Experience With the Norwood Operation for Hypoplastic Left Heart Syndrome

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Introduction and objectives. To describe our experience and to identify risk factors for in-hospital mortality.

Methods. Between October 1991 and June 2005, 42 children underwent the Norwood procedure. In the first 30 patients, pulmonary circulation was established using a modified Blalock-Taussig shunt (Group 1), while a right ventricle to pulmonary artery conduit was used in the remaining 12 (Group 2). Preoperative anatomic features and procedural factors were analyzed with respect to their impact on mortality. Postoperatively, data were collected on arterial blood pressure, arterial and venous oxygen saturation, arterial pH, venous pCO2, the PaO2/FiO2 ratio, tissue oxygen extraction, and dead space fraction. The association between each individual variable and mortality was investigated.

Results. Thirty patients (71.4%) had both aortic and mitral atresia, 8 (19%) had either aortic or mitral atresia, and 4 (9.5%) had no valvular atresia. There was no statistically significant difference in postoperative mortality between the groups 1 and 2 (12/22 [54.5%] vs 7/12 [58.3%]; P = 0.56). The only significant risk factor for in-hospital mortality was a longer cardiopulmonary bypass time (P = 0.01) and, for intraoperative mortality, primary rather than delayed sternal closure (P = 0.004). Venous pCO2, the mean dead space fraction, and tissue oxygen extraction all tended to be higher among infants who died, but the difference was not statistically significant.

Conclusions. Use of a right ventricle to pulmonary artery conduit did not improve postoperative survival. Both a long cardiopulmonary bypass time and primary sternal closure were associated with increased mortality.

Key words: Congenital heart disease. Cardiopulmonary bypass. Hypoplastic left heart syndrome. Norwood operation.

Resultados de la intervención de Norwood para el síndrome del corazón izquierdo hipoplásico

Introducción y objetivos. Describir nuestra experiencia e identificar factores de riesgo de mortalidad hospitalaria.

Métodos. Entre octubre de 1991 y junio de 2005 intervenimos a 42 niños con la técnica de Norwood. Los 30 primeros recibieron una fístula de Blalock-Taussig (grupo 1) y los 12 restantes, un conducto entre el ventrículo derecho y la arteria pulmonar (grupo 2). Se analizaron los factores anatómicos y de la técnica con respecto a la mortalidad. Se recogieron variables del postoperatorio, incluidas la presión arterial, la saturación arterial y venosa de oxígeno, el pH arterial, la pCO2 venosa, la relación PaO2/FiO2, la extracción tisular de oxígeno y el espacio muerto, para estudiar su asociación con la mortalidad.

Resultados. En total, 30 (71.4%) pacientes tenían ateria aórtica y mitral; 8 (19%) tenían ateria aórtica o mitral y 4 (9.5%) no tenían ateria. No hubo diferencias significativas en la mortalidad postoperatoria entre los grupos 1 y 2 (12/22 [54.5%] frente a 7/12 [58.3%]; P = 0.56). El único factor de riesgo de mortalidad hospitalaria fue un tiempo de circulación extracorpórea prolongado (p = 0.01), y el de mortalidad intraoperatoria, el cierre primario del esternón (p = 0.004). La pCO2 venosa, el espacio muerto pulmonar y la extracción tisular de oxígeno fueron superiores en los niños fallecidos, pero las diferencias no fueron significativas.

Conclusiones. El uso de un conducto entre el ventrículo derecho y la arteria pulmonar no mejoró la supervivencia postoperatoria. Un tiempo de circulación extracorpórea prolongado y el cierre primario del esternón se asociaron con un aumento de la mortalidad.


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INTRODUCTION

The hypoplastic left heart syndrome is a serious congenital cardiopathy that leads to surgery in the first days of life. The treatment is palliative and it is made in several stages, of which the intervention of Norwood1 is the first. It attempts to make the right ventricle act like a systemic ventricle, connecting the trunk of the pulmonary artery to the aorta. The pulmonary flow is attained through a fistula between the aorta and the pulmonary artery. Although the results obtained in the last years have improved,2,3 it continues to have a high mortality. The main problem of this intervention is the hemodynamic instability; in order to try and avoid it, in year 2003 the modification of Shunji Sano,4 consisting of the substitution of the fistula for a non-valvulated tube introduced between the right ventricle and the pulmonary artery. In our hospital, the first Norwood intervention was made in 1991,5 and in 2003 we incorporated the Sano modification, based on the good results obtained in others centers.6,7 The objectives of this study are: a) to communicate our experience with the classic Norwood technique and to determine if we have managed to increase the survival with the modification of Sano, and b) to identify prognostic factors of early hospital mortality among the different variables.

