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A DESCRIPTIVE FEASIBILITY STUDY TO EVALUATE SCHEDULED ORAL ANALGESIC DOSING AT HOME FOR THE MANAGEMENT OF POSTOPERATIVE PAIN IN PRESCHOOL CHILDREN FOLLOWING TONSILLECTOMY

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Abstract

Objectives—The purpose of this study, in a sample of preschool children (ages 3 to 5 years; N=47), was to evaluate the feasibility of scheduled analgesic dosing following outpatient tonsillectomy in order to optimize pain management.

Methods—Parents were instructed to give their child acetaminophen with hydrocodone (167mg/5ml) every 4 hours around-the-clock for the first 3 days following surgery. Parents recorded ratings of their child's pain with/without swallowing using the Faces, Legs, Activity, Cry, and Consolability (FLACC) behavioral pain scale, pain relief ratings, and severity of analgesic side effects in a home diary. Audiotaped interviews were conducted with parents to document descriptions of their experiences in managing their child's pain at home.

Results—Mean FLACC scores with/without swallowing were less than 2 at each measurement time and pain relief scores increased over time. Total analgesic dose decreased and the number of missed doses increased over the first 3 days after surgery. Moderate-to-severe daytime sedation, nausea, vomiting, and constipation were reported by parents.

Discussion—Study results suggest that acetaminophen with hydrocodone is effective in relieving preschool children's pain following tonsillectomy, and that parental adherence to a scheduled analgesic regimen decreases over time. Time-contingent dosing was associated with moderate to severe side effects, and should be addressed in discharge teaching with parents. Findings provide insight into parents' perspective of pain management at home following tonsillectomy and methods for relieving their child's pain.

Keywords

tonsillectomy pain; pediatric pain; postoperative pain management; acetaminophen with hydrocodone

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INTRODUCTION

Needed: A New Approach

Findings from numerous studies describe significant post-tonsillectomy morbidity in children following discharge from outpatient surgery with post-surgical pain a significant problem for parents at home (1–6). Standard discharge protocols recommend that parents be taught to give analgesics as needed to manage postoperative pain in children following tonsillectomy. However, recent data suggest that children at home following tonsillectomy and adenoidectomy receive only about 50% of their prescribed analgesics (5,7), even when moderate to severe pain is reported or observed. Given that pain associated with tonsillectomy and adenoidectomy can occur for up to 2 weeks after surgery, with the most severe pain occurring within the first 12 to 36 hours following discharge (5,7–10), an alternative strategy for managing children's pain at home is needed to reduce significant postoperative morbidity.

While acetaminophen and codeine is the most commonly prescribed opioid analgesic for the treatment of moderate to severe pain in children, this analgesic combination of medications is not effective for pain control after tonsillectomy (10–11). Furthermore, safety concerns associated with genetic differences in the metabolism of codeine in a subgroup of patients provides a rationale for evaluation of other opioid analgesics (e.g., acetaminophen and hydrocodone) that may have efficacy and safety profiles superior to that of codeine.

Creation and Implementation of an Innovative Intervention

Findings from the literature and clinical audit data from postoperative calls to parents the day after surgery were utilized to develop an innovative intervention that included comprehensive written pain management instructions and scheduled dosing of acetaminophen and hydrocodone for the first 3 days following surgery. Acetaminophen and hydrocodone is a widely accepted standard treatment for moderate to severe postoperative pain in children, and limited data suggest that it is an effective analgesic for post-tonsillectomy pain relief (12–13). The idea of scheduled analgesic dosing in the presence of persistent pain is not new, and previous research has demonstrated its effectiveness in relieving post-tonsillectomy pain at home for school-age children (13). However, more children are undergoing tonsillectomy at a younger age, given an increased awareness of the potential harm of upper airway obstruction, which has taken the place of recurrent tonsillitis as the most common indication for tonsillectomy in the pediatric population (14–16). Little information is available about postoperative problems experienced by parents caring for a young child at home after outpatient tonsillectomy.

Therefore, the purpose of this prospective, descriptive, feasibility study was to evaluate the feasibility of scheduled analgesic dosing following outpatient tonsillectomy in order to optimize pain management in this population. The specific aims of this study, in a sample of preschool children who were at home recovering from tonsillectomy, were to: 1) determine the intensity of pain experienced by young children, with and without swallowing, based on parental report using a behavioral pain rating scale; 2) evaluate parental adherence with a scheduled analgesic dosing regimen; 3) determine the proportion of young children who experienced adequate pain relief; 4) evaluate children's sleep pattern and ability to consume fluids; 5) determine the proportion of young children who experienced opioid-related side effects; and, 6) evaluate parental experience with the management of post-tonsillectomy pain at home in young children using around-the-clock (ATC) dosing.

MATERIALS AND METHODS

Setting and Sample

Children 3 to 5 years of age scheduled for outpatient surgery were recruited from May 2004 to June 2005 from a 297-bed regional tertiary care center that serves about 950,000 children in Central California. The study was approved by the Institutional Review Board at the study site and at the University of California, San Francisco. Eligibility criteria included no prior history of neurologic impairments (i.e., visual or hearing deficits, learning disability, or motor function deficit); no history of allergies to hydrocodone or acetaminophen; ability of the child to speak English; ability of the parent to read, write, and speak English; and access to a telephone. Patients younger than 36 months, those with significant medical comorbidities (especially bronchopulmonary dysplasia or conditions that reduce the size of the pharyngeal airway), and those receiving concurrent administration of another opioid agonist, central nervous system depressant, or sedative medication, were excluded from this study.

Fifty-three children were enrolled in the study. Forty-seven children completed the study and are included in this analysis. Six children became ineligible to participate or withdrew their consent to participate after surgery and were withdrawn from the study. Three patients were admitted postoperatively for observation due to oxygen requirements and need for respiratory monitoring. Two patients developed intolerable side effects (i.e., persistent nausea and vomiting in one case, and facial swelling in another) that required a change in analgesic medication, and one child was withdrawn after their parents decided upon arriving home that they did not want to participate in the study. Since children who did not complete the study dropped out early on, and provided no data or incomplete data for the first postoperative day, they were not included in the analysis. No differences were found in any of the surgical or parental characteristics between children who did and did not complete the study. The refusal rate for the study was 34%. With the exception of one parent who was too busy to participate, the main reason for refusal was that parents only wanted to give the analgesic as needed. Further explanation was provided by some parents who reported that they did not want to wake their child at night (52%) or that it was difficult to get their child to take oral medication (11%).

