

## Sonohysterographic Evaluation of Cesarean Scar Defect after Purse-String versus Double-Layer Uterine Closure Techniques: A Randomized Controlled Trial

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### ABSTRACT

**Background:** cesarean scar niche is one of the novels mentioned complications of cesarean section due to the rising numbers of cesarean sections and improved imaging modalities. The causes of cesarean scar niche are still being investigated, one of them is the uterine closure method that should be studied to pick up the best one to decrease the incidence of niche after cesarean delivery.

**Objective:** The aim of this work was to find the best way of uterine closure decreasing the incidence of cesarean section niche. **Material and methods:** A prospective randomized controlled study that was conducted between May 2021 and April 2022 at the department of Obstetrics and Gynecology, Zagazig University. Full term ninety-eight primigravida undergoing first elective cesarean section were equally randomized to either purse string or double-layer unlocked suture. Six months after cesarean section, Sonohysterography was done for assessment of cesarean scar integrity. Markers of cesarean scar healing included residual myometrial thickness "RMT", niche depth "D", hypoechoic triangular niche width "W" and healing ratio "D/RMT". All these markers were calculated by experienced sonographers who were not aware of the uterine closure technique. **Results:** In terms of estimated blood loss, there was no significant differences between both groups. However, frequency of appearance of niche in purse-string group was 25% compared to 56.8% in the double layer group (P=0.002). The mean thickness of the residual myometrium covering the defect was significantly higher  $7.8 \pm 1.1$  mm after purse-string than  $5.9 \pm 0.6$  mm after a double-layer closure (P = 0.001). The mean healing ratio in purse-string group was 0.449 versus 0.600 in the double-layer closure (p<0.001).

**Conclusion:** Purse-string uterine closure was associated with better uterine scar healing, higher residual myometrial thickness and lower rate of cesarean scar defect than double layer closure.

**Keywords:** Niche, Uterine scar, Healing ratio, Sonohysterography.

### INTRODUCTION

Cesarean section (CS) is considered the most commonly performed surgery in obstetrics. Because many women are undergoing this surgery every year, it becomes of great importance to study this operation sequels on the female future fertility<sup>1</sup>. Postmenstrual spotting and dysmenorrhea are one of the recent common sequels in women with previous cesarean sections<sup>2, 4</sup>. These sequels are mostly attributed to cesarean scar defect that is called the niche which is defined as "at least 2 mm depth indentation at the site of cesarean scar" that can be seen by the transvaginal ultrasound (TVUS)<sup>3</sup>. Relation between cesarean section niche and presentation of postmenstrual spotting was proved and reported by two studies with 3.1 odd ratio [1.5–6.3] at confidence interval 95% in the first study<sup>2</sup> and 5.5 odd ratio [1.1–26.5] in the second study<sup>4</sup>. According to these studies, by the transvaginal ultrasound, the niche was seen in 50 to 60% in patients undergoing previous cesarean sections. Postmenstrual spotting had a positive relation with the volume of the niche; however, it had a negative relation with the residual myometrium thickness (RMT)<sup>2,4</sup>. However, the ultrasonography (US) had an important role in pregnant uterus scar assessment, its role in non-pregnant uterus scar assessment is still limited<sup>5, 6</sup>. Sonohysterography (SHG) is a better uterine cavity evaluation method as instillation of fluid into the uterine

cavity makes enhancement through anechoic contrast medium. Thus, SHG combines the advantages of both US and hysterosalpingography<sup>7</sup>. Recently, SHG had added significantly to uterine cavity evaluation residual myometrial thickness<sup>8</sup>, adjacent myometrial thickness, depth of the cesarean scar defect (niche) and any presence of intrauterine adhesions that can be scar-related<sup>9</sup>. Uterine closure method should be evaluated according to the possible benefits and the anticipated harm to get the best method for uterine closure in women undergoing cesarean section<sup>10</sup>. Uterine wound integrity is greatly affected by mechanical tension and suturing technique. So, this prospective randomized trial was to compare the classical double layer closure of the uterine incision to the double layer purse-string closure as regards occurrence of postoperative cesarean scar defect "niche" and other short-term results.

