Pediatric heart catheterization in Norway: Rates and types of complications in new terms

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Abstract

We determined the incidence, type and severity of complications after cardiac catheterization in children with heart disease in Norway and present the results in terms of the International Paediatric and Congenital Cardiac Code (IPCCC) nomenclature for complications. All

pediatric cardiac catheterizations in Norway are performed in one clinical center. All procedures performed during a five-year period beginning in 2010 were prospectively registered, and medical records for cases with complications were reviewed to confirm the event and to re-classify the type, severity and attributability of the complication according to the IPCCC nomenclature. Univariate and multivariate analyses were performed to identify possible risk predictors. A total of 1318 catheterizations performed on 941 patients were included in the study, of which 68 % were interventional. The complication and major complication rates were 5.5 % and 1.4 %, respectively. Trauma to vessels or myocardium, hemodynamic adverse events and arrhythmias were the most common types of complications. In the multivariate model, weight < 4 kg (OR, 3.0; 95 % CI: 1.6 – 5.8) and risk category 5 (OR, 5.1; 95 % CI: 2.1 – 12.3) were significant risk predictors for any complication. In spite of a high rate of interventions, the complication rates in this study were similar to older studies, but diverging methods and terminology limit the comparability. We strongly suggest general use of the proposed IPCCC classification system for registration and reports of complications to pediatric heart catheterizations.

Keywords: Congenital heart disease; Cardiac catheterization; Child, Heart disease; Intervention

Introduction

Since the introduction of heart catheterization to the diagnosis and intervention of congenital heart disease, several studies have evaluated the associated complications and risks. After years of heart catheterization utilization, procedures that are more complex have been developed, including catheter interventions employing advanced equipment and devices. Recent studies have reported quite divergent findings with respect to complications. For example, a study including only interventional cases reported a complication rate of 4.1 % (1), while another contemporary study also including diagnostic procedures found a complication

rate of 19 % (2). While some reports have described each complication separately without further grading (1, 3), others have distinguished between minor and major complications (4-8) or used the more recent five-level system developed by Bergersen et al. in Boston(2). The classification of types of complications has also differed (2, 6, 8). Seemingly, the manner in which occurrence, type and severity of complications have been reported has varied, with different inclusion criteria and classification systems, leading to non-comparable results (9).

Clinicians as well as patients and their families should be well informed about the results of and risks associated with different procedures within the local context. Ideally, the same quality and risk level classification systems should be used for all diagnostic and interventional procedures, regardless of geography and population size. However, consensus on how to report and classify the type and severity of complications remains lacking. Based on the work from the Boston group, The International Society for Nomenclature of Paediatric and Congenital Heart Disease (ISNPCHD) has proposed a new system of nomenclature for both procedures for and complications of heart catheterization in children (9, 10). The system for complication severity level first published by Bergersen et al. in 2008 and, to a certain extent, the risk categories also developed by the Boston group have been previously adopted by other groups (4, 11, 12). To our knowledge, no previous clinical reports have been based on the nomenclature proposed by ISNPCHD, namely, the IPCCC classification system for complications.

The aim of this national single-center study is to evaluate the rate of complications related to heart catheterization in children <18 years with heart disease with respect to type, attributability and severity grade. This study also serves as an attempt to describe our results according to the IPCCC nomenclature for complications.

Materials and methods

The Pediatric Department of Oslo University Hospital (OUS) serves as a national center for invasive cardiology in Norway, where the population currently approaches 5.3 million people.

In the past 25 years, approximately 250 heart catheterizations have been performed in the pediatric population annually. Since 2008, all catheterizations have been electronically logged, and complications have been recorded. Consequently, this study includes all heart catheterizations performed on Norwegian children during the five-year study period from January 2010 to December 2014. Electrophysiologic investigations and interventions were excluded. This study was categorized as internal quality assurance and approved by the hospital authorities.

Almost all catheterizations were performed with patients under general anesthesia and by one of three senior physicians who were assisted by junior physicians. The catheterizations were predominantly performed in the Children's Department Angiography Laboratory; however, some catheterizations were performed at bedside in the intensive care units or in the operating theater. Both diagnostic and interventional procedures were recorded. In cases in which several procedures were performed, the most complicated procedure defined the categorization. The presented number of interventions per catheterization represents a minimum due to the potential for multiple uses of balloons, stents or devices. Myocardial biopsy was coded as a diagnostic procedure, as proposed by IPCCC. A five-level risk categorization developed at OUS-RH was used. Details about the patients and catheterizations are listed in table 1.

Data were registered prospectively in the department's catheterization registry, which was established in 2008. The purpose of the registry is to standardize information about all procedures in the department, and it was not specifically dedicated to complications. Within this registry, an electronic report is filed by the performing physician after each catheterization. This report includes general information about the patient and catheterization, including the occurrence of complications. An additional report about the complication is filed when relevant and completed later in cases of delayed presentation or when follow-up is needed. Multicenter US studies, which have been validated for prediction of both high severity complications (13, 14) and death attributed to catheterization (15), have used four

risk levels. In our clinical setting, five risk categories are well established and were used for the analyses (see S2). Case ascertainment of the registry was validated by detailed review of hospital records for all children who underwent a catheterization during the month of November of each study year, representing approximately ten percent of the total catheterizations.

