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Original Article

Complications of paediatric interventional catheterisation: an analysis of risk factors

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Abstract *Objectives:* To identify predictive factors of complications occurring during paediatric interventional catheterisation. *Background:* Interventional paediatric catheterisation is still burdened by a substantial risk. Risk factors, however, have rarely been investigated. *Methods:* We analysed prospectively 1,022 interventional procedures performed over a period of 8 years, excluding 260 procedures for atrial septostomy. We considered several patient-related variables, specifically age, weight, and gender, type of procedure, times required for fluoroscopy and the overall procedure, technical challenge, and the severity of the clinical condition. We also analysed variables linked to the environment, specifically the date of the examination, whether the operator remained in training, the novelty of the material, any breakdown in the installation, and errors made by the operator. We classified complications as those without clinical consequence, those which proved lethal, those requiring cardiopulmonary resuscitation, elective or emergency surgery, hospitalisation in the intensive care unit, and those leading to recatheterisation. *Results:* Our average incidence of complications was 4.1 per cent, which did not change significantly during the period of study. Of the patients, 4 died, 7 needed urgent surgery, 5 elective surgery, 3 hospitalisation in intensive care unit, and 8 recatheterisation. Independent risk factors for complications were technical challenge, critical clinical condition, operator in training, operator error, and breakdown of the installation. Young age was not associated with a higher risk of complications. Patients in whom no cause for complication could be found, either related to their own features or the environment, had a risk of complication of 1.4 per cent (95 per cent confidence intervals from 0.7 to 2.5 per cent). *Conclusions:* Our data show that variables relating either to the patient or the environment of catheterisation are associated with an increased risk of procedural complications. Knowledge of the risk factors can improve the odds of paediatric interventional catheterisation.

Keywords: Congenital heart disease; catheterisation; predictive factors

Interventional catheterisation now plays a significant role in the treatment of congenital heart diseases in children. This technique, despite improvement of technical skills and miniaturisation of interventional tools, is still burdened by substantial risk.[1–3] Previous investigators have examined the incidence of complications during diagnostic and/or interventional catheterisation procedures,[1] and their relationship with various specific procedures.[2,4] Complications have been classified as major or minor, according to their clinical implications, and the principal types of complications have also been examined.[1,3] Analysis of complications, however, can be difficult due to differences in definitions, collection of data, and the length of the period of observation. Analysis of risks can also be subjected to a bias, due to the possible introduction of subjective factors. Predictors of complications have rarely been investigated

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systematically. The aim of our study, therefore, was to investigate the risk factors of paediatric interventional catheterisation, limiting our analysis to severe procedural complications encountered over a period of 8 years.

Patients and methods

In 1997, we developed a database for cardiac catheterisation. This permitted us to record many patient-related variables, such as age, weight, and gender, the time elapsed during fluoroscopy and the overall procedure, the type of interventional procedure, the technical challenge, defined as the need to use more than 2 catheters and 2 guide-wires to accomplish the diagnostic part of the examination, and the severity of the clinical condition, defined as presence of shock or any condition justifying urgent cardiac catheterisation. We chose our definition of technical challenge, because, in our unit, the great majority of studies is performed using 1 or 2 guide-wires and 1 or 2 catheters. We also recorded environmental variables, specifically the date of the investigation, whether the operator had been in training for less than 1 year, whether we were using new material, defined as prostheses or devices used less than 5 times, whether we encountered technical problems because of breakdown of the installation or instrumentation, and any errors that could be identified in the performance of the operator. We classified complications as lethal, those needing cardiopulmonary resuscitation or administration of emergency drugs, those leading to elective or urgent surgery, those resulting in recatheterisation, those needing hospitalisation in intensive care unit for those patients not already hospitalised in the intensive care unit, and those without clinical consequences.

Our definition of complications was relatively narrow in comparison to the literature, since we excluded frequent complications such as transient arrhythmias, not needing treatment, or vascular problems observed after the end of the procedure.

