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Original Article

Comparison of Oxytocin and Carbetocin in the Prevention of Post Partum Haemorrhage Following Vaginal Delivery and Caesarean Section

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ABSTRACT

Background: A safe and stable uterotonic could help lower maternal mortality from PPH in nations where the cold chain is unreliable. Despite this, numerous societies and guidelines do not advocate carbetocin as one of the uterotonics for the prevention of PPH. The present study was therefore conducted to compare oxytocin and carbetocin in prevention of PPH following both vaginal delivery and cesarean section.

Methodology: The present study was conducted at a tertiary care Institute in North India, where a total of 240 antenatal women who delivered vaginally or by cesarean section were included. Participants were randomized into six groups, with 30 women in each group receiving either carbetocin or oxytocin. Outcome was assessed in terms of amount of blood loss, assessment of uterine tone and need for additional uterotonics, blood transfusion and parenteral iron therapy. Categorical data was compared using the chi–square test. A p value of < 0.05 was considered as statistically significant.

Results: Women who were given oxytocin had higher mean blood loss as compared to those who were given carbetocin especially in the emergency cesarean section/high risk patients group and this was statistically significant (p.value $<$ 0.01). Majority across all groups did not involve additional uterotonic administration, blood transfusion and parentral iron, indicating the effectiveness of both Carbetocin and Oxytocin. Carbetocin was found to be consistently higher in cost compared to Oxytocin (p.value < 0.01)

Conclusion: This study supports the use of carbetocin as a potentially effective alternative to oxytocin in specific clinical scenarios like high risk caesarean section but not as a routine prophylaxis in low-risk delivery.

Keywords*: Postpatum hemorrhage, carbetocin, oxytocin, active management of third stage of labour*

INTRODUCTION:

Hemorrhage is the main cause of maternal mortality, especially in developing countries, accounting for more than 30% of direct causes. In order to prevent PPH, the World Health Organization (WHO) currently advises Active Management of the Third Stage of Labor (AMTSL). Three steps make up AMTSL as a preventive intervention package: 1) using a uterotonic drug—preferably oxytocin—as soon as the baby is born; 2) using controlled cord tension (CCT) to deliver the placenta; and 3) measuring the uterine tone following the placenta's delivery. The most crucial action is to give the mother a uterotonic as soon as the baby is delivered. Oxytocin is the most common used uterotonic agent. It has a short half-life of 4–10 min, for sustained uterotonic activity continuous infusion of oxytocin is needed. Carbetocin, is a long-acting synthetic octapeptide, which is an oxytocin analouge that binds to oxytocin receptors on the smooth muscles of the uterus, which results in regular contractions of uterus [1]. As a result, given its identical side effect profile, it might be more beneficial than oxytocin for managing the third stage of labor [2].

A safe and stable uterotonic could help lower maternal mortality from PPH in nations where the cold chain is unavailable or unreliable. Despite this, numerous societies and guidelines do not advocate carbetocin as one of the uterotonics for the prevention of PPH. This is mostly because there is little data to support its efficacy in preventing PPH after vaginal births [3]. Since cesarean delivery is linked to a higher prevalence of severe PPH and necessitates invasive second-line therapy three times more frequently than vaginal deliveries, it is the primary indication for which carbetocin has been advocated. Most of the studies which compared the efficacy of carbetocin versus oxytocin were done either in vaginal delivery or high risk patients or during cesarean section. The present study was therefore conducted to compare oxytocin and carbetocin in prevention of PPH following both vaginal delivery and cesarean section.

MATERIALS AND METHODS

This Prospective randomized observational study was conducted in the Department of Obstetrics and Gynaecology at a tertiary level medical college in North India over a period of 18 months after clearance from Institutional Ethics committee. A written informed consent was taken from all the subjects.

INCLUSION CRITERIA: Following women were included in the study:

1. Women aged 18-35 years
2. Women expected to give birth vaginally or by elective LSCS
3. Cervical dilatation of 6 cm and less (as >6 cm women were too distressed to provide informed consent)
4. Scheduled for elective LSCS (with no evidence of labor pain)
5. Gestational age > 37 weeks
6. Women undergoing emergency cesarean section, women having high risk factors like placenta previa, twins, presence of uterine fibroids

EXCLUSION CRITERIA: women were excluded from the study if there was:

1. History of thromboembolic disorders
2. Chronic medical diseases (cardiac, hepatic, renal)
3. Given general anesthesia
4. Hypersenstivity to carbetocin or oxytocin
5. Women who were transferred to ICU .

