Critical Review Form

Health-Related Quality of Life

Prospective Validation of Clinically Important Changes in Pain Severity Measured on a Visual Analog Scale, *Annals of EM* 2001: 633-638

Objective: "To test the hypothesis that the minimum clinically significant difference in acute pain intensity, as measured by the VAS (visual analog scale) is approximately 13 mm in an independent validation cohort of ED patients with heterogeneous causes of pain." (p 634)

Methods: Prospective, convenience sampling of English and Spanish-speaking patients 18 years or older presenting to 2 urban New York City emergency departments between 8AM-9PM on selected days for nine months with acute pain from any etiology. Acute pain was operationally defined as pain of recent onset (within 24 hours) or exacerbation (also within 24 hours) of preexisting pain of sufficient severity to cause the patient to seek emergency care. Patients with altered mental status or decreased visual acuity were excluded because of inability to score the VAS, as were patients who spoke neither English nor Spanish, and patients with unchanged chronic pain.

Consenting subjects made a VAS vertical mark at 30-minute intervals for 2 hours without access to their previous VAS markings. Concurrently, they also qualitatively assessed their pain at each interval with one of five verbal categorical descriptors: "much less pain", "a little less pain", "about the same pain", "a little more pain", or "much more pain".

Based on Todd's previous work (*Annals EM* 1996;27: 485-489), the authors assumed one-third of subjects would fall into the categories of interest by reporting "a little less pain" or "a little more pain" representing a minimally clinically significant VAS change in pain scores. Their sample size calculation was based on total paired pain contrasts (p. 634). The authors report means, medians, standard deviations, and 95% confidence intervals.

Guide		Comments
I.	**Are the results valid?**	
A.	**Have the investigators measured aspects of patients' lives that patients consider important?**	Yes but only acute pain changes were measured. Pain is the most frequent reason for a visit to an Emergency Department in the U.S. Chronic pain and other factors that influence pain were excluded or not taken into account. Investigators did not ask patients whether "a little less pain" or "a little more pain" was a relevant improvement in this study.

B.	**Did the health-related quality of life (HRQL) instrument work in the intended way?**	Yes, the VAS correlated well with the qualitative pain descriptors. There were only 15% discordant responses.
C.	**Are there important aspects of HRQL that have been omitted? (Construct Validity)**	Probably- some aspects of pain assessment are neglected by this study and using the VAS alone. Many factors influence pain ratings i.e.- socioeconomic, cultural, anxiety, and secondary gain factors to name a few. These are difficult to study and there is no one single validated pain scale that takes these variables into account.
D.	**If there are tradeoffs between quality and quantity of life, or if an economic evaluation has been performed, have the most appropriate measures been used?**	Yes. Currently the VAS is one of the most valid tools for assessing pain. Ideally a multi-component tool that includes pain medication use, objective (nurse, physician, or family-member) assessment, and pain related functional disability would be superior. However, this tool would lack "ease of use" and perhaps reproducibility.
II.	**What are the results?**	
A.	**How can we interpret the magnitude of the effect on HRQL?**	• 70/166 were excluded. • Mean age 37 years, 55% female, 39% African-American, 35% white; 39% with traumatic pain. •For patients reporting pain "about the same" the mean VAS change was 0 mm (95% CI 10-16 mm, median 11 mm) which is exactly the same as Todd's previous results. • 15% of those reporting slight improvement or worsening of pain by these descriptors had 0 mm or discordant VAS pain ratings. **Therefore, based on 2 ED-based studies the minimally clinically significant VAS difference for pain assessment is 13mm (95% C.I. 10-16 mm).**
III.	**How can I apply the results to patient care?**	
A.	**Will the information from the study help patients make informed decisions about treatment?**	This study gives the ED clinician a tool by which to objectively assess ED pain management. It also provides researchers a benchmark for assessing new pain control agents.
B.	**Did the study design simulate clinical practice?**	Yes. This study involved a heterogeneous patient population suffering from pain of variable etiologies in a busy urban ED.

Limitations

1) Convenience sampling used so a *selection bias* may have occured.

2) Excluded non-English/Spanish speakers and visually impaired who may systematically differ in their method of pain reporting or ability to use a VAS.

3) Pediatric patients were excluded; elderly were poorly represented in this study.

4) The construct validity could be debated. Future studies might benefit from a multi-component Gold standard pain assessment tool (taking into account narcotic requirement and alternative person subjective pain assessment, perhaps with a subset receiving PET-scan imaging of CNS pain receptors).

Bottom Line

Urban ED-based study indicating that in English or Spanish-speaking, non visually-impaired adults with acute pain of < 24 hour onset, a change in the VAS of 13 mm (95% C.I. 10-16mm) is the minimally clinically significant change to indicate a qualitative change in subjective pain. Future studies should assess construct validity and reproducibility in a more heterogeneous patient population including children and the elderly.