Original Article

# Sublingual Nitroglycerin in Managing Retained Placenta: A Placebo-controlled Trial

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## Abstract

**Background:** Retained placenta poses significant surgical and hemorrhagic risks, influencing 1%–3% of births. Because it relaxes the uterus, a nitric oxide donor substance called nitroglycerin (NTG) has gained attention as a possible treatment. **Objectives:** This study aimed to evaluate the safety and effectiveness of sublingual NTG versus placebo in the treatment of retained placenta. **Materials and Methods:** A single-blind randomized controlled study was carried out at Babylon Teaching Hospital for Maternity and Children, Babylon, Iraq. A group of 50 females who had a definite retained placenta was assigned to receive either a placebo ($n$ = 25) or 1 mg of sublingual NTG ($n$ = 25). The main outcome was successful placental delivery without the need for surgery. Inside the delivery room, blood pressure, heart rate, blood loss, and side effects were the indicators for secondary outcomes. **Results:** Compared with the placebo group (20%), the NTG-treated group had considerably higher effective placental detachment rates (72%; $P$ = 0.001). There were no appreciable variations in blood loss or placental detachment time across the groups. Compared with the placebo group (8%), those who took NTG (56%) experienced headaches much more frequently ($P$ = 0.0002). **Conclusion:** If sublingual NTG is used to treat retained placenta, it may be more successful than a placebo, although there is a higher chance of headaches. More studies are required to validate these results in more extensive multicenter trials.

**Keywords:** Nitroglycerin, placental detachment, retained placenta, sublingual

## Introduction

Retained placenta is defined as the failure of the placenta to be expelled from the uterus within a specified time frame after delivery, typically exceeding 30 min following an actively managed third stage of labor or 60 min after a physiological management approach. This condition can lead to significant maternal morbidity and is a major cause of postpartum hemorrhage (PPH), which occurs in approximately 1%–3% of deliveries.[1,2] Several risk factors have been identified that increase the likelihood of retained placenta. Extended administration of oxytocin during labor can interfere with normal uterine contractions, contributing to retained placenta. Women who have had multiple pregnancies are at greater risk due to potential uterine atony or structural changes in the uterus. Deliveries occurring before term are associated with higher rates of retained placenta.[1,2] Previous surgical procedures on the uterus can lead to scarring or adhesions that complicate placental separation.[1-3] Structural abnormalities of the uterus, such as a bicornuate uterus, can hinder normal placental detachment.[4] A history of retained placenta in prior deliveries significantly increases the risk in subsequent pregnancies.[1,2]

One important contributing cause of obstetric morbidity is retained placenta, which affects 1%–3% of vaginal deliveries.[5] It is characterized by the inability of the placenta to separate independently during the third stage

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of labor. Excessive PPH before placental separation or remnants of placental tissue following partial expulsion are two possible manifestations.[1] If left untreated, this condition is the second most common cause of PPH and entails significant surgical and hemorrhagic risks.[6]

The present intervention for care is based on surgical processes that increase the potential for hemorrhage and infection, such as manual placental removal and/or uterine curettage.[1] Nevertheless, not everyone can afford these interventions, particularly in low- or middle-income states, where retained placentas are linked to high frequencies of illness and death.[5] Hence, there is an urgent need for alternative interventions for retained placentae that are practical, safe, and suitable in all cases.

Nitric oxide (NO) donors, like nitroglycerin (NTG) under the tongue (glyceryl trinitrate), appear to be a promising therapeutic option, according to new research.[7] The uterus was successfully relaxed by both injectable and sublingual NTG administration.[5] This facilitates manual removal of the placenta or permits regulated cord traction to ensure complete delivery.[1,5,6] However, in two later investigations where intravenous NTG[1] and sublingual NTG failed to achieve effective medical handling of the retained placenta, these outcomes were not consistently duplicated.

