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Impact of chromic catgut versus polyglactin 910 versus fast-absorbing polyglactin 910 sutures for perineal repair: A randomized, controlled trial

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KEY WORDS
Sutures
Episiotomy
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Objective: The goal of our study was to compare the impact of 3 suture materials on perineal pain and on resumption of sexual intercourse.

Study design: This randomized, controlled trial compared 3 types of suture materials (chromic catgut, polyglactin 910, fast-absorbing polyglactin 910) for second-degree perineal laceration or uncomplicated episiotomy. Patients were enrolled in early labor and assigned randomly to 1 of the 3 suture materials. Pain was evaluated at 48 hours, 6 weeks, and 3 months. The study subjects were questioned about residual perineal pain, resumption of sexual activity, and pain-free sexual intercourse. Logistic regression analyses were undertaken.

Results: Of the 192 patients who were assigned randomly to groups, 66 patients had their perineal laceration repaired with chromic catgut; 60 patients had repair with polyglactin 910, and 66 patients had repair with fast-absorbing polyglactin 910. At 48 hours, there was no significant difference according to the pain measurement scores, but the median consumption of analgesics was significantly lower with fast-absorbing polyglactin 910 than with standard polyglactin 910. There was no difference in the resumption of sexual intercourse at 6 weeks after the delivery between chromic catgut (42%) compared with standard polyglactin 910 group (56%; $P = .23$). However, it was more frequent for women in the fast-absorbing polyglactin 910 group (66%; $P = .02$). After adjustment for confounding variables, perineal repair with fast-absorbing polyglactin 910 was associated with a higher rate of sexual intercourse (odds ratio, 2.55; 95% CI, 1.07-6.10) and a higher rate of pain-free sexual intercourse (odds ratio, 2.51; 95% CI, 1.03-6.10) at 6 weeks after delivery.

Conclusion: Fast-absorbing polyglactin 910 for perineal repair is associated with earlier resumption of sexual intercourse when compared with chromic catgut.

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Eighty-five percent of women who give birth by spontaneous delivery will have some form of perineal trauma, and up to two-thirds of these women will have perineal tear repaired.[1,2] A significant number of these mothers will experience perineal pain, not only in the immediate postpartum period, but also months later.[2] As many as 20% will continue to have long-term problems, such as superficial dyspareunia.[1] There is evidence that perineal repair with absorbable synthetic materials, such as standard polyglactin 910 or polyglycolic acid sutures, reduces short-term pain and dyspareunia when compared with chromic catgut.[3-5] However, these synthetic sutures have been associated with an increased risk for the need to remove residual material up to 3 months after delivery.[4-6]

Fast-absorbing polyglactin 910 sutures (Vicryl rapide; Ethicon, Peterborough Ontario, Canada) are now available for perineal repair. This material has all the properties of other synthetic sutures, but because of changes in the manufacturing process, its tensile strength is lost by days 10 to 14, and it is totally absorbed by day 42. These newer and more rapidly absorbed sutures potentially could offer the short-term benefits of synthetic materials without the problems related to delayed suture reabsorption. To date, no randomized trial has compared the 3 most frequently used suture materials. Because we believe that an important outcome is maternal comfort, the goal of our study was to compare the impact of the 3 suture materials on perineal pain in the first 48 hours and at 6 weeks after delivery and on the time to resumption of pain-free sexual intercourse.

Methods

This is a randomized, controlled trial in a tertiary care hospital that compared 3 types of sutures (chromic catgut [chromic surgical gut suture; Ethicon], standard polyglactin 910 [Vicryl; Ethicon], and fast-absorbing polyglactin 910 [Vicryl rapide; Ethicon]) for second-degree perineal laceration or an uncomplicated episiotomy. Inclusion criteria were hemodynamically stable patients with a second-degree perineal laceration or an uncomplicated episiotomy (median or mediolateral) and maternal age of $\geq$18 years. Exclusion criteria were third- or fourth-degree perineal laceration, allergy to nonsteroidal anti-inflammatory agents or aspirin, thrombocytopenia, pregnancy-induced hypertension, a history of coagulation disorder, unexplained hemorrhage, or gastroduodenal ulcer.

