

THE USE OF MISOPROSTOL IN MIDWIFERY PRACTICE

In April 2008, the Auckland College of Midwives hosted an interactive education forum, exploring the current use of Misoprostol within New Zealand maternity care.

Wikipedia has this to say about Misoprostol:

“Misoprostol is a drug that is FDA-approved in the United States for the prevention of NSAID-induced gastric ulcers. It is also used (and approved in other countries) to induce labor and as an abortifacient. It was invented and marketed by G.D. Searle & Company (now Pfizer) under the trade name Cytotec (often misspelt Cyotec), but other brand-name and generic formulations are now available as well.

Chemically, misoprostol is a synthetic prostaglandin E₁ (PGE₁) analogue.”

Exploring off-label use in the United States, Wikipedia notes that misoprostol is considered mostly useful for labor induction and bereavements. It goes on to note:

“The manufacturers of misoprostol have never sought to license misoprostol for labor induction. Recently, however, generic forms of misoprostol have become available, and it is now licensed for labor induction in Egypt and Brazil, and a licensed induction product is expected in the UK in 2008.

The American College of Obstetricians and Gynecologists advocates misoprostol for labor inductions, and it is on the WHO essential drug list for labour induction.”

The last paragraph in Wikipedia reads:“Misoprostol is also used to prevent and treat post-partum hemorrhage, but it has more side effects and is less effective than oxytocin for this purpose.”¹

Here in New Zealand Misoprostol is used as part of an early induction and in the management of the third stage where there is excessive blood loss. What defines a post-partum hemorrhage seems to be debatable, but current thinking in New Zealand appears to fall within the average of 500mls for a vaginal birth and 1000mls for a caesarean section.

Anecdotal feedback at the forum would suggest that the use of misoprostol in the treatment of PPH has become common practice in certain areas of New Zealand. There have been reported instances of misoprostol being used in a primary environment in spite this particular medication being considered a secondary or tertiary level drug. In fact, every time an unapproved drug is used in Zealand it should be reported to the authorities.² It would be fairly safe to assume that this probably doesn't happen often, if at all!

Elaine Grey, from the New Zealand College of Midwives, noted in her presentation that the side effects of misoprostol included shivering, fever, diarrhea, nausea and cramping and that a search of the current literature would suggest that 70% of the time the drug works and that 30% of the time it doesn't work, sometimes with catastrophic results. In fact in a search through the abstracts, the only consistent theme that I identified was that as it was a relatively stable medication it may be suitable for use in developing countries.

¹ <http://en.wikipedia.org/wiki/Misoprostol>

² <http://www.medsafe.govt.nz/profs/Rlss/unapp.asp>

Elaine also noted that as research on misoprostol has been restricted to its use for treating gastric ulcers, the effect on the newborn infant is not known. Further to this, RANZCOG have this to say about misoprostol: "As the use of misoprostol in pregnancy is "off label", clearly no liability would be accepted by the company for adverse reactions."³

To summarise, this drug has little evidence to support its safety or efficacy for use in obstetrics, the manufacturer will accept no liability for any adverse reactions, it is not registered for use in New Zealand as an uterotonic and when used for PPH the potential side effects for a new mother are horrendous; and yet it continues to be used by various practitioners throughout the country!

Google Cytotec and you will invariably end up with the number of horror stories clearly outweighing support for the use of this medication in obstetric practice. On Ina May Gaskin's website I discovered a very useful 2005 summary of research, entitled *A Summary of Articles Published in English about Misoprostol (Cytotec) for Cervical Ripening or Induction of Labor*.⁴

One consistent theme I discovered while surfing was that much of the information about the usefulness (or otherwise) of this drug has been established purely through trial and error. With the 20th Anniversary of the Cartright Inquiry this year, I would like to ask, are New Zealand women and their infants again being submitted to "trial and error" medicine?

Clearly the issues for women lie firmly around their rights to receive services of an appropriate standard, to be fully informed and to give informed consent (or informed refusal). In the case of a PPH, urgency can limit the amount of information that can be effectively provided. However women must be aware that a medication being recommended is not licensed for that use in New Zealand and where possible written consent should also be gained. Midwives have a role to play in not only ensuring that this consent is carried out, but in also having a high awareness of the implications on their own practice of administering or being part of a multi-disciplinary team that administers misoprostol.

Finally, this serves as a reminder to us all that there continues to be very little in the way evidence to support many of the practices in use within the maternity sector.

Jennie Valgre



**This article was originally published in the
MSCC Newsletter No. 71, June 2008**

³ The Use of Misoprostol in Obstetric and Gynecology, RANZCOG College Statement, November 2007

⁴ http://inamay.com/archive/view_article.php?Article_ID=18&page_number=1