

# Randomised study of long term outcome after epidural versus non-epidural analgesia during labour

Charlotte J Howell, Tracy Dean, Linda Lucking, Krysia Dziedzic, Peter W Jones, Richard B Johanson

## Abstract

**Objective** To determine whether epidural analgesia during labour is associated with long term backache.

**Design** Follow up after randomised controlled trial. Analysis by intention to treat.

**Setting** Department of obstetrics and gynaecology at one NHS trust.

**Participants** 369 women: 184 randomised to epidural group (treatment as allocated received by 123) and 185 randomised to non-epidural group (treatment as allocated received by 133). In the follow up study 151 women were from the epidural group and 155 from the non-epidural group.

**Main outcome measures** Self reported low back pain, disability, and limitation of movement assessed through one to one interviews with physiotherapist, questionnaire on back pain and disability, physical measurements of spinal mobility.

**Results** There were no significant differences between groups in demographic details or other key characteristics. The mean time interval from delivery to interview was 26 months. There were no significant differences in the onset or duration of low back pain, with nearly a third of women in each group reporting pain in the week before interview. There were no differences in self reported measures of disability in activities of daily living and no significant differences in measurements of spinal mobility.

**Conclusions** After childbirth there are no differences in the incidence of long term low back pain, disability, or movement restriction between women who receive epidural pain relief and women who receive other forms of pain relief.

## Introduction

Epidural analgesia in labour is used by about 100 000 women in Britain each year.<sup>1</sup> However, not much is known on long term effects of this form of pain relief, and before this study anecdotal or case series had concentrated on more severe side effects, such as extremely rare neurological complications.<sup>2</sup>

There have been several studies into back pain and epidural analgesia (table 1). MacArthur et al first suggested that epidural analgesia might be associated with low back in 1990.<sup>3</sup> They carried out a postal questionnaire survey of 12 000 women who had delivered in Birmingham between 12 months and 9 years earlier. They found an unexpected association between the use of epidural pain relief for labour and long term low back pain (lasting more than three months). They were unable to make any assessment of the severity or aetiology of the low back pain. The authors were aware that this association might not be causal, and they attempted to control for possible confounding factors by statistical adjustment. Despite these adjustments, the

Academic Department of Obstetrics and Gynaecology, North Staffordshire Hospital (NHS) Trust, Stoke on Trent, Staffordshire ST4 6QG

Charlotte J Howell consultant anaesthetist

Linda Lucking research coordinator Richard B Johanson professor of obstetrics

Physiotherapy Department, Staffordshire Rheumatology Centre, Haywood Hospital, Burslem, Stoke on Trent Tracy Dean research physiotherapist

Department of Physiotherapy Studies and Primary Care Sciences Research Centre, Keele University, Keele, Staffordshire Krysia Dziedzic clinical trialist, physiotherapy

Department of Mathematics, Keele University, Keele, Staffordshire ST5 5BG

Peter W Jones professor of medical statistics

Correspondence to: C J Howell charlotte@kogs.freeserve.co.uk

bmj.com 2002;325:357

**Table 1** Previous research into back pain and epidural analgesia in labour

Study	Design*	No of participants	Result for backache (epidural v no epidural)	Authors' conclusion
MacArthur, 1990 <sup>3</sup>	Retrospective postal questionnaire	11701	18.9% v 10.5% at 6 weeks	Relation between backache and epidural analgesia is probably causal
Russell, 1993 <sup>4</sup>	Retrospective questionnaire plus outpatient consultation	1015	17.8% v 11.7% at 6 months	Though new long term backache is reported more commonly after epidural analgesia in labour it tends to be postural and not severe
MacArthur, 1993 <sup>5</sup>	Data extraction from 1990 survey paper and re-examination	1141	18.6% v 9.2% at 6 months	Association with backache is real
Breen, 1994 <sup>16</sup>	Prospective interview and follow up by postal questionnaire	1042	44% v 45% at 1-2 months	Epidural analgesia for labour and delivery did not seem to be associated with back pain 1-2 months postpartum
MacArthur, 1995 <sup>17</sup>	Prospective cohort study with follow up	329	14% v 7% at 6 weeks (relative risk 2.22, 95% CI 0.89 to 5.53)	Women who underwent epidural analgesia during delivery had increased incidence of low back pain only on first day after delivery
MacLeod, 1995 <sup>6</sup>	Retrospective postal questionnaire	2065	26.2% v 1.7% at 1 year	Association between backache and epidural may be causal but bias may be present. Controlled randomised study warranted
MacArthur, 1997 <sup>15</sup>	Retrospective telephone questionnaire	329	10% (chose epidural) v 14% (chose not to have) at 1 year	No increased risk of back pain in women who had used epidural analgesia

\*None of these studies was randomised.

