

Case Series





Investigating the Successful Emergency Cerclage by Double-suture Method in the Presence of Prolapsed Amniotic Membrane: Case Series

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ABSTRACT

Background: Premature childbirth is the most common cause of neonatal morbidity and mortality. Cervical insufficiency is not an all-or-none phenomenon; however, it is a continuous variable that can contribute to preterm deliveries at different gestational ages. An emergency cerclage is recommended for those suffering from cervical incompetence with prolapsed membranes before 24 weeks of gestation.

Objective: The objective of this study is to assess the efficacy and outcomes of emergency cervical cerclage using the double-suture technique in women with advanced cervical insufficiency and prolapsed amniotic membranes, presenting in the late second trimester, with the aim of providing insights into its effectiveness in preventing preterm deliveries and improving neonatal outcomes.

Methods: This is a case series study on eight women treated with cervical cerclage presented in the late second trimester with advanced cervical insufficiency for whom the emergency cervical cerclage by a double-suture technique was conducted from September 2021 to February 2022 in Kowsar and Mehregan hospitals in Qazvin City, Iran. Women with a gestational age of 18 to 24 weeks, a prolapsed amniotic membrane, and cervical dilatation (greater than 3 to 4 cm) on the speculum test met the inclusion criteria. The exclusion criteria were pregnancy with twins, previous failure cerclage, preterm rupture of membrane, and clinical or biological signs of infection. This study aimed to report the outcome with emergency cerclage by double-suture method.

Findings: Cerclage was placed in eight women at a mean gestational age of 19.4 weeks. The average gestational age of delivery was 36.4 weeks of gestation by normal delivery.

Conclusion: The findings demonstrated that the double-suture method provides better cervical support in high-risk women for preterm birth and second-trimester loss. Nevertheless, this procedure requires a trained surgical team and operator. Given the small sample size of our study, it would be more informative if this study was carried out on a wider population sample and compared to other procedures of rescue cerclage.

Keywords:

Cervical cerclage, Cervical incompetence, Fetal death, Premature birth

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Introduction

rent pregnancy loss and premature delivery, along with the complications associated with it remain a serious issue [1]. Preterm labor accounts for nearly 70% of neonatal, 36% of infant deaths, and around 25% and 50% of long-term neurological sequelae cases in youngsters [2]. However, the progress in neonatal care results in a dramatic growth in neonatal continuity. The rising survival of extremely preterm babies is the main cause of the decrease in neonatal mortality. Nevertheless, premature infants are still more likely to suffer from neurological abnormalities that are linked to poor cognitive function and behavioral issues, such as cerebral palsy, and visual, and auditory difficulties [3, 4]. Recurrent pregnancy and premature delivery are because of a variety of multifactorial reasons. The main cause of such complications is cervical insufficiency, which affects 1% of all pregnancies and 8% of women with recurrent mid-trimester losses [5].

espite the recent medical advances, recur-

An important factor in the maintenance of pregnancy is the cervix. Furthermore, it functions as a mechanical blocker to prevent fetal membrane exposure and prolapse, and when paired with the mucus plug, it guards against ascending infection [6]. An incompetent cervix refers to a weak cervix that cannot remain closed until the day of birth. It is a mechanical blockage that prevents the fetal membranes from being exposed or prolapsing, and when paired with the mucus plug, it offers protection against spreading infection [6]. It appears as a painless shortening and softening of the cervix without contractions, which may also be accompanied by swollen fetal membranes [6, 7]. Several elements are implicated in cervical insufficiency, such as acquired mechanical injuries by cone biopsies, loop electrosurgical excision procedures, prior cervical trauma or uterine surgery, uterine or cervical malformation, or inflammatory processes by infection, abortion, sexually transmitted disease, or an unknown cause resulting in early shortening and dilatation [8, 9].

