"CARBETOCIN VERSUS OXYTOCIN IN PREVENTION OF POSTPARTUM HAEMORRHAGE IN PATIENTS UNDERGOING CAESAREAN SECTION"

By

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DISSERTATION SUBMITTED TO

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IN

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Under the Guidance of

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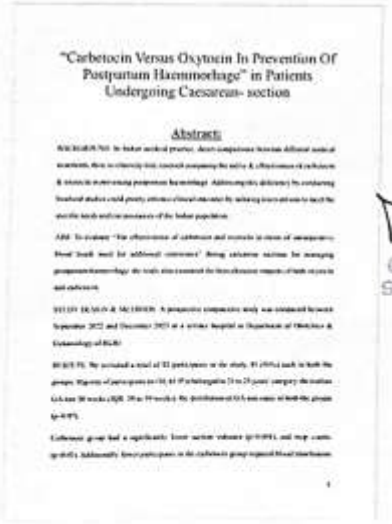

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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
PPH	POSTPARTUM HAEMORRHAGE
C-SECTION	CAESAREAN SECTION
LSCS	LOWER SEGMENT CAESAREAN SECTION
AUC	AREA UNDER CURVE
WHO	WORLD HEALTH ORGANISATION
Hb	HAEMOGLOBIN
SPO2	OXYGEN SATURATION
IQR	INTER QUARANTILE RANGE
NSAID's	NONSTEROIDAL ANTI-INFLAMMATORY DRUGS
APGAR	APPEARANCE, PULSE, GRIMACE, ACTIVITY, AND RESPIRATION
CPD	CEPHALOPELVIC DISPROPOTION
CDMR	CAESAREAN DELIVERY AT MATERNAL REQUEST

“CARBETOCIN VERSUS OXYTOCIN IN PREVENTION OF POSTPARTUM HAEMORRHAGE IN PATIENTS UNDERGOING CAESAREAN SECTION”

ABSTRACT:

BACKGROUND: In Indian medical practice, direct comparisons between different medical treatments, such as the safety & efficacy of carbetocin versus oxytocin for preventing postpartum haemorrhage. Addressing this deficiency by conducting localized studies could greatly enhance clinical outcomes by tailoring interventions to meet the specific needs and circumstances of the Indian population.

AIM: To assess the efficacy of carbetocin and oxytocin in terms of intraoperative blood loss and the need of additional uterotonic in caesarean sections for management of postpartum haemorrhage. The study also examined the hemodynamic effects of oxytocin and carbetocin.

STUDY DESIGN & METHODS: A prospective comparative study was conducted between September 2022 and December 2023 in the Department of Obstetrics & Gynaecology at R L JALAPPA HOSPITAL AND RESEARCH CENTRE in kolar, Karnataka.

RESULTS: We recruited a total of 82 participants in the study, 41 (50%) each in both the groups. Majority of participants (n=34, 41.5%) belonged to 21 to 25 years category. The median GA was 38 weeks (IQR: 38 to 39 weeks). The distribution of GA was same in both the groups (p=0.97).

Participants in the carbetocin group had significantly lower suction volumes (p<0.001), and mop counts (p=0.02). Additionally, fewer participants in the carbetocin group required blood transfusions (0% vs. 7.3%) (p=0.07). Carbetocin group was superior in terms of additional uterotonic requirement (4.9% vs. 29.3%, p=0.003) and additional procedures requirement (0% vs14.6% within the group receiving oxytocin, p=0.01). Metallic taste found to be an important side effect for the carbetocin group (11.9%).

CONCLUSION: Carbetocin more effective than oxytocin in reducing intraoperative blood loss and preventing postpartum haemorrhage (PPH) during caesarean sections, with significantly lower suction volumes, mop counts, and need for additional uterotonics. Despite minor side effects for both drugs, carbetocin shows a more favorable safety and efficacy profile, though it uniquely causes a metallic taste.

INTRODUCTION

INTRODUCTION:

Postpartum haemorrhage characterized by "a blood loss of ≥500 ml ", whereas severe PPH defined "a blood loss of ≥1000 ml".[1] Primary PPH, one of the most common cause occurs within 24 hours after childbirth, while secondary PPH occurs between 24 hours and 6 weeks post delivery.[2,3] Some known Risk factors for postpartum haemorrhage include a previous history of PPH but about 20% cases of PPH arise in women with no prior risk factors.[2] This unpredictability underscores the necessity for healthcare providers to possess the essential knowledge, skills, and resources to effectively identify and manage PPH at every childbirth.[2,3] Furthermore, there are instances where healthcare providers fail to recognize PPH early, leading to delay in applying effective treatments and potentially resulting in preventable maternal mortality.[4,5]

Postpartum haemorrhage (PPH) is a major health issue that significantly contributes to maternal mortality and the need for postpartum hysterectomy.[6] Every year, around the world, approximately 1,40,000 women die due to complications associated with PPH, highlighting its severe impact on global health.[7] Uterine atony is the primary cause of PPH, which accounts for 80% of all cases.[8] Given these alarming statistics there is need for effective preventive measures to reduce maternal mortality. The use of uterotonics immediately after delivery is an key recommendation that can help to decrease the risk of this life-threatening condition.[9] Among the available uterotonics, oxytocin is most frequently used due to its rapid action and well established safety profile.[10] It works by stimulating uterine contractions, thereby preventing excessive bleeding after delivery. However, Oxytocin's clinical utility is limited by its pharmacokinetics as it has a short half-life of only 4 to 10 minutes. This short duration of action requires that it should be administered repeatedly or continuously to maintain its efficacy, which can complicate its use in clinical settings.[11] Despite these challenges, oxytocin

remains a cornerstone in the management of PPH due to its effectiveness and relative ease when compared to other pharmacological options.

Carbetocin, an extended-release synthetic oxytocin analogue, boosts a prolonged duration of action (elimination half-life 40 min as long as 85–100 minutes) compared to oxytocin.[12] Structural disparities render carbetocin more stable, averting degradation by aminopeptidase and disulfide compounds.[13] Studies indicate that carbetocin, in contrast to oxytocin, diminishes blood loss, reduces need for additional uterotonic agents and lowers the risk of PPH following caesarean section".[14-16] In India, the occurrence of postpartum haemorrhage (PPH) is reported to range from 2% to 4% following vaginal delivery and 6% following Caesarean delivery. PPH stands as a significant contributor to maternal mortality, approximately 19.9% of maternal deaths in the country.[17]

In Indian medical practice, direct comparisons between different medical treatments, such as the efficacy and safety of carbetocin versus oxytocin for preventing PPH, are relatively scarce. This gap in research limits the ability of healthcare providers to make informed decisions based on local data, particularly for conditions like postpartum haemorrhage where risk factors and prevalence may vary significantly from global averages. Addressing this deficiency by conducting localized studies could greatly enhance clinical outcomes by tailoring interventions to meet the specific needs and circumstances of the Indian population.

NEED FOR THE STUDY:

Caesarean delivery is becoming more common, which can lead to postpartum haemorrhage because the average blood loss during caesarean section is double that of vaginal delivery. [73] Prevention of postpartum haemorrhage (PPH) is a major issue owing to its effect on maternal morbidity and mortality. The first cause of haemorrhage at the time of delivery is uterine atony therefore, there is general agreement that active management of the third stage of labor rather than expectant management should be initiated. [74] Administration of uterotonic drugs widely prevents the PPH; therefore, it is the main point of active management.

Among uterotonics, oxytocin has proven to be very effective in reducing the incidence of PPH, Although oxytocin is the most widely accepted uterotonic agent, a lot of data from the literature suggest that prophylactic administration of carbetocin may be a good alternative to oxytocin to prevent PPH.

Carbetocin is effective in reducing the use of additional uterotonics, reduction in postpartum haemorrhage, similar safety profile and transfusion when used during caesarean deliveries The purpose of this study to assess the safety and effectiveness of intravenous Carbetocin vs intravenous Oxytocin in minimizing blood loss in patients undergoing elective/emergency caesarean section.

AIMS & OBJECTIVES

AIMS & OBJECTIVES:

1.To Asses the effectiveness of Intravenous Carbetocin and Oxytocin in reducing blood loss in patients undergoing Caesarean Section

2.To Compare the effectiveness of above drugs in assessing intraoperative and postoperative blood loss

REVIEW OF LITERATURE

REVIEW OF LITERATURE:

CAESAREAN SECTION:

A surgical method used to deliver baby is called Caesarean Section(C-section), through which incision is placed over mother's abdomen and uterus.[18] The procedure is usually done when baby or mother or both can be at risk because of vaginal delivery.

CLASSIFICATION OF CAESAREAN SECTION:

C-sections can be classified based on various criteria, including the indication for the surgery, urgency, and site of the incision.

Caesarean Section Types (According To Robinson's Classification):

Robson's classification is a system categorized into ten groups (TGCS). It is standardized system used to classify women undergoing labor and delivery into ten groups depending on obstetric characteristics. This system helps in comparing the rates of this operative procedure and understanding the contributing factors.[19,20]

TABLE 1: ROBSON'S CLASSIFICATION (TGCS):

Group	Obstetric characteristics:
1	Nulliparous woman, single cephalic fetus, GA ≥37 weeks in spontaneous labour
2	Nulliparous woman, single cephalic fetus, GA ≥37 weeks, induced or caesarean before labour
3	Multiparous woman (excluding previous caesarean), single cephalic fetus, GA ≥37 weeks in spontaneous labour

4	Multiparous woman (excluding previous caesarean), single cephalic fetus, GA ≥ 37 weeks, induced or caesarean before labour
5	Previous caesarean delivery, single cephalic fetus, GA ≥37 weeks
6	All nulliparous women, breech pregnancy
7	All breech pregnancies among multiparous women with h/o previous caesarean section
8	Any multiple gestation including those with previous caesarean section
9	Any abnormal lies including those with previous caesarean section
10	Any single cephalic fetus with GA ≤36 weeks including those with previous caesarean section

LUCAS CLASSIFICATION BASED ON URGENCY OF CAESAREAN SECTION: The Lucas classification is used to categorize caesarean sections based on the urgency with which they need to be performed. This system helps prioritize care and resource allocation during delivery.

Table 2: LUCA SCLASSIFICATION BASED ON URGENCY OF C-SECTION:[20]

CATEGORY	DEFINITION
Category 1: Emergency	Carries immediate life threat to
Category 2: Urgent	Not immediately life-threatening to the mother the/fetus but significant compromise to them
Cateogory3: scheduled	Requiring delivery sooner than anticipated, without maternal or fetal compromise
Cateogory 4: Elective	One-time delivery to accommodate both the woman and the maternity team

TYPES OF CAESAREAN DELIVERY BASED ON THE SITE OF INCISION:

1. LOWER SEGMENT CAESAREAN SECTION (LSCS):

- The prevalent form of Caesarean Section
- A horizontal incision is made across the lower part of the uterus.
- Benefits include less bleeding, better healing, and risk of uterine rupture is low subsequently.

2. CLASSICAL CAESAREAN SECTION:

- An incision is made vertically in the upper portion of the uterus.
- This type is rarely performed today due to higher risks of bleeding and uterine rupture.
- Typically reserved for specific situations where access to the baby is difficult (e.g., transverse lie, preterm delivery).

3. LOW VERTICAL CAESAREAN SECTION:

- An incision is made vertically in the lower uterine segment.
- This approach may be used when a transverse incision is not feasible due to the position of the baby or placental location.

4. EXTRAPERITONEAL CAESAREAN SECTION:

- The incision is made to avoid entering the peritoneal cavity.
- This technique is less common and usually reserved for specific medical conditions.

EPIDEMIOLOGY OF CAESAREAN SECTION:

In 2015, caesarean section births made up 21.1% of all births globally. Annually, 20 million caesarean sections are performed worldwide. Between 2003 and 2011, the caesarean section

rate per live birth surged from 21.2 percent to 48 percent. In developed countries, the caesarean rate is noted to be 21%.[21-23] The rise in caesarean sections can be linked to several factors:

- High forceps and challenging mid forceps procedures are increasingly being replaced by caesarean sections.
- There is a rise in caesarean deliveries due to breech presentations.
- Destructive operations are being substituted with caesarean sections.
- Caesarean sections have a lower morbidity and mortality rate, which promotes their use.
- There are more repeat caesarean sections due to the rise in primary caesarean sections.

INDICATIONS FOR CAESAREAN SECTION- MATERNAL CONDITIONS:

- PRIOR CAESAREAN SECTION: Women who has a prior history of caesarean section(s) may require a repeat caesarean due to concerns about uterine rupture.
- LABOR DYSTOCIA: Prolonged labor or failure to progress during labor can necessitate a caesarean delivery.
- PLACENTA PREVIA: Here, the placenta comes down and covers the cervix fully and hence, a vaginal delivery can be dangerous, making a caesarean necessary.
- ABRUPTIO PLACENTA: Placenta prematurely gets separated from the uterus can lead to fetal distress and maternal haemorrhage.
- UTERINE RUPTURE: A tear in the uterine wall during labor is a life-threatening condition requiring immediate caesarean delivery.
- MATERNAL INFECTIONS: Certain infections (HIV/active genital herpes) carries a high probability to get transmitted to the baby during vaginal delivery.
- PREECLAMPSIA/ECLAMPSIA: Severe hypertension or seizures in the mother may require immediate delivery for the mother's and the child's health.

- MEDICAL CONDITIONS: Chronic conditions such as diabetes, heart disease, or severe respiratory issues that complicate labor.

FETAL INDICATIONS FOR CAESAREAN SECTION:

• FETAL DISTRESS: Abnormal heart rate or other signs indicating the baby is not well can prompt an Emergency caesarean section.

• BREECH PRESENTATION: A caesarean section is usually a safer option for delivering a baby positioned feet or buttocks first.

• TRANSVERSE LIE: The baby is lying horizontally in the uterus, making vaginal delivery impossible.

• FETAL MACROSOMIA: An unusually large baby can cause complications during vaginal delivery.

• MULTIPLE GESTATION: Caesarean section deliveries are often required for twins or higher order multiples, especially if they are in abnormal positions.

• CONGENITAL ANOMALIES: Certain birth defects may necessitate a caesarean delivery to minimize the risk of injury during birth.

• CORD PROLAPSE: Occurs when the umblical cord emerges from the cervix ahead of the baby's delivery, requiring immediate caesarean to prevent oxygen deprivation.

• FETAL GROWTH RESTRICTION: Poor growth of the fetus may lead to an early delivery by caesarean for better outcomes.

MATERNAL COMPLICATIONS OF CAESAREAN SECTION:

• INFECTION: Post-operative infections can occur at the incision site, in the uterus or urinary tract.

• HAEMORRHAGE: Excessive bleeding during or after surgery may necessitate blood transfusions.

• ANAESTHESIA COMPLICATIONS: Adverse reactions to anaesthesia such as respiratory issues, low blood pressure or allergic reactions.

• BLOOD CLOTS: thromboembolic disorders in pregnancy.

• SURGICAL INJURY: Potential damage to nearby organs such as bladder or intestines during surgery.

• ADHESIONS: formation of scar tissue that can cause pain and complications in future pregnancies or surgeries.

• EXTENDED RECOVERY PERIOD: Recovery from caesarean section is usually lengthier and involves more discomfort compared to vaginal delivery.

• FUTURE PREGNANCY RISKS: Complications like uterine rupture, is enhanced in subsequent pregnancies.

FETAL COMPLICATIONS OF CAESAREAN SECTION:

- RESPIRATORY ISSUES: Babies born via caesarean, especially before 39 weeks, may have breathing problems such as Transient Tachypnoea.
- SURGICAL INJURY: Accidental cuts or nicks during surgery can occur, its rare.
- DELAYED INITIATION OF BREAST FEEDING: Separation from the mother and anaesthesia effects may delay the start of breastfeeding.
- INCREASED RISK Of ASTHMA and ALLERGIES
- ALTERED GUT MICROBIOTA: Babies born via caesarean may have different gut bacteria compared to those born vaginally, potentially impacting their immune system.

- PREMATURITY: If the caesarean is performed before full term, there is a risk of complications associated with prematurity, such as underdeveloped organs.
- ADMISSION TO NEONATAL INTENSIVE CARE UNIT(NICU): ncreased likelihood of needing NICU care, particularly if there are complications during or after birth.

