Two decision aids for mode of delivery among women with previous caesarean section: randomised controlled trial

Alan A Montgomery,[1] Clare L Emmett,[1] Tom Fahey,[2] Claire Jones,[3] Ian Ricketts,[3] Roshni R Patel,[4] Tim J Peters,[1] Deirdre J Murphy,[5] on behalf of the DiAMOND Study Group

EDITORIAL by Lauer and Betrán

[1]Department of Community Based Medicine, University of Bristol, Bristol BS8 2AA

[2]Department of General Practice, Royal College of Surgeons in Ireland, Mercer's Medical Centre, Dublin 2, Republic of Ireland, and Tayside Centre for General Practice, University of Dundee, Dundee

[3]School of Computing, University of Dundee, Queen Mother Building, Dundee

[4]Academic Unit of Obstetrics and Gynaecology, University of Bristol, St Michael's Hospital, Bristol

[5]Academic Department of Obstetrics and Gynaecology, Trinity College Dublin, Coombe Women's Hospital, Dublin 8, Republic of Ireland, and Department of Obstetrics and Gynaecology, University of Dundee, Ninewells Hospital, Dundee

Correspondence to: A Montgomery
alan.a.montgomery@bristol.ac.uk

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ABSTRACT

Objectives To determine the effects of two computer based decision aids on decisional conflict and mode of delivery among pregnant women with a previous caesarean section.

Design Randomised trial, conducted from May 2004 to August 2006.

Setting Four maternity units in south west England, and Scotland.

Participants 742 pregnant women with one previous lower segment caesarean section and delivery expected at ≥37 weeks. Non-English speakers were excluded.

Interventions Usual care: standard care given by obstetric and midwifery staff. Information programme: women navigated through descriptions and probabilities of clinical outcomes for mother and baby associated with planned vaginal birth, elective caesarean section, and emergency caesarean section. Decision analysis: mode of delivery was recommended based on utility assessments performed by the woman combined with probabilities of clinical outcomes within a concealed decision tree. Both interventions were delivered via a laptop computer after brief instructions from a researcher.

Main outcome measures Total score on decisional conflict scale, and mode of delivery.

Results Women in the information programme (adjusted difference −6.2, 95% confidence interval −8.7 to −3.7) and the decision analysis (−4.0, −6.5 to −1.5) groups had reduced decisional conflict compared with women in the usual care group. The rate of vaginal birth was higher for women in the decision analysis group compared with the usual care group (37% *v* 30%, adjusted odds ratio 1.42, 0.94 to 2.14), but the rates were similar in the information programme and usual care groups.

Conclusions Decision aids can help women who have had a previous caesarean section to decide on mode of delivery in a subsequent pregnancy. The decision analysis approach might substantially affect national rates of caesarean section.

Trial Registration Current Controlled Trials ISRCTN84367722.

INTRODUCTION

Caesarean section has become an increasingly common method of delivery. From 1980 to 2001 the rate in the United Kingdom increased from 9% to 21% of all births[1] and was most recently reported as 23%.[2] Similar increases have been reported in the United States and Australia. Higher rates of caesarean delivery are associated with increased maternal and neonatal morbidity.[3]

Rising rates of caesarean deliveries are assumed to have been driven by obstetricians, reflecting medicolegal concerns about vaginal birth after previous caesarean section (VBAC), vaginal breech delivery, and fetal distress in labour. In contrast, over a similar time period there has been increased emphasis on involvement of patients in making medical decisions. The traditional paternalistic model of care is based on the premise that the obstetrician knows best and by taking the lead on decisions could reduce anxiety and risk for the mother and her baby.[4] The shared model of medical decision making, in which clinician and patient exchange information, reveal preferences for treatment, and jointly come to a decision, is now promoted in preference to other models.[4-6] Decision aids are designed to help people select between various treatment strategies by providing information on the options and outcomes relevant to a person's health. Determining the optimal mode of delivery for a woman who has experienced a previous caesarean section requires consideration of the risks and benefits of repeat section and of vaginal birth after previous caesarean section alongside her views and preferences for a particular type of birth experience.[4] While women may want and be given a larger role in decision making, this may be without access to comprehensive and balanced information about possible risks and benefits.[7 8] There is also the potential for selective use of risk based information that may increase anxiety and unduly influence the decision making process.[9]

We investigated the effects of two computer based decision aids (an information programme and individualised decision analysis) on decisional conflict and actual mode of delivery among a group of pregnant women with one previous caesarean section. We also explored effects on knowledge, anxiety, and satisfaction with the decision.

