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## SCIENTIFIC ARTICLE

# Postoperative Nausea and Vomiting: Validation of the Portuguese Version of the Postoperative Nausea and Vomiting Intensity Score

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### Abstract

**Background and objectives:** The Postoperative Nausea and Vomiting (PONV) Intensity Scale was developed to define clinically important PONV. The aim of this study was to translate, retranslate and validate the PONV Intensity Scale for use in Portuguese Post Anesthetic Care Unit (PACU) settings.

**Methods:** The PONV Intensity Scale was translated and back-translated in accordance with available guidelines. The research team conducted an observational and cohort prospective study in a PACU. One-hundred fifty-seven adult patients admitted after surgery over three weeks were evaluated for PONV. Measurements included nausea visual analogic scale (VAS) at 6 and 24 hours, postoperatively. We assessed reliability and observer disagreement using interclass correlation (ICC) and Information-Based Measure of Disagreement (IBMD). We compared VAS scores between patients with clinically significant ( $\geq 50$ ) and not significant ( $< 50$ ) PONV.

**Results:** Thirty-nine patients (25%) had PONV at 6 hours and 54 (34%) had PONV at 24 hours. Thirty-six and 54 patients experienced nausea at 6 and 24 hours, respectively. Among patients with PONV, 6 patients (15%) and 9 patients (27%) had a clinically significant PONV intensity scale score at 6 and at 24 hours, respectively. The reliability was good both for PONV intensity scale score and for VAS and observer disagreement was slightly higher for VAS. The median nausea VAS scores were higher in patients with clinically significant PONV Intensity score.

**Conclusions:** The PONV Intensity Scale appears to be an accurate and reliable assessment and monitoring instrument for PONV in the PACU settings.

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## Introduction

The incidence of postoperative nausea and vomiting (PONV) is high, ranging between 20% and 30% after general anesthesia<sup>1-5</sup>. However, it can be as high as 70% in high-risk patients<sup>6</sup>. PONV is associated with worst outcomes, increased costs and length of hospital stay<sup>1,7</sup>. PONV is associated with higher rate of complications such as dehydration, electrolyte imbalance, suture dehiscence, bleeding, esophageal rupture and airway compromise<sup>8,9</sup>.

PONV is reported as one of the most undesirable side effects after surgery, as studies that use the willingness-to-pay method to report this event have evaluated<sup>10-13</sup>.

Multiple risk factors for PONV related to the patient, the surgery or the anesthesia have been described in the literature<sup>2</sup>. Apfel et al.<sup>3</sup> developed a risk score for PONV that has been used for prophylactic antiemetic therapy management. In this score, Apfel identified female gender, non-smokers, history of PONV and postoperative use of opioids as independent risk factors of PONV.

A scoring system allows us to estimate the risk of developing PONV<sup>14,15</sup>. Nonetheless, accurately evaluating the occurrence of clinically important PONV is a more difficult task. Up to date, there is no standard method described in the literature. The VAS scale is a score from 0 to 100 mm that is often used to assess pain intensity in the postoperative period<sup>16</sup>; similarly, a VAS score can be used to evaluate nausea. A VAS greater than 75 has been proposed as a screening tool for diagnosis of severe nausea<sup>6</sup>.

Recently, Wengritzky et al. published a study in which they developed and tested a PONV Intensity Scale (Appendix 1)<sup>6</sup> to assess clinically important PONV. A PONV Intensity Scale  $\geq 50$  defined clinically important PONV and was associated with the need of antiemetic therapy, higher rates of complications and prolonged time of recovery. This score was developed and tested in a general surgical population and performed well in the domains of validity, reliability and responsiveness<sup>6</sup>.

The aim of this study is to translate, retranslate and validate the PONV Intensity Scale for use in clinical research and routine use in Portuguese speaking PACU settings.

## Methods

The institutional review board of Hospital de São João approved the study and each study patient provided informed consent preoperatively. This prospective study was carried out in the Post-Anesthesia Care Unit at the Hospital São João, a 1,100-bed community teaching hospital in Porto, Portugal. All adult post-operative patients admitted to the PACU who underwent scheduled or emergency non-cardiac and non-intracranial surgery between May 9<sup>th</sup>, 2011, and May 31<sup>st</sup>, 2011, were eligible for the study.

We excluded from the study patients who did not provide or were incapable of providing informed consent due to intellectual or psychiatric disturbance that precluded complete cooperation, had a history of alcohol or drug dependence, were non-Portuguese speaking, showed distress or any severe pre-existing medical condition that limited objective assessment after operation or had any life-threatening postoperative complication.

