Objectives: To examine the link between preoperative anxiety and resource utilization and to test the efficacy of a home-based, parent-directed pain management protocol in improving clinical, cost, and pediatric patient-based outcomes.

Design: Randomized, controlled trial.

Patients and setting: Patients of a hospital-affiliated group pediatric otolaryngology practice.

Methods: Patients and parents receiving a home pain management protocol (intervention group) were compared to those given standard postoperative instructions (control group).

Main outcome measures: Days missed from school, parent ratings of satisfaction with pain management, nonroutine postoperative utilization, number of minutes spent in the postanesthesia care unit (PACU).

Results: Higher preoperative anxiety was significantly correlated with a longer length of stay in the PACU (Pearson's r = 0.37, P = 0.03). Compared to controls, children in the intervention group missed, on average, one day of school less (P < 0.1) and parents reported higher satisfaction (P < 0.05). No differences were found between groups on nonroutine postoperative utilization.

Conclusions: Attention to and amelioration of a child's preoperative anxiety and postoperative recovery at home could lead to improved outcomes. A home-based, parent-directed pain management protocol may be one strategy for managing pain outcomes in day surgery.

Introduction

Health care systems in the United States increasingly are using home care, early discharge, and day (outpatient) surgery procedures to control costs [1,2]. Pediatric adenoidectomy/tonsillectomy, one of the most commonly performed pediatric surgical procedures [3,4], is an example of this shift—it is now commonly performed on a day surgery basis [5]. Day surgery demands highly efficient pain management, both in the hospital and at home, especially given current pressures for providers to document health outcomes such as morbidity, satisfaction, and cost [6].

Most interventions for pediatric pain outcomes management have focused on the preoperative period, particularly in regard to reducing procedure-related anxiety. Anxiety has been linked to psychological adjustment and coping during painful procedures [7–9] and after surgery [10–12]. Although various interventions have been shown to reduce anxiety [13–18] and to decrease psychological distress in children undergoing surgery [19], researchers have not yet documented the link between anxiety and health outcomes, such as length of stay.

Day surgery places the burden of postoperative pain management on parents, who have difficulty estimating their child's pain level and tend to undertreat their child's pain despite clinically significant pain [20]. Researchers have documented pain management problems in children undergoing tonsillectomy, including inadequate treatment of clinical levels of pain and inadequate pain management instructions [21–23]. However, without valid pain assessment instructions and clear instructions linking the assessment to specific action, effective postoperative pain management is difficult.

Empirical research on nonpharmacologic postsurgical pediatric pain management is sparse, and most of the studies that do focus on nonpharmacologic strategies are anecdotal reports or methodologically flawed [24]. Existing studies examine either minor procedural pain, such as that from venipuncture [25], or pain management in children with chronic illness [26–29]. Because chronically ill children experience pain differently [7], pain management strategies in these populations are unlikely to generalize to acute, normative surgical populations.

Innovation is needed in pediatric pain outcomes management for day surgery procedures. Evidence linking
preoperative anxiety to health outcomes (eg, cost) may facilitate the implementation of interventions designed to reduce preoperative anxiety. There is also a need for studies of home-based postoperative pain management strategies in pediatric populations that assess pain from the child’s perspective and that investigate clinical outcomes, patient and parent satisfaction, and service utilization. The purpose of our study was to examine the link between preoperative anxiety and length of stay in the day surgery center and to examine the efficacy of a parent-directed, home-based pain management protocol.

Methods

Study Design

A prospective, randomized, two-group comparison design was used. The principal variables in the study were clinical outcomes (days missed from school was used as a proxy for morbidity), service utilization (length of stay in the second phase postanesthesia care unit [PACU], telephone calls, additional prescriptions, or office visits for pain-related symptoms), and parent satisfaction. The study protocol was approved by the Institutional Review Board at Children’s Hospital and Health Center.

