Health-related quality of life among prescription opioid-dependent patients: Results from a multi-site study

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Abstract

Background—Although prescription opioid use disorder has recently increased sharply in the United States, relatively little is known about the general well-being of this population. Assessment of quality of life in patients with substance use disorders has been recommended to improve clinical care.

Objectives—Health-related quality of life was examined in prescription opioid-dependent patients at entry to a national multi-site clinical trial, to compare quality of life scores in the study sample to other populations; further, background variables associated with quality of life in the literature were examined.

Methods—Prescription opioid-dependent patients (N=653) were compared to general populations on the Medical Outcome Study Short Form-36 (SF-36) quality of life measure; and the association between patient background variables and quality of life was examined.

Results—Compared to a general population, the current sample of prescription opioid-dependent patients had worse physical (−1.7 points, p<.001) and mental quality of life (−12.3 points, p<.001) as measured by the SF-36, similar to other opioid-use disorder populations. Within our sample, women showed more impairment than men in mental quality of life (−4.3 points, p<.001); older patients scored worse on physical (−5.2 points, p<.001), but not mental, quality of life. Chronic pain was associated with poorer physical quality of life (−9.0 points, p<.001).

Conclusions and scientific significance—The growing focus on wellness underscores the importance of measuring quality of life in addition to substance use outcomes. Routine assessment of health-related quality of life can add an important dimension to overall evaluation of patients' treatment response.

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Declaration of interest
The remaining authors report no conflicts of interest.

INTRODUCTION

Rates of prescription opioid abuse and dependence have increased markedly in the United States during the past decade; over 1.5 million people had a prescription opioid use disorder in 2002, increasing to over 2 million people in 2012.[1] Reasons proposed for this increase include new formulations of prescription opioids, a lower threshold on the part of many physicians to prescribe opioids for pain, and easier access to these medications.[2] Calls to address the assessment needs of this growing population of patients who misuse primarily prescription opioids rather than heroin[2,3] have been followed by research comparing prescription opioid-dependent patients to heroin users.[4–7] For example, in comparison to heroin users, prescription opioid users have been found to be younger,[5] more likely to be white,[5] and more likely to report chronic pain[4] and a history of psychiatric treatment[4]. They are also less likely to have ever used opioids intravenously[7] or to have hepatitis C[5] than heroin users.

Although these findings contribute to an understanding of prescription opioid dependent patients, relatively little is known about their general well-being. Over the last few decades, health-related quality of life has been found to predict subsequent mortality or physical pain in various disease-specific populations such as patients with liver disease[8] and chronic pain.[9] This evidence, combined with the national Healthy People 2010 goals for wellness,[10] suggests that examination of health-related quality of life is important and timely and should be included in the assessment of drug-dependent patients.[11] Indeed, health-related quality of life is an emerging area of research in the addiction field.[12–14]

Early studies of health-related quality of life in substance use disorder (SUD) patients reported worse scores compared to general populations[15–17] and similar[16] or worse[17] scores compared to populations with other chronic diseases, based on one of the most widely used health-related quality of life measures, the Medical Outcome Study Short Form-36 (SF-36, or, alternatively, a 12- or 20-item version). These findings were based on samples with a variety of primary substances of abuse, potentially limiting their generalizability to specific SUD populations.

Studies focused on health-related quality of life exclusively in patients with opioid use disorders have consistently found worse scores for physical and mental domains compared to norms for the general population.[18–23] Studies of the differences between those with opioid use disorders and patients with non-SUD psychiatric disorders have yielded mixed results and are limited to fewer domains.[21,23] As in studies of health-related quality of life in other SUD populations, demographic variables may be associated with quality of life scores among opioid-dependent patients: studies generally suggest that women,[19,24–26] whites,[26] and older individuals[19,20,24,27] exhibit worse quality of life.

