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A randomised comparative clinical study of the efficacy of ondansetron versus chewing gum for prevention of PONV in patients undergoing elective caesarean

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Abstract

Aim: to compare the ondansetron versus chewing gum for prevention of post-operative nausea and vomiting in patients undergoing elective LSCS.

Material and methods: This was prospective Randomized trial done in the Department of Anesthesia..... A total of 120 patients for elective caesarean delivery were included in the study. Patients in Group I were given one strip of sugar free gum to be chewed for 30 minutes every eighth hourly. Patients randomized to Group-II received Inj. Ondansetron 4mg intravenously immediately after cesarean section. The relief of PONV as graded on a four-point verbal descriptive scale, and Five point Likert scale for acceptability, 3) Use of rescue medication for the first 24 hours after surgery 4) Sedation, as assessed with RAMSAY sedation scale and 5) Time to first flatus.

Results: 2 patient in chewing gum group and 19 patients in Ondansetron group had episodes of nausea at 6th hour postoperatively, whereas 2 patient in chewing gum group and 10 patients in Ondansetron group had PONV at 12th hour. However, rescue medication was not required for these patients. It was observed that there was statistically significant difference between the two groups at 6th and 12th hour where the maximum number of events of PONV had occurred. On the scale for relief of PONV, it was observed that there was full resolution of PONV in more number of patients in chewing gum group than in the Ondansetron group. In the Likert scale response, the patients were more comfortable in the chewing gum group than in Ondansetron Group. Our data shows a beneficial effect of gum chewing in terms of better relief of post-operative nausea and shorter mean time intervals to passage of flatus (21.42 versus 30.49 hours) and acceptability.

Conclusion: chewing gum is considered safe, well accepted better alternative to Ondansetron for the treatment of PONV in this randomized controlled study undergoing cesarean delivery under spinal anaesthesia. It also results in rapid resumption of intestinal motility, with potential impact on reducing the overall healthcare costs in case of routine implementation.

Keywords: ondansetron versus chewing gum, elective caesarean

Introductions

Postoperative nausea and vomiting is one of the most important causes of patients' discomfort [1]. Incidence of PONV after surgery is in the range of 20-30% [2]. But it may be up to 50-70% after laparoscopic surgeries [3]. Various patients' related risk factors such as female sex, non-smoking status, history of PONV, and motion sickness have been identified as risk factors for PONV. Several anaesthesia related factors such as use of opioid and nitrous oxide and duration of general anaesthesia have been implicated as risk factors of PONV. Prevention of PONV after laparoscopic surgeries is a challenge to the perioperative physicians as it is distressing for the patients and more and more such surgeries are performed on day care basis. So, an effective prophylactic regimen is highly desirable for early home discharge. The common and distressing symptoms which follow anaesthesia and surgery are pain, nausea and vomiting. Nausea and vomiting are the most common side

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effects in the post-anaesthesia care unit. But post-operative nausea and vomiting have received less attention, though there are extensive literature, data are frequently difficult to interpret and compare. It has been associated for many years with the use of general anesthetics for surgical procedures. In spite of the advances like using less emetic anaesthetic agents, improved pre and post-operative technique and identification of patient predictive factors, nausea and vomiting still occur with unacceptable frequency in association with surgery and anaesthesia, and is described as "the big little problem". Early studies⁴ reported incidence of post-operative nausea and vomiting (PONV) as high as 75-80%. But in the second half of this century, however these incidences have decreased by almost 50% for various reasons. It is noted that incidence is more common in females especially in LSCS under subarachnoid block. PONV may be associated with wound dehiscence, pulmonary aspiration of gastric contents, bleeding, dehydration and electrolyte disturbance. Hence vomiting can potentially delay hospital discharge or lead to unexpected hospital admissions and increased hospital cost^[5] and can result in serious medical and surgical complications.

