British Journal of Obstetrics and Gynaecology
April 1998, Vol. 105, pp. 435–440

The Ipswich Childbirth Study: 1. A randomised evaluation of two stage postpartum perineal repair leaving the skin unsutured

***Beverley Gordon** *Midwifery Clinical Specialist*, ***Carolyn Mackrodt** *Research Midwife*, ***Elizabeth Fern** *Head of Midwifery*, **†Ann Truesdale** *Research Administrator*, **†Sarah Ayers** *Programmer*, **†‡Adrian Grant** *Director*

**Ipswich Hospital NHS Trust, Ipswich; †Perinatal Trials Service, National Perinatal Epidemiology Unit, Oxford; ‡Health Services Research Unit, Aberdeen*

Objective To evaluate a policy of two stage postpartum perineal repair leaving the skin unsutured.

Design A stratified randomised controlled trial using a 2 × 2 factorial design.

Setting The maternity unit at Ipswich Hospital NHS Trust, a district general hospital, between 1992 and 1994.

Sample 1780 women requiring surgical repair of episiotomy or first or second degree tear following a spontaneous or simple instrumental delivery.

Methods A policy of two-stage perineal repair leaving skin unsutured was compared with a policy of three stage repair including skin closure with interrupted or subcuticular sutures. Both groups were assessed by a research midwife, blind to the allocation, completing questionnaires at 24 to 48 hours and 10 days postpartum, and by self-completed questionnaires at three months after birth.

Main outcome measures 1. 24 to 48 hours postpartum: perineal pain; healing; 2. 10 days postpartum: perineal pain, healing and removal of sutures; 3. three months postpartum: perineal pain, removal of sutures, resuturing, dyspareunia, and failure to resume pain-free intercourse.

Results Completed questionnaires were returned for 99% of women at both 24 to 48 hours and ten days and by 93% of women three months postpartum. No differences were detected in perineal pain at 24 to 48 hours (62% *vs* 64%; RR 0·96, 95% CI 0·90–1·03; $2P = 0·3$) and 10 days (25% *vs* 28%; RR 0·90, 95% CI 0·77–1·06; $2P = 0·2$). Significantly fewer women allocated to two-stage repair reported tight stitches at ten days (14% *vs* 18%; RR 0·77, 95% CI 0·62–0·96, $2P = 0·02$); similar numbers of repairs were judged to be breaking down (five compared with seven women). At three months postpartum fewer women allocated to the two-stage repair reported perineal pain and more had resumed pain-free intercourse. Amongst women who had resumed intercourse there was a significant difference in dyspareunia (15% *vs* 19%; RR 0·80, 95% CI 0·65–0·99; $2P = 0·04$). Significantly fewer women in the two-stage repair group (7% *vs* 12%; RR 0·61, 95% CI 0·45–0·83; $2P = < 0·01$) reported removal of suture material. Four women in the two-stage repair group had required resuturing, compared with nine allocated to the three-stage repair.

Conclusions Two-stage repair of perineal trauma leaving the skin unsutured appears to reduce pain and dyspareunia three months postpartum. There are no apparent disadvantages, in particular no evidence of an increased risk of breakdown of the repair and resuturing.

INTRODUCTION

Many women sustain perineal trauma during childbirth that is judged to require surgical repair. Most have pain and discomfort in the puerperium which in a minority persists as chronic pain and dyspareunia[1]. The standard technique for repair is to close the perineal skin edges using interrupted transcutaneous or continuous subcuticular suturing after repair of the vagina and deeper perineal tissues, aiming to reduce the risks of infection, breakdown and need for resuturing. It is possible, however, that the skin sutures themselves may cause some of the morbidity experienced by women. Women commonly complain of tightness, and about one in ten report having material removed, despite repair with absorbable sutures[2]. We report a randomised evaluation of a two-stage technique of repair which includes leaving the skin

Correspondence: Mrs B. Gordon, Midwifery Office, Ipswich Hospital NHS Trust, Heath Road, Ipswich IP4 5PD, UK.

apposed but unsutured, compared with the standard three-stage repair which includes interrupted or subcuticular skin sutures.

