

Pain interference and physical function demonstrate poor longitudinal association in people living with pain: a PROMIS investigation

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Abstract

A primary goal in managing pain is to reduce pain and increase physical function (PF). This goal is also tied to continuing payment for treatment services in many practice guidelines. Pain interference (PI) is often used as a proxy for measurement and reporting of PF in these guidelines. A common assumption is that reductions in PI will translate into improvement in PF over time. This assumption needs to be tested in a clinical environment. Consequently, we used the patient-reported outcomes measurement information system (PROMIS) to describe the topology of the longitudinal relationship between PI in relation to PF. Longitudinal data of 389 people with chronic pain seeking health care demonstrated that PI partially explained the variance in PF at baseline ($r = -0.50$) and over 90 days of care ($r = -0.65$). The relationship between pain intensity and PF was not significant when PI was included as a mediator. A parallel process latent growth curve model analysis showed a weak, unidirectional relationship ($\beta = 0.18$) between average PF scores and changes in PI over the course of 90 days of care, and no relationship between average PI scores and changes in PF across time. Although PI and PF seem moderately related when measured concurrently, they do not cluster closely together across time. The differential pathways between these 2 domains suggest that therapies that target both the consequences of pain on relevant aspects of persons' lives, and capability to perform physical activities are likely required for restoration of a vital life.

Keywords: Pain interference, Physical function, Chronic pain

1. Introduction

Clinical practice guidelines for noncancer pain care recommend measurement of core outcome domains that go beyond pain intensity and reflect an effort to restore the physical, mental, and social health of the person in pain.^{1,2,7,11,25,28} Furthermore, from a health care delivery and policy perspective, improvements in pain intensity and physical function (PF) are the predominant measures used by health insurance payers to justify approval or denial of procedural, rehabilitation, and pharmacological therapies. Insurance denials occur when meaningful changes are not met in both domains, and this is particularly notable with justifying continued use of opioids and procedures. Although measurement of PF is recommended in numerous practice guidelines, self-report outcomes and studies—actual recommended

measurement tools use pain interference (PI) as a substitute or proxy for PF.^{9,20,21,31,32} However, it is unclear to what extent (1) PI correlates with PF at baseline and (2) PI changes track PF changes over time, during treatment of people with chronic pain presenting for clinical care.

This dilemma helped inform our investigation as to whether PI provides an acceptable surrogate measure of PF. The National Institute of Health—Patient-Reported Outcomes Measurement Information System (PROMIS) PI and PF item banks characterize each of these domains. The first step towards developing awareness of the potential interaction between PI and PF, however, is to establish a common language for further discourse. The PROMIS defines PI as a measure of the extent to which pain hinders engagement with physical, cognitive, emotional, cognitive, and recreational activities, as well as sleep and enjoyment in life.⁴ In contrast, PF is defined as a measure of the ability to carry out activities that require physical actions, ranging from self-care to more complex activities that require a combination of skills, often within a social context.¹⁸ It becomes clearer from these definitions that the person's perceived impact of pain on engagement in activities (PI) can be distinct from a person's perceived ability to participate in PF-related activities.^{23,24}

The aims of this study were to examine the potentially complex interaction between PI and PF for people with chronic pain over the short-term course of care, both in terms of their concurrent correlation at the beginning and end of care (aim 1), as well as the longitudinal association between the 2 domains (aim 2). Our hypotheses were that lower PI would be concurrently correlated with higher PF (hypothesis 1), but that this relationship would have weak associations when measured over time (hypothesis 2). This

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PAIN 158 (2017) 1063–1068

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<http://dx.doi.org/10.1097/j.pain.0000000000000881>

second hypothesis was motivated from our clinical experience in which we have noted significant improvements in PI with treatment, without corresponding improvements in PF. Because some studies have demonstrated that baseline pain intensity can be associated with recovery of PF in the acute or postoperative setting for a noncancer (musculoskeletal) pain population,^{3,34} we were also interested in characterizing the potential mediating role that PI could serve between these 2 domains in our population.

