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EFFECT OF PREOPERATIVE PREGABALIN ON STRESS RESPONE DURING LARYNGOSCOPY AND INTUBATION ON POSTOPERATIVE ANALGESIA IN NORMOTENSIVE NORMOGLYCEMIC PATIENTS UNDERGOING ABDOMINAL HYSTERECTOMY

By

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ABSTRACT

Background: Laryngoscopy and intubation is a noxious stimulus, which can provoke many untoward responses, particularly in the cardiovascular system in the form of hypertension, tachycardia, and dysrhythmia, which can be detrimental in cardiovascular compromised patients. For decreasing anxiety and the intubation response, use of nonopioid drugs has become a part of the multimodal regimen. Many recent studies show that drugs such as gabapentin and pregabalin are known to decrease stress response due to laryngoscopy and intubation.

Objective: To evaluate the effect of different doses of pregabalin as oral premedication to attenuate cardiovascular response during laryngoscopy and endotracheal intubation.

Patients and methods: The study included 120 normotensive normoglycemic patients undergoing abdominal hysterectomy who were randomly divided into 4 equal groups: group A received a placebo drug, groups B, C and D received different doses of oral pregabalin (75 mg, 150 mg and 300 mg respectively). The patients were unaware of their group distribution. Patients were carefully selected regarding the demographic data and the medical status. The anesthetic technique included preoperative assessment and preparation, during which the patients were informed about the details of the study, gave their consent, learned how to use VAS, and received the drug of the study. This study was done at Al-Azhar University Hospitals after approval of the medical ethical committee, from December 2019 till July 2021.

Results: There was no significant difference between groups as regards demographic data, duration of intubation or duration of surgery. There were increase in hemodynamic values during intubation compared to the baseline values in all groups. However, the increase in both groups C and D was less than that of groups A and B. Afterwards, there was a gradual decrease in the hemodynamic parameters at 1, 3 and 5 minutes after intubation in all groups. Intraoperative fentanyl consumption decreased in the current study on using pregabalin in doses of 150 mg and 300 mg. A dose of 75 mg did not show such effect. Blood cortisol level decreased in the current study on using pregabalin in doses of 150 mg and 300 mg.

Conclusion: Pregabalin in doses of 150 and 300 mg attenuated the hemodynamic response to laryngoscopy and endotracheal intubation, and decreased the requirement of post-operative analgesia.

Keywords: Abdominal hysterectomy, Blood cortisol level, Endotracheal intubation, Post-operative Analgesia, Pregabalin, stress response.

INTRODUCTION

Endotracheal intubation is considered an integral part of the anesthesiologist's contribution in patient care. However, it is a noxious stimulus that may initiate a transient sympathetic response in the form of increased heart rate, blood pressure, and arrhythmias. Moreover, this response may be marked in some cases (*Gehlot*, 2018).

The appropriate premedications (anxiolytics or adrenergic blocking drugs), smooth induction of anesthesia, laryngoscopy and intubation by an expert anesthesiologist are methods to attenuate the pressor response of laryngoscopy (*Pravin*, 2020).

For decreasing anxiety and the intubation response, use of nonopioid drugs has become a part of the multimodal regimen. Many recent studies show that drugs such as gabapentin and pregabalin are known to decrease stress response due to laryngoscopy and intubation (Abdel Naby et al., 2021).

Pregabalin is a structural analog of the inhibitory neurotransmitter gammaaminobutyric acid (GABA). It has been reported that it modulates the release of many neurotransmitters such as glutamate, noradrenaline, substance-P and calcitonin gene related peptide. In particular, the inhibitory modulation of overexcited neurons allows them to return to a normal state, including a decrease in the hyper excitability caused by tissue damage. Although pregabalin is a structural derivative of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), it does not bind directly to

GABA or benzodiazepine receptors (Goodman and Brett, 2017).

