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Effect of the Single-Layer and Double-Layer Closure on Residual Myometrial Thickness, Isthmocele Occurrence, and Gynecological Disorders: A Prospective Randomized Controlled Study

Tek Kat ve Çift Kat Onarımın Rezidüel Miyometriyal Kalınlık, İstmosel Oluşumu ve Jinekolojik Bozukluklar Üzerine Etkisi: Prospektif Randomize Kontrollü Bir Çalışma

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Abstract

Aim: Physicians are making great efforts to decrease the long-term complications of the cesarean section such as placental adherent syndromes, uterine scar pregnancies, uterine rupture, abnormal menstrual bleeding, or isthmocele. There is a controversy about the closure technique of the cesarean incision. The purpose of that study was to compare the impact of single layer versus double-layer closure of the hysterotomy incision on the residual myometrial thickness, isthmocele, menstrual disorders, dysmenorrhea, and dyspareunia.

Material and Method: A prospective randomized cohort study has been performed in a tertiary center named Bursa Yuksek İhtisas Training Research Hospital between July – October 2021. Patients were randomly assigned to each procedure (1:1) to the Single Layer Locked Continuous group and Double-layer Continuous un-locked group as uterine closure technique. Patients were examined via transvaginal ultrasound to evaluate the isthmocele occurrence, residual myometrium thickness, and inquired about menstrual properties, dysmenorrhea, and dyspareunia. Patients were also divided into groups via underwent first cesarean and more than one cesarean.

Results: The numbers of the women whose hysterotomy incision was closed by single-layer locked continuous(SLLC) technique and double-layer un-locked continuous(DLUC) technique 68 and 71 respectively. There was no statistically significant difference in terms of demographic variables, obstetric history, post-operative complications, neonatal outcomes. The comparison of these groups revealed that there was no significant difference in terms of post-menstrual bleeding, heavy menstrual bleeding, post-coital bleeding, dysmenorrhea, dyspareunia. The incisional residual myometrial thickness was higher in the DLUC group have detected isthmocele (p: 0,941). Patients have also been categorized as women who undergone their first cesarean section (SLLC n: 33 versus DLUC, n:33) and more than one cesarean section (SLLC n: 35 versus DLUC, n:33). Comparing the patients in these subgroups also did not differ significantly in terms of isthmocele occurrence, menstrual disorders, or residual myometrial thickness.

Conclusion: No significant difference had occurred in terms of isthmocele incidence, or menstrual disorders comparing the single layer versus double-layer closure. However, women whose hysterotomy insicions were closed with double-layer unlocked continuous technique have a thicker resudial myometrium than single layer closure group especially women who underwent repeated cesarean.

Keywords: Single layer, double layer, cesarean, isthmocele, residual myometrial thickness

Öz

Amaç: Klinisyenler sezaryenin plasental yapışık sendromları, uterin skarlı gebelikler, uterin rüptür, anormal adet kanaması veya istmosel gibi uzun dönem komplikasyonlarını azaltmak için büyük çaba sarf etmektedirler. Sezaryen kesisinin kapatma tekniği konusunda bir tartışma mevcuttur. Bu çalışmanın amacı, rezidüel miyometriyal kalınlık, istmosel, adet bozuklukları, dismenore ve disparoni üzerindeki histerotomi insizyonunun tek katmanlı ve çift katmanlı kapatılmasının etkisini karşılaştırmaktı.

Gereç ve Yöntem: Temmuz – Ekim 2021 tarihleri arasında Bursa Yüksek İhtisas Eğitim Araştırma Hastanesi adlı üçüncü basamak bir merkezde prospektif bir randomize kohort çalışması yapılmıştır. Hastalar randomize olarak tek katlı kilitli devamlı onarım ve çift katmanlı kilitsiz devamlı onarım gruplarına ayrılmıştır. Hastalar istmosel oluşumunu, rezidüel miyometriyum kalınlığını değerlendirmek için transvajinal ultrason ile muayene edimiştir ve menstrüel özellikler, dismenore ve disparoni hakkında sorgulanmıştır. Hastalar ayrıca ilk sezaryen ve birden fazla sezaryen uygulanan gruplara ayrılmıştır.

