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Original Research Article

Troubleshooting in Leadless System Pacemaker: Thrombus in Micra Delivery

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Abstract:

Background: Implantable cardiac devices such as pacemakers have traditionally used transvenous leads inserted into the heart through the subclavian vein. However, the use of leads poses several complications. Leadless pacemakers have emerged as a promising alternative, and the Micra Transcatheter Pacing System (TPS) is the first and only leadless pacemaker approved by the US Food and Drug Administration (FDA). While the safety and efficacy of Micra TPS have been demonstrated in several studies, there are potential risks associated with its use, including thrombus formation.

Case Summary: In this report, a case of thrombus formation in the delivery system of a Micra TPS is presented. A 40-year-old male with atrial fibrillation was planned for a single-chamber pacing using the Micra TPS. During the procedure, the device was repositioned multiple times due to high pacing impedance values and lack of ventricular capture. A thrombosuction of large layered clot was done, and the device was implanted successfully.

Conclusion: Thrombus formation is a well-known complication of implantable cardiac devices that can lead to device malfunction and potentially life-threatening complications. The incidence of thrombus formation in leadless pacemakers is low, but it may be higher in certain patient populations. Prompt recognition and management of thrombus formation in leadless pacemakers are critical to prevent device malfunction and potential harm to the patient. Thrombosuction and administration of anticoagulation therapy, as done in this case, are effective in resolving the thrombus and preventing further embolic events.

Keywords: Micra Leadless Pacemaker, Atrial Fibrillation, Right Ventricular, Bradycardia, Thrombus.

Introduction

Implantable cardiac devices, such as pacemakers, defibrillators, and cardiac resynchronization therapy devices, have revolutionized the management of various cardiac conditions. These devices have traditionally relied on transvenous leads that are inserted into the heart via the subclavian vein. However, the use of leads is associated with several complications, including infection, lead fracture, and lead dislodgement [1]. Furthermore, the presence of leads can limit patient mobility and increase the risk of lead-related complications.

Leadless pacemakers, which eliminate the need for transvenous leads, have emerged as a promising alternative. The Micra Transcatheter Pacing System (TPS) is the first and only leadless pacemaker approved by the US Food and Drug Administration (FDA). The Micra TPS is a self-contained device that is implanted directly into the right ventricle of the heart via a catheter inserted through the femoral vein [2].

Several studies have demonstrated the safety and efficacy of the Micra TPS, with high rates of implant success and low rates of major complications [3,4]. However, as with any medical device, there are potential risks associated with the use of the Micra TPS. Thrombus formation is a well-known complication of implantable cardiac devices and can occur in both traditional pacemakers and leadless pacemakers. Thrombus formation can lead to device malfunction and potentially life-threatening complications, such as embolization [5]. Thrombus formation is more common in patients with comorbidities such as atrial fibrillation, congestive heart failure, and prior thromboembolic events. However, it can also occur in patients without known risk factors. Prompt recognition and

management of thrombus formation in leadless pacemakers are critical to prevent device malfunction and potential harm to the patient [6].

In this report, we present a case of troubleshooting in a Micra TPS due to the presence of a thrombus in the delivery system, highlighting the importance of careful patient selection, thorough device evaluation, and appropriate management of device-related complications.

Case Presentation

A 40-year-old male with non-structural heart disease presented with atrial fibrillation with a slow ventricular rate(Figure 1). He had a history of a few episodes of giddiness (presyncope) without syncope and no other comorbidity.

In view of the atrial fibrillation, the patient was planned for single-chamber pacing (VVI), and a leadless pacemaker (Micra) was chosen. The device was initially deployed at the midportion of the right ventricular septum, and electrical measurements were checked (Figure 2).

