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The Ipswich Childbirth Study: 2. A randomised comparison of polyglactin 910 with chromic catgut for postpartum perineal repair

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Objective To compare polyglactin 910 sutures with chromic catgut sutures for postpartum perineal repair.

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 who had sustained an episiotomy or first or second degree tear following a spontaneous or simple instrumental delivery.

Methods Policies of repair with polyglactin 910 or chromic catgut were compared. Both groups were assessed by a research midwife completing questionnaires at 24 to 48 hours and at ten 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. ten 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. The two groups were similar at trial entry. Significantly fewer women allocated to the polyglactin 910 reported pain in the previous 24 hours at both 24 to 48 hours (59% *vs* 67%; RR 0·89, 95% CI 0·83–0·95; $2P < 0{\cdot}01$), and ten days (24% *vs* 29%; RR 0·81, 95% CI 0·69–0·95; $2P = 0{\cdot}01$). At three months postpartum there was no clear difference between the groups in terms of perineal pain, dyspareunia or failure to resume pain-free intercourse. More women in the polyglactin 910 group reported that some suture material had been removed (12% *vs* 7%; RR 1·62, 95% CI 1·19–2·21; $2P < 0{\cdot}01$). Three women in the polyglactin 910 group had required resuturing compared with ten in the chromic catgut group (RR 0·30; 95% CI 0·08–1·09; $2P = 0{\cdot}1$).

Conclusions Using polyglactin 910 rather than chromic catgut for perineal repair leads to about one fewer women among every 20 having perineal pain and using analgesia ten days postpartum. Its only apparent disadvantage is that more women, again estimated as 1 in 20, report having material removed during healing. Data from this and other trials suggest that for every 100 women repaired with a polyglycolic acid-based material, about one fewer will require resuturing.

INTRODUCTION

Perineal trauma sustained during childbirth causes pain and discomfort in the postpartum period and sometimes for many months afterwards[1]. Such trauma is common. For example, 1994 data from the former North West Thames Region[2] of England indicate a rate of 64% among women with singleton vaginal deliveries; the equivalent rate at the Ipswich Hospital NHS Trust where the research reported here was conducted was about 40% in 1994 (unpublished observations). Factors which may influence the extent of any subsequent morbidity include the type of suture material used, the suturing technique[2] and the skill of the operator. This paper describes a randomised comparison of two different suture materials.

A systematic review of five trials[3] involving 2278 women comparing different suture materials used in perineal repair showed that, on balance, absorbable

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materials are preferable to non absorbable materials. A further systematic review[4] of six trials involving 1748 women suggested that, of the absorbable materials, polyglycolic acid is preferable to chromic catgut in terms of a reduction of pain in the immediate postpartum period and a lower risk of resuturing. However, the largest trial[5] considered in this review was conducted in a unit in Bristol where chromic catgut had been the standard material with most repairs performed by midwives. This failed to detect any significant difference in short term pain and also indicated that the need to remove material was reported twice as often after polyglycolic acid repair.

Before the study reported here the situation in Ipswich was similar to that observed in Bristol. The midwives were reluctant to change from chromic catgut, with which they were familiar, without clear evidence of benefit. This led to this trial in which polyglactin 910, a new polyglycolic acid-based absorbable suture material, which had never been tested in a formal randomised trial, was compared with chromic catgut. Polyglactin 910 has theoretical advantages over the materials assessed in previous trials. These include, that while it is likely to cause relatively little tissue reaction (and hence pain) such as polyglycolic acid, its absorption may be quicker[6], and hence reduce the need for later removal of material. The Ipswich Childbirth Study[7], which is reported on pages 435–440 of this issue, used a factorial design to compare both the use of polyglactin 910 sutures with the use of chromic catgut and a two-stage perineal repair technique (leaving the skin edges apposed but unsutured) with a three-stage technique.

METHODS

In this part of the study women were randomly allocated to repair with either polyglactin 910 or chromic catgut. Prior to the study the standard technique for perineal repair was a three-stage approach using chromic catgut with the majority of repairs following spontaneous delivery being performed by midwives. Some midwives and obstetricians used a continuous subcuticular suture for skin closure while the majority used various types of interrupted sutures. In preparation for the trial and in conjunction with available evidence[8], midwives were encouraged to use continuous subcuticular suturing for skin closure, and seminars and practical sessions were held to familiarise midwives with polyglactin 910 because its handling and knotting properties are known to differ from chromic catgut[9]. Analyses were similar to those in the first part of the study[7]. Secondary analyses were stratified by the suturing technique (two-stage or three-stage), skin closure technique (continuous or interrupted), and by mode of delivery (spontaneous or instrumental).

