

A prospective cohort multicenter comparison of two episiotomy repair techniques: Skin adhesive strips vs. subcuticular suture

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SUMMARY

AUTHORS' CONTRIBUTION: (A) Study Design · (B) Data Collection · (C) Statistical Analysis · (D) Data Interpretation · (E) Manuscript Preparation · (F) Literature Search · (G) No Fund Collection

Introduction: Episiotomy is one the most common surgical procedure that performed daily. Post-operative pain and wound healing are of great concern to the female.

Aim: To compare adhesive tape and continuous subcuticular suture for episiotomy repair after delivery as regard pain, operative time and wound infection. Design: prospective cohort comparative study.

Methods: One-hundred patients were equally divided into two groups. Group 1 patients delivered in one hospital, they underwent skin repair with adhesive tape, while group 2 are patients delivered in second hospital, and they underwent the episiotomy repair by continuous subcuticular suture. Primary outcome was Pain 6 and 12 hours postoperative and 1 week post-delivery using Wong-Baker faces pain rating scale. Skin closure time and wound infection were secondary outcomes.

Results: Statistically significant difference in pain after episiotomy repair in favor of the adhesive group (p-value <0.05) after 7 days. No statistically significant difference between both groups as regard skin closure time or wound infection.

Conclusion: Skin adhesive tape may be better to subcuticular suture in pain perception resulting from episiotomy repair after delivery.

Keywords: Adhesive tape; Continuous sutures; Episiotomy repair; Pain episiotomy

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INTRODUCTION

Episiotomy was introduced in 1950 as a prophylactic procedure to decrease the risk of vaginal and perineal tears as well as to fasten delivery [1]. In a Cochrane review in 2017 there was no evidence that routine episiotomy has the previously assumed benefits and concluded that more restricted use of episiotomies will result in lesser women with severe perineal or vaginal trauma [2]. WHO recommend episiotomy performance only when there is a strong clinical indication [3].

Perineal tears can cause bleeding, infection and postpartum pain associated with the risk of depression, dyspareunia and adversely affects the quality of life and sexual health [4,5].

Sherif and Al-Shourbagy, 2020 studied the skin adhesive tape on 96 patients in RCT *vs.* interrupted skin suture, they concluded that Skin adhesive tape could be better than skin suturing in postpartum pain resulting from episiotomy repair after birth [6].

The aim of current work was to compare skin adhesive tape in perineal skin closure in episiotomy repair and the second technique was continuous subcuticular suture.

PATIENTS & METHODS

This study was performed in 2 hospitals in Kingdom of Saudia Arabia. Ninety-Six with same indications of episiotomy (Primigravida or Rigid perineum) were equally divided into two groups each group in one hospital (so that the number in each hospital is the same to avoid statistical bias). Forty-Eight patients in Group 1 delivered in one hospital, they underwent skin repair with adhesive tape (Steristrips, 3M, coock medical supply), while another 48 patients in group 2 delivered in second hospital, they underwent episiotomy repair by continuous absorbable subcuticular suture. Both hospitals are of same class and deliveries were handled by same experienced doctors (Registrars and senior registrars).

Primary outcome was Pain postoperative and 1 week post-delivery using Wong-Baker faces pain rating scale. Skin closure time and wound infection were secondary outcomes.

Sample size justification

The study included all women fulfilling the inclusion and exclusion criteria who were admitted between January

2022 and June 2022 at the 2 hospitals and proper informed consents were undertaken from the patient.

Patients after informed consent, were subjected to full history taking (personal, menstrual, detailed obstetric & past surgical history), examination (general, obstetric & local pelvic examination), and routine investigations (C.B.C, Rh, blood grouping and albumin in urine) and ultrasonography to select the patients fulfilling the inclusion criteria which are: age 18 till 40, term pregnancy either primigravida or multigravida, patients in labor either induced or spontaneous onset, Patients excluded from start are those with malpresentations as breech, Preterm pregnancy, multiple pregnancies, suspected macrosomia, polyhydramnios or cases with oligohydramnios or FGA, Third and fourth degree perineal tear

Group 1 underwent skin repair with skin adhesive tape, while group 2 underwent the currently traditional method for episiotomy repair by continuous absorbable subcuticular suture.

