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Case Report / Olgu Sunumu

Outflow graft twisting of Heartmate III left ventricular-assisted device: A case report

Heartmate III sol ventrikül destek cihazının outflow greft bükülmesi: Olgu sunumu

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ABSTRACT

Outflow graft twisting of Heartmate III left ventricular-assisted device is a rare device complication and, due to the recent reports from transplant centers, the firm and the United States Food and Drug Administration have announced explanatory measures. When the outflow graft twisting occurs, the diagnosis and treatment should be done without any delay due to serious decline in the device output and unstable hemodynamics. This article describes the first case of an outflow graft twisting in Turkey.

Keywords: Graft, Heartmate III, left ventricular-assisted device, outflow, twisting.

ÖZ

Heartmate III sol ventrikül destek cihazı ile outflow greft bükülmesi, nadir görülen bir cihaz komplikasyonu olup, nakil merkezlerinden son zamanlarda yapılan bildirimler nedeniyle, firma ve Amerika Birleşik Devletleri Gıda ve İlaç İdaresi önlem amaçlı açıklamalarda bulundu. Outflow greft bükülmesi gerçekleştiğinde, cihaz debisinde ciddi düşüş ve hemodinaminin bozulmasına bağlı olarak, tanı ve tedavisi zaman kaybetmeden yapılmalıdır. Bu yazıda Türkiye'de ilk kez görülen bir outflow greft bükülme olgusu sunuldu.

Anahtar sözcükler: Greft, Heartmate III sol ventrikül destek cihazı, outflow, bükülme.

Heartmate III (Abbott, Abbott Park, IL, USA) is a new-generation centrifugal device with a novel impeller system associated with improved outcomes by lower pump thrombosis events, leading to pump-related malfunction, and reduced incidence of stroke events, compared to the axial flow HeartMate II left ventricular assist device (LVAD).[1-3] This pump has also superior hemocompatibility to other pumps.[4,5] On the shade of these advances, twisting of outflow graft has begun to be reported from different centers which cause hemodynamic failure and reduced pump flow.[6-9] Although the mechanism of this twist has not been clearly identified yet, it has been suggested that this phenomenon may occur due to swivel joint which allows relatively free rotation of this graft once implanted designed to allow repositioning during surgery to correct any torque, twist, or kink.[9] By the time with the movements of cardiac and respiratory frictional forces and turbulent flow due to the centrifugal current, micro-movements of the outflow graft can accumulate to twist the outflow graft and obstruct the flow. Moreover, migration and angular reformation of the LVAD during cardiac remodeling after the implantation procedure may be another reason.

The manufacturer of the HeartMate III conducted a review of this issue based on its entire worldwide experience and, on the date of 6th April, 2018, the firm issued a Field Safety Notice which was, then, updated on 21st May, 2018.[10] In this review, a low overall incidence twist rate of 0.72% (32/4,467, 95% CI: 0.5-1%) was noted.[7] The United States Food and Drug Administration (FDA) terminology for a Field Safety Corrective Action is Recall, which was issued as a Class I Recall, called as a reasonable probability that the use of or exposure to a product can cause serious adverse health consequences or death.[10] This

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recall notice includes removal of the product or the correction of a marketed product. In this case, the FDA did not recommend return of products or avoidance of using the product in new patients.[11] Globally, there are about ten cases reported until now.[6-9]

Herein, we report the first case of Heartmate III outflow graft twisting in Turkey.

CASE REPORT

A 57-year-old man with ischemic cardiomyopathy and a history of coronary artery bypass grafting (CABG), stroke, and mild left arm disability underwent LVAD implantation as bridge to transplantation. He was on a stable course until the event (approximately 5 L/min, 5,500 rpm, 3.5 pi, 4.2 watts). At 13 months of support, he was admitted to the hospital with low flow alarm on the LVAD. The pump flow decreased to 1.9 L/min with no further evidence. There were no signs of thrombus on echocardiogram at the time of admission. Lactate dehydrogenase (LDH) levels were not elevated (174 U/L). Both increasing and decreasing the rpm levels of the LVAD, slick response of flow levels and non-changing prominent arterial pulses were remarkable (Figure 1). However, on Day 1, LDH levels were elevated to 320 U/L. 30 mg of tissue plasminogen activator (tPA), alteplase administered as three separate 10 mg doses of one-hour infusion; however, no change was observed in terms of pump parameters. On contrast-enhanced computed tomography (CT) angiography, no signs of pre- or post-pump obstruction was present. In addition, there was a susceptible obstruction at the beginning of the outflow graft (Figure 2). The patient health status was deteriorated due to the regressing flow of LVAD to 0.9 L/min. Femoral venoarterial (V-A) extracorporeal membrane oxygenation (ECMO) support was administered for hemodynamic stabilization. The patient was taken to catheterization lab. The patient was heparinized to achieve an activated clotting time (ACT) level of 300 sec. The LVAD was stopped, permitting the retrograde flow from the pump. The contrast material was given from the level of distal anastomosis of the outflow graft. The sand-glass shaped obstruction was seen at the beginning of the outflow graft, departing the LVAD (Figure 3).