### PATIENTS AND METHODS

A prospective randomized clinical trial done at the Department of Obstetrics and Gynecology, Zagazig Faculty of Medicine between May 2021 and April 2022. Sample size was calculated by assuming incidence of cesarean section niche in double layer uterine closure (26.3%) at confidence level 95%, power 80%, sample was 98 patients divided in 2 groups, 49 patients in each group. Group (A) included purse string uterine closure women & Group (B)

involved double-layer unlocked uterine closure technique women (Figure 5).

**Ethical consideration:**

The study was approved by the Ethics Board of Zagazig University (IRB#:6723-21-4-2021) and an informed written consent was taken from each participant in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

**Inclusion criteria:** All women with singleton pregnancies undergoing elective primary cesarean delivery at  $\geq 37$  weeks' gestation.

**Exclusion criteria:** Women who refused to participate in the study, women with preterm birth, pregnant before 18 years old, emergency cesarean sections (in prolapsed cord, bleeding in placenta previa, abruptio-placenta, vasa previa, sever preeclamptic toxemia, antepartum eclampsia), previous history of uterine surgery ( uterine perforation, previous myomectomy, previous hysterotomy), systemic diseases (connective tissue disorders or diabetes mellitus), cases with chorioamnionitis, any uterine incision other than Kerr incision, inverted T incision, expanded transverse lower segment incision during surgery or presence of myoma at the site of incision.

**Randomization:** Patients fulfilling the inclusion criteria were randomized into 2 groups (the purse-string uterine closure arm or the traditional double-layer uterine closure arm) through envelopes, which were numbered consecutively, sealed and contains computer-generated numbers (Randomization Generator Version 1.0), then opened after recruitment with allocation ratio 1:1. The group participants were blinded to which group they were in, and two authors performed the operations randomly, also the physician who made the ultrasound was blinded which technique was done in each case examined.

The techniques used for cesarean section was Pfannenstiel and Kerr one without closing the peritoneum. We can summarize the purse-string uterine closure technique (Turan method) that was used in the first group as follows: We started at the corner, closing the uterine incision by no. 1 polyglactin 910 suture (figure 1). Suture of the 1<sup>st</sup> layer passes through the inner myometrial layer transversely while in the 2<sup>nd</sup> layer, it passes transversely the outer myometrium and visceral peritoneum in a continuous manner to form a purse-string. Through this technique, the suture makes a knot by return to the first point. Then figure of eight sutures in closing the uterine incision after the 2 layers of purse-string<sup>10</sup>.

In the other group of patients, we used the conventional double layered uterine closure using

multifilament continuous running sutures for both layers, decidua was included in the first layer included while inverted lambert method in the second layer and if any bleeding point appeared, hemostatic sutures were done (figure 2).



**Figure (1):** purse-string uterine closure technique (Turan method)

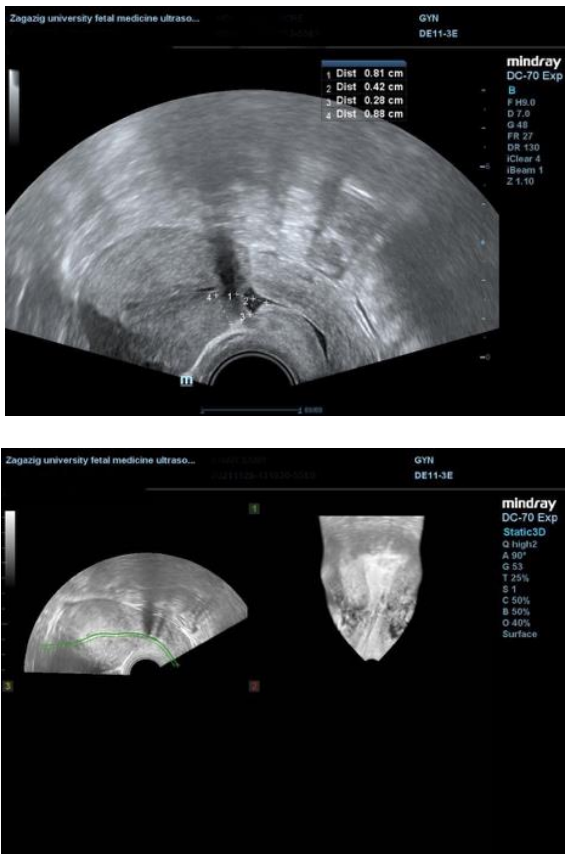


**Figure (2):** traditional double-layer uterine closure technique.

Six months after cesarean delivery, the patients came for follow-up, both groups were subjected to: a) Complete history including menstrual history after delivery, b) Complete gynecological examination including position and size of the uterus and for pelvic infection exclusion, c) TVS to exclude any pathology in the pelvis, d) Transvaginal sonohysterography (SHG) for uterine cavity and CS scar assessment through infusion of saline to act as a contrast media (Sonohysterographic examination was performed using Mindray DC 70 expert with x insight Shenzhen, china.2021, with a transvaginal

