The Use of Oxycodone for Analgesia Post Caesarean Section: Maternal Plasma Levels, Breast Milk Levels and Neonatal Levels; Survey of Use in Australian and New Zealand Obstetric Units.

by

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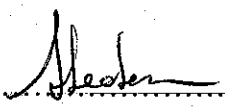

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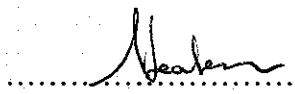

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Abstract

Drug transfer to the feeding infant and the safety of a transferred drug are important considerations for clinicians, yet there is a paucity of reliable studies in humans. Drug product manufacturers are not mandated to provide studies on the transfer of their products into human milk and may advise that the drug not be used in breastfeeding mothers, due to lack of information. This often leads to the cessation of the drug, resulting in suboptimal treatment of the mother, or the highly undesirable outcome of cessation of breastfeeding.

There was a perception that the opioid analgesic drug, *oxycodone*, was becoming a popular choice for oral analgesia post-Caesarean section. A review of the literature revealed no information or recommendations for its use in this setting, and manufacturers advised that the drug should not be used in breastfeeding.

Fifty breastfeeding mothers, taking oxycodone, had blood and breast milk samples analysed for oxycodone levels at 24-hourly intervals after Caesarean section. Forty-one neonates had blood samples analysed at 48 hours and 72 hours after delivery.

Oxycodone was detected in milk of all mothers taking any dose of the drug in the previous 24 hours. The maximum level recorded in milk was 168 ng/ml. There was a strong linear correlation between the maternal blood levels and the milk levels and there was evidence of persistence of oxycodone in the milk of some mothers, up to 37 hours after the last maternal dose. Oxycodone was detected in the plasma of one neonate of 41 tested.

The risk of neonatal exposure was assessed to be minimal in the three days post delivery because of the low volumes of milk ingested by neonates in this period. The benefits of providing effective and convenient analgesia to aid successful initiation of breastfeeding and enable mothers to care for their babies would appear to outweigh the risks of infant exposure to oxycodone in this early period.

The findings in this study are not generalisable to the transfer of oxycodone into mature milk, or exposure of older infants whose mothers may be taking this drug. It would be prudent to be cautious and monitor infants for signs of sedation, poor feeding, gastrointestinal symptoms and respiratory depression if mothers are on large doses of oxycodone.

To determine current practice with respect to the use of oxycodone and other drug components of multimodal analgesia post-Caesarean section 25 Fellows of the Australian and New Zealand College of Anaesthetists completed an on-line survey. Responses indicated that 50 percent of women in metropolitan hospitals and 95 percent in rural/regional hospitals, in the survey sample, would receive oral or rectal oxycodone post-Caesarean section. The popularity of oxycodone as a choice for analgesia in this setting supports the importance of this study.

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I also extend my thanks to Professor Noel Davies for his invaluable input into a chemical extraction method; and for his time spent on HPLC analysis of our samples; and Dr Alison Featherstone and Sue Brandon for chemical extraction of samples.

This work would not have been possible without the assistance of Dr Albert Shugg and Dr Amol Daware (paediatricians), in collecting neonatal blood samples; the midwives and nursing staff of the North West Private Hospital in collecting milk and maternal blood samples; and Richard Hanlon and staff of North West Pathology Services in collecting, storing and shipping samples.

Finally I wish to sincerely thank all the mothers who consented to participate in this study, for their contribution to the advancement of knowledge about the safety of drugs in breast-feeding.

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