ORIGINAL ARTICLE

The Modified Nikaidoh Procedure: Initial Experience and Short and Mid-term Outcomes

Cirugía de Nikaidoh modificada: experiencia inicial y resultados a corto y mediano plazo

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ABSTRACT

Background: The Rastelli operation is the conventional procedure for transposition of the great vessels with ventricular septal defect and pulmonary stenosis. Its results, however, are suboptimal and other surgical alternatives have been postulated. A recent surgical technique, the Nikaidoh procedure, appears as a new therapeutic option.
Objective: The aim of this study was to review our initial experience using the modified Nikaidoh procedure consisting in aortic translocation and biventricular outflow tract reconstruction.
Methods: The study analyzed 11 consecutive patients operated on with the modified Nikaidoh procedure at our institution between 2005 and 2014. Median age was 3 years (25-75% interquartile range: 1-5.5 years) and mean weight was 13.8 ± 5.4 kg. Nine patients had transposition of the great vessels with ventricular septal defect and pulmonary stenosis and 2 had double outlet right ventricle with pulmonary stenosis and transposition physiology. All patients had a ventricular septal defect unrelated to the aorta and one patient also had a hypoplastic right ventricle.
Results: There were no deaths in the immediate postoperative period. One patient developed infective endocarditis needing reoperation. Six patients had some degree of transient left ventricular dysfunction, and one patient only needed ventricular assistance. There was no involved right or left ventricular outflow tract obstruction and only mild aortic regurgitation. At mid-term follow-up (mean of 5.5 ± 2.1 years, range: 2-8.6 years) there were no deaths or reoperations. An interventional cardiac catheterization to dilate the right ventricle to pulmonary artery conduit was performed in one patient. All patients remained in functional class I, with good biventricular function, free from arrhythmias, no left ventricular outflow tract obstruction and no significant aortic regurgitation.
Conclusions: The Nikaidoh operation and its variants are a satisfactory surgical option for patients presenting transposition of the great vessels with ventricular septal defect and pulmonary stenosis, who due to their morphology are inadequate candidates for a Rastelli procedure. In the mid-term follow-up, the left ventricular outflow tract remained without obstruction and there was no significant aortic valve regurgitation.

Key words: Congenital Heart Defects - Cardiovascular Surgical Procedures - Nikaidoh Surgical Procedure - Nikaidoh Modified Procedure - Aortic Translocation - Double Oulet Right Ventricle - Transposition of the Great Vessels - Pulmonary stenosis - Postoperative Follow-up.

RESUMEN

Introducción: El tratamiento convencional de los pacientes con transposición de grandes vasos con comunicación interventricular y estenosis pulmonar es la cirugía de Rastelli. Sin embargo sus resultados son subóptimos. Una técnica reciente es el procedimiento de Nikaidoh.
Objetivos: Analizar nuestra experiencia inicial con la cirugía de Nikaidoh modificada: Translocación aórtica y reconstrucción de ambos tractos de salida ventriculares.
Material y métodos: Se analizaron 11 pacientes consecutivos operados con técnica de Nikaidoh modificada en nuestra institución en el período 2005-2014 con edad mediana de 3 años (Intervalo Intercuartilo 25%-75%=1-5.5 años) y peso medio de 13.8 ± 5,4 Kg. Se incluyeron 9 pacientes con transposición de los grandes vasos con comunicación interventricular y estenosis pulmonar y 2 con doble salida del ventrículo derecho con estenosis pulmonar y fisiología de transposición. Todos tenían comunicación interventricular no relacionada con la aorta y 1 paciente tenía además ventrículo derecho hipoplásico.
Resultados: En el postquirúrgico inmediato no hubo mortalidad, 1 paciente desarrolló Endocarditis infecciosa y requirió reoperación. Seis pacientes tuvieron disfunción ventricular transitoria, solo uno necesitó asistencia ventricular. No se registró obstrucción de los tractos de salida ventriculares ni insuficiencia aórtica mayor que leve.
En el seguimiento a mediano plazo, con una media de seguimiento de 5.5 ± 2,1 años (rango: 2–8.6 años), no hubo mortalidad ni reoperaciones. Se efectuó un cateterismo intervencionista para dilatación del conducto ventrículo derecho-arteria pulmo-