Recently, functional cervical insufficiency has become more common because of an increase in endocrine pathology, different pregnancy types, connective tissue dysplasia, and pregnancies following in vitro fertilization [2]. A constitutional lack of the components of the cervical connective tissue may be related to the pathogenesis of this illness [10], and an innate biological variation in cervical collagen, cervical elastin, and other structural components of cervical connective tissue that

withstand softening, effacement, and dilation. Congenital factors comprise type I pathologies of collagen synthesis and disorders of collagen regulation (Ehlers–Danlos syndrome, which elucidates the high number of cases of cervical failure within families) and uterine anomalies [11, 12]. Additionally, cervical conization, mechanical expansion of the cervical canal during curettage of the uterine cavity, or an improperly healed postpartum cervical laceration can all contribute to cervical insufficiency [11, 12]. Subsequent cervical insufficiency is also caused by emergency cesarean sections performed at full dilatation. According to new theories, the cervix's structural integrity may change due to inflammation and changes in the typical vaginal flora [13].

In pregnant women with cervical insufficiency, cerclage is the most common active intervention. Elective prophylactic cervical cerclage is typically performed in women with a history of unexpected second-trimester miscarriages and preterm delivery, or in subjects who have experienced cervical procedures performed before 16 weeks of gestation via vaginal or transabdominal access. Several studies have been linked with greater reductions in preterm birth or miscarriage [14].

Cervical cerclage may be performed if an ultrasound reveals a short cervix or cervical shortening. Cervical shortening occurs in normal pregnancies gradually throughout pregnancy. Most women have a median cervical length of 35 mm between 20 and 28 weeks of gestation, which will shrink by about 30 mm at term. Premature cervix shortening usually occurs in high-risk patients during the fourth or fifth month of pregnancy, after a significant number of second-trimester spontaneous abortions in the second trimester. There are various specific diagnostic criteria for cervical insufficiency; however, detecting cervical length less than 25 mm at or before 24 weeks gestation via transvaginal ultrasonography is a better predictor of premature birth than the patient's history alone [8, 9]. Conclusions taken from studies corroborate that the frequency of premature labor is not decreased by the cervical suture placed in women whose cervixes are shorter after an ultrasound examination and whose medical history suggests a low risk of preterm labor [5, 15, 16]; rather, it decreases with greater dilatation [17]. Alternative therapies, as demonstrated by evidence, such as the administration of antibiotics, progesterone, tocolytics, or indomethacin, have not consistently improved outcomes [8, 18].

If there are no signs of labor, infection, or considerable vaginal bleeding, but the patient has a dilated cervix and her membranes bulging into the vagina, a rescue cervical suture may be performed [19]. Pregnant women who have cervical dilatation and fetal membrane protrusion in the second trimester of their pregnancy are more likely to miscarry or give birth prematurely. Transvaginal ultrasound, manual examination, and speculum inspection can all detect a dilated cervix. A rescue cerclage is an emergency therapy that prolongs pregnancy [20]. It is possible to assess the effectiveness of emergency cerclage in a single randomized clinical trial. When compared to bed rest alone. The study by Althuisius showed that emergency cerclage can lower the risk of premature birth and newborn morbidity [21].

Emergency suture procedure

After excluding the membranes, the emergency suture was characterized as a suture applied over the cervix with a premature opening and possibly bulging of the membranes into the vagina. This suture is placed as an emergency treatment to extend the duration of the pregnancy [22]. Because inserting an emergency suture is a technically demanding technique, it should only be performed by a well-trained operator. The bulging membranes in the cervix make it difficult to properly place the cervical suture and increase the risk of iatrogenic membrane rupture during surgery. There are numerous ways to place emergency sutures; however, no study has demonstrated the benefit of such techniques [22, 23].

Over the past years, although some techniques have been tried and confirmed to be technically effective for draining a prolapsed fetal membrane, such as moist swabs, a unique uni-concave balloon, amniocentesis, and filling the bladder with physiological saline, insufficient data were available to support their routine use [24–26]. The main goal of this case study is to evaluate the results of the cervical cerclage, with a specific focus on the successful application of an emergency cerclage technique utilizing double sutures and a Foley catheter in pregnant women presenting with prolapsed amniotic membranes.

Materials and Methods

This study utilized a case series design to investigate the outcome of emergency cervical cerclage in pregnant women with prolapsed amniotic membranes during the second trimester (18 to 24 weeks of gestation). The study was conducted at the Qazvin referral hospitals of Kowsar and Mehregan over two years, from September 2021 to February 2022. Ethical considerations were taken into account throughout the study. The study population consisted of women who were enrolled and un-

derwent emergency cervical cerclage during the second trimester at the designated hospital within the specified time frame. A total of 12 patients were included in the study. To be eligible for participation, the patients had to pass several inclusion criteria, such as having a singleton pregnancy, no evidence of uterine contractions, no evidence of premature rupture of membranes, no clinical signs of membrane infection, no history of cervical incompetence, and no previous elective cerclage during the present or past pregnancies. Additionally, cervical dilation \geq 3-4 cm, cervical effacement \geq 50%, and a visible membrane observed during speculum examination were required to be included in the study.

