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Предоперационное использование прегабалина для предотвращения тошноты и рвоты после лапароскопической холецистэктомии

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РЕЗЮМЕ

Обоснование. После лапароскопической холецистэктомии часто развивается тошнота и рвота, которую купируют внутривенным введением противорвотных препаратов. В то же время известно, что прегабалин, назначаемый перорально перед операцией для потенцирования эффекта опиоидов и нестероидных противовоспалительных средств во время анестезии, также обладает противорвотным действием.

Цель: оценить возможность с помощью перорально назначаемого прегабалина снизить частоту послеоперационной тошноты и рвоты при лапароскопической холецистэктомии.

Материалы и методы. Рандомизированное двойное слепое исследование. 100 пациентов I класса по классификации Американского общества анестезиологов были протестированы и разделены на две группы. В 1-й группе никакие противорвотные средства до операции не использовали. Пациенты 2-й группы за 30 минут до начала анестезии получали 75 мг прегабалина перорально. Наблюдение за пациентами после операции осуществляли в послеоперационной палате и в общей хирургической палате в течение 24 часов, фиксируя факт появления тошноты и рвоты, назначения любых противорвотных препаратов и развивающихся их побочных эффектов. Оценку риска развития частоты послеоперационной тошноты и рвоты проводили с помощью шкалы Koivuranta.

Результаты. Статистический анализ с использованием пакета SPSS показал значительное уменьшение частоты послеоперационной тошноты и рвоты у пациентов 2-й группы (прегабалин) по сравнению с 1-й.

Заключение. Предоперационный прием 75 мг прегабалина перорально оказывает противорвотное действие в послеоперационном периоде. Никаких значительных послеоперационных побочных эффектов при этом не отмечено.

Ключевые слова: перорально, прегабалиновая капсула, лапароскопическая холецистэктомия, общая анестезия

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Preoperative pregabalin to prevent postoperative nausea and vomiting in laparoscopic cholecystectomy

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ABSTRACT

Background. Postoperative laparoscopic cholecystectomy period is often associated with nausea and vomiting, which is stopped by an antiemetics injected intravenously. Meanwhile, it is known that the oral pregabalin before surgery to potentiate the effect of opioids and nonsteroidal anti-inflammatory medications during anesthesia also has an antiemetic effect.

The objective was to evaluate the effect of oral pregabalin to reduce the frequency of postoperative nausea and vomiting in laparoscopic cholecystectomy cases.

Methods and Materials. Randomized double blind study. One hundred patients of the American Society of Anesthesiology (ASA) class1 were tested and divided into two groups. The first group did not receive any antiemetics preoperatively. The second group received 75 mg of oral pregabalin 30 minutes before anesthesia. We followed up patients postoperatively in the recovery room and general surgical ward for 24 hours, recorded the incidence of nausea and vomiting, prescription of any antiemetics and developing their side effects. We assessed the risk of developing the incidence of postoperative nausea and vomiting by the use of the Koivuranta score.

Results. Statistical analysis using SPSS showed a significant reduction of postoperative nausea and vomiting in the second group (pregabalin) compared with the first group.

Conclusion. Preoperative 75 mg of oral pregabalin has antiemetic effect on postoperative time. No significant postoperative side effects were noted.

Key words: orally, pregabalin capsule, laparoscopic cholecystectomy, general anesthesia

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Introduction

As long as anesthesia is administered, postoperative nausea and vomiting (PONV) will continue to be frequent and upsetting comorbidity. Vomiting and nausea can significantly slow down recovery, raise staffing and drug expenses, and decrease patient satisfaction during perioperative procedures [3, 10].

Nausea is a conscious recognition of subconscious excitation in an area of the medulla closely associated with or a part of the vomiting center, [8] or it is a sensation of discomfort in the upper abdomen and a sensation of unease with involuntary urge to vomit [15]. While vomiting is a means by which the upper GIT rides its contents when any part of the upper GIT becomes irritated, distended or over-excitable.