REV ARGENT CARDIOL 2014;82:468-474. http://dx.doi.org/10.7775/rac.v82.i6.4256
SEE RELATED ARTICLE: Rev Argent Cardiol 2014;82:454-455. http://dx.doi.org/10.7775/rac.v82.i6.5432

Received: 04/03/2014 *Accepted:* 08/13/2014

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nar. Todos los pacientes permanecen en clase funcional I, con buena función biventricular, sin arritmias, sin obstrucción del tracto de salida ventricular izquierdo y sin insuficiencia aórtica significativa.
Conclusiones: La cirugía de Nikaidoh y sus modificaciones constituyen una buena opción quirúrgica para los pacientes con transposición de los grandes vasos con comunicación interventricular y estenosis pulmonar que por su morfología son malos candidatos para cirugía de Rastelli. En esta serie no hubo mortalidad y todos los pacientes están en clase funcional I. En el seguimiento a mediano plazo, el tracto de salida del ventrículo izquierdo permaneció sin obstrucción ni insuficiencia aortica significativa.

Palabras clave: Cirugía cardíaca, Cardiopatías congénitas, Cirugía de Nikaidoh, , Cirugía de Nikaidoh modificada, Translocación aórtica, Ventrículo Derecho con Doble Salida, Transposición de grandes vasos, Estenosis pulmonar, Evolución postquirúrgica.

Abbreviations

PA	Pulmonary artery	**TGV**	Transposition of the great vessels
VSD	Ventricular septal defect	**RVOT**	Right ventricular outflow tract
DORV	Double outlet right ventricle	**LVOT**	Left ventricular outflow tract
PS	Pulmonary stenosis	**RV**	Right ventricle
IQR	Interquartile range	**LV**	Left ventricle

INTRODUCTION

Transposition of the great vessels (TGV) with ventricular septal defect (VSD) and pulmonary stenosis (PS) represents 0.67% of congenital cardiomyopathies. (1) Despite its low incidence, this disease has always posed a great surgical challenge and several techniques have been described to correct it.

In 1969, Giancarlo Rastelli, at the Mayo Clinic, described a surgical procedure to repair this entity based on redirecting both ventricular outflow tracts by means of left ventricle (LV) to aorta tunnelization using an intracardiac patch and right ventricle (RV) to pulmonary artery (PA) reconnection using a valved homograft conduit. (2-5). This surgery, which bears his name, was the conventional procedure for TGV patients with VSD and PS and was later extended to other cardiac diseases as double outlet right ventricle (DORV) with TGV and PS. Results, however, were not optimal. (6-14) and other alternative surgical procedures were postulated.

In 1984, Hisashi Nikaidoh, at the Children's Medical Center in Dallas, described a new surgical technique consisting in aortic translocation and reconstruction of both ventricular outflow tracts. (15). This surgery, and its subsequent modifications, emerges as an attractive therapeutical option, particularly for the subgroup of TGV patients with VSD and PS whose morphology makes them bad candidates for the Rastelli procedure. The most common unfavorable TGV variants are: VSD in a remote position with respect to the aorta (7), restrictive VSD, overriding atrio-ventricular valves, hypoplastic right ventricle and some coronary anomalies. (16-25)

This study presents our initial experience in aortic translocation and reconstruction of both ventricular outflow tracts using the modified Nikaidoh procedure.

