Institution: University of Birmingham

Unit of Assessment: UoA2

Title of case study: Epidural analgesia: Reducing instrumental delivery and side-effects of epidural analgesia during childbirth

1. Summary of the impact

Instrumental births can cause problems and are needed more often with epidurals. The Comparative Obstetric Mobile Epidural Trial (COMET) was the definitive trial that led to the NICE Intrapartum Care guideline recommendation to discontinue traditional epidurals using high concentration local anaesthetic solutions in favour of low dose epidural techniques which allow women to be mobile during labour. It is estimated that these changes have resulted in about 10,000 fewer instrumental deliveries annually in the UK. Correspondingly, numbers of women experiencing effects of instrumental births such as faecal incontinence will have been substantially reduced. This research has also influenced clinical guidelines and led to changes in practice on the type of epidurals used during labour elsewhere, including Australia and Canada.

2. Underpinning research

Epidural analgesia is the most effective pain relief during childbirth and in the mid-1990s was used by more than 150,000 women in the UK alone and substantially more in North America, Europe, Australia and New Zealand. However, it is associated with increased rates of instrumental vaginal delivery and other effects, which may be related to the dense motor block produced by traditional high dose epidurals. Professor **MacArthur** (Professor of Maternal and Child Epidemiology, University of Birmingham) and colleagues considered that new low dose or "mobile" epidural techniques that preserve motor function might reduce rates of obstetric intervention.

Professor **MacArthur** with anaesthetists at Birmingham Women's NHS Foundation Trust began studying the effects of epidurals in 1988 as part of their Department of Health funded study of health problems following childbirth. This observational study of almost 12,000 women linked women's responses to a questionnaire to data from their obstetric case notes and showed an association between increased reporting of backache and other symptoms in those who had used epidurals for pain relief. Three papers were published in BMJ between 1991 and 1993. Prompted by this work, a group in Harvard also investigated effects of epidurals but failed to find the same associations. Discussions between Professor **MacArthur** and the Harvard team highlighted that they used a new low dose 'mobile' infusion (LDI) epidural in their centre because women liked mobility, rather than the high dose epidurals formerly used. This led Professor **MacArthur** to develop the COMET study. The Birmingham team applied to NHS R&D for funding and formed a collaboration with an obstetrician (Professor Andrew Shennan) in London where a Combined Spinal Epidural (CSE) mobile technique had been developed. Both groups were funded jointly by NHS R&D to undertake a randomised controlled trial to test the effects of mobile techniques relative to traditional epidurals: the Comparative Obstetric Mobile Epidural Trial (COMET, ISRCTN49349244) commenced 1997 and completed 2001 (http://www.controlled-trials.com/ISRCTN49349244/).

COMET was a three-arm, two-centre randomised controlled trial, which compared the effects of two 'mobile' low-dose epidural techniques (LDI and CSE) with high-dose traditional epidural. Between February 1999 and April 2000, 1054 nulliparous women requesting epidural analgesia were randomly assigned to traditional (n=353), LDI (n=350), or CSE (n=351) groups. The primary short term outcome was mode of delivery (spontaneous vaginal birth) and secondary outcomes included labour progress, efficacy of procedure, effect on newborns and women's satisfaction and control. Data were collected during labour and women were interviewed postnatally, then completed a postal questionnaire12 months after birth, to assess long-term symptoms.

The COMET trial demonstrated that both of the low-dose 'mobile' epidural techniques resulted in significantly fewer instrumental deliveries and authors concluded that continued routine use of traditional epidurals might not be justified [1]. There were no differences in pain relief ratings and

satisfaction with mobile techniques, whilst feelings of control in labour were superior [1,2,3]. Follow-up at 12 months showed no long-term disadvantages of using mobile techniques and significantly less faecal and stress incontinence reported by the LDI group and less headache by the CSE group, than the traditional epidural group [3,4]. The main findings were published in the Lancet in 2001 [1] accompanied by a commentary summarising the impact of the research in terms of avoidance of large numbers of instrumental deliveries if mobile rather than traditional techniques were to be used. Numerous subsequent papers have been published in specialist journals [4,5,6,] and the main COMET study paper [1] has been cited over 130 times.

