A descriptive analysis of pediatric post-tonsillectomy pain and recovery outcomes over a 10-day recovery period from 2 randomized, controlled trials

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Abstract

Pediatric tonsillectomy involves an often painful and lengthy recovery period, yet the extended recovery process is largely unknown. This article describes postoperative recovery outcomes for 121 children aged 4 to 15 (mean 6.6 years, SD = 2.3) years enrolled in 1 of 2 clinical trials of analgesia safety and efficacy after tonsillectomy. Postoperative analgesia included scheduled opioid analgesic plus acetaminophen/ibuprofen medication use (first 5 days) and "as-needed" use (last 5 days). Clinical recovery as measured daily by the Parents' Postoperative Pain Measure (PPPM; an observational/behavioral pain measure), children's self-reported pain scores, side-effect assessments, need for unanticipated medical care, and satisfaction with recovery over 10 days was assessed. Higher Parents' Postoperative Pain Measure scores were correlated with poorer sleep, receipt of breakthrough analgesics, distressing side effects, higher self-reported pain scores, and need for unanticipated medical care. Higher self-reported pain scores were associated with more distressing adverse events, including nausea, vomiting, insomnia, lower parent satisfaction, and unplanned medical visits and hospitalizations. Pain and symptoms improved over time, although 24% of the children were still experiencing clinically significant pain on day 10. Scheduled, multimodal analgesia and discharge education that sets realistic expectations is important. This study adds to the emerging body of literature that some children experience significant postoperative pain for an extended period after tonsillectomy.

Keywords: Pediatrics, Tonsillectomy, Acute pain, Pain management, Breakthrough pain, Pain assessment

1. Introduction

Tonsillectomy (with or without adenoidectomy) is one of the most common surgical procedures in the United States, with more than 500,000 procedures performed annually in children younger than 15 years. The procedures are associated with significant postoperative pain that can be challenging to control due to pain severity and duration. The recovery period often extends beyond 1 week, and wide variation in postoperative pain management practices exists.

Pain relief and prevention of common side effects after tonsillectomy are important components of postoperative care, yet pain control remains problematic and there is no standard analgesic protocol. Analgesia administration at home is multifaceted and may result in inadequate pain control as a result of barriers such as inadequate analgesic prescribing (eg, inappropriate medication choice and lack of adequate discharge instructions) and/or inadequate administration (eg, misconceptions about pain medications and child refusal). Home post-tonsillectomy pain management must be improved, but limited research is available to guide pain assessment and effective control at home leading to as many as 54% of caregivers to seek postoperative medical advice from their primary care physician or hospital urgent/emergency care department. Identification and alleviation of pain is a responsibility that falls heavily on parents, making simple home assessment tools critical.

Despite the long recovery period, few studies have reported on recovery beyond the initial 2 to 3 postoperative days, and there are no published studies that have examined observational pain scores as recorded by parents at home over an extended post-tonsillectomy period with respect to other clinical indicators of postoperative recovery (eg, sleep and medication side effects). The

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the PPPM for a period of 10 days. Various trials and side effects (with emphasis on observed pain as measured by postoperative pain scores) have explored clinical recovery following ambulatory tonsillectomy for children enrolled in analgesic clinical trials. A secondary aim was to report on clinical recovery outcomes in the home for 10 days after surgery, using the PPPM along with a wide range of recovery indicators and a longer postoperative follow-up period.

The aim of this study was to describe the pediatric experience of pain and distressing symptoms at home for 10 days following ambulatory tonsillectomy for children enrolled in analgesic clinical trials. A secondary aim was to report on clinical recovery outcomes (eg, pain self-report ratings, medication administration, and side effects) with emphasis on observed pain as measured by the PPPM for a period of 10 days.

2. Methods

2.1. Participants

An explorative observational cohort of 121 children aged 4 to 15 years undergoing outpatient tonsillectomy (with or without adenoidectomy) and their parents or caregivers participated in one of 2 double-blinded, randomized, controlled trials (RCT) that included multiple pain and clinical recovery assessments. The purpose of each RCT was to compare safety and efficacy for different analgesic regimens. Each study had 2 treatment arms, with each treatment arm consisting of scheduled dosing on days 1 to 5 and PRN dosing on postoperative days 6 to 10.