Study Procedures

Enrollment and Preoperative Procedure—The research nurse evaluated the patient's preoperative history and physical completed by the surgeon to determine if the patient met the study's inclusion or exclusion criteria. Children with severe obstructive sleep apnea (OSA) were excluded from the ambulatory surgery program and scheduled for overnight admission to the hospital. On admission to the outpatient surgery setting, parents of eligible children ages 3 to 5 years who were to undergo tonsillectomy, with or without other concurrent minor procedures such as myringotomy tube placement, were approached to participate in the study. Written informed consent was obtained from all parents.

At the time of enrollment, the research nurse obtained baseline data by having the parent complete the Patient/Family Information Sheet and by reviewing the patient's medical record. The research nurse educated the parents in how to use the Faces, Legs, Activity, Cry, and Consolability (FLACC) behavioral pain assessment scale (17), instructing the parents that measures of pain intensity would be obtained twice a day, for the first three days at home following surgery, at rest and with swallowing. Once recruitment and baseline data collection were complete, a preprinted order sheet was completed that indicated the child's weight, and the standardized dose of acetaminophen and hydrocodone elixir (i.e., approximately 0.2 mg/kg/dose of hydrocodone; maximum daily acetaminophen dose of

approximately 73 mg/kg every 4 hours ATC for the first 3 days after surgery), which was signed by the surgeon prior to the procedure and sent to the inpatient pharmacy for preparation and dispensing. The bottles were labeled with the patient's information, the name of the analgesic medication, and dosing instructions. The study drug was delivered to the Day Surgery area and was provided to the parent prior to discharge home.

Surgical Procedure—No attempt was made to standardize the inhalation anesthetics used during surgery, concurrent administration of opioid analgesics, or surgical technique. All but one patient received an intraoperative opioid analgesic as part of the anesthetic technique (morphine [70.2%], fentanyl [21.3%], other opioid [8.5%]), and all but one patient received local anesthetic infiltration of the tonsillar beds by the surgeon.

Perioperative Analgesic Administration—Children received fentanyl (N=26 [55.3%]; 0.25 mcg/kg up to a total dose of 2 mcg/kg) or morphine (N=6 [12.8%]; 0.025 mg/kg up to a total dose of 0.2 mg/kg) intravenously, as needed for pain during the immediate postoperative period in the Post Anesthesia Care Unit and Day Surgery area. Prior to discharge home, children were given the first dose of hydrocodone and acetaminophen, with instructions to administer the first dose of pain medication at home 4 hours after the initial dose was given. If the child experienced nausea/vomiting prior to discharge, parents were instructed to give the initial dose upon arrival home. Parents were given instructions on proper dose measurement and were asked to provide a return demonstration with the first dose administered prior to discharge. Parents were told not to give their child any other pain medication. In addition, they were instructed to call the research nurse if their child experienced fever, unrelieved pain, or intolerable side effects. Parents were provided with a digital timer and instructed to set the timer for each 4-hour dosing interval as a reminder to administer the next scheduled dose.

Postoperative Instructions—When the child was transferred to the Day Surgery area, the research nurse reviewed standard postoperative instructions with all of the parents using a preprinted teaching booklet that was given to the parents to take home. Information was provided on activity restrictions, school attendance, postoperative bleeding, diet, ear and throat pain, possible changes in sleep patterns, expected appearance of the back of the throat, fever, and the follow-up appointment with the surgeon. Additional written instructions were included for children undergoing concurrent myringotomy tube placement. The research nurse reviewed the pain management teaching guide that was incorporated into the preprinted teaching booklet. Information was provided on the reported postoperative pain experience of children following tonsillectomy, the rationale for administration of a nonopioid with an opioid analgesic, the ordered dose and every 4 hour ATC dosing of hydrocodone and acetaminophen, strategies for improving children's adherence with analgesic consumption, and myths about psychological addiction.

In addition, all parents were provided with a home diary and were instructed by the research nurse in how to complete the twice-a-day pain log (using the FLACC behavioral pain assessment scale) (17), at rest and with swallowing; assessment of pain relief; the medication log; and the outcome measures for their child's sleep; oral intake; behavior; and side effects. Initial pain scores assessed using the FLACC were recorded by the parent and reviewed by the research nurse for accuracy prior to the child's discharge from the hospital.

Follow-Up Phone Calls and Coaching Intervention—The research nurse made scheduled follow-up phone calls to all parents on days one and two postoperatively, to evaluate the parent's level of adherence with completing the home diary. In addition, parents received a coaching intervention at the time of the phone calls to promote adherence with the ATC dosing regimen. The coaching intervention included an evaluation of the child's

current condition, review of the pain intensity scores, verification that the child was taking the pain medication, re-education regarding the rationale for ATC dosing, review of strategies to facilitate medication administration, and re-education about potential side effects associated with analgesic administration. At the end of the day 2 phone call, the research nurse scheduled an appointment for a home visit on the fourth day after surgery.

Home Visit—The research nurse collected the home diary and measured the amount of medication that remained in the bottle. An audiotaped interview was conducted with the parents, lasting about 15 minutes, and consisted of thirteen questions relating to expectations of their child's pain following tonsillectomy, parental preparation to manage their child's pain, their experience with administration of the pain medication and its effectiveness, satisfaction with their child's pain relief, concerns about giving the pain medicine, as well as things other than medication that helped them to manage their child's pain, and parent's report of the usefulness of the home diary, nurse's phone calls and teaching booklet in helping them to manage their child's pain, and suggestions for ways to help other parents caring for a child who has pain following a tonsillectomy, to improve their child's pain management.

Instruments

Patient/Family Information Sheet—The Patient/Family Information Sheet was used to collect demographic characteristics of the children and parents at the time of enrollment into the study, in addition to review of the children's medical records to obtain surgical and anesthesia data. Parent's expectation of how much pain their child would experience following surgery was rated using a 0 (no pain) to10 (worst pain imaginable) numeric rating scale, and parents were asked to report whether they thought their child would have difficulty coping with the pain following surgery.

