Türk Göğüs Kalp Damar Cerrahisi Dergisi 2013;21(3):628-632
doi: 10.5606/tgkdc.dergisi.2013.7828

Early- and mid-term results of off-pump pulmonary valve implantation: a single-center experience

Atan kalpte pulmoner kapak implantasyonunun erken ve orta dönem sonuçları: Tek merkez deneyimi

Haşim Üstünsoy,[1] Gökhan Gökaslan,[1] Özerdem Özçalışkan,[1] Hayati Deniz,[1] Cem Atik,[1] Mehmet Kervancıoğlu,[2] Eren Oral Kalbisağde,[1] Alptekin Yasım[1]

[1]Department of Cardiovascular Surgery, Medical Faculty of Gaziantep University, Gaziantep, Turkey
[2]Department of Pediatric Cardiology, Medical Faculty of Gaziantep University, Gaziantep, Turkey

Background: This study aims to assess the early- and mid-term results of off-pump pulmonary valve implantation (PVI).

Methods: Between October 2006 and February 2012, nine patients (5 males, 4 females; mean age 18.4±6.3 years; range 8 to 27 years) underwent off-pump PVI with an injectable stent. Echocardiography revealed severe pulmonary valve regurgitation, progressive right ventricular dilatation and dysfunction in all patients. No residual ventricular septal defect (VSD) was seen.

Results: We implanted a 23 mm valve in one patient, a 25 mm valve in two patients, a 27 mm valve in two patients, a 29 mm valve in three patients and a 31 mm valve in one patient. Postoperative echocardiographic examination revealed no regurgitation in seven patients with mild valve regurgitation in two patients. The mean peak systolic gradient was 12.6±3.7 mmHg, while the mean systolic gradient was 8.3±2.4 mmHg. The mean follow-up was 34±17 months (range, 1.5 to 58 months). None of the patients needed reoperation.

Conclusion: The advantages of off-pump PVI include the applicability without cardiopulmonary bypass, availability of large-sized valves, the absence of any interventional limitation and the opportunity for fixation into the pulmonary artery to avoid valve migration. No-react nature of the valve also minimizes the degeneration risk of the valve.

Key words: Congenital heart disease; off-pump surgery; pulmonary valve; tetralogy of Fallot.

Amaç: Bu çalışmada atan kalpte pulmoner kapak implantasyonunun (PKİ) erken ve orta dönem sonuçları değerlendirildi.

Çalışma planı: Ekim 2006 - Şubat 2012 tarihleri arasında dokuz hastaya (5 erkek, 4 kadın; ort. yaş 18.4±6.3 yıl; dağılım 8-27 yıl) enjekte edilebilen stent ile PKİ yapıldı. Tüm hastalarda ekokardiyografik olarak şiddetli pulmoner kapak yetmezliği, ilerlemiş sağ ventrikül dilatasyonu ve disfonksiyonu vardı. Hiçbir hastada rezidüel ventriküler septal defekt (VSD) görülmedi.

Bulgular: Çalışmada bir hastaya 23 mm, iki hastaya 25 mm, iki hastaya 27 mm, üç hastaya 29 mm ve bir hastaya 31 mm kapak implante edildi. Ameliyat sonrası ekokardiyografik incelemede yedi hastada hiç kapak yetmezliğine rastlanmazken, iki hastada hafif derecede kapak yetmezliği saptandı. Ortalama pik sistolik gradyanı 12.6±3.7 mmHg ve ortalama sistolik gradyanı 8.3±2.4 mmHg olarak hesaplandı. Ortalama takip süresi 34±17 ay (dağılım, 1.5 ila 58 ay) idi. Hastaların hiçbirine tekrar ameliyat gerekmedi.

Sonuç: Atan kalpte PKİ'nin avantajları; kardiyopulmoner baypas olmaksızın uygulanabilmesi, büyük boyutlu kapakların kullanılabilirliği, herhangi bir girişim sınırlamasının olmaması ve kapağın yer değiştirmesini önleyecek şekilde kapağın pulmoner artere tespitine imkan vermesidir. Kapağın no-react özelliği, kapak dejenerasyon riskini de azaltmaktadır.