Patients were enrolled in early labor or when comfortable under regional anesthesia. They were assigned randomly to 1 of the 3 suture materials at the end of the third stage, if the including criteria were met. Randomization was achieved by the use of opaque, consecutively numbered envelopes that each contained a letter with the name of 1 of the 3 suture materials. The next available envelope was opened by the attending obstetrician-gynecologist, and perineal repair was undertaken with the suture that was identified by the attending obstetrician-gynecologist or resident under direct supervision, according to the continuous technique described in the *Williams Obstetrics* textbook.[7] A 2-0 suture was used for continuous suturing to close the vaginal mucosa and submucosa; a 2-0 suture was used for 2 to 4 interrupted sutures placed in the fascia and muscle of the lacerated perineum, and a 3-0 suture was used for continuous downward suturing to close the superficial fascia and subsequently upward as a subcuticular stitch. All women received an indomethacin suppository (50 mg) per rectum on completion of the repair. Patients were not informed of the suture material that was used. A preapproved, standard prescription was given for postpartum care. The prescription included (1) 1 naproxen tablet (500 mg) every 12 hours for 2 doses and every 12 hours subsequently on request by the patient; (2) 1 to 2 codeine (30 mg) + acetaminophen (325 mg) tablets every 4 to 6 hours on request by the patient; and if sufficient analgesia was not achieved, (3) 1 to 2 tablets of hydromorphone (1 mg) every 4 to 6 hours on request by the patient.

Pain was first evaluated at 36 to 48 hours after the delivery by a research nurse who was blinded to the suture type. The short form of the McGill Pain Questionnaire validated by Melzack for perineal pain was used for 3 pain score measurements.[8,9] The first score consisted of 15 pain descriptors, which were rated on an intensity scale from 0 to 3. The second score was the Present Pain Intensity index that rated the intensity of pain from 0 (no pain) to 5 (excruciating pain). The third score was determined on a visual analog scale with which the patient was asked to put a dot on a 10-cm line between the 2 extremities (no pain and worst possible pain). The distance between the "no pain" extremity and the patient's dot was measured, and the score was obtained. Total consumption of the analgesic doses (naproxen 500 mg = 1 dose, codeine 30 mg = 1 dose, hydromorphone 1 mg = 1 dose) and narcotic doses (codeine 30 mg = 1 dose, hydromorphone 1 mg = 1 dose) taken in the first 36 hours was calculated.

At the 6-week standard postpartum visit, a preapproved, objective questionnaire was completed, and a physical examination was performed by the obstetrician in charge of the patient. The following questions were asked of the patient: (1) Do you have residual perineal pain? (2) Have you resumed sexual intercourse since delivery? (3) Do you have pain-free sexual intercourse? (4) Do you still breastfeed?

The physician was requested to determine whether any residual sutures, infection, or wound breakdown were noted at the time of the physical examination.

Table I Characteristics of patients at randomization

Characteristic	Chromic catgut (n = 66)	Standard polyglactin 910 (n = 60)	Fast-absorbing polyglactin 910 (n = 66)	*P* value
Maternal age (y)*	29.7 ± 5.0	30.5 ± 5.9	30.2 ± 5.0	NS
Nulliparous (n)	44 (67%)	33 (55%)	43 (65%)	NS
Gestational age (wk)*	39.6 ± 1.3	39.1 ± 1.9	39.5 ± 1.3	NS
Birth weight (g)*	3502 ± 452	3421 ± 560	3523 ± 485	NS
Birth weight >4000 g (n)	8 (12.1%)	11 (18.3%)	9 (13.6%)	NS
Operative vaginal delivery (n)	11 (16.7%)	12 (20%)	11 (16.7%)	NS
Episiotomy (n)†	29 (43.9%)	25 (41.7%)	29 (43.9%)	NS
Dyspareunia before pregnancy (n)	18 (27%)	15 (25%)	16 (24%)	NS

Proportions were studied by chi-square analysis. *NS*, Not significant.

* Data are given as mean ± SD, by analysis of variance.

† Rate of episiotomy (vs spontaneous perineal laceration). Median episiotomies were performed, except for 1 case of mediolateral episiotomy in the standard polyglactin 910 group.