The study did not include patients who met any of the following exclusion criteria: Women unwilling or unable to provide informed consent for participation, previous failure of cerclage, multiple pregnancies (twins or higher-order multiples), preterm rupture of membranes before the emergency cerclage procedure, and signs of chorioamnionitis, indicating infection of the fetal membranes.

Data collection was performed for the 12 patients who underwent emergency cervical cerclage within the study period. The collected data included patients' demographics, such as age, gestational age at the time of cerclage, patient weight, and body mass index.

All patients included in the study were diagnosed with cervical incompetence and presented with prolapsed amniotic membranes before reaching 24 weeks of gestation, with their cervical dilation ranging from 3 to 4 cm. The emergency cerclage procedure was performed to address the cervical incompetence and prevent further complications related to the prolapsed membranes. Following the emergency cerclage procedure, the participants were closely monitored through regular patient follow-ups until the end of their pregnancies. Among the initial 12 patients included in the study, four patients were subsequently excluded due to having cervical dilation exceeding 8 cm and cervical effacement ranging from 80% to 90%. These conditions rendered the surgeon unable to perform the emergency cerclage procedure in these cases. Descriptive statistics were used to summarize patient demographics and relevant clinical characteristics.

Preoperative preparation

The patients who fulfilled the inclusion criteria were hospitalized for an elective cerclage. Blood investigations, including complete blood count and C-reactive protein test, were obtained, and vital signs were moni-

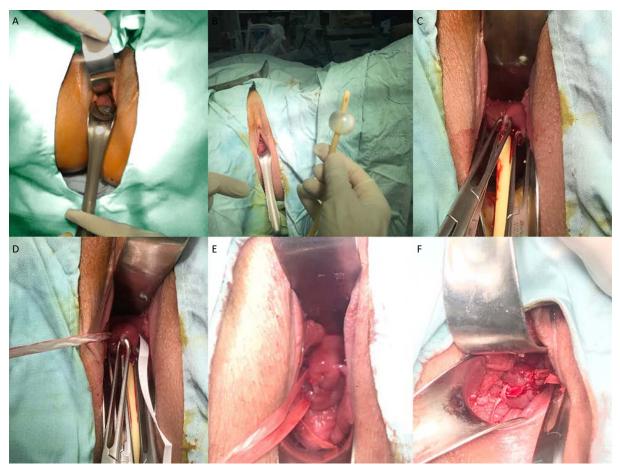


Figure 1. Photograph of the double-suture method

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A) Prolapsed fetal membrane in the vagina, B) Filling the Foley balloon with 50 cm³ of normal saline, C and D) Guiding the amniotic membrane upwards to the uterine cavity, E) Suturing around the internal OS, F) Around the external OS

tored throughout with attention to vaginal discharge, tenderness, and contraction. Prophylactic antibiotics (ampicillin [2 g], azithromycin [1 g], and Amp Proluton [250 mg/intramuscular]) were given to patients regularly during the perioperative phase.

Emergency double-suture procedure

Initially, these patients were admitted to undergo elective surgery due to reports of funneling and a shorter cervix; however, once a bulging amniotic membrane was discovered in the speculum exam, the planned operation was switched to an emergency cerclage in the operating room. Once general anesthesia was administered, the patient was placed in the Trendelenburg position to carefully restore the protruding membranes into the uterus. A Foley balloon catheter no. 24 was inserted into the cervical canal, simultaneously inflated with 50 cm³ of normal saline, and fixed. This approach avoids needle contact with the amniotic membrane during cerclage. The gynecologist then performed cerclage in two phases using

a Mersilene polyester fiber suture. Firstly, by using the McDonald's approach, loosing and tightening were done around the internal OS immediately. The Foley balloon was slowly drained and removed, followed by the last suture, and finally, the cerclage was knotted firmly. In the second step, the operator used the purse-type stitch for tightening around the external OS, respectively. The internal and external OS sutures were then knotted. In the end, the patient was shifted to recovery to receive continuing care (Figure 1).

