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A Rare Complication of Percutaneous Mitraclip Delivery System- Lock Line Malfunction: Management and Review of Literature

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Introduction

Mitral regurgitation (MR) is the most frequent form of valvular heart disease in the United States, and prevalence increases with age [1]. The treatment of MR can be complex and has been treated almost exclusively by cardiothoracic surgeons. In recent years, the creation of a percutaneous edge-to-edge mitral valve repair using the MitraClip device has gained favor among cardiothoracic surgeons and cardiologists for patients who would be at high risk for morbidity and mortality with open cardiac surgery. In the EVEREST II 5-year follow up study, Feldman et al. [2] reported that both percutaneous MitraClip placement and surgical intervention have similar long-term results in MR reduction.

COAPT and MITRA-FR trials have broadened the use of MitraClip even in patients with functional MR [3,4]. We report a case of functional MR requiring Mitraclip placement during which we encountered MitraClip delivery system malfunction wherein the lock line could not be released and upon attempting to remove the Clip Delivery System (CDS) the clip was unlocked becoming a free-floating foreign body in the left atrium attached to the lock line.

Case Report

An 89-year-old female with complex cardiac history including coronary artery disease status post multiple coronary stents and a three-vessel coronary artery bypass in 2001, cardiomyopathy, mild to moderate aortic stenosis and severe mitral regurgitation (MR) presented for management of heart failure. After workup, she was deemed to be a suitable candidate for MitraClip procedure. Procedural planning transesophageal echocardiogram (TEE) was preformed one day prior to MitraClip procedure. TEE revealed left ventricular (LV) ejection fraction of 45%, dilated left atrium (LA), mild to moderate aortic stenosis, and severe MR due to impaired coaptation of the mitral leaflets, LV dilatation and posterior leaflet restriction (Figure 1).

Following TEE, the patient developed new-onset atrial fibrillation in the post-anesthesia care unit requiring cardioversion due to hemodynamic instability. In the Cardiac Intensive Care Unit, the patient was sedated using infusions of midazolam at 2mg/hr and fentanyl at

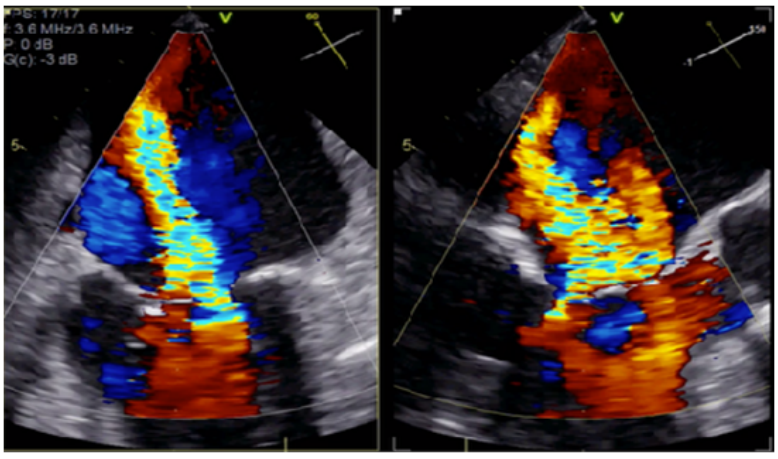

Figure 1: Biplane ME view including ME commissural view on the left and ME long axis view on the right (zoomed in). This image demonstrates the preoperative severity of mitral regurgitation

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100 mcg/hr. Phenylephrine 0.5 mcg/kg/min and dobutamine 5mcg/kg/min were initiated for hemodynamic instability and a right radial arterial line and an 8 Fr Cordis introducer with Swan-Ganz catheter in the right internal jugular vein were placed for monitoring.

The patient was brought into the cardiac catheterization lab and prepared for MitraClip procedure. Midazolam and fentanyl infusions were discontinued and the patient was started on dexmedetomidine at 0.7 mcg/kg/hr along with 0.3 to 0.5 MAC of sevoflurane titrated to a bispectral index of 40-60. The right femoral vein was cannulated by the cardiology team, and a trans-septal puncture kit was used to facilitate the introduction of the MitraClip NT sheath into the left atrium. The height of the trans-septal puncture was measured at approximately 4.5 cm above the mitral annulus. The MitraClip deployment sheath was placed into the right femoral vein, advanced into the right atrium (RA), and finally across the interatrial septum (IAS) into the LA. The MitraClip deployment device was then placed through the femoral venous sheath and into the LA.