RESULTS

A total of 1780 women participated: 889 allocated polyglactin 910 and 891 allocated chromic catgut. Assessment questionnaires at 24 to 48 hours, ten days and at three months postpartum were returned for 1775 (99%), 1771 (99%) and 1664 (93%) women, respectively. The two groups were similar in respect of known prognostic variables at trial entry (Table 1). Eighty-two percent of women allocated polyglactin 910 and 83% allocated chromic catgut had a spontaneous delivery. Six women who had a third degree laceration were recruited in error, but were included in the analysis. The material and method of perineal repair actually used are shown in Table 2. Almost all women in each group were repaired with the allocated suture material. Most repairs were performed by a midwife. Other aspects of the repair were similar in the two groups. Outcomes at 24 to 48 hours postpartum are shown in Table 3. Significantly fewer women allocated to polyglactin 910 reported pain in the previous 24 hours (59% *vs* 67%; RR 0·89, 95% CI 0·83–0·95; $2P < 0·01$). This was also reflected in the number of women allocated polyglactin 910 who reported tight stitches (17% *vs* 23%; RR 0·72, 95% CI 0·60–0·87; $2P = 0·001$) and uncomfortable stitches, (33% *vs* 40%; RR 0·83, 95% CI 0·73–0·93; $2P = 0·003$). There was a correspondingly less frequent use of analgesia in the women allocated polyglactin 910 (42% *vs* 47%; RR 0·89, 95% CI 0·80–0·98; $2P = 0·03$).

At 10 days postpartum (Table 4), women in the polyglactin 910 group reported significantly less pain in the preceding 24 hours (24% *vs* 29%; RR 0·81, 95% CI 0·69–0·95; $2P = 0·01$), were less likely to report that their stitches were uncomfortable (19% *vs* 26%; RR

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

	Polyglactin 910 (*n* = 889)	Chromic catgut (*n* = 891)
Maternal age (years)		
Mean [SD]	28·2 [5·1]	28·4 [4·7]
Previous vaginal delivery	339 (38)	354 (40)
Previous perineal suturing	317 (36)	326 (37)
Not known	0 (0)	5 (1)
Mode of this delivery		
Spontaneous	733 (82)	736 (83)
Instrumental	156 (18)	155 (17)
Birthweight (g)		
Mean [SD]	3517 [480]	3492 [502]
Perineal injury		
Episiotomy	346 (39)	316 (35)
Laceration		
2nd degree	528 (59)	554 (62)
1st degree	11 (1)	15 (2)
3rd degree	2 (0)	4 (0)
Not known	2 (0)	2 (0)

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

	Polyglactin 910 ($n = 889$)	Chromic catgut ($n = 891$)
Material used		
Polyglactin 910 only	876 (98)	5 (1)
Catgut only	6 (1)	882 (99)
Polyglactin 910 and catgut	6 (1)	4 (0)
None	1 (0)	0 (0)
Status of operator		
Midwife	665 (75)	664 (75)
SHO	33 (4)	43 (5)
Registrar/consultant	183 (21)	178 (20)
Student/other	8 (1)	6 (1)
Technique of skin closure		
Subcuticular	127 (14)	120 (13)
Subcuticular and interrupted	3 (0)	2 (0)
Interrupted	361 (41)	370 (42)
Two-stage only	391 (44)	393 (44)
None	7 (1)	6 (1)
Time taken to complete repair (min)		
Mean [SD]	19·6 [10·6]	19·7 [9·9]

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

	Polyglactin 910 ($n = 886$)	Chromic catgut ($n = 888$)
Hours since delivery		
Mean [SD]	33·0 [8·1]	32·6 [7·2]
Any pain in last 24 hours[1]	523 (59)	591 (67)
Mild	311 (35)	328 (37)
Moderate	187 (21)	246 (28)
Severe	25 (3)	17 (2)
Analgesia for perineal pain in last 24 h[2]	372 (42)	420 (47)
Tight stitches[3]	150 (17)	208 (23)
Stitches not comfortable[4]	289 (33)	351 (40)
Appearance of perineum		
Gaping	122 (14)	121 (14)

1. χ^2 for trend = 9·53, 1 df; $2P = 0·002$. 2. $\chi^2 = 4·85$, 1 df; $2P = 0·03$. 3. $\chi^2 = 11·21$, 1 df; $2P = 0·001$. 4. $\chi^2 = 8·85$, 1 df; $2P = 0·003$.