Chewing gum has been prospectively evaluated as a therapy to reduce postoperative paralytic ileus after gastrointestinal surgery. Postulated mechanisms of its effect surround the principle of 'sham feeding', with chewing resulting in increased gastrointestinal activity via cephalic vagal stimulation^[6]. Recent meta-analysis (the largest involving 272 patients across seven randomized controlled trials) have demonstrated a reduced time to first flatus and bowel motion, and a non-significant trend towards earlier hospital discharge^[7-9]. To date, however, no study has examined the effect of gum chewing on PONV.

Material and methods

This was prospective Randomized trial done in the Department of Anesthesia,....., after taking the approval of the protocol review committee and institutional ethics committee. After taking informed consent detailed history was taken from the patient.

Inclusion criteria

A total of 120 patients were included in this study. The patients who gave written informed consent with ASA-I or ASA-II posted for elective caesarian delivery were included in the study. The other inclusion criteria were patients between 18-40 years of age and with full term singleton pregnancy.

Exclusion criteria

Patients with essential hypertension, pre-eclampsia, diabetes, anemia, heart disease, multiple pregnancy, fetal distress, abruptio placentae/placenta previa, any contraindication to spinal anaesthesia, known allergy to local anesthetics, unable to chew gum or complaining of gum or dental problems and who could be exposed to any

intra-operative and post-operative complications were excluded from the study.

Methodology

Pre-operative evaluation was done a day before scheduled surgery. After explaining the procedure, the patients were advised overnight fasting. Spinal anesthesia was given to all patients in left lateral position with 2ml of 0.5% bupivacaine heavy in L₃ L₄ space. The patients were randomly assigned into two equal groups of fifty each. Based on the observer's assessment, when a score of five in alertness/sedation was achieved and the patient was not sleeping in between observations, patients in Group I were given one strip of sugar free gum to be chewed for 30 minutes every eighth hourly. Patients randomized to Group-II received Inj. Ondansetron 4mg intravenously immediately after cesarean section. Rescue anti-emetics i.e. Metoclopramide 10mg IV/ Dexamethasone 4mg IV/Prochlorperazine 12.5mg IV/ Droperidol 0.625mg IV/Promethazine 6.25mg IV were planned to be used if the first-line therapy was not fully successful. The primary outcome measures were the number of episodes of nausea or vomiting immediately after surgery and at 6, 12, 18 and 24 hour post-operatively. The secondary outcome measures, The relief of PONV as graded on a four-point verbal descriptive scale, and Five point Likert scale for acceptability, 3) Use of rescue medication for the first 24 hours after surgery 4) Sedation, as assessed with RAMSAY sedation scale and 5) Time to first flatus.

Table 1: The observers' assessment of alertness/sedation score

Agitated	6
Responds readily to name spoken in normal tone (alert)	5
Lethargic response to name spoken in normal tone	4
Responds only after name is called loudly and/or Repeatedly	3
Responds only after mild prodding or shaking	2
Dose not respond to mild prodding or shaking	1
Doses not respond to deep stimulus	0

Results

There was no statistical difference found between the baseline characteristics i.e. Age and gestational age (Table 2) confirming inclusion of a homogenous population. 2 patient in chewing gum group and 19 patients in Ondansetron group had episodes of nausea at 6th hour postoperatively, whereas 2 patient in chewing gum group and 10 patients in Ondansetron group had PONV at 12th hour. However, rescue medication was not required for these patients. It was observed that there was statistically significant difference between the two groups at 6th and 12th hour where the maximum number of events of PONV had occurred.

On the scale for relief of PONV, it was observed that there was full resolution of PONV in more number of patients in chewing gum group than in the Ondansetron group (table 3).