Translation and back-translation of the PONV Intensity Scale. After permission from Wengritzky et al., translation of the instrument was done according to the guidelines suggested by The Translation and Cultural Adaptation group. This group has proposed guidelines and a model of principles for good practice in the translation process<sup>17</sup>.

The translation process is described as follows: preparation, forward translation, reconciliation, back translation, back translation review, harmonization, cognitive debriefing, review of cognitive debriefing results and finalization and proofreading.

Preparation: We requested and received permission to use the PONV Intensity Scale instrument from its author-developer (Wengritzky R.).

A group of experienced intensive care nurses, the author and a professional translator translated the source text of the English version of the PONV Intensity Scale to Portuguese. This was carried out independently at first, then, they met to compare their translations.

Reconciliation meant solving the discrepancies between original independent translations and sought agreement between individual preferences.

The final Portuguese version was given to a professional translator for retranslation to English that did not see the original version.

The group who had made the original translation compared the retranslated version of the instruments to the original, identifying and correcting discrepancies.

The retranslated version was sent to Wengritzky R. for approval and acceptance of the Portuguese version.

Ten experienced nurses specialized in intensive care were asked to read and examine the translated version to detect any unclear words, concepts or elements that they were unable to understand to finalize the cognitive debriefing.

The findings of the debriefing process were incorporated to improve the translation's efficacy. This involved the validation process, which tested the applicability of the Portuguese version of the PONV Intensity Scale used in a Portuguese PACU.

We obtained consent preoperatively from every patient. Anesthesia was conducted according to the attending anesthesiologist's preference. Data collection occurred at 6 and 24 hours, postoperatively. We recorded details of the anesthetic technique, including medications administered for PONV prophylaxis from the anesthetic record, and postoperative opioid analgesics and antiemetics from the medication chart. We obtained the durations of surgery and anesthesia from the computerised theatre management system (PICIS). We considered surgery to be major if expected surgical time was  $>1$  hour and minor if expected surgical time was  $<1$  hour<sup>18</sup>.

Data collected included gender, smoking status, history of PONV or motion sickness and preoperative antiemetic use. The Apfel simplified risk score was calculated.

Patients were interviewed by one of the investigators at 6 and at 24 hours postoperatively about vomiting, antiemetic medication or complications related to PONV. The PONV Intensity Scale (Appendix 2) and VAS scale for nausea were both

applied at this time. The PONV Intensity scale was developed to identify features of PONV that would describe its intensity and clinical importance. The key features of the scale include the intensity, pattern and duration of nausea. A score was calculated for each patient and a PONV Intensity Scale score of 50 was defined as clinically significant PONV <sup>6</sup>.

Patients were asked to score pain on a 10-point verbal numerical rating scale and nausea on a 100 mm visual analogue scale (VAS). The limits of the nausea VAS were “no nausea” to “nausea as bad as it possibly could be”. A score greater than 70 mm was the cut-off for severe nausea.

Vomiting, which can be objectively measured, was recorded as the total number of patients who vomited and the number of vomits.

Normally distributed data were summarised using mean and standard deviation and skewed data were summarised using median and interquartile range (IQR).

In order to assess the reliability and observer disagreement, different and independent observers to 24 patients applied the PONV intensity scale and VAS for nausea twice. We assessed reliability using Intraclass Correlation Coefficient (ICC) and observer disagreement using Information Based Measure of Disagreement (IBMD) <sup>19, 20</sup>.

We compared VAS scores between patients with clinically significant ( $\geq 50$ ) and not significant ( $< 50$ ) PONV Intensity Scale using the Mann-Whitney U-test. We compared the VAS (VAS score  $> 70$  mm) for patients with severe nausea with severe nausea PONV Intensity Scale (PONV Intensity Scale  $\geq 50$ ).

## Results

The Portuguese translation group met several times at weekly intervals to allow for reflection and a consensus was reached on the instrument’s contents and structure. The original authors of the PONV Intensity Scale, Wengritzky et al., accepted the Portuguese retranslated version of the scale. According to the team involved in the cognitive debriefing and reading of the checklist, there were no unclear words that they were unable to understand. Thus, the PONV Intensity Scale was then evaluated in the described series of adult PACU patients.

