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Analysis of Adverse Effects of Multimodal Gabapentin in Abdominal Wall Reconstruction

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Adverse Effects of Multimodal Gabapentin

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Background: Multimodal analgesia, a key component of enhanced recovery after surgery protocols, emphasizes the use of nonopioid analgesics. Preoperative and postoperative gabapentin is often included within multimodal analgesia because it has been shown to reduce postoperative opioid use. However, the role of gabapentin has been questioned because of concerns of adverse effects, particularly in the elderly. In an effort to better understand the specific role of gabapentin within the context of an established enhanced recovery after surgery protocol, the authors studied the prevalence of its adverse effects in patients undergoing abdominal wall reconstruction.

Methods: Following institutional review board approval, a retrospective review of a prospectively collected database of 267 consecutive patients who underwent abdominal wall reconstruction performed by a single surgeon was conducted. Demographic variables; operative details; postoperative analgesic use; the presence of dizziness, lightheadedness, or altered mental status; hypotension; negative Richmond Agitation Sedation Scale scores; and postoperative falls were recorded and analyzed according to postoperative gabapentin administration.

Results: Two hundred thirteen patients (80 percent) met inclusion criteria, of which 138 (65 percent) received postoperative gabapentin. Postoperative gabapentin use was not associated with dizziness, lightheadedness, or altered mental status; hypotension; negative Richmond Agitation Sedation Scale scores; or falls. Furthermore, even among those aged 65 years or older, postoperative gabapentin use was not significantly associated with these adverse events.

Conclusions: In patients undergoing abdominal wall reconstruction, postoperative gabapentin administration was not associated with an increase in adverse effects. Further prospective analysis may better allow the characterization of the adverse effects of perioperative gabapentin.

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

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Enhanced recovery after surgery protocols have gained popularity, as they have shown reductions in complication rates, hospital length of stay, and overall costs.[1] Multimodal analgesia, a regimen that emphasizes a patient- and procedure-specific approach to pain control through administration of multiple nonopioid analgesics and reduction in opioid use, is now a key component of enhanced recovery after surgery protocols.[2,3] Analgesic

strategies incorporated into multimodal analgesia protocols include the use of both regional and systemic options including neuraxial analgesia, regional analgesic techniques, acetaminophen, nonsteroidal antiinflammatory drugs, and analgesic adjuncts such as gabapentinoids. In addition to decreasing the amount of opioid use as it relates to the opioid epidemic,[4] other benefits of multimodal analgesia may include reduction in opioid-related adverse events (e.g., nausea, vomiting, and constipation).[2]

Although gabapentin was initially designed as an antiepileptic medication, it was later approved for treatment of chronic neuropathic pain and perioperative analgesia. Current perioperative strategies often include preoperative and postoperative scheduled administration.[5,6] Perioperative use of gabapentinoids has been recommended by the American Pain Society,[7] as it has been reported to reduce pain and opioid requirements in a wide variety of surgical subspecialties, including plastic surgery.[8–11] Despite this, a recent systematic review and meta-analysis found no clinically significant analgesic effect for perioperative use of gabapentinoids.[12] In addition, gabapentinoids can increase the risks of adverse events such as dizziness and visual disturbances. In fact, the U.S. Food and Drug Administration recently published an advisory emphasizing concerns relating to gabapentinoids.[13] In an effort to better understand the specific role of gabapentin within the context of an established enhanced recovery after surgery protocol, the authors studied the prevalence of adverse effects—specifically dizziness, drowsiness, falls, and hypotension—in patients undergoing abdominal wall reconstruction.

PATIENTS AND METHODS

Following institutional review board approval (this research protocol was granted approval by The Ohio State University Institutional Review Board no. 2015H0105), a

retrospective review of a prospectively collected database of 267 consecutive patients who underwent abdominal wall reconstruction from September of 2013 through February of 2020 performed by a single surgeon (J.E.J.) at a large academic center was conducted. Exclusion criteria are shown in Figure 1. Patients were excluded if they were routinely prescribed gabapentin (*n* = 36) or pregabalin (*n* = 4) preoperatively, had an additional operation requiring general anesthesia during admission after abdominal wall reconstruction (*n* = 3), or remained intubated/were reintubated following surgery (*n* = 11). This resulted in an analysis of 213 patients.

Fig. 1. Exclusion criteria.

