

The minimum clinically significant difference in acute nontraumatic thoracoabdominal pain in adult emergency department patients in Turkey 土耳其急診科急性非創傷性胸腹疼痛成人患者的有臨床意義的疼痛最小差別

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Objectives: To determine the minimum clinically significant difference (MCSD) in visual analog scale (VAS) pain scores for acute non-traumatic thoracoabdominal pain (TAP) in the emergency department (ED) and to determine its association with sociodemographic features, location and duration of pain. **Methods:** An observational survey of adult ED patients with TAP lasting less than 48 hours was conducted over a six-week period. Demographic information and the duration and location of pain were recorded. Patients indicated their pain level on a 100-mm VAS at baseline and at 20, 40, and 60 minutes thereafter. Subjects were also asked to rate their pain as 'much less', 'a little less', 'about the same', 'a little more', or 'much more' at the 20-, 40-, and 60-minute time points. MCSD was calculated as the difference between the subsequent and preceding VAS scores if a patient reported pain as 'a little less' or 'a little more'. **Results:** Data was available for 306 of the 374 patients with TAP who presented during the study period. For pain comparisons (n=428) categorised as 'a little less' or 'a little more', the MCSD was 24.2 mm (95% CI 22.6-25.7 mm). The MCSD value was not significantly different among the factors of gender, age, level of education, duration, or location of pain. **Conclusions:** The MCSD of ED patients with nontraumatic thoracoabdominal pain in Turkey is 24.2 mm. The MCSD is not affected by gender, age, level of education, location, or duration of pain. (Hong Kong j.emerg.med. 2012;19:171-176)

目標：在急診科（ED）急性非創傷性胸腹疼痛（TAP）患者，使用視覺模擬評分法（VAS）疼痛評分，來確定有臨床意義的最小差別（MCSD），並確定其與社會人口學特徵、疼痛位置和時間的關聯。**方法：**這項研究是為期六週的觀測調查，對象是ED的TAP不少於48小時的成人患者。記錄包括人口統計資料和疼痛的持續時間和位置。患者使用100毫米VAS的疼痛評分，表示他們在基線時和20、40和60分鐘後的疼痛程度。受試者被要求在20-40-60分鐘的時間點評價他們的痛苦為：「少得多」、「少」、「差不多」、「多一點」或「多得多」。如果一個病人報告為「少」或「多一點」的痛苦，MCSD的計算是隨後和之前VAS評分之間的差別。**結果：**研究期間374例的TAP患者，306例有可用的數據。對於疼痛比較分類為「少」或「多一點」（n=428），MCSD是24.2毫米（95%CI為22.6-25.7毫米）。MCSD數值並不因性別、年齡、教育程度、疼痛持續時間或部位不同，而有顯著的

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不同。**結論：**土耳其ED非創傷性胸腹疼痛患者的MCSD是24.2毫米。MCSD是不會受到性別、年齡、教育程度、疼痛位置或持續時間影響。

Keywords: Hospital emergency service, pain measurement, reliability of results, reproducibility of results, visual analog pain scale

關鍵詞：醫院急診服務、測量、結果的可靠性、結果的可重複性、視覺模擬疼痛評分法

Introduction

Acute pain is a common chief complaint of most patients who access the emergency department (ED),¹ and both its perception and expression can vary in different countries.^{2,3} Although the evaluation and management of pain is a core component of emergency medicine practice,⁴ studies have demonstrated that emergency physicians (EP) often under-evaluate and under-treat nociceptive phenomena.⁴⁻⁶ In a Hong Kong study, it was reported that more than 40% of patients suffering from pain were given drugs for pain relief only and they had to wait more than 60 minutes for drugs for pain relief on average.⁷

To evaluate the effectiveness of pain management and novel therapies, differences in pain ratings must be assessed both clinically and statistically.^{8,9} The visual analog scale (VAS) is the most widely used tool for estimating both severity of pain and the extent of pain relief.⁹⁻¹² The VAS is easy-to-use, does not necessitate using a sophisticated device, is highly sensitive in detecting treatment effects, and its results can be analysed by parametric tests.^{11,13-15}