METHODS

A retrospective, cohort study including 11 consecutive patients operated on with the modified Nikaidoh procedure was performed at the Hospital de Pediatría "Prof. Dr. Juan P Garrahan" between January 2005 and May 2014. Median age at the time of surgery was 3 years [interquartile range (IQR) 25-75% = 1-5.5 years] and mean weight was 13.8 ± 5.4 kg. Two anatomical variants were identified: TGV with VSD and PS (9 patients) and DORV with PS and transposition physiology (2 patients). All patients had moderate or severe valvular or subvalvular pulmonary stenosis. No patient presented VSD related to the aorta. An inlet VSD occurred in 6 patients and a muscular VSD in 5. In addition, in 2 cases the muscular VSD was also restrictive. Other associated cardiac anomalies were: hypoplastic RV, (1) situs inversus, (1) dextrocardia, (1), overriding tricuspid valve, (2) interatrial communication, (1) multiple VSD, (2) and double VSD. (1) The diagnosis was based on clinical, radiological, electrocardiographic, and mainly echocardiographic (Figure 1), angiographic (Figure 2) and multislice computed tomography (Figure 3) findings. Nine previous palliative surgeries were performed: subclavian-pulmonary artery anastomoses in 8 cases and caval-pulmonary artery anastomosis (Glenn procedure) in 1 patient with hypoplastic RV. Table 1 describes the characteristics of the 11 patients.

Surgical technique:

The 11 patients underwent median sternotomy and cardiopulmonary bypass through the aortic root and coronary sinus, with moderate hypothermia and cardioplegia.

Following aortic cross-clamping, transection of the great arteries and coronary mobilization was performed in order to relieve the initial trajectory for posterior reimplant without tension. Then, the aortic root was separated from the right ventricular outflow tract (RVOT) and the left ventricular outflow tract (LVOT) was enlarged via opening of the pulmonary annulus and the muscular septum (pulmonary annulus diameter + muscular septum size = posterior aortic translocation). This was followed by aortic root translocation, enlarged VSD tunnelization from the LV to the aorta, allowing a more direct relationship or allignment, and coronary reimplantation. Finally, the Lecompte maneuver was performed to position the pulmonary arteries in front of the aortic root and the RVOT was reconstructed with pulmonary (7 patients) and aortic (4 patients) RV-PA homograft conduits increasing the right ventricular chamber.

Associated procedures were also performed in 4 patients, consisting in apical VSD closure with mattress stitches, (2) with patch (1) and interatrial communication closure. (1)

