



## Cardiac Catheterization for Congenital Heart Disease, What are The Predictors of The Adverse Events, Single-Center Experience

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**Abstract: Background:** Over the last decade, the use of cardiac catheterization (CC) as a primary treatment modality in congenital heart disease has increased. With the expansion of cardiac catheterization for congenital heart disease (CHD) and its shift from being a diagnostic tool to a therapeutic one, adverse events related to CC have become a major concern to pediatric interventional cardiologists. **Objective:** This study determined the predictors of the different adverse events that occurred during diagnostic or interventional cardiac catheterization for patients with congenital heart diseases; their incidence and management at Tanta university hospital. **Patients and Methods:** Our study included 380 patients diagnosed with congenital heart disease and elected for either diagnostic or interventional cardiac catheterization in Tanta university hospital, cardiology department, from July 2016 to July 2018. **Results:** Incidence of overall adverse events (AE) was higher among interventional procedures (84.6%) than diagnostic procedures (15.38%). Risk factor analyses for the studied cases demonstrated that no variable showed significant difference in the occurrence of major adverse events. The variables that showed significant relation to the occurrences of overall adverse events were type of CHD (P 0.045), procedure time (P 0.03), fluoroscopy time (P 0.004) and volume of contrast use (P 0.032). **Conclusion:** From the current study, it was concluded that adverse event incidence of cardiac catheterization for congenital heart disease carried out at cardiology department of Tanta university hospital department is consistent with the incidence of several international renowned centers. Factors that showed significant relation to the occurrence of adverse events and can be considered predictors of adverse events were type of congenital heart disease, procedure and fluoroscopy time and volume of contrast use.

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**Keywords:** Cardiac Catheterization, Congenital Heart Disease, Predictors of The Adverse Events

### 1. Introduction

Congenital heart disease is a structural or functional abnormality of the heart or major blood vessels, which is either present at birth or appears later in life <sup>(1)</sup>.

International classification of diseases, ninth revision (ICD-9) lists 25 congenital heart defects codes, of which, 21 designate specified anatomic or hemodynamic lesions <sup>(2)</sup>.

The true incidence of congenital heart disease is difficult to determine accurately as there is a wide variability among different studies with incidence varying from 4/1,000 to 50/1,000 live births <sup>(3)</sup>.

The role of cardiac catheterization in the diagnosis of CHD has been changing over time, from being a major diagnostic tool to one of lesser application due to development in non-invasive imaging techniques <sup>(4)</sup>.

The indication of cardiac catheterization has expanded and also emerged as an alternative to surgery as in stent implantation for coarctation of

aorta (CoA) and ventricular septal defect (VSD) closure, beside the existing procedures of shunt closure (e.g. Patent foramen ovale (PFO), atrial septal defect (ASD) and patent ductus arteriosus (PDA)) and the approaches for obstructive lesions (e.g. pulmonary artery (PA) stenosis and aortic valve stenosis) and complex lesions (e.g. aortopulmonary collaterals) <sup>(5)</sup>.

The severity of the adverse events, according to recent studies, can be defined by grades ranging from grade 1, no harm to the patient, grade 2, non-life threatening transient change in condition, grade 3, life threatening transient change in condition if not treated, grade 4, change in condition maybe permanent and require intensive care and grade 5, death or need of surgery to avoid death <sup>(6)</sup>.

AE tend to occur more with interventional than with diagnostic producers, but death also occurs with the latter. And as regarding the safety, there is no significant difference between pediatric and adult patients <sup>(6)</sup>.

The most common AE is arrhythmia. Though the

incidence is high, most are non-life-threatening and resolve spontaneously or with simple therapy. Bleeding, vascular events and complications related to access site are also common. Events related to anesthesia are more common in pediatric patients than adults <sup>(7)</sup>.

There is no specific time during CC at which AE occurs. They can occur during sedation, at puncturing for a vascular access, during a diagnostic process or intervention. Early recognition of AE is important <sup>(8)</sup>.

#### **Aim of the Work**

This study determined the predictors of the different adverse events that occur during diagnostic or interventional cardiac catheterization for patients with congenital heart diseases; their incidence and management at Tanta university hospital.