probe 7.5 MHz). During follow-up scan, the participants were examined with a bladder empty and in lithotomy position. The procedure started by a pelvic examination, to exclude any adnexal masses, any tenderness, followed by a routine pelvic U/S & then speculum exposure of the cervix.

Any patient with mucopurulent discharge (contraindication) were postponed until a swab & culture has been performed & proper antibiotic therapy had been administered. povidone iodine was used to swab the cervix as antiseptic solution & then a thin Nelaton catheter (ch/fr10) was placed through the cervical os. The vaginal probe was reinserted into the vagina & sterile saline is instilled under sonographic examination. Usually no more than 10 cc of saline were required to view the cavity) (figures 3 & 4).



**Figure (3):** Sonohysterography in a case after purse-string uterine closure technique



**Figure (4):** Sonohysterography in a case after traditional double-layer uterine closure technique

### Study outcomes:

#### Primary outcome

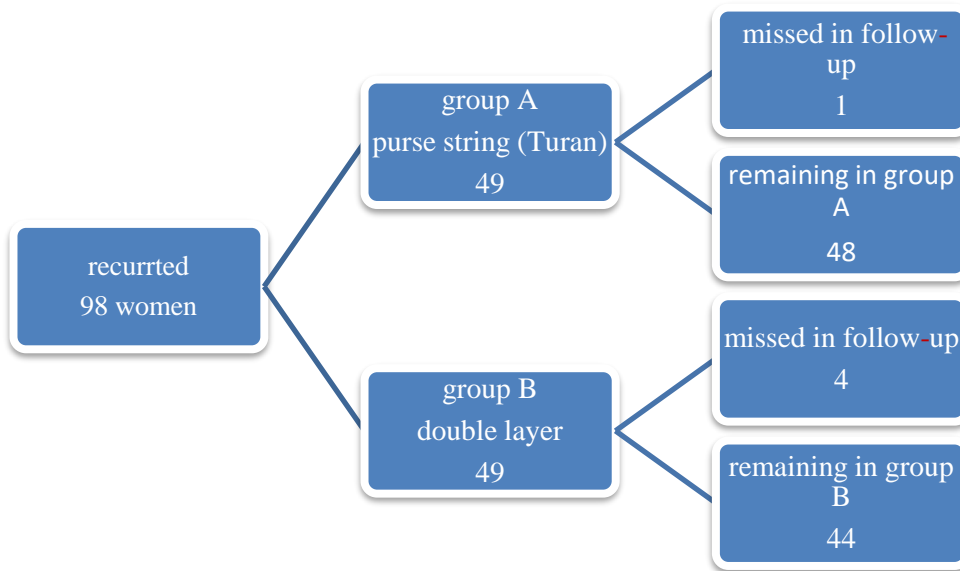
Includes operative time in minutes, count of additional hemostatic sutures, calculated blood loss in ml (CBL) in reference to Nadler’s and Brecher’s formulas<sup>12, 13</sup>.

#### Secondary outcomes

It was measured by cesarean scar “niche” rate seen 6 months after the cesarean section. Niche was defined to be any defect at cesarean section site 2 mm depth or more seen by the SIS.

This includes the niche measurements during SIS {depth, length, width, adjacent myometrium thickness (AMT), residual myometrium thickness (RMT), healing ratio, which means RMT/AMT} modified Delphi method<sup>5</sup>.

**RESULTS**



**Figure (5):** Flow chart

Table (1) described maternal characteristics in both groups and showed that no significant difference in gestational age at delivery in both groups, higher incidence of dysmenorrhea in double layer than in purse-string method. No significant difference in both groups according to maternal age and BMI (pregestational and 6 months after delivery).

