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ORIGINAL ARTICLE

Does low-dose gapapentin reduce opioid use postoperatively?: A randomized controlled trial in women undergoing reconstructive pelvic surgery

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Abstract

Introduction and hypothesis Pre-emptive gabapentin has been shown to decrease postoperative pain in abdominal and vaginal hysterectomy. However, the effect of pre-emptive low-dose gabapentin has not been studied in vaginal hysterectomy combined with concomitant pelvic reconstruction.

Methods A randomized double-blind placebo-controlled trial assessed all women seen for symptomatic prolapse requiring vaginal hysterectomy with concomitant pelvic reconstruction with or without midurethral sling. Gabapentin dosing was 600 mg (<65 years) or 300 mg (>65 years). The primary outcome was reduction in opioid consumption in the first 24 h after surgery. Secondary outcomes included sedation and prolongation of recovery room stay. Sample-size calculations indicated a need for 22 participants/group. Student's *t* test was used to compare differences in oral administration of morphine equivalents in the first 24 h postoperatively, time from end of surgery to leaving the recovery room, and length of recovery room stay. Mann–Whitney *U* test was used to compare visual analog scale (VAS) scores for anxiety, drowsiness/sedation, pain, and nausea.

Results Twenty-one patients received gabapentin and 26 a placebo capsule. Groups were similar with respect to age, menopause status, parity, American Society of Anesthesiologist (ASA) class, and concomitant procedures. There were also no significant differences between groups in opioid requirements within the first 24 h after surgery, time from end of surgery to leaving the recovery room, length of time in recovery room, or VAS scores.

Conclusions Pre-emptive gabapentin at our institutional low doses did not significantly affect postoperative pain and opioid requirements in women undergoing vaginal hysterectomy with concomitant reconstruction.

Trial registration www.clinicaltrials.gov, #NCT02999724.

Keywords Postoperative pain · Pelvic organ prolapse · Stress urinary incontinence · Vaginal hysterectomy · Opioids · Female

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Introduction

Opioids are a common drug of choice for managing postoperative pain. However, they are associated with significant side effects, including sedation, nausea, vomiting, and dizziness. Adjunctive medications given prior to surgery as pre-emptive analgesia can decrease opioid use and therefore decrease potential opioid-related adverse side effects [1, 2].

A third-generation antiepileptic, gabapentin binds to the α2δ subunit of voltage-dependent calcium channels located in the dorsal root ganglia and inhibits the release of excitatory neurotransmitters involved in pain pathways, including glutamate, noradrenaline, and substance P [3–6]. With central and peripheral antinociceptive activity, gabapentin has been shown to be an effective pre-emptive analgesic in decreasing

postoperative opioid use in various surgeries [4–7]. In particular, randomized control trials (RCTs) have demonstrated the benefit of pre-emptive gabapentin in abdominal and vaginal hysterectomies alone [1, 2]. However, pre-emptive gabapentin has not been studied in urogynecologic surgery where vaginal hysterectomy is combined with concomitant pelvic reconstructive procedures, including anterior and posterior colporrhaphies, vault suspension, levator plication, and perineorrhaphy with or without a midurethral sling. The dose of gabapentin used in studies ranges from 300 mg to 1200 mg [1, 2, 4–6]. Our institutional dosing guideline is 600 mg if the patient is <65 years or 300 mg ≥65 based on concerns about excessive sedation and prolonged recovery room stay at higher doses [8]. The most common side effects reported are drowsiness (19–21%), fatigue (11%), dizziness (17–28%), and peripheral edema (1–10%) [9].

We hypothesized that a single dose of pre-emptive gabapentin given 1–2 h prior to vaginal hysterectomy with concomitant pelvic reconstructive procedures would decrease postoperative pain and therefore opioid use in the first 24 h following surgery, without significant sedation or prolongation of recovery room stay.

