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A Comparison of Wound Healing Score between Chromic Catgut and Polyglycolic Acid Perineal Suturing at Seven Days Postpartum: A Single Blind Randomized Controlled Trial

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ABSTRACT

Background: Perineal Injury is a frequent vaginal delivery complication that can result in dyspareunia, urine and fecal incontinence, granulomas, and discomfort, which can contribute to long-term morbidity. The choice of suture material determines the outcome in perineal injury.
Objective: This study aims to compare the wound healing scores between chromic catgut and polyglycolic acid perineal suturing at seven days postpartum
Methods: Randomized control trial study conducted at 3 hospitals in Indonesia. The patient met our criteria was randomly group into Chromic Catgut as a control and Polyglycolic Acid as a treatment group. After 7 days of perineal suturing, the wound healing was assessed with REEDA (redness, edema, ecchymosis, discharge, approximation) score by the chosen operato
Results: No significant difference in each indicator of the REEDA score ($p>0.05$). Most of the indicators are each dominated by a score of 0. The maximum score for redness is 2, the score for edema is 1, the score for ecchymosis and discharge is 0, the approximation score is 1, and the total score is 4. On hematological examination, polyglycolic acid showed lower hemoglobin levels and higher leukocyte levels compared to chromic catgut ($p=0.025$ and 0.005, respectively)
Conclusion: There was no difference in wound healing score between Chromic Catgut and Polyglycolic Acid Perineal Suturing at Seven Days Postpartum

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1. Introduction

Perineal injury is a frequent complication of vaginal delivery and more than 80% of primiparous mothers experience injury to the labia, vagina, or perineum. Labor-related perineal injury is defined as injury to the perineal skin, muscles or, in more severe cases, the anal sphincter complex, and anal epithelium. Approximately 85% of vaginal births are affected by labor-related perineal injury, either spontaneously or because of an episiotomy. Primiparas (90.8 %) are more likely than multiparas to have perineal injury (68.8 %).1, 2

The consequences of labor-related perineal injury include dyspareunia, urinary and fecal incontinence, granulomas, and pain, all of which can lead to long-term morbidity.3 In some postpartum women, recovery is delayed by perineal infection and/or wound dehiscence. The risk of requiring additional surgery following perineal wound dehiscence may be as high as 13.2%. The incidence of postnatal perineal infection has been reported to be between 0.8%-11% and up to 23% in low-and middle-income countries.4

Twenty percent of mothers might continue to experience long-term problems such as superficial dyspareunia. Perineal injury also affects the mental, physical, and social aspects of the mother during the puerperium. Perineal repair-related maternal morbidity can have a significant influence on the mother's overall health, generating a great deal of discomfort and stress. This can have an impact on the mother's capacity to care for her infant and her other family members, and it can even lead to divorce.5, 6

Although episiotomy is still controversial, when it is performed it should be repaired with ideal suture. Study on the ideal suture material is still being carried out. Chromic catgut is still the most suture material

used in developing countries, including Indonesia. Catgut and chromic catgut have poorer tensile strength and wound safety than polyglycolic acid (PGA). The primary application of chromic catgut is to seal wounds in the oral mucosa, perineum, and scrotal skin due to its quick absorption. Chromic catgut is absorbed more rapidly than PGA in the oral mucosa and does not require suture removal.7

Natural sutures, such as chromic catgut, can produce a more severe tissue response than synthetic sutures.7 The results of Ziaie et al. showed that chromic catgut had a lower mean REEDA score in the assessment of hyperemia, edema, ecchymosis, and discharge compared to other absorbable suture material (Vicryl) ($p<0.05$), no significant difference was found in wound closure scores.8 The study of Kettele et al. found that polyglycolic and polyglycolic acid groups were related with reduce discomfort in the first three days when compared to catgut (odds ratio 0.62, 95% confidence interval 0.54 to 0.71), fewer analgesia (odds ratio 0.63, 95% confidence interval 0.52 to 0.77) and fewer suture (0.45 odds ratio, 95% confidence interval 0.29 to 0.70). There was no significant difference in long-term pain (odds ratio 0.81, 95% confidence interval 0.61 to 1.08). Suture material absorption was considerably higher in the polyglycolic acid and polyglactin groups (odds ratio 2.01, 95% confidence interval 1.56 to 2.58). There was no difference in the amount of dyspareunia experienced by mothers.9, 10

The choice of suture material determines the outcome in perineal injury. Each suture material has its own characteristics, advantages, and disadvantages. There has been no study that discusses chromic catgut with polyglycolic acid in wound healing score of perineal injury. This study aims to compare the wound healing scores between chromic catgut and polyglycolic acid perineal suturing at seven days postpartum

