IJMA

International Journal of Medical Arts

Volume 7, Issue 4 (April 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780

Available online at Journal Website
https://ijma.journals.ekb.eg/
Main Subject [Obstetrics and Gynecology]

Original Article

Effect of Autologous Platelet-Rich Plasma Injection in Preventing Cesarean Scar Niche

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Article information

Received: 23-11-2024

Accepted: 20-02-2025

DOI: 10.21608/ijma.2025.338632.2069

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Citation: Serria E, Abohashem UM, Oun AM. Effect of Autologous Platelet-Rich Plasma Injection in Preventing Cesarean Scar Niche. IJMA 2025 Apr; 7 [4]: 5555-5560. doi: 10.21608/ijma.2025.338632.2069.

ABSTRACT

Background: Due to the increasing rates of cesarean deliveries worldwide, the cesarean scar niche has emerged as a significant concern, leading to various obstetric and gynecological complications. Platelet-rich plasma [PRP] has gained considerable attention for its potential to promote angiogenesis, fibroplasia, and reepithelialization, ultimately facilitating tissue regeneration. However, to the authors' knowledge, there is a lack of studies investigating the efficacy of PRP injections in enhancing the thickness and completeness of uterine scars.

Aim of the work: This study aimed to assess the efficacy of autologous PRP injection in preventing the formation of post-cesarean section niche.

Patients and Methods: A prospective randomized controlled trial was conducted involving 58 full-term women who underwent cesarean sections. Participants were randomly assigned to two groups: the intervention group [n = 29] and the control group [n = 29]. After the closure of the uterine incision, the intervention group received an intra-myometrial injection of PRP, extracted from a sample of the patient's blood. In contrast, the control group received an intra-myometrial injection of normal saline [0.9%] along the same incision**.** Transvaginal ultrasound examinations were performed on women in both groups 12 weeks after cesarean delivery to investigate the presence of niches and related parameters.

Results: The rate of niche formation was 13.8% in the intervention group compared to 37.9% in the control group, demonstrating a significant difference between the two groups. When comparing the niche parameters of the PRP group with those of the control group, the PRP group exhibited significantly higher mean values for healing ratio and residual myometrial thickness, as well as significantly lower mean values for niche height and depth.

Conclusion: Intraoperative intra-myometrial injection of autologous PRP is an effective, and safe technique for enhancing myometrial tissue regeneration and thereby preventing CS niche formation.

Keywords: Cesarean Section; Clinical Trial; Niche; Platelet-Rich Plasma; Uterine Scar.

INTRODUCTION

Cesarean section [CS] is the most common major surgical procedure worldwide, with a progressively rising incidence [1]. The World Health Organization estimates that approximately 18.5 million women undergo this procedure annually [2].

In Egypt, mirroring global trends, the rate of cesarean sections has steadily increased, now accounting for 52.0% of all deliveries. This represents an increase of over 100.0% in the CS rate since 2005. The proportion of cesarean sections performed in institutional settings is 67.3%, more than double that of Egypt's regional neighbors, Jordan and Saudi Arabia. Currently, Egypt has the third highest cesarean section rate in the world, following the Dominican Republic [56.4%] and Brazil [55.6%] [3].

One potential consequence of a cesarean section is the development of a uterine niche, also called an isthmocele, diverticulum, or cesarean scar dehiscence [4]. This dehiscence is identified on ultrasound as an anechoic area within the myometrium, relative to the cesarean section scar, indicating a healing defect and discontinuity. An isthmocele is characterized by the presence of an anechoic gap that is at least 2 mm deep at the level of the cesarean scar. The existence of this space, measuring a minimum of 2 mm, distinguishes an isthmocele from a uterine scar, which is a physiological consequence of this surgical procedure [5].

The exact prevalence of cesarean scar niche formation remains uncertain, with estimates ranging from approximately 19.0% to 70.0% [6]. This figure may be an underestimation, as many women are asymptomatic, and clinicians may overlook the niche as a potential cause of symptoms due to unawareness [7].

