In 2009, we² published the results of an exhaustive review of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database regarding the incidence of reported adverse events after Amplatzer device placement. In this review, we found an increasing number of events reported over a 5.5-year period, equivalent estimated mortality for device placement compared with Society of Thoracic Surgeons database surgical closure data, and a much higher need for operation and operative mortality *per adverse event* for device closure compared with surgical closure. After publication of these data, we were contacted by representatives of AGA Medical Association, and their concerns regarding possible interpretations of our results led to a clarification letter in a subsequent issue.³ Since that time we have been also contacted by the FDA, where an updated data mining project is supposed to be ongoing to further observe the trends in reported complications.

Although AGA Medical has made honest attempts at good faith reporting of ongoing results, we continue to believe that a mandatory user registry, identical to what surgeons use for ventricular assist devices, would be useful. The current case report indicates that the long-term complication profile of this device is still unknown. A closer look at the present report also reveals other interesting points that echo the MAUDE registry findings. The fact that the patient presented with new-onset arrhythmia 10 days after device placement is not insignificant inasmuch as arrhythmia was listed as an independent complication of device placement and also was found as a warning sign of device embolization, particularly into the right ventricle.² New-onset arrhythmias in a patient with an Amplatzer device should be taken seriously, including an urgent echocardiographic assessment.

The development of chest pain 1 month before the tamponade episode may also be of relevance. The actual mechanism of the erosion of this device has been hotly debated, but it seems that a gradually progressing erosion process is a real possibility despite the manufacturer's recommendations. Taggart and associates¹ point out that "most reported cases occur within 72 hours of placement," but our MAUDE data show that 24 of 51 known perforations occurred greater than 24 hours from placement, with 8 occurring at 1 to 6 months, 2 at 6 months to 1 year, and at 3 greater than 1 year. The sites of erosion included various combinations of atrium and/or aorta in the FDA reports, and the left atrium was the common site of atrial level perforation. Until the mechanism of erosion and its relationship to sizing and time after placement is better understood, we cannot speculate on individual patient susceptibility.

The increasing number of reported adverse events with the Amplatzer device may simply reflect an increase in the number of devices placed. It is also possible that the known events are just the "tip of the iceberg" with a constant hazard function for erosion that exists over the lifetime of the patient. The only way to get real answers to these important issues is to actively collect short-term outcome data and to continue active surveillance of these devices.

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A technique for implanting outflow cannulas for Berlin Heart EXCOR ventricular assist device in small pediatric patients

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The Berlin Heart EXCOR (Berlin, Germany) ventricular assist device has been used with increasing frequency in younger pediatric patients. The smallest available blood pump has a 10-mL volume, and the smallest outflow cannula tip is 3 mm in diameter. The cannula has a 90-degree angulation with a flanged tip for sewing to the ascending aorta or main pulmonary artery. There is a short, grooved extension from the flange in this design. During a typical cannula insertion, a side-biting clamp is placed on the aorta and the cannula is anastomosed to a matching arteriotomy while the patient

FIGURE 1. Guiding stay sutures ensure the tip of cannula completely inside the graft.

is on cardiopulmonary bypass. The common problem encountered during this maneuver stems from matching a rigid cannula circular tip to an almost slit-like aortotomy. Small tears likely occur along the aortic suture line, resulting in bleeding. We present a technique that simplifies this step of the procedure and helps in hemostasis.

CLINICAL SUMMARY

The patient was a 19-month-old girl, weighing 8 kg, with a diagnosis of Shone syndrome. She had previously undergone aortic coarctation resection followed by 2 mitral valve repairs. The patient had worsening of mitral stenosis and an increase in pulmonary vascular resistance. She was considered for a cardiac transplantation, and a decision was made to use a Berlin Heart EXCOR biventricular assist device as a bridge. The bridge would lower the pulmonary vascular resistance and make her a transplant candidate.

After routine preparation, the patient was placed on cardiopulmonary bypass using normothermia and bicaval cannulation. Because of significant mitral stenosis, a left atrial inflow cannula was placed instead of an apical one. A size 10 polytetrafluoroethylene (PTFE) graft (GORE-TEX; WL Gore & Associates, Flagstaff, Ariz) was anastomosed to the ascending aorta using a side-biting clamp and a running 6-0 PTFE suture. The suture line was further sealed with a tissue sealant before releasing the side-biting clamp. The graft was temporarily clamped. A 6-mm outflow cannula was introduced through the anterior upper abdominal wall and positioned. The PTFE graft was trimmed to produce an optimal height to avoid cannula compression of the right ventricle. Four simple anchoring sutures were passed through the graft and the flange of the cannula (Figure 1). Once the tip of the cannula was placed inside the graft, the sutures were tied, ensuring the edge of the graft was flushed with the flange. A number 2 silk ligature was placed and tied at the groove of the tip of the cannula

FIGURE 2. Silk ligature secures the cannula to the graft.

(Figure 2). The placement of the right side assist device was performed in a routine manner. Once connected and de-aired, the devices were activated and the chest was closed in routine fashion. With this less than 2-cm graft extension, the cannulas' exit sites through the upper abdominal wall remained unchanged because the length of the aortic cannula was minimally altered. The pump function was optimal and hemostasis was excellent, with little bleeding in the operating room and minimal chest tube output in the intensive care unit. The child received a heart after 5 weeks on the device. At the explantation of the ventricular assist device, there was a smooth pseudo-intima covering the graft lumen with no evidence of clot formation.

DISCUSSION

The technique described provides a simple and reliable method for placement of Berlin Heart EXCOR arterial outflow cannulas in small children.^{1,2} It is not uncommon to see bleeding from tearing an aortic suture line while trying to anastomose a rigid circular cannula tip to a slit-like aortotomy. The graft is easily placed and ensures good positioning of the cannula to avoid right ventricle compression and tension on the suture line.

CONCLUSIONS

Bleeding through needle holes, as commonly seen with PTFE grafts, can be minimized using PTFE sutures and tissue sealants.

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