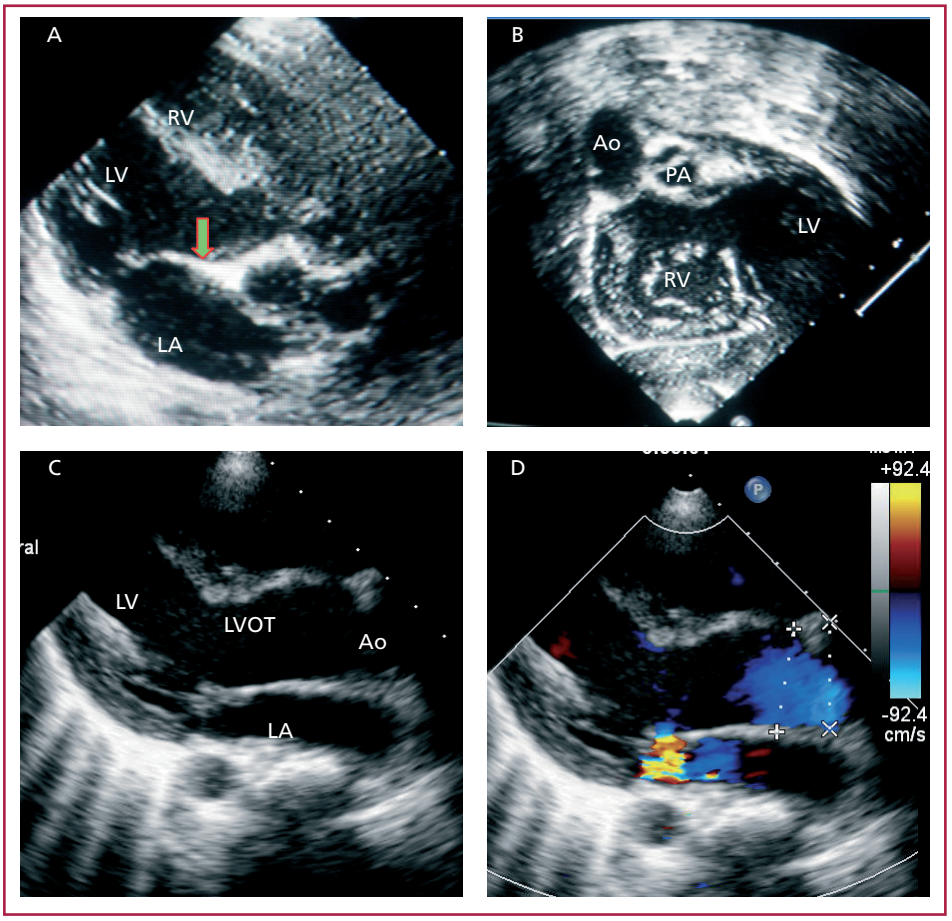

Fig. 1. Echocardiographic images of a patient with double outlet right ventricle + ventricular septal defect + pulmonary stenosis with transposition physiology, before (**A** and **B**) and after (**C** and **D**) aortic translocation surgery. **A** (left ventricular long parasternal axis) and **B** (short axis in anatomical position) show the mitropulmonary discontinuity (arrow) and the relationship of the ventricular septal defect in a remote position with respect to the aorta. **C** and **D** show in postsurgical left ventricular long parasternal axis view the completely normal left ventricular outflow tract morphology without obstruction after the Nikaidoh procedure. LA: Left atrium. Ao: Aorta. AP: Pulmonary artery. LVOT: left ventricular outflow tract. RV: Right ventricle. LV: Left ventricle.

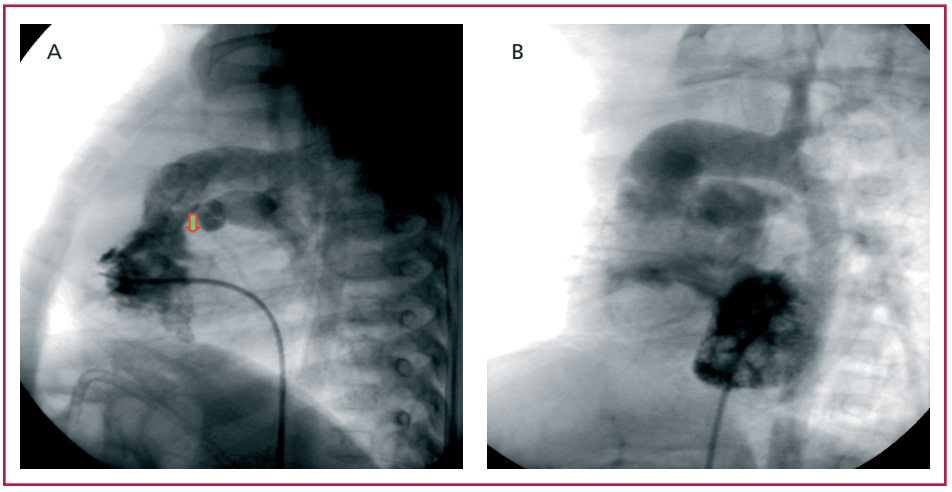

Fig. 2. Coronary angiography of a patient with double outlet right ventricle, transposition of the great vessels and pulmonary stenosis. **A** (right ventriculogram) and **B** (left ventriculogram) show the origin of both vessels from the right ventricle and the ventricular septal defect in a remote position with respect to the aorta and the pulmonary artery due to the presence of a very hypertrophic cone (arrow).

Mean cardiopulmonary bypass time was 238 min (±51 min) and aortic cross-clamp time was 178 min (± 43 min).

Follow-up

All patients were followed-up at our institution from hospital discharge to the end of the study during a mean follow-up period of 5.5 ± 2.1 years (range: 2–8.6 years). Physical exam, thorax teleradiography, electrocardiogram, color Doppler echocardiography, tissue Doppler echocardiography, Holter monitoring and exercise stress test were performed in all cases.

Cardiac nuclear magnetic resonance imaging was also performed in one patient and interventional cardiac catheterization in another (Figure 4).

