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Role and effectiveness of duration while giving oxytocin intra-umbilical for delivery of retained placenta

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Abstract
Delayed placental separation can result in postpartum hemorrhage. Intra-umbilical oxytocin (20 U in 30 mL saline) decreases the time to placental delivery after vaginal delivery, while its effect after cesarean birth is less clear. We conducted a clinical study in 56 elective cesarean patients, where patients were randomly assigned to receive intra-umbilical oxytocin or saline control (saline alone). We measured the time of birth to placenta delivery, blood loss >500 mL, safety, feasibility, completeness of placenta, and manual removal of the placenta. Mean time to placenta delivery was 141 s with oxytocin and 158 s in the saline control group (not significant). Catheter insertion in the umbilical vein was successful in all cases, and no adverse effects were reported. Intra-umbilical oxytocin appears safe, feasible and may provide a decrease in time to placenta delivery; however, further studies of a larger sample size are needed.

Keywords: Postpartum hemorrhage, intra-umbilical oxytocin, caesarean section

Introduction

According to Kassebaum NJ *et al.* (2015) [1], postpartum hemorrhage is the primary cause of maternal mortality in low-income states and accounts for more than one-fourth of all maternal deaths globally. Retained placenta, which affects 0.5% to 3% of women after birth, is one of the primary causes of PPH, maternal morbidity, and maternal death (Grillo *et al.*, 1998) [30].

By aggressively controlling the 3rd stage of labor to reduce the time it takes for the placenta to be delivered, PPH3 and uterine atony can be prevented. The intrapartum recommendations recommend intervention if the placenta is not delivered within 30 minutes of birth when the third stage of labor is being actively managed, or within 60 minutes of delivery when the third stage of labor is being physiologically controlled (NCCWH, 2007).

Manual placenta removal (MROP) typically necessitates general or regional anesthesia in a hospital setting. Serious side effects include bleeding, infection, and genital tract trauma might result from the invasive MROP surgery (BMC Pregnancy Childbirth. 2014) [15]. Women around the world can greatly benefit from a straightforward and secure alternative RP treatment that can be given at the place of birth and lessens the need for MROP (Carroli G, 1998) [16].

Among other factors such uterine atony, delayed placental separation is a significant contributor to postpartum hemorrhage after cesarean delivery, (BMC Pregnancy Childbirth. 2014) [15]. Postpartum hemorrhage can be avoided with proper care of retained placenta. Placental drainage, manual removal, and continuous cord traction are techniques for handling a retained placenta following a cesarean section (Carroli G, *et al.* 1998) [16]. Because it is linked to less bleeding, continuous tension on the umbilical cord is the recommended technique for placenta delivery during caesarean section (Carroli G, *et al.*, 1998) [16]. The operation's overall duration is increased by the time required for cord traction. Other benefit would be avoiding the usual intravenous oxytocin bolus administration during cesarean sections, which might increase mother morbidity.

To find out how well this method works for 3rd stage labor management, numerous little and big experiments were carried out. The majority of trials focused on administering intra-umbilical oxytocin to treat a retained placenta instead of routinely doing so during the 3rd stage of labor (Maher MA *et al.*, 2017; Saleem MAA, *et al.*, 2019) [8, 18].

After vaginal delivery, an intra-umbilical oxytocin injection into the umbilical vein may lessen the requirement for surgical removal of the retained placenta (Nardin JM, *et al.*, 2011) [3]. However, only high-quality RCTs were included in the analysis, and they showed that oxytocin had little or no effect. Twelve A follow-up study was unable to verify the positive impact of intra-umbilical oxytocin (Maher MA, *et al.*, 2017) [8]. Intraumbilical carbetocin 100 mcg in 20 ml normal saline was shown to be more efficient than oxytocin 20 IU in 20 ml saline in treating retained placenta.

One study found that tra-umbilical oxytocin in 50ml saline was superior to intra-umbilical saline alone for routine treatment of the 3rd stage of labor. The effect varied from 10IU to 30IU and was dose-related (Puri M, *et al.*, 2012) [10]. As far as we know, the use of intra-umbilical oxytocin during cesarean sections has not been the subject of any published trials. To determine whether a larger trial was necessary, the goal of this study was to investigate the initial safety, feasibility, and efficacy of intra-umbilical oxytocin in reducing the time to placenta delivery at caesarean section.