NTG must address at least one underlying pathophysiological mechanism to be demonstrably effective in managing retained placentas. In cases of a detached placenta trapped by a constricted myometrial ring, NTG might potentially relax local muscles, facilitating placental detachment. Farley *et al*.[8] proposed that NO-mediated contractions and relaxations along the longitudinal axis of human chorionic villi could serve as an NTG-mediated alternative mechanism for placental release. However, for morbidly adherent placentas, currently available NO donors such as NTG are unlikely to achieve release, necessitating surgical intervention as the primary treatment, as it relaxes the uterus. Moreover, while NTG can be beneficial in certain obstetric scenarios, its potential risks related to PPH necessitate careful monitoring and management. Understanding these risks is crucial for healthcare providers to mitigate complications and ensure maternal safety during and after childbirth.[1,9]

While preliminary evidence suggests NTG's potential for the medical management of retained placenta, a double-blind, randomized, placebo-controlled trial is warranted to definitively determine its efficacy. This study addressed the limitations of previous investigations and provided robust data for clinical practice guidelines.

## Materials and Methods

### Study setting

A single-blinded, prospective, randomized controlled trial was conducted to achieve a comparative understanding of the effectiveness and safety of sublingual NTG versus placebo in managing retained placentas. The study was conducted between March 2022 and December 2022 at the Department of Obstetrics and Gynecology at the Babylon Teaching Hospital for Maternity and Children.

### Ethical considerations

The Scientific Committee of Obstetrics and Gynecology, the Department of Obstetrics and Gynecology at the University of Babylon, the College of Medicine, the Scientific Division of Obstetrics and Gynecology of Babylon Teaching hospital for Maternity and Children, and the Iraqi Council of Medical Specialization all provided ethical approval before the start of the study.

### Patient selection

Females who met the following criteria were enrolled in the study: singleton gestation, confirmed retained placenta after active management of the third stage of labor (defined as placenta not released 30 min after delivery), gestational age of at least 24 weeks, hemodynamic stability, and printed informed consent obtained from both the patient and a family member.

Women with the following conditions were excluded from the study: serious maternal medical conditions such as severe preeclampsia or cardiac disease, suspected placenta previa or accreta/increta identified on ultrasound, and rupture of membranes. Hemodynamically unstable women were also excluded to avoid contraindications associated with NTG administration.

### Data collection

A comprehensive medical history was obtained from each participant, including gestational age, obstetric history (parity, previously retained placenta, etc.), risk factors for retained placenta (uterine scarring and labor induction/augmentation), type of labor (spontaneous, induced, or augmented), general and vital sign examination findings, and details of abdominal and pelvic examination.

### Interventions

Participants were randomly allocated (using a randomization method not specified in the provided details) into two groups of 25 each: the NTG group, which received 1 mg sublingual NTG administered as two 0.5 mg pills (Bristol®, UK), and a placebo group, which received two pills containing saccharine.

### Blinding

The study was designed as single-blinded, meaning that participants were unaware of whether they received

NTG or a placebo. However, the description does not explicitly mention the blinding of the healthcare providers administering the intervention.

### Delivery management

All patients underwent standardized active management of the third stage of labor, which included administration of uterotonic agents, controlled cord traction, and uterine massage, to confirm that the diagnosis of retained placenta was not due to insufficient management but was intrinsic to the patient's condition.

Baseline pulse rate and arterial blood pressure were evaluated before the sublingual administration of the assigned intervention (NTG or placebo). After 5 min, controlled and gentle cord traction was applied for no more than 5 mi.

Successful delivery was defined as complete placental expulsion within the delivery room, without requiring surgical intervention under anesthesia. Patients in whom delivery of the placenta was unsuccessful were transferred to the operating room for manual removal.

### Outcome measures

- Primary outcome: Successful placental delivery within the delivery room without operative intervention.
- Secondary outcomes: pulse rate and arterial blood pressure at 5 and 15 min after interventional medication, blood loss (measured using a combination of gravimetric and direct methods), and side effects, particularly headaches.