Trial 1 (2011–2012) involved comparing the safety and effectiveness of a regimen of codeine with acetaminophen to a regimen of tramadol and was conducted as part of an effort to shift the hospital’s standard post-tonsillectomy prescribing practices away from codeine with acetaminophen shortly before the 2013 FDA black box warning. Further information regarding these trials is available. 

2.2. Procedures

The studies were approved by Children’s Hospitals and Clinics of Minnesota’s (CHC) Institutional Review Board and were registered with clinicaltrials.gov (NCT01267136 [trial 1] and NCT02076893 [trial 2]). All clinicians and parents were blinded to postoperative analgesic regimen. The outpatient hospital pharmacy was responsible for maintaining the blind and sequentially assigning patients to 1 of the 2 opioid analgesic treatment arms using a list of randomly generated numbers. Informed consent and assent (children ≥ 7 years of age) were obtained during a presurgical outpatient visit or on the morning of surgery, after phone contact before the day of surgery. On the day of surgery, the research coordinator instructed parents to complete a 10-day diary around the same time each day and called families every other day to check in and answer questions during the follow-up period. Families received a $25 gift card for returning the diary by mail.

2.3. Measures

The following postoperative recovery information was obtained daily for 10 days. All information including the PPPM was observational with the exception of pain self-report ratings.

2.3.1. Behavioral pain

Parents recorded daily behavioral pain observations using the 15-item PPPM (a score of ≥ 6/15 indicates pain). The scale has been well-validated postoperatively for up to 3 days. Construct validity of the PPPM has not been explored beyond postoperative day 3.

2.3.2. Pain self-report ratings

Pain “now” (0–10), “usually or most of the time” (0–10), and at its “worst” (0–10) was recorded daily using either the FACES Pain Scale-Revised (children aged 4–10 years) or Numeric Rating Scale-11 (NRS-11) for children aged 8 to 15 years. A FACES Pain Scale-Revised or NRS-11 of ≥ 4 was considered clinically significant pain. Construct validity at the time of scale development ranged from $r = 0.84$ to $0.93$ for the FACES Pain Scale-Revised and $r = 0.87$ to 0.89 for the NRS-11.

2.3.3. Pain medication administration

The total number of scheduled study medication doses that were given was recorded for the “scheduled” dosing period (days 1–5), and administration of any breakthrough medication doses (yes/no) was recorded daily during the “breakthrough” dosing period (days 6–10) (ie, actual doses were not recorded).

2.3.4. Sleep quality

Parents indicated daily if their child had trouble falling asleep because of pain (yes/no) or waking because of pain (yes/no).

2.3.5. Common side effects associated with surgery or trial drugs tramadol, gabapentin, or codeine

Checklist included nausea, vomiting, pruritus, sweating, dizziness, headache, constipation, sleepiness, and fever. Parents selected all applicable side effects that their child experienced each day.

2.3.6. Doctor’s office/urgent care/emergency department visits

Parents recorded whether or not their child had any unplanned office visits or hospitalizations each day (yes/no).
2.3.7. Parent’s global satisfaction with their child’s recovery as measured on day 10

Parents provided a single visual analogue rating on a scale of 0 = very dissatisfied to 10 = very satisfied to indicate their overall satisfaction with their child’s recovery process.

2.4. Analysis

Patient characteristics and outcomes for each observational and self-report measure were summarized over the 10-day period with standard summary statistics (eg, mean values and percentages). Associations between PPPM scores and other clinical outcomes over the 10-day period were assessed using Spearman’s correlations and generalized mixed-effects regression models, with linear and logistic models used for numeric (eg, pain self-reported score) and binary (eg, waking because of pain—yes/no) outcomes, respectively. McNemar’s test was run to explore differences in medication administration before and after the switch to scheduled dosing. Trends over the 10-day postoperative recovery period were modeled as a cubic polynomial of postoperative day and a subject-specific random effect accounted for within-patient correlations. Linear regression was used to assess associations between PPPM and overall satisfaction on day 10. Statistical significance was set at the 5% level. All analyses were performed in SAS or R.