2. Methods

Clinical Trial Design and Subject Selection

This is a randomized control trial study which was conducted in a multicenter at the Obstetrics and Gynecology Division of Dr. RSUD. Soeselo Slawi, RSUD RA. Kartini Jepara and RSU Purwogondo Kebumen. This study's inclusion criteria include spontaneous vaginal birth, perineal laceration, and consent to undergo a wound healing assessment that includes a history and physical examination. Meanwhile, the exclusion criteria for this study are having pregnancy complications or comorbidities such as preeclampsia (without or with aggravating symptoms), systemic lupus erythematosus, premature rupture of membranes, infection, diabetes mellitus and heart disease.

Data Collection and Intervention

The technique of selecting study subjects was done by simple random sampling. The subjects met the criteria were separated into two groups: the control group received subcuticular suturing with chromic catgut, while the treatment group received subcuticular suturing with polyglycolic acid. Randomization is accomplished using a computer. After being randomized by the computer, envelopes containing suture material of either chromic catgut or polyglycolic acid will be numbered.

Blinding technique used was single blinds. Because the suture material was easily identifiable, the operator who asses the REEDA score data on the seventh day after perineal suturing was not blinded. Operators were selected based on the results of the best score on written questions about the theory of knowledge of perineal lacerations and their management. The selected operators were trained and then evaluated using 21 images of perineal lacerations to check the reliability from 3 different operators. After 7 days of intervention, the REEDA score was assessed by the operator to determine wound healing score.

Data analysis

To assess the different between control and treatment groups, data were analyzed using independent sample T-Test and Mann-Whitney test for interval variables. For nominal variables, data were analyzed using Chi-Square test and Fischer Exact. To assess the reliability between 3 different operators, we used Intraclass Correlation Coefficient. SPSS version 25 for windows was used to analyze the data.

Ethical Approval

The ethical approval was given by the Research and Development Ethics Committee (KEPK) No. 915/EC/KEPK-RSDK/2021 and ethical review from each hospital. All participants signed a consent form informing them of the study, confidentiality, anonymity, and the right to withdraw at any time during the study.

Subjects Characteristic

3. Results

There were 84 subjects that met the criteria and were divided into 42 subjects of the PGA group and 42 subjects of the chromic group. The subject characteristic is shown on table 1.

Chromic catgut group showed a higher BMI than the PGA group (p=0.024). The PGA group was more often assisted by obstetrics and gynecology specialists, while the chromic group was more often assisted by general practitioners (p=0.011). On hematological examination, polyglycolic acid showed lower hemoglobin levels and higher leukocyte levels compared to chromic catgut (p=0.025 and 0.005, respectively).

Table 1. Characteristics of the study sample

Parameters	Chromic Catgut (n=42)	PGA (n=42)	p-value
Age (years)	27.62±5.21	28.52±5.61	0.634[T]
Education			0.842[C]
Elementary school	2 (4.9%)	3 (7.1%)	
Junior high school	14(34.1%)	11 (26.2%)	
Senior high school	23 (56.1%)	25 (59.5%)	
Diploma/Bachelor	2 (4.9%)	3 (7.1%)	
Occupation			0.710[C]
Household	32 (78%)	34 (81%)	
Teacher	2 (4.9%)	2 (4.8%)	
Self-employed	7 (17.1%)	5 (11.9%)	
Health Workers	0 (0%)	1 (2.4%)	
Gravida			
G1	22 (52.4%)	24 (57.1%)	0.824[F]
G2	12 (28.6%)	11 (26.2%)	
G3	5 (11.9%)	5 (11.9%)	
G4	2 (4.8%)	2 (4.8%)	
G6	1 (2.4%)	0 (0%)	
Parity			
P0	23 (54.8%)	24 (57.1%)	0.945[F]
P1	12 (28.6%)	11 (26.2%)	
P2	4 (9.5%)	5 (11.9%)	
P3	3 (7.1%)	2 (4.8%)	
Abortion			
A0	38 (90.5%)	41 (97.6%)	0.280[C]
A1	3 (7.1%)	1 (2.4%)	
A2	1 (2.4%)	0 (0%)	
BMI (Kg/m^2)	23.5(20.3-38.7)	22.4 (18.7-32.4)	0.024*[M]
Birth Weight (g)	2.941.7±394	2.863±389	0.464[T]
Length of Labor Second Stage (minutes)	41.92±31.05	49.52±35.84	0.295[M]
Birth attendant			0.011*[C]
Midwife	30 (71.4%)	32 (76.2%)	
General practitioner	10 (23.8%)	2 (4.8%)	
Obstetric specialist	2 (4.8%)	8 (19%)	
Hematology			
Hemoglobin (Hb) level	11.7 (9.8-13.7)	11.2 (9.9-15.4)	0.025*[M]
Leukocytes	10.200 (8.340-15.940)	11.600 (10.800-29.100)	0.005*[M]
Platelets	259.777±86870	278.369±68320	0.290[T]
Hematocrit	36.83±3.21	37.96±3.16	0.116[T]
MCH	28,8 (20,9-33,2)	28,8 (21,7-33,2)	0.741[M]
MCHC	33,4 (24,8-36,4)	33,4 (28,4-35,7)	0.817[M]
MCV	87,8 (65,3-96,1)	85,8 (26,4-98,2)	0.330[M]
Remaining suture	30 (0-75)	25 (10-80)	0.376[M]

