



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.

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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

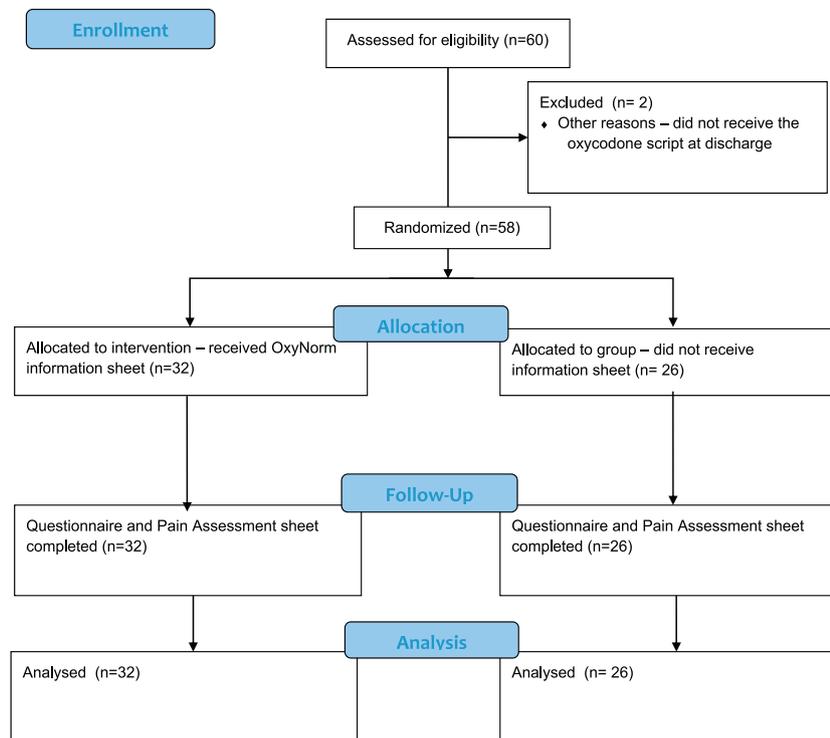


Fig. 1. CONSORT analysis of study design.

of the oxycodone information sheet on the parents' satisfaction and knowledge of oxycodone use, pain management and children's pain perception, in day 3, 5 and 7. This variable has been controlled in the general linear model.

When gender, as a confounding factor is controlled in the analysis, there is an overall significant oxycodone information effect ($F = 7.96, p < 0.001$) on parents' perception about oxycodone use (Table 2). It was found that satisfaction and knowledge of oxycodone use, and pain management in day 3, 5 and 7 following the oxycodone use was superior with the allocation of an oxycodone information sheet. Univariate analysis identified that the oxycodone information sheet has significant effect on parent's satisfaction and knowledge and superior day 7 children's pain management. The knowledge of oxycodone use has a moderate effect size, suggesting the information provided to parents has greater effect on knowledge of parents in oxycodone use than other factors in the study.

When gender as a confounding factor is controlled in the analysis, there is an overall significant oxycodone information effect ($F = 3.11, p = 0.03$) on children's pain perception (Table 3). Univariate analysis identified that allocation of an oxycodone information sheet had a significant effect on children's pain perception seen on day 5 and day 7. The effect size in day 7 is the greatest with small effect size of 0.13 suggesting the oxycodone information given to parents has greater effect on day 7 pain perception perceived by children, than any other factors in the study.

There is a significant and positive relationship observed between parent's perception of the child's pain and the self reported children's scoring of pain in day 3, day 5 and day 7. This score has a low correlation efficient level (Table 4). All of the above correlations have reached statistically significance with p value at 0.001 level.

4. Discussion

This randomised double-blinded trial has shown that patients who receive information sheets have superior analgesia control,

parents are more knowledgeable regarding postoperative analgesia and the overall satisfaction is higher.

Information sheets have been widely used before. In a study by Dawes and Davison [16] over half the patients surveyed complained about postoperative anxiety and over half thought information sheets would be reassuring. It has been shown by Gibbs et al. [17] that information sheets improve patient's knowledge about their condition, treatment and potential side effects, without necessarily increasing pre-operative anxiety.