The niche may present with gynecological symptoms, such as metrorrhagia and pelvic pain, affect fertility, manifest as an obstetric complication in a subsequent pregnancy, or remain completely asymptomatic. When a patient with an isthmocele becomes pregnant, there is an increased risk of abnormal implantation in the uterine scar area, leading to a condition known as Cesarean scar pregnancy. There are also risks associated with the placenta, including accreta, increta, and percreta, as well as the potential for uterine rupture [5].

Cesarean section wound healing is a complex biochemical process that involves various peptides and growth factors, including platelet-derived growth factor [PDGF], vascular endothelial growth factor [VEGF], transforming growth factor beta [TGF–β] isoforms, and tumor necrosis factor-alpha [TNF–α]. Any factor that impedes one or more of the four stages of surgical site repair comprising hemostasis, inflammation, proliferation, and remodeling, can predispose women to cesarean scar defects [8].

The injection of autologous platelet-rich plasma [PRP], derived from a patient's blood, represents an innovative approach in regenerative medicine. This technique involves the application of high concentrations of platelets, which release a variety of growth factors beneficial for tissue regeneration. Platelet-rich plasma contains platelet concentrations exceeding 1,000,000/µl in every 5 mL of plasma, along with a diverse array of cytokines and growth factors. Specifically, the growth factors include platelet-derived growth factor, transforming growth factor-β, and vascular endothelial growth factor, while the cytokines include interleukins [IL-1, IL-6, IL-8], matrix metalloproteinase [MMP-9], tumor necrosis factor-α, and interferon-α [9, 10]. To date, PRP has gained significant popularity across various fields of medicine, including orthopedics, sports medicine, plastic, cosmetics procedures, dermatology, and ophthalmology, to accelerate tissue repair and regeneration, resulting in excellent therapeutic and healing outcomes [10]. Given the association between niche formation and various obstetric and gynecologic complications, it is crucial to develop preventive strategies. Consequently, we hypothesized that platelet-rich plasma could serve as a simple preventive treatment that may reduce niche incidence following cesarean deliveries. Furthermore, there is a lack of studies examining the efficacy of autologous platelet-rich plasma injection in preventing post-cesarean section niche, as far as the authors know. Hence, the current study aimed to assess the efficacy of autologous platelet-rich plasma injection in preventing post-cesarean section niche formation.

PATIENT AND METHODS

Study design and settings: A prospective randomized single-blinded controlled trial was conducted in the obstetrics and gynecology department at Damietta Faculty of Medicine, Al-Azhar University, New Damietta, Egypt from July 2023 to March 2024.

Sampling Technique and patients' selection: A non-probability [convenient] sample was done. All patients fulfilling the following inclusion and exclusion criteria were recruited until the total target sample size was reached. Inclusion criteria were women undergoing elective cesarean delivery; term pregnancy [≥37 weeks of gestation; singleton pregnancy; and agreed to participate. Exclusion criteria involving those with thrombocytopenia [platelet count < 150×10^3 per µl]; presence of maternal morbidity including diabetes, pre-eclampsia, and hemolysis/ elevated liver enzymes/ low platelet count [HELLP] syndrome; obese women [BMI >30 kg/m^2]; women receiving anticoagulant therapy; previous history of uterine surgeries, excluding cesarean sections, such as myomectomy; the presence of placenta previa or uterine pathologies such as fibroid, polyp, and chorioamnionitis; and malformed uterus [uni-cornuate, bicornuate, septate uterus].

Sample size: The sample size was calculated using the G power program [version 3.1.9.4], setting the power at 0.8 and the significance value at 0.05. Previous data indicated that the percentage of the post-cesarean niche was 13.3 % and 46.7% in the PRP-injected and control groups, respectively [8]. Accordingly, a sample size of 29 women was calculated in each group.