Now it has been widely used in the management of neuropathic pain (NP) all over the world. PGB targets α -2- δ (alpha-2-delta) ligands of calcium channel. It acts on voltage-gated calcium channels. PGB is a drug that binds to the α -2- δ subunit of calcium channels and its use in the neuropathic pain caused by diabetic peripheral neuropathy (DPN), postherpetic peripheral neuralgia (PHN), spinal cord injury, and fibromyalgia (*Raman et al.*, 2016).

Oral pregabalin premedication is effective for attenuation of hemodynamic pressor response of airway instrumentation in a dose-related fashion. There is no affection of perioerative hemodynamic stability and no prolongation of recovery time (*Rastogi et al.*, 2012).

Postoperative pain in the form of hyperalgesia caused by surgical trauma can lead to chronic postoperative pain (*Chapman and Vierck*, 2017).

This study aimed to evaluate the effect of different doses of pregabalin as premedication oral to attenuate cardiovascular response during laryngoscopy and endotracheal intubation. Intubation-induced hyperglycemia and blood cortisol level was also assessed in addition to the effect of the drug on postoperative analgesia in normotensive normoglycemic patients undergoing abdominal hysterectomy.

PATIENTS AND METHODS

One hundred and twenty patients enrolled in this study were chosen from those attending pre-anesthesia check-up clinics in the hospital. A written, informed and valid consent was taken from every participant after proper explanation of the study procedure and the expected outcome in a clear language. The study was carried out at Al-Azhar University Hospitals.

The study was performed from December 2019 to July 2021. Patients were divided into 4 equal groups as follows:

Group A received a placebo drug (two multivitamin tablets).

Group B received 75 mg oral pregabalin (one 75 mg Lyrica tablet and one multivitamin tablet).

Group C received 150 mg oral pregabalin (two 75mg Lyrica tablets).

Group D received 300 mg oral pregabalin (two 150 mg Lyrica tablets).

Inclusion Criteria: Females aged from 30 to 60 years normotensive normoglycemic, and Mallapati I and II, ASA I and II patients scheduled for elective abdominal hysterectomy surgery under general anesthesia.

Exclusion Criteria: Cardiovascular disease patients, patients with known hypersensitivity to study drugs, anticipated difficult airway (Mallapati III and IV), coagulopathy, patients received preoperative analgesics, and patients on chronic neuroleptic medications.

Evaluation and preparation: On the day before surgery, each patient was assessed carefully. A full detailed history was taken. Demographic data (age, weight, height) were recorded. A thorough clinical

examination of the heart and chest was done. Blood pressure and heart rate were measured and recorded. Preoperative laboratory tests such as CBC, full coagulation profile, kidney function tests, and liver function tests, as well as ECG and chest X-ray were checked. Preoperative fasting blood sugar was measured. A fasting value of 126 mg/dl (7.0 mmol/L) or higher was considered diabetic.

General Anesthesia Technique: Patients were preoxygenated for 3 minutes with 100 oxygen. They were connected to standard monitoring equipments (ECG, pulse oximeter and non-invasive blood pressure). Baseline data were recorded before induction of anesthesia: heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean blood pressure (MBP). An 18 gauge intravenous cannula was inserted, and an infusion of 500 ml Ringer's acetate solution was set.

Induction of anesthesia was done intravenously using fentanyl sulphate (1microgram/kg), propofol (2 mg/kg) and atracurium besylate (0.5)mg/kg). Anesthesia was maintained by isoflurane 1.2 % in 60 oxygen. Two minutes after injection of atracurium, laryngoscopy and oral intubation were done using an appropriate size of endotracheal tube. Correct intubation was confirmed by capnograghy and auscultation of the chest by a stethoscope was done to make sure of equality of air entry and to exclude endobronchial intubation.

Skin incision was done 15 minutes after intubation. Additional intraoperative analgesia (fentanyl 0.5 microgram/kg) was given after skin incision if there was

20% or more increase in heart rate and blood pressure compared to the baseline values. Intraoperative fluids were given to each patient according to the fasting and maintenance needs. No dextrose 5 solution was administered to any patient. Reversal of the muscle relaxant effect of atracurium was done by the use of neostigmine (0.05 mg/kg) and atropine sulphate (0.02 mg/kg) intravenously. The patient was transferred to postanesthetic care unit (PACU).

