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Congenital heart disease cardiac catheterization at Uganda Heart Institute, a 12-year retrospective study of immediate outcomes

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Abstract

Background Cardiac catheterization is an invasive diagnostic and treatment tool for congenital heart disease (CHD) with potential complications.

Objective To describe the immediate outcomes of patients who underwent cardiac catheterization for CHD at the Uganda Heart Institute (UHI).

Methods The study was a retrospective chart review of 857 patients who underwent cardiac catheterization for CHD at UHI from 1st February 2012 to 30th June 2023. Precardiac catheterization clinical data, procedure details, and post-procedure data were recorded. The statistical software SPSS was used for data analysis.

Results We studied 857 patients who underwent cardiac catheterization for CHD at UHI. Females comprised 62.8% ($n = 528$). The age range was 3 days to 64 years, with a mean of 5.1 years (SD 7.4). Advanced heart failure was present in 24 (2.8%) of the study participants. The most common procedures were patent ductus arteriosus device closure ($n = 500$, 58.3%), diagnostic catheterization ($n = 194$, 22.5%), and balloon pulmonary valvuloplasty ($n = 114$, 13.0%). PDA device closure had 89.4% optimal results while BPV had 75.9% optimal performance outcome.

Adverse events occurred in 52 out of 857 study participants (6.1%). Clinically meaningful adverse events (CMAES) occurred in 3.9%, ($n = 33$), high severity adverse events in 2.9% ($n = 25$) and mortality in 1.5% ($n = 13$).

Advanced heart failure at the time of cardiac catheterization, was significantly associated with clinically meaningful adverse events (OR 52 p -value < 0.001) and mortality (OR 564, p value < 0.001).

Conclusion Many patients with CHD have benefited from the cardiac catheterization program at UHI with high optimal procedure outcome results. Patients with advanced heart failure at the time of cardiac catheterization have less favorable outcomes emphasizing the need for early detection and early intervention.

Keywords Congenital Heart Disease, Cardiac Catheterization, Uganda

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Background

Cardiac catheterization plays a vital role in the diagnosis and treatment of patients with congenital heart disease (CHD) [1]. Interventional catheterization has evolved from balloon atrial septostomy in the 1970s to a wide range of procedures such as valvular dilatations and percutaneous implantation of various devices. Transcatheter interventional therapy is a standard treatment modality for stenosed heart valves and blood vessels, occlusion of abnormal vascular channels or surgical shunts, and suitable intracardiac defects [1–3]. Being an invasive procedure, cardiac catheterization carries significant risks and has a potential for several complications.

Many studies, especially in developed countries have reported complications of cardiac catheterization ranging from 2 to 24% including death, arrhythmias, vascular complications, device embolization and severe infections [4–17]. However, there has been paucity of data about CHD cardiac catheterization outcomes from low- and middle-income countries (LMICs). To address this gap an International Quality Improvement Collaborative Congenital Heart Disease Catheterization Registry (IQIC-CHDCR) was established to report on outcomes of CHD cardiac catheterizations in LMICs. The results from 12 countries participating in the IQIC-CHDCR between the years 2019 and 2020 indicated a mortality rate of 1% (34/3287) and serious adverse events (SAE) in 2.8% (93/3287) [18]. Data from Uganda was not included in this report. This study is reporting outcomes from Uganda, which is also a low-income country found in Sub-Saharan Africa.

Previously a report on the starting and operation of a cardiac catheterization laboratory for both acquired and congenital heart diseases at UHI and the number of cases done by then, has been published [19]. The authors at that time never focused on procedure performance outcomes and adverse events. Therefore, there was a need to understand the outcomes of congenital cardiac catheterization at UHI and compare them with other centers performing congenital cardiac catheterization. Results from this study will help guide the UHI center to know the performance of the past twelve years and then devise ways of improving the performance in the years to come. Clinicians can use this information to counsel patients with CHD regarding the available procedures at UHI and the potential risks of the interventions.

The aim of this study was therefore to report the immediate (from the beginning of the procedure up to patient discharge or death) outcomes of CHD cardiac catheterization at UHI.

Methods

Study setting

This study was carried out at the UHI which is located at Mulago National Referral Hospital in the capital city Kampala, and it is the only public tertiary referral cardiac center in Uganda offering comprehensive cardiovascular services. It has an outpatient department, general inpatient wards with 28 beds, a coronary care unit with 12 beds, a high dependency unit with 12 beds, an intensive care unit initially with four beds during the study period, recently upgraded to 11 beds, eight private rooms, one catheterization laboratory (Cath lab), one operating theatre and a well-equipped laboratory. There are seven paediatric cardiologists, two of them being interventional cardiologists, five cardiac surgeons, two being paediatric cardiac surgeons, 10 cardiac anesthesiologists, ICU nurses and several other medical and non-medical specialists working together to deliver quality cardiovascular medical services. The pediatric cardiac catheterization program at the UHI began in February 2012, when two patients underwent balloon pulmonary valvuloplasty (BPV) under fluoroscopy guidance using a mobile C-arm. With the installation of a fully equipped Cath lab with a biplane Siemens Artis Zee machine in April 2012 the range of pediatric catheterization procedures performed at the UHI has evolved to include both diagnostic and interventional procedures such as hemodynamic and anatomic studies, percutaneous valve and blood vessel dilatations (pulmonary valve and coarctation of the aorta), and occlusion of defects such as patent ductus arteriosus (PDA), secundum atrial septal defects (ASD) and suitable ventricular septal defects (VSD). Initially, procedures were done by visiting teams working with local paediatric cardiologists. From 2014 the local team started performing procedures independently. For the past 12 years, an average of 80 catheter-based procedures have been performed at the UHI annually. The pediatric cardiac catheterization program at the UHI also treats adults with CHD [19].

