#### ORIGINAL

# Determining the relationship between the type of suture used and the incidence and severity of cesarean scar defects (niche) in patients with a history of cesarean: A Double-blind randomized clinical trial

Determinación de la relación entre el tipo de sutura utilizado y la incidencia y gravedad de los defectos de la cicatriz de la cesárea (nicho) en pacientes con antecedentes de cesárea: Un ensayo clínico aleatorio doble ciego

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#### Abstract

*Introduction:* One of the complications of cesarean is cesarean section defect (Niche syndrome). One of the etiologies of this disease is incomplete or incorrect closure of the cesarean section, without closing the deep muscle layers due to improper sutures or not allocating enough time for this. The type of suture used to close the cesarean section is an important challenge in predicting this complication. Therefore, our study was performed to determine the relationship between the type of suture used and the incidence and severity of cesarean section defects in patients with a history of cesarean section.

*Methods:* This study was a prospective clinical trial. 50 patients underwent cesarean section and were randomly divided into two groups of 25 (chromic suture group and vicryl suture group). After 2 months, patients were called to the clinic and underwent vaginal ultrasound by a specialist doctor for cesarean section defects. The information included: the incidence of cesarean section defects, the type of suture used and the amount of cervical dilatation were recorded in a pre-prepared questionnaire. Data was collected by SPSS version 22 and data analysis was performed using frequency distribution tables and statistical tests.

**Results:** Of the 50 patients studied, 8 (16%) had Niche. Also, 9 patients (18%) had cervical dilatation. The results showed that there was a statistically significant difference between the frequency distribution of Niche according to the type of suture used in the studied patients and the frequency of Niche in patients who used chrome thread was significantly higher (p = 0.021). Also, no statistically significant difference was found between the frequency distribution of Niche in terms of cervical dilatation in the studied patients (p = 0.196). There was no statistically significant difference between the frequency distribution of cervical dilatation according to the type of suture used in the studied patients (p = 0.325).

**Conclusion:** According to results, can be concluded that the use of chromic thread is associated with more cesarean defects. Therefore, the use of Vicryl thread instead of chromic is recommended to reduce the incidence of cesarean scar defects.

Keywords: Cesarean, niche syndrome, suture.

#### Resumen

Introducción: Una de las complicaciones de la cesárea es el defecto de cesárea (síndrome de Niche). Una de las etiologías de esta enfermedad es el cierre incompleto o incorrecto de la cesárea, sin cerrar las capas musculares profundas debido a suturas inadecuadas o a no asignar el tiempo suficiente para ello. El tipo de sutura utilizado para cerrar la cesárea es un reto importante para predecir esta complicación. Por lo tanto, nuestro estudio se realizó para determinar la relación entre el tipo de sutura utilizado y la incidencia y gravedad de los defectos de la cesárea en pacientes con antecedentes de cesárea.

*Métodos:* Este estudio fue un ensayo clínico prospectivo. 50 pacientes se sometieron a una cesárea y se dividieron aleatoriamente en dos grupos de 25 (grupo de sutura crómica y grupo de sutura de vicryl). Al cabo de 2 meses, se citó a las pacientes en la clínica y un médico especialista les hizo una ecografía vaginal para detectar los defectos de la cesárea. En un cuestionario preparado de antemano se registraron los siguientes datos: la incidencia de los defectos de cesárea, el tipo de sutura utilizado y la cantidad de dilatación cervical. Los datos se recogieron con el SPSS versión 22 y el análisis de los datos se realizó mediante tablas de distribución de frecuencias y pruebas estadísticas.

**Resultados:** De las 50 pacientes estudiadas, 8 (16%) tenían Niche. Además, 9 pacientes (18%) tenían dilatación cervical. Los resultados mostraron que había una diferencia estadísticamente significativa entre la distribución de frecuencias de Niche según el tipo de sutura utilizado en las pacientes estudiadas y la frecuencia de Niche en las pacientes que utilizaron hilo de cromo fue significativamente mayor (p = 0,021). Tampoco se encontraron diferencias estadísticamente significativas entre la distribución de frecuencias de Niche en función de la dilatación cervical en las pacientes estudiadas (p = 0,196). No hubo diferencias estadísticamente significativas entre la distribución de la frecuencia de la dilatación cervical según el tipo de sutura utilizado en las pacientes estudiadas (p = 0,325).

