A new pulmonary valve cusp plasty technique markedly decreases transannular patch rate and improves midterm outcomes of tetralogy of Fallot repair

Zhongdong Hua*, Shoujun Li, Liqing Wang, Shengshou Hu, De Wang

Pediatric Heart Center, Fuwai Hospital and Cardiovascular Institute, National Center for Cardiovascular Diseases, 167 Beilishi Road, Beijing 100037, People’s Republic of China

Received 10 September 2010; received in revised form 11 February 2011; accepted 16 February 2011; Available online 31 March 2011

Abstract

Objectives: To assess the operative and mid-term outcome of a very aggressive pulmonary annulus preservation strategy and pulmonary valve leaflet plasty technique which achieved 95% freedom of transannular patch (TAP) in complete tetralogy repair. Methods: From August 2006 through May 2010, 139 consecutive patients underwent repair of tetralogy of Fallot at a median age of 6.5 months, with median weight 7.2 kg. None of the patients had a prior shunt. A total of 132 patients (95%) had pulmonary valve annulus-sparing procedures, predominantly through a transatrial and transpulmonary approach (n = 120%, 86.3%). Special techniques included generous pulmonary supra-valve patch, bicuspid pulmonary leaflets plasty, or augmentation to maximally preserve pulmonary annulus. All the patients who survived were followed up closely. Results: Only seven (5.0%) patients had a TAP. Among them, five (71.4%) had double committed subarteriolar defect. None of the tricuspid pulmonary valves need TAP. Preoperative size of pulmonary annulus < 6 is associated with TAP (p < 0.001). A total of 12 (13.7%) patients needed repump to do either a ventriculotomy and patch the incision or a TAP to relieve residual stenosis. One patient needed a third pump run to do a TAP. The operative mortality was 0.7%, and there was one late death due to hemoptysis. The pulmonary regurgitation of non-TAP patients was less than mild in 105 (79.5%) and mild to moderate in 27 (20.5%) patients. Three patients had peak gradient greater than 50 mmHg across the right ventricle and pulmonary artery at 1-month follow-up, but the gradient dropped to less than 50 mmHg in two patients at 6-month follow-up. One patient had a persistent 50–55 mmHg gradient across pulmonary valve and he is under close follow-up. Conclusions: Excellent outcome can be achieved even with 95% freedom of TAP in complete repair of tetralogy. The function of most patients’ pulmonary valve was well preserved.

Keywords: Tetralogy; Transannular patch; Pulmonary valve plasty

1. Introduction

The immediate outcome of tetralogy of Fallot (TOF) surgical treatment is expected to be excellent. Irrespective of the timing of repair and surgical technique, the aim of the surgical repair of TOF in the current era should concentrate on avoiding long-term complications and decreasing the probability of early and late reinterventions. Transannular patch (TAP) is associated with postoperative pulmonary insufficiency, progressive right ventricular dysfunction, and long-term intervention, even sudden death [1–4]. Since August 2006, one of our surgical group has used pulmonary annulus preservation strategy, mainly through a transatrial—transpulmonary approach, for repair of TOF to avoid TAP and pulmonary insufficiency [5–8]. In the subset of patients who did not have adequate size of pulmonary annulus or pulmonary valve cusp area, we used the technique of pulmonary root enlargement at the supra-annulus level, as well as augmentation of the native pulmonary valve tissue with autologous pericardium. We hypothesized that it would lead to an improved early outcome for transatrial—transpulmonary TOF repair.

2. Patients and methods

2.1. Patient population

The Committee on Ethics for Human Research at Fuwai Hospital approved the retrospective study. The study group consisted of all patients with isolated TOF (n = 139) who underwent complete repair at Fuwai Hospital between August 2006 and May 2010 in one surgical group. Patients with TOF who had prior shunt procedure, or with
complex associations such as complete atroventricular septal defect, absent pulmonary valve, and discontinuous pulmonary arteries were excluded, as were those with pulmonary atresia and ventricular septal defect. Our indication of tetralogy repair and shunt procedure is as follows: except for very hypoplastic pulmonary artery, such as McGoon < 1.0 or Nakata less than 100 by Echo, we try a complete tetralogy repair, otherwise we carry out a shunt procedure. Preoperative echo is not an accurate tool to assess McGoon and Nakata for very hypoplastic pulmonary arteries, so we do an angiography for these patients. Further decision would be made in the operating room (OR) depending on the size of the probe that the surgeon would pass through pulmonary arteries. A total of 101 TOF patients had two pulmonary sinuses patch at supra-valvular level. Another 30 patients had one pulmonary sinus patch. Twenty-one patients had pulmonary valve leaflet augmentation with an autologous pericardial patch to increase the pulmonary valve cusp area. Seven patients underwent repair with a TAP.