**Table (1):** Demographic data & maternal characteristics in both groups

|                                    |   | Technique  |            | Test | P     |
|------------------------------------|---|------------|------------|------|-------|
|                                    |   | A<br>N=48  | B<br>N=44  |      |       |
| <b>Maternal age (years)</b>        |   | 29±3       | 28±4       | -1.9 | 0.055 |
| <b>BMI (gestational)</b>           |   | 30 (27-40) | 31 (27-39) | -1.8 | 0.068 |
| <b>BMI (6 months postdelivery)</b> |   | 29 (23-38) | 28 (24-35) | -2.0 | 0.067 |
| <b>Dysmenorrhea</b>                | N | 43 (89.6%) | 32 (72.7%) | 4.3  | 0.037 |
|                                    | Y | 5 (10.4%)  | 12 (27.3%) |      |       |
| <b>GA at delivery</b>              |   | 39 (37-42) | 39 (37-41) | -0.6 | 0.521 |

Table (2) showed that duration of surgery was longer in purse-string than in the double layer technique (p <0.001), estimated blood loss showed no significant difference. Number of extra sutures was higher in purse-string technique (p=0.003).

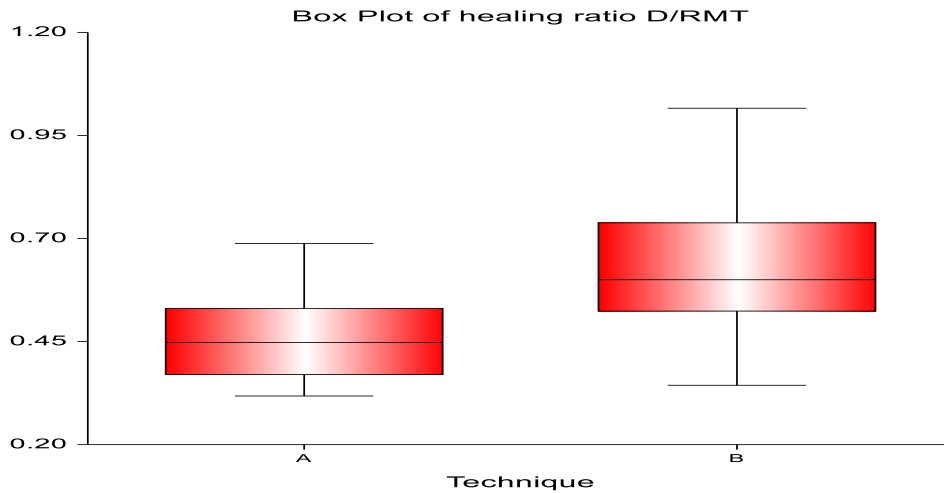
**Table (2):** Intra-operative parameters in both techniques

|                                   |   | Technique  |            | Test | P      |
|-----------------------------------|---|------------|------------|------|--------|
|                                   |   | A<br>N=48  | B<br>N=44  |      |        |
| <b>Duration of surgery(min)</b>   |   | 46 (30-57) | 38 (33-41) | -7.9 | <0.001 |
| <b>Calculated Blood loss (ml)</b> |   | 451±52     | 450±88     | -1.1 | 0.272  |
| <b>Extra Sutures</b>              | N | 19 (39.6%) | 31 (70.5%) | 8.8  | 0.003  |
|                                   | Y | 29 (60.4%) | 13 (29.5%) |      |        |
| <b>Number of Extra Sutures</b>    | 0 | 19 (39.6%) | 31 (70.5%) | 11.5 | 0.009  |
|                                   | 1 | 17 (35.4%) | 4 (9.1%)   |      |        |
|                                   | 2 | 8 (16.7%)  | 7 (15.9%)  |      |        |
|                                   | 3 | 4 (8.3%)   | 2 (4.5%)   |      |        |