Randomization, allocation, and masking: Randomization was done using a block design in which eligible patients were assigned to either an intervention or a control group. The randomization ratio was 1:1. The block size was 4 with the last block including only 2 patients. The allocation was concealed in sequentially numbered opaque sealed envelopes, using computer-generated randomization numbers [https://www.randomizer.org/#randomize], each containing one of two group assignments. All the envelopes were combined and shuffled thoroughly. Then, we placed them into a plastic container ready for use. These sealed envelopes, each corresponding to a study group, were given to the patients before entering the operating theatre to choose one and then the patient was assigned to the group specified in that envelope. The group assignments were masked to the patients. Allocation was never changed after opening the closed envelopes.

Study tools: Patients were subjected to the following:

Pre-operative: Complete history including personal history, any current medical complaint, past medical and surgical operations, as well as obstetric history including gravidity, and parity; Through clinical examination including general body examination [such as vital signs, and body mass index] and obstetric examination; Laboratory investigations include a complete blood count, coagulation profile, ABO, and Rh typing; ultrasound examination to ensure viability and determine the gestational

age, the presenting part, the position of the placenta, the amniotic fluid, as well as the estimated fetal weight using a convex transducer with a frequency of 4–8 MHz [Voluson P8- GE Ultrasound system. LTD]; In all cesarean sections, women received prophylactic antibiotics 30 minutes before skin incision in the form of a cefazolin vial. 2g, I.V. Also, before all cesarean sections, preoperative vaginal preparation with povidone-iodine scrub was done

In the operating room: All cesarean sections were performed by the same team of surgeons using the same technique of cesarean section [11]. After closing the uterine incision with continuous double-layer suture using No. 1 Vicryl, participants in the intervention group received an injection of platelet-rich plasma into the uterus [intra-myometrial] along the incision, while the control group received an injection of 0.9% normal saline into the uterus [intra-myometrial] along the incision.

Platelet-Rich Plasma Preparation: Under strict aseptic conditions, 10 ml of venous blood was drawn from the patient's peripheral vein 20 to 30 minutes before surgery using a syringe containing 2 ml of sodium citrate solution, an anticoagulant that prevents platelet activation and degranulation. This procedure resulted in a total volume of 12 ml. A two-stage centrifugation process was then performed using a rotary angle centrifuge. Initially, the sample was centrifuged at 4,000 rpm for 4 minutes, yielding three distinct layers: red blood cells at the bottom, a buffy coat in the middle [comprising platelet-rich plasma and white blood cells], and platelet-poor plasma [PPP] at the top. Subsequently, the top two layers were transferred to a separate tube without anticoagulant and centrifuged again at 4,000 rpm for 10 minutes to collect 2 to 3 ml of platelet-rich plasma at the bottom of the tube, which was then prepared for injection using an insulin needle **[12].**

Postoperative Evaluation: All study participants were invited to the gynecologic clinics 12 weeks after their surgery for a transvaginal sonographic assessment of the uterine scar. This evaluation utilized a C8-4v endocavitary transducer with a frequency range of 4–8 MHz [Voluson P8, GE Ultrasound System, LTD]. The uterus was examined for the presence of cesarean section scars using parallel sagittal planes from left to right, and it was also scanned in the transverse plane. When a niche was identified, it was measured in the sagittal plane where the niche exhibited the greatest depth. The measurements included the depth of the niche, the residual myometrium at the scar site, and the adjacent normal myometrium. A niche was defined as the hypoechoic part at the site of the CS scar with a depth of ≥ 2 mm as observed on transvaginal sonography [2]. The height of the cesarean scar niche was defined as the distance between the proximal and distal parts of the myometrium of the anterior uterine wall measured at the surface of the endometrium/endocervix of the posterior uterine wall. The depth was defined as the distance between the surface of the endometrial/endocervical layer of the posterior uterine wall to the tip of the hypoechoic triangle. The residual myometrial thickness was the distance from the tip of the hypoechoic triangle to the surface of the anterior uterine wall **[13].** The healing ratio was calculated by dividing the residual myometrial thickness by the adjacent myometrial thickness **[6].**

