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Patient reported outcome measures of pain intensity: Do they tell us what we need to know?

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HIGHLIGHTS

- Pain intensity and activities of daily living are not highly predictive of each other.
- Pain intensity scores of chronic pain patients are not predicted by etiology.
- Pain intensity scores vary for different time periods: e.g., 2 weeks vs 24 h.
- Pain intensity is problematic as a sole primary outcome variable for chronic pain.
- Mixed methodology is a promising approach for chronic pain research.

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ABSTRACT

Objective: To determine the relationship between chronic pain patients' responses to self-report measures of pain intensity, and self-reported strategies when completing such measures.
Participants: Ambulatory outpatients suffering from one of the following chronic pain conditions: painful HIV neuropathy, painful diabetic neuropathy, chronic Low-Back Pain.
Method: As part of a previously reported study using qualitative methods, participants completed standard pain intensity questionnaires as well as a measure of pain related disturbances in activities of daily living. In the previous study, participants' responses during a focus group were then used to identify their strategies and beliefs about their approach to completing the questionnaires. Among the beliefs were: (1) difficulties averaging pain over different time periods (i.e., "what was your average pain during the last 24 h" versus "what was your average pain during the last 2 weeks"); (2) difficulty in comparing pain from different etiologies; (3) difficulties in reporting sensations of pain in a manner unaffected by issues and situations secondary to the pain experience, such as difficulties in activities of daily living. In the present paper we use ANOVA (analysis of variance) and partial correlation to determine whether the qualitatively derived perceptions are reflected in the quantitative pain intensity scores.
Results: Participants' belief that it was difficult to "average" pain intensity over different time periods was supported. The data do not support their belief that pain intensity scores are affected by other factors: their specific pain diagnosis, and the extent to which pain interfered with their activities of daily living.
Conclusions: (1) Patients tend to report different levels of pain intensity when asked to report their pain over different periods; (2) insofar as it can be said to exist, the relationship between measures of intensity and interference with activities of daily living is minimal; (3) participants tend to report similar levels of pain intensity, irrespective of etiology.
Implications: (1) Chronic pain patients' elicited beliefs and strategies concerning how they complete pain intensity questionnaires are sometimes, but not invariably, reflected in their responses to these measures. Thus, purely qualitative methodologies alone cannot provide completely reliable information and point to the need to use a "mixed methods" approach combining both qualitative and quantitative data; (2) the lack of association between pain intensity measures and interference with activities of daily living, as well as relative insensitivity to different etiologies underlines the problem in relying on pain intensity measures as the primary means of evaluating the success of a treatment, either for pain management or in clinical research.

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1. Introduction

In the case of chronic pain there are two major challenges to reliable and meaningful measurement of outcome. The first is that pain is a sensory experience without a directly observable correlate; therefore all outcome data are derived from patient-self report [1]. The second challenge is that patients' self-report of pain can in some instances be affected by factors other than the sensory experience of pain itself, such as the extent to which patients perceive their pain as interfering with their activities of daily living [2,3].

We have been investigating how these challenges manifest themselves from the patient's point of view. In a recent paper [4] we investigated this question in patients with non-malignant chronic pain conditions using a focus group to elicit the cognitive, affective, and situational difficulties participants experienced in filling out measures of pain intensity. Among the difficulties we elicited were the following: (1) cognitive difficulties, in particular averaging pain over different time periods (i.e., "what was your average pain during the last 24 h" versus "what was your average pain during the last 2 weeks"); (2) difficulty in comparing pain from different etiologies; (3) difficulties in reporting sensations of pain in a manner unaffected by issues and situations secondary to the pain experience, such as difficulties in activities of daily living.

The question then arises whether any of these difficulties identified using qualitative methods actually affect the quantitative levels of pain intensity patients report. Thus, for example, do patients report different levels of pain intensity simply because they must average their pain intensity over 2 weeks versus 24 h? Similarly, is it the case that patients' perceptions of difficulties in activities of daily living affect the level of pain intensity they report? In the present paper we address the question by determining whether there are any statistically detectable patterns in scores on three measures of pain intensity and one measure of interference with activities of daily living.

2. Methods

2.1. Participants

Participants were volunteers compensated for time and expenses. They were ambulatory outpatients with one of three chronic pain conditions: HIV Distal Symmetric Polyneuropathy (HIV-DSP); Diabetic Peripheral Neuropathy (DPN), and chronic Low-Back Pain (cLBP). The study was approved by the Mount Sinai Medical Center Institutional Review Board and informed consent was obtained from all participants prior to entering the study.

2.2. Procedure

In the course of the qualitative study participants completed three measures of pain intensity as well as a measure of the extent to which pain interferes with activities of daily living on two occasions. The first occasion was 1–3 weeks *before* participation in a focus group, the second, 1–3 weeks *after* participation in a focus group. Further details will be found in the earlier paper [4].