Bulgular: Histerotomi insizyonu tek kat kilitli devamlı (TKKD) ve çift kat kilitsiz devamlı (ÇKKD) teknikle kapatılan kadın sayısı sırasıyla 68 ve 71'dir. Demografik değişkenler, obstetrik öykü, postoperatif komplikasyonlar, neonatal sonuçlar açısından istatistiksel olarak anlamlı fark bulunmamıştır. Bu grupların karşılaştırılmasında adet sonrası kanama, ağır adet kanaması, ilişki sonrası kanama, dismenore, disparoni açısından nalamlı fark olmadığı görülmüştür. İnsizyonel rezidüel miyometrial kalınlık p değeri 0,007 ile ÇKKD grubunda daha yüksekti. TKKD grubunda 6 hasta ve ÇKKD grubunda 5 hastada istmosel saptandı (p: 0,941). Hastalar ayrıca ilk kez sezaryen (TKKD n: 33'e karşı ÇKKD, n:33) ve birden fazla sezaryen (TKKD n: 35'e karşı ÇKKD, n:38) olan kadınlar olarak kategorize edilmiştir. Bu alt gruplardaki hastaların karşılaştırılması da istmosel oluşumu, menstrüel bozukluklar veya rezidüel miyometrial kalınlık açısından anlamlı farklılık görülmemiştir.

Sonuç: İstmosel insidansı veya menstrüel bozukluklar açısından, tek kat ile çift kat kapatma karşılaştırıldığında anlamlı bir fark meydana gelmemiştir. Ancak, histerotomi insizyonları çift kat kilitsiz devamlı teknikle kapatılan kadınlarda, özellikle tekrarlanan sezaryen uygulanan kadınlar, tek kat kapatma grubuna göre daha kalın bir rezidü miyometriyuma sahip bulunmuştur.

Anahtar Kelimeler: Tek kat, çift kat, sezaryen, istmosel, rezidü miyometrial kalınlık

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INTRODUCTION

Cesarean section is the most common surgery in the USA and probably in the whole over the world.^[1] The cesarean section used to be performed to save the life of the fetus whether the mother was about to die in ancient times and even considered as a mortal operation till the end of the 19th century.^[2] To date, the authors have been discussing the harm of the cesarean delivery which were performed via patients' requests due to the possible complications.[3] The World Health Organization has declared a recommendation that the maximum cesarean rate should not exceed more than 15% whereas the rate was almost more than 30% in most of the countries.^[4,5] That recommendation was to avoid the complications such as hemorrhage during the operation, wound site infection, endometritis, or adjacent organs injuries.^[6] Besides these issues, the long-term complications could be considered as related to consequent pregnancy complications and pregnancy independent complications. Uterine scar pregnancy, placenta previa, uterine scar rupture or dehiscence, intra-abdominal severe adhesions, and even hysterectomy were the long-term complications of the cesarean section related to concomitant pregnancies. ^[6-8] Chronic pelvic pain, incisional endometriosis, and cesarean scar defect were complications that were not related to pregnancy.^[6,9] Isthmocele which was also called as cesarean scar defect, niche, or pouch, is the disruption of the continuity of myometrium in where the hysterotomy had been performed for the cesarean operation. The symptoms have varied through abnormal uterine bleeding, prolonged bleeding, post-menstrual spotting, menorrhagia, chronic pelvic pain, dysmenorrhea, or even secondary infertility.^[10] The healing process of the patient might be the major factor of the formation of isthmocele, however, the dilation of the cervix before the operation, version of the uterus, and operational technique were the other accused reasons. There was no consensus on the closure technique of the hysterotomy scar incision to decrease or prevent the isthmocele process. The purpose of this present study was to evaluate the effect of single-layer locked continuous suture, and the double-layer un-locked continuous suture during cesarean on the formation of isthmocele, menstrual disorders, residual myometrial thickness.

MATERIAL AND METHOD

A prospective randomized cohort study was achieved in Bursa Yuksek İhtisas Training Research Hospital between 1 July – 30 September 2021 after the approval of the Bursa Yüksek Ihtisas Training and Research Hospital Ethical Committee (Project Number: 2011-KAEK-25 2020/06-02)

Women who were admitted to the delivery room were informed about the study and a written informed consult was obtained. Women who had an indication for cesarean delivery and accepted to be a participant were included in the study. The patients were included in the study in a manner of one by one respectively (One patient included in the single-layer suture group, and the next one into the double-layer suture group).