BLOOD LOSS IN CAESAREAN SECTION:

After childbirth, losing 500 mL of blood is considered physiologically acceptable, with amounts exceeding this defined as postpartum hemorrhage.[24] For vaginal delivery, blood loss over 500 mL is the threshold, while for caesarean section, the cutoff is over 1500 ml. Postpartum bleeding is categorized into primary and secondary.[25] The primary postpartum haemorrhage (PPH) occurs in Five percent of all births. Secondary postpartum haemorrhage (PPH) is characterized by significant blood loss through vagina that takes place after 24 hours after delivery.[26]

EPIDEMIOLOGY:

PPH significantly contributes to maternal morbidity, and it ranks as the primary cause of maternal mortality, constituting up to one-fourth of maternal deaths. [27-29] In 2017, an estimate showed that PPH alone contributed over 1.27 lakhs maternal deaths worldwide.[28] However, PPH is largely preventable and treatable.[30] The World Health Organization (WHO) has approximated that almost three-fourths of maternal mortality in LMICs are due to postpartum haemorrhage, with more than 40% of these fatalities happening solely sub-Saharan-Africa.[31-33] Early detection, and prompt, evidence-based skilled management are the mainstay of maternal death prevention.[34,35]

ETIOLOGY AND RISK FACTORS OF POSTPARTUM HEMORRHAGE:

COMMON CAUSES:

- Uterine Atony: The most frequent cause, after delivery, the uterus unable to contract properly.
- Cervical or Vaginal Tear: Tears in the cervix or vaginal wall during delivery.
- Adherent Placenta: Placenta that remains attached to the uterine wall.
- Uterine Angle Extension: Extension of a uterine incision into the broad ligament or other structures.
- Retained Placenta: Fragments of the placenta remaining in the uterus post-delivery.

RISK FACTORS:

- Antepartum Haemorrhage: Bleeding before childbirth.
- Accelerated Labor: Rapid labor can increase the risk.
- Chorioamnionitis: Infection of the fetal membranes.
- Foetal Macrosomia: Birth weight over 4,000 grams.
- Maternal Anemia: Low haemoglobin levels in the mother.
- Maternal Obesity: Increased body mass index.
- Multifetal Gestation: Pregnancy with twins or more.
- Prolonged Labor: Extended duration of labor.
- Preeclampsia: High blood pressure and protein in the urine during pregnancy.
- Primiparity: First-time pregnancy.

PATHOPHYSIOLOGY:

Uterine atony can result from factors such as high parity, chorioamnionitis, prolonged administration of oxytocin, and general anesthesia (GA). Uterine distension can take place in a few conditions like polyhydramnios, multiple gestations, and uterine fibroids. Factors contributing to uterine inversion include a shortened umbilical cord and excessive pulling on the cord, and placental attachment at the fundus. Genital tract injuries may occur due to surgical vaginal delivery or a rapid birth. A Retained Placenta and improper placentation can happen if the placenta is partially delivered, has a succenturiate lobe, or due to prior uterine surgery. Coagulation problems are frequently observed in high-risk patients such as intrauterine foetal demise, abruptio placenta , sepsis, disseminated intravascular coagulation, or hereditary coagulation deficiencies. High-risk factors for PPH include bleeding during and after delivery, a previous history of PPH, low haematocrit (< 30%), morbidly adherent placenta, Hypotension or Tachycardia during and after delivery. [37]

ATONIC POST-PARTUM HAEMORRHAGE:

Atonic postpartum haemorrhage is linked to factors such as multiple pregnancies, placenta previa, history of previous PPH, BMI over 30, prolonged labor, fetal macrosomia over 4 kg, and first-time mothers over the age of 40. Protective factors, such as caesarean delivery, and risk factors, such as nulliparity and vaginal birth after caesarean delivery, are associated with haemorrhage due to uterine atony.[38]

In a study by Azar Mehrabadi etal.[39], both vaginal and caesarean deliveries showed an increase in atonic postpartum haemorrhage, regardless of prior caesarean deliveries. Atonic postpartum haemorrhage was most common in caesarean deliveries across all subcategories, including those without labor, with spontaneous labor, and with labor induction. Additionally, those who

underwent instrumental vaginal delivery had a increased incidence of atonic postpartum haemorrhage in contrast to those who had a standard vaginal delivery.

CALCULATION OF BLOOD LOSS DURING PPH:

Blood loss calculation is done by the following way-

- Clinical methods
- Direct methods
- Laboratory-based measurement
- Others

Clinical Methods:

Subjective characteristics are used to determine blood loss, including The Shock Index (SI) is determined by "dividing the systolic blood pressure by heart rate". SI often ranges between 0.5 and 0.7. An SI value between 0.9 and 1.1 indicates significant haemorrhage.

RULE OF 30: Patients are considered to have lost 30% of their blood volume if the following parameters are identified:

- A drop in systolic blood pressure (SBP) by 30 mmhg
- A rise in pulse rate of 30 beats per minute
- A 30 breaths per minute rise in respiratory rate
- Haematocrit decreased by 30%
- Urine-output less than 30 ml per hour

ACCORDING TO SEVERITY OF HAEMORRHAGE : Gutierrez et al.[40] classified into four classes: (Table 3).

Table 3: CLASSIFICATION OF HEMORRHAGE[40]

Parameters	Class I	Class II	Class III	Class IV
Blood loss (ml)	< 750 ml	750-1500 ml	1500-2000 ml	>2000 ml
Blood loss (%)	<15%	15 to 30%	30 to 40%	More than 40%
Pulse (Per minute)	N	100 to 120	121 to 140	>140
BP	N	D	D	D
RR (breaths/min)	14-20	20-30	30-40	>40
Urine output	>30ml/hour	20-30 ml/hour	5-15 ml/hour	Negligible
CNS symptoms	N	anxious	Lethargic	Confused

N=Normal, D=Decreased

VISUAL ESTIMATION:

The approach that is most frequently used to estimate blood loss is visual estimation, offering primary advantages of real-time evaluation and result correlation. However, several studies have highlighted significant disparities between clinical estimations and actual measurements.

For instance, Prasertcharoenusk et al.[41] found that the prevalence of postpartum haemorrhage {PPH} using visual estimation is usually underestimated. Similarly, Duthie et al.[42] reported the blood loss during caesarean section is significantly underestimated. Khan et al.[43] observed a higher preponderance to underestimate blood loss, especially when the calculated amount exceeded 1000 ml.

Estimations for Common Items:

A 10 x 10 cm swab amounts 60 ml loss.

A swab of 30 x 30 cm size amounts 140 ml loss.

A swab of 45 x 45 cm amounts 350 ml loss.

A soaked swab weighing one kilogram equals a loss of 1000 ml

Tentatively, 50 cm floor spill equals to 500 ml of loss.

Whereas 75 cm floor spill equals to 1000 ml loss.

And 100 cm of floor spill equals to 1500 ml

Direct Methods:

Direct methods are the oldest techniques used to assess blood loss. Tools and methods employed for normal delivery include:

- Bed pan and measuring jar,
- One rubberized blood mat,
- One Kelly's-pad,
- Callibrated drape-method

The gravimetric method:

The gravimetric method, straightforward approach for calculating blood loss during a caesarean section. It involves two key techniques:

Patient Weighing: Weighing the patient before and after the procedure to estimate blood loss.

Swab Weighing: Weighing blood-soaked swabs to determine the amount of blood absorbed.

Patient Weighing Method:

The patient's weight is measured before and after surgery to estimate blood loss. Adjustments should be prepared for infusions, drainage, removal of tissue, and water loss.

Swab-Weighing Method:

This is considered the gold standard method. the difference in weight between swabs taken before and after the operation indicates the blood absorbed by the swabs.[41]

A gram of weight gain equals one millilitre of blood lost.

Errors due to evaporation can be minimized by weighing the soaked pads immediately after surgery, which helps reduce measurement inconsistency or inter-observer variation. Because it provides a practically real value, it is regarded as a standard method for comparability.[44]

Laboratory-Based Measurements:

CALORIMETRIC METHOD [45]:

In this method, measured volume of tap water is used to wash the contaminated blood swabs. Ammonium hydroxide, serving as a deforming agent, is added to create a 1 in 1000 dilution. The resultant solution's concentration is then assessed after blood collection in suction container & mixed with the water.

Blood loss is expressed in milliliters (ml) as follows: (Hb% of the washing fluid × volume of washing fluid) / (Hb% of the patient's blood × patient's Hb% dilution factor).

ACID HEMATIN OR(ALKALINHEMATIN) METHOD:

Blood collected is mixed with a standardized solution, which converts haemoglobin into acid hematin or cyanomethemoglobin can be measured using spectrophotometer or colorimeter.

ELECTROLYTE CONDUCTIVITY METHOD:

"This method employs an automated blood loss meter based on the electrolyte conductivity to measure blood loss".

RADIOACTIVITY METHOD:

A known amount of radioisotope is injected intravenously preoperatively. During surgery, the radioactivity of the blood-soaked swabs is measured to determine blood loss.

MEASUREMENTS OF BLOOD VOLUME:

THE DYE METHOD:

Dye used to measure blood volume is Evans blue dye which is neither catabolized nor rapidly removed from the circulation.

RADIOISOTOPE METHOD:

Before surgery, a radioisotope such as Iodine-131 (serum albumin) or Chromium-51 labelled red blood cells (RBCs) is injected into the patient. Postoperative radioactivity is then measured using a Geiger-Muller counter to determine blood loss.

CARBETOCIN:

Carbetocin is a long-acting synthetic analogue of oxytocin mainly used to prevent PPH after a caesarean section. It works by mimicking the natural action of oxytocin, binding to oxytocin receptors in the uterine muscle to induce rhythmic contractions, increased uterine tone, and reducing bleeding. The half-life of carbetocin is forty minutes.

STRUCTURE OF CARBETOCIN:

Carbetocin is a modified form of oxytocin, where the "hydrogen on the phenolic hydroxy group is replaced by a methyl group, the amino group on the cysteine residue is substituted with hydrogen, and the sulfur in the cysteine residue is replaced by a methylene group" (Figure 2).[46] Similar to oxytocin, carbetocin induces uterine contractions and functions as an oxytocic agent.

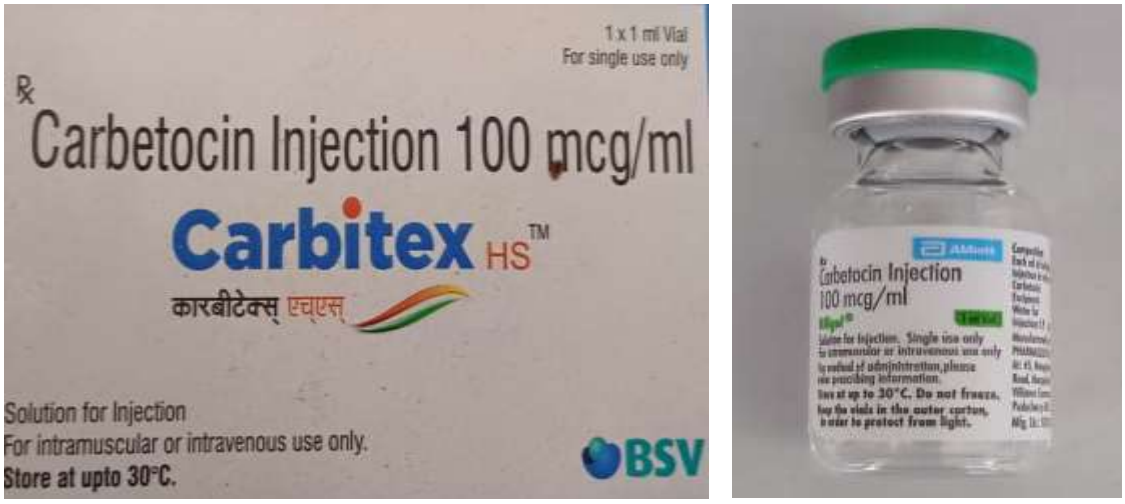


Figure 1: Carbetocin & Chemical structure of carbetocin (Source: 47)

PHARMACODYNAMICS AND PHARMACOKINETICS:

Carbetocin's half-life is longer than oxytocin, resulting in prolonged uterotonic effects, which reduces the need for repeated dosing. It is administered intravenously or intramuscularly and typically exhibits its peak effect within 10 minutes of administration, sustaining uterine contractions for approximately one hour.[47]

EFFICACY:

A study by Clinical studies have consistently demonstrated that carbetocin is effective in reducing blood loss intraoperatively and the additional need of uterotonic agents during caesarean sections. A study by Boucher et al. showed that "single dose of carbetocin has significantly decreased the need for additional uterotonic drugs compared to oxytocin".[47]

Similarly, Dansereau et al. found that carbetocin is more effective than oxytocin in preventing postpartum haemorrhage in high-risk patients undergoing caesarean section.[48]

SAFETY AND SIDE EFFECTS:

Similar to oxytocin, carbetocin has a safety profile that is generally well-tolerated. Common Side effects include nausea, headache and abdominal pain. Unique side effects such as metallic taste have been reported but are relatively rare. Fawzy et al. reported that side effects were generally mild and did not require discontinuation of the drug.[49]

The side effects of carbetocin can include:

- Nausea and vomiting
- Abdominal pain
- Headache
- Dizziness
- Flushing or hot flashes
- Tremors
- Chills
- Hypotension (low blood pressure)
- Tachycardia (rapid heartbeat)
- Uterine cramping
- Sweating

CLINICAL GUIDELINES:

International guidelines including those from the WHO recommend carbetocin alternatively to oxytocin for preventing PPH.[50] Its use is particularly advantageous in preventing PPH during caesarean sections, where it has been shown to be highly effective.

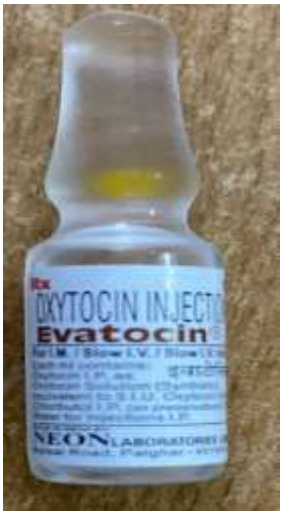
OXYTOCIN:

The posterior pituitary gland secretes oxytocin, a hormone and neurotransmitter that is naturally occurring and generated in the hypothalamus. It has a significant function in delivery of foetus and lactation, promoting uterine contractions and milk ejection. As a medication, synthetic oxytocin is widely used to induce labor, augment labor, and prevent and treat postpartum haemorrhage (PPH).