Enhanced Recovery after Surgery and Multimodal Analgesia Protocols

The established abdominal wall reconstruction enhanced recovery after surgery protocol within our institution focuses on a patient-specific approach to multimodal analgesia. The authors have previously described the analgesic regimen used for these patients, which is shown in Figure 2.[14] Gabapentin is administered both preoperatively, 300 mg orally 2 hours before surgery, and postoperatively, 300 mg three times daily for 14 days if the patient is younger than 65 years, and twice daily if aged 65 years or older (based on creatinine clearance). It is not given to patients with a history of obstructive sleep apnea on continuous positive airway pressure or if they are allergic.

Fig. 2. Multimodal analgesia protocol for abdominal wall reconstruction. (From Barker JC, Joshi GP, Janis JE. Basics and best practices of multimodal pain management for the plastic surgeon. *Plast Reconstr Surg Glob Open* 2020;8:e2833.)

Data Collection and Analysis

Data were abstracted from the electronic medical record and recorded in a Microsoft Excel (Microsoft Corp., Redmond, Wash.) worksheet. Demographic variables included age; history of hypertension; diabetes mellitus; chronic obstructive pulmonary disease; and baseline hemoglobin, creatinine, and estimated glomerular filtration rates. Kanters Modified Hernia Grading Scale,[15] operative details, and postoperative analgesic medications were also recorded.

Primary outcomes recorded were inpatient falls or within 30 days of discharge and a negative Richmond Agitation Sedation Scale score during postoperative days 1 to 2. The Richmond Agitation Sedation Scale was designed as an objective measure of sedation and agitation in intensive care unit patients and is shown in Table 1. Negative Richmond Agitation Sedation Scale scores range from −1 (drowsy) to −5 (unarousable), and represent a spectrum of sedation.[16] The timing and number of negative Richmond Agitation Sedation Scale scores were recorded for patients who had hospital lengths of stay of 2 days or longer (n = 202). Receipt of analgesic medications within 8 hours before a negative Richmond Agitation Sedation Scale score was reviewed. Additional secondary outcomes include reported dizziness, lightheadedness, or altered mental status; the presence of hypotension (defined as <80 percent of the patient's baseline mean arterial pressure); and the amount of oral morphine equivalents given per day during the patient's admission.

Table 1. Richmond Agitation Sedation Scale*

Score	Term	Description
+4	Combative	Overly combative or violent; immediate danger to staff

+3	Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient-ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	
−1	Drowsy	Not fully alert, but has sustained (>10 sec) awakening, with eye contact, to voice
−2	Light sedation	Briefly (<10 sec) awakens with eye contact to voice
−3	Moderate sedation	Any movement (but no eye contact) to voice
−4	Deep sedation	No response to voice, but any movement to physical stimulation
−5	Unarousable	No response to voice or physical stimulation

*Sessler CN, Gosnell MS, Grap MJ, et al. The Richmond Agitation-Sedation Scale: Validity and reliability in adult intensive care unit patients. *Am J Respir Crit Care Med*. 2002;166:1338–1344.

Variables were analyzed according to whether the patient received postoperative gabapentin, and an additional analysis was performed among those aged 65 years or older. Categorical variables were compared using the Pearson chi-square or Fisher's exact test, when applicable. Shapiro-Wilk test of normality was performed on all continuous variables. None showed normality at 0.05 significance; thus, continuous variables were analyzed using the Mann-Whitney *U* test. A value of $p < 0.05$ was determined to be statistically significant. Statistical analysis was performed using IBM SPSS Statistics for Macintosh, version 27.0 (IBM Corp., Armonk, N.Y.).

RESULTS

One hundred thirty-eight patients (65 percent) received postoperative gabapentin. Reasons for not receiving gabapentin included before the attending surgeon routinely prescribed it ($n = 53$), history of obstructive sleep apnea on continuous positive airway pressure ($n = 16$), allergy ($n = 4$), and postoperative acute kidney injury with worsening renal function ($n = 2$). Demographics and baseline preoperative characteristics in patients

who received gabapentin versus those who did not are listed in Table 2. No statistically significant differences in demographics or medical comorbidities, including Kanters Modified Hernia Grading Scale, were found between groups. Patients had similar rates of baseline hypertension (gabapentin, 38 percent; no gabapentin, 45 percent; $p = 0.326$), syncope (gabapentin, 8 percent; no gabapentin, 8 percent; $p = 0.994$), and vertigo (gabapentin, 6 percent; no gabapentin, 4 percent; $p = 0.750$) between those receiving and not receiving postoperative gabapentin. Patients receiving gabapentin more often had a synthetic mesh placed during the procedure compared with their counterparts (gabapentin, 76 percent; no gabapentin, 51 percent; $p = 0.001$), although there were no significant differences in whether patients received a mesh or not (gabapentin, 96 percent; no gabapentin, 95 percent; $p = 0.744$). There were no other differences in operative procedure, as shown in Table 3.