Table II Outcomes at 36 to 48 hours

Outcome	Chromic catgut (n = 64)	Standard polyglactin 910 (n = 55)	Fast-absorbing polyglactin 910 (n = 65)	*P* value
Evaluation of perineal pain				
McGill Pain Questionnaire score	6 (0-30)	5 (0-31)	4 (0-23)	.25
Present Pain Intensity	2 (0-3)	2 (0-3)	1 (0-5)	.07
Visual Analog Scale	3 (0-9)	3 (0-10)	2.5 (0-9)	.13
Consumption of analgesics				
No. of doses of any analgesic*	7 (2-30)	8 (0-25)	6 (0-21)	.02†
No. of doses of narcotic‡	1 (0-13)	2 (0-15)	0 (0-12)	<.01†
Infection at the site of perineum repair	0	0	0	

Data are given as medians (minimum-maximum), by the Kruskal-Wallis test.

* One dose of analgesic included any of the following: naproxen 500 mg, codeine 30 mg, or hydromorphone 1 mg.

† $P < .05$ between polyglactin and fast-absorbing polyglactin.

‡ One dose of narcotic included either codeine 30 mg or hydromorphone 1 mg.

Infection or wound breakdown were considered if subsequent treatment or follow-up examination was necessary. At 3 months, an attempt was made to contact each woman by phone, and the same 4 questions were asked. Based on a power analysis before the beginning of the study, 1200 women were supposed to be enrolled. After 6 months of enrollment, however, the study was stopped because 1 of the suture materials, chromic catgut, was removed from our hospital inventory for reasons not related to our trial. Subsequently, we calculated that our study had the power to detect an approximately 100% difference, instead of a 20% difference as previously planned, in the primary outcome between the groups.

The primary outcome that was planned before the beginning of the study was the first McGill Pain Questionnaire score at 36 to 48 hours. The secondary outcomes were (1) the median amount of analgesic consumption during the first 36 hours after delivery, (2) the median amount of narcotic consumption during the first 36 hours after delivery, (3) the rate of pain-free sexual intercourse at 6 weeks after delivery, (4) the rate of pain-free sexual intercourse at 3 months after delivery, and (5) the rate of residual sutures at 6 weeks after delivery.

Statistical analyses were performed with the Pearson's chi-square test, the Kruskal-Wallis test, and analysis of variance, when appropriate. Step-wise logistic regression analyses included parity, birth weight >4000 g, breastfeeding, operative vaginal delivery, spontaneous tear or episiotomy, and type of suture material. SPSS software (version 11.5; SPSS Inc, Chicago, IL) was used for the analyses. Probability values of <.05 were considered to be statistically significant.

Results

Of the 192 patients who were assigned randomly in the study, 66 patients had their perineal laceration repaired with chromic catgut; 60 patients had repair with polyglactin 910, and 66 patients had repair with fast-absorbing polyglactin 910 sutures. There were no significant differences according to randomization group for maternal age, gestational age, birth weight, rate of spontaneous perineal laceration or episiotomy, rate of operative vaginal delivery, and rate of prepregnancy dyspareunia (Table I). One hundred nine patients had

Table III Outcomes at 6 weeks after the delivery

Outcome (n)	Chromic catgut (n = 53)	Standard polyglactin 910 (n = 43)	Fast-absorbing polyglactin 910 (n = 58)	*P* value
Breastfeeding	39 (74%)	27 (63%)	46 (79%)	.18
Persistent perineal pain	5 (9%)	3 (7%)	3 (5%)	.68
Resumption of sexual intercourse after delivery	19/45 (42%)	20/36 (56%)	29/44 (66%)	.08*
Pain-free sexual intercourse	12/45 (27%)	15/36 (42%)	21/44 (48%)	.11*
Residual suture	0	1 (2.3%)	0	.27
Incomplete healing	1 (1.9%)	2 (4.7%)	2 (3.4%)	.75

Proportions were studied by chi-square analysis.
* $P < .05$, between chromic catgut and fast-absorbing polyglactin.

