

Perineal Repair with Standard versus Rapidly Absorbed Sutures after Vaginal Birth: a Randomised Controlled Trial

T WONG MBChB, MRCOG, FHKAM (O&G) Medical Officer

HL MAK MBBS, MRCOG, FHKAM (O&G) Associate Consultant

HK WONG MBBS, FRCOG, FHKAM (O&G) Consultant (Chief of Service)

Department of Obstetrics and Gynaecology, Queen Elizabeth Hospital, Hong Kong

KY LEUNG MBBS, MSc (ECOM&ICOM), FRCOG, FHKAM (O&G), Dip (Epid & Appl Stat) Consultant

Department of Obstetrics and Gynaecology, The University of Hong Kong, Queen Mary Hospital, Hong Kong

Objective:

The aim of this randomised controlled trial was to test whether rapidly absorbed polyglactin suture can reduce visible stitches rate.

Materials and Methods:

From January 2002 to December 2002, all women having vaginal birth in Queen Elizabeth Hospital who needed episiotomy repair were asked to join the study. The repairing procedure was a three-layered technique. Vaginal and perineal muscle was repaired by chromic catgut separately. Subcuticular layer was repaired either by standard polyglactin 910 or rapidly absorbed polyglactin 910 suture. All women were then randomly allocated to these two different suture materials. They were later contacted by telephone on day 5, 2 weeks, and 3 months after delivery to evaluate visible stitches rate, removal of stitches, insufficient healing and/or resuturing and perineal pain perception.

Results:

Five hundred and ten women, including 468 spontaneous vaginal delivery and 42 ventouse delivery, were recruited with written consent. Two hundred and forty-two women of spontaneous vaginal delivery and 19 of ventouse delivery were repaired by standard polyglactin 910 material. Remaining women, including 226 spontaneous vaginal delivery and 23 ventouse delivery, used rapidly absorbed polyglactin 910 suture. Within 3 months, women sutured with standard polyglactin 910 had significantly more visible stitches rate of 38 (14.9%) versus 19 (8.0%) cases when compared to rapidly absorbed polyglactin 910. The difference in visible stitches rate became significant starting from 2 weeks after delivery.

Conclusion:

The use of rapidly absorbed polyglactin in continuous subcuticular perineal repair can significantly reduce the occurrence of visible stitches.

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Keywords: Episiotomy wound, Perineal repair, Polyglactin 910, Randomised trial

Introduction

After vaginal deliveries, about 60-70% of women require perineal repair for an episiotomy wound or a spontaneous tear^{1,2}. After perineal repair, up to 37% of women have complaints related to wound problems. Short-term problems include perineal pain, gapped wound, and uncomfortable sutures. Women may complain of dyspareunia a few months after their

deliveries. The type of suturing material used, as well as other factors including the extent of trauma, skill of

Correspondence to: Dr T WONG, Department of Obstetrics and Gynaecology, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon, Hong Kong.

Tel: (852) 2958 6049

Fax: (852) 2384 5834

Email: wongt1@ha.org.hk

the operator, technique of repair affect the occurrence of these wound problems³.

Standard polyglactin 910 (Vicryl®) has been used to repair episiotomy for a long time. The use of the standard polyglactin 910 suture material is associated with less perineal pain, analgesic use, wound dehiscence and resuturing when compared to catgut suture material^{4,5}. However, women often complain of irritation, tightness and pain from residual sutures even weeks after delivery, when the tissues have healed. In one study by Mahomed et al⁶, 18% and 26% of the mothers with subcuticular sutures had the sutures removed at 10 days and 3 months after delivery respectively. So, the absorption rate of ordinary vicryl seems to be a major problem.

A rapidly absorbed polyglactin 910 suture material (Vicryl rapide®) is now available for perineal repair. This suture material degrades more rapidly and is absorbed completely in 42 days but it takes about 60 days for standard polyglactin 910⁷. The rapidly absorbed polyglactin 910 has been shown to cause less perineal pain or discomfort than the standard polyglactin 910^{8,9}. In a randomised controlled trial of the standard and rapidly absorbed polyglactin 910 sutures by Gemynthe et al¹⁰, the number of women with visible stitches or requiring removal of stitches was higher, although not significantly, in women sutured with standard polyglactin 910. A recent large trial¹¹ of 1542 women, all had a spontaneous vaginal delivery, showed that the more rapidly absorbed polyglactin 910 material obviates need for suture removal up to 3 months postpartum for one in 10 women sutured.