Surgical procedure

Episiotomy: When crowning occurred (the vulvovaginal opening is dilated by the largest fetal head diameter, infiltration of 1% lidocaine and a medio-lateral episiotomy was done, scissors were positioned at 7 o'clock, and the incision was extended 3 to 4 cm towards the ischial tuberosity.

Perineal repair following delivery: As soon as birth was completed the initial assessment performed gently and sensitively to classify the perineal trauma caused by episiotomy. Third and fourth degree trauma excluded from the research. After full explanation of the procedure to the mother, she was placed in a position allowing good visualization, vulval/perineum washed and draped with sterile drapes. The vagina inspected and the apex of the episiotomy or perineal tear identified. If needed, another infiltration with 1% Lignocaine up to a total of 20mls to the area. A gauze maternity tampon was inserted into the upper vagina, above the trauma to absorb any bleeding from the uterus, which may obscure the field of operation.

The vagina was sutured after good visualization of the apex of the wound starting approximately 0.5cm above this point and the vaginal wall was repaired using a continuous non-locking stitch Continued to the hymen, then the needle placed behind the hymenal remnants and emerge in the center of the perineal muscle. After checking the depth of trauma, the perineal muscles were repaired in one or two layers with the same continuous stitch leaving no dead space [7-9]. Follow up of all women were followed up at the first visit postpartum for pain by using of VAS score, wound healing and wound infection.

The time started to be calculated and cases were divided as follows:

Group 1 Steri-strips (3M™ Steri-Strip™ 6 mm x 100 mm; reinforced skin closure) applied perpendicular to the wound by lifting the skin edges up with gloved finger,

placing the first 1/2 of steri-strip tape with 90 degree angle over the first edge, pressing firmly, ensure edges are met together then placing the other half and press firmly. 3 to 4 tapes placed with approximately 0.5 cm spaces in between.

Group 2 polyglactin 910 (Vicryl Rapid™ 2-0) was used as follow: After repairing the muscular layer the continuous suture was then carried upward as a subcuticular stitch and the final knot was tied at the end of the cut.

The procedure timing stopped for both groups and recorded.

Outcome measures

As the local injectable lidocaine become effective within 5-10 minutes, and lasts on average from 45 minutes to 1 hour [10], all participants were evaluated for pain 6 hours 12 hours and 7 days after delivery, using Wong-Baker faces pain rating scale with verbal expression for pain intensity.

Before discharge, after brief explanation, all women participating were instructed to put dressing and cover the area of steri-strips and to avoid wetting of the dressing with underneath steri-strips as possible and they were instructed to come and replace steri-strips in case they got wet and fall.

Patients were instructed to complete a home daily postnatal pain score chart of 7 days duration using the same scale. When the results of the first 7 days were recorded, the patients were asked to return to the hospital for second evaluation. The patients were able to contact hospital by visit or telephone all through the 7 days, in case of fall of steri-strips.

In the second visit (seven after delivery) evaluations of the wound were done using REEDA score (redness, edema, ecchymosis, discharge and wound approximation), and the patients were asked to complete a second questionnaire, evaluating their satisfaction depending on pain intensity during daily activities using the same pain scale.

Statistical analysis

Numerical data will be explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Data will be presented as median and range values. For non-parametric data Mann-Whitney U test will be used to compare between the two groups. Qualitative data was done by using Chi-square test or Fisher's exact test, when appropriate. The significance level will be set at $P \leq 0.05$. Statistical analysis will be performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY:IBM Corp.

