A ma promo d'affreux, « Et tes prothèses » : Antonin, Amélie, Jean Baptiste, Mathieu et Romain
pour tous ces bons souvenirs depuis notre premier DES à Angers !

En particulier à Mathieu et Jean Baptiste, malgré les hauts et les bas, on est éternellement liés par cette coloc ; pour tous ces souvenirs dont on se souvient, et ceux dont on se souvient moins.
A Amélie, pour tous ces moments « hors cardio », une amie en or. Je te souhaite le meilleur pour la suite et j'espère qu'on ne se perdra pas de vue !

A Chadi, Nicolas, Gaïane et Justine, pour toutes ces aventures en MIR au CHRO !

Aux plus jeunes ! A Roxane pour les précieuses données, à Marie pour ces gardes affreuses.
A Jad pour ces longues discussions sur l'être et le sens de la vie !
Ivann, Mathieu J, Yassine et Ahmad ; la relève est assurée !

<u>A mes amis de longue date</u>

A Quentin, Corentin, René, et Anthony, pour toutes ces confs, ces cinés, ces restos, ces randos foireuses et j'en passe. Grandir à vos côtés était une CHANCE !
A Jean Yves, Virgil, Valentin, Victor, Thibaud L, Maxime G, Denis, Mathieu B, vous êtes la seconde famille !
A Christ A, qui m'a dit, dès les premiers jours de P1 « on passera ensemble mon pote »

A tous mes amis d'enfance, du collège et du lycée au Liban ; aux 4 coins du monde.
A tous les profs qui m'ont inspiré pendant ma scolarité.
J'espère que nos chemins seront amenés à se recroiser. Mes souvenirs à vos côtés sont précieux.

A Laura, la plus belle surprise de cette année. Merci pour tout le bonheur que tu m'apportes au quotidien, pour les bons moments passés et à venir.

A toute ma famille et en premier lieu à mes parents, qui m'ont permis d'être ce que je suis aujourd'hui. Vous êtes mes exemples et je vous dois tout. Merci pour votre amour sans fin et vos sacrifices. J'espère, par ce travail, vous rendre fiers de moi.

A mes grands-mères et mon oncle qui nous ont quitté durant ces études.
Vous rêviez de ce jour ; vous étiez ma force et ma motivation pour aller jusqu'au bout.
Cette thèse vous est dédiée.

RÉSUMÉ

INTRODUCTION: Les stimulateurs cardiaques conventionnels se sont imposés comme le traitement de référence des bradycardies symptomatiques et des troubles conductifs irréversibles. Ils sont néanmoins sujets aux complications liées au boitier et aux sondes. Plusieurs études ont montré l'efficacité et la sécurité de la stimulation cardiaque sans sonde comme alternative aux pacemakers conventionnels. L'objectif de l'étude était de rapporter l'expérience d'un centre à haut volume d'implantation.

MÉTHODES: Cette étude observationnelle rétrospective a inclus les 300 premiers patients ayant bénéficié d'une tentative d'implantation d'un stimulateur cardiaque sans sonde au CHRU de Tours depuis juillet 2015. Durant le suivi, les évènements évalués étaient les complications post-opératoires précoces et tardives, ainsi que les paramètres électriques. Ceux-ci étaient recueillis après consultation des dossiers médicaux ou après entretien téléphonique avec le patient ou les membres de sa famille et ce jusqu'en mai 2021.

RÉSULTATS: La principale indication d'implantation était la fibrillation atriale associée à un trouble conductif atrio-ventriculaire. Le taux de succès d'implantation était de 99,3%. Le seuil de stimulation est resté stable et <2V chez 97,3% des patients. Après une durée moyenne de suivi de 420 jours, le taux de complication était de 8,6%, dans les 30 jours post-implantation dans 62% des cas. Aucune infection du système n'a été notée. Le diabète et l'implantation lors de l'expérience initiale du centre étaient indépendamment associés à un taux de complications plus élevé, passant de 15,6% avant le 65ème cas à 3,4% au-delà. La survenue d'une complication précoce était indépendamment associée à une mortalité 3 fois plus élevée au cours du suivi (p=0,002).

CONCLUSIONS: L'implantation d'un stimulateur cardiaque sans sonde est une alternative sûre et efficace à la stimulation conventionnelle. L'existence d'une courbe d'apprentissage, et l'impact des complications péri-opératoires sur leur pronostic souligne l'importance de référer les patients à des centres à haut volume d'implantation.

Mots clés: stimulation cardiaque sans sonde, complications péri-opératoires, courbe d'apprentissage

ABSTRACT

INTRODUCTION: Permanent cardiac pacing is the standard therapy for irreversible conduction disorders. However, transcatheter pacing systems are subject to lead and pocket linked-complications. Several studies have shown the efficacy and safety of leadless cardiac pacing as an alternative to conventional pacing. The aim of this study was to report the experience of a high-volume implantation center.

METHODS: This observational retrospective study has included the first 300 patients who underwent an implantation attempt of a leadless pacemaker at the Tours University Hospital since July 2015. During follow-up, early and late postoperative complications as well as electrical parameters were evaluated. These were collected by a review of hospital records, local physicians' consultation reports and by phone interviews of patient or family members until May 2021.

