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Health-related quality of life changes associated with buprenorphine treatment for opioid dependence

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Abstract

Background—Few studies have described improvement in health-related quality of life (HRQOL) associated with opioid dependence treatment with buprenorphine (ODT-B).

Objective—To evaluate HRQOL changes in domain scores, physical and mental component summaries, and health utilities (HUs) associated with ODT-B using the Short Form 36 (SF-36).

Methods—We assessed HRQOL changes in a substudy of a pharmacokinetic study that compared buprenorphine oral tablet and liquid dosage formulations over 16 weeks. Individuals, aged 18–65 years, were screened for opioid dependence. They were excluded if they would not agree to birth control or had a serious medical condition. Subjects received psychosocial counseling and weekly group therapy. The SF-36 was administered upon enrollment and at 4-

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week intervals. We used the SF-6D to estimate HUs. We performed intention to treat (ITT) analyses based on the last observation available for each subject. Paired t tests of each domain and HU, limited to remaining patients at each 4-week interval, were also conducted.

Results—Of 96 subjects enrolled, cumulative dropouts over time resulted in 80, 69, 59, and 44 subjects remaining at 4, 8, 12, and 16 weeks. There were no significant differences in opioid-positive urines, dropout rates, or dosage changes between formulations. In the ITT analyses, HRQOL improvements over time were bodily pain (62.1 vs. 69.1, $P = 0.017$), vitality (49.8 vs. 56.5, $P = 0.001$), mental health (59.9 vs. 66.0, $P = 0.001$), social function (66.4 vs. 74.7, $P = 0.001$), role emotional (59.4 vs. 71.9, $P = 0.003$), role physical (60.9 vs. 70.6, $P = 0.005$), and mental component summary (41.9 vs. 45.4, $P<0.001$). HU scores also improved (0.674 vs. 0.715, $P = 0.001$). Results from paired *t* tests, with only concurrently enrolled patients, showed similar improvements from baseline to 4, 8, 12, or 16 weeks.

Conclusion—Buprenorphine, accompanied with psychosocial counseling, was associated with improved HRQOL and HUs.

Keywords

Buprenorphine; Opioid dependence; Quality of life; Health utility

Introduction

The Food and Drug Administration approved buprenorphine as a treatment for opioid dependence in 2002. Buprenorphine may have a more favorable side effect profile than other opioid substitution treatments while remaining virtually equal in efficacy [1, 2]. Potential advantages are due to its pharmacological properties; it is a partial mu agonist and kappa antagonist as opposed to methadone, a mu agonist, thus causing less respiratory depression and euphoria. Expanding treatment availability was a primary objective of Drug Addiction Treatment Act (DATA) which allowed office-based opioid dependence treatment with buprenorphine (ODT-B), using outpatient prescriptions [3]. The training requirements for prospective prescribers of ODT-B specify that treatment be accompanied with appropriate psychosocial counseling, which is standard care for treatment of opioid addiction [4].

A disadvantage to ODT-B is the high cost of the drug which is about 10 times greater than methadone. These costs may be offset through decreased addiction-related morbidity and mortality associated with expanded treatment access [4–6]. Furthermore, DATA may expand opioid addiction treatment to new populations who might avoid methadone maintenance, such as patients addicted to prescription opioids [7, 8]. As opposed to methadone maintenance programs, health care costs associated with observation of dosing by health care personnel are avoided [5, 9]. Cost-effectiveness (CE) analyses comparing buprenorphine to methadone have been mixed, with favorable results in 2 modeling studies [5, 10] and a clinical trial [11], while another result from a clinical trial was less favorable [12].