From 9 January 1997 to 1 January 2005, we performed 3,955 catheterisations in children. Of these, 1,282 were interventional procedures. We analysed only severe procedural complications of these interventional procedures in this study. We also excluded 260 procedures from consideration performed to achieve atrial septostomy, this procedure being performed by all physicians of our cardiology department, and sometimes outside the catheterisation laboratory. Thus, we analysed 1,022 interventional catheterisations performed in children. During the period of study, the installation itself did not change, albeit that the composition of the medical team changed in part in September 2001, when one of our number (PB) moved from Paris to London. Procedures were performed by 4 senior operators, and by 10 operators in training. Catheterisation reports were filed by the operator, under supervision of the head of the catheterisation laboratory. The number, type, and difficulty of interventions did not change during the period of study.

Statistical analysis

We obtained descriptive statistics for the total population and all complications, using a χ^2-test to study the relation between complications and all variables.

Independent risk factors for any complication were sought using stepwise multiple logistic regression analysis. Factors that were tested included age, weight, and gender of the patient, the severity of the clinical condition, the type of procedure, the time elapsed for fluoroscopy and the overall procedure, the technical challenge, the date of the investigation, whether the operator was in training, the newness of the material, any breakdown in the installation, and identification of any errors by the operator.

The stepwise logistic regression was performed using SAS Institute Software (Version 8.02, Cary, North Carolina). A p value of less than 0.10 was used for selection for entry into the model, with a p value of less than 0.05 necessary for retention.

Results

Complications occurred in 4.1 per cent of patients. We show the clinical characteristics of these patients, along with the type and consequences of the complications identified, in Table 1.

Of the patients, 4 died (0.68 per cent). These were the consequence of infundibular tearing in 2 patients undergoing dilatation of the pulmonary outflow; of embolic stroke in 1 patient undergoing dilatation of aortic recoarctation, and due to cardiac arrest in 1 patient with palliated functionally single ventricle with pulmonary atresia, who had embolisation of 1 major aorto-pulmonary collateral artery.

Cardiopulmonary resuscitation and administration of emergency drugs was necessary in 6 patients, 3 of whom died during the procedure. These were 1 patient who suffered a stroke during dilatation of aortic recoarctation, 1 patient needing urgent surgery due to occlusion of a shunt, and 1 patient undergoing attempted closure of a patent arterial duct of 16 millimetres diameter. Urgent surgery was required in 7 patients (0.89 per cent). This was because of retention of a coil in a major coronary artery during attempted embolisation of a fistula in 1 patient, because of migration of a duct occluder to the descending aorta during attempted closure of the arterial

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duct in another patient, to migration of a stent into the right ventricle during a procedure on the right ventricular outflow tract in 3 patients, to aortic dissection during primary stenting of native aortic coarctation in 1 patient, and to occlusion of a Blalock–Taussig shunt during dilatation of the shunt in the final patient. Elective surgery was needed 5 times (0.6 per cent). This was because of displacement of a device used to close an atrial septal defect in 2 patients, to tearing of the atrial septum during the same procedure in 2 further patients, and to traum to the femoral nerve after device-assisted suture of the femoral artery in 1 patient.

Recatheterisation was needed 8 times (1 per cent), to retrieve devices used in attempts to close an atrial septal defect in 4 patients, and for attempted closure of the arterial duct in 4 further patients.

Hospitalisation in the intensive care unit was needed in 2 patients, because of a stroke occurring during dilatation of aortic recoarctation and because of

Table 1. Characteristics of the patients with complications, type, and consequences of complications.

