West Berkshire perineal management trial

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Abstract

One thousand women were allocated at random to one of two perineal management policies, both intended to minimise trauma during spontaneous vaginal delivery. In one the aim was to restrict episiotomy to fetal indications; in the other the operation was to be used more liberally to prevent perineal tears. The resultant episiotomy rates were 10% and 51% respectively. An intact perineum was more common among those allocated to the restrictive policy. This group experienced more perineal and labial tears, however, and included four of the five cases of severe trauma. There were no significant differences between the two groups either in neonatal state or in maternal pain and urinary symptoms 10 days and three months post partum. Women allocated to the restrictive policy were more likely to have resumed sexual intercourse within a month after delivery.

These findings provide little support either for liberal use of episiotomy or for claims that reduced use of the operation decreases postpartum morbidity.

Introduction

There is a dearth of scientific evidence on which to base the practice of episiotomy.[1 2] Some people claim that the operation should be used liberally on the grounds that this will reduce both serious vaginal and perineal tears as well as longer term problems such as stress incontinence and vaginal prolapse.[3 4] Others maintain that episiotomy should be largely restricted to fetal indications because they believe that perineal tears cause women fewer problems than the episiotomies done to prevent them.[5-7]

These differing views are reflected in the widely varying use of the operation; a recent survey of British maternity units reported hospital rates ranging from 14% to 96% in primiparas and from 16% to 71% in multiparas (M J House, personal communication). In particular, this variation is an expression of differing opinions about the use of the operation for *maternal* indications in non-instrumental delivery.

In the light of these contradictions we mounted a randomised controlled trial to compare liberal and restrictive use of episiotomy for maternal indications in otherwise normal vaginal deliveries.

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Patients and methods

The study was conducted at the maternity unit of the Royal Berkshire Hospital in Reading; study design and protocol were approved by the hospital ethics and research committee for west Berkshire. All women booked to deliver in the hospital during the study period were given a letter in the last trimester of their pregnancies seeking their collaboration in research into delivery techniques aimed at reducing pain and discomfort after delivery. Women were eligible for entry to the study if (*a*) they had a live singleton fetus of at least 37 completed weeks' gestational age presenting cephalically, and (*b*) spontaneous vaginal delivery was expected towards the end of the second stage of labour. During the five month study period in 1982, 1077 women met these entry criteria. Of these, 77 were not recruited to the trial for the following reasons: precipitate delivery (14 cases), private patient (eight), mother's request not to be included (seven), elective episiotomy (six), other reasons (42). (During the five month period of recruitment there were 201 operative vaginal deliveries and 62 emergency caesarean sections of singleton babies of at least 37 completed weeks' gestational age presenting cephalically.)

Entry to the trial, which was signalled by opening a sealed opaque envelope, was postponed until the attending midwife had decided to "scrub up" in expectation of a spontaneous vaginal delivery. One thousand women (93% of those who met the criteria for entry) were allocated at random to one of two management policies, both of which aimed at minimising perineal trauma during spontaneous vaginal delivery. In one the midwife was instructed to "try to avoid episiotomy," the intention being that she should restrict episiotomy to fetal indications (fetal bradycardia, tachycardia, or meconium stained liquor) so far as possible (498 subjects). In managing the other group the midwife was instructed to "try to prevent a tear," the intention being that she should use episiotomy more liberally to prevent tears (502 subjects). The groups generated were similar in several important respects (table I). All 1000 women went on to have spontaneous vaginal deliveries and were delivered by people of comparable status. When performed, episiotomies were mediolateral. Perineal trauma in the two groups was repaired in a similar way by operators of similar experience, 5% of whom were senior obstetricians, 86% junior obstetricians, and 9% medical students under supervision. A continuous suture was used to repair the vagina. Interrupted stitches were used for the deeper tissues and subcuticular (40%) or interrupted sutures (60%) used to repair the perineal skin.