* : Significant [T] : [M] : Mann-Whitney U [C] : *Chi Square* [F] : *Fischer Exact*

Reliability Test Between Three Observers

Three operators selected from each institution have good reliability in scoring REEEDA as shown in table 2.

Examination on Day Seventh of Perineal Suturing

The Examination on Day Seventh of Perineal Suturing as shown on table 3.

The REEDA score did not show a significant difference for each indicator (p>0.05). Most of the indicators are each dominated by a score of 0. The maximum score for redness is 2, the score for edema is 1, the score for ecchymosis and *discharge* is 0, the approximate score is 1, and the total score is 4. In this study, most of the subjects were given analgesia therapy with paracetamol and no significant difference was found (p = 0.616). There was no significant difference in the NPS scores of the two groups (p=0.279). With low NPS scores, most groups did not require extra analgesia therapy (0.241).

Table 2. Intraclass Correlation Coefficient on 3 Operator of REEDA Score

Parameter	***Correlation Coefficient* (ICC)**
Redness	0.782
Edema	0.840
Ecchymosis	1,000
Discharge	0.880
Approximation	0.844

Table 3. Examination on Day Seventh of Perineal Suturing

Parameter	**PGA** (n=42)	**Chromic** (n=42)	**p-value**
Score REEDA			
Redness	0.17±0.437	0.24±0.484	0.408[M]
Score 0	36 (85.7%)	33 (78.6%)	0.633[C]
Score 1	5 (11.9%)	8 (19%)	
Score 2	1 (2%)	1 (2.4%)	
Edema	0.02±0.154	0.00±0.00	0.317[M]
Score 0	41 (97.6%)	42 (100%)	>0.999[F]
Score 1	1 (2.4 %)	0 (0%)	
Ecchymosis	0.00±0.00	0.00±0.00	>0.999[M]
Score 0	42 (100%)	42 (100%)	-
Discharge	0.00±0.00	0.00±0.00	>0.999[M]
Score 0	42 (100%)	42 (100%)	-
Approximation	0.10±0.297	0.02±0.154 0.169	M[Score]
0	38 (90.5%)	41 (97.6%)	0.360[F]
Score 1	4 (9.5%)	1 (2.4%)	
Total score	0 .29±0.742	0.26±0.544	0.808[M]
Score 0	34 (81%)	33 (78.6%)	0.611[F]
Score 1	6 (14.3%)	7 (16.7%)	
Score 2	1 (2.4 %)	2 (4.8%)	
Score 4	1 (2.4%)	0 (0%)	
Paracetamol analgesic therapy	41 (97.6%)	39 (92.9%)	0.616 [F]
Extra Analgesia	3 (7.1%)	0 (0%)	0.241[F]
NPS (Numeric Pain Score)	1.31±1.33	1.36±0.85	0.279[M]

* : Significant [T] : [M] : Mann-Whitney test U [C] : *Chi Square* [F] Test *Fischer Exact*

4. Discussions

This study showed that there was no difference in the REEDA and NPS scores on the seventh day in patients with PGA and chromic catgut. In a previous study, PGA and polyglactin sutures showed less pain than catgut on the third day. However, the results of this study only had an odds ratio of 0.62 with 95% CI 0.54-0.71.9 In addition, other studies also showed a risk ratio of 0.83 with 95% CI 0.76-0.90.11 Chromic catgut is obtained from catgut threating with the chromate salt to increase its strength, delay its absorption and delay its inflammatory respon.12 This indicates that the use of absorbable, which are considered superior to catgut or chromic catgut, might help reduce pain but only minimal pain reduction occurs. Even if only temporary pain relief is achieved, the use of absorbable suture material in individuals with a low pain threshold or low pain sensitivity may be explored to reduce postpartum morbidity.13