In a systematic review¹², because of the fast absorption rate, chromic catgut was shown to have a significantly higher rate of suture dehiscence and resuturing of wound than absorbable synthetic suture material. Thus it is postulated that rapidly absorbed polyglactin 910 will lead to an increase in wound breakdown. However, whether the rapidly absorbed polyglactin 910 is associated with insufficient healing has not been proven. Besides, there were no studies on the use of different suture materials in Chinese women.

We, therefore, aimed to compare the standard polyglactin 910 and the rapidly absorbed polyglactin 910 in continuous subcuticular perineal repair in Chinese

women.

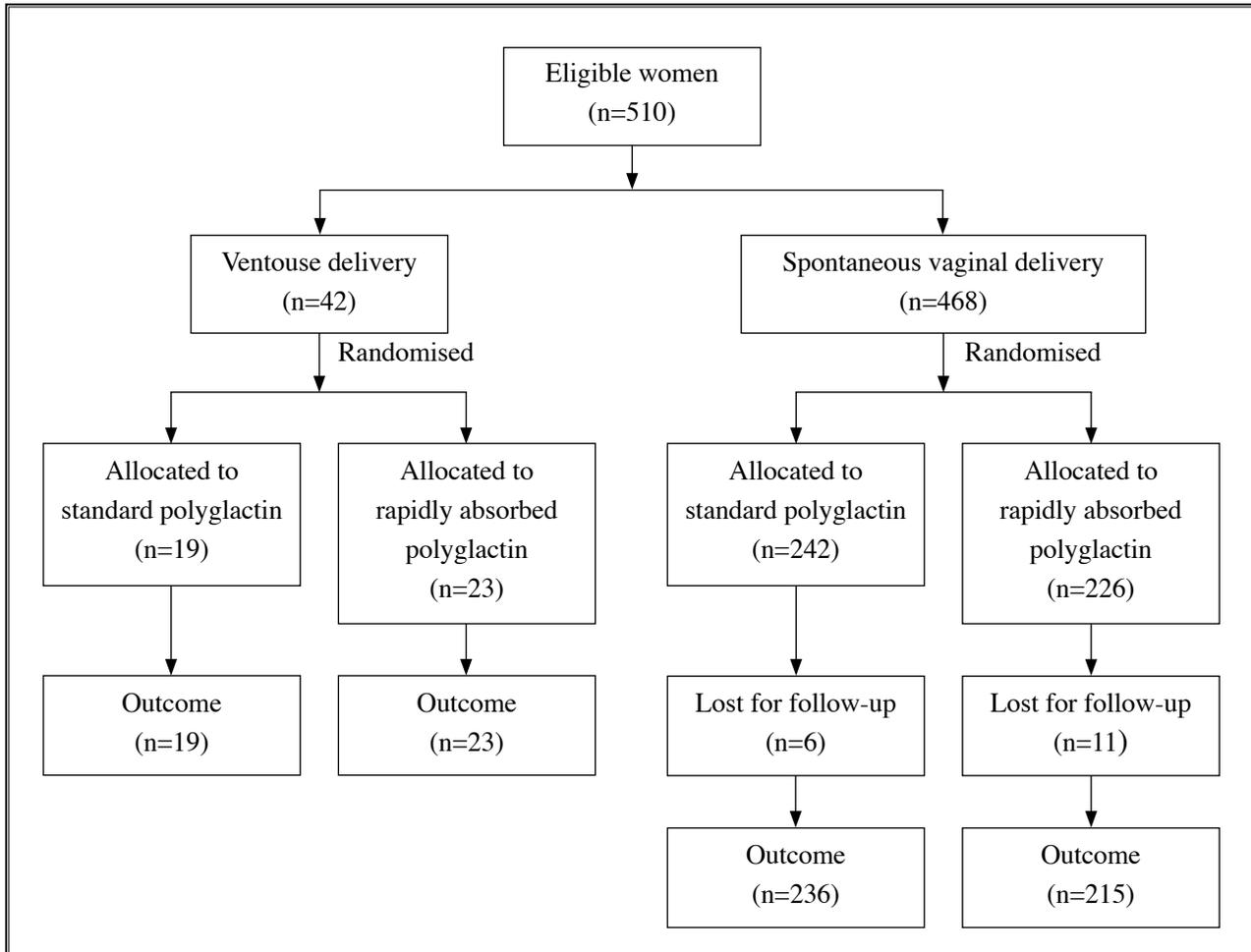
Methods

A prospective randomised control trial was conducted in Queen Elizabeth Hospital (QEH) from January 2002 to December 2002. The total number of deliveries of the hospital was 4316 in this year. The Hospital Research Ethics Committee has approved the study. All women who had an episiotomy or spontaneous tear needing repair were asked to join the study. The eligible participants should be mothers who received antenatal care in QEH with or without shared care with a Maternal and Child Health Centre. They planned for vaginal delivery and required repairing of episiotomy wound or perineal tear. Exclusion criteria included language barrier, planning for Caesarean delivery, delivery shortly after admission before consent is obtained and non-Hong Kong resident in which follow-up would be difficult. Explanation of the study was given to all women from 34 weeks of gestation onwards or earlier if she went into labour before 34 weeks.

After an eligible woman had a vaginal delivery, the midwife responsible for her care would check the availability of the consent form and her perineum. Any woman with an extensive perineal tear or episiotomy wound would be excluded from the study. Those suitable women after spontaneous vaginal delivery and instrumental delivery were allocated separately and randomly to one of the two groups according to a list of random numbers generated from a random table. The random numbers were put inside a series of consecutively numbered, opaque, and sealed envelope. The two groups were the standard polyglactin group and the rapidly absorbed polyglactin group. The only difference in the management between the two groups is the type of suture material used for perineal repair.