Oxycodone has a standard product information sheet enclosed within the packaging; however, one must appreciate that this is purely for information purposes and specifics of the analgesia regime is ultimately at the merit of the prescriber. This study has found that a set of instructions for an analgesia regime and specific details regarding the postoperative analgesia is superior to standard orders given in routine discharge information.

It has been widely found that analgesia in the postoperative period is insufficient. Homer et al. [18] found that children did not receive adequate analgesia in the postoperative period following discharge from hospital. This study regime included oxycodone analgesia regularly in combination with paracetamol. Verbal orders were given to all patients, with the oxycodone information sheet given a written document of the instructions. Hixson et al. [19] described that deciding on the correct analgesic formulation, dose and frequency for a child receiving pain relief at home can be challenging for parents. The various postoperative analgesia options for tonsillectomy patients have been described elsewhere, this study has found that the use of an information sheet is superior to simple verbal routine discharge instructions. There are various indications for tonsillectomy in children, once such reason being obstructive sleep apnoea. As such, a surgeon must have heightened awareness for discharging a patient home with opioid analgesia with known medical comorbidities potentially interacting with the adverse effects of analgesia.

One aspect of the study was the parent's satisfaction with pain relief. This is imperative in the discharge of a postoperative patient. As young children are unable to effectively communicate their pain

Table 1
Descriptive statistics in participants and perceptions on oxycodone information.

	Received oxycodone information (n=29)	Did not received oxycodone information (n=29)	χ^2 or <i>T</i>	<i>p</i>
Age median (range)	6 (2–15)	6 (2–16)	<i>T</i> =0.23	0.81
Gender, <i>n</i> (%)				
Boys	11 (37.9%)	19 (65.5%)	<i>T</i> =4.42	0.03
Girls	18 (62.1%)	10 (34.5%)		
Satisfaction of parents, <i>M</i> (SD)	13.72(1.96)	12.03 (1.80)	<i>T</i> =3.42	<0.001
Knowledge of oxycodone – correct responses, <i>n</i> (%)				
Score 1	0 (0)	2 (6.9)	29.53	<0.001
Score 2	1 (3.4)	4 (13.8)		
Score 3	2 (6.9)	15 (51.7)		
Score 4	5 (17.2)	6 (20.7)		
Score 5	21 (72.4)	2 (6.9)		
Pain score on day 3 by parents, <i>M</i> (SD)	3.31 (2.07)	4.38 (1.92)	<i>T</i> =−2.04	0.05
Pain score on day 5 by parents, <i>M</i> (SD)	3.86 (2.37)	4.45 (2.08)	<i>T</i> =−1.00	0.32
Pain score on day 7 by parents, <i>M</i> (SD)	3.45 (1.90)	5.00 (2.94)	<i>T</i> =−2.39	0.02
Pain score on day 3 by child, <i>n</i> (%)				
No hurt	1 (3.4)	0 (0)	χ^2 =4.35	0.50
Hurts a little bit	4 (13.8)	1 (3.4)		
Hurts a little more	3 (10.3)	5 (17.2)		
Hurts even more	14 (48.3)	12 (41.4)		
Hurts a whole lot more	5 (17.2)	8 (27.6)		
Hurts worst	2 (6.9)	3 (10.3)		
Pain score on day 5 by child, <i>n</i> (%)				
No hurt	0	0	χ^2 =9.66	0.04
Hurts a little bit	4 (13.8)	2 (6.9)		
Hurts a little more	10 (34.5)	2 (6.9)		
Hurts even more	8 (27.6)	15 (51.7)		
Hurts a whole lot more	4 (13.8)	8 (27.6)		
Hurts worst	3 (10.3)	2 (6.9)		
Pain score on day 7 by child, <i>n</i> (%)				
No hurt	1 (3.4)	1 (3.4)	χ^2 =8.33	0.14
Hurts a little bit	9 (31.0)	2 (6.9)		
Hurts a little more	8 (27.6)	9 (31.0)		
Hurts even more	7 (24.1)	7 (24.1)		
Hurts a whole lot more	4 (13.8)	7 (24.1)		
Hurts worst	0 (0)	3 (10.3)		

Statistical significance: *p* < 0.05.**Table 2**
Multivariate analysis on the effect of oxycodone information on parents' perceptions about pain management following the oxycodone information use.

