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Antiemetic Prophylaxis with Ondansetron for Post-discharge Nausea and Vomiting after Hip Arthroscopy Performed under Neuraxial Anesthesia: A Prospective, Randomized, Placebo-controlled Trial

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Abstract

Background: Post-Discharge Nausea and Vomiting (PDNV) remain common complaints after ambulatory surgery. This study investigated whether continuation of an anti-emetic regimen for two days postoperatively would reduce PDNV.

Methods: A prospective, randomized placebo-controlled trial of 76 patients undergoing ambulatory hip arthroscopy was initiated. All patients received a spinal or combined spinal epidural and intravenous sedation. No intraoperative opioids were given. Prophylatic anti-emetics (dexamethasone, ondansetron) were given. Postoperatively, two groups either received oral placebo or ondansetron for two days.

Results: On postdischarge day 1, nausea occurred in 54% of the placebo group and 46% of the oral ondansetron group (p=0.49). On postdischarge day 2 and 3, nausea occurred in 16% and 11% of the placebo group; 18% and 10% of the oral ondansetron group (p=0.84 and p=0.94), respectively.

Conclusion: Postdischarge prophylactic oral ondansetron, administered for two days, did not reduce the incidence or severity of nausea in ambulatory hip arthroscopy patients.

Keywords: Postoperative nausea and vomiting; Oral ondansetron; Ambulatory; Hip arthroscopy

Introduction

Despite the use of prophylactic anti-emetics, post-discharge nausea and vomiting (PDNV) remain a common and distressing complaint after ambulatory surgery. In one survey, 72% of patients stated that nausea and vomiting was the post-operative symptom which they most desired to avoid [1]. High risk groups have been identified, and guidelines suggest use of multimodal interventions and anti-emetics [2,3]. However, PDNV remains problematic, with a reported incidence of up to 55% [4].

Hip arthroscopy is a painful procedure with pain scores commonly found to be in the 8/10 to 10/10 in the immediate postoperative period [5]. Potent opioids are therefore necessary for post-operative pain control. Pain and/or oral opioids are thought to contribute to a high incidence of PDNV [6]. A preliminary survey of twenty-one patients conducted at our institution revealed an incidence of 48% of PDNV on the first postdischarge day (PDD1) after hip arthroscopy under neuraxial anesthesia (unpublished data). This high rate occurred despite following the recommended Society for Ambulatory Anesthesia's (SAMBA) guidelines to prevent postoperative nausea and vomiting (e.g. regional technique, no volatile agents, no intraoperative opioids, and routine administration of ondansetron) [2].

A previous study demonstrated that prophylactic administration of oral disintegrating tablet (ODT) ondansetron to patients at high-risk for emesis significantly reduced the incidence of PDNV (57% to 20%, over a recovery period of 120 hours) [4]. The study population underwent outpatient laparoscopic gynecological surgeries with general anesthesia. All patients had at least three emetic risk factors (female, non-smoker, postoperative nausea and vomiting [PONV] history, or motion sickness). The objective of this prospective, double-blinded, randomized study was to determine whether prophylactic administration of oral ondansetron would reduce the incidence of PDNV in patients undergoing ambulatory hip arthroscopy after neuraxial anesthesia.

Materials and Methods

After IRB approval (IRB #29015) and written informed patient consent, 76 outpatient hip arthroscopy patients entered the study. Inclusion criteria were age over eighteen, ability to follow study protocol, and willingness to complete a daily diary and be interviewed daily for three days after discharge. Exclusion criteria included inability to undergo a spinal or epidural anesthetic, prior history of nausea or vomiting, use of drugs with anti-emetic properties within 24 hours of the surgery, chronic opioid use, hypersensitivity and/or allergy to ondansetron, intraoperative use of volatile anesthesia, contraindication to a short course of non-steroidal anti-inflammatory drugs, and allergy or intolerance to hydrocodone.