### Statistical investigation

Data analyses were performed using the Statistical Package for the Social Sciences, version 22 software (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated, including mean, standard deviation, range, frequency, and percentage. Student's *t* test and chi-square test (with appropriate corrections) were employed to assess variations between groups for quantitative and qualitative data, respectively. Statistical significance was set at a *P* value of <0.05.

## Results

### Maternal characteristics

The highest percentage of retained placenta cases occurred in the 30- to 39-year-old age range for both groups (approximately 66%). There was no significant difference in age distribution between the two groups ($P = 0.917$). Preterm labor (<37 weeks) was more frequent than term labor (≥37 weeks) in both groups (33 preterm vs. 17 term). There was no significant difference in gestational age distribution between the groups ($P = 0.697$). The frequency of retained placentas increased with the number of previous pregnancies (multiparity). There was no significant difference in parity distribution between the study groups ($P = 0.816$) [Table 1].

Table 2 examines the risk factors for females with retained placentas.

The NTG group had a higher percentage (36%) of women with a previously retained placenta than the placebo group (20%). This variation was not statistically significant ($P = 0.207$). More women in the NTG group (24%) had a prior cesarean section (C-section) compared with the placebo

**Table 1: Maternal characteristics of the two study groups**

| Parameter | | Placebo group *N* (%) | Nitroglycerin group *N* (%) | Total | *P* value |
|---|---|---|---|---|---|
| **Age (years)** | 20–29 | 5 (20) | 5 (20) | 10 (20) | 0.917 |
| | 30–39 | 17 (68) | 16 (64) | 33 (66) | |
| | ≥ 40 | 3 (12) | 4 (16) | 7 (14) | |
| | Total | 25 (100) | 25 (100) | 50 (100) | |
| | Mean ± SD | 35.2 ± 5.1 | 34.7 ± 4.8 | | |
| **Gestational age (weeks)** | 24–28 | 9 (36) | 7 (28) | 16 (32) | 0.697 |
| | 29–33 | 5 (20) | 8 (32) | 13 (26) | |
| | 34–38 | 5 (20) | 6 (24) | 11 (22) | |
| | ≥39 | 6 (24) | 4 (16) | 10 (20) | |
| | Total | 25 (100%) | 25 (100%) | 50 (100) | |
| | Mean ± SD | 31.36 ± 5.47 | 32.12 ± 5.35 | | |
| **Parity** | 0 | 3 (12) | 2 (8) | 5 (10) | 0.816 |
| | 1–3 | 10 (40) | 9 (36) | 19 (38) | |
| | ≥4 | 12 (14) | 14 (56) | 26 (52) | |
| | Total | 25 (100) | 25 (100) | 50 (100) | |
| | Mean ± SD | 3.3 ± 1.8 | 3.2 ± 1.7 | | |

SD: standard deviation.

Significant variation between proportions using the chi-square test at a *P* value of 0.05 level

**Table 2: Risk factors of retained placenta among the included females**

| Risk factor | | Placebo group *N* (%) | Nitroglycerin group *N* (%) | Total | *P* value |
|---|---|---|---|---|---|
| Previous history of retained placenta | Yes | 5 (20) | 9 (36) | 14 (28 %) | 0.207 |
| | No | 20 (80) | 16 (64) | 36 (72%) | |
| | Total | 25 (100%) | 25 (100%) | 50 (100%) | |
| Previous scar (C/S) | Yes | 4 (16) | 6 (24) | 10 (20%) | 0.479 |
| | No | 21 (84) | 19 (76) | 40 (80%) | |
| | Total | 25 (100%) | 25 (100%) | 50 (100%) | |
| Previous myomectomy | Yes | 2 (8) | 3 (12) | 5 (10%) | 0.637 |
| | No | 23 (92) | 22 (88) | 45 (90%) | |
| | Total | 25 (100%) | 25 (100%) | 50 (100%) | |
| Previous curettage | Yes | 10 (40) | 8 (32) | 18 (36%) | 0.555 |
| | No | 15 (60) | 17 (68) | 32 (64%) | |
| | Total | 25 (100%) | 25 (100%) | 50 (100%) | |

C/S: cesarean section.