TABLE I—*Comparability of treatment groups*

	Restrictive policy (n = 498)	Liberal policy (n = 502)
Mean (SD) maternal age, in years	26·6 (5·2)	26·7 (5·3)
No (%) primiparous	201 (40·4)	219 (43·6)
No (%) married	445 (89·5)	435 (86·7)
Mean (SD) gestational age, in weeks	39·8 (1·2)	39·8 (1·2)
Mean (SD) birth weight, in g	3393 (448)	3367 (438)
Person conducting delivery (No (%) of cases):		
Sister	163 (32·7)	157 (31·3)
Staff midwife	150 (30·1)	161 (32·1)
Student midwife	150 (30·1)	155 (30·9)
Medical student	26 (5·2)	25 (5·0)
Doctor	9 (1·8)	4 (0·8)

The consequences of the two policies were compared in terms of maternal and infant morbidity immediately after delivery and at 10 days and three months post partum.

The principal measures of outcome (with their expected incidences and methods of measurement) were as follows: (*a*) severe maternal trauma, predefined as extension through the anal sphincter or through to the rectal mucosa or to the upper third of the vagina (expected incidence 5%, assessed by the operator performing the repair "blind" to the allocation); (*b*) Apgar score less than 7 at one minute (expected incidence 5%, assessed by the senior midwife

at the delivery); (*c*) severe or moderate perineal pain 10 days after delivery (expected incidence 20%—standardised questionnaire administered by community midwife blind to the allocation); (*d*) admission to special care baby unit in first 10 days of life (expected incidence 5%—standardised questionnaire administered by community midwife blind to the allocation); (*e*) perineal discomfort three months after delivery (expected incidence 20%—standardised postal questionnaire self administered by the mother, in most cases blind to the allocation); (*f*) no resumption of sexual intercourse three months after delivery (expected incidence 5%—standardised postal questionnaire self administered by the mother, in most cases blind to the allocation).

Based on these expected incidences the trial size was preset at 1000 subjects. Power calculations before the trial indicated that a trial of this size would have a 90% chance of finding a significant difference (two tailed $\alpha = 0.05$) if, in truth, the restrictive policy doubled the incidence of an outcome expected in 5% of cases, and a 95% power of detecting an increase of 50% in an outcome expected in 20% of cases. All analyses were based on the unbiased comparisons between all women randomly allocated to either the restrictive or liberal policy whether or not they sustained an episiotomy or a tear.

The follow up rate at both 10 days and three months after delivery was 89%.

The χ^2 and Student's *t* tests were used to compare discrete and continuous variables respectively in the two groups.

Results

The episiotomy rate was 10% in the group allocated to the restrictive policy and 51% in the liberal policy group. This difference reflected the different numbers of both primiparas and multiparas in whom episiotomy was performed for maternal reasons (table II).

There was wide variation in the time interval between entry to the trial and delivery. While some babies were born immediately after the envelope had been opened, the interval was more than 20 minutes for 8% in the liberal group and 12% in the restrictive group ($\chi^2 = 3.4$; $p = 0.07$).

TABLE II—*Actual use of episiotomy. Figures are numbers of subjects (percentages in parentheses)*

	Restrictive policy (n = 498)	Liberal policy (n = 502)
Episiotomy	51 (10·2)	258 (51·4)
Primiparas	36 (17·9)	147 (67·1)
Multiparas	15 (5·1)	111 (39·2)
Maternal indications	18 (3·6)	228 (45·4)
Primiparas	12 (6·0)	130 (59·3)
Multiparas	6 (2·0)	98 (34·6)
Fetal distress	33 (6·6)	30 (6·0)
Primiparas	24 (11·9)	17 (7·8)
Multiparas	9 (3·0)	13 (4·6)

The different episiotomy rates resulted in different patterns of maternal trauma sustained at delivery. As expected, there were both more posterior tears and more intact perineums among those allocated to the restrictive policy. In addition, this group also sustained more anterior labial tears (table III; relative risk 1·52, 95% confidence limit 1·19-1·94).