The UHI Cath Lab has one director who is an interventional adult cardiologist. The lab is shared by adult and paediatric cardiology teams. Initially, the paediatric team which deals mainly with congenital heart diseases was allocated two days a week which later changed to one day, due to inadequate anesthesia coverage. During camps by visiting teams, children have procedures done free of charge. During routine work, patients pay a subsidized fee of about 900 USD. Even then most families cannot afford this fee, only about 25% are able to pay part or the whole of the subsidized fee [19].

Selection criteria

All patients who underwent cardiac catheterization for CHD were included in the study.

Study design

This was a retrospective cohort study.

Study procedures

Charts of patients who underwent cardiac catheterization for CHD at UHI from 1st February 2012 to 30th June 2023 were reviewed. During the study period, charts of patients in the procedural log maintained by the paediatric intervention cardiologists were retrieved from the records store by a records officer and more data was obtained from electronic records of UHI.

We collected the following data: Demographics (name, age, gender), clinical findings (weight, height, oxygen saturation, and any clinical syndromes), presence of advanced heart failure (defined in this study as New York Heart Association class III or IV heart failure), baseline laboratory data (hemoglobin, creatinine), patient's cardiac diagnosis (based on echocardiogram), a summary of catheterization procedure, occurrence of an adverse event during or after the procedure and interventional procedures performance outcome. Procedure outcomes for PDA device closure, ASD device closure, Coarctation of the aorta stenting and balloon pulmonary valvuloplasty were categorized as optimal, adequate and inadequate basing on a previously published similar work [20]. Supplementary Table 1 shows description of procedure outcome grading for the different procedures.

The severity of adverse events was categorized as level 1 (none), level 2 (minor), level 3 (moderate) further subdivided into a-c, level 4 (Major) and level 5 (catastrophic) based on previously published work [21]. Events in levels 3b, 3c, 4 and 5 were categorized as clinically meaningful events (CMAES), while level 4 and 5 events were categorized as high severity adverse events (HSAEs). Supplementary Table 2 shows the definitions of the different severity levels of the adverse events.

We categorized patients according to Procedural Risk in Congenital Cardiac Catheterization (PREDIC3T) case type risk groups 0, 1, 2, 3, 4 and 5 [22].

We obtained data from the time of admission up to the point of discharge or death.

We do not perform genetic studies routinely at the UHI. Clinical diagnosis of genetic syndromes was made by the reviewing paediatric cardiologist.

Statistical analysis

The statistical software SPSS for windows, version 24.0 (SPSS, Inc Chicago, IL) was used for data analysis.

Categorical variables were reported as absolute numbers and percentages (%). Continuous variables were expressed as means (\pm SD) and medians (IQR) as appropriate. Comparison of continuous data was performed using Student's t-test for paired data. Categorical variables were compared in univariate analysis using the chi-square test. Variables with a p -value of ≤ 0.21 at univariate analysis were entered into logistic regression multivariate analysis model to identify predictors of clinically meaningful adverse events among the study participants. A p -value of < 0.05 was considered statistically significant.

Ethical approval

The study was approved by Makerere University College of Health Sciences School of Medicine Research and Ethics Committee (SOMREC) REC REF 2020-190 and Uganda National Council of Science and Technology (UNCST) HS 1081ES. A waiver of informed consent was given by SOMREC for reviewing charts for participants retrospectively.

Results

Cohort characteristics

A total of 857 patients with CHD underwent cardiac catheterization at the UHI during the study period and all were enrolled into this study (Fig. 1).

Females comprised 61.6% ($n=528$). The age range of the study participants was 3 days to 64 years with a mean of 5.1 years (SD 7.4 years). Forty-six study participants (5.4%) had severe acute malnutrition, 48(5.6%) had Down's Syndrome, 8(0.9%) had Noonan's syndrome and advanced heart failure (AHF) was present in 24(2.8%). There were 522(60.9%) patients in PREDIC3T risk category 2, 291(33.9%) category 1, 36(4.2%) category 3, eight patients (0.9%) in category 5 and none in category 0 and 4 (Table 1).

The most common cardiac conditions included PDA ($n=518$; 60.4%), pulmonary stenosis (PS) ($n=112$; 13.3%), VSD ($n=70$; 8.1%), ASD ($n=33$; 3.8%) and D Transposed arteries ($n=27$, 3.2%) (Fig. 2). Others included atrioventricular septal defects ($n=27$, 3.2%), coarctation of the aorta ($n=10$, 1.2%), tricuspid valve atresia ($n=7$), tetralogy of Fallot ($n=11$), double outlet right ventricle ($n=10$), pulmonary atresia ($n=6$), severe pulmonary hypertension ($n=2$), aorto-pulmonary window ($n=4$), interrupted aortic arch ($n=6$), anomalous right pulmonary artery origin ($n=4$), anomalous left coronary artery origin from pulmonary artery ($n=2$), mitral valve atresia ($n=3$), hypoplastic left heart syndrome ($n=1$), and truncus arteriosus ($n=2$).