Home Diary—The Home Diary obtained information on pain intensity, presence and severity of opioid-related adverse effects, and medication use. Pain intensity, with and without swallowing, was rated by the parent prior to the child's bedtime and upon awakening, using the FLACC behavioral pain assessment scale. Severity of opioid-related adverse effects (i.e., nausea, vomiting, constipation, daytime sedation, lightheadedness or feeling dizzy, and nightmares) were evaluated each evening using a Likert-type scale ranging from did not have, slight, moderate, severe, and very severe. Parents rated the child's oral intake and sleep during the night using a 0 to 10 rating scale (i.e, 0 = drinking well, 10 = not drinking at all; 0 = slept well, 10 = didn't sleep at all, respectively). Parents recorded the number of times they had to get up with their child during the night because he/she was hurting.

Parents completed the pain medication log on a daily basis. Parents recorded the volume (in milliliters) and the times they administered the pain medication to their child. The research nurse recorded in the diary the volume and the times that the parents should administer the pain medication based on the time that the first dose of the pain medication was given just prior to discharge from Day Surgery. Parents were instructed to circle the times in the diary when they administered the pain medication to their child. In the event that the dosing schedule needed to be modified (e.g., excessive sedation that resulted in a skipped dose, with subsequent breakthrough pain prior to the next scheduled dose of the analgesic), parents were instructed to revise the dosing schedule by drawing a line through the times previously written in, and entering new times at 4-hour intervals, beginning with the time of the dose just given.

Pain Ratings—Pain intensity, at rest and with swallowing, was rated by the parent at the time of discharge from the hospital, then twice a day (i.e., prior to bedtime and upon awakening), for the first three days at home, using the FLACC behavioral pain assessment scale (17). The FLACC is an interval scale that measures pain by quantifying pain behaviors with a total score between 0 and 10. Five categories of behavior are included in the scale: facial expression, leg movement activity, cry, and consolability. Parents recorded a score for each category based on behavioral descriptors using a three point scale (0 to 2, 0 = absent, 2 = intense or frequent), and then summed the individual category scores to obtain a total FLACC score. The FLACC scale has been validated for assessment of postoperative pain in children between the ages of two months and seven years (17–19).

Pain Relief Ratings—Parental assessment of their child's pain relief from the pain medicine was recorded at discharge, then twice a day, for the first three days at home, using a 0 to 10 numeric rating scale (0 = no change in pain, 10 = pain is all gone).

Structured Home Interview—The research nurse conducted an audiotaped interview with the parent to solicit responses to the following questions: a) Did your child have more pain after his/her surgery than you expected?; b) Did you feel adequately prepared to manage your child's pain at home after surgery? If not, what additional information would have been helpful to you? c) How did things go in terms of giving the pain medicine every 4 hours for the past three days? d) Did you encounter any difficulties in giving the pain medicine? If so, what were they? e) Do you think that the pain medicine helped your child? f) Did you have any concerns about giving the pain medicine to your child? g) On a scale of 0 to 10, with 0 being completely dissatisfied and 10 being completely satisfied, how satisfied were you with the amount of pain relief that your child received from the pain medicine? h) Other than giving the pain medicine, what kinds of things did you do to help your child feel better? i) Could you comment on the usefulness of the home log in helping you to manage your child's pain? j) Could you comment on the usefulness of the nurse's phone calls in helping you to manage your child's pain? k) Could you comment on the usefulness of the teaching booklet in helping you to manage your child's pain? l) What ideas do you have about better ways to help parents who are caring for a child who has pain following a tonsillectomy? and, m) Do you think your child's pain management could have been improved? If so, how?

Data Analysis

Data were analyzed using SPSS Version 12. Descriptive statistics were performed to summarize sample characteristics. Differences over time in pain intensity scores (i.e., with and without swallowing), pain relief scores, and analgesic consumption were determined using repeated measures analysis of variance (RMANOVA) with a within subjects factor (i.e., time with 4 levels [day of surgery, and postoperative days 1, 2, and 3] or 7 levels [first evening at home following surgery, and morning and evening measurement points for the first 3 days following surgery]). When the RMANOVA within subjects factors were found significant, Bonferroni pairwise post hoc tests were performed to determine which means differed.

Each side effect was recoded into a dichotomous response (i.e., 0 = did not have symptom or had slight symptom or 1 = symptom that was moderate, severe, or very severe) to make the comparisons more clinically meaningful in terms of children who did and did not experience significant side effects. The Cochran Q test was used to assess for changes over time in the frequency of moderate-to-severe side effects. For those variables in which the Cochran's Q was significant, McNemar's test of pairwise proportions was used to determine where the significant differences were.

The structured interviews with parents were analyzed using qualitative methods, with the exception of one question in which descriptive statistics were used to summarize parents' ratings of their satisfaction with the amount of pain relief that their child received from the pain medicine using a 0 to 10 rating scale (i.e., 0 = completely dissatisfied and 10 = completely satisfied).

Nine questions produced answers that could be itemized and tabulated (i.e., Did your child have more pain after his/her surgery than you expected?; Did you feel adequately prepared to manage your child's pain at home after surgery?; Did you encounter any difficulties in giving the pain medicine?; Do you think the pain medicine helped your child?; Did you have any concerns about giving the pain medicine to your child?; Do you think your child's pain management could have been improved?; Could you comment on the usefulness of the home log in helping you to manage your child's pain?; Could you comment on the usefulness of the nurse's phone calls in helping you to manage your child's pain?; and, Could you comment on the usefulness of the teaching booklet in helping you to manage your child's pain?). Five questions (i.e., How did things go in terms of giving the pain medicine every 4 hours for the past three days?; Other than giving the pain medicine, what kinds of things did you do to help your child feel better?; What ideas do you have about better ways to help parents who are caring for a child who has pain following a tonsillectomy?; and What additional information would have been helpful to you?) elicited answers that necessitated the identification of themes and categories.