Statistical analysis

Microsoft Office Excel 2013© was used for data storage and the analysis was performed using Statistix 8.0© statistical package.

Qualitative variables were expressed as absolute values and/or percentages of the total number of cases, and quantitative variables as mean and standard deviation or median and

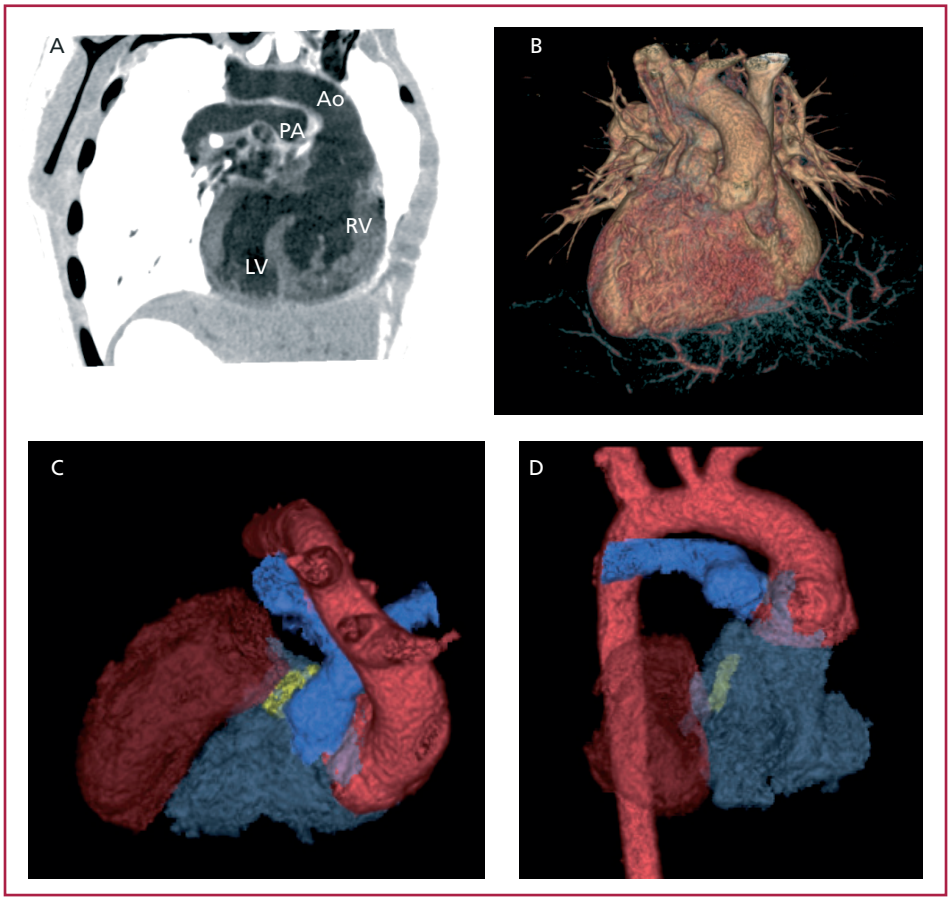

Fig. 3. Multislice angiotomography with 3D reconstruction of a patient with situs inversus, dextrocardia and double outlet right ventricle with transposition of the great vessels and pulmonary stenosis. This study confirmed the relationship of the great vessels with the ventricular septal defect. **C** and **D** show both vessels (aorta in red and pulmonary artery in blue) originating from the right ventricle (blue) and the ventricular septal defect (yellow) in a remote position with respect to the aorta. Ao: Aorta. PA: Pulmonary artery. RV: Right ventricle. LV: Left ventricle. Refer to the web edition to see the color references.

IQR, according to normal or non-normal data distribution.