Data analysis and management: The collected data were analyzed using the Statistical Package for Social Sciences [SPSS] version 22. Categorical data were presented in frequency tables and percentages. The Chi-square test was used to examine the association between categorical variables. If the expected cell count was less than 5 in a four-cell table, the Fisher Exact Test [FET] replaced the Chi-square test. In cases where the expected cell count was less than 5 in tables with more than four cells, the Monte Carlo Exact Test was utilized. Numerical data were tested for normality using the Shapiro-Wilk test and were presented as mean ± standard deviation if parametric or median [minimum-maximum] if non-parametric. The independent sample t-test was used in parametric variables, whereas the Mann-Whitney test was used in non-parametric variables to compare groups. A p-value of ≤0.05 was considered statistically significant.

RESULTS

Table [1] shows no significant differences between the two groups in terms of age, gravidity, parity, gestational age [weeks], body mass index [BMI], as well as indications of CS. The most common indication for CS in both PRP and control groups was previous CS followed by breech presentation and cephalopelvic disproportion. Table [2] illustrates no significant difference between the PRP and control groups regarding hemoglobin level and platelet count pre- and post-operatively. In the 12th week follow-up of the patients after CS, the rate of niche formation was 13.8% [4 out of 29] in the PRP group compared to 37.9% [11 out of 29] in the control group, with a significant difference between both groups, as shown in **Figure [1].**

Regarding transvaginal ultrasound examination of the cesarean scar niche, **table [3]** showed that the mean values of niche depth and height were significantly lower in the PRP group compared to the control group, while the mean values of residual myometrial thickness and healing ratio were significantly higher in the PRP group than in the control group. The adjacent myometrial thickness showed no significant difference on comparing the two groups.

Table [1]: Demographic and clinical data of study participants

Variable		PRP group [n= 29]	Control group [n= 29]	p-value
Age [years] [Mean ± SD]		23.93 ± 3.88	24.67 ±3.84	0.418
Gravidity [Median [Min-Max]]		2 [1-5]	2 [1- 4]	0.546
Parity [Median [Min-Max]]		2 [1- 4]	2 [1- 4]	0.987
Gestational age [weeks] [Mean ± SD]		39.38 ± 1.57	39.48 ± 1.72	0.812
BMI [kg/m^2] [Mean ± SD]		27.35 ± 1.39	27.70 ± 1.49	0.335
Indications of CS	Previous CS	16 [55.2]	18 [62.1]	0.867
	Breech presentation	9 [31.0]	8 [27.6]	
	Cephalopelvic disproportion	4 [13.8]	3 [10.3]	

Table [2]: Hematological parameters of the study participants

	Parameter	PRP group [n= 29]	Control group [n= 29]	p-value
Hemoglobin level [gm/dl]	Preoperative	10.88 ± 0.37	10.74 ± 0.55	0.261
	Postoperative	10.44 ± 0.41	10.22 ± 0.56	0.092
Platelet count [×10^3/mm^3]	Preoperative	271.24 ± 19.12	267.24 ± 13.35	0.359
	Postoperative	266.28 ± 18.84	264.10 ± 14.00	0.620