The patients were closely observed in terms of any symptoms of surgical failure (such as vaginal bleeding, ruptured membrane, tachycardia, tachypnea, fever, abdominal pain, and odor discharge). Moreover, administration of a non-steroidal anti-inflammatory drug (the suppository of indomethacin 100 mg/BD, and ampicillin 2 g/QID, intravenous for the first 48 h) was considered. Those patients who were in 24 weeks took Amp betamethasone 12 mg, two doses per day. After discharge from the hospital, the antibiotic treatment with azithro-

mycin, and amoxicillin 500 mg/daily continued for one week. The center's outpatient system followed up on all patients. The patients were directed to the Obstetrics Department weekly for ultrasounds up to the end of pregnancy. In cases of condition changes or uterine contractions, the gynecologist ended the pregnancy.

Results

All eight patients were subjected to double-suture emergency cerclage (transvaginal), under general anesthesia. Four patients were omitted from the trial due to labor imminent in dilated cervix cervical 8-9 cm and effacement 90%, which made the surgeon unable to do the cerclage. The patients' ages ranged from 19 to 37 (average=31 years). The patients' average gestational age ranged from 18 weeks to 21 weeks, and the patient weight ranged from 61 to 71 kg, with a body mass index of 21-26. All patients survived. Preterm labor occurred in one patient. A baby was admitted to the neonatal intensive care unit and was discharged after 4 weeks. Meanwhile, seven newborns survived with satisfactory prognoses. The mean gestational age at admission and delivery time was 19.4 weeks and 36.4 weeks, respectively. All patients were delivered by normal delivery followed by labor pain. The average baby weight was 2.829 g. The patients were followed up to 48 h after childbirth (Table 1).

Discussion

This research described eight cases of effective emergency cerclage using the double-suture procedure in women with a bulging amniotic membrane. In these cases, we observed an average pregnancy extension of 19 weeks. Despite the dismal prognosis, this type of cerclage was beneficial in pregnancy prolongation for those individuals. It demonstrates satisfactory results for a continuing pregnancy, with a mean gestational age at birth of 36.4 weeks.

In a study by Szmulewicz et al. [27], successful outcomes of the emergency vaginal cervico-isthmic cerclage were also confirmed. Three people had their stitches placed in an emergency. The average pregnancy length was increased by 17 weeks without any neonatal complications. This technique involved performing an anterior semi-circular colpotomy at the cervicovaginal junction after gently pushing prolapsed membranes back into the uterus. A non-absorbable sling was placed and tightened around the cervico-isthmic junction. At a mean gestational age of 21.5 weeks, the emergency cerclage was carried out. Tanaka et al. [28] observed comparable results when investigating bridge sutures for effective McDonald cerclage outcomes. The initial stitch was introduced as a bridge suture in the internal OS, followed by a McDonald cerclage. They reported the first bridge suture

being performed with no problems, fetal loss, or preterm labor. The mean gestational age at cerclage was 22.5 weeks. Meanwhile, the mean gestational age at delivery was 30.7 weeks and the mean interval between cerclage and delivery was 8.2 weeks. Canadian researchers who examined the data of 12 patients receiving emergency cervical cerclage found the same findings. They achieved an average pregnancy prolongation of 7 weeks [29] compared to our data, which is a shorter time scale.

In the study by Saremi et al., the modified McDonald's cerclage was presented. The suture was placed using this technique in the uppermost part of the cervix. The bladder and vagina are raised to prevent injury to the sutures as much as possible. Without going inside the bladder, a semicircle was constructed around the anatomical border of the organ. Cerclage is carried out at the most advanced level and close to the inner OS [30]. We employed twin sutures in our procedure. The upper or right anterolateral and then the left anterolateral (2 and 10 o'clock) were meticulously sutured as part of the modified McDonald cerclage. The exterior OS was sutured in the following stage. The filling Foley catheter passes through the cervix and leads the amniotic membrane into the uterine cavity, thereby reducing the rate of rupture of both the bladder and the amniotic membrane. Subsequently, the external OS was sutured. The filling Foley catheter through the cervix led the amniotic membrane into the uterine cavity to reduce the rate of rupture of the amniotic membrane and the bladder.

