


# Exploring procedure duration and risk for serious adverse events during congenital cardiac catheterization

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## ABSTRACT

**Objectives** While procedure length is considered an important metric for cardiothoracic surgical procedures, the relationship between procedure length and adverse events (AEs) in congenital cardiac catheterizations has little published data available. Furthermore, most existing congenital cardiac catheterization risk prediction models are built on logistic regression models. This study aimed to characterize the relationship between case length and AE occurrence in congenital cardiac catheterization while adjusting for known risk factors and to investigate the potential role of non-linear analysis in risk modeling.

**Design** Age, case type, and procedure duration were evaluated for relationships with the primary outcome using logistic regression. Non-linearity of the associations with continuous risk factors was assessed using restricted cubic spline transformations.

**Setting and participants** All diagnostic and interventional congenital cardiac catheterization cases performed at Boston Children's Hospital between January 1, 2014 and October 31, 2019 were analyzed.

**Main outcome measure** The primary outcome was defined as the occurrence of any clinically significant (level 3/4/5) AE.

**Results** A total of 7011 catheterization cases met inclusion criteria, with interventional procedures accounting for 68% of cases. Median case duration was 97 min. A multivariable model including age, procedure type, and case duration showed a significant relationship between case duration and AE occurrence (OR 1.07 per 10 min increase, 95% CI 1.06 to 1.09,  $p < 0.001$ ).

**Conclusions** This study demonstrated the importance of procedure duration as a potential frontier for procedure risk management. Better understanding of the role of procedure duration in cardiac catheterizations may provide opportunities for quality improvement in patient safety and resource planning.

## INTRODUCTION

Minimizing the amount of time required to complete a surgical procedure has been shown to significantly impact outcomes in cardiothoracic surgery and has been considered of paramount importance.<sup>1</sup> However, the relationship of prolonged case duration on the occurrence of adverse events (AEs) has not been explored in cardiac catheterization

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ While procedure length is considered an important metric for cardiothoracic surgical procedures, the relationship between procedure length and adverse events in congenital cardiac catheterizations has little published data available.

## WHAT THIS STUDY ADDS

⇒ In this single center analysis, a multivariable model including age, procedure type, and case duration showed a significant relationship between case duration and adverse event occurrence in congenital cardiac catheterization (OR 1.07 per 10-minute min increase, 95% CI 1.06, to 1.09,  $p < 0.001$ ).

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study demonstrated the importance of procedure duration as a potential frontier for procedure risk management. Better understanding of the role of procedure duration in cardiac catheterizations may provide opportunities for interdisciplinary quality improvement work in patient safety and resource planning.

for congenital heart disease. In previous work, risk factors were identified in this population, most importantly the type of procedure performed and the age of the patient undergoing cardiac catheterization.<sup>2-4</sup> In this analysis, we sought to explore the relationship between case length and AE occurrence in congenital cardiac catheterization, while adjusting for known risk factors.

## METHODS

All diagnostic and interventional congenital cardiac catheterization cases performed at Boston Children's Hospital between January 2014 and October 2019 were analyzed. Type of procedure (diagnostic only or interventional) and patient age at catheterization were extracted from local databases. Case length was defined as time from sheath-in to



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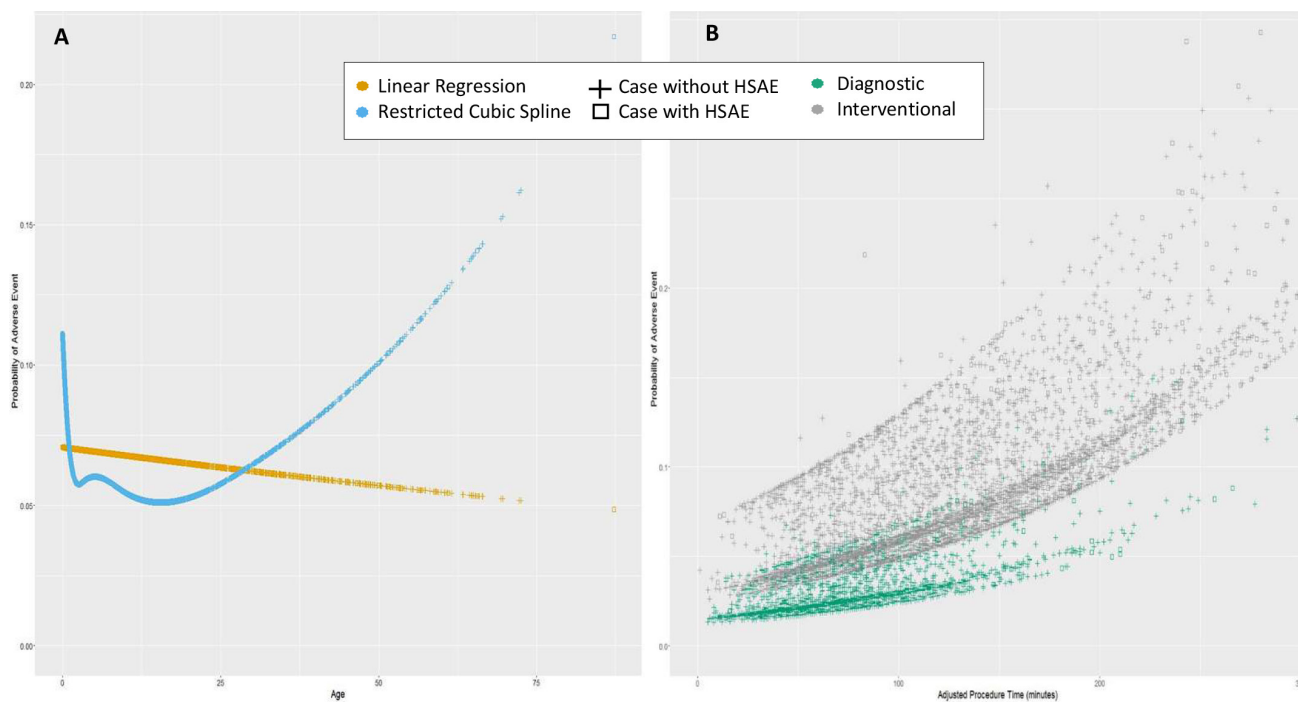
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sheath-out minus minutes spent managing an AE in cases with complications. The primary outcome was any clinically significant AE defined as any change in condition or unintended potentially harmful event possibly or definitely due to the catheterization procedure that was or could become life-threatening requiring invasive monitoring or treatment, in accordance with complication severity levels 3, 4 and/or 5 defined by the International Pediatric and Congenital Cardiac Code.<sup>5</sup>