N	Age (years)	Weight (kg)	Diagnosis	Type of intervention	Type of complications	Consequences of complications
1	0.4	5.8	PVS	PV dilatation	Infundibular tearing	Death
2	2.3	8.4	PA-VSD	PB stenting	Stent migration	Urgent surgery
3	18	59	Fallot	Coronary fistula embolisation	Coil migration	Urgent surgery
4	12	45	ASD	ASD closure	Septal tearing	Elective surgery
5	14	47	PA-IS	PFO closure	Device embolisation	Recatheterisation
6	11	45	AS	AS dilatation	Femoral nerve trauma	Elective surgery
7	4	12	PA-VSD	PB dilatation	Femoral vein dissection	None
8	1.5	10	FSV	B/T dilatation*	B/T occlusion	Urgent surgery
9	4	3	PA-IS	PA perforation	Infundibular tearing	Death
10	5	18	ASD	ASD closure	Device embolisation	Recatheterisation
11	2	10	PAD	PAD closure	Device embolisation	None
12	15	96	Recoarctation	Direct stenting	Stent migration	None
13	0.2	3.5	PAD	PAD closure	Device migration	None
14	18	56	ASD	ASD closure	Femoral vein dissection	None
15	0.1	1.5	PVS	PV dilatation*	Stroke	Intensive care unit
16	17	54	Fallot	PB stenting	Stent migration	None
17	15	39	PAD	PAD closure	Device migration	None
18	3	14	PAD	PAD closure	Device migration	None
19	6	16	VSD	VSD closure	Haemothorax	Intensive care unit
20	5	17	ASD	ASD closure	Septal tearing	Elective surgery
21	15	65	Mustard	SCV stenting	Haemopericardium	None
22	0.7	7	Mustard	SCV stenting	SCV tearing	None
23	14	52	ASD	ASD closure	Device embolisation	Elective surgery
24	0.5	6	PAD	PAD closure	Device migration	None
25	5d	3	PA-IS	PA perforation	Infundibular perforation	None
26	16	71	ASD	ASD closure	Device migration	Elective surgery
27	0.9	7.5	PAD	PAD closure	Device migration	None
28	7	26	Recoarctation	Aortic dilatation	Aortic dissection	Urgent surgery
29	0.4	5	Recoarctation	Aortic dilatation*	Stroke	Death
30	11	40	ASD	ASD closure	Mild mitral incompetence	None
31	9	38	ASD	ASD closure	Device migration	Recatheterisation
32	1.5	10	PAD	PAD closure	Device migration	Recatheterisation
33	18	56	Mustard	SCV stenting	SCV tearing	None
34	0.5	9	PAD	PAD closure	Device migration	Recatheterisation
35	10	38	PA-VSD	PB stenting	Stent migration	Urgent surgery
36	18	81	Fallot	PB stenting	Stent migration	Urgent surgery
37	4	16	PAD	PAD closure	Device migration	Recatheterisation
38	17	58	PAD	PAD closure	Device migration	Urgent surgery
39	4	15	Fallot	PB dilatation	PB dissection	None
40	12	39	ASD	ASD closure	Device migration	Recatheterisation
41	6	13	PAD	PAD closure	Cardiac arrest	Intensive care unit
42	0.8	6	FSV and PA	MAPCA embolisation*	Cardiac arrest	Death

Abbreviations: PVS: pulmonary valve stenosis; PA: pulmonary atresia; VSD: ventricular septal defect; ASD: atrial septal defect; IS: intact septum; AS: aortic stenosis; FSV: functionally single ventricle; PAD: patent arterial duct; PB: pulmonary branch; PFO: patent foramen ovale; B/T: Blalock–Taussig shunt; SCV: superior caval vein; MAPCA: major aorto-pulmonary collateral artery. *Critical clinical condition

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haemothorax occurring during trans-jugular closure of a ventricular septal defect. Development of aortic regurgitation is often considered a complication of aortic valvar dilatation. In our series, dilatation of aortic stenosis was performed 51 times. This produced moderate to severe aortic regurgitation in 5 patients and mild to moderate regurgitation in 5 patients. Only 1 patient needed elective repair of the aortic valve. Thus, in accordance with our criterions, the incidence of complications after aortic valvar dilatation was 2 per cent. When we included the appearance of new aortic incompetence, it increased to 19.6 per cent.

The incidence of complications was 4.9 per cent in 1997, 2.5 per cent in 1998, 5.8 per cent in 1999, 4 per cent in 2000, 5.3 per cent in 2001, 6.6 per cent in 2002, 4 per cent in 2003, and 0.7 per cent in 2004.

Age and weight were strictly linked variables (r equal to 0.84). Age, when considered in accordance with our criterions, was not a risk factor for complication. Indeed the incidence of complications was 1.94 per cent in newborns, defined as those aged from birth to 30 days, 5.4 per cent in infants aged from 1 to 12 months, 5.58 per cent in children from 1 to 6 years old, and 5.54 per cent in patients older than 6 years (Fig. 1).