**Conclusiones:** Según los resultados, se puede concluir que el uso de hilo cromado se asocia a más defectos de cesárea. Por lo tanto, se recomienda el uso de hilo Vicryl en lugar de crómico para reducir la incidencia de defectos de cicatriz de cesárea.

Palabras clave: Cesárea, síndrome del nicho, sutura.

### Introduction

Cesarean section is one of the women's most frequent surgeries in the world, which has increased considerably in recent years. According to the World Health Organization, 10-15% of all live births are delivered by cesarean section. Studies conducted in the last two decades have concluded that it is possible that Cesarean section to have many complications that some of which occur during a long period of time. Some of these complications are known such as Placenta Previa and Placenta Accreta. Cesarean section defect or isthmus cell or Niche syndrome are among the complications that have been currently highly considered<sup>1-3</sup>.

In fact, the disease is a sac-like myometrial defect in the anterior wall of the isthmus of the uterus (usually) that is caused by a previous cesarean section scar. This defect changes pathologically the wall of the myometrium that cause symptoms in the patient. In this disease, a hypoechoic zone is developed in the myometrium of the uterine isthmus. The size of this defect should be at least 2 mm. Some studies have defined myometrial defect as an echo-free-myometrial thickening higher than 1 mm<sup>4-6</sup>.

The actual prevalence rate of this complication is not recognized. The prevalence rate of isthmus cell in women who experienced one or more cesarean section was estimated to be between 24-70% in transvaginal ultrasound examinations and between 56-84% in Sonohysterography examinations in a systematic review study. This value has been higher in patients who have symptoms and has been estimated between 19.4% to 84%<sup>2,7</sup>.

No diagnostic criterion is detected to diagnose isthmus. It is possible to use various imaging methods such as ultrasound, Sonohysterography, histography, MRI to observe and examine the anterior abdominal wall and diagnose the disease<sup>8,9</sup>.

The type of suture applied to sew different layers of the body is an important challenge in predicting possible complications. Studies have compared different sutures in wound healing of various surgeries. Synthetic sutures such as Vicryl and natural sutures such as chrome are commonly applied in gynecological surgeries. Different studies have examined the results of using these two types of sutures in various sites such as Episiotomy repair, subcutaneous layer repair and fascia, etc., but no comprehensive study has been conducted in order to compare these two types of sutures in myometrial repair has been performed<sup>10</sup>.

The rate of cesarean section is increasing and consequently, the possible complications such as defects in the cesarean section scar, which can provide further complications such as uterine rupture or gynecological

complications such as non-pregnancy bleeding and infertility, etc. are also increasing, accordingly, it is effective to study possible influencing factors such as the type of suture applied in repair to improve the patients' quality of life<sup>11</sup>. Thus, the present survey was conducted to determining the relationship between the type of suture used and the incidence and severity of cesarean scar defects (niche) in patients with a history of cesarean as a double-blind randomized clinical trial.

## Materials and methods

#### Patient population

The study was conducted in 2020 and was a randomized and prospective clinical trial. We included all women who experienced cesarean section for the first time in the study, and excluded patients with a history of previous cesarean section, diseases such as diabetes, hypertension, pre-eclampsia, and multiple pregnancies.

#### Ethical consideration

This study was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran and registered with the protocol number "IR.SSU. MEDICINE.REC.1398.141" this trial was also registered in Iranian Clinical Trial Registry (IRCT20210423051055N1) and was conducted in accordance with the Declaration of Helsinki.

#### Intervention

We included 50 women who experienced cesarean section in this study and classified them in terms of inclusion and exclusion criteria in two groups of 25 people. One group experienced suture with chromium after cesarean section and the other group experienced suture with Vicryl. The study was double-blind and patients and physicians were not informed of the way of grouping them. Patients were asked to refer to the clinic at least 2 months after cesarean section, and specialist physician examined them by vaginal ultrasonography a for cesarean section defects (Niche). Niche diagnosis on ultrasound was based on the observation of a hypoechoic zone as a defect. The considered information included: detection of cesarean section defects (Niche), type of suture used and cervical dilatation rate were recorded in a pre-prepared questionnaire (consort flow diagram).