Under the ECMO support, left anterior thoracotomy was undertaken from the seventh intercostal space to expose the beginning of the outflow graft. For better

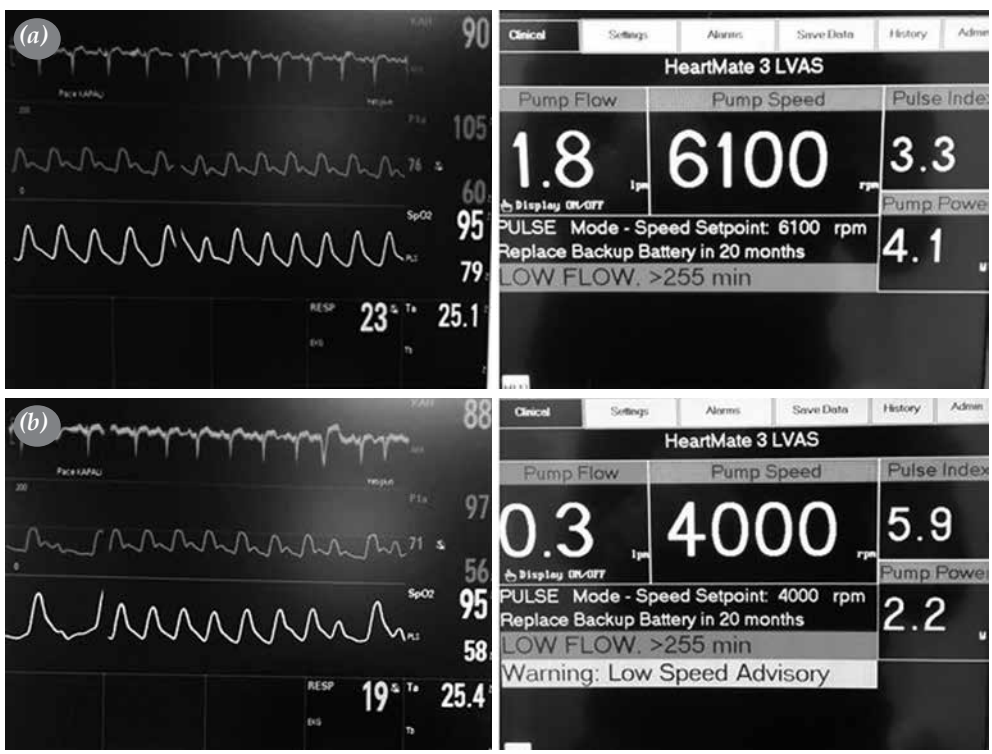

Figure 1. Arterial pulsatility was not affected, when the pump speed increased **(Row A)** or decreased **(Row B)** due to low flow of left ventricular assist device even at a high rpm.

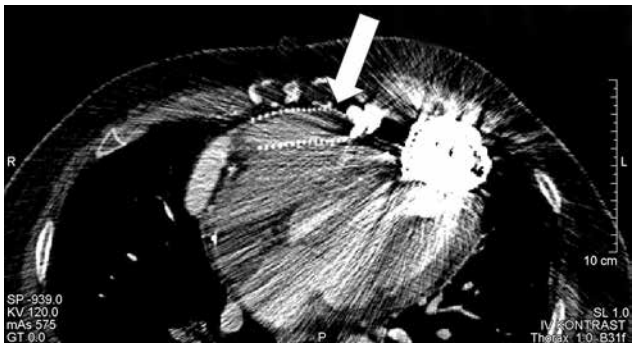

Figure 2. A computed tomography angiography showing susceptible counter clockwise twisting in the beginning of outflow graft.