Significant variation using the chi-square test at a *P* value of 0.05 level between proportions

**Table 3: Clinical characteristics of study groups**

| Risk factor | | Placebo group *N* (%) | Nitroglycerin group *N* (%) | Total | *P* value |
|---|---|---|---|---|---|
| **Types of labor** | Spontaneous | 9 (36) | 8 (32) | 17 (34) | 0.845 |
| | Induction | 5 (20) | 4 (16) | 9 (18) | |
| | Augmentation | 11(44) | 13 (52) | 24 (48) | |
| | Total | 25 (100) | 25 (100) | 50 (100) | |
| **Placental detachment** | Yes | 5 (20) | 18 (72) | 23 (46) | 0.001 |
| | No | 20 (80) | 7 (28) | 27 (54) | |
| | Total | 25 (100) | 25 (100) | 50 (100) | |
| **Blood loss (mL)** | M ± SD | 339.4 ± 69.3 | 344.6 ± 83.8 | | 0.405 |
| | Range | 200–450 | 180–490 | | |
| **Detachment time (min)** | M ± SD | 7.0 ± 1.6 | 6.8 ± 2.0 | | 0.411 |
| | Range | 5–9 | 3-10 | | |

SD: standard deviation.

Significant variation using the chi-square test at a *P* value of 0.05 level between proportions

group (16%), which was not statistically significant ($P$ = 0.479). A similar number of women in each group had a previous myomectomy (approximately 10%), which was not significantly different ($P$ = 0.637). The frequency of prior curettage was similar in both groups (approximately 36%). Again, this variation was not statistically significant ($P$ = 0.555).

Table 3 and Figure 1 display the clinical characteristics of the study subjects and compare the NTG and placebo groups. The differences between the groups were not significant in terms of the type of labor (spontaneous, induction, or augmentation). The most crucial finding was that the success rate of placental detachment (72%) was significantly higher in the NTG group than in the placebo group (20%; $P$ = 0.001). A total of 23 women (46%) in both groups achieved successful detachment. Neither blood loss nor detachment time showed statistically significant differences between the groups. Both groups had an average blood loss within the normal range and no cases of PPH requiring blood transfusion.

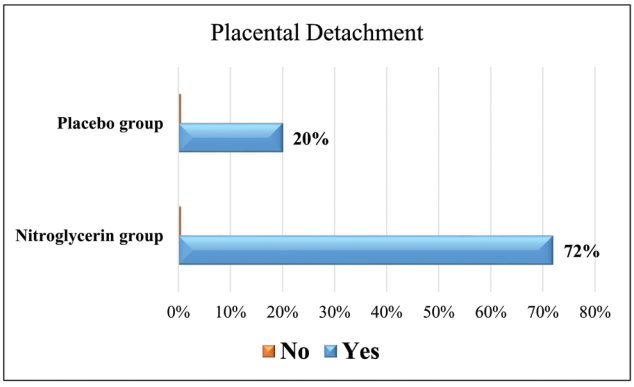


**Figure 1:** Placental detachment distribution in the study groups

Table 3 shows that NTG was more effective than placebo in promoting placental detachment in women with retained placentas.