Using TEE and radiographic guidance, the MitraClip was positioned between the anterior (A2) and posterior (P2) leaflets. Multiple attempts were required to successfully grasp both leaflets simultaneously, after which the clip was deployed and grippers engaged. Adequate tissue bridging was confirmed with 2D and 3D TEE prior to deployment. Due to the presence of persistent moderate MR, a decision was made to place a second clip lateral to the First clip.

The second CDS was advanced to the mitral valve. Using TEE and Fluoroscopy, the clip was positioned immediately lateral to the First clip. Prior to deployment, adequate tissue bridge was observed between the A2/A3 and P2/P3 scallops of the mitral valve. Deployment sequence was initiated per the instructions for use [5]. The lock line was flossed without issue. Upon removal of the lock line, increasing resistance was noted. A knot was suspected in the lock line, dictating that the lock line was left in place, and the deployment sequence continued. The gripper line was removed and the clip was successfully deployed. The CDS was planned to be straightened first so the lock line could then be removed. While slowly straightening the CDS to prepare for removal from the LA, the MitraClip completely detached from the mitral leaflets. The MitraClip was noted to be fully inverted, freely floating in the LA, tethered to the lock line which remained across the IAS. As the clip was fully inverted, it was not possible to retract it into the Steerable Guide Catheter (SGC) for removal from the LA. Tension was applied to the lock line in attempt to retract the clip into the RA. Upon applying tension the clip retracted slightly into the transeptal puncture site, however, it was unable to be fully retracted across the IAS into the RA. A 6 Fr multipurpose snares and gooseneck snare were advanced across the IAS to attempt to snare the clip, however multiple attempts proved unsuccessful. The SGC was advanced across the IAS and lock line was pulled to retract the clip tight against the tip of the SGC. The entire system, SGC with free clip pulled tight to the tip, was retracted into the right atrium. Resistance and bowing of the IAS from left to right was observed. With significant force, the SGC and free clip were successfully retracted into the RA (Figure 2). The system was then withdrawn into the IVC and femoral vein, facilitating clip extraction.

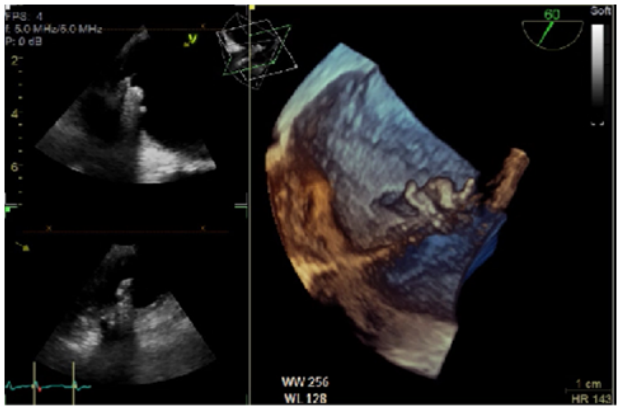

Figure 2: 3D image of the interatrial septum looking from the left atrial side. During initial attempts to remove the MitraClip across the interatrial septum, we can see the completely detached and inverted MitraClip on the left atrial side of the septum.

A comprehensive TEE was performed following removal of the free clip to evaluate for potential structural damage. The MR was noted to be reduced from severe to moderate with the initial clip placement. Iatrogenic atrial septal defect from the trans-septal puncture, measuring 0.8 cm with a left to right Flow was evident on color Flow Doppler. No damage to the mitral apparatus was identified and remainders of TEE Tindings were unchanged from preoperative assessment. Following TEE interrogation and multi-disciplinary discussion, consensus was to not proceed with another clip placement for persistent moderate MR as the access was lost due to SGC removal. The MitraClip delivery system was sent to the manufacturer for investigation.

The patient was transported to the cardiovascular intensive care unit on 5 mcg/kg/min of dobutamine and 0.7 mcg/kg/min of phenylephrine. She was extubated on post-operative day (POD) 2 and weaned off vasoactive medication on POD 5. Her postoperative course was complicated by fever and shock liver, which improved by POD 5. The patient was discharged to a subacute rehabilitation facility on POD 10 in stable condition.