The following data were monitored and recorded:

- 1. Duration of laryngoscopy and intubation: If it exceeded 20 seconds or there was more than one trial of intubation, the patient was excluded from the study.
- 2. Blood pressure (systolic, diastolic and mean) and heart rate: They were recorded before induction, during intubation and at 1, 3 and 5 minutes after intubation. Then, they were recorded every 10 minutes till complete recovery from anesthesia.
- 3. Blood glucose levels: Capillary blood samples were taken to assess blood glucose levels. After the baseline sample which was taken one hour before induction of anesthesia, a second sample was taken 5 minutes after intubation. A third sample was taken just before skin incision.
- 4. Blood cortisol levels: Capillary blood samples were taken to assess blood cortisol levels. After the baseline sample which was taken after premedication with pregabalin and before induction of anesthesia, a

- second sample was taken 1 hour postoperatively.
- 5. Calculation of the total intraoperative fentanyl consumption.
- 6. Duration of surgery: It was calculated from time of skin incision to time of closure of skin. If surgery extended more than 2 hours, the patient was excluded from the study.

Postoperative Care: The duration of the study extended 36 hours postoperatively. After arrival to PACU, continuation of monitoring of blood pressure, heart rate and arterial oxygen saturation was done. The patients were kept for 90 minutes in PACU to fulfill the study recordings.

The following data were monitored and recorded in PACU and in the patient's room:

- 1. Time to first request of analgesia: VAS was assessed and recorded at that time.
- 2. Sedation score: It was calculated twice by Modified Ramsay Sedation Score half an hour after arrival to PACU and before discharge from PACU.

Statistical analysis:

Recorded data were analyzed using the statistical package for the social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). A oneway analysis of variance (ANOVA) when comparing between more than two means. Post hoc (Tukey's test) was used for multiple comparisons between different variables. P value < 0.05 was considered significant.

RESULTS

Demographic data: As regards age, statistically significant differences weight and height, there was no between the groups (**Table 1**).

Table (1): Comparison between groups according to demographic data

Groups Parameters	Group A (N=30)	Group B (N=30)	Group C (N=30)	Group D (N=30)	P-value
Age (years)	51.26±5.03	52.4±6.18	51.84±4.80	51.09±7.16	0.819
Weight (kg)	66.44±12.26	68.5±11.18	69.15±12.59	68.72±9.45	0.801
Height (cm)	157.42±6.8	155.71±7.1	156.23±9.23	157.05±7.85	0.828

Data presented as mean \pm SD.

Regarding HR, for all patients in the 4 groups, HR was measured before induction of anesthesia (baseline values), during intubation, and at 1, 3 and 5

minutes after intubation. There was no statistically significant difference between groups as regards baseline values between groups (**Table 2**).

Table (2): Comparison between the four groups as regards heart rate

groups	Group A	Group B	Group C	Group D	P-value
HR (beats/min)	(N=30)	(N=30)	(N=30)	(N=30)	r-value
Baseline	85.26±11.74	86.7±12.2	81.45±10.27	82.2±14.7	0.305
during intubation	124.7±15.56	123.62±14.4	93.65±10.7	94.3±15.33	< 0.001
1 min after intubation	125.15±14.89	124.75±15.26	92.89±14.22	91.25±12.15	< 0.001
3 min after intubation	117.84±12.45	118.6±13.7	89.41±12.46	88.67±14.35	< 0.001
5 min after intubation	114.23±11.17	117.3±15.43	102.23±11.87	101.44±12.7	< 0.001

Data presented as mean \pm SD.

HR values during intubation and at 1, 3 and 5 minutes after intubation were

considered highly significant compared to baseline values (P-value< 0.01).

