Removal of Caesarean Section Skin Scar and Subcutaneous Release Versus Non-Removal in Repeated CS: A Randomized Clinical Trial

Original Article

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ABSTRACT

Background: Women who have had a caesarean section (CS) may have complications related to the healing of their skin scars. These complications might include insufficient scar formation, which can result in wound dehiscence, or excessive scar development in the form of hypertrophic or keloid scarring.

Objective: To Compare cosmetic and skin complications of removal or non-removal of skin scar in repeated CS.

Methods: This randomized control trial research was done on 667 participants with clinical criteria of women with repeated CS, Pregnant women 37 weeks or more. Patients were divided into two groups: group1 skin removal G; in which removed skin scar be incision just above and below the old scar with subcutaneous skin release. G2 non skin removal G; just opening in the previous scar.

Results: After 3 months, the observer-scale POSAS score was significantly lower (5) in CS scar removal than 12 for CS scar non removal. The total patient-scale POSAS score was significantly lower (8) for the group with CS scar removal than 18 for CS scar non removal. Technique was the only predictor that affects both Patient and observer POSAS scores ($p<0.001^{*}$).

Conclusions: Removal of skin scar is important for wound healing and cosmotic appereance of skin scar .POSAS scores is suitable for assessing scar tissue.

Key Words: CS skin Scar, non-removal, subcutaneous release.

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INTRODUCTION

Caesarean section (CS) is a commom procedure worldwide, and the expanding CS rates show no indication of being manageable, therefore presenting a continuing risk to maternal health and life. This heightened risk may be attributed, in part, to complications such as haemorrhage, infections, and other adverse outcomes resulting from CS[1].

Women who have had CS may have difficulties in the healing of their skin scars, which may manifest as either insufficient scar formation resulting in wound dehiscence, or excessive scar development in the form of hypertrophic or keloid scarring[2]. The objective of any skin closure approach is to achieve proper skin approximation and sufficient healing while reducing discomfort, wound problems, expenses, and scarring. The technique must be quick, cost-effective, and uncomplicated, while increasing wound healing and patient satisfaction. The effects of scarring have a major effect on patient psychological health and behavior, physical comfort and social functioning and confidence[3].

Different techniques are used in cesarean sections for closure of skin scarring such as sutures or staples to achieve good healing and reduce complications. In our study, we used the same suture material for all patients, but different technique (removal or non-removal of the scar) to evaluate the cosmetic outcomes of the skin scar. Various approaches have been used to analyse scar tissue in order to anticipate and assess the effectiveness of therapy. These assessments include both objective and subjective evaluations. The Patient and Observer Scar Assessment Scale (POSAS) is a subjective instrument used to assess scars. It involves the patient providing a self-reported score for factors such as pain, itching, colour, thickness, flexibility, and surface relief of the scar tissue. Additionally, an observer provides a score for factors such as vascularity, pigmentation, thickness, flexibility, and surface relief of the scar tissue[4]. Therefore, this research was conducted to compare the cosmetic outcomes of removal or non-removal of CS scar.

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PATIENTS AND METHODS

The study was done from June 2021 to April 2023 after approval from medical committee of institutional review board of Faculty of Medicine, Assiut women health hospital, Egypt, (IRB 17101430). The study protocol is registered at clinical trials. gov with NCT05150678.

This study conducted a randomized clinical trial with 667 participants who met the clinical criteria of women having multiple cesarean sections at 37 weeks or later. The exclusion criteria were diabetes mellitus, keloid scar, bleeding diathesis, preeclampsia (PET), prior history of wound infection, chronic steroid use, and female individuals who declined to participate in the randomized controlled trial (RCT). All patients were subjected to full history taking, BMI, general examination, assessment of vital data, cardiac, chest examination, abdominal examination, L.L examination, vaginal exam- Canula was inserted and blood sample was obtained for investigation [coagulation profile Random blood sugar and complete blood count (CBC)], and ultrasound examination.

Randomization:

All eligible participants who accepted to participate in the study were assigned by computer generated random number with consecutively numbered opaque envelops used to assign each patient to one of the two groups, after meeting the enterance criteria and providing written consent, patients were assigned to one of two groups by selecting the next numbered envelope.

Intervention:

All Patients who met the criteria went to operative theatre for elective cesarean section after complete fasting and investigations after exclusion of anemia or any bleeding tendency.

Patient entered the operating room and sterilized then operator scrubbed.

Scrubbing and cleaning of the abdomen starting from the level of xiphisternum till the knee, using povidone iodine 7.5% antiseptic solution, then10% iodine was washed.