2.2. Operative details

The operative technique is outlined in Fig. 1. Cardiopulmonary bypass was established through bicaudal and aortic cannulation. Moderate hypothermia was used (26–32°C).

The heart was arrested with antegrade cold cardioplegia. The right atrium was opened longitudinally and the left heart was vented through the foramen ovale. A longitudinal incision was made in the main pulmonary artery and bifurcated into two sinuses of the pulmonary valve to annulus level. The valve was inspected.

We deal with different situations of pulmonary valve and pulmonary root with different techniques: (1) when main pulmonary has an adequate size, we use one sinus patch technique. This technique is often used in non-cyanotic TOF patients. A longitudinal incision was made in the main pulmonary artery and extended into one sinus of the pulmonary valve to annulus level. The other part of the surgery was done with a similar technique described by other authors who use transatrial–transpulmonary approach for TOF repair [5–7]. (2) When main pulmonary is small in size, we use the two sinuses augmentation technique. A longitudinal incision was made in the main pulmonary artery and bifurcated into two sinuses of the pulmonary valve to annulus level. The valve was inspected. If the pulmonary valves minimally tethered to the pulmonary artery wall with anticipated enough orifice after division of commissural fusion, then we do regular repair in a similar fashion with other authors who use transatrial–transpulmonary approach for TOF repair [5–7]. If the pulmonary valves severely tethered to the artery wall and are usually at a high level with a very small orifice, simple division of commissural fusion will detach most part of the pulmonary valves and cause pulmonary insufficiency. In this situation, we do pulmonary valve leaflet plasty, as outlined in Fig. 1. We incise both the pulmonary valve leaflets in the midportion of the free edge, extending the incision all the way down to several millimeters above the nadir of the valves. Pridicted Hegar dilator is probed through tricuspid valve to pulmonary valve to make sure it can pass through the pulmonary valve level. Next, we harvest a triangular fresh autologous pericardium after calculation of the predicted length of the free edge of the leaflets. A 7/0 propylene suture is used to patch the leaflets with the pericardium. The remaining part of the surgery is similar to what we have described earlier. (3) When the main pulmonary artery was small and the diameter of pulmonary annulus was tiny and could not pass a 3 standard deviation below the normal predicted annulus diameter for the patient’s weight, then TAP was applied [3]. In two of the patients in this group, we did pulmonary valve cusp augmentation with an autologous pericardial patch according to the technique described by Sung and associates [9]. On the other five patients, we did TAP with a glutaraldehyde-treated autologous pericardium.

Excision of the parietal extension of the infundibular septum was performed through the tricuspid valve. Hegar dilators were then passed through the tricuspid valve toward the main pulmonary artery. Our routine is that, if the pulmonary valve annulus can pass a 3 standard deviation below the normal predicted annulus diameter for the patient’s weight, we give the patient a chance to avoid TAP. The division of the remaining obstructing muscular and fibrous bands was performed through the tricuspid valve and pulmonary valve. The ventricular septal defect was closed through the tricuspid valve. Pulmonary arteriectomy was closed with an appropriately sized single fresh pericardial...
patch. The foramen ovale was closed with a temporary purse string suture, the heart was de-aired, and the aortic clamp was removed. After weaning off from cardiopulmonary bypass, the right ventricle (RV) inlet, outlet, and pulmonary artery (PA) pressures were directly measured through an RV inlet, RV subpulmonary valvar, and pulmonary patch puncture using a 21-gauge spinal needle connected to a pressure transducer. Left ventricular (LV) pressures were also measured through transseptal puncture. Not solely depending on 70% rule as indicated by other authors,[6,10], we take other variables, such as PA pressure, heart rate, dose of inotropic, and central venous pressure, also into consideration. If RV pressures are greater than 70% of LV pressure and other variables (such as PA pressure less than 15 mmHg) support the existence of any residual lesions, then the right ventricular outlet (RVOT) is revised. If transesophageal echocardiography and pressure measurement demonstrated the residual obstruction at the level of the annulus, then a transaortic incision was made and a glutaraldehyde-treated pericardial patch was inserted. If the residual gradient was in the subvalvar RVOT, then an infundibular incision and subvalvar pericardium patch were placed.