Interviews were transcribed. The research nurse who collected the data reviewed all of the transcriptions and when possible filed in all blanks that occurred as a result of inaudible comments on the tapes. Answers to all of the questions were reviewed and themes and categories were identified. Independently, two members of the research team coded the transcriptions of the interviews. Data for each response category were tabulated. Discrepancies in coding were resolved by consensus between a third member of the research team and the two original coders.

All calculations used actual values. Adjustments were not made for missing data. Therefore, the cohort for each analysis was dependent on the largest complete set of data across groups. A p value of less than 0.05 was considered statistically significant.

RESULTS

Sample Characteristics

Demographic, parental, and surgical characteristics are summarized in Table 1.

Analgesic Consumption

A repeated measures ANOVA demonstrated a significant within-subjects main effect for total analgesic dose ($F(2,90)=3.82$, $p=0.033$). Post hoc tests revealed that analgesic consumption was significantly higher on the first postoperative day compared to the third day after surgery ($p=0.027$).

A repeated measures ANOVA demonstrated a significant within-subjects main effect for missed doses ($F(2,92)=4.73$, $p=0.017$). Mean number of missed doses were 1.19 (SD=0.58), 1.47 (SD=1.06), and 1.72 (SD=1.25) for the first three postoperative days. Post hoc tests revealed that the number of missed doses was significantly higher on the third postoperative day compared to the first day after surgery ($p=0.036$). More than 90% of parents missed at least one scheduled dose each day for the first 3 days after surgery.

Pain Intensity Scores

At the time of discharge from the hospital, the mean FLACC score was 0.59 (SD=1.48). FLACC scores were not significantly different across time with or without swallowing for the first three postoperative days ($F(6,258)=0.96$, $p=0.45$ and ($F(7,315)=2.00$, $p=0.07$, respectively). On average, mean pain intensity scores were less than 2 for each measurement time, with and without swallowing. Parents reported the FLACC score to be an accurate assessment of their child's pain for 98% of all pain measurements. When parents disagreed with the FLACC score, most parents rated their child's pain as higher (i.e., FLACC score = 0, parent rating "mild discomfort," (N=11); FLACC score = 5, parent rating "severe pain" [N=1]). Two parents reported lower pain ratings (i.e., FLACC score = 5, parent rating "mild discomfort"; FLACC score = 7, parent rating "mild discomfort").

Pain Relief Scores

A repeated measures ANOVA demonstrated a significant within-subjects main effect ($F(7,196)=18.38$, $p<0.0001$). Post hoc analyses revealed that parental ratings of pain relief were significantly lower prior to discharge from the hospital compared to parents' ratings of pain relief at home ($p<0.0001$). On average, children received their initial dose of acetaminophen and hydrocodone 34 minutes prior to discharge home (SD=25.73; range 3 to 135 minutes; N=33). Pain relief scores were not significantly different for the first three postoperative days.

Sleep and Oral Intake

A repeated measures ANOVA demonstrated a significant within-subjects main effect for quality of sleep ($F(2,92)=4.99$, $p=0.012$), the number of times that parents had to get up during the night because of their child's pain ($F(2,90)=4.64$, $p=0.019$), and quality of oral fluid intake ($F(3,135)=3.40$, $p=0.029$). Mean scores for quality of sleep were 2.51 (SD=2.82), 1.51 (SD=2.22), and 1.28 (SD=2.18) on the first 3 mornings following surgery. Post hoc analyses revealed that sleep was significantly improved on the second postoperative night, compared to the first night after surgery ($F(1,46)=7.61$, $p=0.008$). On average, the number of times that parents were up during the night for pain-related issues were 1.26 (SD=2.16), 0.74 (SD=1.53), and 0.52 (SD=0.96) times for each of the first 3 nights after surgery. Post hoc analyses revealed a statistically significant decrease between the first and second postoperative nights in the number of times that parents were up during the night because of their child's pain ($F(1,45)=4.35$, $p=0.043$). Mean scores for quality of oral intake were 2.33 (SD=2.90), 2.04 (SD=2.55), 2.09 (SD=2.54), and 1.15 (SD=1.85) for the day of surgery, and the first 3 postoperative days. Post hoc analyses revealed a significant improvement in oral intake on the third postoperative day compared to the second day after surgery ($F(1,45)=10.23$, $p=0.003$).

Side Effects

On each postoperative evening, the following side effects were assessed: daytime sedation, nausea, vomiting, constipation, lightheadedness/feeling dizzy, and nightmares. Table 2 shows the proportion of children who experienced moderate-to-severe side effects for the first 3 days following surgery. There was a significant decrease in the proportion of children who demonstrated moderate-to-severe daytime sedation over the four postoperative assessments (Cochran $Q = 17.33$, $P=0.001$), with daytime sedation occurring more frequently on the day of surgery compared to each of the 3 days following surgery ($p=0.004$, 0.035, and 0.008, respectively). There was a significant decrease in the proportion of children who demonstrated moderate-to-severe nausea (Cochran $Q = 8.33$, $p=0.04$) and vomiting (Cochran $Q = 9.69$, $p=0.021$) over the four postoperative assessments. Nausea occurred more frequently on the first and second postoperative days ($p=0.012$ and 0.016,

respectively), and vomiting occurred more frequently on the day of surgery (p=0.012) and second postoperative day (p=0.031), compared to the third day following surgery. There was a significant increase in the proportion of children who demonstrated moderate-to-severe constipation over the four postoperative assessments (Cochran Q = 12.78, p=0.005), with constipation occurring more frequently on the first postoperative day compared to the day of surgery (p=0.016). The proportion of children who demonstrated moderate to severe lightheadedness, feeling dizzy (Cochran Q =7.20, p=0.07) or nightmares (Cochran Q = 3.00, p=0.39) did not change over time.

Parental Preoperative Assessment

Parents expected that their child would experience moderate-to-severe pain intensity following tonsillectomy (mean = 6.08 + 1.89). The majority of parents (62%) were unsure about whether their child would have difficulty coping with the pain, 30% reported that their child would not have any difficulty in coping with the pain, and 8% reported that their child would have difficulty coping with the pain.

Parent's Experience at Home

A summary of parent's responses to the home interview questions is provided in Table 3. With the exception of the parent satisfaction question, responses are reported as percentages calculated based on the number of responses for each question.