All women were subjected to full history taking, general and obstetrical examination. Relevant investigations were done. Pre-operative hemoglobin percentage was done in all the patients and repeated after 24 hours postpartum. Patients included in this study were randomized into 6 groups as follows; with 40 women in each group:
Group I (a) - women having vaginal delivery who were given carbetocin
Group I (b) - women having vaginal delivery who were given oxytocin
Group II (a) - women having elective LSCS who were given carbetocin
Group II (b) - women having elective LSCS who were given oxytocin
Group III (a) - women who had emergency cesarean section /women having high risk factors who were given carbetocin
Group III (b) - women who had emergency cesarean section/women having high risk factors who were given oxytocin.

Randomization was done by assigning even and odd numbers to subjects. The even one's were given carbetocin and the odd one's oxytocin. A single intramuscular injection of either carbetocin at a dose of 100 mcg or oxytocin at a dose of 10 IU was given after delivery of the baby.
Primary outcome was assessed in terms of:

1. Amount of blood loss
2. Assessment of uterine tone and need for additional uterotonics.
3. Need for blood transfusion.

1. Amount of blood loss

A. In vaginal delivery the blood loss was estimated by a plastic absorbent drape placed under the women buttocks. Blood going into the bucket was collected and measured. The drape with blood was weighed by a digital weighing scale with the weight recorded in grams and converted to volume after weight of the drape was subtracted at the final stage.
B. Blood loss in caesarean section was estimated by:

a. Visual estimation
b. Number of mops used.
c. Blood in suction jar

Amniotic fluid was sucked out and amount was measured and noted, and then amniotic fluid volume was subtracted from the total amount in suction machine jar.
In all the patients, last haemoglobin (Hb) concentration before the delivery and the Hb concentration after 24 hours was recorded. Change in Hb concentration before and after 24 hours post delivery was estimated.

2. Administration of further uterotonics (injection carboprost 250 mcg intramuscularly or tab misoprostol 800 mcg sublingually): when there was excessive blood loss (>1000 ml during casarean delivery and >500 ml in vaginal delivery) associated with hypotension, tachycardia or when there was decreased uterine contractility and tone. Uterine tone was assessed by palpating on the fundus and anterior wall of uterus. The presence of boggy uterus with extra heavy bleeding or increasing uterine fundal height was taken as uterine atony, also need for additional uterotonics was recorded as primary outcome measure .

3. Need for blood transfusion
Post partum haemorrhage was defined as a decline in the Hb concentration of more than 2 g/dl, and severe PPH by a reduction in Hb> 4 g/dl. Normally one unit of packed red cells is expected to increase the Hb concentration by 1 g/dl in a patient of average height and weight. We had made this half to take into account the impact of hemodilution in pregnancy. Accordingly, the postoperative Hb of women with transfusions was estimated according to the following formula: "postoperative Hb = 0.5 × number of blood cells transfused."

Any blood transfusion or parentral iron injection postpartum or incidence of post partum haemorrhage were recorded in the first 48 hours post delivery. Secondary outcome was assessed by cost effectiveness and side effect of the given drugs. Cost effectiveness: amount was calculated for both drugs, cost of additional uterotonic, blood transfusion and parentral iron therapy was added to the respective group. Total cost was calculated and compared. Throughout the first 24 hours following birth, the patients were watched for any adverse medication reactions and side effects. Additionally, the patients were watched for symptoms of flushing, perspiration, trembling, and vomiting.

Statistical Analysis
Data was analysed using the statistical package SPP (version 2.2, for windows, IBM SPSS INC., CHICAGO, IL). Data was expressed as mean ±standard devaiation (SD), median (interquartile range), or as number (%). Categorical data was compared using the chi–square test. A p value of < 0.05 was considered as statistically significant.