RESULTS

Immediate postoperative period:

Median hospital stay was 10 days (25%-75% IQR = 7–34), respiratory mechanical assistance was 5.5 days (25%-75% IQR = 3.7–19) and inotropic drugs were used for 7.5 days (25%-75% IQR = 5-21.7). One patient required reoperation after developing methicillin-resistant Staphylococcus aureus infective endocarditis. Mitral valve and RV-PA homograft replacements were performed one month after surgery, with subsequent discharge 5 days after reintervention. Six patients presented some degree of transient ventricular dysfunction controlled with medical treatment except for one case which required ventricular assistance for 72 h. No patient presented LVOT or RVOT obstruction. Five patients had competent aortic valve and six showed evidence of mild aortic regurgitation by color Doppler echocardiography. Three patients presented transient arrhythmias: 1 patient had complete atrioventricular block which recovered to sinus rhythm 7 days later and 2 presented nodal tachycardia with adequate response to medical treatment.

Mid-term follow-up

No deaths were recorded during the follow–up period of 5.5 ± 2.1 years (range: 2–8.6 years). All patients were in functional class I, free from arrhythmias, without LVOT obstruction (Figure 1) and good biventricular function. The aortic valve presented mild regurgitation in 7 patients and was competent in 4. The RV-PA homograft evolved with mild stenosis in 6 patients and moderate to severe stenosis in 1; it also developed mild regurgitation in 4 and moderate in 6 patients. One patient who required interventional catheterization to dilate the RV-PA homograft 41 months after surgery, underwent a successful procedure. (see Figure 4). No patient needed reoperation.

DISCUSSION

The conventional treatment for TGV with VSD and PS has been the Rastelli operation, but its results are suboptimal. (6-14)

Anatomical variants, as VSD in a remote position with respect to the aorta (7), restrictive VSD, overriding atrio-ventricular valves, hypoplastic RV and some coronary anomalies complicate this surgical technique. (16-25)

In this subgroup of patients, the Nikaidoh technique, with its posterior modifications, emerges as an attractive alternative with better mid-term outcome than the Rastelli procedure (18, 26, 27)

This retrospective study evaluates our initial experience with this surgical technique with very

Table 1. Main characteristics of the 11 patients undergoing the modified Nikaidoh procedure.

P*	Diagnosis	Associated anomalies	Previous surgeries (age)	Age at cx in years	Weight at cx in kg	Follow up in months	Outcome	Reoperation (months after surgery)	Interventional catheterization (months after surgery)
1	TGV + muscular VSD + PS	-	LSPA (4m)	7	22	104	FC I, good biventricular function, free LVOT, competent aorta, mild PS, moderate PR.	-	-
2	TGV + muscular VSD + PS	Overriding tricuspid valve	-	2.2	13	89	FC I, good biventricular function, free LVOT, competent aorta, moderate PR, mild PS, moderate TR.	-	-
3	TGV + muscular restrictive VSD + PS	Wide ASD + double VSD (high + midventricular muscular)	-	1	8	88	FC I, good biventricular function, free LVOT, mild AR, mild MR, mild PR, mild PS.	-	-
4	TGV + inlet VSD + PS	Multiple apical VSD	RSPA (2m) LSPA (16m)	5.6	15	78	FC I, good biventricular function, free LVOT, mild AR, mild PR, mild PS.	-	-
5	TGV + inlet VSD + PS	-	LSPA (1m)	3	11	76	FC I, good biventricular function, free LVOT, competent aorta, moderate PR, mild PS, normally functioning mitral valve prosthesis	Mitral valve and RV-PA conduit replacement due to postoperative infective endocarditis (1 month)	-
6	TGV + inlet VSD + PS	Hypoplastic RV + overriding tricuspid valve	RSPA (1m)	10	24	68	FC I, good biventricular function, free LVOT, severe PS, moderate PR, slight AR.	-	RV-PA homograft balloon angioplasty (41 months)
7	TGV + muscular VSD + PS	-	RSPA (2m)	0.11	9	54	FC I, good biventricular function, free LVOT, mild AR, mild PR.	-	-
8	DORV + inlet VSD+PS	Situs inversus Dextrocardia	RSPA (2.5m)	2.9	12	45	FC I, good biventricular function, free LVOT, mild AR, mild PR, mild PS.	-	-
9	TGV + inlet VSD + PS	Multiple apical VSD	RSPA (11days) LSPA (18m)	3.6	18	24	FC I, good biventricular function, free LVOT, competent aorta, moderate PR.	-	-
10	DORV + inlet VSD + PS	-	LSPA (3m)	0.10	8	33	FC I, good biventricular function, free LVOT, mild AR, moderate PR.	-	-
11	TGV + muscular restrictive VSD + PS	-	LSPA	4.6	12	3	FC I, good biventricular function, free LVOT, mild AR, free RVOT.	-	-

