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Prospective Trial

Unreliability of the Visual Analog Scale in Experimental Pain Assessment: A Sensitivity and Evoked Potentials Study

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Background: Pain is a universal but subjective experience, making it difficult to obtain objective information about the experiential dimensions of pain. Although the visual analog scale (VAS) is ubiquitously used in pain assessment, its reliability has been questioned. The properties of this rating scale, especially its anchor points likely to be reinterpreted by subjects, may bias the results.

Objective: To determine whether the VAS commonly used to assess experimental pain is a reliable tool for obtaining objective information about the experiential dimensions of pain and to assess whether subjects may erroneously interpret anchor points of the classical pain-VAS, ranging from "no pain" to "unbearable/worst pain. "

Study Design: A randomized, controlled prospective trial.

Setting: Laboratory of cognitive neurosciences in France.

Methods: Forty healthy volunteers were enrolled. We analyzed subjects' ratings of the same high-intensity (painful) and low-intensity (non-painful) thermal laser stimulations on 2 computerized VAS during 2 successive sessions: the classical pain-VAS ("no pain" – "unbearable pain") and a pleasantness-VAS ("very unpleasant" – "very pleasant"). Concomitantly, somatosensory evoked potentials (SEPs) were recorded. We investigated the correspondence between these psychophysical measures and specific somatosensory evoked potential (SEP) components elicited by thermal stimulation as a function of its intensity.

Results: Low-intensity thermal laser stimulations rated as painful on the pain-VAS were labeled pleasant on the pleasantness-VAS. The cerebral responses following these low-intensity thermal stimulations reflected activation of C-fibers, known to convey non-painful warm sensations, and not activation of Aδ-fibers, which transmit painful heat stimulations. SEP results therefore agreed with subjects' ratings on the pleasantness-VAS rather than on the pain-VAS.

Limitations: Study limitations include the lack of SEP and psychophysical measures of thermal stimulation intensities eliciting a neutral sensation / corresponding to subjects' pain threshold.

Conclusions: Taken together, our psychophysical and SEP results suggest that healthy individuals reinterpret the "no pain" anchor on the classical pain-VAS commonly used in the experimental assessment of pain, by rating the intensity of the stimulation rather than pain perception.

Key words: Visual analog scale, experimental pain assessment, pain, pleasantness, misuse, anchor points, reinterpretation, evoked potentials

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Pain is a universal but subjective experience, making it difficult to obtain adequately objective information about the experiential dimensions of pain. Many studies have compared pain rating scales in different populations (see (1) for a review), but few have clearly recommended the use of one scale over another.

Visual analog scales (VAS) are unidimensional pain rating scales used ubiquitously to measure the sensory component of pain. The most commonly used VAS consists of a horizontal line ranging from "no pain" to "unbearable/worst pain, " on which subjects are asked to make a mark representing their level of perceived pain intensity. The scale is scored by measuring the distance from the "no pain" end to the patient's mark. Despite its being the most difficult of the commonly used pain rating scales to apply in clinical practice, the VAS is often recommended in applied research (2,3) because of its greater sensitivity and its statistical robustness (4). Although several studies suggested that this scale would be a valid and reliable tool for assessing chronic and acute pain (5-9), others have been more critical regarding the reliability, validity, and interpretation of its results (10,11), in particular regarding the frequently observed inter- and intra-individual variability in subjects' responses to the stimulations. Indeed, a subject's rating of the same physical stimulus can vary during multiple sequential assessments of pain (5,11).