The PONV is the most feared postoperative symptom and can lead to impaired dressing, surgical repairs, and increased bleeding, pain and risk of gastric contents aspiration. If this is prolonged, it leads to electrolytes, fluid imbalance and dehydration. The PONV occurs after up to 90% of operative procedure. The common risk factors of PONV are young age, female gender, history of (PONV motion sickness) those, non–smokers, early mobilization after surgery, early drinking and eating after operation procedures (as laparoscopic gynecological, abdominal, ENT, squint), postoperative severe pain, narcotic premedication, possibly prolonged general anesthesia, gastric distention, stimulation of the pharynx, hypoxemia, hypotension, and dehydration [6, 9, 12].

The PONV can be reduced by avoiding triggers where possible, using antiemetic medications, techniques and procedures associated with a low incidence of PONV (e.g., propofol), and injecting intravenous fluids. With prophylaxis, the incidence is usually under 30% in high-risk cases. An effective approach for the prevention of PONV is the use of multiple strategies and different medications [9].

Pregabalin (C8H17NO2) is a newer drug and recently introduced in 1990 [13] as anticonvulsive medication [2]. We evaluated the effect of oral pregabalin on postoperative nausea and vomiting in laparoscopic cholecystectomy cases.

Materials and Methods

After obtaining the Ethical Code from the Al-Najaf Health Director, the study took place at AL-Sader Medical City in AL-Najaf AL-Ashraf, in the operating theatre, during the period from the 1st. of November 2021 to the10th of July 2022. One hundred patients were included in this study. Inclusion criteria*:* age⩾18 – <55 years, for both gender (male and female), patients ASA physical status 1, procedures with a high risk of postoperative nausea and vomiting, elective operations under general anesthesia with laparoscopic cholecystectomy. Exclusion criteria: age ⩾ 55 years, emergency operations, patient refusal, allergy to pregabalin, pregnant patients, patients taking preoperative antiemetic medication, patients with cardiac, respiratory, and endocrine diseases, total intravenous maintenance general anesthesia, and thiopental as an induction agent. The study was also approved by a local Committee of the Scientific Council of Anesthesia and Intensive Care. The data were enrolled using a pre-constructed form sheet. The detailed history was taken from each patient. Clinical examination was performed by general examination and vital signs measurement.

Patient data collection forum. Demographic data. Age, sex, weight, medical history, history of previous surgery, history of nausea and vomiting, history of motion sickness, history of smoking, history of allergy, ASA physical status, blood pressure, pulse rate, Spo2%, duration of surgery, postoperative nausea and vomiting, postoperative nausea, postoperative vomiting, postoperative antiemetic requirement, side effect of medications and Koivuranta score.

Patients were enlisted in this randomized trial, double-blind study, divided into two equal groups: the first group (50 patients) did not receive any antiemetic premedication preoperatively, and the second group (50 patients) received 75 mg of oral pregabalin capsule (Lyrica) with a small amount of pure water 30 minutes before anesthesia given to the patients by the anesthetist's hand. On the day of the operation, the anesthesia team and surgical team prepared the operating room, equipment and medications, then let the patient sit on the operating table, intravenous line, pulse oximetry probe, non-invasive blood pressure cuff were placed and secured, the baseline measurements of the vital signs were carried out. Three minutes' pre-oxygenation, general anesthesia started by propofol and atracurium, gentle manual ventilation and endotracheal intubation were done, start of mechanical ventilation, 1% isoflurane as maintenance, intravenous fluid injection, continuous monitoring of the patient parameters throughout the time of operation, surgery started with the supine position then change to reverse Trendelenburg position with left lateral tilt. During surgery, intravenous paracetamol of 10 mg/kg was injected with intravenous fluid and no antiemetic medications was given with continuous monitoring of patient parameters. As for the postoperative period, the research subjects were all admitted patients, the parameters that were used for assessment 24 hours postoperatively were duration of surgery (<or > 60 minutes), postoperative nausea, postoperative vomiting, postoperative nausea and vomiting, any antiemetic requirement, any side effect that could arise unexpectedly and Koivuranta score.