Type of analysis	OxyNorm information use	Parents perceptions	<i>F</i>	<i>p</i>	Effect size
Multivariate analysis	Received oxycodone information	Parents perception on oxycodone use	7.96	<0.001	0.44
	Gender		0.76	0.58	0.07
Univariate analysis	Received oxycodone information sheet	Satisfaction of oxycodone information	10.34	0.02	0.16
		Knowledge of oxycodone medication	39.31	<0.001	0.42
		Pain score in day 3 by parents	3.11	0.08	0.05
		Pain score in day 5 by parents	1.38	0.25	0.03
		Pain score in day 7 by parents	7.30	0.009	0.12

Table 3
Multivariate analysis on the effect of the oxycodone information sheet on children's perception of pain following the oxycodone information use.

Type of analysis	OxyNorm information use	Children's perceptions	<i>F</i>	<i>p</i>	Effect size
Multivariate analysis	Received oxycodone information	Children's perception of pain	3.11	0.03	0.15
	Gender		1.57	0.21	0.08
Univariate analysis	Received oxycodone information	Pain score in day 3 by children	1.43	0.24	0.03
		Pain score in day 5 by children	4.28	0.04	0.07
		Pain score in day 7 by children	7.94	0.007	0.13

amount and frequency, a parent must be aware of the subtle cues for administering analgesia. At the same time they must be aware of the vital signs and symptoms of overdose. The oxycodone information sheet aimed to reduce parental guesswork by including specifics of the analgesia and templates for assessment.

This study has found that the oxycodone information group had superior satisfaction using the prescribed analgesia. The FLACC and faces scale used were standard templates used in postoperative paediatric wards. They were used for the simplicity and quantitative score of the assessment and have been validated by Willis et al.

Table 4

Correlation between pain score reported by parents and children.

	Day 3 pain score by child	Day 5 pain score by child	Day 7 pain score by child
Day 3 pain score parents	0.35***		
Day 5 pain score parents		0.37***	
Day 7 pain score parents			0.42***

Kendall's Tau Rank Correlation coefficient was used to indicate the correlation level.

*** $p < 0.001$.

[13]. No education was provided regarding the use of the templates. Previous studies by Aremu et al. [10] and Courtney [20] using an information booklet have shown similar improvements in patient's satisfaction and understanding. The results from this trial have shown that information sheets used in postoperative analgesia has superior parental satisfaction when compared to verbal routine discharge instructions.

Butow and Sharpe [21] describe that good communication between health providers and patients can improve outcome. The application of an oxycodone information sheet has shown to provide for superior analgesia control and improved knowledge surrounding oxycodone use. The shared decision making model, which includes giving patients evidence based scope of practice, has been shown to be effective by Elwyn et al. [22]. The application of this information sheet with effective communication surrounding the use of analgesia is a well-rounded approach to ensuring a patient is discharged as effectively as possible.

Improvements to trial can be aimed towards previous knowledge and use of prescribed analgesia prior to this application along with the extent to which the parent explored other resources for information. This study has made no attempt to control for specific individual characteristics, which is essential in the routine discharge framework. The previous parent education or knowledge of analgesia for previous surgeries using opioid analgesia would be beneficial as it could be controlled for and explored for its significance. There was no indication that the allocation of an information sheet resulted in improved knowledge; instead, it has

been found that there is a correlation between higher knowledge of postoperative analgesia and the information sheet. The extent to which parents explored other resources is potentially one significant variable that is underestimated. The various resources available to parents were not controlled nor was it directly asked. Follow up with patients, roughly at 3 months, could have included a more in depth analysis or another questionnaire regarding the effectiveness of the information sheet and if any side effects or adverse responses to the prescribed analgesia was found.

Overall the information sheet provided for a significant difference to the pain rated by the child and parent. Therefore, the application of this information sheet provided for superior analgesia.

5. Conclusion

Information sheets are useful for education surrounding postoperative analgesia. 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. The primary objective to explore the efficacy of the information sheet has proved to be successful in this setting. Thus, an information sheet included in the parent and patient shared decision model of analgesia leads to improved control in the management of postoperative analgesia.