Materials and methods

An RCT was conducted comparing pre-emptive gabapentin to placebo in women undergoing vaginal hysterectomy with concomitant pelvic floor reconstructive procedures. The study was performed in a university-affiliated tertiary referral center with four attending urogynecologists participating. All new patients aged ≥18 seen for symptomatic prolapse with or without stress urinary incontinence (SUI) and requiring vaginal hysterectomy with concomitant pelvic reconstructive procedures were eligible. Possible concomitant pelvic reconstructive procedures included anterior colporrhaphy, McCall culdoplasty, posterior colporrhaphy, levator plication, perineorrhaphy, and tension-free vaginal tape (TVT), which was offered if patients had clinically significant SUI objectively demonstrated. Patients were counseled regarding the options of concomitant repair at the time of prolapse repair or a step-wise approach, with a possible second procedure.

All patients were initially seen at an outpatient urogynecologic clinic and underwent standard urogynecologic assessment, including history, physical examination, urodynamic testing, and relevant laboratory investigations. Urinary investigations included measurement of postvoid residual (PVR) by urethral catheter or bladder scan, uroflowmetry, filling cystometrogram, urethral pressure profilometry, and cystoscopy. They were invited to participate in the study at the usual pre-operative visit occurring 2–3 weeks prior to surgery and were recruited and consented by a member of the study team who was not directly involved in patient care. Patients were randomized to one of the two parallel groups, with an allocation ratio of 1:1.

As per institutional dosing guidelines, the single pre-emptive dose of orally administered gabapentin was 600 mg for those <65 and 300 mg for those ≥65 years. Medication and placebo were over-encapsulated by an external pharmacy to look alike to facilitate blinding of both patients and researchers. Patients were given either gabapentin or placebo ~1 or 2 h prior to surgery at the same time as other routine pre-operative medications, such as a single-dose celecoxib (400 mg <65 years and 200 mg if ≥65) or acetaminophen (1 g), which were ordered at the discretion of the attending urogynecologist.

Perioperative anesthetic and surgical pathways remained unchanged. Patients underwent either general or spinal anesthetic at the discretion of the attending anesthesiologist. Spinal anesthetic was administered without long-acting narcotics. Local anesthetic—lidocaine 1% and/or bupivacaine 0.5% with epinephrine—was typically infiltrated circumferentially around the cervix for vaginal hysterectomy and in vaginal walls for anterior and posterior colporrhaphies and perineum for perineorrhaphy. For tension-free TVT, local anesthetic was typically infiltrated in the suprapubic region and periurethral tunnels.

Anterior colporrhaphy was performed with plication of the pubocervical fascia using an absorbable suture of polyglycolic acid. Similarly, posterior colporrhaphy, levator plication, and perineorrhaphy were performed using polyglycolic acid. Permanent nonabsorbable mesh was not used in any prolapse procedures. McCall culdoplasty was performed using delayed absorbable polydioxanone suture. Tension-free TVT was performed with a retropubic TVT-Exact (Johnson & Johnson©). In the recovery room, postoperative analgesia medications were provided at the discretion of the anesthesiologist, usually morphine or fentanyl IV. Antiemetics used were ondansetron, dimenhydrinate, and/or metoclopramide. In the postoperative surgical ward, standard postoperative order sets were oral oxycodone 5 mg every 4 h as needed, with the option of morphine or hydromorphone IV, as needed. Patients were also provided with celecoxib, acetaminophen, and antiemetics orally, as needed. Most patients were discharged the day following surgery.

Primary outcome was the difference in total opioid consumption in the first 24 h after surgery between those who received pre-emptive gabapentin and those given a placebo. Data was collected prospectively from paper and electronic charts. All opioids were converted to morphine equivalents according to potency to allow for a single continuous variable. Secondary outcomes addressed the side effects of gabapentin, such as sedation. We examined time from end of surgery to extubation in those who underwent general anesthesia, time from end of surgery to leaving the operating room in the case of general anesthesia, and total duration of recovery room stay,

excluding administrative discharge delays. We also collected visual analog scale (VAS) scores (1–10) of anxiety and drowsiness/sedation upon arrival in the operating room; drowsiness/sedation, pain, and nausea 2 h after surgery; and nausea on the morning of postoperative day 1.

