ORIGINAL ARTICLE

A Comparative Study Efficacy of Ondansetron versus Granisetron to Prevent Perioperative Nausea and Vomiting among Patients Under going Gynaecological Surgery under Spinal Anaesthesia in a Tertiary Care Hospital of Western India

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ABSTRACT

Background: A randomized double blind study was conducted to compare efficacy of Ondansetron versus Granisetron among patients undergoing gynaecological surgery under the spinal anaesthesia.

Objective: To compare Ondansetron and Granisetron for prevention of postoperative nausea and vomiting in patients undergoing gynaecological surgery under spinal anaesthesia.

Material and methods: Total 60 consecutive patients, age between 18-58 years, ASA grade I and II undergoing gynaecological surgery under the spinal anaesthesia were randomized into two groups of 30 each. One group received I.V. Ondansetron 4.0 mg and the second received I.V. Granisetron 2.0 mg 5 minutes before induction of anaesthesia. For the first 24 hours postoperatively all episodes of nausea and vomiting were recorded. The observations were tabulated and analysed.

Results: In this study found that during early postoperative period (0-3 hrs) there was no statistically significant difference in the study groups. Statistically significant difference was found in the study groups in the late postoperative period (3-24 hrs).

Conclusion: In the early postoperative period both Ondansetron and Granisetron are equally effective in preventing postoperative nausea and vomiting in patients undergoing gynaecological surgery under spinal anaesthesia. Granisetron is better than Ondansetron in the late postoperative period of upto 24 hrs.

Key words: ondansetron, granisetron, perioperative nausea and vomiting, anaesthesiology

INTRODUCTION

In India Post-Operative Nausea and vomiting (PONV) is a particularly distressing problem for both patients as well as treating Doctors.[1]There are many antiemetic drugs available, despite of it problem still persists and novel methods and medicines continue to be searched for PONV. There is no drug which is 100% effective in prevention of PONV and combinations of various drugs have a lot of side effects.[2] Incidence of PONV less in regional anaesthesia as compared to general anaesthesia but its effects are no less distressing. PONV can add to hospital cost for patient care as it leads to various complications like bleeding, wound dehiscence, electrolyte imbalance, dehydration, aspiration pneumonitis etc. In various study gynaecological surgery has been found as independent risk factor for PONV.[3,4] The incidence of PONV is reported to be between 20-30% in patients underwent to surgery, but it can increase up to 80% in high risk patients.[5]A newer class of antiemetic are 5-HT3 receptor antagonists which have only headache and dizziness as their adverse effects in the doses used for PONV.[4] Ondansetron is commonly used drug for PONV and its quite effective to Prevent PONV.[6] Granisetron, a newer drug, shown to be more potent and longer acting than Ondansetron against emesis caused by Cisplatin.[7]

A randomized double blind study was conducted to compare efficacy of Ondansetron versus Granisetron among patients undergoing gynaecological surgery under the spinal anaesthesia, these are the population of patients which most likely to suffer from PONV.[8]

MATERIAL AND METHODS

In this study sixty (n=60) consecutive patients between age 18-58 years, in ASA grade 1-2, undergoing gynaecological surgical procedure under the spinal anesthesia were randomized to two groups by com-

puter generated random allocation, one group receiving Ondansetron (4 mg intravenously) and the other receiving Granisetron (2 mg intravenously) in perioperative period. All patients' age, weight, height, body mass index (BMI) and the prior history of motion sickness, vertigo, nausea and vomiting will be noted. Patients who refused for participation or patients with prior history of motion sickness, nausea or vomiting, steroid intake within last 24 hours, BMI more than 30, pregnancy or hypersensitivity to anaesthetic drugs were excluded from the study.

All patients underwent detailed pre anaesthetic check-up which included all routine investigations. An informed consent was taken from study participants. Patients were kept fasting from 9 PM the day before the surgery. Baseline parameters were noted after shifting the patient to operation theatre. Preloading with Ringer's lactate (RL) 10-15 millilitre per kilogram body weight was done and prophylactic dose of an antiemetic was given 3-5 minutes before the spinal anaesthesia. Drugs were given by an investigator not involved in post-operative assessment of symptoms in the study. With all aseptic precautions lumbar puncture was done in L3- L4 or L4-L5 space using 25 gauge Quincke's needle in lateral decubitus position in midline, 3.0 ml of 0.5 % hyperbaric Bupivacaine was injected after confirming free flow of Cerebrospinal fluid with an aim to obtain level of anaesthesia till 7th or 6th thoracic vertebra. Standard intraoperative monitoring was done any fall in blood pressure was managed by intravenous (i.v) fluids and injection Mephentermine 3.0 mg i.v. Intramuscular injection of Diclofenac 75 mg was given before shifting the patient for analgesia and prescribed twice a day dose or on request by the patient.

In study nausea was defined as an unpleasant sensation with urge to vomit and vomiting was defined as forceful expulsion of gastric contents from the mouth. Complete response was defined as no nausea or vomiting and no need for rescue antiemetic. Injection Dexamethasone 8.0 mg intravenous was used as rescue antiemetic. All episodes of PONV were recorded by an investigator blinded to the study groups. The results were tabulated and analysed using chi-square test.