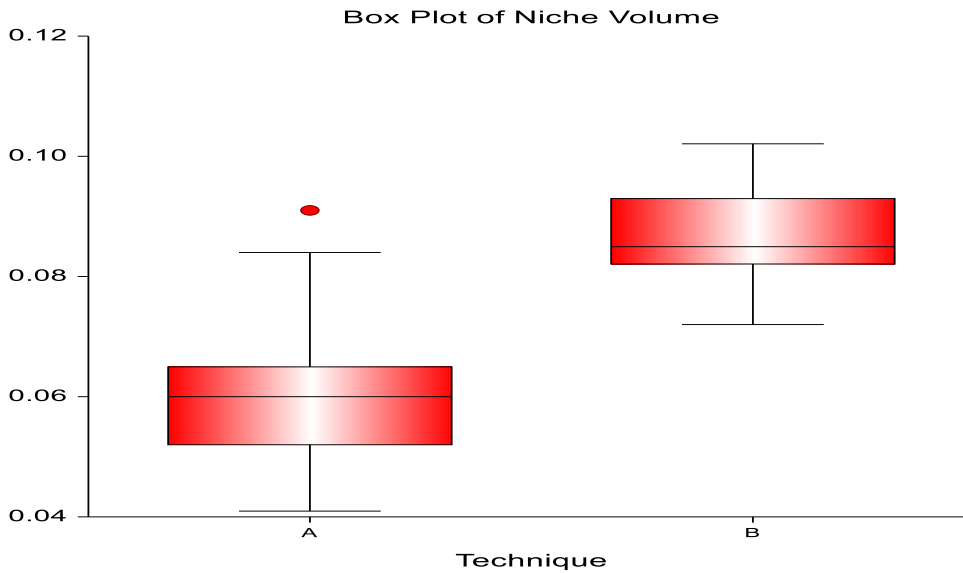
Table (3 and figures 6 & 7) showed that prevalence of niche was higher in double layer than in purse-string uterine closure technique (p 0.002). All parameters of niche (including length, depth, width, RMT, niche volume and healing ratio) were higher in the double layer than in purse-string method (p <0.001).

**Table (3):** Niche prevalence and details in both techniques

|                      | Technique           |                     | Test | P      |
|----------------------|---------------------|---------------------|------|--------|
|                      | A<br>N=48           | B<br>N=44           |      |        |
| Prevalence of niche  | 12 (25.0%)          | 25 (56.8%)          | 9.5  | 0.002  |
| Depth of niche mm    | 2.5±0.3             | 4.9±0.5             | 28   | <0.001 |
| Length of niche mm   | 9±2.1               | 16±3.8              | 11.1 | <0.001 |
| Width of niche mm    | 8±1.8               | 18±5.1              | 12.7 | <0.001 |
| RMT*                 | 7.8±1.1             | 5.9±0.6             | -5.1 | <0.001 |
| healing ratio D/RMT* | 0.449 (0.317-0.689) | 0.600 (0.344-1.017) | -3.8 | <0.001 |
| Niche Shape*         | D                   | 9 (36.0%)           | 10.6 | 0.006  |
|                      | S                   | 12 (48.0%)          |      |        |
|                      | T                   | 4 (16.0%)           |      |        |
| Niche Volume*        | 0.060 (0.041-0.091) | 0.085 (0.072-0.102) | -5.5 | <0.001 |



**Figure (6):** Box-plot diagram for the range of the healing ratio D/RMT in the studied groups





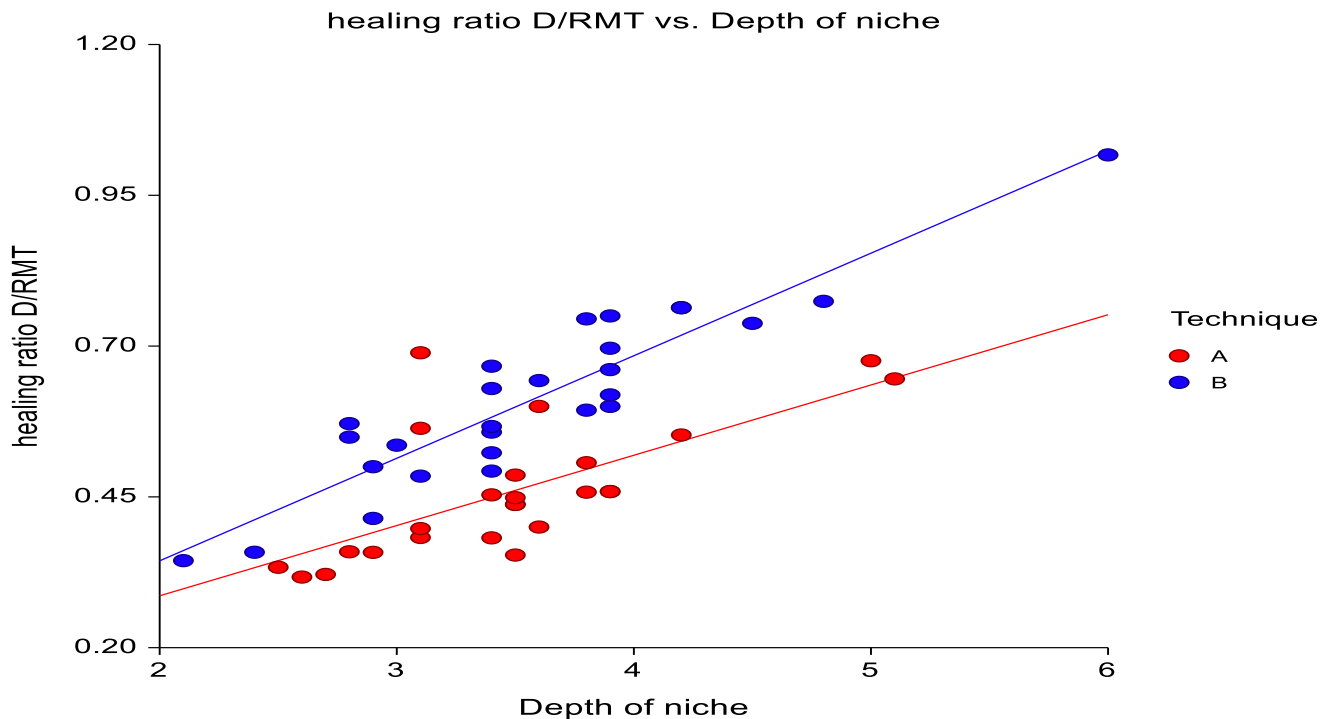
**Figure (7):** Box-plot diagram for the range of the niche volume in the studied groups