0·73, 95% CI 0·62–0·87; $2P < 0·001$), and were less likely to have taken analgesics (6% *vs* 10%; RR 0·65, 95% CI 0·47–0·90; $2P = 0·01$). Although the wound was judged to be 'gaping' less often following a repair with polyglactin 910 (16% *vs* 26%; RR 0·64, 95% CI 0·54–0·78; $2P \leq 0·001$) than for those allocated to chromic catgut, there was no detectable difference in the rate of breakdown of perineal repair (five compared with seven women) at this time.

By three months after delivery (Table 5) there was no clear difference between the groups in terms of perineal pain (χ^2 for trend = 1·0, 1 df; $2P = 0·3$), time to resumption of intercourse, and dyspareunia. More women in the polyglactin 910 group reported that some suture

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

	Polyglactin 910 ($n = 884$)	Chromic catgut ($n = 887$)
Days since delivery		
Mean [SD]	10·2 [1·2]	10·3 [1·1]
Any pain in last 24 hours[1]	208 (24)	257 (29)
Mild	121 (14)	151 (17)
Moderate	65 (7)	89 (10)
Severe	22 (2)	17 (2)
Analgesia for perineal pain in last 24 h[2]	56 (6)	86 (10)
Tight stitches	137 (15)	152 (17)
Stitches not comfortable[3]	169 (19)	231 (26)
Appearance of perineum		
Gaping[4]	145 (16)	227 (26)
Nature of healing		
1st intention[5]	741 (84)	660 (74)
2nd intention	136 (15)	220 (25)
Breaking down	5 (1)	7 (1)
Not known	2 (0)	0 (0)
Sutures removed	51 (6)	42 (5)

1. $\chi^2 = 6·50$, 1 df; $2P = 0·01$. χ^2 for trend = 3·96, 1 df, $2P = 0·05$. 2. $\chi^2 = 6·33$, 1 df; $2P = 0·01$. 3. $\chi^2 = 11·75$, 1 df; $2P < 10^{-3}$. 4. $\chi^2 = 21·31$, 1 df; $2P < 10^{-5}$. 5. $\chi^2 = 23·18$, 1 df; $2P < 10^{-5}$.

Table 5. Outcome at 3 months postpartum. Values are given as *n* (%) in allocate groups unless otherwise stated.

	Polyglactin 910 ($n = 829$)	Chromic catgut ($n = 835$)
Days since delivery		
Mean [SD]	98 [12]	99 [15]
Any pain in last week	67 (8)	84 (10)
Mild	50 (6)	65 (8)
Moderate	13 (2)	17 (2)
Severe	4 (1)	2 (0)
Analgesia for perineal pain in last week	6 (1)	2 (0)
Not known	4 (1)	4 (1)
Resumption of sexual intercourse		
Not tried yet	99 (12)	101 (12)
Tried, but too painful	19 (2)	28 (3)
By 3 months	115 (14)	116 (14)
By 2 months	425 (51)	399 (48)
By 1 month	171 (21)	190 (23)
Not known	0 (0)	1 (0)
Dyspareunia at first, if resumed	374 (45)	373 (45)
Any dyspareunia now, if resumed		
Mild	93 (11)	96 (11)
Moderate	46 (6)	43 (5)
Severe	3 (0)	9 (1)
Not known	3 (0)	2 (0)
Failure to achieve pain-free intercourse	260 (31)	277 (33)
Suture material removed at any time*	97 (12)	60 (7)
Resutured	3 (0)	10 (1)

*$\chi^2 = 9·40$, 1 df; $2P = 0·002$.

material had been removed (12% *vs* 7%; RR 1·62, 95% CI 1·19–2·21; $2P \leq 0{\cdot}01$); the main reason was tight stitches. Three women in the polyglactin 910 group had required resuturing compared with ten in the chromic catgut group (RR 0·30, 95% CI 0·08–1·09; $2P = 0{\cdot}1$).

