

Complications of catheterization in congenital heart diseases: A new Risk-Adjusted Score (RIGA-S)

Abstract

Catheter interventions have significantly increased over the last 30 years, emerging as a new safe, and effective alternative for the treatment of children and adults with Congenital Heart Disease (CHD). The procedures can present complications, with severe and/or catastrophic ones posing a risk to the patient's life. The risk-adjusted variables that are conventionally considered are age, the complexity of the procedure, the volume of cases/year of each institution, cases per year of the operator, and existing comorbidities. The American Society of Anesthesiologists (ASA) can also be taken into account in relation to anesthetic risk. The diversity of heart diseases, the incorporation of new techniques, and the use of different devices forced the prediction of adverse events. Different risk-adjusted scores emerged, adjusted by data taken from the results of catheterization, called 'hemodynamic vulnerability indicators'. These values, along with the procedure time, the radiation received, and the type of anesthesia (with or without endotracheal intubation) have no predictive value and arise from the analysis after the procedure. The case history presented with the new Risk-Adjusted Score (RIGA-S) score is extensive over the years, involving the same operator and covering all stages of the specialty when initially therapeutic catheterizations were only referred to as Rashkind balloon septostomy. In the last stage, the interventions were varied and complex, representing the majority of cases per year in hemodynamics services. This new score is simple, easy to calculate, and predictive, as it analyzes existing data before the procedure, based on the variables: age, type of Congenital Heart Disease (CHD), type of procedure, and previous clinical status: outpatient, admitted to the Intensive Care Unit (ICU) and/or in the immediate postoperative period of cardiovascular surgery. In this way, the case is stratified, the potential risk to the patient and their parents is posed, it allows planning of the procedure with experienced operators, and it warns about the availability of admission to the Intensive Care Unit and/or the need for rescue surgery.

Keywords: Complication • Risk-adjusted score • Congenital heart diseases

Introduction

Interventional cardiology in children and adults with congenital heart disease has been incorporated as a therapeutic tool, complementing conventional cardiovascular surgery. These are procedures not exempt from complications, which can put the patient's life at risk. A Risk-Adjusted Score (RIGA-S) is presented and the current issues are analyzed. The industry presents new devices for interventions, which require special training and clinical trial programs. This scenario carries the possibility of difficulties and new complications that arise in practice.

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Literature Review

Problem presentation and discussion

Catheter interventions in Congenital Heart Diseases (CHD) in children have evolved significantly over the last 30 years. Since the report of the first intervention performed by William Rashkind in a Newborn (NB) with transposition of The Great Arteries (TGA) [1], the growth was exponential. In recent years it has been extended to the group of adults with CHD, who for various reasons had not received surgical treatment in childhood or in whom their heart disease had gone unnoticed [2]. The first pulmonary valvuloplasty was performed by Kan, et al. in 1982 practically with the same current technique [3]. Our experience in Argentina began in 1985 when we used femoral dissection as the approach and required to stand-by surgery. In adults, we use the technique of double and triple unequal balloons, based on a table designed to calculate the deformed valvular area and the double-triple balloon/area ratio. The use of balloons of different diameters aims to maintain a pulmonary flow between the balloons during maximum dilation, avoiding low cardiac output phenomena [4]. If we consider the 8 most common CHDs, interventional catheterization has a preponderant role in all (Table 1).

Table 1: Most common congenital heart diseases and their catheter intervention	
Heart disease	Type of intervention
Ventricular Septal Defect (VSD)	Device closure
Patent Ductus Arteriosus (PDA)	Device closure
Atrial Septal Defect (ASD)	Device closure
Pulmonary Stenosis (PS)	Valvuloplasty
Aortic Stenosis (AS)	Valvuloplasty
Coarctation of the Aorta (CoA)	Angioplasty/Stent
Tetralogy of Fallot (ToF)	TSVD Stent, RRPP Stent
Transposition of the Great Arteries (TGA)	Rashkind balloon

Note: TSVD: Right Ventricular Outflow Tract; RRPP: Pulmonary Branches

In TGA, the Rashkind balloon septostomy maintains the same original technique. The balloons improved and we started this practice in 1988 *via* the umbilical route, under transthoracic echocardiographic control in the Intensive Care Unit (ICU). In this way, we avoid the stress of transferring a critical and hypoxemic newborn, maintaining their body temperature in the ICU crib. A recent Romanian study shows their experience in this field [5].