Table 4 reviews the side effects experienced by participants in the NTG and placebo groups. The results revealed that

**Table 4: The side effects experienced by participants in the nitroglycerin (NTG) and placebo groups**

| Side effects | | Placebo group | NTG group | *P* value |
|---|---|---|---|---|
| Headache | Mild (tolerable) | 2 (8) | 6 (24) | 0.001 |
| | Uncertain | 0 | 2 (8) | |
| | Severe (debilitating) | 0 | 6 (24) | |
| | Total | 2 (8) | 14 (56) | |
| Tachycardia | Mild, transient, asymptomatic | 8 (32) | 8 (32) | 0.39 |
| | Severe, prolonged, symptomatic | 1 (4) | 4 (16) | |
| | Total | 9 (36) | 12 (48) | |
| Hypotension | Mild, slight blood pressure drop, asymptomatic | 7 (28) | 4 (16) | 0.56 |
| | Severe, significant drop, symptomatic | 1 (4) | 6 (24) | |
| | Total | 8 (32) | 10 (40) | |

Significant variation using the chi-square test at a *P* value of 0.05 level between proportions

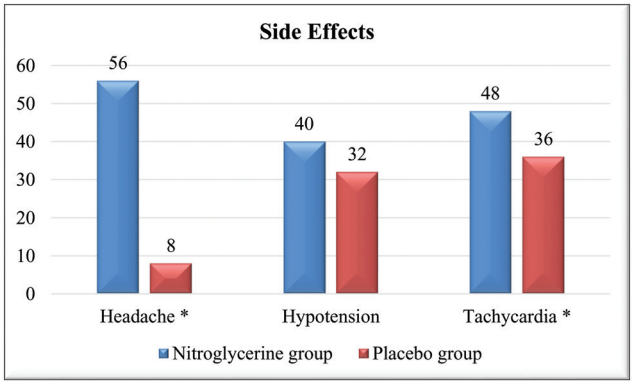


**Figure 2:** The side effects distribution in the study groups

there was a significant difference between females in the NTG group (56%) compared to those in the placebo group (8%) regarding headaches. years ($P$ = 0.0002), respectively. The incidence of tachycardia or hypotension was not significantly different between groups. NTG use was associated with a significantly increased incidence of headaches compared with placebo. However, tachycardia and hypotension were not significantly more frequent in the NTG group [Figure 2].

## Discussion

While retained placentas are an infrequent obstetric complication in the delivery unit, it is crucial to identify patient risk factors and comprehend care in an attempt to reduce this morbidity. Active management of the third labor stage, including oxytocin, controlled traction of the umbilical cord, and uterine massage, might help facilitate spontaneous placental separation and reduce the potential for PPH.[10-12] The traditional method of treating a retained placenta involves administering spinal or general anesthesia to allow manual separation of the placenta from the uterus. This practice entails dangers associated with the anesthetic and infection, and special facilities are required.[13] The placenta may be delivered without the need for intrusive treatment if uterine relaxing medications (tocolytics) are used either by themselves or in conjunction with other medicines (uterotonics) to promote uterine contractions.[1,14]

In thisstudy, we found significantly higher success rates for placental detachment in the NTG group (72%) than in the placebo group (20%). This suggests that NTG may be a more effective treatment for retained placentas. NTG is an NO donor with strong smooth muscle relaxation and potent, short-lived tocolytic activity.[5] It can be administered sublingually or intravenously. It is metabolized to its active compound, NO, which exerts its effect using cyclic guanosine monophosphate as a second messenger.[15-17] A phenomenon similar to that found in the current study is a prospective study exposing the sublingual efficacy of NTG (1 mg) after oxytocin administration in the delivery of retained placenta. The study described success rates of 87.5% of placental deliveries without manual intervention.[18] Another study reported similar conclusions.[19]

However, the administration of NTG for the retained placenta is clouded with indecision because several other trials failed to support the beneficial effectiveness of NTG in this field[1,10] and stated that NTG is neither effective nor cost-effective and has increased adverse effects.[5] The currently available data indicate that the use of NTG by itself does not lessen the requirement for placenta removal by hand. The frequency of severe PPH and the requirement for hemotransfusions were not increased by this strategy. In terms of hemodynamics, NTG significantly but subtly affected pulse rate and blood pressure. These results seem to be consistent with our findings that there is no significant association between the administration of NTG and the incidence of adverse symptomatic hypotension compared with the placebo group.