RESULTS: The main indication for pacing was atrial fibrillation associated with an atrioventricular bloc. Implantation success rate was 99.3%. The pacing threshold remained stable and <2V in 97.3% of patients. After a mean follow-up time of 420 days, the complication rate was 8.6%, within 30 days of implantation in 62% of cases. No Micra infection was noted. Diabetes and initial implantation experience were independently associated with a higher complication rate, from 15.6% before the 65th case to 3.4% beyond. The occurrence of an early complication was independently associated with a 3-fold all-cause mortality (p=0.002).

CONCLUSIONS: Leadless cardiac pacing implantation is a safe and effective alternative to conventional pacing. The existence of a learning curve and the impact of perioperative complications on prognosis emphasize the importance of referring patients to high-volume centers.

Key words: leadless cardiac pacing, peri-operative complications, learning curve

TABLE DES MATIÈRES

ABBREVIATIONS

AF: Atrial fibrillation

AV: Atrio-ventricular

COPD: Chronic obstructive pulmonary disease

EKG: Electrocardiogram

HR: Hazard Ratio

IDE: Investigational Device Exemption

MRI: Magnetic Resonance Imaging

OR: Odds Ratio

PCT: Pacing Capture Threshold

PICM: Pacing-induced cardiomyopathy

TM: Trademark

TPS: Transcatheter Pacing System

TV-PPM: Transvenous Pacemaker

INTRODUCTION

Permanent cardiac pacing is the standard therapy for irreversible conduction disorders, improving the lives of countless patients with benefits on morbidity and mortality.
Conventional pacing systems consist of a pulse generator inserted below the clavicle in a subcutaneous pocket, and one or more leads advanced towards the right-sided heart through supra-caval venous system, delivering the pacing therapy.

Despite being effective, these two components are prone to complications, the majority of which occur in the short-term following implantation.(1) In fact, up to 12 % of patients are exposed to these adverse events.(2) The weakest link in this conventional system remains the transvenous lead, which placement may be complicated with dislodgment, infection, cardiac perforation, pneumothorax and failure. (3,4) Pocket complications include hematoma, skin erosion, which may lead to infection.

Over the past few years, leadless pacemakers - the Micra Transvenous Pacing System (Medtronic Inc, Minneapolis, MN, USA) is the only system approved on the market - have been developed to avoid the aforementioned complications. (5) It consists in a small cylindrical capsule implanted directly into the right ventricle through a femoral venous approach.

This device has shown a high implant success rate along with excellent electrical parameters.(6) In addition, very low rates of pericardial effusion, groin puncture complications, infections and dislodgments were observed in early and late investigational studies. (7,8) These results were also confirmed in the real-world settings, thereby reducing the rate of major complications up to 63 % compared with traditional pacing systems.(9,10)

In this study, we present a 6-year Micra implantation experience in the CHRU of Tours, assessing the safety and efficacy of this procedure in our center. We sought to evaluate implantation of leadless pacemakers in a very-high volume experienced center, and the impact of experience on peri-operative complications, hence the existence of a learning curve.

METHODS

Patient characteristics and study design

This observational retrospective single center study has included the first 300 patients with a Micra TPS implantation attempt, since July 2015, in our cardiology department.

Baseline characteristics were collected after consulting medical records on date of admission.

Patient consent was not sought. Written informed consent was, however, obtained for all patients undergoing Micra implantation. The study was conducted retrospectively, patients were not involved in its conduct, and there was no impact on their care.

Procedure

The Micra (Medtronic, Minneapolis, MN, USA) is a leadless intracardiac pacing system.
It's about the tenth the size of a conventional pacemaker.
The first generation of Micra (VR) delivers VVI(R) pacing, whereas the second generation (AV) has the potential to provide AV synchronous pacing triggered by mechanical atrial contraction sensing.
All of its components are MRI compatible.
It is implanted through a femoral venous using a 23-F internal diameter/ 27-F outer diameter introducer, and advanced through the tricuspid valve to the right ventricular septum with a steerable catheter. The procedure is realized under fluoroscopic control.
If the measured electrical parameters (impedance, pacing capture thresholds, and R-wave amplitude) are adequate, the tethers are cut from the outside, withdrawn and the Micra TM is finally released.
Patients were generally discharged 24 hours after the implantation, during which they were continuously monitored with telemetry, after checking the EKG, chest X-ray, puncture site, and the absence of pericardial effusion.

Follow-up

After Micra implantation, patients and device status were systematically reported respectively at discharge, at 1 month, then at least once a year, and data were censored at the time of last known follow-up.

Outcomes

Freedom from adverse events for safety, and pacing capture threshold for efficacy were evaluated.

Early and late complications were collected by a review of hospital records, local physicians' consultation reports and by phone interviews of patient or family members until May 2021.

Pacing capture thresholds were collected at each consultation at the CHRU of Tours, and have been recovered from the referring cardiologist when the patients were followed elsewhere.

