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A COMPARATIVE STUDY OF COMBINED EFFECT OF CARBOPROST - OXYTOCIN & CARBOPROST AND OXYTOCIN ALONE IN REDUCING BLOOD LOSS AT CESAREAN DELIVERY

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ABSTRACT

Aim & Objective:-The aim of this study was to compare safety, efficacy and ability to maintain adequate uterine tone to reduce the incidence and severity of post-partum haemorrhage in women at risk with low dose of two drugs125 µgm carboprost & 10 IU Oxytocin as compared to high dose of both drugs 250 µgm carboprost, 20 IU of Oxytocin alone in reducing blood loss at cesarean delivery.

Introduction

Every day approximately 830 women die from preventable causes related to pregnancy and childbirth postpartum hemorrhage is responsible for about a third of maternal deaths.

Postpartum hemorrhage (PPH) refers to > 500 ml blood loss within 24 h following vaginal delivery, >1,000 ml of blood loss following cesarean delivery, or the requirement for a blood transfusion within 24 h of delivery.

Uterine atony accounts for 70% of primary postpartum haemorrhage . Nowadays the incidence of fatal PPH has decreased because of active management of third stage of labor which includes controlled cord traction, uterine fundal massage, and administration of pharmacological uterotonic agents. Oxytocin is the gold standard drug for prevention and treatment of PPH

Carboprost tromethamine is the synthetic 15 methyl analogue of prostaglandin F2á, and has been reported to be 84-96% effective in the treatment or persistent hemorrhage due to uterine atony .

Regarding high incidence of anaemia in pregnant woman, even a small reduction of blood loss might be clinically valuable and decreases patients' distress. In general synergistic effect of two agents would allow a reduction in dose for both agents and therefore limit the side effect while improving efficacy. We hypothesized that the combined use of lower dose of oxytocin and carboprost may decrease the blood loss after cesarean section with minimal side effect compared to oxytocin infusion and carboprost alone. To test our hypothesis we designed this randomized comparative study of the combined use of lower dose of oxytocin and carboprost versus oxytocin infusion and carboprost alone to reduce blood loss at cesarean section.

Material and Method

Patient: - Pregnant females at near term pregnancy between 35 40 weeks having high risks ofPPH who were scheduled to undergo cesarean section under spinal anesthesia at S.K.M.C.H. Muzaffarpur, Bihar, India between May 2015 to April 2016 were included this study Patient were randomly divided into three groups and received different uterotonics (oxytocin, carboprost and oxytocin & carboprost) during cesarean section following delivery of baby.

Patients having contraindication of receiving prostagladdin drugs were excluded from the study. All patients were provided with written informed consent for the study.

Patients were randomly allocated to one of the three patient groups of 50 each. The oxytocin group (group O) received 20 IU oxytocin 10IU bolus and 10 IU in 500ml of ringer lactate. i.v drip carboprost group (group C) received 250 µgm carboprost i.m, the carboprost oxytocin (CO group) received 125

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µgm of carboprost i.m and 10 I.U of oxytocin 500 i.v drip

The main out-come measures were the determination of blood loss at cesarean section, change in hemoglobin levels, need for additional oxytocin, and drug-related side effects. The volume of blood in the suction bottle and blood-soaked sponges was measured. Hemoglobin values were determined both before surgery and 24 hrs following surgery.

Hemodynamic variables were recorded before spinal anesthesia, 5 min after spinal anesthesia, 10 and 20 min after administration of oxytocic drugs during surgery. The need for additional oxytocic therapy, operating time, need for blood transfusion, side effects of study drug, and any significant puerperal morbidity were also recorded.

Sample size estimation was based on the previous studies which reported that the mean amount of blood loss with the use of oxytocin during a CS is 600 cc, and carboprost can reduce it by 200 cc .,

Results

One hundred fifty patients were recruited for study. There were no significant differences between the three groups regarding the demographic properties (age,gestational age, and duration of surgery), the difference of volume sucked in the suction bottle after placental delivery in ml was significantly lower in CO group (234.8 + 92.5) than C (294.4 + 109.01) and O (285.74 +139.68) groups (p = 0.04).