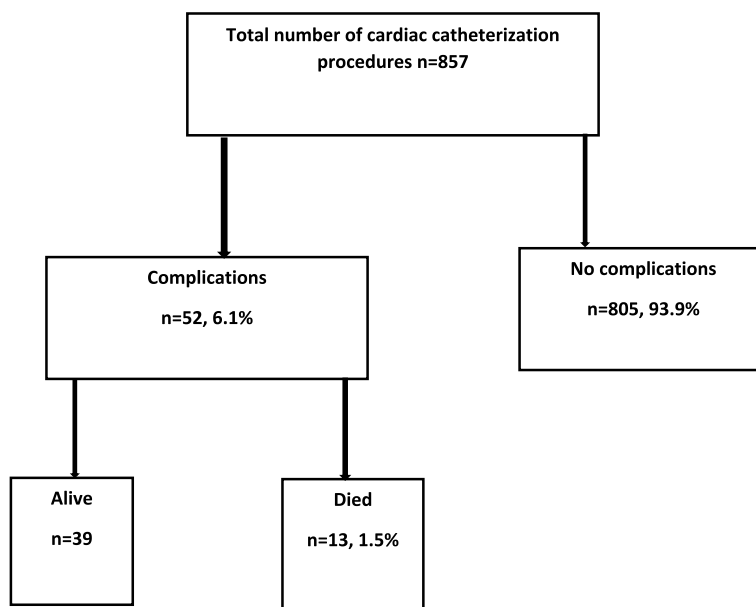


Fig. 1 Study flow diagram

Table 1 Cohort characteristics

Variable	Category	Number	Frequency (%) N= 857
Age	≤ 30 days	14	1.6
	31 days- < 1 year	141	16.5
	1-18 years	662	77.3
	> 18 years	40	4.6
Gender	Male	329	38.4
	Female	528	61.6
Weight(kg)	< 3 kg	6	0.7
	≥ 3 kg	851	99.3
Hemoglobin	Mean (SD)	12.148(2.8)	
Advanced Heart Failure	Absent	833	97.2
	Present	24	2.8
Single ventricle	Yes	4	0.4
Severe acute Malnutrition (weight for height Z score < -3SD)	Absent	811	94.6
	Present	46	5.4
Genetic syndromes	None	794	92.7
	Yes	63	7.3
Procedure characteristics	Diagnostic	194	22.6
	Interventional	663	77.4
PREDIC3T risk category	0	0	0
	1	291	33.9
	2	522	60.9
	3	36	4.2
	4	0	0
	5	8	0.9
Discharge post procedure n=682	< 48 h	556	81.5
	≥ 48 h	126	18.5

Syndromes: Downs = 48 patients, Noonan's = 8, others = 7

Procedures done and performance outcomes

The most common procedure done was PDA device closure (n=500, 58.3%), followed by diagnostic catheterization (n=194, 22.5%), then balloon pulmonary valvuloplasty (BPV) (n=112, 13%) (Fig. 3).

Procedure outcome was optimal in 100% of ASD device closures and 83.4% for coarctation of the aorta stenting. PDA device closures yielded 89.4% optimal outcomes while BPV showed 75.9% optimal results, Fig. 4

Adverse events

Overall adverse events occurred in 52 study participants (6.1%; 95%CI: 4.5–7.7). Clinically meaningful adverse events occurred in 33 participants (3.9%); while high severity adverse events occurred in 25 participants (2.9%) Fig. 5.

Common adverse events included the following: Death (n = 13; 1.5% 95%CI: 0.7–2.3), device embolization (n = 11; 1.2%), vascular complications (loss of or reduced arterial pulse, injury to external iliac vein) (n=7; 0.8%), arrhythmias (n=8, 0.9%) and cardiac arrest with successful resuscitation (n=6; 0.7%). Less common adverse events included severe pneumonia (n=4; 0.5%), severe anemia (n=5, 0.6%), pulmonary edema (n=5, 0.6%), sepsis (n=2; 0.2%), respiratory failure (n=1; 0.1%), and right ventricular out-flow tract (RVOT) tear (n=1; 0.1%). More details are in Tables 2, 3 and 4.

There were 18 patients with CMAES in PREDIC3T risk category 1 (6.2%), 14 in category 2 (2.9%) and one patient (2.8%) in category 3. Ten deaths occurred in PREDIC3T

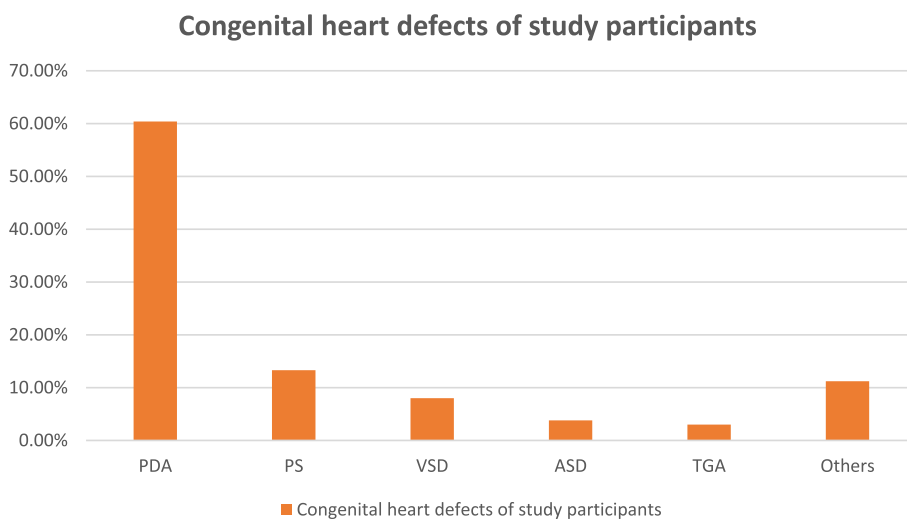


Fig. 2 Congenital heart defects of study participants. ASD = atrial septal defect, PS = pulmonary valve stenosis, PDA = patent ductus arteriosus, TGA = transposed great arteries, VSD = ventricular septal defect