## **2. Patients and methods**

### **I. Patients:**

This retrospective study included 380 patients diagnosed with congenital heart disease and elected for either diagnostic or interventional cardiac catheterization in Tanta university hospital, cardiology department, from July 2016 to July 2018.

### **Ethical approval and written informed consent:**

An approval of the study was obtained from Tanta University academic and ethical committee. Every patient signed an informed written consent for acceptance of the operation.

### **II. Methods of the study**

All patients were subjected to:

#### **1. Full History taking:**

Proper history was taken with special emphasis on; age, sex, weight, presenting symptoms, indications for catheterization and mode of admission whether elective or emergency.

#### **2. Full Clinical examination:**

General examination for signs of heart failure and pulmonary congestion and assessment of hemodynamics.

**3. Twelve-lead surface ECG:** to identify evidence of any of the following: rate and rhythm disturbance, abnormal axis deviation, chamber enlargement.

**4. Plain chest X-ray:** Posteroanterior view for evidence of chamber enlargement enlarged main pulmonary artery, pulmonary congestion and chest infection.

#### **5. Routine pre-catheterization Laboratory investigations:**

- Complete blood picture (CBC).
- International normalized ratio (INR).
- Kidney function tests.
- Virology (HBV, HCV).
- Serum sodium, potassium.

- Arterial blood gases.
- C - Reactive proteins (CRP).

#### **6. Echocardiography:**

• Initial full echocardiography study was performed using 2D, M mode and color flow Doppler to verify the anatomy of the heart.

• Imaging was performed from sub costal, parasternal, apical, and supra sternal windows with the patient supine or in left lateral decubitus position.

• Sub costal view for detection of cardiac situs, atrial septum assessment to detect atrial septal defect or patent foramen ovale.

• Apical four and five chamber views for ventricular septum assessment and visualization of VSD, assessment of cardiac chamber size, mitral, tricuspid and aortic valves. Short axis parasternal views at aortic valve, mitral valve, and papillary muscle levels for assessment of great vessels relations, identification of the VSD location, establishing its number assessment of right ventricular outflow tract and pulmonary valve.

• Parasternal long axis for detection of left ventricular function and left atrial size.

• Suprasternal view was done for visualization of aortic arch and its branches, PDA, coarctation of aorta and pulmonary venous drainage.

#### **7. Steps of cardiac catheterization:**

• Antibiotic prophylaxis: Amoxicillin 50-100 mg/kg IV is given for all patients 30-60 minutes (min) before the procedure.

• Anesthesia: procedure was done under general or local anesthesia according to patient age and type of procedure that was done.

• Sterilization was done using betadine form the umbilicus to the knee and both groins then the patient were covered with sterile drapes.

• Vascular access: Patient arterial and venous accesses were gained using the Seldinger's technique. Right femoral artery and vein were accessed. In patient which difficult to obtain right femoral access, left femoral access was used. Other access sites such as subclavian or jugular were used according to procedure type <sup>(9)</sup>.

• 50-100 IU/Kg heparin was administered intravenously in arterial intervention procedures, half dose with arterial puncture and other half with device or stent implantation.

• Size of sheaths and catheters used ranged from 4 Fr to 6 Fr according to patient's age and larger long sheaths or deliveries were used during intervention.

#### **8. Detailed cardiac catheterization sheet:**

Including: type of catheterization, number of interventions, airway management, access information, procedure time, fluoroscopy time (min),

volume of contrast (cc), type and size of catheters, the sizes of the balloon, device and stent, the result of catheterization and further steps needed either medical treatment or need for surgical intervention.

**9. Post catheterization care:** The patient stays in the hospital overnight for post device observation and is usually discharged home the following day. Prior to discharge, a physical examination, an ECHO, ECG, and a chest radiograph are performed to assess the device or stent and to look for any potential complication. Patients are routinely maintained on aspirin 3-5 mg/kg or 150 mg for adults daily with equivalent antiplatelet therapy for 6 months. Patients are instructed to receive routine antibiotic therapy for 1-2 weeks.

#### 10. Grouping and collection of adverse events:

- Patients were grouped according to age into three groups: <2 months, 2 months-15 years and > 15 years.

- Procedures were divided into diagnostic and therapeutic.

- All immediate intra procedural and short term adverse events were recorded in a special sheet.

- Adverse event was defined as any anticipated or unanticipated event from which injury could have occurred or did occur, potentially or definitely because of performing the catheterization.