Statistical analysis. Data were entered and analyzed using the statistical package for social sciences (SPSS) software for windows, version 24. Descriptive statistics are presented as mean, standard deviation, frequencies, and proportions (%). The Chi-square test was used to compare the studied groups in categorical variables, while the student's t-test was used to compare means. The level of significance was set at (⩽ 0.05) to be a

Table 1. **Demographic characteristics of the studied groups**

Variable		Pregabalin group (N=50)		Control group (N=50)		P. value
		№	%	№	%	
Age (year)	< 30	19	38.0	12	24.0	0.34
	30 – 39	16	32.0	16	32.0	
	40 – 49	10	20.0	17	34.0	
	≥50	5	10.0	5	10.0	
	Mean±SD*	33.9±8.4	–	36.3±8.8	–	0.24
	Range	20 –50	–	20 –51	–	–
Gender	Male	10	20.0	6	12.0	0.28
	Female	40	80.0	44	88.0	
Smoking	Yes	3	6.0	6	12.0	0.30
	No	47	94.0	44	88.0	

* SD – standard deviation.

Table 2. **History of nausea and vomiting and motion sickness of the studied groups**

Variable		Pregabalin group (N=50)		Control group (N=50)		P. value
		№	%	№	%	
History of nausea and vomiting	Yes	5	10.0	10	20.0	0.16
	No	45	90.0	40	80.0	
History of motion sickness	Yes	3	6.0	6	12.0	0.30
	No	47	94.0	44	88.0	

significant difference or correlation. Finally, the results are presented in tables and figures with an explanatory paragraph for each using the Microsoft Word program version 2010.

Results

There were 100 patients managed with Laparoscopic cholecystectomy enrolled in this study and assigned into two groups with 50 patients in each. The demographic characteristics of the studied groups are shown in the table 1. There were no statistically significant differences between both groups in age, gender, or smoking history, (P>0.05). Furthermore, the mean age was 33.9±8.4 (range: 20–50) years in the studied group and it was 36.3±8.8 (range: 20–51) years in the control group. Regarding gender, females were predominant in both groups.

As shown in the table 2, 5 patients (10%) in the pregabalin group and 10 patients (20%) in the control group had a history of nausea and vomiting; additionally, a history of motion sickness was reported in 3 patients (6%) of the pregabalin group and 6 patients (12%) of the control group. However, no statistically significant differences were reported between both groups neither in the history of nausea and vomiting nor the history of motion sickness, in both comparisons (Pvalue >0.05).

Regarding the duration of surgery, it was<60 minutes in the vast majority of patients, 96% of total patients in both groups (Fig. 1). Only 1 patient in the pregabalin group and 3 patients in the control group had a duration of > 60 minutes.

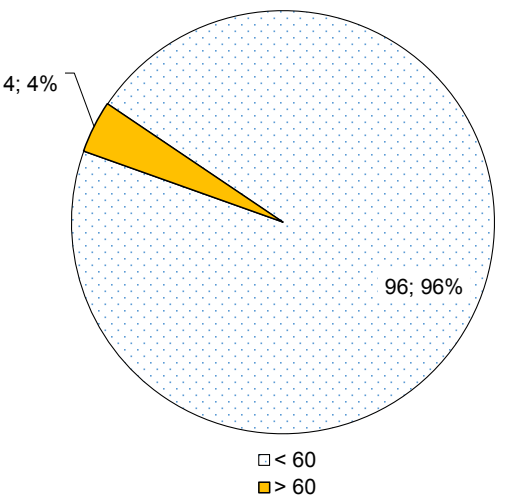

Fig. 1. Distribution of duration of surgery among total studied patients (N=100)

As shown in the table 3, none of the patients in the pregabalin group required antiemetics postoperatively compared to 4 (8%) patients in the control group, and the difference was statistically significant (P=0.041), that patients who received pregabalin were less likely to require antiemetics postoperatively. Furthermore, none of the patients who received pregabalin developed side effects.