However, there could be a tendency to overestimate the clinical importance of a small difference in VAS score. A measured statistical differences might not represent clinically important changes in pain or truly meaningful differences to patients, considerable emphasis has been placed on measuring the minimum clinically significant difference (MCSD) in ED-based analgesia research.^{4,8-11,16,17}

The reported magnitude of the MCSD might vary with patient types, cause of pain and settings. Todd et al first explored the concept of MCSD in pain using a VAS, and a MCSD mean value of 13 mm was

calculated for 48 ED patients with acute trauma.¹⁰ Gallagher et al calculated the MCSD to be 16 mm in 101 adult ED patients with acute abdominal conditions.¹⁷ A study in Australian ED setting found that the MCSD to be only 9 mm and it was not affected by age, gender or the cause of pain.¹⁶ However, Mark et al in a Hong Kong ED setting reported the MCSD was 17 mm and it was affected by genders and types of pain (traumatic vs. non-traumatic).¹⁸

This study aimed to identify the MCSD in adult ED patients with non-traumatic thoracoabdominal pain (TAP) in ED setting of Turkey; and to evaluate the relationship between MCSD and demographic variables, pain location, and pain duration prior to the ED visit.

Methods

The protocol for this prospective, cross-sectional observational study was reviewed and approved by the Institutional Review Board of the local university. The study was carried out in ED of a tertiary-care 600-bed university medical centre in the city of Izmir, a city of approximately 3.5 million populations on the Aegean coast. The ED yearly census was approximately 40,000 patients, the majority of them were from families with government employee insurance. Between August 1 and September 15, 2002, consecutive adult patients (≥ 17 years old) presenting to the ED with acute non-traumatic TAP of less than 48 hours duration were approached for inclusion in the study. Eligible patients giving written informed consent were interviewed regarding the location of pain (flank, epigastrium, non-epigastric abdomen, lower back, upper back, chest) and its duration prior to the ED visit and demographic information were recorded. All eligible patients

underwent usual stabilisation as well as diagnostic and therapeutic procedures prompted by their conditions. Pain management measures were carried out at the discretion of the EPs and were not altered by the study protocol. Those with a psychiatric disorder, recent neuropsychiatric drug use, altered mental status, history of alcohol, opiate or other drug abuse, haemodynamic instability as evidenced by abnormal vital signs, inability to answer the study questions, or inability to use the VAS were excluded from analysis.

On presentation (time zero), patients marked their baseline pain levels on a 100-mm VAS scale. They were also requested to report the severity of pain at time zero as either 'much less', 'a little less', 'about the same', 'a little more', or 'much more' on a Likert scale verbally to their attending physician. At 20-minute intervals thereafter, they were asked again to rate their pain as either 'much less', 'a little less', 'about the same', 'a little more', or 'much more' on a Likert scale, as well as the VAS. A maximum of three assessment (i.e., at 20, 40, and 60 minutes) were recorded for each patient. Patients were not reminded of their previous ratings, and the treating physicians were not aware of the variables collected and their analysis for this study.

The MCSD was calculated to be the absolute mean difference between the current and previous VAS scores only when the patient reported his/her pain as 'a little less' or 'a little more'. Ratings scored as 'much less' or 'much more' were not used in the MCSD calculation.

Data were entered in the Statistical Package for Social Sciences for Windows®, version 11.0 (SPSS Inc., Chicago, USA). Descriptive statistics were used to determine the mean, median, SD, and 95% confidence intervals (CI) of the sample as a whole. Student's *t*-test and analysis of variance (ANOVA) was used to identify significant differences (defined as $p < 0.05$).

Results

During the study period, 4,620 patients presented to the ED, of whom 532 had acute non-traumatic TAP.

A total of 158 patients were missed or discharged before evaluation could be made for MCSD. Of the remaining 374 patients, all of them consented to the participation in the study, thus the overall participation rate was 70.3%. Of these, 68 patients (18%) were excluded due to a history of trauma ($n=2$), visual impairment ($n=2$), absence of pain on presentation ($n=4$), illiteracy ($n=9$), inability to cooperate ($n=1$), inadequate documentation ($n=23$) and pain for more than 48 hours at presentation ($n=27$). The study group comprised the remaining 306 patients (mean age 42 ± 16 years; range, 17 to 83 years; 40.2% male). The level of education was missing in 14 cases. The characteristics of the study population are summarised in Table 1.