- Severity of the adverse events were divided into low and high and ranged from level 1 to level 5 and categorized into none, mild, moderate, severe and catastrophic.

- Congenital heart diseases were graded as simple congenital heart disease (mild), congenital heart disease with moderate severity (moderate), and congenital heart disease with great complex (severe) according to the Task Force 1 of the 32<sup>nd</sup> Bethesda Conference of the American college of cardiology in 2001<sup>(10)</sup>.

- Risk factors for adverse events were age, gender, weight, Type of CHD, severity of CHD, type of the procedure, type of anesthesia, procedure time (min), fluoroscopy time (min), amount of contrast use (cc) and type of admission.

#### III. Statistical analysis:

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as median with inter-quartile range (IQR) when their distribution found non parametric. Also qualitative variables were presented as number and percentages. The comparison between two groups regarding qualitative data was done by using *Chi-square test* and *Fisher exact test* instead of Chi-square test when the expected count in any cell found less than 5. The comparison between two independent

groups with quantitative data and non-parametric distribution was done by using *Mann-Whitney test* while the comparison between more than two groups was done by using *Kruskal-Wallis test*. *Logistic regression analysis* was used to assess the predictors of patients with complications and also with major complications with their odds ratio and 95% confidence interval (CI). The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant at  $p < 0.05$ .

#### 3. Results

The present study included 380 patients admitted at Tanta university hospital, department of cardiology, who were diagnosed with congenital heart disease and elected for cardiac catheterization, either diagnostic or interventional during the period from July 2016 to July 2018.

##### Demographic and clinical data:

A total of 380 cardiac catheterizations were performed on 380 patients during the two years study period. All patients were admitted to intermediate care unit. (Table 1)

<sup>a</sup>Others refers to pulmonary stenosis, aortic stenosis, transposition of great arteries, coarctation of aorta, tricuspid atresia, pulmonary atresia, common atrio-ventricular canal, post Glenn shunt operation and congenital branch pulmonary artery stenosis.

**According to sex**, the current study revealed that female patients represented the higher percentage (59%). **According to age**, group between 2 months-15 years represented the higher number of cases (77.4%), then group >15 years (20.5%) and group < 2 months (2.1%). **According to body weight**, studied cases weights ranged from 2 Kg to 80 Kg with median weight of 17 Kg. **According to type of CHD**, they were atrial septal defect (ASD), ventricular septal defect (VSD), patent ductus arteriosus (PDA), patent foramen ovale (PFO), and others. Others included: pulmonary stenosis (PS), aortic stenosis (AS), transposition of great arteries (TGA), coarctation of aorta (CoA), tricuspid atresia, pulmonary atresia, common atrio-ventricular canal, post Glenn shunt operation and congenital branch pulmonary artery stenosis. ASD represented the most common type with ratio of (33.7%) then others in descending order were PDA (28.4%), VSD (17.9%), others (16.8%) and PFO (3.2%). **According to severity of CHD**, cases were graded into mild, moderate and severe. The moderate grade represented the higher percentage (91.6%), the severe grade (5.3%), and the mild grade had the lower percentage (3.2%). **According to method of anesthesia**, the majority of the procedures (92.1%) were performed under general anesthesia and (7.9%) were performed under sedation.

**Table (1): Demographic and clinical data of the studied cases:**

		No. = 380
Sex	Female	223 (59.0%)
	Male	155 (41.0%)
Age	Age 0-2 Months	8 (2.1%)
	Age >2Months-15 years	294 (77.4%)
	Age>15 years	78 (20.5%)
Body weight (Kg)	Median (IQR)	17 (10 – 32)
	Range	2 – 80
Type of disease	ASD	128 (33.7%)
	VSD	68 (17.9%)
	PDA	108 (28.4%)
	PFO	12 (3.2%)
	Others <sup>a</sup>	64 (16.8%)
Severity of disease	Mild	12 (3.2%)
	Moderate	348 (91.6%)
	Severe	20 (5.3%)
Mode of admission	Intermediate care unit	380 (100.0%)
Method of anesthesia	GA	350 (92.1%)
	Sedation	30 (7.9%)

ASD = atrial septal defect; GA = general anesthesia; IQR = inter-quartile range; Kg = kilogram; PDA = patent ductus arteriosus; PFO = patent foramen ovale; VSD = ventricular septal defect.