RESULTS

Tab. 1. showed that there was no statistical Significant difference between adhesive strip group and vicryl suture closure regarding the demographic data. **Tab. 2.** shows difference between suture closure and adhesive strip

group regarding 6 and 12 hours postoperative pain and 7 days postpartum. **Tab. 3.** shows REEDA score healing assessment in the 2nd visit (7 days after birth).

DISCUSSION

Calculating the time of skin procedure only, decreased the bias of other delays, which may have happened and gave a precise idea about the real timing of the procedure; however, the main difficulty with application of the skin adhesive tape in the current study was keeping the wound dry, which was felt to cause a substantial loss of time with the procedure, this may be attributed to the nature of the perineum and the episiotomy process itself. However, other studies as Ghosh A, et al. [8] reported wound closure with adhesive tape to be easier and faster although the results were insignificant as compared to intracuticular suture closure after coronary artery bypass grafting; however, there was significantly less redness and edema in the adhesive tape group.

The current study showed no significant difference in pain 6 hours and 12 hours after birth in favor of the Steri-strips group, which can be explained to the effect of local anesthesia given before episiotomy and analgesia given. Our results showed a significant difference in pain score 7 days after delivery in advance of the adhesive tape group, this finding may be caused by exaggerated body response to the sutures although the second evaluation using the REEDA score showed insignificant differences between both groups, and there were no cases of wound infection in either group. There was also an insignificant difference between both groups in the time of skin closure, although the adhesive tape group had a wider time range, which may be attributed to more operators' experience in skin suturing.

Sherif and Al-Shourbagy studied the skin adhesive tape on 96 patients in RCT *vs.* interrupted skin suture, they concluded that Skin adhesive tape could be better than skin suturing in postpartum pain resulting from episiotomy

Tab. 1. Difference between adhesive strip group and vicryl suture closure and regarding the demographic data.

Variables	Group 1 [Adhesive strip Group] (n=48)	Group 2 [Suture closure Group] (n=48)	Test value	P
Age (Years)				
Range	19 – 38	18 – 39	U:1.672	0.152
Median (IQR)	27 (21.8–32)	29 (23–33)		
Gestation at Delivery (weeks)				
Range	38 – 41	38 -41	U:0.731	0.633
Median (IQR)	39.6 (38.8 – 40.4)	39.7 (38.8 – 40.3)		
Number of cases with episiotomy	28 (58.3%)	30 (62.5%)	χ^2 :0.175	0.676
Number of cases with 1 st & 2 nd degree perineal tear	20 (41.7%)	18 (37.5%)	χ^2 :0.175	0.676

U: Mann-Whitney U-test; Chi-square test; p-value >0.05 is insignificant

Tab. 2. Difference between suture closure and adhesive strip group regarding pain evaluation in the 1st day after birth.

Pain score	Group	No	Mild	Moderate	Severe	Very Severe	Worst Pain	χ^2	P
6 hours	Suture	0 (0.0%)	19 (39.6%)	26 (54.2%)	3 (6.3%)	0 (0.0%)	0 (0.0%)	3.378	0.337
	Adhesive	1 (2.1%)	26 (54.2%)	19 (39.6%)	2 (4.2%)	0 (0.0%)	0 (0.0%)		
12 hours	Suture	0 (0.0%)	19 (39.6%)	25 (52.1%)	4 (8.3%)	0 (0.0%)	0 (0.0%)	1.137	0.566
	Adhesive	0 (0.0%)	24 (50.0%)	20 (41.7%)	4 (8.3%)	0 (0.0%)	0 (0.0%)		
7 days	Suture	18 (37.5%)	23 (47.9%)	7 (14.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6.509	0.039*
	Adhesive	27 (56.3%)	20 (41.7%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		

Chi-square test; p-value >0.05 is insignificant; *p-value <0.05 is significant

Tab. 3. REEDA score healing assessment in the 2nd visit (7 days after birth).