Several factors may account for this variability, including combinations of physical, physiological, and/or psychosocial factors (12,13). This variability, however, may also be due to variations in scale usage resulting from the properties of the rating scale itself. Such variations may include a variety of response biases common to magnitude scaling procedures, such as changes in the response criteria or in the interpretation of scale magnitude (14). In fact, the anchor points, "no pain" and "unbearable pain, " of the VAS may be particularly subject to such response biases. For example, when a group of patients with chronic pain were asked to use their own terms to indicate the meanings of the anchor points on a pain scale, these patients redefined the "no pain" endpoint as "normal pain" (15). Similarly, in a study focusing on the psychometric properties of different pain rating scales, healthy subjects had to rate the perceived pain of 7 different stimulation intensities on a VAS ranging from "no pain" to "the most intense pain imaginable" (16). Although 3 stimulation intensities were up to 4°C below their pain threshold, subjects (healthy younger and older adults) rated these stimulations as painful on the VAS, with mean numerical ratings 5-15% from the "no pain" anchor, indicating a reinterpretation of this endpoint. These findings suggest that healthy individuals may also mis- or re-interpret the "no pain" anchor, although differently than patients with chronic pain (15), and rate the intensity of the stimulation rather than the pain itself.

We sought to determine whether the VAS commonly used to assess experimental pain (17-19) is a reliable tool for obtaining objective information about the experiential dimensions of pain. Healthy volunteers were asked to rate, during 2 distinct sessions, thermal laser stimulations on the classical pain-VAS ("no pain" – "unbearable pain") and a pleasantness-VAS ("very unpleasant" – "very pleasant") commonly used in sensory assessment (20,21), while somatosensory evoked potentials (SEPs) were recorded. SEPs induced by noxious laser stimulation (heat) consist of a negative-positive biphasic wave (N2P2) in the 160-390 ms latency range (22), indicating Aδ-fiber activation. In contrast, non-painful laser stimulations resulting only in a sensation of warmth elicit ultra-late evoked potentials (approximately 750-1100 ms) (23) associated with C-fibers (24). We therefore investigated the consistency of subjects' ratings of the same physical stimuli on both VASs and the correspondence between these psychophysical measures and specific SEP components elicited by thermal stimulation as a function of its intensity.

Experimental Procedures

Subjects

We enrolled 40 healthy volunteers (23 females, 17 males, mean age 35.5 ± 17.6 years). All participants were paid and provided informed consent prior to participation, in accordance with the guidelines of the local Ethics Committee, which approved the study. All subjects were right-handed. Subjects completed the French version (25) of the Dallas Pain Questionnaire (26) to exclude any individuals with chronic pain.

Test Stimuli

Thermal stimulations were performed using an infrared (1450 nm) light-emitting diode (LED, power: 40 W). The surface of the LED beam was adjusted to 300 mm², and the stimulation was delivered to the dorsum of the non-dominant (left) hand. Subjects held the stimulator probe themselves and were asked to move the beam to a neighboring cutaneous region after each stimulation to avoid heating injuries and increases in

receptor activation thresholds. Four stimulus intensities were delivered by adjusting the duration of the stimulation while maintaining the power and the diameter of the beam constant. The intensities of the thermal stimulation were 5.3 mJ/mm² (I1), 7.3 mJ/mm² (I2), 11.3 mJ/mm² (I3), and 13.2 mJ/mm² (I4). These thermal stimulation intensities were based on pain thresholds determined in subjects not enrolled in this study: I1 and I2 stimuli have been shown to yield only low thermal and non-painful warm sensations, while I3 and I4 stimuli induce painful "pricking" sensations.

Experimental Design

Tests were performed on subjects sitting comfortably in a quiet room. Each subject participated in 2 experimental sessions. During one session, subjects rated the intensity of pain induced by the thermal stimulations, whereas, during the other session, they rated the pleasantness of the same thermal stimulations. Subjects were clearly instructed to rate pain intensity as 0 when the stimulus felt only warm but not painful. The order of experimental sessions was counterbalanced across subjects. Forty trials (10 stimulations per intensity) were presented in a random order, with inter-stimulus intervals varying randomly from 10 to 20 seconds, with steps of 2 seconds. After each stimulation, the subjects were asked to rate the perceived pain or pleasantness by moving, with their dominant (non-stimulated) hand, a cursor on a computerized VAS. The lowest values (left end) of the pain and pleasantness scales represented "no pain" and "very unpleasant, " respectively, whereas the highest values (right end) represented "unbearable pain" and "very pleasant, " respectively (Fig. 1). At the beginning of each trial, the cursor was placed at the median position of the VAS. Each VAS was digitized into 100 units for statistical analysis. Each VAS subtended 18.2° of visual angle at a 70 cm distance from the computer screen. The duration of the entire experiment did not exceed one hour.