Statistical analyses

All analyses were performed using JMP software version 9.0 (SAS Institute Inc., Cary, NC, USA). Continuous data were presented as mean ± standard deviation if normally distributed, median (interquartile range; min-max) if not. Categorical data were reported as frequencies and percentages. Comparisons used the $\chi 2$ or Fisher's exact test for categorical variables and Student's t test or Mann–Whitney–Wilcoxon test, when appropriate, for continuous variables. The main confounding factors were first tested in univariable analysis, and parameters with an apparent association with the assessed outcome (p-value <0.10) were selected for analyses in a multivariable model. Categorical parameters derived from continuous numerical variables were determined using receiver operating characteristic (ROC) curves analyses to obtain accurate cutoff values. Logistic regression was performed to identify the factors independently associated with peri-operative complications. A Cox proportional hazard model was used to assess the factors independently associated with long-term mortality. Survival curves were calculated using the Kaplan-Meier method, and a log-rank test was used to evaluate overall differences between groups. A two-tailed p-value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics

A total of 300 consecutive patients were included in our analysis, from July 2015 to December 2020. Baseline characteristics are displayed in **Table 1**. They were more mostly men (n=183, 61%), mean age was 78 ± 11 years. Comorbidities were frequent, mainly AF (n= 196, 65%), chronic renal failure (n= 149, 50%), and heart failure (n=121, 40%). 190 patients (63%) took an anticoagulant agent.

Implantation characteristics

The main indication for pacing was AV block and chronic AF (n=135, 45%) whether it was related to AV junction ablation or slow conducting AF. It was followed by AV block with sinus rhythm (n=83, 28%), syncope (n=47, 15%), sinus dysfunction (n=21, 7%) and brady/tachy syndrome (n=14, 5%). Most Micra devices were 1st generation (VR) models (n=278, 93%).
Micra TPS implantation was successful in 298 patients (99%), with an acute pacing threshold of 0.57 ± 0.33 V. The median total hospitalization length was 1 day (ranging from 0 to 27 days).

Efficacy and Safety during follow up

Mean duration of follow-up was 420 days (median 810 days).

Patients were often stimulated as the mean percentage of ventricular pacing was 94%. The mean pacing capture threshold remained stable, measured at 0.56 ± 0.37 V, 97.3% of the patients having a mean threshold < 2.0 V. Chronic thresholds were significantly lower in cases 201 to 300, as compared to cases 1 to 100 (0.50 vs 0.63 V, p=0.03) (**Figure 1**).

There were 26 complications in 26 patients (8.6%) whether severe or not.
The majority were peri-operative complications within the first month (n=16, 5.3%), mainly pacing threshold elevation >2.0 V (n=8, 2.7%). All of these had persistent elevated thresholds with only 3 having required system revision. There were 5 groin complications, 2 of which required stenting and 1 that required embolization. No device embolization was observed. 3 procedures led to pericardial effusion, one of which resulted in patient death. This frail patient underwent urgent pericardial drainage but died of refractory cardiogenic shock on the same day. No other procedure-related death was reported.

All chronic complications were pacing-related. 5 pacing-induced cardiomyopathies (PICMs) with heart failure occurred, and necessitated an upgrade to cardiac resynchronization therapy. 5 other patients had pacemaker syndrome, and were later upgraded to either a conventional dual-chamber pacemaker or a Micra AV. The mean time to chronic complication was 225 days (median 587 days).
There was no infectious complication related to the Micra. Although 70 patients (23%) had an active infection at the time of implantation, whether related or not to a pacing system, no evidence of Micra infection was found during follow up.

A total of 88 patients died, of which one was adjudicated as procedure-related (death from refractory cardiogenic after cardiac tamponade). Mean time to death was 330 days (median of 720 days).

Predictors of peri-operative complications

Using multivariate analyses, we found that case number ≥65 was the most important predictor of early complications (OR 0.19, 95%CI 0.07-0.53, p=0.002). In fact, cumulative complication rate was assessed at 15.6 % for cases number 1 o 64, versus 3.4% for cases ≥65 (**Figure 2**). This significantly lower rate of complications seemed to result from a decrease of early complications rate (**Figure 3**).
Diabetes mellitus was also significantly and independently associated with peri-operative complications (OR 3.78, 95%CI 1.39-11.0, p=0.009).
The other comorbidities had no significant association.

Predictors of all-cause mortality

Incidence of all-cause mortality was significantly higher (p <0.0001**)** in patients who had suffered a complication compared to those who did not (**Figure 4**).
Using multivariate analyses, we found that the occurrence of a peri-operative complication (HR 3.02, 95%CI 1.54-5.39, p=0.002) was the strongest predictor of all-cause mortality (**Table 5**). Active infection at implantation (HR 1.72, 95%CI 1.03-2.80, p=0.04) and chronic renal failure (HR 1.62, 95%CI 1.02-2.58, p=0.04) were also independent predictors of death. Heart failure and ischemic heart disease were associated with a higher mortality in the univariate analysis, but this association was not significant after multivariable analyses.

DISCUSSION

We sought to report our experience with the first 300 Micra transcatheter pacing system implantations in patients having an indication for permanent cardiac pacing. To our knowledge, this is the largest single center report of Micra implanted patients. Leadless pacing is emerging as an alternative to conventional pacing systems, particularly when the expected risk of complication is high, although implantation rates remain low in European centers. (11)

In our experience, the device was successfully implanted in 298 patients (99%), with 2 failures having occurred among the first 10 patients. This excellent success rate is in line with the rates obtained in the multicenter investigational and post approval studies. (8,10)

