Expanded polytetrafluoroethylene membranes to wrap surfaces of circulatory support devices in patients undergoing bridge to heart transplantation

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Abstract

Objective: Because of a lack of donor hearts, an increasing number of patients with heart failure must now undergo bridge to cardiac transplantation with a mechanical circulatory support device. Moreover, support periods have become longer. As a result, pericardial adhesions may develop while the support device is implanted, increasing the risk of injury at resternotomy and bleeding after transplantation. Use of expanded polytetrafluoroethylene (ePTFE) pericardial substitutes (membranes) may prevent such adhesions.

Patients and methods: From January 1997 to December 1999, ePTFE membranes were used in 23 patients to wrap portions of an implanted left ventricular assist device (LVAD) or total artificial heart (TAH). Any complications during mechanical support or at cardiac transplantation were recorded. Six ePTFE membranes removed at transplantation were studied histologically.

Results and conclusions: At resternotomy for transplantation, the plane of dissection between tissues, ePTFE membranes, and surfaces of the mechanical support device were easily discerned. No adhesions were observed between tissues and membranes. There were no injuries during resternotomy and no patient had to undergo reoperation because of bleeding. One patient given a TAH had an infection during circulatory support that was controlled by antibiotic therapy. In another patient, clots developed between the device and an ePTFE membrane; these were removed successfully. Histologic studies of removed ePTFE membranes showed no infiltration of the membranes interstices by collagen or cellular components. Use of ePTFE membranes in patients undergoing bridge to transplantation with either an LVAD or a TAH limited adhesions between tissues and device surfaces without increasing the risk of infection.

Keywords: Left ventricular assist device; Total artificial heart; Expanded polytetrafluoroethylene; Pericardial substitute; Adhesions

1. Introduction

Despite therapeutic improvements, advanced heart failure remains one of the leading causes of death in developed countries. Cardiac transplantation is the treatment of choice for this disease when medical therapy is no longer effective. However, because of the limited availability of donor hearts, an increasing number of critically ill patients with heart failure must be supported by a mechanical circulatory device while awaiting transplantation. Moreover, the duration of mechanical support has increased from a few weeks to many months. In our institution, for example, the mean length of the support period has risen from less than 20 days before 1997 [1] to about 60 days currently.

In patients in whom a circulatory support device is used for only a short time, problematic pericardial adhesions generally do not develop. However, with the increase in the time to transplantation to months after implantation of a support device, device-related adhesions may represent a considerable challenge on resternotomy, increasing the risk of tissue injury and damage to the mechanical device tubes. In addition, adhesions extend the time required for dissection of the native heart, thereby prolonging the risk of prolonged ischemia of the donor organ, and they also increase the risk of bleeding after transplantation [2]. Moreover, in patients in whom a total artificial heart (TAH; Cardiowest Technologies, Inc, Tucson, AZ) has been implanted for 3 months or longer, we have observed considerable pericardial thickening, which can lead to cardiac allograft restriction requiring pericardectomy.

In 1997, in an attempt to limit adhesions in patients undergoing bridge to cardiac transplantation, we began to use expanded polytetrafluoroethylene (ePTFE) pericardial substitutes (Preclude Pericardial Membrane, W.L. Gore & Associates, Inc, Flagstaff, AZ) to wrap surfaces of circulatory support devices at implantation. We here report our 3-
2. Patients and methods

2.1. Clinical data

Patient information was obtained retrospectively from medical records. Between January 1997 and December 1999, 57 patients treated at our institution received mechanical circulatory support. Of these, 30 had bridge to transplantation with either an LVAD \((n = 12)\) or a TAH \((n = 18)\). ePTFE membranes were used in 23 of these patients \((77\%)\), nine of whom received an LVAD and 14 of whom received a TAH. Membranes were used in all patients who had implantation of a circulatory support device in 1999. Of the 23 patients given ePTFE membranes, 14 \((61\%)\) underwent heart transplantation after a mean \((\pm SD)\) duration of circulatory support of 60 \(\pm 57\) days \((range 17\n\nWhen a potentially suitable donor heart became available, the donors hemodynamic status and the quality of the graft were assessed by the harvesting team. If the findings were satisfactory, the heart recipient was placed under anesthesia as soon as possible and sternotomy for transplantation was performed. In some cases, the ePTFE membranes removed during this procedure were preserved for histologic study.