m: months. P: Patient. cx: surgery. RSPA: Right subclavian-pulmonary artery anastomosis. LSPA: Left subclavian-pulmonary artery anastomosis. ASD: Atrial septal defect. VSD: Ventricular septal defect. DORV: Double outlet right ventricle. PS: Pulmonary stenosis AR: Aortic regurgitation. MR: Mitral regurgitation. PR: Pulmonary regurgitation; TR: Tricuspid regurgitation. TGV: Transposition of the great vessels. RVOT: Right ventricular outflow tract. LVOT: Left ventricular outflow tract. RV: Right ventricle. RV-PA: Right ventricle-pulmonary artery

favorable immediate postsurgical and mid-term outcomes.

In accordance with other series, there was no immediate surgical or mid-term mortality (16, 28, 29) This is no minor fact since aortic translocation and both outflow tract reconstructions is technically very demanding as it combines elements from other surgeries such as the Ross, Konno and Jatene procedures, which the acting surgeons must have previous experience with.

Potentially expected ventricular dysfunction and arrhythmias in the immediate postoperative period were not a major problem in our population and were pharmacologically controlled (except for a case requiring ventricular assistance for 72 hours). Contrary to other studies, no ventricular dysfunction or arrhythmias were registered at mid-term follow-up. (18, 26, 29)

The original Nikaidoh procedure did not include coronary transfer; however, similar to other groups, we performed it in all cases to avoid coronary torsion or tension with concomitant ischemic dysfunction, a complication described in the literature (26) which was not found in our series.

No patient developed LVOT obstruction. (16, 28-30) This confirms one of the main objectives of the Nikaidoh procedure: achieve better LVOT allignment with the aorta to avoid a long intracardiac tunnel in its reconstruction and thus reduce the risk of subaortic obstruction.

In our population four patients preserved a competent aortic valve and seven presented trivial or mild regurgitation, a result similar to that described by some series (15, 26, 28, 31) but different from that published by other authors. (16, 29)

Absence of significant aortic regurgitation is expected, since the native aortic valve is implanted in the systemic circulation with its natural anatomy and geometry. We believe, as other surgical teams, (18, 29) that the key to maintain aortic valve competence is in the surgical technique, by carefully placing the homograft in the LVOT avoiding aortic root distortion and minimizing dilation risk.

Patients undergoing the Nikaidoh procedure preserve the aortic root and the morphologically normal left semilunar valve and thus would not be exposed to later dilation of the sinotubular junction, different from what has been described in patients with arterial switch or the Ross procedure.

A patient developed severe RVOT obstruction requiring RV-PA homograft angioplasty. As expressed, the Nikaidoh procedure, achieves better anatomical allignment between the ventricular outflow tracts and their corresponding great vessels. Aortic translocation to a posterior position leaves more room for the RV-PA conduit, avoiding exposure to sternal anterior compression. Similar to other groups (16, 32) we consider that this would result in greater durability and consequently lower number of reinterventions. Since mean RV-PA conduit replacement time is approximately 5 years in patients undergoing the Rastelli procedure (7), a longer follow-up period is necessary to confirm this hypothesis in our series.

CONCLUSIONS

The Nikidoh operation and its variants constitute a good surgical option for TGV patients with VSD and PS who due to their morphology are inadequate candidates for the Rastelli procedure. This series showed no mortality and all patients continue in functional class I. At mid-term follow-up, the LVOT remained with out obstruction and no significant aortic regurgitation was registered. Long-term results with a larger number of patients and a longer follow-up period are still necessary to confirm these results.

Conflicts of interest

None declared.
(See authors' conflicts of interest forms in the web / Supplementary Material).

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