Methodology

Study design

The investigation was carried out at a tertiary hospital in India. The hospital is one of the province's leading referral healthcare facilities with a large number of deliveries annually,

Participants

Women who had elective cesarean sections performed at the hospital were included in the study. A live fetus and a pregnancy longer than 34 weeks were prerequisites for eligibility. Women with known life-threatening fetal abnormalities, a serious medical condition affecting the mother, a high risk of postpartum hemorrhage, etc., or who were unable to give consent or chose not to participate were not included. 56 women in all participated in the study.

Ethical clearance

The ethical committee gave its approval to the project. The management of the hospital provided written consent. All of the ladies who took part in the study gave their informed consent.

Procedure

An intra-umbilical infusion of 30 milliliters of saline was given to the control group (n = 28) of the eligible women, and 20 units of oxytocin in 10 milliliters of saline and then 20 milliliters of saline were given to the oxytocin group (n = 28). These groups were formed at random. An independent researcher established a numbered series of identical ampoules carrying 20 units of oxytocin, or one line, using a computer-generated random sequence. Along with the caesarean section theater in the labor ward, the experimental solution was kept in a closed refrigerator.

Following placenta delivery, all participating females received a routine iv injection of oxytocin (20 units) administered to 200 milliliters of saline at a rate of 100 milliliters per hour. The surgeon entered the patient's information and the subsequent ampoule number into the trial registration just prior to starting the c-section. The trial solution was then prepared from the selected ampoule, and 10 milliliters of regular saline were added. The environment was sterile. Additionally, another syringe containing 20ml of regular, simple saline was created. An newborn feeding tube size 8 was fitted with the first syringe containing the experimental solution. The trial solution was already in the newborn feeding tube. Standard operating procedures were followed during the cesarean section.

Infusion of 20 units of oxytocin diluted in 200 milliliters of ordinary saline was prepared by the aestheticist. The cord was clamped 30 seconds after the baby was delivered. A scalpel was used to partially cut the umbilical vein transversely. The fluid was administered when the baby feeding tube was removed from the umbilical vein by 5 cm after it had been implanted until resistance was felt. Following this, 20 ml of regular saline was injected once more to accomplish complete capillary filling. The placenta was then pulled steadily with 1-2 kg until it was delivered, and the cord was clamped once more on the placental side. The anesthetist was instructed to begin the prepared oxytocin infusion at a rate of 100 milliliters per hr once the placenta was fully delivered. Each person's trial register was updated with the number of seconds that passed between the baby's birth and the placenta's complete delivery.

Data Analysis

Microsoft Excel was used to enter the gathered data into a spreadsheet. The data was analyzed using SPSS 20 version. The duration between the baby's birth and the placenta's full delivery, blood loss above 500 milliliters, the necessity of manually removing the placenta, and the placenta's completeness were all examined in order to assess the preliminary efficacy. By witnessing the successful catheter insertion and solution injection, feasibility was evaluated. By looking into the procedure's negative impacts, safety was discouraged.

Results

The participants' sociodemographic attributes at baseline, both groups had good balance for clinical and sociodemographic factors, as seen in Table 1. The mean age of the patients in oxytocin group was 27.53±4.89 and 29.94±5.39 in control group the study participants' BMI and mean weight of the oxytocin group (71.41±6.53) and control group (68.82±5.87) differed significantly.

Table 1: The participants' sociodemographic attributes

variable	Oxytocin group n=28	Control n=28	P value
Age (yrs) Mean ±SD	27.53±4.89	29.94±5.39	0.016 S
Weight (kg) Mean ±SD	71.41±6.53	68.82±5.87	0.043 S
Height (cm) Mean ±SD	159.64±7.13	160.73±6.82	0.45 NS
BMI (kg/m2) Mean ±SD	29.67±4.69	27.52±5.18	0.024 S

The data on obstetrics history of the study participants shows that in oxytocin group 46% of participants had a history of previous abortion as compared to 21% in control group. The mean gestational age of the study participants was 30.62±6.53 in oxytocin group and 34.28±7.59 in control group.

