A 77-year-old man was referred for treatment of a secundum type atrial septal defect (ASD). Transthoracic echocardiography and transesophageal echocardiography showed a 20-mm atrial ASD (Figure [A]) with important enlargement of the right ventricle. A 24-mm ASD Ultrasent II (Cardia Inc, Eagan, MN) closure device was successfully implanted (Figure [B]) after the first attempt with no residual shunt. The Ultrasent II device was loaded and deployed in a similar manner to Amplatzer devices. The nickel-titanium frame of the Ultrasent II device has 2 discs covered with a polyvinyl alcohol (PVA) membrane (Figure [C] and [D]). PVA is a synthetic polymer with a long history of permanent implant in the medical field. Three months later, routine transthoracic echocardiography revealed a recurrent significant left-to-right shunt through the device, which appeared implanted properly. A transesophageal echocardiography at 4 months showed multiple perforations with an unusual irregular surface of the discs (Figure [E] and [F]; Movie in the Data Supplement). Surgical device removal and Gore-Tex patch repair were performed successfully along with a tricuspid annuloplasty. Intraoperative and explanted views showed an intact device frame with almost complete disappearance of the PVA membranes and no evidence of infection (Figure [G] and [H]). In follow-up at 8 months the patient was well. Thereafter, a routine transthoracic echocardiography was performed at 3 months of all patients (n=9) implanted with the ASD Ultrasent II device in our institution. Implantation of a second device within the defective device was discussed, but surgery repair was preferred because of the unclear mechanism of the malfunction. Two similar cases were previously reported1 with the ASD Atriasept II (Cardia Inc, Eagan, MN) closure device, a previous generation of the device used in the current cases, which also uses a PVA-based material. The mechanism of PVA membrane disappearance was not reported. PVA is a water-soluble polymer, which becomes insoluble for medical purposes with formaldehyde or glutaraldehyde cross links. The biocompatibility of PVA is recognized as good.2 Intolerance reactions to PVA are not known. A recent literature review did not indicate unexpected biodegradability of PVA membranes in ASD closure devices.3 An usual procedure followed for our 2 cases included soaking of the device in sterile saline before loading in the delivery sheath. A severe adverse event notification form was sent to the manufacturer. The 2 devices were not from the same manufacturing lot. The explanted devices were macroscopically and microscopically examined. The metallic frame and all sutures used to attach the PVA membrane to the frame were intact. Examination of the residual PVA membrane was unremarkable. All processes used to create the PVA membranes were reviewed. Several chemical reactions were tested. To date, the manufacturer has not identified a definitive cause of PVA membrane degradation. As of the date of the adverse event occurrence, 2500 Ultrasent II

Discussion

Two early malfunctions of the PVA membrane were observed in a series of 9 consecutive patients treated with ASD Ultrasent II closure device in our institution. Implantation of a second device within the defective device was discussed, but surgery repair was preferred because of the unclear mechanism of the malfunction. Two similar cases were previously reported1 with the ASD Atriasept II (Cardia Inc, Eagan, MN) closure device, a previous generation of the device used in the current cases, which also uses a PVA-based material. The mechanism of PVA membrane disappearance was not reported. PVA is a water-soluble polymer, which becomes insoluble for medical purposes with formaldehyde or glutaraldehyde cross links. The biocompatibility of PVA is recognized as good.2 Intolerance reactions to PVA are not known. A recent literature review did not indicate unexpected biodegradability of PVA membranes in ASD closure devices.3 An usual procedure followed for our 2 cases included soaking of the device in sterile saline before loading in the delivery sheath. A severe adverse event notification form was sent to the manufacturer. The 2 devices were not from the same manufacturing lot. The explanted devices were macroscopically and microscopically examined. The metallic frame and all sutures used to attach the PVA membrane to the frame were intact. Examination of the residual PVA membrane was unremarkable. All processes used to create the PVA membranes were reviewed. Several chemical reactions were tested. To date, the manufacturer has not identified a definitive cause of PVA membrane degradation. As of the date of the adverse event occurrence, 2500 Ultrasent II
devices have been implanted with no other similar concern according to the manufacturer. Thus, the 2 cases presented here represent an incidence of 0.08%. Macroscopic findings of explanted devices suggest that the possibility of using a second device (such as the Cribriform Amplatzer occluder or Uniform Occlutech occluder) within the Ultrasept II device could be discussed to avoid surgery.

Disclosures

None.

References


Figure. A and B, Transesophageal echocardiography (TEE) views before and after atrial septal defect closure device implantation. C and D, Right and left discs of the Ultrasept II closure device. E and F, TEE views at 4 months showing multiple left-to-right shunts through the device with an irregular surface of the discs. G, Intraoperative view showing the right disc of the device with a polyvinyl alcohol membrane almost totally disappeared. H, Left disc of the explanted device including the margins of the defect with minimal neoendothelium around the frame.
Early Malfunction of Polyvinyl Alcohol Membrane–Covered Atrial Septal Defect Closure Devices

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