Appendix A. Assessment Sheet and Questionnaire

*FLACC Scale – please circle the **average** for day 3, 5 & 7 for how you, as a parent, feel the child is looking*

FLACC SCALE – (Face, Legs, Activity, Cry, Consolability)

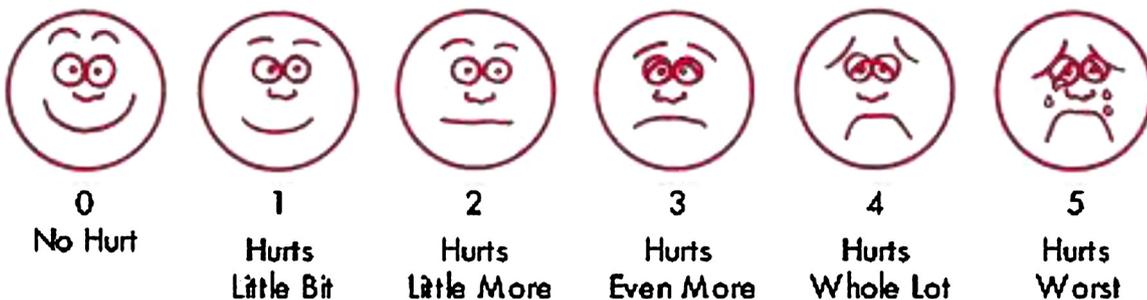
Instructions: Rate patient in each of the five measurement categories.
Add together to determine total pain score

	0	1	2
FACE	No particular expression or smile, eye contact and interest in surroundings	Occasional grimace or frown, withdrawn, disinterested, worried look to face, eyebrows lowered, eyes partially closed, cheeks raised, mouth pursed	Frequent to constant frown, clenched jaw, quivering chin, deep furrows on forehead, eyes closed, mouth opened, deep lines around nose/lips
LEGS	Normal position or relaxed	Uneasy, restless, tense, increased tone, rigidity, intermittent flexion/extension of limbs	Kicking or legs drawn up, hypertonicity, exaggerated flexion/extension of limbs, tremors
ACTIVITY	Lying quietly, normal position, moves easily and freely	Squirming, shifting back and forth, tense, hesitant to move, guarding, pressure on body part	Arched, rigid, or jerking, fixed position, rocking, side to side head movement, rubbing of body part
CRY	No cry or moan (awake or asleep)	Moans or whimpers, occasional cries, sighs, occasional complaint	Crying steadily, screams, sobs, moans, grunts, frequent complaints
CONSOLABILITY	Calm , content, relaxed, does not require consoling	Reassured by occasional touching, hugging, or talking to, distractible	Difficult to console or comfort

Merkel, SI, Voepel-Lewis, T., Shayevitz, JR, & Malviya, S. (1997). The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing*, 23(3): 293-297.

Instructions:

Please circle the most appropriate response on each day for the **average** of how the pain is rated by the child on day 3, 5 & 7:



Hockenberry MJ, Wilson D: *Wong's Nursing Care of Infants and Children*, ed 8, St. Louis, 2007, Mosby

Day 10 Questionnaire:*To be conducted on day 10 post procedure**Please bold/circle/highlight the most appropriate response**Parent Satisfaction:***1. Overall, how satisfied were you with the pain relief of the medicines prescribed?**

1 2 3 4 5

2. Overall, how well informed were you about pain relief following the procedure?

1 2 3 4 5

3. Overall, did you feel comfortable using the prescribed medicine for pain relief?

1 2 3 4 5

*Oxycodone Knowledge:***4. Circle which answer is a significant risk with the use of oxycodone?**

- A) Lack of sleep
- B) Not eating
- C) Slowing of breathing
- D) Increased agitation

5. Can oxycodone and Painstop be used together?

- A) Yes
- B) No

6. If your child is still in pain is it okay to use the oxycodone more frequently than the prescribed 6 hours between doses?

- A) Yes
- B) No

7. Can these pain medications be used in a drowsy child?

Paracetamol syrup Yes / No
Oxycodone syrup Yes / No

8. Based on your use of oxycodone would you be comfortable using it again for your child's pain relief?

Yes / No

Key:

1 = Not at all satisfied

2 = Less than satisfied

3 = Average

4 = Somewhat Satisfied

5 = Very Satisfied

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