The incidence of complications varied from 0 to 23 per cent, in accordance with different types of procedure (Fig. 2). Technical challenge (p less than 0.001), critical clinical condition (p less than 0.001), installation breakdown (p less than 0.001), and operator error (p less than 0.001), were variables highly associated with an increased risk of complications. The first operator remaining in training, and utilisation of new material, were weakly associated with complications (p equal to 0.05).

Technical challenge was encountered in 70 patients (8.9 per cent). This was judged to have occurred in 43.5 per cent of instances of stenting the right ventricular outflow tract, in 42.5 per cent cases of closure of a ventricular septal defect closure, in 31.3 per cent of instances of perforation or stenting venous channels, and in 28.6 per cent of cases involving closure of a Fontan fenestration. In these patients, we encountered 20 complications (28.6 per cent). Urgent cardiac catheterisation was needed in 9 patients (1.1 per cent) because of their unstable clinical condition. In 1 child, there was profound desaturation due to stenosis of a shunt, 2 had right ventricular dysfunction due to severe obstruction of the right ventricular outflow tract, 5 had low cardiac output due to aortic recoarctation or aortic stenosis, and 1 had pulmonary oedema due to pulmonary venous stenosis. Of the 9 patients who needed urgent catheterisation, 8 were less than 1-month old, and 3 of the 9 suffered a complication (Table 1).

An operator in training performed 95 examinations (12 per cent). No correlation was found between the operator being in training and either the type of procedure or the anatomical challenge. In the patients treated by an operator in training, there

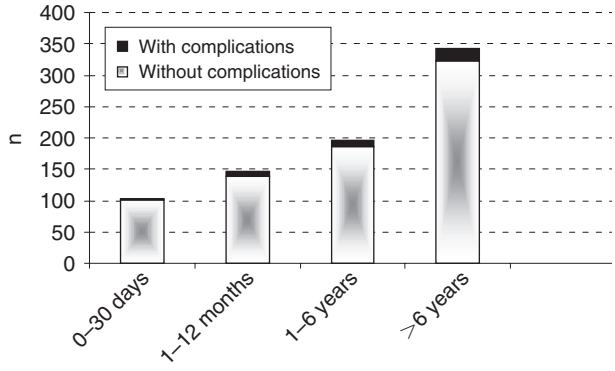

Figure 1.
Age of patients and incidence of complications.

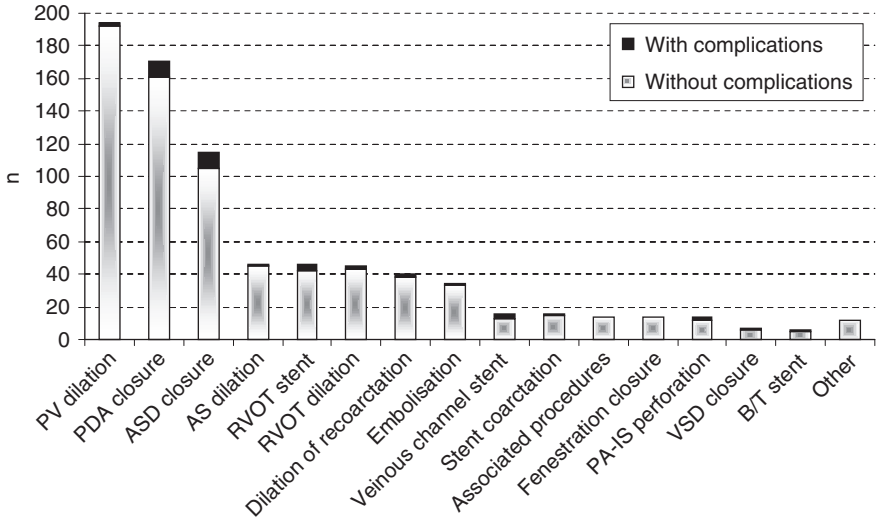

Figure 2.
Type of interventional catheterisation and incidence of complications. PV: pulmonary valve; PAD: patent arterial duct; ASD: atrial septal defect; AS: aortic stenosis; RVOT: right ventricular outflow tract; PA-IS: pulmonary atresia and intact ventricular septum; VSD: ventricular septal defect; B/T: Blalock–Taussig shunt.