CHEMICAL STRUCTURE: Oxytocin is a cyclical, nonapeptide hormone having "an amino acid sequence CYIQNCPLG, and it also functions as a neurotransmitter in the brain"(Figure 1). Oxytocin is the primary hormone responsible for uterine contractions and milk ejection from the posterior-pituitary gland. Additionally, it acts as an oxytocic and a vasodilator. Classified as a peptide hormone, oxytocin is also a heterodetic cyclic peptide. [46]

PHARMACODYNAMICS AND PHARMACOKINETICS:

Oxytocin binds to receptors in the uterus, triggering contractions & enhancing uterine tone, reduces postpartum bleeding. Because of its short half-life (1-6 minutes), continual intravenous infusion is required to sustain its effects during labor and delivery.[52]



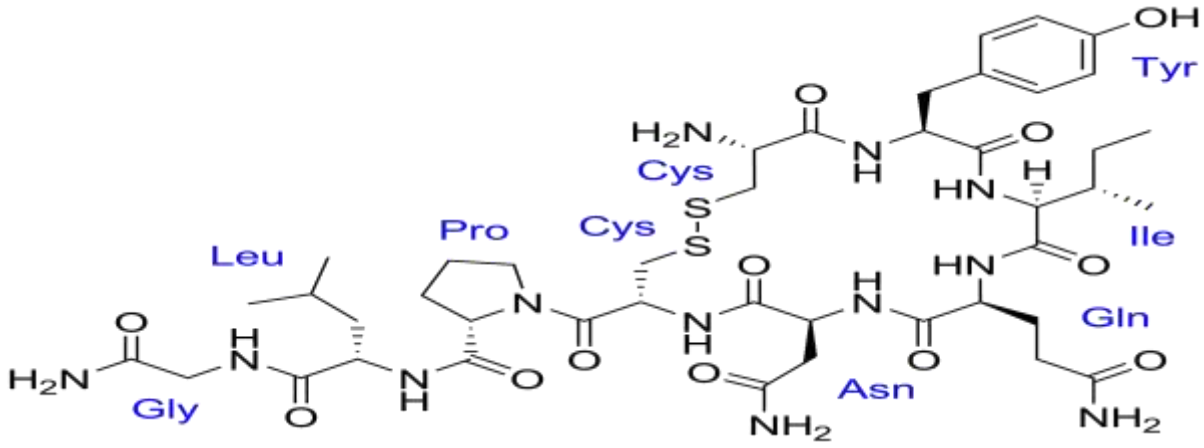


Figure 2: Oxytocin, Chemical structure of oxytocin (*Source:51)*

EFFICACY:

Oxytocin is highly effective in inducing labor and managing PPH. Numerous studies have demonstrated its efficacy in reducing the incidence of PPH , administered prophylactically in the third stage of labor. For instance, a Cochrane review found that prophylactic oxytocin significantly decreased the risk of PPH by 50% compared to placebo or no treatment.[53] Additionally, oxytocin is the first-line treatment recommended by various obstetric guidelines for managing PPH due to its proven effectiveness in promoting uterine contractions and reducing blood loss.

SAFETY AND SIDE EFFECTS:

Oxytocin is usually safe, but it may be associated with some potential side effects. Major adverse effects include nausea, vomiting, and headaches. More serious adverse effects can occur, such as uterine hyperstimulation, which may lead to fetal distress, uterine rupture, or water intoxication due to its antidiuretic effect. A study by Dyer et al highlighted the importance of careful monitoring and dose adjustments to minimize these risks during labor induction and PPH management.[54]

The adverse effects of oxytocin can include:

- Nausea and vomiting
- Headache
- Rapid or irregular heartbeat
- Low blood pressure
- Excessive uterine contractions
- Uterine rupture
- Water intoxication (when given in large doses)
- Allergic reactions (e.g., rash, itching, swelling)
- Bleeding after childbirth
- Foetal distress or hypoxia (reduced oxygen supply)
- Hyperbilirubinemia in the newborn
- Seizures (in rare cases)

CLINICAL GUIDELINES:

International guidelines, including those from the WHO and the American College of Obstetricians and Gynaecologists (ACOG), recommended “oxytocin as the first-line agent for

the prevention and treatment of PPH".[50,55] Its widespread availability, established efficacy, and relatively low cost make it a cornerstone of obstetric care worldwide.

COMPARISON BETWEEN CARBETOCIN & OXYTOCIN:

Attilakos et al.,[19] compared the efficacy of carbetocin & oxytocin for PPH prevention following caesarean sections. The double-blinded randomized study was conducted at a teaching-hospital in Bristol, UK, which handles approximately 6,000 deliveries each year. The study population included term pregnant women undergoing a caesarean section performed under regional anesthesia, either elective or emergency with exclusions for conditions like placenta praevia, multiple gestation, and placental abruption. Participants were assigned randomly to receive either 100 μg of carbetocin or 5 IU of oxytocin intravenously post-delivery. Standard perioperative care was maintained, and the use of additional uterotonics was determined by obstetrician. An intention treat analysis was done by the authors. The primary outcome targeted on the percentage of women requiring additional pharmacological uterotonic interventions. The findings revealed that a noticeably greater proportion of women in oxytocin group required additional uterotonics in comparison to the carbetocin group (45.5% vs. 33.5%, RR 0.74, 95% CI 0.57 to 0.95), despite majority of these women received oxytocin. The secondary outcomes namely significant PPH, the need for blood products, and changes in the haemoglobin levels did not have a notable difference. The study concluded that while carbetocin was linked to a reduced need for additional oxytocic's, it remains uncertain whether this reduction can also decrease the rates of PPH and the necessity for blood transfusions. [19]

Kang et al comparing efficacy and safety of carbetocin and oxytocin in prevention of PPH following elective caesarean sections among a high-risk Chinese group. In this randomized, open-label trial involving 852 pregnant women, the participants were identified with one or multiple risks for PPH. These women were randomized to either the oxytocin or carbetocin

groups. The Main measure of efficacy was the need for additional uterotonics. Results indicated that 442 women received carbetocin and 410 received oxytocin, with both groups showing similar baseline characteristics. The carbetocin group exhibited a significantly lower requirements for additional uterotonics(18.4% vs. 24.4%, p=0.03). However, the differences were not significant in terms of the amount of intrapartum or postpartum blood loss, postpartum drop in haemoglobin levels, usage of hemostatics, rates of blood transfusion, need for additional interventions, and requirement for uterine massage between the two groups. A slightly higher incidence of mild asphyxia was noted in the carbetocin group (2.1% vs. 1.3%). Overall, no significant adverse maternal or neonatal outcomes were reported in either group. The study concluded that carbetocin leads to a lower rate of additional uterotonic use in high-risk Chinese women undergoing elective caesareans, performing comparably to oxytocin in terms of postpartum blood loss and other significant health outcomes. [56]

Larceprit et al compared the effectiveness of oxytocin and carbetocin in relation to blood loss and compared their hemodynamic effects and the need for additional uterotonics in caesarean sections at high risk of PPH. Women in the carbetocin group received a 100 µg IV bolus, while the other group(Oxytocin) were received 20 IU of oxytocin(in a 1000 ml 0.9% NaCl solution) IV at 150 mL/hour. The primary parameters evaluated were "The hemodynamic effects of the drugs and the need for additional uterotonic agents". The study also compared the decrease in haemoglobin levels, uterine tone, uterine fundal state, and diuresis. Results indicated that both drugs caused hypotensive effects, with a more significant drop in blood pressure seen in the oxytocin group. A notably higher percentage of women in the oxytocin group required additional uterotonic agents (nearly one-fourth vs. none, $p < 0.01$). there were no significant differences in estimated blood loss or the decrease in haemoglobin levels ($p > 0.05$). However, diuresis levels were significantly greater in the carbetocin group (1300 ml vs. 1100 ml). The authors concluded that "A single injection of carbetocin was more effective than continuous

infusion of oxytocin in preventing PPH". the hemodynamic profile was similar and a minor antidiuretic effect.[57]

Patil et al conducted a study "To compare the effectiveness of carbetocin with oxytocin in managing the third stage of labor" considering the significant global impact of postpartum haemorrhage (PPH) on maternal mortality. Oxytocin's challenges in resource-limited settings due to its short half-life and heat sensitivity prompted the exploration of carbetocin, which does not require cold storage. This prospective study recruited 200 primigravida women. While one group was administered with carbetocin(100 μg) & the other group received oxytocin(10IU). Postpartum Blood loss, additional need of uterotonic agents, blood products, surgical management for PPH, and postoperative haemoglobin were compared. Comparing the mean blood loss (377.68 ml) between the carbetocin and oxytocin groups, the latter had much less (345.34 ml). Side effects were similar in both the groups. Postpartum, the oxytocin group experienced a significant 7% incidence of haemorrhage compared to the carbetocin group. The authors concluded that In the active management of the third stage of labor, carbetocin proved to be more effective than oxytocin as evidenced by a notable drop in the incidence of PPH and a reduced requirement for supplementary uterotonic medications.[58]

Nahaer et al from Bangladesh evaluated oxytocin and carbetocin's effectiveness and safety in avoiding PPH after caesarean sections. Between June 2016 and June 2017, a full year of twelve months was spent conducting the randomized experiment. Following surgery, 100 term women randomized receive either carbetocin(100 μg) or oxytocin(10IU). Primary PPH, blood loss, t requirement for extra uterotonic medication, blood transfusion, and side effects were among the outcome measures. The authors found that 6% of patients in the oxytocin group experienced massive blood loss, and 20% required blood transfusions. In contrast, the carbetocin group had no cases of massive blood loss, and only 2% required immediate blood transfusions. Furthermore, compared to the oxytocin group, comparatively fewer patients in the carbetocin

group required extra uterotonics. None of the two groups experienced major adverse effects, and no participants in the carbetocin group developed PPH. On the contrary, 8% participants in the oxytocin group had PPH. The study concluded that "carbetocin has greater efficacy than oxytocin in preventing postpartum haemorrhage following caesarean sections". [59]

Boucher et al compared the efficacy and safety of a single 100 µg iv injection of carbetocin, with a standard oxytocin infusion during caesarean section through a double-blind, randomized study. The primary outcomes were blood loss, safety, and the ability to maintain uterine tone. Fifty-seven pregnant women undergoing elective caesarean section post-placental delivery received either carbetocin or oxytocin. A sensitive colorimetric technique was used to measure the amount of blood loss during surgery, and assessments were conducted up to 24 hours post-operation. The authors found that "carbetocin was as more effective than continuous oxytocin infusion in controlling intraoperative blood loss" (Carbetocin had 29 ml less blood loss than oxytocin). Carbetocin also promoted early postpartum uterine involution, with more patients showing the fundus below the umbilicus at various time points. Importantly, there were no significant differences in safety parameters between the two groups. Carbetocin was well tolerated and required less intervention for PPH or uterine atony compared to oxytocin.[47]

The authors concluded that In terms of maintaining adequate uterine tone and preventing excessive intraoperative blood loss during caesarean section post-placental delivery. A single 100 µg intravenous injection of carbetocin was found to be more reliable and equally effective than a standard continuous infusion of oxytocin.

In a meta-analysis conducted by Voon et al The efficacy of carbetocin was compared to oxytocin in preventing PPH during caesarean deliveries considering the significant maternal mortality burden due to uterine atony in developing countries. The outcomes analyzed included PPH, the additional use of oxytocic's, and the need for transfusion.[60]

Findings from seven trials with patients from 2012 demonstrated a significant decline in PPH rates, additional uterotonic usage, and transfusion requirements when carbetocin was used instead of oxytocin. However, significant heterogeneity was noted across studies, particularly regarding additional uterotonic usage. The meta-analysis concluded that "carbetocin effectively reduces the need for additional uterotonics, PPH, and transfusions during caesarean deliveries". Despite these benefits, the cost difference between carbetocin and oxytocin highlights the need for locoregional cost-effectiveness analyses before considering the routine use of carbetocin for prophylaxis.

MATERIALS & METHODS

MATERIALS & METHODS:

STUDY AREA : Department of Obstetrics and Gynaecology, RL JALAPPA HOSPITAL AND RESEARCH CENTRE attached to SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTRE, Tamaka, Kolar.

STUDY POPULATION: This study was conducted on all women admitted to Department of Obstetrics and Gynaecology, at RL JALAPPA HOSPITAL AND RESEARCH CENTRE attached to SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH CENTRE, Tamaka, Kolar , who fulfilled the inclusion criteria and had undergone emergency/ elective caesarean section, were eligible to take part in the study.

STUDY DESIGN: PROSPECTIVE COMPARATIVE STUDY

SAMPLE SIZE: 82 patients were recruited in the two groups, Group-A (Oxytocin) & Group-B(Carbetocin)

Sample size was calculated by considering prevalence of PPH as per WHO (Reference) p = 28.37% and q=(100-p)= 71.63% and alpha error =0.05% and 90% power of the test, also allowable error (l) = 10% , so sample size will be 82.

SAMPLING METHOD: Every alternative eligible patients were selected alternatively until the desired sample size is obtained.

STUDY DURATION: September 2022 to December 2023

INCLUSION CRITERIA:

- Pregnant women age between 19 years to 40 years with Gestational age between completed 37weeks to 42 weeks.
- Singelton pregnancy

- Pregnant women undergoing Emergency/ Elective Lower Segment Caesarean Section under Spinal anaesthesia.

EXCLUSION-CRITERIA:

- Antepartum Haemorrhage
- Preterm (Gestational age < 37 weeks)
- Preeclampsia, Eclampsia, Epilepsy
- Prior history of Liver/cardiac/renal diseases
- Allergy to Carbetocin/ Oxytocin
- Coagulation disorders, Intrauterine foetal demise, Polyhydramnios, Fibroid Uterus, DIC, Anticoagulant therapy, previous history of myomectomy

ETHICAL CONSIDERATIONS: Study was approved by institutional human ethics committee. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and voluntary nature of participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

METHODOLOGY: A Prospective Comparative Study was designed for patients aged 19-35 years, with gestational age >37 weeks, undergoing emergency or elective caesarean section under spinal anaesthesia at the Department of Obstetrics and Gynaecology, RLJH, Kolar after obtaining ethical clearance.

The participants were recruited at the hospital. they were alternatively assigned to two groups: the carbetocin group (Group A) and the oxytocin group (Group B).

Group A will receive oxytocin injection, where 20 units of oxytocin will be administered in 1 liter of Ringer's lactate solution at a rate of 1000 cc per hour, IV infusion after the delivery of baby.

Group B will receive carbetocin injection, administered as a 100-µg bolus dose IV immediately after delivery of the baby.

Outcome: Primary outcomes of this study include following:

- Assessment of vitals during and after operation,
- Estimated blood loss (both per operative and within the first 24 hours post-surgery),
- Changes in haemoglobin levels preoperatively & postoperatively,
- Incidence of primary PPH,
- Need for blood transfusions,
- Adverse effects.

Secondary outcomes focused on the following:

- Need for Additional oxytocic/ uterotonic agents,
- Need for Additional procedures to control postpartum haemorrhage,
- Assessment of haemoglobin difference by comparing haemoglobin levels at admission and measured postoperatively.

Blood loss was evaluated immediately after the delivery, defining haemorrhage as blood loss exceeding 1000 ml. Estimates of blood loss were based on visual inspection, measurement of collected blood in suction containers excluding amniotic fluid , and by weighing all blood-soaked mops and clots.

Blood pressure (in mmHg), urine output (ml/hr) ,uterine tone(contracted/not) ,were monitored at 2, 12, and 24 hours after the operation.

OBSERVED PARAMETERS:

- BLOOD LOSS MEASUREMENT: The quantity of mops and pads saturated with blood, as well as the suction volume, excluding amniotic fluid, was recorded.

- HAEMOGLOBIN LEVELS: Preoperative and postoperative haemoglobin levels were monitored.
- VITALS: SpO2, pulse rate, urine output, blood pressure, and respiratory rate were measured. During the surgery, vital signs were recorded every 5 minutes for the first 30 minutes after injection, and subsequently every 10 minutes throughout the procedure.
- COMPLICATIONS: Any complications observed preoperatively and postoperatively were documented, with particular attention to respiratory or cardiovascular issues, as well as symptoms including headache, nausea, and vomiting.

STATISTICAL ANALYSIS:

The Statistical analysis for this study was conducted to assess several outcome variables. Firstly, the need for additional uterotonic agents was analyzed using descriptive statistics to determine the proportion of patients in each treatment group requiring additional agents. A comparison of the drop in haemoglobin levels between admission and 24 hours post-delivery was performed either Wilcoxon signed-rank tests or paired t-tests, based on the data's distribution. Blood loss, defined as Haemorrhage at 1000 ml or more, was evaluated immediately after caesarean section. Blood loss estimation was conducted using visual estimation, measuring collected blood in suction containers excluding amniotic fluid, and weighing all blood-soaked mops and clots. Changes in blood pressure over time were analysed using repeated measures ANOVA or Friedman tests, with post-hoc tests for pairwise comparisons. Uterine tone, position, and other categorical variables compared by Chi-square tests/ Fisher's exact tests, as appropriate. Incidence of PPH and requirement for blood transfusion were reported as proportions, and differences between groups were assessed using Chi-square tests.

