

Prospective randomized control trial comparing chromic catgut 1-0 versus fast absorbing polyglactin 910 2-0 for episiotomy repair in a semi-urban Indian population group

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Abstract

Episiotomy is most commonly performed surgery for assisting vaginal delivery in indicated cases. Mediolateral episiotomy is most commonly performed in view of its benefits over other types. Postoperative complications and morbidity of patients is most important which should be given thought. One of the factor that plays a major role is type of suture material used. In our study we are comparing traditionally used chromic catgut with the fast acting polyglactin 910.

Materials and Methods: The new prospective study and randomized control study compares long term and short term results of suturing episiotomy with Chromic Catgut 1.0 and polyglactin 910 (2.0). The parameters taken into consideration were pain and analgesia, gaping, dyspareunia etc. Total sample size was 560 consisting of 280 pts in each group.

Results: The present study showed that the results of fast acting polyglactin 910 was definitely better than chromic catgut. Also morbidity in relation to pain, wound healing and other complications was found to be lesser in group of polyglactin 910.

Conclusion: The present trend of suturing episiotomy with polyglactin is definitely better in terms of results and reduced morbidity.

Keywords: Episiotomy, Chromic catgut, Fast absorbing polyglactin 910, Morbidity.

Introduction

Literally meaning a cut on the vulva, episiotomy is a surgical incision of the vagina and perineum carried out by a skilled birth attendant to enlarge the vaginal opening.¹

Episiotomy, the commonest procedure in the history of obstetrics was introduced in the 18th century to prevent perineal tears, prevent future sexual dysfunction and prevent the incontinence that resulted from vaginal births.²

Episiotomies were still liberally in use in the 20th century because besides the suggested maternal beneficial effects of an episiotomy, it is suggested that it protects the neonate from a prolonged second stage of labour, from fetal asphyxia, cranial trauma, cerebral haemorrhage and mental retardation.

Most common injury to the genitalia occurring in vaginal deliveries are perineal tear occurring spontaneously and by surgical incision like episiotomy.³ Episiotomy has got advantage over perineal tear as anal sphincter damage is prevented due to controlled incision.⁴ Episiotomies was being continued till 1993 in cases in which it was not indicated also so restricted rather than routine policy was recommended.⁵

Commonly used types of episiotomies include Median; associated with more risk of perineal lacerations; mediolateral- the most common type, easy to extend and gives adequate widening of the introitus and lateral, which has the worst morbidity profile.²

The results of episiotomy surgery with respect to morbidity and symptomatic relief to the patient depends on many factors and most important being suture material which is used for stitching.

An ideal suture material needs to be sterile, causing minimal irritation to tissues leading to lesser inflammation

and discomfort, giving a good hold, having a favourable tensile strength as well as an absorption time suited to the patient and procedure. Optimal healing with minimal patient discomfort is the key to finding the right absorbable suture for an episiotomy.⁶

Two types of suture material is available for suturing episiotomy. Since long time chromic catgut which is natural material produced from the sheeps intestine is being in used but found to have some disadvantages like more inflammation, early loss of tensile strength which was affecting the healing procedure so the search of new material was started and it was found that polyglactin was found to be better.

By taking different trials it was found that fast absorbing polyglactin 910 was having advantages over chromic catgut like reduction in pain in postpartum period and less requirement of gaping and re-suturing.⁴ By using fast absorbing polyglactin 910 there is less tendency for wound to become hard, and stitches on the perineum is comfortable due to less tissue reaction and absorption is good.⁷

The main aim of this study is to compare fast absorbing polyglactin 910 (2-0) and Chromic Catgut (1-0) with respect to morbidity, analgesic requirement, wound healing time and need for re-suturing in a semi-urban Indian population group in patients with similar profiles and backgrounds.

Aims and Objectives

Aim: To conduct a prospective randomized control trial comparing the short and long-term results of the suturing of episiotomy wounds in all three layers using Chromic Catgut 1-0 or fast absorbing polyglactin 910 (2-0) in a semi-urban Indian population group.