Patients' demographic properties, obstetric history, postpartum events and neo-natal outcomes were recorded. Cesarean section was performed by a resident under the supervision of a gynecologist. Women who had a cervical dilation of above 4 cm, premature rupture of membranes, twin pregnancy, placental anomaly, diabetes mellitus, or known connective tissue disease or immunodeficiency disorder were excluded from the study.

Generally, at the hospital where the study was held, the hysterotomy incisions were closed via single-layer closure technique using locked continuous multi-filament sutures. In the study group where the hysterotomy was closed as a double layer, the incision was closed un-locked and continuous multi-filament sutures. The endometrial edges have been included within the first layer, and the second layer had imbricated the edges of the first layer. The second layer was also un-locked continuous style.

Cesarean section indications, perioperative complications, and postoperative complications have been recorded. Patients were re-evaluated at the post-operative 6th month for isthmocele occurrence. All ultrasonography examinations were performed by the same physician with a Voluson 730 expert (GE Medical Systems) with a 4-9MHz transvaginal transducer probe in the early follicular phase of the menstruation period. Isthmocele has been diagnosed as the existence of an anechoic area at the previous cesarean scar with at least 1 mm depth as Vaate et all described.[11] The measurements have been obtained in the sagittal plane of the uterus. The length and the depth of the isthmocele, the residual myometrium thickness which was measured between scar tissue to the serosa of the uterus. To ensure compatibility with the literature, measurements were made as Stegwee et al described.^[12]

The women who underwent the first cesarean section and the women who had the second or more cesarean delivery have been evaluated individually. The primary aim of the study was to expose the effect of the uterotomy closure technique on the occurrence of isthmocele, residual myometrial thickness, menstrual symptoms, and dyspareunia.

Statistical Analysis

The sample size of the study was calculated by using NCSS statistical program by evaluating similar studies.^[12,13] (24). To achieve 80% power with 5% type 1 error to detect a minimum clinically significant difference at least 32 individuals must be recruited for each group. The SPSS (version 24) was used to perform the statistical analysis of the study. The normal distribution of the variables was determined by the Shapiro Wilks test. Normally distributed variables were expressed with mean and standard deviation, whereas non-normally distributed continuous variables were expressed as median (minimum-maximum). Mann Whitney U test was used to

compare non-normally distributed continuous variables between two groups while Chi-square or Fisher's exact test was performed for categorical variables. Fisher-Freeman Halton test was used to compare categorical data for more than two groups. An overall p-value of less than 0, 05 was considered a statistically significant result.

RESULTS

The number of patients included in the study was 139. The numbers of the women whose hysterotomy incision was closed by single-layer locked continuously (SLLC) style and double-layer un-locked continuous (DLUC) style were 68 and 71 respectively. The comparison of the major groups which could be assumed as SLLC and DLUC revealed that there was no statistically significant difference in terms of age, body mass index, number of gravidity and parity, previous abortion numbers, and indication of cesarean. The demonstration

of the patients' demographic and obstetric characteristics were presented in Table 1. The menstrual symptoms and the ultrasonography evaluation of the patients have exposed that there was no significant difference in terms of postmenstrual bleeding, heavy menstrual bleeding, post-coital bleeding, dysmenorrhea, dyspareunia, wound site infection. Although it could be considered clinically non-significant, the incisional residual myometrial thickness was higher (5,3mm versus 5 mm) in the DLUC group with a p-value of 0,007. The evaluation of these parameters was shown in Table 2. Six patients in SLLC and 5 patients in the DLUC group have detected isthmocele. The comparison of the groups did not differ significantly. The evaluation of the depth, the width of the isthmocele, and the residual myometrial thickness did not also differ statistically significantly. The demonstration of the ultrasonographic evaluation and comparison of the groups have shown in Table 3.