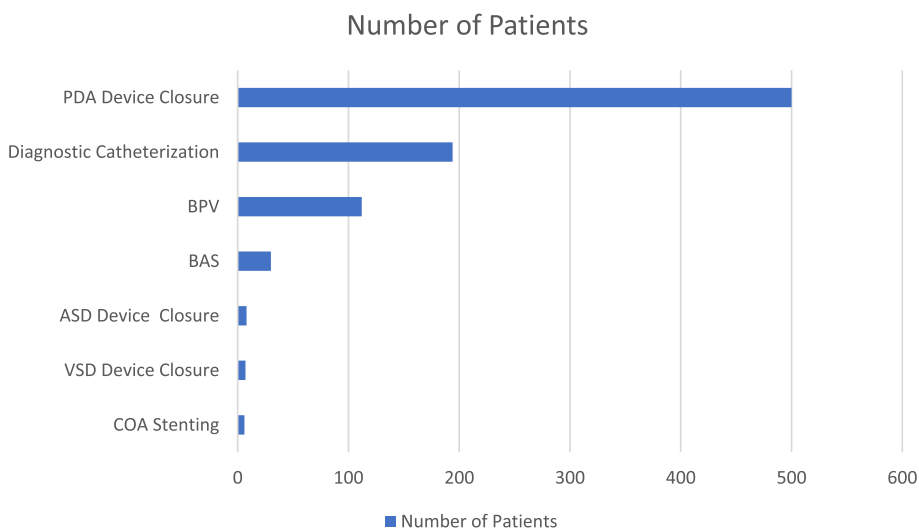


Fig. 3 Numbers CHD cardiac catheterization procedures performed at UHI. ASD = atrial septal defect, BAS = balloon atrial septostomy, BPV = balloon pulmonary valvuloplasty, COA = coarctation of the aorta, PDA = patent ductus arteriosus, VSD = ventricular septal defect

category 1, 2 in category 2 and 1 in category 3 Table 5. Majority of CMAES, HSAES and deaths occurred in PREDIC3T categories 1 and 2 Fig. 6.

Risk factors for adverse events

At univariate analysis, only advanced heart failure was significantly associated with CMAEs and mortality p value < 0.001 Table 5. Gender, weight and advanced heart failure were entered into logistic regression multivariate analysis model. Only advanced heart failure was found significantly associated with CMAEs (OR

52, 95%CI 20-131, p value < 0.001). Advance heart failure was also significantly associated with mortality at multivariate analysis (OR 564 95%CI 68-4640, p value < 0.001).

Discussion

The aim of this study was to establish the immediate outcomes among patients who underwent cardiac catheterization for CHD at the UHI. We found adverse events in 6.1% of the patients that underwent congenital cardiac catheterization and 3.9% of the study population had

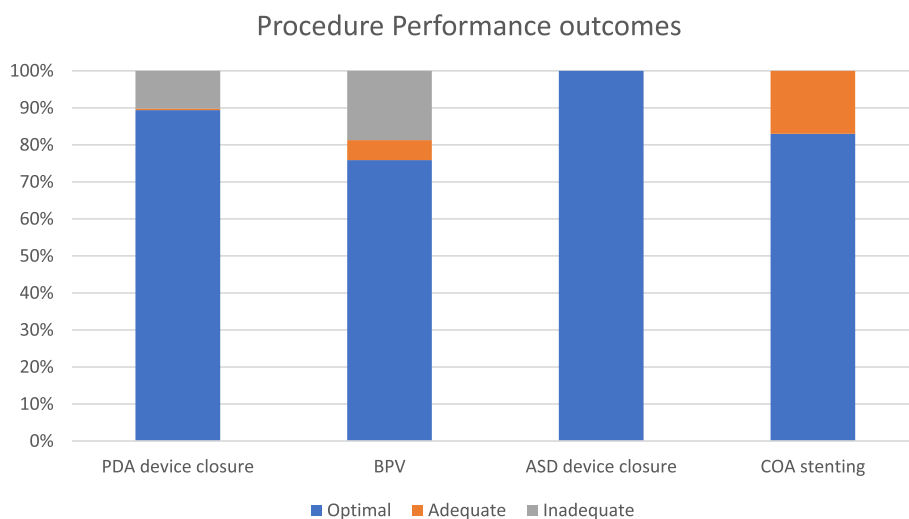


Fig. 4 Procedure performance outcomes at UHI for PDA and ASD device closures, COA stenting and BPV. ASD = atrial septal defect, BPV = balloon pulmonary valvuloplasty, COA = coarctation of the aorta, PDA = patent ductus arteriosus

