Tether fracture in Leadless pacemaker during repeated recapture

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Short title: Tether fracture in LLPM during repeated recapture

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**Introduction**

Micra transcatheter pacemaker system (Micra, Medtronic, Minneapolis, MN, USA) is a leadless pacemaker recently available in several countries and an alternative to traditional transvenous pacemakers (TV-PPM) with high safety and efficacy.\(^1\) The reposition of Micra is required to achieve a lower pacing threshold for the long-term longevity of the battery at the device implantation. A tether, connecting the delivery catheter to the Micra, allows the Micra reposition. This tether is enough to touch to retract Micra by pulling back maneuver. In the best of our knowledge, only one case of tether failure has been reported in the past.\(^2\)

We report a case with the tether fracture during Micra implantation after multiple attempts of deployment.

**Case report**

A 50-year-old woman with symptomatic 2:1 atrioventricular block and acute congestive heart failure. Her comorbidities were diabetic nephropathy on maintenance hemodialysis, panic disorder, and attention deficit hyperactivity disorder. During the management of heart failure, a complete atrioventricular block developed with a reduced heart rate of 30 beats/min on the 4th hospital day. On the 8th hospital day, the patient developed torsade de pointes due to bradycardia induced QT prolongation (QTc 593ms), followed by ventricular fibrillation. Cardiopulmonary resuscitation was performed, and she was successfully resuscitated by defibrillation. The echocardiography showed normal LV systolic function with LVEF 70%, LV diastolic and systolic diameter were 50mm and 28mm, and no valvular diseases.

Under the support of a temporary pacemaker in the right ventricle (RV), Leadless pacemaker implantation was performed by the patient’s strong preference in place of the transvenous pacemaker. The delivery catheter system was advanced to the inferior vena cava through the right femoral vein. Micra was deployed in the septal side of the apex at the first attempt (Figure1 A,B). The threshold value was high (>2.0V/0.4ms) and we changed the implantation site to the lower or middle septum and basal septum near the tricuspid annulus (Figure1 C). The threshold was still high at the seventh attempt of deployment.

After the seventh attempt, the retraction of Micra was no longer possible, even keeping the head of the Micra coaxial with the recapture cone. Then we tried to retrieve the Micra by moving the position of the tip of the sheath. However, the head of the Micra could not be stored in the Recapture cone (Figure1 D). We thought that the Micra was entangled in the complex structure in the RV basal
endocardium and could not be pulled out with normal force. During continuous pulling of the tether with strong power, the tether finally was broken (Figure 1E).

We used another system of Micra and finally implanted the Micra in the high septum after 6 attempts with a better pacing threshold (0.38 V/0.4 ms) (Figure 2A,B).

After that, we successfully retrieve the first locked Micra using a deflectable sheath (Agillis, Abbott, MN USA) and 25mm snare catheter (Amplatz Goose Neck Snare, Medtronic) (Figure 2C-E).

Finally, we observed the broken tether had no abrasion (Figure 3). After Micra implantation, the patient became ventricular pacing dependent. An echocardiogram did not show the apparent tricuspid regurgitation.

During 13 months follow-up after implantation, the pacing threshold was still acceptable (0.25V/0.24ms) and The ECG showed normal QTc of 420ms. And there were no episodes as syncope or high ventricular episode in a clinical course.

Discussion

We reported a rare complication of the tether fracture of Micra. More than 100,000 of Micra have been implanted since Micra as the 1st leadless pacemaker was launched. Only one case report was published concerning the tether fracture. 2)

The tether is made of polyether and coated with polytetrafluoroethylene. It can withstand very high tension and does not fail during normal retrieval procedures. From the data of the manufacturer, the strength of the tether is expected to be the weight of 2kg.

In previous reports, more than 6 redeployments frequently lead to pericardial effusions in high-risk patients. 4) In our case, the deployment Micra was difficult, and attempted seven deployments of Micra before the fracture of the tether. After the seventh deployment at the basal septum, Micra was never retracted to the recapture cone. Repeated recapture may increase the risk of retraction failure.

The basal septum of RV has a complicated anatomical structure with the tendon chordae and papillary muscle of the tricuspid valve. This complicated anatomical structure was related to the catheter entrapment in the tricuspid valve as already reported.3) We speculated that the Micra became entangled and fixed in a complex RV basal endocardium during the deployment process. As a result, the tether broke when pulled with a strong force beyond the durability of the tether. Fortunately, the extraction of fixed Micra was successfully possible without the destruction of the tricuspid valve.

A previous report described that the tether was weakened by abrasion due to repeated retraction if the angle between the device and the recapture cone was too steep during
recapture. 2) The tether had no abrasion in this case, therefore we did not consider this phenomenon as the reason for tether fracture. Another explanation is the excessive force over the durability of the tether, which was weakened by repeated deployment. Fixed entrapment of Micra in the complex RV endocardium structure and the weakened tether by repeated redeployment may be the underlying cause of the fracture of the tether in this case.

Conclusion

We report a case of tether fracture during Micra implantation. The implantation of the Micra at the basal RV endocardium has the potential risk of entrapment of the complex RV structure. In addition, the repetitive recapture probably caused a risk for tether fracture.

References

2) Tsz Kin Tam, Yat Sun Joseph Chan , Chin Pang Gary Chan , Kin Yin Anna Chan, Chi Yuen Chan.
Figure 1  A, B: Contrast RVography demonstrated the location of Micra at the initial attempt of delivery. A: RAO 30°, B: LAO 60° C: The position of Micra before the tether fracture close to the TV. D: The Micra cannot be stored in the recapture cone even by hard pulling. E: The tether has finally broken during continuous pulling the tether.

CDE: RAO30°

RV: Right ventricle, RAO: Right anterior oblique, LAO: Left anterior oblique, TV: Tricuspid valve,
Figure 2  AB: The deployment of the 2nd Micra at high RV septum  A: RAO30°, B: LAO60°. C: The goose neck snare caught the tail of Micra supported by delectable sheath. D: Strong traction finally dislodged the Micra from the myocardium. It moved into the right atrium on the spur of movement. E: The Micra was caught with Snare in SVC and successfully retrieved it.  CDE: RAO30°
Figure 3  The broken tether. No abrasion was observed.
Key teaching points

1. Micra transcatheter pacemaker system (Micra, Medtronic, Minneapolis, MN, USA) is an alternative to traditional transvenous pacemakers (TV-PPM) with high safety and efficacy. We reported a rare complication of tether fracture during Micra implantation after multiple attempts of deployment.

2. Multiple repeated deployments may result in the tether fracture, following the device entrapment in RV endocardium.

3. The implantation of the Micra at the basal RV endocardium has the potential risk of entrapment of the complex RV structure.