#### Sampling and blinding

The significant level is 5% and the test power is 80% and the minimum difference is 35% in the previous studies in the two types of sutures, accordingly, 25 people are required in each group (12). We included 50 women who experienced cesarean section in this study in terms of inclusion and exclusion criteria and randomly classified them into two groups of 25 people based on a table of random numbers. **Figure 1** shows the consort flow design of the present study.

#### Statistical analysis

All registered data were analyzed using SPSS software version 20 for Windows (SPSS, Chicago, IL). For descriptive statistics, the Mean  $\pm$  SD index was used for quantitative variables with normal distribution. The chi-square test and T-test was used for comparison of data between the two groups. P values of less than 0.05 were considered significant for all analyses.

Figure 1: Consort flow design of the present study.



### **Results**

The results achieved by the study conducted on the frequency distribution of cesarean section defects in the studied patients indicated that among 50 patients 8 (16%) had Niche and 42 patients (84%) had not Niche. The results achieved by the study conducted on the frequency distribution of cervical dilatation in the studied patients indicated that 9 patients had cervical dilatation.

The results achieved by the study conducted on the frequency distribution of niche according to the type of suture applied in the studied patients indicated that 7 (28%) had Niche among 25 people who used chrome for suturing. **Table I** shows other information. Analyzing table using Chi-Square test indicates that a statistically significant difference is observed between the frequency distribution of Niche in terms of the type of suture applied in the patients; so that, the frequency of Niche was significantly higher in patients who used chrome suture.

**Table II** shows the results achieved by the study conducted on the Niche frequency distribution in terms of cervical dilatation in the studied patients. Analyzing the table using Chi-Square test indicates that no statistically significant difference is observed between the Niche frequency distribution in terms of cervical dilatation in the studied patients.

**Table III** also shows the results achieved by the study conducted on the frequency distribution of cervical dilatation based on the type of suture in the studied patients. Analyzing Table using Chi-Square test indicated that no statistically significant difference was observed between the rates of cervical dilatation according to the type of suture applied in the studied patients.

Table I: Frequency distribution of	niche according to	the type of suture applied
in the studied patients.		

Niche	Type of suture		Total
	Chrome	Vicryl	
Have	7(28%)	1(4%)	8(16%)
Have not	18(72%)	24(96%)	42(84%)
Total	25(100%)	25(100%)	50(100%)
P-value		0.021	

 Table II: Frequency distribution of niche according to the cervical dilatation in the studied patients.

Cervical dilatation	Nich e		Total
	Have	Have not	
0-3.9	0(0%)	2(40%)	2(22.2%)
4-7.9	1(25%)	2(40%)	3(33.3%)
8-10	3(75%)	1(20%)	4(44.4%)
Total	4(100%)	5(100%)	9(100%)
P-value		0.196	

 Table III: Frequency distribution of cervical dilatation according to the type of suture applied in the studied patients.

Cervical dilatation	Type of suture		Total
	Chrome	Vicryl	
0-3.9	2(40%)	0(0%)	2(22.2%)
4-7.9	1(20%)	2(50%)	3(33.3%)
8-10	2(40%)	2(50%)	4(44.4%)
Total	4(100%)	5(100%)	9(100%)
P-value		0.325	

### **Discussion**

Our study was conducted in order to determine the relationship between the type of suture and the rate and severity of cesarean section defects in patients who experienced cesarean section. Our study that was conducted on 50 patients who experienced cesarean section showed that Niche frequency syndrome was 16% (8 cases). The prevalence rate of isthmus cell in women who experienced one or more cesarean section was estimated to be between 24-70% in transvaginal ultrasound examinations and between 56-84% in Sonohysterography examinations in a systematic review study. This value has been higher in patients who have symptoms and has been estimated from 19.4% to 84%<sup>2</sup>.