While these studies suggest significantly impaired health-related quality of life in patients with opioid use disorders, most such studies either consider only those who primarily use heroin or fail to separate findings by heroin vs. prescription opioid use. One study that did focus on quality of life in prescription opioid abusers reported lower health-related quality of life compared to population norms on all domains of the SF-36: vitality, physical and social

function, physical and emotional role limits, mental health, general health, and bodily pain; with women exhibiting more impairment than men.[28] That study was limited, however, by its targeted sampling of patients in private treatment centers, limiting generalizability. A recent opioid-dependence treatment study found no difference in mental or physical domains between heroin-dependent patients and prescription opioid-dependent patients,[6] although this study included only a small sample of prescription opioid users (n=61).

Because health-related quality of life measures have been useful in other SUD research but have received little attention to date in patients with prescription opioid-use disorders, utilization of these measures in this burgeoning population has been recommended. This represents an effort to evaluate the effect of treatments beyond a mere measure of amount of drug use, to assess such domains as consequences of use and overall functioning.[29] Indeed, research shows that standard measures of drug consumption have not been associated with quality of life scores.[15,23] In accordance with recommendations to assess quality of life in patients with SUD, we examined health-related quality of life in prescription opioid-dependent patients at entry to a large, national clinical trial.[30] This study is novel in extending a validated measure to a new population, comparing scores of prescription opioid-dependent patients to general populations, and examining correlates of health-related quality of life.

METHODS

Data were collected as part of the Prescription Opioid Addiction Treatment Study sponsored by the National Drug Abuse Treatment Clinical Trials Network, a multi-site randomized controlled trial (N=653) that examined different lengths of buprenorphine-naloxone treatment and varying intensities of counseling in the treatment of patients with prescription opioid dependence (see details of the parent study[30]). At the time that the main trial was designed, most studies examining the role of counseling in patients receiving opioid agonist treatment had focused on heroin-dependent patients receiving methadone maintenance treatment. Only one study had examined different intensities of counseling in patients receiving office-based buprenorphine-naloxone; most were heroin users (86%).[31] The only prior treatment study of prescription opioid users was a small feasibility study (n=15 nonrandomized patients), 7 of whom also used heroin.[32] It is not clear that findings regarding either length of pharmacotherapy or role of counseling from previous studies could be generalized to patients seeking office-based buprenorphine-naloxone treatment for prescription opioid dependence. In light of the increased prevalence of prescription opioid dependent patients[1] and the increasing use of buprenorphine (most commonly as buprenorphine-naloxone) by physicians in office-based treatment[33], we decided to study different durations of buprenorphine-naloxone and different intensities of counseling in the treatment of patients dependent upon prescription opioids. After approval by the Institutional Review Board at each of ten sites across the United States, patients entering treatment for prescription opioid dependence at the study sites were recruited.

Participants from the Prescription Opioid Addiction Treatment Study were all included in this analysis (N=653); they met DSM-IV criteria for current opioid dependence and were at least 18 years of age. Key exclusion criteria included heroin use on 4 days in the past

month, a lifetime diagnosis of opioid dependence due to heroin alone, a history of ever injecting heroin, a need for continued pain management with opioids, currently unstable psychiatric illness, or concurrent formal SUD treatment (see details[30]).

Measures

Quality of life was measured by the *Medical Outcome Study Short Form-36 (SF-36)* Health Survey,[34] which was administered to all patients at intake to the treatment study. This measure was designed for a variety of uses, from policy evaluation to clinical practice, and has been widely used in a variety of populations; strong psychometric properties have been reported (e.g., McHorney and colleagues[35]). As expected, internal consistency was strong in our sample (Cronbach's alpha=.88). A user's manual[36] presents scores derived from a national probability sample, balanced geographically, with a 68% response rate, for a general population (N=7003) and for subsets of that population, including a healthy population (n=1963) and disease-specific populations (e.g., depression; n=1006). Scores from our sample of prescription opioid users were compared to the population scores.

The Standard Version, which covers quality of life over the past four weeks, was used in the current study. Patients responded to 36 Likert-scaled items covering eight domains: vitality, physical and social function, physical and emotional role limits, mental health, general health, and bodily pain. Physical and Mental Component Summary scores were then computed. Scores are norm-based and range from 0–100 after transformation, with higher scores indicating better quality of life.

