Outcome of 40 consecutive cases of modified Ross procedure using novel Dacron valved conduit

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Abstract

Objective The Ross procedure is an established option for aortic valve disease in children. Due to limited availability of pulmonary homograft, we devised a novel technique for right ventricular outflow tract (RVOT) reconstruction by preparing indigenous Dacron valved conduit.

Methods Forty consecutive cases of modified Ross procedure done at our center (2013–2018) were analyzed. Thirty-seven patients (95%) were followed up with median duration of 2.5 (0.08–5.5) years. Median age was 12 (5–39) years. Nineteen (47.5%) patients had rheumatic aortic valve disease, while 19 (47.5%) had congenital aortic valve disease. Aortic root replacement with pulmonary autograft was performed in all patients. Dacron conduit for RVOT reconstruction was used with on table sewn bileaflet valve using Dacron patch ($n = 22$), expanded polytetrafluoroethylene (ePTFE) membrane ($n = 10$), bioprosthetic valve ($n = 4$), and pericardium ($n = 4$). Additional surgical procedures included mitral valve repair ($n = 10$), septal myectomy ($n = 2$), ascending aorta replacement ($n = 1$), ruptured sinus of valsalva (RSOV) repair ($n = 1$), and ventricular septal defect (VSD) closure ($n = 1$).

Results There was one in-hospital mortality while one late death occurred at 3.5 years postoperatively. The neo-aortic valve regurgitation on echocardiographic evaluation at last follow-up was trivial ($n = 28$), mild ($n = 7$), and moderate ($n = 2$). Mild RVOT obstruction was present in 8 patients while 18 patients had mild pulmonary regurgitation. No patient required reintervention during follow-up.

Conclusion Our early results of modified Ross procedure are encouraging, however, long-term follow-up is required.

Keywords Modified Ross procedure · RVOT reconstruction · Dacron valved conduit

Introduction

Ross procedure was first described by Sir Donald Nixon Ross in 1967 [1]. Ross procedure is based on the principle of replacing an unrepairable diseased aortic valve with a pulmonary autograft and reconstructing RVOT with homograft. The original subcoronary implantation technique was later replaced by root replacement technique (aortic root replaced with pulmonary root) which is widely used in majority of centers [2].

In children and young adults, Ross procedure is a valid option for aortic valve disease with potential for annulus growth and added advantage of low thrombogenicity and superior hemodynamics [3]. Ross procedure has its own limitations like complex surgical procedure, risk of reintervention for autograft and homograft and is a double-valve intervention [4, 5].

In Ross procedure, pulmonary homograft is the gold standard for RVOT reconstruction. Due to cost and limited availability of homografts, several alternatives have been reported. We devised a novel technique for RVOT reconstruction by preparing indigenous valved Dacron conduit.

Aim of the study

In this study, we evaluated the outcomes of modified Ross procedure using the valved Dacron conduit for RVOT reconstruction.

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Patients and methods

Clinical records of forty consecutive cases of modified Ross procedure done at The Mission Hospital, Durgapur, West Bengal, from January 2013 to November 2018 were retrospectively analyzed. This was an observational study. The statistical power of the study is 80%. Inclusion criteria for modified Ross procedure were patients of both genders with irreparable aortic valve lesion, acquired and congenital aortic valve disease, and age ≥ 5 years. Exclusion criteria were pulmonary valve anomalies, coronary artery disease, aortic annulus > 30 mm, and connective tissue disorder. Primary and secondary end points were reported according to 2008 Society of Thoracic Surgeons/American Association for Thoracic Surgery/European Association for Cardio-Thoracic Surgery guidelines [6]. Primary end point was death resulting from any cause and was classified into early and late mortality. Secondary end points included valve reintervention, thromboembolic events, valve thrombosis, endocarditis, major hemorrhage, neo-aortic valve dysfunction, and RVOT conduit dysfunction. The mean age was 13.04 ± 5.83 years (median 12 years, range 5–39 years). Mean body weight was 31 ± 12.13 kg (median 28.5 kg, range 12–60 kg.). Majority (80%) of the patients were ≤ 15 years of age. The mean aortic annulus diameter was 20.32 ± 3.07 mm (range 15–27 mm). Demographic data and preoperative details of the patients are described in Table 1.