REEDA score helps to assess the inflammatory process and wound healing.14, 15 In this study, the REEDA score was measured on the seventh day to assess the inflammatory process. The wound healing process on the seventh day has passed the inflammatory process and the connective tissue proliferation process is occuring.16 The results of this study showed that there was no difference in REEDA scores in the PGA and chromic catgut. The study on late 80s century also showed that PGA and chromic catgut was previously observed for perineal injury and the finding also showed no significant difference among groups aside from the PGA acid required less short-term analgesia. Although PGA was more likely require removal than chromic catgut, PGA appeared to lessen the requirement for resuturing.17 No difference was found in the two groups presumably because both PGA and chromic catgut sutures were well absorbed on the seventh day and there were also no complications of wound infection in the present study.

On the other hand, the late 70s century study showed chromic catgut led to higher wound dehiscence compared to PGA.18 Risk factors for wound dehiscence in perineal injury included ASA classification ≥ 4, history of smoking, chronic obstructive pulmonary disease, BMI ≥ 35 kg/m2 and closure with a flap.19 There was no wound dehiscence in this study due to the risk factor was not identified among the subjects.

In a previous study, chromic catgut well absorbed on the seventh and tenth days. The REEDA score on days 7-10 chromic catgut sutures in the previous study showed a result of 0.53±1.00.20 This result is slightly higher than this study, which is 0.26±0.544. However, both results still showed a mean below 1 which indicated that the chromic catgut had a low REEDA score on the seventh day.

Compared with chromic catgut, PGA has the advantage of lower reactivity and better prevention of bacterial infection. Despite no significant difference was found, the redness score on PGA was dominated by a score of 0 which was more than chromic catgut. This might be due to the PGA sutures' decreased reactivity, which reduces the inflammatory response.21 The tissue reaction of the sutures is demonstrated by the inflammatory response, which usually develops during the first 2 to 7 days. Suture material with low tissue reactivity produces a minimum inflammatory response, which should not delay wound healing or raise infection rates.22

Even though PGA sutures have a lower reactivity than chromic catgut sutures, PGA had higher leukocyte than chromic catgut in this present study. Previous studies have shown that the normal leukocyte level in pregnant women after delivery is 13,390 ± 240 /L.23 In this study, both the chromic catgut and PGA groups were still within normal range.

BMI values in the chromic catgut were significantly higher than BMI levels in the PGA group. The average body weight of women before pregnancy was 73.25 kg (BMI 27.7kg/m2). Then, women gained an average of 14.5 kg during pregnancy and had a 1-year average postpartum weight of 78.3 kg (BMI 29.4kg/m2).24 In this study, both groups had normal BMI values. However, it should be underlined that the BMI value in previous studies is the BMI value in American women who have a higher BMI threshold than Asian women.

High BMIs, even obesity, are linked to several postoperative complications, particularly when it comes to wound healing. This is attributed to alterations in the anatomical tissue attaching to adipose, vascular insufficiency, cellular modifications and composition, oxidative stress, immunological mediator changes, and nutritional deficiencies.24 As a result, the higher REEDA score in this study is very likely to be affected by the BMI value.

This study also found that Hb levels in the PGA group were lower than in the chromic catgut. Higher Hb levels contribute to better tissue oxygenation, which can speed up the wound healing process.25 The association between Hb levels and the type of suture material is remain unclear. Thus, a change in Hb level in this study

for postpartum women might effect from another variables instead of suture material itself.26

The limitation of this study is that the subjects were obtained from 3 different hospitals. Although at first the agreement test was carried out on the REEDA score assessors and good reliability was obtained, other variability is still very possible such as differences in the types of routine blood measuring devices, wound care, subjectivity of NPS assessment, and others. Previous study has shown that although the REEDA score has good agreement reliability, the REEDA score must be modified to obtain better accuracy between operators.20 Furthermore, this study did not look at long-term results, instead focusing on the seventh day.

5. Conclusion

There was no difference in wound healing score between chromic catgut and polyglycolic acid perineal suturing at seven days postpartum. Future study on the long-term outcome and morbidity of chromic catgut and polyglycolic acid is required.

Ethical Approval

All procedures have been approved by the issuance of ethical clearance

Conflicts of Interest

The authors declare that there was no conflict of interest.

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Author Contributions

All of the authors developed the plan and design of the study together. Conceptualization, SA, E; methodology, SA, E; software, validation, formal analysis, investigation, SA, E; resources, SA, E; writing—original draft preparation, SA; writing—review and editing, SA, E; visualization, SA; supervision, E; project administration, SA; funding acquisition SA, E

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