The electrical performance was outstanding as 97.3% of the patients had stable thresholds <2.0 V, despite a long follow up time. It confirms the efficacy of this technology which has been already established in previous studies. Threshold stability is crucial in our cohort of patients who are often paced and sometimes fully pace-dependent. It allows a good projected longevity, thus avoiding multiple reinterventions and system revisions. Piccini et al. showed in a study on 711 patients of the Micra IDE cohort that when the capture threshold was <2.0 V, it respectively decreased to ≤1.0 V in 82% of the patients who had a pacing threshold between 1.0 and 1.5 V at implant, and in 75% of the patients who had a pacing threshold >1.5 V at implant. (12) Therefore, the corollary is that Micra device repositioning may not be necessary in this category of patients. The 2 V threshold is not an arbitrary choice. Beyond this value, the Micra battery life is greatly reduced. (13)

The procedure appeared safe as only 16 patients (5.3%) experienced a peri-operative complication, and 10 patients (3.3%) had a chronic complication, regardless of their severity. No device dislodgment, embolization nor infections were reported. The use of a leadless pacemaker avoided complications linked to the main components of a conventional transvenous pacemaker: the lead and the pocket. (2)
Groin complications rates were low (1.7%), with three patients having required surgical or interventional treatment, subsequent outcome was favorable. None of these events lead to death. However, rates in literature were even lower, ranging from 0.6 to 0.7%. (9,10) This finding is satisfying, given the size of the Micra introducer, but underlines the importance of systematic vascular ultrasound guidance for the

venous puncture.

Cardiac injuries resulting in pericardial effusion were rare (1%), 2 of the 3 patients required intervention, and one eventually led to death. This rate is comparable to what has been found in the real-world setting, around 0.8%, and reflects the importance of radioscopic controls to confirm the correct positioning of the system on the interventricular septum.(10) It is also similar to the perforation rate in conventional pacing systems, as shown in the meta-analysis of Vamos et al., analyzing 28 studies on TV-PPM lead perforation. (14) Mont et al. reported that pericardial effusion with Micra was associated with advanced age, female sex, congestive heart failure, chronic lung disease, non-AF indications, and Micra repositioning. (15)

8 patients had an acute pacing threshold elevation >2 V, which accounted for half of all acute complications, with no decrease below this threshold on follow up. 3 of these required a new pacing system later. Piccini et al. showed in the same study cited above that when the acute pacing threshold was 2 V at implantation, 45.5% remained >2 V at 6 months follow up.(12) Kiani et al. studied the predictive factors of elevated thresholds in a cohort of 1,843 patients. The primary endpoint was a combination of PCT ≥2 V, ≥1.5 V increase from baseline PCT at 12 months and system revision for elevated PCT at any timepoint after implantation within 12 months. Diabetes, male sex, elevated PCT, and low impedance are independent predictors of elevated thresholds at 12 months. (13)

Despite the implantation of 23% of Micra devices during the active phase of a systemic infection, related or not to a preexisting pacing system, there was no evidence of Micra infection during follow-up. This result is very significant given the high infection-risk profile of our population. Avoiding material infections with Micra is of utmost importance.

In a systematic review of 60 studies, Polyzos et al. found that the average conventional device infection rate was 1.6%. Multivariable analyses showed that the following procedure-related factors predicted device infections: pre-procedural fever, temporary pacing, early re-intervention, lack of antibiotic prophylaxis, procedure duration, revision procedures, hematoma.(16) Significant patient related factors were diabetes mellitus, renal disease, COPD, and heart failure, which are frequent comorbidities in our cohort. These infections expose the patient to an increased risk of morbidity and mortality, and have a considerable cost, up to 23,000 € as shown in a nationwide cohort study by Clementy et al. (17)

The specific case of transvenous system infections in pacemaker dependent patients is very problematic, and necessity of material retrieval supports the use of Micra in this indication.
El Chami et al. found no evidence of Micra infection in 105 patients with a recent CIED infection requiring extraction and antibiotic treatment, with a mean follow up of 7 months. (18) Beurskens et al. also found no evidence of TPS infection after explantation of infected conventional pacemakers, with a longer follow up (16 ± 12 months). (19) El Chami et al. have shown no recurrence of bacteremia after antibiotic cessation in 16 patients from the Micra IDE cohort affected by a serious infectious event (bacteriemia or endocarditis) (20). In a population of 99 critically ill patients requiring prolonged cardiac pacing, Clementy et al. found no evidence of late device related infection. (21)

The absence of Micra infections in the setting of bacteremia might be explained by reduced surface, absence of contact with the skin, encapsulation in the right ventricle, and reduction of bacterial adherence by the parylene coating layer on titanium. (22) Micra could therefore have its place as a first choice in high-risk populations, such as dialysis patients. El Chami et al. showed no case of device-related infection in 201 dialysis patients implanted with Micra, with the additional benefit to spare the veinous circulation for later use. (23)

Chronic complications consisted essentially of pacing complications, which are not specifically related to Micra. Pacing-induced cardiomyopathy with heart failure occurred in 5 patients who were later upgraded. Pacemaker syndrome also occurred in 5 patients who were upgraded to either a conventional dual-chamber pacemaker or a Micra AV model. Implantation of the latest version of the Micra device in patients with sinus rhythm could reduce the burden of pacemaker syndrome. In fact, it has been shown that atrioventricular synchrony is feasible by accelerometer-based sensing, decreasing pacemaker syndrome, improving stroke volume and quality of life. (24)

The incidence of death was high among the first 300 implanted patients during follow up, including one procedure-related death. This can be explained by the patients' old age, multiples comorbidities such as heart failure, ischemic heart disease, chronic renal failure, COPD, and diabetes.