Stratified analyses showed no significant interactions between the two components of the factorial design. There were no clear differences in respect of any pain at two days, failure to resume pain-free intercourse, and removal of sutures by three months, when the analyses were stratified by the suturing method, the skin closure technique (continuous or interrupted) and by mode of delivery (Fig. 1).

DISCUSSION

Because of the high frequency of pain and discomfort felt by women after childbirth (reported by over 60% of women in this study at 24 to 48 hours, for example), identifying even relatively modest improvements would be important. Such effects may be difficult to distinguish from biases or random errors, however, unless the research is both rigorously conducted and on a large scale. We believe that this study meets these stringent requirements: arrangement of the randomisation process was fastidious; compliance with the allocated material was near 100%; high rates of follow up were achieved; outcome was assessed as far as possible by someone who was blinded to the allocation; and the trial was the largest of its type ever mounted worldwide. The results are therefore very unlikely to be biased seriously, and most of the estimated differences observed between polyglactin 910 and chromic catgut were sufficiently precise to rule out chance as an explanation—in other words, the confidence intervals are generally well away from unity.

The trial indicates clear advantages of polyglactin 910 over chromic catgut. For every 20 women sutured, about one fewer had pain and one fewer was using analgesia at ten days postpartum. The only apparent disad-

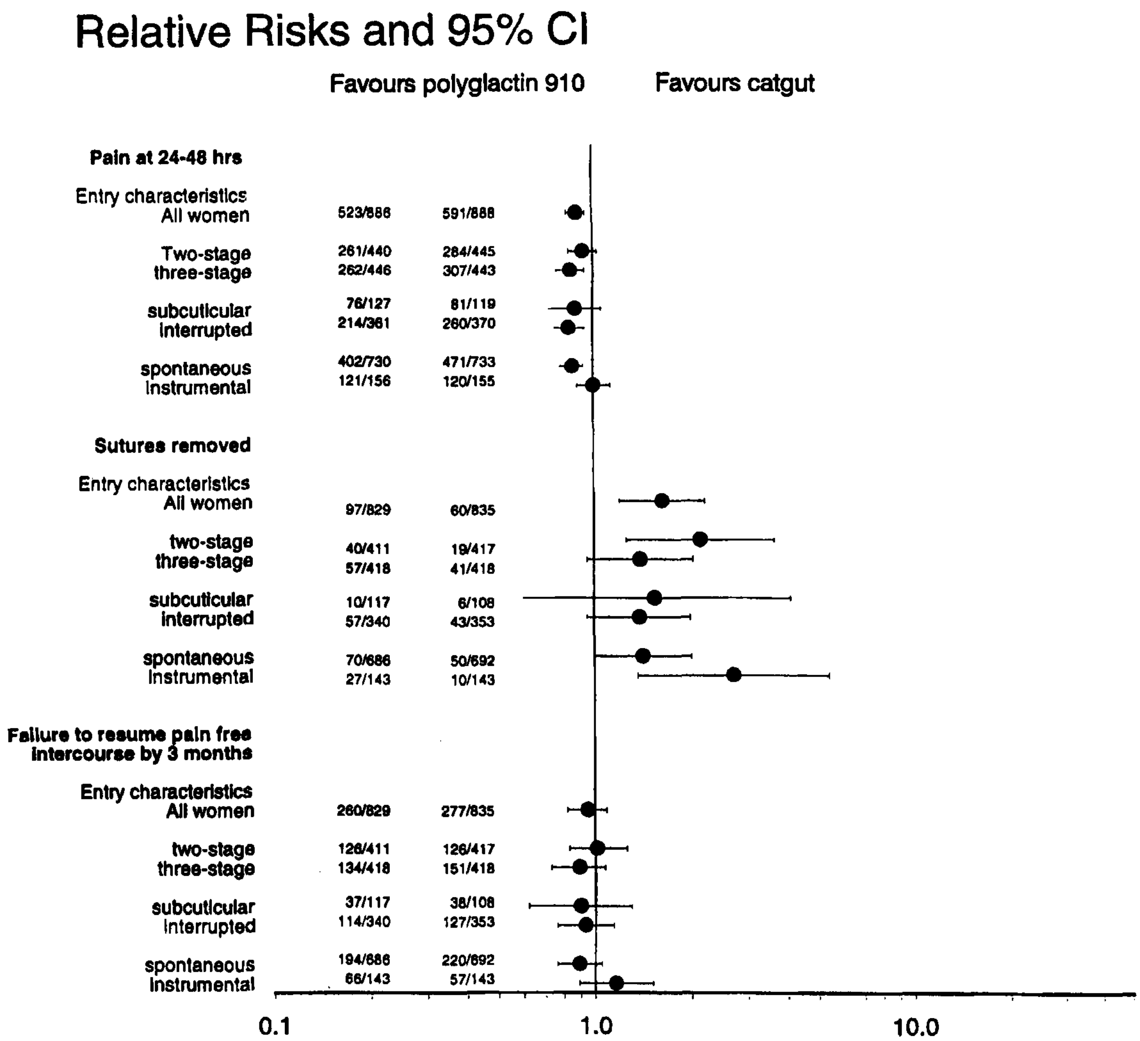

Fig. 1. Effects of polyglactin 910 *versus* catgut suturing policy on short term pain, removal of sutures and failure to resume pain-free intercourse.

vantage was that more women (again about 1 in 20) reported having material removed during healing. Otherwise, there was no definite difference between the groups at the longer term follow up, although there was a nonsignificant lower rate of resuturing in the polyglactin 910 group. Putting the results reported here in the context of previously reported broadly similar randomised trials (all of which evaluated polyglycolic acid sutures rather than polyglactin 910) further reinforces these conclusions. The clear pattern is of lower rates of short term pain and use of analgesia associated with polyglycolic acid, with no difference at three months. The apparent reduction in the need for resuturing seen in the trial reported here is consistent with all three similar trials for which data are available. The crude numbers of women requiring resuturing, including data from this report are now four out of 1191 (0·3%) repaired with a polyglycolic acid derivative, compared with 18 out of 1191 (1·5%) repaired with chromic catgut, a