Table IV Outcomes at 3 months after delivery

Outcome (n)	Chromic catgut (n = 43)	Standard polyglactin 910 (n = 33)	Fast-absorbing polyglactin 910 (n = 40)	*P* value
Breastfeeding	27 (63%)	16 (49%)	26 (65%)	.31
Persistent perineal pain	7 (16.3%)	3 (9.1%)	3 (7.5%)	.40
Resumption of sexual intercourse after delivery	40 (93%)	29 (88%)	39 (98%)	.27
Pain-free sexual intercourse	26 (60%)	22 (67%)	26 (65%)	.84

Proportions were studied by chi-square analysis.

a spontaneous second-degree perineal laceration; 82 patients had an uncomplicated median episiotomy, and 1 patient had an uncomplicated mediolateral episiotomy. Of the 192 women who were assigned randomly, 184 women (96%) agreed to meet the research nurse and completed the 36- to 48-hour postpartum evaluation. At 36 to 48 hours, there was no significant difference according to the 3 pain measurement scores ($P = .25$; $P = .07$; $P = .13$). However, the median consumption of analgesics or narcotics in the early postpartum period was significantly lower with fast-absorbing polyglactin 910 than with standard polyglactin 910 (Table II).

Table III shows the results that were collected by the collaborating obstetricians at 6 weeks after delivery in 154 of the 192 women (80%) who were assigned randomly. No difference was found in the rate of breastfeeding, the rate of residual sutures, or wound breakdown among the 3 groups. There was no difference in the resumption of sexual intercourse at 6 weeks between women in the chromic catgut group (42%) compared with women in the standard polyglactin 910 group (56%; $P = .23$); however, it was more frequent for women in the fast-absorbing polyglactin 910 group (66%; $P = .02$). After adjustment for confounding variables by step-wise logistic regression, the variables that remained in the model for the resumption of sexual intercourse at 6 weeks after delivery were the type of perineal repair and birth weight >4 kg (odds ratio, 0.40; 95% CI, 0.15-1.12). Compared with chromic catgut, perineal repair with fast-absorbing polyglactin 910 was associated with a higher likelihood of resumption of sexual intercourse at 6 weeks (odds ratio, 2.55; 95% CI, 1.07-6.10) but not standard polyglactin 910 (odd ratio, 1.76; 95% CI, 0.72-4.33). Perineal repair with fast-absorbing polyglactin 910 was also associated with a higher likelihood of the resumption of pain-free sexual intercourse at 6 weeks (odds ratio, 2.51; 95% CI, 1.03-6.10) but not standard polyglactin 910 (odd ratio, 1.96; 95% CI, 0.77-5.01). Three-month follow-up evaluations were obtained for 116 women (60%). No difference was found among the 3 groups in terms of breastfeeding, perineal pain, and resumption of sexual intercourse or pain-free sexual intercourse (Table IV). No significant differences in terms of maternal age, gestational age at birth, parity, episiotomy or spontaneous tear, and previous dyspareunia were found between patients included in the study and those evaluated at 48 hours, 6 weeks, and 3 months after delivery.

Comment

Traditionally, the type of suture material that was chosen for perineal repair was left to the discretion of the surgeon. Despite several reports that showed the short-term benefits of synthetic materials for perineal repair, chromic catgut has remained the material of choice by many physicians. With our trial, we hoped to provide more long-term objective evidence to help in the choice of suture material for perineal repair. Our study indicated that fast-absorbing polyglactin 910, which is used for perineal repair, is associated with significantly lower consumption of narcotics in the first 36 hours after delivery and with a trend toward a decrease in pain scores. Fast-absorbing polyglactin 910 was also linked

with earlier resumption of sexual intercourse, compared with chromic catgut and standard polyglactin 910, but there was no more difference in the rate of pain-free sexual intercourse at 3 months after delivery. These results are in agreement with the Cochrane systematic review, which included 8 randomized trials, that compared absorbable synthetic versus catgut sutures for perineal repair. The conclusion was that absorbable synthetic material appears to decrease a woman's experience of short-term pain.[5] However, the length of time for the synthetic material to be absorbed remained of concern. Three trials reported on the rate of dyspareunia at 3 months after delivery and found no difference between the 2 groups.[4,6,10]

In January 2000, McElhinney et al[11] published the first trial that compared standard polyglactin 910 and fast-absorbing polyglactin 910. Although they observed no difference in analgesic requirements between the 2 groups, they noted a significant difference in terms of dyspareunia at 6 weeks after delivery in favor of fast-absorbing polyglactin 910. In a very large trial that involved 1542 women, Kettle et al[12] found no significant pain differences at 10 days after delivery and for dyspareunia at 3 months after delivery between standard and fast-absorbing polyglactin 910 that were used for perineal repair. However, rapidly absorbed sutures were associated with significantly lower scores on several secondary pain measures at 10 days and also with a lower rate of suture material removal. There was no evaluation of pain or dyspareunia at 6 weeks after delivery.