All participants operated under general or spinal anesthesia. According to their condition, Preoperative prophylactic antibiotics: Prior to making an incision in the skin, all women were given a prophylactic antibiotic called ceftriaxone. The ceftriaxone, manufactured by Sandoz in Holzkirchen, Upper Bavaria, Germany, was delivered intravenously at a dosage of one gram. In cases where the woman's weight was less than 80, one gram of ceftriaxone was given. However, in obese women with a BMI more than 30, a dosage of two grams was supplied. Assessment of the scar was done; decision was made by removal or non-removal of scar according to randomization. the assessment done by the same surgeon (senior obstetrician), using the same suture material, but different technique.

Group 1 SKIN removal G; in which removed skin scar be incision just above and below the old scar with subcuteous skin release.

G2 non skin removal G; direct open in the middle of the previous scar. Closure of subcutaneous tissue was done if its depth was 2cm or more.

In all participants after finishing the Cs, the skin was closed by subcuticular stitches using polyglycolic acid braided & absorbable suture vicryl (2-0)].

A picture was taken after closure of the incision then covering of the wound by sterile dressing.

Operative time was calculated from skin incision to skin closure.

The dressing was removed after 24 hours postoperatively, then closed by another dressing which removed 5 days later. Oral Postoperative antibiotics started for 5 days postoperative (1gm amoxicillin clavulanic acid) according to our local center protocol.

Follow up; A follow up 12 weeks postoperative to assess the healing and any additional data regarding wound infection, also to assess the cosmetic outcome of the patient by the same surgeon who done the preoperative assessment. Picture taken for assessment three months later.

The standardized scar assessment was done by the following: POSAS, OSAS; the assessment was done preoperative for the previous scar, and for the new scar postoperative 3 months.

Numerical scores are assigned to all items on both scales. The patient evaluates the scar based on its color, pain, thickness, stiffness, itching, and irrigularity, while the observer assesses the scar's vascularity, pigmentation, pliability, thickness, and relief.

The Patient Scar Assessment Scale (PSAS) had six variables. The scoring method assigned 10 points to each item, which were then added together to get a total score ranging from 6 to 60. A score of 6 indicated normal skin without any accompanying symptoms[5].

The OSAS evaluates five variables. Each variable had a scoring system ranging from 1 to 10, where 1 indicated normal skin. The ratings of different criteria may be added together to obtain a total score that ranges from 5 to 50. A score of 5 indicates normal skin[5].

Research outcome measures:

a. Primary (main)

1.Score of the healing of the scar 3months after operation

b. Secondary (subsidiary)

1. Duration of the surgery
2. Subcuteous bleeding during surgery
3. Postoperative pain score
4. Score of the scar of 3 months
5. The overall satisfaction of the patient

Sample Size Calculation:

Utilizing a cross-sectional cohort design, we conducted a randomized clinical trial with a significance level (1-alpha) of 0.05 and a power of 80%. The sample size ratio between the unexposed and exposed groups was 1:1. The percentage of individuals in the unexposed group with the outcome was 14%, while the percentage in the exposed group was 7%. The odds ratio was 0.46, and the risk/prevalence ratio was 0.5. The risk/prevalence difference was -7. The study had a sample size of 298 patients who were exposed and 298 patients who were not exposed, resulting in a total sample size of 596 individuals.

Statistical analysis:

The data gathered over time was subjected to a fundamental clinical evaluation, and the resulting outcome measures were organized, inputted, and analyzed using Microsoft Excel software. The data was then imported into the Statistical Package for the Social Sciences (SPSS version 21.0) program for analysis. Qualitative data is represented by numbers and percentages, whereas quantitative data is represented by the mean ± standard deviation. The following tests were employed to determine the significance of differences and associations: the Chi square test (X2) for qualitative variables. Comparisons between independent groups using a t-test to analyze quantitative data. The significance threshold for results was established at a *P value* of <0.05 for significant findings and <0.001 for very significant findings.

RESULTS

A total of 667 women were evaluated for eligibility in this research. Out of these, 67 women did not match the requirements, with 20 patients declined to participate. The remaining patients were randomly assigned to two equal groups, with 300 patients in each group. Statistical analysis was conducted on all assigned patients throughout the follow-up period (Figure 1).

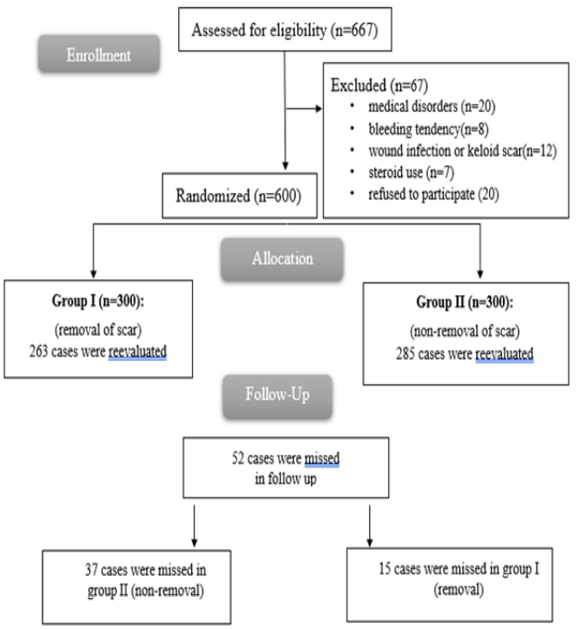

Fig. 1: CONSORT flowchart of the enrolled patients.