RESULTS

RESULTS:

A total of 82 subjects were included in the final analysis

TABLE 4: DISTRIBUTION OF AGE BY GROUPS(N= 82):

Age(years)	Study groups				p-value
	Oxytocin (N =41)		Carbetocin (N =41)		
	N	Percentage (%)	N	Percentage (%)	
19-20	5	12.2	5	12.2	0.96
21-25	19	46.3	17	41.5	
26-30	12	29.3	14	34.2	
31-35	5	12.2	5	12.2	

We recruited a total number of 82 participants in the study, 41 (50%) each in both the groups. Majority of participants (n=34, 41.5%) belonged to 21 to 25 years' category. When compared between the two groups, the age distribution was similar in both groups. The difference was statistically not significant (p=0.96) (Table 4, Figure 3)

FIGURE 3: DISTRIBUTION OF THE OXYTOCIN AND CARBETOCIN IN DIFFERENT AGE GROUPS (N= 82):

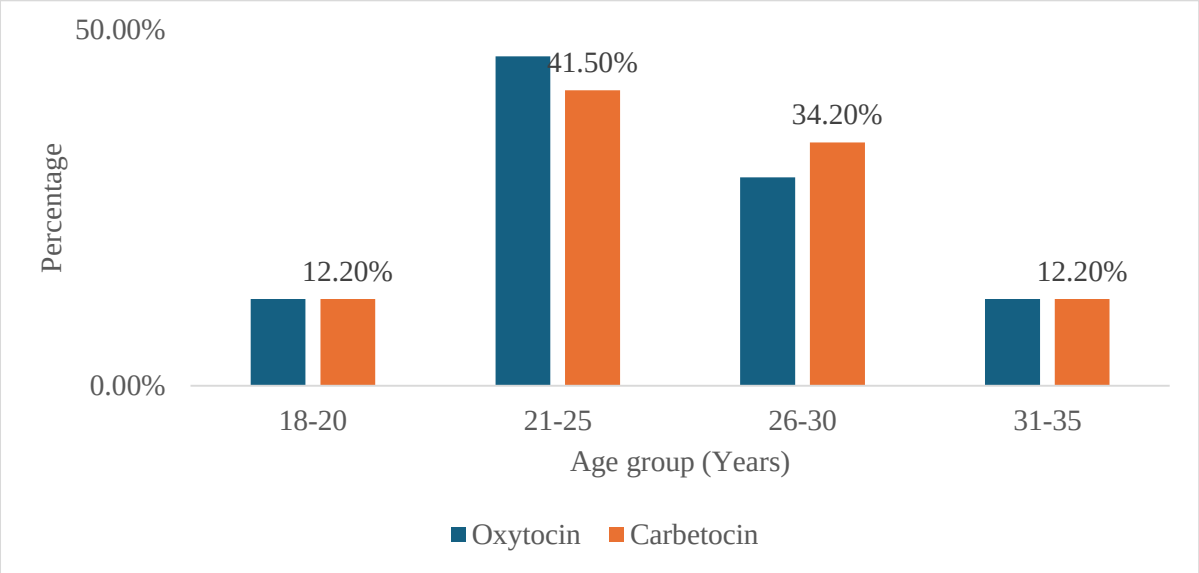


TABLE 5: COMPARISON OF GESTATIONAL AGE BETWEEN OXYTOCIN & CARBETOCIN GROUP(N= 82):

Gestational age(Weeks)	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
37- 40	33	78.4	32	76	0.96
40+1 - 42	8	21.6	9	24	

Overall, the median GA was 38 weeks (IQR: 38 to 39 weeks). the distribution of GA was same in both the groups (p=0.97). While the median GA was 38 weeks (IQR: 38 to 39 weeks) for oxytocin group, the median GA was 39 weeks (IQR: 38 to 39 weeks) for carbetocin group. While 78.4% in the oxytocin group were within 40 weeks of GA, the proportion was 76% in the carbetocin group (Table 5, figure 4). This difference was not statistically significant (p=0.96)

FIGURE 4: COMPARISON OF GESTATIONAL AGE BETWEEN THE OXYTOCIN& CARBETOCIN GROUP (N= 82):

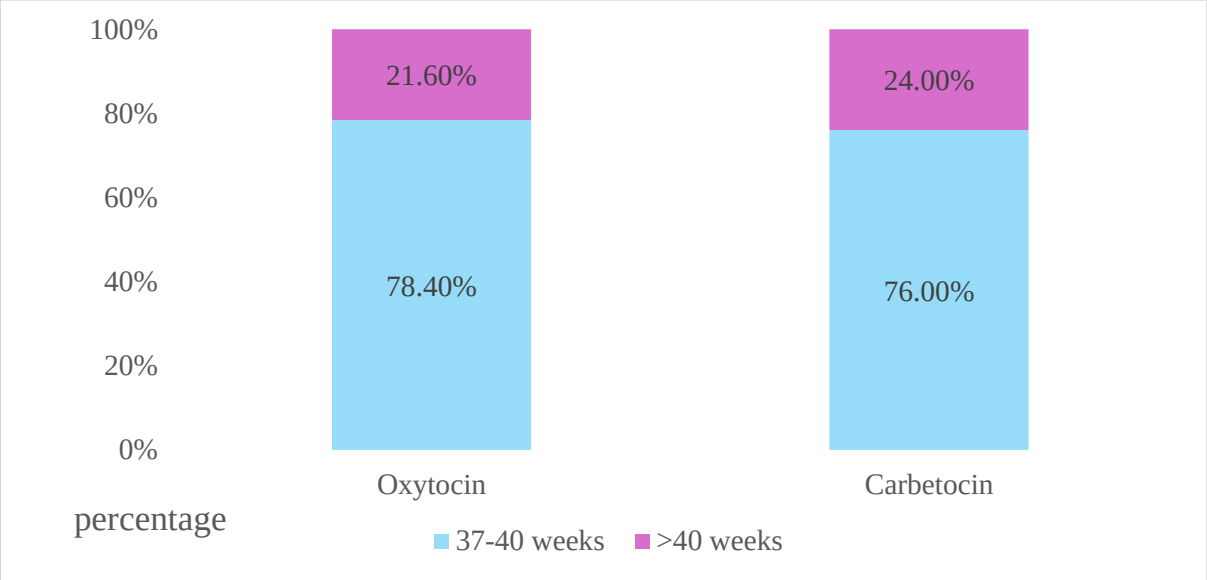


TABLE 6: COMPARISON OF GRAVIDA BETWEEN OXYTOCIN & CARBETOCIN GROUP(N= 82):

Gravida	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Primi	12	29.3	17	41.5	0.25
Multi	29	70.7	24	58.5	

Overall, majority of the participants belonged to multigravida (n=53, 64.6%) than primigravida (n=29, 35.4%).

When divided into two groups, the oxytocin group had more multigravida participants (n=29, 70.7%) than the carbetocin group (n=24, 58.5%). There was no statistically significant difference though (p=0.25) (Table 6, Figure 5).

FIGURE 5: COMPARISON OF DISTRIBUTION OF GRAVIDA IN TWO GROUPS(N= 82):

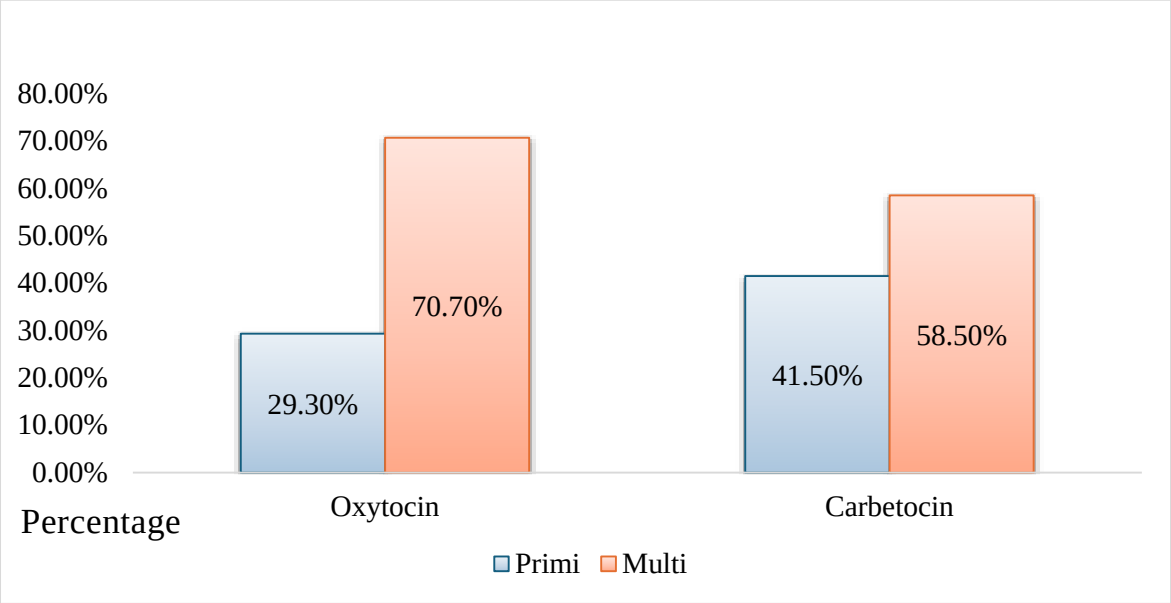


TABLE 7: COMPARISON OF TYPE OF CAESAREAN SECTION BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

Type of Caesarean section	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Elective	17	41.5	15	36.6	0.65
Emergency	24	58.5	24	63.4	

Comparison of type of Caesarean section between the oxytocin and carbetocin group:

Overall, majority of the participants underwent emergency LSCS (n=50, 61%) than elective (n=32, 39%) (Table 7, Figure 6). When divided into two groups, the oxytocin group had more emergency LSCS (n=31, 75.6%) than the carbetocin group (n=24, 58.5%). The difference was not statistically significant though (p=0.65) (Table 8, Figure 7).

FIGURE 6: COMPARISON OF TYPE OF CAESAREAN SECTION BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

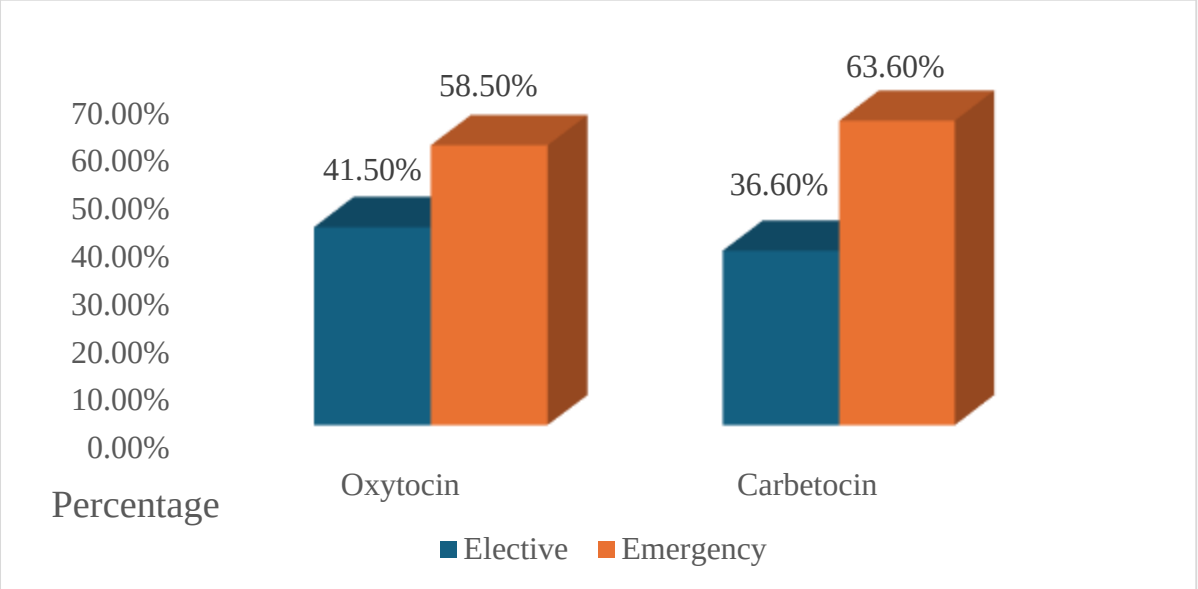


TABLE 8: COMPARISON OF INDICATIONS OF CAESAREAN SECTION BETWEEN THE OXYTOCIN & CARBETOCIN GROUP(N= 82):

Indication for Caesarean Section	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
CDMR	0	0	3	7.3	0.32
CPD	1	2.4	0	0	
Foetal distress	7	17.1	12	29.3	
Malpresentation	3	7.3	1	2.4	
Oligohydramnios	3	7.3	4	9.8	
Previous LSCS	22	53.7	17	41.5	
Impending scar rupture	3	7.3	3	7.3	
Obstructed labour	1	2.4	1	2.4	
Contracted pelvis	1	2.4	0	0	

Overall, the major indication for LSCS is previous LSCS (n=38, 47.6%). the other indications were foetal distress, Oligohydramnios, malpresentation, CDMR, and CPD (Table 8, Figure 7). Indication in both the groups. The frequency of all indications are similar in both the groups (p=0.32)

FIGURE 7: COMPARISON OF INDICATION OF LSCS BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP (N= 82):

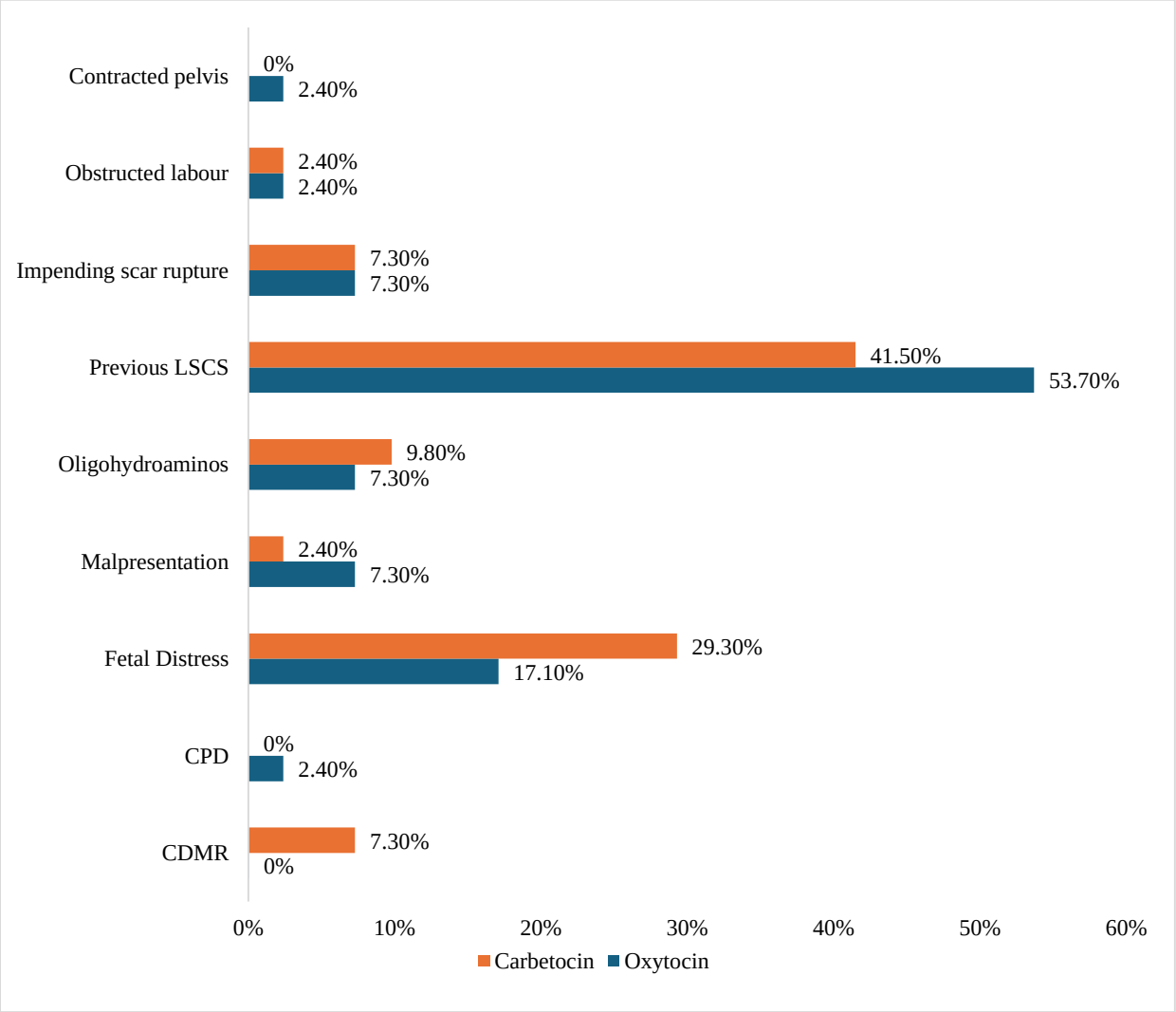


TABLE 9: COMPARISON OF PRE-OPERATIVE HEMOGLOBIN (HB) LEVEL BETWEEN OXYTOCIN & CARBETOCIN GROUP (N= 82):