METHODS

Participants

The sample comprised pregnant women with one previous lower segment caesarean section, no current obstetric problems, and delivery expected at

≥37 weeks. Women of all parities were included, but their most recent delivery must have been a caesarean section. We excluded women with limited ability to speak or understand English.

Recruitment setting and procedures

Three maternity units in south west England and one unit in Scotland recruited women from May 2004 to January 2006. The rates of caesarean section for these units ranged from 22% to 25%, which is representative of the UK national rate. A research midwife recruited women during their initial booking visit at the antenatal clinic, usually at around 10-20 weeks' gestation. Women received an information sheet, a consent form, and a baseline questionnaire.

Randomisation

After administering the baseline questionnaire and receiving written informed consent, the trial coordinator randomised women to one of three groups.

Interventions

Both interventions were computer based. Women allocated to receive an intervention had an appointment with a researcher to allow the decision aid to be delivered with a laptop computer, usually in the woman's own home. After a brief training session the woman was left to navigate through the programme at her leisure.[10 11]

Usual care—This comprised the usual level of care given by the obstetric and midwifery team. Women in the two intervention groups also received usual care.

Information programme—This provided information about the outcomes associated with planned vaginal delivery, elective caesarean section, and emergency caesarean section, including descriptions of possible health outcomes for both mother and baby. The programme gave the probabilities of having and not having the event, in both numerical and pictorial format.[12] At the end of the appointment, women received a password that allowed them to access the information programme again through the internet.

Decision analysis—Firstly, women were given information about the outcomes associated with planned vaginal delivery, elective caesarean section, and emergency caesarean section. This comprised descriptions, but not explicit probabilities, of outcomes for both mother and baby. Secondly, women were required to consider the value they attached to possible outcomes by rating each on a visual analogue scale from 0 to 100. We combined the values with the probabilities of each outcome in a decision tree to produce a recommended "preferred option" based on maximised expected utility. Women received a computer printout of the outcome of the decision analysis and were encouraged to discuss this with their midwife or obstetrician at subsequent antenatal visits.

Both intervention groups—Women in both intervention groups were contacted again by letter at 35 weeks' gestation to encourage discussion of the intervention with their obstetrician or midwife, or both, when they attended the clinic at 36-37 weeks to finalise their birth plan.

Outcome measures

Decisional conflict scale—This is a 16 item questionnaire that measures degree of uncertainty about which course of action to take and the main modifiable factors contributing to uncertainty.[13]

Actual mode of delivery (vaginal birth v *caesarean section)*—The interventions were not designed to promote one mode of delivery over another. Any change in the proportions of vaginal birth or caesarean delivery, however, might have a substantial impact on healthcare providers. The study was therefore powered to detect any such effects.

Secondary outcomes—We investigated anxiety,[14] knowledge, subscales of the decisional conflict scale,[13] and satisfaction with the decision.[15]

Collection of follow-up data

The primary follow-up for questionnaire based outcomes was at 37 weeks' gestation. This was timed for three to seven days after a scheduled clinic visit at around 36 weeks when women met with their obstetric team to discuss and finalise their plans for delivery. We obtained data on mode of delivery from hospital maternity records and assessed satisfaction with the decision in a further follow-up questionnaire about six weeks after delivery.

Sample size

To allow for preterm deliveries, malpresentations, and losses to follow-up, we originally aimed to recruit 660 women to the trial. However, this underestimated the number of participants for whom we could not obtain follow-up data so we increased the number to 740 and extended the recruitment period once realistic estimates of attrition emerged. More details are on bmj.com.