There was no statistically significant difference in demographic data between the two randomly assigned groups (Table 1).

Table 1: Baseline demographic data:

Baseline demographic data	Group I (*n*= 300)		Group II (*n*= 300)		*P*-value
	No.	%	No.	%	
Age: (years) Mean±SD	29.99±5.08		29.41±4.62		0.142
Residence:					
Urban	199	66.3%	208	69.3%	0.432
Rural	101	33.7%	92	30.7%	
Occupation:					
Housewife	153	51.0%	150	50.0%	0.806
Working	147	49.0%	150	50.0%	
Education:					
Educated	147	49.0%	149	49.7%	0.870
Illiterate	153	51.0%	151	50.3%	
BMI: Mean±SD	27.35±1.51		27.51±0.92		0.125

Values are presented as mean_+SD or number %, *p* value is significant if <0.05.

There is no statistically significant difference between the two randomized groups regarding their obstetric data (Table 2).

Table 2: Obstetric data:

Obstetric data	Group I (*n*= 300)		Group II (*n*= 300)		*P*-value
	No.	%	No.	%	
Parity: Median (Range)	2.0 (1.0-9.0)		2.0 (1.0-7.0)		0.114
No. of previous CS: Median (Range)	2.0 (1.0-7.0)		2.0 (1.0-5.0)		0.161
Duration from previous CS: (years) Median (Range)	2.0 (1.0-12.0)		2.0 (1.0-8.0)		0.321
Site of previous CS:					
AUH	134	44.7%	115	38.3%	0.115
Private clinic	166	55.3%	185	61.7%	
Gestational age: (weeks) Mean±SD	38.24±0.97		38.37±0.91		0.099

The group without CS scar removal (44 minutes Vs 42minutes) with statistically significant difference (*p* value= 0.001*) (Table 3).

Table 3: Operative time:

Operative time (min)	Group I (*n*= 300)	Group II (*n*= 300)	*P*-value
Mean±SD	44.31±7.08	42.43±6.80	0.001*

OSAS of previous scar, there is no significant difference between the two study groups regarding all the variables (Table 4).

Table 4: OSAS of previous scar:

	Group I (*n*= 300)	Group II (*n*= 300)	*P*-value
	Median (Range)	Median (Range)	
Vascularization	2.0 (1.0-5.0)	2.0 (1.0-4.0)	0.520
Pigmentation	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.441
Thickness	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.243
Relief	1.0 (1.0-4.0)	2.0 (1.0-4.0)	0.149
Pliability	1.0 (1.0-4.0)	1.0 (1.0-4.0)	0.072
Total score OSAS	8.0 (5.0-20.0)	8.0 (5.0-20.0)	0.403

POSAS of previous scar, there is no significant difference between the two-study group regarding all the variables (Table 5).

Table 5: POSAS of previous scar:

	Group I (*n*= 300)	Group II (*n*= 300)	*P*-value
	Median (Range)	Median (Range)	
Pain	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.737
Itching	2.0 (1.0-4.0)	2.0 (1.0-5.0)	0.640
Color	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.101
Stiffness	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.557
Skin regularity	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.166
Thickness	2.0 (1.0-4.0)	2.0 (1.0-4.0)	0.895
Total score of PSAS	12.0 (6.0-22.0)	12.0 (6.0-24.0)	0.529

A statistically significant difference was found between the two groups in all the components of the scale used. (Table 8). group 2 show increase in all the components of the scale.by median 12 in comparison with group (1) median 5 (Table 6).

Table 6: OSAS after 3 months post-operative:

	Group I (*n*= 285)	Group II (*n*= 263)	*P-value*
	Median (Range)	Median (Range)	
Vascularization	1.0 (1.0-4.0)	2.0 (1.0-5.0)	0.000*
Pigmentation	1.0 (1.0-4.0)	2.0 (1.0-5.0)	0.000*
Thickness	1.0 (1.0-4.0)	2.0 (1.0-5.0	0.000*
Relief	1.0 (1.0-4.0)	2.0 (1.0-5.0)	0.000*
Pliability	1.0 (1.0-4.0)	2.0 (1.0-5.0)	0.000*
Total score of OSAS	5.0 (5.0-20.0)	12.0 (5.0-25.0)	0.000*

A statistically significant difference was found between the two groups in all the components of the scale used.