Preoperative Haemoglobin	Study Groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
Mean Hb (SD)	Mean	SD	Mean	SD	
	11.0 gm/dL	SD 1.7 gm/dL	11.5 gm/dL	SD 1.2 gm/dL	0.63

While mean haemoglobin Was 11.0 gm/dL (SD 1.1 gm/dL) in the oxytocin group, mean was 10.7 gm/dL (SD 1.2 gm/dL) in the carbetocin group. The difference between the carbetocin and oxytocin group was statistically not significant (p=0.63) (Table 9, figure 8)

FIGURE 8: COMPARISON OF PRE-OPERATIVE HEMOGLOBIN (HB) LEVEL BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP (N=82):

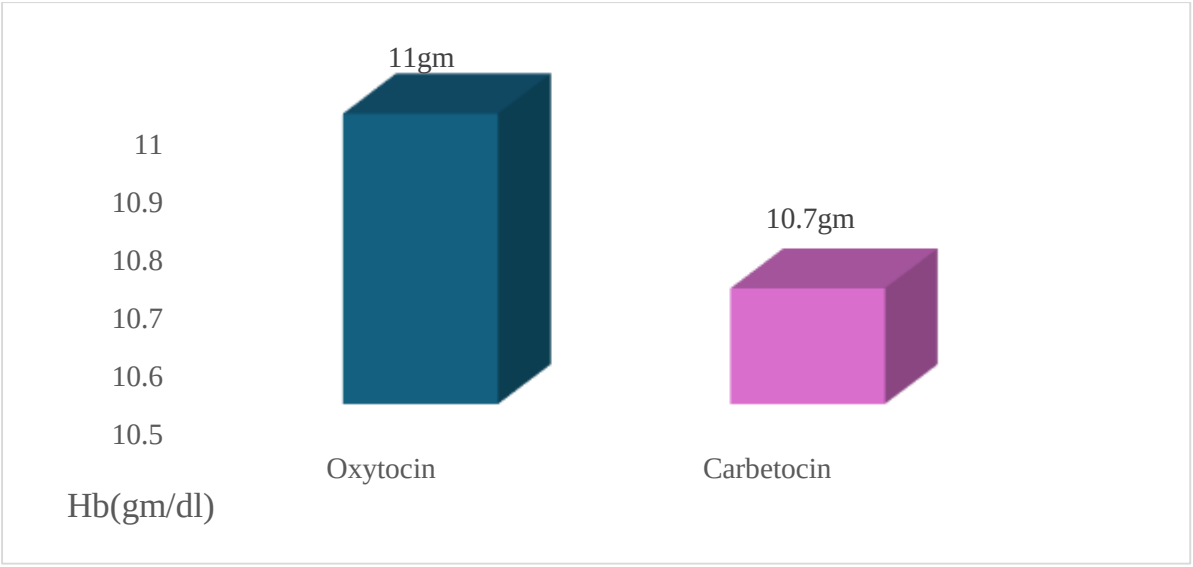


TABLE 10: COMPARISON OF SUCTION VOLUME BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP (N= 82):

Suction volume (ml)	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
601 to 800 ml	4	9.5	0	0	<0.001*
401 to 600 ml	18	43.9	4	9.8	
200 to 400 ml	15	35.7	24	58.5	
<200 ml	4	9.5	13	31.7	

*Statistically significant

Comparison of suction volume between the oxytocin and carbetocin group: Suction volume was high (400 to 800 ml) in the oxytocin group (n=22, 53.7%) than the carbetocin group (n=4, 9.8%). The difference between two groups was statistically significant (p<0.001) (Table 10, Figure 9).

FIGURE 9: COMPARISON OF SUCTION VOLUME BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP (N= 82):

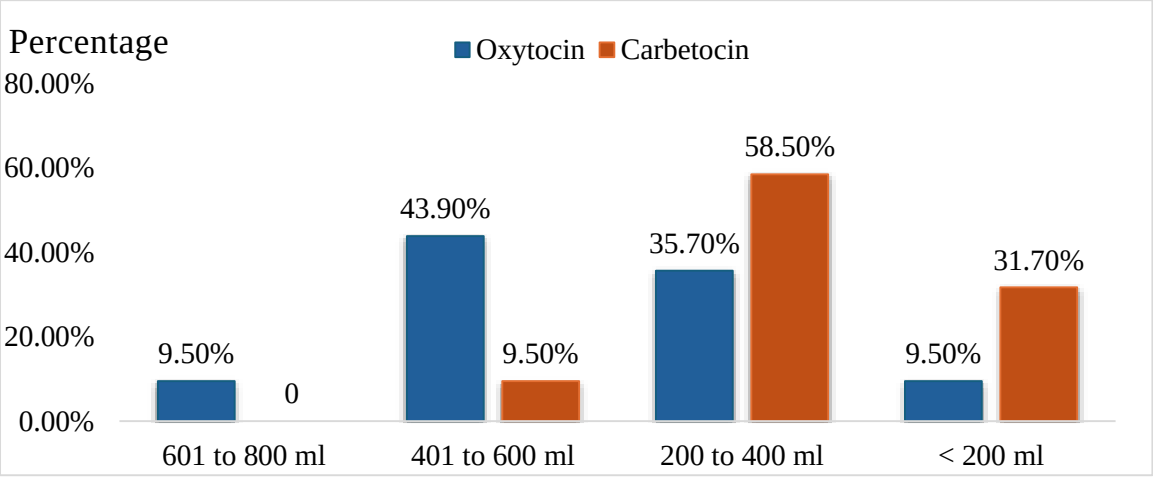


TABLE 11: COMPARISON OF MOP COUNTS BETWEEN OXYTOCIN & CARBETOCIN GROUP(N= 82):

Mops counts (number of mops used)	Study Groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
2	0	0	8	19.5	<0.001*
3	1	2.4	30	73.2	
4	22	53.7	3	7.3	
5	15	36.6	0	36.6	
6	3	7.3	0	7.3	

*Statistically significant

While the participants received oxytocin had a mop count of up to 6, the number of mops required for the carbetocin group was limited up to 4 (n=41, 100%). The difference in mop count between the carbetocin and the oxytocin groups was statistically significant ($p<0.001$) (Table 11, figure 10) the median mop count was 4 (IQR 4 to 5) for the oxytocin group, and 3 (2 to 3) for the carbetocin group.

FIGURE 10: COMPARISON OF MOP COUNT BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

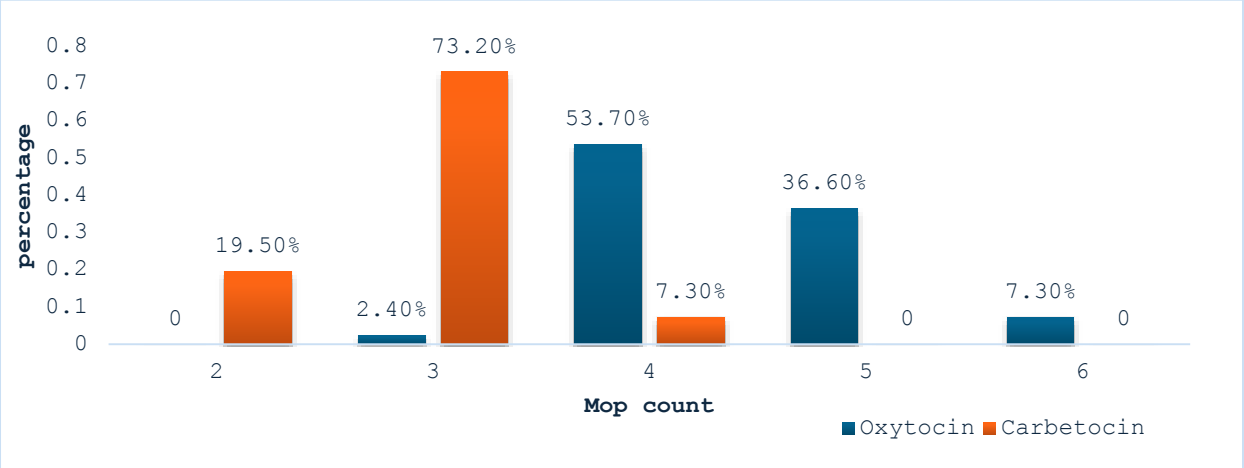
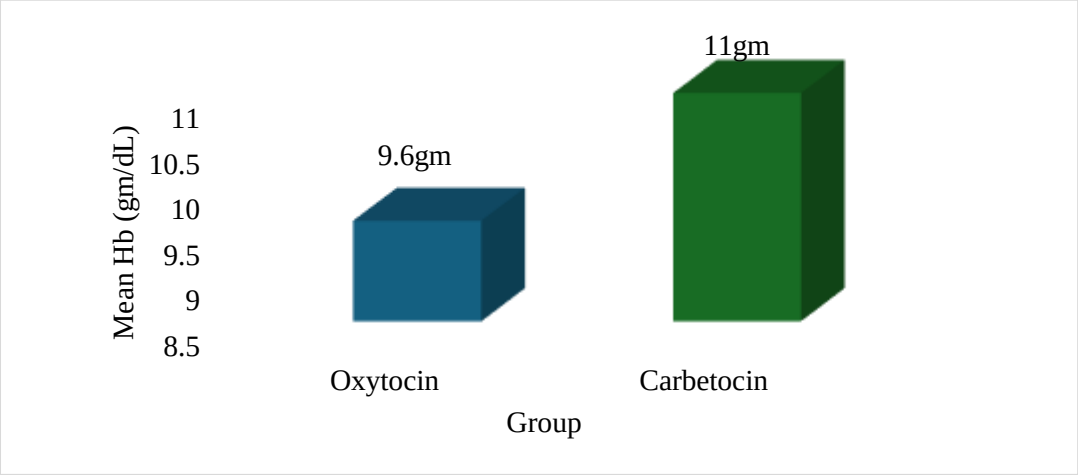


TABLE 12: COMPARISON OF POST-OPERATIVE HB LEVEL BETWEEN OXYTOCIN & CARBETOCIN GROUP(N= 82):

Postoperative haemoglobin	Study Groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
Mean Hb (gm/dl) (SD)	Mean	SD	Mean	SD	
	9.6 gm/dL	SD 1.7 gm/dL	11 gm/dL	SD 1.2 gm/dL	0.19

While the mean post-operative Hb level was 10.6 gm/dL (SD 1.2 gm/dL) for the oxytocin group, the mean Hb level was 11.0 gm/dL (SD 1.2 gm/dL) in the carbetocin group (Table 12, figure 11). Thus, the carbetocin group had 0.4 gm/dL (95% CI: -0.2 to 0.9, p=0.19) more post-operative Hb than oxytocin group.

FIGURE 11: COMPARISON OF POST-OPERATIVE HB LEVEL BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):



The mean reduction of Hb was 1.4 gm/dL (95% CI: 0.8 to 2.0, p=0.003*) for the oxytocin group. The Hb reduction was statistically significant. On the other hand, Hb increased by 0.3 gm (95% CI: -0.7 to 0.9 gm/dL), though statistically not significant.

TABLE 13: COMPARISON OF ANAEMIABETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

Anaemia (Hb <10gm/dL)	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Elective	3	7.3	0	0	0.07
Emergency	38	92.7	41	100	

While 3 (7.3%) participants had anaemia after LSCS in oxytocin group, none of participants in carbetocin group developed anaemia. Difference between the carbetocin and oxytocin group was statistically not significant (p=0.07) (Table 13, figure 12)

FIGURE 12: COMPARISON OF OF ANAEMIA BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

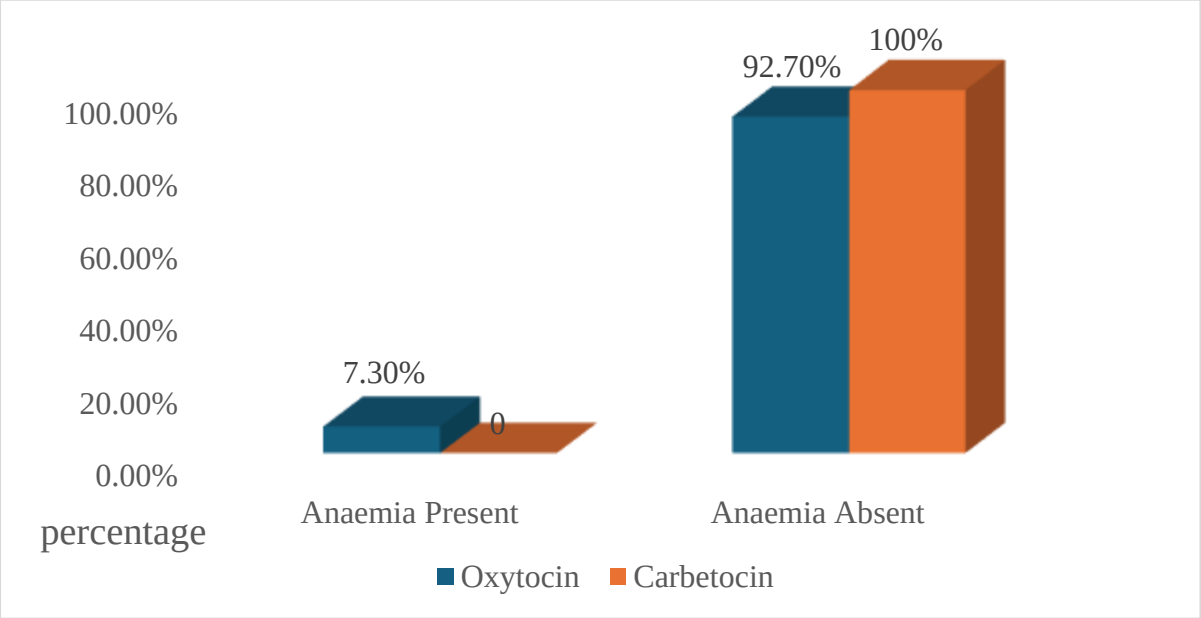


TABLE 14: COMPARISON OF NEED FOR BLOOD TRANSFUSION BETWEEN OXYTOCIN AND CARBETOCIN GROUP(N= 82):

Blood transfusion	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Required	3	7.3	0	0	0.07
Not Required	38	92.7	41	100	

While 3 (7.3%) participants required blood transfusion after LSCS in oxytocin group, none of participants in carbetocin group required transfusion. the difference was not statistically significant (p=0.07) (Table 14, figure 13)

FIGURE 13: COMPARISON OF NEED FOR BLOOD TRANSFUSION BETWEEN OXYTOCIN AND CARBETOCIN GROUP(N= 82):