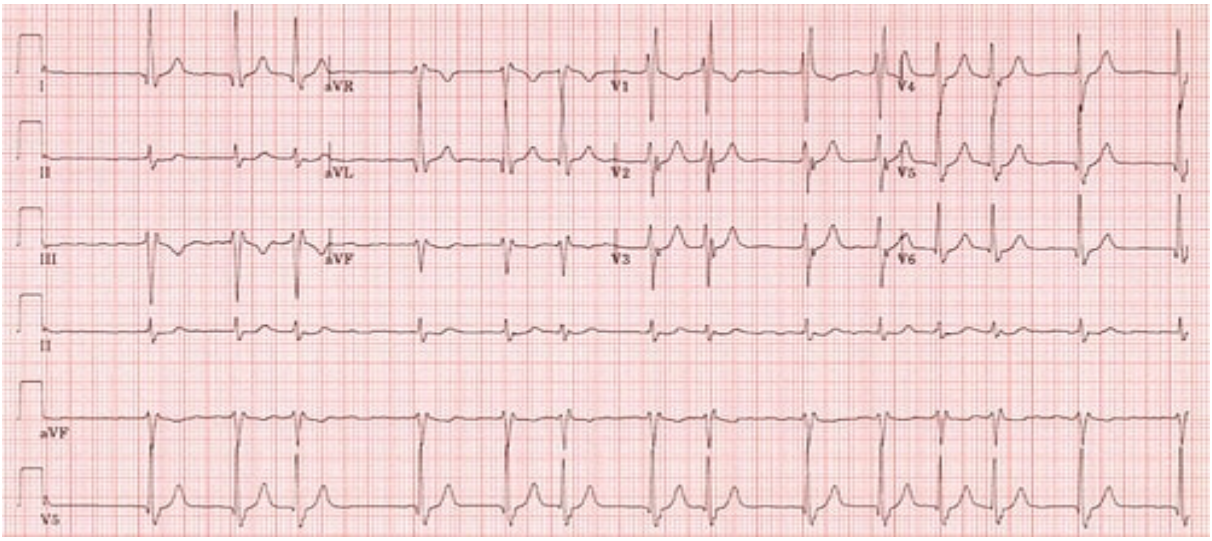


Figure 1: Atrial fibrillation with a slow ventricular rate

However, very high pacing impedance values were observed, and there was a lack of ventricular capture. The device was then retracted and repositioned to a more apical position of the septum, but high pacing impedance was again observed. The leadless pacemaker was repositioned several more times to different positions in the right ventricle (midseptum, apical septum, and even the septal aspect of the right ventricular outflow tract) with similar electrical parameters observed (threshold more than 2).

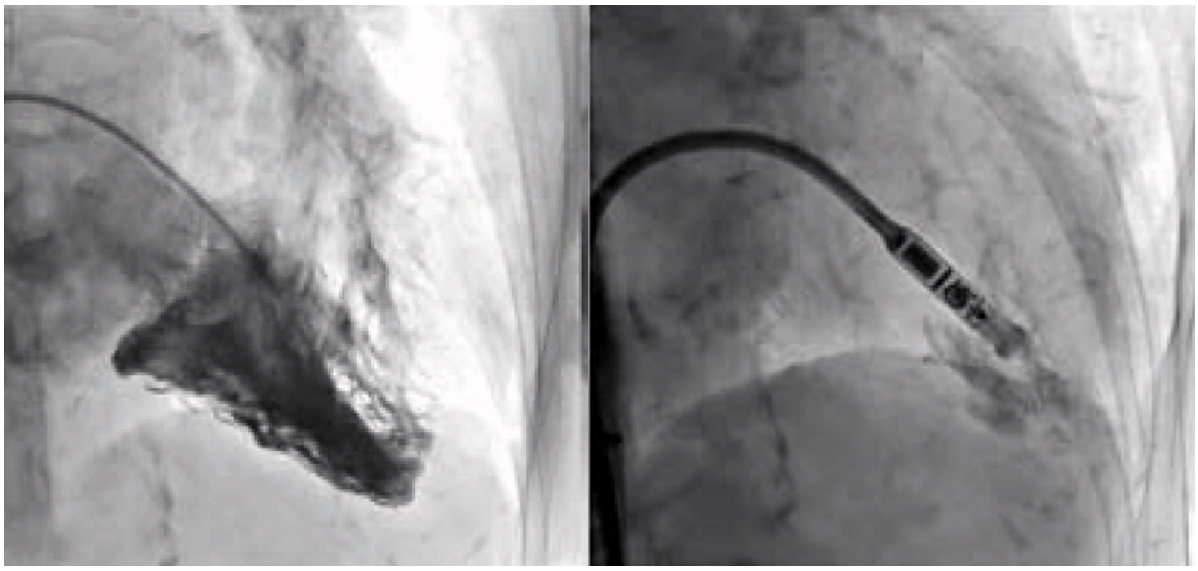
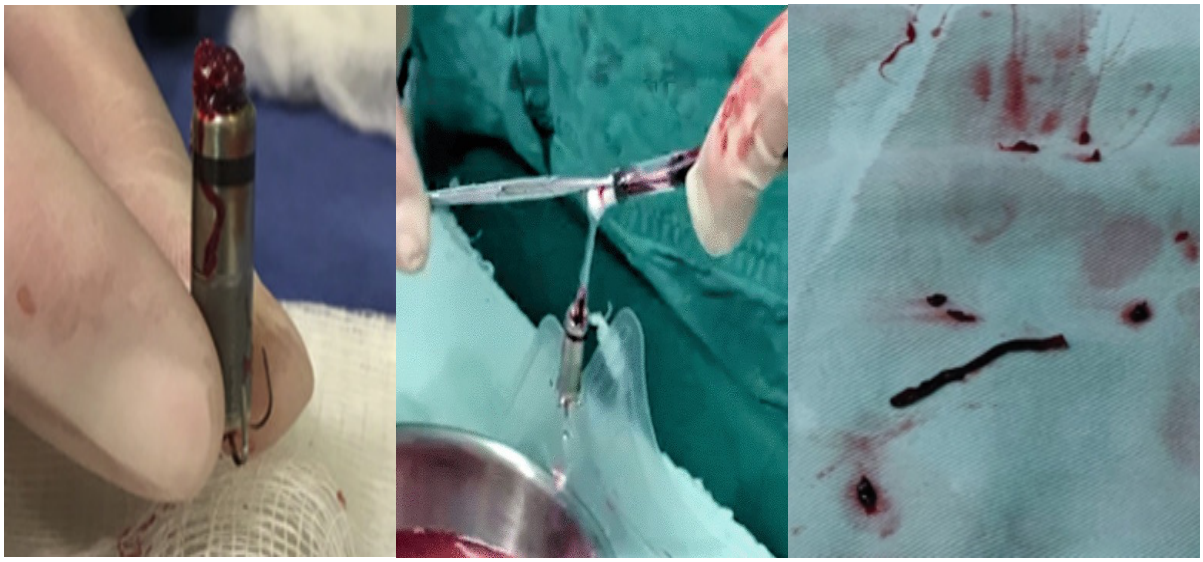