**Table (2): Distribution of adverse events according to different types of CHD:**

Adverse event	ASD		VSD		PDA		PFO		Others		Test value	P-value
	No.	%	No.	%	No.	%	No.	%	No.	%		
Arrhythmia	0	0.0%	6	50.0%	6	50.0%	0	0.0%	8	57.1%	12.164	0.016
Hematoma	6	50.0%	0	0.0%	2	16.7%	0	0.0%	2	14.3%	10.919	0.027
Hypoxia	0	0.0%	4	33.3%	2	16.7%	0	0.0%	4	28.6%	2.335	0.674
Hypotension	0	0.0%	0	0.0%	2	16.7%	0	0.0%	4	28.6%	18.876	0.001
Cardiac perforation	2	16.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	6.933	0.139
Femoral arterial thrombosis	1	8.3%	0	0.0%	0	0.0%	0	0.0%	1	7.14%	6.933	0.139
Coil embolization	2	16.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	6.933	0.139

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)\*: Chi-square test

ASD = atrial septal defect; PDA = patent ductus arteriosus; PFO = patent foramen ovale; VSD = ventricular septal defect.

**Regarding the relation between the different types of CHD and the incidence of adverse events,** as shown in **table (2)**, there was a significant relation between the type of CHD and arrhythmia, occurring in equal percentage (50%) of complicated cases of each of VSD and PDA, and a higher percentage (57.1%) among other types of CHD. Most cases of arrhythmia required only monitoring and resolved spontaneously, some cases of bradyarrhythmia required medical intervention by atropine to be resolved.

There was a significant relation between hematoma at access site and the type of CHD, occurring in (50%) of complicated cases of ASD. It

occurred in a ratio of (16.7%) of complicated cases of PDA and (14.3%) of complicated cases of other types of CHD. Hematoma required adequate and prolonged compression at the access site to be resolved. In cases where large size sheath (more than 9 Fr) was used, figure of eight suture at the access site was preferred to be done before sheath removal. Hypotension also showed a significant relation, occurring in (28.6%) of complicated cases of other types of CHD and in (16.7%) of complicated cases of PDA. Hypotension resolved spontaneously except in one case which required medical intervention by adrenaline. Hypoxia occurred in the different types of CHD with no significant relation to a specific type and was due to

laryngeal spasm after ex-tubation and was resolved by vigorous jaw thrust and application of CPAP with 100% oxygen. Cardiac perforation in the form of left atrial perforation occurred in two complicated cases of ASD in a ratio of (16.7%). The two cases were transferred for surgical closure of the perforation and the defect. Femoral arterial thrombosis occurred in one complicated case of ASD in a ratio of (8.3%) and in one complicated case of other types of CHD in a ratio of (7.14%). In one case, arterial access was gained for the purpose of performing a hemodynamic study and in the other case, arterial access was gained to perform a coronary angiography. The two cases were referred to vascular surgery department and surgical thrombectomy was successfully done on the same day. Coil and device embolization occurred in two complicated cases of ASD in a ratio of (16.7%). The embolized coils were successfully removed.

<sup>a</sup>Others refers to pulmonary stenosis, aortic stenosis, transposition of great arteries, coarctation of aorta, tricuspid atresia, pulmonary atresia, common atrio-ventricular canal, post Glenn shunt operation and congenital branch pulmonary artery stenosis.

There was no significant relation between the different risk factors and the occurrence of adverse events except for fluoroscopy time which showed significance relation to occurrence of adverse events (P 0.044). (Table 3).

Adverse events were divided into two groups; minor and moderate group and major group. There was significant relation between these two groups and the predictors regarding the body weight being significant with major adverse events occurring in weight range 8-11 Kg and the type of CHD being highly significant with major complications occurring in ASD type. (Table 4)

**As regarding predictors of adverse events**, risk factor analysis for the studied cases demonstrated the no risk factor showed significant relation to the occurrence of major adverse events. The risk factors that showed significant relation to the occurrences of overall adverse events were type of CHD (P 0.045), procedure time (P 0.03), fluoroscopy time (P 0.004) and volume of contrast use (P 0.032). (Table 5)

N.B. Different types of anesthesia were not studied.