Table (3): Comparison of HR values inbetween groups

HR (beats/min)					
Post hoc (Tukey's test)		Group A	Group B	Group C	
	Group B	0.643			
Baseline	Group C	0.186	0.076		
	Group D	0.376	0.202		
	Group B	0.781			
during intubation	Group C	< 0.001	< 0.001		
	Group D	< 0.001	< 0.001	0.848	
1 min after intubation	Group B	0.918			
	Group C	< 0.001	< 0.001		
	Group D	< 0.001	< 0.001	0.632	
3 min after intubation	Group B	0.822		_	
	Group C	< 0.001	< 0.001		

	Group D	< 0.001	< 0.001	0.831
5 min after intubation	Group B	0.381		
	Group C	< 0.001	< 0.001	
	Group D	< 0.001	< 0.001	0.804

Regarding the mean blood pressure (MBP), Statistical analysis showed that MBP values during intubation, 1, and 3 minutes after intubation were highly significant compared to the baseline

values. The mean arterial blood pressure increased after intubation in all groups but less in the group C and group D and decreased gradually 1, 3 and 5 min after intubation in all groups (**Table 4**).

Table (4): Comparison between the four groups as regards mean blood pressure

Groups	Group A	Group B	Group C	Group D	P-value
MABP (mmHg)	(N=30)	(N=30)	(N=30)	(N=30)	r-value
Baseline	97.51±7.47	97.98±9.9	95.3±9.27	94.69±9.68	0.422
During intubation	108.18±7.28	107.7±7.54	101.45±6.1	100.88±8.06	<0.001
1 min after intubation	107.83±5.5	107.39±7.68	101.79±6.98	101.01±8.8	<0.001
3 min after intubation	105.86±7.5	106.1±8.18	99.64±7.53	99.4±8.97	<0.001
5 min after intubation	104.10±7.45	103.47±7.13	99.51±7.17	99±8.47	0.015

Data presented as mean \pm SD.

Regarding serum cortisol level, baseline serum cortisol level after premedication with pregabaline and 1-hour post-operative were measured and were comparable in all groups. There was

a statistically significant between four groups regarded Cortisol level at 1 hour postoperative. There was elevated serum cortisol level in all groups, but less than in the group C and group D (**Table 5**).

Table (5): Blood cortisol values in the four groups

Cortisol level (nmol/L)	Group A (N=30)	Group B (N=30)	Group C (N=30)	Group D (N=30)	P-value
Baseline	405.6±27.26	404.95±34.65	392.2±42.95	390.8±36.5	0.221
Postoperative (1 hour)	674.8±30.57	675.23±40.4	503.4±28.62	501.67±31.7	< 0.001

Data presented as mean \pm SD.

There was a significant difference between Group A and B with group C and D as regard cortisol level 1 hour postoperative. As regards time to first

DISCUSSION

In this study, there was a careful selection of the patients regarding age, weight, height and ASA status. Extremes of age were excluded. All patients of the study were ASA I. This was done in order to avoid the effect of any of the

request of analgesia postoperatively, there was a significant statistical difference between the groups (**Table 5**).

demographic data or the medical condition on the results of the study and thus, the only effective element would be the difference in effect of pregabalin according to its dosage.

Cardiovascular response to laryngoscopy and intubation is well

known and is linked to increases in catecholamine blood levels. There were marked changes in hemodynamics during laryngoscopy and intubation in the present study. These changes were variably affected by different doses of pregabalin.

Yousef Abd-Allah et al. (2020) compared the Efficacy of preoperative oral gabapentin for patients undergoing intracranial surgery and showed that gabapentin effectively attenuated blood pressure, heart rate, and catecholamine levels compared to the placebo after intubation, which is consistent with the results of our study.

Similarly, in a study by Esmat and Hanan (2015), in elective laparoscopic cholecystectomy. Patients were divided into three groups, 25 each to receive either oral paracetamol 1 g (group I, control group) or pregabalin 150 (group II) or 300 mg (group III), 2 h before surgery. Postoperative pain was evaluated based on visual analog scale over a period of 6 h time for rescue analgesia. Postoperative sedation, hemodynamic changes, serum cortisol level, and side effects were also evaluated. they found as serum cortisol level, there was significant difference postoperatively between group (II) and group (III) in comparison to group (I) at 1 h postoperatively. There was no significant difference between group (II) and group (III) 1 postoperatively as regards the time for the first requirement for analgesia and serum cortisol level, which is consistent with the results of our study.

