

Comparison of a Single-Knot Versus Three Layered Technique of Perineal Repair After Vaginal Delivery in Women Requiring Episiotomy: A Double Blind Randomized Controlled Trial

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Abstract

Objective: Episiotomy is a common procedure performed after vaginal deliveries and perineal pain along with discomfort are the major morbidities associated with it. Exploring various options to make this procedure less painful would benefit a large number of women. We compared a single-knot technique of repair with the traditional three layer technique, for duration of the surgery and postoperative pain using visual analogue scale (VAS) in this study.

Materials and Methods: After consent, 110 women having spontaneous vertex delivery and requiring episiotomy were randomly allocated to either the traditional repair in three layers (n=55) or to the single-knot (S-knot) technique (n=55). Main outcome measures were postoperative pain within 12 hours and the duration of surgery in seconds. Duration of surgery and visual analogue scale (VAS) scoring for pain was recorded by an independent observer at the time of discharge, and at follow up visit after 7 days. Data was analyzed using standard statistical methods.

Results: The episiotomy rate was 75% at our setting. The mean age of the study population was 27±5 years (range 19-38 years). Both the study groups were similar in variables like age, socioeconomic status, parity, gestation, length of episiotomy and suture material used. The mean VAS score for postoperative pain in the first 12 hours and the mean duration of surgery were significantly lower in the S-knot technique compared to the traditional technique (3.5 versus 5.5, $p=0.000$ and 232.6 versus 317.3 sec, $p=0.000$, respectively).

Discussion: S-knot technique was less painful within the first 12 hours of surgery and was quicker to perform as compared to the traditional technique.

Keywords: episiotomy, single-knot technique, VAS score, duration of surgery

Özet

Vajinal Doğum Sonrası Epizyotomisi Olan Kadınlarda Tek Sütür ile veya Üç Tabakalı Olarak Yapılan Perine Onarımının Karşılaştırılması: Çift Kör, Randomize, Kontrollü Çalışma

Amaç: Epizyotomi vajinal doğum sırasında sık kullanılan bir işlemdir ve sonrasında gelişen ağrı ve rahatsızlık hissi epizyotominin en belirgin morbiditesini oluşturur. Bu işlemin daha az ağrılı olmasını sağlayacak her seçenek birçok kadına fayda sağlayacaktır. Bu çalışmada, görsel analog skala kullanarak geleneksel üç aşamalı perine onarımı ile tek sütür ile yapılan onarımı postoperatif ağrı ve cerrahinin süresi açısından karşılaştırdık.

Materyal ve Metot: Baş geliş ile vajinal doğum yapan 110 kadın onamları alınarak geleneksel üç tabakalı perine onarımı (n=55) veya tek düğüm tekniği ile perine onarımı (n=55) grubuna randomize edildiler. Araştırılan ana değişkenler postoperatif ilk 12 saat içinde gelişen ağrı ve saniye olarak cerrahinin süresiydi. Cerrahinin süresi ve görsel analog skala ile hesaplanan ağrı, hastanın taburculuğu sırasında ve postoperatif 7. günde yapılan kontrollerinde bağımsız bir gözlemci tarafından ölçüldü.

Sonuçlar: Epizyotomi oranımız %75 idi. Çalışma grubunun ortalama yaşı 27±5 idi (19-38). Her iki grup yaş, sosyoekonomik durum, gebelik sayısı, epizyotomi uzunluğu ve kullanılan sütür materyali açısından benzerdi. Tek düğüm tekniğinde hem ilk

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12 saat içinde duyulan ağrı az idi hem de ortalama operasyon süresi geleneksel üç tabakalı onarımdan kısa idi (VAS: 3.5 ve 5.5, $p < 0.001$; cerrahi süresi 232.6 ve 517 sn, $p < 0.001$).

Tartışma: Geleneksel perine onarımı ile karşılaştırıldığında tek düğüm tekniği hem ilk 12 saat içinde daha az ağrıya yol açıyordu, hem de daha çabuk uygulanabiliyordu.

Anahtar sözcükler: epizyotomi, tek düğüm tekniği, görsel analog skalası, operasyon süresi, ağrı

Introduction

Health professionals caring for women during child birth have been exploring different ways to make this experience more comfortable for women. Majority of women experience some form of perineal trauma that needs suturing. Episiotomy rates in primigravidae vary from 67% (1) to 92.3% (2). The associated morbidity in the form of pain, infection and perineal discomfort disrupts breastfeeding, family life and sexual relations (3). The type of suturing material, the technique of repair and the skill of the operator are the three main factors that influence the outcome of perineal repair. Different techniques and suture materials used for perineal repair have been studied. A Cochrane systematic review of eight RCTs (4), in 3642 primiparous and multiparous women found that absorbable synthetic material when compared with catgut suture material was associated with less short term morbidity. Another Cochrane systematic review of four RCTs (5) involving 1681 primiparous and multiparous women found that a continuous subcuticular technique of perineal skin closure, when compared with interrupted transcutaneous stitches, was associated with less short term pain.