Anahtar sözcükler: Doğuştan kalp hastalığı; atan kalpte cerrahi; pulmoner kapak; Fallot tetrolojisi.

Available online at
www.tgkdc.dergisi.org
doi: 10.5606/tgkdc.dergisi.2013.7828
QR (Quick Response) Code

Received: October 19, 2012 *Accepted:* January 02, 2013

Correspondence: Haşim Üstünsoy, M.D. Gaziantep Üniversitesi Tıp Fakültesi, Kalp ve Damar Cerrahisi Anabilim Dalı, 27310 Şehitkamil, Gaziantep, Turkey.
Tel: +90 342 - 360 60 60 e-mail: hustunsoy@yahoo.com

By improving experiences in the surgical repair of tetralogy of Fallot (TOF), long-term survival rates of patients have apparently increased. Thus, late complications, such as pulmonary regurgitation (PR), have been encountered more frequently. Severe PR after the repair of TOF leads to chronic volume overload resulting in progressive dilatation and dysfunction of the right ventricle (RV), impaired exercise tolerance, malignant arrhythmias, and risk of sudden death.[1] The timing of the reoperation is the key to treating the PR and its related complications. Pulmonary valve replacement (PVR) is preferable for these patients as it has been reported to normalize RV dimensions within the scope of remarkable clinical improvement.[2] Since Berdat and Carrel[3] first reported it in 2006, off-pump PVR has marked a new era for cardiovascular surgeons since it can be performed without cardiopulmonary bypass (CPB) while also minimizing surgical trauma with satisfactory results. Marianeschi et al.[4] suggested that off-pump surgical PVR has advantages, for example the implantation of larger valve sizes and no access limitations. In this report, we present early and mid-term results of nine off-pump PVR patients.

PATIENTS AND METHODS

The ethics committee of our hospital approved this retrospective study. Between October 2006 and February 2012, nine patients (5 males, 4 females; mean age 18.4±6.3 years; range 8 to 27 years) underwent off-pump PVR with the Shelhigh injectable stented pulmonic valve (Shelhigh Inc, Union, NJ, USA). All of the patients had a history of total correction with transannular patch plasty due to TOF. In addition, they had severe PR, progressive RV dilatation, RV dysfunction, and no residual ventricular septal defect (VSD) on their echocardiographic evaluations. Furthermore, the patients were also symptomatic with exercise intolerance. The mean interval between the initial repair and the actual operation was 6.9±3.2 years (range, 3.1 to 11.7 years). In all of the patients, off-pump surgical PVR indications included the combination of severe PR, symptoms of diminished exercise capacity related to right heart failure, and progressive RV dilatation or dysfunction. The preoperative demographic data of the patients is detailed in Table 1. Postoperative evolution of RV function and improvement in dilatation were achieved with echocardiography since cardiac magnetic resonance imaging (MRI) is not available at our institution.

Surgical technique

A transesophageal echocardiography (TEE) probe was inserted immediately after intubation, and all operations were performed via a median sternotomy. First, the RV and pulmonary artery (PA) with its bifurcation were carefully dissected. Two purse string sutures were then placed onto the right ventricular outflow tract (RVOT) about 2.5 cm proximal to the pulmonic valve. Next, heparin was administered in doses of 100 IU/kg. After an incision was made at the middle of the sutured site, the introducer tip was put into place with the injector gun, and sutures were snugged down to avoid bleeding. After sliding the introducer tip back, the correct position of the trocar was confirmed by TEE. When this could be verified visually, the plunger was pressed down, and the valve was fully ejected. The purse string sutures were then tightened after the injector was gently pulled out from the RVOT incision. This was followed by inserting three or four sutures at the proximal and distal site of the valve to prevent valve migration. After assessing the valve performance and localization, the sternum was closed in a routine fashion.

Table 1. Preoperative demographic data of patients

Patient number	Age (years)	Gender	BSA	Diagnosis in prior surgery	Time interval to previous repair (years)
1	20	Male	1.64	Tetralogy of Fallot	11
2	15	Female	1.23	Tetralogy of Fallot	7.5
3	19	Female	1.47	Tetralogy of Fallot	10
4	8	Female	0.92	Tetralogy of Fallot	3
5	12	Male	1.13	Tetralogy of Fallot	4
6	17	Male	1.47	Tetralogy of Fallot	7
7	27	Female	1.52	Tetralogy of Fallot	6.5
8	17	Male	1.61	Tetralogy of Fallot	11
9	23	Male	1.79	Tetralogy of Fallot	12

BSA: Body surface area.