"Severe maternal trauma" was much less common than expected. There were only four cases in the restrictive group and one in the liberal group. Both women with severe perineal injuries had been allocated to the restrictive policy; in one, a primipara, the rectal mucosa was damaged; in the other, a multipara, the anal sphincter was completely torn. In the other three cases, all primiparas, there was extension of the injury to the upper third of the vagina.

More of the women allocated to the liberal policy than to the restrictive policy required suturing (78% *v* 69%—$\chi^2 = 9.99$; $p < 0.01$); this difference was more striking in primiparas (89% *v* 74%) than in multiparas (69% *v* 66%). Apart from the four cases of severe trauma described above there was no evidence that trauma was more extensive in those women in the restrictive group who actually sustained perineal injury. Overall, women allocated to the liberal policy required 100 more packets of suture material ($p < 0.01$) and 13 more hours of time to repair the trauma that they had sustained ($p < 0.01$).

TABLE III—*Maternal trauma at delivery. Figures are numbers of subjects (percentages in parentheses)*

	Restrictive policy (n = 498)	Liberal policy (n = 502)
Posterior trauma		
None	169 (33·9)	122 (24·3)
Primiparas	62 (30·8)	32 (14·6)
Multiparas	107 (36·0)	90 (31·8)
Episiotomy alone	45 (9·0)	227 (45·2)
Primiparas	32 (15·9)	125 (57·1)
Multiparas	13 (4·4)	102 (36·0)
Perineal tear alone	278 (55·8)	123 (24·5)
Primiparas	103 (51·2)	40 (18·3)
Multiparas	175 (58·9)	83 (29·3)
Episiotomy plus extension	6 (1·2)	30 (6·0)
Primiparas	4 (2·0)	22 (10·0)
Multiparas	2 (0·7)	8 (2·8)
χ^2 test = 205·27 (3 df); $p < 0.0001$		
Anterior trauma		
None	367 (73·7)	415 (82·7)
Primiparas	135 (67·2)	170 (77·6)
Multiparas	232 (78·1)	245 (86·5)
Labial tears	131 (26·3)	87 (17·3)
Primiparas	66 (32·8)	49 (22·4)
Multiparas	65 (21·9)	38 (13·4)
χ^2 test = 11·29 (1 df); $p < 0.001$		

There were no significant differences in neonatal outcome. A total of 5·4% of babies in the restrictive group and 4·6% in the liberal group had Apgar scores below 7 at one minute, and the figures for admission to the special care baby unit in the first 10 days of life were 5·7% and 7·6% respectively.

On the tenth day after delivery 3% of mothers in the restrictive group and 2% in the liberal group used oral analgesics. The incidence of pain reported by mothers was very similar in the two groups both at 10 days after delivery (table IV) and at three months (table V). A similar proportion (12%) of women in each group had sought medical advice because of perineal problems. Consultation was more frequent among primiparas (19%) than multiparas (9%).

Thirty seven per cent of women allocated to the restrictive policy (33% of primiparas, 39% of multiparas) compared with 27% in the liberal group (22% of primiparas, 32% of multiparas) resumed sexual

TABLE IV—*Pain in past 24 hours 10 days post partum. Figures are numbers of subjects (percentages in parentheses)*

	Restrictive policy (n = 439)	Liberal policy (n = 446)
Mild	62 (14·1)	65 (14·6)
Primiparas	34 (18·5)	38 (19·4)
Multiparas	28 (11·0)	27 (10·8)
Moderate	33 (7·5)	35 (7·8)
Primiparas	19 (10·3)	22 (11·2)
Multiparas	14 (5·5)	13 (5·2)
Severe	4 (0·9)	1 (0·2)
Primiparas	2 (1·1)	1 (0·5)
Multiparas	2 (0·8)	0 (0·0)
Total	99 (22·6)	101 (22·6)
Primiparas	55 (29·9)	61 (31·1)
Multiparas	44 (17·3)	40 (16·0)
χ^2 test = 1·91 (3 df); NS		

