Determining responsiveness of FCEs, mission impossible?

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Determining Responsiveness of FCEs, Mission Impossible?

To the Editor:

We applaud the compilation of a Special Topic Series of [*The Clinical Journal of Pain* (May/June 2005, Volume 21, Issue 3)] on functional capacity testing. The issue certainly contributes to the much-needed body of knowledge on functional capacity evaluations (FCEs). In the introduction of the issue, it was suggested that the responsiveness of functional tests be researched.[1] Others[2,3] have also suggested this. Recently, we have attempted to perform responsiveness research using an existing data set of the material handling tests of FCE performances before and after a rehabilitation program in patients with nonspecific chronic low back pain (CLBP). Differences in performances before and after treatment were observed (Table 1). However, during the study we experienced 2 major difficulties in our 2 approaches.

Our first approach to the analysis of responsiveness was to compare the change in FCE results to an external criterion (gold standard). A change in FCE performance implicates a change in functional status. Therefore, external criteria should be related to the construct functional status. However, neither self-reports of function nor actual functioning, eg, in work, can be used as external criterion because it has been demonstrated that performances during functional testing and self-reported measures of function are substantially different and weakly to moderately related.[4,5] Similarly, weak relationships exist between FCE performance and work status.[6–8] These findings were confirmed in our study. Relationships between FCE performances and differences in pain intensity, in self-reported disability, and in self-reported limitations in performing lifting tasks were weak or insignificant (not presented). It appears that a gold standard is unavailable.

In a second approach to the analysis of responsiveness, we compared the observed change in performance with the "natural variation" in the measurement. The natural variation (also known as *limits of agreement*) may serve as an internal or statistical criterion to demonstrate improvement over time. The natural variation of FCE measurements has been studied in patients with CLBP and in healthy patients.[9,10] The results of these studies showed that this natural variation is substantial, eg, in the lifting performance of patients with CLBP, the limit of agreement is ± 19.8 kg.[10] This means that a progress of 19.8 kg in lifting performance must be observed to exceed the natural variation of the measurement. The clinical relevance of this criterion should therefore be questioned.

Although differences in FCE performances before and after treatment were found (Table 1), we are unable to determine whether these differences represent clinically important changes in the observed functional performance because of the absence of a valid external criterion and a substantial natural variation of "normal" performance. Although it is clear that the responsiveness of FCEs must be studied, the question remains as to which external criterion should be used.

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TABLE 1. Manual Material Handling Performances Before and After Treatment

	Lifting Low (n = 58)	Lifting High (n = 57)	Carry Short (n = 56)	Pushing Static (n = 44)	Pulling Static (n = 44)
Mean 1 (SD)	28.6 (15.1)	16.0 (6.5)	33.6 (16.6)	35.8 (10.4)	43.8 (13.7)
Mean 2 (SD)	31.2 (17.7)	16.0 (6.5)	36.7 (16.5)	38.7 (13.0)	46.1 (16.2)
Mean difference (SD) (kg)	− 2.6 (9.6)*	− 0.00 (2.6)	− 3.0 (11.1)*	− 2.9 (7.5)*	− 2.3 (9.8)
Range of difference (kg)	− 30 to 16	− 4 to 6	− 48 to 22	− 21 to 11	− 30 to 20
95% CI of difference (kg)	− 5.1 to − 0.06	− 0.68 to 0.68	− 6.0 to − 0.07	− 5.2 to − 0.66	− 5.3 to 0.65

*Significant difference at $P \leq 0.05$ (paired samples t test).

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Opioid Tolerance Remains Unaddressed

To the Editor:

Opioids use for non-cancer pain remains a contentious topic. Despite medical societies' endorsement, debate continues over their use for chronic non-cancer pain. While this is a topic beyond the scope of this letter, we like to offer some critique to Markenson et al[1] on their study of the efficacy of controlled-release (CR) oxycodone for treatment of osteoarthritic pain over a 90-day period.

Tolerance is a major concern with the long-term use of opioids. Markenson et al were limited in addressing this issue. They suggested in this article that patients did not become tolerant since dose remained relatively low. The short follow-up period and the small number of patients that completed the entire study (36 of 107) make conclusions about whether or not tolerance was developing speculative at most. Furthermore, the method of data analysis used in this study was intent to treat (ITT) with the last observation carried forward (LOCF) of all patients that received at least 1 dose of drug. However, by carrying forward the last observation, the data may have marginalized the impact of tolerance by integrating data from patients that discontinued before tolerance could develop with data from patients that continued until day 90. Indeed, the report displays a discrepancy when completers of the study are examined alone. Among completers the average pain decrease was not significant against placebo at day 90. In addition, despite remarks of the relatively low dose used during the study, the average daily dose of CR oxycodone did increase after initial titration. No explanation is offered for the increase in average dosing after a seemingly adequate minimum of 15 days to titrate dosing. Other studies investigating opioid treatment for chronic non-cancer pain have examined long-term outcomes through use of open-label extensions. However, the potential bias associated with open-labels and the minority of patients electing to continue through these extensions do not allow conclusions regarding tolerance.[2] Two studies examining opioid efficacy in chronic non-cancer pain have indicated that pain intensity levels began to rise after 4 weeks.[3,4] Whether, as one of author suggests, a 30-day period for titration is inadequate to achieve pain control or whether tolerance developed is uncertain.[3] However, these trends stress the need for stringent investigation into the development of tolerance with long-term opioid treatment of non-cancer pain.

The study by Markenson's et al cannot support their conclusion. In fact, we believe it creates confusion among pain management providers when it alludes to CR oxycodone being a drug of choice for osteoarthritis when the evidence presented is weak at best.

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