Patients

Eligible consecutive patients of a group pediatric otolaryngology practice affiliated with Children’s Hospital in San Diego were recruited for the study. Patients were eligible for the study if they were 5 years of age or older and admitted to the Children’s day surgery center for simple tonsillectomy or adenoidectomy/tonsillectomy. Patients were excluded if they were non-English speaking or had non-English-speaking parents or had other underlying complicating conditions (eg, obstructive apnea) or developmental delay. Patients who agreed to participate were randomly assigned, based on a predetermined assignment, to either the intervention group or the standard care group.

Intervention

The intervention was a pain management protocol consisting of two parts—a valid instrument for pain measurement and an algorithm relating the pain scores to the appropriate pain medication. Because effective pain management is very difficult without accurate pain assessment, we provided the parents with a validated pain assessment instrument, the Varni/Thompson Visual Analogue Scale (VAS) (Figure 1), and a booklet containing instructions on its use. The VAS employs a 10-cm line with no numbers, marks, or descriptive vocabulary along the length of the line and is anchored with developmentally appropriate pain descriptors (eg, not hurting, hurting a whole lot) and happy and sad faces. This study used a mechanical VAS, which consisted of a VAS printed on a plastic card with a sliding marker for children to manipulate and a centimeter scale on the back for
scoring. The instructions for the VAS ask the child to slide the marker along the line to represent the intensity of pain along the continuum from no pain to severe pain. The VAS has demonstrated excellent construct validity in pediatric postoperative medication studies [31,32]. It is considered to have properties of both direct scaling, in which the length of the line measures the intensity of the pain [33], and ratio rather than interval scaling [34]. The VAS has been shown to be a reliable and valid measure of pain perception in children as young as 5 years [9]. In the intervention protocol, parents were instructed to assess their child’s pain via the VAS at least twice daily (morning and night) for 10 days and were told they could use the VAS as often as they wanted to help them manage their child’s pain.

Parents were also given an algorithm explaining how to relate the VAS pain scores to medication administration. This algorithm was developed based on consultation with the pediatric surgeons, anesthesiologists, and nurses most familiar with the VAS and this pediatric day surgery population. Standard postoperative discharge instructions are to give acetaminophen every 4 hours and acetaminophen with codeine as necessary. For many parents, “as necessary” is too vague a descriptor [20,22,23]. Thus, the experimental intervention gave parents precise instructions linking assessment to medication administration. Parents were instructed as follows: “If the VAS score is 3.5 or below, give acetaminophen. If the VAS score is above 3.5, give acetaminophen with codeine.”

Preoperative Assessments
Children in both groups received standard preoperative instructions that included practice with the anesthesia mask, a description of what to expect, and instructions to the parents. In addition, patients in the intervention group and their parents were taught by a nurse how to measure preoperative anxiety. Specifically, McGrath has demonstrated that a VAS rating of anxiety in children aged 3 to 11 years undergoing lumbar puncture correlated highly with nurse and parent ratings of anxiety [9]; Jay and colleagues [36] have shown that children aged 3 to 12 years awaiting bone marrow aspirations were able to use a Faces Scale to rate their own anxiety; and May [37] demonstrated the clinical utility of using a Faces Scale to assess anxiety in children awaiting painful procedures. PACU nurses were unaware of preoperative anxiety scores. The standard instructions for explaining how to use the Faces Scale were as follows: “Explain to the child that each face is for a person who feels happy because there is no worry or sad because there is some or a lot of worry. Ask the child to choose the face describing his or her own worry.”

Home-based Assessments
Parents were instructed to record school days missed and postoperative utilization in a log. Number of school days missed was defined as days missed as a result of illness or complications related to the surgery. Weekend days during which the child could not participate in regular activities were counted as missed days to eliminate day-of-the-week effects. Postoperative utilization was defined as nonroutine (e.g., concern about pain) telephone calls to the physician, additional prescriptions filled for analgesic medications, or physician office visits for postoperative concerns in the 10 days following the surgery.