Conduit characters

Gelweave™ (Vascutek Terumo; Vascutek Ltd., Scotland, UK) gelatin impregnated polyester woven vascular prosthesis was used as conduit (Fig. 1). The conduit was folded on itself inside out at one end for a length of 1 cm more than the width of the strip of material being used for making valve. The extra 1 cm was kept for suturing the conduit to the opened RVOT (Fig. 2). To make the valved conduit, a broad strip of Dacron patch (BARD® Sauvage® Filamentous knitted polyester fabric; BARD Peripheral Vascular Inc., AZ, USA) or ePTFE membrane (GORE® PRECLUDE® Pericardial membrane; W.L.Gore & Associates, Inc. AZ, USA) or autologous pericardium was cut with a width two-third the diameter of the conduit. The folded end of the conduit was sutured to the strip of Dacron patch along its circumference and the extra length of the patch was cut (Fig. 3). The free ends of the patch were sutured to each other and to the conduit to form one of the commissure of the bileaflet valve (Fig. 4). Another commissure was created at diagonally opposite end by suturing the patch to the conduit (Fig. 5). The suturing for preparing the conduit was done with 6–0 polypropylene suture (Centenial Surgical Suture). Once commissures were created, the folded end of conduit was unfolded so that the valved Dacron conduit was ready for use (Fig. 6).

Surgical procedure

After standard aortic and bicaval cannulation, cardiopulmonary bypass was established with moderate hypothermia (up to 32°C). Myocardial protection was achieved with combined antegrade and retrograde single dose of Del Nido cardioplegia and warm blood reperfusion. Coronary buttons were harvested and aortic valve excised. Pulmonary autograft harvested preserving first septal artery. Pulmonary autograft was implanted using total root replacement technique with coronary buttons reimplanted on the autograft. RVOT reconstruction was done using valved Dacron conduit. Proximal anastomosis of the conduit to the RVOT was done using single continuous 4–0 polypropylene suture (Centenial Surgical Suture) and distal anastomosis done using continuous 5–0 polypropylene suture (Centenial Surgical Suture) (Fig. 7). The conduit size ranged from 18 to 26 mm. The conduit size for adults was based on the size of the distal pulmonary artery. The size of conduit for pediatric patients was based on minimal acceptable pulmonary valve ring diameter as proposed by Pacifico, Kirklin, and Blackstone [7]. Every attempt was made to insert a conduit as large as possible.

Transesophageal echocardiography was done after weaning from cardiopulmonary bypass to evaluate autograft and conduit function. Operative data is described in Table 2.

Postoperative management

Patients were started on oral antiplatelets from first postoperative day. Mean hospital stay was 13.45 ± 4.87 days. At discharge, transthoracic echocardiography was done to evaluate autograft (neo-aortic valve regurgitation/stenosis), RVOT gradient across conduit, conduit valve regurgitation, left ventricle (LV) function, and mitral valve (MV) assessment in patients who underwent MV repair.

Follow-up

Follow-up was scheduled at 1 month, 6 months, and then annually. Each follow-up visit comprised of detailed history, physical examination, electrocardiogram, chest radiograph, and transthoracic echocardiographic assessment. Postoperative events were classified according to the 2008 Society of Thoracic Surgeons/American Association for Thoracic Surgery/European Association for Cardio-Thoracic Surgery guidelines [6]. Early mortality was defined as death due to any cause occurring in the hospital or within 30 days of the surgery; late mortality was defined as death occurring after that period. RVOT conduit dysfunction was defined as a peak systolic gradient of > 35 mmHg (moderate conduit stenosis) or the presence of moderate to severe conduit valve regurgitation.

