

# Could a randomised trial answer the controversy relating to elective caesarean section? National survey of consultant obstetricians and heads of midwifery

Tina Lavender, Carol Kingdon, Anna Hart, Gill Gyte, Mark Gabbay, James P Neilson

Department of Midwifery Studies, University of Central Lancashire, Preston PR1 2HE  
Tina Lavender  
*professor of midwifery and women's health*  
Carol Kingdon  
*research fellow*

Lancashire School of Health and Post Graduate Medicine, University of Central Lancashire  
Anna Hart  
*principal lecturer*

Cochrane Pregnancy and Childbirth Group, University of Liverpool, Liverpool Women's Hospital, Liverpool L8 7SS

Gill Gyte  
*consumer panel coordinator*

University of Liverpool, Liverpool L69 3GB  
Mark Gabbay  
*senior lecturer in general practice*

continued over

BMJ 2005;331:490-1

International concerns about rising rates of caesarean section are counterbalanced by arguments that planned caesarean section without specific clinical indication (such as breech presentation or HIV infection) falls within legitimate maternal choice.<sup>1</sup> Professional opinion is divided. To perform a caesarean section without clinical reason is seen as ethical, in response to maternal request, by the American College of Obstetricians and Gynecologists; is enshrined in law in Italy; but is viewed as unethical by the International Federation of Gynecology and Obstetrics. The National Institute for Health and Clinical Excellence recommends that a second opinion should be offered.<sup>2</sup> A well designed, randomised controlled trial of planned caesarean section compared with planned vaginal birth could provide important evidence.<sup>3</sup>

## Participants, methods, and results

We aimed to survey all consultant obstetricians and heads of midwifery (gatekeepers to such a trial) practising in England between January 2003 and May 2004. We explored their views of women's requests for caesarean section without clinical indication and of a possible randomised controlled trial in a postal survey. We used semistructured questionnaires with closed questions followed by free text spaces to provide supporting rationale. Comparisons were made between professionals and according to parental status, sex, and type of unit where they worked. We

used  $\chi^2$  tests to compare the proportion of respondents saying "yes" to each question. Two of the authors (TL, CK) manually analysed qualitative responses.

Altogether 660/924 (71%) eligible obstetricians and 123/169 (73%) midwives responded (table). Almost half of the obstetricians and a quarter of midwives believed that a woman should choose her method of delivery. A minority thought a trial was feasible, ethical, or desirable. Female obstetricians were less likely to support a trial than male ones. Whether or not the obstetrician and midwife had children did not influence their responses; nor did the type of unit in which the professionals worked.

A full description of qualitative findings will be presented elsewhere. Most respondents providing qualitative commentary wished they had the results of a randomised controlled trial. Obstetricians and midwives who were opposed to a trial offered similar reasons, motivated by unease with routine caesarean section (interference with nature, maternal morbidity, and impact on organisational resources and professional roles). Marked differences occurred in the responses of health professionals who supported a trial: obstetricians mainly believed that lack of evidence prevented women making informed choices, whereas midwives were confident that a trial would prove that vaginal birth was superior.

This article was first posted on [bmj.com](http://bmj.com) on 22 August 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38560.572639.3A>

Findings of survey. Values are numbers (with rounded percentages) of participants unless otherwise indicated

Survey question	Answer	Consultant obstetricians			$\chi^2$ test comparing sexes†	Heads of midwifery (n=123)	$\chi^2$ test comparing professional groups‡
		All (n=660)	Male (n=468)	Female (n=188)*			
Do you believe that primigravid women (in the absence of clinical indications) should choose their method of delivery?	Yes	321 (49)	254 (54)	67 (36)	P<0.001	33 (27)	P<0.001
	No	325 (49)	207 (44)	117 (62)		85 (69)	
	Missing	14 (2)	7 (1)	4 (2)		5 (4)	
Is a randomised controlled trial of elective caesarean section v vaginal birth ethical?	Yes	246 (37)	189 (40)	57 (30)	P=0.013	26 (21)	P<0.001
	No	367 (56)	252 (54)	114 (61)		86 (70)	
	Missing	47 (7)	27 (6)	17 (9)		11 (9)	
Is a randomised controlled trial of elective caesarean section v vaginal birth feasible?	Yes	159 (24)	128 (27)	31 (17)	P=0.001	35 (29)	P=0.32
	No	434 (66)	297 (64)	136 (73)		72 (59)	
	Missing	67 (10)	43 (9)	20 (11)		16 (13)	
Is a randomised controlled trial of elective caesarean section v vaginal birth desirable?	Yes	294 (45)	218 (47)	76 (41)	P=0.15	39 (32)	P=0.005
	No	318 (48)	223 (48)	94 (50)		73 (59)	
	Missing	48 (7)	27 (6)	17 (9)		11 (9)	
Would you recruit women to a randomised controlled trial of caesarean section v vaginal delivery?	Yes	247 (37)	186 (40)	61 (32)	P=0.073	21 (17)	P<0.001
	No	376 (57)	259 (55)	116 (62)		89 (72)	
	Missing	37 (6)	23 (5)	11 (6)		13 (11)	
Would you consider an elective caesarean section for yourself (or partner)?	Yes	216 (33)	180 (39)	35 (19)	(P<0.001)§	9 (7)	(P<0.001)§
	No	316 (48)	189 (40)	127 (68)		100 (81)	
	N/A	98 (15)	80 (17)	18 (10)		0	
	Missing	30 (5)	19 (4)	8 (4)		14 (11)	

\*Sex was unknown for four.