**Table (3): Relation between risk factors and presence of adverse events:**

		No adverse events No. = 328	Adverse events No. = 52	Test value	P-value	Sig.
Sex	Female	189 (58.0%)	34 (65.4%)	1.018	0.313	NS
	Male	137 (42.0%)	18 (34.6%)			
Age	Age 0-2 Months	6 (1.8%)	2 (3.8%)	5.065	0.079	NS
	Age >2Months-15 year	260 (79.3%)	34 (65.4%)			
	Age>15 years	62 (18.9%)	16 (30.8%)			
Weight (Kg)	Median (IQR)	17 (10 - 30)	17.5 (11 - 50)	-0.579	0.562	NS
	Range	2 – 80	5 – 75			
Type of disease	ASD	116 (35.4%)	12 (23.1%)	7.247	0.123	NS
	VSD	56 (17.1%)	12 (23.1%)			
	PFO	10 (3.0%)	2 (3.8%)			
	Others	50 (15.2%)	14 (26.9%)			
Severity of disease	Mild	10 (3.0%)	2 (3.8%)	0.830	0.660	NS
	Moderate	302 (92.1%)	46 (88.5%)			
	Severe	16 (4.9%)	4 (7.7%)			
Mode of admission	Intermediate care unit	328 (100.0%)	52 (100.0%)	NA	NA	NA
Procedure type	Interventional	276 (84.1%)	44 (84.6%)	0.007	0.931	NS
	Diagnostic	52 (15.9%)	8 (15.4%)			
Procedure time (min)	Median (IQR)	35 (26.5 - 43)	37.5 (30 - 60)	-1.829	0.067	NS
	Range	18 – 160	18 – 170			
Fluoroscopy time (min.)	Median (IQR)	20 (12 - 29)	22.5 (15 - 46)	-2.013	0.044	S
	Range	8 – 130	10 – 130			
Volume of contrast (cc)	Median (IQR)	80 (60 - 100)	80 (60 - 120)	-0.877	0.381	NS

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)\*: Chi-square test

ASD = atrial septal defect; cc= cubic centimeter; IQR = inter-quartile range; Kg = kilogram; min= minutes; PDA = patent ductus arteriosus; PFO = patent foramen ovale; VSD = ventricular septal defect.

<sup>a</sup>Others refers to pulmonary stenosis, aortic stenosis, transposition of great arteries, coarctation of aorta, tricuspid atresia, pulmonary atresia, common

atrio-ventricular canal, post Glenn shunt operation and congenital branch pulmonary artery stenosis.

**Table (4): Relation between risk factors and severity of adverse events:**

		Minor & Moderate group No. = 48	Major group No. = 4	Test value	P- value	Sig.
Sex	Female	32 (66.7%)	2 (50.0%)	0.453	0.501	NS
	Male	16 (33.3%)	2 (50.0%)			
Age groups	Age 0-2 Months	2 (4.2%)	0 (0.0%)	2.294	0.318	NS
	Age >2Months-15 year	30 (62.5%)	4 (100.0%)			
	Age >15 years	16 (33.3%)	0 (0.0%)			
Weight (Kg)	Median (IQR)	19 (12 - 53.5)	9.5 (8 - 11)	-2.271	0.023	S
	Range	5 - 75	8 - 11			
Type of disease	ASD	8 (16.7%)	4 (100.0%)	14.444	0.006	HS
	VSD	12 (25.0%)	0 (0.0%)			
	PDA	12 (25.0%)	0 (0.0%)			
	PFO	2 (4.2%)	0 (0.0%)			
	Others <sup>a</sup>	14 (29.2%)	0 (0.0%)			
Severity of disease	Mild	2 (4.2%)	0 (0.0%)	0.565	0.754	NS
	Moderate	42 (87.5%)	4 (100.0%)			
	Severe	4 (8.3%)	0 (0.0%)			
Mode of admission	Intermediate care unit	48 (100.0%)	4 (100.0%)	NA	NA	NA
Method of anesthesia	GA	44 (91.7%)	4 (100.0%)	0.361	0.548	NS
	Sedation	4 (8.3%)	0 (0.0%)			
Procedure type	Interventional	40 (83.3%)	4 (100.0%)	0.788	0.375	NS
	Diagnostic	8 (16.7%)	0 (0.0%)			
Procedure time (min)	Median (IQR)	33 (30 - 80)	51 (42 - 60)	-1.181	0.238	NS
	Range	18 - 170	42 - 60			
Fluoroscopy time (min)	Median (IQR)	19 (15 - 63)	32 (25 - 45)	-0.897	0.370	NS
	Range	10 - 130	25 - 45			
Volume of contrast (cc)	Median (IQR)	80 (60 - 120)	90 (90 - 90)	-0.691	0.490	NS
	Range	40 - 230	90 - 90			