2.3. Clinical data

The medical records of all patients were reviewed. For each patient, we gathered data on the operative repair including cardiopulmonary bypass time, aortic clamp time, description of the RVOT management, and additional surgical procedures performed. The postoperative course was then reviewed. The date of extubation, the date of discharge from the intensive care unit (ICU), and the date of discharge from the hospital were used to calculate days intubated, days in the ICU, and days hospitalized. All of the complications were recorded. Late complications, follow-up interventions, and reoperations were noted.

2.4. Echocardiographic data

All preoperative and postoperative echocardiograms were reviewed. The branch pulmonary artery diameter was measured and the McGoon index was calculated. Tricuspid regurgitation was graded as follows: 0 = none; 1 = trivial; 2 = mild; 3 = moderate; and 4 = severe. PI severity was graded in a similar fashion. Patients with mild or less insufficiency were grouped and compared with those with moderate or severe insufficiency. For all the patients without TAP, we reviewed the follow-up echocardiogram to investigate whether there was progression in the degree of PI.

2.5. Statistical analysis

All data were analyzed with SPSS 10.0. Variables with a normal distribution are expressed as the mean ± standard deviation. Variables without a normal distribution are expressed as median and range. Differences were examined for significance by univariate analysis. Comparisons were made between the patients who underwent transannular patching and those who had two types of valve preservation procedures. Continuous variables were compared with two-tailed, unpaired Student’s t-test, and categorical data were compared with two-tailed Fisher’s exact test.

3. Results

Mean aortic clamp time was 63 min (57 min for regular valve-sparing group, 72 min for valve leaflet augmentation group, 85 min for TAP group; there was no significant difference among the three groups). The operative mortality was 0.7%. One patient who underwent regular PV-sparing technique died 5 days after surgery. The patient was an 8-month-old boy who had a very smooth course in the OR. Postoperative transesophageal echo (TEE) showed no obvious residual lesions and the gradient across RVOT was 32 mmHg. Direct pressure measurement showed that RV systolic pressure was 46 mmHg, while pulmonary artery systolic pressure was 20 mmHg. However, the patient had junctional ectopic tachycardia several hours after surgery which was treated with amiodarone. Soon after that, he developed low blood pressure, severe hypoxemia, and acute renal failure. We suggested putting him on extracorporeal membrane oxygenation, but his parents were reluctant to accept the procedure. His chest was left open for 5 days with peritoneal dialysis treatment and there was no sign of recovery, and the family chose to withdraw. There was one late death. She was a 4-month-old girl, who underwent the regular valve-sparing repair. She had recurrent hemoptysis after extubation. Although discharged from the ICU, she had pulmonary aspiration and developed severe infection and died 40 days after surgery while still in hospital. There was a patient with a 3.5-mm residual VSD in the regular valve-sparing group. He is currently under follow-up.

Of the 139 patients repaired, 132 had valve-sparing procedures and seven had TAPs. The surgical approach for the 139 patients with valve-sparing procedures is listed in Table 1. Among the seven patients with TAPs, two (30%) had attempts at valve-sparing procedures before intraoperative conversion to TAP because of RV/LV pressure ratios greater than 0.7. Among TAP patients, five (71.4%) had doubly committed subartrial ventricular defect and none of the doubly committed subarterial ventricular defect patients underwent successful pulmonary valve-sparing technique. None of the tricuspid pulmonary valves need TAP or pulmonary valve leaflet augmentation. Preoperative size of pulmonary annulus < —6 is associated with TAP. The preoperative data and postoperative course and discharge data of the three groups of patients are shown in Table 2. Twenty-nine of the 139 patients lost to follow-up. Three patients in the regular group had gradient more than 50 mmHg at 1-month follow-up, but the gradient dropped to less than 40 mmHg 6 months after surgery in two patients. One had a persistent 50–55 mmHg gradient and required reintervention for subvalvar pulmonary

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stenosis although he was symptomatic. The second patient had persistent subvalvar pulmonary stenosis. At a median follow-up of 27 months (range 1–45 months), five of the seven patients TAP (71%) had moderate or severe PI at follow-up. Three (14%) patients who underwent pulmonary valve leaflet augmentation had a progression of PI when compared with the degree of PI at discharge. All the other patients in this leaflet augmentation group had less than mild or mild PI. A total of 21 patients (six of them were newly developed) in the regular valve-sparing group had moderate or severe PI.