Results: A total of 240 women were included in the study. Table 1 shows the distribution of patients according to region, parity, age and BMI. Each subgroup within the groups consists of a total of 40 participants, making the distribution equal across all subgroups. The statistical analysis shows significant differences in age among the groups ($p < 0.01$). Specifically, Group II (Elective CS) participants were older (mean age 32.52 years) compared to other groups. These findings suggest that age may play a role in the selection of delivery method, with older mothers potentially opting for elective cesarean sections. Mean BMI was slightly higher in the Oxytocin groups of Group II (24.10 ± 2.88) and III (24.20 ± 3.65) compared to the Carbetocin groups (23.37 ± 3.07 in Group II and 23.23 ± 3.48 in Group III), but these differences were not statistically significant. However, no significant differences were observed in BMI across the groups ($p = 0.645$).

Table 2 shows the change in the hemoglobin concentration (post delivery), amount of blood loss, need for additional drug, blood transfusion and parentral iron therapy in various groups. There was no significant variation in hemoglobin levels pre- and post delivery among the various groups (p-value > 0.05). The majority of deliveries across all groups did not involve additional drug administration, with percentages ranging from 82.5% to 95%. Overall, majority of cases across all groups did not necessitate blood transfusion and administration of parentral iron, indicating the effectiveness of both Carbetocin and Oxytocin in reducing the need for blood transfusions during childbirth. It was seen that all groups who were given oxytocin had higher mean blood loss as compared to groups who were given carbetocin especially in the emergency cesarean section/high risk patients group (Group III a versus III b) and this was statistically significant (p.value < .01) (Table 2 and Figure 1).

Table 3 and Figure 2 represents the comparative analysis of various cost factors among different groups, with Carbetocin being consistently higher in cost across all delivery modes compared to Oxytocin (p.value < 0.01). Additionally, differences are observed in the cost of blood transfusion among the groups. However, no significant differences are noted in the cost of additional uterotonic or parenteral iron across the groups. Table 4 represents the incidence of side effects among different groups. The majority across all groups experienced no side effects, with percentages ranging from 85.0% to 95.0%.

DISCUSSION:
This prospective randomized observational study involved a sample size of 240 antenatal women. Significant differences in age distribution pointed to a preference for cesarean sections among older participants, but BMI showed no significant variation. Manyeh AK et al [4] evaluated the socio-demographic characteristics of the participants, revealing a mean age of 28.01 years (SD = 7.06). Regarding obstetric characteristics, parity showed a relatively even distribution among the participants, with 26.58% being first-time mothers and 30.52% having three or more children. Regarding the need for transfusion, the majority of cases across all groups did not require transfusion (100% in Group I and Group I, and 97.5% in Group III). These findings highlight the effectiveness of both Carbetocin and Oxytocin in reducing the need for blood transfusions during childbirth. Across all groups, majority didn't involve parentral iron administration. The authors did not find any relevant study which relates to Distribution of Study Subjects according to the need for Parentral Iron.

The majority of deliveries across all groups did not involve additional drug administration with percentages ranging from 82.5% to 95%. Erkan Kalafat et al found that risk of PPH is same in patients given carbetocin / oxytocin, but carbetocin is associated with decrease use of additional uterotonics in both vaginal delivery and caesarean section [5].

Eman Zein El Abdeen MD et al found that the need for further oxytocics after delivery and uterine atony differed significantly between the two groups in their study. However, there was no statistically significant fall in haemoglobin and vaginal bleeding between the two study groups [6].

It was seen that all groups who were given oxytocin had higher mean blood loss as compared to groups who were given carbetocin and this was statistically significant (p.value < 0.01). Chen et al found that in vaginal delivery patients who received carbetocin / oxytocin there was no significant increase in PPH when both drugs are compared but in caesarean section patients who were given carbetocin had less amount of blood loss [7].

Kok-Min Seow et al reported that while comparing mean estimated blood loss (871 ± 305 and 922.8 ± 430 mL, respectively) between the patients who were given carbetocin and the control group, the difference was not statistically significant (P = 0.06). Additionally, there was no discernible difference in the two groups' hemoglobin level drop [8]. In our study also, when comparing mean pre-operative and post-operative hemoglobin levels among various groups, no significant variation was observed (p > 0.05). Liu Hua et al reported that both groups who received oxytocin or carbetocin showed comparable rates of PPH (blood loss ≥500 mL and ≥1 000 mL) (29.6% vs. 26.8%, P = 0.48) and (3.2% vs. 3.5%, P = 0.83) [9].