METHODS

The trial was carried out at the Ipswich Hospital NHS Trust from 1992 Until 1994 with the approval of the local research ethics committee. Initially women who had sustained an episiotomy or laceration (first or second degree) during a normal spontaneous delivery and who had given their informed consent to participation, were eligible to enter the study. From early 1993 the trial was extended to include women delivered by means of a simple (nonrotational forceps or vacuum extraction) instrumental delivery.

Before the study the standard technique used in Ipswich Hospital was a three-stage approach for perineal repair; most of these repairs were undertaken by midwives. Some operators used a continuous subcuticular suture for skin closure while most used interrupted sutures. This was compared with a two-stage approach. The vagina was repaired in the usual way. During repair of the perineal muscles, the aim was to leave the skin edges no more than half a centimetre apart with the woman in the lithotomy position. Instruction and training of staff was given in preparation for the study. In the light of available evidence[3] operators were encouraged to use continuous subcuticular suturing for skin closure. Nevertheless, the repair actually performed was left to the operator's discretion; skin sutures could be used for women allocated the experimental approach if this was judged necessary. The study therefore was a pragmatic comparison of two suturing policies as they might be used in practice. Within a 2 x2 factorial design, the study also compared two absorbable materials, polyglactin 910 (Vicryl, Ethicon Ltd, Edinburgh, UK) and chromic catgut; this is reported separately in the accompanying paper[4].

Randomisation occurred after completion of the third stage of labour when the operator established that perineal repair was required and that the woman was still willing to take part in the study. The randomisation schedule used balanced blocks varying in size between four and twelve and was stratified by type of delivery. Serially numbered, sealed, opaque envelopes containing the allocation details, suture material, and a data sheet to be completed by the operator immediately after the repair, were prepared and sealed in advance by an independent research assistant. The three separate maternity floors providing intrapartum care at the Ipswich Hospital NHS Trust each had its own sequence of envelopes. Trial entry was signalled by the operator opening the next envelope in sequence. All envelopes were accounted for. The number of minutes taken to complete the repair was estimated by mentally noting the time at the beginning and end of the procedure and so was not measured precisely.

At 24 to 48 hours, and at 10 days after the birth, a research midwife blinded to the allocation carried out a face-to-face interview followed by an examination of the woman's perineum with the woman lying in the left lateral position. The wound was judged to be 'gaping' if the perineal skin edges were more than half a centimetre apart. Healing was judged to be by 'first intention' if the edges were apposed and by 'second intention' if they were not. Observations of the presence or absence of bruising, oedema, infection, inflammation, and haemorrhoids were also recorded. At three months postpartum a questionnaire with a pre-paid addressed envelope was sent to each woman for self-completion and return to the trial centre in Ipswich. For quality control, data were entered twice, firstly at Ipswich and secondly at the National Perinatal Epidemiology Unit (NPEU). Data analysis was carried out at the NPEU.

The primary analysis was by intention-to-treat for all women enrolled and the statistical tests were two-sided. Relative risks (RR) or difference of means with 95% confidence intervals (CI) were calculated where appropriate. Assuming a 50% prevalence of pain at two days postpartum[5], we considered it essential to identify a difference of 10%, but judged a difference of 5% to be of questionable clinical importance. A trial with 900 women in each group has 95% power to detect a 10% difference at the 1% level of significance, and 50% power to detect a 5% difference at the 5% level of significance. Secondary analyses were stratified by the suturing material used (eg, Polyglactin 910 *versus* chromic catgut within the factorial design), operator's skin suturing technique (eg, subcuticular sutures used in 90% or more of repairs, interrupted sutures used in more than 90% of repairs, or subcuticular and interrupted sutures used), and by type of delivery (eg, spontaneous or instrumental).

An independent data monitoring committee reviewed the accumulating data on two occasions. Through previous discussion with health economists the trial was designed to incorporate an economic evaluation, the type of analysis depending on trial findings[6].