EEG Recording

Electroencephalographs (EEG) were recorded using Ag/AgCl active electrodes (BioSemi® Amsterdam) mounted in an elastic cap. One electrode was placed at the Cz site according to the 10/20 system (27), with ear lobes as references (averaged offline), and sampled at a rate of 512 Hz (bandpass 0.02–500 Hz). To monitor ocular artifacts, vertical and horizontal electrooculographic potentials (EOG) were recorded from bipolar derivations using Ag/AgCl electrodes. Ocular artifact rejection and the duration of the averaging epoch ranged from 100 ms before to 2000 ms after stimulus onset. These artifacts, based on amplitude threshold, were excluded from the analysis of any segment containing eye movements or eye blinks. After rejecting invalid trial data, analyses were performed on a mean of 29 trials. Ultra-late positivity following low-intensity (i.e., I1 and I2) thermal stimulations was obtained in 13 subjects. N2P2 component following high-intensity (i.e., I3 and I4) thermal stimulations was obtained in 21 subjects. EP peak latencies were calculated from the onset of the stimuli. Subjects were asked to concentrate on the stimulated cutaneous region and to refrain from moving to avoid muscular artifacts in the EEG recordings.

Results

All subjects were asked to rate thermal stimulations successively on 2 different VASs, a pain- and a pleasantness-VAS. Low-intensity thermal stimulations

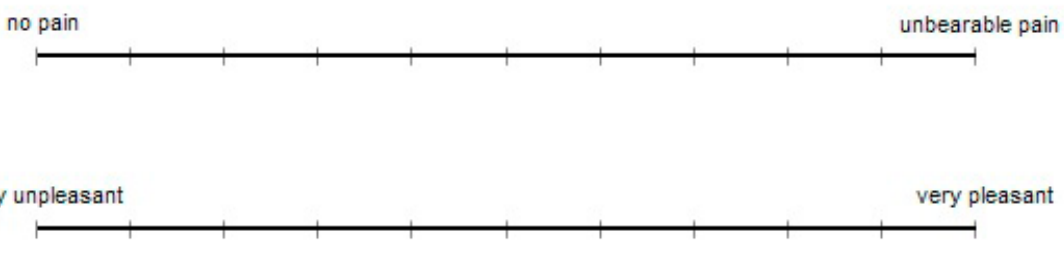

Fig. 1. *Pain- and pleasantness-visual analog scales (VAS).*

were rated as painful on the pain-VAS, with mean numerical ratings for I1 and I2 of 9.35 and 12.55, respectively (Fig. 2A), making them significantly higher than 0 ("no pain"), t[39] = 4.96, $P < 0.01$, for I1 and t[39] = 6.2, $P < 0.01$, for I2. The mean numerical rating of I1 and I2 did not differ significantly ($P = 0.25$, Newman Keuls post hoc test).

When asked to evaluate the same thermal stimulations (i.e., I1 and I2) on the pleasantness-VAS, subjects rated the stimulations as pleasant, with mean numerical ratings of 6.2 and 4.8, respectively (Fig. 2B), both of which were significantly greater than 0, representing a neutral sensation (i.e., neither pleasant nor unpleasant), t[39] = 4.31, $P < 0.01$, for I1, and t[39] = 3.52, $P < 0.01$, for I2. The mean numerical ratings of I1 and I2 stimulations on the pleasantness-VAS did not differ significantly ($P = 0.50$, Newman Keuls post hoc test).

The mean numerical ratings of I3 and I4 on the pain-VAS were 38.57 and 50.48, respectively (Fig. 2A), with both being significantly greater than 0, t[39] = 10.96, $P < 0.01$, for I3, and t[39] = 13.86, $P < 0.01$, for I4. The mean numerical rating of I3 and I4 differed significantly ($P < 0.01$, Newman Keuls post hoc test).

