

Bacteraemia after leadless pacemaker implantation

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Abstract

Background: Transvenous permanent pacemaker related infection is a severe condition associated with significant morbidity and mortality. Leadless pacemakers may be more resistant to bacterial seeding during bloodstream infection because of its small surface area and encapsulation in the right ventricle. This study reports the incidence and outcomes of bacteraemia in patients implanted with a Micra leadless pacemaker. We present 18F-FDG PET/CT findings obtained in a sub-group of patients. Methods: We report a retrospective cohort study of 155 patients who underwent a Micra TPS implant procedure at the University Hospitals of Leuven between July 2015 and July 2019. We identified the patients who developed an episode of bacteraemia, proved by ≥ 2 positive blood cultures. Results: Of the 155 patients, 15 patients presented an episode of bacteraemia at a median of 226 days (range: 3-1129) days after the implant procedure. Gram positive species accounted for 73.3% (n=11) of the bacteraemia including *Staphylococcus* (n=5), *Enterococcus* (n=3) and *Streptococcus* (n=3). The source of infection was identified in 9 patients (60%) including endocarditis in 4 patients, urinary tract in 3 patients, and skin in 2 patients. 18F-FDG PET/CT imaging performed in 6 patients did not show sign of infection around the leadless pacemaker. Bacteraemia was resolved in all patients after adequate antibiotherapy. Four patients died early during follow up. For all other patients, there were no recurrence of bacteraemia during a median follow up of 263 days (range 15-1134). Conclusion: In our small cohort, no leadless pacemaker endocarditis was observed among patients with bacteraemia.

Introduction

The infection of cardiac implantable electronic devices (CIEDs) is a feared and devastating complication associated with a high morbidity, mortality and healthcare costs^{1,2}. Removal of the infected device and extraction of the leads followed by prolonged administration of intravenous antibiotics are the core of the treatment. The incidence of CIEDs infection ranges from 0.5 to 2.2 % for permanent pacemakers and implantable cardiac defibrillators^{3,4}. In the setting of bacteraemia, the risk for CIED infection depends on the offending species. *Staphylococcus aureus* carries a higher risk of device involvement as compared to gram negative bacilli except with *Pseudomonas aeruginosa* and *Serratia marcescens*^{5,6}. While diagnosis of CIED pocket infection can be generally confirmed by local inflammatory signs, the diagnosis of lead infection may be more challenging. To improve the diagnostic yield of CIED infection, the European Society of Cardiology and Heart Rhythm Society have suggested that the use of ¹⁸F-fluorodeoxyglucose (FDG)-PET/CT imaging might provide helpful evidence for inconclusive cases in their guidelines^{1,7}. The uptake of ¹⁸F-FDG, a glucose analogue, by the leukocytes has a high sensitivity in detecting infection using PET imaging and the combination of PET/CT imaging in recent systems provide the location of infectious foci with high spatial resolution⁸⁻¹⁰.

Leadless pacing system has been recently introduced for patients requiring ventricular pacing to overcome pocket and lead-related complications¹¹. The updated results of the Micra Post-Approval Registry consistently showed the safety and the efficacy of leadless pacing with lower rates of complications including device infection as compared to a historical patients cohort with conventional permanent pacing¹². Leadless pacemakers may be more resistant to bacterial seeding during bloodstream infection because of their

intrinsic characteristics including a small surface area and encapsulation in the right ventricle^{11,13,14}. In the present study, we report the incidence and outcome of bacteraemia in patients implanted with a Micra Transcatheter Pacing System (TPS) (Medtronic, Minneapolis, MN, US) in our institution. We also present ¹⁸F-FDG PET/CT findings obtained in a patients sub-group.

Methods

Patient Cohort

We conducted a retrospective study which examined all patients aged over 18 years old with class I or II guideline recommendations for ventricular pacing who underwent a successful Micra TPS implantation in our centre between July 2015 and July 2019¹⁵. Patients data were collected from our electronic institutional database. We searched bacteriological reports to identify all patients with positive blood culture. Bacteraemia was confirmed in the presence of at least 2 positive peripheral blood cultures with elevated white blood cell count. We identified patients who underwent ¹⁸F-FDG PET/CT imaging in the setting of the bacteraemia. The protocol was approved by the Ethics Committee of the University Hospitals of Leuven.