Additional standardized assessments were administered to all participants. The *Composite International Diagnostic Interview*[37] was used to diagnose SUDs and other selected psychiatric disorders (major depressive disorder and posttraumatic stress disorder). The *Pain and Opiate Analgesic Use Histo*ry, developed for this study, was administered at baseline to assess opioid use history, with a focus on the relationship between pain and opioid use. *The Fagerstrom Test for Nicotine Dependence*[38] is a 6-item measure with scores that range from 0–10, with higher scores indicating greater severity. *The Addiction Severity Index-Lite* (ASI)[39] is a semi-structured interview that measures the severity of problems related to substance use across seven different domains: alcohol, drug, legal, medical, psychiatric, family/social, and employment. ASI composite scores range from 0 to 1, with higher scores indicating greater problem severity; this measure was used to assess external validity for the SF-36 in this new population.

Statistical analysis

Comparisons to other populations[36] used z-tests, and associations between background variables and health-related quality of life used independent t-tests and analysis of variance; to adjust for multiple testing, we report only differences significant at the .001 level. Data were analyzed using SPSS v.20.[40]

RESULTS

Sample description

Most of the 653 study participants (91.3%) were white, and 40.0% were female. At baseline, mean age was 33.2 (sd=10.2), and mean years of education was 13.0 (sd=2.2). About half (49.9%) had never been married, and most (62.9%) were employed full-time. Approximately one-quarter (23.0%) reported lifetime heroin use; current chronic pain was common (42.0%). Oxycodone, extended-release, was the most commonly-abused opioid in the month prior to study entry (35.2% of the study population), followed by hydrocodone (32.3%), oxycodone, immediate-release, (18.7%), methadone (6.4%), morphine (2.1%), and other (5.3%).

Comparison to other populations

The SF-36 has been administered to large samples of the general population, as well as specific populations, permitting comparison of our sample to others. As expected, this sample of prescription opioid-dependent patients scored significantly worse (p<.001) than a healthy population and a general population on both the Mental (−15.3 points vs. healthy population; −12.3 vs. general population) and Physical Summary (−7.1 points vs. healthy population; −1.7 points vs. general population) scores; the differences were discernibly greater for the Mental Summary score (Fig. 1). Further, this sample scored significantly worse than a population with back pain, but similar to a depressed population on the Mental Summary score (−10.0 points vs. population with back pain, p<.001; +1.3 points vs. depressed population), and significantly better than both of these comparison populations on the Physical Summary score (+2.6 points vs. population with back pain; +2.4 points vs. depressed population; Fig. 1). The subset of patients in our study with a lifetime diagnosis of major depressive disorder (n=226) scored significantly worse on the Mental Summary score compared to a depressed population but were similar on the Physical Summary score (−5.2 points for Mental; and +1.5 points for Physical Summary scores).

Male prescription opioid-dependent patients in our study sample scored significantly worse on the Physical Summary score than their gender-matched counterparts in a general population (−2.0 points, p<.001); they were similar on the Mental Summary score. Women in our study sample scored considerably worse on the Mental Summary score than a general population of women (−13.7 points, p<.001), but were similar on the Physical Summary score (−1.7 points).

Next, our patient sample was compared by age to a general population, using categories reported in the SF-36 manual.[36] Only 1 patient was >64 years old, so the oldest age category was dropped. For each age category, the Physical and Mental Summary scores were significantly worse for the prescription opioid-dependent patients (with mean differences ranging from −3.6 to −5.0 points for Physical Summary scores and from −7.1 to −13.4 points for Mental Summary scores; all p values <.001), with one exception: the oldest age category (i.e., 55–64) was similar for the Physical Summary score. These age differences were also seen when men and women were examined separately.

Correlates of quality of life

Background characteristics that have been reported to be correlated with quality of life in other samples were examined in this population (Table 1). Men scored better than women on Mental Summary scores. Quality of life did not vary by race. Older age was associated with worse Physical Summary scores, as expected; age was not associated with Mental Summary score.