Table 2. Demographics and Preoperative Characteristics in Patients Undergoing Abdominal Wall Reconstruction

	Gabapentin (%)	No Gabapentin (%)	Total (%)	*p*
No.	138	75	213	
Mean age ± SD, yr	55 ± 20	57 ± 17	56 ± 19	0.941
Mean BMI ± SD, kg/m^2	33 ± 8	32 ± 10	33 ± 9	0.489
Hypertension	53 (38)	34 (45)	87 (41)	0.326
Chronic obstructive pulmonary disease	5 (4)	7 (9)	12 (6)	0.118
Diabetes mellitus	31 (23)	14 (19)	45 (21)	0.517
Vertigo	8 (6)	3 (4)	11 (5)	0.750
Syncope	11 (8)	6 (8)	17 (8)	0.994
Narcotic use	45 (33)	21 (28)	66 (31)	0.487
Mean baseline arterial pressure ± SD, mmHg	91 ± 15	92 ± 16	92 ± 16	0.840
Mean baseline hemoglobin ± SD, g/dl	13.5 ± 2.1	13.6 ± 2.4	13.5 ± 2.2	0.769
Mean baseline creatinine ± SD, mg/dl	0.9 ± 0.4	0.9 ± 0.3	0.9 ± 0.4	0.723
Kanters Modified Hernia Grading Scale				0.053

1	23 (17)	14 (19)	37 (17)	
2	91 (66)	38 (51)	129 (61)	
3	24 (17)	23 (31)	47 (22)	

BMI, body mass index.

Table 3. Operative Details in Patients Undergoing Abdominal Wall Reconstruction

	Gabapentin (%)	No Gabapentin (%)	Total (%)	*p*
No.	138	75	213	
Mesh	132 (96)	71 (95)	203 (95)	0.744
Mesh type				0.001
Biologic	27 (20)	33 (44)	60 (28)	
Synthetic	105 (76)	38 (51)	143 (67)	
Unilateral component separation	38 (28)	12 (16)	50 (24)	0.058
Bilateral component separation	55 (40)	31 (41)	86 (40)	0.834

During the postoperative period, patients receiving postoperative gabapentin received lower amounts of postoperative oral morphine equivalents per day throughout their admission [gabapentin: median, 28 (interquartile range, 48); no gabapentin: median, 65 (interquartile range, 76); $p < 0.001$]. These patients were no more likely to have a mean arterial pressure less than 80 percent of baseline (gabapentin, 68 percent; no gabapentin, 59 percent; $p = 0.168$) or report dizziness, lightheadedness, or altered mental status (gabapentin, 20 percent; no gabapentin, 20 percent; $p = 0.960$), as shown in Table 4. In addition, hospital length of stay was similar between groups [gabapentin: median, 5 days (interquartile range, 2 days; no gabapentin: median, 5 days (interquartile range, 3 days); $p = 0.107$). Four patients experienced a fall within 30 days after discharge. All four received postoperative gabapentin, although this was not statistically significant (gabapentin, 3 percent; no gabapentin, 0 percent; $p = 0.300$). An additional analysis was performed for patients aged 65 years or older. In this cohort of 48 older adults, postoperative gabapentin was not significantly associated with increased rates of

dizziness, lightheadedness, or altered mental status (gabapentin, 31 percent; no gabapentin, 25 percent; $p = 0.746$), symptomatic hypotension (gabapentin, 78 percent; no gabapentin, 56 percent; $p = 0.178$), or negative Richmond Agitation Sedation Scale scores (gabapentin, 27 percent; no gabapentin, 14 percent; $p = 0.462$). Furthermore, no patients aged 65 years or older experienced a fall in the postoperative period.