The results of the present study showed that the rate of retained placenta increased with maternal age. Older women are more likely to experience a retained placenta. A maternal age of ≥40 years is a risk factor for retained placenta, as reported earlier,[20] which is consistent with the outcomes of several other researchers.[21,22] In addition,

it is well recognized that maternal age is also linked to higher placental dysfunction, previous C-section, malpresentations, and multiple gestations, which also indicate C-section.[23] The majority of research supports the long-established correlation between a higher number of pregnancies with retained placenta and an older mother's age, which may be due to the replacement of myometrial fibers by fibrous tissue, which increases the risk of uterine atony.[24] However, there is no evidence to support an early cutoff point for manual placental removal or a safe window of time before PPH.[25]

However, due to the small population size, our trial is underpowered to identify underlying baseline or clinical variations that might explain this finding completely, in the context of other contradictory researchers, who concluded that lower maternal age is markedly associated with retained placenta.[26] Their justification was that lower uterine perfusion at older ages is a result of more myometrial sclerotic lesions than at younger ages, which restricts blood flow during labor.

The percentage of retained placenta in the present study was higher in multiparity. In agreement with these results, Nigussie *et al*. reported an increased postpartum bleeding frequency in multipara women older than 40 years but not in nullipara,[27] which is also in agreement with the findings of Coviello *et al*.[22] Gynecologists have increasingly recognized that non-medical factors, such as the heightened nervousness of both doctors and mothers due to advanced maternal age.[20] In the case of multiparous females with earlier obstetrical complications.[20,28-30] In contrast, another study showed that multiparity is not related to an increased potential of retained placenta.[31]

In several previous studies, increased gestational age was associated with an increased rate of placental retention in preterm labor.[14] Placental hypoperfusion disorders are another risk factor for retained placentas. In a Swedish study of all singleton primiparous births, physicians found an increased association between hypoperfusion placental disorders[1] and retained placenta; however, they could not recognize a shared pathology.

Numerous studies have shown that retained placenta is significantly associated with preterm labor.[4,32] It was anticipated that preterm delivery may be due to fibrinoid degeneration or infarction of the decidual vasculature that leads to anomalous adherence of the placenta.[33]

The pathophysiology of a retained placenta involves several factors that contribute to the failure of the placenta to be completely delivered after birth. The glutathione peroxidase-1 antioxidative enzyme level is decreased in retained placentas, indicating a potential role in this pathophysiology. Certain risk factors, such as maternal age, parity, and history of recurrent miscarriage, are associated with an increased risk of a retained placenta.[2]

This study showed that females with scarred uterus, previous myomectomy, or curettage had an increased incidence of retained placenta. This phenomenon is consistent with previous studies.[3,4]

According to research findings, numerous cases of retained placenta appear with enhanced labor or induction labor, but very few cases of retained placenta present with spontaneous labor. These findings concur with those reported by Adelusi *et al*.[34]

NO was known to be involved in the mechanisms underlying vascular-based headaches, including migraine and/or cluster headaches, by inducing neurogenic inflammation and activating neurons that provide sensory impulses to the trigeminal ganglion.[35] Neither tachycardia nor hypotension differed significantly between the groups. These findings were consistent with those of Kashanian *et al*.[36] The NTG group exhibited a noteworthy reduction in arterial pressure and an elevation in heart rate, as described in a previous study.[37]

## Conclusion

This trial suggests that sublingual NTG may be a valuable tool for managing retained placentas. Compared with a placebo, it significantly increased successful detachments without surgery. This could reduce the need for invasive procedures and improve patient outcomes. However, the limitations include the single-blinded design and small sample size. Headaches were more frequent in the NTG group.

Additional research in larger trials is needed to confirm these results and to explore the optimum dosage and side-effect profile. Investigating the mechanisms by which NTG can lead to more targeted therapies. While promising, more research is required to definitively establish the role of NTG in managing the retained placenta.

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### Conflicts of interest

There are no conflicts of interest.

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