RESULTS

Overall, 1780 women participated, with 890 allocated to each policy. Questionnaires at 24 to 48 hours, the 10th day, and three months postpartum were returned for 1775 (99%), 1771 (99%) and 1664 (93%) women, respectively. The two groups were similar at trial entry (Table 1). Overall, 39% of women had had a previous vaginal delivery and 36% a previous perineal repair; 83% had a spontaneous delivery and 37% an episiotomy. Six women who had a third degree laceration were recruited in error but were included in the analysis.

Table 1. Description of groups at trial entry. Values are given *n* (%) in allocated groups unless otherwise shown.

	Two-stage (*n* = 890)	Three-stage (*n* = 890)
Maternal age		
Mean [SD]	28·5 [4·8]	28·2 [5·0]
Previous vaginal delivery	353 (40)	340 (38)
Previous perineal suturing	329 (37)	314 (35)
Not known	2 (0)	3 (0)
Mode of this delivery		
Spontaneous	735 (83)	734 (82)
Instrumental	155 (17)	156 (18)
Birthweight (g)		
Mean [SD]	3507 [500]	3503 [482]
Perineal injury		
Episiotomy	321 (36)	341 (38)
Laceration 2nd degree	550 (62)	532 (60)
1st degree	12 (1)	14 (2)
3rd degree	6 (1)	0 (0)
Not known	1 (0)	3 (0)

Table 2. Management after entry into trial. Values are given *n* (%) in allocated groups unless otherwise shown.

	Two-stage (*n* = 890)	Three-stage (*n* = 890)
Technique of skin closure		
Subcuticular	20 (2)	227 (26)
Subcuticular and interrupted	2 (0)	3 (0)
Interrupted	88 (10)	643 (72)
Two-stage only	775 (87)	9 (1)
None	5 (0)	8 (1)
Status of operator		
Midwife	658 (74)	671 (75)
SHO	36 (4)	40 (4)
Registrar/consultant	186 (21)	175 (20)
Student/other	10 (1)	4 (0)
Material used		
Polyglactin 910 only	434 (49)	447 (50)
Catgut only	450 (51)	438 (49)
Polyglactin and catgut	5 (1)	5 (1)
None	1 (0)	0 (0)
Time taken to complete repair (min)		
Mean [SD]	19·3 [10·4]	19·9 [10·2]

Table 2 describes the actual repair. Twelve percent allocated the two-stage technique had skin sutures inserted, usually because the operator judged that this was necessary to hold the perineal skin together. Interrupted rather than subcuticular sutures were used in a ratio of 3:1 in the control group. Most repairs were performed by a midwife. The material used was similar in the two groups with 50% repaired with polyglactin 910 and 50% with chromic catgut reflecting the factorial design. The difference in time taken was not significant (0·6 minutes, 95% CI 1·6 to −0·3).

Table 3 describes the outcomes at 24 to 48 hours postpartum. No clear differences were detected in pain (62% *vs* 64%; RR 0·96, 95% CI 0·90–1·03; $2P = 0·31$), although women allocated to the two-stage repair were less likely to report tight stitches (18% *vs* 22%; RR 0·83, 95% CI 0·69–1·00; $2P = 0·06$). As would be expected, there was a highly significant difference in clinically assessed gaping (23% *vs* 4%; RR 5·10, 95% CI 3·68–7·06; $2P < 10^{-7}$).

Table 3. Outcome at 24–48 hours. Values are given *n* (%) in allocated groups unless otherwise shown.

	Two-stage (*n* = 885)	Three-stage (*n* = 889)
Hours since delivery		
Mean [SD]	32·8 [7·5]	32·8 [7·9]
Any pain in last 24 h	545 (62)	569 (64)
Mild	303 (34)	336 (38)
Moderate	222 (25)	211 (24)
Severe	20 (2)	22 (2)
Analgesia for perineal pain in last 24 h	400 (45)	392 (44)
Tight stitches	162 (18)	196 (22)
Stitches not comfortable	308 (35)	332 (37)
Appearance of perineum		
Gaping*	203 (23)	40 (4)

*$\chi^2 = 125·9$, 1 df; $2P < 10^{-7}$.