ASD = atrial septal defect; cc = cubic centimeter; GA = general anesthesia; IQR = inter-quartile range; Kg = kilogram; min = minute; PDA = patent ductus arteriosus; PFO = patent foramen ovale; VSD = ventricular septal defect.

<sup>a</sup>Others refers to pulmonary stenosis, aortic stenosis, transposition of great arteries, coarctation of aorta, tricuspid atresia, pulmonary atresia, common atrio-ventricular canal, post Glenn shunt operation and congenital branch pulmonary artery stenosis.

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value < 0.01: highly significant (HS)\*: Chi-square test

**Table (5): Risk factor analysis for adverse events:**

	Over all adverse events				Major adverse events			
	P-value	Odds ratio	95% C.I. for OR		P-value	Odds ratio	95% C.I. for OR	
			Lower	Upper			Lower	Upper
Sex	0.314	0.73	0.396	1.347	0.507	2.000	0.258	15.532
Age	0.134	1.621	0.862	3.048	0.292	0.313	0.036	2.711
Weight (Kg)	0.309	1.006	0.994	1.019	0.152	0.820	0.625	1.076
Type of disease	<b>0.045</b>	1.228	1.005	1.501	0.995	0.000	0.000	0.000
Severity of disease	0.64	1.267	0.469	3.42	0.812	0.686	0.031	15.200
Method of anesthesia	0.954	0.968	0.324	2.896	0.999	0.000	0.000	0.000
Procedure type	0.931	0.965	0.43	2.168	0.999	0.000	0.000	0.000
Procedure time (min)	<b>0.003</b>	1.012	1.004	1.021	0.799	0.997	0.970	1.024
Fluoroscopy time (min)	<b>0.004</b>	1.014	1.004	1.023	0.801	0.996	0.965	1.028
Volume of contrast (cc)	<b>0.032</b>	1.009	1.001	1.017	0.824	0.997	0.974	1.021

cc = cubic centimeter; Kg = kilogram; min = minute

#### 4. Discussion

The current study included 380 patients diagnosed with congenital heart disease and elected for either diagnostic or interventional cardiac catheterization in Tanta university hospital, cardiology department, from July 2016 to July 2018.

Our aim was to determine the predictors of the different adverse events that occur during cardiac catheterization for congenital heart disease, their incidence and management.

**Regarding the incidence of adverse events;** the two year study of CC for CHD in our center found that the incidence of overall adverse events was (13.7%) and the incidence of major adverse events was (1.1%). There were no cases of in-hospital mortality.

**Lee, et al.** <sup>(11)</sup> evaluated complications of CC and the associated risk factors in a tertiary center over 10 years from January 2004 to December 2013 on a total of 2071 cases. The overall complications, major complications and mortality rates were (16.2%), (1.15%) and (0.19%) respectively.

**Holzer et al.** <sup>(12)</sup> reported procedural characteristic and adverse events of patients who have undergone selected catheterization procedures from January 2011 to June 2013. The data was collected in the Improving Pediatric and Adult Congenital Treatment registry. In a total of 8021 cases, the overall adverse events rate was (12.0%), major adverse events occurred in (1.4%) and mortality rate was (0.1%).

**Bergersen et al.** <sup>(7)</sup> sought to understand adverse events rates in pediatric and congenital cardiac catheterization and identify vulnerable populations. Between January 2004 and June 2005, 1727 hemodynamic, biopsy, and interventional cases were performed in 1227 patients. Overall adverse events

incidence was (19%), major adverse events occurred in (2.7%) of cases, and mortality rate was (0.4%).

These above mentioned before studies reported overall adverse events rate ranging between (7.8-19%). Incidence of major adverse events ranged from (1.15-2.7%). Mortality rate ranged from (0.1-2.6%). Results from our study showed a similar incidence rates that agreed with these several, recent, large and multi-central studies.