2. Methods

2.1. Participants and data collection

We leveraged the learning health care system platform, Collaborative Health Outcomes Information Registry (CHOIR; <http://choir.stanford.edu>), to characterize the concurrent changes in PI, PF, and pain intensity (average intensity over the past 7 days) at baseline, and after receiving approximately 30, 60, and 90 days of care. People seeking treatment at a specialty pain management center within an academic medical institution (Stanford Pain Management Center) were enrolled in CHOIR and their PI and PF were assessed at the time of their initial consultation visit and on subsequent visits as part of their routine clinical care. The patient population was a heterogeneous mix of people with various chronic, noncancer (musculoskeletal) pain disorders.

Routine clinical care would involve consultation and treatment recommendations from an interdisciplinary team of physicians, psychologists, physical therapists, nurse practitioners, physician assistants, and complex care managers (a social worker and nurse), all of whom specialize in pain medicine. Typical treatments would include optimization of analgesic medications, psychological therapies (eg, group and individual cognitive-behavioral therapy, acceptance and commitment therapy, biofeedback training), physical therapy (eg, recommendations for an individualized therapeutic exercise program, yoga, and Tai Chi), interventional procedures (eg, nerve blocks, radiofrequency ablation, spinal cord stimulators), complementary approaches (eg, acupuncture, nutraceuticals), and self-management approaches through pain education and experiential training (eg, action planning, problem solving, and goal setting).

The PROMIS measure of PI has been linked for comparison with other PI legacy instruments²⁷ such as the 15-item Brief Pain Inventory^{10,20} and the 2-item Short-Form 36 Bodily Pain Scale.²⁶ Results indicate that the PROMIS PI item bank, which use both Item Response Theory and Computer-Adapted Testing (CAT) methods, is a psychometrically sound instrument with regard to reliability (0.96–0.99 for T score range 50–80), construct validity, and discriminate validity across pain intensity, disability levels, and chronic conditions ($P < 0.0001$).⁴ Approximately one-third of the 13 total items in the PROMIS PI item bank are dedicated to physically focused activities, ranging from sitting, standing, and walking tolerance, to the ability to perform work duties and household chores. The PROMIS PF item bank scores, which also use both Item Response Theory and CAT methodology, have been linked for comparison with the Medical Outcome Study Short-Form 36 Survey (Legacy PF-10) and Health Assessment Questionnaire.⁸

Compared with the Legacy PF-10 and HAQ, the PROMIS PF item bank has demonstrated superior or equal reliability (precision) and sensitivity to change.¹³ Specifically, the PROMIS PF instrument demonstrated greater precision of 0.90 or better in comparison with the Legacy PF-10 with a higher number of SD range of values covered. For example, the PROMIS PF covered 4.8 SD (20-item static version) to 6.3 SD (10-item CAT version), in comparison with the Legacy PF-10, which covered 2.4 SD.¹³ Improvement in PF was defined as raw score changes of at least

0.5 SD from baseline (a 5-point change in t score), over the course of a 90-day treatment period. Data were captured at baseline (first appointment) and at each subsequent appointment. We included patients who completed at least 3 follow-up treatments within a 90-day time period for analysis.

PROMIS measures were administered using a CAT approach^{5,15}; rather than assessing a set number of items per subscale; the CAT approach identifies the optimal items within each domain based on previous responses from the respondent. CAT assessments are considered superior to traditional standard scale assessments because of the smaller number of items needed for effective assessment of each construct, as well as increased reliability of measurement.^{12,19} CHOIR includes CAT versions of the PROMIS measures adapted with an in-house algorithm (CHOIR-CAT). CHOIR-CAT was implemented using the same CAT algorithm as the Northwestern University Assessment Center, which has provided open access to PROMIS instruments.¹⁵ PROMIS measures are normed against the U.S. population and have a mean of 50 points and an SD of 10 points.⁶

2.2. Ethical considerations

Study procedures, which involved exclusively retrospective review of clinical data, were approved by the Institutional Review Board at the Stanford University School of Medicine.