Table 2: Obstetric history of study participants

Variable	Oxytocin group n=28	Percentage %	Control n=28	
Parity				
0	1	3.57%	3	10.71%
1-6	27	96.42%	25	89.28%
>6	0	0%	0	0
Gravidity				
PG	12	42.85%	18	64.28%
2-5	15	53.57%	10	35.71%
>-6	1	3.57%	0	0
Previous abortion				
No	15	53.57%	22	78.57%
Yes	13	46.42%	6	21.42%
Gestational Age (wks)	30.62±6.53		34.28±7.59	

Table 3 shows that mean time from birth to placental delivery was 141 seconds for oxytocin gp, whereas the control groups was 158 seconds. A statistically significant difference did not exist. When the placental delivery was delayed for more than three minutes, the risk ratio [RR] was 0.6, and when the delay was longer than four minutes, the RR was 0.4. Although there was less blood loss in the oxytocin group (614.39+-189.48 in ml) than in the control group (689.56+-124.76 in ml). The placenta was delivered in the majority of instances in both groups with no discernible difference in incomplete removal.

In all 58 cases, the catheter was successfully inserted, and the majority of the solutions were injected, confirming the procedure's feasibility. 10% of the cont group and 13% in the oxytocin group experienced issues with the infusion injection. This resulted from a small amount of saline infusion leaking around the umbilical cord cut. There were no negative effects of the procedure found.

Table 3: Results presented as proportions (%) or mean + standard deviation

Variable	Oxytocin group n=28	Percentage %	Control n=28	
Time from birth to placntal delivery in seconds (mean+-SD)	141+_41		158+_47	
Delayed placental delivery(>3mins)	5	17.85%		
Delayed placental delivery(>4mins)	1	3.57%		
Bleeding in ml	614.39+-189.48		689.56+-124.76	
Manual removal need of placenta				
Yes	10	35.71%	15	53.31%
No	18	64.28%	13	46.42%
Blood transfusion				
No	22	78.57%	26	92.85%
Yes	6	21.42%	2	
Hb (Immediately before delivery)	10.29+-0.58		10.98+-0.52	7.14%
Hb (Immediately after delivery-post-partum)	9.06+-0.67		19.96+-0.68	

Discussion

Even now, postpartum bleeding from a retained placenta remains one of the leading causes of maternal morbidity and mortality. Although it is a component of basic Emergency Obstetric Care (EmOC), removing manually the retained placenta is challenging to implement in a basic healthcare setting. Thus, there is an urgent need for an inexpensive medical solution that may be used even in the most basic healthcare settings. When it comes to administering utero-tonic medications through the umbilical vein, the WHO advises a uterotonic drug injection as the initial course of cure for RP.

This treatment is not commonly used, most likely due to the lack of a large RCT and uncertainty about the best medication and dosage schedules (Purwar MB: *et al.*, 2001; Puri M, *et al.*, 2012) [30, 10]. The use of intrauterine oxytocin in retained placentas has been the subject of numerous research, with varying degrees of success.

Oxytocin injected into the umbilical vein is ineffective in treating RP12, according to a Cochrane Collaboration review. According to a another double-blind, placebo-controlled study that involved mothers from the UK, Uganda, and Pakistan, oxytocin injected alter the requirement for MROP (Weeks A, *et al.*, 2013). The placenta removal rate manually with saline and oxytocin was significantly lower than that of placebo, according to a meta-analysis that comprised 10 trials. When compared to a placebo, another study by Ivalingam and Surinder demonstrated that using saline plus oxytocin reduced the need for manual placenta removal (Carroli G, Bergel E. 2001; Sivalingam N, Surinder S. 2001) [23, 24].

Because of their potent uterotonic qualities, prostaglandins have been utilized since 1976 to treat postpartum hemorrhage and uterine atony. Nowadays, prostaglandins are frequently utilized as preventative measures. Bider compared the effects of saline solution and injections of prostaglandin F2 alpha into the umbilical vein. When compared to a placebo, saline plus prostaglandin significantly decreased the requirement for manual placenta removal, but there was no discernible difference (Bider D, *et*

al., 1996) [25].