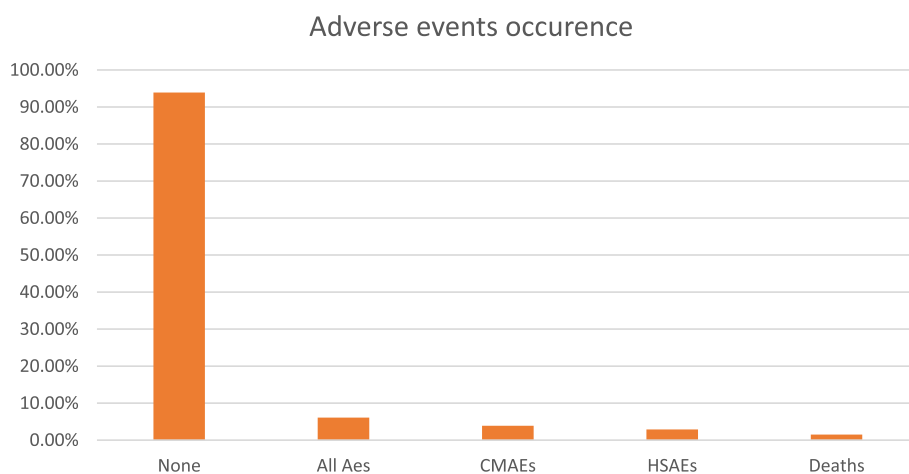


Fig. 5 Summary of adverse events occurrence at UHI for CHD cardiac catheterization. AEs = adverse events, CMAEs = clinically meaningful adverse events, HSAEs = high severity adverse events

clinically meaningful adverse events. Mortality occurred in 13 patients (1.5%). The most common interventional procedures done were PDA device closure and balloon pulmonary valvuloplasty with optimal results in 89.4% and 75.9% respectively. In our setting PDA is the second most common CHD after VSD [23], hence making it the most common lesion treated by cardiac catheterization.

Procedure outcomes

Two interventional procedures were mainly done in substantial numbers at our center; PDA device closure and BPV. Among PDA device closures about nine out of ten patients had optimal results. Compared to results from other low- and middle-income countries reported by

Ali F et al. where PDA device closure had 67% optimal results [18], UHI PDA device closures showed higher optimal results. Inadequate results of PDA device closure (10.2%), were due to failure of closure of some ducts because of lack of appropriate available device sizes, complex duct morphologies, and development of complications, mainly device embolizations. In our settings we often have devices from a single manufacturer (majorly Occlutech duct occluder) which may not be suitable for some duct morphologies.

Pulmonary valvuloplasty at UHI resulted in 75.9% optimal results, 5.4% adequate and 18.7% inadequate results. Inadequate results were due to high peak systolic gradients and adverse events of level 4–5 severity that

Table 2 Detailed description of device embolization/malposition and arrhythmia level 2-4 adverse events that occurred among the patients

AE Severity	Type of procedure	Age	Events	Intervention
4	PDADC	1y	Device embolization to RPA	Surgical retrieval & PDA ligation
4	PDADC	2y	Aortic obstruction by device	Surgical retrieval, PDA ligation
4	PDADC	11 m	Device embolization to LPA	Surgical retrieval & PDA ligation
4	PDADC	2y	Device embolization to RPA	Surgical retrieval & PDA ligation
4	PDADC	9 m	Device embolization to RPA	Surgical retrieval & PDA ligation
4	BPV	11y	Glide wire fractured & embolized to MPA	Surgery
3a	PDADC	22y	Device embolization to RPA	Catheter retrieval, PDA closed by another device
3a	BAS ^a	29y	Device embolized to aorta	Catheter retrieval, referred for ligation
3a	PDADC	1y	Device embolization to RPA	Catheter retrieval, referred for ligation
3a	PDADC	7y	Device embolization to aorta	Catheter retrieval, referred for ligation
3a	PDADC	2y	Device embolization to LPA	Catheter retrieval, referred for ligation
3a	PDADC	1y	SVT during procedure	Adenosine, amiodarone
2	PDADC	1y	SVT during procedure	Spontaneous resolution
2	BPV	2 m	Bradycardia	Atropine
2	BPV	5 m	Bradycardia	Atropine
2	BPV	2y	Bradycardia	Atropine
2	BPV	2y	Bradycardia	Atropine

BAS balloon atrial septostomy, BPV balloon pulmonary valvuloplasty, DC diagnostic catheterization, LPA left pulmonary artery, PDADC patent ductus arteriosus device closure, RPA right pulmonary artery, SVT supraventricular tachycardia

^a This was balloon atrial septostomy and insertion of an atrial flow regulator device in a 29 years old female. She had late repair of total anomalous pulmonary venous return to the coronary sinus at 16 years of age. Later she developed progressive pulmonary hypertension with stage IV heart failure. She was oxygen dependent and wheel chair bound

occurred in this population including cardiac arrests, pulmonary edema and mortality in seven cases. These inadequate BPV results occurred mostly in earlier years, influenced by effects of patients presenting late with critical illness, effects of the learning curve and operator experience. These results are similar to other low- and middle-income countries where BPV had 27% inadequate results [24]. Though small number of patients underwent ASD device closure, VSD device closure and COA stenting at UHL, because these procedures were mainly done during camps with support of visiting teams, these procedures resulted in high optimal outcomes. Our local team is capable of closing ASD by device, however in our settings, most symptomatic cases referred are usually unsuitable for device closure.