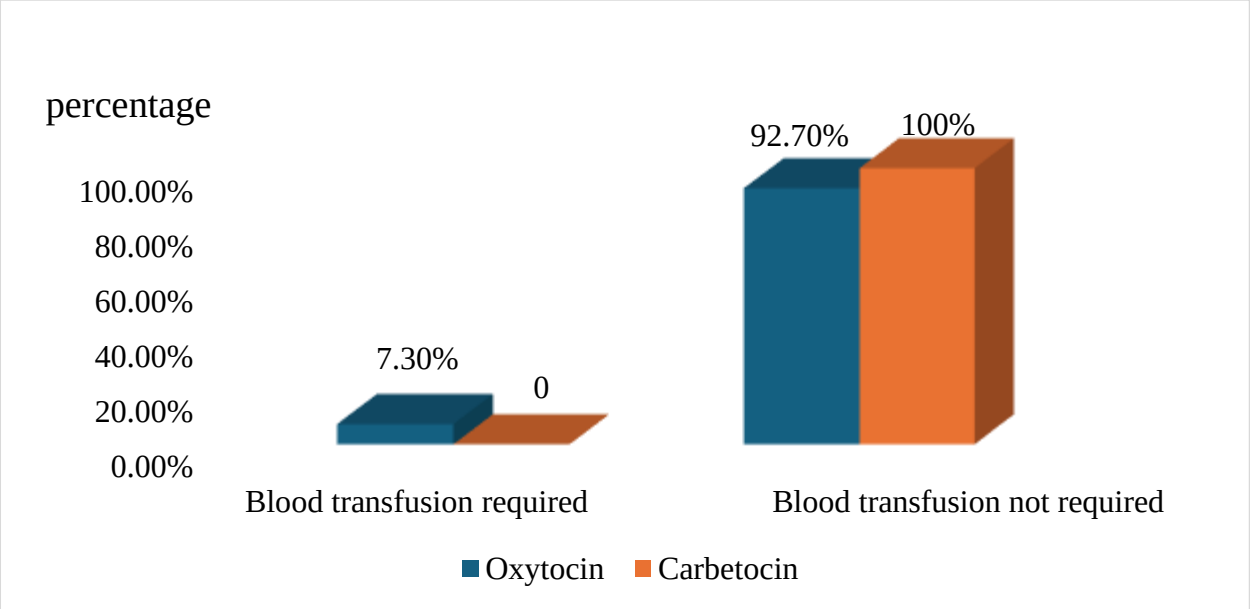


TABLE 15: COMPARISON OF NEED FOR UTEROTONICS BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

Need for uterotonics	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Required	12	29.3	2	4.9	0.003*
Not Required	29	70.7	39	95.1	

*Statistically significant

While 12 (29.3%) participants required uterotonics in oxytocin group, two participants (4.9%) in carbetocin group required uterotonics. A statistically significant difference was present. (p=0.003) (table 15, figure 14)

FIGURE 14: COMPARISON OF NEED FOR UTEROTONICS BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

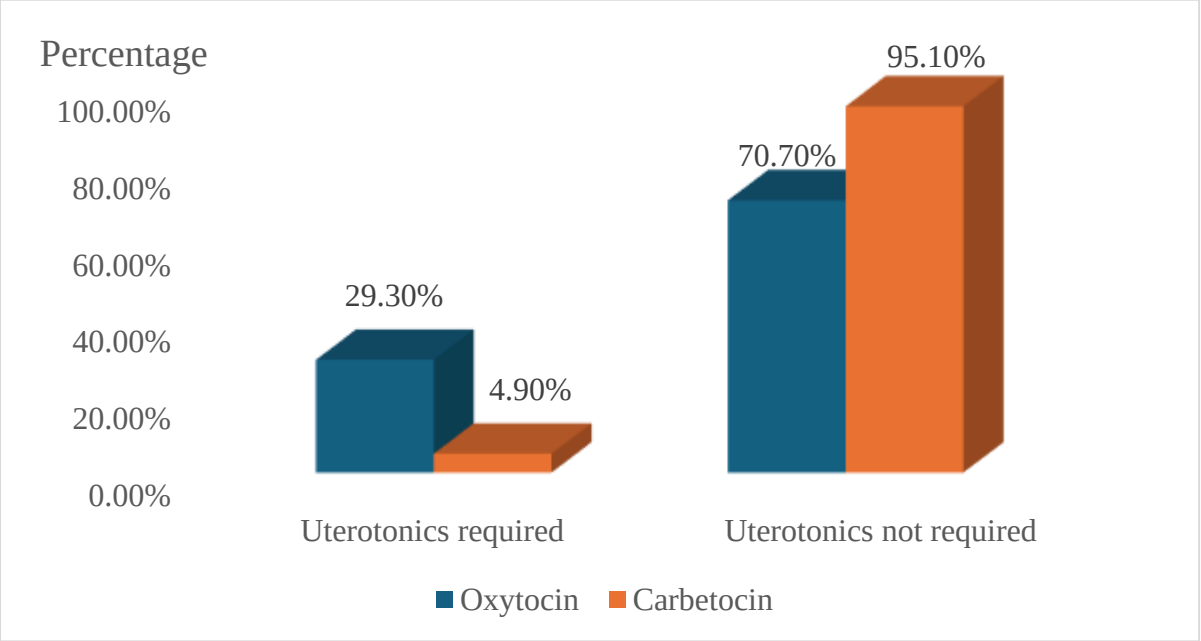


TABLE 16: COMPARISON OF NEED FOR ADDITIONAL SURGICAL PROCEDURES BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

Additional surgical procedures	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Required	6	14.6	0	0	0.01*
Not Required	35	85.4	41	100	

*Statistically significant

While 6 (14.6%) participants required additional surgical procedures in oxytocin group, none of the participants in carbetocin group required additional procedures. A statistically significant difference was present (p=0.01) (table 16, figure 15)

FIGURE 15: COMPARISON OF NEED FOR ADDITIONAL SURGICAL PROCEDURES BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

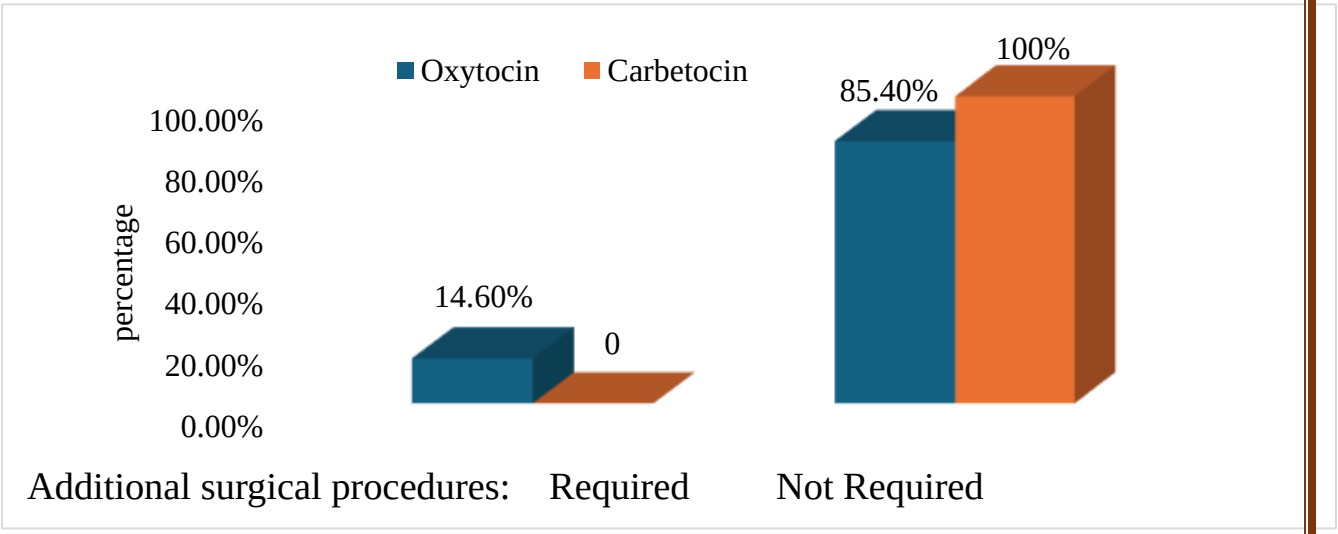


TABLE 17: COMPARISON OF SIDE EFFECTS BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):

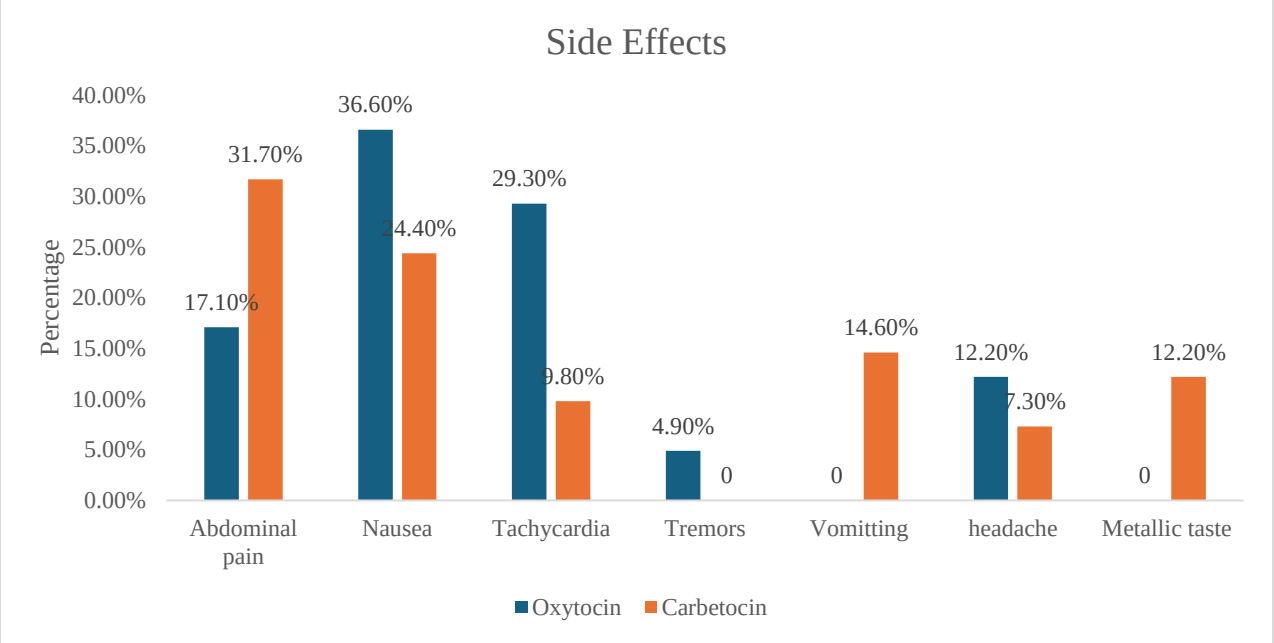
Side effects	Study groups				p-value
	Oxytocin (N=41)		Carbetocin (N=41)		
	N	Percentage (%)	N	Percentage (%)	
Abdominal pain	7	17.1	13	31.7	0.03*
Nausea	15	36.6	10	24.4	
Tachycardia	12	29.3	4	9.8	
Tremors	2	4.9	0	0	
Vomiting	0	0	6	14.6	
Headache	5	12.2	3	7.3	
Metallic taste	0	0	5	12.2	

*Statistically significant

All participants had minor side effects in both the groups. While nausea was the most common side effects (n=15, 36.6%) in oxytocin group, abdominal pain (n=13, 31.7%) was

the most common side effects in carbetocin group. Besides, the five (12.2%) participants had metallic taste which was unique to this group only. On the other hand, two (4.9%) participants experienced tremor in oxytocin group. (Table 17, Figure 16).

FIGURE 16: COMPARISON OF SIDE EFFECTS BETWEEN THE OXYTOCIN AND CARBETOCIN GROUP(N= 82):



DISCUSSION

DISCUSSION:

In this study, we aimed to assess and compare the efficacy and haemodynamic effects of oxytocin and carbetocin in the management of postpartum haemorrhage during caesarean sections. We recruited 82 participants, equally divided into two groups of 41 each, ensuring a balanced comparison between the two uterotonic agents.

The baseline characteristics of the study participants were well-matched across both groups, ensuring that any differences observed in the outcomes could be attributed to the effects of the drugs rather than confounding variables. the majority of participants (41.5%) were between 21 and 25 years old, and the gestational age (GA) the groups' distributions were comparable, with the oxytocin group having median gestational age of 38 weeks and the carbetocin group having median gestational age of 39 weeks. This negligible difference (p=1.0) suggests homogeneity in terms of pregnancy duration.

Gravidity was another important characteristic, with a higher proportion of multigravida participants overall (64.6%). the oxytocin group had more multigravida participants (70.7%) compared to the carbetocin group (58.5%), although this difference was statistically insignificant (p=0.25). This distribution indicates a slight skew towards more experienced mothers in the oxytocin group, which could potentially influence outcomes like blood loss and uterine response.

The nature of the caesarean sections also aligned closely between the groups, with a predominance of emergency lower segment caesarean sections (LSCS) overall (61%). the oxytocin group had a higher proportion of emergency LSCS (75.6%) compared to carbetocin group (58.5%), but this difference was not statistically significant (p=0.65). The primary indication for LSCS was previous caesarean section (47.6%), followed by foetal distress,

oligohydramnios, malpresentation, and other conditions, with similar frequencies of indications in both groups (p=0.32).

Preoperative haemoglobin levels, a critical parameter for assessing potential blood loss and overall maternal health, were comparable between the groups. the mean haemoglobin was 11.7 gm/dl in oxytocin group and 11.5 gm/dl carbetocin group, with no statistically significant difference (p=0.63). This baseline parity in haemoglobin levels reinforces reliability of our comparative analysis on intraoperative blood loss and the need for additional uterotonics.

Overall, the preliminary baseline characteristics demonstrate a well-balanced study cohort, setting a foundation for evaluating the primary and secondary outcomes related to efficacy and haemodynamic effects of carbetocin and oxytocin. This balanced distribution ensures that observed differences in intraoperative blood loss, additional uterotonic needs, and haemodynamic parameters can be confidently attributed to the specific effects of the drugs under investigation.

HEMODYNAMIC EFFECTS:

SUCTION VOLUME:

The results showed a significant difference in suction volume between the two groups. A higher proportion of participants in the oxytocin group experienced significant blood loss, with suction volumes excluding amniotic fluid ranging from 400 to 800 ml in 53.7% of cases , compared to only 9.8% in the carbetocin group. This difference was statistically significant ($p<0.001$), indicating that carbetocin is more effective than oxytocin in reducing intraoperative blood loss. These findings are consistent with previous studies that have demonstrated the effectiveness of carbetocin in minimizing blood loss during caesarean sections. For instance, a study by Borruto et al. (2015) found that carbetocin significantly reduced intraoperative blood loss compared to oxytocin, attributing this to carbetocin's longer half-life and stronger uterotonic effect.[61]

Similarly, Leung et al. (2012) reported that carbetocin led to lower estimated blood loss & reduced need for additional uterotonics in caesarean sections.[62]

The significant reduction in blood loss with carbetocin observed in our study can be explained by its pharmacological properties. Carbetocin is a long-acting oxytocin analogue, providing sustained uterine contractions and thus better hemostasis during the perioperative period.[63] This advantage is particularly crucial in managing PPH, where prompt and effective uterine contraction can significantly impact maternal outcomes (Table 18).

Overall, the substantial difference in suction volumes between the oxytocin and carbetocin groups in our study highlights the effectiveness of carbetocin in reducing intraoperative blood loss, corroborating findings from previous research. This reinforces the potential of carbetocin as a preferred uterotonic agent in caesarean sections to manage PPH more effectively.

Table 18: Comparison of suction volume in different studies:

Study	Populations	Suction volume difference
Borruto et al.[61]	138	400 to 800 ml loss: oxytocin group 32%, carbetocin group 8%
Leung et al.[62]	162	400 to 800 ml loss: oxytocin group 22.1%, carbetocin group 5.5%
Present study	82	400 to 800 ml loss: oxytocin group 53.7%, carbetocin group 9.8%

MOP COUNT:

Another key metric assessed in our study was the number of surgical mops required during the caesarean sections, which serves as an indirect measure of blood management efficacy. the data showed that participants in the oxytocin group required a higher number of mops, upto 6, whereas the carbetocin group required fewer, with counts limited to 4 for all participants (n=41, 100%). This difference was statistically significant ($p<0.001$), as highlighted. Furthermore, the median mop count was 4 (IQR 4 to 5) in oxytocin group compared to 3 (IQR 2 to 3) in carbetocin group, which was also statistically significant ($p=0.02$).

This outcome supports that carbetocin provides more effective control of bleeding during caesarean sections than oxytocin. The requirement for fewer mops in the carbetocin group indicates less blood loss and fewer interruptions to manage bleeding, which can facilitate smoother surgical procedures and potentially reduce the duration of surgery and related complications.