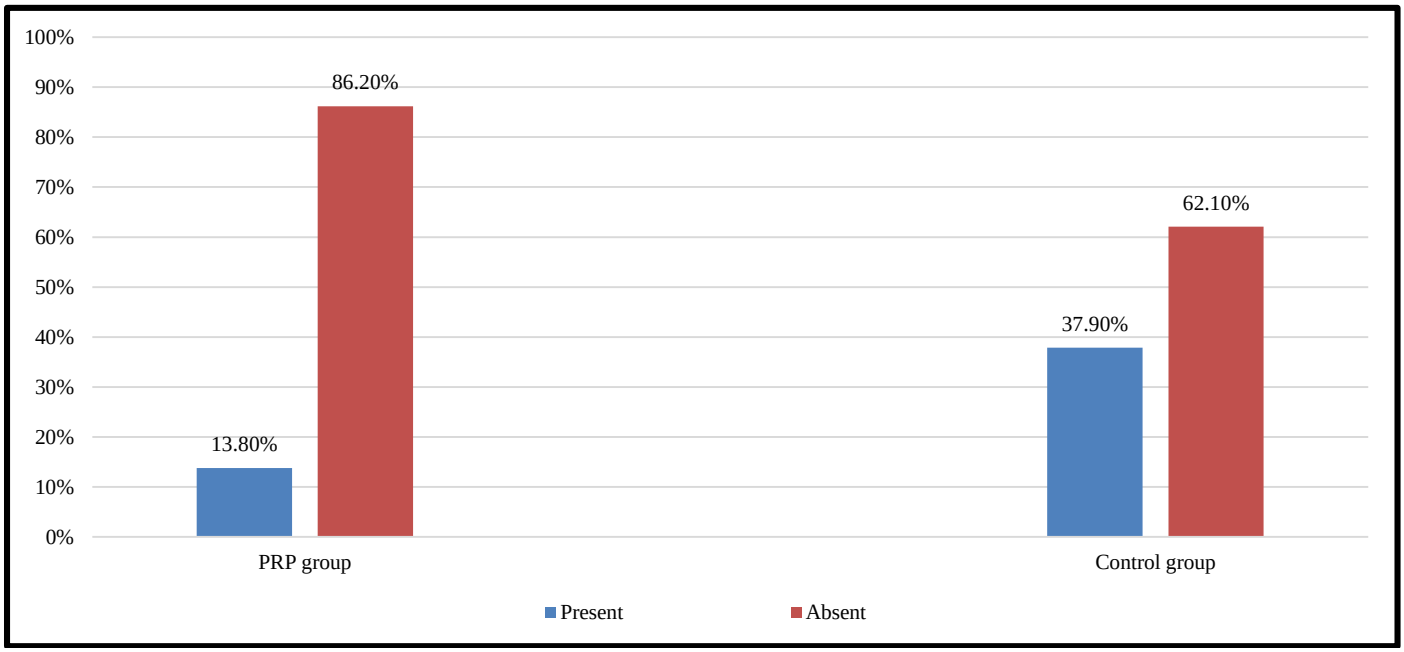

Figure [1]: Bar chart showing the ultrasound distribution of CS niche among study participants

Table [3]: Ultrasound parameters of niche among study participants

Parameter	PRP group [n= 4]	Control group [n= 11]	p-value
Depth [mm]	2.50 ± 0.18	4.51 ± 0.53	< 0.001**
Height [mm]	2.15 ± 0.34	5.40 ± 0.48	< 0.001**
Residual myometrial thickness [mm]	7.63 ± 0.80	5.34 ± 1.25	0.005*
Adjacent myometrial thickness [mm]	8.57 ± 0.75	8.38 ±0.59	0.584
Healing ratio [a]	0.89 ± 0.04	0.64 ± 0.15	0.007*

*$p \leq 0.05$ is statistically significant; **$p < 0.001$ is highly statistically significant; [a] Healing ratio: residual myometrial thickness/adjacent myometrial thickness.