difference which is very unlikely to be due to chance. This suggests that, for every 100 women, about one fewer will require resuturing. The only apparent disadvantage of polyglactin 910 is the more frequently reported need for material to be removed during healing, reflecting its slower rate of absorption. It is difficult to judge whether polyglactin 910 is an improvement over the polyglycolic acid sutures in this respect because no direct comparison has been made. Although reports of removed polyglycolic acid suture material were lower in this trial than those reported in the only other trial for which comparable data are available[5], this applied to both groups and the relative risks for the comparison of the polyglycolic acid derivative with chromic catgut are very similar (1·62 compared with 1·68) in the two trials.

The results reported here should be widely generalised. This applies, in particular, to trauma sustained after spontaneous vaginal delivery and repaired by midwives. The results are similar following interrupted or subcuticular repair. Extrapolation to repair following instrumental delivery is more a matter of judgement, however. The trial did include 311 such women, and taken at face value the results from this group alone suggest no difference in pain at 24 to 48 hours (Fig. 1). The estimates of effect from just this stratum are too imprecise to be reliable on their own, however, and an equally valid interpretation is that they are compatible with the results from the spontaneous group: there was no statistical evidence of an interaction, and the confidence intervals are widely overlapping with those for the spontaneous group. In our view the overall trial result is likely to provide a more reliable estimate of effects among operative deliveries than the data from the operative group alone[10], particularly when taken in the light of data from other trials, although others may disagree with this.

Polyglactin 910 appears to behave in a similar way to other polyglycolic acid-based materials. It causes less pain and more secure healing than chromic catgut. Its disadvantage is persistence of material that commonly needs removing. The recent development of a more rapidly dissolving polyglycolic acid suture (Vicryl Rapide) is therefore potentially important, and this should now be compared with conventional polyglycolic acid-derived materials in formal randomised controlled trials. The importance of the findings reported here must be placed in context. The benefits for individual women of choosing one material rather than another may not seem large or even important to some people, but when extrapolated to the three quarters of a million women who give birth in the UK each year there are obviously very significant implications for women and the services that provide their care.

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