



Egyptian Society of Cardiology
The Egyptian Heart Journal

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ORIGINAL ARTICLE

Adverse events in pediatric cardiac catheterization: Initial experience of Sohag university hospital



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Received 18 September 2014; accepted 1 June 2015

Available online 25 June 2015

KEYWORDS

Adverse event;
Cardiac catheterization;
Complication

Abstract Objective: To determine incidence and risk factors of adverse events associated with pediatric cardiac catheterization in the initial experience of our institution.

Patients and methods: The retrospective cohort study was conducted on 262 children with congenital heart disease who received cardiac catheterization in our catheterization between April 2010 and April 2013. Diagnostic CC was performed in 176 patients and therapeutic CC in 86 patients. All children's electronic and paper chart records were reviewed to obtain demographic, procedural, and treatment data. The severities of AE were further classified into minor, moderate and higher severity AE including levels 3, 4 or 5 AE.

Results: Of 262 patients (147 females, 55.4%), AE occurred in 31 studies (11.8%), in children ranging in age from 3 days to 16 years. There were 7 patients with higher severity AE (2.7%), 7 patients with moderate AE (2.7%) and 17 patients (6.5%) with minor AE. Vascular complications represented the majority ($n = 12$; 38.7%). Two children died within 24 h (0.7% of total case numbers). The risk factors for a complication included patient low body weight and the second year of our institution experience.

Conclusions: Pediatric cardiac catheterization by well trained team of pediatric cardiologists in a new center is effective. The rate of occurrence of AEs approximated to those which are reported by various interventional pediatric cardiology centers around the world. The lower body weight and the second year of initial experience are risk factors for occurrence of AE.

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1. Introduction

Cardiac catheterization has revolutionized the management of pediatric cardiac disease. Pediatric cardiac catheterization laboratories are now increasingly being used for therapeutic

procedures. Also, diagnostic catheterizations still play an important role in hemodynamic study. Both therapeutic and diagnostic procedures are associated with some risks because of their invasive nature.^{1–3} Cardiac catheterization associated complications including arrhythmia, massive bleeding, heart perforation, cardiac tamponade, thromboembolism, shock, hypoxemia and vessel occlusion remain a major concern for performing the procedure.^{4–7} A large multicenter experience with life-threatening events in congenital cardiac

Abbreviations: AE, adverse event(s); CC, cardiac catheterization; PDA, patent ductus arteriosus; CHD, congenital heart disease
Peer review under responsibility of Egyptian Society of Cardiology.

<http://dx.doi.org/10.1016/j.ehj.2015.06.001>

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catheterization was reported a low incidence of life-threatening events (2.1%) and mortality (0.28%) despite the complexity of modern patients and procedures.⁸ This finding is well documented in Vitiello et al's series of 4500 pediatric CCs in 10 years (2.1% major complications, 9.3% minor complications and 0.14% CC-related mortality).² Our study aimed to evaluate the incidence of adverse events and risk of pediatric cardiac catheterization in our center in its initial experience.

2. Methods and patients

The study was conducted on 262 children who received cardiac catheterization in our tertiary care hospital between the period of April 2010 and April 2013. All CCs were performed by pediatric cardiologists. Informed consents were obtained from the parents of children after complete explanation to all possible minor or major adverse events of the procedure. Their medical records, CC reports, medications and interventions on the catheterization system were reviewed retrospectively by one pediatric cardiologist.

Children were prepared and anesthetized according to the definite protocol. Critically ill children, those with circulatory insufficiency symptoms scheduled for examinations on an urgent or emergency basis, as well as neonates and infants below 6 months of age were not premedicated. Children above 6 months of age received midazolam 30 min before the procedure. General anesthesia with endotracheal intubation was applied in neonates and infants below one year of age, patients qualified for cardiac interventional procedures necessitating using transesophageal examination, and those with the symptoms of circulatory failure scheduled for urgent and emergency examinations. Deep sedation was applied in pulmonary valvuloplasty and transcatheter PDA closure in children more than 6 months.