RESULTS

The sizes of the implanted prosthetic valves were determined according to the preoperative transthoracic and intraoperative TEE. We implanted 23 mm, 25 mm, 27 mm, 29 mm, and 31 mm valves in one, two, two, three, and one patient, respectively. The mean implanted prosthetic valve size was 27.2±2.5. No procedural complications were encountered during the surgery, and the postoperative course was uneventful for all of the patients. The postoperative echocardiographic examination revealed no regurgitation in seven patients and a mild degree of regurgitation in two. The mean peak systolic gradient was 12.6±3.7 mmHg, and the mean systolic gradient was 8.3±2.4 mmHg. Additionally, the mean intubation time was 3.7±1.1 hours, and the mean hospital stay was 3.8±1.2 days. There were no reoperations needed during the mean follow-up period of 34±17 months (range, 1.5 to 58 months). Scar formation between the injectable pulmonic valve and the PA wall is normally represented by calcification and degeneration, but we did not observe this in our patients, even in those who were followed-up for five years. The postoperative data is detailed in Table 2.

DISCUSSION

Innovations in surgical and medical management strategies have led to an increase in the survival rates of TOF patients, with a 20-year survival rate now approaching 90%.[5] Pulmonary regurgitation is the most common cause of reinterventions in TOF patients[6] because it causes chronic volume overload in the RV which results in progressive RV dilatation, RV dysfunction, malignant arrhythmias, and exercise intolerance.[1]

One of the most important parameters in PR development involving TOF patients is whether a transannular patch was applied in prior surgery. The transannular patch repair rate varies between centers, but it is accepted that this type of repair is an independent risk factor, especially in patients who have undergone an extended right ventriculotomy.[2] The patch leads to PR, RV enlargement, and an increase in QRS duration.[1] In a recent large, multi-center study, Gatzoulis et al.[7] demonstrated that outflow tract patching significantly increases the incidence of ventricular tachycardia and sudden cardiac death. In addition, PVR in patients with PR and dilatation of the RV demonstrated a decrease in ventricular arrhythmias and improvement in RV functions.[8] In all of our patients, a transannular patch was applied during previous surgery, and they had severe PVR. However, we did not encounter preoperative or postoperative arrhythmia and saw no calcification over these patches during surgery.

Although PVR should be performed without hesitation in severe PR, the optimal timing for PVR still remains controversial. Thus far, exercise intolerance, ventricular arrhythmias, progressive RV dilatation, and the onset of tricuspid regurgitation have been used as indicators for reintervention.[9] Furthermore, in asymptomatic patients with RV dilatation, PVR has been considered for the prevention and reduction of RV dilatation. A more aggressive approach with the timely correction of PR is advocated by Marianeschi et al.[4] It is also interesting to note that Buechel et al.[10] observed that none of their patients with a right ventricle end-diastolic volume (RVEDV) above 200 mL/m^2 showed normalization of RV function. Although there are different indication aspects for PVR, generally the combination of severe PR and diminished exercise capacity and/or clinical arrhythmia secondary to right heart failure are recognized as indications for PVR.