In the last 15 years, interest and surveillance of adverse events have increased, the publication of the Sick Children’s Hospital in Toronto, led by Lee Benson in 2008, raised the situation and generated critical awareness on the subject [6]. The increase in Hemodynamics and Pediatric Cardiology centers allowed for

evidence of complications, even catastrophic events. The new techniques with balloons and devices produced various problems that include femoral artery thrombosis, material ruptures, fractures, embolizations, and tears/ruptures of vascular structures [6-16].

A range of complications between 6.7% and 24% has been reported [6-9]. Our work shows 5% of adverse events, with 1.9% of major and 3.1% minor [15].

The C3PO project emerged as a registry to monitor and document complications, analyzing and comparing in a multi centric way interventional hemodynamics services, a variety of cases, and operators. It included the surveillance of the radiation dose [11].

The variables related to the risk of an adverse event emerged after an analysis of data from hemodynamics centers. These were patient age, type, and complexity of the procedure, time of the same, volume per year of cases of each center volume/year of cases of the operator [14], type of anesthesia, genetic comorbidity, renal, biventricular *vs.* univentricular physiology, received radiation, among others. A critical scenario is patients in postoperative conventional cardiovascular surgery with poor evolution: Low cardiac output, the persistence of respiratory assistance, the need for inotropics, and/or persistent hypoxemia. Situations present both in hyper-acute or acute periods. Catheterization, even diagnostic, in these critically ill patients, presents greater complications. Despite the advancement and refinement of non-invasive techniques (Color Doppler Echocardiography, multi-slice tomography, and magnetic resonance), diagnostic catheterization remains current and subject to complications. The incorporation of the “complex heart disease” category in the RIGA-S score was fundamental, showing statistically superior complications to many interventions [15].

Over more than 30 years we participated in the different stages of hemodynamics, with dramatic changes in both indications and techniques. In the last years of the 80s, only femoral dissection was performed (internal saphenous vein, femoral, and/or artery), using the percutaneous route by the Desilets Hoffman method only in children over 10 kg in weight. Only 5 Fr introducers existed on the market as a smaller size. They represented the initial stage, with 7.4% of the cases, but only with a venous tear that required surgery (0.4%). We had no more vascular complications at this stage. We started the umbilical venous route for the Rashkind balloon septostomy in 1988. We incorporated the right axillary arterial dissection, to study neonatal aortic coarctation. From 1992, the only route used was the femoral percutaneous, venous, and/or arterial, regardless of weight and age. We continue with the umbilical venous approach routinely in newborns with a few days of life. In cases of critical aortic stenosis of the newborn, we prefer to access *via* the right carotid route, through surgical dissection with the help of cardiovascular surgeons. At the Institute of Cardiology

and Cardiovascular Surgery Favaloro Foundation, from the year 1992, we analyzed the first 13 years. Complications remained stable, despite the tripling of interventions and the complexity of the procedures.

The age difference, the incorporation of the adult into Pediatric Services, and the variety of heart diseases and procedures gave a combination of variables that needed to be grouped and categorized. This scenario motivated the development of several scores adjusted to risk [17-23].

Our casuistry is not an institutional experience [15], but personal throughout work in successive institutions. This eliminates the “institutional” and “inter-operator” biases in the analysis of events. Procedures performed by other interventionists were not included.

There is, in the consensus of experts, a series of items in relation to the probability of complications [6-15]:

- Children are at higher risk than adolescents and adults
- Therapeutic interventions carry more adverse events than diagnostic catheterizations
- Patients with Pulmonary Hypertension (PH)
- Immediate postoperative cardiovascular surgery
- General anesthesia

Complications have prevalence with some variations dependent on each study. The main ones are arrhythmias and those dependent on vascular access, along with those related to complications of interventions: Device embolization, poor position, rupture/fracture, and rescue surgery, which also occupy a prominent place [6-15]. We had a ranking of complications identifying the five interventions with the most adverse events (data not published in the original work) (Table 2).