Statistical analysis

The primary analyses comprised three pairwise intention to treat comparisons between usual care and the information and decision analysis groups for each of the two primary outcomes. We used appropriate multivariable regression models, adjusted for maternity unit, initial preference regarding mode of delivery, and value of the outcome variable at baseline. We used Tukey's procedure to adjust P values. Secondary outcomes were analysed in the same way and without any additional adjustment for multiple comparisons between groups.

We used preplanned subgroup analyses with appropriate interaction terms in the regression models to ascertain any differential effects of the interventions on the two primary outcomes according to previous caesarean section occurring before or after labour; previous successful vaginal delivery; and preferred mode of delivery at baseline.

Table 1 | Descriptive statistics for primary outcomes at follow-up

	Usual care	Information	Decision analysis
Mean (SD) total score on DCS	27.8 (14.6) (n=201)	22.5 (13.2) (n=201)	23.6 (15.1) (n=198)
No (%) with mode of delivery:			
Elective caesarean	118 (50)	117 (49)	97 (41)
Emergency caesarean	48 (20)	53 (22)	50 (21)
Vaginal birth	72 (30)	70 (29)	88 (37)

DCS=decisional conflict scale.

RESULTS

Participants

Of 1148 women invited to participate in the trial, 742 were randomised, and primary outcome data were obtained for 600 (81%) for the decisional conflict scale and 713 (96%) for mode of delivery (figure on bmj.com). Women who consented to participate were slightly older (32.5 *v* 31.9 years, P=0.05) and less deprived (P=0.02) than those who did not take part. See on bmj.com for characteristics of the study sample and outcome data at baseline. Overall mean (SD) age at randomisation was 32.6 (4.7) years, and mean gestational age was 19.0 (4.4) weeks. Most women (91%) had had only one previous live delivery. Overall mean (SD) score on the decisional conflict scale at baseline was 38.6 (17.0) on a scale of 0-100, with higher scores indicating greater decisional conflict. Scores exceeding 37.5 are associated with delay in decision making or feeling unsure about implementation. Around twice as many women had a preference for a vaginal delivery compared with elective caesarean section, but over a third were uncertain about their preferred mode of delivery. Of 250 women allocated to the information group, 59 (24%) accessed the intervention again through the website at least once.

Primary analyses

Decisional conflict—Total decisional conflict was reduced in all three groups at follow-up compared with baseline (table 1). Both interventions reduced decisional conflict more than usual care, with effect sizes of 0.31 SD (95% confidence interval 0.22 to 0.51) and 0.24 SD (0.09 to 0.39), respectively, for information programme and decision analysis (table 2). There was no evidence of any difference between the intervention groups (table 2).

Mode of delivery—A higher proportion of women in the decision analysis group (37%) delivered vaginally compared with in the usual care (30%) and information programme groups (29%) (table 1). The lower 95% confidence limits for the odds ratios, however, are consistent with no difference between decision analysis and the other groups (table 2), and the observed increased rate of vaginal birth in this group could be a chance finding.

Secondary analyses

Decisional conflict, anxiety, knowledge, and satisfaction—Scores of <25 on the decisional conflict scale are associated with implementing decisions.[13] Women in the information programme and decision analysis groups were more likely than women in usual care to report decisional conflict scores below this level (see bmj.com). Anxiety and knowledge scores were higher in all three groups at 37 weeks' gestation compared with baseline), though women in the two intervention groups had lower anxiety scores and higher knowledge scores that those in the usual care group. In all the women the overall satisfaction with the decision measured six weeks after delivery was 4.3 out of a possible 5. Compared with usual care, satisfaction was higher in the decision analysis group but not in the information programme group. There were no differences between the interventions for anxiety, knowledge, or satisfaction.