The repairing procedure was a three-layered technique. Vaginal and perineal muscle was repaired separately by chromic catgut. Then, standard polyglactin 910 or rapidly absorbed polyglactin 910 suture materials were used to close the subcuticular layer continuously in the Vicryl and Vicryl rapide group respectively. An on duty medical officer, a house officer or a well-trained midwife, to whom a certificate of perineal repair was issued after an internal assessment, could perform the repair. Only the operator knew the type of suture

Figure. Flow diagram through randomisation



material. Midwives in the labour ward would record down the maternal demographic data and third-stage complication, if any, into a data sheet immediately after delivery. Women and staff who cared them in the postnatal period were unaware of the type of suture material. The maternal outcomes were collected from day 1 after delivery to the day of discharge. Women were then contacted by telephone on day 5, 2 weeks, and 3 months after delivery for further assessment. The primary outcome measure was the visible stitches rate. Secondary outcome measures included the need for removal of stitches, perineal pain perception (visual analogue scale from 1 to 10), insufficient healing, and the need for resuturing. All data were recorded on standardised forms and checked. Double data entry, data editing and reduction were performed.

Statistical Analysis

In a preliminary survey done in our department, the visible stitches rate after a repair with standard polyglactin 910 was around 10%. We expect that the use of rapidly absorbed polyglactin 910 would halve the rate.

With the error of 0.05 (one-sided), and power of 0.8, from the statistical table for the design of clinical trials¹³, the sample size for each arm was 343. So the total sample size was 686. All data were analysed according to an intention-to-treat principle. The X^2 and unpaired t test were used to compare categorical data and continuous variables respectively. P values less than 0.05 were considered significant. All analyses were performed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago [IL], USA) for Windows version 11.0.