Objectives

With the two types of sutures, assess

1. The amount of pain and analgesia required at 24 hours, 48 hours, 3 days, 10 days, 6 weeks and three months post-partum.
2. The time taken for wound healing and complications such as infection and wound gaping.
3. Time taken for resumption of sexual intercourse and superficial dyspareunia.

To assess short and long term morbidity with each type of suture in a semi-urban Indian population group.

Materials and Methods

This is a Prospective Randomized Control Trial to compare the short and long term morbidity in episiotomy wound suturing using Chromic Catgut 1-0 or fast absorbing polyglactin 910 2-0.

Materials

1. Study was carried out in the Department of Obstetrics and Gynaecology of Dr. D.Y. Patil Medical College and Hospital, Pimpri, Pune and included patients presenting to the labour room in latent or active phase of labour.
2. Absorbable suture Catgut 1-0.
3. Absorbable suture fast absorbing polyglactin 910 2-0.

Methods:

1. The permission of ethical committee for conducting this study was obtained by its prior approval.
2. Sample Size 280 women in each group were randomly allocated wound repair with either fast absorbing polyglactin 910 2-0 or Chromic Catgut 1-0.
3. The calculation of sample size was based on study by Joseph et al, which came out to be 280. For that proportion of pain at 5 percent significance level with 80 percent of power was calculated by taking proportion of pain at 48 hrs as 40 percent in fast absorbing polyglactin and 52 percent in chromic catgut. WINPEPI software was used.⁸
4. The result was seen at 24 hours, 48 hours, 3 days, 10-14 days, 6 weeks and 3 months post-partum with respect to analgesia required, wound healing, patient comfort, wound and need for re-suturing. Dyspareunia were also assessed at 3 months after delivery.
5. All patients were put on Tablet Voveron 75 mg twice a day for three days and analgesia required was in addition to this dose.
6. All patients were put on Tablet Cefixime 200 mg twice a day, Tablet Metronidazole 400 mg thrice a day and an antacid twice daily for a total of 3 days from the day of delivery. Inspection of wound was done at the end of 1st day, 2nd day, 3rd day, 42 days and 90 days. Also note was taken on inflammation, infection and gaping rate. Other sutures were also checked for at 6 weeks and 3 months.
7. In case of complaints or signs of infection, a per vaginal exam was carried out to determine presence of

haematomas, dehiscence, abscesses, foul smelling lochia or retained swabs or packs.

Type, period and place of Study: The period of this Randomized Control study was planned for 2 n half years from July 2015. The place decided for this Prospective study was Obstetrics and Gynaecology department of our institution that is Dr. D.Y Patil Medical College and Hospital, Pimpri, Pune.

Software used to analyze data: Data was entered in Excel and analyzed using SPSS 18. Quantitative data was summarized using Mean and SD ratio and Qualitative Data was summarized using Proportion.

Tests used to analyze data was Repeated Measures ANOVA and Chi Square.

Study Design

Inclusion Criteria: All Primigravida in the reproductive age group with singleton pregnancy with vertex presentation, delivering vaginally and having a surgically planned incision in the perineum (episiotomy) to facilitate delivery of head, who provide written informed consent. This includes preterm delivery, vacuum assisted deliveries, instrumental deliveries using outlet forceps, extension of episiotomy wounds or vaginal tears and twin deliveries.

Exclusion Criteria:

1. All women with intrapartum fever, cervical tears, a previous perineal surgery other than primary repair after childbirth, HIV or Hepatitis B positive patients, patients with
2. Gestational Diabetes Mellitus or Diabetes Mellitus, any infection, breech or face to pubis presentations, women on corticosteroids, chemotherapy or radiotherapy.

Randomization: All patients in the reproductive age group who fulfilled above criteria were randomly divided into two groups of 280 women each. Alternate deliveries were sutured with either Catgut 1-0 or with fast absorbing polyglactin 910 2-0.