Studies have demonstrated similar advantages of carbetocin in other settings. For instance, a meta-analysis by Su et al. (2012) reported that carbetocin consistently resulted in less postpartum haemorrhage compared to other uterotonics, aligning with our findings.[63] The ability of carbetocin to maintain stronger and more prolonged uterine contractions likely contributes to this outcome, reducing the need for additional interventions to control bleeding (Table 19).

Table 19: Comparison of mop count in different studies:

Study	Populations	Mop count difference (Mean ± SD)
Su et al. [63]	2,635	Carbetocin group: 4.1 (**±0.7)** Oxytocin group: 5.2 (**±1.1)**
Present study	82	Carbetocin group: 3 (**±1.1)** Oxytocin group: 5 (**±1.0)**

The significant reduction in mop count in our study not only tells about the efficacy of carbetocin as a uterotonic but also suggests its potential benefits in improving operational efficiencies and patient safety during caesarean sections. By reducing the need for additional bleeding control measures, carbetocin may help shorten the length of the procedure, decrease the risk of infection, and improve overall maternal outcomes.

POST-OPERATIVE HAEMOGLOBIN LEVELS:

An essential aspect of our study was to evaluate the hemodynamic impact of the carbetocin versus oxytocin, specifically examining post-operative haemoglobin (Hb) levels as an indicator of overall blood loss management. Our findings show that mean post-operative Hb level in oxytocin group was 10.6 gm/dL (SD 1.2 gm/dL), compared to slightly higher mean of 11.0 gm/dL (SD 1.2 gm/dL) in the carbetocin group. the mean difference of 0.4 gm/dL in Hb levels between the groups, although indicating a trend towards better blood conservation with carbetocin, had not reach statistical significance (95% CI: -0.2 to 0.9, p=0.19).

The preservation of higher haemoglobin levels in the carbetocin group may suggest more effective bleeding control during and after caesarean delivery. Carbetocin's pharmacological advantage of providing prolonged uterine contraction likely contributes to this outcome, minimizing intraoperative and immediate postoperative blood loss. Despite this, the results'

lack of statistical significance suggests that while the trend is favorable, it may not be clinically significant or could be influenced by factors not accounted for in the study.

Other comparative analyses have shown inconsistent findings. For example, a study by Boucher et al. observed that post-operative haemoglobin levels were slightly but not significantly higher in patients treated with carbetocin compared to those who received conventional oxytocin therapy, mirroring our findings.[64] This suggests that while carbetocin might offer some advantages in managing blood loss, the clinical impact of these advantages needs further investigation to establish their significance (Table 20).

Table 20: Comparison of post-op haemoglobin in different studies:

Study	**Populations**	**Hb difference (Mean ± SD)**	**p-value**
Boucher et al.[47]	160	Carbetocin group: 11.2 (SD 1.0 gm/dL) Oxytocin group: 11.0 (SD 0.9 gm/dL)	0.27
Present study	82	Carbetocin group: 11.0 (SD 1.2 gm/dL) Oxytocin group: 10.6 gm/dL (SD 1.2 gm/dL)	0.19

Hence, our data indicates a potential for better conservation of haemoglobin levels with carbetocin, which aligns with its enhanced uterotonic effect. However, the clinical relevance of this advantage remains uncertain and warrants further exploration in larger, possibly multicentric studies to provide more definitive evidence.

REQUIREMENT FOR A BLOOD TRANSFUSION:

A critical measure of the efficacy of uterotonic agents in managing postpartum haemorrhage is the requirement for subsequent blood transfusions. In our study, blood transfusions were necessary for 3 participants (7.3%) in the oxytocin group following lower segment caesarean

section (LSCS), In contrast, no individual in carbetocin group needed a blood transfusion. Although result suggests a trend towards a reduced need for blood transfusions with carbetocin use, the difference was statistically insignificant (p=0.07)

Absence of blood transfusion requirements in the carbetocin group may indicate its efficacy in providing more stable and decreasing blood loss and prolonged uterine contraction, thus effectively reducing significant postpartum haemorrhage that would necessitate transfusion. This observation aligns with previous studies that have noted the effectiveness of carbetocin in decreasing the PPH incidence compared to oxytocin.[65,66] A systematic review by Su et al. suggests that carbetocin could potentially decreases the use of therapeutic uterotonics and interventions such as blood transfusions, though they also noted that the evidence was not always statistically significant across all studies [63] (Table 21).

Table 21: Comparison of need for Blood Transfusion in different studies:

Study	**Populations**	**Need for Blood Transfusion (%)**	**p-value**
Mousa et al.[66]	4,052	Carbetocin group: 0.7% Oxytocin group: 1.7%	0.78
Su et al.[63]	2,635	Carbetocin group: 1.8% Oxytocin group: 0.9%	0.54
Present study	82	Carbetocin group: 0 Oxytocin group: 7.3%	0.19

Despite the non-significant p-value, the observed trend is clinically relevant, especially in settings where blood resources are scarce or where minimizing intervention post-surgery is a priority. Future research with larger sample sizes may be necessary to statistically confirm the

potential benefits of carbetocin observed in this and similar studies, ensuring a broader understanding and validation of these preliminary findings.

NEED FOR ADDITIONAL UTEROTONICS:

The necessity for more uterotonic drugs is an important indicator of the efficacy of primary uterotonic drugs in preventing postpartum haemorrhage (PPH) during caesarean sections. In our study, 29.3% of the oxytocin group participants required additional uterotonics, whereas only 4.9% of participants in the carbetocin group needed them. This significant disparity (p=0.003) underscores the superiority of carbetocin over oxytocin in providing adequate uterine tone and minimizing the need for supplementary interventions to control bleeding.

The reduced need for additional uterotonics with carbetocin is consistent with its pharmacological profile, characterized by prolonged duration of action and stronger uterotonic effect compared to oxytocin. These properties enable carbetocin to sustain uterine contractions more effectively, thereby decreasing the risk of uterine atony and subsequent PPH. The findings of our study are supported by previous research demonstrating similar trends favouring carbetocin in reducing need for additional uterotonics agents during operative deliveries [47,67] (Table 22).

Table 22: Comparison of need for uterotonics in different studies

Study	**Populations**	**Additional uterotonics requirement (%)**	**p-value**
Boucher et al.[47]	160	Carbetocin group: 6.2% Oxytocin group: 18.9%	0.04
Present study	82	Carbetocin group: 4.9% Oxytocin group: 29.3%	0.003

The clinical implications of minimizing the need for supplementary uterotonics are significant, as it not only reduces the risk of adverse effects associated with multiple drug administrations but also streamlines clinical management and optimizes resource utilization in obstetric practice. By minimizing the need for additional interventions, carbetocin offers a more efficient and potentially safer approach to preventing PPH during caesarean sections, particularly in high-risk settings where rapid and effective haemostasis is paramount.

In conclusion, our findings highlight the distinct carbetocin's superiority over oxytocin in lowering the requirement for additional uterotonic agents during caesarean sections, thereby enhancing maternal safety and optimizing clinical outcomes.

NEED FOR ADDITIONAL PROCEDURES:

The necessity for additional procedures during or after caesarean sections serves as a crucial measure of the efficacy of uterotonic agents in preventing postpartum haemorrhage (PPH) and ensuring optimal obstetric outcomes. In our study, none of the people in carbetocin group needed additional surgical interventions, whereas 14.6% of those in the oxytocin group needed them. This significant difference ($p=0.01$) highlights the superior effectiveness of carbetocin in reducing the need for additional procedures to manage bleeding complications.

The lack of additional procedures in the carbetocin group indicates its potent uterotonic effect and ability to maintain uterine tone, thereby reducing the risk of excessive bleeding and subsequent interventions. These findings align with previous research demonstrating carbetocin's favorable hemostatic profile compared to oxytocin in preventing PPH during caesarean deliveries.[47,64]

A study by de Lloyd et al stated that the incidence of additional procedures following the administration of carbetocin versus oxytocin during caesarean sections and reported a significantly lower need for additional interventions with carbetocin. This supports our study's

findings and further substantiates the clinical benefits of carbetocin in optimizing obstetric outcomes. (Table 23).

Table 23: Comparison for the need of additional procedures in different studies:

Study	**Populations**	Additional procedure requirement (%)	**p-value**
Boucher et al.[47]	160	Carbetocin group: 5% Oxytocin group: 14%	0.04
Dansereau et al. [64]	694	Carbetocin group: 2% Oxytocin group: 18%	<0.001
Present study	82	Carbetocin group: 4.9% Oxytocin group: 29.3%	0.003

Minimizing the need for additional procedures has clinical significance beyond immediate postoperative care, as it enhances patient safety, reduces healthcare costs, and improves overall satisfaction with obstetric care. Carbetocin's ability to reduce the need for further interventions marks a significant advancement in managing PPH during caesarean sections, providing obstetricians with a reliable and effective option for ensuring favourable maternal outcomes.

ADVERSE EFFECTS:

Understanding the side effect profile of uterotonic agents is crucial for optimizing maternal safety and tolerability during caesarean sections. In our study, participants in both the oxytocin and carbetocin groups experienced minor side effects, though with varying frequencies and characteristics.

In the oxytocin group, the most common adverse effect was nausea, affecting 36.6% of participants, while abdominal pain predominated in the carbetocin group, observed in 31.7%

of participants. In contrast, tremor was reported by 4.9% of participants in the oxytocin group, demonstrating a different set of side effects compared to carbetocin, where a metallic taste was noted exclusively in 12.2% of participants.

The occurrence of abdominal pain as the predominant side effect in the carbetocin group is consistent with previous literature, which has identified this symptom as a common adverse event associated with carbetocin administration.[68,69] The emergence of metallic taste as a unique side effect in the carbetocin group warrants attention and further investigation to elucidate its etiology and impact on patient comfort and compliance.

Nausea and tremors, commonly reported side effects of oxytocin, assuring the well-established safety profile of this agent.[70] Despite its efficacy in preventing postpartum haemorrhage, oxytocin's side effect profile necessitates careful monitoring and management to mitigate potential discomfort and adverse reactions.

In our study, we found that metallic taste is an important side effect of the carbetocin (11.9%) group. Other studies have reported the same metallic taste for the carbetocin group. However, the same side effects are not seen in the oxytocin group[71,72] (Table 24).

Table 24: Comparison of need for additional procedures in different studies

Study	**Populations**	**Metallic taste (%)**
Elbohoty et al.[71]	88	Carbetocin group: 5.7%
Elgazayerli et al.[72]	60	Carbetocin group: 1.7%
Present study	82	Carbetocin group: 11.9%

Overall, the occurrence of minor side effects in both groups underscores the importance of individualized risk assessment and patient counselling regarding the potential adverse effects of uterotonic agents. Clinicians should remain vigilant in monitoring for side effects and promptly address any concerns to ensure optimal maternal outcomes and patient satisfaction.

SUMMARY

SUMMARY:

The efficacy and side effects of oxytocin and carbetocin were compared in our study in managing PPH during caesarean sections. Carbetocin demonstrated superior efficacy in several areas: participants in the carbetocin group showed considerably reduced suction volumes ($p<0.001$) and mop counts ($p=0.02$) than those in the oxytocin group, indicating better control of intraoperative blood loss. Additionally, fewer participants in the oxytocin group required blood transfusions (0% vs. 7.3%), although this difference was statistically insignificant ($p=0.07$). Importantly, the need for additional uterotonics was significantly lower in the carbetocin group (4.9% vs. 29.3%, $p=0.003$), and none required additional procedures compared to 14.6% in the oxytocin group ($p=0.01$). The mean post-operative haemoglobin level was slightly higher in the carbetocin group (11.0 gm/dL) than in oxytocin group (10.6 gm/dL), though this difference was statistically not significant ($p=0.19$). Side effects were minor in both groups, with nausea being more common in the oxytocin group (36.6%) and abdominal pain in the carbetocin group (31.7%). Unique to the carbetocin group was a metallic taste (12.2%), while tremor was noted in the oxytocin group (4.9%).

CONCLUSION

CONCLUSION

- Carbetocin reduces intraoperative blood loss more effectively than oxytocin during caesarean sections, as indicated by significantly lower suction volumes and mop counts.
- Carbetocin is more effective at preserving uterine contractility and preventing Postpartum haemorrhage, as seen by the significantly reduced need for further uterotonics in group.
- Although this difference was not statistically significant, participants in the carbetocin group showed a tendency towards higher post-operative haemoglobin levels than those in the oxytocin group.
- No additional procedures were needed for any of the individuals in the carbetocin group to manage PPH, highlighting its effectiveness in preventing severe bleeding complications.
- Side effects were generally minor for both drugs; however, carbetocin was associated with a unique side effect of metallic taste, while oxytocin was linked to nausea and tremor.
- This study shows that Carbetocin is more effective in management of postpartum haemorrhage during caesarean section with favourable safety profile than Oxytocin.

LIMITATIONS

LIMITATIONS:

STUDY DESIGN: The study is an observational study and not a clinical trial. Hence, the evidence in the present study might not be as strong as could be in a clinical trial. As a prospective observational study, it may be subject to selection bias and confounding factors that could influence the outcomes.

LACK OF RANDOMIZATION: The absence of randomization could introduce bias, affecting the reliability of the comparative results between the two groups.

SAMPLE SIZE: The sample size of the study is relatively small with 82 participants might limit the generalizability of the findings.

SINGLE-CENTER STUDY: The present study was conducted in a single tertiary medical college in Karnataka. The results might not be applicable to other regions or healthcare settings within India.

SHORT FOLLOW-UP PERIOD: The present study could not capture long-term side effects of the drugs.

RECOMMENDATIONS

RECOMMENDATIONS:

CLINICAL PRACTICE:

- Preferential Use of Carbetocin: Consider carbetocin as the first-line uterotonic agent for preventing postpartum hemorrhage (PPH) in caesarean sections due to its superior efficacy in reducing intraoperative blood loss and the need for additional interventions.
- Monitoring Side Effects: Implement monitoring protocols to identify and manage side effects, particularly unique ones such as metallic taste in the carbetocin group and tremor in the oxytocin group.

FURTHER RESEARCH:

- Larger Studies: Conduct larger, multicenter trials to confirm the observed trends in higher post-operative hemoglobin levels and reduced need for blood transfusions with carbetocin.
- Long-term Outcomes: Investigate the long-term maternal outcomes and potential delayed side effects associated with carbetocin and oxytocin.
- Cost-effectiveness Analysis: Perform cost-effectiveness analyses to evaluate the economic benefits of using carbetocin over oxytocin in different healthcare settings.

GUIDELINES AND TRAINING:

- Update Clinical Guidelines: Update obstetric clinical guidelines to reflect the findings of recent studies, recommending carbetocin as a preferred option for PPH management during caesarean sections.
- Healthcare Provider Education: Enhance training programs for healthcare providers on the use of carbetocin, including administration protocols and side effect management.

RESOURCE ALLOCATION:

- Ensure Availability: Ensure that carbetocin is readily available in healthcare facilities, especially in high-risk settings where effective management of PPH is critical.

OPTIMIZE RESOURCE USE: Utilize carbetocin to potentially reduce the need for additional uterotonic agents and procedures, thereby optimizing resource use and improving patient outcomes.

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ANNEXURES

ANNEXURE-1:

PATIENT INFORMATION SHEET

STUDY TITLE: CARBETOCIN VERSUS OXYTOCIN IN PREVENTION OF POSTPARUM HAEMMORHAGE AFTER CAESAREAN SECTION

STUDY LOCATION: R L Jalapa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar. Patients who are admitted and undergoing/ underwent elective/emergency LSCS in OBG department of R L Jalapa hospital attached to Sri Devaraj Urs medical college are recruited in the study after obtaining patient information consent.

DETAILS-

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study we will collect information (as per proforma) from you or from a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication. The relevant investigations which are required others than regular investigations will be funded by me.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

Dr.KANDREGULA MEGHANA SAI

Post graduate, Department of obstetrics and Gynaecology

R L Jalapa hospital, Kolar .