4. Discussion

The strategy for our avoidance of the use of a TAP comes from the many reports showing the problems of long-term PI. Exercise testing has shown that functional status is impaired in TOF patients with long-term PI [11,12]. Image examination of TOF patients late after repair has shown that PI is closely associated with TAP and that PI results in marked RV dysfunction, even in asymptomatic patients [13,14].

PI causes chronic volume load to the right ventricle after TOF repair, which leads to dilation of the ventricle and predisposes the patient to late life-threatening ventricular tachycardia and sudden death [15–18]. The late impact of TAP and PI on both RV and patient functional status are further supported by the increasing number of reports on the symptomatic relief and ventricular improvement achieved with pulmonary valve insertion late after TOF repair [19–21]. Several groups have described strategies to limit the size of the right ventriculotomy and reduce the incidence of PI. The Northwestern University group recommends avoidance of a TAP with preservation of the annulus of the pulmonary valve [18]. They perform transatrial closure of the ventricular septal defect, extensive commissurotomy, transpulmonary, and transatrial RVOT muscle resection, and, when needed, augmentation of the infundibulum with a separate patch that does not cross the annulus. They accept a right ventricular to left ventricular systolic pressure ratio of 0.7, because their main goal is to preserve the annulus, more than the valve cusps.

We have adopted their treatment strategy for TOF repair in one surgical group since August 2006. We tried our best to preserve pulmonary annulus, sometimes instead of pulmonary valves. At the same time we had very low chance of TAP. We also found that some patients had moderate or severe pulmonary regurgitation after discharge. It is quite possible that the aggressive valvotomy accounts for the relatively high incidence of PI at midterm follow-up. Therefore, we decided to modify the strategy. Based on our experience of valve patch plasty (in our experience of valve plasty, we found that if a limited patch was used to patch a valve leaflet, as long as the attaching edge of the valve was not involved, the valve leaflet morphology and the valve function can be preserved in the longterm), we started to try this new valve leaflet augmentation technique since 2007 on TOF, although we understand this finding needs more evidence; research on it was going on at the same time in our hospital.

We used fresh autologous pericardium instead of glutaraldehyde-treated pericardium based on the fact that in many patients with a pericardium patch on low pressure vessels, the pericardium was found alive and not calcified when we
did a redo surgery and when the patched vessels were dissected. Pathological findings and the physical characteristics such as elasticity, softness, etc., supporting the pericardium were alive even though we did not culture them. However, we used glutaraldehyde-treated autologous pericardium when we did TAP because we were concerned about the manner in which high RV could potentially degenerate the fresh pericardium.

Hirsch and associates [22] at Michigan found that an RV/LV pressure ratio greater than 0.7 was a risk factor for reoperation among 61 neonates after primary repair of TOF. The Alabama, Birmingham group showed a decrease in the RV/LV pressure ratio with time, with the greatest reduction seen by those patients with the highest immediate postoperative ratios [19,20]. Our group chose RV/LV pressure ratio more than 0.7 as a cutoff point to do a repump run and infundibular patch [21]. However, this was not the only factor we considered for decision making. Patients’ volume status, pulmonary resistance, heart rate, and inotropic dosage, etc., all have an effect on the pressure measurement. Two patients had a very high pulmonary vascular resistance after bypass, their PA pressure was more than systemic pressure, so was their RV pressure. We ignored the ratio measurement and on the first day after surgery, the RV pressure dropped to less than 0.7 systemic. Since then, when we did a pressure measurement, we took PA pressure as a reference as well. If PA pressure was more than 20 mmHg, it often meant there was no obvious obstruction at RVOT.

