Learning outcome, instructions for completing the evaluation, and statements of disclosure can be found on page 168.

Assessing Use of Pain Medication After Pediatric Cardiac Catheterizations

Emily Moore, Arlene Armatage, Jennifer Keylon, Matthew D. Files, and Jack C. Salerno

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Little data exist regarding pain after a pediatric cardiac catheterization and whether there is a requirement for opioids. As part of an improvement activity, a prospective cohort study was performed to assess pain related to cardiac catheterization and subsequent usage of pain medication following a cardiac catheterization. Of 745 patients studied, the majority had either no pain or pain controlled by acetaminophen. There were 14 (1.9%) patients who had pain unrelieved by acetaminophen, with 7 of these patients having pain at their vascular access site with associated complications. Findings indicate a limited number of pediatric patients require opioid pain relief following cardiac catheterization. This study changed practice surrounding post-procedural pain related to cardiac catheterization because opioids were no longer prescribed. Nurse follow up occurred within 48 hours of each procedure, and any patient experiencing pain was immediately triaged and evaluated by the healthcare team. The study showed persistent pain following a cardiac catheterization is an important sign of potential complication. Although pain control is important, it is also important to target pain relief to the appropriate level required for comfort.

Key Words: Cardiac catheterization, pain, pediatrics, quality improvement.

Pain control after a pediatric cardiac catheterization historically has not been studied. Additionally, the use of pain medication related to cardiac catheterization is not supported by evidence. A cardiac catheterization can be a stressful experience associated with a high incidence of child behavioral changes, including aggression, separation issues, regression, and anxiety, with more severe effects observed in younger children (LeRoy et al., 2003). Surprisingly, little data exist on the painful nature of pediatric cardiac catheterizations. Data are especially scarce on the degree and duration of pain post-discharge, which is particularly important for same-day procedures, such as a cardiac catheterization (Russell, von Ungern-Sternberg, & Schug, 2013). Current evidence suggests that severe pain in children has significant long-term effects, including lasting fear of the medical setting and behavioral problems (Brasher et al., 2014). Therefore, treating post-cardiac catheterization pain appropriately is important.

Significance

The most commonly reported incidence of congenital heart defects in the United States is between 4 and 10 per 1,000, clustering around 8 per 1,000 lives births (American Heart Association [AHA], 2013). Approximately two to three of these infants are estimated to have critical disease requiring cardiac catheterization or cardiac surgery shortly after birth and throughout their life span (LeRoy et al., 2003). The overall complication rate associated with cardiac catheterization is low. The incidence of adverse events within the catheterization laboratory was 5.4%, which was lower than the multi-institutional average of comparable pediatric hospitals, where the overall risk of an adverse event was 15% (Bergersen et al., 2011). Bergersen and colleagues (2011) defined adverse events as any anticipated or unanticipated event for which injury could have occurred, or did occur, potentially or definitely as a consequence of performing the catheterization. Pain at the vascular access site is considered an adverse event, and appropriate pain management is necessary; however, the use of analgesia that exceeds the requirement for pain management is a safety concern.

Emily Moore, MSN, RN, CCRN, CPNP-PC, *is a Registered Nurse Practitioner, Division of Cardiology and Cardiac Surgery, Heart Center at Seattle Children's Hospital, Seattle, WA.*

Arlene Armatage, BSN, RN, *is a Cardiac Catheterization Nurse, Division of Cardiology and Cardiac Surgery, Heart Center at Seattle Children's Hospital, Seattle, WA.*

Jennifer Keylon, BSN, RN, *is an Electrophysiology Nurse, Division of Cardiology and Cardiac Surgery, Heart Center at Seattle Children's Hospital, Seattle, WA.*

Matthew D. Files, MD, *is an Assistant Professor, Division of Pediatric Cardiology, Department of Pediatrics, University of Washington, Seattle, WA.*

Jack C. Salerno, MD, *is a Professor, Division of Pediatric Cardiology, Department of Pediatrics, University of Washington, Seattle, WA.*

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The need for opioid pain medication following cardiac catheterization is questioned given the risks of opioid use involved. Clearly defining pain related to cardiac catheterizations would help describe the adequacy of analgesics, specifically the use of acetaminophen post-cardiac catheterization, while also examining factors associated with inadequate analgesics post-cardiac catheterization. The driving factor for this study was the concern regarding appropriateness of pain treatment, specifically, whether opioids were indicated. Although pain control is important, it is also important to target pain relief to the appropriate level required for comfort.