2.3. Statistical analysis

Correlation analysis was performed between PI and PF at baseline, and at each of the subsequent time points (follow-up treatment appointments) within a 90-day time period to investigate the interaction between these 2 domains over a short-term course of care (aim 1). Age and gender were added as covariates to the correlations. Correlation sizes were defined as low = 0.30, moderate = 0.50, high = 0.80 to 0.90, and very high = 0.90 to 1.0.¹⁶ Correlation level of significance was set at the 0.01 level (2-tailed). A parallel process latent growth curve analysis was then performed on PI and PF, to help determine the longitudinal association between these 2 domains (aim 2). Cross-sectional and longitudinal mediation analysis was performed using a structural path modeling approach to determine whether PI mediated the relationship between pain intensity (average over the past 7 days) and PF. Adequacy of model fit was determined using the χ^2 test of model fit, Comparative Fit Index (CFI), Tucker–Lewis Index (TLI), the Root Mean Square Error of Approximation (RMSEA), and the Standardized Root Mean Square Residual (SRMR). Scores of 0.90 or higher on the CFI and scores below 0.05 for RMSEA and SRMR parameters were used as benchmarks to determine good model fit.¹⁷

2.4. Software

Correlation analyses and computation of descriptive statistics were performed using SPSS (Windows version 20, Chicago, IL). Cross-sectional path modelling and parallel process latent growth curve modelling were conducted using Mplus (Version 6.12, Los Angeles, CA: Muthén & Muthén).

3. Results

3.1. Participant demographics

A total of 3259 people with chronic noncancer pain completed the CHOIR surveys between August 2013 and May 2016. Of these, 392 new patients had at least 3 follow-up treatments over

the course of a 90-day time period and were considered for longitudinal analysis. Patient demographics with regard to age, gender, race, and ethnicity are described in **Table 1**. Mean values (\pm SD) at baseline were PI = 66.7 (\pm 6.0); PF = 34.3 (\pm 6.9). The mean value for Pain Intensity (average over the past 7 days) = 5.8 (\pm 1.9). The mean number of painful regions checked off on an interactive pain body map was 14.8 (\pm 14.4) out of a total of 74 possible regions (**Table 1**).

3.2. Correlations between PI and PF (aim 1)

Cross-sectionally, lower PI was moderately correlated with higher PF at the beginning of care across the entire chronic pain population ($r = -0.50$, $n = 389$; **Fig. 1**). The covariates of age and gender did not change the direction or significance of the findings. Further cross-sectional analysis showed lower PI was related to higher PF after 90 days of care across the entire chronic pain population ($r = -0.65$, $n = 305$; **Fig. 2**). Of the 392 people with at least 3 follow-up treatments within a 90-day time period, 34 people (8.7%) had improved PI and PF at the 90-day (fourth follow-up) care visit.

Improvement was defined as reaching a minimum threshold value of at least 0.5 SD from baseline (corresponding to 5-point change in t score). Compared with the initial visit, 281 of the 392 individuals (71.7%) did not improve in either the PI or PF domains. In contrast, 82 of the 392 individuals (20.9%) showed improvement in PI, and 63 of the 392 individuals (16.6%) showed improvement in PF. Of the 82 individuals who reported improvement in PI, 34 showed a corresponding improvement in PF, whereas 48 individuals did not show a corresponding improvement in PF. Of the 63 individuals who reported improvement in PF, 34 showed a corresponding improvement in PI, whereas 29 individuals did not show a corresponding improvement in PI. The intraclass correlation coefficients of PI and PF, respectively, were 0.87 and 0.93.

3.3. Mediating role of PI between pain intensity and PF

Cross-sectional analysis showed PI was a mediator of the relationship between pain intensity and PF ($ab = -0.224$, $P < 0.01$). The direct relationship between pain intensity and PF,

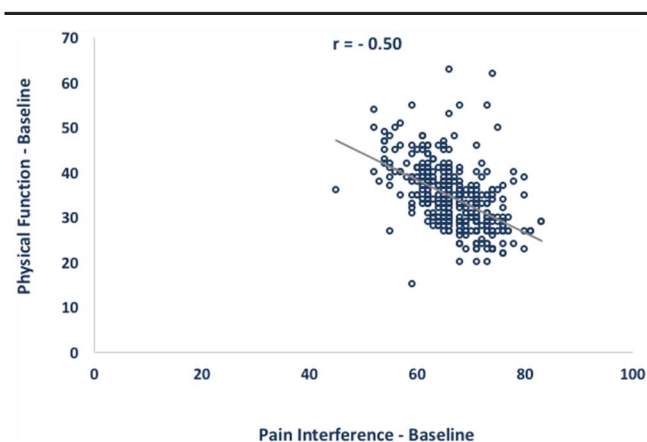


Figure 1. Cross-sectional analysis showed that lower pain interference was moderately related to higher physical function at the beginning of care across the entire chronic pain population ($r = -0.50$, $n = 389$).

which was significant without PI in the model ($\beta = -0.298$, $P < 0.001$), was reduced to nonsignificance when PI was included as a mediator ($** = P < 0.01$, $ab = 0.22$, $P < 0.05$; **Fig. 3**).

