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Improving postoperative tonsillectomy pain management in children – A double blinded randomised control trial of a patient analgesia information sheet

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ABSTRACT

Objectives: To evaluate paediatric post-tonsillectomy pain management using oxycodone when a specific analgesia information sheet is included with standard postoperative information.
Methods: Oxycodone information sheets were randomly allocated to half the study children's post-tonsillectomy information pack. The trial was double-blinded to the surgeon, anaesthetist, nursing and administrative staff. Parents and children completed the pain assessment on day 3, 5 and 7. On day 10 the parents completed a questionnaire.
Results: A postoperative analgesia information sheet provides for higher satisfaction and knowledge for parents using oxycodone ($p < 0.001$) and children have improved postoperative pain control, most significantly at day 5 ($p < 0.05$). Parent assessment of the child's analgesia was superior with the oxycodone information sheet, most significantly at day 3 and 7 post operatively ($p < 0.05$). There is also a positive correlation between the parents' observed pain score and children's self reported pain score, with a low correlation efficient level observed ($p < 0.001$).
Conclusions: Information sheets are useful in education and use of postoperative analgesia. The primary objective to explore the efficacy of the information sheet has proved to be successful in this setting. Given risks of opioid analgesia, it is recommended that postoperative information sheets be given to all parents, to provide for improved analgesia control and safe management of children in the postoperative period.

1. Introduction

Postoperative analgesia for paediatric patients undergoing tonsillectomy is a debated topic with most Otolaryngologists. Currently, with focus on short-term hospital stay and early discharge, there is a level of anxiety from surgeons discharging a postoperative patient with opioid analgesia following tonsillectomy and adenoidectomy. The pain following tonsillectomy and adenoidectomy can be severe in children and can be very stressful for parents to manage at home.

Oxycodone (OxyNorm) is available in an oral liquid opioid preparation for analgesia that has strong benefits for children, however, currently is not registered for use in children on the Pharmaceutical Benefits Scheme [1]. A study by Fortier et al. [2] described significant post-tonsillectomy pain observed in children following day case operative surgery and is a significant problem for parents. Wiggins et al. [3] found that children at home following tonsillectomy and adenoidectomy receive only about half of their prescribed analgesics, mostly due to fear of incorrect dosage. Regular paracetamol and codeine is commonly prescribed for the treatment of moderate to severe pain in children; however, this analgesic combination is not effective for pain control after tonsillectomy [4]. Other preparations such as non-steroidal anti-inflammatory drugs have recently been shown in a Cochrane Database Review to have insufficient evidence to exclude increased risk of bleeding [5] and thus are not routinely used.

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Codeine is a weak opioid agonist that requires conversion to morphine by endogenous enzymes to provide analgesia. Unfortunately, there is significant inter-individual genetic variability. Slow metabolisers are unable to convert enough needed for an analgesic response, whereas ultrafast metabolisers may be at risk of opioid toxicity, including life-threatening respiratory depression [6]. Furthermore, infants and young children have an increased susceptibility to the adverse effects of opioids. As a result, codeine is becoming less favourable for postoperative analgesia in children. There was a Boxed Warning from the United States Food and Drug Administration [7] in February 2013 regarding the use of codeine in children after tonsillectomy, with reports of deaths in children with obstructive sleep apnoea who received codeine.

Much trust is placed on parent's ability to adequately administer potent analgesia for postoperative children in a safe and effective regime. The significant side effects of opioids such as respiratory depression, confusion, nausea and vomiting may all become apparent once the child is home. Kankkunen et al. [8] found that many parents do not feel confident using the analgesia and thus receive inadequate postoperative analgesia. Norrington et al. [9] found that parents have a higher level of anxiety in the immediate time frame upon discharge for day cases, compared with overnight admission. Parents are often given a regime of analgesia to follow on discharge that some may find confusing, hard to follow or inadequate to meet the child's needs and thus are discharged less than satisfied.

As a result, some surgeons are using patient handouts routinely for information and providing documentary support for the parents. Previous investigation by Aremu et al. [10] have shown that further education and handouts about an operation and potential side effects lead to improved recall. As a result, providing an information sheet for parents to read with specifics regarding the use of analgesia should be beneficial to postoperative analgesia. This trial explored the efficacy of a parent handout on postoperative analgesia in children undergoing tonsillectomy.