Parent satisfaction was assessed with two questions adapted from the Postoperative Pain Management Quality Assessment Survey (PPMQAS), an assessment instrument developed by the American Pain Society [38] to measure satisfaction with postoperative pain management in adults. In the absence of research validating this instrument for use in parents’ ratings of their child’s pain management, items were chosen for face validity. In this study, parents were asked, “How satisfied overall were you with the pain relief your child received after surgery?” (Response scale: Very dissatisfied, Dissatisfied, Satisfied, Very satisfied) and “If your child needed surgery again, would you want the pain treated in the same way?” (Response scale: Yes, No).

All parents were given a booklet containing the log for recording school days missed and postoperative utilization, satisfaction questions, and a stamped envelope. At the end of 10 days, morbidity and utilization information were collected via telephone, and the parents were reminded to complete and mail back the satisfaction questionnaires.
Hospital Assessment
Length of stay was defined as the number of minutes spent in the second stage PACU and was recorded by nurses on a form designed for this study.

Statistical Analysis
A Pearson’s product-moment correlation was performed to test the correlation between preoperative anxiety and length of time in the PACU. To test the efficacy of the home-based pain management protocol, the intervention group and control group were compared. In the absence of significant covariates, independent-sample t tests were used to compare days missed from school and parent satisfaction, and a chi-square test was used to compare postoperative utilization.

Results
A total of 66 patients (53% girls) completed the protocol. The average age of the children (± SD) was 8.5 years (± 3.2 years). Family characteristics, based on ZIP code, indicated a median household income (± SD) of $42,300 (± $14,200) and an average education level (± SD) of 13.9 years (± 1 year). There were no demographic differences between the intervention and control groups. Study participants were more likely than the overall population of tonsillectomy patients at the hospital to be white (as opposed to Hispanic) and to have private insurance (versus Medicaid) (Table 1).

The correlation between preoperative anxiety and time in the PACU was 0.37 ($P$ = 0.03). Preoperative anxiety accounted for 13.7% of the variance in PACU minutes. Higher ratings of preoperative anxiety were associated with longer recovery time postoperatively in the PACU. Figure 2 shows the scatterplot of these two variables as well as the regression line of PACU minutes regressed against preoperative anxiety.

Children in the intervention group (mean school days missed = 4.6, SD = 2.7) missed on average approximately one full day of school less than children in the control group (mean school days missed = 5.7, SD = 2.9), although this difference was not statistically significant ($t_{55} = 1.7, P < 0.1$). Parents in the intervention group were, on average, more satisfied with their child’s pain management than were parents in the control group ($t_{55} = -2.0, P < 0.05$). Missing satisfaction data were equally likely to be from parents in the control and intervention groups. Regarding postoperative utilization, 38% of children in the intervention group, as opposed to 44% of children in the control group, called the physician or visited the office for concerns after the surgery, although this difference was not statistically significant. No patients in either group visited the emergency department or were rehospitalized.

Discussion
This study presents initial data regarding preoperative and postoperative strategies for pain outcomes management in pediatric tonsillectomy. These data show that preoperative anxiety is linked to the number of minutes patients stay in the PACU. Patients with higher preoperative anxiety were more likely to stay longer in the PACU. The absolute size of this correlation is in the medium effect range, as defined by Cohen [39], and indicates that, on average, preoperative anxiety accounts for 13.7% of the variance in PACU minutes. This variance accounted for in postoperative surgical care is more impressive considering that streamlined and efficient pathways for tonsillectomy were already in place at Children’s Hospital and Health Center. Over the past 5 years, the otolaryngology department has designed and implemented a tonsillectomy/adenoidectomy clinical pathway that has resulted in more standardized processes and cost reductions of approximately 60%. The net effect of this pathway has been a reduction in the variation of outcomes such as length of stay. Given that correlations are attenuated by restriction of range in the correlated variables [40], a large correlation at an institution with an efficient pathway implies that the effect size may be greater in institutions that have not undergone a restructuring designed to reduce practice and outcome variance.