Results

Five hundred and ten women were recruited in the study period as shown in the Figure. An early termination of the study was considered because the data already indicated a clear and significant benefit of rapidly absorbed polyglactin 910 on visible stitches rate. Seventeen women could not be contacted after their discharge from the hospital probably because a wrong telephone number was recorded. Standard and rapidly absorbed polyglactin 910 was used in 6 and 11 of them respectively. Of the remaining 493 mothers, 451 were spontaneous vaginal

Table 1. Participants' characteristics at baseline

	Standard polyglactin (n=255)	Rapidly absorbed polyglactin (n=238)
Age in years (mean [standard deviation])	29.83 (5.3)	29.44 (5.5)
Median (range) weeks of gestation	39 (35-41)	39 (29-41)
Primigravida	157 (61.6%)	150 (63.0%)
Mode of delivery		
Normal vaginal delivery	236 (92.5%)	215 (90.3%)
Instrumental delivery	19 (7.5%)	23 (9.7%)
Surgeons		
Medical officer	35 (13.7%)	30 (12.6%)
Midwife	164 (64.3%)	160 (67.2%)
House officer	56 (22.0%)	48 (20.2%)
Third-stage complication		
Postpartum haemorrhage	6	1
Retained placenta	7	6
Wound haematoma	0	1
Shoulder dystocia	2	0

deliveries and 42 were ventouse deliveries. Two hundred and sixty-one women were allocated to use standard polyglactin 910 suture and 249 were allocated to use rapidly absorbed polyglactin 910 suture.

There were no significant differences in the characteristics of women between the study and control group (Table 1). Three hundred and twenty-four (66%) episiotomy wounds or tears were repaired by midwives. Medical officers mainly repaired those perineal wound after instrumental deliveries. Third-stage complications were uncommon in both groups.

Outcomes

Overall, 57 women complained of visible stitches within the first 3 months (Table 2). Nine women in each group had visible stitches on day 5 post-delivery. A significant difference in visible stitch rate was noted starting from 2 weeks after delivery. Within 3 months, women sutured with the standard polyglactin 910 had significantly more visible stitches rate of 38 (14.9%) versus 19 (8.0%) cases when compared to the rapidly absorbed polyglactin 910 ($p=0.02$; relative risk [RR]=0.50; 95% confidence interval [CI], 0.28-0.89).

Significantly more women required removal of stitches when using the standard polyglactin 910 (Table 2). Two weeks after delivery, fewer women (8 [3.4%]) sutured with rapidly absorbed polyglactin 910

required removal of stitches than those (19 [7.5%]) with standard polyglactin 910 [$p=0.04$; RR=0.43; 95% CI, 0.19-1.00]. In addition, the need for a medical follow-up for wound problems within 3 months after delivery was significantly greater in the standard polyglactin group of 44 (17.3%) than the rapidly absorbed polyglactin group of 25 (10.5%) [$p=0.03$; RR=0.56; 95% CI, 0.33-0.95]. Visible stitches requiring removal was the main reason for medical follow-up. Wound pain or discomfort, wound infection or gap wound were also the common complain problems but they were not significantly different in respect of both suture materials.

There was no significant difference in insufficient wound healing, resuturing and perineal pain between the two groups (Table 2).

Discussion

In our study, about 65% of women delivered vaginally had an episiotomy and about 5% of multiparous women had a perineal tear. Therefore, 70% of women delivered vaginally required perineal repair. If there was 10% wound complication rate after the repair with a standard polyglactin 910 suture material, around 300 women required some kind of follow-up assessment or even intervention including wound treatment and removal of the suture. Removal of the suture is a very unpleasant and painful experience. Women need to take care of their newborn baby at home and do not like to