3. Results

3.1. Sample characteristics and Parents’ Postoperative Pain Measure Scores

Parents of 121 children completed the take-home diaries (Fig. 1). Children were 4 to 15 (mean 6.6 years, SD = 2.3) years of age on average. Over half were girls (n = 70, 58%), and the majority were Caucasian (n = 105, 87%). Most children underwent tonsillectomy with adenoidectomy (n = 115, 95%). There were no differences in PPPM scores by age, sex, race, or procedure throughout the recovery period.

3.2. Trends for all clinical outcomes over 10 days

The average PPPM score on day 1 (day of surgery) was 8.4/15 (SD = 3.4). Average scores decreased (improved) throughout the 10-day follow-up period, with a small increase from day 5 to 6, then a steady decline to an average PPPM score of 3/15 (SD = 3.5) on day 10. Despite this decrease in pain scores, 24% were still experiencing clinically significant pain (defined as PPPM score $\geq 6/15$) on day 10. Overall, clinical improvements with respect to numeric pain ratings, sleep, need for analgesic rescue medication, side effects, and occurrence of unplanned medical visits during the follow-up period (outpatient or inpatient) were found. Parent ratings for global satisfaction with recovery were high as measured on day 10, with a median score of 8/10 (with 10 being most satisfied) (Q1, Q3: 7, 10). Associations between PPPM scores and all clinical outcome measures are described in the following sections.

3.3. Associations between Parents’ Postoperative Pain Measure scores and clinical outcomes

3.3.1. Numeric pain ratings and their association with Parents’ Postoperative Pain Measure scores

Daily PPPM$^6$ scores (0–15/15) were associated with pain scores (FACES Pain Scale-Revised$^{17}$ or Numeric Rating Scale-11 (NRS-11)$^{22}$ measured “now” (0–10/10), “usually or most of the time” (0–10/10), and at its “very worst” (0–10/10) (Table 1). The correlation between PPPM and self-report pain scores varied over the 10-day period, with correlations appearing strongest on later days and with the “very worst” pain scores (Fig. 2). For example, the Spearman correlation between PPPM score and pain measured “now” was 0.35 ($P < 0.001$) on day 1, whereas it was 0.54 ($P < 0.001$) on day 10. Higher PPPM scores were also associated with experiencing side effects, visiting an outpatient clinic or hospital, and using breakthrough medication for persistent pain. Scheduled use of the study medication was not associated with PPPM scores during days 1 to 5. See Table 1 for details.

3.3.2. Sleep and its association with Parents’ Postoperative Pain Measure scores

Higher PPPM scores were associated with difficulty sleeping. For every 1-point increase in PPPM score, the odds of the child having trouble falling asleep was 1.64 times higher (95% CI: 1.46, 1.78), and the odds of a child waking up in pain was 1.43 times higher (95% CI: 35%, 53%). Sleep issues followed a similar pattern to average daily PPPM scores, with sleep difficulties being reported more frequently on days 6 to 7 than any other days. For example, on day 7, 22 (20.8%) children had difficulty falling asleep, and nearly half of the sample (n = 45, 42.5%) woke up because of pain.

3.3.3. Medication administration and its association with Parents’ Postoperative Pain Measure scores

Parents’ Postoperative Pain Measure scores were not associated with number of scheduled (“around-the-clock”) medications given during the first 5 days of recovery, when children received scheduled opioid analgesia every 6 hours plus “as-needed” breakthrough (or “PRN” [pro re nata]). Starting on day 6, all analgesics were “PRN only.” However, PPPM scores were associated with use of breakthrough pain medication (yes/no) during days 6 to 10. On day 6, 97 (88%) patients used breakthrough medicine, and on day 7, 95 (90%) children used breakthrough medication. This was compared with 52 (55%) on day 5. The difference between breakthrough medication use on day 6 compared with day 5 reached statistical significance ($P < 0.0001$ via McNemar’s test). Overall, the use of breakthrough pain medications was 1.2 more likely for every 1-point increase in PPPM score (95% CI: 1.13, 1.27).