**Table 2** Comparability of women allocated to receive epidural analgesia or other form of pain relief during labour. Figures are means (SD) unless stated otherwise

	Epidural (n=151)	Non-epidural (n=155)
Maternal age (years)	24.4 (5.1)	23.5 (4.7)
No (%) with subsequent pregnancy	36 (24)	35 (23)
Time since delivery of index pregnancy (months)	26.6 (12.5, range 11-62)	25.9 (12.1, range 12-62)
Gestation at delivery (weeks)	40 (1.6)	40 (1.5)
Birth weight (g)	3440 (385)	3429 (490.9)
No (%) with spontaneous labour	125 (83)	122 (79)

association between epidural pain relief for labour and the reporting of long term low back pain remained.

In a further retrospective observational study Russell et al found that 18% of women who received epidural analgesia had long term low back pain compared with 12% of those who used other forms of pain relief.<sup>4</sup> Although there were suggestions that the excess low back pain might stem from a “popular notion that epidurals cause long term backache,” MacArthur et al maintained that the association was real.<sup>5</sup> Two years later, MacLeod et al, in another retrospective study, reported an even greater difference, with 26% of women who had epidurals for analgesia complaining of low back pain compared with only 2% in the non-epidural group.<sup>5</sup>

Given the great human, medical, and economic costs of chronic low back pain<sup>7</sup> we considered that a prospective controlled study with objective assessment of long term outcome was urgently needed. We had already undertaken a randomised controlled trial of epidural and non-epidural analgesia in labour, in which we examined the immediate effects of the different forms of analgesia on progress of labour, satisfaction, and health after childbirth.<sup>8</sup> We used the same general health questionnaire as MacArthur et al,<sup>3</sup> which incorporated questions on low back pain. However, this did not allow an objective assessment of any back pain in terms of severity or the interference with mobility and activities of daily living.

We investigated long term differences in self reported and objective measures of low back pain between women who received epidural pain relief and those who received other forms of pain relief during labour.

## Methods

### Participants

For the original pain relief study we had recruited 369 primigravidas with a cephalic presentation at term. All these women were invited to participate in this follow up study (151 from the epidural group and 155 from the non-epidural group agreed to participate). In the original study 184 women were randomised to receive an epidural and 123 received it, and 185 were randomised to other methods of pain relief but 52 had an epidural (see figure). The study had local ethics committee approval, and all women had given signed informed consent to participate.

### Procedures

Assessment of low back pain is complex as it involves the patient's personal and subjective experience of pain and disability as well as objective assessment of physical impairment.<sup>7</sup> We used the Roland and Morris question-

naire, which has been validated for assessing disability in activities of daily living due to low back pain.<sup>9</sup>

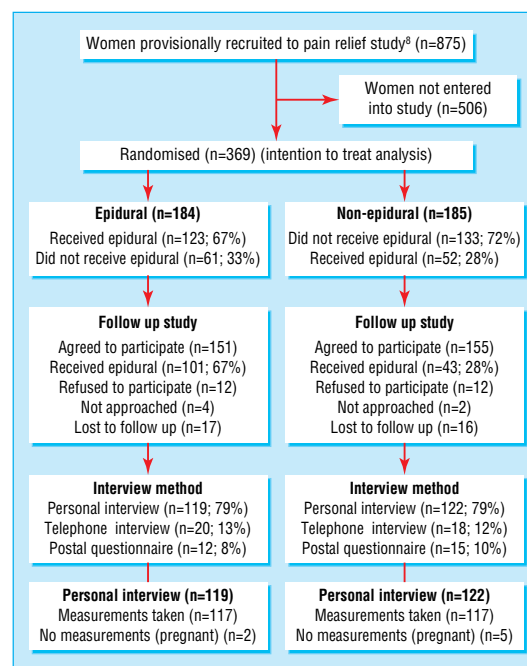
We chose objective physical measurements that had previously been shown to identify those patients with low back pain and that were significantly associated with self reported disability in activities of daily living.<sup>10</sup> The range of movements included straight leg raising, spinal flexion and extension, lateral flexion, and ability to sit up. Additional measurements included the modified Schober distance and the fingertip to floor method of assessing forward bending.<sup>7 11 12</sup> Before the study started we standardised assessment and carried out training to reduce intraobserver variability. TD undertook all assessments and was blinded to both the original group allocation and the method of pain relief actually received. Inevitably some women revealed this information during the course of the interview, and this was recorded.