¹⁸F-FDG PET/CT protocol

The acquisition of the PET/CT scan was performed within 2 weeks after diagnosis of the bacteraemia. PET-CT scans were performed on a Biograph Truepoint 40 (Siemens, Erlangen, Germany) or Discovery 670 MI (General Electric Healthcare, Milwaukee, WI, USA). PET imaging was performed 45-60 minutes after the administration of 4.5 MBq/kg of ¹⁸F-FDG. Patients were instructed to use a carbohydrate poor, fat and protein rich diet for 24h prior to suppress the physiological glucose metabolism of the myocytes and in addition fast for a minimum of 6 hours prior to injection. Blood glucose levels were controlled and below 180 mg/dL at the time of intravenous ¹⁸F-FDG administration. Patients received 20 mg Propranolol hydrochloride to minimise uptake in brown fat.

¹⁸F-FDG PET/CT images analysis

CT staging was performed using contrast-enhanced high dose CT images obtained from the PET/CT scanner. CT images were interpreted independently by an experienced radiologist. The PET part of the PET/CT was analysed by an experienced nuclear medicine. Attenuation-corrected as well as non-attenuation-corrected images were reviewed to avoid misinterpretation of attenuation-correction artefacts due to the proximity of dense materials (e.g. device related). Qualitative analysis of the images was done by visualisation of the areas with increased ¹⁸F-FDG uptake. The presence of increased ¹⁸F-FDG activity that could not be explained by physiological uptake was considered as a potential site of inflammation. PET and CT findings were integrated in a final hybrid PET/CT finding.

Statistics

Data collected in all patients after Micra TPS implantation were included in the statistical analysis. Continuous variables were tested for normal distribution by the Kolmogorov-Smirnov test. Since all parameters deviated significantly from the normal distribution, data were summarized using median and interquartile ranges, unless specified otherwise. Categorical variables were presented as numbers and percentages. Continuous variables were compared between the groups using the non-parametric Mann-Whitney-U testing. Categorical variables were compared using the chi-square test. P-values <0.05 were considered significant. All statistical analyses were performed using SPSS (IBM statistics, version 25).

Results

A total of 155 patients underwent a Micra TPS implant procedure from July 2015 to July 2019 of which 15 patients (9.7%) developed a bacteraemia during follow-up. Bacteraemia occurred at a median of 226 days (range: 3-1129) after the implant procedure. Median duration of follow-up after the bacteraemia was 263 days (range: 15-1134). The baseline characteristics of the population is summarized in Table 1. Patients with bacteraemia had a median age of 81-years (77-82) and were largely similar to the other patients with two exceptions. First, they had a more frequent history of valve intervention (66.7% vs.27.9%, p=0.002) and

secondly, there was a higher incidence of severe renal dysfunction requiring haemodialysis (20% vs. 3.6%, $p=0.006$).

Gram positive species accounted for 73.3 % ($n=11$) of the bacteraemia including *Staphylococcus* ($n=5$), *Enterococcus* ($n=3$) and *Streptococcus* ($n=3$) (Table 2). The source of infection was identified in 9 patients (60%) including endocarditis in 4 patients, the urinary tract in 3 patients, and the skin in 2 patients. All patients underwent at least one transoesophageal echocardiography that did not reveal the presence of vegetation on the Micra. Thirteen patients were successfully treated with intravenous antibiotics. Two patients with endocarditis underwent valvular replacement with preventive removal of the Micra in the absence of definite signs of device infection including negative transoesophageal echocardiography. In both, the culture of the explanted device remained negative. All treatments led to negative conversion of the blood cultures and no patient experienced any recurrent bacteraemia during follow-up. Four patients died during follow-up of which 3 patients with endocarditis. Both patients who had removal of the Micra with valve replacement for endocarditis died of multi-organ failure respectively 14 and 43 days after surgery. A third patient also died of multi-organ failure 20 days after valve surgery for endocarditis. The fourth patient died at home from causes unrelated to the bacteraemia.

^{18}F FDG PET/CT imaging was performed in 6 patients to identify the site of infection. No patient had abnormal ^{18}F -FDG uptake detected around the Micra on the PET/CT fusion images (Figure 1). Two patients with endocarditis had increased ^{18}F -FDG uptake on infected valves confirmed by positive post-operative valve culture. Two other patients had increased focal ^{18}F -FDG uptake compatible with infectious arthritis (Table 2).