The immediate and late moderate or severe PI in the valve leaflet augmentation group compares favorably with the relative high incidence in the TAP group and regular valvular-sparing group. There are several reasons for this: (1) we did not start this valve leaflet strategy in the early stage of this study period; therefore, some of the patients underwent an aggressive commissural division, which might have made significant PI. (2) Pulmonary cuspid augmentation TAP strategy, which might decrease PI in immediate postoperative period, was first introduced in 2008 in our institution. We only applied it on two TAP patients. There is certainly some percentage of patients that did not benefit from the PV valvular-sparing technique and a number of tetralogy patients’ pulmonary valve function could not be preserved even though surgeons tried very hard to do that. However, for the patients benefit, it is worth a trial and we believe there will be some patients who do not have to undergo a TAP and a subsequent future reintervention. Our study covers almost 4 years of experience in one surgery group and there was a learning curve in the early stage in terms of decision making and surgical technique which made some patients have more than moderate residual PI.

What were the chances of avoiding TAP? There is no answer yet. Based on our experience, maybe we could make the decision as follows: if we patched the supra-valvar level and resected all the pulmonary valve leaflets, and if the predicted size probe could pass through the tricuspid valve to the pulmonary artery, then it is very likely we do not need to do TAP.

Our series of patients with TOF with pulmonary stenosis demonstrates that an pulmonary valve leaflet augmentation approach can lead to a very low rate of transannular patching and might improve long-term outcomes. In our experience, it can be applied only in a certain subgroup of patients who have a small pulmonary annulus with hypoplastic inadequate native pulmonary valve tissue.

The limitation of the study is that it is nonrandomized retrospective. Because of the time limit and many changes happening in China, including telephone system, telephone number, and relocation of many patients, we did not finish all the follow-up of our patients and our follow-up time is limited to mid-term range. Despite all of the limitations, the pulmonary valve leaflet augmentation with autologous pericardium is not hard to perform, does not significantly prolong the operation, reduces the degree of PI in the immediate postoperative period, and improves the early outcome on severe pulmonary stenosis patients, who otherwise require a TAP. We will continue to follow these patients to determine whether this reconstruction is durable or not.

References

Appendix A. Conference discussion

Dr T. Ebels (Groningen, Netherlands): You describe an interesting new technique in 139 patients. I am a little bit worried about the relatively large number of patients that were lost to follow-up. There are 29 patients, if I read your manuscript correctly, that were lost to follow-up. That is more than 20%. And in the worst-case scenario, they did not turn up because something was wrong. So I think it would be wise to go after them and find out what happened to them.

I am a little bit surprised by the fact that you saw such a small number of very small annuluses because there were only 7 patients that had an annular size smaller than 2 minus 3. And in my experience, that is unusual. We see many more small annuluses, so maybe this is a favorable regional phenomenon or something.

The major question is, what happens to the pericardium with which you augment the leaflets? You described in one of the last slides that there were quite a number of patients that had developed some PI a number of years after the operation.

And my question then is, what is the modus of the PI that has developed? What happens to that pericardium, the fresh pericardium that you use? Does it prolapse or what happens?

Dr Hua: The reason why we use fresh pericardium is based on our experience that if you use fresh pericardium in patients in a low-pressure vessel, then during the second operation, the redo operation, you find some of the pericardium is still alive and can grow. So we use fresh autologous pericardium for this kind of repair hoping that it can grow as native tissue.

Regarding the pulmonary insufficiency after the repair, I think there are two situations I described. One is a bicuspid pulmonary valve, and the other one is high tethering with a small opening.

I think that, for the bicuspid valve with low tethering (the second situation - where the orifice to the nadir is low) if you patch this leaflet where the valve is low, it is prone to prolapse.

Dr Ebels: Maybe you could comment on what causes it?

Dr Hua: It could prolapse a little bit, and the pressure in the pulmonary artery may not be enough to support the round shape.

Dr Ebels: But does it prolapse because you measured it inadequately, or is it that the pericardium stretches or something?

Dr Hua: I do not think it is going to stretch, but according to the literature, fresh pericardium is different from glutaraldehyde-treated pericardium. Just in the short term, it might stretch a little bit, but in the long term I think it will not stretch.

Dr Ebels: Because everything is about the long-term results, isn’t it? I mean, your follow-up is pretty brief just now, the longest follow-up being 4 years. But it is more like 14 years that is the important thing. That will remain to be seen. Dr Hua: I agree. Long-term follow-up is needed.