2.3. Measurement tools

(1) *Visual Analogue Scale* (VAS) [1]: participants filled out two versions of the VAS. In one version, participants rated their average pain during the last 24 h. In the other version participants were asked to rate their average pain during the last 2 weeks. The latter version is part of the Short *Form McGill Pain Questionnaire* [5]. To distinguish the two versions we will refer to the latter version as the MVAS, and the former version as the VAS24.

(2) *Numeric Rating Scale* (NRS) [1]: patients rate their average pain during the last 24 h on a 0–10 scale where the anchors are "No Pain" and "Worst Possible Pain".

(3) Interference sub-scale of the *Brief Pain Inventory* (ISBPI) [6,7]: patients rate how much during the last 24 h, their pain interfered with seven aspects of daily living: general activity, mood, walking ability, normal work, social relations, sleep, and enjoyment of life. Patients make their ratings on a 0–10 scale anchored by "Does Not Interfere" and "Completely Interferes."

2.4. Data analysis

Inferential statistical analyses addressed three questions. The first two questions were whether there was an effect of different chronic pain conditions, and whether there was an effect of having to "average" pain intensity scores over different time periods. To address these questions we analyzed the data as split-plot factorial designs using analysis of variance (ANOVA) [8]. To examine the third question, the effect of interference with activities of daily living on pain intensity reports, we used partial correlation. All analyses were done using SPSS statistical software [9].

3. Results

Completed questionnaires from 33 of the 36 participants in the previous study were available for analysis.

The mean pain intensity scores as measured by the NRS are shown in Table 1. These data were analyzed using ANOVA as a 2×3 split-plot factorial (SPF) with visit (i.e., *before the focus group* versus *after the focus group*) as a within subjects factor, and pain diagnosis (i.e. *HIV-DSP* versus *DPN* versus *cLBP*) as a between subjects factor. There was no main effect of visit ($F(1,29) = 1.053$, ns) or pain diagnosis ($F(2,29) = 1.239$, ns), nor was there a visit $\times$ pain diagnosis interaction ($F(2,29) = 2.203$, ns). This analysis shows that the NRS scores were unaffected by participation in the focus group, or by pain diagnosis; that is, all three diagnostic groups reported on both occasions statistically indistinguishable levels of pain intensity.

The mean pain intensity scores as measured by the VAS24 and MVAS are shown in Table 2. These data were analyzed using ANOVA as a $2 \times 2 \times 3$ SPF. This analysis is similar to the analysis of the NRS, but in addition to the factors of visit and pain diagnosis, there was the within-subjects factor of VAS form (i.e., *VAS24* versus *MVAS*). There was no main effect of pain diagnosis ($F(2,27) = 1.016$, ns) or VAS form ($F(1,27) = 2.132$, ns), nor was there a diagnosis $\times$ VAS form interaction ($F(2,27) = 1.481$, ns). These results show that as in the case of the NRS, participants reported similar levels of pain on both forms of the VAS, irrespective of pain diagnosis. There was a main effect of visit ($F(1,27) = 14.601$, $p = 0.001$) and a visit $\times$ VAS form interaction ($F(1,27) = 4.305$, $p = 0.048$). This pattern indicates that participants reported different levels of pain depending on whether they were asked about their pain when averaged over a 24 h period versus a 2-week period, and further, that this difference changed after participation in the focus group. To more precisely characterize this pattern, we re-analyzed the pre- and post-focus

Table 1
Pre-focus group and post-focus group numeric pain rating scale scores as a function of diagnosis: means and (standard errors) ($N = 32$).

	HIV ($N = 11$)	DPN ($N = 10$)	cLBP ($N = 11$)	Total ($N = 32$)
Pre-focus group	5.00 (0.62)	4.40 (0.87)	4.73 (0.59)	4.72 (0.39)
Post-focus group	4.36 (0.67)	3.10 (0.79)	5.45 (0.68)	4.34 (0.43)

HIV, HIV Distal Symmetric Polyneuropathy; DPN, Diabetic Peripheral Neuropathy; cLBP, chronic Low-Back Pain; pre-focus group, prior to participation in focus group; post-focus group, following participation in focus group.

Table 2
Pre-focus group and post-focus group VAS24 and MVAS scores (in centimetres) as a function of diagnosis: means and (standard errors) ($N = 30$).

	HIV ($N = 11$)	DPN ($N = 8$)	cLBP ($N = 11$)	Total ($N = 30$)
Pre-focus group				
VAS24	4.83 (0.647)	3.85 (0.938)	4.60 (0.707)	4.51 (0.427)
MVAS	5.61 (0.794)	5.63 (0.939)	6.39 (0.583)	5.90 (0.429)
Post-focus group				
VAS24	4.02 (0.6.27)	3.70 (0.990)	5.26 (0.764)	4.41 (0.463)
MVAS	4.09 (0.584)	4.53 (0.102)	6.25 (0.701)	4.99 (0.452)

VAS24, Visual Analogue Scale for 24 h period; MVAS, Visual Analogue Scale for 2-week period; HIV, HIV Distal Symmetric Polyneuropathy; DPN, Diabetic Peripheral Neuropathy; cLBP, chronic Low-Back Pain; pre-focus group, prior to participation in focus group; post-focus group, following participation in focus group.