Score	Group	0	1	2	χ^2	P
Redness	Suture	23 (47.9%)	25 (52.1%)	0 (0.0%)	0.042	0.838
	Adhesive	25 (52.1%)	23 (47.9%)	0 (0.0%)		
Edema	Suture	46 (95.8%)	2 (4.2%)	0 (0.0%)	0.000	1.000
	Adhesive	46 (95.8%)	2 (4.2%)	0 (0.0%)		
Ecchymosis	Suture	48 (100.0%)	0 (0.0%)	0 (0.0%)	--	--
	Adhesive	48 (100.0%)	0 (0.0%)	0 (0.0%)		
Discharge	Suture	48 (100.0%)	0 (0.0%)	0 (0.0%)	--	--
	Adhesive	48 (100.0%)	0 (0.0%)	0 (0.0%)		
Approximation	Suture	47 (97.9%)	1 (2.1%)	0 (0.0%)	0.000	1.000
	Adhesive	47 (97.9%)	1 (2.1%)	0 (0.0%)		
Total	Suture	22 (45.8%)	23 (47.9%)	3 (6.3%)	1.043	0.594
	Adhesive	23 (47.9%)	24 (50.0%)	1 (2.1%)		

Chi-square test; p-value >0.05 is insignificant

repair after birth [6]. This is accordance with the results of our study

Kindberg et al (2018) compared interrupted, inverted stitches with continuous stitches for perineal repair and leaving the skin without suturing, they concluded that all three methods appear to be equivalent, there were no difference seen in perineal pain 10 days after birth using The Visual Analogue Score and in wound healing evaluated by the REEDA scale at 24–48 hours and 10 days postpartum, which is similar to the results of the REEDA score found in the current study [7].

Calculating the time of skin procedure only, decreased the bias of other delays, which may have happened and gave a precise idea about the real timing of the procedure; however, the main difficulty with application of the skin adhesive tape in the current study was keeping the wound dry, which was felt to cause a substantial loss of time with the procedure, this may be attributed to the nature of the perineum and the episiotomy process itself. However, other studies Ghosh et al., (2015) reported wound closure with adhesive tape to be easier and faster although the results were insignificant as compared to intracuticular suture closure after coronary artery bypass grafting; however, there was significantly less redness and edema in the adhesive tape group [8].

Up to our knowledge the current study is the first to compare skin adhesive tape with continuous suture in episiotomy skin closure, yet other studies compared adhesive glue to sutures as Feigenberg et al (2014) targeting a heterogeneous sample of primiparous and multiparous with a total number of 100 and 97 women respectively both supported the potential benefits of glue use, as a better alternative to sutures as regards procedure time and reduced pain sensation although there was insignificant difference between both groups at 7 and 30 days [9]. However, the cost of glue use may be an issue especially in a developing country with limited resources like Egypt, while Lazar et al., reported increase in pain sensation in the sutured arm when comparing skin adhesive tape to suturing the skin in surgeries other than obstetric [10].

Main limitation of this study is inadequate number of patients as Arab women backward Islamic culture limits their participation in clinical trials, also lack of randomization in this study because there are no RCT units in these hospitals, the private patients refuse the idea non wound suturing and the hospital ethical committee

was not encouraging the idea stating that we are not a governmental hospital

Further studies are needed to evaluate effective way of episiotomy skin closure

CONCLUSION

Skin adhesive tape may be superior to skin suturing in decreasing perineal pain after birth

ETHICS APPROVAL

Study approved by Ethical Committee of 2 hospitals

CONSENT FOR PUBLICATION

Non applicable

AVAILABILITY AND DATA MATERIAL

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

COMPETING INTERESTS

The authors report there are no competing interests to declare

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This study received no financial support.

AUTHORS' CONTRIBUTIONS

All authors jointly contributed to conception and design of the study.

Nada Alayed: Design of the study, helped in review of literature, revision of results and data analysis and contributed in writing the manuscript and corresponding author.

Amr Sobhy: Surgical intervention and delivering the patients in first group; design of the study, revision of review of literature.

Hanan Shehata: Design of the study, revision of review of literature.

Doaa Fouad: surgical intervention and delivering the patients in second group.

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