RESULTS

As shown in table 1 p value is >0.05 means patients in both the groups were statistically comparable with respect to age, body mass index and duration of surgery and anaesthesia. During early postoperative period (0- 3 hrs) the incidence of PONV in the Ondanseron group was more (nausea – 6; 20.0%, vomiting – 5; 16.66%) as compared to the Granisetron group (nausea 5;16.66%, vomiting 4;13.33%) but the difference was not significant statistically.

Table 1: Demographic profile

Variables	Ondansetron group(n=30)	Granisetron group(n=30)	P value
Age (years)	42.25+8.47	45.24+8.31	>0.05
BMI*	24.82+1.1	24.92+1.4	>0.05
Duration of surgery#	99.88+13.44	97.93+12.56	>0.05

* Kg/Sq. meter; # minutes

Table2: Incidence of PONV in early postoperative period (0-3 hrs)

Parameters	Ondansetron group (n=30)	Granisetron group (n=30)	P value
Nausea	6 (20.00)	5 (16.66)	>0.05
Vomiting	5 (16.66)	4 (13.33)	>0.05
Rescue antiemetic	5 (16.66)	4 (13.33)	>0.05

Figure in parenthesis indicate percentage.

Table 3: Incidence of PONV in late postoperative period (3-24 hrs)

Parameters	Ondansetron group (n=30)	Granisetron group (n=30)	P value
Nausea	10 (33.33)	4 (13.3)	<0.05
Vomiting	9 (30.00)	3 (10.00)	<0.05
Rescue antiemetic	7 (23.33)	2 (6.66)	<0.05

Table 4: Complete drug response in early postoperative period (0-3 hrs)

Study groups	Complete drug response
Ondansetron (n=30)	23 (76.66)
Granisetron (n=30)	24 (80.00)
P value	>0.05

Table 5: Complete drug response in late postoperative period (3-24 hrs)

Study groups	Complete drug response
Ondansetron (n=30)	17 (56.66)
Granisetron (n=30)	26 (86.66)
P value	<0.05

Table 6: Incidence of adverse effects

Adverse effect	Ondansetron group (n=30)	Granisetron group (n=30)
Headache	3 (10.00)	2 (6.66)
Dizziness	2 (6.66)	2 (6.66)
Others	0 (0.0)	0 (0.0)

Similarly, need for rescue antiemetic was in 5(16.66%) patients in Ondansetron group and 4(13.33%) in Granisetron group, which was statisti-

cally insignificant. Complete drug response in both groups in early postoperative period was comparable, 23(76.66%) in Ondansetron group, 24(80.00%), p value > 0.05.

In the late postoperative period 10(33.33%) patients had nausea in Ondansetron group where as 4 (13.3%) patients had nausea in Granisetron group, the difference was statistically significant. Vomiting was present in 9(30.0%) patients in Ondansetron group as compared to 3(10.0%) patients in Granisetron group which was statistically highly significant. (Table 3) In the Ondansetron group rescue antiemetic was needed in 7(23.3%), but in the Granisetron group it was needed in 2(6.66%) again significant statistically.

As regards complete response to drug (absence of nausea and vomiting), in the early postoperative period, it was statistically insignificant (Ondansetron 23;76.66%, Granisetron 24;80.00%) In the late postoperative period the difference was statistically significant in favour of Granisetron (Ondansetron 17;56.66%, Granisetron 26; 86,67%) as is evident from table 5.

There was minimal incidence of side effects of headache and dizziness ranging from 3.33%-10.0% across both groups, difference between groups was statistically insignificant (Table 6).

DISCUSSION

From the beginning PONV is a major challenging problem and continues to trouble in spite of many available drugs and advances in surgery as well anaesthesia. It has multiple etiological factors like gynaecological surgery, age, weight, pre - existing disease conditions, history of nausea, vomiting, anxiety or smoking. 5 HT-3 receptor antagonists are effective in preventing emesis caused by radiotherapy as well as chemotherapy. From many years Ondansetron has been widely used for prevention of PONV. A newer drug, Granisetron, has not been studied in local setting for PONV prevention on gynaecology surgery under the spinal anaesthesia. The doses of drugs used were as reported in previously done studies.[9,10] In this study both groups Ondansetron and Granisetron were matching with regards to demographic profile and anthropometric parameters. Other parameters like duration of gynaecological surgery and anaesthesia, intraoperative haemodynamics were also similar.