2.2. ePTFE wrapping technique in patients receiving a TAH

After homeostasis is achieved and placement of the ventricles tested during temporary chest closure, the sternum is retracted again to wrap the TAH with an ePTFE membrane (Fig. 1) Three interrupted monofilament 4/0 sutures are passed into the pericardium into the left side of the chest-one close to the left inferior pulmonary vein, one close to the diaphragm, and the third between the other two. The sutures are placed as deep as possible, posteriorly to the phrenic nerve. Sutures are then passed through the edge of an ePTFE membrane \((a sheet of 15 \times 20 \text{ cm that is } 0.1 \text{ mm thick})\). The membrane is slid down the sutures, between the artificial ventricles and pericardium, and secured. The same technique is used to place a second ePTFE membrane between the pericardium and right atrium on the right side of the chest. The free edges of the two membranes are then overlapped anteriorly along the middle line. The inferior edge of the membrane on the left side is secured with two interrupted sutures on the anterior edge of the diaphragm, over the drive line for the TAH. The superior edge of the membrane on the right side is passed over the aorta and pulmonary artery and secured on the left side. In some cases, a few other sutures are added to avoid creases and folds in the ePTFE membranes, but no attempt is made to produce a watertight seal around the heart.

For our most recent cases, the wrapping technique in patients with a TAH has been modified in two ways. First, a third ePTFE membrane is used to isolate the artificial ventricles from the diaphragm plane. If the anterior overlap of the two lateral ePTFE membranes is insufficient, a fourth membrane is inserted. Second, the ePTFE membranes are sutured deep in the pericardium immediately after excision of the native ventricles and left to fold in upon themselves during implantation of the TAH. The membranes are brought back together anteriorly before the chest is closed.

At chest closure in all patients in whom ePTFE membranes are used to wrap a TAH, a pericardial drainage tube is inserted into the membrane-limited cavity. Another drainage tube is placed anteriorly to the membranes, posteriorly to the sternum.

2.3. ePTFE wrapping technique in patients receiving an LVAD

Because the LVAD implantation procedure involves leaving the native heart in place and the strongest adhesions develop between the mechanical device and the pericardium, only the inflow and outflow tubes of the LVAD are wrapped with ePTFE membranes. A full sheet of ePTFE is wrapped around the entire length of the outflow tube, and a smaller piece is wrapped around the inflow tube. The ePTFE
membranes are either secured with interrupted monofilament sutures or left free.

3. Results

At resternotomy for cardiac transplantation in all patients in whom ePTFE membranes were used, the plane of dissection between tissues, the membranes, and the surfaces of the mechanical support device were easily discerned. No adhesions were observed between the tissues and the membranes. Typically, the ePTFE membranes had become entirely translucent (Fig. 2) but were not torn, split, shrunken, or displaced. In contrast, in patients in whom a support device had been implanted for several months, device parts and tissues not covered with an ePTFE membrane, such as the diaphragm surface in contact with the drive lines for a TAH, had extensive, strong adhesions. There were no injuries during resternotomy in patients in whom ePTFE membranes were used and none of these patients required reoperation because of bleeding. Moreover, none of the patients in whom a TAH had been implanted had pericardial thickening that required reoperation.

Of the 23 patients given ePTFE membranes, infection developed in one, a 17-year-old male patient in whom a TAH was implanted for 3 months. The patient had drainage around a TAH drive line and a recurrent low-level fever for 6 or 7 weeks before transplantation. Culture of a drainage sample showed *Staphylococcus aureus*. The patient was treated with antibiotics given intravenously and local dressings applications. The infection remained controlled throughout the circulatory support period. At cardiac transplantation, the patient was found to have a purulent pericarditis due to *S. aureus*, but the transplantation procedure was successful. Management of the infection after transplantation was similar to that used for mediastinitis occurring after cardiac surgery.

Another of the 23 patients in whom ePTFE membranes were used underwent reoperation after 51 days of circulatory support with a TAH because of increasing pericardial effusion. Computerized tomography showed clots between the TAH and an ePTFE membrane and compression of the right atrium. Reoperation was performed through a subxiphoid incision. After the plane of dissection between the diaphragm and the ePTFE membrane was established, the membrane was opened easily and the clots were removed by suction. No other adverse events occurred, and the patient underwent transplantation 15 days later.