As shown in Table 2, hemoglobin decreased slightly after birth in all of three groups, but the mean decline of hemoglobin in CO group, (1.1 + 0.08 mg/dl) was smaller than that in the O group (1.38 + 0.13 mg/dl) and in the C group (1.14 + 0.29 mg/dl).

Table 1 Demographic data associated with the study

	C	O	CO	P value
Age (years)	27.92 ± 5.39	27.32 ± 4.3	27.42 ± 5.4	0.082
Gestational age (weeks)	37.68 ± 1.62	38.36 ± 1.72	37.94 ± 1.55	0.11
Duration of surgery (min)	38.12 + 2.33	37.58 ± 1.72	37.1 ± 2.49	0.07

Values are presented as mean ± SD
C carboprost O oxytocin CO combined carboprost-oxytocin

table 2 Main outcome measures

	C	CO	O	P value
volume sucked in the suction bottle	294.4 ± 109.01	234.8 ± 92.54	285.74 ± 139.68	0.04
Hemoglobin difference (g/dl)	1.14 ± 0.29	1.1 ± 0.08	1.38 ± 0.13	<0.001
Additional oxytocin requirement	8 (16 %)	7 (14 %)	7 (14 %)	1

All data are expressed as mean + SD except additional oxytocin requirement which was presented as number of patients (%)
C carboprost, O oxytocin, CO combined carboprost-oxytocin

Table 3 Hemodynamic change using repeated measure analysis

Variable	HR			MAP		
Group	CO	C	O	CO	C	O
5 Min before SA	91.46 ± 17.48	94.63 ± 17.7	97.63 ± 16.37	84.08 ± 11.36	79.4 ± 16.58	80.76 ± 20.4
After SA	91.46 ± 16.93	95.2 ± 19.25	97.33 ± 14.1	97.14 ± 13.6	81.04 ± 15.79	76.76 ± 17.02
10 min after drug	97 ± 15.57	93.33 ± 16.42	100.66 ± 1378	79.1 ± 12.68	80.23 ± 11.41	76.64 ± 15.49
20 min after drug	96.56 ± 14.9	96.56 ± 14.9	101.26 ± 13.7	70.91 ± 13.72	75.67 ± 12.78	73.94 ± 14.7
P value	0.23			0.38		

.3SA spinal anesthesia, HR beat per minute MAP mean arterial pressure, Ccarboprost, O oxytocin CO combined carboprostoxytocin

The difference of the mean decline of hemoglobin between the three groups were statistically significant (p=0.001). The amount of additional oxytocin requirement were not statistically significant among the three groups (p>0.05).

As shown in Table 3. Comparison of mean arterial pressure (MAP) (P=0.38) and heart rate (HR) (p=0.23) changes during spinal anesthesia and surgery failed to reveal any statistically significant differences between all groups through repeated measure analysis.

As shown in Table 4, no significant differences in terms of intraoperative and postoperative side effects including pruritus, nausea, vomitting, shivering, chest pain and respiratory depression were found in the three groups.

Table 4 Side effects observed in the study groups

Side effects	Groups			
	C	O	CO	P value
Nausea	11(22%)	7(14%)	6(12%)	0.153
Vomiting	4(8%)	2(4%)	1(2%)	0.856
Dyspnea	1(2%)	0	1(2%)	0355
Shivering	3(6%0)	0	0	0.129
Chest pain	3(6%)	0	3(6%)	0.70
Fever	2(4%)	1(2%)	2(4%)	0.340

Data are presented as number of patients (%)

C Carboprost O oxytocin CO combined carboprost oxytocin

Discussion

The results of the present study demonstrated that carboprost- oxytocin was more effective at preventing PPH that oxytocin and carboprost alone in patients at a high risk of PPH undergoing cesarean delivery. The side-effects observed in the three groups were similar with the exception of vomiting, which was more common in the patients who receieved carboprost.