Table 1 Demographic and preoperative details of the patients

		<i>n</i>	%
Age groups	≤ 5 years	2	5.0
	6–10 years	12	30.0
	11–15 years	18	45.0
	16–30 years	7	17.5
	> 30 years	1	2.5
Sex	Male	20	50.0
	Female	20	50.0
Aortic valve etiology	Congenital	19	47.5
	Rheumatic	19	47.5
	Infective endocarditis	2	5.0
Aortic valve hemodynamic lesion	Regurgitation	11	27.5
	Stenosis	17	42.5
	Combined lesion	12	30.0
Aortic valve morphology	Tricuspid	21	52.5
	Bicuspid	17	42.5
	Unicuspid	2	5.0
Associated rheumatic mitral valve lesion	Regurgitation	7	17.5
	Stenosis	2	5.0
	Combined lesion	1	2.5
Additional lesion	RSOV	1	2.5
	VSD	1	2.5
	Septal hypertrophy	2	5.0
	Ascending aortic aneurysm	1	2.5
	Tricuspid regurgitation	1	2.5
Left ventricle function	Normal (EF ≥ 55%)	38	95.0
	Mild dysfunction (EF 45–54%)	1	2.5
	Moderate dysfunction (EF 30–44%)	1	2.5
Previous aortic valve procedure	Balloon aortic valvuloplasty	1	2.5

RSOV, ruptured sinus of valsalva; VSD, ventricular septal defect; EF, ejection fraction

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 24.0. Quantitative variables are presented as mean ± standard deviation or median, while qualitative variables are presented as absolute numbers (*n*) and percentages (%). The 2 groups were compared using the Wilcoxon matched pairs signed rank test. The Kaplan–Meier method was used to evaluate survival which is presented as 95% confidence intervals. *P* values < 0.05 were considered statistically significant.

Results

There was one early mortality. Patient was a 15-year-old girl diagnosed to have rheumatic severe aortic regurgitation with moderate LV dysfunction. Patient developed severe low cardiac output in immediate postoperative period refractory to maximum inotropic support and succumbed to it. There was

one late postoperative death at 3.5 years postoperatively due to non-cardiac cause (acute fulminant hepatitis A).

Thirty-seven patients (95%) were followed-up with mean duration of 2.45 ± 1.56 (median 2.5, range 0.08–5.5) years. At last follow-up, none of the patients had infective endocarditis of autograft/conduit or any episodes of thromboembolism or major hemorrhagic event. The 5-year survival rate was 94.8% (95% confidence interval 81.6–99%) (Fig. 8).

At the time of discharge, all patients were in normal sinus rhythm. The peak gradient across the RVOT conduit was 15.12 ± 4.18 mmHg. No patient had peak RVOT gradient of > 35 mmHg. Mild conduit valve regurgitation was reported in 14 patients (Table 3).

At the time of last follow-up, all patients continued to have normal sinus rhythm. The peak gradient across the conduit had significantly increased to 19.75 ± 6.24 mmHg (*p* value = 0.003). Eight patients had peak gradient between 21 to 35 mmHg suggestive of mild conduit stenosis. No patient had moderate or severe conduit stenosis. Mild conduit valve

Fig. 1 Gelweave™ Dacron conduit of 24 mm size. The arrow shows the direction in which the conduit is folded

regurgitation was present in 18 patients (Table 3). Neo-aortic valve regurgitation was trivial ($n = 28$), mild ($n = 7$), and moderate in 2 patients. Patients with moderate neo-aortic valve regurgitation are being managed medically and closely monitored for LV dimension and occurrence of symptoms. No mitral stenosis (MS)/mitral regurgitation (MR) was present in patients who underwent mitral valve repair. None of the patients had right ventricle (RV) dysfunction or severe tricuspid regurgitation (TR) on echocardiography at last follow-up. No patient required intervention on autograft or conduit during follow-up.