All catheterizations with complications were identified. In case of more than one, the most severe complication was used in the analyses. Medical records were then reviewed in order to confirm type, severity and course of the complications based on consensus in the author group. Beginning in 2008, the complications were graded as incident/minor/major. However, in light of recent literature, we wanted to apply the classification system proposed by IPCCC. Hence, the complications were re-classified into severity grades 1 to 5 and sorted by type and attributability (9). For descriptions of severity level definitions, see Supplementary Table S1. Preventability and timing were difficult to re-classify retrospectively using the IPCCC system and were not included in this study.

Statistical analyses were performed using SPSS® version 23. The unit of analysis was defined as catheterizations (N=1318), not persons (N=941), and were therefore not completely independent. Univariate and multivariate effects were estimated using logistic regression models and are reported as odds ratios with 95 % confidence intervals and p-values based on the Wald test.

Results

Population and catheterizations

From January 2010 to December 2014, 1318 cardiac catheterizations were performed on 941 patients. Information regarding the patients' age, weight, height, gender, diagnosis and procedure type was recorded at the time of the catheterization. General information about the patients and procedures are presented in table 1. Of the 1318 catheterizations, 902 (68.4 %) were interventional, and the rest were diagnostic. In the 902 interventional catheterizations,

1004 separate procedures were recorded (see table 2). Closures of atrial septal defects and patent ductus arteriosus were the most common procedures. Catheterizations were assigned to one of five risk levels. These risk categories were developed at OUS based on the work of The Congenital Cardiac Catheterization Project on Outcomes (C3PO) (16) (see Supplementary Table S2 for a detailed description).

Complications

The occurrence, type, severity and attributability of complications are summarized in tables 3-5. Of the 1318 catheterizations, a total of 72 complications (5.5 %) were registered. Only two additional complications were identified through validation of the registry data, indicating excellent completeness of the registry. All complications occurred in different individuals except two complications in two patients.

In accordance with the IPCCC system, a total of 31 (43.0 %) complications were categorized as device or intervention adverse events; these were the most commonly identified complications (table 3). Included within this category were stent complications, which included stent embolization (n=3), stent thrombosis (n=3) and stent dislocation (n=1), and device complications, which included device embolization (n=4) and device displacement (n=2). Three complications occurred as a result of balloon dilation; these complications included one event in which the introducer was stuck, another incident in which the balloon would not deflate, and one case with hemodynamic instability after balloon dilation. Coil complications (n=6) included coil embolizations (n=4), one incident in which the coil would not detach, and one event with hemolysis secondary to coil closure. Access complications included perforation of the vessels (n=4) and hematomas (n=3), and biopsy complications included two events with complete but temporary AV-block after several biopsies, which occurred in the same patient. The most common single type of complication was trauma to vessels or myocardium, including perforation of the myocardium (n=12), perforation of vessels (n=2), papillary muscle rupture (n=1) and worsening of subpulmonary atrioventricular valve regurgitation (n=1). A number of arrhythmias were also noted, including atrial flutter

(n=4), atrioventricular block (n=4), and supraventricular tachycardia (n=1). Hemodynamic complications included a coronary spasm (n=1) and hemodynamic incidents such as bradycardia, desaturation and hypotension (n=9). Of these complications, four ended in cardiac arrest, including two fatalities.

When categorizing adverse events according to attributability (table 4), complications related to catheter manipulation were the most common. Access-, device (i.e. stent, coil, device)- or dilation-related complications accounted for a majority of the remaining complications.

Concerning severity levels (table 5), 50 (3.8 %) were considered at least moderate complications ($\geq$ level 3), and 19 (1.4 %) complications were graded as major ($\geq$ level 4). The distinction between normally occurring events and a complication of severity level 1 is not always clear, and minor complications without any consequences are most likely underreported in our study. In particular, this applies to complications related to the anaesthesia and hemodynamic instability, such as need for bolus doses of fluid and inotropic support. Three patients (0.23 %) died following catheterization, and all of these patients had severe and complex cardiac diseases. Two of these complications were attributed to the catheterization itself; pulmonary embolism following extensive pulmonary angioplasty was identified in a seven-year-old child, and atelectasis due to bronchial stenosis causing persistent desaturation was the explanation in a 4-month-old child during preoperative evaluation for Fontan surgery. Death occurred 15 minutes and 12 hours after the procedures of the seven-year-old and four-month-old child, respectively. The third death was attributed to a preexisting condition. This fatality occurred as a consequence of hemodynamic instability 20 hours after the opening of an atretic pulmonary valve in a newborn infant.