Evaluation of Parameters: The women who fulfilled the above criteria underwent an episiotomy and sutured using either fast absorbing polyglactin 910 2-0 (36 mm ½ circle double reverse cutting and round bodied needle) or Chromic catgut 1-0 (30 mm, ½ circle round bodied needle). All episiotomies were Left Mediolateral. The vaginal mucosa were sutured using continuous interlocking sutures, the perineal muscle using simple interrupted sutures with a crown stitch at the musculo-cutaneous junction and the skin using mattress sutures. A per rectal examination was done after the episiotomy is complete. The type of local anaesthetic given before episiotomy, time taken for episiotomy and analgesic used post- episiotomy were noted. All parameters were compared between the two groups for significant differences.

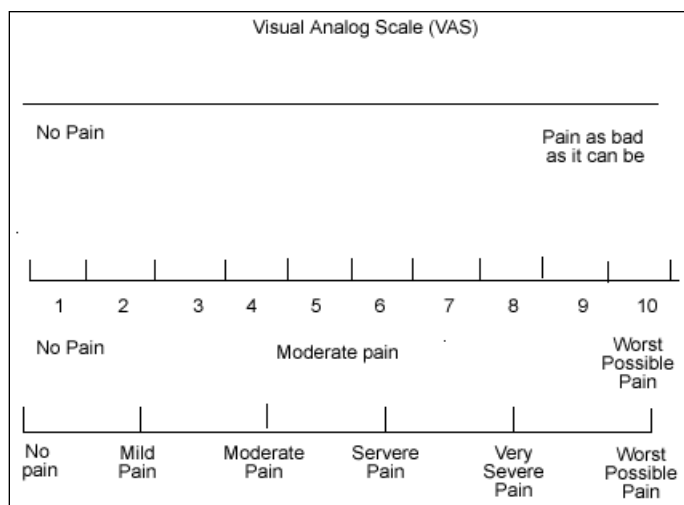
Both groups were assessed at 24 hours, 48 hours, 3 days, 10-14 days, 6 weeks post-partum and 3 months post-partum.

Vas method was used for assessment of pain which consists of pain intensity ranging from 1 to 10 as shown in table below at 10-14 days, 42 days and 90 days after

delivery. In this method of visual analog scale patients are asked to place a line in the chart perpendicular to baseline

and that is recorded. The measurement is done by using a ruler marked from 1 to 10 cm.

The higher score indicate greater pain intensity. Following cut off point on the pain VAS have been recommended:



All the material was recorded in a proforma formatted for our study.

Proforma was filled by researcher on the basis of general and local examination of episiotomy wound as well as answers obtained.

Statistical Analysis: Was done using tests of significance to know the results of comparing suturing of episiotomy wounds with Chromic Catgut 1-0 or fast absorbing polyglactin 910 2-0.

Observations and Results

As mentioned above two groups of patients were made for the comparison. They were comparable with each other with respect to age group, body mass index, mean gestational age and mean birth weight and was confirmed by applying test of significance with z and p value which was found to be non-significant.

Sample size was 560, consisting of two groups of 280 each
 Group 1-fast absorbing polyglactin 910 no.2-0
 Group 2-chromic catgut no 1-0

Table 1: Immediate analgesia needed in Group I and Group II

Immediate analgesia	Group I (%)	Group II (%)	Total (%)
Yes	81 (28.93)	98 (35)	179 (31.96)
No	199 (71.07)	182 (65)	381 (68.04)
Total	280 (100)	280 (100)	560 (100)

Chi-square = 2.37, P=0.12

As shown in this table number of patients requiring immediate analgesia was recorded which was 28.3 percent in first group and 35 percent in second group. Statistically it is not that significant.

Table 2: Perineal pain at 24hours, 48hours, 3days, 10-14days, 6weeks and 3months in group I and group II

Perineal pain	Group I (n=280)	Group II (n=280)	Chi-square	P Value	
At 24 Hours	Mild	104	73	8.46	0.015
	Moderate	147	167		
	Severe	29	40		
At 48 Hours	Mild	111	73	26.43	<0.0001
	Moderate	131	161		
	Severe	16	38		
	No	22	8		
At 3 days	Mild	136	103	16.62	0.001
	Moderate	109	134		
	Severe	11	28		
	No	24	15		

At 10 - 14 days	Mild	131	74	44.46	<0.0001
	Moderate	49	103		
	Severe	9	26		
	No	91	77		
At 6 Weeks	Mild	7	24	63.41	<0.0001
	Moderate	8	58		
	Severe	1	7		
	No	264	191		
At 3 Months	Mild	5	20	11.55	0.009
	Moderate	4	4		
	Severe	0	2		
	No	271	254		

Subjects at the end of 1st day, 2nd day, 72 hours, 10-14 days, 42 days and 90 days in both groups were taken into account. It was observed that at all these follow ups degree of pain was lesser in first group in comparison to second

group. With respect to complete relief of pain the first group got early relief than the second group. At the end of 42 days number of patient getting freedom from pain was significantly high, 264 and 191 in first group.