In our study we compared a technique of episiotomy involving a single knot with the traditional technique with multiple knots. Our hypothesis was that the single-knot method would be less painful. Pain and perineal discomfort are the two main short term morbidities. The outcome measures selected were pain and duration of surgery. Unlike the previous studies we have used an objective method of pain assessment, visual analogue scale (VAS; 0-10) which has been extensively used for such measurements (6) and is validated in the assessment of pain severity and pain relief (7).

Materials and Methods

This was a randomized controlled study carried out from January 2002 to May 2006 at Islamic International Medical Complex (IIMC), Islamabad.

Women registered at IIMC for delivery were offered to enter the study after approval from the ethical committee. In this hospital, in spite of advocacy of a restrictive approach to episiotomy there is high episiotomy rate. The sample size was calculated to detect a difference in visual analogue score of 2 after consulting previous studies (8) with 90% power at 5% level of significance. Altogether 150 women who had an episiotomy after a spontaneous vaginal delivery were

recruited. Women with assisted deliveries and or perineal tears were excluded. After obtaining consent, the data about age, parity, gestation and socioeconomic status was collected. Women were allocated to intervention or the control group by simple random sampling through computer generated numbers. The author performed all the procedures in both the control and the intervention group. All the episiotomies were mediolateral. The suture material used was primarily polyglactin 910 2/0 as a policy, but in a few because of cost constraints/non availability, chromic catgut 2/0 was also used and since these women were already randomized, these were not excluded from the study.

The traditional technique used for episiotomy was the three layer technique, in which vaginal mucosa was sutured with a continuous running stitch. Muscle layer was sutured by

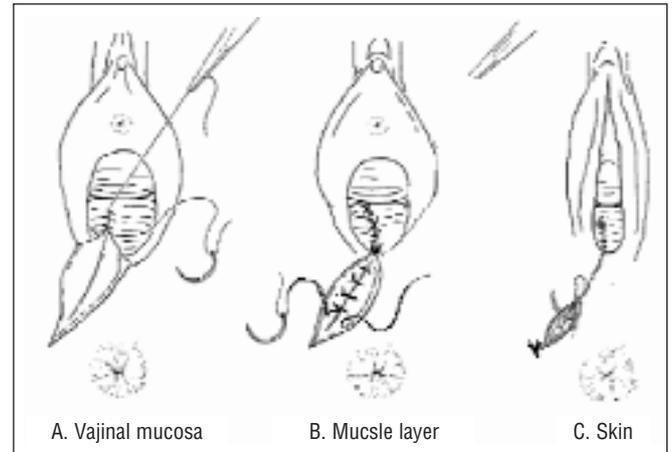


Figure 1. Traditional three layered technique of episiotomy repair.

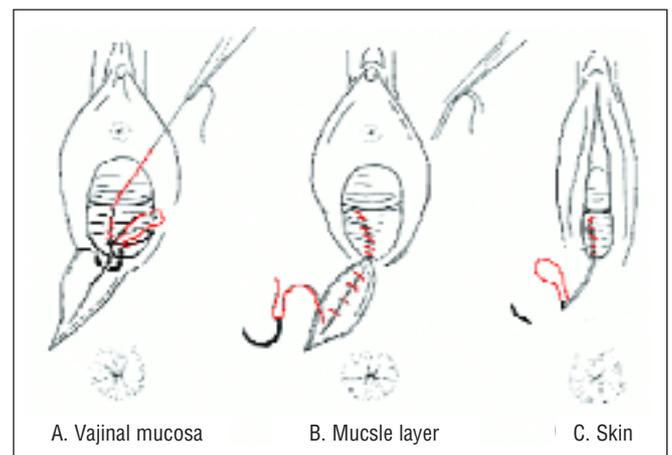


Figure 2. Single-knot technique of episiotomy repair.

interrupted sutures in two layers, and skin by subcuticular sutures ending with a knot (Figure 1). In the single-knot technique there is only one knot at the apex of the vaginal mucosa. Vaginal wall is then sutured with a continuous running stitch. The same suture is then continued in the muscles which are sutured continuously in two layers reaching the introitus again. The same stitch is then carried in the skin and subcuticular sutures are used to reach the end of the incision. The needle is then passed through the muscles lateral to the episiotomy and the suture material is taken out and 4-5 cm of the suture is left to hang without a knot (Figure 2).