3.3.4. Side effects and their association with Parents’ Postoperative Pain Measure scores

Experience with adverse effects improved for all side effects assessed over the 10-day follow-up period. On day 1 (day of surgery), both nausea and vomiting occurred in 44 (36%) children, respectively, but the percentage of children experiencing distressing symptoms decreased in the first few days and continued to decline (Fig. 3). Fever was experienced by 19 (16%) to 20 (17%) of children on days 2 and 3, but this decreased daily, and no parents reported fever beyond day 6. Constipation was experienced by a notable percentage of patients between days 2 to 10, with the highest daily percentage of patients experiencing constipation on days 2 to 4 (33%–35%). On day 10, constipation was only reported by 9 (9%) children. Dizziness was experienced by 26 (22%) to 28 (32%) children during the first 3 days of recovery, dropping off steadily during after the scheduled dosing period (days 1–5) with only 4 (4%) reporting dizziness on day 10. The percentage of children experiencing headaches fell within the
11% to 19% range throughout the 10-day recovery period, with the highest percentage of headaches occurring on days 2 and 3 (n = 23, 19% each day). Headaches were the only side effect experienced by over 10% of the sample on day 10 (n = 13, 12%). When we examined the association of PPPM scores (ie, parent-observed pain) with the likelihood of experiencing side effects, we found that for every 1-point increase in PPPM score, the odds of experiencing each of the known side effects were significantly higher (Table 1).

### 3.3.5. Unplanned medical visits and their association with Parents’ Postoperative Pain Measure scores

Unanticipated doctor’s office, urgent care, and hospital admission rates were low overall, with the highest being on days 1 to 2 (around 3%). Nineteen (16%) of children who completed the study and whose parent(s) returned the diary had at least one hospital/urgent care-office visit during the 10-day follow-up period. The odds of having a hospital/urgent care/office visit were 1.3 (1.14, 1.52) times higher for every 1-point increase in PPPM score. The most common reasons for readmissions were pain (throat, ear) and parental concerns about dehydration.

### 3.3.6. Day 10 global satisfaction and its association with Parents’ Postoperative Pain Measure scores

Parents’ Postoperative Pain Measure scores during each of the first 5 days of the 10-day recovery period were significantly associated with parents’ global satisfaction with recovery on day 10. For example, on day 1, a 1-point increase in the PPPM score was associated with a 0.21 point lower global satisfaction on day 10 (95% CI: −0.32, −0.09). Associations on days 2 through 5 had similar magnitudes.
with pain, higher likelihood of receiving breakthrough analgesics, emergency department/urgent care/medical office visits, and unplanned hospitalization. Observation of pain behaviors in the first few days after surgery was associated with lower parent satisfaction with the overall recovery process 10 days later. Identifying these behaviors early on in the recovery process may facilitate better prevention of pain and symptom management by parents and health care teams.

More than 20% of children who undergo surgery are moderately to severely affected by pain 1 month after discharge. Even more concerning is that, in these children, a higher level of pain is also associated with a decrease in health-related quality of life. For many, acute pain persists, transitioning to chronic postsurgical pain at 1 year after surgery with reported incidence ranging from 12% to 80%. The prevailing risk factor for prolonged and chronic pain is believed to be poorly controlled postoperative pain, and transition from acute postoperative pain to chronic pain is not well understood. The main cause of morbidity after tonsillectomy is oropharyngeal pain, which may result in decreased oral intake, dysphagia, dehydration, and weight loss. Despite being one of the most common surgical interventions in children, there has been surprisingly little emphasis on the experience of pain and distressing symptoms after tonsillectomy at home outside the immediate postoperative period. The one study reporting that pain was experienced for up to 12 days postoperatively was limited in that PPPM pain was the only recovery outcome reported. For many, acute pain persists, transitioning to chronic postsurgical pain at 1 year after surgery with reported incidence ranging from 12% to 80%. The prevailing risk factor for prolonged and chronic pain is believed to be poorly controlled postoperative pain, and transition from acute postoperative pain to chronic pain is not well understood. The main cause of morbidity after tonsillectomy is oropharyngeal pain, which may result in decreased oral intake, dysphagia, dehydration, and weight loss. Despite being one of the most common surgical interventions in children, there has been surprisingly little emphasis on the experience of pain and distressing symptoms after tonsillectomy at home outside the immediate postoperative period. The one study reporting that pain was experienced for up to 12 days postoperatively was limited in that PPPM pain was the only recovery outcome measured. Our findings are strengthened by the additional information gained as a result of considering multiple clinical recovery indicators simultaneously, including their associations over a longer recovery period.