Table 2. Pre- and postoperative echocardiographic measurements

Patient number	Implanted valve size	RVEDD (mm)				RVESD (mm)				RVEDV (mL/m^2)				RVESV (mL/m^2)				RVEF (%)				PR	
		Preop.	Postop.			Preop.	Postop.			Preop.	Postop.			Preop.	Postop.			Preop.	Postop.			Preop.	Postop.
			a	b	c		a	b	c		a	b	c		a	b	c		a	b	c		
1	23	56	39	37	36	33	21	20	18	90.5	52.4	50.1	48.2	75.5	27.1	25.1	24.4	50	60	60	65	Severe	None
2	25	53	40	39	34	29	20	18	15	83.1	45.1	42.5	41.3	47.9	18.4	18.0	17.5	66	76	75	75	Severe	None
3	25	54	31	30	27	31	19	18	17	71.3	49.2	47.7	45.4	54.2	22.4	21.8	21.6	60	68	70	70	Severe	Mild
4	27	59	33	31	28	28	21	20	18	80.2	48.5	47.1	45.5	57.9	25.3	25.0	24.4	40	49	52	55	Severe	Mild
5	31	61	38	38	35	34	22	21	18	91.4	47.3	45.0	44.4	58.3	26.4	25.8	25.0	45	58	60	60	Severe	None
6	29	57	34	31	30	31	19	19	18	86.7	50.2	45.7	44.6	43.3	21.8	21.2	20.2	50	57	62	65	Severe	None
7	29	56	31	29	29	30	18	17	17	81.2	44.6	43.7	43.1	46.2	20.6	20.0	20.1	52	58	61	65	Severe	None
8	27	52	35	32	–	32	20	19	–	74.8	50.9	48.7	–	39.6	13.6	13.2	–	65	73	73	–	Severe	None
9	29	49	30	28	–	31	20	18	–	70.3	35.0	33.2	–	38.2	12.9	12	–	60	63	64	–	Severe	None

RVEDD: Right ventricle end diastolic diameter; RVESD: Right ventricle end systolic diameter; RVEDV: Right ventricle end diastolic volume; RVESV: Right ventricle end systolic volume; RVEF: Right ventricle ejection fraction; PR: Pulmonary regurgitation; Preop: Preoperative; Postop: Postoperative; a: First week; b: First month; c: First year.

Also, moderate-to-severe RV enlargement may be another indication, but what constitutes this degree of enlargement is not yet clear.[6] In our patients, the preoperative mean RVEDV was 82 mL/m^2, and we considered severe PR and diminished exercise capacity for PVR indication. Our two patients (patients 4 and 5) who had a considerably short time interval between the TOF repair and off-pump PVR, had RVEDVs of 80.2 and 91.4 along with RV ejection fraction (RVEF) rates of 40% and 45%, respectively. We decided on an early PVR for these two patients because of diminished EF rates in conjunction with severe PR and exercise intolerance.

Percutaneous pulmonary valve implantation is an option in patients with severe PR. It minimizes invasiveness and may be considered in suitable cases. However, there are disadvantages with this procedure, including access limitation, valve size inadequacy, and migration of the device.[11] Although Khambadkone and Bonhoeffer[12] reported that percutaneous pulmonary valve sizes ranging from 18 mm to 22 mm are available, the annular size of the PA in this patient population is often larger than 22 mm due to the natural progression of the PR. Hazekamp et al.[2] reported a mean diameter of 25±1.8 mm in 51 patients who underwent late conventional surgical PVR after repair of TOF. These mean diameters show that the small size of percutaneous pulmonary valves is a significant limitation to the use of this technique when compared with the surgical option. Nonetheless, the ability to utilize transmural suturing to avoid valve migration after deployment is another important advantage of percutaneous pulmonary valve implantation. Marianeschi et al.[4] reported the early results of 12 patients from three different centers (including two from our institution) who underwent off-pump pulmonary valve implantation, and the mean implanted prosthetic valve size was 26.8±2.9. In our nine patients, although there was one case with a 23 mm valve (patient # 1), the mean implanted prosthetic valve size was 27.2±2.5 mm. In patients implanted with small-sized valve (patient # 1) preoperatively there were no gradients over RVOT, and the measured pulmonary annulus diameter allowed only up to a 23 mm valve implantation. However, our patient with the 23 mm valve remains free of valve degeneration symptoms.

It is essential to use CPB when there is left-to-right shunt and/or tricuspid valve regurgitation related to RV dilatation. These defects should be repaired under CPB, and injectable pulmonic valve implantation should be performed after the repair. Our patients had neither residual septal defects nor moderate or severe tricuspid valve regurgitation, so CPB was not necessary. This may have been due to our surgical PVR indication criteria which does not allow severe RV dilatation and prevents severe tricuspid insufficiency.