Table 2. Complication rate after episiotomy repair

	Vicryl (n=255)	Vicryl rapide (n=238)	Relative risk (95% confidence interval)
Visible stitches			
Day 5	9 (3.5%)	9 (3.8%)	1.074 (0.419-2.754)
At 2 weeks*	28 (11.0%)	11 (4.6%)	0.393 (0.191-0.808)
Within 3 months*	38 (14.9%)	19 (8.0%)	0.495 (0.277-0.886)
Removal of stitches			
Day 5	6 (2.4%)	4 (1.7%)	0.709 (0.198-2.546)
At 2 weeks*	19 (7.5%)	8 (3.4%)	0.432 (0.185-1.000)
Within 3 months	25 (9.8%)	13 (5.5%)	0.532 (0.265-1.065)
Gaped episiotomy wound			
Day 5	7 (2.7%)	11 (4.6%)	1.717 (0.654-4.504)
At 2 weeks	17 (6.7%)	12 (5.0%)	0.743 (0.347-1.591)
Within 3 months	25 (9.8%)	23 (9.7%)	0.844 (0.456-1.563)
Resuturing within 3 months	0	1 (0.4%)	
Medical follow-up for wound complication within 3 months*	44 (17.3%)	25 (10.5%)	0.563 (0.332-0.953)
Visible stitches	38 (86.4%)	19 (76.0%)	0.495 (0.277-0.886)
Gap wound	25 (56.8%)	23 (92.0%)	0.844 (0.456-1.563)
Wound pain or discomfort	16 (36.4%)	8 (32.0%)	0.520 (0.218-1.237)
Infection	3 (6.8%)	1 (4.0%)	0.354 (0.037-3.431)
Mean (standard deviation) pain score			
Day 1	4.60 (2.23)	4.38 (2.29)	
Day 2	4.04 (1.89)	4.00 (1.97)	
Day 5	3.16 (1.83)	3.05 (1.88)	
At 2 weeks	1.60 (1.11)	1.43 (0.94)	
At 3 months	1.03 (0.23)	1.00 (0.00)	

* p<0.05

stay in hospital for wound care or resuturing.

Our study has shown that fewer Chinese women reported visible stitches after the repair with a rapidly absorbed polyglactin 910 sutures than that with a standard polyglactin 910 (RR, 0.49). In addition, the need for removal of stitches at 2 weeks was also less after the repair with a rapidly absorbed polyglactin 910 (RR, 0.39). Our findings were consistent with the findings of previous studies on Caucasian women in terms of the rate of visible stitches and removal of stitches^{8,9,11}.

Our study has shown an interesting finding in that significantly fewer women required medical follow-up after the repair with a rapidly absorbed polyglactin 910. Complaints of visible stitches, wound pain or discomfort, and infection were less common in association with the use of the rapidly absorbed suture material (Table 2).

Although rapidly absorbed polyglactin 910

degrades much faster and there is a concern about poor and insufficient wound healing, in our study the occurrence rate was low (around 2% at day 5 and 3% at 2 weeks). No differences were found between the control and the study group.

The fast absorption of rapidly absorbed polyglactin 910 is due to an irradiation process but it still retains 50% tensile strength at 5 days, by which most of skin wound heals. In addition, sutures begin to fall off in 10 to 14 days⁷. It is these physical characteristics that cause less visible stitches 2 weeks after repair. Thus, fewer cases required removal of stitches in the study group. Repairing technique and local infection are the main factors for poor wound healing within the first 2 weeks¹⁴. Therefore, the standard and rapidly absorbed polyglactin 910 has similar insufficient healing rate.

Like the other studies^{9,11}, our results were not able to demonstrate any difference in overall perineal

pain perception between the two groups at 2 weeks or 3 months. Various type of analgesic (panadol, dologesic or ponstan) was used in both groups and so it was difficult to compare pain tolerance between the two groups. In addition, the mean pain score in our study population was low (around 4) even on day 1 or 2 and it dropped to around 3 on day 5. At 2 weeks, the mean score was only 1.5. Different ethnic groups have different response to pain perception¹⁵. It is not known whether Chinese women may be more tolerable to pain or they are more embarrassed to disclose their feeling including pain.

The sample size of our study was too small for subgroup analyses: doctors versus midwives, and instrumental deliveries versus spontaneous vaginal deliveries. Therefore, larger studies are needed to study

the use of a rapidly absorbed suture material after instrumental deliveries and by operators with different experience.

The use of a rapidly absorbed polyglactin in continuous subcuticular perineal repair can significantly reduce the occurrence of visible stitches and the need for medical follow-up. A rapidly absorbed polyglactin suture material should be used widely in perineal repair.

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