METHODS

Patients

The study was planned as prospective, descriptive, and observational, to be carried out in the period between October 1991 and June 2005. We included a total of 42 diagnosed children with hypoplastic left heart syndrome from the Hospital Virgen del Rocío of Seville. Among the anatomical characteristics of the cardiopathy we emphasized that the average diameter of the ascending aorta was 3.4 mm (rank, 1-8 mm); in 23 (54.8%) children it was ≤3 mm, in 12 (28.6%) it was between 3 and 5 mm, and in 7 (16.7%) it was ≥5 mm. In 30 (71.4%) patient the diagnosis was aortic atresia and mitral atresia, in 8 (19%), aortic atresia or mitral atresia and in 4 (9.5%), of aortic stenosis and mitral stenosis. 40.5% (17/42) had another associated cardiopathy and coarctation of the aorta was the most frequent.

Surgical Intervention

The intervention was made at an mean age of 10.1 days (range, 3-24 days) and an mean weight of 3.3 kg (range, 2.3-4.6 kg). The first 30 patients (group 1) underwent the classic Norwood technique, receiving a modified Blalock-Taussig fistula of different diameters, and in the other 12 (group 2) the Sano4 variant was used. All the interventions were made under extracorporeal circulation (ECC) under deep hypothermia, and periods of circulatory shutdown for the reconstruction of the aortic arch were employed, done in most of cases (30/42; 71%) by means of a terminoterminal suture between the pulmonary artery and the aorta; when, by technical reasons, this was not possible (12/42; 28.6%), we used an aortic graft. At the beginning of the operation dobutamine was administered at doses of 5 µg/kg/min, low doses of adrenalin that oscillated between 0.05 and 0.1 µg/kg/min, and a milrinone perfusion at 0.5 µg/kg/min. During the process of retrieval from ECC, we administered to an inspiratory fraction of oxygen of 100% and inhaled nitric oxide at 20 ppm, attempting to reduce the pulmonary vascular resistance to the maximum, which were increased at that moment. The P50 of the ECC time, aortic clamping and circulatory shutdown was of 185.5 min (range, 173-267), of 56.5 min (range, 50-65), and 56 min (range, 49-72), respectively. In 19 (45.2%) cases the thorax was left open in the operating room, deciding on a deferred closure of the sternum in the pediatric intensive care unit (PICU) due to hemodynamic instability upon finalizing the intervention.

Postoperative Treatment

The PICU treatment initiated in the operating room was continued, with the objective to optimize cardiac output and to reduce to the systemic and pulmonary vascular resistance to the maximum. The inspiratory fraction of oxygen and nitric oxide were being reduced progressively, once a stable SaO2 in the optimal accepted range was obtained, which we considered between 75% and 80%. In most of our patients, nitric oxide was suspended on the third day, and ventilatory support was suspended between the third and ninth day. Sedation and analgesia were obtained with midazolam and fentanyl, and we only resorted to the neuromuscular paralysis with vecuronium in children whose sternal closure was deferred. The process of weaning off the respirator began once the child was hemodynamically stable and when the thorax had been closed, in children with deferred closure. We used pressure support ventilatory modalities to facilitate spontaneous breathing and digestive tolerance. We initiated enteral nutrition through a transpyloric tube on the second postsurgical day, preferentially with hydrolyzed maternal milk or proteins. In the analytical control we measured arterial and venous blood gases, oxygen saturation (SO2) by

ABBREVIATIONS

PICU: pediatric intensive care unit
PaO2/FiO2: respiratory quotient
Vd/Vt=(PaCO2–EtCO2/PaCO2): lung dead space
EtO2=(SaO2–SvO2/SaO2): tissue oxygen extraction
noninvasive, and continuous pulse-oxygenometry and the carbon dioxide (CO₂) through capnography. We made an immediate postsurgical heart ultrasound to evaluate ventricular function, the size of the auricular defect, the competence of the tricuspid valve, and the flow through the fistula, or the ventriculopulmonary tube.