At 10 days postpartum (Table 4) there were no clear differences in pain (25% *vs* 28%; RR 0·90, 95% CI 0·77–1·06; $2P = 0·23$) or analgesia use, although fewer women allocated to the two-stage group reported tight stitches (14% *vs* 18%; RR 0·77, 95% CI 0·62–0·96; $2P = 0·02$). The difference in gaping persisted but was less marked (26% *vs* 16%; RR 1·56, 95% CI 1·30–1·88; $2P < 10^{-5}$). There was no detectable difference in the rate of breakdown of perineal repair (five compared with seven women).

By three months after delivery (Table 5) women in the two-stage repair group reported less pain in the preceding week (overall 8% *vs* 10%; RR 0·74, 95% CI 0·55–1·01 $2P = 0·07$; χ^2 for trend in severity = 6·0, 1 df; $2P = 0·01$). More women had resumed pain-free intercourse (70% *vs* 66%; RR 1·06, 95% CI 0·99–1·13; $2P = 0·12$) and of those women who had resumed intercourse significantly fewer reported dyspareunia (15% *vs* 19%; RR 0·80, 95% CI 0·65–0·99; $2P = 0·04$). Four women in the two-stage repair group required resuturing, compared with nine in the three-stage group (RR 0·45, 95% CI 0·14–1·45; $2P = 0·27$). Consistent with the findings at ten days, significantly fewer women in the experimental group reported that some suture material had been removed (7% *vs* 12%; RR 0·61, 95% CI 0·45–0·83; $2P = 0·002$).

When the groups were stratified by the suture material used, mode of delivery and operator's method of

Table 4. Outcome at 10 days. Values are given *n* (%) in allocated groups unless otherwise shown.

	Two-stage ($n = 886$)	Three-stage ($n = 885$)
Days since delivery		
Mean [SD]	10·2 [1·1]	10·3 [1·2]
Any pain in last 24 hours	221 (25)	244 (28)
Mild	134 (15)	138 (16)
Moderate	69 (8)	85 (10)
Severe	18 (2)	21 (2)
Analgesia for perineal pain in last 24 h	73 (8)	69 (8)
Tight stitches[1]	126 (14)	163 (18)
Stitches not comfortable	194 (22)	206 (23)
Appearance of perineum		
Gaping[2]	227 (26)	145 (16)
Nature of healing		
1st intention[3]	661 (75)	740 (84)
2nd intention	219 (25)	137 (15)
Breaking down	5 (0)	7 (0)
Not known	1 (0)	1 (0)
Sutures removed[4]	26 (3)	67 (8)
Not known	0 (0)	1 (0)

1. $\chi^2 = 5{\cdot}41$, 1 df; $2P = 0{\cdot}02$; 2. $\chi^2 = 22{\cdot}21$, 1 df; $2P < 10^{-5}$; 3. $\chi^2 = 21{\cdot}21$, 1 df; $2P < 10^{-4}$; 4. $\chi^2 = 18{\cdot}21$, 1 df; $2P < 10^{-4}$.

Table 5. Outcome at three months postpartum. Values are given *n* (%) in allocated groups unless otherwise shown.

	Two-stage ($n = 828$)	Three-stage ($n = 836$)
Days since delivery		
Mean [SD]	98 [15]	99 [14]
Any pain in last week[1]	64 (8)	87 (10)
Mild	53 (6)	62 (7)
Moderate	10 (1)	20 (2)
Severe	1 (0)	5 (1)
Analgesia for perineal pain in last week	1 (0)	7 (1)
Not known	3 (0)	5 (1)
Resumption of sexual intercourse		
Not tried yet	104 (13)	96 (11)
Tried, but too painful	20 (2)	27 (3)
By 3 months	112 (14)	119 (14)
By 2 months	423 (51)	401 (48)
By 1 month	169 (20)	192 (23)
Not known	0 (0)	1 (0)
Dyspareunia at first, if resumed	361 (44)	386 (46)
Any dyspareunia now, if resumed†	128 (15)	162 (19)
Mild	83 (10)	106 (13)
Moderate	38 (5)	51 (6)
Severe	7 (1)	5 (1)
Not known	3 (0)	2 (0)
Resumption of pain free intercourse	576 (70)	551 (66)
Resutured	4 (0)	9 (1)
†Known suture material removal at any time[3]	59 (7)	98 (11)