Only 1 other trial has compared rapidly absorbed polyglactin 910 with chromic catgut for perineal repair.[13] Of 1361 women who were assigned randomly to one or the other material, two-thirds of the women in each group required sutures for perineal repair, and 87% of the women received the appropriate allocated suture. Interestingly, they reported less uterine cramping pain at 24 to 48 hours after delivery with fast-absorbing polyglactin 910, but there was no difference in the proportion of women who took analgesics. No difference was detected between the groups at 10 to 14 days, but again there was a significant reduction in uterine cramping pain and a decrease in analgesic use with fast-absorbing polyglactin 910 at 6 to 8 weeks after delivery compared with chromic catgut.

Three important limitations could potentially affect the interpretation of our results: (1) premature arrest of the trial, (2) potential knowledge by the patient, research nurse, or obstetrician who performed the clinical examination of the suture materials, and (3) the number of patients who were lost to follow up. We believe that these limitations were unlikely to significantly impact our results, but we probably would have obtained more significant results with higher recruitment; unfortunately, the trial was terminated prematurely. On the other hand, we believe that our findings were not biased by those limitations for the following reasons: (1) the premature arrest of the trial was related to a factor completely independent to the study; (2) because the color of the suture was approximately the same, it would be very difficult to differentiate the type of suture at 48 hours or at 6 weeks after delivery; and (3) the patients who were lost to follow-up evaluation were comparable in terms of maternal age, gestational age at birth, parity, episiotomy or spontaneous tear, and previous dyspareunia.

On the basis of the results of this and previous trials, we believe that fast-absorbing polyglactin 910 or an equivalent type should be chosen as first-line suture material for uncomplicated, second-degree perineal lacerations or episiotomy.

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Discussion

Stephen H. Cruikshank, MD, MBA. As you may have noted, this paper is the Central Prize Award manuscript. The Program Committee had only blinded abstracts from which to choose. I must say that Drs Leroux and Bujold produced a simple, but most effective randomized trial. The study can be performed by others, if needed, and all the data to reproduce or counter the authors' results are evident throughout the study. It just goes to show us that many times the most effective study is the simplest.

1. Do you think a perineal tear versus a well-timed incisional episiotomy would make a difference in your results?
2. How many of the final 160 patients who were included had episiotomies? How many had tears?
3. Because this is the first such randomized trial, what would be the power of the study for others who wish to achiever/counter your results?
4. How many obstetricians who performed the repair were attending physicians and how many were residents? Do you think this made a difference?
5. Does tissue handling of a second-degree tear have any bearing on the results? What techniques were used?
6. What would you do differently to decrease the limitations of your study?

Dr Bujold (Closing statement). I would first like to thank both Dr. Cruikshank and the CAOG for their interest in our work and for such welcome recognition and honors.

In our study, we did not find any difference in terms of perineal pain or resumption of sexual intercourse between patients who had a spontaneous perineal laceration and patients who had an episiotomy. However, our study was not designed to address this specific question, and it is possible that a larger trial could have found such a difference. Of the 154 patients whose condition was followed at 6 weeks after delivery, 67 women had an uncomplicated episiotomy, and 87 women had a spontaneous second-degree perineal laceration. On the basis of our results and depending on the primary outcome chosen, we believe that approximately 400 to 600 women should be assigned randomly to detect significant differences between the groups in terms of short- and long-term perineal pain.

Most physicians who perform the repairs were obstetric-gynecology residents under direct supervision by the attending obstetrician-gynecologist. Moreover, it was mandatory to use the same continuous technique that was described in the *Williams' Obstetrics* textbook, independently of the type of suture that was used. Because the allocation (randomization) of the type of suture was independent of the expertise level of the physician, we do not believe that this factor could have made a difference in our results.

Finally, in a future trial, because suture type has an important impact on the resumption of sexual activity and potential long-term outcomes, I would take more precautions to decrease the number of patients who are lost to follow up.