Sample size calculations were based on a previous randomized control trial examining opioid requirements in patients undergoing vaginal hysterectomy [2] and any prolongation in recovery room stay >30 min from the standard discharge time of 120 min. Using equivalents of a fentanyl bolus of 50 μg, Rorarius et al. found that patients given preoperative gabapentin for vaginal hysterectomy (without pelvic reconstructive surgeries) had a 40% reduction in total opioid requirements—from 1150 μg (i.e. 23 boluses) to 700 μg (i.e. 14 boluses) [2]. Using an estimated standard deviation of 400 μg (i.e., 8 boluses), a power of 90%, two-tailed alpha of 5%, and Student's *t* test, sample size was 17 per group. Since our study had additional reconstructive procedures compared with the Rorarius study with vaginal hysterectomy alone, we believed that the difference in pain and narcotic use in our study would be at least as significant as that seen in the Rorarius study. We also ensured that the study was adequately powered to detect any difference in recovery room stay, which typically may last up to 120 min. A 30-min prolongation would be clinically significant to the medical team and those involved in patient flow through the recovery room. Therefore, using a standard deviation (SD) of 30 min, a power of 90%, two-tailed alpha of 5%, and Student's *t* test, the final sample size was 22 per group.

Computer-based simple randomization was used without stratification or minimization. A research assistant generated a randomized list, which indicated whether each pill package for study subject 1, 2, etc., would contain two gabapentin pills (300 mg each) or two placebo pills. On the day of surgery, patients were assigned a study number and were randomized to either group on a sequential basis. Patients <65 received two capsules and those ≥65, one. The randomization list remained concealed until the required sample size was reached and the trial was completed. Patients were excluded if they were already taking gabapentin for another indication, had a proven allergy, sensitivity, or contraindication to it, or were unable to understand spoken English since a translator would not be readily available in the operating and recovery rooms.

Data collected comprised patient demographics including age, parity, menopausal status, body mass index (BMI), and American Society of Anesthesiologist (ASA) physical status classification, perioperative anesthetic medications, surgical procedures, total opioids used in the first 24 h following surgery, times from the end of surgery to recovery room, total duration of recovery room stay, and VAS scores for anxiety, sedation, pain, and nausea. If patients remained in hospital for >24 h, only the first 24 h of medications from the end of surgery were recorded.

The two-tailed Student's *t* test was used to compare the difference in opioid consumption in the first 24 h after surgery and time from the end of surgery to leaving the recovery room and total duration of recovery room stay between groups. Two-tailed Fisher's exact test was used to compare categorical variables between groups, including menopausal status, general or spinal anesthetic, and concomitant pelvic reconstructive procedures. VAS scores for anxiety, drowsiness/sedation, pain, and nausea were compared using two-tailed Mann-Whitney *U* test. A *P* value <0.05 was considered statistically significant.

Results

After obtaining institutional ethics board approval (MSH REB #16–0262), the study began in January 2017. Over a 6-month period, 61 consecutive patients were deemed eligible, of whom 47 consented to participate. Eight were excluded, four declined, one consented but was not randomized or given the premedication, and one had already received preoperative gabapentin before she could be consented to participate (Fig. 1). Of the eight excluded patients, one was deemed ineligible as she was already taking pregabalin. Twenty-six patients were randomized to receive placebo and 21 to receive gabapentin. However, one patient in the gabapentin group received long-acting opioid in the spinal anesthetic and was removed from analysis. Another patient in the placebo group had the procedure converted to a trachelectomy due to significant dense adhesions in the posterior cul-de-sac and was excluded.