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Studies have applied generic HRQOL instruments to measure the impact of opioid dependence treatment [13–20]. Three studies have incorporated the SF-36 or SF-12 to assess HRQOL among subjects with opioid dependence [15, 20, 21]. The SF-6D can be used to convert scores on the SF-36 to health utilities (HUs) [22]. HUs associated with health state descriptions were elicited from a healthy population in the United Kingdom to develop the validated scoring algorithm, SF-6D [22–24]. HUs provide an overall assessment of HRQOL along a scale in which 0 represents death and 1 represents optimal health [25–27]. Changes in HUs obtained longitudinally are used to calculate quality-adjusted life years (QALYs) which are used as the denominator in CE analyses, allowing comparisons of treatments between and within disease states [5, 11]. In a search of published literature, we found no previous studies of ODT-B in which the SF-36 was used to calculate HUs.

Our objectives were to evaluate the impact of ODT-B on (1) HRQOL domains of the SF-36 and (2) HUs obtained using the SF-6D. The results will help clinicians and policy makers assess the relative benefits of this treatment.

Methods

The SF-36 responses were collected during a pharmacokinetic study comparing buprenorphine tablets with buprenorphine liquid in outpatient treatment of opioid dependence [28]. The SF-36 was collected upon enrollment (B) and at 4-week intervals during the 16-week trial (W4, W8, W12, and W16).

Description of parent study

The parent study was a blinded, randomized clinical trial that was approved by the institutional review board and conducted between 1996 and 1998 [28]. The purpose of the parent study was to assess bioequivalence of the two buprenorphine formulations. Outpatients received both liquid (2 vials of active or placebo) and tablets (up to 4 tablets of 8 mg active or placebo) each day to achieve the dose required at each study time point. There were 2 groups: Group 1 received active liquid/placebo tablets for 12 weeks, followed by placebo liquid/active tablets for the last 4 weeks. Group 2 received placebo liquid/active tablets for 12 weeks, followed by active liquid/placebo tablets for 4 weeks. Dosage decreases were allowed for subjects experiencing side effects. All doses were given in clinic under observation. When the study ended at week 16, subjects were tapered off buprenorphine over time. To assure consistency of psychosocial interventions, all subjects were enrolled in a neurocognitive treatment program with required attendance at weekly group counseling sessions. Further study details are available in the parent study publication [28].

Study subjects—Potential subjects completed informed consent. Subjects were screened and met Diagnostic and Statistical Manual Version IV (DSM-IV) criteria for opioid dependence. Although subjects could also be abusing non-opioids, their primary dependence was to opioids. Other inclusion criteria were age 18–65 years, and males or non-pregnant, non-nursing females. Exclusion criteria were any acute or unstable medical condition such as infection or uncontrolled, chronic conditions such as diabetes; daily use of anticonvulsants, disulfiram, or neuroleptics; dependence upon alcohol or sedative/hypnotics;

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females of childbearing age who refuse birth control; and subjects not expected to be available the entire length of the study. There were no follow-up data collected after completing the 16-week study.

SF-36 survey data collection and summation

The SF-36 was chosen for this study because it is used in many illnesses, is self-administered by the patient in less than 15 min, and is understandable to most populations [29]. Scoring functions for the SF-36 have been validated and the instrument shown to be reliable [30, 31]. Subjects completed the survey using a computer program on a stand-alone microcomputer. The computer program was initiated by entry of a valid subject randomization number by study personnel, and then the subject completed the survey independently. Data were transformed and summated according to the scoring manuals provided by the Medical Outcomes Trust, New England Medical Center [32]. These computations result in physical and mental component summaries as well as scores for each domain ranging from 0 to 100, with 100 being the highest score. Norm-based scoring, whereby the population mean is 50 and standard deviation is 10, was also performed. We applied the formula for the SF-6D developed by Brazier and colleagues to convert SF-36 responses to HUs at each data collection time point [33–35]. This validated formula is based upon a framework that is consistent with theoretical concepts of HUs [26, 36–38].