Discussion

Our study supports the hypothesis that leadless devices are less prone to haematogenous pacemaker infections. In our population, the rate of bacteraemia was almost 10% suggesting that this was a high-risk group. One of the most relevant finding of the study is that patients who were previously implanted with a leadless pacemaker, do not seem to require systematic pacemaker removal in case of bacteraemia.

Haematogenous seeding of CIED during bacteraemia is a severe condition that is associated to significant morbidity and mortality if unsuccessfully managed^{1,16}. In case of pacemaker infection, the complete removal of the hardware is a clear indication in the guidelines^{2,7}. *Staphylococcus aureus* bacteraemia has been associated with a high risk of cardiac device related infection⁵. This is a result of the high propensity of the pathogen to adhere to foreign material implanted in the body including pacemaker leads¹⁷.

As leadless pacing technology is relatively new in clinical use, there are only few reports on the risk of device infection^{18,19}. In our study, none of the patients had definite sign of Micra infection in the setting of or after bacteraemia even involving gram positive *Staphylococcus*. In 2 cases, the absence of device infection was confirmed by negative culture of the device following its preventive removal during valve surgery for endocarditis while there was no sign of device infection on preoperative transoesophageal echocardiographic images for both patients and on additional ^{18}F FDG PET/CT imaging for one of the patients. Overall, the absence of device infection in our series is also ascertained by the absence of recurrent bacteraemia reported during the follow up after antibiotic treatment and surgery when appropriate. Our results are in accordance with those reported by El Chami et al. for patients with systemic infection from the Micra IDE study¹⁸. Among 720 patients implanted with a Micra, the authors reported the occurrence of 21 serious infectious events (bacteraemia or endocarditis) in 16 patients that were successfully treated with antibiotics without evidence of leadless pacemaker infection during follow up.

For the first time, this study reported on the use of ^{18}F -FDG/PET imaging to rule out leadless pacemaker infection during bacteraemia. In this small series of 6 patients, there was no increased metabolic activity detected around the device. Previous studies have shown the utility of ^{18}F -FDG PET/CT for diagnosing CIED infection⁸⁻¹⁰. The sensitivity in detecting infection was higher for infection of the generator pocket as compared to pacing leads¹⁰. ^{18}F -FDG PET/CT also enabled to differentiate device infection from residual inflammation in the early phase post-implantation⁸. Adding PET/CT results to Duke criteria increased

the diagnostic sensitivity in detecting infection by the reduction of cases classified as possible infective endocarditis⁹.

The absence of Micra related infection detected during bacteraemia is reassuring. First, it might be explained by the intrinsic characteristics of the device: the use of a parylene coating seems to have protective effect against bacterial grow and adhesion while its reduced size with a small surface area in contact with the bloodstream might also be protective against bacterial seeding^{11,20}. Secondly, the reported progressive fibrous encapsulation of the device could also contribute to reduce the risk of infection. Autopsies have revealed partial device encapsulation as early as 2 months after implantation and complete encapsulation at 1 year^{13,14}. Finally, the absence of a pacemaker pocket and the use of a catheter delivery system avoid all manual manipulation of the device during the implant procedure and are also potential factors contributing to the reduction of the risk of bacterial seeding as compared to conventional pacemaker.

Previous studies have identified host-related risk factors for CIED that include diabetes mellitus, end stage renal disease, chronic obstructive pulmonary disease, corticosteroid use, history of previous infection, renal insufficiency, malignancy, heart failure, pre-procedural fever, anticoagulant use and skin disorders^{1,3,21}. In our case series, patients who developed bacteraemia after Micra implantation had a higher incidence of end-stage renal disease treated by dialysis and of previous valve intervention. The use of leadless pacemaker might be of interest in these patients, reducing the risk of device-related infection/endocarditis.

Study limitations

The single centre experience and the small number of patients included in the study are the main limitations of this study. The duration of the follow-up may also have influenced our results. Furthermore, we cannot exclude unreported serious infectious events that could have occurred in our patients during hospitalization in another institution. Another limitation to be considered is the absence of direct comparison with a group of patients receiving a conventional single chamber pacemaker.

Conclusion

In our cohort of patients, no leadless pacemaker endocarditis was observed after an episode of bacteraemia. This should be confirmed in large scale trials before setting recommendations about the preferential use of leadless pacemakers in patients with a high risk of infection.