The mean VAS scores of the patients at time zero, 20, 40, and 60 minutes were 67 ± 25 mm, 46 ± 27 mm, 33 ± 29 mm, and 20 ± 25 mm, respectively. Mean VAS scores of patients describing their pain as 'mild', 'moderate' and 'severe' at time zero were 26 ± 13 mm, 53 ± 12 mm, and 87 ± 13 mm, respectively (Table 1).

Table 2 shows the mean interval differences in VAS scores at 20, 40, and 60 minutes (total of 918 comparisons) corresponding to the pain ratings as 'much less', 'a little less', 'about the same', 'a little more', or 'much more'. Of these, 290 were categorised as 'about the same'; the magnitude of difference in VAS scores for this group was essentially zero (95% CI, -2.0 to 6.1).

Among the 376 comparisons of pain categorised as 'a little less' pain, the mean difference in VAS was 25 mm (95% CI, 22.9 to 26.4). Among the 52 comparisons of pain categorised as 'a little more' pain, the mean difference in VAS was 21 mm (95% CI, 17.4 to 23.8) (*t*-test, $p=0.174$). As a result, the pooled MCSD using these 428 comparisons was calculated to be 24 ± 16 mm (95% CI, 22.6 to 25.7). The calculated value of MCSD was not significantly affected by gender ($p=0.416$), age groups (ANOVA, $p=0.728$), level of education (ANOVA, $p=0.236$), duration of pain prior to ED visit (ANOVA, $p=0.586$), or location of pain (ANOVA, $p=0.077$).

Table 1. Demographic and clinical characteristics of the 306 study participants

	N	%
Age (years)		
<20	12	3.9
20-29	80	26.1
30-39	60	19.6
40-49	52	17.0
50-59	48	15.7
60-69	35	1.4
≥70	19	6.2
Sex		
Male	123	40.2
Female	183	59.8
Education		
Unschoolled	9	3.1
Primary school	60	20.5
Secondary school	31	10.6
High school	94	32.2
University	98	33.6
Location of pain		
Flank	62	20.3
Abdomen (<i>excl. epigastrium</i>)	131	42.8
Epigastrium	50	16.3
Lower back	25	8.2
Chest	32	10.5
Upper back	6	2.0
Pain duration		
0-2 hours	64	20.9
3-12 hours	121	39.5
13-24 hours	69	22.5
>24 hours	52	17.0
Degree of pain		
Mild	36	11.8
Moderate	116	37.9
Severe	154	50.3

Discussion

While the evaluation of clinically significant pain constitutes a challenge for the practitioner,^{9,16} the VAS remains a useful tool for pain assessment with its reproducibility and sensitivity in detecting treatment effects.⁸⁻¹¹ Nonetheless, overestimating the clinical importance of small quantitative differences in VAS or other scores because they are statistically significant may occur. Statistical significance does not always correspond to clinical significance; and clinicians naturally place interpretation on the impact of a change in VAS in pain management.^{9,10,16,18}

Todd et al first described the MCSD as the mean difference in VAS ratings that corresponding to the verbal ratings of 'a little more' and 'a little less'; and they reported MCSD to be 13 mm in a study involving 48 trauma victims.¹⁰ In an Australian study of 152 patients, Kelly et al reported the MCSD to be 9 mm¹⁶ while Powell et al found an MCSD of 10 mm in a group of 73 children.⁸ Gallagher et al enrolled 96 patients with and without trauma in 2000 and their 141 comparisons resulted in an MCSD of 13 mm.¹¹ In 2001, a study of 101 patients with acute abdominal pain reported an MCSD of 16 mm.¹⁷ Mark et al reported MCSD to 17 mm among local Chinese patients with age >15 years attending emergency department in Hong Kong.¹⁸ In our study of patients with thoracoabdominal pain, a mean MCSD of 24 mm and median MCSD of 21 mm were derived from 428 comparisons. Thus, MCSDs in ED patients reported to date, in order of magnitude, would be 24 mm in the present study from Turkey, 17 mm in a Hong Kong