**Table 1 - Type of surgery (n = 157).**

General surgery n (%)	54 (34)
Bariatric surgery n (%)	4 (3)
Head and neck n (%)	14 (9)
Breast surgery n (%)	5 (3)
Laparoscopic surgery n (%)	13 (8)
Laparotomy n (%)	18 (11)
Orthopedic n (%)	31 (20)
Urology n (%)	26 (17)
Gynecology n (%)	16 (10)
Vascular surgery n (%)	15 (10)
Plastic surgery n (%)	14 (9)
Otolaryngology n (%)	1 (1)

After excluding 17 patients, we enrolled 157 patients in this study and completed data collection. The reasons for the exclusions were: 7 patients were admitted in a surgical intensive care unit, 3 patients were incapable of providing informed consent or had a mini-mental scale examination (MMSE)  $< 25$ , 3 patients were not submitted to surgery, 1 patient was submitted to neurosurgical surgery, 1 was less than 18 years old, 1 did not speak Portuguese and 1 refused to participate.

**Table 2 - Description of the total number of patients (n = 157).**

Patient Characteristics	
Age mean (SD)	55 (16)
Male n (%)	74 (47)
Body Mass Index (kg.m <sup>-2</sup> ) mean (SD)	27 (6)
ASA physical status $\geq$ III n (%)	33 (21)
RCRI $>2$ n (%)	11 (6)
Apfel risk factors n (%)	
Non-smokers	124 (79)
Female	83 (53)
Previous motion sickness	19 (21)
Opioids	119 (76)
Apfel score n (%)	
0 or 1	32 (18)
2	76 (43)
3 or 4	69 (39)
Risk surgery n (%)	
Minor	26 (17)
Major	131 (83)
Type of anesthesia n (%)	
General anesthesia	105 (67)
Regional anesthesia	31 (20)
Combined anesthesia	19 (12)
Sedation/analgesia	2 (1)
Anesthetics n (%)	
Opioids	119 (76)
NMB	102 (65)
Antiemetics n (%)	
Droperidol	11(7)
Metoclopramide	107(68)
Ondansetron	32(20)
Dexametasona	44(28)
Nº of prophylactic antiemetics given n (%)	
0	37 (24)
1	65 (41)
2	36 (23)
3	19 (12)
Duration of anesthesia (min) median (P25-P75)	135 (90-200)
Duration surgery median (P25-P75)	90 (60-150)
Length of PACU stay (hours) median (P25-P75)	100 (67-142)
Length of Hospital stay (days) median (P25-P75)	5 (3-8)

RCRI: Revised Cardiac Risk Index; NMB: Neuro Muscular Blockers.

**Table 3 - Postoperative Nausea and Vomiting (PONV) evaluation at 6<sup>th</sup>- and 24<sup>th</sup>-hour evaluation in the 157 patients.**

	Evaluation at:	
	6h	24h
	n (%)	n (%)
NVPO	39 (23)	54 (34)
Vomiting or retching	19 (12)	30 (19)
Nausea experienced	36 (25)	54 (34)

**Table 4 - Description of patients with Postoperative Nausea and Vomiting (PONV).**

	PONV	
	at 6 hours n = 39	at 24 hours n = 54
Actively treated, n (%)	19 (53)	24 (44)
Nausea pattern, n (%)		
Varying	37 (95)	53(98)
Constant	2 (5)	1(2)
Nausea pattern description n (%)		
Sometimes	19 (57)	30 (56)
Often or most of the time	14 (33)	19 (35)
All the time	3(10)	5 (9)
Duration of nausea, n (%)		
Varying	69 (72)	74 (76)
Constant	55 (53)	55 (53)
Number of vomits n		
0		
1-2	12	21
3-4	3	5
Dry-retching n	4	4
VAS >70 n (%)	5 (13)	7 (13)
VAS, m median (P25-P75)	4 (2-6)	5 (1-5)
PONV Intensity scale $\geq$ 50 n (%)	6 (15)	9 (17)
PONV Intensity scale median (P25-P75)	2 (0.6-25)	4 (1-25)

The median time taken to complete the PONV Intensity Scale at the six-hour interview was one minute (the range was one to three minutes).

Table 1 describes the type of surgery for patients enrolled in the study. General surgery and orthopedics account for more than 50% of surgical procedures.