Table 1. Demographic Characteristics of Intervention and Control Groups

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group ($n = 33$)</th>
<th>Control Group ($n = 36$)</th>
<th>All Other Tonsillectomy Patients ($n = 233$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD (yrs)</td>
<td>8.3 ± 3.3</td>
<td>8.6 ± 3.5</td>
<td>8.5 ± 3.1</td>
</tr>
<tr>
<td>Sex (% boys)</td>
<td>49</td>
<td>44</td>
<td>45</td>
</tr>
<tr>
<td>Race*</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>% White</td>
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<td>53</td>
<td>46</td>
</tr>
<tr>
<td>% Black</td>
<td>6</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>% Hispanic</td>
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<td>28</td>
<td>45</td>
</tr>
<tr>
<td>% Other</td>
<td>15</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Insurance†</td>
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</tr>
<tr>
<td>% Commercial</td>
<td>79</td>
<td>81</td>
<td>66</td>
</tr>
<tr>
<td>% Medicaid</td>
<td>21</td>
<td>19</td>
<td>34</td>
</tr>
<tr>
<td>Median household income</td>
<td>$46,500</td>
<td>$43,500</td>
<td>$41,400</td>
</tr>
<tr>
<td>Average level of education (yrs)</td>
<td>14.0</td>
<td>14.2</td>
<td>13.8</td>
</tr>
</tbody>
</table>

*χ² = 34.4, $P < 0.001$, comparing study group to other tonsillectomy patients.
†χ² = 5.2, $P = 0.023$, comparing study group to other tonsillectomy patients.
The parent-directed, home-based pain management protocol was designed to increase parents’ confidence and effectiveness regarding postoperative pain management in the home. The strategy used—providing an assessment and management protocol—is similar to that used in pediatric asthma and diabetes patients. In terms of postoperative outcomes management, the data suggest that a protocol for parent-directed, home-based pain management may improve health outcomes. Children in the intervention group missed, on average, one day of school less than children in the control group, although this difference was not statistically significant at the \( P < 0.05 \) level. Parents in the intervention group were more satisfied with their child’s pain management than were parents in the control group. Postoperative utilization was not affected by the intervention.

One reason this study did not detect a larger effect may be the fidelity with which parents implemented the pain management protocol. Fidelity to treatment was not monitored, but several parents informally admitted that although they found the intervention to be helpful, they stopped using it after 1 or 2 days. Further, there is no information regarding whether parents followed the algorithm for medication administration. That is, parents could have used the VAS but still withheld the acetaminophen with codeine because of fears such as addiction. We have analyzed the data based on intention to treat. It would be useful to compare parents with and without treatment fidelity. In the absence of such data on fidelity, however, we could not perform this analysis. It also may be the case that a larger sample is necessary to achieve statistically (as opposed to clinically) significant differences. Future research will need to address these issues by monitoring intervention fidelity and medication dosage and accruing a larger sample.

This study illustrates one way in which pediatric outcomes management differs from that in adults: special efforts are needed on the part of parents and professionals to help children express themselves. Children are often unable to express pain intensity accurately and clearly without the help of valid measures of pain intensity like the VAS. Indeed, a common flaw in much of the previous pediatric postoperative pain research is the reliance on proxy measures of pediatric pain [20,41,42]. Self-report pain measures comprise the “gold standard” in pain assessment [43], are the most reliable method for the assessment of pain in children older than 5 years of age [12], and have been shown to be a valid assessment strategy in children recovering from tonsillectomy [44]. Reliance on observational or physiologic pain measures may lead to inaccurate assessment of pediatric pain and consequently to inappropriate, ineffective, or more costly pain management [20,22]. This point is noteworthy, especially in light of the fact that pediatric pain has historically been undertreated [12,45], due in part to the lack of reliable, valid, age-appropriate pain assessment tools [46,47]. In the current environment of provider accountability, providers must constantly be vigilant for opportunities to improve the quality of the care delivered. Those who can understand and assess the comprehensive health-related needs of children are better positioned to enhance health outcomes in their pediatric patients.
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38. American Pain Society. Quality assurance standards for

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