Similarly, in a study by *Karbić et al.* (2014), for an abdominal hysterectomy were randomly assigned to the GBP administration 1 h before surgery (n=30)

pts), or to the placebo group (n=30 pts). Blood samples were collected before and 24 h after the surgery. VAS pain score at rest was significantly lower in the GBP in group than the placebo group. **Application** of **GBP** significantly decreased the plasma cortisol level 24 h after the operation in comparison to the placebo group. They found significant positive correlation between the VAS pain score and concentration of cortisol in all patients. GBP reduced the concentration of catecholamines, which is consistent with the results of our study.

Talikoti et al. (2015) compared effect of oral pregabalin and oral clonidine for attenuation of hemodyamic response after endotracheal intubation in 60 patients who were submitted to elective surgeries under general anesthesia. The patients were divided into 2 groups, 30 patients each. One group received 200µg oral clonidine and the other group received 150 mg pregabalin 90 minutes before surgery. They found that pregabalin reduced the hemodynamic response more than clonidine with a significant statistical difference, which is consistent with the results of our study.

The prospective, randomized and double-blind study done by *Abdullah and Akcan (2014)* showed that preoperative administration of pregabalin (300 mg) or pregabalin (300 mg) plus dexamethasone (8 mg) improved early pain control and decreased tramadol consumption within the postoperative period after septoplasty. Moreover, pregabalin or pregabalin plus dexamethasone reduced the frequency of rescue analgesia, but there was no statistically significant difference between the single dose of pregabalin or when

added to dexamethasone, which is consistent with the results of our study.

Singh et al. (2019) also studied oral Pregabalin as Premedication on anxiolysis and stress response to laryngoscopy and intubation endotracheal in patients undergoing laparoscopic cholecystectomy were randomly allocated into two groups receiving either oral placebo or oral mg, 60 min before pregabalin 150 induction of anesthesia, pregabalin showed a decrease in VAS and attenuation of stress response to laryngoscopy and intubation compared to that of placebo, which was consistent with the results of our study.

Similarly, in a study by *Dhananjaya et* al. (2017), they compared pregabalin with gabapentin and a placebo drug in elective surgery under general anesthesia. Patients were divided into three equal groups received vitamin capsules, gabapentin 800 mg or pregabalin 150 mg, 90 minutes before the scheduled surgery. Pregabalin and gabapentin were found to attenuate significantly the rise in HR and MAP at 1 and 5 minutes after intubation compared to the placebo group. However, there was no statistical difference between pregabalin and gabapentin, which is consistent with the results of our study.

Intraoperative total fentanyl consumption was calculated for each patient in the current study. It was nearly the same in groups C and D with no difference significant between both groups. In group B (75 mg pregabalin), fentanyl consumption was a significant when compared to both groups C and D. This showed that pregabalin in a dose of 75 mg did not decrease the consumption of intraoperative fentanyl. Moreover, the study revealed that a dose of 300 mg pregabalin did not differ from a dose of 150 mg as regards reduction of intraoperative narcotic consumption.

On the contrary, after analysis of many studies, *Fabritius et al.* (2017) did not confirm a distinct relationship between the preoperative dose of gabapentin and postoperative consumption of opioids, dividing all treatments into subgroups single or multiple doses, preoperative or postoperative administrations. However, this analysis was concerned with gabapentin and not pregabalin.

Nausea occurred in all groups. Although the number of patients who had nausea in groups C and D was less than in groups A and B, yet there was no statistically significant difference between groups.

CONCLUSION

Pregabalin in doses of 150 and 300 mg attenuated the hemodynamic response to laryngoscopy and endotracheal intubation, and decreased the requirement of post-operative analgesia.