Intention-to-treat analysis was performed on the final 25 patients in the placebo group and 20 in the gabapentin group. One patient in each group underwent a laparoscopic-assisted vaginal hysterectomy, and both were analyzed in their respective groups. There were missing VAS scores for anxiety and sedation upon arrival in the operating room for one patient in the placebo group who underwent general anesthesia before this data could be collected; these were considered missing data points in the analysis. The original intended sample size was 22 patietns per group, or 44 patients total. The study sample was increased to 47 patients, as we realized during the study that some patients would be excluded from the final analysis due to the protocol deviations listed above. Table 1 shows baseline demographic data for both groups. There were no significant differences between groups with respect to age, menopausal status, parity, BMI, and American Society of Anesthesiologists (ASA) physical status classification.

There were no significant differences for perioperative outcomes, including type of anesthesia or amount of local anesthesia (Table 2). There were no significant differences in concomitant pelvic reconstructive procedures between groups (Table 3).

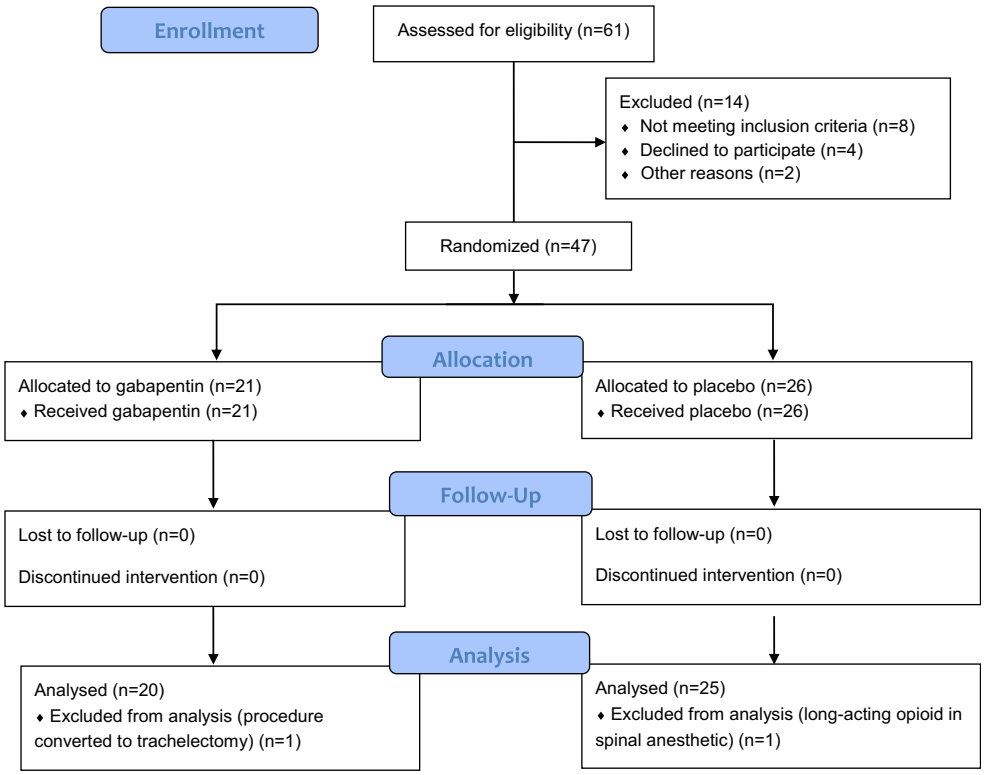

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) 2010 for this study

The primary outcome was the difference in orally administered morphine equivalents between groups, which was not statistically significant: 25.2 ± 25.6 mg (0–80) in the gabapentin vs. 29.5 ± 29.2 mg (0–111) in placebo group; $p = 0.604$. There were also no significant differences in perioperative analgesic and antiemetics (Table 4). There were no significant differences in preoperative celecoxib or acetaminophen use: 160 ± 167 mg (0–400) vs. 136 ± 150 mg (0–400); $p = 0.614$; 550 ± 510 mg (0–1000) vs. 440 ± 506 mg (0–1000), $p = 0.475$. There also were no significant differences in postoperative celecoxib or acetaminophen use: 320 ± 136 mg (0–400) vs. 280 ± 129 mg (0–400), $p = 0.319$; 3128 ± 807 mg (1000–3900) vs. 2728 ± 1176 mg (0–4550), $p = 0.203$).