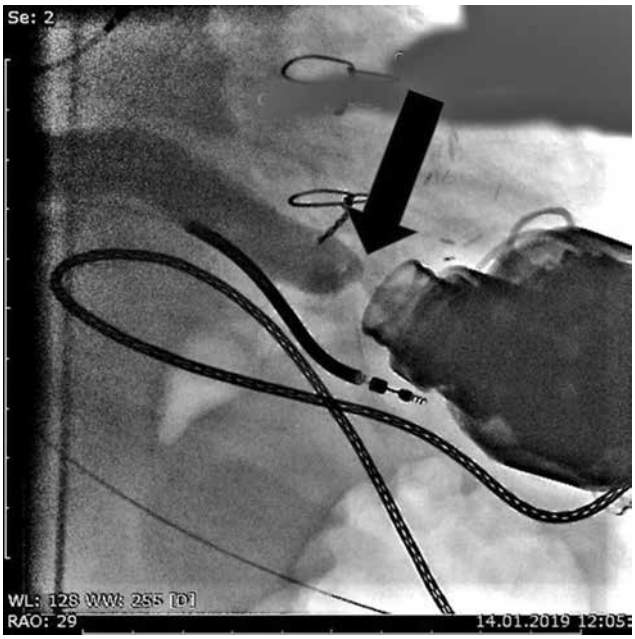

Figure 3. During conventional angiography, contrast material was given retrogradely from aortic inlet following pump stoppage.

exposure, the medial intercostal cartilage was cut and the swivel joint was exposed. The outflow graft protector cuff was removed by its special removal clamp, and a counter-clockwise (approximately 120°) twisted outflow graft was revealed (Figure 4). The outflow graft was turned opposite to its twisting direction from the swivel joint. In addition, the outflow graft protector cuff was re-attached to its original position. Following the rotation, LVAD parameters returned to normal levels. The ECMO was gradually weaned off using transesophageal echocardiography and pulmonary artery pressure monitorization in the operation room. The patient was extubated next day and discharged 15 days after the operation.

Figure 4. Intraoperative swivel joint and counter clockwise twisted outflow graft.

A written informed consent was obtained from the patient.

DISCUSSION

A systematic evaluation conducted by Mehra et al.[7] addressed the presence of outflow graft twist as a low frequency event (incidence 1.6%, 95% CI: 0.7-3.0%) during two-year MOMENTUM 3 trial. Outflow graft twisting is a slowly progressing condition, mostly occur after the first year (mean duration 544 [range 347 to 698] days).[6-9] As a new clinic, in our center, LVADs were implanted to 43 patients within 1.5 years, and 30 of them were Heartmate III. To the best of our knowledge, this is the first case in our center, as well as in Turkey.

The decline of pump flow in our case was around 2.5 to 3 L/min. There were no significant alterations in other pump parameters. In the MOMENTUM 3 study group, the median reduction in the recorded pump flow was 1.6 L/min (range, 0.7 to 3.6 L/min).[7]

In our routine practice, we perform echocardiography, chest X-ray, biochemistry, complete blood count, and international normalized ratio (INR) testing. In addition, we hold records of pump parameters, driveline dressing, and blood pressure of every visit. Once significant alterations occur in a hemodynamic parameter, we examine the patient with serial echocardiograms and apply contrast-enhanced CT angiography. Migration of the LVAD can be diagnosed by repetitive chest X-rays from the implantation. However, in this case, there was no significant angulation change from the implantation to twist.

Contrast imaging studies such as CT angiography and conventional angiography are suggested to conclude the diagnosis.[7,9] In the MOMENTUM 3 database, eight patients were diagnosed with an outflow graft twist. Diagnosis was made with CT angiography in five patients, with ventriculography in two patients, and with echocardiography in one patient. In our case, CT angiogram was initially applied; however graft occlusion was clearly seen in conventional angiography. Computed tomography angiography may not provide enough information where the obstruction is close to the LVAD due to metal artifact formation.

The levels of LDH may remain silent in half of patients as shown in the MOMENTUM 3 study group.[7] In our case, LDH was two-fold increased. Initially, we infused totally 30 mg of alteplase to the patient. The reason was suspected undiagnosed pre-pump thrombosis or resolution of possible thrombosis due to outflow twisting. The tPA infusion did not change any pump-related or hemodynamic parameters.

In the previous reports, surgical intervention was applied to all patients. This approach typically include the turning of the outflow graft opposite of the twisting. Only Potapov et al.[9] introduced a titanium cuff which was useful to stabilize the swivel joint to the outflow graft. In our case, we also countered the twisted outflow graft from the swivel joint. In addition, fixation of the protector cuff of the outflow graft to the diaphragm with sutures can be another solution.

In conclusion, outflow graft twisting of the Heartmate III is a rare complication and has been recently reported from several centers across the world. It must be kept in mind that sudden drop of the pump flow without signs of pump thrombosis may result from this scenario. The definitive treatment of this complication is surgically manual re-twisting of the graft from the swivel joint. Although some additional experimental devices have been introduced, there is still no definite solution to prevent this complication.

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