Procedure	Number	CT and (%)
Complex stent: Ductal, TSVD	14	5 (35,7)
Park's septostomy	10	3 (30)
Aortic valvuloplasty	37	8 (21,6)
Stent in CoAo	70	12 (17.1)
VSD closure	13	2 (15.3)

Note: CT: Total Complications (major and minor); TSVD: Right Ventricular Outflow Tract; CoAo: Coarctation of the Aorta; VSD: Ventricular Septal Defect

Age as an independent variable

Newborns (NB, less than 1-month-old) and children under one year of age have more complications in all bibliographic reports. They are patients with severe and complex CC, usually in a critical state. Vascular complications are usually present, due to the

conflict in relation to the size of the vessels, vascular access, and angioplasty balloons. Alteration of flow in the femoral artery post-catheterization has been published, using vascular Doppler. The independent risk variables were age, introducer size, and arterial cannulation time [16]. In our case series, complications were greater in this age group compared statistically with the rest of the series (Table 3). Vascular complications in NB and children under one year were 35% of the total. There were three major events, which required surgery, in the era of dissection: A carotid tear, another of the axillary artery, and the femoral vein in a septostomy with a Rashkind balloon. In the percutaneous route stage, there was a tear of the suprahepatic veins in a septostomy with a Rashkind balloon, which caused death within 24 hours. That patient arrived from ICU to the hemodynamics room, with the right femoral vein and the umbilical vein occupied with catheters for infusion of prostaglandins and inotropes, which complicated access and the performance of the procedure. Therapists mustn't cannulate the right femoral vein in a NB with TGA. There was also a carotid tear due to dissection performed by the surgeon, in a NB with critical aortic stenosis, which was resolved in the hemodynamics room. Hypoxia crises occurred in the initial stage when Tetralogy of Fallot and pulmonary atresias were still being studied in hemodynamics, currently evaluated with Angiotomography (AngioCT). The advent of this non-invasive technique was decisive. Radiation exposure, attenuated by QRS-triggered studies, was less than in diagnostic catheterization. The study time was 15-20 seconds and general anesthesia was one minute, without femoral vessel approach. There have been no hypoxia crises since then. A relevant fact regarding the age variable as an independent data associated with complications was that we demonstrated that adults have the same events as children under one year and less than children between 1 and 17 years old.

n (817)	CM (%)	Deaths (%)	Cm (%)	Total (%)
RN y<1 a	25 (3)	8 (0.97)	48 (5.8)	73 (8.8)
Children>1 year and adults	41 (1.5)	7 (0.2)	63 (2.3)	104 (3.8)
p	0.005	0.0017	<0.0001	<0.0001

Note: CM: Major Complications; Cm: Minor Complications; RN: Newborn

Diagnostic catheterizations and interventions

The studies agree that interventions present more complications than diagnostic studies. The NCDR IMPACT Registry study stratifies diagnostic procedures into risk category 2 (low) when patients are over 1 year old, risk 4 (intermediate) if they are between 30 days old and 1 year old, and risk category 6 (high) when they are less than 30 days old. In other words, they adjust for age. The RIGA-S score divides heart diseases into simple and complex.

Diagnostic catheterizations in complex CC present similar adverse events as interventions. Therefore, a patient with complex CC undergoing a diagnostic procedure should be performed by experienced operators and may have more complications than pulmonary valvuloplasties and closure of the arterial duct.

Pulmonary hypertension

It is reported that catheterizations in children and adults with PH involve an increased risk of adverse events. Hemodynamics is the “gold standard” for the evaluation of pathology. Both in Primary Pulmonary Hypertension (PPH) and in that associated with CC (HP-CHD), hemodynamics is necessary to document the values of pulmonary pressure (systolic, diastolic, and mean), the minute volume by thermodilution with Swan-Ganz catheter or through the calculation by the Fick method of QP/QS in cases with CC.

The assessment of diastolic pulmonary pressure is important. Also crucial are the calculation of total pulmonary resistances (arteriolar and venular), with their indices in Wood Units in relation to the body surface. The wedged pulmonary pressure (wedge pressure) and the transpulmonary gradient are determined. Most hemodynamic laboratories make these calculations using the published tables of assumed oxygen consumption. The determination by the actual measurement of oxygen consumption implies the need for complex technology and methodology.

We use the hemodynamic study following this protocol:

- Document pressures and resistances
- Wedge angiography, to define three variables: arterial thinning in the right lower lobe (between 2.5 and 1.5 mm in diameter), circulatory time, and the appearance of the “vascular stain” (winter tree)
- Perform Endovascular Pulmonary Ultrasound (IVUS) in cases of PPH, determining the thickness of the muscular middle layer with respect to the external diameter of the vessel and analyzing the appearance of the endothelium. These data allowed us to infer who were the more “muscularized” cases, presumably responding better to vasodilator medications. Patients with more altered endothelium, theoretically, needed a rigorous adjustment of anticoagulation and priority for cardiopulmonary transplantation (unpublished data)
- Pulmonary Vasoreactivity Test (ATV), with Nitric Oxide (NO), in cases with PPH, to define the patients who would benefit from the use of calcium blockers. The use in patients with CC (HP-CHD) is debatable, due to the error incurred in hemodynamic calculations when the actual oxygen consumption cannot be determined. The administration of NO with O₂ increases mixed venous saturation and alters hemodynamic calculations.