The analysis aimed to explore the cost-effectiveness with Carbetocin being consistently higher in cost across all delivery modes compared to Oxytocin (p.value< 0.01). But its overall effectiveness could offset the higher upfront cost by reducing the need for additional interventions. Gil-Rojas Y et al. [10] compared the cost associated with carbetocin versus oxytocin in vaginal and cesarean deliveries. Cost increased with more severe PPH scenarios, with carbetocin consistently resulting in higher costs compared to oxytocin as seen in our study.

Hian Yan Voon reported that when administered after caesarean deliveries, carbetocin effectively lowers postpartum bleeding, the need for extra uterotonics, and the need for transfusions. Despite the possible advantages shown in this meta-analysis, authors opined that a locoregional cost-effectiveness analysis should be carried out prior to choosing to use it for routine prophylaxis [11].

Overall, the majority across all groups experienced no side effects, with percentages ranging from 85.0% to 95.0% similar to the study by Mannaerts D et al.[12].

When comparing the drugs, mean blood loss was significantly lower for groups administered Carbetocin compared to those receiving Oxytocin, especially notable in emergency cesarean sections but there was no significant difference in the change in the hemoglobin concenteration (post delivery), need for additional uterotonic drug, blood transfusion and parentral iron therapy in various groups. Carbetocin was generally more expensive than Oxytocin. The side effects were low across all groups, indicating good tolerability for both drugs. However, further research with larger sample sizes is warranted to confirm these observations.

CONCLUSION:

Key findings from the study showed that carbetocin was associated with less blood loss especially in cases of cesarean delivery. The cost analysis indicated that carbetocin is more expensive per dose than oxytocin. The incidence of side effects was low with no severe adverse events reported, suggesting both drugs are generally well-tolerated. This study supports the use of carbetocin as a potentially effective alternative to oxytocin in specific clinical scenarios like high risk caesarean section but not as a routine prophylaxis in low-risk delivery especially in low resource settings.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest

Ethical statement The authors state that the study was approved by the Institutional Research and ethics committee and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards

Informed consent An informed consent was obtained from all the individual participants in the study

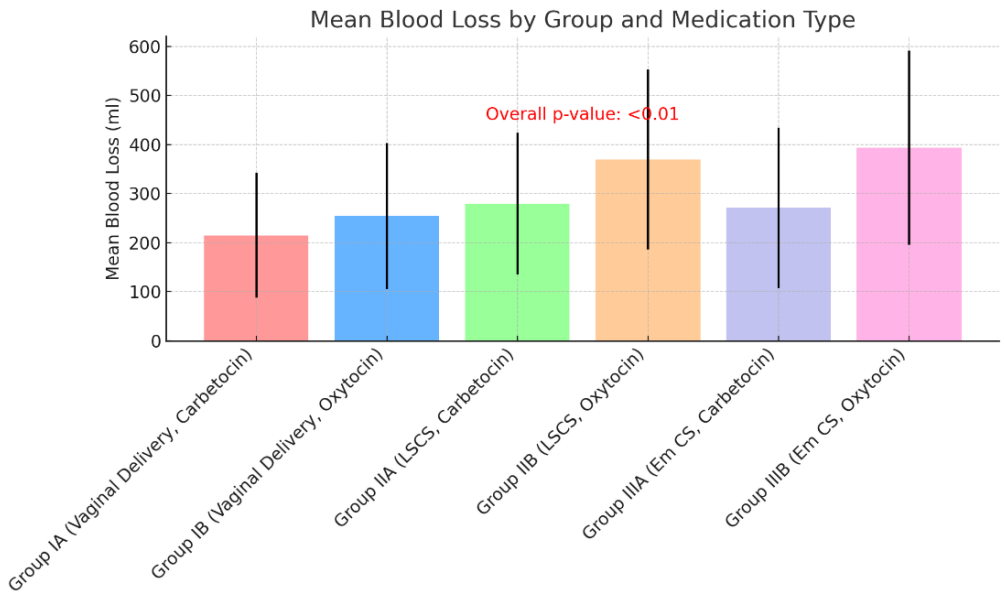

Figure 1 : Showing mean blood loss in various groups.