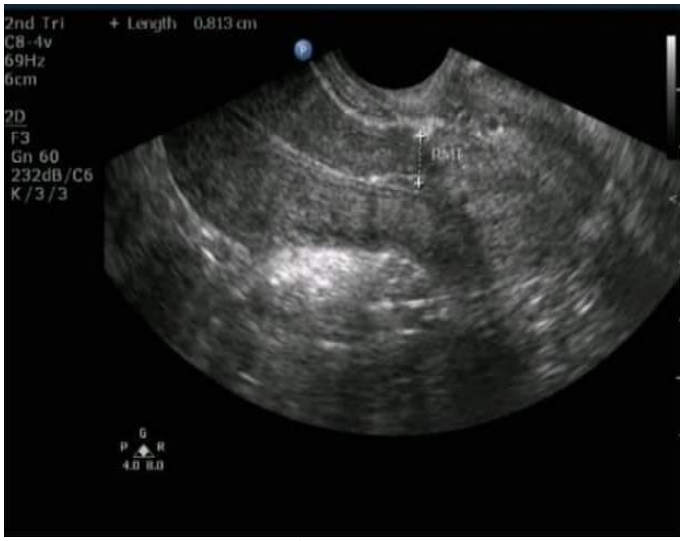

Figure [2]: Ultrasound measurement of residual myometrial thickness in the intervention group

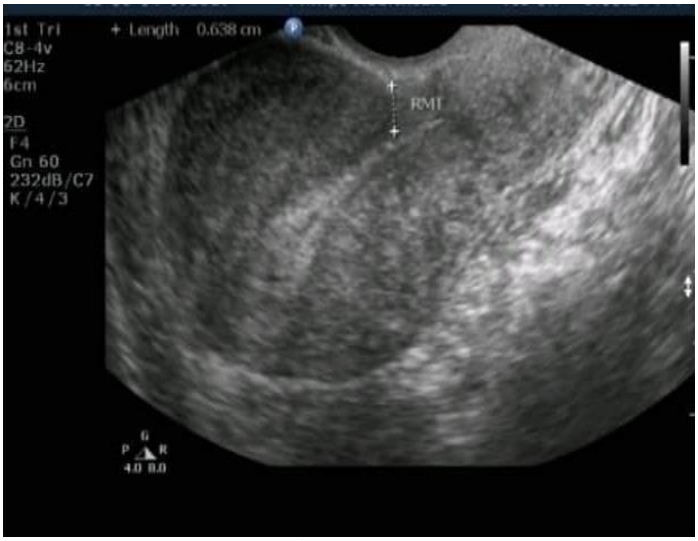

Figure [3]: Ultrasound measurement of residual myometrial thickness in the control group

DISCUSSION

With increasing rates of cesarean delivery worldwide, uterine scar defects have become a significant concern [14,15]. The emergence of various gynecological and obstetric complications in women with a history of cesarean scar defects has prompted researchers to improve diagnostic and management techniques [16].

The rate of CS niche formation in the current study was 13.8% in the intervention group [PRP group] compared to 37.9% in the control group in the 12th-week follow-up of the patients after CS. The reported prevalence of niche varied between 24.0% and 68.0% using Transvaginal Sonography in other relevant studies that included a random population of women with a previous history of cesarean deliveries [15, 17-20].

This discrepancy in the rates of CS niche between the current study and other studies could be due to variance in the criteria used for diagnosis, type of ultrasound machine used, the experience of the operator, the duration of follow-up after CS as well as the difference in the inclusion

and exclusion criteria of the enrolled participants. The lower rate in the intervention group could be related to injection with PRP intra-myometrial after the closure of the uterine incision. Platelet-rich plasma contains a significantly higher concentration of platelets compared to standard plasma. It is abundant in growth factors and cytokines that promote the proliferation, differentiation, and migration of various cell types, including fibroblasts, epithelial cells, endothelial cells, and mesenchymal stem cells, all of which play crucial roles in wound healing. Additionally, these factors are involved in hemostasis, angiogenesis, collagen synthesis, and the revascularization of damaged tissue [21]. Consequently, the application of PRP has gained significant attention in regenerative medicine, particularly within obstetric practice [22].

The current study revealed that compared to the control group, the PRP group [intervention group] exhibited a significantly reduced rate of cesarean section niche formation, characterized by smaller depth and height. Additionally, this group showed greater residual myometrial thickness and a higher healing ratio. Our findings demonstrated the beneficial effects of PRP injection on scar thickness and integrity during cesarean sections. This was in line with **Chaichian *et al.*** who carried out a randomized double-blinded, placebo-controlled clinical trial to evaluate the effectiveness of PRP in improving the thickness and completeness of the uterine scar [8].