3. References to the research

1. Comparative Obstetric Mobile Epidural Trial (COMET) study group UK Effect of low-dose mobile versus traditional epidural techniques on mode of delivery: a randomised controlled trial. *The Lancet* 2001; 358(9275): 19-23. http://www.ncbi.nlm.nih.gov/pubmed/11454372

2. Comparative Obstetric Mobile Epidural Trial (COMET) study group UK. Randomised controlled trial comparing traditional with two "mobile" epidural techniques: anaesthetic and analgesic efficacy. *Anesthesiology* 2002; 97(6):1567-75. http://www.ncbi.nlm.nih.gov/pubmed/12459686

3. Cooper GM, MacArthur C, Wilson M, Moore P, Shennan A. Satisfaction, control and pain relief: short and long term assessments in a randomised controlled trial of low-dose and traditional epidurals and a non-epidural comparison group. *International Journal of Obstetric Anaesthesia* 2010; 19(1): 31-37. http://www.ncbi.nlm.nih.gov/pubmed/19945274

4. Wilson MJ, Moore PA, Shennan A, Lancashire RJ, MacArthur C. Long term effects of epidural analgesia in labor: a randomized controlled trial comparing high dose with two mobile techniques. *Birth*. 2011; 38(2):105-110. http://www.ncbi.nlm.nih.gov/pubmed/21599732

5. Wilson M, MacArthur C, Cooper GM, Bick D, Moore PA, Shennan A. Epidural analgesia and breastfeeding: a randomised controlled trial of epidural techniques with and without fentanyl and a non-epidural comparison group. *Anaesthesia* 2010; 65(2): 145-153 http://www.ncbi.nlm.nih.gov/pubmed/19912160

6. Wilson M, MacArthur C, Cooper GM, Shennan A. Ambulation in labour and delivery mode: a randomised controlled trial of high-dose versus mobile epidural analgesia. *Anaesthesia 2009;* 64(3):266-272. http://ncbi.nlm.nih.gov/pubmed/19302638

4. Details of the impact

Impact on Public Policy

This research on the effects of epidurals at the University of Birmingham has directly influenced and changed clinical practice in the UK and internationally. The COMET trial is the definitive (and only) trial in the review of traditional versus modern regimens of epidural infusion in the UK NICE Intrapartum Care guideline updated in 2008 and still current, and led to the recommendation stating that: *'traditional high concentration local anaesthetic solutions (0.25% or above of bupivacaine or equivalent) should not be used routinely for either establishing or maintaining epidural analgesia'* [1]. It had previously been calculated by others that such changes would result in 10,000 fewer instrumental deliveries year on year in the UK (Thornton JG, Capogna G. Reducing likelihood of instrumental delivery with epidural anaesthesia. The Lancet 2001; 358: 2001). Forceps births are known to be associated with increased problems for women, such as faecal incontinence, perineal pain and pain on intercourse (dyspareunia).

These changes to UK policy are reinforced by Royal College of Anaesthetists Guidelines (2009, 2013) on the provision of Obstetric Anaesthesia Services, which recommends that units should be able to provide low dose regional analgesia, citing COMET as the sole reference [2].

Internationally, the COMET trial has influenced clinical policy in Canada and Australia. The Canadian Agency for Drugs and Technologies in Health (2010) clinical guidelines on effectiveness and safety of ambulatory epidural analgesia in obstetrics [3] includes references to the main Lancet paper and several of the subsequent COMET papers. These subsequent papers have provided evidence on safety and leg strength in relation to ambulation, urinary catheterisation and anaesthetic outcomes such as speed of analgesia, drug utilisation and requirement for anaesthetist re-attendance. In Western Australia, the research was referenced in 2010 in the Department of Health's Women and Newborn Health Service, obstetrics and midwifery clinical guidelines [4].