The study ran from September 1995 to December 1997 (recruitment to the original pain relief study ended in September 1996). We contacted women who had taken part in the pain relief study and had given birth over 12 months previously. In previous studies researchers have found it difficult to get women to come to hospital for follow up assessments<sup>4</sup> so we usually interviewed women in their own homes but appointments could be arranged at the hospital if this was more convenient. When a woman did not want to participate in a face to face interview we used a telephone interview or a postal questionnaire.

### Power calculations and analysis

With 150 women in each group we calculated that we could be 80% confident of detecting (at  $P=0.05$ ) a clinically significant 10% difference in objective measurements of low back pain at two years.<sup>3</sup>

We analysed data on an intention to treat basis. Continuous data are expressed as mean (SD), and we assessed differences with *t* tests. Frequency data were



Flow chart showing entry into follow up study

**Table 3** Women's answers to pain questionnaire according to allocation to epidural analgesia or other method of pain relief during labour. Figures are numbers of women

	Epidural (n=151)	Non-epidural (n=155)
Experienced back pain	115	112
Pain began during pregnancy	87	83
Pain began after delivery (time):		
Shortly after	14	12
1-2 months	2	1
2-4 months	4	2
6-12 months	0	1
12-18 months	0	1
18-24 months	0	1
>2 years	1	0
Some other time	7	11
Pain lasted >1 year	47	64
Still experiencing pain now	64	70
Pain in past week	46	47
Last episode of pain:		
Very bad/unbearable	17	13
Moderate/quite bad	67	67
Little pain	30	25
No reply	1	7
Most common site of pain:		
Lumbar/upper sacral region	90	76
Multiple areas	19	20
Other areas	4	11
Site not specified	2	5
Pain alters during menstruation	26	25

analysed with the StatXact Turbo package (CYTEL, Cambridge, MA, USA).

## Results

Table 2 shows basic data for the two groups. These data reflect the validity of the original randomisation. The mean time since delivery of the index pregnancy was over two years in both groups.

The figure shows the entry flow for the study. The proportion of women who received their allocated method of pain relief in the original study was similar in both groups, as were the proportions by method of follow up and the proportions in which the assessor remained blind to the original method of analgesia (epidural 126/151 *v* non-epidural 138/155).

The incidence of self reported low back pain during or after pregnancy was high (table 3). There were no significant differences in terms of the timing of onset. Back pain was common in both groups and more women reported severe pain in the epidural group, but pain lasting more than one year, persistent

pain, and recent pain were all more common among women who had not had an epidural.

We measured a range of movements in 117 of 119 women in the epidural group who were interviewed and 117 of 122 in the non-epidural group (table 4). The seven women who were not examined at all were pregnant at the time of the assessment, and measurements were omitted at the request of the woman or on the advice of the research physiotherapist. There were no significant differences between the groups in any of the measurements of mobility. There were also no differences in responses to questions about everyday tasks that may be more difficult in the presence of low back pain (table 5).

## Discussion

In this controlled comparison of the long term effects of epidural and non-epidural analgesia we found no significant differences in self reported low back pain or disability and in objective measurements of spinal mobility after more than two years. The validity of these findings is affirmed by the randomised study design, the objective measures of outcome, and the high follow up rate.

## Limitations

The interpretation of our findings is limited by the number of crossovers between groups. This is inevitable in trials that compare epidural and non-epidural pain relief<sup>35</sup> but was lower in our study than in others. This study could therefore be considered as showing the differences between liberal and restricted use of epidural analgesia in labour. The absolute difference in epidural use was 40%. Despite the real life crossover between groups we found a significant association between use of epidural analgesia and the rate of assisted delivery, being 30% compared with 19% in the non-epidural group.<sup>8</sup> If an increased incidence of low back pain was also attributable to the use of epidurals, it too could have been shown despite the crossover. Our analysis was on an intention to treat basis for valid scientific reasons<sup>14</sup> and also because this is the standpoint from which women will approach labour. They may be intending to use particular forms of analgesia, but in the real world some women may find non-epidural methods insufficient or may be managing so well that they do not use the epidural that they planned. The findings are also limited by the moderate numbers of women included, meaning that rare events of harm could not have been reliably detected.