As reported in other clinical studies, we also observed excellent RV remodeling after off-pump pulmonary valve implantation. A marked decrease in RVEDV and increase in RVEF were seen even in the first-week echocardiographies, and this improvement in RV functions progressed in the subsequent echocardiography controls. Van Straten et al.[13] reported that both diastolic and systolic functions of RV normalize late in the PVR process in patients after the primary repair of TOF. Furthermore, Dave et al.[14] showed a strong and significant correlation between preoperative RVEDV and its value at the postoperative sixth month. Similarly, the fast RV improvement after surgery in our patients could be related to performing the surgical intervention before the development of severe RV dilatation.

We determined that off-pump pulmonary valve implantation has many advantages for select patients, including PVR without bypass, the applicability of large valve sizes, no access limitation, and opportunities for fixation. Even though larger series and longer term follow-up periods are needed, our early and mid-term results are encouraging regarding off-pump pulmonary valve implantation in patients suffering from PR, especially after TOF correction.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

REFERENCES

1. Nollert GD, Däbritz SH, Schmoeckel M, Vicol C, Reichart B. Risk factors for sudden death after repair of tetralogy of Fallot. Ann Thorac Surg 2003;76:1901-5.
2. Hazekamp MG, Kurvers MM, Schoof PH, Vliegen HW, Mulder BM, Roest AA, et al. Pulmonary valve insertion late after repair of Fallot's tetralogy. Eur J Cardiothorac Surg 2001;19:667-70.
3. Berdat PA, Carrel T. Off-pump pulmonary valve replacement with the new Shelhigh Injectable Stented Pulmonic Valve. J Thorac Cardiovasc Surg 2006;131:1192-3.
4. Marianeschi SM, Santoro F, Ribera E, Catena E, Vignati G, Ghiselli S, et al. Pulmonary valve implantation with the new

Shelhigh Injectable Stented Pulmonic Valve. Ann Thorac Surg 2008;86:1466-71. doi: 10.1016/j.athoracsur.2008.06.085.
5. Nollert G, Fischlein T, Bouterwek S, Böhmer C, Klinner W, Reichart B. Long-term survival in patients with repair of tetralogy of Fallot: 36-year follow-up of 490 survivors of the first year after surgical repair. J Am Coll Cardiol 1997;30:1374-83.
6. Burchill LJ, Wald RM, Harris L, Colman JM, Silversides CK. Pulmonary valve replacement in adults with repaired tetralogy of Fallot. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 2011;14:92-7. doi: 10.1053/j.pcsu.2011.01.016.
7. Gatzoulis MA, Balaji S, Webber SA, Siu SC, Hokanson JS, Poile C, et al. Risk factors for arrhythmia and sudden cardiac death late after repair of tetralogy of Fallot: a multicentre study. Lancet 2000;356:975-81.
8. Therrien J, Provost Y, Merchant N, Williams W, Colman J, Webb G. Optimal timing for pulmonary valve replacement in adults after tetralogy of Fallot repair. Am J Cardiol 2005;95:779-82.
9. van der Wall EE, Mulder BJ. Pulmonary valve replacement in patients with tetralogy of Fallot and pulmonary regurgitation: early surgery similar to optimal timing of surgery? Eur Heart J 2005;26:2614-5.
10. Buechel ER, Dave HH, Kellenberger CJ, Dodge-Khatami A, Pretre R, Berger F, et al. Remodelling of the right ventricle after early pulmonary valve replacement in children with repaired tetralogy of Fallot: assessment by cardiovascular magnetic resonance. Eur Heart J 2005;26:2721-7.
11. Nordmeyer J, Coats L, Bonhoeffer P. Current experience with percutaneous pulmonary valve implantation. Semin Thorac Cardiovasc Surg 2006;18:122-5.
12. Khambadkone S, Bonhoeffer P. Percutaneous pulmonary valve implantation. Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 2006:23-8.
13. van Straten A, Vliegen HW, Lamb HJ, Roes SD, van der Wall EE, Hazekamp MG, et al. Time course of diastolic and systolic function improvement after pulmonary valve replacement in adult patients with tetralogy of Fallot. J Am Coll Cardiol 2005;46:1559-64.
14. Dave HH, Buechel ER, Dodge-Khatami A, Kadner A, Rousson V, Bauersfeld U, et al. Early insertion of a pulmonary valve for chronic regurgitation helps restoration of ventricular dimensions. Ann Thorac Surg 2005;80:1615-20.