1. χ^2 for trend = 6·0, 1 df; $2P = 0{\cdot}01$; 2. $\chi^2 = 4{\cdot}17$, 1 df; $2P = 0{\cdot}04$; 3. $\chi^2 = 9{\cdot}71$, 1 df; $2P = 0{\cdot}002$.
† Data derived from both 10 day and three month questionnaires and denominators are all women randomised ($n = 890$ and $n = 890$).

skin closure, there were no clear differential effects in respect of pain at two days, removal of sutures, and failure to resume pain-free intercourse by three months (Fig. 1). Nevertheless, suture material removal was no more common after three-stage repair by an operator consistently using subcuticular sutures, although a difference was observed when the operator was characterised by using interrupted sutures or both techniques for skin closure during the trial.

DISCUSSION

Every day in the UK about 1000 women have postpartum perineal repair which includes skin sutures. This trial suggests that this may be suboptimal care. No adverse effects of a two-stage method which includes leaving the skin unsutured were detected. If anything, the data suggest reduced risk of wound breakdown and need for resuturing, although the confidence intervals are too wide to rule out a clinically important adverse effect in these respects. A clear advantage was that fewer women in the two-stage group reported that suture material had been removed, particularly when compared with three-stage repair using interrupted sutures. Contrary to expectation, no differences were detected in perineal pain or analgesia use at 24 to 48 hours and 10 days. At three months, differences did emerge: there was less perineal pain, a tendency for more women to resume pain-free intercourse, and there were fewer reports of dyspareunia in the experimental group. Thus the improved outcomes in the experimental group were also associated with reduced resource use in terms of time taken for removal of suture material. The two-stage technique was both more effective and less costly making it 'dominant' in health economic terms.

We think it very unlikely that selection bias has materially affected the findings. Randomisation was strictly monitored; the groups were comparable at trial entry (Table 1); the rate of follow up was extremely high and similar in the two trial groups; and all analyses are based on intention-to-treat. The research midwife who undertook the assessments was blinded to the allocation before the assessment, but the extent of gaping did differ between the groups, particularly at the first assessment, and so would have given some indication of the likely allocation. The women were discouraged from giving information to the research midwife about the group to which they had been allocated. If the women did favour the experimental policy, it is questionable whether this would have been sustained to three months, when the principal differences were observed.

This was a comparison of a two-stage policy (which included leaving the skin unsutured) with a three-stage policy; the allocation was known at the start of the repair, so the comparison is not simply between skin