Patients were randomized in a double-blinded fashion preoperatively into two groups. The pharmacy utilized a randomization table assigning the use of placebo versus ondansetron as instructed on the randomization table. All co-investigators as well as the patient were blinded to the randomization assignment.

The study group received intraoperative intravenous ondansetron

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and postdischarge oral ondansetron (8 mg each day for two days [4]). The control group received intravenous ondansetron intraoperatively and then oral placebo for 2 days. The placebo pills had the same appearance as the active pills.

All patients received a standardized anesthetic. Patients were sedated with intravenous midazolam and propofol (opioids were not given). A neuraxial anesthetic was performed (spinal or combined spinal epidural), with mepivacaine 1.5% as the spinal agent. Epidural local anesthetic, if needed, consisted of 2% lidocaine. Intraoperative intravenous medications included ondansetron (4 mg), famotidine (20 mg) and ketorolac (15 mg if <60 kg, 30 mg if ≥60 kg). Postoperative pain management consisted of hydrocodone/acetaminophen (5/325, q3-4 hours as needed) and naproxen (500 mg twice daily). If needed, intravenous hydromorphone was administered in the Post-Anesthesia Care Unit (PACU) (0.5 mg at a time, to maximum of 2 mg). Antiemetic rescue consisted of intravenous metoclopramide (10 mg) if needed in the PACU, and prochlorperazine (10 mg q8 hours as needed) if needed at home.

Baseline information, including patient demographics, operative details, and medical history was collected. Patients were instructed to complete a daily questionnaire for three postoperative days to record daily incidence and severity of emetic symptoms and pain, and the need for antiemetic rescue. In addition, the daily questionnaire assessed the impact of emetic symptoms and pain on their functional daily activities. An investigator interviewed and assessed the patients 24 hours post-anesthesia by telephone to review the daily questionnaire. Patients submitted their daily questionnaires to their surgeon's office on their postoperative follow up appointment.

Sigmastat for Windows version 3.01 (SPSS Inc, Chicago, IL) was used for statistical analysis. The incidence of nausea and vomiting were modeled as a function of time (postoperative days 1, 2, and 3) using linear regression with inference based on the generalized estimating equations (GEEs) method [7]. This approach provided more robust inference than traditional normal based regression analysis. Changes in incidence of nausea and vomiting over time were detected using appropriate linear contrasts. Nausea severity and quality of life questions were tabulated using descriptive statistics. Significance was determined using Pearson's Chi-square tests. In instances where frequencies were small (below 5), Fisher's exact test was employed. On the basis of our survey and limited data in the literature on PDNV, we estimated our incidence of nausea to be 50% in the control group and 25% in the treatment group. Power analysis indicated that a sample size of 38 per group was needed to detect such difference in proportion with a power of 0.80 and an alpha of 0.05. A critical p-value of 0.05 was used for all hypothesis tests.

Results

Demographics

Patients were enrolled from April 2009 until January 2010. Ninety-eight patients were enrolled in the study. Twenty-two patients were excluded from the final data analysis: ten patients did not receive the standard postoperative analgesia, seven patients withdrew consent and five patients did not take the anti-emetic medication. Of the remaining 76 patients, 37 were in the placebo-control group (Group I) and 39 were in the ondansetron-study group (Group II). The overall demographics, including age, gender, and Body Mass Index scores, were similar between groups (see Table 1). Of the 76 patients, 39 (51%) were male. The majority of patients (78%) underwent an osteochondroplasty and labral debridement. Average patient age was 39 ± 13 years old with an average Body Mass Index of 25 ± 3. The majority of both groups were nonsmokers (95% in both the placebo and ondansetron groups), had no history of PONV (87% in both the placebo and ondansetron groups), no history of opioid intolerance (92% in the placebo group and 87% in the ondansetron group), and no history of motion sickness (76% in the placebo group and 90% in the ondansetron group).