The characteristics of the total sample (n = 157) are described in Table 2. Thirty-nine patients (23%) had PONV at 6 hours and 54 (34%) had PONV at 24 hours (Table 3). Table 3 also describes the vomiting or retching and nausea experienced in the 157 patients enrolled in this study. Among patients with PONV, 6 patients (15%) and 9 patients (17%) had a clinically significant PONV intensity scale score at 6 and at 24 hours, respectively (Table 4). Table 4 describes the remaining characteristics of patients with PONV.

Different and independent observers applied the PONV intensity scale and VAS for nausea twice in 24 patients. The reliability was good for the PONV Intensity Scale, ICC = 0.899 (95%CI 0.783-0.955) and for VAS, ICC = 0.977 (95%CI 0.948-0.990).

We found a higher observer disagreement for VAS than for PONV Intensity Scale, however without statistical significance, IBMD = 0.064 (95%CI 0.000-0.162) vs IBMD = 0.116 (95% CI 0.013-0.226).

The nausea VAS score among those with a clinically significant PONV Intensity Scale score at the six-hour interview (median = 75 mm; IQR: 50 to 83 mm) was higher than those with clinically not significant PONV according to PONV Intensity Scale, median = 30 mm; IQR: 10 to 50 mm (p = 0.009).

Considering severe nausea - a score of VAS greater than 70 mm - there were 5 cases of severe nausea at the six-hour interview and 3 (60%) of those had clinically significant PONV Intensity Scale score. From the remaining 34 cases of non-severe nausea (VAS  $\leq$  70 mm), 31 (91%) of those also had clinically not significant PONV according to PONV Intensity Scale.

The nausea VAS score among those with a clinically significant PONV Intensity Scale score at the 24-hour interview, median = 70 mm; IQR: 55 to 80 mm, was also higher than those with clinically not significant PONV Intensity Scale, median = 30 mm; IQR: 10 to 50 mm (p = 0.001).

Considering severe nausea a score of VAS greater than 70 mm, there were 7 cases of severe nausea at the 24-hour interview and 4 (57%) of those had clinically significant PONV Intensity Scale score. From the remaining 47 cases of nonsevere nausea (VAS  $\leq$  70 mm), 42 (89%) of those had also clinically not significant PONV according to PONV Intensity Scale.

## Discussion

This study suggests that the Portuguese PONV Intensity Scale is a reliable and valid tool in detecting postoperative nausea and vomiting in patients. In this study, we followed the guidelines for translation and cultural adaptation of the ISPOR TCA task force<sup>17</sup>. The translated PONV Intensity Scale underwent a full validation process prior to its use, according to the TCA task force's recommendations<sup>17</sup>. A group of researchers and professional translators translated the PONV Intensity Scale, preserving the meaning of words and concepts specific to the postoperative context. All the investigators were enrolled in the processes of planning, baseline, and education phases. In our study, the physicians observed all the patients and recorded the data collected at 6 and 24 hours. The reliability coefficient achieved for PONV Intensity Scale and Nausea VAS scale was excellent, indicating that this scale is a reliable instrument to identify significant PONV. In addition to its reliability, the study demonstrated that physicians can easily learn and apply the Portuguese version of the PONV Intensity Scale in their daily clinical practice.

The correlation of the PONV Intensity Scale score with the nausea VAS at the sixth and the 24<sup>th</sup> hour interviews supported its validity, indicating that a higher score was associated with a greater postoperative nausea experience. A clinically important PONV Intensity Scale score was also significantly related to the incidence of vomiting at the

Assessment	Score
<b>A. At 6 hours after surgery (or time of discharge if after ambulatory surgery)</b>	
Q1 Have you vomited or had dry-retching*? a) No b) Once or twice c) Three or more times	0 2 50
Q2 Have you experienced a feeling of nausea (“an unsettled feeling in the stomach and slight urge to vomit”)? If yes, has your feeling of nausea interfered with activities of daily living, such as being able to get out of bed, being able to move about freely in bed, being able to walk normally or eating and drinking? a) No b) Sometimes c) Often or most of the time d) All of the time	0 1 2 25
Q3 Has your nausea been mostly: a) varying (“comes and goes”)? b) constant (“is nearly or almost always present”)?	1 2
Q4 What was the duration of your feeling of nausea (in hours [whole or fraction])?	__ . __ h
For Part A, if answer to Q1 = c), score A = 50; otherwise, select the highest score of Q1 or Q2, then multiply x Q3 x Q4	PONV intensity score (0-6 h) <b>A =</b>

\*Count distinct episodes: several vomits or retching events occurring over a short time frame, say 5 min, should be counted as one vomiting/dry-retching episode; multiple episodes require distinct time periods without vomiting/dry-retching

**Scoring for Clinical Importance of PONV**

Total Score	Score
Clinically important PONV is defined as a total score ≥50 at any time throughout the study period. Scores at 6 and 24 (and, if considered important in the clinical context, 72) hours can be added for quantification of the entire period, or sub-scales used for each period.	Final PONV intensity score (0-72 h)
<b>A + B + C =</b>	

Appendix 1 - The Postoperative Nausea and Vomiting Intensity scale.

six-hour and 24-hour time points, which supports vomiting occurrence being associated with a greater experience of PONV and, thus, validates the scale.