Our study has demonstrated a strong impact of the operator's experience on the safety and efficacy outcomes, thus proving the existence of a clear learning curve effect.
In fact, the complication rate was almost five times significantly lower beyond the 65th implanted patient

when compared to the previously implanted cases. This difference seems to result mainly from acute complications, with a gap between the curves that widen early (<3 months) and which is maintained at 1-year follow up. This finding is not surprising as chronic complications are not related to the system itself, but rather to the chronic ventricular stimulation.
The learning curve also impacted the efficacy, as the mean acute threshold was significantly lower in the 100 most recently implanted patients with a lower dispersion of the threshold values.
This learning curve effect is in favor of a centralization of the Micra implantations in high volume experienced centers.

However, data on the relationship between operator experience and transcatheter pacing systems in the literature are contradictory. In a paper dating from 2017, El Chami et al. showed no clear learning curve effect on safety and efficacy between lab trained operators and locally trained operators; implant case number was not a determinant of the procedural success, nor the major complications (25). On the other hand, the initial Swiss experience study which enrolled only 92 patients implanted in four different centers – i.e. an average of 23 implantations per center –, reported a rather high 9.8% rate of complications, suggestive of a link between early experience and the occurrence of complications (26). Whereas Tjong et al., in a study dating from 2018, proved the existence of a learning curve with the Nanostim LP system (Abbott), another transcatheter pacing device (27). The implant was performed in 1,439 patients by 171 implanters, and major complications dropped from 7.4 to 4.5% after more than 10 implants per operator.

We analyzed the factors associated with peri-procedural complications. An important finding of our study is the significant association between diabetes mellitus and operator experience on one hand, and peri-operative complications on the other hand. Diabetic patient had almost four times more risk of peri operative complications than the non-diabetics. This might be explained by a more vulnerable state before the procedure. Interestingly, there was a trend towards more complications in heart failure patients without a statistically significant association.

Lastly, we assessed the predictors of all-cause mortality. In multivariate analyses, patients with an active infection and chronic renal failure had a significantly higher mortality, which is not surprising regarding their comorbidities and higher risk of death. The strongest predictor of all-cause mortality was the existence of a peri-operative complication, with a 3-fold higher risk. This suggests a potential association

between operator experience and overall mortality, and might be an additional element supporting patient management in high-volume centers.

Limitations

We acknowledge several limitations to our work. The main limitation of this study is inherent to its retrospective observational nature. There was missing date regarding baseline characteristics, acute thresholds and some patients were lost to follow up or didn’t respond to our calls. The non-randomized design and the absence of a control group leaves a risk of residual confounding factors and biased associations.

CONCLUSIONS

Micra implantation in our center is growing and the results of the current study are satisfying. The high implantation success rate, outstanding electrical performance and low complication rate highlight the benefits of this procedure, which appears to be a safe alternative to conventional pacing in high-risk populations. A clear learning curve effect was shown and emphasizes the importance of referring the patients to high-volume centers.

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TABLES

Table 1. Patients' characteristics at admission.

	ALL (N=300)
Age (years)	78 ±11
Male gender (%)	183 (61)
Body mass index ($kg.m^{-2}$)	28 ±6
Heart failure (%)	121 (40)
Ischemic heart disease (%)	68 (23)
Valvular heart disease (%)	62 (21)
Other (%)	18 (6)
Atrial fibrillation (%)	196 (65)
Chronic renal failure (%)	148 (49)
Chronic pulmonary disease (%)	64 (21)
Diabetes mellitus (%)	91 (30)
Cancer (%)	84 (28)
Antiplatelet agent (%)	71 (24)
Anticoagulation agent (%)	190 (63)

Table 2. Implantation characteristics.

	ALL (N=300)
Pacing indication	
AV block and sinus rhythm (%)	83 (28)
Paroxysmal	20
Chronic	63
Sinus dysfunction (%)	21 (7)
Paroxysmal	12
Chronic	9
Brady/Tachy syndrome (%)	14 (5)
AV block and chronic AF (%)	135 (45)
AV junction ablation	60
Slow conducting / complete AV block	75
Syncope + abnormal EP study (%)	47 (15)
Long HV interval	45
Carotid sinus hypersensitivity	2
Model VR / AV (%)	278 (93) / 22 (7)
Implantation success (%)	298 (99)
Acute pacing threshold (V)	0.57 ± 0.33
Peri-operative (≤30 days) complications (%)	16 (5.3)
Groin complication (%)	5 (1.7)
Cardiac injury	3 (1.0)
Pacing threshold elevation >2.0 V	8 (2.7)
Procedure-related death*	1 (0.3)
From implantation to discharge (days)	1 [0-27, 0]

* Cardiac tamponade

Table 3. Follow-up.

	ALL (N=300)
Total follow-up (days)	420 [1-1950, 810]
Chronic (>30 days) complications (%)	10 (3.3)
Pacemaker syndrome (%)	5 (1.7)
Pacing-induced cardiomyopathy (%)	5 (1.7)
Time to complication (days)	225 [14-960, 587]
Chronic pacing threshold (V)	0.56 ± 0.37
Percentage of ventricular pacing (%)	94 [0-100, 79]
Death of any cause (%)	88 (29)
Time to death (days)	330 [1-1860, 720]

Table 4. Predictors of peri-operative (≤30 days) complications.