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were 9 complications (9.5 per cent). We had used new material 34 times (4.3 per cent), encountering 6 complications (17.6 per cent).

Multivariate analysis of the variance is illustrated in Table 2. This shows that independent risk factors for complications were anatomical challenge, critical clinical condition, operator in training, installation breakdown, and operator error. In patients in whom no patient or environment-related cause for complications was present, the risk of complications was 1.4 per cent, with 95% confidence intervals from 0.7 to 2.5 per cent.

Discussion

Development of interventional catheterisation has led to percutaneous treatment of various congenital cardiac malformations. This approach to treatment, however, is still burdened by a risk of complications. The analysis of complications can be difficult and subjected to bias, due to lack of guidelines on collection of data, definition of the events deemed to be complications, and varied systematic follow-up of patients for occurrence of late clinically unapparent complications, such as occlusion of femoral vessels. Studies on complications of such catheterisations in children are retrospective or prospective, limited to diagnostic or interventional catheterisation, or to particular types of interventions.[4] The difference of methods and objectives in collecting data for analysis of complications can at least in part explain the variability of results.

We defined any event as a complication having, or not having, clinical consequences, but needing elective surgery, recatheterisation, or causing uneventful damage to cardiac or vascular structures. We are aware that this approach could have introduced a bias, mostly linked to exclusion of minor complications. We included deliberately, nonetheless, only those procedural complications having an impact on clinical conditions and/or treatment.

The overall incidence of complications was lower in our series compared to those reported by other authors, which vary from 12 to 24 per cent.[4] As already indicated, however, our data was limited to procedural complications, thus the incidence of early and late events, such as vascular complications and cerebral events, was underestimated. In addition, we did not chart transient uneventful complications needing no treatment, such as transient supraventricular arrhythmias or ventricular extrasystolic beats.

Table 2. Independent risk factors for complications.

Variable	Adjusted odds ratio (95% confidence levels)	p value
Technical challenge	14.5 (6.3, 33.3)	<0.001
Critical clinical condition	8.5 (1.4, 51.1)	0.02
Training operator	4.4 (1.7, 11.3)	0.002
Installation breakdown	38.3 (9.4, 156.1)	<0.001
Human error	47.8 (10, 228.6)	<0.001

We lost 0.39 per cent of our patients. Previous reports describe mortality varying from 0.14 to 6 per cent.[1,5,6] Mortality is known to be higher in infants and newborns, and to be lower over 2 years of age.[3,6–8] This is likely due to the underlying disease of young patients, in whom cardiac catheterisation can be complicated by ventricular fibrillation, stroke, or cardiac arrest.[1,2] We confirmed that mortality is influenced by age, occurring only in patients aged below 1 year. It was the consequence of an error by the operator in 2 of our 4 cases, due to infundibular tearing because of use of a large balloon. In our other two cases, one infant suffered stroke with low cardiac output following attempted relief of severe aortic recoarctation, and the other suffered cardiac arrest during attempted palliation of pulmonary atresia. Thus, in agreement with other authors, we affirm that diligent manipulation of catheters, and correction of any abnormal metabolic parameters, is mandatory in critically ill infants in order to minimise mortality.

Urgent surgery was needed in 1 per cent of cases, and elective surgery in 0.6 per cent, giving a global need of surgical intervention of 1.6 per cent. This result is also comparable to data from other authors.[9] In 2 of our patients, the surgery was performed in the catheterisation laboratory as a rescue procedure for infundibular tearing. In neither instance, however, did it restore stable cardiac activity, and the patients died. In all the remaining cases (0.76 per cent of patients), urgent or elective surgery allowed retrieval of embolised material and repair of the underlying defect. A previous report has pointed to the excellent results of urgent surgery performed after failed interventional catheterisation.[9]

Also in keeping with others,[9] we found the most frequent type of complication in our series to be embolisation of a device. This occurred 22 times, and led to urgent or elective surgery on 7 occasions, and recatheterisation on 8 occasions. The second most frequent event in our patients was perforation of cardiac structures, or tearing of great vessels, occurring in 0.7 per cent of cases. In 2 cases it was fatal. In other series, cardiac perforation has been reported in 0.2–0.34 per cent of cases,[1,3] but was not fatal.