ANNEXURE-2:

PROFORMA

NAME:

AGE:

ADDRESS:

UHID NO:

I.P NO:

DATE/ TIME OF ADMISSION:

DATE/ TIME OF DISCHARGE:

SOCIO ECONOMIC STATUS:

BOOKED/UNBOOKED:

CHIEF COMPLAINTS:

OBSTETRICAL HISTORY: booked/ unbooked/ referred

married life: consanguinous marriage: yes/ no

Obstetrical score:

MENSTRUAL HISTORY

a. Age of menarche – years

b. Past menstrual cycle

Regular/irregular, Amount of flow- scanty/ moderate/ excessive

Dysmenorrhoea – yes/no, Associated clots - yes/no

PAST HISTORY

TB/DM/HTN/Bronchial asthma/any surgeries/ thyroid/ cardiac diseases.

H/O use of oral contraceptives in the past

FAMILY HISTORY :TB/DM/HTN/Bronchial asthma/any surgeries, Any similar complaints in the family

PERSONAL HISTORY

Diet – Veg/mixed, Appetite – Normal/ decreased, Sleep – Normal/ disturbed,

Bowel – regular / irregular, Bladder – Normal/ increased/ decreased

GENERAL PHYSICAL EXAMINATION

Built / Nourishment

Icterus/clubbing/cyanosis/pallor/pedal/ edema/Lympadenopathy

Temperature – Febrile / afebrile

Pulse - BP - RR- SPO2-

SYSTEMIC EXAMINATION

Cardiovascular system

Respiratory system

Abdominal examination

d. Auscultation – Any bruit- present/absent

PER SPECULUM EXAMINATION

PER-VAGINAL EXAMINATION

PROVISIONAL DIAGNOSIS:

INVESTIGATION:

BLOOD GROUPING AND TYPING:

Antenatal Hemoglobin

Postnatal Hemoglobin

Hemoglobin Difference

Blood Loss Through Mops And Pads:

Volume Of Blood In Suction Container:

Mode Of Delivery:

Maternal Outcome:

Postpartum Haemorrhage :

Need For Blood Or Blood Components Transfusion: Yes/No

Puerperal Complication: Yes/No

Death: Yes/No

ANNEXURE-3:

INFORMED CONSENT FORM

I Mr./Mrs. _____ have been explained in my own understandable language, that I will be included in a study which is **"CARBETOCIN VERSUS OXYTOCIN IN PREVENTION OF POSTPARUM HAEMMORHAGE AFTER CAESAREAN SECTION"**

I have been explained that my clinical findings, investigations, postoperative findings will be assessed and documented for study purpose.

I have been explained my participation in this study is entirely voluntary, and I can withdraw from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.

I have been explained about the interventions needed possible benefits and adversities due to interventions, in my own understandable language.

I have understood that all my details found during the study are kept confidential and while publishing or sharing of the findings, my details will be masked.

I have principal investigator mobile number for enquiries.

I in my sound mind give full consent to be added in the part of this study.

Signature of the patient:

Signature of the witness:

Name:

Name:

Relation to patient:

Date:

Place:

ಮಾಹಿತಿ ಕಾನ್ಸೆಂಟ್ ಫಾರ್ಮ್

ನಾನು ಶ್ರೀ / ಶ್ರೀ. _____ ಅನ್ನು ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, ಇದನ್ನು ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಿಕೊಳ್ಳುತ್ತೇನೆ, ಅದು "ತೃತೀಯ ಆರೈಕೆ ಕೇಂದ್ರದಲ್ಲಿ ಓವರಿಯನ್ ಮಾಸ್‌ಗಳ ಕ್ಲಿನಿಕೊ-ಹಿಸ್ಟೊಪಾಥೊಲಾಜಿಕಲ್ ಅಧ್ಯಯನ"

ನನ್ನ ಕ್ಲಿನಿಕಲ್ ಆವಿಷ್ಕಾರಗಳು, ತನಿಖೆಗಳು, ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುವುದು ಮತ್ತು ಅಧ್ಯಯನದ ಉದ್ದೇಶಕ್ಕಾಗಿ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ, ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಮತ್ತು ಇದು ನನ್ನ ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಗೆ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.

ನನ್ನ ಸ್ವಂತ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ, ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಕಾರಣದಿಂದಾಗಿ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲತೆಗಳ ಅಗತ್ಯವಿರುವ ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕಂಡುಬರುವ ನನ್ನ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗಿದೆ ಮತ್ತು ಸಂಶೋಧನೆಗಳನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ ಹಂಚಿಕೊಳ್ಳುವಾಗ, ನನ್ನ ವಿವರಗಳನ್ನು ಮರೆಮಾಚಲಾಗುತ್ತದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ವಿಚಾರಣೆಗಾಗಿ ನನ್ನ ಬಳಿ ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ ಮೊಬೈಲ್ ಸಂಖ್ಯೆ ಇದೆ.

ಈ ಅಧ್ಯಯನದ ಭಾಗದಲ್ಲಿ ಸೇರಿಸಲು ನನ್ನ ಸಂಪೂರ್ಣ ಮನಸ್ಸಿನಲ್ಲಿ ನಾನು ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ.

ರೋಗಿಯ ಸಹಿ:

ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ:

ಹೆಸರು:

ರೋಗಿಗೆ ಸಂಬಂಧ:

MASTER CHART

Serial number	Group (O=Oxytocin, C= Carbetocin)	Age(years)	GA(weeks)	Gravida (P=Primi, M= Multi)	C- section (El- elective, Em- emergency)	Indication for caesarean section	Suction vol (ml)	Mops used	Pre-op Hb(gm/dl)	Post-op Hb(gm/dl)	Hb difference	Need for Uterotonics	need for additional procedure	Anaemia	Blood transfusion	Side effects
1	O	<=20	37	M	El	Previous c-section	< 200	4	9.8	8.6	1.2	No	No	No	No	Nausea
2	O	26-30	38	P	Em	Foetal distress	200-400	5	8.4	7.5	0.9	Yes	Yes	Yes	Yes	Tachycardia
3	O	26-30	38	M	El	Foetal distress	400-600	4	10.1	9.2	0.9	No	No	No	No	Nausea
4	O	21-25	38	P	Em	Foetal distress	200-400	4	11.5	9.4	2.1	No	No	No	No	Tachycardia
5	O	<=20	39	P	Em	CDMR	200-400	5	12.3	10.6	1.7	No	No	No	No	Tachycardia
6	O	21-25	37	M	El	Previous c-section	200-400	4	14.1	13.1	1	No	No	No	No	Tachycardia
7	O	26-30	38	M	El	Previous c-section	200-400	5	12.5	11.2	1.3	No	No	No	No	Tachycardia
8	O	26-30	39	M	El	Previous c-section	200-400	4	11.8	10.3	1.5	No	No	No	No	Nausea
9	O	26-30	38	M	El	Previous c-section	200-400	5	10.9	9.4	1.5	No	No	No	No	Pain
10	O	26-30	40	P	Em	Foetal distress	200-400	5	9.6	8.4	1.2	No	No	No	No	Pain
11	O	21-25	38	P	Em	CPD	200-400	5	8.7	7.2	1.5	Yes	Yes	Yes	Yes	Tachycardia
12	O	<=20	37	P	Em	Oligohydramnios	200-400	4	9.8	8.6	1.2	No	No	No	No	Pain
13	O	26-30	39	M	Em	Oligohydramnios	200-400	5	8.4	7.5	0.9	Yes	No	Yes	Yes	Tachycardia
14	O	26-30	39	P	Em	Malpresentation	200-400	4	10.1	9.2	0.9	No	No	No	No	Pain
15	O	<=20	37	M	Em	Foetal distress	<200	4	11.5	9.4	2.1	No	No	No	No	Pain
16	O	<=20	38	P	Em	Foetal distress	<200	5	12.3	10.6	1.7	No	No	No	No	Nausea
17	O	21-25	40	P	Em	Foetal distress	<200	4	14.1	13.1	1	No	No	No	No	Pain
18	O	21-25	38	P	Em	Oligohydramnios	400-600	5	12.5	11.2	1.3	No	No	No	No	Nausea
19	O	26-30	39	M	Em	Foetal distress	400-600	4	11.8	10.3	1.5	No	No	No	No	Tachycardia
20	O	26-30	37	P	Em	Foetal distress	400-600	5	10.9	9.4	1.5	No	No	No	No	Nausea
21	O	26-30	38	M	Em	Foetal distress	400-600	5	9.6	8.4	1.2	No	No	No	No	Pain
22	O	26-30	39	P	Em	CPD	400-600	5	8.7	7.2	1.5	Yes	No	Yes	Yes	Tachycardia
23	O	21-25	38	P	Em	Foetal distress	400-600	4	9.8	8.6	1.2	No	No	No	No	Nausea

24	O	21-25	38	M	El	Foetal distress	200-400	5	8.4	7.5	0.9	Yes	No	Yes	Yes	Tachycardia
25	O	21-25	38	M	El	Previous c-section	200-400	4	10.1	9.2	0.9	No	No	No	No	Nausea
26	O	21-25	37	P	Em	Malpresentation	200-400	4	11.5	9.4	2.1	No	No	No	No	Tremors
27	O	21-25	38	M	El	Previous c-section	400-600	5	12.3	10.6	1.7	No	No	No	No	headache
28	O	21-25	39	P	Em	CPD	400-600	4	14.1	13.1	1	No	No	No	No	headache
29	O	21-25	37	M	El	Previous c-section	400-600	5	12.5	11.2	1.3	No	No	No	No	Nausea
30	O	21-25	38	M	Em	Foetal distress	400-600	4	11.8	10.3	1.5	No	No	No	No	Pain
31	O	21-25	39	M	Em	Foetal distress	400-600	5	10.9	9.4	1.5	No	No	No	No	headache
32	O	26-30	38	M	Em	Foetal distress	400-600	5	9.6	8.4	1.2	No	No	No	No	headache
33	O	26-30	39	M	Em	Foetal distress	400-600	5	8.7	7.2	1.5	Yes	No	Yes	Yes	Tremors
34	O	26-30	37	P	Em	Foetal distress	400-600	4	9.8	8.6	1.2	No	No	No	No	headache
35	O	26-30	38	M	Em	Foetal distress	400-600	5	8.4	7.5	0.9	Yes	No	Yes	Yes	Nausea
36	O	21-25	39	M	Em	Oligohydramnios	400-600	4	10.1	9.2	0.9	No	No	No	No	Pain
37	O	21-25	38	M	Em	Foetal distress	400-600	4	11.5	9.4	2.1	No	No	No	No	Nausea
38	O	21-25	40	P	Em	Foetal distress	400-600	5	12.3	10.6	1.7	No	No	No	No	Nausea
39	O	21-25	38	M	Em	Foetal distress	400-600	4	14.1	13.1	1	No	No	No	No	Nausea
40	O	<=20	37	M	Em	Foetal distress	400-600	5	12.5	11.2	1.3	No	No	No	No	headache
41	O	26-30	38	M	Em	Malpresentation	400-600	4	11.8	10.3	1.5	No	No	No	No	Nausea
42	C	<=20	39	M	El	Previous c-section	<200	2	10.9	10.4	0.5	No	No	No	No	Nausea
43	C	21-25	37	P	Em	Foetal distress	200-400	3	9.6	9.4	0.2	No	No	No	No	Vomiting
44	C	26-30	38	M	Em	Foetal distress	400-600	2	8.7	8.2	0.5	No	No	No	No	Tachycardia
45	C	21-25	37	M	El	Foetal distress	<200	2	11.2	10.8	0.4	No	No	No	No	Vomiting
46	C	<=20	38	M	El	Previous c-section	200-400	3	12.4	12.1	0.3	No	No	No	No	Nausea
47	C	21-25	39	P	Em	CDMR	200-400	3	11.7	11.3	0.4	No	No	No	No	Tachycardia
48	C	21-25	37	P	Em	Foetal distress	200-400	3	10.1	9.7	0.4	No	No	No	No	Tachycardia
49	C	21-25	38	P	Em	Foetal distress	200-400	2	10.9	10.4	0.5	No	No	No	No	Vomiting
50	C	<=20	39	P	Em	Foetal distress	200-400	3	9.6	9.4	0.2	No	No	No	No	Nausea
51	C	26-30	39	P	Em	Oligohydramnios	400-600	3	8.7	8.2	0.5	No	No	No	No	Nausea
52	C	>=31	40	P	Em	Foetal distress	400-600	3	11.2	10.8	0.4	No	No	No	No	Tachycardia
53	C	21-25	38	M	El	Previous c-section	<200	2	12.4	12.1	0.3	No	No	No	No	Vomiting

54	C	21-25	37	M	El	Previous c-section	200-400	3	11.7	11.3	0.4	No	No	No	No	Nausea
55	C	<=20	37	M	El	Foetal distress	200-400	2	10.1	9.7	0.4	No	No	No	No	Vomiting
56	C	26-30	39	M	El	Previous LSCS	200-400	2	10.9	10.4	0.5	No	No	No	No	Tachycardia
57	C	21-25	37	P	Em	Oligohydramnios	200-400	3	9.6	9.4	0.2	No	No	No	No	Tachycardia
58	C	21-25	38	P	Em	Oligohydramnios	<200	3	8.7	8.2	0.5	No	No	No	No	Tachycardia
59	C	26-30	40	P	Em	Malpresentation	400-600	3	11.2	10.8	0.4	No	No	No	No	Tachycardia
60	C	<=20	39	P	Em	CPD	400-600	2	12.4	12.1	0.3	No	No	No	No	Pain
61	C	<=20	39	P	Em	CPD	<200	3	11.7	11.3	0.4	No	No	No	No	Pain
62	C	26-30	38	M	El	Previous c-section	<200	3	10.1	9.7	0.4	No	No	No	No	Vomiting
63	C	26-30	38	1	Em	Foetal distress	200-400	3	10.9	10.4	0.5	No	No	No	No	Pain
64	C	<=20	39	2	El	Previous c-section	200-400	2	9.6	9.4	0.2	No	No	No	No	Tachycardia
65	C	<=20	39	1	Em	Foetal distress	<200	3	8.7	8.2	0.5	No	No	No	No	Pain
66	C	26-30	40	1	Em	Foetal distress	400-600	2	11.2	10.8	0.4	No	No	No	No	Pain
67	C	26-30	38	2	El	Previous c-section	400-600	2	12.4	12.1	0.3	No	No	No	No	Pain
68	C	<=20	39	2	El	Previous c-section	400-600	3	11.7	11.3	0.4	No	No	No	No	Pain
69	C	26-30	38	2	El	Foetal distress	400-600	3	10.1	9.7	0.4	No	No	No	No	Pain
70	C	26-30	39	2	El	Previous c-section	200-400	3	10.9	10.4	0.5	No	No	No	No	Pain
71	C	<=20	40	1	Em	Foetal distress	200-400	2	9.6	9.4	0.2	No	No	No	No	Pain
72	C	26-30	38	1	Em	Foetal distress	200-400	3	8.7	8.2	0.5	No	No	No	No	Pain
73	C	26-30	40	1	Em	Oligohydramnios	200-400	3	11.2	10.8	0.4	No	No	No	No	headache
74	C	<=20	39	1	Em	Malpresentation	200-400	3	12.4	12.1	0.3	No	No	No	No	Pain
75	C	21-25	39	2	El	Previous c-section	200-400	2	11.7	11.3	0.4	No	No	No	No	Pain
76	C	21-25	39	2	El	Previous c-section	200-400	3	10.1	9.7	0.4	No	No	No	No	headache
77	C	21-25	38	2	El	Previous c-section	200-400	2	10.9	10.4	0.5	No	No	No	No	Pain
78	C	21-25	39	1	Em	Foetal distress	200-400	2	9.6	9.4	0.2	No	No	No	No	Pain
79	C	21-25	39	1	Em	Foetal distress	200-400	3	8.7	8.2	0.5	No	No	No	No	Pain
80	C	21-25	39	2	El	Foetal distress	200-400	3	11.2	10.8	0.4	No	No	No	No	Pain
81	C	21-25	38	1	Em	Foetal distress	400-600	3	12.4	12.1	0.3	No	No	No	No	headache
82	C	26-30	39	2	Em	Foetal distress	400-600	2	11.7	11.3	0.4	No	No	No	No	Pain