Statistical analyses

The two-sided, overall level of statistical significance was alpha equal to 0.05. We compared treatment group assignment using an independent *t* test for number of positive urines and chi-square tests for retention rates and dose changes. Furthermore, repeated measures analysis of variance (ANOVA) with drug assignment (Group 1 or 2) as the grouping factor and HU over time (baseline vs. week 4 vs. week 8 vs. week 12 vs. week 16) as the repeating factor was conducted to assess whether there were differences in HU over time between the two groups. To determine whether the assumption of sphericity was violated, the Greenhouse-Geisser estimate was calculated and used to correct the degrees of freedom. Repeated measures ANOVA restricts data to those subjects in which observations are available for every time point; thus, only subjects who completed the protocol were suitable for this analysis.

After no differences between treatment groups were found, we combined HRQOL data from all patients and assessed changes in SF36 domain scores and HUs from baseline to each time point using paired t tests [9, 39, 40]. Thus, each subject’s baseline measure served as his/her own “control” value. We also conducted an intention to treat analysis, assuming HRQOL among subjects who left treatment early would not improve further had they remained on treatment, so the last HRQOL domain scores and HU values were used for subjects who dropped out prior to completing all 16 weeks. We applied a family-wise Bonferroni adjustment for these analyses ($P \leq 0.01$), because baseline scores were used repeatedly.

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Results

Four subjects dropped out prior to receiving study drug; therefore, the total sample consisted of 96 subjects. There were 66 men and 30 women. Their mean (±SD) age was 37.7 ± 9.7 years. Demographic information is displayed in Table 1.

Comparisons between treatment groups

Retention and positive urines are primary clinical outcomes in opioid addiction treatment research; therefore, we compared these outcomes between the two treatment groups [2, 41]. Mean number of opioid-positive urine test results was not significantly different (two tailed *t* test, $P = 0.384$) between Group 1 (2.4 ± 1.8) and Group 2 (2.2 ± 1.7). As commonly occurs in opioid treatment studies [39, 40, 42], forty-five patients (55.2%) dropped out or terminated prior to the completion of the 16-week study. There was no difference (chi-square, $P = 0.53$) in retention to study completion between treatment groups (Group 1:49% (24 of 49), Group 2: 43% (20 of 47)). Of 13 subjects who required dosage reductions due to medication effects (nausea, headache, or sedation), six had been randomized to Group 1 and seven had been randomized to Group 2 (chi-square, $P = 0.705$). No subjects died or were incarcerated. No subjects terminated from the study due to serious adverse drug reactions. Repeated measures ANOVA comparisons of the HU values between the two groups were non-significant for treatment group assignment ($F = 1.09$, $P = 0.301$, Greenhouse-Geisser estimate of sphericity: $\varepsilon = 0.833$). However, the main effect of time was significant ($F = 4.42$, adjusted degrees of freedom 3.33, 136.59, $P = 0.004$), indicating improvement of HU over time.

SF-36 domain scores, norm-based scores, physical and mental component summaries, and health utilities

Significant improvements from baseline were found for bodily pain (W8, W12), vitality (W8, W12, W16), social functioning (W4, W8), mental health (W4, W8), physical component summaries (W8), mental component summaries (W4, W8, W16), and HUs (W4, W8, W12, W16). In addition, ITT analyses demonstrated significant improvements from baseline for HUs, the mental component summary, and the domains of role physical, bodily pain, vitality, social function, role emotional, and mental health (Table 2). Results were similar for norm-based scores.

Discussion

Our results indicate that HRQOL improved through ODT-B; thus, the SF-36 was sensitive to improvements in HRQOL associated with ODT-B. During treatment, subjects in our study sustained improvements in 6 of the 8 domains of HRQOL (ITT analysis); the exceptions were physical functioning and general health (Table 2). Improvements were also found for mental component but not physical component summaries. The identification of improvement of specific domains of HRQOL provides insight into the benefits of opioid dependence treatment. It has been reported that opioid addicts may have increased sensitivity to pain, and chronic pain is a risk factor for opioid dependence [43–45]. The improvement in the domain of bodily pain suggests that ODT-B impacted this problem. The

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improvements in vitality, social functioning, role physical, role emotional, and mental health reflect changes in both physical and psychological aspects of HRQOL. A potential for future research involves identifying relationships between the SF-36 and other measures, such as scores from other clinical measures of addiction treatment and long-term treatment success.