Other background characteristics of particular interest in understanding prescription opioid-dependent patients were examined, including chronic pain and use of other substances (Table 1). Patients with chronic pain scored worse on the Physical Summary score than those without chronic pain. Patients with an SUD other than opioid dependence scored worse on the Mental Summary score compared to patients dependent only on opioids. Quality of life did not vary by lifetime heroin use. While the dichotomous measure of smoking (yes or no) was not related to quality of life scores, the correlation between the Physical Summary score and the Fagerstrom Test for Nicotine Dependence among smokers was significant, with better quality of life scores (r=−.19, p<.001) associated with lower severity of nicotine dependence. Patients with major depressive disorder scored worse on the Mental Summary score, but not the Physical Summary score, whether this was a past-year or lifetime diagnosis.

Because the most consistent associations with SF-36 scores in this sample were for gender and chronic pain, we considered whether these variables might be associated. This was not the case: 44.4% of women and 40.3% of men had chronic pain ($\chi^2(1)$=1.10, p=.29). Further evidence of the independent association of gender and chronic pain with quality of life was provided by analyses adjusted for both variables.

DISCUSSION

This secondary analysis of a multi-site study of prescription opioid-dependent patients (N=653) evaluated their health-related quality of life, thus providing insight into the overall functioning of these patients.

Comparison to other populations

The current sample of prescription opioid-dependent patients had worse physical and mental quality of life than a healthy population or a general population,[36] similar to other opioid-use disorder populations.[18,20–22] However, they had better self-reported physical quality of life and similar mental quality of life compared to a depressed population, partially contradicting studies showing decrements in some physical and mental subscores among other opioid-use disorder populations[20,23] when compared to depressed patients. This may reflect the relatively short opioid use histories of our sample and the fact that 68% of them were seeking opioid dependence treatment for the first time. Patients in the current sample with a lifetime diagnosis of major depressive disorder in addition to prescription opioid dependence, however, did score worse on the Mental Summary scale than the depressed comparison population, similar to reports on patients with a mix of SUDs.[41]

Correlates of quality of life

The association between quality of life and other baseline characteristics was largely consistent with existing literature on health-related quality of life in patients with SUD. In the current sample, women showed more impairment in health-related quality of life than men, although only Mental Summary scores were significant; this is similar to findings in the general population,[36] as well as samples of patients with opioid dependence,[26] prescription opioid abusers,[24] patients receiving methadone maintenance treatment,[25] and patients with a variety of other SUDs.[17,42] Not surprisingly, given the small number of non-whites in this sample, scores were not significantly different across race. Other research has shown that older age was associated with worse physical and mental quality of life,[19,24,27] whereas, in the current sample, older patients scored worse on the Physical Summary score only, similar to reports on heroin-dependent patients.[20]

Our finding of worse physical quality of life in patients with chronic pain is not surprising since people with chronic pain have more physical problems. This supports earlier studies showing that health-related quality of life is worse in patients with chronic pain compared to the general population.[9,43] Other studies have shown that those with severe chronic pain were more likely to have mood and anxiety disorders,[44] suggesting worse mental quality of life as well, unlike the patients in our study; perhaps patients with moderate pain such as those in our sample are less likely to have lower mental quality of life than those with severe pain. Further, chronic pain has been implicated as a significant motivating factor for initiating opioid use among patients with prescription opioid dependence.[45]

A lifetime history of heroin use was not associated with poorer health-related quality of life at baseline, perhaps because our sample excluded regular heroin users. This finding supports earlier literature demonstrating discrepancies between other measures of drug use severity (i.e., heroin use) and quality of life[15] and adds to evidence suggesting that measures of health-related quality of life may provide additional useful information in determining functional status of patients.[15,29]

Although the presence or absence of current smoking was not related to health-related quality of life in this sample, higher scores on the Fagerstrom Test for Nicotine Dependence were associated with worse health-related quality of life. In contrast to our finding, other studies of health-related quality of life have shown that current smokers exhibit worse quality of life than nonsmokers on at least some domains of the SF-36.[46,47] Our findings, however, lend support to studies (e.g., Laaksonen and colleagues[46]) showing that this difference is driven by heavy smokers.