Adverse events

The prevalence of all adverse events and clinically meaningful events in our study is similar to studies in other centers that have reported the rate of complications between 2-24% [4-17]. Device embolizations occurred in 11 patients, 10 in PDA device closure (2% of PDA device closures) and one 29 years old female with severe PHT. Previously she had repair of total anomalous pulmonary venous return cardiac type draining to coronary sinus at 16 years of age. She later developed progressive

PHT, heart failure stage IV, was oxygen dependent and wheel chair bound. She underwent atrial septostomy and unsuccessful insertion of an atrial flow regulator (AFR) device. The device embolized to the descending aorta and was retrieved by catheter. A decision was made not to reinsert the AFR. Due to the 5 mm inter-atrial septal defect created, her symptoms improved greatly she was weaned off oxygen and began ambulating without support. Atrial septostomy for adults and paediatric patients with severe PHT has been shown to improve symptoms of heart failure [25-27]. Five of the device embolizations were retrieved by transcatheter method, the other six, were retrieved by surgery. Similar to our findings, Abali Y Z et al. in 2022 reported device embolization rate of 1.4% in Istanbul Turkey [28].

We found vascular access related adverse events in seven (0.8%) of all patients. Five patients developed thrombus formation in the accessed right femoral arteries causing cool right lower limbs, thin or absent distal pulses. These patients received heparin and recovered with no immediate residual effects. Of the five patients with cool lower limbs, four were aged two years and below implying small sized vessels that are easily injured and thrombosed. Age of the patient, vascular sheaths sizes and procedure duration have been shown to contribute to vascular injuries [29]. Six of the patients with vascular complications

Table 3 Detailed description of hemodynamic, respiratory, infectious, hematological and vascular access related level 2-4 adverse events that occurred among the patients

AE Severity	Type of procedure	Age	Events	Intervention
4	DC	1y	Cardiac arrest post procedure	CPR
4	BPV	4y	RVOT tear, cardiac arrest	CPR, surgical repair of RVOT tear
4	BPV	2y	Intraprocedural Cardiac arrest	CPR
4	PDADC	6 m	Severe anemia, cardiac arrest	CPR, blood transfusion
4	BPV	3y	Intraprocedural Cardiac arrest	CPR
4	BPV	1y	Intraprocedural Cardiac arrest	CPR
4	BPV	2y	Pulmonary edema	Ventilation, furosemide
3c	PDADC	2y	Septicemia, severe anemia	Intravenous antibiotics, Blood transfusion
3b	PDADC	3y	Severe pneumonia	Intravenous antibiotics, O2 therapy
3b	PDADC	3y	Septicemia	Intravenous antibiotics
3b	PDADC	1y	Septicemia	Intravenous antibiotics
3b	PDADC	7y	Severe anemia	Blood transfusion
3b	PDADC	2y	Severe anemia	Blood transfusion
3b	DC	2y	Severe anemia	Blood transfusion
3a	DC	9 m	Severe pneumonia	Intravenous antibiotics
3a	PDADC	6 m	Femoral artery thrombus with cool leg	Heparin
3a	PDADC	1y	Femoral artery thrombus with cool leg	Heparin
3a	PDADC	6 m	Right iliac vein dissection, femoral artery thrombus	Heparin
3a	COA stenting	11y	Femoral artery thrombus	Heparin
3a	PDADC	2y	Femoral artery thrombus	Heparin
3a	BPV	9y	Retained stiff wire in the femoral vein	Surgical cut down
2	PDADC	4y	Excessive bleeding form access site	Stitch, pressure compression

AE adverse event, BPV Balloon pulmonary valvuloplasty, COA coarctation of the aorta, CPR cardiopulmonary resuscitation, DC diagnostic catheterization, PDADC patent ductus arteriosus device closure

had a 4 French catheter in the femoral artery during PDA device closure, only one 11 years old male during coarctation stenting had a 12 French catheter in his right femoral artery. We use 4 French femoral artery catheters in most of our patients and occasionally 5 French catheters. Therefore the catheter size was unlikely the cause of artery thrombus formation among these patients. Arrhythmias occurred at a rate of 0.9% of all patients. Significant arrhythmias occurred in two patients that developed ventricular tachycardia, one post diagnostic catheterization of an adult with PDA and severe PHT and the other in an eight months old child undergoing BPV. Both patients died as a result of these adverse events. Vitiello et al. reported a rate of vascular complications of 3.7% and arrhythmias in 2.6% [4]. These rates are higher than what was found in our study. The rate of vascular complications may be underreported in situations where clinical monitoring is the only tool used to detect the events as it was in this study. Kocis et al. using doppler monitoring reported a 32% incidence of flow compromise in arterial pulse after arterial cannulation [8]. A systematic review by Fatima et al. reported prevalence of arrhythmias among right heart catheterization patients of less than 1% which is similar to our findings [30].

Reperfusion pulmonary edema among our study participants occurred in 3.6% of all BPV participants. Lee K E et al. reported a 2.27% rate of respiratory complications in their Korean study, majority had mild complications with only 0.05% having severe manifestation [31]. Pulmonary edema in our participants followed successful BPV and increased pulmonary blood flow following relief of pulmonary valve obstruction. In the year 2017 a policy to administer intravenous furosemide 1 mg/kg during the procedure was adopted, patients were electively admitted into the intensive care unit, remained intubated, and intravenous furosemide was maintained till the patient was deemed stable for discharge. These interventions have possibly reduced the complication given a reduction in the prevalence of post BPV pulmonary edema from 5.9% between 2012 and 2017 to 1.6% between 2018 and 2023. Pulmonary edema also occurred in a patient who underwent diagnostic catheterization. Following administration of high flow oxygen, pulmonary vascular resistance index (PVRI) reduced from 6.1 to 2.8 wood units. The patient developed pulmonary edema, severe respiratory distress, and died. On the other hand, a PHT crisis occurred in a patient with a large secundum ASD and a