Data Recovery and Analyzed Variables

Hospital mortality, constituted by intrasurgical and postsurgical mortality was analyzed before discharge. In addition, groups 1 and 2 were compared in relation to mortality, intrasurgical, and postsurgical. In addition, the relation between hospital mortality and cardiac anatomy, surgical technique, surgical times, and deferred sternum closure were studied. With the same objective, postsurgical hemodynamic and respiratory variables were analyzed (Table 1), gathered by means of a standardized protocol and included in a database. The analyzed variables were systolic, diastolic, and mean arterial pressure, the arterial and venous saturation of oxygen, arterial pH, venous pCO₂, PaO₂/FiO₂ relation, tissue oxygen extraction (SaO₂–SvO₂/SaO₂), and the pulmonary dead space (CO₂ arterial–etCO₂/CO₂ arterial). Tissue oxygen extraction (EtO₂) measures the oxygen consumption by waves, so that when tissue perfusion is jeopardized, it slows blood flow and increases its extraction, lowering the SvO₂ and increasing the venous pCO₂. The tissue oxygen extraction and venous pCO₂ allow the determination of cardiac output. The reason to have chosen, in addition, pulmonary dead space space (Vd/Vt) was based on the fact that, in the intervention of Norwood, the pulmonary flow is jeopardized and zones of the lung have a predominance of ventilation over perfusion. This fact produces an increase of the dead space, which is translated in a difficulty to exhale carbon dioxide. Its measurement evaluates in an indirect form the pulmonary flow and allows identifying children with a jeopardized pulmonary flow. The fraction of the pulmonary dead space is considered normal if between 0.2 and 0.4. The successive determinations of the variables previously mentioned were done in the following sequence: first, in operating room when coming out of ECC; second, after the immediate admission into the PICU; third, at 24 h of the first day; fourth, at 8 h of the second day; fifth, at 18 h of the second day; sixth, at 8 h of the third day; and the seventh and last one, at 18 h of the third day.

Follow-Up

We analyzed, additionally, late mortality and the patients who underwent a second and third procedures, that is the Glenn and Fontan procedures, were classified. The degree of function of survivors was determined during their last check-up in the outpatient clinic of cardiology.

Statistical Analysis

Descriptive statistic of the qualitative variables was done, using absolute and relative frequencies. Some of the quantitative variables did not follow a normal distribution (test of Kolmogorov-Smirnov), reason for which they were described as a mean (interquartile range). The comparison of variables according to groups was made with the test of χ² for the qualitative variables, and with the Mann-Whitney U for the quantitative variables. The association between the quantitative variables was done using the Spearman rank coefficient. All the analyses were made with SPSS software, version 14.0. A P value less than .05 was considered significant.

RESULTADOS

Global hospital mortality was 64.3% (27/42), 66.6% (20/30) in group 1, and 58.3% (7/12) in group 2 (Table 2). The age and the weight of the children at the moment of the intervention did not have a significant statistical relationship with mortality (Table 3). In relation to the cardiac anatomy, hospital mortality was 73.3% (22/30) in the group of children with mitral and aortic atresia, 35% (4/11) in the group with mitral or aortic atresia, and of 25% (1/4) in the group with stenosis (Table 4). The children who had an ascending aorta diameter of ≤3 mm presented a hospital mortality of 69.6% (16/23); those that had a diameter between 3 and 5 mm, of 66.7% (8/12), and those that had a diameter ≥5 mm, of 42.9% (3/7) (Table 5). These differences, which relate the cardiac anatomy to hospital mortality, although spectacular, did not have statistical meaning. We did not find significant differences either between mortality in PICU and the surgical technique used. The one obtained in group 1 was 54.5% (12/22), after excluding from the analysis 8 children who died in the operating room, and for group