DISCUSSION

Findings from recent investigations further support the need for a time-contingent analgesic dosing regimen for the management of pain in children at home following tonsillectomy (2, 20), demonstrating that even when instructions for analgesic administration are linked to specific pain ratings, parents do not administer analgesia to children at home following tonsillectomy. In contrast, results from this study demonstrate that preschool children who received a scheduled, weight-based, therapeutic dosing regimen of acetaminophen with hydrocodone for the first three days following tonsillectomy had minimal pain. FLACC scores were less than 2 at each assessment interval, with and without swallowing, representing lower pain scores than were reported by school-age children receiving the same analgesic regimen at home following tonsillectomy (13). Unlike previous research that reported increased pain with swallowing in 3 to 7-year-old children receiving as needed doses of acetaminophen (6) and 6 to 15-year-old children receiving scheduled dosing of acetaminophen and codeine (10) or acetaminophen and hydrocodone (13), higher pain scores with swallowing were not observed, and parents reported minimal problems with their child's fluid intake. While definitive conclusions cannot be drawn because of the lack of a control group, findings from this study suggest that children had little pain following tonsillectomy when acetaminophen and hydrocodone were administered on a schedule.

Surgical technique may have influenced the low incidence/severity of children's postoperative pain. Most children had coblation-assisted tonsillectomy. Unlike other techniques, coblation preserves the integrity of healthy tissue surrounding the tonsils, and generates relatively little heat and little thermal injury. Clinical studies that evaluated both intracapsular and total coblation tonsillectomy have reported less postoperative pain compared to other surgical techniques (21–24). However, findings from a recent review suggest the evidence is not adequate to determine whether coblation tonsillectomy is more effective than other methods of tonsillectomy in reducing morbidity, including postoperative pain (25). Additional research is warranted on the interactions between surgical procedures and analgesic regimens and their effects on postoperative pain.

The sedative properties of acetaminophen and hydrocodone may have effected the interpretation of behavioral observations and contributed to lower FLACC scores. However, FLACC scores remained consistently low while daytime sedation decreased over the first 3 days after surgery, which suggests that scheduled analgesic dosing relieved the child's pain rather than merely blunting the child's behavioral expressions of pain.

Parent ratings of their child's postoperative pain have been reported to predict the development of sleep difficulties in children following tonsillectomy, wherein children with more postoperative pain had significant sleep decrements (26). Parents reported low FLACC scores and minimal sleep disturbance related to pain for both the child and the parent, suggesting a similar association between postoperative pain and sleep.

Nearly all parents indicated that the pain medicine helped to relieve their child's pain, and parents were very satisfied with the amount of pain relief that their child received. Only 2 parents (4.3%) reported that their child's pain management could have been improved. Parents' expectations for pain relief were not evaluated, which if low, could contribute to high parent satisfaction. Acetaminophen and hydrocodone is a widely accepted standard treatment for moderate to severe acute postoperative pain. Although not well-studied in younger children, these data suggest that preschool children's pain management at home following tonsillectomy can be optimized by providing around-the-clock dosing of acetaminophen and hydrocodone.

Interpretation of pain behaviors using observational scales requires consideration of the context of behaviors (27). Parents, like children, are individuals and they have varied opinions about children's reactions to painful experiences, particularly those of their own child (28). Parents usually know their child's typical behavioral responses to pain and can identify behaviors unique to the child that can be included in their assessment of pain (29). Parents in this study were asked to interpret their child's pain/distress behaviors considering the context of the situation, and report a global rating of their child's pain using a descriptive rating scale if they disagreed with the FLACC score. Parents' concurred with 98% of recorded FLACC scores, with 1.7% of parents' pain ratings being higher and 0.3% being lower than the FLACC scores.

The accuracy of parent-assigned pain ratings using the FLACC was reported previously reported (30), and similarly required minimal training and was easy for parents to use. Parents' did not rely on FLACC scores to determine analgesic administration. Rather, the FLACC was selected as a tool to promote parent's recognition of pain, and to provide a mechanism to evaluate effectiveness of the analgesic regimen. The FLACC has well-established psychometric properties, as well as good clinical and research utility, and is recommended as the preferred behavioral measure of postoperative pain assessment for children in the hospital (27). Although it has not been validated outside of the clinical setting, study findings suggest that the FLACC is a useful tool to assist parents to assess preschool children's postoperative pain at home. Further research that compares the FLACC with the recently developed and validated Parent's Postoperative Pain Measures (31) is needed to ascertain the validity of the FLACC as an observational measure of pain by parents in the outpatient setting.

Opioids are the cornerstone of pain management following tonsillectomy in children. Findings from this study demonstrate that a scheduled opioid analgesic dosing regimen is feasible and effective in preschool children, albeit not without associated side effects. Particularly noteworthy in children with a history of obstructive sleep apnea is the high incidence of reported daytime sedation (35.5%) on the first postoperative day. Sedation usually precedes respiratory depression with acute administration of an opioid analgesic, and

children with obstructive sleep apnea may be at greater risk for the respiratory depressant effects of opioids (32–33). Although primary risk reduction strategies were implemented to identify high-risk children and exclude them from the ambulatory surgery program, 3 children (5.6%) developed respiratory complications following surgery that necessitated admission to the hospital for observation. None of the children presented with respiratory complications following discharge home. However, it is important to note that the majority of younger children with obstructive sleep apnea who undergo tonsillectomy and adenoidectomy do so with only a clinical diagnosis, and that these children remain susceptible to airway obstruction and all of the problems arising from obstructive sleep apnea for several weeks postoperatively (34).

Findings from this study are consistent with previous reports that identify postoperative nausea and vomiting during home recovery as one of the commonest causes of significant morbidity after tonsillectomy in children (3,5,10,35–36). Prophylactic anti-emetic administration is frequently addressed in the perioperative management of children undergoing tonsillectomy. However, the incidence of persistent postoperative nausea and vomiting following discharge from the hospital is sufficiently high to warrant consideration of ongoing anti-emetic prophylaxis at home and/or a prescribed rescue therapy in the early postoperative course. Future studies should investigate the use of a standardized approach to the management of opioid-related nausea/vomiting in children at home following outpatient tonsillectomy.