Discussion

Ross procedure in young adults has an excellent long-term survival comparable with the general population; although

Fig. 2 The conduit is folded on itself inside out at one end

Fig. 3 A strip of Dacron patch with a width of 2/3rd the size of conduit (16 mm) is sutured along the circumference of the folded end of the conduit

with a risk of reoperation [8]. As compared to mechanical prosthetic aortic valve replacement, Ross procedure seems to be a better alternative with comparable [9] or even better long-term survival [10] with advantage of avoiding anticoagulation and less valve-related mortality with significantly less risk of stroke and bleeding. Despite these advantages, Ross

Fig. 4 The free ends of the patch sutured to each other and to the conduit to form one of the commissure of the bileaflet valve

Fig. 5 Two commissures are created diagonally opposite to each other. The arrow shows the direction in which the conduit is unfolded

Fig. 6 Dacron valved conduit is ready for use. Arrows show the bileaflet valve

Fig. 7 Intraoperative photograph post completion of modified Ross procedure showing pulmonary autograft (A) and Dacron valved conduit (C)

procedure is not performed frequently at many centers. Reason being the limitations of the procedure like complex surgical technique, need for a double-valve intervention, and an increased risk of reoperations for RVOT conduit dysfunction [4, 5].

The cryopreserved pulmonary homograft is the graft of choice for RVOT reconstruction in Ross procedure with good late results. David et al. reported that the probability of reoperation on pulmonary homograft after Ross procedure at 20 years is 8.2% [11]. In a study by the German Ross Registry which comprised of 1779 adult patients, freedom from reoperations at 15 years involving pulmonary allografts was 92.3% [12]. In pediatric age group, freedom from reoperation on allograft after the Ross procedure is less and varies with the age of the patient population. In a study on 305 patients by the Italian Pediatric Ross Registry, freedom from reintervention on allograft at 15 years is 82% [13].

The immunological response to donor cell antigen in allograft results in its degeneration overtime. To decrease the immunogenicity to the allografts and hence to improve their durability, concept of decellularized allograft was introduced. Allograft is decellularized leaving only connective tissue, which is then repopulated with host cells, therefore reducing immunogenicity. Dohmen et al. studied 23 patients receiving decellularized pulmonary allograft or xenograft, coated with fibronectin, and then seeded with autologous vascular endothelial cells. They showed that tissue-engineered heart valves had excellent hemodynamic performance during mid-term follow-up [14]. On the contrary, Bibevski et al. demonstrated that there was higher incidence of conduit dysfunction, pulmonary insufficiency, and stenosis among patients who received conventional allografts compared to the patients with Syngraft (decellularized pulmonary allografts) [15].

Table 2 Operative data

Cardiopulmonary bypass time (min), mean $\pm$ SD	180.70 $\pm$ 47.34
Aortic cross clamp time (min), mean $\pm$ SD	148.47 $\pm$ 43.08
Concomitant procedures	
Mitral valve repair	10
Ascending aorta replacement	1
Septal myectomy	2
RSOV repair	1
VSD closure	1
Tricuspid valve repair	1
RVOT reconstruction	
Dacron graft size (mm), mean $\pm$ SD	22.45 $\pm$ 2.25
Dacron graft size (mm), <i>n</i> (%)	
18	3 (7.5)
20	10 (25)
22	5 (12.5)
24	19 (47.5)
26	3 (7.5)
Material used for valve in conduit, <i>n</i> (%)	
Dacron patch bileaflet valve	22 (55)
ePTFE membrane bileaflet valve	10 (25)
Pericardial bileaflet valve	4 (10)
Bioprosthetic valve	4 (10)

SD, standard deviation; RSOV, ruptured sinus of valsalva; VSD, ventricular septal defect; RVOT, right ventricle outflow tract; ePTFE, expanded polytetrafluoroethylene

The limited availability of allografts has resulted in search for other alternatives for RVOT reconstruction in Ross procedure. Alternative grafts for RVOT reconstruction that have been used over years include porcine root grafts, pericardial xenografts, bovine jugular venous conduits, autologous tissue, and synthetic valved conduits like polytetrafluoroethylene (PTFE) and Dacron conduits.