To date, PPH remains a leading cause of maternal morbidity and mortality in India as well as in many underdeveloped countries the main causes of, PPH are uterine atony, residual trophoblastic tissue, genital tract trauma and clotting disorders. Of these, uterine atony is the most common and is apparent in 70% of all cases of PPH

Oxytocin is the most commonly used drug for the prevention and treatment of excessive bleeding following delivery. The most significant benefit of oxytocin is rapid action without causing elevated blood pressure or tetanic uterine contractions. Studies have demonstrated that the routine prophylactic use of oxytocin may reduce the need for additional uterotonics however; the use of oxytocin is limited by the dose. Myometrial oxytocin receptor saturation may affect its effectiveness and excessive dosages may result in coronary artery contraction, hypotension and antidiuretic effect induced water intoxication.

Therefore, other uterotonics may be required in patients at high-risk of PPH. Abdel-Aleem et al compared carboprost and methylergometrine in 150 females who were randomly assigned to receive one of the two drugs and observed that the duration of the third stage of labor and mean blood loss were significantly less in the carboprost group. Oleen and mariano reported that carboprost effectively controlled bleeding in 208 out 237 (87.8%) cases of PPH.

It may also act on the thermoregulatory center, increasing the basal body temperature patients may experience hot flashes sweating and increased irritability. Lamont et al compared carboprost and syntometrine for

the prevention of PPH and revealed that although the two drugs were as effective in the prevention of PPH, diarrhea occurred in 21% of the patients who received carboprost/ compared with only 0.85 of the patients who received syntometrine. Despite the aforementioned potential side-effects, serious side-effects are rare and self-limited.

Although, due to the synergistic effect of oxytocin with carboprost on patients undergoing cesarean in the CO group were prominent.These finding were not statistically significant and unproblematic from the clinical point of view. The authors assumed that hemodynamic changes were controlled easily. Nevertheless this is partially contrary by WHO recommendation for PPH management, which suggests that the simultaneous administration of carboprost with treatment doses of oxytocin is not advisable.

Limitation Of the study

- The trial was not double blinded.
- Limitation in accuracy of collection of blood due to possibility of mixing with amniotic fluid and spattering of blood.

Conclusion:

Based on the data found in our study, it was concluded that administration of lower dose of carboprost + oxytocin siginificantly reduced amount of blood loss during and after cesarean section compared to oxytocin and carboprost alone. An added advantage is that it can be used in patient with hypertension, cardiovascular disease and severe anaemia which is highly prevalent in our part of territory.

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CLINICAL OUTCOME OF POSTPLACENTAL IUCD INSERTION IN WOMEN DELIVERED BY CEASAREAN SECTION

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ABSTRACT

Aim and objective *Short interconception period after caesarean section and its associated risk of increased morbidity, mortality and surgical intervention could be avoided by postplacental IUCD insertion during the procedure.*

The clinical outcome (safety, efficacy expulsion and continuation rates) of PPIUCD in ceasarean section is 150 women undergoing cesarean section during March 2015 to June 2015 in the department of obstetrics & gynaecology of SKMCH, Muzaffarpur were reviewed and followed for 1 year. At the end of 1 year continuation rate was found to be 90% failure rate of 1.33%, removal rate 8.67%, with cumulative expulsion rate of 10%.

CONCLUSION *PPIUCD insertion is a safe and effective method of contraception for spacing with high continuation rate, low expulsion and low complication rate.*

INTRODUCTION-

Post-partum contraception can reduce 30% of maternal mortality and 10% neonatal mortality if pregnancies are > two years apart. Return of fertiliy is unpredictable in post-partam period and women are more vulnerable to uninteded pregnancies. If pregnancy does occur within 24 months of previons birth they have increased incidence of adverse pregnancy outcome like abortion, pre-term birth,preterm premature rupture of membanes (PPROM), small for gestational age baby ,increased neonatal mortality and morbidity, anaemia and post-partum haemorrhage . Women are easily motivated to accept family planning measures in immediate post partam period. After adoption of institutional delivery under Janani Suraksha Yojana,Janani shishu Surksha Karyakram,by Govt of India more and more women seek this facility due to conditional cash transfer scheme too. Also Cu- T is supplied free of cost under national post partum family planning programme. The increased institutional delivery gives the health care provider an opportunity to effectively counsel and motivate for PPIUCD Insertion.