TABLE V—*"Worst pain in past week," three months post partum. Figures are numbers of subjects (percentages in parentheses)*

	Restrictive policy (n = 438)	Liberal policy (n = 457)
Mild	20 (4·6)	26 (5·7)
Primiparas	13 (7·6)	15 (7·4)
Multiparas	7 (2·6)	11 (4·3)
Moderate	11 (2·5)	8 (1·8)
Primiparas	5 (2·9)	5 (2·5)
Multiparas	6 (2·3)	3 (1·2)
Severe	2 (0·5)	1 (0·2)
Primiparas	0	0
Multiparas	2 (0·8)	1 (0·4)
Total	33 (7·6)	35 (7·7)
Primiparas	18 (10·5)	20 (9·9)
Multiparas	15 (5·7)	15 (5·9)
χ^2 test = 2·58 (3 df); NS		

intercourse within a month after delivery ($\chi^2=8{\cdot}67$; $p<0{\cdot}01$). This difference was only partly explained by the different proportions of women with intact perineums in the two groups. Overall, 90% of women had resumed sexual intercourse within three months after delivery, and the proportions were the same in the two trial groups. Of the women who had resumed intercourse, 52% in the restrictive group and 51% in the liberal group had experienced dyspareunia at some time, and 22% and 18% respectively still had this problem three months post partum. There was no difference between the two groups in the extent to which babies were being wholly or partially breast fed at 10 days (70%) and three months (48%) after delivery. Nineteen per cent of women in both groups had involuntary loss of urine three months after delivery, and 6% sometimes needed to wear a vulval pad. This problem was more common in multiparas (22%) than primiparas (15%) but did not differ significantly between the two trial groups when compared within parity strata.

Analyses stratified by status of the person who had actually conducted the delivery showed that the differential effects of the policies were little affected by the experience of the attendant. Analyses stratified by time interval between entry to the trial and delivery disclosed that, although trauma was less common in those women who delivered very soon after entry to the trial, the overall effects of the two policies were still evident in these cases.

Both women who sustained severe perineal trauma had painful constipation in the immediate puerperium. Three months later one was problem free but constipation still occasionally troubled the primipara, in whom the tear had extended into the rectal mucosa; she was also one of those who did not resume sexual intercourse within three months after delivery. When contacted again 21 months after delivery she described herself as back to normal apart from a ridge along the line of the repair to the vagina, which she noticed when she inserted a tampon during her periods. It had taken 18 months for sexual intercourse to become completely comfortable. Of those whose trauma had extended to the upper third of the vagina, the one woman in the liberal group had mild perineal pain and dyspareunia when contacted three months post partum, and one of the two women in the restrictive group had dyspareunia, for which she had sought medical advice. At 21 months both were "back to normal." This had taken 18 months in the first case and six months in the second.

Discussion

This randomised controlled trial was designed to compare two policies[8] for managing the perineum in spontaneous vaginal deliveries as they would be used in everyday practice. The research was mounted in a busy district general hospital and the deliveries performed by those who normally conduct spontaneous vaginal deliveries in the hospital. The overall episiotomy rate in the unit before the trial was 61% (52% in spontaneous vaginal deliveries) and near the middle of the range for British maternity hospitals reported by M J House (personal communication). All the episiotomies were mediolateral, which, in contrast with other parts of the world,[2] is the standard in Britain.

Ninety three per cent of eligible women were successfully recruited to the trial, and the study population may be considered to be representative of all spontaneous vaginal deliveries in the hospital. Random allocation generated two groups of women who were similar in several important respects (table I) and who were delivered by people of comparable status, 94% of whom were midwives. Although it was not possible to blind all the participants in the trial to their treatment allocation because of a prior decision to tell those who wished to know, fewer than one in 10 requested this information. Thus most women did not know their treatment allocation when completing their questionnaires. The follow up rate (89% at both 10 days and three months after delivery) was high for this type of study, and there was no evidence that those lost to follow up differed between the two groups.