Although arrhythmias are a well-known complication of catheterisation in children, and we frequently observed arrhythmias during diagnostic catheterisation (data not shown), such arrhythmias were transient, and never required pharmacological or endovascular interventions. Due to this, they were not included in the present analysis. It goes without

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saying, nonetheless, that judicious catheter manipulation and correction of any metabolic abnormality is again needed to prevent serious arrhythmias.

Vascular complications are considered the most frequent complications of cardiac catheterisation.[1] In our series, we identified only 2 acute vascular complications, probably due to injudicious manipulation of the catheter. The incidence of vascular injury can certainly be reduced by using low profile tools, by percutaneous use of balloons to diminish the size of sheaths, and by avoiding arterial access whenever possible. The true incidence of arterial compromise after interventional catheterisation is unknown, and probably underestimated.[10]

Like other authors, we found that different types of interventions had markedly different incidences of complications.[2,4] Dilatation of the aortic valve is generally considered a high risk procedure, and most authors regard development of aortic incompetence as a complication.[1,2,4] Despite the fact that, in our series, the development of aortic insufficiency following aortic valvar dilatation was relatively frequent, only 1 patient required early surgery.

Predictors of complications have rarely been investigated systematically. A consensus exists that young age is a risk for occurrence of a complication, that interventional procedures have a risk more elevated than diagnostic procedures, and that some types of interventions are particularly risky.[1,3]

We confirmed that gender, fluoroscopy, and procedural time were not risk factors for complications, but were unable to show that age and the date of the study were independent risk factors for complications, as suggested by others.[1] This probably relates to the fact that, in our institution, fewer interventional procedures are required in newborns and infants than in older patients. Recent miniaturisation of tools has also lowered the overall rates of complication. This could also be due to the fact that exclusion of arterial pulse loss and arrhythmias could have particularly affected the incidence of complications in the younger patients. We confirmed an increased incidence in mortality, nonetheless, in our young patients.

We identified a number of patient-linked and environment-linked variables associated with the occurrence of complications and, although complications occurred despite there being no risk factors, optimisation of the clinical condition of the patient, improvement in the design of equipment, and improvement in technical expertise may all minimise the risk of complications in the future.

An "operator in training" was weakly associated with an increased incidence of complications. Thus, the constant presence of a senior member, and strict surveillance, are mandatory during training. Although technical challenge cannot be avoided, challenging examinations should probably be performed by a senior member of the team. Nevertheless, due to the definition of technical challenge as need of utilising more than 2 catheters and 2 guide-wires to accomplish the diagnostic part of the examination, a bias could have been introduced for examinations performed by operators in training.

Complications observed during the use of new material were likely due to the learning curve. They generally consisted in embolisation of devices, and occurred only during the first few uses. This variable was weakly associated with complications as the introduction of any new technique was rapidly brought into common application. The installation used for our catheterisations dates from 1991. Breakdown, occurring mostly after 2000, was another independent risk factor for complications. In accordance with others,[11] we consider that replacement of equipment when aged should enhance the safety of catheterisation in children.

Sometimes cardiac catheterisation is an urgent procedure performed in critically ill infants. In these patients in particular, optimisation of the metabolic condition and environmental factors is essential in order to minimise the risk of complications. The last but not least independent risk factor for complications was operator error. Definition of operator error is subjected to bias, as no guidelines exist regarding technique and type of material to be used for each type of interventional catheterisation.

Our study has several potential limitations, due to the fact that it is restricted to analysis of immediate complications of interventional paediatric procedures. Due to the lack of guidelines for analysis of complications, the variables to be analysed were chosen by the members of the catheterisation laboratory. In addition, a bias could have been introduced when giving a definition to single variables. Establishment of guidelines for definition of an event as a complication, data collection, choice of variables to be analysed, and length of post-procedural follow-up are all to be encouraged so as to make future investigations more comparable.

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