Fig. 8 Kaplan–Meier survival curve for the patients who underwent modified Ross procedure

Stentless xenografts have been studied as an alternative to homograft for Ross procedure. Juthier et al. studied 61 patients receiving stentless porcine root prosthesis. They concluded that xenografts are an acceptable alternative for RVOT reconstruction with good early and mid-term results when pulmonary homografts are unavailable [16]. In contrast to this, Christ et al. showed that stentless xenografts as pulmonary valve substitute in Ross procedure led to lower freedom from pulmonary valve reoperation and inferior long-term survival compared with homograft [17]. Similar results were shown in a meta-analysis where porcine root grafts were used during Ross procedure in 137 patients (7 studies). It revealed that the xenografts were associated with a rate of structural valve deterioration of 7.1% at 45 months of follow-up and rate of reintervention was 2.1% [18]. For pediatric RVOT reconstruction, bovine jugular venous conduits have been studied and shown 10-year freedom from reintervention of 60–70% which depends on the conduit size and patient's age [19].

Autologous tissue for RVOT reconstruction has also been proposed. Initial attempt for doing an entirely autogenous Ross operation by Ross failed. They manufactured a RVOT conduit with patient's own living pericardium or fascia lata. But in all 21 patients, the conduit failed due to stenosis. It was proposed that the cusps that were inserted within Dacron conduit got thickened and stiffened [20]. DeLeon et al. reimplanted the native diseased aortic valve in pulmonary position which functioned well with trivial stenosis and insufficiency [21]. In a study by Chotivatanapong et al., 31 patients received autologous valved conduit made from glutaraldehyde fixed autologous pericardium. At 5 years of follow-up, no conduit-related complication was detected thus making it a feasible option in Ross procedure [22]. Chang et al. proposed the concept of double-switch Ross procedure. A stepladder-shaped aortic autograft was harvested and the diseased aortic valve was reimplanted into the aortic autograft for RVOT reconstruction. They concluded that it was a good alternative with a functioning tricuspid aortic valve, late stenosis prevention, and potential for growth [23]. The same group proposed the use of autologous pedicled pericardial valved conduit for RVOT reconstruction with a short segment of autologous aortic tube interposed between the conduit and RVOT as a good alternative for RVOT reconstruction in Ross procedure [24]. All these studies involved a small number of patients and conduits were not evaluated for long-term results.

All biological grafts (pulmonary allografts and xenografts) are susceptible to deterioration caused by immunological factors. Therefore, the use of synthetic grafts for RVOT reconstruction looks attractive.

Table 3 Echocardiography data

	At discharge (<i>n</i> = 37)	At last follow-up (<i>n</i> = 37)	<i>p</i> value
Conduit valve regurgitation, <i>n</i> (%)			
None	23 (62.2)	19 (51.3)	0.67
Mild	14 (37.8)	18 (48.7)	0.64
Moderate/severe	0	0	
RVOT gradient (mmHg) mean ± SD			
Peak	15.12 ± 4.18	19.75 ± 6.24	0.003

RVOT, right ventricle outflow tract; SD, standard deviation

PTFE conduits have good biocompatibility, low antigenicity, and are resistant to degeneration and calcification [19]. Takabayashi et al. used a handmade valved conduit for RVOT reconstruction for Ross procedure in 11 patients. PTFE and Dacron conduits were equipped with ePTFE tricuspid valve. The conduit had acceptable hemodynamic results at midterm follow-up, particularly in older children [25]. In another recent study, Sharifulin et al. used PTFE conduits for RVOT reconstruction in 28 patients for Ross procedure. The inflow and outflow components of the conduit were made from PTFE vascular grafts while the middle component containing 3 leaflets and sinuses was made from a 0.1-mm-thick ePTFE membrane. The PTFE conduit demonstrated acceptable hemodynamic results at midterm follow-up [26]. Thus, the follow-up periods for all PTFE conduits described in the literature are relatively short. Moreover, the disadvantages of a handmade prosthesis include additional intraoperative time and precise technical requirement needed to fabricate them and the absence of hemodynamic testing before implantation, possibly leading to bleeding or early conduit failure.