	UNIVARIATE		**MULTIVARIATE**	
	OR [95% CI]	p	OR [95% CI]	p
Age (years)*	0.99 [0.95-1.03]	0.53		
Male gender	1.00 [0.36-2.60]	0.99		
Body mass index ($kg.m^{-2}$)*	1.03 [0.95-1.10]	0.47		
Heart failure	2.46 [0.94-6.86]	*0.07*	2.47 [0.90-7.25]	0.08
Ischemic heart disease	0.97 [0.27-2.82]	0.96		
Atrial fibrillation	1.07 [0.40-3.14]	0.90		
Infection	0.64 [0.15-2.02]	0.47		
Chronic renal failure	0.64 [0.23-1.66]	0.36		
Chronic pulmonary disease	0.44 [0.07-1.62]	0.24		
Diabetes mellitus	3.95 [1.50-11.1]	*0.006*	3.78 [1.39-11.0]	*0.009*
Cancer	0.99 [0.31-2.72]	0.98		
Antiplatelet agent	1.67 [0.56-4.48]	0.34		
Anticoagulation agent	1.17 [0.44-3.44]	0.76		
Case number (N)*	0.99 [0.99-1.00]	*0.006*		
Case ≥65	0.19 [0.07-0.50]	*0.001*	0.19 [0.07-0.53]	*0.002*

* OR, odds ratio, per 1-unit increase for continuous variables.

Table 5. Predictors of all-cause mortality.

	UNIVARIATE		MULTIVARIATE	
	HR [95% CI]	p	HR [95% CI]	p
Age (years)*	1.01 [0.98-1.03]	0.66		
Male gender	1.19 [0.77-1.87]	0.44		
Body mass index ($kg.m^{-2}$)*	1.00 [0.96-1.04]	0.95		
Heart failure	1.59 [1.04-2.41]	*0.03*	1.53 [0.99-2.37]	0.06
Ischemic heart disease	1.60 [0.99-2.51]	*0.05*	1.50 [0.92-2.37]	0.10
Atrial fibrillation	1.55 [0.97-2.55]	*0.06*	1.55 [0.96-2.60]	0.07
Infection	1.63 [0.99-2.58]	*0.06*	1.72 [1.03-2.80]	*0.04*
Chronic renal failure	1.77 [1.14-2.76]	*0.01*	1.62 [1.02-2.58]	*0.04*
Chronic pulmonary disease	1.45 [0.90-2.28]	0.13		
Diabetes mellitus	1.48 [0.94-2.28]	*0.09*	1.23 [0.78-1.92]	0.37
Cancer	1.35 [0.84-2.12]	0.21		
Peri-operative complication	3.16 [1.63-5.59]	*0.001*	3.02 [1.54-5.39]	*0.002*
Case number (N)*	1.00 [1.00-1.01]	0.16		

* HR, hazard ratio, per 1-unit increase for continuous variables.

FIGURES

Figure 1. Evolution of chronic pacing thresholds related to implantation case number.