Non-invasive monitoring (pulsioxymetry, indirect blood pressure measurements, ECG, body temperature) was initiated before the induction of anesthesia. In children with severe circulatory insufficiency requiring vascular agents, arterial pressure was measured invasively.

After the diagnostic or interventional procedure, patients were sent to the postoperative care unit or recovery room and observed for several hours. Those conscious, with efficient respiration and stable circulation (appropriately to the heart defect and pre-procedure status) were transferred to the cardiac intensive surveillance unit.

Invasive procedures were carried out by the team of well trained interventional pediatric cardiologists from well established experienced centers and from our institution. Examinations were carried by a double-plane angiograph imaging. Fluoroscopic time of each examination was recorded automatically by the CC system.

2.1. Definition of AEs

AEs were defined as any anticipated or unanticipated event from which injury could have occurred or did occur, potentially or definitely because of performing the catheterization. Events were recorded at the time of identification, either at the time of the case or later if determined to be related to the procedure. We used previously established and tested definitions for AE severity ranging from levels 1–5. For this

analysis, clinically important higher severity AE was defined as levels 4, or 5 AE. So adverse events were defined as (1) adverse events related to the catheterization procedure, (2) identified during or after the procedure resulting in a change in patient condition, (3) life-threatening if not treated, (4) requiring major intervention, such as invasive monitoring or major transcatheter bailout procedure (severity level 4), and (5) resulting in death and emergency surgery or failure to wean from extracorporeal membrane oxygenation (severity level 5).^{9,10}

Statistical analyses were done using intercooled STATA program version 9.2. Data were presented as mean and standard deviation for quantitative data or as number and percent if data were qualitative. Logistic regression analysis was used to calculate both odds ratio and *P* values. *P* values less than 0.05 were considered significant.

3. Results

A total of 262 children with CHD received cardiac catheterization in our tertiary care hospital between the period of April 2010 and April 2013. Among those patients, 86 patients received diagnostic CC and 176 patients received therapeutic CC consisted of six different procedures as in Fig. 1:

(1) 12 (6.8%) patients had coil embolizations for patent ductus arteriosus with COOK detachable and PFM coils, (2) 32 (18.1%) patients received septal occluder procedures for atrial septal defect, (3) 63 (35.8%) patients received balloon valvuloplasty procedures for valvular pulmonary stenosis or aortic stenosis, (4) 7 (3.9%) patients who had transposition of the great arteries received balloon atrioseptostomy procedures, (5) 58 (32.9%) patients had received PDA closure by Amplatzer Duct Occluder and (6) 4 (2.3%) patients had received VSD closure by different types of Amplatzer muscular VSD and Duct occluders.

AEs occurred in 31 of the total 262 patients (11.8%), including 9 out of 86 diagnostic CC (10.4%) and 22 out of 176 therapeutic CC (12.5%). The AEs were classified into three categories minor, moderate and higher severity according to the severities level of previously established definition of AE. Higher severity (level 4 or 5) AE occurred in 7 patients (2.7%) of cases among the total 262 CC procedures. Moderate complications occurred in 7 patients (2.7%). Minor complications occurred in 17 patients (6.5%) of cases. All different kinds of AE were categorized into four groups as shown in Table 1. Group 1—arrhythmias: 6 patients (19.3%) with symptoms including transient bradycardia, 1st to 3rd degree of atrioventricular block, paroxysmal supraventricular tachycardia and ventricular tachycardia. Group 2—hypoxia: 4 patients (12.9%) with symptoms ranging from transient oxygen desaturation to remarkable apnea and bradycardia requiring cardiopulmonary resuscitation and even endotracheal intubation.

Group 3—femoral vessel injury: 12 patients (38.7%) who suffered temporary loss of femoral artery pulsation, one patient who suffered significant bleeding at the puncture sites and required blood transfusion and 3 patients who suffered from femoral artery thrombosis requiring systemic heparinization. Group 4—miscellaneous: Six patients (19.4%) with symptoms including Embolization of devices, cardiac tamponade and rupture of balloon during pulmonary valvuloplasty.

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