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Figure legend:

Figure 1: Example of ^{18}F -FDG PET/CT images in a 74-year-old-man (patient 15) with an infective endocarditis of a bioprosthetic aortic valve and native mitral valve with positive blood culture for *Staphylococcus lugdunensis*. Micra TPS was implanted 3 months before the infectious event. Columns A and B show images centred on aortic prosthesis (white arrow) and mitral valve (yellow arrow). PET/CT images show

an increased ^{18}F -FDG uptake in the region of the prosthetic aortic valve and native mitral valve. Columns C and D show images centred on the Micra leadless pacemaker. PET/CT fusion images show no increased ^{18}F -FDG uptake around the device.

Figure 1:

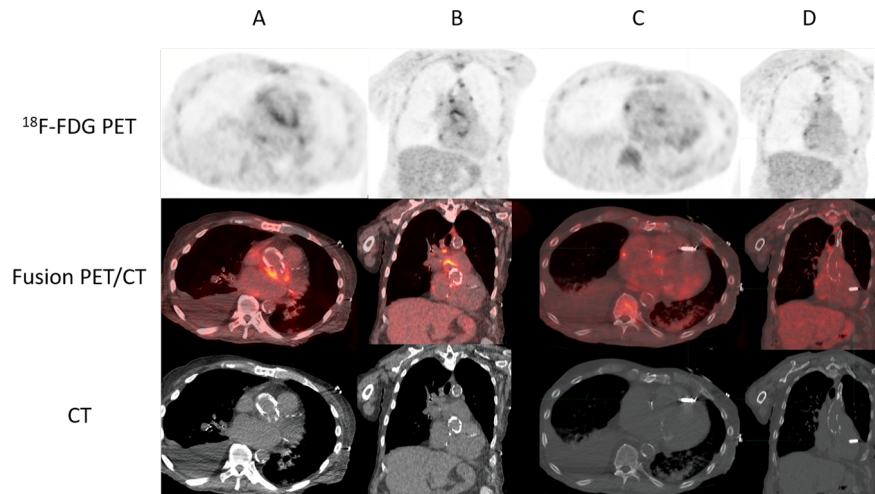


Table 1. Population characteristics

	All (n=155)	No bacteraemia (n=140, 90.3%)	Bacteraemia (n=15, 9.7%)	p-value
Follow-up (days)	623 (358 – 1061)	621 (402 – 1035)	649 (233 – 1140)	0.540
Age (y)	83.0 (77.0 – 87.0)	83.0 (78.0 – 87.0)	81.0 (77.0 – 82.0)	0.077
Male	96 (61.9%)	86 (61.4%)	10 (66.7%)	0.691
BMI (kg/m ²)	25.9 (23.8 – 28.5)	25.9 (23.8 – 28.5)	25.7 (23.5 – 28.4)	0.896
History of AF	93 (60.0%)	82 (58.6%)	11 (73.3%)	0.267
Indication for pacing				
High degree AV block	81 (52.3%)	72 (51.4%)	9 (60.0%)	0.432
Sick sinus syndrome	21 (13.5%)	18 (12.9%)	3 (20.0%)	
AF with bradycardia	53 (34.2%)	50 (35.7%)	3 (20.0%)	
Anticoagulation	103 (66.5%)	91 (65.0%)	12 (80.0%)	0.242
CHADS-VASc	4.0 (3.0 – 5.0)	4.0 (3.0 – 5.0)	4.0 (3.0 – 5.0)	0.421
Creatinine (mg/dL)	1.11 (0.91 – 1.41)	1.09 (0.89 – 1.39)	1.37 (0.97 – 2.06)	0.070
Renal function (eGFR, mL/min)	60.7 (45.0 – 77.0)	61.6 (46.0 – 77.0)	50.1 (36.3 – 69.2)	0.182
Dialysis	8 (5.2%)	5 (3.6%)	3 (20.0%)	0.006
LVEF (%)	55.0 (53.0 – 60.0)	55.0 (54.5 – 60.0)	60.0 (56.3 – 60.0)	0.052
Arterial hypertension	111 (71.6%)	99 (70.7%)	12 (80.0%)	0.448
Coronary artery disease	54 (34.8%)	49 (35.0%)	5 (33.3%)	0.898