Purpose and Aims

The purpose of this study was to determine the amount of pain experienced after a cardiac catheterization by assessing pain, as well as the use and adequacy of analgesics post-cardiac catheterization. The primary aim was to establish and understand the degree of pain following each procedure, which would then direct appropriate treatment of post-procedural pain in the future.

The specific aims of this study were to a) assess pain level reported post-cardiac catheterization, b) describe medication usage post-cardiac catheterization, c) describe the adequacy of analgesics used post cardiac catheterization, and d) examine factors associated with inadequate analgesics post-cardiac catheterization.

Background

In part, this study was expedited as a result of a sentinel event involving an opioid dosing error following an outpatient procedure. The error prompted a thorough evaluation of policy and procedure regarding appropriate treatment of acute post-procedural pain. This event directly affected patients undergoing cardiac catheterization. Prior to the sentinel event, patients were routinely sent home with an opioid prescription without close follow up. Establishing and maintaining an institutional pain performance improvement plan is a Joint Commission (2011) requirement. Thus, the need to determine treatment of pain post-cardiac catheterization is of high importance. According to the American Academy of Pediatrics (AAP), post-procedural pain management encompasses the use of different classes of drugs, including opioid and non-opioid analgesics (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001). Opioids are indicated to manage moderate to severe post-procedure pain. The use of other analgesics, such as acetaminophen and nonsteroidal anti-inflammatory agents in combination with opioids, can reduce the amount of drug required (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001).

Pain, as described in the formal definition, "is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (International Association for the Study of Pain [IASP], 2015). This, in conjunction with any medical intervention that may be potentially painful or cause anxiety, can be referred to as procedural pain (IASP, 2015). Due to its procedural nature, cardiac catheterization may cause procedural pain. Effective treatment of pain is contingent upon appropriate pain assessment at regular intervals, as well as re-assessment after pain relief interventions (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001). Pain can be assessed using self-report, behavioral observation, or physiologic measures, depending on the age of the child and his or her communication capabilities. Because pain is a subjective experience, individual self-report is often favored; however, it is important to be sure that children, particularly those between 3 and 7 years of age, are competent to provide information before their report of location, quality, intensity, and tolerability are accepted (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001). Seemingly, acute pain is undertreated due to inadequate pain assessment. In a sample of physicians and nurses, Anderson and colleagues (2000) found lack of pain assessment was one of the most problematic barriers to achieving pain control (Wells, Pasero, & McCaffery, 2008). Thus, to implement and properly treat patients, assessment of pain needs to be well understood.

There is no clear information regarding pain management after cardiac catheterization. Opioids are often prescribed without evidence of need. The need for opioids post-catheterization has not been historically assessed. A literature search was conducted to identify evidence related to pain and cardiac catheterization in children. A Cochrane Database and PubMed search of articles was conducted using the search terms *pain, pediatrics, post-procedure, procedural pain*, and *cardiac catheterization*. Selection criteria included randomized studies comparing opioid, local anesthetic, anxiolytic, no treatment, or placebo administered for alleviation of pain or discomfort of the femoral sheath removal procedure. Two major reviews were found. The first was specifically related to preparing children for invasive cardiac procedures and appropriate therapeutic pain control pre-cardiac catheterization, but it did not address post-catheterization pain strategies (LeRoy et al., 2003). The second was in relation to pain after sheath removal in the adult population (Wensley, Kent, McAleer, Price, & Stewart, 2008). This review concluded that some patients experienced pain at the time of sheath removal but not generally after. It also stated, with the initiation of topical anesthetics, pain scores were significantly reduced.

Research has proven the psychological effects of poor pain management has the potential to cause long-term consequences, such as increased anxiety, avoidance, somatic symptoms, parental distress, and overall fear of the healthcare setting (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001). An important responsibility for any provider taking care of children is appropriate pain control. According to the AAP, pain is an inherently subjective multifactorial experience, and should be assessed and treated as such (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001).

Methods

Design

The design was consistent with the quality improvement nature of the study, meaning continuous pro-

cess improvement (CPI) goals were identified and methodology was used. CPI is the institutional ongoing approach to management and treatment of a particular patient population or diagnosis or services. Given the nature of this CPI study, a prospective cohort study using a phone survey was created and then conducted. From April 2012 to November 2013, 1,074 patients came through the cardiac catheterization lab. Patients undergoing pacemakers and cardioverter-defibrillation implantation were excluded. Within 24 to 48 hours post-cardiac catheterization, nurses placed follow-up phone calls. Using age-appropriate tools, families and/or patients were asked a series of questions to assess the presence, location, intensity, and treatment of pain after their procedure.