**Table 4** Roland and Morris questionnaire and measurements of movement. Figures are means (SD) unless stated otherwise

	Epidural (n=119)	Non-epidural (n=122)	95% CI for difference in means or %
Modified Schober distance (cm)	6.9 (1.3), n=115	6.8 (1.3), n=116	-0.237 to 0.437
Fingertip to floor distance (cm)	1.8 (5.6), n=117	2.1 (5.8), n=117	-1.77 to 1.17
Right lateral flexion (cm)	22.1 (4.7), n=116	22.6 (4.4), n=117	-1.68 to 0.675
Left lateral flexion (cm)	22.3 (4.6), n=116	22.9 (4.5), n=117	-1.77 to 0.575
Total spinal flexion—prone (cm)	9.7 (2.5), n=117	10 (2.4), n=113	-0.937 to 0.337
Total spinal extension—prone (cm)	4.1 (2.1), n=117	3.8 (2.2), n=104	-0.27 to 0.87
Straight right leg raised—supine (cm)	86 (11.5), n=117	87.7 (9.7), n=116	-4.45 to 1.05
Straight left leg raised—supine (cm)	86.3 (12.1), n=116	88.3 (9.4), n=116	-4.8 to 0.803
No (%) able to sit up with knees flexed, hip/knee flex/ext	60 (52%), n=115	52 (47%), n=110	-8.2% to 18%
No (%) able to hold position for 5 seconds	108 (94%), n=115	103 (93%), n=111	-5.4% to 7.6%

**Table 5** Effects of backache on lifestyle in women according to allocation to epidural analgesia or other method of pain relief during labour

	Epidural (n=151)	Non-epidural (n=155)
I stay at home	3	1
I change position frequently	35	38
I walk more slowly than usual	8	10
I avoid jobs around the house	4	2
I use handrail to get upstairs	2	6
I lie down and rest more often	9	12
I hold on to something when getting up from a chair	5	8
I get other people to do things for me	6	5
I get dressed more slowly than usual	6	4
I stand for only short periods of time	9	18
I try not to bend down or kneel	20	16
I find it difficult to get out of a chair	11	3
My back is painful most of the time	6	9
It is difficult to turn over in bed	21	13
My appetite is not good	2	0
I have trouble putting socks on	8	6
I only walk for short distances	2	8
I sleep less well	21	21
I get dressed with help from someone else	1	0
I sit down for most of the day	3	2
I avoid heavy jobs around the house	15	19
I am irritable and bad tempered	10	14
I go upstairs more slowly	4	11
I stay in bed for most of the time	2	1

### Previous studies

MacArthur and coworkers reviewed six comparative studies which examined the association between epidural analgesia and postpartum low back pain.<sup>15</sup> The three studies that showed a significant effect were all retrospective, while the prospective surveys showed no significant differences.<sup>16-17</sup> This important difference in findings illustrates the potential for bias in retrospective studies and similarly supports the value of carefully designed prospective studies, even if it is not feasible to generate a randomised cohort of patients.

### Back pain in pregnancy

We found that reported rates of low back pain were high during pregnancy and at long term follow up in both groups of women. The proportions were similar to those observed by Ostgaard and Andersson in their prospective study of 817 women during pregnancy who were followed up for 12 months or more after delivery.<sup>18</sup> They found that more than 67% of women experienced low back pain directly after delivery and 37% at the later follow up examination. Factors associated with persistent pain were the presence of low back pain before or during pregnancy, physically heavy work, and multiple pregnancy. This figure is somewhat higher than the overall prevalence of low back pain in women in developed countries.<sup>15</sup> It is also significantly

higher than the prevalence found in men, which supports the view that pregnancy may influence the development (or course) of low back pain.<sup>18-20</sup>

### Further research

Although our study was powered to detect an absolute difference of 10% in the incidence of back pain, the findings of almost equal numbers in each group with most outcomes measured means that future controlled comparisons would require many thousands of participants. Given our findings, further research into complications of epidural analgesia will need to be based on large national cohorts of patients to identify risks for rare problems.