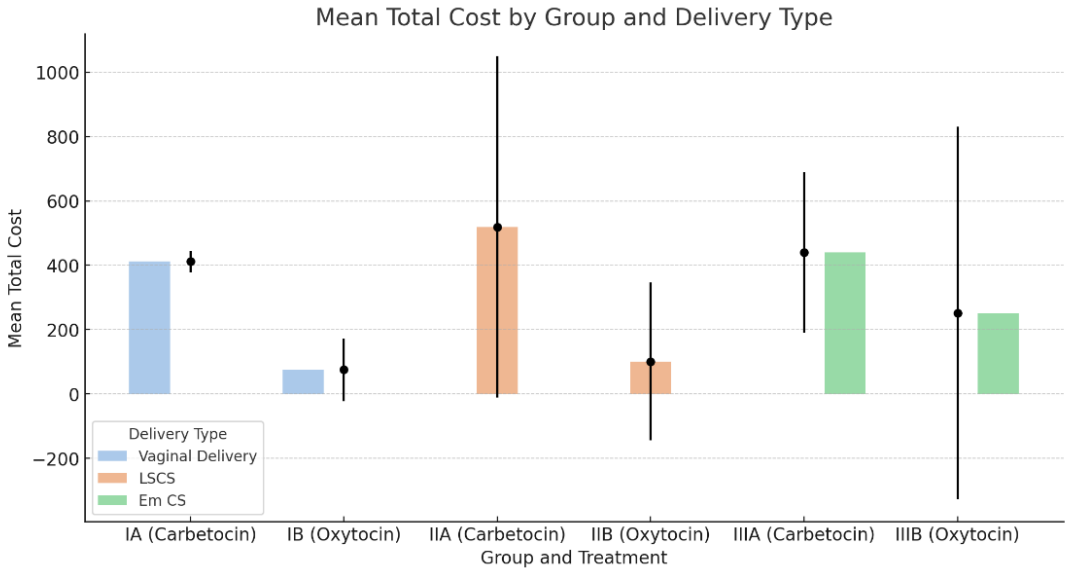

Figure 2 Cost of treatment and cost effectiveness among various groups.

Table 1. Distribution of study participants according to region, parity, age and BMI

	Group I (Vaginal Delivery)		**Group II (LSCS)**		**Group III (Em CS)**		**p-Value**
	Group IA (Carbetocin)	**Group IB (Oxytocin)**	**Group IIA (Carbetocin)**	**Group IIB (Oxytocin)**	**Group IIIA (Carbetocin)**	**Group IIIB (Oxytocin)**	
Area n (%)							**> 0.05**
Urban	18(45%)	20 (50%)	18 (45%)	19 (47.5%)	22 (55%)	18 (45%)	
Rural	22(55%)	20 (50%)	22 (55%)	21 (52.5%)	18 (45%)	22 (55%)	
Parity n (%)							**> 0.05**
Primi	15 (37.5%)	15 (37.5%)	8 (20%)	22 (55%)	24 (60%)	22 (55%)	
1	15 (37.5%)	20 (50%)	16 (40%)	10 (25%)	6 (15%)	12 (30%)	
2	6 (15%)	4 (10%)	10 (25%)	7 (17.5%)	5 (12.5%)	5 (12.5%)	

≥3	4 (10%)	1(2.5%)	6 (15%)	1 (2.5%)	5 (12.5%)	1 (2.5%)	
Age (in Years) Mean ± SD	27.78 ± 4.57	27.97 ± 4.17	30.52 ± 4.33	32.52 ± 6.30	29.10 ± 4.13	29.38 ± 4.51	**<0.01**
BMI (kg/m^2) Mean ± SD	23.65 ± 3.75	23.30 ± 2.41	23.37 ± 3.07	24.10 ± 2.88	23.23 ± 3.48	24.20 ± 3.65	0.645

Table 2 : Change in the hemoglobin concenteration (post delivery), need for additional drug, blood transfusion, parentral iron therapy and amount of blood loss in various groups.