Our secondary outcomes examined the side effects of gabapentin, particularly any prolongation in time to extubate or duration of recovery room stay. There were no significant differences (Table 5).

There were no significant differences between groups with regard to VAS scores for anxiety and sedation upon arriving in the operating room; pain, sedation, and nausea 2 h postoperatively; and nausea on postoperative day 1 (Table 6).

Table 1 Patient demographics

Demographics	Gabapentin ($N = 20$)	Placebo ($N = 25$)	P value
Age (years)[a]	64.8 ± 11.0 (43–85)	63.6 ± 12.7 (34–86)	0.75
Menopausal[a]	95% ($N = 19$)	84% ($N = 21$)	0.36
Parity[a]	2.6 ± 1.1 (0–5)	2.2 ± 0.6 (1–3)	0.17
Previous Surgeries[b]	75% ($N = 15$)	80% ($N = 20$)	0.70
Body Mass Index (kg/m^2)[a,b]	27.0 ± 3.7 (22.3–33.9)	27.8 ± 4.3 (19.5–38)	0.53
ASA class[a,b]	2.1 ± 0.3 (2–3)	2.6 ± 0.6 (1–3)	0.83

BMI body mass index, *ASA* American Society of Anesthesiologists physical status classification

[a] Continuous data mean (± standard deviation) and compared between groups using Student's *t* test

[b] Categorical data summarized as frequency (%) and compared between groups using Fisher's exact test

Table 2 Perioperative Anesthetics

Peri-operative	Gabapentin ($N = 20$)	Placebo ($N = 25$)	P value
General Anesthetic*	70% ($N = 14$)	80% ($N = 20$)	0.50
Spinal Anesthetic*	30% ($N = 6$)	20% ($N = 5$)	0.50
Local Lidocaine 1% with Epinephrine (mg)**	8.8 ± 9.4 (0–24)	6.6 ± 8.4 (0–20)	0.41
Local Bupivacaine 0.5% with Epinephrine (mg)**	16.7 ± 13.0 (0–40)	18.8 ± 12.6 (0–40)	0.59

*Categorical data summarized as frequency (%) and compared between groups using Fisher's exact test, **continuous data summarized as mean (± standard deviation) and compared between groups using Student's *t* test

Table 3 Concomitant Surgeries

Concomitant Surgery*	Gabapentin ($N = 20$)	Placebo ($N = 25$)	P value
Anterior colporrhaphy	95% ($N = 19$)	100% ($N = 25$)	0.44
Posterior colporrhaphy	90% ($N = 18$)	88% ($N = 22$)	1.00
Levator plication	85% ($N = 17$)	64% ($N = 16$)	0.18
Perineorrhaphy	90% ($N = 18$)	88% ($N = 22$)	1.00
McCall culdoplasty	70% ($N = 14$)	64% ($N = 16$)	0.76
Tension-free vaginal tape	60% ($N = 12$)	64% ($N = 16$)	1.00

*Categorical data summarized as frequency (%) and compared between groups using Fisher's exact test

Finally, there were also no significant side effects or adverse events reported in either group.