AIM & OBJECTIVE This study aim to evaluate clinical outcome (safety, efficacy, expulsion, continuation rates and other adverse events) following PPIUCD insertion in cesarean section.

MATERIAL AND METHOD This study was a prospective observational study carried out in Department of Obstetrics and Gynecology of S.K.M.C.H Muzaffarpur during March 2015 to June 2015, immediately following delivery of placenta in cesarean section.

They were followed upto 12 months according to WHO standard criteria of follow up schedule at 1, 3, 6, & 12 months

A total of 150 women who underwent cesarean section were recruited for study in above period.

Inclusion criteria

Age 19- 35 years

Term caesarean section

Lower segment caesarean section

Exclusion criteria

Immediate ante- partum fever

Antepartum hemorrhage

Uterine Malformation

Post partum hemorrhage

PROM more than 18 hours

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All patients were provided with written informed consent for the study.

The participant was asked to return for scheduled follow up visits at 1, 3, 6, & 12 months or earlier in case of any adverse event like pelvic pain, foul smelling vaginal discharge or excessive bleeding.

At each visit a detailed history along with general physical and pelvic examination, ultrasonography at first visit to ascertain the location of IUCD and at subsequent visit if the IUCD thread not visible were done. Data were summarized and parameters studied were continuation rate of PPIUCD,complication rate and failure rate also calculated.

RESULT

Demographic profile based on age, parity, literacy, socio-economic status, time of counseling & type of L.S.C.S were tabulated.

Parameters	Number	Percentage
Age Group(yrs)		
⩽ 20	8	5.33
21-25	98	65.33
26-30	44	29.3
Parity		
1	103	68.7
2	45	30
3	2	1.3
Literacy		
Literate	96	64
Illiterate	54	36
Socioeconomic Status		
Low	108	72
Middle	42	28
Upper	Nil	
Time Of Counseling		
Antenatal period	46	30.67
Early labour/before L.SCS	104	69.33
Type of L.SCS		
Emergency	125	83.33
Elective	25	16.67

Table 2

Complication	Number	Percentage
Pain and fever	14	9.33
Lochia with foul Odour/ Puerperal Sepsis	2	1.3
Menstrual Bleeding	14	9.33

Table 3:- Follow up of PPIUCD.

Follow up	1 month (%)	3 months (%)	6 months (%)	12 months (%)
Continuation rate	149 (100%)	143(95.33%)	140(93.33%)	135(90%)
Adverse Events				
Discharge p/v	30(20%)	33(22%)	14(9.33%)	7(4.67%)
Menstrual complaints	20(13.33%)	13(8.67%)	13(8.67%)	14(9.33%)
Pelvic pain	19(12.67%)	35(23.33%)	16(10.67%)	10(6.67%)
Pelvic infection	1(.67%)	0	0	0
Other complaints*	23(15.33%)	19(12.67%)	17(11.33%)	14(9.33%)
Pregnancy	0	0	1(.67%)	1(.67%)
String visibility with Cu T in uterine cavity				
String visible	92(61.33%)	104(69.33%)	112(74.67%)	115(76.67%)
String not visible	55(36.67%)	40(26.67%)	29(19.33%)	20(13.33%)
Spontaneous Expulsion				
Complete expulsion	0	0	2(1.33%)	1(.67%)
Partial expulsion	2(1.33%)	2(1.33%)	1(.67%)	0
Reasons for cu T removal				
Pelvic pain	0	0	1(.67%)	0
Menstrual complaints	0	0	2(1.33%)	1(.67%)
Pelvic infection	1(.67%) removed	0	0	0
Psychosocial cause	1(.67%)	0	2(1.33%)	3(2%)
Failure/pregnancy	0	0	1(.67%)	1(.67%)
Opting for permanent sterilization	0	0	0	10(6.67%)

·Weakness, weight loss, fatigue, generalized body pains.