Table 3: Analgesia doses used at 24 hours, 48 hours, 3 days, 10-14 days, 6 weeks, 3 months in group I and group II

Analgesia used		Group I (n=280)	Group II (n=280)	Chi-square	P Value
At 24 Hours	Dose 1	152	110	21.60	<0.0001
	Dose 2	111	133		
	Dose 3	17	26		
	Dose 4	0	11		
At 48 Hours	Dose 1	177	149	12.97	0.005
	Dose 2	63	89		
	Dose 3	12	23		
	Dose 4	0	1		
	No	28	18		
At 3 days	Dose 1	151	174	9.50	0.05
	Dose 2	73	59		
	Dose 3	8	13		
	Dose 4	0	2		
	No	48	32		
At 10 - 14 days	Dose 1	29	46	4.45	0.035
	No	251	234		
At 6 Wks	Dose 1	13	45	19.69	<0.0001
	No	267	235		
At 3 Months	Dose 1	0	5	FET	0.061
	No	280	275		

When dose of analgesia required for post-delivery pain was compared, it was found that first group was required less analgesia as compared to second group after 1st day, 2nd day, 3rd day, 10-14 days and 42 days which was statistically

significant. At the end of 90 days both group showed no requirement of analgesia.

Difficulty in passing urine at 24hrs,48hrs, 3 days, 10-14days was also calculated by Chi squar and it was statistically not significant (p>0.05).

Table 4: Discomfort due to suture at 24hrs, 48hrs, 3days, 10-14days, 6 weeks And 3 months in Group I and Group II

Discomfort due to suture	Group I (n=280)	Group II (n=280)	Chi-square	P Value
At 24 hours	135 (48.21%)	179 (63.93%)	14.04	<0.0001
At 48 hours Table 10: Discomfort due to suture at 24hrs, 48hrs, 3days, 10-14 days, 6 weeks and 3	107 (38.21%)	153 (54.64%)	15.19	<0.0001
At 3 days	56 (20%)	105 (37.50%)	20.93	<0.0001
At 10-14 days	31 (11.07%)	66 (23.57%)	15.27	<0.0001
At 6 weeks	4 (1.43%)	6 (2.14%)	2.63	0.10
At 3 months	1 (0.36%)	2 (0.72%)	FET	1

When degree of comfort was compared it was found that in first group number of patient was statistically significant when observed for different durations upto at least 3 months p.(0.05)

Table 5: Gaping at 3days, 10-14days, 6wks in Group I and Group II

Gaping	Group I (n=280)	Group II (n=280)	Chi-square	P Value
At 3 days	0	4 (1.43%)	FET	0.12
At 10 - 14 days	3 (1.07%)	7 (2.5%)	1.63	0.20
At 6 wks	0	5 (1.79%)	FET	0.061

When compared for the gaping rate in post-delivery patients upto 42 days more number of patients showed gaping in second group which was statistically significant. p(0.05).

Table 6: Dyspareunia wise distribution of cases in Group I and Group II

Dyspareunia	Group I (%)	Group II (%)	Total (%)
Yes	4 (2.2)	13 (9.42)	17 (5.33)
No	178 (97.8)	125 (90.58)	302 (94.67)
Total	182 (100)	138 (100)	319 (100)

Chi-square = 8.14, P=0.004

The above table compared dyspareunia in Group I and Group II. Less number of subjects in Group I experienced dyspareunia compared to subjects in Group II. Chi square values were calculated and it was statistically significant (p<0.05).