Table 4. Outcomes in Patients Undergoing Abdominal Wall Reconstruction

	Gabapentin (%)	No Gabapentin (%)	Total (%)	*p*
No.	138	75	213	
OME/day, mg				<0.001
Median	28	65	42	
IQR	48	76	60	
LOS, days				0.107
Median	5	5	5	
IQR	2	3	3	
Negative RASS	21 (16)	17 (24)	38 (19)	0.147
MAP <80% of baseline	94 (68)	44 (59)	138 (65)	0.168
Reported dizziness/lightheadedness/altered mental status	28 (20)	15 (20)	43 (20)	0.960
Inpatient fall or within 30 days of discharge	4 (3)	0 (0)	4 (2)	0.300

OME, oral morphine equivalents; IQR, interquartile range; LOS, length of stay; RASS, Richmond Agitation Sedation Scale; MAP, mean arterial pressure.

Of the 213 patients analyzed, 202 had a length of stay of 2 days or longer. Thirty-eight patients (19 percent) had at least one negative Richmond Agitation Sedation Scale score during postoperative days 1 to 2, for a total of 129 negative scores. There was no significant difference in the number of patients who experienced negative Richmond Agitation Sedation Scale score between patients receiving and not receiving postoperative gabapentin, although patients receiving gabapentin were less likely to

experience one of these negative scores (gabapentin, 16 percent; no gabapentin, 24 percent; $p = 0.147$).

Medications administered in the 8 hours before a negative Richmond Agitation Sedation Scale score for each event were recorded and are listed in Table 5. Although there was a total of 46 negative scores in patients who received postoperative gabapentin, in only 24 (52 percent) of these scores did the patient receive gabapentin in the 8 hours prior. Ten events in this cohort of 24 were linked to a gabapentin dose less than 300 mg, which is the typical dose for the authors' institutional enhanced recovery after surgery policy for abdominal wall reconstruction.

Table 5. Analgesic Medications Administered within 8 Hours of Negative Richmond Agitation Sedation Scale Score

	No. (%)
Total	129
Acetaminophen	54 (42)
Ibuprofen	5 (4)
Celecoxib	10 (8)
Gabapentin	24 (18)
Opioid	85 (65)

DISCUSSION

This study investigated the postoperative adverse effects of gabapentin as they relate to hypotension, dizziness, and falls in patients undergoing abdominal wall reconstruction performed by a single surgeon. Gabapentin is often used as part of a patient- and procedure-specific multimodal analgesia regimen within enhanced recovery after surgery protocols, and has shown success in lowering the amount of oral morphine equivalents prescribed in the postoperative period.[17] Although gabapentin has generally

been considered safe because of a decrease in opioid-related side effects, central nervous system depression (notably confusion, dizziness, and respiratory depression) remains a concern.[12,13] Hypotension is a documented, though less studied, side effect of gabapentin, and has been shown to coincide with gabapentin administration in animal models[18] and as a part of enhanced recovery after surgery protocols.[19]

Postoperative orthostatic intolerance is characterized by symptoms of dizziness, nausea, vomiting, blurred vision, or syncope during sitting and standing during early mobilization. It is usually a transient condition that resolves within 24 to 48 hours. Its incidence ranges between 12 and 60 percent and is higher in patients undergoing more invasive surgical procedures.[20] Risk factors include female sex and use of opioids and antihypertensive medications. Although the exact pathophysiology is unclear, it is most likely attributable to attenuated endogenous vasopressor response during ambulation and increased vagal output, potentially associated with inflammatory activation from the surgical stress response.[20] Consequences of orthostatic intolerance and hypotension may delay ambulation and adversely influence recovery, and has been observed in 34 percent of patients undergoing abdominal surgery.[21] A physiologic connection between orthostatic hypotension and falls has been suggested, and a recent meta-analysis of adults aged 65 years or older showed a positive association between the two.[22] The enhanced recovery after surgery protocol for abdominal wall reconstruction at our institution encourages ambulation on the same day of the operation, which could potentially put these patients at high risk for both orthostatic hypotension and falls. Although our analysis did not directly assess orthostatic hypotension, no differences in hypotension (defined as <80 percent of baseline mean arterial pressure) between groups suggests that

gabapentin does not increase hypotension postoperatively. More importantly, gabapentin administration did not lead to an increase in inpatient falls or within 30 days of discharge despite our early and frequent postoperative ambulation protocol.

