Initial experience with polytetrafluoroethylene leaflet extensions for aortic valve repair†

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Abstract

OBJECTIVES: The purpose of this study is to evaluate our initial experience with aortic valve repair using polytetrafluoroethylene (PTFE) leaflet extensions in congenital valvular disease.

METHODS: From October 2008 through February 2011, 13 patients underwent aortic valvuloplasty by PTFE leaflet extensions. All valves were repaired in a tri-leaflet configuration using PTFE leaflet extensions. The median age at operation was 14 years (1.8–19.7 years) and the median weight was 58 kg (9.5–86 kg). Previous interventions included balloon valvuloplasty in two patients, aortic valvuloplasty in one and coarctation repair in one patient. Eight (73%) patients had combined aortic stenosis and insufficiency, three (23%) had isolated insufficiency and two (15%) had stenosis only. In 10 (77%) patients, a bicuspid aortic valve was present.

RESULTS: The follow-up ranged from 2 to 30 months (mean follow-up 14.8 ± 9 months). At the latest echocardiography follow-up, six patients had none or trace aortic insufficiency, six patients had a mild aortic insufficiency and one patient had a mild-to-moderate insufficiency. The mean aortic insufficiency degree decreased from 1.8 ± 1.2 preoperatively to 0.8 ± 0.6 at the follow-up (P < 0.01). The mean gradient across the aortic valve decreased from 56 ± 40 mmHg preoperatively to 12 ± 13 mmHg at the follow-up (P < 0.0008). All patients are alive. There were no reoperations. The median hospital stay was 9 days (4–21 days).

CONCLUSIONS: The use of PTFE leaflet extensions is an effective technique for aortic valve reconstruction in congenital valvular disease. Long-term follow-up is necessary to assess the durability of this type of repair.

Keywords: Congenital · Aortic disease · Aortic valvuloplasty · Polytetrafluoroethylene

INTRODUCTION

Aortic valvuloplasty by leaflet extensions is gaining popularity for both acquired and congenital aortic disease. The encouraging early- and mid-term results with this technique in the acquired group [1–3] have also been repeated in the group with congenitally affected aortic valve with good results [4–8]. However, the ideal material for leaflet extension still remains controversial. Glutaraldehyde-treated autologous pericardium has been most consistently used for aortic valve repair. It has shown excellent short-term results, but its long-term function is associated with an increased reoperation rate due to structural valve degeneration [2, 4, 7, 8]. Based on these results and on our own experience with glutaraldehyde-treated autologous pericardium, we have been trying to find an inert, pliable and durable material for leaflet extensions. Favourable experience with the use of polytetrafluoroethylene (PTFE) in the pulmonary position encouraged us to consider a new material for leaflet extensions [9–11]. We report our initial experience with the use of PTFE leaflet extensions for aortic valve repair in the congenitally affected aortic valve.

MATERIALS AND METHODS

From October 2008 through February 2011, 13 patients underwent aortic valvuloplasty by PTFE leaflet extensions. All patients had a congenital aortic disease. The median age at operation was 14 years (1.8–19.7 years) and the median weight was 58 kg (9.5–86 kg). Three patients were aged below 10 years, the youngest patient being 22 months old. Previous interventions included balloon valvuloplasty in two patients, surgical valvuloplasty in one and coarctation repair in one patient. Eight (73%) patients had combined aortic stenosis and insufficiency, three (23%) had isolated insufficiency and two (15%) had stenosis only. In 10 (77%) patients, a bicuspid aortic valve was present. The mean preoperative aortic insufficiency degree was 1.8 ± 1.2. The mean preoperative gradient across the aortic valve was 56 ± 40 mmHg. Preoperative patient characteristics are summarized in Table 1. All valves were repaired in a tri-leaflet configuration using 0.1 mm PTFE leaflet extensions.
Operative procedure

The aortic valve was accessed by high transverse aortotomy. Raphe and fused commissures (if present) were incised into the aortic wall creating a tri-leaflet configuration of the valve. The thickened leaflet edges were excised, leaflets were shaved and nodular lesions were excised. The length of the free edge of leaflets was measured using a silk tie. The height of the leaflet extension was determined by measuring the depth of the native left coronary leaflet. Based on these two measurements, rectangular 0.1 mm PTFE extensions (Preclude membrane, W.L. Gore & Assoc., Flagstaff, AZ, USA) were sewn to the free edge of each cusp by 6.0 polypropylene sutures. The median height of the extensions was 15 mm (9–19.5 mm). The new commissures were then created by sewing each of the two leaflets and aortic wall together upwards towards the new sinotubular junction (Fig. 1).

All patients received aspirin for 6 months after surgery.

Clinical follow-up

All patients underwent transoesophageal echocardiography upon completing the aortic valve repair in the operating theatre. Transthoracic echocardiography was performed before discharge, 3 months after surgery and periodically thereafter. The mean follow-up duration was 14.8 ± 9 months (range 2–30 months).