Discussion

EVEREST trials helped to illustrate the efficacy and safety of the MitraClip procedure and solidified its role as an alternative to conventional surgical approaches in high-risk patients with degenerative MR [6,7]. To further extend the indications, Stone et al. have recently published the results of the COAPT trial, wherein they showed that transcatheter mitral valve approximation using the MitraClip on a background of guideline-directed medical therapy (GDMT) was superior to GDMT alone in reducing heart failure hospitalization and mortality in symptomatic patients with grade 3-4+ secondary MR [3]. In contrast to the results of COAPT trial, MITRA-FR investigators have demonstrated that percutaneous implantation along with medical therapy did not differ significantly from medical therapy alone [4]. The debatable outcomes seen in COAPT and MITRA-FR trials could be due to the differences in inclusion/exclusion criteria for MR severity, LV dimensions and LV dysfunction [8]. As our case report is focusing on a complication associated with the procedure, we shall move on with the discussion here and wait for the results of the RESHAPE-HF2 trial. Although MitraClip procedure has been shown in studies to have superior safety when compared to surgery, it is not without complication. There are several complications reported in literature associated with percutaneous MitraClip implantation including bleeding, pericardial tamponade, stroke, mitral leaflet injury, partial clip detachment, clip embolization, conversion to open surgery and death [9,10]. The largest cohort of patients studied for risks and complications is from the German TRAnscatheter Mitral Valve Interventions (TRAMI) registry. Eggebrecht et al. reported a complication rate of 12.8% in this cohort of 828 patients [10]. Bleeding complications requiring transfusions represented the greatest portion of major complications followed by partial clip detachment [7,10]. The reported incidence of partial/complete clip detachment was 2.0 -5.3% and clip embolization occurred in 1.2% of cases [10-12]. there are two cases of clip embolization reported in the literature, both describing placement of three or more clips for edge to edge repair [12,13]. In one case the missing clip was found in the right axillary artery and in the other case, it was found in the renal artery. It was reported that there were no sequelae in both the cases at follow up [13,14]. The presented case differs from free clip embolization as our clip was free Floating in the LA but remained tethered to the lock line preventing systemic clip embolization (Figure 3).

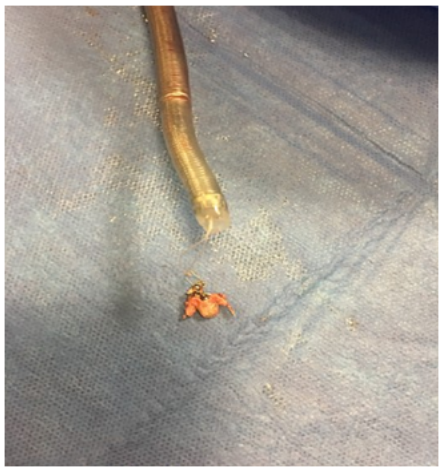

Figure 3: Steerable Guide Catheter with inverted MitraClip attached via lock line after retrieval.

Device malfunction has been rarely reported in the literature. Argenziano et al have reported one case of device malfunction in 107 patients from the EVEREST phase I registry [15]. Malfunction resulted in an inability to unlock and reposition the clip after initial placement. There was also a class I recall by Abbott due to 9 reports of cases where the clip delivery system could not be detached from the clip due to malfunction of the device [16]. In a similar fashion, the lock line became stuck on to the deployed clip resulting in clip detachment from the mitral tissue in the presented case. Fortunately, the clip remained tethered to the lock line and was retrieved without any major complication.

Following the presented case, the MitraClip NT device was sent to Abbott for further investigation. The manufacturer reported a knot in lock line, likely limiting its ability for removal. They could not replicate the incident in a testing environment and there were no similar reports from the batch of MitraClip NT systems with similar manufacture date. In correspondence from Abbott they state "there is no indication of a product quality issue with respect to design, manufacture or labeling of the device and given the size and location of the knot, it is possible that lock line became knotted at the end after the unwrapping process. The complete clip detachment was a result of troubleshooting maneuvers (pulling on the lock line) during the inability to remove the lock line and removing the CDS". In retrospect, we could not discern any specific defect leading to knot in the lock line during the preparation phase of the CDS. The interventional cardiology industry is experiencing explosive growth with a multitude of new devices coming to market and constant revisions to existing device delivery platforms [17]. It is critical that operators of these devices understand the intricate details of the medical devices, as a minor Flaw during preparation or functional inspection of the device can lead to a catastrophic complication.

In conclusion, this case report intends to expose clinicians to a novel complication with the percutaneous MitraClip procedure: lock line malfunction causing complete clip detachment. Reporting of such rare occurrences not only helps the medical fraternity to be cognizant of the complications they might encounter, but also assists the Food and Drug Administration with post-market surveillance [9].

Summary

This case describes an intra-procedural complication during elective MitraClip placement. Lock line malfunction due to a knot led to complete detachment of the MitraClip from mitral leaflets. The complication was immediately recognized with TEE examination and on Fluoroscopy, avoiding potentially life-threatening embolism of the completely detached MitraClip and guiding with the retrieval of the detached MitraClip tethered to the lock line.

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