Table (4) and figure (8) showed that there was direct significant linear correlation between the healing ratio and depth of niche in technique A, technique B and both techniques together with  $r = 0.684, 0.875$  and  $0.679$  respectively, however no other significant correlation was found between the depth of niche in each technique and other study parameters.

**Table (4):** Spearman linear correlation between the depth of niche and other studied parameters

| Parameters                 | Depth of niche |        |    |             |        |    |            |        |    |
|----------------------------|----------------|--------|----|-------------|--------|----|------------|--------|----|
|                            | Technique A    |        |    | Technique B |        |    | Both Tech. |        |    |
|                            | r              | P      | N  | r           | P      | N  | r          | P      | N  |
| <b>RMT</b>                 | 0.055          | 0.796  | 25 | -0.052      | 0.798  | 27 | -0.028     | 0.843  | 52 |
| <b>healing ratio D/RMT</b> | 0.684          | <0.001 | 25 | 0.875       | <0.001 | 27 | 0.679      | <0.001 | 52 |
| <b>Niche Volume</b>        | 0.229          | 0.272  | 25 | 0.348       | 0.075  | 27 | 0.226      | 0.106  | 52 |
| <b>Maternal age</b>        | -0.056         | 0.79   | 25 | -0.084      | 0.676  | 27 | -0.064     | 0.654  | 52 |
| <b>gestational BMI</b>     | -0.024         | 0.91   | 25 | 0.293       | 0.138  | 27 | 0.146      | 0.302  | 52 |
| <b>6M postdelivery BMI</b> | 0.038          | 0.857  | 25 | 0.036       | 0.857  | 27 | 0.035      | 0.808  | 52 |
| <b>GA at delivery</b>      | -0.430         | 0.052  | 25 | -0.326      | 0.097  | 27 | -0.368     | 0.067  | 52 |
| <b>Duration of surgery</b> | -0.185         | 0.375  | 25 | -0.038      | 0.851  | 27 | -0.115     | 0.417  | 52 |
| <b>Blood loss</b>          | -0.426         | 0.272  | 25 | -0.424      | 0.282  | 27 | -0.424     | 0.281  | 52 |
| <b>No. Extra Sutures</b>   | -0.033         | 0.874  | 25 | -0.096      | 0.635  | 27 | -0.069     | 0.628  | 52 |

r = Correlation Coefficient,  $P \leq 0.05$ = significant  $P < 0.001$  highly significant and  $P > 0.05$  non-significant.



**Figure (8):** Spearman linear correlation between the depth of niche and healing ratio in both techniques

## DISCUSSION

The way of uterine closure is of great importance for wound healing and prevention of future cesarean section complications<sup>11,14</sup>. So, we have to get the best surgical technique that decreases the incidence of cesarean section niche and its related complications on the women health and fertility<sup>10</sup>.