Figure 2: Deployment of Micra device

At this point, the device and the steerable transfemoral catheter delivery system were removed to the introducer, and a thrombosuction of a large layered clot was performed (Figure 3).



(A) (B) (C)

Figure 3: A. Thrombus in the Micra device. B. Removal of thrombus. C. Removed thrombus

Subsequently, a 1000-U bolus of intravenous heparin was administered, and the system was again inserted through the long introducer. The transcatheter leadless pacemaker was deployed at the midseptum of the right ventricular endocardium, in a position very similar to that previously implanted several times, and 770 ohms impedance was achieved, along with a 0.5 V @ 0.24 ms threshold. A tug test confirmed successful implantation, and 3 tines were confirmed in RV tissue.

Discussion

In this case report, we presented a case of thrombus formation in the delivery system of a Micra Transcatheter Pacing System (TPS), a leadless pacemaker. The patient had atrial fibrillation and was planned for a single-chamber leadless pacemaker implantation.

During the procedure, the device was repositioned multiple times due to high pacing impedance values and lack of ventricular capture. Subsequently, a thrombosuction of large layered clot was done, and the device was implanted successfully. Thrombus formation is a well-known complication of implantable cardiac devices and can lead to device malfunction and potentially life-threatening complications such as embolization. The incidence of thrombus formation in leadless pacemakers is reported to be low, ranging from 0.7% to 3.8% [2,7].

However, the incidence may be higher in certain patient populations, such as those with comorbidities such as atrial fibrillation, congestive heart failure, and prior thromboembolic events [8,9]. The pathophysiology of thrombus formation in leadless pacemakers is not well understood, but several factors may contribute to its development. These factors include the presence of foreign materials, such as the delivery system and the pacemaker itself, endothelial damage during the implantation procedure, and patient-related factors such as blood stasis and hypercoagulability [10]. Prompt recognition and management of thrombus formation in leadless pacemakers are critical to prevent device malfunction and potential harm to the patient. Thrombosuction and administration of anticoagulation therapy, as done in our case, are effective in resolving the thrombus and preventing further embolic events. Adequate heparinized saline flow rate was recommended by the authors [11,12]. After the previous experience, we modified our Micra implantation technique and have not encountered any further problems. Prior to Micra deployment, we now flush the system under pressure through the port access using a syringe filled with heparinized saline. Since adopting this technique, we have observed faster tether retrieval and no further clot formation. Based on our experience, we recommend re-evaluating the current standard recommendations for delivery system flushing and suggest that heparin infusion diluted in normal saline be used throughout the procedure to prevent thrombus formation.

Conclusion

In conclusion, thrombus formation is a potential complication during the implantation of leadless pacemakers that can result in device malfunction and potentially life-threatening complications. Prompt recognition and management of thrombus formation are critical to ensure successful implantation and prevent harm to the patient.

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