All procedures with case length between 5 and 300 min were included. Univariate logistic regression models were used to evaluate the relationships between age, case type, and case length and the primary outcome. The existence of nonlinear relationships between case length and age with AE occurrence were assessed by performing likelihood ratio tests (LRT) between two nested models: (1) a model with the linear continuous variable and (2) a model with a restricted cubic spline expansion of the continuous variable. A restricted cubic spline expansion can flexibly model a non-linear relationship by splitting a range of values into intervals and fitting separate curves within each interval. An LRT  $p < 0.05$  was considered statistically significant. To determine the presence of an independent relationship between procedure duration and occurrence of AE, a model adjusting for type of procedure and age was created. We also fit models stratified by diagnostic vs interventional catheterizations, again adjusting for age.

## RESULTS

A total of 7011 catheterization cases met inclusion criteria in infants (27%), children (61%), and adults (12%). Interventional procedures were performed in 68% of the population. Median case duration was 97 min, with longer case times among interventional cases (116 min, compared with 69 min for diagnostic only,  $p < 0.001$ ). The AE rate in the cohort was 6.9%. AE rates were higher among interventional cases, 8.6% vs 3.2% in diagnostic only procedures (OR 2.84, 95% CI (CI) 2.20 to 3.66,  $p < 0.001$ ). For cases with an AE, the median case duration was 131 min compared with 95 min in cases without an AE ( $p < 0.001$ ) and a linear relationship was observed between case duration and the log odds of AE (OR 1.08, CI 1.07 to 1.10,  $p < 0.001$  for each additional 10 min of case length). The restricted cubic spline expansion did not provide a better fit for case length but did for age. AEs were more common among neonates and adults over the age of 35 years, and thus age was subsequently included in the multivariable model using a restricted cubic spline (figure 1A). A multivariable model including age, procedure type, and case duration showed a significant relationship between case duration and AE occurrence (OR 1.07 per 10 min increase, 95% CI 1.06, 1.09,  $p < 0.001$ ) (figure 1B). When stratified by diagnostic only versus interventional procedures the same pattern emerged, with a higher OR for each additional 10 min case length increase for diagnostic cases than interventional cases.



**Figure 1** (A) Linear (orange) and restricted cubic spline (non-linear) (blue). Relationships between the probability of a high severity adverse event (HSAE) and patient age at catheterization (n=7,011). Likelihood ratio test,  $\chi^2(3)=33.77$ . (B) Fitted values for the probability of a high severity adverse event by adjusted procedure time, adjusting for age and procedure type, stratified by diagnostic catheterizations (green) and interventional catheterizations (grey).

## DISCUSSION

Cardiac catheterization case duration was found to be an independent and important factor related to patient risk in congenital cardiac catheterization procedures in this population. Because of the technical aspects of performing different procedures and variation in established risk of different interventions, further research is needed into the relationship between case-specific factors such as individual interventions and procedure duration. However, a significant relationship is identified in the diagnostic only cases, which may minimize the impact of these factors. In addition, common procedure durations for isolated procedure types will be necessary for comparative outcome reporting and quality improvement work. These findings provide an opportunity for interdisciplinary quality improvement work due to potential relationships with sedation, preoperative case management, and equipment preparation as a few factors that may relate to both procedure time and patient outcomes.

While this cohort primarily included pediatric patients, interventional catheterization is increasingly common among adults with congenital heart disease and procedure time vulnerability will be equally important.<sup>6</sup> In clinical practice, attention to procedure duration will improve efficiency and based on these findings may also mitigate patient risk. Efforts to minimize procedural duration must not result in compromised quality of the procedure performed and unintended consequences in either domains of safety or procedural effectiveness. These will be critical balancing measures in any quality improvement initiative pursued as it relates to improving procedural efficiency.

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