When asked to evaluate the same thermal stimulations on the pleasantness-VAS, subjects rated I3 and I4 as unpleasant, with mean numerical ratings of -11.67 and -20.25, respectively (Fig. 2B). These mean ratings were significantly below 0, t[39] = 6.01, $P < 0.01$, for I3, and t[39] = 8.96, $P < 0.01$, for I4. The mean numerical ratings of I3 and I4 on the pleasantness-VAS differed significantly ($P < 0.01$, Newman Keuls post hoc test).

While rating the thermal stimulations, SEPs were recorded. The grand averages of SEPs elicited by the low-intensity stimulations are shown in Fig. 3A. We observed a late positive component with peak latencies in the 750–1200 ms range, suggesting the activation of fibers with low conduction speeds (i.e., unmyelinated C-fibers). The mean latencies of the P2 component for I1 and I2 were 980 ms (sdm = 107.2) and 920 ms (sdm = 138), respectively; the difference between these latencies was not significant, t[12] = 1.24; $P = 0.24$. The mean amplitudes of the P2 component were similar for I1 (mean = 30.27 μV, sdm = 10.5) and I2 (mean = 27.3 μV, sdm = 8.4) stimulations (t[12] = 0.84; $P = 0.42$).

SEPs elicited by high-intensity stimulations (i.e., I3 and I4) resulted in an NP complex with N2 peak latencies suggesting the activation of myelinated Aδ-fibers (Fig. 3B). The mean latencies of the N2 component for I3 and I4 stimulations were 154.3 ms (sdm = 30.3) and 157.3 (sdm = 25.6), respectively, a difference that was not statistically significant, t[20] = 0.57; $P = 0.6$. The mean N2/P2 peak-to-peak amplitude was significantly higher for I4 (mean = 55.9 μV, sdm = 21.4) than for I3 (mean = 45.1 μV, sdm = 22.2) stimulations, t[20] = 3.24; $P = 0,004$.

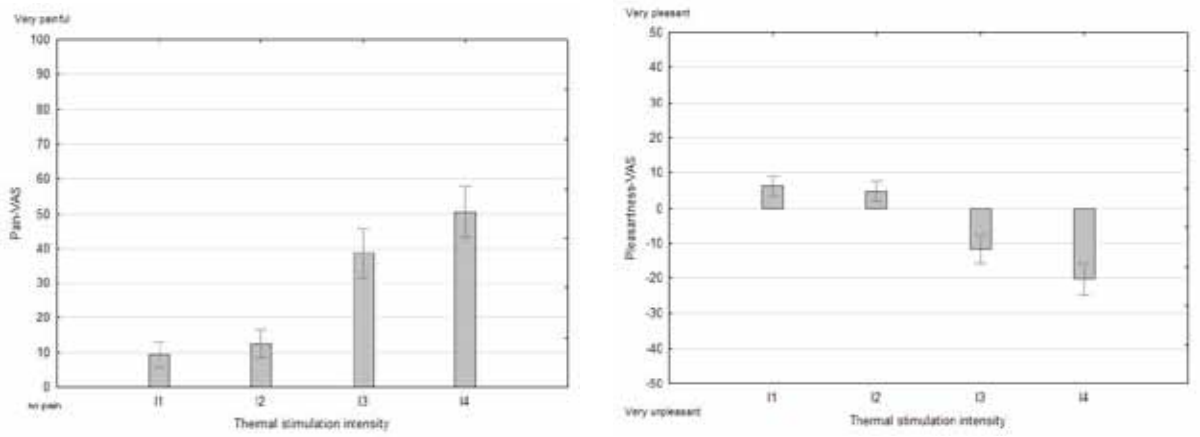

Fig. 2. *Mean numerical ratings on the (A) pain-VAS and (B) pleasantness-VAS of thermal laser stimulations. I1 (5.3 mJ/mm², I2 (7.3 mJ/mm²), I3 (11.3 mJ/mm²) and I4 (13.2 mJ/mm²).*