Table 1. Demonstration	of the patients' of	demographic and	d obstetric characteristics	5
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	Single layer locked continuous Group (n=68)	Double layer un-locked continuous (n=71)	P value
Age (year)	28.7± 5.3	30± 6.1	0.212
Body Mass Index (kg/m²)	26.2 (19.4-41.6)	26.8 (18.6-37.5)	0.836
Gravidity (n)	2 (1-8)	2 (1-6)	0.079
Number of cesarean (n)	2 (1-4)	2 (1-4)	0.892
Indication of cesarean (n) -History of cesarean section -Acute fetal distress - Malpresentation -Macrosomia - Cephalopelvic disproportion - Maternal indications -Others	33 (48.5%) 13 (19.1%) 5 (7.4%) 6 (8.8%) 8 (11.8%) 3 (4.4%) 0 (0%)	25 (35.2%) 15 (21.1%) 14 (19.7%) 8 (11.3%) 6 (8.5%) 2 (2.8%) 1 (1.4%)	0.277
Number of previous vaginal birth (n)	0 (0-5)	0 (0-5)	0.043
Previous abortion numbers (n)	0 (0-4)	0 (0-2)	0.281
Birth weight (gram, minumum-maximum)	3370 (2300-4400)	3300 (2500-5000)	0.950
Smoking (n,%)	7 (10.3%)	19 (26.8%)	0.023

Table 2. Comparison of the groups in terms of the symptoms and ultrasonographic evaluation.

	Single layer locked continuous Group (n=68)	Double layer un-locked continuous (n=71)	P value
Post-menstrual bleeding (n,%)	4 (5.9%)	3 (4.2%)	0.715
Heavy menstrual bleeding (>7 days) (n,%)	4 (5.9%)	5 (7%)	1.000
Post-coital bleeding (n,%)	3 (4.4%)	2 (2.8%)	0.676
Dysmenorrhea (n,%)	6 (8.8%)	11 (15.5%)	0.347
Dyspareunia (n,%)	12 (17.6%)	16 (22.5%)	0.612
Wound site infection (n,%)	3 (4.4%)	5 (7%)	0.719
Version of the uterus Anteversion (n,%) Retroversion (n,%)	55(80.9%) 13 (19.1%)	56 (78.9%) 15 (21.1%)	0.933
Incisional residual myometrial thickness (milimeter, minumum-maximum)	0.5 (0.30-0.70)	0.53 (0.31-0.69)	0.007

Table 3. Demonstration of the ultrasonographic evaluation and comparison of the groups.				
	Single layer locked continuous Group (n=68)	Double layer un-locked continuous (n=71)	P value	
Numbers of the women detected isthmocele	6 (8.8%)	5 (7%)	0.941	
Depth of isthmocele (milimeter)	2.9 (0.9-3.9)	3.2 (1.4-5.9)	0.792	
Width of isthmocele (milimeter)	3.4 (2.6-7)	9 (2.7-10.4)	0.177	
Residual myometrial thickness (milimeter)	4.7 (3.2-6.3)	4.3 (3.8-11.2)	0.931	

These two groups were also divided into two groups due to the number of cesarean performed. Women who underwent the first cesarean were also divided into two groups as SLLC (n:33) and DLUC (n:33). Patients who had more than one cesarean were also divided into two groups as SLLC (n: 35) and DLUC (n: 38). Comparison of these individually revealed that no statistically significant difference had occurred in terms of demographics variables, obstetrics history, isthmocele occurrence, menstrual disorders, dysmenorrhea, post-coital bleeding, and dyspareunia. Although there was no significant difference in terms of isthmocele incidence, closure of the hysterotomy incision via double layer un-locked continunous technique in the women who underwent repeated cesarean section have thicker residual myometrium. The evaluations of these patients were demonstrated in **Tables 4** and **5**. The technique of the measurements in women with isthmocele and without isthmocele have been demonstrated in Figure 1 and 2 respectively.