Subjects

All cardiac catheterization laboratory patients within our institution, ranging from one day of life up to 23 years of age, were included. Because the study took place at a pediatric hospital, the majority of patients were school age or younger. Patients older than 20 years of age had been treated within our institution for many years and had been followed for pediatric-specific cardiac disease. The patient population ranges from those who have the most complex congenital cardiac defects requiring interventions within the first hours of life to patients with normal hearts having an elective electrophysiology procedure. Pediatric cardiac catheterizations can take 3 to 5 hours and are most often performed with general anesthesia.

Setting

The study was conducted in a 371-bed pediatric tertiary care center that serves the entire Pacific Northwest, including Washington, Wyoming, Alaska, Montana, and Idaho. These five states cover approximately one-quarter of the nation's land mass. The center has two pediatric catheterization laboratories that sit within a 15-unit operating room bay. The labs are staffed by seven University of Washington physicians performing the procedures. Pre- and post-cardiac catheterization care is provided by seven cardiovascular advanced practice providers.

Instruments

After reviewing the hospital policy and procedures for post-surgical and procedural follow up, in combination with the pain service, a questionnaire was designed to specifically assess post-cardiac catheterization pain. The pain service consult was made to help the cardiac team fully understand the nature of pain, assessment, and treatment. The pain service physician and advance practice provider aided in developing a tool adapted from the standard hospital post-surgical follow-up questionnaire. The questionnaire is specific to the institution regarding post-surgical/procedural telephone follow up. It contained six questions. Basic questions for all patients consisted of assessing for the presence of pain. These questions included asking if the child was acting differently, was the child unusually fussy or hard to console, and does the child appear comfortable. Information obtained from the telephone interview was documented. Specifically, pain was differentiated between vascular access sites or generalized muscular skeletal pain. Lastly, the use of acetaminophen was recorded in a post-procedure log book kept in the cardiac catheterization lab. If used, post-medication pain scores were assessed. If another language was spoken, interpreters were used.

To assess pain on a more standard scale by means of a remote phone call, the Wong-Baker FACES scale was used. This tool was originally created with children to help them communicate about their pain. Now it is used around the world with people ages 3 years and older, improving pain assessment to achieve proper pain management (Jacob, 2007). In the 1980s, Donna Lee Wong and Connie Morain Baker conducted a study to validate and determine reliability of six pain scales, The FACES scale was included in these studies. Their finding concluded that children ages 3 to 18 years old preferred the FACES scale over the other scales. Despite this preference to one standardized scale, it was demonstrated there was no specific superiority in validity or reliability to any one pain scale (Wong & Baker, 1988). The FACES scale consists of six faces ranging from smiling to a tearful face. Pain is rated from 0 to 10. A child is told that each face represents a person and emotion. For example, a person feels happy because there is no pain or a person is very sad because there is a lot of pain (Jacob, 2007). This scale historically has worked well for children over 3 years old due to both the faces and numerical rating of the instrument. Self-report is the most reliable method of pain assessment. Obtaining an accurate measurement of pain is vital to gauging baseline discomfort and response to therapy (Garra et al., 2010).

Procedures

After obtaining exemption from the hospital's Institutional Review Board, the cardiac catheterization nurses attended a training session regarding pain and pain assessment in preparation for data collection. Pain severity assessment as required by The Joint Commission (2011) is intended to improve the quality of pain management. A standard procedure was implemented by the catheterization lab staff for how follow-up calls would take place. Nurses called patients and families within 24 to 48 hours of their procedure, implementing the questionnaire to assess pain. If unable to contact the patient, the nurse left a message. An attempt was made to call again if patients did not call back.

Prior to the start of each catheterization, nurses met with patients and parents explaining the need for post-procedure pain assessment. Typically, post-procedure pain is greatest within the first two days following a procedure (Brasher et al., 2014). Therefore, families were told they would receive a call from a cardiac catheterization lab nurse within 24 to 48 hours post-catheterization. Due to the nature of congenital heart disease and the need for semi-regular cardiac catheterizations to monitor heart disease, a large portion of patients treated had been through the catheterization lab more than once. Because pain is considered the fifth vital sign, and assessment of pain is standard practice, these patients had an increased familiarity with the FACES scale. This was confirmed by asking parents and patients prior to the administration of anesthesia how familiar they were with the FACES scale. Those not familiar with the FACES scales were given additional education regarding age-appropriate pain tools in the pre-operative area.