	Group I (Vaginal Delivery)		**Group II (LSCS)**		**Group III (Em CS)**		**p-Value**
	Group IA (Carbetocin)	**Group IB (Oxytocin)**	**Group IIA (Carbetocin)**	**Group IIB (Oxytocin)**	**Group IIIA (Carbetocin)**	**Group IIIB (Oxytocin)**	
	40 patients	**40 patients**	**40 patients**	**40 patients**	**40 patients**	**40 patients**	
Haemoglobin Status	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Pre-partum Hb	11.48 ± 1.39	11.53 ± 1.62	11.13 ± 1.51	11.60 ± 1.37	11.25 ± 1.59	11.83 ± 1.43	0.345
Post-partum Hb	10.47 ± 1.43	10.05 ± 1.41	10.55 ± 1.43	10.70 ± 1.27	10.40 ± 1.34	10.65 ± 1.58	0.364
Fall in Hb level	1.01	1.48	0.58	0.90	0.85	1.18	0.442
Need for Additional Drug							
Yes	6 (15.0%)	5 (12.5%)	5 (12.5%)	4 (10.0%)	2 (5.0%)	7 (17.5%)	
No	34 (85.0%)	35 (87.5%)	35 (87.5%)	36 (90.0%)	38 (95.0%)	33 (82.5%)	0.625
Need for Blood Transfusion							
Yes	0 (0.0)	0 (0.0)	1 (2.5%)	1 (2.5%)	1 (2.5%)	3 (7.5%)	0.292
No	40 (100.0%)	40 (100.0%)	39 (97.5%)	39 (97.5%)	39 (97.5%)	37 (92.5%)	
Need for Parentral Iron							
Yes	0 (0.0)	0 (0.0)	1 (2.5%)	0 (0.0)	1 (2.5%)	3 (7.5%)	0.137
No	40 (100.0%)	40 (100.0%)	39 (97.5%)	40 (100.0%)	39 (97.5%)	37 (92.5%)	
Amount of blood loss	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	214.82±126.97	253.90±149.00	279.58±144.89	369.40±183.63	271.00±162.98	393.50±198.21	**<0.01**

Table 3 Cost of treatment and cost effectiveness among various groups.

Variable	Group I (Vaginal Delivery)		Group II (LSCS)		Group III (Em CS)		p-Value
	Group IA (Carbetocin) Mean ± SD	Group IB (Oxytocin) Mean ± SD	Group IIA (Carbetocin) Mean ± SD	Group IIB (Oxytocin) Mean ± SD	Group IIIA (Carbetocin) Mean ± SD	Group IIIB (Oxytocin) Mean ± SD	
Cost of Drug used	400.0 ±0.0	67.00 ± 96.03	382.00 ± 79.46	40.00 ± 0.00	400.00 ± 0.00	40.00 ± 0.00	**<0.01**
Cost of Additional Uterotonic	11.70 ± 33.31	8.65 ± 26.48	37.13 ± 113.69	23.08 ± 75.45	3.00 ± 13.99	29.05 ± 92.17	0.217
Cost of Blood Transfusion	0.0	0.0	37.50 ± 237.17	37.50 ± 237.17	37.50 ± 237.17	112.50 ± 400.12	0.295
Cost of Parenteral Iron	0.0	0.0	64.10 ± 400.32	0.0	0.0	62.50 ± 395.29	0.543
Total cost	411.70±33.31	75.15±97.19	519.12±531.05	100.58±245.29	440.50±249.74	251.03±579.19	**<0.01**

Table 4: Distribution of Study Subjects according to the Side Effects Observed from both the drugs.

Side Effects	Group I (Vaginal Delivery)		Group II (LSCS)		Group III (Em CS)	
	Group IA (Carbetocin) n (%)	Group IB (Oxytocin) n (%)	Group IIA (Carbetocin) n (%)	Group IIB (Oxytocin) n (%)	Group IIIA (Carbetocin) n (%)	Group IIIB (Oxytocin) n (%)
Tachycardia	2 (5.0%)	0 (0.0)	1 (2.5%)	1 (2.5%)	1 (2.5%)	2 (5.0%)
Vomiting	0 (0.0)	1 (2.5%)	1 (2.5%)	0 (0.0)	0 (0.0)	1 (2.5%)
Nausea	0 (0.0)	2 (5.0%)	3 (7.5%)	1 (2.5%)	1 (2.5%)	3 (7.5%)
Headache	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.0%)	0 (0.0)
Chills	0 (0.0)	1 (2.5%)	0 (0.0)	1 (2.5%)	1 (2.5%)	0 (0.0)
No	38 (95.0%)	36 (90.0%)	35 (87.5%)	37 (92.5%)	35 (87.5%)	34 (85.0%)
Total	**40 (100%)**	**40 (100%)**	**40 (100%)**	**40 (100%)**	**40 (100%)**	**40 (100%)**

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