Findings indicate that constipation occurs early in the child's recovery when opioid analgesics are given at home for acute pain management. Standard postoperative instructions to parents for children undergoing tonsillectomy generally do not address this potential side effect of opioid analgesia. Study findings highlight the need to include information regarding possible opioid-related side effects, and guidelines for management, in discharge instructions provided to parents caring for children following tonsillectomy. Further research is needed to determine if a less aggressive analgesic dosing regimen would achieve the same benefit in pain control while reducing the incidence of side effects that were observed in this study.

Findings underscore parents' need for appropriate information and support from clinicians. Most parents expected their child would experience moderate-to-severe pain following tonsillectomy, and reported feeling adequately prepared to manage their child's postoperative pain at home. The use of standardized, detailed instructions for postoperative care, including information regarding the expected trajectory for postoperative pain and the rationale for scheduled analgesic dosing following tonsillectomy in children, likely contributed to this finding. The teaching booklet and home diary were both reported to be useful resources for parents to know what to expect, what to do, what their child was feeling, and to be aware of their child's symptoms. The daily phone calls from the nurse helped parents to manage problems that may otherwise have required a call or visit to the child's physician, and were also a source of emotional support to parents.

Little is known about what postoperative pain management interventions are feasible in the home environment (5). Parents recognized the importance of adhering to the prescribed analgesic regimen, and advised other parents to do the same. However, adherence to the scheduled analgesic dosing was negatively impacted by various factors including difficulties in getting the child to take the pain medicine (bad taste, painful swallowing), side effects, and the amount/frequency/timing of medication administration, especially at night. Fear of addiction was not a significant concern. Parents validated the utility of dietary suggestions included in the teaching booklet and standard discharge instructions, such as cold things and soft foods, and emphasized the importance of other non-pharmacologic interventions as

adjuncts to analgesic administration (e.g., distraction, physical attention, empathy, and emotional support). Findings suggest the need to evaluate alternate routes of analgesic administration, longer-acting analgesics, approaches to managing opioid-related side effects, and to include non-pharmacologic interventions as part of the pain management plan for children at home following tonsillectomy.

Several limitations of this study need to be acknowledged. The first issue is that of parents as proxies for reporting on preschool children's acute pain in the home setting. Although significant positive correlations were identified between parent's reports of their child's pain behavior (Postoperative Pain Measure for Parents) (31), and the child's self-report of pain intensity following tonsillectomy (7), limited research has examined children's self-report of pain in relationship to FLACC scores. A recent review of behavioral pain measures reported the FLACC to have moderate concurrent validity with the Wong-Baker FACES scale (37) and good concurrent validity with the visual analogue scale (27). In a sample of thirty postoperative patients 3 to 7 years of age, Willis and colleagues (19) reported significant and positive correlations between the FLACC and FACES. However, when data were analyzed separately for children < 5 and those 5 years of age and older, FLACC and FACES scores did not correlate in the younger group. Whenever feasible, behavioral measurements of pain should be used in conjunction with self-report, as previous research has demonstrated that parents tend to underestimate their children's surgical pain (38–39). Second, pain intensity ratings were only obtained twice a day, in the morning upon awakening and in the evening before going to bed, rather than at regular intervals during the day or in conjunction with analgesic administration. Pain intensity ratings were for present pain intensity with and without swallowing, and did not evaluate ratings of least or worst pain during the day and night. The generalizability of the study findings is limited to post-surgical pain management in preschool children for the first three days at home following tonsillectomy.

Study findings suggest that a standardized approach to postoperative pain management, with scheduled dosing of acetaminophen and hydrocodone, provides safe and effective postoperative pain relief at home following tonsillectomy in preschool children with mild obstructive sleep apnea in which significant comorbid conditions were not present. Parents need to be educated about regular analgesic administration in order to improve patient outcomes, and innovative strategies are needed to address identified barriers to adherence with a scheduled analgesic regimen. Additionally, attention must be given to educating parents in the application of non-pharmacologic interventions as adjunctive pain management strategies. Time-contingent dosing of acetaminophen with hydrocodone for the first three days following tonsillectomy does result in moderate to severe opioid-related side effects in a significant proportion of preschool children. However, with knowledge of the frequency and severity, clinicians can provide guidance to parents to prevent and/or minimize the occurrence and impact of these side effects on children recovering at home following tonsillectomy. Further studies are warranted to determine whether the benefits of scheduled analgesic dosing can be achieved in other outpatient pediatric surgical populations.

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References

1. Doshi J, Damador M, Gregory S, et al. Post-tonsillectomy morbidity statistics: are they underestimated? J Laryngol Otol. 2008; 122:374–377. [PubMed: 17367557]