Limitations

The SF-36 is one of the most widely-used health-related quality of life measures. Advantages include ease of administration (i.e., self-report, similar to other quality of life measures) and low time burden (i.e., 5–10 minutes for completion). Some researchers argue that an expanded construct of quality of life overall, not simply health-related quality of life, constitutes the most important measure of outcome.[48] The current sample provides a broader perspective on the decrements in health-related quality of life among prescription opioid-

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dependent patients, but cannot be generalized to patients who abuse both heroin and prescription opioids regularly or to samples from different sociodemographic statuses.

Research & clinical implications

Examination of health-related quality of life has been shown to be useful over the last two decades due to its contribution to the quantification of costs,[49] impairment,[50] and changes in health status[10] for a wide variety of illnesses. Indeed, health-related quality of life is one of the key patient-reported outcomes that have gained prominence in the evaluation of the impact of new treatments.[51] Perhaps patient self-perception can be useful in assessing level of functional impairment and targeting areas to facilitate recovery in the clinical care of prescription opioid-dependent patients. This can be particularly germane for prescription-opioid dependent patients with chronic pain; while the proximal target of treatment may be the cessation or reduction of opioid use, the ultimate goal is, of course, improved functioning. Correlating reduction in opioid use with changes in functioning can help guide an overall treatment strategy. Indeed, research in depression and anxiety disorders[52] has shown that quality of life assessments can add an important dimension to overall evaluation of patients' treatment response, as symptom measures do not always present a complete picture of a patient's overall functioning or recovery. Furthermore, brief, widely-used measures of health-related quality of life such as the SF-36 enable comparisons of these factors between different patient populations that can inform both clinical treatment selection and policy decisions about the allocation of health care resources.

Acknowledgements

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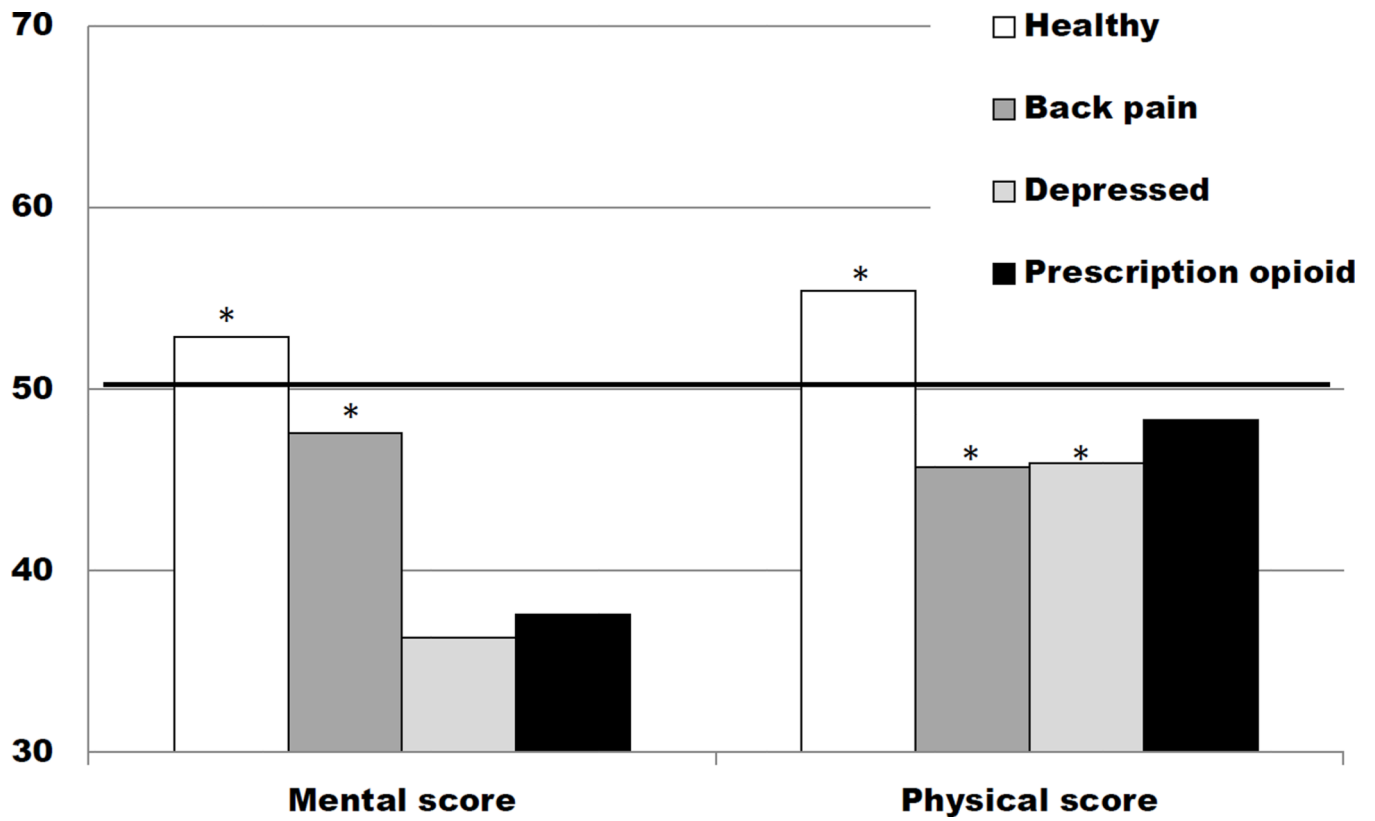
Figure 1.
Quality of life Mental and Physical Component Summary scores for various populations[29] compared to the prescription opioid samplea