Capmas et al. [31] did a retrospective multicentric analysis on 135 patients with protruding membranes between the ages of 18 and 23+6 weeks of pregnancy. For patients who had previously failed McDonald's cerclage, they conducted vaginal cervico-isthmic cerclage. Cervico-isthmic cerclages are inserted higher above the internal cervical opening than other types of cerclages. They found no statistically significant difference in expenses between classic cerclage and vaginal cervicoisthmic cerclage groups. The other issue was that the vaginal cervico-isthmic cerclage procedure had a greater risk of fetal death and preterm labor. The double-suture associated with the Foley catheter can be valuable in qualifying patients for the rescue cerclage procedure. A skilled surgeon is needed for this procedure. Further clinical research needs to be done to assess the outcomes and drawbacks of this approach and combine it with alternative approaches. This procedure necessitates the use of a skilled surgeon. More clinical trials should be conducted to evaluate the results and complications of this treatment, as well as to compare it to other methods.

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Table 1. Emergency cerclage in pregnancy: Patient data and outcomes

Type of Delivery	At 39 weeks by normal vaginal de- livery	At 36 weeks by normal vaginal de- livery	At 37 weeks+5 days by nor- mal vaginal delivery	At 31 weeks and 6 days by normal vagi- nal delivery
Weight	3200 g	2830 g	2980 g	1950 g
Apgar	Baby boy; Apgar 9/10/10	Baby boy; Apgar 8/9/10	Baby girl; Apgar was 9/10/10	Baby girl; Apgar 7/8/9 NICU for 28 days
Diagnostic Method	Emergency cerclage tech- nique	Emergency cerclage tech- nique	Emergency cerclage tech- nique	Emergency cerclage tech- nique
Primary Symptom	 Cervical dilation 3-4 cm with prolapsed membranous in speculum exam No fever, contraction, discharge ESR and CRP at normal levels 	Funneling cervix with cervical length 22 mm reported in sonogaraphy Cervical dilation (4-5 cm) and with prolapsed membranous No fever, contraction, discharge ESR and CRP at normal levels	 Cervical length 19 mm reported in sonography Cervical dilation 4-5 cm and with prolapsed membranous No fever, contraction, discharge ESR and CRP at normal levels 	 Cervical length 30 mm reported in sonography Cervical dilation 4-5 cm and with prolapsed membranous No fever, contraction, discharge ESR and CRP at normal levels
Body Mass Index (kg/ m²)	24	26	25	26
Fundamental Disease	Dilation and curet- tage Infertility for 10 years	Infertility for 4 years Laparoscopy and salpingectomy for an ectopic preg- nancy	No history of infertility Dilation and curettage due to miscarriage	Infertility for 10 years History of preterm labor At the moment treatment of pro- luton weekly due to the history of preterm labor
Gestational Weeks	18 weeks Cervix length=19 mm	18 weeks+5 days Cervix length=19 mm	18 weeks+2 days Cervix length=19 mm	21 weeks Cervix length=18 mm
Pregnancy and Child- birth Times	G2P0Ab;1	G3P0Ab;2	G2P0Ab;1	G4P1Ab;2
Age (y)	58	31	19	37
Pa- tient No.	t t	8	m	4