Post-Anesthesia Care Unit (PACU)

In the PACU, prior to the administration of the study capsule (ondansetron) or placebo on post-discharge day 1, the incidence of nausea/vomiting significant enough to require treatment with metoclopramide was 5% in the placebo group and 15% in the ondansetron group. The incidence of recalcitrant nausea/vomiting severe enough to require metoclopramide and dexamethasone or ondansetron was 3% in the placebo group and 5% in the ondansetron group. The majority of patients in both groups received opioids while in the PACU in the form of intravenous hydromorphone (73% in the placebo group, 69% in the ondansetron group). All study patients received hydrocodone/acetaminophen in the PACU. A minority of patients in both groups had severe enough pain that required oral oxycodone/acetaminophen (8% in both groups). Overall, pain scores as recorded by the PACU nurses were mostly moderate to severe (pain

Variable	Group I: Placebo-Control Group (n=37)	Group II: Ondansetron Study Group (*n*=39)	Overall (n=76)
Age, yr (mean ± standard deviation)	37 ± 11	42 ± 14	39 ± 13
Body Mass Index (mean ± standard deviation)	24 ± 3	25 ± 3	25 ± 3
Sex, *n* (%)			
Male	18 (49)	21 (54)	39 (51)
Female	19 (51)	18 (46)	37 (49)
Race/ethnicity, *n* (%)			
Caucasian	36 (97)	34 (87)	70 (92)
African american	--	1 (3)	1 (1)
Asian	--	1 (3)	1 (1)
Native american	--	1 (3)	1 (1)
Hispanic	1 (3)	2 (5)	3 (4)
Patient Smokes, *n* (%)	2 (5)	2 (5)	4 (5)
History of post-operative nausea/vomiting, *n* (%)	5 (13)	5 (13)	10 (13)
History of intolerance to narcotics, *n* (%)	3 (8)	5 (13)	8 (11)
History of motion sickness, *n* (%)	9 (24)	4 (10)	13 (17)

Table 1: Distribution of demographic characteristics.

Variable	Group I: Placebo-Control Group (n=37)	Group II: Ondansetron Study Group (*n*=39)	Overall (n=76)
Oral Hydrocodone/Acetaminophen 5/500 Received, *n* (%)	37 (100)	37 (95)	74 (97)
Oral oxycodone/acetaminophen 5/325 received, *n* (%)	3 (8)	3 (8)	6 (8)
IV hydromorphone received, *n* (%)	27 (73)	27 (69)	54 (71)
NRS[1] pain score 3-10/10, *n* (%)	28 (76)	27 (69)	55 (72)
Metoclopramide received, *n* (%)	2 (5)	6 (15)	8 (11)
Additional anti-emetic received, *n* (%)	1 (3)	2 (5)	3 (4)

[1]NRS=Numeric Rating Scale.

Table 2: Medications given and NRS pain scores in the recovery room.

	Post discharge day 1		Post discharge day 2		Post discharge day 3	
	Group I	Group II	Group I	Group II	Group I	Group II
Oral opioid intake	5.0 ± 3.6	6.0 ± 3.5	1.9 ± 2.5	3.2 ± 3.3	0.8 ± 1.7	1.3 ± 2.2
Nausea incidence	20 (54)	18 (46)	6 (16)	7 (18)	4 (11)	4 (10)
p-value	--	0.49[a]	--	0.84[a]	--	0.94[a]
	--	--	--	--	--	0.67[b]
Nausea severity	N=37	N=39	N=37	N=39	N=37	N=39
No nausea	17 (45.9%)	21 (53.8%)	31 (83.8)	32 (82.1)	33 (89.2)	35 (89.7)
Mild nausea	8 (21.6)	9 (23.1)	4 (10.8)	4 (10.3)	2 (5.4)	2 (5.1)
Moderate nausea	7 (18.9)	5 (12.8)	1 (2.7)	1 (2.6)	2 (5.4)	0 (0)
Severe nausea	5 (13.5)	4 (10.3)	1 (2.7)	2 (5.1)	0 (0)	2 (5.1)
p-value	--	0.83[c]	--	1.00[c]	--	1.00[c]
NRS[1] pain at rest	3.2 ± 2.0	2.8 ± 2.4	2.5 ± 1.8	1.8 ± 1.8	2.0 ± 1.8	1.7 ± 1.7
NRS[1] pain with movement	5.8 ± 1.9	5.3 ± 2.7	4.3 ± 2.0	3.9 ± 2.2	4.0 ± 2.0	3.2 ± 2.2

[a]Pearson's Chi Square test.
[b]Analysis of General Estimating Equation parameter estimates.
[c]Fisher's exact test.
[1]NRS = Numeric Rating Scale.