As shown in the table 4, postoperatively, nausea and vomiting were significantly less frequent among patients in the pregabalin group compared to the control group; 4 patients (8%) in the pregabalin group had nausea compared to 32 patients (64%) in the control group, (P<0.001). Similarly, vomiting was reported in

Table 3. **Antiemetic required and side effects of Pregabalin of the studied groups**

Variable		Pregabalin group (N=50)		Control group (N=50)		P. value
		№	%	№	%	
Antiemetic required	Yes	0	0.0	4	8.0	0.041
	No	50	100.0	46	92.0	
Side effect	Yes	0	0.0	–	–	–
	No	50	100.0	–	–	

Table 4. **Postoperative nausea and vomiting status among the studied groups**

Variable		Pregabalin group (N=50)		Control group (N=50)		P. Value
		№	%	№	%	
Postoperative nausea	Yes	4	8.0	32	64.0	<0.001
	No	46	92.0	18	36.0	
Postoperative vomiting	Yes	4	8.0	31	62.0	<0.001
	No	46	92.0	19	38.0	
Postoperative nausea and vomiting	Yes	7	14.0	32	64.0	<0.001
	No	43	86.0	18	36.0	

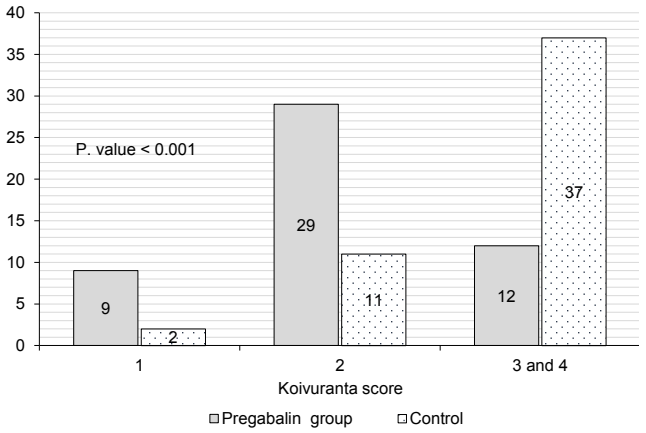

Fig. 2. Comparison of Koivuranta score among the studied group

4 patients (8%) in the pregabalin group and 31 (62%) in the control group, (P<0.001). Both nausea and vomiting were found in 7 patients (14%) in the pregabalin group and it was more frequent in 32 patients (64%) in the control group, (P<0.001).

Fig. 2 demonstrates the comparison of Koivuranta scores in the pregabalin group and the control group. It had been significantly found that patients in the pregabalin group had generally lower Koivuranta scores where 9 patients had a score of 1, 29 with a score of 2 and 12 patients with a score of 3 or 4 while in the control group only 2 patients had a score of 1, 11 had a score of 2 and 37 had a score of 3 or 4. The differences were statistically significant, (P<0.001).

The relationship of postoperative nausea, vomiting, and Koivuranta score with the age of patients in the pregabalin group are shown in the table 5; it is not statistically significant.

Relationship of postoperative nausea, vomiting, and Koivuranta score with the gender of patients in the pregabalin group are shown in the table 6. The only significant relationship was found between Koivuranta score and gender, (P<0.001), where females had significantly higher Koivuranta score. None of the males in the pregabalin group had a score of 3 or 4 compared to 12 females (30%). While 70% of males had a score of 1 compared to 5% of females.

Discussion

In our study, we found no statistically significant differences between both groups in age, gender, or smoking history (p>0.05). Regarding gender, female were predominant in both groups. On the other hand, there was no statistically significant differences reported between both groups neither in history of nausea and vomiting nor the history of motion sickness (p>0.05), and it's also reported in the Isazadehfar, Mendes, M Arslan and their groups [1, 11, 14]. In the vast majority of total patients, the duration of surgery was less than 60 minutes. In our study, none of the patients in the pregabalin group required antiemetic premedication compared to the control group (8%) and the difference was statistically significant (p=0.04); so the patients who received pregabalin were less likely to require antiemetic postoperatively and none of them developed side effects.