Clinically important PONV - defined by a PONV Intensity Scale score of 50 - was recorded in 54 patients (34%) in the first 24 hours postoperatively, which is similar to the rate of clinically important PONV reported in a general surgical population by the developers of the PONV Intensity Scale <sup>6</sup>. Nausea of some form was reported in 54 patients (34%) and vomiting or retching was experienced by 19%, which is consistent with the high Apfel scores recorded (3 or 4 risk factors in 39%). Therefore, clinically important PONV was less common than any PONV symptom in this study, which is to be expected if the PONV Intensity Scale is able to discriminate between trivial and clinically important PONV.

In spite of the high incidence of patients with Apfel score 3 or 4, only 35% patients received double or triple anti-emetic therapy. This can be explained by a lack of preoperative identification of risk factors or the anesthesiologist’s valuing of PONV <sup>21</sup>.

This study has several limitations. The time period of assessment was limited to 24 hours; therefore, we may have missed patients presenting late PONV. The sample size also limited the value of our PONV risk assessment results and prophylaxis guidelines compliance.

In summary, the Portuguese version of the PONV Intensity Scale showed a good correlation with the original version. The PONV Intensity Scale appears to be an accurate and reliable assessment and monitoring instrument for PONV in the PACU settings.

**Anexo 2 - Escala de intensidade de Náuseas e Vômitos Pós-Operatórios (Portuguese version).**

Questionário	Pontuação
<b>A) 6 horas após a cirurgia (ou na hora da alta, em caso de cirurgia ambulatorial)</b>	
<b>Q1) Vomitou ou teve esforço de vômito não produtivo?</b>	
a) Não	0
b) 1 ou 2 vezes	2
c) 3 ou mais vezes	50
<b>Q2) Sentiu náuseas (“uma indisposição gástrica e ligeira vontade de vomitar”)? Se a resposta for sim, a sensação de náusea interferiu em suas atividades cotidianas, como levantar-se da cama, movimentar-se sem restrições na cama, caminhar normalmente ou comer e beber?</b>	
a) Não	0
b) Às vezes	1
c) Frequentemente ou a maior parte do tempo	2
d) Sempre	25
<b>Q3) Os episódios de náusea foram predominantemente:</b>	
a) intermitentes (“surgem e desaparecem”)?	1
b) constantes (“sempre ou quase sempre presentes”)?	2
<b>Q4) Qual foi a duração do episódio de náuseas?</b>	__:__ horas
(em horas ou fração de horas)	
Para a parte <b>A</b> se a resposta a <b>Q1 = c)</b> pontuação <b>A = 50</b> ; de outro modo, selecione a pontuação mais elevada de <b>Q1</b> ou <b>Q2</b> e multiplique <b>X Q3xQ4</b>	Pontuação de Intensidade de NVPO = _____
Para a parte <b>A</b> se <b>Q1= c</b> então <b>A = 50</b>	NVPO = _____
De outro modo, selecione a pontuação mais elevada de <b>Q1</b> ou <b>Q2</b> e multiplique por <b>Q3xQ4</b>	

*\*Registre a ocorrência de episódios distintos: a ocorrência de vários episódios de vômito ou ânsia de vômito não produtivo durante um pequeno período de tempo; por exemplo, cinco minutos devem ser registrados como um episódio; episódios múltiplos devem ser considerados se intervalados por períodos sem vômitos/ânsia de vômito não produtivo.*

**Pontuação para a importância clínica dos NVPO**

	Pontuação
NVPO clinicamente importantes são definidos como uma pontuação $\geq 50$ em qualquer período do estudo. As pontuações obtidas em 6 e 24 horas (e em 72 horas, se consideradas importantes no contexto clínico) podem ser somadas para quantificação do período total ou podem ser subescalas usadas para cada período.	Pontuação final da escala de intensidade de NVPO (0-72h)

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