Confusion or delirium are other important considerations for postoperative patients and occurs in as many as 50 percent of older patients following surgery.[23] In a large population-based study, higher gabapentin doses were shown to be associated with higher rates of altered mental status among adults older than 65 years.[24] Forty-eight patients in our cohort were aged 65 years or older, but there were no significant differences in the rates of dizziness or confusion among those younger or older than 65 years of age. In addition, among this group of elderly adults, postoperative gabapentin did not increase rates of dizziness, confusion, altered mental status, symptomatic hypotension, or falls. However, in conjunction with our team of pharmacists, multimodal gabapentin administration within our enhanced recovery after surgery protocol emphasizes a patient-specific approach. As a result, the dose of gabapentin is lowered in those aged 65 years or older or as otherwise indicated, below the standard 300 mg three times daily that our institutional enhanced recovery after surgery protocol follows, which has been reported by members of our group,[17] and others.[11] It may be possible that these efforts contribute to our data showing no significant differences in adverse events.

Further supporting our findings of its safety, when specifically assessing the safety of perioperative gabapentin in a mixed surgical cohort, Hah et al. found no significant differences in one or more serious adverse events between receiving gabapentin 600 mg three times daily versus placebo.[25] In addition, Leung et al. showed that gabapentin administration was associated with lower rates of postoperative

delirium.[26] However, the authors appropriately note that the lower rates of delirium may have been influenced by a concomitant decrease in hydromorphone patient-controlled analgesia use seen in the study's gabapentin group. Regardless, our data, in addition to those reported by others, suggests that perioperative gabapentin can be used as a safe adjunct to analgesic regimens while lowering the administered amount of daily inpatient oral morphine equivalents.

Limitations

The retrospective nature of this study may prevent complete and accurate data collection. Baseline mean arterial pressure was defined as the value recorded in the preoperative history and physical examination. The exact hospital setting and medications administered before blood pressure measurement were not standardized and thus may have led to variability in baseline measurements. All patients were operated on and under the care of a single surgeon at a single institution, limiting generalizability. Exact plasma concentrations of gabapentin were not measured at the time of each outcome, only whether the patient received the medication. Gabapentin is known to have cumulative effects, which complicates the analysis of its role in negative Richmond Agitation Sedation Scale scores, as it may be possible that patients could have identifiable plasma concentrations of the drug if it was taken multiple times previously, but not within 8 hours from the time of an event. Pain scores were not collected and analyzed, limiting the ability to draw conclusions about the analgesic efficacy of postoperative gabapentin.

CONCLUSIONS

This retrospective analysis of 213 patients undergoing abdominal wall reconstruction assessed postoperative complications of perioperative gabapentin. Postoperative gabapentin administration was no more associated with hypotension, negative Richmond Agitation Sedation Scale score, or inpatient falls or those within 30 days of discharge. However, all four patients who experienced a fall had received postoperative gabapentin, and providers should be aware of the potential for increased falls. Further larger prospective analyses may better allow the characterization of the side effects of perioperative gabapentin by controlling opioids and other analgesic medications.

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Figure 1

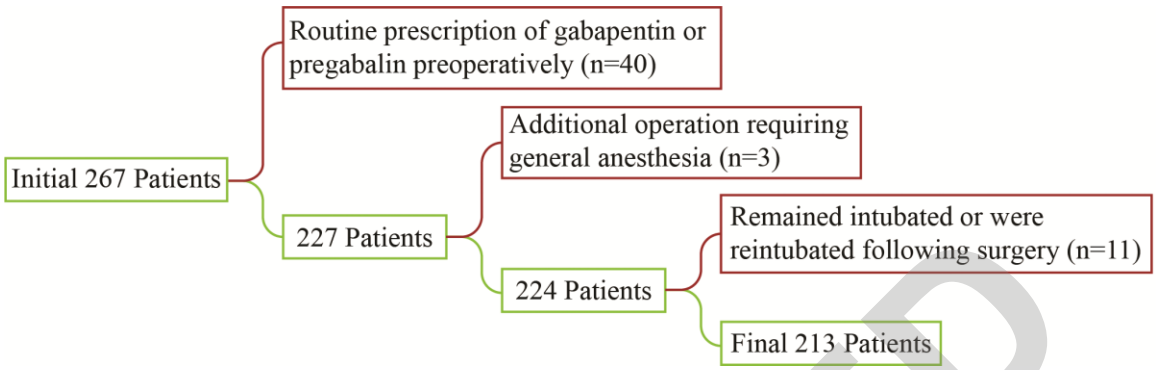

Figure 2