Risk predictors

Table 6 shows the frequencies of complications in relation to the type of catheterization (diagnostic or interventional), age, weight, risk category 1-5, and procedure time. Univariate associations between these variables and the occurrence of any complication and high severity

complications are shown as odds ratios. Age, weight, risk category and procedure time were identified as the most important univariate predictors of complications.

In table 7, the same predictors except for age and procedure time are included in two multivariate models with the same response variables: any complication and high severity complications. Due to a high correlation between age and weight (Spearman's rho, 0.82), only weight was included in the multivariate analysis. Since procedure time may well be a consequence of the actual complication, its predictive value may be limited, and therefore this variable was not included in the multivariate model. After controlling for type (diagnostic or intervention), weight and risk category 5 remained the strongest predictors of complications.

Discussion

This study reports national data on the type, attributability and severity grade of complications related to pediatric heart catheterization in Norway during a five-year period and is, to our knowledge, the first publication based on the IPCCC nomenclature.

Complications

We found a total complication rate of 5.5 %, which is at the lower end of the range from 4 % to 19 % presented in several other studies (1, 2, 5-8, 11, 17-20). One explanation for this relatively large variation could be the use of different definitions and inclusion criteria for complications. Further, the number of complications may be dependent on the type of patients and procedures. In general, the complexity associated with both patients and procedures has increased over the years; however, few previous studies have presented detailed descriptions of risk stratification according to patients and/or procedures. Our study has the highest reported proportion of interventions, and we find no reason to believe that the low rate of complications could be explained by the simplicity of the cases. However, there has been less discrepancy in previously described incidences of both mortality and major events, with previously reported high severity events ranging from 3.9 % to 9 % (2, 11-13, 16, 21) and major events ranging from 1.4 % to 2.9 % (2, 6-8, 14, 16, 18, 22). In our study, high severity

complications, defined as severity level ≥ 3 , occurred in 3.8 % (n=50) of all cases, and major complications, defined as severity level ≥ 4 , occurred in 1.4 % (n=19) of all cases. The mortality rate of 0.23 % identified in our study is in accordance with previous studies in which the rate varied from 0.14 % to 0.68 % (1, 2, 5-8, 11, 14, 18, 20).

Trauma to myocardium or vessels, hemodynamic complications and arrhythmias were the most common complications among our patients. Although direct comparison is difficult, arrhythmias have been reported as one of the most frequent types of complication in several recently published studies (2, 5-7, 11, 14, 18) and in some of the first reports published on the subject (10, 11). It is, however, difficult to compare results from different centers, as the classification of complications may differ considerably between institutions.

Risk factors

In the multivariate model, we found low weight to be associated with both any complication and high severity complications. This inverse relationship has been well documented in other studies (2-5, 14, 23, 24). There was also a significant univariate effect of low age (< 1 month) on complications, which is also in accordance with other studies (2, 5, 6, 8, 14). Since weight and age are highly correlated, we only included weight in our multivariate model, as we considered it the more clinically relevant variable.

Several studies have reported significant risk differences between interventional and diagnostic catheterizations, with interventional procedures carrying the highest risk (2, 5, 8, 17, 20). We also found higher complication rates for interventional than diagnostic catheterizations: 6.3 % vs 3.6 % for any complication ($p = 0.047$) and 4.7 % vs. 1.9 % for high severity complications ($p = 0.019$). Even though this variable (diagnostic vs. intervention) was not significant in the multivariate model, we decided to include it in the final model as a control variable.

Risk categories

After all patients had been designated into a risk category (1-5; see S2), we found a significant association between the three highest risk groups and any complication and the two highest risk groups and high severity complications within the univariate analysis. In the multivariate analysis the effect of risk category 5 remained highly significant for both any complication and high severity complications.

Limitations

The physicians performing the catheterizations in this study prospectively collected data, and there may have been inaccuracies when filing each catheterization report. As mentioned, minor complications are most likely underreported in our study. The reclassification of complication type, attributability and severity level in retrospect is also a possible source of error. However, all complications were reviewed in detail according to instructions that included clinical examples. While some postprocedural complications had been registered, two late complications not in the registry were recognized by chart review. The effect of missing data is most likely limited. The use of catheterizations instead of individuals as cases in the study could be questioned with respect to independency. However, growth, surgical treatment and hemodynamic conditions probably outweigh pure interindividual differences. Besides, the low recurrence rate does not affect the results.

Conclusion

Norwegian national data used in the assessment of risks associated with cardiac catheterization in children were comparable with similar international publications in spite of a high rate of interventions. Based on 1318 catheterizations in 941 patients, we found an overall complication rate of 5.5 %. Weight and risk category were major determinants of complications. Diverse reporting systems remain an obstacle for more extensive comparisons across centers. However, we were able to classify most of our cases into meaningful categories using the IPCCC system. With the use of established international systems, the opportunity for more consistent reporting of complications from different centers increases.

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Conflicts of Interest

None.

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