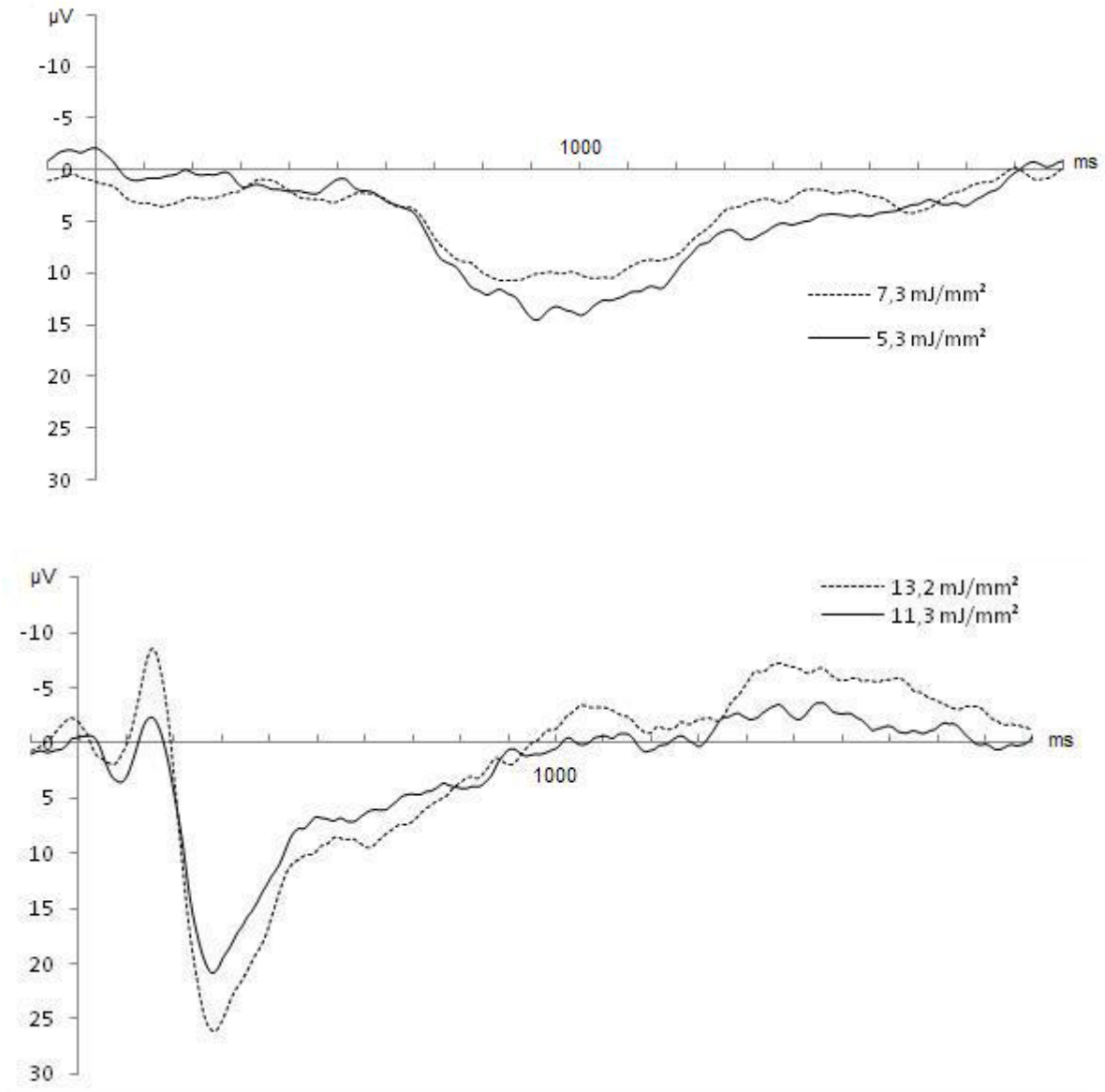

Fig. 3. *Grand average of SEPs, recorded on Cz (referred to the ears), for (A) I1 (5.3 mJ/mm², solid line) and I2 (7.3 mJ/mm², dashed line) stimulations and (B) for I3 (11.3 mJ/mm², dashed line) and I4 (13.2 mJ/mm², solid line) stimulations.*

