Use of the Visual Analog Scale to Rate and Monitor Severity of Nausea in the Emergency Department

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Abstract

Objectives: The objective was to describe the association between verbal descriptors of nausea severity and visual analog scale (VAS) ratings in an undifferentiated emergency department (ED) population and to calculate the minimum clinically significant difference (MCSD) in VAS rating of nausea severity in this population.

Methods: A prospective observational study was conducted at three EDs on a convenience sample of stable, consenting adult patients presenting with nausea as part of their symptom complex. Data included demographics, adjectival description of nausea severity (none, mild, moderate, or severe), and VAS rating (standard 100-mm line) at enrollment, 30 minutes, and 60 minutes. At 30 and 60 minutes they were also asked to describe any change in nausea severity from the previous rating (''a lot less,'' ''a little less,'' ''the same,'' ''a little more,'' ''a lot more''). The MCSD was defined as the average VAS change when a patient reported ''a little less'' or ''a little more'' nausea.

Results: A total of 247 patients provided 693 matched adjectival ratings and VAS scores. Median age was 45 years, and 100 (40%) were male. The median VAS measures for none, mild, moderate, and severe nausea were 2, 23, 53, and 83 mm, respectively. VAS distributions in the verbal categories were statistically different from each other (Spearman rank correlation coefficient = 0.90; $p < 0.0001$). The MCSD was 22 mm (95% CI = 20 to 24 mm).

Conclusions: There is very good correlation between verbal descriptors of nausea and VAS ratings. The MCSD for VAS nausea ratings in an ED population is 22 mm.

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People presenting to the emergency department (ED) commonly suffer from nausea and/or vomiting as either their primary or their secondary complaint. Relief of these symptoms is desirable for both patient comfort and the prevention of further health problems, such as dehydration, hypokalemia, esophageal tears, and aspiration.

The ability to grade the severity of nausea is desirable for both guiding initial therapeutic choices and monitoring patient progress. Research into the efficacy of antiemetic agents has largely taken place in the fields of oncology[1–3] and anesthetics,[4–7] where the use of emetogenic drugs is a common part of therapy. Measurement tools used for the grading of nausea severity in antiemetic efficacy studies in these fields have included adjectival scales, ratings of associated incapacity, numerical scales,[1–7] and the visual analog scale (VAS).[1,4–8] More recent studies in the fields of oncology[9] and postoperative nausea and vomiting (PONV)[10] have demonstrated good correlations between VAS score ranges and symptom severity on an adjectival scale, but this has not been validated in ED patients where nausea and vomiting can be associated with a broad range of underlying conditions. One recent study by Hendey et al.[11] investigated the concept of a minimum clinically significant difference (MCSD) in the VAS measure for nausea in ED patients. A figure of 15 mm was reported for the total population, but the sample size did not allow examination of potential differences

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between severity subgroups.[11] Antiemetic efficacy studies have also reported mean change in VAS scores as an outcome measure,[4–6] but the one ED-based study acknowledged that issues around the MCSD still needed clarification.[6]

We aimed to validate the correlation between adjectival description of nausea severity and the VAS in an undifferentiated ED population and to calculate the change in nausea severity on VAS measures that would define an MCSD for this population. As a secondary aim we determined to calculate the MCSD in VAS measures for each severity subgroup on the adjectival scale (mild, moderate, severe) and to compare these with the population measure.

METHODS

Study Design

A prospective observational study was conducted in the ED of two community teaching hospitals and one university-associated tertiary referral hospital in Melbourne, Australia. The conduct of the study was approved by the human research ethics committees for all sites.

Study Setting and Population

The two community teaching hospitals (Dandenong Hospital and Western Hospital) each have an annual ED census of 47,000 patients. The tertiary referral hospital (Monash Medical Centre) has an annual ED census of 40,000 adult patients. The study included a convenience sample of patients presenting to these three EDs with nausea and/or vomiting. Patients were eligible for enrollment if they reported the presence of nausea as a primary or secondary complaint (any known or presumed underlying ''cause'') at any time during their ED episode of care. The exclusion criteria were age < 18 years, systolic blood pressure < 100 mmHg, altered mental state, the need for time-critical interventions, inability to understand the study explanation for any reason, or unwillingness to participate. Patient recruitment took place between September 2007 and March 2008.