- The demonstration of pulmonary vasodilation through positive ATV has not been shown to correlate with a safe indication of CC surgery without the risk of persistent HP in the postoperative period. The conclusions of the ATV in PPH secondary to CC are not extrapolable. It has been proposed to administer vasodilator drugs beforehand, perform surgery, and maintain therapy in the postoperative period. There is a long way to go to draw conclusions

It is clear that the best thing is to operate the CC and HP early, before the 4th/6th month of age, but the reality is that in developing countries parents and children may arrive late for consultation.

A recent report studied IVUS patients with HP and CC and showed a better correlation between pulmonary arterial stiffness (pulsatility index) and the data of “favorable hemodynamics”[24]. Our experience with IVUS did not include the pulsatility index (unpublished data).

We had no more complications in cases with HP and if we only take minor complications, they were more frequent in cases without HP (Table 4). Therefore, our safety and efficacy margin was high, compared to what was published.

Table 4: Catheterizations and pulmonary hypertension

CAT (n: 1679)	CM (%)	Deaths (%)	Cm (%)	Total (%)
With HP n: 345	3 (0.8)	1 (0.28)	2 (0.57)	5 (1.4)
Without HP n: 1845	26 (1.1)	7 (0.3)	56 (2.5)	82 (3.6)
p statistic	0.367	0.95	0.009	0.008

Note: CAT: Cateterismos; CM: Complicaciones Mayores; Cm: Complicaciones menores; HP: Hipertension Pulmonar

Immediate postoperative cardiovascular surgery (CCV)

Patients in poor immediate postoperative evolution of cardiovascular surgery represent a delicate and unstable group for diagnostic or therapeutic studies. Catheterization in these critically ill patients presents greater complications.

In a recent publication, 41% of deaths occurred in these cases [13].

However, another report mentions safety and efficacy in this particular group of cases, with 43% of them undergoing the procedure under the Extracorporeal Circulation Membrane (ECMO), which provides a safety margin [25].

At the Favaloro Foundation, from 1992 and in the first 2,500 cases, we encountered more major complications in diagnostic studies in the immediate postoperative period of CCV than in cases admitted to the Intensive Care Unit (ICU) (p: 0.01) and outpatient cases (p<0.0001) (Table 5). In some surgical centers, surgeons perform vascular sutures in a technique called “Greek

guard” (e.g., pulmonary branches) using appropriate materials that allow tolerating angioplasties in “hyper-acute” periods without major complications. Rupture of a stenotic pulmonary branch post-angioplasty in the immediate postoperative period is a complication with high mortality [9]

Table 5: Major complications according to previous clinical status.

Clinical status	CM	Death
AMB		
n: 2097	26 (1.2%)	4 (0.19%)
DIAG n: 1313	DIAG: 0.2%	
INT n: 784	INT: 1%	
ICU		
n: 292	11 (3.8%)	3 (1%)
DIAG n: 201	DIAG: 0.5%	
INT n: 91	INT: 3.3%	
POP CCV		
n: 111	5 (4.5%)	3 (2.7%)
DIAG n: 80	DIAG: 5%	
INT n: 31	INT: 3.2%	

Note: CM: Major Complications; AMB: Outpatient; DIAG: Diagnosis; INT: Intervention; ICU: Intensive Care Unit; POP CCV: Immediate Postoperative of Cardiovascular Surgery. statistical significance (p) between UCI DIAG (n: 201) vs. POP CCV DIAG (n: 80) p=0.01, and between AMB DIAG (n: 1313) vs. POP CCV DIAG (n: 80), p<0.0001

General anesthesia

A recent study presents general anesthesia as an independent factor that leads to greater complications in diagnostic procedures for children with ventricular septal defects [26].

The RIGA-S does not consider this item due to its lack of predictive value. All children and adults undergoing an interventional procedure were performed under general anesthesia. The anesthesiologist decided on the type of anesthesia and the possibility of a laryngeal mask or endotracheal intubation. Patients undergoing simultaneous Transesophageal Echocardiography (TEE) were mandatorily intubated, as in the closure of atrial septal defects/foramen oval. Only cases of simple studies or adults undergoing diagnostic catheterizations received sedation. Therefore, the majority of cases were performed under general anesthesia without identifying any inherent complications.