Table 4 Description of study participants who died (adverse events severity level 5)

Case	Age	Sex	Kg	Diagnosis	Procedure type	Year	Procedure success Yes /No	Events leading to death	Post-procedure survival
1	4yrs	M	16	Severe PS RV failure	BPV	2012	Yes	Pulmonary edema post procedure	9 h
2	9yrs	M	21	Critical PS RV failure	Failed BPV	2013	No Failed to cross PV	Cardiac arrest post catheterization	4.5 h
3	3yrs	F	15	Trisomy 21, Large PDA, severe PHT	Failed Device closure	2014	No Available device 12/10 slipped into the PA	Severe pneumonia, febrile convulsions	24 h
4	6yrs	F	15	Large PDA, severe PHT	Device closure	2014	No	Device embolization, surgery, Bleeding, cardiac arrest	14.5 h
5	6wk	M	2	DTGA, tiny PFO	BAS	2014	Yes	Self extubation, hypoxia	12 h
6	2yrs	M	10	Large VSD, severe PHT	DC	2014	Yes	Pulmonary edema	3 h
7	2yrs	M	11	Severe PS	BPV	2015	Yes	Pulmonary edema	12 h
8	1 yr	M	8	Severe PS	BPV	2016	Yes	Pulmonary edema, self extubation, cardiac arrest	26 h
9	1 yr	F	10	Severe PS, small PFO, RV failure	BPV	2019	No	Failed to cross pul- monary valve, Cardiac arrest	During procedure
10	6yrs	F	17	Large secundum ASD, severe PHT	DC	2019	Yes	PHT crisis, hypoxia, acidosis, hypotension	12 h
11	31yrs	F	47	Large PDA, severe PHT	DC	2019	Yes	Fever, respiratory distress, ventricular tachycardia	5 h
12	8mo	M	7	Severe PS, 5 mm PFO	BPV	2020	No	Recurrent intraproce- dural cardiac arrests, Ventricular tachycardia and fibrillation	5 h
13	3 yrs	M	13	Severe PS	BPV	2023	Yes	2 cardiac arrests dur- ing BPV, hypoxic brain injury,	5 days

BAS balloon atrial septostomy, BPV balloon pulmonary valvuloplasty, DTGA D transposed great arteries PDA-patent ductus arteriosus, PHT pulmonary hypertension, PS pulmonary valve stenosis, PV pulmonary valve, VSDventricular septal defect, number of BPV done from 2012 to 2017 = 51, 2018–2023 = 61

PVRI of 9.7 wood units on high flow oxygen. Post diagnostic catheterization, she got hypoxia, acidosis, hypotension, and died. These cases of death after diagnostic catheterization emphasize the fact that no procedure is completely safe, vigilance is important at all times.

The risk factor significantly associated with occurrence of a clinically meaningful adverse event and mortality after cardiac catheterization in our study was advanced heart failure at the time of cardiac catheterization. Death occurred in 50% of the 24 patients who had advanced heart failure compared to 0.12% mortality in those who did not have advanced heart failure at the time of cardiac catheterization. Patients with heart failure were generally very ill and this increased their risk of developing CMAES including death. Previous studies have reported younger age and interventional procedures being significantly associated with complications [4] but in our study age did not predict complications.

Other studies have reported that the risk factors for complications among cardiac catheterization procedures include younger age, larger sheath and catheter, urgent procedure, long procedure duration, prior heparin use, more contrast dye use, the presence of pulmonary hypertension, therapeutic procedures, and the procedure year [29, 32–37]. We observed some complications among our study participants because of factors such as young age, long procedure duration, therapeutic procedures compared to diagnostic and presence of PHT. However, these factors were not statistically proven most likely because of small numbers. We did not encounter complications related to contrast use and no evaluation was done to determine the effect of procedure urgency. None of our study participants had been on anticoagulation treatment days prior to the cardiac catheterization procedure.

Table 5 Predictor associations with clinically meaningful adverse events (level 3b, 3c, 4 & 5) or mortality alone

Patient characteristic	Category	No of cases	n (%) CMAES	P value	n (%) deaths	P Value
Age	0 days- < 1year	155	5 (3.2%)	0.96	2 (1.3%)	0.68
	≥ 1 year	702	28 (3.9)		10 (1.4%)	
Gender	Male	329	18 (5.6%)	0.11	7 (2.2%)	0.24
	Female	528	15 (4.6%)		6 (1.2%)	
Weight(kg)	< 3kg	6	1 (16.7%)	0.21	1 (6.7%)	0.08
	≥ 3kg	851	32 (3.8%)		12 (1.4%)	
Advanced Heart Failure	Yes	24	16(66.7%)	< 0.001	12 (50%)	< 0.001
	No	833	17 (2.0)		1 (0.1%)	
Severe acute Malnutrition (weight for height Z score < -3SD)	Yes	46	1 (2.1%)	0.71	0 (0%)	0.83
	No	811	32 (3.9%)		13	
PREDIC3T risk category	1 and 2	813	32 (3.9%)	0.57	12(1.5%)	0.67
	3 and 5	44	1 (2.3%)		1 (2.3%)	
Procedure characteristics	Diagnostic	194	5 (2.6%)	0.29	3 (1.6%)	0.97
	Interventional	663	28 (4.2%)		10 (1.5%)	