Study Protocol

On obtaining consent, baseline data, including age, sex, time of presentation, major presenting symptoms, and duration of illness were recorded. Participants were asked to rate the severity of their nausea on both an adjectival scale and a VAS at enrollment, 30 minutes, and 60 minutes. They were also asked to describe the change in their nausea severity from the prior rating at both 30 and 60 minutes. The different scales were presented in random order (by block randomization). Participation in the study did not preclude or delay any therapy, which was at the treating physician's discretion. At the conclusion of the study period, antiemetic drug administration, intravenous fluid use, and final diagnosis were recorded.

Outcome Measures

The adjectival scale used the severity ratings ''none,'' ''mild,'' ''moderate,'' and ''severe.'' The VAS was a 100-mm line marked ''no nausea'' at the left-hand end and ''unbearable nausea'' at the right-hand end. The change in nausea severity from the prior rating at both 30 and 60 minutes was described as ''a lot less,'' ''a little less,'' ''the same,'' ''a little more,'' or ''a lot more.'' Ratings were obtained on up to three occasions per patient depending on the patient's ED length of stay and clinical state, with all ratings obtained being included in the analysis.

Data Analysis

Baseline variables are presented descriptively as medians with interquartile range (IQR) or number and proportion as appropriate. The relationship between the VAS scores and the adjectival scale for severity are presented as median values with IQR by group and compared for difference using the Kruskal-Wallis test and for correlation using the Spearman rank correlation coefficient. The MCSD in VAS score for both the study population and each severity subgroup are presented as mean plus 95% confidence interval (CI), while all changes in severity for each subgroup are presented as medians with a range of centile values, because not all distributions were normal. Comparisons were made using Kruskal-Wallis tests where appropriate. All comparisons performed that involved multiple ratings from the same patients were adjusted for clustering.

The one previous ED study[11] suggested that the sample size should be dictated by the secondary aim of difference in MCSD between the severity subgroups. Assuming that the distribution of severity subgroups would be similar to those reported previously, a sample size of about 260 patients would have 80% power to detect a significant difference in MCSD between subgroups at the 0.05 level. This sample size would also have > 80% power to detect a Spearman Correlation coefficient of $R^2 > 0.80$ for the association between adjectival and VAS severity ratings.

Data were analyzed using the Stata version 8.0 statistical package (StataCorp, College Station, TX). Data were entered by one investigator (RM) and a random sample of 10% was checked for accuracy by a second investigator (XFH).

RESULTS

Of the 247 patients enrolled, 112 (45.3%) were recruited from Western Hospital, 87 (35.2%) from Dandenong Hospital, and 48 (19.4%) from Monash Medical Centre. Median age was 45 years (IQR = 28–61 years), 100 (40%) of the sample were male, and 58% presented between 08:00 and 16:00 hours. Baseline variables, including described severity and median VAS rating at enrollment, are shown for each study site in Table 1. Participants were somewhat younger at one of the community hospitals, while a relatively higher proportion of people with severe nausea was recruited at the tertiary referral hospital. The nine most common diagnostic groups are shown in Table 2. These accounted for 169 (68.4%) of the patients.

A total of 190 patients (76.9%) received antiemetic drugs. Of these, 49 (25.7%) received multiple agents. Metoclopramide was the first line agent for 164 patients

Table 1
Baseline Variables at Enrollment for Each Study Site

	Western Hospital (*n* = 112)	Dandenong Hospital (*n* = 87)	Monash Medical Centre (*n* = 48)	p-value*
Age (yr), median (IQR)	51 (33.5–63.5)	39 (25–52)	50 (31–64.5)	<0.01
Male, *n* (%)	49 (43.8)	33 (37.9)	18 (37.5)	0.64
Presentation hours 08:00–16:00, *n* (%)	73 (65.2)	44 (50.6)	25 (52.1)	0.08
VAS rating at enrollment, median (IQR)	47.5 (26–65.5)	50 (35–76)	61.5 (44–84)	<0.01
Adjectival rating at enrollment				
None, *n* (%)	4 (3.6)	3 (3.5)	0 (0.0)	<0.01
Mild, *n* (%)	43 (38.4)	29 (33.3)	6 (12.5)	
Moderate, *n* (%)	43 (38.4)	34 (39.1)	19 (39.6)	
Severe, *n* (%)	22 (19.6)	21 (24.1)	23 (47.9)	

*Kruskal-Wallis test.
IQR = interquartile range; VAS = visual analog scale.