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Type of Delivery	At 36 weeks and 3 days by normal vagi- nal delivery	At 36 weeks and 3 days by normal vagi- nal delivery	At 37 weeks and 3 days by normal vagi- nal delivery	At 36 weeks and 5 days by normal vagi- nal delivery
Weight	2800 g	2950 g	3050 g	2870 g
Apgar	Baby girl; Apgar 8/9/10	Baby girl Apgar was 9/9/10	Baby boy; Apgar 8/9/10	Baby boy; Apgar 8/9/10
Diagnostic Method	Emergency cerclage tech- nique	Emergency cerclage tech- nique	Emergency cerclage tech- nique	Emergency cerclage tech- nique
Primary Symptom	 Cervical length 30 mm reported in sonography Cervical dilation 4-5 m and with prolapsed membranous No fever, contraction, discharge ESR and CRP at normal levels 	 Cervical length 22 mm reported in sonography Cervical dilation 4-5 cm and with prolapsed membranous No fever, contraction, discharge ESR, and CRP at normal levels 	 Cervical length 19 mm reported in sonography Cervical dilation 5-6 cm and with prolapsed membranous No fever, contraction, discharge ESR, and CRP at normal levels 	 Cervical length 30 mm reported in sonography Cervical dilation 6 cm and with prolapsed membranous No fever, contraction, discharge ESR, CRP at normal levels
Body Mass Index (kg/ m²)	25	26	23	22
Fundamental Disease	Secondary infertil- ity for 6 years	No history of infertility Dilation and curetage twice due to miscarriage	No history of infertility	No history of infertility Dilation and curettage due to miscarriage
Gestational Weeks	19 weeks +4 days Cervix length=20 mm	22 week+4 days Cervix length = 23 mm	18 weeks Cervix length=19 mm	19 weeks+6 days Cervix length=19 mm
Pregnancy and Child- birth Times	G3P1Ab;1	G4P1Ab;2	G1PoAb;0	G2P0Ab;1
Age (y)	37	36	78	29
Pa- tient No.	۵	9	~	∞

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Abbreviations: ESR: Erythrocyte sedimentation rate; CRP: C-reactive protein; NICU: Neonatal intensive care unit.



Conclusion

The results of the study show that emergency cerclage significantly lowers the rate of preterm birth in women who have painless cervical dilatation and protruding fetal membranes. By efficiently extending the gestational age, this technique contributes to better results for the mother and the infants. One of the key advantages observed in our study is the significant reduction in preterm birth rates following emergency cerclage. By addressing cervical insufficiency promptly, we could provide critical support to the cervix, preventing its further dilation and mitigating the risk of premature labor. This positive impact on the rate of preterm birth is of paramount importance, as it directly correlates with better neonatal outcomes and increased survival rates for newborns.

Furthermore, we observed that emergency cerclage did not increase the risk of chorioamnionitis, a condition characterized by infection and inflammation of the fetal membranes and amniotic fluid. This finding highlights the safety of the procedure, as it did not exacerbate the risk of potentially harmful infections during pregnancy.

Additionally, our study revealed that emergency cerclage did not lead to an increased incidence of preterm premature rupture of membranes. This is a significant finding, as maintaining the integrity of the amniotic membranes is crucial for the well-being of the developing fetus and preventing complications associated with preterm birth.

The results of this study underscore the importance and efficacy of emergency cerclage in managing advanced cervical insufficiency during pregnancy. By reducing preterm birth rates, prolonging gestational age, and safeguarding against complications, such as chorioamnionitis and preterm premature rupture of membranes, emergency cerclage emerges as a valuable intervention to enhance maternal and neonatal outcomes.

Study limitations

While these findings are promising, it is critical to recognize the study's limitations, which include its small sample size and potential confounding factors. Therefore, further large-scale studies and randomized controlled trials are warranted to validate and strengthen the evidence presented here.

Study recommendations

Our study contributes valuable insights to the medical community, reinforcing the significance of emergency cerclage as a viable and effective intervention in managing cervical insufficiency and ultimately leading to improved pregnancy outcomes and neonatal survival rates. By continuing to explore and refine such interventions, we can continue to advance the field of obstetrics and provide the best possible care to expectant mothers and their newborns. However, due to the lack of consensus that exists among observational studies regarding the operative treatment of draining a prolapsed fetal membrane, further studies with a higher level of evidence are needed. Further larger-scale studies with a controlled design and statistical analysis, such as randomized controlled trials, are warranted to corroborate these findings and establish more robust evidence regarding the effectiveness and safety of emergency cervical cerclage in this specific population. The results of this study may guide clinicians in making informed decisions and improving the management of highrisk pregnancies in similar cases.

Ethical Considerations

Compliance with ethical guidelines

The participants provided their informed consent before the patients were included in the trial. The Research Ethics Committee of Qazvin University of Medical Sciences approved this study (Code: IR.QUMS. REC.1399.247). Every experiment was carried out in compliance with all applicable laws and rules.

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Authors' contributions

Supervision: Masoumeh Dadashaliha; Data organization and original draft preparation: Ali Emami: Methodology, writing, review, and editing: Somayeh Fallah.

Conflict of interest

The authors declared no conflict of interest.

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