The aim of both policies was to minimise maternal trauma. The reasons for the tears in the liberal group ("prevent a tear") largely reflected this—"expected to deliver intact" (56 cases); "tear caused by shoulder" (25); "delivered too quickly to perform episiotomy" (43). There was good compliance with the restrictive policy. There were 18 cases (3·6%) in this group in which an episiotomy was performed for reasons other than fetal distress—"thick perineum" or "previous episiotomy" (11 cases); "large baby" (three); "to prevent a tear" (four).

The overall rate of severe maternal trauma was much lower than expected from other published studies. Nevertheless, the only justification from this study for recommending an episiotomy rate as high as 50% in normal deliveries is that there were more cases of "severe maternal trauma" among women allocated to the restrictive policy. This difference may have reflected a real effect of the restrictive policy, but despite the fact that 1000 women were entered into this trial it is still possible that the difference was due to chance. Of the five women who sustained severe trauma, two were problem free by three months and three were problem free by 21 months.

Looking at the restrictive policy in another way, it is noteworthy that despite the fact that episiotomy was used in only one in 10 women, 69% nevertheless required suturing. Similarly high rates of spontaneous trauma have been reported in other studies in developed countries.[2] In a randomised controlled trial of a birth chair for delivery[9] the episiotomy rate among those delivered in the chair (20%) was lower than in the group delivered in the conventional dorsal position (43%). The spontaneous tear rate, however, was higher in the birth chair group (52% compared with 41%) and the overall trauma rates were 72% and 84% respectively. Lower spontaneous trauma rates have been reported from other settings, and this may reflect differences in other aspects of the management of pregnancy, labour, and delivery or wider differences in social behaviour such as lifetime squatting for defecation.

In our study, restricting the use of episiotomy to fetal indications resulted in neither an increase nor a major decrease in the problems experienced by mothers in the three months after delivery; the only difference observed was a tendency for women allocated to the restrictive episiotomy policy to resume sexual intercourse sooner. These results of an experiment controlling for selection bias are in striking contrast with the findings of studies based on comparisons using observational data,[2 5 6] all of which suggest that the discomfort after perineal tears is considerably less than after episiotomy.

The saving in medical staff time spent suturing associated with the restrictive policy was of the same order as the saving in midwifery time managing delivery associated with the liberal policy. The more restrictive policy did, however, result in savings in suture materials (and if our results are extrapolated to the whole of England and Wales adopting a restrictive policy would save an estimated £65 000 worth of suture materials a year). It is perhaps worth noting that the episiotomy rate in spontaneous vaginal deliveries at the Royal Berkshire Hospital is now only 20%.

As expected, multiparas had fewer episiotomies, fewer anterior tears, and more intact perineums than primiparas, but they also sustained more posterior tears. They were half as likely as primiparas to have pain 10 days and three months after delivery but more likely to suffer involuntary loss of urine. When the two perineal management policies were compared within parity groups, however, the patterns of the results closely resembled that of the unstratified analysis for the total trial population; in both parity strata the incidences of pain and involuntary loss of urine associated with the two perineal management policies were very similar.

A large proportion of women (19%) had involuntary loss of urine three months after delivery, but there is no evidence from this study that liberal use of episiotomy prevents this problem. It is still possible that it may prevent stress incontinence and vaginal prolapse in the longer term, however, and we therefore plan to contact the mothers again three years after delivery.

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SHORT REPORTS

Unilateral sacroiliac overuse syndrome in military recruits

Although sacroiliac strain is frequently diagnosed, objective evidence of such a disorder is generally lacking and the whole subject is controversial. We report four soldiers who developed pain in the sacroiliac region after excessive physical activity with abnormal scintigrams which resolved when the symptoms improved.