	All (n=155)	No bacteraemia (n=140, 90.3%)	Bacteraemia (n=15, 9.7%)	p-value
COPD / pulmonary fibrosis	16 (10.3%)	14 (10.0%)	2 (13.3%)	0.687
Chronic cortisone use	11 (7.1%)	10 (7.1%)	1 (6.7%)	0.946
Diabetes Mellitus	37 (23.9%)	33 (23.6%)	4 (26.7%)	0.789
History of heart failure	19 (12.3%)	18 (12.9%)	1 (6.7%)	0.487
History of valve intervention	49 (31.6%)	39 (27.9%)	10 (66.7%)	0.002
History of pacemaker extraction due to infection	13 (8.4%)	12 (8.6%)	1 (6.7%)	0.800
Implant procedure duration (min)	42.0 (36.0 – 58.0)	43.0 (36.0 – 58.8)	38.0 (33.0 – 50.0)	0.261
Device redeployments during the implantation				
0	110 (71.0%)	99 (70.7%)	11 (73.3%)	0.849
1	28 (18.0%)	25 (17.9%)	3 (20.0%)	0.849
[?]2	17 (11.0%)	16 (11.4%)	1 (6.7%)	

BMI: body mass index; AF: Atrial Fibrillation, eGFR: estimated glomerular filtration rate; LVEF: left ventricular ejection fraction; COPD: chronic obstructive pulmonary disease.

Table 2 : Specific characteristics of patients with bacteraemia

Patient n°	Microorganism	Source of infection	18-F FDG PET/CT	Treatment
1	Gram positive <i>Streptococcus group G</i>	Unknown	NA	Antibiotics Cefepime- Vancomycin Duration: 10 days
2	Gram negative <i>Escherichia coli</i>	Pyelonephritis	NA	Antibiotics Piperacillin- Tazobactam Duration: 10 days
3	Gram positive <i>Streptococcus gallolyticus</i>	Unknown	Negative	Antibiotics Amoxicillin Duration: 14 days
4	Gram negative <i>Escherichia coli</i>	Unknown	NA	Antibiotics Amoxicillin -Clavulanic acid Duration: 14 days

Patient n°	Microorganism	Source of infection	18-F FDG PET/CT	Treatment
5	Gram positive <i>Enterococcus faecalis</i>	Prosthetic aortic valve endocarditis	FDG uptake on aortic valve prosthesis	Antibiotics Amoxicillin -Gentamycin Duration: 6 weeks
6	Gram positive <i>Enterococcus faecium</i>	Unknown	Negative	Antibiotics Vancomycin Duration: 14 days
7	Gram negative <i>Klebsiella pneumoniae</i> Gram negative <i>Pseudomonas aeruginosa</i>	Urosepsis	NA	Antibiotics Piperacillin-Tazobactam Duration: 14 days
8	Gram positive Streptococcus bovis	Unknown	NA	Antibiotics Amoxicillin-Clavulanic acid Duration: 14 days
9	Gram positive <i>Staphylococcus epidermidis</i>	Cutaneous	Negative	Antibiotics Vancomycin Duration: 10 days
10	Gram positive <i>Staphylococcus aureus</i>	Unknown	NA	Antibiotics Amoxicillin-Clavulanic acid Duration: 14 days
11	Gram negative <i>Proteus mirabilis</i>	Urosepsis	NA	Antibiotics Amoxicillin-Clavulanic acid Duration: 14 days
12	Gram positive <i>Staphylococcus epidermidis</i>	Aortic and mitral valves endocarditis	NA	Antibiotics Vancomycin – Rifampin Duration: 6 weeks Heart surgery Aortic and mitral valve replacement + Micra extraction
13	Gram positive <i>Staphylococcus aureus</i>	Mitral endocarditis	Negative	Antibiotics Flucloxacillin Duration: 3 weeks (until death) Heart surgery Mitral and aortic valve replacement + tricuspid valve annuloplasty
14	Gram positive <i>Enterococcus faecium</i>	Cutaneous	NA	Antibiotics Vancomycin Duration: 14 days

Patient n°	Microorganism	Source of infection	18-F FDG PET/CT	Treatment
15	Gram positive <i>Staphylococcus lugdunensis</i>	Aortic and Mitral valve endocarditis	FDG uptake on mitral valve	Antibiotics Flucloxacillin Heart surgery Duration: 6 weeks Aortic and Mitral valve replacement + Micra extraction

NA: not available