Table 2
Most Common Diagnoses

Diagnosis	Number	Percent
Gastroenteritis or gastritis (any type: viral, alcohol related, etc.)	50	20.2
Infective illness (nongastrointestinal, including respiratory and urinary tract infections)	33	13.4
Acute abdominal conditions (including small bowel obstruction, appendicitis, and pancreatitis)	20	8.1
Chest pain presentation (any underlying cause)	15	6.1
Abdominal pain (no specific cause nominated)	12	4.9
Hyperemesis gravidarum	11	4.5
Renal colic	11	4.5
Vertigo	10	4.0
Headache (any underlying cause)	7	2.8
Other diagnoses	78	31.6

and was used in a total of 166 (87.4%) patients. Ondansetron was the first-line agent for 18 patients and was used in a total of 47 (24.7%) patients. Ten patients (5.3%) received prochlorperazine, all of whom had vertigo as a presenting symptom. None of the study patients received any other antiemetic drugs. A total of 151 patients (61.1%) received intravenous fluid during the period of data collection.

Of the 247 patients who provided ratings on enrollment, 237 (96.0%) provided ratings at 30 minutes, and 209 of these (88.2%) provided further ratings at 60 minutes. The population's median VAS ratings and number in each severity subgroup at each time interval show that nausea tended to lessen over time (Table 3).

A total of 693 adjectival and VAS severity ratings were available for analysis: three sets of ratings from 209 patients, two sets from 28 patients, and one set from 10 patients. The mean values (adjusted for clustering) for none, mild, moderate, and severe nausea were 5.0 mm (95% CI = 3.2 to 6.8), 25.1 mm (95% CI = 23.4 to 26.8), 55.0 mm (95% CI = 52.5 to 57.5), and 82.3 mm (95% CI = 79.5 to 85.1), respectively. There was some skewing of the distribution for ''none,'' but the remainder approximated normal. As the statistical adjustment for clustering led to a minimal increase (approximately 10%) in the standard error for each unadjusted mean value, it is reasonable to demonstrate overlap between descriptors using a range of centile values from the total data (Table 4). The distributions were significantly different from each other ($p < 0.0001$ Kruskal-Wallis test) and yielded a Spearman Rank Correlation coefficient of 0.90 ($p < 0.0001$). There was no significant difference in the median VAS rating for each severity category between the three study sites.

There were a total of 446 ratings of change in nausea severity (237 from enrollment to 30 minutes and 209

Table 3
Population VAS Ratings and Distribution of Severity at Enrollment, 30 Minutes, and 60 Minutes

	Time 0 (*n* = 247)	Time 0 + 30 min (*n* = 237)	Time 0 + 60 min (*n* = 209)
Population VAS, median (IQR)	51 (34–76)	27 (12–48)	15 (2–40)
Adjectival ratings, *n* (%)			
None	7 (2.8)	55 (23.2)	78 (37.3)
Mild	78 (31.6)	102 (43.0)	79 (37.8)
Moderate	96 (38.9)	61 (25.7)	40 (19.1)
Severe	66 (26.7)	19 (8.0)	12 (5.7)

IQR = interquartile range; VAS = visual analog scale.

Table 4
VAS Measures for Each Adjectival Severity Rating

	VAS Measure (mm) for Each Centile				
Adjectival Rating	10th	25th	50th	75th	90th
Severe (n = 97)	67	75	83	93	96
Moderate (n = 197)	39	45	53	63	74
Mild (n = 259)	11	16	23	33	43
None (n = 140)	0	0	2	6	13

Table 5
Range of Change in VAS for Each Subjective Change in Severity for the Total Population

	Change in VAS Measure (mm) for Each Centile				
Subjective Change	10th	25th	50th	75th	90th
A lot less (n = 146)	5	16	28	52	67
A little less (n = 128)	5	10	20	30	42
The same (n = 132)	−6	−1	1	4	10
A little more (n = 29)	−43	−23	−16	−9	10
A lot more (n = 11)	−83	−48	−23	−5	2

from 30 to 60 minutes). The mean values of the change in VAS between ratings (adjusted for clustering) for ''a lot less,'' ''a little less,'' ''the same,'' ''a little more,'' and ''a lot more'' were 33.3 mm (95% CI = 29.3 to 37.3), 21.5 mm (95% CI = 18.9 to 24.1), 0.9 mm (95% CI = –0.9 to 2.7), –16.3 mm (95% CI = –22.6 to –10.1), and –29.8 mm (95% CI = –46.1 to –13.5), respectively. All distributions approximated normal, and the adjustment for clustering led to a < 1% change in the standard error for each unadjusted mean, so again it was considered reasonable to demonstrate the amount of overlap between each category of change using a range of centile values calculated from the total data (Table 5). The differences in VAS for each amount of change were significantly different from each other (p = 0.0001, Kruskal-Wallis test) with a Spearman rank correlation coefficient 0.47 (p < 0.001).