Table 4 : Place of Cu T removal.

Place of Cu T removal	No. of patients	%
OPD	13	8.67%
OT	6	4%

4 % of acceptor had to be administered anesthesia in OT for Cu-T removal. In 8.67% acceptors we were able to remove Cu-T in OPD.

DISCUSSION: - Population explosion is the worldwide problem. Unmet need of contraception is still high in India. Government of India is working hard to achieve this goal by institutional delivery under Janani surksha Yojna (JSY) scheme and Janani shishu surksha karyakram (JSSK) scheme. Conditional cash transfer under this scheme is also promoting more institutional deliveries and this is a great opportunity for women to pain access to post-partum family planning program. Women are easily motivated to accept family planning during this period especially immediately after caesarean section.

Its' advantages are:-

- No effect on breast feeding.
- Immediate return of fertility after removal.
- Decreased perception of pain and bleeding.
- Saves time and additional visit.
- No risk of perforation.

Risks are judged at the time of operation and then applied. PPIUCD is an effective long acting and reversible method of birth control. Follow-up care after immediate PPIUCD insertion is a vital component for ensuring high continuation rate and detecting early expulsion. In the present study, follow up was scheduled at 1, 3, 6 and 12 months of IUCD insection. None of the women lost to follow-up, this emphasized the significance of good counseling and constant contact with the clients, to ensure optimal follow-up. The observed decrease in the number of follow-up visits was due to terminal events like, expulsion removal and failure. More than 90% women successfully completed 12 month follow-up. Expulsion of PPIUCD is an important limiting factor affecting efficacy.

In the present study 8 IUCD were expelled 3 complete(2%) and five partial expulsion(3.33%) total expulsion rate as (5.33%). It is observed that majority of expulsion were within 6 months i.e (4.67%). Partially expelled IUCD were promptly removed as its contraceptive efficacy is uncertain. Our observations are similar to those of chie et al. However, celin at al have reported a high cumulative expulsion rate of 17.6 per 100 women-years. In our study expulsion rate was 10% at the end of 1 yr.

Visibility of strings is important as it assures both IUCD user and health care provider about proper placement of the device and provides ease for removal. In PPIUCD insertions, though at the time of insertions threads are not visible outside cervical os, involution of uterus makes it visible in most cases at first visit, however in a few cases threads may get curled up and not seen at external os indicating expulsion,malposition or perforation.

In our study strings were visible in 61.33% at first visit and visibility increased to 76.67% at 12 months.

Ultrasound was done in all cases to ensure proper placement of IUCD.

In our study strings were not visible in 13.33% cases at the end of 1 year despite ultrasonographic confirmation of IUCD in place. Bhutta et al showed strings visibility in 92% at 6 months. But in our study it was 74.67%. The higher incidence of missing strings in our study could be because of use of Cu-T 380 A that has shorter strings compared to multiload 375 inserted in the Bhutta et al.

The common adverse events observed during follow-up were discharge p/v,menstrual complain & persistant pelvic pain.

According to ICMR study on urban women pelvic pain is a common symptom reported in 25% user of interval IUCD insertion.

All women with pelvic infection were treated conservatively and all recovered except one women who developed puerperal sepsis, required cu -T removal. The cumulative removal rate of PPIUCD at 1 month is 2 (1.33%) at 6 month 7(4.67%) at one year is 5 (3.33%) The commonest cases of removal was psychosocial than menstrual irregularity.

There were 2 cases (1.33%) of unintended pregnancy of at the end of 1 year. These observations were little higher to previously reported cumulative pregnancy rate less than 1/100 women-years within 1 year of use.

Limitations of PPIUCD are:-

- The study was in a small sample size.
- Increased missing strings compared to conventional IUCD insertion.
- Sometimes removal of IUCD may

ed intravenous anesthesia

Conclusion:-

PPIUCD insertion can be ecommended as safe and effective method with w expulsion and high continuation rates for st partum contraception. It can contribute gnificantly to decrease unintended pregnancy post-partum period and PPIUCD can be cepted as long acting, reversible traception in Indian population.

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