3.4. Longitudinal associations between PI and PF (aim 2)

A parallel process latent growth curve model showed a weak, unidirectional relationship ($\beta = 0.18$, $P < 0.05$) between mean PF scores and changes in PI over the course of 90 days of care (**Fig. 4**). However, this same analysis did not show a significant unidirectional relationship ($\beta = 0.16$, $P < 0.10$) between average PI scores and changes in PF over the course of 90 days of care. All coefficients were standardized. Notably, measures of model fit indicated poor fit according to the χ^2 test $24 = 121.0$ ($P < 0.0001$) and RMSEA = 0.102. Other fit indices were as follows: CFI = 0.949; TLI = 0.941; and SRMR = 0.058. The mean intercept for PI was 66.72, and the mean intercept for PF was 38.30. The proportional reduction of variance (r^2) for the slope of PI and PF were 0.032 and 0.024, respectively. These results indicate that 3.2% of the variance in PI scores, and 2.4% of the variance in PF scores were accounted for by the other factor, suggesting small relationships between these variables. A longitudinal mediation model (estimated using cross-lagged paths across time points) examining PI as a mediator of the longitudinal effect of pain

Table 1

Patient demographics.

Age, y (mean \pm SD)	48.9 \pm 14.5
Gender (n; F:M)	392; 258:134
Race (n)	
White/Caucasian	292
Asian	26
African American	10
Hispanic/Latino	1
Native American/Pacific Islander	2
Unknown/declined	61
Ethnicity (n)	
Non-Hispanic/Latino	353
Hispanic/Latino	25
Unknown/declined	14
Pain interference (mean \pm SD)	66.7 \pm 6.0
Physical function (mean \pm SD)	34.3 \pm 6.9
Pain intensity, average (mean \pm SD)	5.8 \pm 1.9
Body map count (mean \pm SD) (total regions possible = 74)	14.8 \pm 14.4

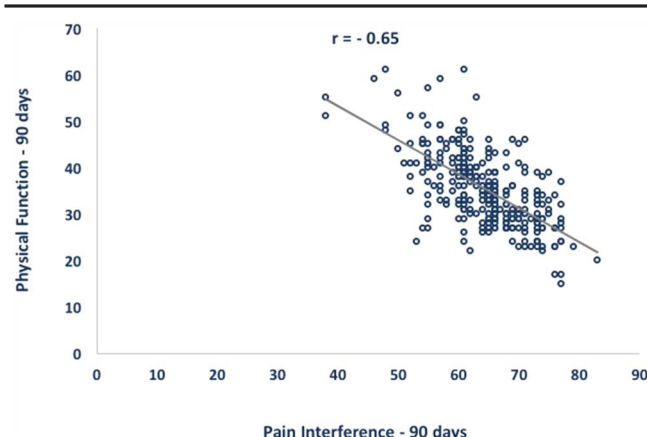


Figure 2. Cross-sectional analysis showed that lower pain interference was strongly related to higher physical function after 90 days of care across the entire chronic pain population ($r = -0.65$, $n = 305$).

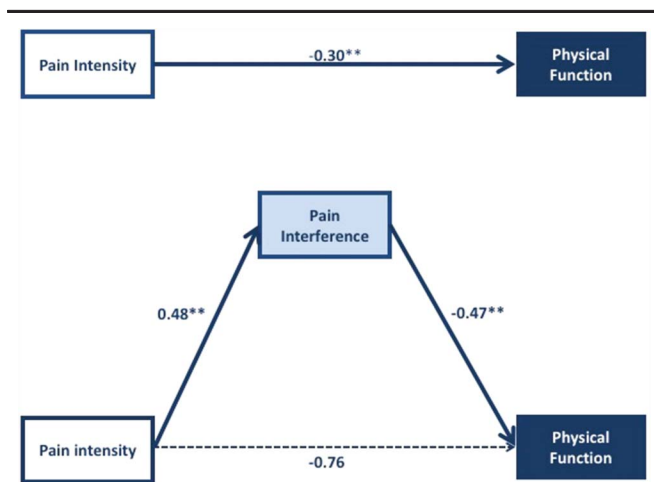


Figure 3. Cross-sectional analysis showed that pain interference (PI) was a mediator of the relationship between pain intensity and physical function (PF). The relationship between pain intensity and PF was insignificant when PI was included as a mediator.