Figure 1. Transvaginal ultrasonographic view of the woman with isthmocele. isthmocele width isthmocele depth residual myometrial thickness

residual myometrial thickness Adjacent Myometrial Tissue

Table 4 Evaluation of the women who had first cesarean section and comparison of these patients by the different closure techniques of the uterus			
	First cesarean Single-layer locked continuous Group (n=33)	First cesarean Double layer un-locked continuous (n=33)	P value
Age (year)	27.4 ± 5.2	29.2± 7.1	0.243
Body Mass Index (kg/m²) (kg/m²)	26.1 (20.4-41.6)	25.9 (19.5-34.7)	0.812
Gravidity (n)	1 (1-8)	2 (1-6)	0.214
Previous abortion numbers (n)	0 (0-4)	0 (0-1)	0.964
Birth weight (gram, minumum-maximum)	3413.48 ± 516.73	3528.79 ± 506.42	0.363
Smoking (n,%)	1 (3%)	10 (30.3%)	0.008
Post-menstrual bleeding (n,%)	2 (6.1%)	1 (3%)	1.000
Heavy menstrual bleeding (>7 days) (n,%)	2 (6.1%)	1 (3%)	1.000
Post-coital bleeding (n,%)	0 (0%)	1 (3%)	1.000
Dysmenorrhea (n,%)	2 (6.1%)	3 (9.1%)	1.000
Dyspareunia (n,%)	5 (15.2%)	8 (24.2%)	0.536
Wound site infection (n,%)	2 (6.1%)	3 (9.1%)	1.000
Numbers of the women detected isthmocele	2 (6.1%)	2 (6.1%)	1.000
Incisional residual myometrial thickness (milimeter, minumum-maximum)	0.53 (0.37-0.70)	0.57 (0.31-0.69)	0.207

Table 5 Evaluation of the women who had more than one cesarean section and comparison of these patients by the different closure techniques of the uterus

	More than one cesarean Single-layer locked continuous Group (n=33)	More than one cesarean Double layer un-locked continuous (n=33)	P value
Age (year)	30.06 ± 5.26	30.68 ± 5.23	0.611
Body Mass Index (kg/m²) (kg/m²)	27.88 ± 5.42	27.96 ± 4.41	0.939
Gravidity (n)	2 (2-7)	3 (2-4)	0.132
Previous cesarean numbers (n)	2 (2-4)	2 (1-4)	0.397
Birth weight (gram, minumum-maximum)	3309 ± 453.29	3267.24 ± 375.84	0.669
Smoking (n,%)	6 (17.1%)	9 (23.7%)	0.688
Post-menstrual bleeding (n,%)	2 (5.7%)	2 (5.3%)	1.000
Heavy menstrual bleeding (>7 days) (n,%)	2 (5.7%)	4 (10.5%)	0.676
Post-coital bleeding (n,%)	3 (8.6%)	1 (2.6%)	0.344
Dysmenorrhea (n,%)	4 (11.4%)	8 (21.1%)	0.428
Dyspareunia (n,%)	7 (20%)	8 (21.1%)	1.000
Wound site infection (n,%)	1 (2.9%)	2 (5.3%)	1.000
Numbers of the women detected isthmocele	4 (11.4%)	3 (7.9%)	0.703
Incisional residual myometrial thickness (milimeter, minumum-maximum)	0.42 (0.30-0.65)	0.51 (0.39-0.62)	<0.001



Figure 2. Transvaginal ultrasonographic view of the woman without isthmocele Residual myometrial thickness

DISCUSSION

The cesarean section can be considered one of the most essential operations for the fetus and the patient. It provides a safe consequence for the baby, mother, and even for the obstetrician. Besides the serious complications that can occur even in a primary cesarean, that should be kept in mind that if it is not performed in the proper situations, the results could be more disastrous. The other biggest problem of the cesarean section is the possible risks during the consequent pregnancies especially the placental adherent syndromes. Isthmocele and the thin residual myometrial thickness are also consequences of the cesarean section. In this present study, the aim was to evaluate the effect of the cesarean section on these parameters. This was a unique study due to being the prospective randomized cohort trial. The limitation of the study was the small study population and the lack of long-term follow-up. The rate of the women who detected have isthmocele was 7.9%. This was a serious result due to the high cesarean rates worldwide. In a recent study, the rate of isthmocele was declared as 45.6%.^[13] This is a remarkable result due to the possible risks. The cesarean scar defect is the major risk factor for placenta accreata spectrum (PAS) which is one of the most difficult condition to operate in obstetrics and gynecology. In a recent opinion, it was depicted that PAS is related to uterine dehiscence, not placental invasion!.[14] The lower segment of the uterus consisted of more fibrous tissue and less muscle fiber than the upper segment of the uterus. Some researchers have declared that the incision at the lower segment may cause an inadequate healing process which leads to scar defects thus the hysterotomy incision could be done at the upper limit of the uterine lower segment for better healing and to decrease the risk of inadequate uterine scar healing.^[14,15] Besides the place of the hysterotomy during a cesarean, the patients' healing process is also the major step of the adequate consequences. In a recent study, it was declared that the healing process can continue up to six months or more,^[16] therefore the women underwent ultrasonography in the 6th month after the operation, and all

the ultrasonography examinations have been performed by the same physician in the present study.