Postoperative nausea and vomiting were significantly less frequent in the pregabalin group and more frequent in the control group: 8% in the pregabalin group had nausea compared to 64% in the control group, and 8% in the pregabalin group had vomiting compared to 62% in control group. 64% in the control group had both nausea and vomiting compared to 14% in the pregabalin group, while patients who had the same feature of surgery that treated with ondansetron showed to be more incidence of PONV 22.5% and much higher with metoclopramide 65% [16].

Following laparoscopic surgery, the prevalence of PONV ranged from 30% to 41% in patients who received dexamethasone and ondansetron, and it

***Table 5*. Relationship of postoperative nausea, vomiting, and Koivuranta score with the age of patients in the Pregabalin group**

Variable		Age (year)								P. Value
		<30 (*n*=19)		30–39 (*n*=16)		40–49 (*n*= 10)		≥50 (*n*=5)		
		№	%	№	%	№	%	№	%	
Post-operative N&V	Yes	3	15.8	2	12.5	1	10.0	1	20.0	0.95
	No	16	84.2	14	87.5	9	90.0	4	80.0	
Post-operative Nausea	Yes	2	10.5	1	6.3	0	0.0	1	20.0	0.56
	No	17	89.5	15	93.8	10	100.0	4	80.0	
Post-operative Vomiting	Yes	2	10.5	1	6.3	1	10.0	0	0.0	0.87
	No	17	89.5	15	93.8	9	90.0	5	100.0	
Koivuranta Score	1.0	2	10.5	4	25.0	3	30.0	0	0.0	0.34
	2.0	11	57.9	11	68.8	4	40.0	3	60.0	
	3&4	6	31.6	1	6.3	3	30.0	2	40.0	

***Table 6*. Relationship of postoperative nausea, vomiting, and Koivuranta score with the gender of patients in the Pregabalin group**

Variable		Male (*n*=10)		Female (*n*=40)		P. Value
		№	%	№	%	
Post-operative N&V	Yes	1	10.0	6	15.0	0.68
	No	9	90.0	34	85.0	
Post-operative Nausea	Yes	1	10.0	3	7.5	0.79
	No	9	90.0	37	92.5	
Post-operative Vomiting	Yes	0	0.0	4	10.0	0.30
	No	10	100.0	36	90.0	
Koivuranta Score	1.0	7	70.0	2	5.0	<0.001
	2.0	3	30.0	26	65.0	
	3&4	0	0.0	12	30.0	

decreased to 28% with an increased dose of both medications [4, 5], this number is still higher than our reported study with using pregabalin medication.

In the current study, we had significantly found that patients in the pregabalin group had lower Koivuranta scores compared to the control group. So postoperative nausea and vomiting were reduced in the pregabalin group compared to the control group. There were no statistically significant differences across postoperative nausea and vomiting and Koivuranta score in relation to age in the pregabalin group, so the incidence of postoperative nausea and vomiting is less likely to be affected by the age of the patients in the pregabalin group. Females in the pregabalin group had significantly higher Koivuranta scores compared to males, so females in the pregabalin group was more prone to nausea and vomiting postoperatively. One possible explanation is that the use of pregabalin, which is a GABA agonist agent by some mechanism, reduces nausea, vomiting, and antiemetic requirements, which was reported by other authors in support of our findings; Michael et. al. [7]. Concluded that the preoperative pregabalin is associated with significant reduction of postoperative nausea and vomiting and should not only be considered as part of a multimodal approach to postoperative analgesia but also for prevention of postoperative nausea and vomiting.

Conclusion

The preoperative oral pregabalin of 75 mg gives a significant antiemetic effect postoperatively extending beyond anesthesia time and reduce the requirements for antiemetic medication. No significant postoperative side effects due to the use of pregabalin were noted.

Recommendation

From the findings of our study, we suggest that anesthesiologists should select the best antiemetic treatment for their patients undergoing laparoscopic cholecystectomy on an individual basis until further studies on oral pregabalin are available. It is recommended to:

1. Use of preoperative oral pregabalin to reduce postoperative nausea and vomiting.
2. Use of preoperative oral pregabalin in other surgery.

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Conflict of Interests. The authors state that they have no conflict of interests.

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