intensity on PF was also estimated; however, fit indices suggested poor model fit ($\chi^2(29) = 194.6, P < 0.001$; RMSEA = 0.149; CFI = 0.900; TLI = 0.783; SRMR = 0.115). As the poor model fit was assumed to be due to the relatively weak longitudinal association between PF and PI noted previously, we opted not to report path estimates from this model.

4. Discussion

Our results support our first hypothesis that lower PI would be concurrently correlated with higher PF ($r^2 = 0.29$). This in and of itself was not surprising. More importantly, while there was a moderate correlation between PI and PF measured concurrently across the various time points of care, the latent growth model analysis demonstrated that these variables do not show the same degree of associations when measured across time. We were also interested in characterizing the potential mediating role that PI could serve between pain intensity and PF. Cross-sectionally, the relationship between pain intensity and PF was no longer significant when PI was included as a mediator. These data suggest that the context of

the person's pain perception, ie, the consequences of pain on the relevant aspects of one's life, is more closely associated with the person's level of PF in comparison with the non-contextual dimension of pain intensity.

The results of this study also support our second hypothesis, that the relationship between PI on PF would have poor associations when measured over time. Across time, mean score changes in PF were weakly associated with improvement in PI, and mean score changes in PI were weakly associated with improvement in PF. In other words, while PI and PF are at least moderately correlated when measured concurrently, these effects do not seem to extend to longitudinal changes in PI and PF. The poor model fit when measured over time would suggest that using PI as a surrogate measure for PF, or PF as a surrogate measure for PI is not a useful approach (ie, they do not reproduce the data accurately). From a self-management and therapeutic perspective, our longitudinal analyses indicate that only a small subgroup of individuals who reported improvement in PI also showed a corresponding improvement in PF. This weak relationship would imply that to more effectively improve PI—which is the perception of the extent to which pain hinders engagement in physical, recreational, as well as social, cognitive, and emotional activities—the treatment plan would likely be better informed to focus on the context of the patient's thoughts and behaviors with respect to their engagement in specific activities.

4.1. Implications for clinical practice guidelines and health care policy

Our study provides evidence that changes in PI and PF do not seem to show the same strong correlations across time as they do when measured concurrently; hence, PI does not provide an acceptable surrogate for PF. Our results also suggest that the language and recommendations put forth in current practice guidelines should be clear to distinguish these terms and not interchange them. As guidelines are being increasingly used for insurance approval and denials for provided care, it is important that our language and use of the words PI and PF are clearly defined and measured. A common narrative from the patient perspective is that PI is the primary limiting factor in participating in physical and social activities. This study provides further insight and challenges this common expectation that if PI improves, PF will concurrently improve. For most individuals who did report a reduction in PI, an improvement in PF did not occur.

4.2. Limitations

While some strengths of this pragmatic study consist of broad inclusion criteria and a diverse environment (high external validity), some limitations include less data control and potential variability with interventions and clinician knowledge level (low internal validity). We were unable to discern which particular treatment was received for each of the patients, given the nonrandomized, retrospective nature of this study. This bundled treatment approach limits the interpretation of the data to specific treatment approaches. The heterogeneous mix of people with chronic noncancer pain, while pragmatic in nature, limits the interpretation to specific subpopulations of people with chronic pain. The 90-day treatment period analysed limits longer-term outcomes of PI and PF. Additionally, and given the probability of continued patient attrition across time, analysis of paired assessments over time may be susceptible to accumulation of measurement error.