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تأثير اعطاء عقار بريجابلين عند وضع أنبوبة القصبة الهوائية بواسطة المنظار الحنجرى وتأثيره كمسكن للآلام بعد إجراء إستئصال الرحم جراحيا عن طريق البطن للمريضات ذوات ضغط الدم الطبيعي وسكر الدم المنضبط

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خلفية البحث: وضع أنبوبة القصية الهوائية بواسطة المنظار الحنجرى من المنبهات الضارة والتي يمكن أن تثير العديد من الاستجابات الغير مرغوبة، لا سيما في أنظمة القلب والجهاز الدورى على شكل إرتفاع ضغط الدم، وعدم إنتظام ضربات القلب والتي يمكن أن تكون ضارة عند المرضى الذين يعانون من إضطرابات في وظائف القلب والجهاز الدورى. لذلك أصبح استخدام العقاقير الغير مخدرة جزءًا من نظام متعدد الوسائط لتقليل هذه المنبهات الضارة. وتظهر العديد من الدراسات الحديثة أن الأدوية مثل الجابابنتين والبريجابالين معروفة بتقليل الاستجابات الغير مرغوب فيها بسبب استخدام المنظار الحنجرى عند وضع أنبوبة القوائية.

الهدف من البحث: دراسة مقارنة تأثير الجرعات المختلفة لعقار بريجابلين عند اعطائه عن طريق الفح قبل العمليات الجراحية على تقليل العلامات الحيوية لرد فعل القلب والجهاز الدوري.

المريضات وطرق البحث: تضمنت الدراسة 120 مريضة تم اختيارهن بعناية من حيث مواصفات السن وحالتهن الصحية. وقد تم تقسيمهن عشوائيا الى أربعة مجموعات متساوية: تم إعطاء مريضات المجموعة (أ) كبسولات فيتامينات، وتم اعطاء مريضات كلا من المجموعات (ب) و (ج) و (د) عقار بريجابلين بجرعات مختلفة وهي 75 ميلليجرام و 150 ملليجرام و 300 ميلليجرام على التوالى. ولم تعلم أي مريضة الجرعة المستخدمة لها في الدراسة. وشمل التخدير الكلي فحص وتجهيز المريضات حيث تم تعريفهن بالدراسة، وأخذ موافقتهن كتابيا، واعطائهن

عقار البريجابلين، وتعليمهن كيفية تقييم الألم باستخدام مقياس الآلام البصرى المستخدم في الدراسة في مستشفيات جامعة الأزهر بعد موافقة لجنة أخلاقيات مهنة الطب، من ديسمبر 2019 حتى يوليو 2021.

نتائج البحث: لم يكن هناك فرقاً إحصائي بين المجموعات في بيانات السن أو مدة تركيب الأنبوبة داخل القصبة الهوائية، أو مدة الجراحة. وكان هناك زيادة ملحوظة في ضغط الدم ومعدل ضربات القلب أثناء تركيب الأنبوبة داخل القصبة الهوائية بالمقارنة بالمقارنة بالقراءات الأولية قبل العملية. وقد لوحظ أن هذه الزيادة كانت اقل في المجموعة (ب). كذلك أثبت القل في المجموعة (ب). كذلك أثبت هذه النتائج قدرة عقار البريجابلين على تقليل التأثير الناتج من تركيب الأنبوبة داخل القصبة الهوائية على العلامات الحيوية عند إستخامه بجرعات 150 مجم و داخل القصبة الهوائية على العلامات الحيوية من عقار الفنتانيل أثناء الجراحة بعد اعطاء عقار البريجابلين بجرعات 150 مجم و مهذا المنتزير. وأثبتت هذه الدراسة قدرة عقار البريجابلين على تقليل نسبة الكورتيزون بالدم الناتج عن تركيب أنبوبة داخل القصبة الهوائية بنسبة أكبر في المجموعة (ج) والمجموعة (د) عن المجموعة (ب).

الاستنتاج: أثبت هذه النتائج قدرة عقار البريجابلين على تقليل التأثير الناتج من تركيب الأنبوبة وكذلك فعالية على العلامات الحيوية وكذلك فعالية البريجابلين في تسكين الألام عند استخدامها بجرعات 150 و 300 مجم.

الكلمات الدّالة: إستئصال الرحم، تسكين الألم، عقار البريجابلين، مستوى نسبة الكورتيزون، أنبوبة القصبة الهوائية.