<table>
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<tr>
<th>TABLE 1. Analyzed Variables</th>
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<tr>
<td>Age and weight at the time of the intervention</td>
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<tr>
<td>Anatomy of the cardiopathy</td>
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<tr>
<td>Diameter of the ascending aorta</td>
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<tr>
<td>Associated congenital cardiopathies</td>
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<td>Surgical techniques (Norwood vs Sano)</td>
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<tr>
<td>Time on extracorporeal circulation</td>
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<tr>
<td>Time of cardiac arrest</td>
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<tr>
<td>Deferred sternum closure</td>
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<tr>
<td>Arterial oxygen saturation (SaO₂)</td>
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<tr>
<td>Venous oxygen saturation (SvO₂)</td>
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<tr>
<td>Arterial pH (pHₐ)</td>
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<td>Systolic arterial pressure</td>
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<tr>
<td>Dyastolic arterial pressure</td>
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<tr>
<td>Mean arterial pressure</td>
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<tr>
<td>Respiratory coefficient (PaO₂/FiO₂)</td>
</tr>
<tr>
<td>Tissue oxygen extraction (SaO₂–SvO₂/SaO₂)</td>
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<tr>
<td>Pulmonary dead space (CO₂ arterial–CO₂ arterial)</td>
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2 it was 58.3% (7/12) (\(P = .561\)) (Table 2), and in this group no child died (Table 5). This difference of operating room mortality between groups 1 and 2 turned out to be significant (\(P = .05\)) (Table 2). In relation to the surgical times, only the time of ECC was associated significantly with mortality, so that it was greater in those that died in the operating room (Table 6) and in PICU (Table 3). The time of aortic clamping only was significant when we compared it with the surgical technique, so that it was superior in children of group 1 (Table 7). The children to whom the thorax was closed in the operating room (19 cases) had a greater intrasurgical mortality than the children with closure deferred to the PICU (\(P = .004\)) (Table 6). Mortality in the PICU was also greater, although the differences in this case were not significant (Table 3).

Deferred closure was most frequently made in children in-group 2 in relation group 1 (\(P = .014\)) (Table 7). As far as the postsurgical monitoring in the PICU, there were no significant differences between the groups of survivors and deceased in the following variables: SaO₂, arterial SₐO₂, pH, PaO₂/FiO₂, and systolic, diastolic, and mean arterial pressure. Nevertheless, although there were no differences in the P₅₀CO₂, the EtO₂ and the pulmonary dead space (Vd/Vt), the deceased displayed superior numbers.

Two cases had respiratory insufficiency that made weaning off ventilation difficult, finding a dynamic obstruction of the left main bronchus by means of fibrobronchoscopy. The study of the airways by means of computerized tomography (CT) with three-dimensional reconstruction and magnetic resonance (MR) demonstrated that it was produced by an extrinsic compression of the neoaoıta. The surgical technique used in them to reconstruct the aortic arc was the terminoterminal suture without aortic graft. Both patients...
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TABLE 7. Differences Among the Variables of Groups 1 and 2*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P</th>
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</thead>
<tbody>
<tr>
<td>Operating room deaths</td>
<td>8/30; 26.7%</td>
<td>0/12; 0%</td>
<td>.050†</td>
</tr>
<tr>
<td>Deaths in PICU</td>
<td>12/22; 54.5%</td>
<td>7/12; 58.3%</td>
<td>.561</td>
</tr>
<tr>
<td>Time ECC, min</td>
<td>216.5 (175-291)</td>
<td>176.5 (141-191.5)</td>
<td>.103</td>
</tr>
<tr>
<td>Time CA, min</td>
<td>59 (55-71)</td>
<td>50 (43-55)</td>
<td>.013†</td>
</tr>
<tr>
<td>Time Ca, min</td>
<td>57.5 (51-77.5)</td>
<td>50 (44-56)</td>
<td>.111</td>
</tr>
<tr>
<td>Deferred sternum closure</td>
<td>10/30 (33.3%)</td>
<td>9/12 (75%)</td>
<td>.014†</td>
</tr>
<tr>
<td>Hour ventilation</td>
<td>216 (120-480)</td>
<td>76.5 (8-389.5)</td>
<td>.167</td>
</tr>
<tr>
<td>Hours of stay in the PICU</td>
<td>480 (384-624)</td>
<td>76.5 (8-492)</td>
<td>.056†</td>
</tr>
</tbody>
</table>

*AC indicates aortic clamping; ECC, extracorporeal circulation; CA, cardiac arrest; PICU, pediatric intensive care unit.
†Statistical significance.
Group 1: classic Norwood.
Group 2: Sano variant.
Numeric variables expressed in percentiles: P50 (P25–P75).