In early postoperative period (0-3 hrs) both Ondansetron and Granisetron were effective in PONV prevention with statistically non-significant difference (p value>0.05.This is in congruence with the findings of previous studies of Fujii et al [10], Bhattachary et al. [11] Chaudhari et al in his comparative study of Ondansetron and Granisetron to prevention of PONV in elective lower segment Caesarean section and found Granisetron better during 24 hours of postoperative period. [12] In this study during late postoperative period Granisetron was more effective in preventing PONV than Ondansetron with a statistically significant difference. Variance in need for rescue antiemetic and complete response incidence was statistically significant in favour of Granisetron probably because of long duration of action. Fuji et al found similar incidences of PONV with Granisetron in their study.[13] It has been found headache and dizziness are the most common side effects of 5 HT-3 receptor antagonists.[14] No statistically significant difference was found in the incidence of adverse effects in both groups in our study which is similar as found by Fujji et al [13] and Kim et al. [15]

CONCLUSION

In conclusion, both Ondansetron and Granisetron were equally effective on preventing PONV during the early postoperative period in patients undergoing gynaecological surgery under spinal the anaesthesia. In the late postoperative period, however, Granisetron was found better with less incidence of PONV and less need for rescue antiemetic. Also the adverse effects were not found significant with Granisetron as well as Ondasetron.

REFERENCES

1. Kapur PA. The big "little problem". Anesth Analg [Internet]. 1991 Sep [cited 2018 Oct 24];73(3):243–5. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1831014
2. Habib AS, Gan TJ. Combination therapy for postoperative nausea and vomiting-a more effective prophylaxis? [Internet]. Vol. 9, Ambulatory Surgery. 2001 [cited 2018 Oct 24]. Available from: www.elsevier.com/locate/ambsur
3. Kenny GN. Risk factors for postoperative nausea and vomiting. Anaesthesia [Internet]. 1994 Jan [cited 2018 Oct 24];49 Suppl:6–10. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8129161
4. Watcha MF, White PF. Postoperative nausea and vomiting. Its etiology, treatment, and prevention. Anesthesiology [Internet]. 1992 Jul [cited 2018 Oct 24];77(1):162–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1609990
5. Candiotti KA, Kovac AL, Melson TI, Clerici G, Joo Gan T, Palonosetron 04-06 Study Group. A Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Three Different Doses of Palonosetron Versus Placebo for Preventing Postoperative Nausea and Vomiting. Anesth Analg [Internet]. 2008 Aug [cited 2018 Oct 24];107(2):445–51. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18633022
6. McKenzie R, Tantisira B, Karambelkar DJ, Riley TJ, Abdelhady H. Comparison of ondansetron with ondansetron plus dexamethasone in the prevention of postoperative nausea and vomiting. Anesth Analg [Internet]. 1994 Nov [cited 2018 Oct 28];79(5):961–4.

7. McNulty R. Are all 5-HT3 receptor antagonists the same? J Natl Compr Canc Netw [Internet]. 2007 Jan [cited 2018 Oct 28];5(1):35–43.

8. American Society of Anesthesiologists. CC, Läärä E, Koivuranta M, Greim C-A, Roewer N. Anesthesiology. [Internet]. Vol. 91, Anesthesiology: The Journal of the American Society of Anesthesiologists. [American Society of Anesthesiologists, etc.]; 1999 [cited 2018 Oct 28]. 693-693 p. Available from: http://anesthesiology.pubs.asahq.org/article.aspx?articleid=1946036

9. Fujii Y, Tanaka H, Toyooka H. Optimal anti-emetic dose of granisetron for preventing post-operative nausea and vomiting. Can J Anaesth [Internet]. 1994 Sep [cited 2018 Oct 29];41(9):794–7.

10. Fujii Y, Tanaka H, Toyooka H. Granisetron prevents nausea and vomiting during spinal anaesthesia for caesarean section. Acta Anaesthesiol Scand [Internet]. 1998 Mar [cited 2018 Oct 29];42(3):312–5.

11. Bhattacharya D, Banerjee A. Comparison of ondansetron and granisetron for prevention of nausea and vomiting following day care gynaecological laparoscopy [Internet]. Vol. 47, Indian J. Anaesth. 2003 [cited 2018 Oct 29]. Available from: http://medind.nic.in/iad/t03/i4/iadt03i4p279.pdf

12. Chaudhari SA, Walande S S, Sirsat V S, Pachore p j. International journal of pharmacology and therapeutics a comparative study between ondansetron and granisetron preoperatively for prevention of postoperative nausea and vomiting in elective lscs under spinal anaesthesia [Internet]. Vol. 4. [cited 2018 Oct 29]. Available from: www.earthjournals.org

13. Fujii Y, Saitoh Y, Tanaka H, Toyooka H. Comparison of ramosetron and granisetron for preventing postoperative nausea and vomiting after gynecologic surgery. Anesth Analg [Internet]. 1999 Aug [cited 2018 Oct 29];89(2):476–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/10439770

14. McKenzie R, Kovac A, O'Connor T, Duncalf D, Angel J, Gratz I, et al. Comparison of ondansetron versus placebo to prevent postoperative nausea and vomiting in women undergoing ambulatory gynecologic surgery. Anesthesiology [Internet]. 1993 Jan [cited 2018 Oct 29];78(1):21–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/8424561

15. Kim SI, Kim SC, Baek YH, Ok SY, Kim SH. Comparison of ramosetron with ondansetron for prevention of postoperative nausea and vomiting in patients undergoing gynaecological surgery. Br J Anaesth [Internet]. 2009 Oct [cited 2018 Oct 29];103(4):549–53.