Misoprostol has been used extensively and successfully to treat postpartum bleeding placenta, either by alone or in conjunction with umbilical vein oxytocin. Its thermostable and affordable nature is another advantage. In several investigations, misoprostol has also been utilized and shown to be successful in ejecting a retained placenta. It has been administered via various ways and compared to contro (Bider D, *et al.*, 1996; van Beekhuizen and Tarimo V., 2013) [25, 26].

In order to shorten the period before placental delivery via caesarean surgery, this study investigated the initial safety, feasibility, and effectiveness of intra-umbilical oxytocin. According to the study's findings, intra-umbilical oxytocin infusion is safe, practical, and may shorten the time needed for placental delivery during a caesarean surgery.

The participants' sociodemographic attributes at baseline, both groups had good balance for clinical and sociodemographic factors, as seen in Table 1. In the oxytocin group, the patients' mean age was 27.53±4.89, while in the control group, it was 29.94±5.39. The study participants' BMI and mean weight of the oxytocin group (71.41±6.53) and control group (68.82±5.87) differed significantly.

The data on obstetric history of the study participants shows that in oxytocin group 46% of participants had a history of previous abortion as compared to 21% in control group. The mean gestational age of the study participants was 30.62±6.53 in oxytocin group and 34.28±7.59 in control group.

The mean time was 141 secs from birth to placental delivery for oxytocin group, whereas the control group's was 158 s. When the placental delivery was delayed for more than three minutes, the risk ratio [RR] was 0.6, and when the delay was longer than four minutes, the RR was 0.4. Although there was less blood loss in the oxytocin group (614.39+-189.48 in ml) than in the control group (689.56+-124.76 in ml). In most cases, the placenta was delivered in both groups, and there was no appreciable difference in the percentage of incomplete removals.

Assuming partial transplacental transfer, a dosage of 20 units of oxytocin was selected to guarantee sufficient dosing to the placental bed. However, tra-umbilical oxytocin was found to be more efficacious up to 30 units in a subsequent trial (Puri *et al.*, 2017) [10]. Furthermore, the latter study used a larger fluid volume (50 ml). The impact of intra-umbilical oxytocin on retained placenta during vaginal delivery has been the subject of numerous investigations (Maher MA, *et al.*, 2017; Salem MAA, *et al.*, 2019) [8, 9].

The overall success rate for oxytocin-assisted placenta removal was 66.7% (64/96) (Puri *et al.*, 2017) [10]. The "Release Study" that followed was unable to reproduce those findings (Weeks AD, *et al.*, 2010) [10, 22]. In contrast, several studies indicated that intra-umbilical oxytocin administration was advantageous (Tehseen F, *et al.*, 2008) [5]. In order to aid placental separation during caesarean surgery, this study provides new record on safety, possibility, and promise of intra-umbilical uterotonic injection. Because oxytocin has circulatory effects, intravenous bolus doses of the hormone can cause severe hypotension in mothers. It has been suggested that oxytocin be administered slowly during a cesarean section.

Compared to using a quick bolus injection, this will increase the mother's safety but might postpone the period for placental separation. If proven to be successful, intra-umbilical oxytocin may be a viable substitute for targeted oxytocin delivery to the placental bed, especially in individuals who are already compromised, in order to prevent the systemic blood pressure changes that come with bolus intravenous injection. It is important to acknowledge the limitations of the study when evaluating the results. Due to the small sample size, the pilot study's ability to identify even slight changes between the two groups was constrained. Only a small amount of the infusion fluid leaked, and it was unlikely to have an impact on the outcomes.

Despite these drawbacks, this study advances our understanding of how intra-umbilical oxytocin can be used to hasten placenta delivery during cesarean sections. Although there is not sufficient literature to carry the usual use of traumbilical oxytocin during caesarean sections, the study does show promise as a backup plan in the event that placental separation is delayed. To more conclusively ascertain the effectiveness of intra-umbilical oxytocin in facilitating placental delivery during c-section, more studies with bigger sample numbers are needed.

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