Risk-adjusted scores

There are different published risk-adjusted scores for catheterizations in CC in children and adults [17-23]. They analyze various items, including renal and genetic comorbidities, among others. Several

scores use variables called “hemodynamic vulnerability indices” (Table 6) [17-20,23].

Table 6: Hemodynamic vulnerability indicators. Taken from the PREDIC3T Score [23]

Hemodynamic vulnerability indicators
Low systemic arterial saturation: BV<95%, VU<78%
Low mixed venous saturation: BV<60%, VU<50%
High pulmonary pressure: BV>45 mm Hg (systolic); VU>17 mm Hg (average)
High PFD systemic ventricle: >18 mm Hg
QP/QS>1.5
Pulmonary vascular resistance>3 iUW

BV: Biventricular Physiology; VU: Univentricular Physiology; PFD: End-Diastolic Pressure; QP/QS: Pulmonary Flow/Systemic Flow Ratio; iUW: Resistance index in Wood Units.

The CHARM [20], score considers eight risk variables:1) age; 2) renal failure; 3) univentricular physiology; 4) type of procedure; 5) low systemic saturation; 6) low mixed venous saturation; 7) high-end pressure of diastole of the systemic ventricle, and 8) high pulmonary pressure 15 mm Hg.

The last four data can only be obtained during the procedure, which limits the predictability.

The CRISP [21,22] score was validated and published in 2019. It consists of 10 independent variables that award up to 20 risk-adjusted points. The variables are 1) clinical status; 2) age; 3) weight; 4) inotropes; 5) respiratory status; 6) systemic commitment; 7) ASA score (American Society of Anesthesiology); 8) physiological category, 9) CHD, and 10) type of procedure [17,18].

The new score PREDIC3T [23], was published in 2022. Data were collected for all cases performed at sites participating in the C3PO (Congenital Cardiac Catheterization Project on Outcomes) multicenter registry. Between January 2014 and December 2017, 23.119 cases were recorded in 13 participating institutions, of which 88% of patients were <18 years of age and 25% were <1 year of age; a high-severity adverse event occurred in 1193 (5.2%). Six hemodynamic indicator variables were empirically assessed, and a novel hemodynamic vulnerability score was determined by the frequency of high-severity adverse events (Table 6).

These are data that must be obtained during catheterization and, therefore, lack predictive value. Obtaining them non-invasively before catheterization reduces their methodological strength. The RIGA-S presents data that can be easily obtained before the procedure, with independent variables being age, type of CC (unique to other scores), type of procedure, and previous clinical status. It does not include variables obtained during the procedure.

Conclusion

The growing interest and surveillance of complications in catheterization interventions in congenital heart diseases is a challenge to optimize the technique, increase patient safety, and assess the safety and efficiency of Hemodynamics Services.

The age range and variety of interventions sparked interest in the development of a risk score. The Toronto group (2008), publishing their complications, was very inspiring.

The RIGA-S presents particular aspects:

- This case series allows comparison, with statistical support, of the beginnings of interventions in CC at the end of the 80s, with the final complex and varied stage, carried out with the participation of the same operator in successive Hemodynamics Services. In this way, institutional and inter-operator biases were excluded.
- It reveals the importance of risk even in diagnostic catheterizations, by incorporating the complex diagnostic item, not presented in other publications. The score specifies the type of heart disease, in addition to the type of procedure. It is shown that complex diagnoses present more complications than simple interventions, such as closure of the arterial duct and pulmonary valvuloplasties.
- The score is predictive. It does not incorporate the “hemodynamic vulnerability indicators” whose data are obtained during catheterization.
- Our case series showed that among the first 500 cases since the end of the 80s, with only 13.8% of interventional catheterizations and the last 500 with 69.2%, there were no more major complications (1.4% *vs.* 2.2%, *p*: 0.341). Complexity increased, including “off-label” cases, but complications did not significantly increase.
- Stratification is obtained simply, even by paramedical personnel, before the procedure.
- The RIGA-S allows each case to be pinpointed in 3 risk categories (green, yellow, and red), plan the strategy with experienced hemodynamicists, (both the main operator and his assistant), anticipate in the ICU the need for a bed for post-surgery, prepare active rescue surgery and explain to the patient and their parents about the potential risks of the procedure.

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