Table 2: Demographic profile of the patients

Variable	Group I (chewing gum)	Group II (ondansetron)	P Value
Age (in Years)	26.38 ± 3.71	26.66 ± 4.71	NS
Gestational Age (in Weeks)	39.32± 1.77	39.62± 4.14	ns
Immediate PONV (n)	2 (3.33%)	2 (3.33%)	NS
PONV at 6 th hour (n)	2 (3.33%)	19 (31.67%)	< 0.0001
PONV at 12 th hour (n)	2(3.33%)	10 (16.67%)	< 0.05
PONV at 18 th hour (n)	3 (5%)	0	NS
PONV 24 th hour (n)	0	0	
Time to First Flatus (in Hrs)	21.42 ± 2.21	30.49 ± 2.46	< 0.0001

In the Likert scale response, the patients were more comfortable in the chewing gum group than in Ondansetron Group (table 4). All the patients of either groups were at level two on Ramsay sedation scale.

The time to first flatus was shorter in chewing gum group than in Ondansetron group. The difference was observed to be statistically significant (Table 2).

Table 3: Relief of PONV verbal scale

Parameter	Group 1 chewing gum	Group 2 ondansetron
Worse		
No change	2	3
Partial resolution	3	23
Full resolution	55	34

Table 4: Likert scale response

Parameter	Group 1 chewing gum	Group 2 ondansetron
Not at all acceptable		
Slightly acceptable	3	2
Moderately acceptable	1	18
Very acceptable	0	0
Completely acceptable	56	40

Discussion

PONV during spinal anaesthesia for elective cesarean delivery may occur in upto 66% of patients. The risk factors of emetic symptoms in pregnancy are hormonal changes, smoking habit, age, pain, history of motion sickness or previous postoperative emesis, hypotension, surgical procedure, and anaesthetic technique [10]. Our treatment groups were similar with regard to maternal demographic and operating management that considered being risk factors for postoperative emetic symptoms. Therefore, the difference in incidence and severity of nausea and vomiting among the study groups can be attributed to the study drug administration. Our data shows a beneficial effect of gum chewing in terms of better relief of post-operative nausea and shorter mean time intervals to passage of flatus (21.42 versus 30.49 hours) and acceptability.

Zhang, L *et al.*, conducted a meta-analysis on a total of 13 RCTs which included 2233 patients. The results showed that chewing gum after cesarean delivery can effectively shorten the recovery time of bowel sounds, passage of flatus and first defecation [11]. Ajuzieogu, O.V. *et al.* conducted a study to evaluate the effect of chewing gum on post-operative ileus in 200 women who underwent cesarean sections and found that there was a statistically significant earlier onset of bowel sounds in the chewing group when compared to the control [12]. Perriera, G. *et al.* [13] and Ciardulli A. *et al.* [14]. Both conducted systematic reviews on more than 3,000 women (17 trials) who had just had cesarean section, mostly from Asia and the Middle East. While all the studies

demonstrated a consistent improvement in rate of ileus and time to first flatus, they were largely inconsistent in demonstrating complete relief of PONV. They however do suggest that the simplicity, frugality, and safety of chewing gum makes it a viable option to offer women undergoing cesarean section.

Macones, George A. *et al.* have formulated the Guidelines for ERAS (Enhanced Recovery after Surgery) after cesarean delivery Part 3. They recommend the use of chewing gum in the postoperative period for early return of bowel activity. However, they consider this a weak intervention due to inability to do blinding for chewing gum in the studies reviewed in the meta-analysis. [15]

Sugar free chewing gum that contains the artificial sweetener sorbitol and other hexitols might be having side effect such as bloating, gas, and abdominal cramps. However, there are no such reports in this study. The intervention in our study is non-invasive, very economical and highly patient compliant. It also avoids all side effects of ramosetron, palonosetron, dexamethasone and even ephedrine which are being tried in newer studies [16-18].

Conclusion

We concluded that the chewing gum is considered safe, well accepted better alternative to Ondansetron for the treatment of PONV in this randomized controlled study undergoing cesarean delivery under spinal anaesthesia. It also results in rapid resumption of intestinal motility, with potential impact on reducing the overall healthcare costs in case of routine implementation.

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