Gender, weight and advance heart failure were entered into multivariate analysis model for CMAE while weight and advanced heart failure were entered for mortality Advance heart failure was the only factor significantly associated with both clinically meaningful adverse events and mortality

CMAES, HSAES AND Deaths among varoius PREDIC3T categories

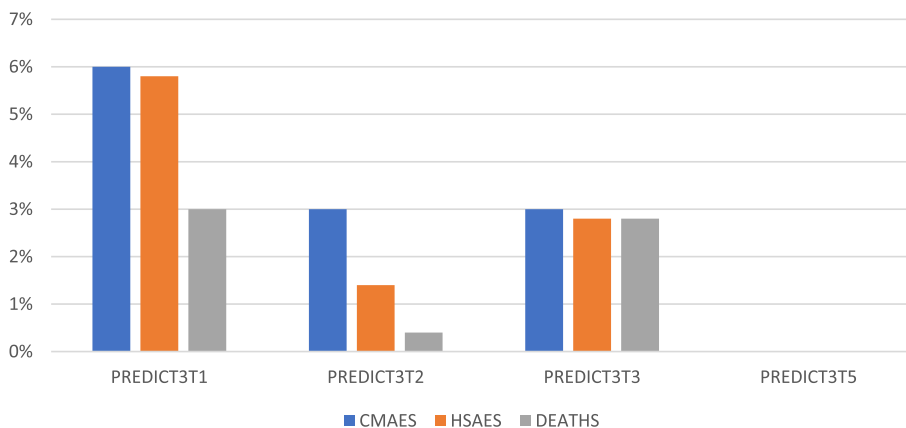


Fig. 6 Occurrence of CMAES, HSAES and deaths categorized by PREDIC3T groups. CMAES = clinically meaningful adverse events, HSAES = high severity adverse events, PREDIC3T = Procedural Risk in Congenital Cardiac Catheterization

Mortality

The mortality rate in this study was found to be 1.5%. This is generally a high mortality related to cardiac catheterization. The years with the highest number of deaths were 2014 (n=4) and 2019 (n=3). The higher number of deaths in earlier years is attributable to the learning curve since the team has been gaining experience over time. Previous studies have reported mortality rates ranging from 0.14% to 1.5% [4, 5, 7] The differences in mortality rates are explained by differences in center experience, the accessible facilities and the nature of lesions being handled. In

our study majority of deaths (7 of 13 patients) occurred after balloon pulmonary valvuloplasty, two after failed PDA device closure, three after diagnostic catheterization studies and one after Balloon atrial septostomy. Deaths in severe pulmonary valve stenosis patients occurred mainly due to cardiac arrests during or after procedure and due to reperfusion pulmonary edema. Most of these patients presented late with right ventricular systolic dysfunction and heart failure. This meant that they were generally high-risk patients. Other factors like learning curve and operator experience also contributed to high mortality rates. Hasan

S et al. reported an evaluation of 270 cases of patients undergoing BPV in the C3PO registry and none of the patients died [24]. These were standard risk patients none of them being admitted for being very ill. In our cohort however, some of the BPV patients were very ill, referred with critical stenosis and heart failure hence high risk for mortality. In one study in Toronto, mortality was highest among critically ill patients and infants below one year [4].

Reflective statement

From our results discussed above, we have learnt that congenital cardiac catheterization can be done with good results even in low resource settings. Partnerships with experienced centers is very key and sponsors are very vital in supporting patients who cannot afford the costs. Adverse events can occur following cardiac catheterization. However thorough evaluation, optimization of patients and taking extra care could help mitigate the magnitude of such adverse events. Early detection of CHD is still lacking in our country and the number of cases done annually is still low. We hope to establish a separate paediatric Cath Lab in the near future so that more days and staff will be dedicated to congenital cardiac catheterization. Coupled with training of more paediatric cardiologists for all regional referral hospitals, we will expect improved early diagnosis and an increased number of CHD cases accessing cardiac catheterization. We are planning to increase VSD device closures, ASD device closures and start doing PDA stenting for patients who need such procedures.

Strengths of this study

This is the first study to describe outcomes of patients who have undergone cardiac catheterization in Uganda. The sample size was adequate. We obtained data for 100% of the patients with CHD who underwent cardiac catheterization during the study period.

Limitations of the study

There were charts with missing information which prevented us from studying some variables such as procedure duration, amount of contrast used, sheath sizes and type of anaesthesia.

We did not do Cardiac Hemodynamic Vulnerability Score risk assessment due to limited resources in our setting.

Conclusions and recommendations

Many patients with CHD have benefited from the cardiac catheterization program at UHI with high optimal results. CHD patients in heart failure at the time

of cardiac catheterization have less favorable outcomes emphasizing a need for early detection and early intervention.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12872-024-04085-6>.

Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions

N.M, T.A and L.S contributed to protocol development, data collection, data analysis, and initial manuscript writing. All other authors contributed to data collection and manuscript review.

Authors' information

Authors include two paediatric interventional cardiologists, five paediatric cardiologists, two cardiac surgeons, two cardiac anaesthesiologists and five paediatric cardiology fellows.

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Availability of data and materials

The dataset used and analyzed during the current study is available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

The study was approved by Makerere University College of Health Sciences School of Medicine Research and Ethics Committee (SOMREC) REC REF 2020-190 and Uganda National Council of Science and Technology (UNCST) HS 1081ES. A waiver of informed consent was given by SOMREC for reviewing charts for participants retrospectively.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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