The duration of surgery in seconds was recorded by an independent observer blinded to the technique used. The time was recorded from the start of the first stitch till the end of the last suture was cut.

The postoperative pain was assessed at the time of discharge which was within the first 12 hours of delivery in all the cases and on the postnatal visit on the 7th day. VAS scoring was explained to the women and a trained independent observer blinded to the method used, recorded the findings. Women were also blinded to the type of technique used. VAS scale (0-10) was used to score the pain where 0 meant no pain, and 10 was the maximum pain imaginable.

Secondary outcome measures were pain at the postnatal visit after 7 days of delivery, use of analgesia and any other complications. Postoperatively Mefenemic acid was prescribed to all the women for use only if required. And they were asked to keep a tablet count. VAS scoring was repeated at the follow up visit after 7 days. Any complications and use of analgesics by number of tablets used were also noted at this visit.

Statistical analysis

The main null hypothesis we tested was that the single-knot suturing technique used for perineal repair after spontaneous vaginal delivery is less painful and takes less time to suture compared to the three layered technique. Comparisons were made between the two methods using continuous variables (mean VAS scores and time in seconds). All analyses were performed using the Statistical Package for Social Sciences version 15. The *t* test was performed for the continuous variables to assess differences between the two methods.

Results

A hundred and ten women completed the study out of the 150 women enrolled (consort flowchart). The two groups were comparable for socio-demographic and other features