As previous studies have shown, the PPPM is a valuable observational tool for not only parents at home, but also a tool for the practitioner looking for more information than a single pain score can offer. We found that the PPPM was very useful during a longer recovery period (10 days), capturing patients’ worst pain over time, suggesting that the parents’ observations of their child’s pain-related behavior may most accurately mirror children’s ratings when they are in greater pain. Higher PPPM scores were also associated with trouble falling asleep, waking up during the night with pain, higher likelihood of receiving breakthrough analgesics, emergency department/urgent care/medical office visits, and unplanned hospitalization. Observation of pain behaviors in the first few days after surgery was associated with lower parent satisfaction with the overall recovery process 10 days later. Identifying these behaviors early on in the recovery process may facilitate better prevention of pain and symptom management by parents and health care teams.

4. Discussion

This study adds to the emerging body of literature that children suffer from a large number of distressing symptoms (eg, nausea and vomiting) following tonsillectomy with or without adenoidectomy, including clinically significant pain. Postoperative pain treatment in this patient population is a known challenge, and this study offers a more precise description of the course of pain and associated clinical outcomes. Children’s pain lasted longer than 10 days after the procedure for 24% of the sample. This is a significant number of children, suggesting some children may be more vulnerable to ongoing postoperative pain, which is consistent with earlier findings. Higher PPPM scores were associated with trouble falling asleep, waking up during the night

### Table 1

| Variable                      | Estimate (95% CI)† | P    |
|-------------------------------|-------------------|------|
| Pain at its worst, past 24 h  | 0.27 (0.23, 0.31) | <0.001 |
| Pain on average               | 0.24 (0.21, 0.27) | <0.001 |
| Pain at time of diary entry   | 0.26 (0.22, 0.30) | <0.001 |
| Pain at its worst, past 24 h  | 0.27 (0.23, 0.31) | <0.001 |
| Pain on average               | 0.24 (0.21, 0.27) | <0.001 |
| Pain at time of diary entry   | 0.26 (0.22, 0.30) | <0.001 |

* The estimate is the coefficient of the PPPM term from a mixed-effects regression model and can be interpreted as the change associated with a 1-point increase in PPPM on any given day.

† The estimate is the odds ratio of the PPPM term from a mixed-effects logistic regression model and can be interpreted as the multiplicative change in odds associated with a 1-point increase in PPPM on any given day.

Figure 2. A comparison of daily pain scores during a 10-day post-tonsillectomy follow-up period for children as assessed with the PPPM and FACES Pain Scale-Revised or NRS-11: worst, average, and current (time of survey). PPPM, Parents’ Postoperative Pain Measure.

Figure 3. Daily percentage of children experiencing side effects during the 10-day postoperative recovery period.
analgesics, multiple side effects (eg, nausea, constipation, and headaches), and the likelihood of requiring unanticipated medical follow-up care. We found the odds of a child waking up in pain was 1.43 times higher for every 1-point increase in PPPM score and that sleep issues were most troublesome on days 6 to 7 than any other days with nearly 1/4 of children having difficulty falling asleep and nearly half waking up because of pain. Although our data support Berghman et al.’s (2014) finding that 37.1% of children woke up during the first 3 postoperative nights (ie, their scheduled analgesic prescribing period), our data suggest even greater difficulties during the period when scheduled dosing was over, and shedding and scabbing were likely to be co-occurring. Poorer sleep quality after surgery has been associated with greater next-day pain intensity, and care teams should pay close attention to this period in the recovery process.

We found the PPPM to be a particularly helpful assessment tool from recovery day 5 onward. Day 5 was the last day of scheduled study medications. Our findings support previous study findings indicating that the PPPM may be a particularly helpful tool for parents during the “as-needed” medication administration period because they are responsible for acting in their child’s best interest in deciding if and when to administer medications for pain. We found that parents were still giving their children breakthrough pain medication doses, which may mean that 5 days of scheduled opioid analgesia may have been inadequate.