Children older than age 7 years were given the Wong-Baker FACES scale. Children ages 3 to 7 years were assessed by cardiac catheterization nurses prior to anesthesia regarding each child's ability to rate pain using the FACES scale. Parents were present at the time of the assessment for teach-

ing purposes. The inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is needs appropriate pain-relieving treatment (IASP, 2015). Thus, parents of children birth to 3 years, developmentally delayed patients, and those who appeared unable to use the FACES scale were given increased education regarding different indications for pain.

Once initial pain assessment was completed, each patient was evaluated by an anesthesiologist. The vast majority of patients are put under general anesthesia. If the patient is particularly anxious, the anesthesiologist may opt to administer an anxiolytic medication (commonly oral midazolam) several minutes prior to the start of the catheterization. After the procedure, the child is then transported to the anesthesia care unit (PACU) for further observation until fully awake.

Before and after each procedure, patients and families were given post-cardiac catheterization discharge instructions. This was to provide appropriate anticipatory guidance for pain and potential complications once home. Patients were instructed to limit themselves to light activity for 48 hours, avoid any added stress on the vascular access site, and remove their pressure dressing at 24 hours post-procedure. Patients were advised that bruising is normal, and the presence of a bruise at the time of dressing removal is common. If the bruise increased in size or a hematoma forms, or a large knot formed under the skin, they were instructed to call the cardiologist. Additionally, they were to call if there was any fever, redness, or drainage noted. Lastly, they were to call if there was numbness, tingling, or pain not relieved by acetaminophen.

Data Analysis

Patients were assigned to one of two groups: those who experienced pain and those who did not. SPSS statistical software version 19 was used to evaluate the data (SPSS, Inc., Chicago, IL). A *p*-value of less than 0.01 determined statistical significance using Fishers exact test.

Results

Sample Characteristics

A total of 1,074 procedures were performed during this period. Of the total sample, 72% completed the survey within 48 hours of the procedure (see Table 1). The remaining 28% constituted patients who received either pacemakers or implantable cardioverter defibrillator devices, patients who were in the cardiac intensive care unit intubated and sedated, and patients who were unable to be contacted within the first 48 hours after the procedure. The age of patients undergoing procedures ranged from 1 day to 23 years, with a median age of 7.9 years. The majority of patients were Caucasian (78%). Just over half were male (55%). Most patients had a cardiac intervention performed during their catheterization, while the remainder underwent a diagnostic procedure. Most procedures were performed by the cardiac catheterization service; the rest were electrophysiology procedures. All patients had venous access obtained; half also had arterial access.

Table 1.
Demographics and Case Detail for Pediatric Cardiac Catheterization Patients

	n (%)
Total number of procedures	1,045
Total number contacted	745 (72)
Gender	
Male	409 (55)
Ethnicity	
Caucasian	581 (78)
African American	60 (8)
Asian American	60 (8)
Native American	30 (4)
Other	15 (2)
Type of procedure	
Diagnostic	231 (31)
Interventional	395 (53)
Electrophysiology	120 (16)
Access	
Arterial	417 (56)
Venous	731 (98)
Phone follow-up	
Patients taking acetaminophen	274 (37)
Pain unrelieved by acetaminophen	14 (2)
Causes of unrelieved pain*	
Musculoskeletal pain	7
Access site hematoma	6
Pseudoaneurysm	1

*Unrelieved pain associated with complications ($p < 0.01$).

Pain Assessment

In the study, 731 (98%) of 745 patients had either no pain or pain that was relieved by acetaminophen. There were 14 patients with pain unrelieved by acetaminophen. Of these 14 patients, 9 were female, 11 were Caucasian, and 11 were greater than 10 years of age. Out of the 14 patients who reported pain not relieved by acetaminophen, half had an important clinical complication at the site of vascular access. The complications included six patients with hematomas at the access site and one with a pseudoaneurysm. The patient with a pseudoaneurysm had undergone placement of a larger aortic stent to

treat coarctation of the aorta. These patients were all void of pain once the vascular complication was treated. The remaining 7 patients whose pain was not relieved by acetaminophen had generalized discomfort related to lying flat for several hours during the procedure. Instructions were given to these patients to take a nonsteroidal anti-inflammatory, such as ibuprofen, and reassess pain one hour after taken. Upon reassessment, these patients had no complaints. Based on a Fisher's exact analysis, post-procedural pain unrelieved by acetaminophen had a statistically significant association with complications ($p < 0.01$).