The Consort Flowchart

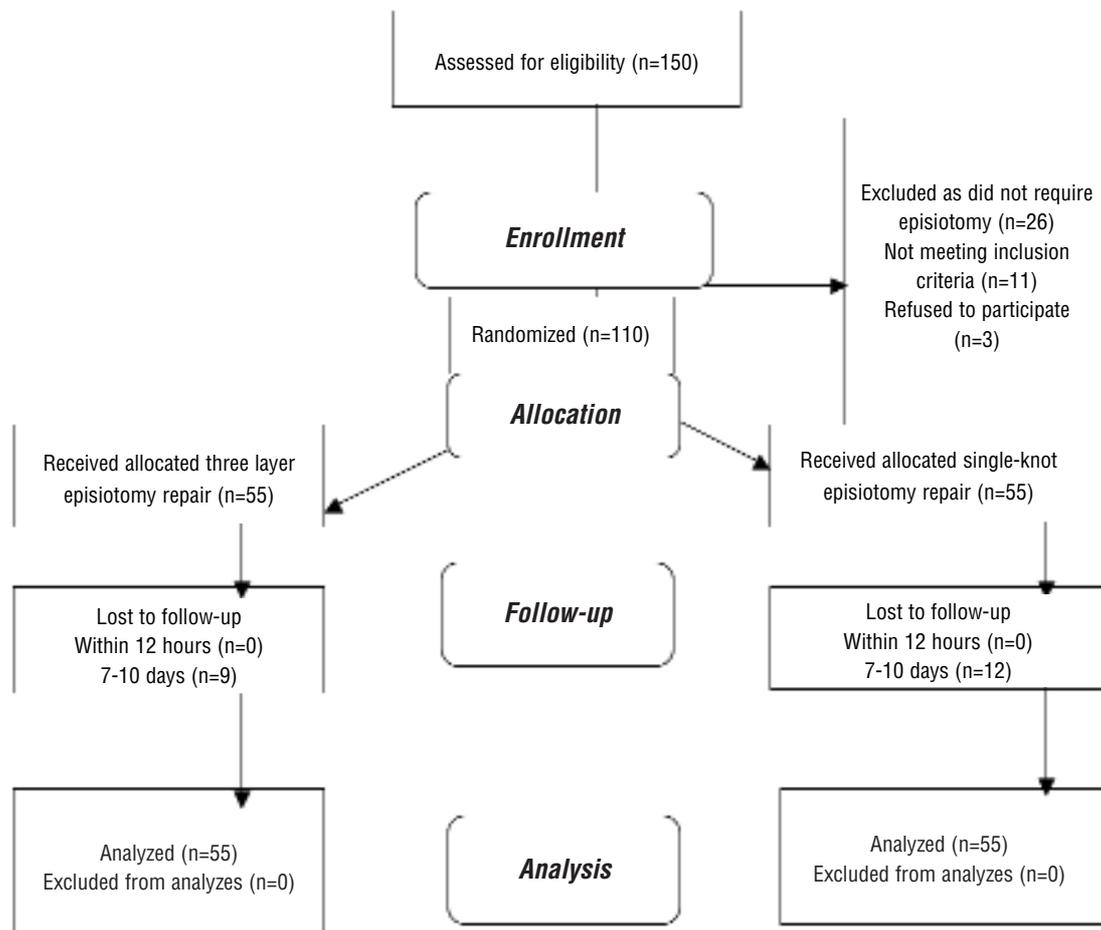


Table 1. Demographic characteristics of the two groups

	Traditional technique	Single-knot technique	<i>p</i> (<i>t</i> -test)
Mean age in years (\pm SD)	27.20 \pm 4.9	27.16 \pm 5	0.97
Mean gestation in weeks (\pm SD)	38 \pm 1	38 \pm 1.2	0.93
Parity			
Zero	19	16	0.58
One	9	19	
Two	17	10	
Three	6	9	
Four	4	1	
Socioeconomic status			
Upper	18	19	1.00
Middle	35	33	
Poor	2	3	

Table 2. Comparison of the primary outcome measures in the two groups

	Single-knot technique (mean \pm SD)	Traditional technique (mean \pm SD)	<i>p</i> (<i>t</i> -test)
VAS pain scores after 12 hours	3.5 \pm 1.51	5.7 \pm 2.06	0.000
Duration of surgery in sec	232.6 \pm 27.7	317.3 \pm 46.5	0.000

at trial entry (Table 1). The length of the episiotomy was also comparable for the study and control group, respectively (3.45 cm vs 3.5 cm). All perineal repairs were performed by a single surgeon. All the repairs were undertaken in the lithotomy position. Overall, protocol adherence was good. The suture material used was mostly polyglactin 910 but in the initial phase of the study, because of cost constraints/non availability chromic catgut was also used in a few. The use of chromic catgut was comparable in the study and control group, respectively (9 vs 7 cases). There was no loss to follow up for the primary outcome measure, whereas 29% women could not make it for 7th day postnatal follow up due to distance between their residences and the IIMC. The loss to follow up was comparable in the two groups.

The benefits of the single knot technique were seen within 12 hours of suturing as significantly lower VAS scoring observed at 12 hours as compared to the three layered technique group (Table 2). This difference persisted up to 7 days after delivery ($p=0.02$). This finding was consistent irrespective of the suture material used.

Majority of the women failed to keep a count of analgesic tablets, but in the single-knot group fewer women (6/43) were using the analgesic as compared to the other group (15/46) at 7th postnatal day. There were no reports of wound dehiscence, but two women in the single-knot group had superficial skin non approximation at the outer edge of the episiotomy.

Discussion

There is considerable evidence to suggest that continuous repair techniques are better than interrupted suture methods in terms of perineal pain (9-12). Our findings concur with the results of previous studies though we have used an objective method of measuring pain. One study which reported a low incidence of postpartum perineal pain with continuous non-locking technique was only observational (13). A large randomized controlled trial including 1542 women reported less pain with continuous technique but pain was assessed on day 10 by the subjective complaint of the women (14).

Our study has demonstrated a definite benefit of single-knot technique of repair within 12 hours of surgery apparent by the lower pain scores. There was also a significant difference in the duration of surgery between single-knot technique and traditional technique. The single-knot technique consumed less time which can be due to the fact that no time is spent on tying and the cutting of the knots. There was no operator bias, as a single operator performed all the surgeries.

Adherence to treatment allocation was high and women were not told the type of repair that they had received, though we cannot possibly completely mask women's subjective assessment of outcome. The difference in pain scores between the two suturing methods probably is due to increased suture tension at the site of the knots. With single-knot repair, tension is transferred throughout the whole length of the single suture and avoids excessive pain at one site.

It is already established that skin sutures inserted into the subcutaneous tissue avoid nerve endings in the skin surface and reduce perineal pain. We used subcutaneous suture for skin closure in both the groups to remove its confounding effect to this reduction in pain. Though there is no data available on the perineal repair techniques used in different hospitals in Pakistan, our observation is that majority still use the interrupted method with transcutaneous stitches inserted to close perineal skin. Therefore, results of our study will help in changing this practice. Since there is a rising concern about the perineal injury sustained during childbirth, our exploration of a less painful procedure will make normal vaginal delivery a more desirable outcome. These results should be shared with women themselves and to those health professionals who care for women in childbirth.

Conclusion

The suturing technique with single-knot would reduce overall time spent on the surgery and the perineal pain.

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