Subgroup analyses—The effects of the interventions on total scores on the decisional conflict scale at 37 weeks' gestation did not differ according to whether the previous caesarean section was elective or emergency (P=0.70) or the preferred mode of delivery at baseline (P=0.66). The effect may differ, however, depending on whether women had had a previous vaginal delivery: the information programme seemed to have a greater effect among women who had successfully delivered vaginally previously (P=0.07).

For actual mode of delivery, there was no evidence of any interaction between study group and type of previous caesarean section (P=0.97), previous successful vaginal delivery (P=0.27), or preferred mode of delivery at baseline (P=0.35).

Table 2 | Comparisons of primary outcomes between groups

	Crude figure	Adjusted figure* (95% CI)	P value†
Difference between groups in total score on DCS			
Information *v* usual care	−5.3	−6.2 (−8.7 to −3.7)	<0.001
Decision analysis *v* usual care	−4.2	−4.0 (−6.5 to −1.5)	0.005
Decision analysis *v* information	1.1	2.2 (−0.3 to 4.7)	0.19
Odds ratio for vaginal *v* elective/emergency caesarean section			
Information *v* usual care	0.95	0.93 (0.61 to 1.41)	>0.9
Decision analysis *v* usual care	1.38	1.42 (0.94 to 2.14)	0.22
Decision analysis *v* information	1.45	1.53 (1.01 to 2.30)	0.11

DCS=decisional conflict scale.
*Adjusted for preferred mode of delivery at baseline, hospital, and value of outcome variable at baseline (for DCS only).
†Adjusted for multiple comparisons with Tukey's procedure.

DISCUSSION

Summary of main findings

Computer based decision aids can reduce decisional conflict among pregnant women with one previous caesarean section. Both decision aids in our study were associated with greater knowledge and less anxiety compared with usual care. The intervention based on decision analysis was associated with a higher proportion of women achieving a vaginal birth.

Strengths and limitations of the study

We achieved a high rate of recruitment and a low loss to follow-up, reflecting the importance placed by women and health professionals on this aspect of

WHAT IS ALREADY KNOWN ON THIS TOPIC

Pregnant women with a previous caesarean section must decide between planned vaginal birth and elective repeat caesarean section

The optimal approach to decision making in these circumstances is unclear

WHAT THIS STUDY ADDS

Computer based decision aids can reduce decisional conflict and anxiety and increase knowledge

A decision analysis based approach might result in more women delivering vaginally

obstetric care. The study was comparatively large and the results are of direct clinical relevance to care of patients. In addition to the usual questionnaire based outcomes, we defined mode of delivery as a primary outcome and powered the trial accordingly. Our target odds ratio of at least 2.1, in the context of continually rising rates of caesarean section and falling rates of vaginal birth after previous caesarean section, however, was probably overly optimistic, and a larger sample size may have improved the precision around a smaller but still clinically important effect size. The choice of a clinically important effect size is often a matter of judgment, but from the effect observed in our study, use of the decision analysis intervention by women with a previous caesarean section could result in about 4000 fewer caesarean sections a year in England and Wales.[1 2]

Comparison with existing literature

For decisional conflict and knowledge, our findings are consistent with those of a Cochrane review of decision aids for patients developed and evaluated in various settings and conditions.[16] Notably, women in the intervention groups in our study reported reduced anxiety compared with those in usual care. This is an important finding as detailed descriptions and probability information about obstetric complications might be considered as potentially alarming. Our results show that use of a decision aid early in pregnancy may be able to address many questions and concerns that women have and that this effect persists through to delivery.

For mode of delivery, the results are intriguing. A recent randomised trial of a paper based decision aid for women with a previous caesarean section found a reduction in decisional conflict but no evidence of an effect on mode of delivery.[17] An earlier comparison of verbal versus leaflet interventions aimed at promoting vaginal birth among women with a previous caesarean section found no difference between groups in terms of mode of delivery but did report an overall higher proportion of women delivering vaginally compared with the national average.[18] Given the lower confidence limits of the odds ratios in our trial it is certainly possible that this is a chance finding.