**Regarding age,** studied cases were grouped as less than 2 months (Group 1), 2 months-15 years (Group 2), and more than 15 years (Group 3). Group 2 represented the higher percentage (77.4%) and group 1 represented the lower percentage (2.1%). Incidence of adverse events was higher among group 2 with a ratio of (65.4%) of the complicated cases, age Group 3 represented (30.8%) and age group 1 (3.8%). Age itself was not a predictable risk factor for adverse events. This may relate to the small percentage of the neonatal age group in our study.

In discordance to our study, the study conducted by **Mehta et al.** <sup>(13)</sup> showed age range from 1 day to 19 years with a median age of 4.13 years. (16%) of complications occurred in children <6 months of age (14% incidence in neonates) and the fewest was in those >10 years of age (4.6%). (32%) of all deaths occurred in neonates. (41%) of the major and (35%) of the minor complications occurred in children <6 months of age, while those >10 years of age had the least; (18%) and (16%) respectively.

**Lee et al.** <sup>(11)</sup> grouped age as less than 1 month, 1-12 months, 1-8 years, 8-15 years, 15-20 years and more than 20 years. Age ranged from 1 day-59 years with median age of 5.5 years. Younger patients showed higher incidence of adverse events with great significance (3-fold) in patients aged less than 1 month. These results disagree with our study.

**Regarding sex**, in the current study, female patients represented the higher percentage (59.0%). Sex was not a predictable risk factor for adverse events.

In concordance with our study, **Safaa** <sup>(14)</sup> conducted a study on 262 patients to determine incidence and risk factors of adverse events associated with pediatric cardiac catheterization in the period between April 2010 and April 2013. Female patients represented (55.4%) of the cases.

**Regarding body weight** of the studied cases, our study showed weight range from 2-80 Kg with a median weight of 17 Kg. Our study compared adverse events occurring in two groups; mild and moderate events group and major events group. Rate of major events showed significant relation to average body weight of 8-11 Kg and median weight of 9.5 Kg, compared with mild and moderate events group with weight range of 5-75 Kg and median weight of 19 Kg, indicating that lower body weights were associated with higher incidence of major complications. Body weight itself was not a predictable risk factor for adverse events.

In concordance to our results, **Rhodes et al.** <sup>(15)</sup> studied the impact of body weight on the frequency of complications of pediatric CC on 2042 patients over 7 years period. Patients were divided into 2 groups: patients weighing  $\leq 5$  kg and patients weighing  $> 5$  kg. The group  $\leq 5$  kg was further divided into 2 subgroups: patients weighing  $\leq 2.5$  kg and patients weighing 2.5-5 kg. (17.5%) of cases weighed  $\leq 5$  kg and (83.5%) weighed  $> 5$  kg. Within the group  $\leq 5$  kg, (2.6%) weighed  $\leq 2.5$  kg and (14.9%) weighed 2.5 to 5 kg. For patients weighing  $\leq 5$  kg, compared with patients  $> 5$  kg, overall (25% vs. 10.1%), major (8% vs. 1.4%) and minor (17% vs. 5.5%) complication rates were significantly higher. Children  $\leq 5$  kg accounted for (43%) of the complications while making up only (17.5%) of the patients.

**Regarding the type of procedure**, in the current study, adverse events rate were higher in interventional than diagnostic procedures. (84.2%) of cases underwent interventional catheterization while (15.8%) underwent diagnostic catheterization. (84.6%) of complicated cases were interventional and (15.38%) were diagnostic. Overall incidence of adverse events in interventional procedures was (11.57%) and in diagnostic procedures was (2.1%). In our study there was no significance difference in the incidence of adverse events and type of procedure.

These results agreed with **Lee et al.** <sup>(11)</sup> in term of overall adverse events rate in interventional procedures which was (16.4%), while overall rate for diagnostic procedures was (14.4%).

In discordance to our results, **Mori et al.** <sup>(6)</sup> studied 2134 patients from which, (74%) underwent

diagnostic procedures and (18.4%) underwent interventional procedures. This study also differs from ours in that relation between type of the procedure and incidence of adverse events was not studied separately and electrophysiological procedures were also included.