2. Fortier MA, MacLaren JE, Martin, et al. Pediatric pain after ambulatory surgery: where's the medication? Pediatrics. 2009; 124(4):e588–e596. [PubMed: 19736260]
3. Huth MM, Broome ME. A snapshot of children's postoperative tonsillectomy outcomes at home. J Spec Pediatr Nurs. 2007; 12(3):186–195. [PubMed: 17594298]
4. Jones DT, Yoon MJ, Licameli G. Effectiveness of postoperative follow-up telephone interviews for patients who underwent adenotonsillectomy. Arch Otolaryngol Head Neck Surg. 2007; 133(11): 1091–1095. [PubMed: 18025311]
5. Wiggins SA, Foster RL. Pain after tonsillectomy and adenoidectomy: "Ouch it did hurt bad". Pain Manag Nurs. 2007; 8(4):156–165. [PubMed: 18036503]
6. Wilson ME, Helgadottir HL. Patterns of pain and analgesic use in 3- to 7-year-old children after tonsillectomy. Pain Manag Nurs. 2006; 7(4):159–166. [PubMed: 17145490]
7. Helgadóttir HL, Wilson ME. Temperament and pain in 3 to 7-year-old children undergoing tonsillectomy. J Pediatr Nurs. 2004; 19:204–213. [PubMed: 15185249]
8. Gedaly-Duff V, Ziebarth D. Mothers' management of adenoid-tonsillectomy pain in 4- to 8-year olds: a preliminary study. Pain. 1994; 57:293–299. [PubMed: 7524009]
9. Warnock FF, Lander J. Pain progression, intensity and outcomes following tonsillectomy. Pain. 1998; 75:37–45. [PubMed: 9539672]
10. Sutters KA, Miaskowski C, Holdridge-Zeuner D, et al. A randomized clinical trial of the effectiveness of a scheduled oral analgesic dosing regimen for the management of postoperative pain in children following tonsillectomy. Pain. 2004; 110:49–55. [PubMed: 15275751]
11. Moir MS, Bair E, Shinnick P, et al. Acetaminophen versus acetaminophen with codeine after pediatric tonsillectomy. Laryngoscope. 2000; 110:1824–1827. [PubMed: 11081593]
12. Bean-Lijewski JD, Kruitbosch SH, Hutchison L, et al. Post-tonsillectomy pain management in children: Can we do better? Otolaryngol Head Neck Surg. 2007; 137(4):545–51. [PubMed: 17903568]
13. Sutters KA, Miaskowski C, Holdridge-Zeuner D, et al. A randomized clinical trial of the efficacy of scheduled dosing of acetaminophen and hydrocodone for the management of postoperative pain in children after tonsillectomy. Clin J Pain. 2010; 26(2):95–103. [PubMed: 20090434]
14. Deutsch ES. Tonsillectomy and adenoidectomy: changing indications. Pediatr Clin North Am. 1996; 43(6):1319–1338. [PubMed: 8973515]
15. Sargi Z, Younis RT. Tonsillectomy and adenoidectomy techniques: past, present and future. ORL J Otorhinolaryngol Relat Spec. 2007; 69(6):331–335. [PubMed: 18033968]
16. Smith SL, Pereira KD. Tonsillectomy in children: indications, diagnosis and complications. ORL J Otorhinolaryngol Relat Spec. 2007; 69(6):336–339. [PubMed: 18033969]
17. Merkel SI, Voepel-Lewis T, Shayevitz JR, et al. The FLACC: a behavioral scale for scoring postoperative pain in young children. Pediatr Nurs. 1997; 23(3):293–297. [PubMed: 9220806]
18. Manworren RC, Hynan LS. Clinical validation of FLACC: preverbal patient pain scale. Pediatr Nurs. 2003; 29(2):140–146. [PubMed: 12723828]
19. Willis MH, Merkel SI, Voepel-Lewis T, et al. FLACC behavioral pain assessment scale: a comparison with the child's self-report. Pediatr Nurs. 2003; 29(3):195–198. [PubMed: 12836995]
20. Unsworth V, Franck LS, Choonara I. Parental assessment and management of children's postoperative pain: a randomized clinical trial. J Child Health Care. 2007; 11(3):186–194. [PubMed: 17709354]
21. Chan KH, Friedman NR, Allen GC, et al. Randomized, controlled, multisite study of intracapsular tonsillectomy using low-temperature plasma excision. Arch Otolaryngol Head Neck Surg. 2004; 130:1303–1307. [PubMed: 15545586]
22. Chang KW. Intracapsular versus subcapsular coblation tonsillectomy. Otolaryngol Head Neck Surg. 2008; 138(2):153–157. [PubMed: 18241707]
23. Parsons SP, Cordes SR, Comer B. Comparison of posttonsillectomy pain using the ultrasonic scalpel, coblator, and electrocautery. Otolaryngol Head Neck Surg. 2006; 134:106–113. [PubMed: 16399189]
24. Temple RH, Timms MS. Paediatric coblation tonsillectomy. Int J Pediatr Otorhinolaryngol. 2001; 61:195–198. [PubMed: 11700188]

25. Burton MJ, Doree C. Coblation versus other surgical techniques for tonsillectomy. Cochrane Database Syst Rev. 2007; (3):CD004619. [PubMed: 17636769]
26. MacLaren JE, Kain ZN. Prevalence and predictors of significant sleep disturbances in children undergoing ambulatory tonsillectomy and adenoidectomy. J Pediatr Psychol. 2008; 33(3):248–257. [PubMed: 17855728]
27. von Baeyer CL, Spagrud LJ. Systematic review of observational (behavioral) measures of pain for children and adolescents aged 3 to 18 years. Pain. 2006; 127:140–150. [PubMed: 16996689]
28. Schechter NL. The undertreatment of pain in children: an overview. Pediatr Clin North Am. 1989; 36(4):781–794. [PubMed: 2666929]
29. Herr K, Coyne PJ, Key T, et al. Pain assessment in the non-verbal patient: position statement with clinical practice recommendations. Pain Manag Nurs. 2006; 7(2):44–52. [PubMed: 16730317]
30. Suraseranivongse S, Kraiprasit K, Petcharatana S. Postoperative pain assessment in ambulatory pediatric patients by parents. J Med Assoc Thai. 2002; 85(Suppl 3):S917–S922. [PubMed: 12452230]
31. Chambers CT, Reid GJ, McGrath PJ, et al. Development and preliminary validation of a postoperative pain measure for parents. Pain. 1996; 68(2–3):307–313. [PubMed: 9121819]
32. Brown KA, Laferriere BA, Moss IR. Recurrent hypoxemia in young children with obstructive sleep apnea is associated with reduced opioid requirement for analgesia. Anesthesiology. 2004; 100:806–810. [PubMed: 15087614]
33. Waters KA, McBrien F, Stewart P, et al. Effects of OSA, inhalational anesthesia, and fentanyl on the airway and ventilation of children. J Appl Physiol. 2002; 92:1987–1994. [PubMed: 11960949]
34. Lerman J. Obstructive sleep apnea: a pediatric epidemic. Seminars in Anesthesia, Perioperative Medicine and Pain. 2006; 25:109–116.
35. Bolton CM, Myles PS, Nolan T, et al. Prophylaxis of postoperative vomiting in children undergoing tonsillectomy: a systematic review and meta-analysis. Br J Anaesth. 2006; 97(5):593–604. [PubMed: 17005507]
36. Fujii Y. Current management of vomiting after tonsillectomy in children. Curr Drug Saf. 2009; 4(1):62–73. [PubMed: 19149526]
37. Wong D, Baker C. Pain in children: Comparison of assessment scales. Pediatr Nurs. 1998; 14(1): 9–17. [PubMed: 3344163]
38. Chambers CT, Reid GJ, Craig KD, et al. Agreement between child and parent reports of pain. Clin J Pain. 1998; 14:336–342. [PubMed: 9874013]
39. Bellman MH, Paley CE. Pain control in children: parents underestimate children's pain [letter; comment]. Br Med J. 1993; 307:1563. [PubMed: 8274939]