Discussion

This randomized double-blinded, placebo-controlled trial found that a single dose of pre-emptive gabapentin had no effect on postoperative pain and therefore opioid requirements in the first 24 h following vaginal hysterectomy with concomitant pelvic floor reconstructive procedures. Furthermore, there were no significant effects from gabapentin when considering delays in time to extubation, length of recovery room stay, and VAS scores. The nonsignificant findings may largely be explained by our institutional dosing policy for gabapentin. We administered a single gabapentin dose of 600 mg to those <65 and 300 mg to those ≥65 years. Most studies examining the effect of pre-emptive gabapentin on postoperative pain considered doses of 1200 mg [4–7]. For instance, in a meta-analysis of 18 studies, Peng et al. found that 12 studies used 1200 mg, and only two studies of spine surgery and laparoscopic cholecystectomy used 300 mg [4]. In gynecology specifically, a systematic review and meta-analysis by Alayed et al. of 14 studies examining pre-emptive gabapentin in abdominal hysterectomy found that pre-emptive administration of gabapentin significantly decreased postoperative pain and therefore morphine consumption [1]. Gabapentin used in these 14 studies ranged from 300 mg to 1200 mg. Seven studies used 1200 mg, with two administering multiple doses and the eighth using daily doses of 1800 mg [1]. In the two studies that used a much lower dose of 300 mg, an additional dose was given the night prior to surgery [1]. Gabapentin has also been shown to decrease postoperative opioid requirements in vaginal hysterectomy alone [2]. In a randomized, double-blinded study, Rorarius et al. found that a single dose of 1200 mg gabapentin given 2–2.5 h prior to surgery reduced postoperative opioid requirements by 40% [2]. Furthermore, there were no significant differences between groups with regard to side effects of

Table 4 Analgesics and Antiemetics

Analgesics*	Gabapentin ($N = 20$)	Placebo ($N = 25$)	P value
Morphine Equivalents orally	25.2 ± 25.6 (0–80)	29.5 ± 29.2 (0–111)	0.60
Celecoxib preoperatively (mg)	160 ± 167 (0–400)	136 ± 150 (0–400)	0.61
Acetaminophen preoperatively (mg)	550 ± 510 (0–1000)	440 ± 506 (0–1000)	0.48
Celecoxib postoperatively (mg)	320 ± 136 (0–400)	280 ± 129 (0–400)	0.32
Acetaminophen postoperatively (mg)	3128 ± 807 (1000–3900)	2728 ± 1176 (0–4550)	0.20
Dimenhydrinate IV (mg)	5 ± 9.4 (0–25)	16 ± 26.9 (0–100)	0.09
Ondansetron IV (mg)	1.4 ± 2.4 (0–8)	1.7 ± 2.6 (0–8)	0.71

*Continuous data summarized as mean (± standard deviation) and compared between groups using Student's t test

Table 5 Perioperative Times

Times (min) *	Gabapentin ($N = 20$)	Placebo ($N = 25$)	P value
Anesthesia	158 ± 40.9 (67–228)	151 ± 42.6 (72–257)	0.58
Surgery	118 ± 36.7 (39–196)	111 ± 39.7 (43–221)	0.57
Surgery end to Extubation	8.2 ± 3.4 (1–15)	8.6 ± 4.7 (0–22)	0.79
Surgery end to Recovery Room	9.4 ± 3.5 (1–15)	11.6 ± 7.3 (2–39)	0.20
Recovery Room stay	210 ± 123 (43–555)	207 ± 97.9 (66–401)	0.90

*Continuous data summarized as mean (± standard deviation) and compared between groups using Student's t test

Table 6 Visual analog scales

Visual Analog Scale*	Gabapentin ($N = 20$)	Placebo ($N = 25$)	Mann-Whitney U test
Upon arrival in Operating Room			
Anxiety	4.1 ± 2.9 (1–10)	3.5 ± 2.4 (1–9)	208 (NS)
Sedation	2.6 ± 2.1 (1–6.5)	1.8 ± 1.4 (1–5)	189 (NS)
2 h postoperatively			
Sedation	5.3 ± 2.5 (2–10)	4 ± 3.0 (1–10)	175.5 (NS)
Pain	4.2 ± 2.6 (1–10)	4 ± 2.6 (1–9.5)	244.5 (NS)
Nausea	2.1 ± 2.2 (1–8)	2.2 ± 2.1 (1–8)	243.5 (NS)
Postoperative day 1 nausea	1.5 ± 1.4 (1–6)	1.3 ± 1.1 (1–5)	235 (NS)