**Regarding severity of CHD**, in the current study, type of CHD was graded according to severity into mild, moderate and severe. Moderate type represented the higher percentage (91.6%), severe type (5.3%) and mild type (3.2%). In complicated cases, incidence of adverse events in mild, moderate and severe types was (16.7%), (13.2%) and (20.0%) respectively. Major adverse events occurred only in moderate type of CHD with a rate of (8.7%). Severity of CHD itself was not a predictable risk factor for adverse events.

In concordance to our results, **Lee et al.** <sup>(11)</sup> used the same severity grading as in our study, the majority of cases was also in the moderate type (53.8%), severe type rate was (35.5%) and mild type was (10.7%). Patients with severe type of CHD had a significantly higher risk of overall complications than those with mild and moderate types.

**Regarding the method of anesthesia**, in our study, general anesthesia was the prevailing method (92.1%) in comparison to sedation (7.9%). In complicated cases, (92.3%) underwent general anesthesia while (7.7%) of cases was sedated. All cases with major complications underwent general anesthesia. Method of anesthesia itself was not a predictable risk factor for adverse events.

In cases studied by **Lee et al.** <sup>(11)</sup> (71.1%) of cases were managed with sedation, (9.6%) of cases were performed under general anesthesia and (19.9%) of cases were performed under local analgesic anesthesia. In agreement with our study, procedures performed under general anesthesia were associated with moreover all and severe complications.

**Regarding the procedure**, in our study, procedure time range was 18-170 min with a median of 35 min, fluoroscopy time range was 8-130 min with a median of 20 min and volume of contrast use range was 30-230 cc with a median of 80 cc. Longer procedures were associated with longer fluoroscopy time and more use of contrast. Complicated cases had median procedure time of 37.5 min, median fluoroscopy time of 22.5 min and median volume of contrast of 80 cc. Cases with major adverse events had median procedure time of 51 min, median fluoroscopy time of 35 min and median volume of contrast of 90 cc. In our study, procedure and fluoroscopy time and volume of contrast showed significant relation to the occurrence of adverse events and were considered a predictable risk factor for overall adverse events but



showed no significant difference in the occurrence of major adverse events.

In the study conducted by **Lee *et al.*** <sup>(11)</sup> mean procedure time was 57.4±31.6 min, mean fluoroscopic time was 17.2±12.5 min and mean amount of contrast dye per weight was 2.5±1.7 cc/kg. In agreement with our study, procedure time was an important risk factor for overall complications but in disagreement with our study procedure time was also a risk factor for severe complications.

**Regarding prevalence of adverse events**, in our study, minor adverse events were the most common (9.7%) and major adverse events were the least common (1.1%). The most common category of adverse events was arrhythmia with a ratio of (38.5%) followed by hematoma as access site and hypoxia with an equal ratio of (19.2%) each. The incidence of hypotension was (11.5%). Coil embolization incidence was (3.8%). Major events in the form of cardiac perforation and femoral arterial thrombosis occurred in an equal incidence of (3.8%) each.

In agreement with our study in regard to prevalence of adverse events, **Mori *et al.*** <sup>(6)</sup> studied 2134 patients and showed that arrhythmia was the most common type of overall complications and major complications with rates of (50.0%) and (61.5%) respectively. Bleeding was the second most common form (18.4%). Neurological problems were the second most common major complication (30.8%).

In disagreement with our study, the study conducted by **Pepine *et al.*** <sup>(16)</sup> in Chicago hospital from 2006 to 2008 on 1000 cases of congenital heart disease, found that among (22%) of complicated cases, vascular complications represented the majority (35%). The second most common complication was arrhythmia (27.2%).

Our study results suggested that type of congenital heart disease, procedure and fluoroscopy time and volume of contrast use, are predictors of overall adverse events.

## Conclusion

From the current study, it was concluded that adverse event incidence of cardiac catheterization for congenital heart disease carried out at our department is consistent with the incidence of several international renowned centers.

The most common adverse event occurred were reversible arrhythmias followed by hematoma at access site and hypoxia with equal incidence.

The majority of the adverse events that occurred in this study were related to interventional procedures and not diagnostic procedures.

In this study, risk factors that showed significant relation to the occurrence of adverse events and can

be considered predictors of adverse events were type of congenital heart disease, procedure and fluoroscopy time and volume of contrast use.

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