†P values for  $\chi^2$  test comparing proportions of "yes" replies between sexes for obstetricians.

‡P values for  $\chi^2$  test comparing proportions of "yes" replies between professional groups.

§Not applicable. Values have been omitted from the analysis.

**What is already known on this topic**

Caesarean section, in the absence of clear clinical indication, is one of the most contentious issues in modern obstetrics, fuelling debates about the possible need for a randomised trial of delivery methods

Evidence about the extent to which obstetricians support women's requests for caesarean section is conflicting, and views on the need for a trial of planned caesarean section versus planned vaginal birth have not been reported

**What this study adds**

A minority of consultant obstetricians and heads of midwifery would support a randomised trial of planned caesarean section compared with planned vaginal birth

**Comment**

Our quantitative findings indicate that a minority of professionals would recruit to a trial comparing planned caesarean section with planned vaginal birth. However, the qualitative finding—that midwives who favoured a trial did so because of their confidence in the benefits of vaginal birth—adds complexity because it negates the necessary individual professional equipoise.<sup>4</sup> We explored the opinions of senior obstetricians and midwives simultaneously and nationally, and we identified views about a possible randomised trial. To gain unbiased views, we deliberately did not present participants with a protocol,

rather than give the impression that a trial was planned. We also believe that evidence about benefits and risks is insufficient to develop a protocol.

If caesarean birth were shown to be as safe as normal birth in a non-inferiority trial, the NHS would have to consider whether it would be willing to offer such a choice, given the huge resource implications.<sup>2</sup> If the cost makes offering choice to all women unfeasible then carrying out a trial would be unethical. The ethical, moral, and practical challenges to a trial are considerable and would require involvement of women and society at large.

The authors acknowledge the support of Ruth Cattrell, research midwife, all of the heads of midwifery, and consultant obstetricians who participated.

Contributors: TL, CK, GG, MG, and JPN designed the study. TL, CK, and AH analysed the data. TL, CK, and AH wrote the paper. TL, CK, AH, GG, MG, and JPN reviewed and amended drafts of the paper. All authors contributed critical comments to the paper. TL is the principal investigator of the survey and principal guarantor of the paper.

Funding: University of Central Lancashire, University of Liverpool and Liverpool Women's Hospital NHS Trust.

Competing interests: None declared.

Ethical approval: Liverpool Research Ethics Committee (twice; reference 01/008-08/03/2001, reference 01/008-11/03/2003).

- 1 Minkoff H, Chervenak F. Elective primary cesarean delivery. *N Engl J Med* 2003;348:946-50.
- 2 National Collaborating Centre for Women's and Children's Health. Caesarean section clinical guideline. London: RCOG Press, 2004.
- 3 Ecker JL. Once a pregnancy always a cesarean? Rationale and feasibility of a randomized controlled trial. *Am J Obstet Gynecol* 2004;190:314-8.
- 4 Weijer C, Shapiro SH, Glass KC, Enkin MW. Clinical equipoise and not the uncertainty principle is the moral underpinning of the randomised controlled trial. *BMJ* 2000;321:756-8.

(Accepted 6 July 2005)

doi 10.1136/bmj.38560.572639.3A

School of Reproductive and Developmental Medicine, University of Liverpool, Liverpool Women's Hospital, Liverpool L8 7SS

James P Neilson  
professor of obstetrics  
and gynaecology

Correspondence to:  
T Lavender  
tinalav@yahoo.co.uk

## Ten year follow-up of a randomised controlled trial of care in a stroke rehabilitation unit

Avril E R Drummond, Ben Pearson, Nadina B Lincoln, Peter Berman

Decreased mortality and reduced disability are well recognised short term benefits of care in a stroke unit.<sup>1</sup> Early organised management improves survival up to five years after stroke.<sup>2</sup> Only one study has examined the effects of care in a stroke unit for longer than five years,<sup>3</sup> and it showed that treatment in a combined acute and rehabilitation stroke unit in Norway conferred benefit even 10 years after stroke. We aimed to examine whether the benefits of a non-acute stroke rehabilitation unit persist for 10 years after stroke. This study was a continuation of the five year follow-up by Lincoln and colleagues.<sup>2</sup>

**Participants, methods, and results**

We identified participants who had been randomly allocated to receive treatment in a non-acute stroke unit or on conventional wards (general medical wards or wards for the elderly) as part of an earlier trial.<sup>4</sup> Ten years after that randomisation, we traced them on hospital and

general practice databases. We asked survivors to consent to follow-up with a postal questionnaire. Participants needing help to complete the questionnaire were visited by researchers who were blind to original group allocation and to five year results for individuals.

We recorded place of residence. We used the Barthel index to measure independence in personal activities of daily living<sup>5</sup>: we classified participants as disabled (0-17) or independent (18-20). We obtained age, sex, and date of stroke from previous records. We compared survival for participants in the two groups (stroke unit and conventional ward) over 10 years using Kaplan-Meier survival curves.

In the original study, 176 participants were randomly allocated to receive treatment in a stroke unit and 139 to receive treatment on a conventional

Division of Ageing and Rehabilitation, Queen's Medical Centre, Nottingham NG7 2UH

Avril E R Drummond  
research occupational therapist

Derbyshire Royal Infirmary, Derby DE1 2QY

Ben Pearson  
consultant physician in emergency medicine

continued over

*BMJ* 2005;331:491-2

This article was posted on *bmj.com* on 10 August 2005: <http://bmj.com/cgi/doi/10.1136/bmj.38537.679479.E0>