Table 1

Sample Characteristics (n= 47)

	Mean (SD)
Age (months)	53.53 (8.99)
Weight (kg)	19.66 (6.20)
Surgery Time (minutes)	12.13 (8.30)
Anesthesia Time (minutes)	30.40 (8.30)
	% (n)
Sex	
Male	55.3% (26)
Female	44.7% (21)
Mother's Ethnicity	
Hispanic	46.8% (22)
Caucasian	40.4% (19)
African American	6.4% (3)
Other	6.4% (3)
Father's Ethnicity	
Hispanic	50.0% (23)
Caucasian	23.9% (11)
African American	13.0% (6)
Asian	2.2% (1)
Other	10.9% (5)
Type of Surgical Procedure	
Tonsillectomy/Adenoidectomy (A)	87.2% (41)
Tonsillectomy (T)	2.1% (1)
T&A/myringotomy tube(s)	10.7% (5)
Surgical Technique	
Tonsils	
Coblator dissection	91.5% (43)
Electrocautery dissection	12.8% (6)
Adenoids	
Coblator dissection	55.3% (26)
Electrocautery dissection	61.7% (29)
Intraoperative local anesthetic	97.9% (46)

Table 2

Frequency of Moderate to Severe Opioid-Related Side Effects

	Time Point				
	Day of Surgery	**POD1**	**POD2**	**POD3**	**Statistical Analysis**
	% (n)	**% (n)**	**% (n)**	**% (n)**	
Daytime Sedation	35.5% (16)	8.9% (4)	15.5% (7)	8.9% (4)	Cochran Q = 17.33 p=0.001
Nausea	26.7% (12)	28.9% (13)	24.4% (11)	8.9% (4)	Cochran Q = 8.33 p=0.04
Vomiting	22.7% (10)	13.6% (6)	15.9% (7)	2.3% (1)	Cochran Q = 9.69 p=0.021
Constipation	2.4% (1)	19.0% (8)	16.7% (7)	11.9% (5)	Cochran Q = 12.78 p=0.005
Lightheadedness, Feeling Dizzy	13.9% (6)	9.3% (4)	2.3% (1)	2.3% (1)	Cochran Q = 7.20 p=0.07
Nightmares	0	0	2.3% (1)	2.3% (1)	Cochran Q = 3.00 p=0.39

POD, postoperative day

Table 3

Parent Responses to Home Interview Questions

	Yes	No	Unsure
	% (n)	% (n)	% (n)
Did your child have more pain after his/her surgery than you expected?	23.4% (11)	74.5% (35)	2.1% (1)
Did you feel adequately prepared to manage your child's pain at home after surgery?	93.6% (44)	6.45 (3)	0% (0)
Do you think that the pain medicine helped your child?	95.7% (45)	4.3% (1)	0% (0)
Do you think your child's pain management could have been improved?	4.3% (2)	0% (0)	14.9% (7)
			% (n)
How did things go in terms of giving the pain medicine every 4 hours for the past three days?			
No concerns identified (fine, good, pretty good)			61.7% (29)
Pain medicine tasted bad			25.5% (12)
Concerns regarding nighttime administration of pain medicine			23.4% (11)
Difficulties getting the child to take the pain medicine			8.5% (4)
Concerns regarding the timing, frequency of pain medication			4.3% (2)
Painful swallowing			2.1% (1)
Side effects (e.g., nausea, constipation)			2.1% (1)
Parental concerns about giving the pain medicine			
No concerns identified			57.4% (27)
Side effects (groggy, drowsy, sleepy, nausea)			31.9% (15)
Amount of medicine (too much, too strong)			17.0% (8)
Timing of medication administration (too frequent, for too long and pain not present)			4.3% (2)
Addiction			4.3% (2)
Usefulness of the home log			
Helpful, keeping track, knowing what to do			68.1% (32)
Helpful, awareness of their child's symptoms			12.8% (6)
Helpful, knowing how their child was feeling			5.1% (2)
Not helpful			8.5% (4)
No response			6.4% (3)
Usefulness of the nurse's phone calls			
Helpful in managing problems			42.6% (20)
Helpful, knowing that someone cared			38.3% (18)
Helpful, no qualifying response			19.1% (9)
Usefulness of the teaching booklet			
Helpful in managing their child's pain			83% (39)
Knowing what to do, validation			55.3% (26)
Knowing what to expect			27.7% (13)

	Yes	No	Unsure
	% (n)	% (n)	% (n)
Did not use			14.9% (7)
Did not find it helpful			2.1% (1)
Other than giving the pain medicine, parent strategies to help their child feel better			
Comfort measures (being with the child, holding them, loving them, catering to their wishes, giving them attention)			75% (35)
Cold things by mouth			44.7% (21)
Providing distraction (watching TV, reading books, playing with the child)			27.7% (13)
Giving fluids			14.9% (7)
Suggestions to help other parents caring for a child after tonsillectomy			
Give the pain medicine as ordered			61.7% (29)
Comfort measures (catering to the child, comforting them, baby them, physical attention, lots of love)			23.4% (11)
Patience, empathy			10.6% (5)
Be prepared, know what to expect			10.6% (5)
Cold things by mouth			8.5% (4)
Take time off work, be there for the child			4.3% (2)
Provide diversion, distraction for the child			4.3% (2)
Suggestions for food choices offered			4.3% (2)
Use the teaching booklet			4.3% (2)
Use the home log			2.1% (1)
			Mean (SD) (n=47)
Parent satisfaction with pain relief provided by the pain medicine (0=completely dissatisfied, 10=completely satisfied)			9.62 (0.86)

Note: Parents provided more than one response for some questions