The observed difference in rates of vaginal birth, however, is clinically important and warrants consideration. Why should a decision aid influence the mode of delivery? Why should a more complex intervention based on decision analysis be more effective than the simpler information programme? The key elements of decision analysis are the ascertainment of utilities by the woman herself (values placed on possible outcomes) and the provision of a recommended method of delivery by computer printout. The technique combines utility and probability information and recommends the option that gives the best chance of achieving an outcome(s) that is valued. It is more commonly used to inform policy decisions and is not universally supported as an individual decision aid for patients.[19] Our results add to other empirical evidence that individualised decision analysis is feasible and acceptable and has value as an aid to patients' decision making.[20-22]

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Equitable utilisation of Indian community based health insurance scheme among its rural membership: cluster randomised controlled trial

M Kent Ranson,[1] Tara Sinha,[3] Mirai Chatterjee,[3] Fenil Gandhi,[3] Rupal Jayswal,[3] Falguni Patel,[3] Saul S Morris,[2] Anne J Mills[1]

EDITORIAL by De Allegri and Sauerborn

[1]Health Economics and Financing Programme, Health Policy Unit, London School of Hygiene and Tropical Medicine, London WC1E 7HT
[2]Nutrition and Public Health Intervention Research Unit, London School of Hygiene and Tropical Medicine
[3]SEWA Reception Centre, Bhadra, Ahmedabad, India 380 001
Correspondence to: M Kent Ranson kent.ranson@lshtm.ac.uk

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ABSTRACT

Objective To evaluate alternative strategies for improving the uptake of benefits of a community based health insurance scheme by its poorest members.

Design Prospective cluster randomised controlled trial.

Setting Self Employed Women's Association (SEWA) community based health insurance scheme in rural India.

Participants 713 claimants at baseline (2003) and 1440 claimants two years later among scheme members in 16 rural sub-districts.

Interventions After sales service with supportive supervision, prospective reimbursement, both packages, and neither package, randomised by sub-district.

Main outcome measures The primary outcome was socioeconomic status of claimants relative to members living in the same sub-district. Secondary outcomes were enrolment rates in SEWA Insurance, mean socioeconomic status of the insured population relative to the general rural population, and rate of claim submission.

Results Between 2003 and 2005, the mean socioeconomic status of SEWA Insurance members (relative to the rural population of Gujarat) increased significantly. Rates of claims also increased significantly, on average by 21.6 per 1000 members ($P<0.001$). However, differences between the intervention groups and the standard scheme were not significant. No systematic effect of time or interventions on the socioeconomic status of claimants relative to members in the same sub-district was found.

Conclusions Neither intervention was sufficient to ensure that the poorer members in each sub-district were able to enjoy the greater share of the scheme benefits. Claim submission increased as a result of interventions that seem to have strengthened awareness of and trust in a community based health insurance scheme.

Trial registration Clinical trials NCT00421629.

INTRODUCTION

Poor people in developing countries are less likely to seek care when sick than those who are better off.[1-3] Community based health insurance can potentially protect people from healthcare costs and ensure equitable pooling of risk between richer and poorer, and sick and healthy, members.[4] The World Health Organization has called for investigation of mechanisms to bring the poor into such schemes.[5]

The scope for equitable redistribution of resources through community based health insurance schemes may be limited. Membership is generally small[6]; schemes cover on average around 10% of target populations.[7] Community based health insurance has tended to exclude the poorest people from membership,[8 9] generally charging a flat premium that is unaffordable.[8] Utilisation of health care by insured members has been found to be higher among households located close to health facilities, probably the better off ones.[8 10] Studies in Rwanda and the Philippines found that utilisation by socioeconomic status was equity neutral among insured people and inequitable among uninsured people.[11 12]

According to WHO, more than 75% of total expenditure on health in India is private.[13] We assessed interventions aimed at improving the distributional impact of a community based health insurance scheme in rural India.

METHODS

Since 1992, the Self Employed Women's Association (SEWA)—a trade union of more than half a million poor women working in the informal sector and based in the Indian state of Gujarat—has been providing insurance to its members and their families. The insurance is voluntary, combining insurance for assets,