Statistical analysis

Patient characteristics were summarized as frequencies and percentages for categorical variables and values were expressed as mean ± SD or median (range). Statistical analysis of continuous variables was done by the paired t-test (JMP 5.0.1, SAS Institute Inc.). A P-value of <0.05 was considered to be statistically significant. An informed consent was obtained for each of our patients and included a detailed explanation of the novel nature of material used for leaflet extensions. The use of the PTFE material and the study was approved by the ethics committee and the institutional board.

RESULTS

The follow-up ranged from 2 to 30 months (mean follow-up 14.8 ± 9 months). There were no early or late reoperations and all patients are alive. The median duration of cardiopulmonary bypass was 138 min (96–227 min). The median duration of aortic cross-clamp was 95 min (72–144 min). Additional procedures included reduction of the ascending aorta in two patients.

Postoperatively, one patient required LVAD support due to persistent ventricular tachycardia. He was successfully weaned after 48 h of support after the tachycardia had subsided. None of the patients developed infectious endocarditis early or late postoperatively. Other postoperative complications included pleural effusions in four patients and respiratory infection in one. The median length of postoperative stay was 9 days (4–21 days).

Follow-up

The follow-up was complete in all patients. At the latest echocardiography follow-up, six patients had none or trace aortic insufficiency, six patients had a mild aortic insufficiency and one patient had a mild-to-moderate insufficiency (Fig. 2). The mean aortic insufficiency degree decreased from 1.8 ± 1.2 preoperatively to 0.8 ± 0.6 at the follow-up (P < 0.01). The mean gradient across the aortic valve decreased from 56 ± 40 mmHg preoperatively to 12 ± 13 mmHg at the follow-up (P < 0.0008). The mean left ventricular end-diastolic volume (LVDd) indexed to body surface area (BSA) decreased from 35 ± 12 mm to 31 ± 7 mm at follow-up (P = 0.03).
DISCUSSION

The lack of an ideal valve substitute in the congenitally affected aortic valve has raised interest in aortic valve repair. The leaflet extension technique by pericardium first described by Duran et al. [12] and Al Fagih et al. [13] has provided excellent short- and midterm results in the acquired aortic disease group. These results were successfully repeated in the group of congenitally affected aortic valve [4–8]. The limiting factor of the long-term function of extended aortic leaflets seems to be the durability of the material used for extensions. Various materials have been tried for aortic valve repair. Of these, fascia lata, dura mater, bovine and fresh autologous pericardium have shown durability issues in the short-term period [14–17]. Glutaraldehyde-treated autologous pericardium for aortic valve repair in congenital aortic disease has shown excellent short- and midterm results, but its long-term function is associated with a higher degeneration rate [4, 5, 7, 8]. In the long-term follow-up, structural valve degeneration caused by leaflet fibrosis, thickening and calcification has been reported [1, 2]. Another issue described in the series where glutaraldehyde-treated pericardium was used is the incidence of bacterial endocarditis [1–3]. Al Halees et al. [2] reported a 4.5% incidence of this complication early and late postoperatively, while Jeong et al. [3] reported a 7% incidence in the acquired aortic disease group.

In the presented series, we describe our initial experience with expanded 0.1 mm PTFE material used for aortic leaflet extensions. PTFE has been quite commonly used for leaflet repair in atrio-ventricular valves or as a leaflet or chordae substitute and has shown the ability to withstand prolonged mechanical stress [9, 18]. Moreover, expanded PTFE demonstrated favourable characteristics in a variety of right ventricular outflow tract reconstructions [10, 11, 19]. Ando and Takahashi [11] reported preservation of PTFE valve function in the pulmonary position of up to 10 years. Findings on explanted PTFE valve substitutes have shown preserved pliability of leaflets and neointimal and endothelium formation on histological examination [9, 11]. However, the long-term function of PTFE as a valve substitute is still unclear. Concerns have been raised about leaflet thickening and decreased mobility after valve repair using 0.4 and 0.6 mm PTFE material [9, 19].

In our experience, the 0.1 mm PTFE membrane used for leaflet extensions has proved a reliable material with good pliability. Regarding concerns about friability of this material in the aortic position, we have not observed any technical issues working with the tiny PTFE membrane. In our limited series, there were no mortalities or reoperations during the course of the follow-up period for up to 30 months. In the short-term follow-up, the valves were functioning very well with no signs of degeneration. The preoperative mean aortic insufficiency degree and gradient decreased significantly postoperatively and remained so during the follow-up. None of our patients developed infectious endocarditis postoperatively. We found functional improvement of left ventricular function, as demonstrated by the decrease in the indexed LVDd. During the LVAD support in one of our patients, the PTFE extended leaflets kept functioning well with no signs of increased insufficiency.

The limitation of this series lies in its retrospective nature, small cohort and short follow-up.