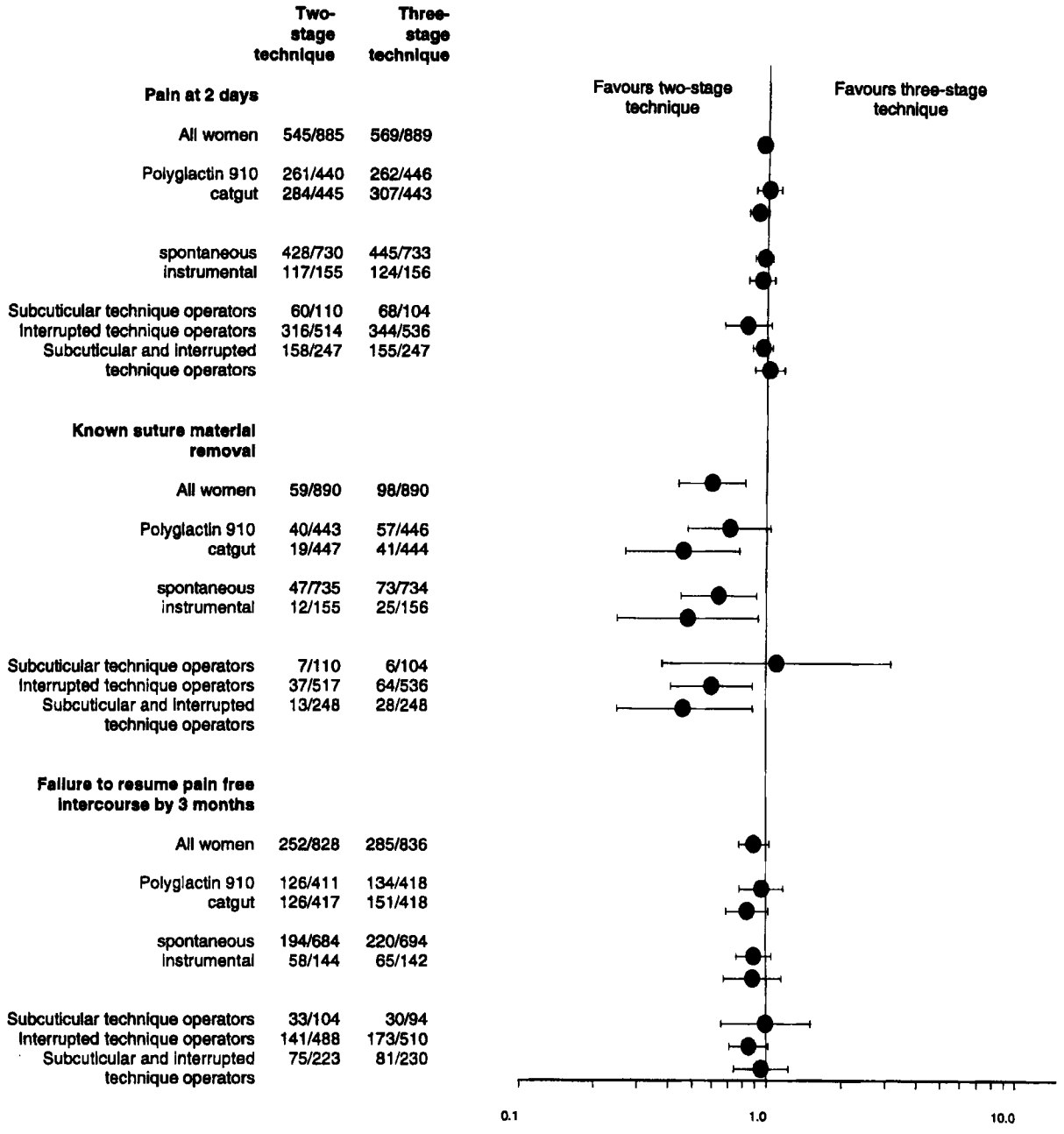

Fig. 1. Effects of a two-stage compared with a three-stage suturing policy on short term pain, removal of sutures and failure to resume pain-free intercourse.

sutures and no skin sutures. The repair of the vagina was the same in the two groups. The difference was in perineal tissue repair, the aim in the two-stage group being to leave the skin apposed. The average estimated time taken to complete repair was only 0·6 minutes shorter in the two-stage group, suggesting, as might be expected, that extra care was taken repairing the perineal tissues in this group (although it should be remembered that the method of measurement was imprecise). In the event, 12% of those allocated to the two-stage group actually had some skin sutures inserted. Nevertheless, there were clear differences between the policies as indicated by the sixfold greater reporting of gaping in the experimental group at 24 to 48 hours. It is noteworthy that, in the control group, gaping was reported more often at 10 days than at 24 to 48 hours, such that the difference between the two groups was much less marked at that stage. The difference in tight stitches was sustained, however, and was still 4% despite an overall fall in prevalence.