(Table 9). group 2 show increase in all the components of the scale.by median 18 in comparison with group (1) median (8) (Table 7).

Table 7: POSAS after 3 months post-operative:

	Group I (*n*= 285)	Group II (*n*= 263)	*P*-value
	Median (Range)	Median (Range)	
Pain	1.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Itching	2.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Color	1.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Stiffness	1.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Skin regularity	1.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Thickness	1.0 (1.0-4.0)	3.0 (1.0-5.0)	0.000*
Total score of POSAS	8.0 (6.0-24.0)	18.0 (6.0-30.0)	0.000*

DISCUSSION

There has been a global increase in the use of cesarean sections (CS), making them among the most popular surgical procedures[6]. The global use of CS has been consistently rising and is projected to continue its upward trend during the present decade, with the simultaneous presence of both unmet demand and excessive usage[7]. The objective of any skin closure method is to achieve sufficient wound healing while minimizing consequences such as pain, scarring, and expense[8]. Extrinsic factors that do not rely on the patient include the procedural method, the length of the surgery, and after care, which include wound care[9]. Various methods have been used to analyze scar tissue in order to anticipate and assess the effectiveness of therapy. These assessments include both objective and subjective evaluations. The POSAS is a subjective tool used to evaluate scars. It involves the patient providing a self-reported score for factors such as pain, itching, color, thickness, flexibility, and surface relief of the scar tissue. Additionally, an observer provides a score for factors including vascularity, pigmentation, thickness, flexibility, surface relief, and surface area of the scar tissue[4]. The POSAS was developed by Draaijers[10] To assess different types of scarring. The POSAS is a comprehensive assessment that combines the measurements of both the PSAS and OSAS.

The aim of the current study was to Compare cosmetic outcomes of removal or non-removal of skin scar in repeated CS.

To our knowledge there are no studies compare cesarean scar removal versus non removal in the obstetric population; Other studies compare the type of sutures used during caesarian section while the strength of our study is that it is first and novel in this field and used to compare the effectiveness in removal of scar tissue of caesarian section and the benefits of this procedure in improving the quality of life of the female.

In agreement with Cromi[11] The objective of this study was to assess and evaluate the quality of scars resulting from various wound closure techniques after CS. The Vancouver Scar Scale, the POSAS, and a visual analog scale were used as instruments for evaluating scars.

Along with our study Lindeboom[12] Examined images of linear scars using an adapted Observer Scale, which linked the score categories to clinical descriptions of the scars. Bianchi *et al*.[14] used the POSAS to assess the progress of healing in facial scars resulting from trauma or surgery. It has been shown that the POSAS is an effective instrument for assessing surgical and posttraumatic facial scars. In addition, Ekin *et al*.[13] conducted a study to assess the cosmetic outcome of patients who had primary cesarean birth using the Patient and Observer Assessment Scale (POSAS). The study found that the technique used significantly influenced the observer's POSAS ratings (p=0.001). It should be noted that our findings are based on the patient's personal assessment of their cs scar. Patients in both groups reported modest ratings for scar pain and pruritus as compared to other PSAS components. They represent the acute component of wound complications and indicate the amount of time between surgery and reporting. Similarly, increased colour, stiffness, and thickness ratings in the control group imply that chronic wound complications are regarded better by patients in the test group. This finding further supports the dependability of the scar evaluation method developed by patients used in this research. These results go hand in hand with those conducted by Chae *et al*.[14] who performed a study on twenty-three patients. Three independent ratings assessed observers using the observer component of the POSAS and the Vancouver scar scale (VSS). The patient component of the POSAS was used for patient self-assessment. A spectrophotometer and ultrasonography were used to more objectively evaluate scar color and scar thickness. They discovered that inter-observer reliability was high with both the VSS and the POSAS observer component (average measure intraclass coefficient correlation, 0.76 and 0.80, respectively). The observer component consistently shown substantial relationships with patient assessments for the POSAS parameters (all *p-values* 0.05). The association between subjective POSAS evaluation and objective spectrophotometer and ultrasound assessment was weak.

RECOMMENDATIONS & LIMITATIONS

Recommendations: Larger sample size. Multi center study. Continuing research is required to Compare cosmetic and skin complication of removal or non-removal of skin scar in repeated CS.

Limitations: A single center research was conducted. Most validated scar evaluation techniques available featured components that may be difficult to evaluate in a black-skinned lady, such as vascularity and skin color; others need the use of equipment for correct assessment. As a result, the tools were correctly adjusted. The research was similarly brief.

CONCLUSIONS

The use of CS for scar eradication led to improved development of scar tissue. The POSAS tool is appropriate for evaluating scar tissue, since there is concurrence between the ratings provided by patients and researchers.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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