CONCLUSION

The use of PTFE leaflet extensions is an effective and reproducible technique for aortic valve reconstruction in congenital valvular disease. Long-term follow-up is necessary to assess the durability of this type of repair.

Conflict of interest: none declared.

REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr M. Kostelka (Leipzig, Germany): I commend you for your courage in using a new product designed for a completely different purpose, but which works well.

My first question is, what are your indication criteria because you have patients with a moderate stenosis and moderate insufficiency, a mean of 1.8 and a mean gradient of 54. If we have a patient with an isolated stenosis, the indication is based on the gradient across the aortic valve and on the progression of the left ventricular hypertrophy. On the other hand, in a patient with pure aortic insufficiency, the indication is based on the amount of insufficiency and the progression of left ventricular end systolic diameter on echocardiographic measurement.

Dr Kostelka: Do you have any proof that the mechanical characteristics of this very tiny, awkward 1 mm membrane are superior to autologous pericardium? Did you test it in vitro in any way?

Dr Nosál: We did not test this valve in vitro, but tests have been performed. From personal communications with people who were involved in testing those PTFE valves, we know that this is quite a stress-resistant material, this PTFE membrane. But those were pure PTFE valves. We have previously had a pretty large experience with around 35 patients who underwent this type of operation with glutaraldehyde-treated pericardium, so we can compare with this group, but this group is still a little bit small.

Dr Kostelka: Do you expect different behaviour in the aortic position under systemic pressure above 100 in comparison to the right side? There are well-known papers from one group in Florida, and another group in Japan, with a trileaflet pulmonary valve reconstruction, or bileaflet, because they are under a pressure of 22 mm and there is 122. Did you see any changes in the mobility of the cusp during the time of the follow-up?

Dr Nosál: I think this situation is a little bit different than the complete PTFE valve in the pulmonary position because, as you saw in the video, a significant portion of the valve remains in situ, so we just extend the leaflets.

And as for the echocardiographic follow-up, we do not have a special method to assess the mobility of the leaflets. Honestly, it is more difficult to assess these valves, I mean, to see the leaflets on the echo because the echogenicity of these PTFE extensions is different. But we follow the patients closely, and if the valves tend to fail, they fail because of increased insufficiency. So it is clearly seen on the echocardiographic follow-up.

Dr Nosál: Do you think also that anticoagulation for just six months is sufficient for thromboembolic prophylaxis?

Dr Kostelka: Yes, we keep them calm. For at least the first months, we advise not much physical activity, and they come back for check-up at six months and at one year. We always base our recommendations on the left ventricular measurements, and if the left ventricle improves and the patient is one or one and a half years after the operation, we would advise mild, but very mild, physical activity.

Dr J. Calhoon (San Antonio, Texas): Have you decided what the proper height or the amount of leaflet coaptation that should be created with your prostheses? And secondly, is there a size at which the annulus is too small for you to apply this? All yours had normal annular sizes. Is there a cut-off for that?

Dr Nosál: For the length of the leaflet, we would measure the free edge of the particular leaflet by a silk tie. For the height of the leaflet, at the start of the operation we just put a simple ruler into the left coronary sinus, and we measure the height of the native left coronary leaflet, and this is the height we apply. We do not have any other specific measurements for this.

I would probably not use this technique in small infants and neonates, and in very small aortic annuli. In my opinion it does not make much sense. Although we did have one small patient who was 22 months old and got this type of plasty, but he had endocarditis on both valves, on the aortic and pulmonary valves.

Dr V. Hraska (Sankt Augustin, Germany): I have just a very brief comment. There is an overall tendency to reconstruct nearly every valve. Seeing the results from the Ross, the reason is obvious. We are very good in reconstruction. We know how to do it, consequently the immediate results are very encouraging. However, the mid-term and long-term outcome is questionable because we have not been able to find durable material which lasts longer, therefore I think it is extremely important to have data like this. I would like to commend the authors for these results and for really a great step forward in using a different type of material for aortic valve reconstruction.


EDITORIAL COMMENT

Polytetrafluoroethylene leaflet extensions for aortic valve repair

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In this issue of EJCTS, Nosál et al. [1] have published their initial experience with polytetrafluoroethylene (PTFE) leaflet extensions for aortic valve (AV) repair in congenital patients. Although this is a small series, the authors must be congratulated on their excellent results.

The main objective in AV repair is to restore the matching between the quantity of cusp tissue and the valve orifice in order to achieve good and durable coaptation. To avoid recurrence of aortic insufficiency (AI) and/or stenosis after AV repair, a systematic surgical approach determined by leaflet as well as aortic disease (the functional aortic unit—FAA) must be adhered to [2]. In pure AI, due to the dilatation of the FAA, generally there is enough tissue to achieve this goal without addition of tissue. Hence, one should be cautious in applying leaflet extensions liberally to situations where there is sufficient quantity of cusp tissue. However, in paediatric population, rheumatic

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