To whom do these suggested benefits apply? Most women in the trial had sustained trauma after spontaneous vaginal delivery, with the majority of repairs

performed by midwives. The estimates of effects from the instrumental delivery stratum are consistent with the overall results but taken on their own are too imprecise to be reliable. The overall pattern of results was also broadly similar in the other secondary analyses stratified by operators' pre-stated preferred technique for skin repair, and by the suture material used. Generalisability of the comparison to subcuticular repair is limited by the fact that only a minority of women were repaired by operators who used this method. Known suture material removal was no more common in the three-stage group after repair by an operator using the subcuticular technique, but this is based on small numbers (7 *vs* 6; Fig. 1) and so is also statistically compatible with the overall trial result.

If these results can be generalised, wide adoption of the two-stage policy could have important public health consequences. Of the 1000 women having postpartum repair each day in the UK, about 40 fewer would experience tight stitches at 10 days, 40 fewer would have dyspareunia at three months postpartum, and 50 fewer would have material removed. There seem to be no disadvantages, particularly in respect of breakdown and need for resuturing. We recognise that adoption of a two-stage policy would be a significant practice change necessitating retraining of staff, the costs of which should also be considered. While some people may be convinced by our results, others may decide that our trial needs replicating by operators in other settings.

Acknowledgements

The authors of the Ipswich Childbirth Study (parts 1 and 2 reported in this issue of the *Journal*) thank all the women who took part in this study for their co-operation, support and enthusiasm, all the midwives and obstetricians employed by the Ipswich Hospital NHS Trust, particularly Mrs C. Colbourne and Mrs N. Cole, and Mr P. Brocklehurst, Dr D. Elbourne, Mrs R. McCandlish and the Economics Group at the NPEU.

We would also like to acknowledge the following: Profesor G. Chamberlain, Dr D. Elbourne, Ms J. Sleep, Mrs J. Gordon, Ms K. Gallagher, Ms L. Mallia (data entry); Mrs L. Nurse and Ms C. Busby (secretarial support); The National Birthday Trust and the East Anglia Region Locally Organised Research Scheme for funding; and Ethicon Ltd for supplying much of the suture material.

References

1 Grant A. Repair of perineal trauma after childbirth In: Chalmers I, Enkin MW, Keirse MJNC, editors. *Effective Care in Pregnancy and Childbirth.* Oxford University Press, 1989: 1170–1181.

2 Johanson RB. Absorbable vs non-absorbable sutures for perineal repair [revised 14 Apr 1994]. In: Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C, editors. Pregnancy and Childbirth Module. In: *The Cochrane Pregnancy and Childbirth Database* [database on disk and CDROM]. The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995. [Available from London: BMJ Publishing Group.]

3 Johanson RB. Continuous vs interrupted sutures for perineal repair [revised 10 Mar 1994]. In: Keirse MJNC, Renfrew MJ, Neilson JP, Crowther C, editors. Pregnancy and Childbirth Module. In: *The Cochrane Pregnancy and Childbirth Database* [database on disk and CDROM]. The Cochrane Collaboration; Issue 2, Oxford: Update Software; 1995. [Available from London: BMJ Publishing Group.]

4 Mackrodt C, Gordon B, Fern E, Ayers S, Truesdale A, Grant A. The Ipswich Childbirth Study: 2. A randomised comparison of polyglactin 910 with chromic catgut for postpartum perineal repair. *Br J Obstet Gynaecol* 1998; **105**: 441–445.

5 Mahomed K, Grant A, Ashurst H, James D. The Southmead perineal suture study. A randomised comparison of suture materials and suturing techniques for repair of perineal trauma. *Br J Obstet Gynaecol* 1989; **96**: 1272–1280.

6 Donaldson C, Hundley V, McIntosh E. Using economics alongside clinical trials: why we cannot choose the evaluation technique in advance. *Health Economics* 1996; **5**: 267–269.

Received 22 July 1997
Returned for revision 26 August 1997
Accepted 6 January 1998