Impact on Clinical Practice and Patient Care

There has been impact on patients throughout the 2008-2013 impact period resulting both from these policy changes as well as earlier guidelines that were still current during this time. The Obstetric Anaesthetists' Association (OAA) / The Association of Anaesthetists of Great Britain and Ireland (AAGBI) *Guidelines for Obstetric Anaesthetic Services* [5] had recommended in 2005 (with COMET as the sole reference) that units should have guidelines for management of epidural blocks and should be able to provide low-dose regional analgesia. Together, the original research and the subsequent guidelines and policy changes, have moved the UK from a situation just before the COMET trial in which only 24% of units offered low dose techniques in 1996/7 (Burnstein R, Buckland R, Pickett JA, A survey of epidural analgesia for labour in the United Kingdom. Anaesthesia 1999; 54(7): 634-640) to one in which UK units rarely use the traditional high dose technique for standard labour analgesia. This change in approach can be directly linked to the COMET study through these changes in policy and guidance. This work has also been incorporated into local unit guidelines e.g. cited in Guidelines for the Practice of Obstetric Anaesthesia in Nottingham University Hospitals [6]. The COMET trial has also influenced clinical care through its incorporation in textbooks on pain management: an example is the Oxford Handbook on pain management [7], which references the COMET trial.

Economic Impact

The impact of a reduction in the instrumental delivery rate has had a corresponding effect on reducing the costs of deliveries. This is because, if a woman has an instrumental rather than a spontaneous delivery, the costs rise due to an obstetrician being required for instrumental deliveries, the costs of the instruments and the cost of an associated increase in the length of the hospital stay. The cost-effectiveness study that formed part of the COMET trial demonstrated reduced obstetrician attendance and duration of stay. At the time the overall cost saving in clinical time and hospital stay was offset by the greater cost of the use of the newer drug, but these drugs are now less costly. In addition, several studies have shown that forceps deliveries are associated with an increase in faecal incontinence, haemorrhoids, constipation, perineal pain and dyspareunia occurring after birth, such problems incurring greater costs to both the NHS and women themselves. Little is known about these symptoms in the longer term following instrumental births, except for faecal incontinence which has been shown to persist for many years even in women who have had only one forceps delivery thus continuing additional costs (evidenced in other research by **MacArthur** [8]). The prevalence of persistent faecal incontinence (including less severe symptoms) at 12 years postpartum in the largest postpartum cohort study was 4.6% in women who had only had spontaneous vaginal deliveries, whereas it was 9.3% in women whose delivery history included a forceps birth [8].

5. Sources to corroborate the impact

1. National Institute for Health and Clinical Excellence. Intrapartum Care. Care of healthy women and their babies during childbirth. NICE Guidance,CG55 London: NICE: September 2007. http://guidance.nice.org.uk/CG55 Revised print 2008, http://guidance.nice.org.uk/CG55/Guidance/pdf/English

2. Royal College of Anaesthetists. Guidelines for the provision of anaesthetic services. Chapter 9. Obstetric Anaesthesia Services. London: RCOA; 2013.

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3. Canadian Agency for Drugs and Technologies in Health. Ambulatory Epidural Analgesia in Obstetrics: Clinical Effectiveness, Safety, and Guidelines. Ottawa: CADTH; November 2010.http://cadth.ca/media/pdf/K0271_Ambulatory_Epidurals_Obstetrics_abs.pdf

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5. The Association of Anaesthetists of Great Britain and Ireland/ Obstetric Anaesthetists' Association. OAA/AAGBI Guidelines for Obstetric Anaesthetic Services. Revised edition 2005. AAGBI/OAA; 2005. http://www.aagbi.org/sites/default/files/obstetric05.pdf

6. Nottingham University NHS Trust. Guidelines for the Practice of Obstetric Anaesthesia, ninth revision. Nottingham: Nottingham University Hospitals NHS Trust; January 2008. http://www.docstoc.com/docs/38608919/Obstetric-guidelines---NEMSAnet

7. Brook P, Connell J, Pickering T (eds). Oxford Handbook of pain management. First edition. Oxford; OUP; 2011. ISBN13: 9780199298143 ISBN10: 0199298149

8. MacArthur C, Wilson D, Herbison P, Lancashire R, Hagen S, Toozs-Hobson P et al. Faecal incontinence persisting after childbirth: a 12 year longitudinal study, BJOG2013; 120(2): 169-179. DOI: 10.1111/1471-0528.12039 http://www.ncbi.nlm.nih.gov/pubmed/23190303