...died due to respiratory insufficiency before a tensile stent could be implanted in the bronchial light.

Of the 15 given children discharged from PICU, 5 died before the second surgery and in 8 of the 10 survivors a Glenn procedure was made, with a survival of 100%. Six of the patients belonged to group 1 and 2 to group 2. The mean age and the weight of them in the last review was 19 months (range, 8-31) and 9 kg (range, 6.8-11.3 kg), and all were in Class I of the New York Heart Association classification.

DISCUSSION

Surgical treatment of the hypoplastic left heart syndrome has been a reason for worry among surgical teams due to its elevated mortality. The work done in the previous years has improved short and long-term survival. This fact is related in part with the introduction of a modification in the classical Norwood technique, consisting in the substitution of the fistula for a tube connecting the right ventricle with the pulmonary artery. This procedure improves the growth of the pulmonary arteries with a more uniform distribution. It has been shown, additionally, that the children present a more hemodynamically stable postoperative phase, therefore achieving a reduction in the interstage mortality. For these motives, in 2003 we decided to introduce the Sano modifications at our hospital.

The hypoplastic left heart syndrome is a cardiopathy with many anatomical variants that are frequently associated with other malformations or genetical alterations; its proper evaluation and presurgical diagnosis allows us to establish a prognosis, which is independent of the surgical technique and the postsurgical care. In this sense some authors have found a larger mortality among children with associated genetical alterations or extracardiac malformations in the univariate analysis, such as a lower gestational age or unbalanced atrioventricular canal diagnosis, and low birth weight <2.5 kg in the univariate analysis. In contrast, in the multivariate analysis, only low birth weight and extracardiac malformations were considered as risk factors for mortality. Others found other variables that conditioned an early mortality, such as the body surface area at the moment of intervention, the size of the ascending aorta, the function of the left ventricle, and the origin of the pulmonary flow (fistula vs ventriculopulmonary tube). Among the variables related to the surgical procedure, only the duration of ECC was an independent risk factor. There is even a evaluation of preoperative risk scale published, in which a series of variables are scored such as the ventricular function, the presence of tricuspid regurgitation, the diameter of the ascending aorta, the characteristics of flow through an atrial septal defect and the age at the moment of intervention. A score of ≥7 points to a low probability of death, while a score <7, indicates the opposite.

In our series, though mortality was higher in the group with mitral and aortic atresia (Table 4), as well as in children with an aortic diameter of <5 mm (Table 5), these anatomical variations, though noticeable, were not statistically associated to mortality. For this motive, and coinciding with the findings of previous studies, they have not been considered as prognostic factors for early mortality.

We did not find significant differences between the mortality in the PICU and the surgical technique employed (groups 1 and 2) (Table 7), probably due to the low number of patients currently included in group 2. Other authors, nonetheless, have found a difference and promote the use of the tube from the left ventricle to the pulmonary artery because of the good results so far obtained. In our series of cases, of the 20 children that died in the first group, 8 did so in the operating room because it was impossible to take them off ECC (Table 7). Because of this, some authors support the systematic use of ventricular assist devices in the operating room and during the patients stay in the PICU, arguing that it improves cardiac output and therefore the survival, of these patients. Since its introduction into our hospital in 2003, 12 children have...
been intervened and none of them has died in the operating room (Table 2), indicating that they tolerate better the process of weaning from the ECC.