2. Material and methods

An envelope containing information about the trial was given to all patients in the preanaesthetic area by the surgeon. The envelope included information about the trial and survey forms. Approximately half the patients ($n = 32$) were given a specific patient information sheet about oxycodone. Allocation of the oxycodone information sheet was completed via an online random number generator [11]. The completed sealed envelopes for allocation were kept by the surgeon and given out in order as randomly allocated.

Sixty patients were enrolled in the study from May 2013 until March 2014. The inclusion criteria were; children 2–16 years old, undergoing tonsillectomy or adenotonsillectomy or adenotonsillectomy with insertion of tympanostomy tube. The treating team included a single Otolaryngologist and a single anaesthetist, at the John Flynn Private Hospital, Queensland, Australia. The surgical technique included bipolar tonsillectomy for complete dissection in all patients, with a power setting of 15, (Force FX, Electrosurgical generator, Valley Lab, Boulder, Co., 80301-3299, USA). Ethics approval was sought prior to beginning the trial and was approved by The Greenslopes Research Ethics Committee ethics counsel in May 2013 with approval number of 13/18. The trial was registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR) number ACTRN12615000054516. The surgeon, anaesthetist, nursing and clerical staff were double blinded with regard to allocation of information sheets.

All children's parents were given a routine verbal outline of a suggested oral regime for analgesia by the surgeon following the operation. Parents were provided the opportunity to ask questions regarding the study and also the ability to withdraw from the study at the same time. Routine nursing information was given to the children and parents. All parents were instructed not to open the envelope until they were home. The analgesia regime recommended was paracetamol 15 mg/kg every 6 h, oxycodone 0.1 mg/kg every 6 h or as needed, and Diflam® every 6 h or as needed (Spray, Local Oral; Benzydamine Hydrochloride 1.5 mg/mL, iNova Pharmaceuticals (Aust) Pty Ltd.).

There were three survey tools used for the assessment. The Faces, Legs, Arms, Cry and Consolability – FLACC scale [12], is an assessment tool that the parents used to quantify pain using five categories of facial expression; legs, activity, cry and consolability to accumulate to a score from 0 to 10. It is a valid tool used widely in paediatric nursing and has significant comparison to a child's self reported pain [13]. The Wong Baker Faces Pain Scale [14] was the second assessment tool used, which has been shown in a systematic review by Tomlinson et al. [15] to be effective in pain assessment of paediatric patients. Children were asked to point to the face that best described their pain. These scales were completed on day 3, 5 and 7. The principal researchers designed the Day 10 Questionnaire, which was sent to the parents on day 10. It is a combination of knowledge and satisfaction questions using a 5-point scale and yes/no questions and one multiple-choice question. Parent satisfaction score was derived by summing up first three questions in relation to parents' satisfaction of pain relief following the procedure, information provision about pain relief, and prescribed medicine. The score ranged from 0 to 15. The knowledge score was calculated by summing the six questions relating to oxycodone use. The score ranged from 0 to 6. A higher score indicated better satisfaction and knowledge.

Fifty-eight questionnaires and assessment forms were returned. Two children were omitted from the study, as they were discharged from hospital without receiving a prescription for oxycodone (Fig. 1). The completed forms were placed in a box at clinic follow-up or returned by post.

Statistical analysis was conducted using SPSS version 22. Perceptions on oxycodone information were all normally distributed. The descriptive analysis results in demographic characteristics and perceptions of oxycodone information were presented as frequency and percentage for categorical variables, and mean and standard deviation for continuous variables. The effect of oxycodone information on parents' perceptions about pain management following the oxycodone information use was analysed by multivariate analysis of variance (MANOVA). When multivariate results demonstrated a significant effect, univariate analyses were used to identify which factors in relation to parents perception on oxycodone use contributed to the multivariate effect. The effect of the oxycodone information sheet on children's pain perception was also analysed by MANOVA and univariate analyses were used to identify whether children's perception of pain on day 3, 5 and 7 contributed to the multivariate effect. The correlation between children and parents' pain scores on day 3, 5, and 7 were analysed by Kendall's Tau Rank Correlation test to validate the pain perceived by parents on day 3, 5 and 7 after the medication was taken by the children.

3. Results

There was a statistically significant difference between the two groups. There was higher level of parent's satisfaction, knowledge of oxycodone use, and superior management of the child's pain control on day 3 and day 7 with the oxycodone information sheet group. There was a statistically lower pain scores in the oxycodone information sheet group on day 7, judged by both the parents and child (Table 1).

As there is significant difference between the two groups in the proportion of gender distribution, gender may confound the effect