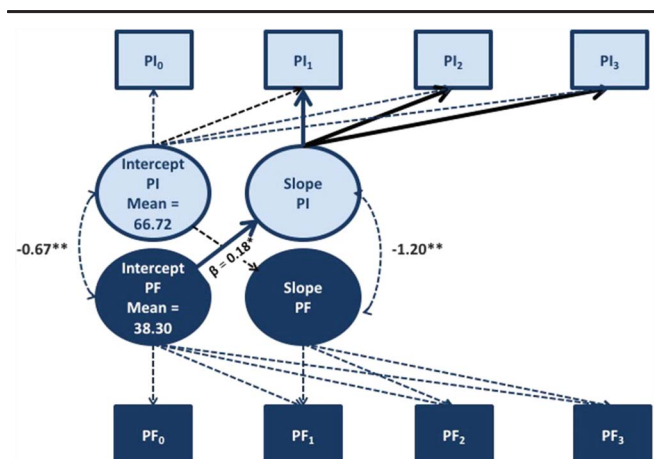


Figure 4. A parallel process latent growth curve model showed a weak, unidirectional relationship ($\beta = 0.18, P < 0.05$) between physical function and pain interference over the course of 90 days of care.

We thus urge replication of our findings in more structured longitudinal studies, where assessments are likely to be more regular and reliable.

4.3. Future directions

While fatigue and depression were not the focus of this study, evidence suggests that they should be considered in future investigations. For example, Sturgeon et al. have demonstrated, cross-sectionally, that for people with chronic noncancer pain from the same specialty pain management center used in this study, fatigue explained a significant proportion of the relationships of both PI and PF with pain intensity, sleep disturbance, and depression.³⁰ The finding that PF would also be correlated with fatigue would not be surprising given that the assessment of fatigue partly relates to the measuring of the impact it has on physical and social activity participation, but should be explored for validation. Previous research has also found that individuals with depression tend to have lower levels of PF at baseline, and across time, and that lower levels of PF at baseline is associated with subsequent onset of depression.²⁹ This finding would also not be surprising, given that the PROMIS depression bank is weighted toward items related to the identification of reduced positive affect and physical and social engagement.

It is also possible that other psychological factors, such as anxiety, may be more closely linked to PF. Stegenga et al.²⁹ found that individuals with anxiety or a combination of depression and anxiety had significantly lower PF at baseline compared with individuals with depression alone. Other studies have also exemplified the significant role that anxiety plays in PI,¹⁴ and the role of fear-avoidance beliefs in disability and return to work status.³³ As pain-related cognitions, stress, and coping styles are known to influence PI and PF, future studies could examine the specific mediating and moderating role(s) that these and other psychosocial variables play in explaining the relationship between these 2 distinct domains. For example, in addition to psychological distress and pain-related fear of movement, Lee et al.²² have shown that self-efficacy also mediates the relationship between pain intensity and disability.

A mixed methods approach to investigating the barriers to improve self-reported PF is an interesting area of future investigation, particularly if connected to relevant constructs such as return to work for people who are labelled as disabled because of chronic pain, either from a societal or individual perspective. Further controlled efficacy studies could also examine treatment responsiveness to a motivational interviewing approach focused on key PROMIS PF or PI items using a longitudinal assessment paradigm. Finally, as respondents were involved with a wide range of medical, physical, and psychological treatment approaches, future research aimed at identifying how the strength of the relationships observed in the current study vary with different treatment approaches would be insightful. Physiotherapy integrated with behavioral therapy (ie, acceptance and commitment therapy) could play an important role in affecting the outcomes of PI and PF for people living with chronic pain.

4.4. Conclusions

Collectively, our data suggest that PI and PF are related constructs, but over time, relate with one another in only a relatively indistinct, unidirectional, and weak pathway (ie, mean changes in PF appeared to be weakly associated with improvements in PI, but not vice versa). Because of the largely divergent

characteristics between PF and PI, this lends support of using choice instruments to measure both these distinct domains, rather than using PI alone as a surrogate measure of PF.

Conflict of interest statement

The authors have no conflicts of interest to declare.

N. V. Karayannis and J. A. Sturgeon are funded under the NIH T32 Program Award—Fellowship in Interdisciplinary Research Training in Pain and Substance Use Disorders [3T32DA035165]. S. C. Mackey is funded under the NIH (K24DA029262, R01AT008561, and P01AT006651) and the Redlich Pain Endowment.

Acknowledgements

The authors thank Ms. Christine Junge and Dr. Ravi Prasad for their editing.

Article history:

Received 23 May 2016

Received in revised form 25 January 2017

Accepted 9 February 2017

Available online 16 February 2017

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