Various hypotheses have been introduced as the etiology of Niche syndrome. The factors such as the duration of delivery, cervical dilatation, stage of delivery and the site of cesarean section have been considered as effective factors in the detection of isthmus cell in one of these hypotheses<sup>7</sup>. We also examined the relationship between cervical dilatation and the detection of Niche

syndrome in our study. Although, the frequency of Niche cases was higher than 0-3.9 cm dilatation in 8-10 cm cervical dilatation, but this relationship is not statistically significant. It is possible to consider the limited number of samples as a reason for this insignificant relationship. The results achieved by another study conducted in 2018 on 321 women who experienced cesarean section and referred with gynecological complaints such as abnormal bleeding, indicated that previous cesarean section and retroflex uterine incisions are the most significant factors in developing Niche<sup>4</sup>.

Another hypothesis introduced in the etiology of Niche syndrome is incorrect surgical technique. Incomplete or incorrect closure of the cesarean section, without suturing the deep muscle layers because of using improper sutures or not spending enough time for this, causes to irregular closure of the myometrium and increases the risk of disease. The results achieved by our study indicates that 7 (28%) had Niche among 25 people who applied chrome for suturing, and a statistically significant difference was observed between the Niche frequency distribution according to the type of suture used in the patients; so that, the Niche frequency was significantly higher in patients who used chrome suture.

Other studies have explained that a relationship between sutures and the detection of Niche syndrome has been confirmed. Basbug et al. conducted a study in Turkey and examined the thickness of the myometrial layer 6-9 months after cesarean section by ultrasound in two groups repaired with monofilament and suture and multifilament. The results explained that applying monofilament suture affects better increasing the thickness of the myometrium layer at the site of cesarean section<sup>12</sup>.

The results achieved by a study conducted in Croatia in 2003 also explained that Vicryl group had the best repair and the lowest rupture and catgut group had the highest number of uterine ruptures<sup>13</sup>. Brocklehurst et al. conducted a study in 2002 and compared different techniques in cesarean section. Vicryl was most commonly used suture to repair the uterus<sup>14</sup>. A study conducted in Iran examined the comparison of complications because of using Vicryl suture and Catgut Plain in suturing the subcutaneous layer of the abdomen in cesarean section. The results showed that Vicryl showed less complications in subcutaneous layer repair<sup>15</sup>.

Nasrollahi et al. conducted a study on 690 pregnant women in three groups (subcutaneous repair with Plain suture, Vicryl and non-subcutaneous repair), and realized that the rate of wound dehiscence in three groups of subcutaneous repair with Plain suture, subcutaneous repair with Vicryl and no subcutaneous repair were 7%, 2.6% and 0.9%, respectively that there was a statistically significant difference in the rate of wound dehiscence in the three groups. Only two patients showed wound infection and both of them were in the subcutaneous repair group. There was no statistically significant difference in the detection of infection in the three groups<sup>16</sup>.

Ziaeeie conducted a study in Gilan on 102 pregnant women in two groups of 51, episiotomy with chromic suture and Vicryl suture repair, and realized that there was no statistically significant difference between two groups in terms of age, gestational age, number of deliveries, length of the second stage of delivery, the interval between delivery and episiotomy repair, the duration of episiotomy repair and the education level. The mean scores of redness at the repair site, edema, ecchymosis and secretion from the wound in the Vicryl group were significantly lower than the Catgut group, but no statistically significant difference was observed between the two groups in the item near the wound edges<sup>17</sup>.

Sekhavat et al. conducted a study in Yazd on 100 pregnant women in two groups of 50 people (Vicryl suture and control group) and realized that both groups were same in terms of age, number of deliveries, type of anesthesia and type of incisions. Suppurative infection (positive culture) was observed in 2 cases and 5 patients in control group and dehiscence were observed in 7 cases and 17 people in control group<sup>18</sup>. Similar findings have been reported in previous surveys<sup>19-21</sup>.

In general, as the findings of the mentioned studies show, it is possible to state that using Vicryl suture in cesarean section sutures has less complications.

## Conclusion

Our According to the results of the study, it can be concluded that there is a relationship between the type of thread used with the incidence of cesarean scar defects (niche), so that the use of chrome thread is associated with more incidence of cesarean scar defects. Therefore, the use of Vicryl thread instead of chrome is recommended to reduce the incidence of cesarean scar defects.

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# **Conflict of Interest**

The authors declare that there is no conflict of interest in the publication of this paper.

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