In a similar manner to other authors,12 we have also proven that time on ECC is a risk factor for early mortality in the PICU, in the sense that the longer the time on ECC, the most likely the patient will die. On the contrary, time of anoxia and cardiac arrest were not significant (Table 3). Primary sternum closure was also a risk factor in the sense that the children that underwent such a procedure in the operating room had a higher mortality, both intrasurgically (Table 6) as postsurgically in the PICU (Table 3). Based on this finding, we propose the systematical deferred closure of the sternum in all of the children intervened for this cardiopathy, avoiding in this manner cardiac compression and low output that is the result of closing the thorax.

All of our patients underwent hyperfiltration during their time on ECC, without any complications, and without the necessity of suspending it owing to hemodynamic instability. Its use has demonstrated in other studies an improvement in hemodynamics, reflected as a reduction in the heart rate and an incremented in the systolic and diastolic pressure.15

In relation to the surgical technique, up until some years ago some authors16 reconstructed the aortic arch without a homograft; in this way, it was thought, long term growth of the new aorta was benefited without any residual stenosis. In our hospital the reconstruction without a homograft was performed in as a first option in 30 patients (71%) and with it in (29%), who where those in which the first technique could not be done. Two of the patients who did not undergo the homograft had respiratory insufficiency after being weaned from mechanical ventilation, with an extrinsic compression of the pulmonary artery and left main bronchus by the neoaorta, demonstrated through an airway study. This experience has made us consider the possibility of using a homograft in a systematic manner, as is being done by other authors with good results,12 to elevate the position of the aortic arch and reducing the possibility of compressing adjacent structures.

Of the 34 children admitted to the PICU after the intervention, 19 died, which constitutes early hospital mortality in the PICU of 55.9% (Table 2). This mortality can be considered high if we compare it with that obtained by other authors.7,10 As mentioned previously, the Norwood procedure was started in our hospital in 1991 and the first 3 cases were published in 1994.5 Having operated 42 patients in 15 years has not allowed us to acquire sufficient experience yet. In a 12-year period, the Birminghams Children Hospital (England) intervened 333 patients, with a current mortality of 16%.12 The concentration of patients in a reference center of our autonomous community will allow the intervention of more patients, which will let us gain more experience and, in consequence, increase survival. Another possible cause that could justify mortality is the elevated proportion of children in our series with unfavorable anatomy, such as aortic and/or mitral atresia, and a reduced aortic valve diameter (Tables 4 and 5).

In relation to the analysis of the collected variables during postsurgery, children who died had higher Vd/Vt values than survivors, as a consequence or a more compromised pulmonary flow. Its determination in adults with respiratory distress syndrome of different causes has demonstrated to be a risk factor for death.17 The P CO2 and EtO2 values were also higher in the children that died, as a consequence of a low cardiac output and the slowing of tissue perfusion. Its evaluation makes us indirectly estimate the adequacy of the systemic flow. Differences found in P CO2, EtO2, and Vd/Vt, between both groups, did not have any statistical value, probably due to the small sample size. Their determination has the advantage that it can be carried out easily with the common monitorization of PICU. The study of these variables is undergoing with the objective of carrying out a new analysis when the size of the sample is higher.

Medical treatment was based on a strategy of pharmacological reduction of the pulmonary and systemic vascular resistance. This way we minimized the fluctuations in the systemic and pulmonary resistance and maintained a stable circulatory and respiratory state.18 The increase in systemic resistance in these children increases the myocardial workload and oxygen consumption, which explains sudden and unexpected death that is present in these patients.19 For that we employed, as previously described in the methods section, nitric oxide and milrinone, the former as an exclusively pulmonary vasodilator and the latter as a pulmonary and systemic vasodilator.

Due to the advancements in medical and surgical treatments, survival of these children in the past years has increased, but they must be intervened 3 times throughout their life, with the risk inherent to this. The future, though still a ways off, will probably be the undertaking of a single procedure in the catheterism lab.20

CONCLUSIONS

We have not demonstrated an increase in survival of children in the PICU who underwent surgery using the Sano-modified of the classic Norwood technique.

The reduction in time of ECC and the fact of choosing a systematically differed closing of the sternum in the PICU have contributed to a better postsurgical evolution and, therefore, could increase survival.

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We wish to express our thanks to all of the professionals of our hospital who are related to cardiology, as well as to the Asociación de Padres Corazón y Vida for their enthusiasm and the continued work developed in the caring of these children.

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