Table 3: Opioid intake, nausea and patient-reported pain scores.

scores 3 to 10, out of 10), 78% and 69% in the placebo and ondansetron groups, respectively. The fraction of patients reporting moderate or severe nausea on the night after surgery (before taking the study medication) was 30% (placebo) vs. 23% (ondansetron).

Postdischarge Day (PDD) 1

The incidence of nausea was at its highest on PDD1: 54% in the placebo group and 46% in the ondansetron group (p=0.49). There was no difference in the fraction of patients reporting moderate or severe nausea in the first 24 hours after discharge: 32% (placebo) vs. 23% (ondansetron) (p=0.83).

The incidence of vomiting 24 hours after surgery was 8% (placebo) and 13% (ondansetron). The oral consumption of opioids was similar in both groups: 5 ± 3.5 pills (placebo) vs.6 ± 3.5 pills (ondansetron). The pain scores were similar in both groups. Numeric Rating Scale (NRS) pain scores at rest were 3.2 ± 2.0 (placebo) vs. 2.8 ± 2.4 (ondansetron). NRS pain score with motion were 5.7 ± 1.9 (placebo) vs. 5.3 ± 2.7 (ondansetron).

On PDD 2 and 3, the incidence of nausea declined in both groups (PDD2: placebo=16% and ondansetron=18%; PDD3: placebo=11% and ondansetron=10%). Also, the oral opioid intake was reduced to 1.9 ± 2.5 pills (placebo) and 3.2 ± 3.3 pills (ondansetron) on day 2 and 0.8 ± 1.7 pills (placebo) and 1.3 ± 2.2 pills (ondansetron) on day 3. Incidence rates of nausea showed no statistical significance between treatment groups for the three days following surgery (p=0.67, by general estimating equations).

Results from the QOL questionnaire indicated that nausea and vomiting had an impact on the patient's quality of life (30%, placebo vs. 18%, ondansetron; p=0.23) (Table 3). Nausea modestly affected the patient's appetite (19%, placebo vs. 15%, ondansetron), physical activities (14%, placebo vs. 10%, ondansetron) and enjoyment of life (14%, placebo vs. 10%, ondansetron). Nausea had little effect on sleep (5%, placebo vs. 0%, ondansetron), and social life (5%, placebo vs. 3%, ondansetron).

The majority of patients with a history of PONV (80%, placebo vs. 100%, ondansetron), and all patients reporting history of intolerance with narcotics were women (Table 4).

On PDD 1 the overall incidence of nausea was 54% (placebo) vs. 46% (ondansetron). Men reported nausea incidence of 44% (placebo) vs. 29% (ondansetron) while women reported an incidence of 63% (placebo) vs. 67% (ondansetron). Only one male patient (6%, placebo) complained of nausea lasting more than 1 hour while among female patients 37% (placebo) vs. 22% (ondansetron) had nausea lasting more than 1 hour. Among men, 28% (placebo) and 10% (ondansetron) complained of moderate to severe nausea (p=0.22) compared with rates for women of 37% (placebo) vs. 39% (ondansetron). Only one male patient vomited (placebo), while among women 11% (placebo) vs. 28% (ondansetron) vomited.

Discussion

This study enrolled mostly nonsmokers without a history of PONV or motion sickness. Patients received a regional anesthetic without volatile anesthesia, nitrous oxide or intraoperative opioids. The study protocol followed Society of Ambulatory Anesthesia (SAMBA) guidelines to prevent postoperative nausea and vomiting (e.g., regional technique, propofol, no opioids, and intraoperative use of ondansetron) [2], but patients had a high incidence of PDNV (54%, placebo vs. 46%). This high incidence underscores the difficulty in preventing PDNV.