Discussion

Using psychophysical measures combined with SEPs, we investigated whether the VAS commonly used in assessment of experimental pain (i.e., ranging from "no pain" to "unbearable pain") is a reliable tool for obtaining objective information about the experiential dimension of pain. Healthy adults may reinterpret the scale endpoints during assessments of experimental pain, considerably distorting the interpretation of the results. To assess whether subjects erroneously interpret the anchor points on the classical pain-VAS, we analyzed, during 2 successive experimental sessions, subjects' ratings of the same painful and non-painful

thermal stimulations on the classical pain-VAS and on a pleasantness-VAS. If the anchor points on the pain-VAS were considered adequately, subjects' ratings on both VASs would be consistent: painful stimulations would be rated as unpleasant on the pleasantness-VAS and stimulations rated as pleasant on the pleasantness-VAS would be judged as non-painful on the pain-VAS.

We found, however, that low-intensity thermal stimulations rated as painful on the pain-VAS were rated as pleasant on the pleasantness-VAS. A parallel can be drawn between this astonishing incongruity and the results of other studies. For example, healthy subjects rated stimulations of intensities below the pain threshold as painful on the classical pain-VAS (16). Taken together with these findings, our results suggest that subjects may reinterpret the anchor descriptors, especially for the "no pain" anchor, of the classical pain-VAS. Nevertheless, this conclusion is based on subjective measures (i.e., subjects' ratings on the 2 VASs) and its veracity may therefore be questionable. By concomitantly recording SEPs and investigating the correspondence between the psychophysical measures and the specific SEP components elicited by different thermal stimulations, we were able to obtain objective measures of subjects' somatosensorial perception. Indeed, SEPs recorded during psychophysical measurements provided further evidence that subjects misinterpret the "no pain" anchor point of the VAS. SEPs elicited by painful laser heat stimulations were found to result in an NP complex indicating activation of Aδ-fibers (22). Hence, painful sensations are expected to result in such NP components in the 160 - 390 ms latency range. We found, however, that low-intensity thermal laser stimulations, despite being rated as significantly painful on the pain-VAS, resulted in an ultra-late positive component with peak latencies in the 750–1200 ms range, suggesting that C-fibers, but not Aδ-fibers, were activated. C-fibers are known to convey non-painful warm sensations (28). Furthermore, the fact that ultra-late components related to acute painful stimulations (i.e., secondary diffuse pain) cannot be observed (29-31) strengthens our hypothesis that subjects were not experiencing pain during low intensity stimulations. Thus, SEP measurements support our hypothesis of a misuse of the classical pain-VAS due to a reinterpretation of the anchors. Indeed, the cerebral responses observed following low-intensity thermal stimulations were in agreement with subjects' ratings on the pleasantness-VAS, but not on the pain-VAS. The confirmation of the subjects' real sensation by electrophysiological data appears to be quite reliable since the amplitudes of EP components are highly correlated to rating magnitudes. Indeed, we found that amplitudes of the ultra-late positive wave did not differ between the 2 stimulation intensities (i.e., I1 and I2), and in parallel, pain and pleasantness ratings of both stimulation intensities were also similar. Similar findings were also observed at the higher intensities, which gave rise to significantly higher EP amplitudes and ratings for I4 than for I3.

To summarize, our psychophysical and SEP results indicate that healthy individuals reinterpret the "no pain" anchor on the pain-VAS, in that they rate the intensity of the stimulation rather than pain perception. One plausible explanation may be that subjects asked to rate many non-painful stimuli (i.e., 20 out of 40 in the present study) on a pain-scale, may be reluctant to respond 0 on half of the trials. These findings suggest that measures of experimental pain on pain rating scales anchored by "no pain" should be interpreted with caution. A rating scale ranging from "no sensation" to "unbearable pain", allowing subjects to rate stimulus intensities that are perceived but are not painful, may reduce this bias and be more reliable for experimental pain assessment.

Conclusion

The VAS commonly used to assess experimental pain (i.e., ranging from "no pain" to "unbearable pain") appears to be unreliable for obtaining objective information about the experiential dimensions of pain. Indeed, individuals reinterpret the scale endpoints and seem to rate the intensity of the stimulation, not pain perception.

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