Table 2. The mean differences of VAS scores rated at 20, 40, and 60 minutes corresponding to ratings of 'much less', 'a little less', 'about the same', 'a little more', or 'much more' on a Likert scale

Change of pain on Likert scale	No. of comparisons	Mean difference in pain on VAS (SD), (mm)	Median (mm)	Range (mm)	95% CI* (mm)
'much less'	191	-36.3 (26.5)	-29	-100, 13	-40.1, -32.5
'a little less'	376	-24.6 (16.6)	-22	0, 100	-22.9, -26.4
'about the same'	290	2.1 (0.3)	0.0	0, 6	-2.0, 6.1
'a little more'	52	20.7 (11.4)	18.5	1, 55	17.4, 23.8
'much more'	9	65.8 (27.2)	58	30, 100	44.8, 86.7
'a little less' and 'a little more'	428	24.2 (16.1)	21.5	0, 100	22.6, 25.7

* confidence interval

(Chinese) study by Mark, 13 mm in American studies by Todd and Gallagher, and 9 mm in the Australian study by Kelly. The differences in the reported MCSD values might be explained by the effect of ethnic, cultural, and socioeconomic characteristic in addition to the variations in sampling methods and types of pain being studied. Besides, the extent and method of pain relief might also affect the perception of pain by the patients which could be quite different among the ED settings of different countries. The frequent use of opioid agents in our academic ED, combined with a more opioid naïve clientele (oral opioids are not prescribable for outpatients in Turkey), may have contributed to the relatively rapid pain relief and consequently higher MCSD values seen in the present study.

We believed that the experience of pain could be a subjective phenomenon affecting by a myriad of cultural and ethnic factors. Not all elements of pain sensation could be represented in numerical form. The decision on initiate or titration of pain relieving measures needs should be guided by the MCSD concept together with other considerations such as questions on the patient's desire for medication, sex and age differences.^{9,16} The present study demonstrated that MCSD was not related to the level of education, location of pain, or duration of pain prior to the ED visit.

One should not assume that the pain severity comparisons 'a little less' and 'a little more' are equal in magnitude in the same context. Similar to previous studies, we found that MCSD of 'a little less' pain (25 mm) was greater than that of the MCSD of 'a little more' pain (21 mm). This phenomenon could be attributed to the tendency to express the magnitude of increasing pain more strongly than that of alleviated discomfort. Initial pain scores generally tend to be close to the high end of the scale, and there were more studies focused on 'a little less' than 'a little more' comparisons.^{8-10,16}

Our finding that patients were more inclined to report pain as 'a little less' after an hour of repeated questioning, even when the VAS had hardly changed.

Whether this positive reporting could be due to a desire to please the doctor, a subtype of learned helplessness, or a veiled attempt to escape an ED which did not address pain adequately would need further study. We would caution against simply asking patients if they want more pain medication in the absence of any other assessment, since these answers could be affected by side-effects of prior medication and could result in clinicians using time instead of analgesics to treat patients' pain.

Limitations of our study included inclusion of only adults with non-traumatic thoracoabdominal pain, and recruitment of only 70% of eligible patients. During busy hours, patients with serious and life-threatening pain who necessitated rapid evaluation and treatment, as well as those who were missed or quickly discharged from the ED, were not enrolled in the study (30% of the overall population). Our findings should not be extrapolated to children or to patients with traumatic or chronic pain.

Another limitation of the present study was that the physician who carried out the treatments also obtained the pain ratings concurrently. This was due to a shortage of research personnel who would have been able to independently administer the VAS and Likert scale questions. Thus, patients might have been influenced by the general satisfaction of patient care in their subjective statements regarding pain relief. The construct of pain relief, doctor-patient relationship, and autonomy may be understood differently in Turkey than in other locations. Larger multinational studies should be performed to determine MCSD in patients with different types of pain in other cultural settings.

Conclusion

In patients with non-traumatic thoracoabdominal pain in our university hospital ED in Turkey, the minimum clinically significant difference in pain values is 24 mm, as measured on a 100-mm visual analog scale. The MCSD is not influenced by gender, age, level of education, location, or duration of pain.

Acknowledgements

We wish to thank John R. Fowler Jr. MD. who assisted with obtaining reference materials and editing the manuscript.

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