Dacron is a polyester fiber, a condensation polymer of ethylene glycol and terephthalic acid. Dacron, developed by DuPont company in 1950, is a synthetic polymer which is more stable and resistant to deterioration when exposed to biological fluids [27]. Dacron conduit equipped with bioprosthetic valve has been used in past for RVOT reconstruction for complex congenital lesions.

Stented xenografts conduits used included porcine Hancock conduits and Carpentier Edward conduit. Hancock conduits were the first stented xenograft available for use with the advantages of availability in a range of sizes [28]. Hancock conduits showed encouraging early results, but the long-term benefits were inferior to homografts with a conduit failure rate of 30% at 6 years follow-up [29]. Pseudo-intimal peel formation in proximal and distal segment of the conduit resulted in early stenosis especially in small conduits [30].

The Carpentier–Edwards conduit had the advantage of ready availability, molded well in the limited retrosternal space, and good intermediate results with no evidence of failure or deterioration up to 7 years after insertion [31]. When comparing Hancock and Carpentier–Edwards

conduits, Dearani et al. concluded that there were no data to suggest one was better than the other [32]. In a study by Belli et al., 214 patients with Hancock conduit for RVOT reconstruction in complex congenital lesions were followed up for 17 years which included 10 patients with Ross procedure. They found that Hancock valved conduit is a safe and reliable alternative to homografts particularly in patients with limited pulmonary vascular bed and high pulmonary artery pressures [33].

In our study, 4 patients received stented xenograft conduit including Carpentier–Edward PERIMOUNT pericardial valve in 2 patients, Hancock porcine valve in 1 patient and St Jude Medical EPIC porcine valve in 1 patient. All 4 patients are doing well with well-functioning conduits at last follow-up.

Dacron graft has suboptimal handling characteristics being relatively stiff, do not conform to the anatomy as easily as homograft, are difficult to sew to RVOT and pulmonary arteries of infant and small children and have poor hemostasis. Stented valve although have the benefit of protection from mechanical compression but are difficult to position in small chest. The bioprosthetic valve gets calcified with time particularly in young children [33, 34].

Takabayashi et al. used conduits with synthetic valve for RVOT reconstruction in Ross procedure. A PTFE conduit was used in 8 patients and a Dacron graft was used in 3 patients while these conduits were equipped with a handmade tricuspid valve made from ePTFE. They showed promising results [25]. We used Dacron conduit with a bileaflet valve made from ePTFE in 10 patients in the initial 2 years of study and later shifted to Dacron patch as ePTFE is expensive as compared to Dacron patch.

But use of valved Dacron conduit with bileaflet valve made from Dacron patch has not been studied so far as we searched in literature. Twenty-two patients in our study received Dacron conduit with a bileaflet valve made from Dacron patch. Dacron patch is readily available and cost-effective. The ease of making the bileaflet valved conduit on table makes it a good alternative for RVOT reconstruction when homografts are not available.

Dacron simulates an aggressive inflammatory reaction which may result in fibrosis resulting in stenosis at later

follow-up [27]. So further follow-up is needed to study this outcome and its consequences on conduit function.

Limitations

The study included few patients and follow-up period was also relatively short. To know the durability of the conduit and material used for the valve, we need to follow the patients for a longer duration. The study lacked the homogeneity of the valved Dacron conduit as the bileaflet valve was made from Dacron patch, ePTFE, and pericardium. A longer follow-up of patients with Dacron valved conduit with a bileaflet valve made from Dacron patch is necessary to know the outcomes related to conduit dysfunction.

Conclusion

Modified Ross procedure using valved Dacron conduit for RVOT reconstruction has encouraging results. Dacron valved conduit could be considered as an alternative substitute for RVOT reconstruction during the Ross procedure.

Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional ethics committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent for the surgery was obtained from the parents or guardians in case the patient was a minor and from individual participant in case patient was a major. The study was a retrospective review of clinical data of patients who underwent Modified Ross procedure, and for this type of study, formal consent is not required.

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