Discussion

This study has been taken up with the aim of providing objective evidence to guide the choice of suture material for the repair of episiotomy wound following vaginal delivery.

Demographically both the samples were comparable with each other regards to characters like age, BMI and also regarding perineal pain in which first group experienced definitely more relief of pain as compared to the second group.

The findings of our study co-related well with a Cochrane review by Kettle et al, in the year 2010 which comprised of 18 trials with 10,171 women and compared various types of sutures, with 9 trials comparing Chromic Catgut with synthetic sutures. Compared with Catgut, perineal repair with standard synthetic sutures such as polyglactin 910 and fast absorbing polyglactin 910 were associated with less pain up to three days after delivery and less analgesia up to ten days postpartum (risk ratio(RR) 0.83, 95% confidence interval (CI) 0.76 to 0.90, nine trials, 4017 women).⁴

A WHO Reproductive Health Library Commentary included 18 randomized control trials comparing various types of sutures out of which 11 studies compared Chromic Catgut use with absorbable synthetic sutures. The primary outcome was short-term pain (maternal pain up to three and 4-10 days). Less women in the synthetic suture group experienced short-term pain at or before 3 days and between 4-10 days after delivery compared with those in the Catgut group (three trials, 2044 women).⁹ our study also got similar findings.

A similar Indian study of 100 women done by Bose et al in the year 2012-2013 found that compared to Chromic

Catgut, fast absorbing polyglactin 910 produced significantly less pain among patients following episiotomy wound repair in sitting, walking and lying- down posture at 24 hours, 48 hours and 6 weeks postpartum. (p- value< 0.001 at 24 and 48 hours).³ Our results were found to be similar to them.

Similar to our study, in the RCT by Leroux et al there was a statistically significant difference in the median consumption of analgesics and narcotics in the early postpartum period, the consumption being more in the Chromic Catgut group (p value=0.02, p value <0.01).¹⁰

Corresponding with our results, a comparative Indian study done by Bharathi et al in the year 2013, included 400 with episiotomies that were randomly allocated to repair with either fast absorbing polyglactin 910 or Chromic Catgut (200 each). The fast absorbing polyglactin 910 group was associated with less pain (32.5% vs 57%) and a lesser need for analgesia (15.5% vs 0.5) at 3-5 days and pain was 85.5% in the Chromic Catgut group as compared to 79% in the Fast absorbing polyglactin 910 group at 6 weeks postpartum.⁷

The Ipswich childbirth study comparing polyglactin 910 with Chromic Catgut for perineal repair also showed similar results in relation to the wound gaping.^{11,12}

Kurian Joseph et al in Chennai in a study of 150 women demonstrated that fast absorbing polyglactin 910 had the least complications as compared to Standard polyglactin 910 and Chromic Catgut and needed no analgesic after the 30th day. The difference was statistically significant (p-value< 0.05).¹³ Results were similar to our study.

Inflammation was checked for at the episiotomy site at 24 hours, 48 hours and 3 days. Less number of subjects in the fast absorbing polyglactin 910 group experienced inflammation at episiotomy site postpartum as compared to the Chromic Catgut group at 24 hours (6.79% vs 10.71%) and 48 hours (3.57% vs 7.14%) whereas it was the same at 3 days in both groups.

A detailed study on identifying the perfect suture was published in the year 2009 by Greenberg and Clark.⁶

Similar to our study, several other studies (Greenberg et al, Leroux et al, Kurian et al) also found no difference in the wound healing at 6 to 8 weeks.^{14,6,15,13}

A study by McElhinney et al in May 2000 compared the amount of pain post-partum and long term morbidity in mothers with episiotomies or perineal tears sutured with standard polyglactin 910 versus fast absorbing polyglactin 910. At six weeks the fast absorbing polyglactin 910 group had a much lesser dyspareunia score than the standard polyglactin 910 group.¹⁶ Our study also agreed with the same findings.

Conclusion

Thus, by our study we conclude that fast absorbing polyglactin 910 is definitely superior with respect to results of wound healing, morbidity and symptomatic comfort and also associated with less perineal pain and discomfort in the early postpartum period as compared to chromic catgut similar to other studies done.

Conflict of Interest: None.

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