In our study, there was no significant difference in both groups regarding maternal age, BMI and gestational age at delivery in both groups. This comes in accordance with **Turan et al.**<sup>(10)</sup> who compared the double layer purse-string uterine closure to the classical double layer uterine closure in cesarean section. According to operative time in our study, it was longer in the purse-string technique 46 minutes (30-57) versus 38 minutes (33-41) in double layer ( $p < 0.001$ ) which comes in contrast to **Turan et al.**<sup>(10)</sup> who found that operative time was similar in both groups ( $28.5 \pm 10.6$  vs  $27.9 \pm 4.8$ )  $p = 0.177$ . This difference may be attributed to that purse string is a novel technique which takes a time to master in contrast to conventional double layer established one.

Uterine scar defect prevalence was reported in some studies to be 20-60% in classic uterine closure modalities<sup>11, 12, 15,16,17</sup>, which is consistent with our study (56.8%) in the double layer closure group. The prevalence of niche in the present study was lower in purse-string closure technique than in the traditional double layer (25% [12/48] vs 56.8% [25/44]). This comes in accordance with **Turan et al.**<sup>(10)</sup> where the incidence of CS niche was lower in purse-string than in traditional double layer technique (23.5% [12/ 51] vs 60% [39/65]), also the length of uterine incision was shorter (3.7 cm vs 8.5 cm).

There are no too much studies comparing the purse string and traditional double layer techniques but in randomized, prospective study, done by **Sevekt et al.**<sup>(18)</sup> to assess RMT and healing ratio as markers of uterine scar healing 6 months after cesarean section comparing double layer with single layer techniques. They found that RMT increased significantly in double layer versus single layer modalities ( $9.95 \pm 1.94$  vs  $7.53 \pm 2.54$  mm). Also, the healing ratio was higher significantly in double layer versus single layer ( $0.83 \pm 0.1$  vs  $0.67 \pm 0.1$ ;  $p = 0.004$ ). They suggested that double layer uterine closure techniques (either locked or unlocked) have a lower incidence of cesarean scar niche. The cesarean scar niche means that uterine incision is incomplete with bad healing. One of the mechanisms of this poor healing can be the too much tension suture by the continuous running suture method either transverse or horizontal<sup>10</sup>. Another explanation of cesarean scar defect seen in the conventional double layered uterine closure is that horizontal direction of the suturing does not respect the postpartum uterine circumferential involution that means relaxation at the center and too much tension at the

corners of the suture line and so decrease in the oxygenation and tissue perfusion along the suture line<sup>14</sup>.

One of the benefits of the novel purse-string uterine closure method that it decreased the incidence of cesarean scar defect with a thicker residual myometrium when compared to the double layer technique. However, long term outcomes as subfertility, dysmenorrhea or postmenstrual spotting are not still well evaluated and needs more studies to be established, but we think that all niche-related complications will decrease together with the decrease in niche prevalence and so prediction of the best method of uterine closure regarding niche development and RMT will be of great importance<sup>17</sup>.

## Strengths and limitations

The first strength is that it is randomized blinded study, the second strength is that we excluded women with active labor to exclude factors that can affect the process of healing. Also, we delayed evaluation of uterine scar for 6 months after complete healing to be ensured. Modified Delphi method was used for uterine scar ultrasound examination. Finally, including women with primary CS avoided the bias of non-homogeneity of the population study.

This study had some limitations, especially that the patients' number were relatively small in the study groups. Another limitation point was the non-visibility of the niche in cases with retroverted uterus, this could be owed to the abnormal uterine position that makes the surface of the lower segment internal surface is aligned together that resulted in a smaller scar size and so limits the niche visibility. Another point of weakness was exclusion of women with active labor and cervical dilatation more than 4 cm, which could be a study bias as thin, dilated, effaced myometrium may have a different response as reported by **Osser et al.**<sup>19</sup> that advanced labor cesarean section increased the risk of cesarean scar defect. So, more randomized studies should take place to include patients in active labor.

## CONCLUSION

We found that purse-string uterine closure was associated with good uterine healing and lower incidence of uterine scar niche with no increase in any maternal morbidities. There was no significant difference in the calculated blood loss, however there was increased operative time in purse-string technique. Moreover, uterine scars in the purse-string uterine closure group were thicker significantly than in the double layer closure group.

**Conflict of interest:** the authors declare no conflict of interest.

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