The closure technique of the hysterotomy incision has been debated for years. Even the Cochrane Review exposed that the single-layer closure technique was related to faster operation time and less blood loss, however, a recent metaanalysis has remarked the inadequate powers of the studies. ^[17,18] In the present study, there was no statistically significant difference in terms of the abnormal menstrual bleeding, dysmenorrhea, dyspareunia, isthmocele occurrence, and the residual myometrial thickness comparing the single-layer locked continuous technique and double-layer un-locked continuous technique. In a contemporary study, the authors have investigated the uterine closure technique in the cesarean. They have performed transvaginal ultrasonography at the 6th week and the 24th month postoperatively and depicted that there was no statistical difference comparing the residual myometrial thickness and isthmocele occurrence. At the long-term follow-up, the double-layer closure group had higher residual myometrial thickness.^[19] Our results were similar to that study.

The occurrence of isthmocele has been declared with a rate of 45% to 86% in several studies.^[13,20] In the present study, the rate was 7.9%. The major reason for that difference might be the different considered thresholds for diagnosis. The increased cesarean rate was the major risk factor that can be easily estimated. The version of the uterus has been depicted as a risk factor, however, in the present study, anteversion and retroversion of the uterus did not differ statistically difference. ^[20] The single-layer closure of the uterus was also relieved as a risk factor for isthmocele in a systematic review.^[20] The rates of isthmocele in the single layer and double layer uterine closure were 8,8 % and 7% respectively. The rate was higher in the single-layer group however comparison of the group did not differ statistically. That might be related to the few diagnosed cases of isthmocele. That result was also similar to a recent meta-analysis.[21]

As aforementioned, the comparison of uterine closure technique was not a nowel investing subject. However, there was lacking prospective randomized controlled studies. The purpose of that study was to fill that issue. As the limitation of the study, more women should be included in the study, and longer follow-up is necessary. As a summary of the literature; comparing the double versus single closure technique: No statistical difference was detected in terms of isthmocele incidence,^[19,21] uterine dehiscence, and rupture,^[21-23] thicker residual myometrium in double-layer technique,^[19,21,22,24] less dysmenorrhea in double-layer closure.^[22]

Overall comparison of single and double technique no difference in uterine rupture, however, the risk increased in locked single technique than double-layer closure,^[23] less uterine rupture in the double-layer group.^[25] The operative time was 3.9 minutes longer and niche prevalence was 4.7% higher after double-layer closure.^[26] The double-layer

is associated with a thicker lower segment in the following pregnancy at the late third trimester of pregnancy.^[27] Single-layer closure was associated with more bladder adhesion yet similar abdominal adhesion. However, no data has been exposed about the injury of the bladder.^[28]

CONCLUSION

To sum up, the literature has exposed that endometrium should be included through the repair procedure. There was no strong evidence upon to support whether single layer closure or double layer closure technique. Women whose hysterotomy insicions were closed with double-layer un-locked continuous technique have a thicker resudial myometrium than single layer closure group despite the lack of significant difference in terms of isthmocele incidence, or menstrual disorders comparing the single layer versus double-layer closure. Although there was no significant difference in terms of isthmocele incidence, closure of the hysterotomy incision via double layer un-locked continunous technique in the women who underwent repeated cesarean section have thicker residual myometrium. Reviewing the literature might give us clues about decreasing using locked sutures while closing the incision. New data are needed to determine the appropriate place (the upper side of the lower segment) for hysterotomy in the cesarean section for secure and better healing.

ETHICAL DECLARATIONS

Ethics Committee Approval: This study was approved by Bursa Yuksek Ihtisas Training and Research Hospital Ethical Committee (Project Number: 2011-KAEK-25 2020/06-02).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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