aThe horizontal black line indicates general population means=50 (sd=10.0), by definition.

*p value <.001 compared to the prescription opioid sample

Table 1

Quality of life Physical and Mental Component Summary scores (SF-36)[a] at baseline by background characteristics among prescription opioid-dependent patients (N=653)

Background characteristics		Physical	Mental
Gender	Male (392)	49.0 (9.1)	39.5 (12.3)
	Female (261)	47.3 (10.8)	35.2 (13.0) [b]
White race	Yes (596)	48.5 (9.8)	37.7 (12.6)
	No (56)	46.5 (10.5)	38.1 (14.5)
Age	18–24 (150)	49.9 (9.1)	39.0 (12.2)
	25–34 (279)	49.1 (9.6)	37.2 (12.2)
	35–44 (115)	47.7 (10.7)	36.7 (13.4)
	45–54 (93)	44.7 (10.1) [c]	38.8 (14.6)
	55–64 (15)	46.5 (7.3)	38.2 (10.6)
Chronic pain	Yes (274)	43.1 (9.6)	37.6 (13.0)
	No (379)	52.1 (8.2) [d]	37.9 (12.5)
Non-opioid SUD	Yes (103)	47.3 (9.7)	32.5 (12.4)
	No (550)	48.5 (9.9)	38.8 (12.6) [e]
Heroin use, lifetime	Yes (150)	49.4 (9.4)	38.2 (12.9)
	No (503)	48.0 (10.0)	37.6 (12.7)
Smoker	Yes (489)	48.2 (9.8)	38.1 (12.7)
	No (164)	48.8 (10.2)	36.8 (12.9)
Major depressive disorder, lifetime	Yes (226)	46.9 (9.8)	31.1 (11.9)
	No (427)	49.1 (9.8)	41.3 (11.7) [f]
Major depressive disorder, past year	Yes (141)	46.5 (9.5)	27.3 (10.6)
	No (512)	48.8 (9.9)	40.7 (11.7) [g]

[a] Higher SF-36 scores indicate better quality of life, with a population average set to 50.

[b] $t_{(651)} = -4.35$, p<.001

[c] $F_{(4, 647)} = 4.91$, p<.001; Post hoc tests showed that scores were worse for 45–54 year olds compared to the two youngest age categories (i.e., 18–24 and 25–34)

[d] $t_{(530.2)} = 12.59$, p<.001

[e] $t_{(651)} = 4.65$, p<.001

[f] $t_{(651)} = 10.56$, p<.001

[g] $t_{(651)} = 12.25$, p<.001