Has nausea affected	Post-discharge day 1			Post-discharge day 2			Post-discharge day 3		
	Group I N=37	Group II N=39	p-value[a]	Group I N=37	Group II N=39	p-value[a]	Group I N=37	Group II N=39	p-value[a]
Quality of living	11 (30)	7 (18)	0.23	2 (5)	3 (8)	1.00	2 (5)	3 (8)	1.00
Nausea affected appetite[b]	7 (19)	6 (15)	0.75	2 (5)	2 (5)	0.52	1 (3)	0 (0)	0.58
Nausea affected sleep[b]	2 (5)	0 (0)	0.06	2 (5)	2 (5)	0.51	1 (3)	2 (5)	0.30
Nausea interfered with physical activities[b]	5 (14)	4 (10)	0.97	2 (5)	1 (3)	0.51	1 (3)	1 (3)	0.34
Nausea interfered with social life[b]	2 (5)	1 (3)	0.82	1 (3)	1 (3)	0.97	1 (3)	1 (3)	0.34
Nausea Interfered with enjoyment of life[b]	5 (14)	4 (10)	0.66	2 (5)	1 (3)	0.40	1 (3)	1 (3)	0.19

[a]Pearson's Chi Square test. Fisher's Exact tests for each metric showed similar results; therefore, Pearson's Chi-Square used to report overall trends.
[b]Data represents combination of response of "Quite a Bit" and "Very Much".

Table 4: Patient quality of life responses.

Variable, n (%)	Male		Female	
	Group I (n=18)	Group II (n=21)	Group I (n=19)	Group II (n=18)
History of post-operative nausea/vomiting	1 (6)	0 (0)	4 (21)	5 (28)
History of intolerance to narcotics	0 (0)	0 (0)	3 (16)	5 (28)
Nausea incidence on PDD1[1]	8 (44)	6 (29)	12 (63)	12 (67)
Reported nausea lasting over 1 hour	1 (6)	0 (0)	7 (37)	4 (22)
Nausea severity				
No nausea	10 (56)	15 (71)	7 (37)	6 (33)
Mild nausea	3 (17)	4 (19)	5 (26)	5 (28)
Moderate nausea	4 (22)	1 (5)	3 (16)	4 (22)
Severe nausea	1 (6)	1 (5)	4 (21)	3 (17)
p-value		0.22		1.00
Patient vomited	1 (6)	0 (0)	2 (11)	5 (28)
Nausea affected quality of life	3 (17)	2 (10)	8 (42)	5 (28)
Nausea affected appetite[a]	3 (17)	2 (10)	8 (42)	6 (33)
Nausea affected sleep[a]	2 (11)	1 (5)	5 (26)	0 (0)
Nausea interfered with physical activities[a]	3 (17)	2 (10)	3 (16)	3 (17)
Nausea Interfered with social life[a]	1 (6)	1 (5)	2 (11)	1 (6)
Nausea interfered with enjoyment of Life[a]	3 (17)	2 (10)	5 (26)	4 (22)

[a]Data represents combination of response of "Quite a Bit" and "Very Much".
[1]PDD1=Post Discharge Day 1

Table 5: Nausea characteristics distributed by gender.

The majority of studies done on PONV involve patients who underwent general anesthesia [2-4,8]. There is only limited information in the literature about PDNV. We are not aware of any study on post-discharge prophylactic anti-emetic regimen in ambulatory patients undergoing hip arthroscopy, nor are we aware of any studies on PDNV in ambulatory patients after regional anesthesia.

PDNV probably has multiple causes. Patients at increased risk for PONV include nonsmokers, women, and individuals with a history of PONV or motion sickness. Anesthetic risk factors include the use of volatile anesthetics, nitrous oxide, and opioids. Surgical risk factors are duration (>30 minutes) and type of surgery (e.g. strabismus, middle ear surgery, laparoscopy, abdominal, and gynecologic) [2].