*Visual analog scales summarized as mean (± standard deviation) and compared between groups using two-tailed Mann-Whitney U test

premedication, including drowsiness, dizziness, headache, blurred vision, or dry mouth [2]. We found no significant differences with regards to drowsiness and sedation in terms of the time needed to extubate or the length of recovery room stay. In the Rorarius study, gabapentin was administered 2–2.5 h prior to surgery [2]. It may be suggested that premedicating 1–2 h prior to surgery may have also contributed to the negative effects observed in our study, as gabapentin reaches its peak concentration after 2–3 h [10]. However, other studies administered pre-emptive gabapentin 1 h prior to surgery and found that given at this time significantly reduced postoperative opioid requirements [1].

There are several limitations to our work. First, the single dose of 300 mg of gabapentin was used based on hospital policy, and our study was not powered to compare doses of 300 vs. 600 mg between groups. Furthermore, our sample size calculations were based on a study that used a single dose of 1200 mg in vaginal hysterectomy [2]; our study may have been underpowered to detect a statistically significant difference between the lower doses of 300 and 600 mg. Furthermore, the concomitant pelvic floor reconstructive procedures in this study were anterior and/or posterior colporrhaphies, McCall culdoplasty, levator plication, and perineorrhaphy, with or without TVT. We did not consider other vault-suspension procedures at the time of vaginal hysterectomy. We also did not include other midurethral slings. Third, we did not consider whether the procedures were completed by attending urogynecologists, fellows, and/or residents. All surgeries were supervised by the attending urogynecologists, and often, students completed different components of the surgeries considering the appropriate level of their training. The participation of students affected operative times and therefore possibly the amount of anesthetic required. However, this academic setting is representative of many urogynecologic referral centers and may increase the external validity of our study. Fifth, we did not control for intraoperative anesthetics; however, this did not lead to any significant difference between groups. Fourth, our data was collected from patients' paper and electronic charts, which were completed by various perioperative nursing staff and included medications given and times for extubation and recovery room stay. In the recovery room, medications were charted on both paper and electronic charts at the same times, and there were occasionally missing data. However, by comparing paper and electronic charts and times of medication administration, we confirmed that all opioids given were accounted for in data collection. Furthermore, there were occasional delays in charting times due to acuity of the recovery room. Finally, we did not collect data regarding postoperative complications or indications for prolonged hospital admissions beyond the typical overnight stay. Nevertheless, postoperative complications and hospital admissions >1day are uncommon at our institution.

In a climate of fiscal restraints in healthcare spending, our study has several important clinical implications. As we found that preemptive gabapentin at our current institutional doses had no significant effect compared to placebo in reducing postoperative opioid requirements, physicians may consider omitting this premedication for patients and the pre-operative order sheets might be re-designed to exclude gabapentin as an option altogether. Over time, the omission of pre-emptive gabapentin at our institutional doses would add up to considerable economic savings. Conversely, if a future study demonstrates that pre-emptive gabapentin at higher doses reduces postoperative pain and therefore opioid use, then the reduction of adverse opioid-related side effects and improved pain control may facilitate earlier hospital discharge. Our patients are admitted overnight, and most are discharged the following day. However, there is a growing movement toward discharging patients the day of surgery. That being said, the advantages of a higher dose of gabapentin may be offset by greater side effects, including sedation.

This is the first study to consider gabapentin as an adjunct medication in urogynecologic surgery where vaginal hysterectomy is combined with concomitant pelvic floor reconstruction. We found no statistical significance in postoperative pain and therefore opioid use between women who received a single dose of pre-emptive gabapentin of either 300 mg or 600 mg and those given a placebo. There was also no significant difference in sedation or prolongation of recovery room stay between groups. Future research directions include comparing a dose-response relationship between pre-emptive gabapentin and postoperative pain, opioid use, and side effects of gabapentin, including sedation.

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Compliance with ethical standards

Conflict of interest None.

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