Discussion

The specific aims related to this study were to assess pain level and pain treatment post cardiac catheterization. After following many patients post-cardiac catheterization, it was determined that pain is generally not experienced. Patients who experience pain generally attain relief using acetaminophen with no further analgesics or opioids needed. For the few patients who experienced pain not relieved by acetaminophen, half had clinical complications at their vascular sites, which required additional medical attention.

This study was completed as part of a CPI project using CPI principles. The target of a safe recovery with minimal pain experienced following a cardiac catheterization was identified as the institutional CPI goal. A plan was set in place with the cardiac catheterization lab nurses to assess pain and follow up with all patients post-catheterization. Prior to starting the study, families were provided with detailed instructions for managing pain after cardiac catheterization. To focus on actual patient needs and to eliminate the concern that removal of opioid prescriptions may result in a detrimental impact on post-procedural pain, a phone survey was designed with age-appropriate pain assessment tools. Any patient identified to have pain unrelieved by acetaminophen was immediately discussed with the team and appropriate action taken. Within the first few months of follow-up phone calls, it became evident that pain following a cardiac catheterization is typically mild. More importantly, it was learned that pain unrelieved by acetaminophen could be associated with clinical complications. Had it been decided to implement a plan of providing opioids based on assumption and former standard practice, many patients could have been exposed to opioids and the possible side effects of respiratory depression and constipation. This study protected patients from iatrogenic injury and provided an early warning sign about vascular complications.

Having a better understanding of pain gave insight to forming a comprehensive pain management plan post-cardiac catheterization.

Significant gaps remain in the management of post-procedural pain in pediatrics. This study is one of the first to evaluate pain in the outpatient setting. This study demonstrated that the most patients either experienced no pain or pain was relieved by acetaminophen. Given these profound results, no major intervention or practice change was needed. Opioids were no longer prescribed, and the important question of whether pediatric patients required opioid analgesia following invasive cardiovascular procedures was resolved. A transition was made from a state of limited information to one where patients and caregivers were fully informed and pain needs were adequately addressed. This study demonstrated pain following an invasive cardiovascular procedure is minimal.

Limitations and Strengths

The process used in this study for cardiac catheterizations and post-procedure treatment is specific to one institution and may not be generalizable across other facilities. Collection of pain assessment by phone may not have provided accurate information; however, such pain assessment is commonly performed in clinical practice. Self and parent report of pain was taken as described knowing that as a limitation, different numbers and faces have different meaning to different children. Additionally, although all cardiac catheterization nurses attended the same training, it is possible not all calls were consistent with the designed procedures. It is noted in literature that parents underestimate their child's pain, which has the potential to skew data (AAP Committee on Psychosocial Aspects of Child and Family Health, Task Force on Pain in Infants, Children, and Adolescents, 2001).

Conclusion

Little data exist regarding pain after cardiac catheterization. Through continuous process improvement methodology and a patient safety study, a clearer understanding of post-cardiac catheterization pain was obtained. Having a better understanding of pain gave insight to forming a comprehensive pain management plan post-cardiac catheterization. This eliminated unnecessary prescriptions for opioids and reduced the safety risk associated with overdosing pain medications. Findings from this study helped and will continue to help prepare patients and families regarding anticipated pain post-cardiac catheterization, and should also alleviate any concerns regarding pain. Most importantly, these results will inform clinicians that persistent pain following a cardiac catheterization after the use of acetaminophen should be assessed immediately because it may represent a complication.

Practice Implications

In response to a patient safety event, a clinical practice change occurred prior to the initiation of this study. Opioids were no longer prescribed routinely after a cardiac catheterization. This study supported this practice change, and opioids have continued to not be prescribed. Additionally, post-cardiac catheterization phone calls were initiated as part of this study. Throughout the study, the importance of these phone calls and early recognition of pain-related complications was made evident. The risk of complications related to pain post-cardiac catheterization was low, which is consistent with other reported studies (Bergersen et al., 2011). The importance of early recognition and

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Learning Outcome

After completing this learning activity, the learner will be able to discuss post-catheterization pain strategies, including opioid administration, in pediatric patients undergoing cardiac catheterization.

Learning Engagement Activity

Ask yourself the following questions:

1. *Does your pediatric cardiac catheterization lab have established guidelines for pain management post-procedure?*
2. *Do you think a clinical practice change should be evaluated in your pediatric cardiac catheterization lab regarding pain management?*

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treatment of pain necessitated a practice change. Post-cardiac catheterization follow up and pain assessment has become an institutional standard of care.

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