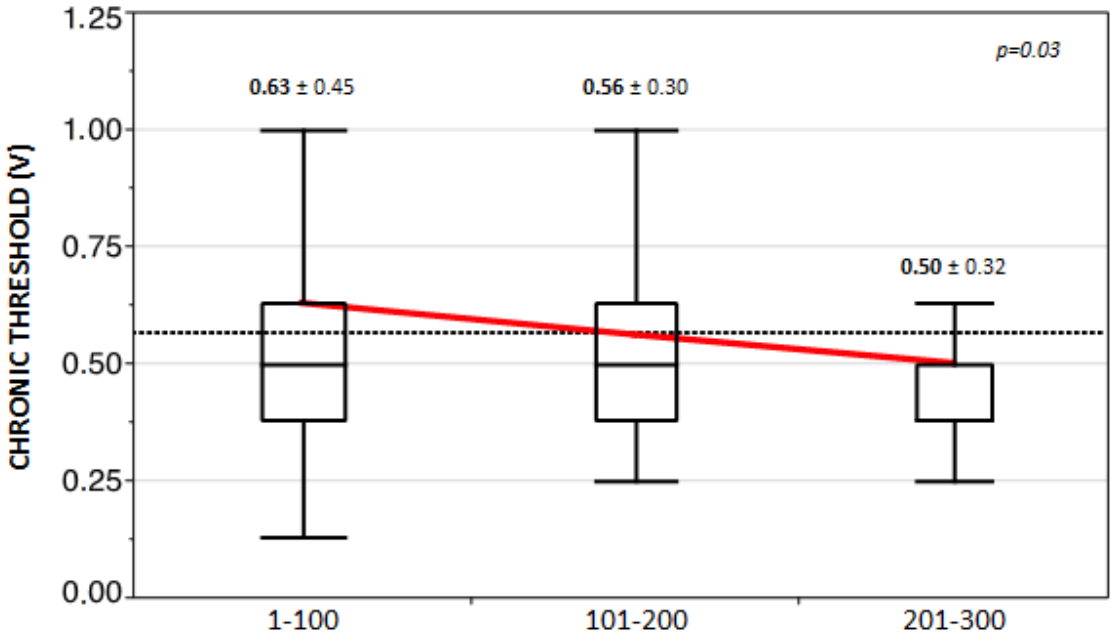


Figure 2. Incidence of complications before and after case number 65

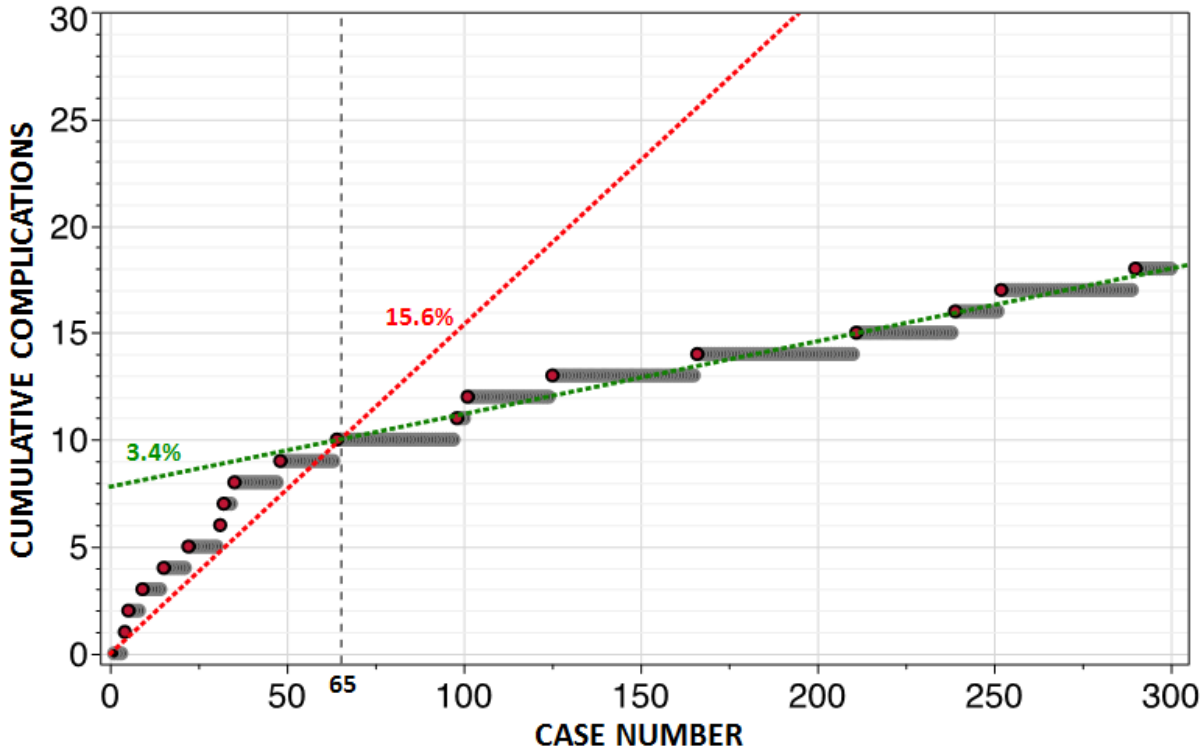


Figure 3. Freedom from complication at one year before and after case number 65

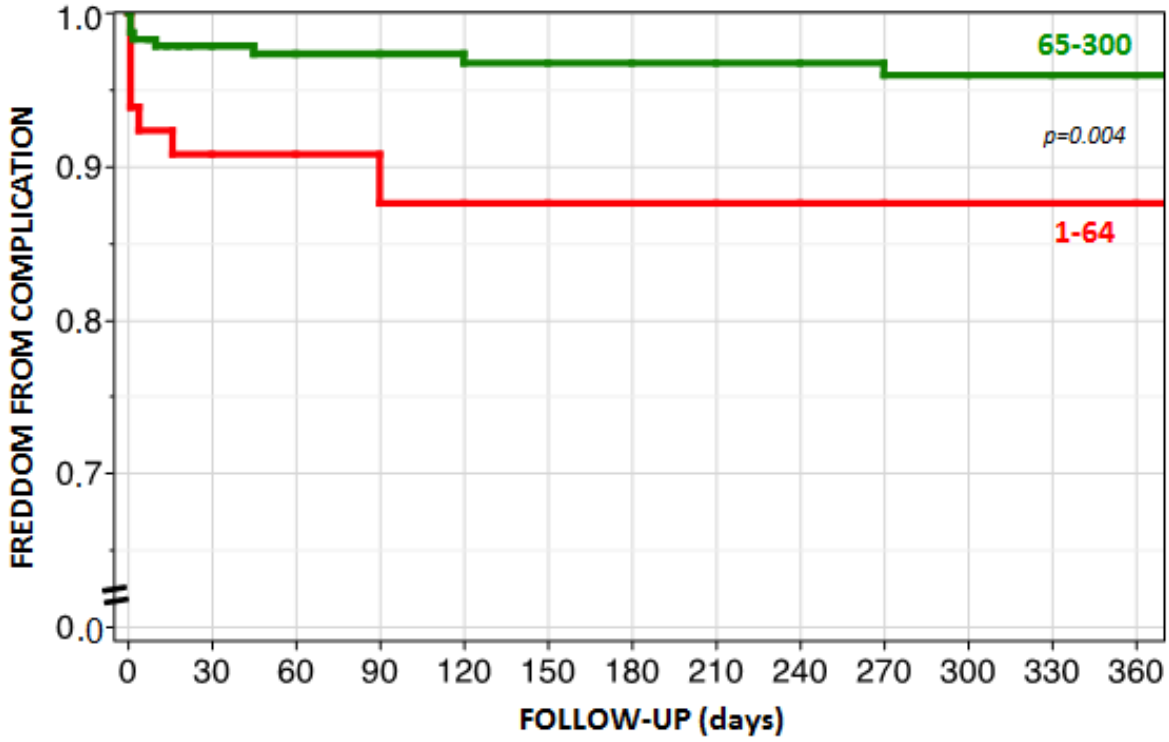
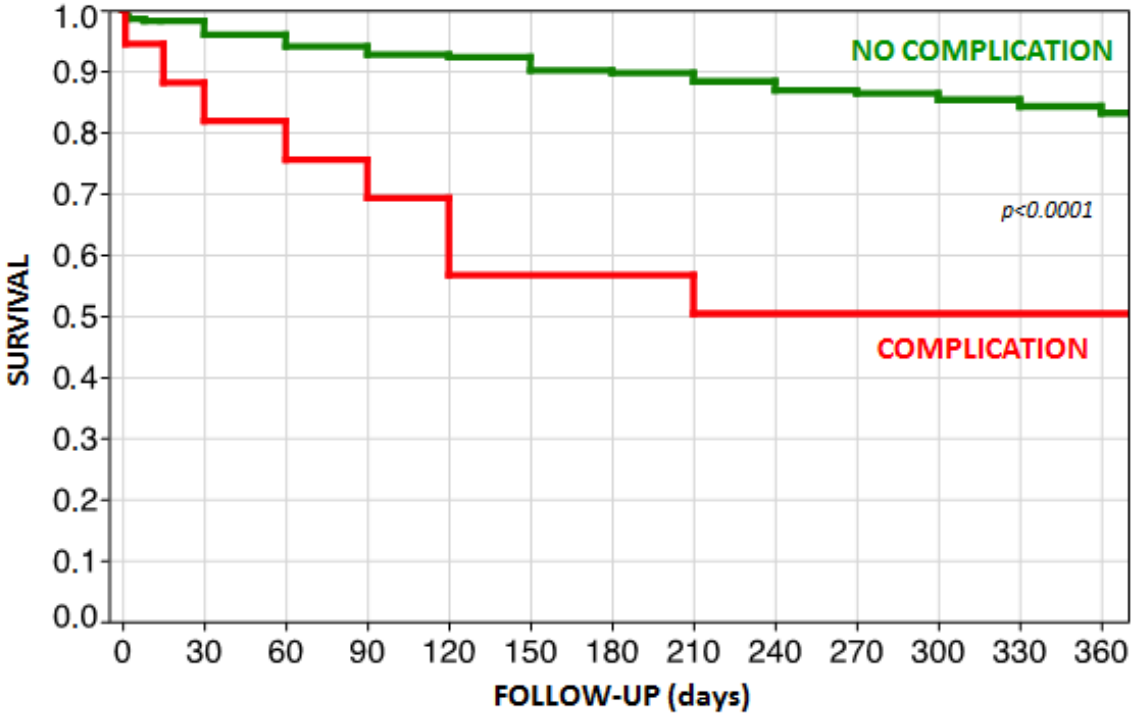


Figure 4. Incidence of all-cause mortality in patients with complications versus non complication during follow-up.



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39 pages – 5 tableaux – 4 figures

Résumé :

Introduction : Les pacemakers conventionnels se sont imposés comme le traitement de référence des bradycardies symptomatiques et des troubles conductifs de haut grade. Ils sont néanmoins sujets aux complications liées au boitier et aux sondes. Plusieurs études ont montré l'efficacité et la sécurité de la stimulation cardiaque sans sonde comme alternative aux pacemakers conventionnels. L'objectif de l'étude était de rapporter l'expérience d'un centre à haut volume d'implantation.

Méthodes : Cette étude observationnelle rétrospective a inclus les 300 premiers patients ayant bénéficié d'une tentative d'implantation d'un stimulateur cardiaque sans sonde au CHRU de Tours depuis juillet 2015. Durant le suivi, les évènements évalués étaient les complications post- opératoires précoces et tardives, ainsi que les paramètres électriques. Ceux-ci étaient recueillis après consultation des dossiers médicaux ou après entretien téléphonique avec le patient ou les membres de sa famille et ce jusqu'en mai 2021.

Résultats : La principale indication d'implantation était la fibrillation atriale associée à un trouble conductif atrio-ventriculaire. Le taux de succès d'implantation était de 99,3%. Le seuil de stimulation est resté stable et < 2V chez 97,3 % des patients. Après une durée moyenne de suivi de 420 jours, le taux de complication était de 8,6%, dans les 30 jours post-implantation dans 62% des cas. Aucune infection du système n'a été notée. Le diabète et l'implantation lors de l'expérience initiale du centre étaient indépendamment associés à un taux de complications plus élevé, ce dernier passant de 15,6% avant le 65ème cas à 3,4% après. La survenue d'une complication précoce était indépendamment associée à une mortalité 3 fois plus élevée (p=0,002).

Conclusions : L'implantation d'un stimulateur cardiaque sans sonde est une alternative sure et efficace à la stimulation conventionnelle. L'existence d'une courbe d'apprentissage, et l'impact des complications péri-opératoires sur leur pronostic souligne l'importance de référer les patients à des centres à haut volume d'implantation.

Mots-clés: stimulation cardiaque sans sonde, complications péri-opératoires, courbe d'apprentissage

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Date de soutenance : Mardi 26 octobre 2021