Of the total 446 descriptions of change, 157 (35.2%) reported nausea to be ''a little less'' or ''a little more.'' The distribution of the VAS rating changes for these combined subgroups approximated normal. The mean change in the VAS measure (adjusted for clustering) was 21.8 mm (95% CI = 19.5 to 24.0), defining the MCSD.

The mean changes (adjusted for clustering) in the VAS when ''a little less'' nausea was reported for the prior severity subgroups of mild, moderate, and severe were 14.7 mm (95% CI = 12.2 to 17.2), 23.5 mm (95% CI = 19.6 to 27.4), and 34.0 mm (95% CI = 28.7 to 39.3), respectively. These equated with the MCSD for each severity subgroup. While values for ''a little less'' nausea were normally distributed, this was not the case for all categories of change in all prior severity subgroups, so these are reported as medians in Table 6. The median values for ''a little less'' nausea were significantly different from each other across the severity subgroups (p < 0.0001, Kruskal-Wallis test), but the IQRs show some amount of overlap. There appeared to be little difference across the severity categories between the three study sites, but numbers were quite small in some subgroups.

DISCUSSION

We found a very good correlation between initial verbal descriptors of nausea and VAS ratings. This is consistent with the previous literature from oncology[9] and for PONV[10] and supports the hypothesis that nausea severity is described in a similar way on a VAS by an undifferentiated ED population as it is by people receiving emetogenic agents in oncology and anesthesia. It is also consistent with the more extensive literature concerning the rating of pain severity where the VAS has been reported to correlate well with adjectival and numerical scales and to be easy for patients to use and understand.[12,13]

We found that the MCSD for nausea severity was 21.8 mm (95% CI = 19.5 to 24.0). Although this is higher than the 15.4 mm (95% CI = 10.8 to 20.0) reported by Hendey et al.[11] in the one previous, smaller ED study, the limits of the 95% CIs overlap and both figures are within the range for the MCSD, which has been reported for other subjective symptoms such as

Table 6
Median Change in VAS for Each Change in Severity by Prior Severity Subgroup

Initial severity rating	A Lot Less (n = 146)	A Little Less (n = 128)	The Same (n = 132)	A Little More (n = 29)	A Lot More (n = 11)
Severe: median change (n)	65 (51 to 72) (n = 30)	32 (26 to 41) (n = 28)	0.5 (−6 to 4) (n = 22)	6 (−12 to 24) (n = 2)	NA (n = 0)
Moderate: median change (n)	40.5 (30 to 54) (n = 41)	23 (12 to 31) (n = 51)	0 (−3 to 4) (n = 44)	−16 (−17.5 to 2) (n = 9)	−5 (−16.5 to −0.5) (n = 5)
Mild: median change (n)	20 (13 to 26) (n = 59)	12 (9 to 20) (n = 46)	3 (−1 to 6) (n = 40)	−19.5 (−26 to −12) (n = 14)	−38.5 (−45 to −27) (n = 4)
None: median change (n)	3.5 (0.5 to 8.5) (n = 16)	0 (−3 to 8) (n = 3)	1 (0 to 3) (n = 26)	−28.5 (−48 to −15) (n = 4)	−70.5 (−92 to −49) (n = 2)

Values are mm (IQR).
VAS = visual analog scale.

pain,[14–22] and asthma severity.[23] Sampling differences and minor variations in study methods are likely to lead to some variability in results as has occurred in research of pain severity in the ED.[14–22] For example, in the study by Hendey et al., patients with mild initial nausea were excluded, up to four ratings per patient were obtained at 15-minute intervals, and the phrases at each end of the VAS were ''less severe'' and ''more severe,'' compared with ''no nausea'' and ''unbearable nausea'' as used in this study.

The concept of the MCSD was first explored by Todd et al.[14] with regard to pain research and it has since been used as the target for clinical significance in analgesic efficacy studies.[24,25] This may now be the case for antiemetic efficacy studies, which have been difficult to compare in the past due to the variety of outcome measures that have been used.[1–7] With regard to future efficacy studies, we would recommend using a single figure of 20 mm as the MCSD. This is just above the lower limit of the 95% CI and would be practical and easy to apply, particularly given its consistency with the MCSD from pain research. Although a range of MCSD values between 13 and 29 mm have been recommended for pain from different studies,[14–22] a level of 20 mm has support as a reasonable consensus view.[18–22]