Patients, methods, and results

A large group of highly motivated military recruits were evaluated in a prospective study of stress fractures. All soldiers had an evaluation before and after training and were followed throughout this. The soliders had free access to the medical staff as well as mandatory three week check ups and were followed until the resolution of any orthopaedic problem. Soldiers with symptoms compatible with stress fractures were given three days' rest and if they still had symptoms on return to activity stress fractures were diagnosed on the basis of Tc^{99} MDP late phase scintigraphy, with the activity rated from 1 to 4. The scan was repeated when clinically indicated.

Four soldiers in this study presented with unilateral pain in their sacroiliac region (table). The pain was proportional to effort, relieved by rest, and did not respond to treatment with non-steroidal anti-inflammatory drugs by immediate relief. All the symptomatic sacroiliac joints were tender to direct palpation of the area and showed positive Gaenslen tests. There was no limitation of the range of motion in the lower back of the four soldiers. The results of blood and urine analysis were normal, including tests for rheumatoid factor and HLA-B27, as were x ray films taken near to the time of the onset of the pain and after relief. None of the soldiers had had lower back complaints or pain in the region of the sacroiliac joint before army training and after a period of rest all returned to normal activity, in cases 3 and 4 as combat soldiers and the rest in less demanding duties.

Comment

The existence of sacroiliac strain is doubted.[1 2] Cyriax states that it occurs only in women between the ages of 15 and 35 and may be differentiated from arthritis spondylitis, in which the pain comes and goes independently of exertion and is often bilateral.[1] By contrast, the pain of sacroiliac stress is evoked by exertion, avoided by resting, never alternates, and is always unilateral.

To identify true sacroiliac pain requires proper physical examination because most "sacroiliac pains" are referred pains from irritation of the nerve roots and should properly be called gluteal pains. Finding a tender spot "over the joint" is misleading. The joint is in fact far from the palpable posterior iliac border. The key to diagnosis is exerting tension on the sacroiliac joint without affecting the lumbar spine (for example, Gaenslen test).

Relying on scintigraphy to confirm clinical suspicion of sacroiliac strain has many problems. A high proportion of false positive results has been reported from using this technique in evaluating sacroiliitis.[3-5] Ayres *et al* point out that many of these "false" positives actually reflect lesions. It is known that patients with abnormal postural loads on their sacroiliac joints may show increased activity, as also occurs in metastatic cancer and Hodgkin's disease and in patients with renal transplants and some patients with lower back pain.

We conclude that the four patients we describe with unilateral sacroiliac pain and corresponding scintigraphic findings represent an overuse strain syndrome of the sacroiliac joint. Supporting this conclusion are the following: (*a*) the scintigraphic findings resolved simultaneously with the resolution of the pain; (*b*) the extreme intensity of the unilateral sacroiliac activity on these scane; (*c*) the results of clinical examination were consistent with pain from sacroiliac origin; (*d*) the fact that the pain was proportional to exertion and relieved by rest, and was unilateral; (*e*) the normal results from laboratory investigations; (*f*) the fact that no other soldier in the study group, in which 181 soldiers had bone scans, had abnormal sacroiliac activity.

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Features in case histories

Case No	Age	Sacroiliac joint pain history (days)	Weeks of training before onset of pain	Side of sacroiliac joint pain	Other stress fractures during training training course	^{99}Tc scan hot spot at time of pain	Rest period (weeks)	Pain after rest	Repeated ^{99}Tc scan after rest after rest	Assignment of duty
1	18	17	5	R	R proximal femur	R sacroiliac joint R proximal femur	8	Relieved nagging pain	Total sacroiliac resolution	Less demanding duty
2	18	21	3	R		R sacroiliac joint	16	Relieved	Total sacroiliac resolution	Less demanding duty
3	20	14	2	R	R tibia. R and l femurs	R sacroiliac joint. R tibia (two foci) Distal femurs	3	Relieved	Considerable sacroiliac resolution after eight weeks	Combat soldier
4	18	28	20	R	12 stress fractures in pubic bones and legs	11 hot spots	3 (partial rest)	Relieved	Total sacroiliac resolution	Combat soldier