The surgical procedure itself may be a contributing factor to the nausea. Hip arthroscopy frequently requires operating times of 1 to 2.5 hours. Fluid extravasation into the abdominal cavity, though uncommon, has been reported in the literature [9]. It is possible that small amounts of fluid extravasation may induce nausea. Pain after hip arthroscopy can often be severe. Studies have shown that visceral or pelvic pain may be a common cause of postoperative nausea/emesis [6,10]. Moreover, the majority of patients required frequent use of oral opioids on postoperative day 1, constituting a risk factor for nausea, despite intraoperative avoidance of volatile anesthetics and opioids.

PDNV is a common complaint often not self-reported by patients and therefore often overlooked by health care personnel [11]. In one study, most of the patients did not experience PONV in the recovery room but developed nausea several hours after discharge, usually within the first 24 hours [11].

The majority of patients in this study did not develop nausea until several hours after being discharged from the hospital, despite having moderate to severe pain and receiving opioids in the PACU (Table 2). The highest incidence of nausea in both groups (54%, placebo and 46%, ondansetron) did not occur until 24 hours after discharge. It is possible that the delayed onset of nausea is due to persistent effects of intra-operative administration of ondansetron and / or propofol. Anti-emetic properties of propofol can last between 4 to 24 hours [12]. Other possible reasons for delayed onset of nausea include events that occur at home (e.g. premature ambulation, sudden motion, diet or oral intake, etc.).

A recent study compared a single intraoperative dose of intravenous ondansetron to a treatment group that received both 8 mg of intravenous dexamethasone and multiple doses of ODT ondansetron (first dose in the PACU), and found that treatment reduced post-discharge nausea (57% to 20%) over the period between 8 to 120 hours after discharge [4]. The reduction of nausea did not occur on PDD 1 but in PDD 2 and 3. The patient population (high emetic risk patients consisting of women with a history of PONV or motion sickness) and the use of general

anesthesia were not comparable to this study's patient population (hip arthroscopy patients under a regional technique). It is unclear if the reduction in nausea was due to continuation of ondansetron or to administration of dexamethasone [4]. For this reason, the current study compared the effects of oral ondansetron to placebo, hypothesizing a significant reduction in PDNV.

This study did not verify the utility of prophylactic continuation of ondansetron administration. PDNV was reported by nearly 50% of patients regardless of treatment used. There were no significant differences between the study and control groups. The study confirmed that women are more prone to PDNV, as expected from the PONV literature (Table 5).

The QOL questionnaire demonstrated that nausea has affected women's QOL, appetite, and enjoyment of life more than men. As expected, women were more likely to have PONV. The trends in the data suggest that for women receiving postdischarge ondansetron nausea persists and is as severe, but of shorter duration. For men, nausea appears to be less frequent and less severe while under ondansetron.

Limitations of the study include the exclusion of the amount of irrigant used by the surgeon for the hip arthroscopy and the amount of intravenous hydration administered perioperatively. We also did not record the length of the surgery nor did we stratify the type of arthroscopy performed (e.g. labral debridement versus labral repair) which may vary in pain level. Another limitation is that there are notable trends in the study that may become more significant if the sample size was increased.

In conclusion, addition of postdischarge prophylactic oral ondansetron appears to have no benefit for ambulatory hip arthroscopy patients. This study accentuates the need to include other anti-emetics (e.g. dexamethasone, prochlorperazine, promethazinen, scopolamine) or non-opioid analgesia (e.g. peripheral nerve blockade) after hip arthroscopy especially on PDD1. This study also suggests that use of postdischarge opioids after painful procedures often causes PDNV, despite intraoperative avoidance of volatile anesthetics and opioids. Future studies could investigate the use of other antiemetics or a long-acting nerve block that would reduce pain and decrease the use of opioid consumption on PDD1, possibly reducing the incidence of PDNV.

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