Results showed a statistically significant lower number of niches with smaller heights and greater residual myometrium thicknesses were found in the intervention group compared to the control group. The creation of a niche in the PRP-treated group was almost one-fourth of the control group, and this difference was significant. Similarly, **Mikheeva *et al.*** conducted a randomized controlled trial to evaluate the effects of PRP injections on uterine scar formation following metroplasty in patients with placenta accreta spectrum [23]. The study results showed a significantly lower incidence of niche formation in the intervention group [31.2 %] compared to the control group [65.4 %] [$p<0.001$] and the residual myometrial thickness was significantly higher in the intervention group than in the control group.

Furthermore, **Martynov and his colleagues** in 2022 carried out a randomized controlled trial aiming at enhancing the results of laparoscopic metroplasty in patients with cesarean scar defects [24]. The study included two groups. Both groups were subjected to laparoscopic metroplasty. The second group was also injected with 5 ml of PRP into the myometrial repair zone. On comparing the two methods, the second group showed an increase in the newly formed scar thickness compared to the first by 3.9 mm and 2.9 mm, respectively, with a significant difference between both groups [$p = 0.029$].

Also, the current study findings were supported by previous studies conducted by **Tehranian et al., Wanas et al. and Kamel** to evaluate the effect of autologous PRP on wound healing after cesarean section. These studies demonstrated reductions in the Vancouver scar scale [VSS], visual analogue scale [VAS] of pain, as well as the redness, edema, ecchymosis, discharge, and approximation [REEDA] score in the intervention group [with PRP application] in comparison to the control group [25- 27].

On the contrary, other studies deny any beneficial effect of using PRP in different surgical procedures, such as muscle or tendon repair [28-30]. Possibly, these contradictory results might be attributed to different fields of surgical procedures as well as different patient selection criteria. Besides, most of the patients studied were in emergency traumatic situations, while the current study was conducted on patients undergoing elective surgery.

Strengths and limitations:

The study has several strengths involving the randomized trial design in which randomization was done using computer-generated randomization numbers, the absence of emergency surgeries, and the fact that all surgeries were performed under elective conditions by the same team of surgeons using the same technique of cesarean section. Another strength is that all postoperative evaluations were performed standard for women using the same transvaginal sonography method. Although the present study yielded important data, its limitations are worthy of mentioning, including a single-centric study with a small sample size and a short duration of follow-up.

Conclusion:

The current study findings revealed that the PRP group showed a significantly lower rate of CS niche formation with smaller depth and height, as well as more residual myometrial thickness and a higher healing ratio than the control group. Therefore, intraoperative intra-myometrial injection of autologous PRP is an effective, and safe technique for improving myometrial tissue regeneration and thereby preventing CS niche formation.

Recommendations and implications for future research:

The incorporation of PRP injection into the routine practice of obstetricians during CS is an easy-to-handle regenerative method for preventing CS niche formation. Additionally, our study needs to be confirmed with further multicentric studies with larger sample sizes and longer durations of follow-up to allow the implementation of the study results on a wider scale.

Ethics approval and consent to participate:

Approval was obtained from the Institutional Review Board [IRB] of the Damietta Faculty of Medicine at Al-Azhar University, and the study was conducted following the Declaration of Helsinki. Informed written consent was obtained from each participant sharing in the study. Participants were provided with detailed information regarding the study including the title, objectives, and procedures, as well as assurances of participant data confidentiality and anonymity with data never to be used for purposes other than scientific research. Participation in the present study was completely voluntary, and study participants were free to withdraw at any time.

Financial and non-financial activities and conflict of interest: None

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IJMA

International Journal of Medical Arts

Volume 7, Issue 4 (April 2025)

http://ijma.journals.ekb.eg/

P-ISSN: 2636-4174

E-ISSN: 2682-3780