This paper is dedicated to Richard Johanson, who died a few months before publication. Dr G Waddell gave advice on methodology. We are grateful to all the women who participated.

**Contributors:** The study was conceived by CJH and RBJ. CJH, TD, KD, PWJ, and RBJ contributed to the design. CJH and RBJ supervised the execution of the study. TD collected the data. LL was data manager. PWJ and LL analysed the data. The paper was written jointly by all authors. CJH is guarantor.

**Funding:** National Back Pain Association. RJ, KD, and LL's clinical trials activities are supported by grants from the NHS(E) West Midlands research and development programme.

**Competing interests:** None declared.

- 1 Chamberlain G, Wraight A, Steer P. *Pain and its relief in childbirth. The results of a national survey conducted by the National Birthdays Trust.* Edinburgh: Churchill Livingstone, 1993.
- 2 Scott DB, Hibbard BM. Serious non-fatal complications associated with extradural block in obstetric practice. *Br J Anaesth* 1990;64:537-41.
- 3 MacArthur C, Lewis M, Knox EG, Crawford JS. Epidural anaesthesia and long term backache after childbirth. *BMJ* 1990;301:9-12.
- 4 Russell R, Groves P, Taub N, O'Dowd J, Reynolds F. Assessing long term backache after childbirth. *BMJ* 1993;306:1299-303.
- 5 MacArthur C, Knox G, Lewis M. Epidural analgesia during childbirth. Association with backache is real. *BMJ* 1993;307:64.
- 6 MacLeod J, Macintyre C, McClure JH, Whitfield A. Backache and epidural analgesia. *Int J Obstet Anaesth* 1995;4:21-5.
- 7 Waddell G, Allan DB, Newton M. *Clinical evaluation of disability in back pain. The adult spine: principles and practice.* New York: Raven Press, 1991:155-68.
- 8 Howell CJ, Kidd C, Roberts W, Upton P, Lucking L, Jones PW, et al. A randomised controlled trial of epidural compared with non-epidural analgesia in labour. *Br J Obstet Gynaecol* 2001;108:27-33.
- 9 Roland M, Morris R. A study of the natural history of back pain. Part 1: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141-4.
- 10 Waddell G, Somerville D, Henderson I, Newton M. Objective clinical evaluation of physical impairment in chronic low back pain. *Spine* 1992;17:617-28.
- 11 Macrae IF, Wright V. Measurement of back movement. *Ann Rheum Dis* 1969;28:584-9.
- 12 Gauvin MG, Riddle DL, Rothstein JM. Reliability of clinical measurements of forward bending using modified fingertip-to-floor method. *Phys Ther* 1990;70:443-7.
- 13 Howell CJ. Epidural vs non epidural analgesia for pain relief in labour. *Cochrane Database Syst Rev* 2000;(3):CD000331.
- 14 Moher D, Schulz KF, Altman DG, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191-4.
- 15 MacArthur AJ, MacArthur C, Weeks SK. Is epidural anaesthesia in labor associated with chronic low back pain? A prospective cohort study. *Anesth Analg* 1997;85:1066-70.
- 16 Breen TW, Ransil BJ, Groves PA, Oriol NE. Factors associated with back pain after childbirth. *Anesthesiology* 1994;81:29-34.
- 17 MacArthur A, MacArthur C, Weeks S. Epidural anaesthesia and long term back pain after delivery: a prospective cohort study. *BMJ* 1995;311:1336-9.
- 18 Ostgaard HC, Andersson GB. Postpartum low-back pain. *Spine* 1992;17:53-5.
- 19 Svensson HO, Andersson GBJ, Hagstad A, Jansson PO. The relationship of low-back pain to pregnancy and gynecologic factors. *Spine* 1990;15:371-5.
- 20 Orvieto R, Achiron A, Ben-Rafael Z, Gelernter I, Achiron R. Low-back pain of pregnancy. *Acta Obstet Gynecol Scand* 1994;73:209-14.

(Accepted 21 March 2002)

### What is already known on this topic

Previous research has suggested an association between epidural analgesia during labour and low back pain

It is not known whether this association is causal

### What this study adds

This long term follow up study found no evidence of a causal link between epidural analgesia during labour and low back pain