National data from 36 children’s hospitals shows that revisits occurred in 7.8% (range 3%–12.6%) of children within 30 days after this elective surgery (with over one-third of these patients being readmitted), with bleeding, vomiting, and dehydration accounting for three-quarters of all revisits. Not surprisingly, our study showed a strong correlation between higher pain scores and re-hospitalization, despite our relatively low rates overall. We saw the highest rates of unplanned medical visits on day 8, which followed an increase in side effects on days 6 to 7, which coincided with a switch from scheduled to PRN dosing on day 6. Better analgesia at home might in fact help prevent unplanned readmissions and clinic visits. The same is true for preventing unplanned clinic visits for complaints of dehydration. For example, dehydration may have been avoided in some of our patients if there were greater emphasis on discharge education on the importance of liquid intake and analgesia. However, the parents in our studies received extra discharge education as well as phone reminders from the research coordinator about how to avoid dehydration. This, coupled with a shorter duration of postoperative tracking, may have resulted in the lower rates of unplanned medical care required by our patients. We suspect that the natural timing of the shedding of postsurgical scabs and the day 6 switch to PRN dosing coincided, resulting in greater pain and the choice by many parents to continue a round-the-clock dosing schedule on the first day of the PRN dosing period. We also noted an increase in other side effects on days 6 and 7. Scheduled pain medications may result in better analgesia than “as-needed” administration of analgesics.

Despite receiving clear instructions and reminders every other day to give the study medication doses as prescribed, some parents chose not to follow the scheduled dosing plan during the scheduled dosing period. This has been identified as an issue with posttonsillectomy home management in a recent literature review of pediatric pain management at home after surgery. When an adequate prescription is given, both parental and child factors may be to blame for inadequate analgesia. For example, a parent may have misguided fear about addiction or (s)he has not been instructed in how to recognize and assess his/her child’s pain.

Not surprisingly, the more pain children experienced based on PPPM scores, the less satisfied parents were with their recovery. The PPPM items that assessed outward expressions of pain (eg, whining or complaining more than usual) early on were predictive of lower parent satisfaction at the end of the observation period. These findings point to educational opportunities that encourage routine, early assessment and efforts to manage pain, including paying close attention to early behaviors, such as worrying.

4.1 Limitations

Some families dropped out of the study early due to adverse events that occurred during the recovery period, requiring the need to switch pain medications. Because the diary was paper and pencil and it was completed at home (ie, in an uncontrolled environment), we were unable to enforce consistent PPPM completion on a daily basis for all parents, despite calling families every 2 days during the study follow-up. The same was true for analgesic administration because we were unable to monitor adherence at home. Therefore, some data may be incomplete or under-reported as if often the case with studies relying on self-report. Individual missing PPPM items were treated as “No” with the assumption that the child did not exhibit the behavior. Therefore, underestimation of pain was possible in some cases. This report combines data collected from 2 RCTs using the same data collection methods; however, we were unable to control for any differences in patient or parent experiences due to the trials themselves (eg, different opioids and different research staff conducting reminder calls).

5. Conclusion

Pain lasts longer than 10 days after tonsillectomy in many children, suggesting certain children are more vulnerable to pain. Higher pain scores were associated with more distressing adverse events, including nausea, vomiting, insomnia, unplanned medical visits, and hospitalizations, and a substantial number of children were still experiencing these distressing events 10 days after surgery. Scheduled analgesia beyond 5 days may be more effective than as-needed (or “PRN”) medications due to many parents reporting PRN dosing similar mirroring what was prescribed during the initial scheduled dosing period. Postoperative pain assessment and management in children who undergo tonsillectomy (with or without adenoidectomy) can be challenging, with parents being responsible for most care at home over an extended recovery period. The better the pain control, the higher parents’ satisfaction. Failure to adequately monitor and manage pain can lead to adverse events and unplanned health care visits, while placing the child at risk of transitioning to chronic pain. This study offers further insight into the lengthy post-tonsillectomy recovery process and offers suggestions for health care teams in following up with children and parents and setting realistic recovery expectations.

Disclosures

The authors have no conflicts of interest to declare.

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