Our secondary aim was to investigate possible differences in the MCSD between groups of people with different levels of nausea severity. This was unable to be explored by Hendey et al.[11] due to sample size, so the potential importance of any differences remained unclear. It had been reasonable to combine measures for ''a little less'' and ''a little more'' nausea to define the MCSD for the total population, as had been done in the previous nausea[11] and pain research,[14–22] since both mean values and distributions were very similar, but the small numbers of people reporting nausea to be ''a little more'' in the severity subgroups meant that combining the ratings for subgroup analysis was likely to affect accuracy. So in these subgroups we believed that the MCSD was best reflected by data only from people who reported nausea to be ''a little less,'' which is not unreasonable given that in antiemetic efficacy studies, or in monitoring progress of routine therapy in the ED, the aim is to reduce nausea. We found that the MCSD measures were significantly different between those whose prior nausea severity was ''severe'' versus ''moderate'' or ''mild,'' being 34, 24, and 15 mm, respectively. This suggests that application of the proposed population MCSD of 20 mm in antiemetic efficacy studies may be problematic with regard to the subgroup who have ''mild'' nausea. It appears likely that those with ''moderate'' or ''severe'' nausea who report changes in VAS of less than 20 mm will not have noticed any meaningful improvement in their symptoms, but some with ''mild'' nausea may have done so. This is consistent with the findings from severity subgroup analyses using the VAS in pain research[17,21] and is largely a property of the VAS itself. ''Mild'' nausea correlates with a mean VAS measure of 25 mm, so a reduction by 20 mm must equate with near resolution of symptoms, and the majority of people in this subgroup reported this level of change as being ''a lot less'' rather than ''a little less.'' Some researchers assert that the VAS is not a true ''linear'' measure because it gives rise to issues such as this near the ends of the scale.[26-28] This is demonstrated in our finding that the range of responses at the extremes (such as severe nausea becoming ''a lot more'' or mild nausea becoming ''a lot less'') were skewed, while more midrange changes such as moderate nausea becoming ''a little less'' have a normal distribution. So in practice, use of a population MCSD for drug efficacy studies may lead to the risk that the lesser changes reported on the VAS by those with ''mild'' symptoms could lead to Type 2 error. This issue has been recognized and addressed in some studies by the exclusion of those with only ''mild'' symptoms, because if efficacy is shown for those with moderate or severe symptoms, then those with mild symptoms may also be presumed to benefit.[5,11]

LIMITATIONS

The use of convenience samples always leaves the possibility that those who were not recruited during the study period may have been systematically different from those who did take part. Given the reasonably broad range of diagnoses present, and the spread in age, sex, and times of presentation, we are confident this is not a significant issue. Additionally, we believe that external validity is strengthened by recruitment from three different sites. The failure to recruit to the calculated sample size led to the risk that significant differences may not have been demonstrated, but recruitment proved to be sufficient. With regard to potential measurement bias, we used scales and descriptive terminology that have been used in many previous studies. We attempted to minimize the possibility of the response on one scale systematically influencing the response on the other scale by randomizing the order of the scales on the page. Participants also did not refer to their previous ratings so that these would not directly influence the subsequent ratings. We included all ratings from each patient in the analysis of correlation between adjectives and VAS measure for severity, which meant that the same patient could have provided up to three VAS measures for the same adjective if their nausea severity did not change. It did occur that two VAS measures for the same adjective were obtained from the same patient on 29 occasions, but statistical adjustment for the effect of clustering was performed. It was also arbitrary to obtain ratings 30 minutes apart. It was felt that since the majority of participants would receive some combination of antiemetic drugs, intravenous fluids, and other therapies for their primary conditions, it was likely that most would experience changes in the severity of their nausea fairly quickly, but we also wanted information on the amount of difference in VAS measures when people reported the severity as being ''the same.'' This interval proved satisfactory with 55 of 237 (23.2%) reporting no change between enrollment and 30 minutes and 77 of 209 (36.8%) reporting no change from 30 to 60 minutes. Finally, it is not possible to know from this study whether or not nausea associated with any particular condition yields significantly different results from

other conditions, but this was not found to be an issue in VAS research for pain.[17]

CONCLUSIONS

We found a very good correlation between verbal descriptors of nausea severity and visual analog scale ratings. The change in nausea severity on the visual analog scale, which defined the minimum clinically significant difference in this ED population, was 21.8 mm. We suggest that it would be practical to use a visual analog scale difference of 20 mm to equate with clinical significance in ED antiemetic efficacy research, although subgroup analysis did highlight problems that might stem from the inclusion of people with ''mild'' nausea in such study cohorts.

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