Six explanted ePTFE membranes were studied histologically. The surfaces of the membranes were covered with loose accumulations of fibrous connective tissue that did not infiltrate the interstices of the membranes. Loosely adherent fragments of collagen were occasionally observed in focal regions along one surface (Fig. 3). The interstices of the membranes were multifocally infiltrated by amorphous proteinaceous material and proteinaceous fluid. There was no evidence of bacterial infection or calcification.

4. Discussion

We found ePTFE membranes to be safe and effective in preventing adhesions when used to wrap surfaces of an LVAD or a TAH implanted for a prolonged period to provide a bridge to heart transplantation in patients with advanced heart failure. Minimization of adhesions is associated with a decreased risk of life-threatening injury of the heart, damage to the circulatory device tubes, and phrenic nerve injury at resternotomy for transplantation, and of bleeding after transplantation.

Membrane technology allows control of adhesions between tissues and artificial surfaces by modulation of the size of a membranes interstices. In our patients, we
used ePTFE membranes with interstices of less than 1 μm. This ‘pore size’ minimizes adhesions because it is too small to allow tissue penetration. The explanted ePTFE membranes that were examined histologically showed loosely adherent cells at the tissue-membrane interface and no evidence of collagen or cellular infiltration.

The most commonly used pericardial substitutes are made of either preserved animal pericardium (chiefly bovine) or a synthetic membrane (e.g. polyurethane, ePTFE, rubber, and polyester). In a study in ewes that compared bovine pericardium, ePTFE, and two types of polyglycolic acid mesh (Dexon), Bunton et al. [3] showed that after 6 months, marked adhesions to the bovine pericardium prosthesis and one type of polyglycolic acid mesh developed. Results with the other type of polyglycolic acid mesh were inconsistent. In addition, one of the bovine pericardium substitutes was found to have calcified by 6 months after implantation. In a multicenter survey, Heydorn et al. [4] reported comments from 89 surgeons on 236 reoperations in patients given a variety of pericardial substitutes, including devices made of silicone rubber or polyester, three different bovine pericardium products, and ePTFE. There was a high level of dissatisfaction with the substitutes, especially the silicone rubber devices and the xenografts, because of dense adhesions, intense pericardial reactions, pericarditis-related perioperative fever, graft rejection, and infection. The level of satisfaction with ePTFE (86%) was significantly higher (P = 0.0004 by chi-square analysis) than that with the other substitutes (38 to 50%).

The usefulness of ePTFE pericardial substitutes in providing a clear plane of dissection and minimizing adhesions has also been documented in both experimental investigations [5] and clinical studies in patients in whom additional cardiac surgery may be necessary, such as those with congenital heart defects [6–10] and those undergoing coronary artery bypass grafting [7,11,12]. Moreover, Vitali et al. [13], like us, had no complications in 20 patients in whom ePTFE membranes were used to wrap the outflow cannula of an LVAD. Vitali et al. also observed, as we did, no problematic adhesions between the membranes, chest wall, extracardiac conduit, and underlying epicardium at resternotomy. Their study did not include patients in whom a TAH was used or a histologic assessment of explanted ePTFE membranes.

Holman et al. [14] used ePTFE membranes to reconstruct the pericardium, but not to wrap the ventricular support device, in seven patients. They found that the membranes protected grafts to the great vessels and the right ventricle from injury on resternotomy and that the plane of dissection between the heart and the pericardium was easy to discern. Infection occurred in two patients, but one developed only after a second operation and the other, like the one in our series, was managed successfully with antibiotic therapy. Indeed, implantation of a circulatory support device is known to increase the risk of infection [15,16], regardless of whether ePTFE membranes are used. Fortunately, such infections generally do not preclude heart transplantation [16]. We do not believe that the use of ePTFE membranes increased the risk of infection in our patients.

One patient in our series had to undergo reoperation because of a pericardial effusion. It is known that patients in whom a circulatory support device is implanted have an increased risk of pericardial infarction. Even in patients given a TAH, this complication can lead to atrial compression and cardiac tamponade. We did not observe an increase in the pericardial effusion rate among our patients in whom ePTFE membranes were used to wrap a support device. Furthermore, since the new cavity created with such membranes is not watertight, membrane use does not increase the risk of compression.

In summary, we found that use of ePTFE membranes in patients undergoing bridge to transplantation with either an LVAD or a TAH prevented adhesions between tissues and device surfaces without increasing the risk of infection. As a result, reoperation was easier and safer. We initially wrapped only the surfaces of TAHs with ePTFE membranes, but because of the good results achieved with that procedure, we now wrap the native heart in all patients given an LVAD.

References


