Cuff leakage, not paravalvular leakage, in the Carpentier Edwards PERIMOUNT Magna Ease aortic bioprosthesis

Shigehiko Tokunaga a,*, Tomoki Cho a, Ryo Izubuchi a and Munetaka Masuda b

a Department of Cardiovascular Surgery, Kanagawa Cardiovascular and Respiratory Center, Yokohama, Japan
b Department of Cardiovascular Surgery, Yokohama City University Hospital, Yokohama, Japan

* Corresponding author. Department of Cardiovascular Surgery, Kanagawa Cardiovascular and Respiratory Center, 6-16-1 Tomioka-Higashi, Kanazawa-ku, Yokohama 236-0051, Japan. Tel: +81-45-7019581; fax: +81-45-7864770; e-mail: tokunaga@kanagawa-junko.jp (S. Tokunaga).

Received 30 April 2015; received in revised form 1 July 2015; accepted 7 July 2015

Abstract

Though the Carpentier Edwards PERIMOUNT Magna Ease valve is a bioprosthesis with documented excellent haemodynamics and easy implantability, this valve has a gap between the cobalt–chromium–nickel alloy stent and silicone sewing ring. This gap, which is widest just below each of the three commissural struts, lacks silicone and leaves the two-layer polytetrafluoroethylene fabric unsupported and unprotected. If the needle of a valve suture is placed in this structurally weak area of the sewing ring, the resultant fabric tear may result in a true cuff leakage, not the usual paravalvular leakage. We describe this pitfall in the context of a recent operation to alert surgeons everywhere that suture placement too close to the stent (missing the silicone sewing ring) can result in postoperative cuff leakage. We need to be very careful to include the silicone ring in each stitch to prevent injury to the valve cuff of this prosthesis and to avoid cuff leakage.

Keywords: Carpentier Edwards PERIMOUNT Magna Ease valve • Cuff leakage • Aortic valve replacement

INTRODUCTION

The Carpentier Edwards PERIMOUNT Magna Ease (CEPME) aortic bioprosthesis (Edwards Lifesciences, Irvine, CA, USA) has excellent haemodynamics and easy implantability [1, 2]. In this prosthesis, there is a persistent narrow gap between the metal stent and the silicone ring. This structurally weak point was the cause of cuff leakage after aortic valve replacement (AVR) in a recent operation despite our experience in implanting over 125 of these valves over the last 5 years.

CASE

A 65-year old female with severe aortic valve stenosis and regurgitation and paroxysmal atrial fibrillation underwent AVR and pulmonary vein isolation. The aortic valve was tricuspid with severe calcification on the cusps and annulus. All cusps were resected and the severe annular calcification was carefully removed with the Cavitron Ultrasound Surgical Aspirator (CUSA EXcel Plus, Integra LifeSciences Corporation, NJ, USA). The 19-mm CEPME aortic bioprosthesis was implanted supra-annularly with 2-0 Ethibond EXCEL (ETHICON, Inc., Somerville, NJ, USA) pledgetted non-everting mattress sutures throughout except simple interrupted suture at the Left-Right (L-R) commissure. Trans-esophageal echocardiogram (TEE) prior to coming off bypass showed mild to moderate leakage at the L-R commissure (Fig. 1). We regarded this leakage as paravalvular and decided to repair the leakage. Three Ethibond EXCEL pledgetted mattress sutures were placed on the aortic side of the sewing ring around the L-R commissure and passed outside of the aortic wall. These sutures were tied outside of the aortic wall with pledget. Repeat TEE still showed mild to moderate leakage at the L-R commissure after the second aortic declamping. The heart was arrested a third time and the prosthesis was carefully retrieved and examined. A

Figure 1: Moderate cuff leakage at the L-R commissure just after aortic valve replacement on Trans-esophageal echocardiogram. The direction of the leakage is perpendicular.
hole in the polytetrafluoroethylene (PTFE) fabric of the sewing cuff just below the L-R stent post was identified as the cause of the leakage. There was a clear gap between the silicone SR and the metal stent in this area, leading us to believe this was a cuff leak, not a paravalvular leak. We repaired this hole in the fabric with 5-0 Prolene (ETHICON, Inc.) suture with figure-of-8 fashion and performed redo AVR with the repaired prosthesis in a supra-annular position. Intraoperative TEE then showed trivial leakage, only at the R-N commissure site after third aortic declamping.

The patient was discharged on the 58th postoperative day, because of postoperative complications, such as arrhythmia and renal failure. Twelve months after surgery, postoperative transthoracic echocardiogram showed persistent trivial leakage. Blood work showed no significant haemolysis.

COMMENT

Many Japanese patients, especially elderly patients, have a small aortic annulus. The CEPME aortic bioprosthesis is widely used for the patients with a small aortic annulus, because of its excellent haemodynamics. In these circumstances, we often try to put valve sutures on the innermost part of the sewing ring that is closest to the stent of the prosthesis. We have found that if we put valve sutures on the outer part of the sewing ring, the valve sits too tightly in the annulus. In CEPME aortic bioprostheses, there is a gap between the metal stent and the silicone ring and this gap is the widest just below each stent post. The weak area is not only just below the stent post, but also at the circumferential narrow space between the metal stent and silicone ring. The suture placed at this area is unsupported by the silicone ring, and places all of the stress on the PTFE fabric; this may cause the fabric to tear, as it appears to have done in this case, and cause a valvular cuff leak. Placing the valve sutures squarely in the SR should prevent cuff leakage as described in this report. Missing the silicone ring, especially with interrupted sutures, could result in a significant intraoperative or postoperative cuff leak. This can be repaired, as we did intraoperatively using 5-0 Prolene suture. Alternatively, a pledged suture may also work.

We reproduced this cuff leakage ex vivo. An interrupted 2-0 Ethibond EXCEL suture was placed at the innermost part of the sewing ring of a CEPME #19 valve just below the stent post, easily avoiding the silicone ring. The other side of the needle was passed through a black sponge. The suture was tightly tied, which made a small hole through the fabric of the cuff (Fig. 2A and B). This cuff defect was likely the cause of the leak observed in our case.

We are aware of three similar case reports in the literature [3-5]: CEPME aortic bioprostheses, CEP aortic bioprostheses and Mosaic mitral prosthesis. All 3 cases were reported by anaesthesiologists in non-surgical journals. This is the first report in a surgical journal of an occasional problem with an otherwise useful valve. All 3 previously reported cases were managed conservatively with success. Our experience and the other reports indicate that TEE is useful for the detection of this complication. If the cuff leakage were trivial to mild, we might be willing to observe until after the administration of protamine. But if the leakage were substantial, we would recommend repairing the defect while the patient is still in the operating room.

ACKNOWLEDGEMENTS

We express our gratitude to Gregory and Susan Kay in Los Angeles, CA, USA, for comments on this manuscript.

Conflict of interest: none declared.

REFERENCES