Table 3
NRS and VAS24: zero order, and partial correlations controlling for ISBPI score.

	Zero order correlation	Partial correlation controlling for ISBPI
Pre-focus group		
	$r = 0.897$; $R^2 = 0.805$	$r = 0.846$; $R^2 = 0.716$
	$n = 33$	$n = 33$
	$p < 0.001$	$p < 0.001$
Post-focus group		
	$r = 0.943$; $R^2 = 0.889$	$r = 0.919$; $R^2 = 0.845$
	$n = 32$	$n = 32$
	$p < 0.001$	$p < 0.001$

NRS, Numeric Rating Scale; VAS24, Visual Analogue Scale for 24 h period; ISBPI, Interference sub-scale of the Brief Pain Inventory; pre-focus group, prior to participation in focus group; post-focus group, following participation in focus group.

group data using ANOVA as two separate 2×3 SPF designs. For the pre-group there was a main effect of VAS form ($F(1,32) = 16.646$, $p < 0.001$), while for the post-group, the effect of VAS form was only marginally significant ($F(1,28) = 4.109$, $p = 0.052$). These further analyses establish two points. First, that the participants rated their average pain higher for a 2-week period than for a 24 h period. Second, that following participation in the focus group this difference was substantially reduced, but not completely eliminated.

The final question is the extent to which interference with activities of daily living, as measured by the ISBPI, affects measures of pain intensity. To address this question we compared zero order correlations (using Pearson's r) between two measures of pain intensity with partial correlation in which any relationship with the ISBPI has been controlled for. The extent to which the partial correlation is less than the zero order correlation is an indicator of the extent to which the ISBPI score is associated with the pain intensity scores. Table 3 shows zero order correlations between two measures of pain intensity (NRS, VAS24) as well as the partial correlations in which association with the ISBPI has been removed. As can be seen in Table 3, the zero order and partial correlations differ little from one another and in fact none of the differences approach statistical significance ($p > 0.40$, Fisher's r to Z transformation [10]). These analyses support the conclusion that effect of interference with activities of daily living as measured by the ISBPI, assuming it exists, is at most minimal.

4. Discussion

In addition to replicating previous findings that the VAS and NRS are essentially equivalent in their ability to detect changes in pain intensity [11–13], the present results support three conclusions. First, participants have difficulty "averaging" pain intensities over different time periods. Specifically, they consistently rated their pain higher over a 2-week period than over a 24 h period, although this tendency diminished following participation in the focus group. This difficulty is consistent with participants' expectations reported in our previous paper. Second, all participants consistently reported statistically indistinguishable levels of pain intensity. This result occurred across three different etiologies and three different pain intensity scales. This finding is the exact opposite of patients' expectations as elicited in the focus group. The inability to distinguish pain intensity across all three groups is particularly surprising, given the lack of any entry level criteria of pain and the mixture of pain medications. While this finding could be the result of the small sample size in the present study, it is one worthy of future investigations with more appropriately powered studies. Third, measures of pain intensity failed to account for little, if any, of the variance associated with the ISBPIS, a measure assessing the impact of pain on activities of daily living. Again, this finding is contrary to patients' expectations as elicited in the focus group. Here it is more difficult to attribute this finding to small sample size, since even leaving questions of statistical significance aside, the effect of interference of activities of daily living would not account for more than 9% of the observed variance, in other words, a small to medium effect in Cohen's terminology [14].

The current study raises two issues worthy of future consideration. The first issue is methodological. Specifically, the sometimes mismatch between the qualitative data of the previous study and the statistical findings of the present paper indicate the importance of utilizing "mixed methods" analyses where qualitative data (as in the previous study) are combined with the purely quantitative reported in the present study [15,16].

The second issue concerns the clinical and research utility of the concept of pain intensity. Some measure of pain intensity is typically the primary outcome variable in clinical trials for pain medications, as well as a key component of the entry criteria for many clinical trials. Further, the management of chronic pain tends to focus on reduction of pain intensity. Thus our latter two findings reinforce a concern previously expressed by the *Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials* (IMMPACT) consensus group [17]: whether reduction in pain intensity alone is an appropriate primary outcome variable in clinical trials or a sole primary goal in clinical interventions. And if measures of pain intensity are not an appropriate primary outcome variable, what is a suitable supplement or replacement? Future investigations will profitably overcome two notable limitations of the current study, small sample size and the limited number of chronic pain conditions studied.

Conflicts of interest

Dr. Simpson received fees for consultancies, advisory services, and/or industry sponsored lectures from: Acorda Therapeutics Inc.; Allergan, Inc.; Astellas Pharma, Inc.; Merz Pharmaceuticals, LLC; Pfizer Inc.; Syntaxin, and Viromed. Dr. Tamler received fees for consultancies with Sanofi-Aventis. None of the other authors reported potential conflicts of interest.

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