Improvements in HUs and implications for cost-effectiveness

The baseline HU was higher in our study (0.67) than shown in a previous study that compared methadone to buprenorphine for opioid dependence treatment (0.59), which used the Australian Quality of Life instrument [11]. In addition to differences in subjects, the variation from the previous study may be due to differences in HU instruments. These variations have been demonstrated across other instruments and in other conditions and reflect diversity in development, design, and theoretical constructs [46, 47]. However, we note that the HU improvements associated with buprenorphine found in our study are similar to the previous study (0.04) [11]. In a literature review, the minimally important clinical difference of HU using the SF-6D algorithm was found to be 0.033 (range 0.010–0.048) [24]. Since this value was exceeded (Table 2), our results suggest that the HU improvement is clinically important. It is also comparable to improvements associated with other health care treatments [24, 48–50].

Limitations

We note that our results do not necessarily generalize to all patients receiving ODT-B or other opioid addiction treatment programs. Also, the data were collected in the late 1990s. Changes in the populations of opioid-dependent individuals who are seeking treatment (older, lower percentage of injectable heroin usage, increases in proportion of non-Hispanic white ethnicity) have occurred over time [51]. Therefore, our results do not generalize directly to the current population of opioid-dependent individuals. Another limitation of this study is that all subjects received active treatment. Thus, comparisons are within subjects. Although we were unable to compare our results to an inactive treatment, it is unlikely that untreated subjects would experience similar improvements in HRQOL.

We acknowledge the high dropout rate, which is common in opioid addiction treatment research [39, 40, 42]. Our dropout rate of 40% at 12 weeks is very similar to a previous study of buprenorphine in which dropout rate was 45% at 12 weeks [39]. Also, since no data were collected after disenrollment, it is unknown whether improvements in HRQOL among subjects who dropped out were sustained. A previous study comparing buprenorphine with methadone demonstrated that improved HU was sustained over a 1-year ongoing treatment period [11].

A potential limitation of using the SF-6D to determine HUs is that the scoring algorithm was derived from a healthy population in the United Kingdom. There is controversy in HRQOL literature regarding use of population studies among healthy individuals to derive HUs from HRQOL surveys [52, 53]. A study comparing the US versus UK versions of the EQ-5D demonstrated the versions to have similar psychometric properties [54].

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Conclusion

We found that HRQOL improved among subjects who received ODT-B. The changes were maintained while patients remained in treatment. Our result demonstrates that the SF-36 and its HU conversion, the SF-6D, may be helpful in measuring outcomes of opioid dependence treatment.

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Table 1

Demographic characteristics

Characteristic	Specification	Value
Gender	Female	30 (31%)
	Male	66 (69%)
Age (years)	Mean (SD), range	37.7 (9.7), 18–65
Race	White	50 (52%)
	Black	8 (8%)
	American Indian	3 (3%)
	Asian/Pacific Islander	4 (4%)
	Hispanic—Mexican	26 (27%)
	Hispanic—Cuban	1 (1%)
	Other Hispanic	5 (5%)
Addiction severity index composite scores (higher scores = more severe)	Medical status, mean (SD)	0.06 (0.17)
	Employment/support status, Mean (SD)	0.50 (0.32)
	Drug use, mean (SD)	0.30 (0.09)
	Alcohol use, mean (SD)	0.05 (0.08)
	Legal status, mean (SD)	0.09 (0.16)
	Family social relationships, mean (SD)	0.15 (0.19)
	Psychiatric status, mean (SD)	0.08 (0.17)

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Table 2

SF-36 domain scores, component summaries, health utilities (HUs), and HU changes during the study, mean ± standard deviation

Domain/HU	Baseline *n* = 96	Week 4 *n* = 80	Week 8 *n* = 69	Week 12 *n* = 59	Week 16 *n* = 44	Intention to treat analysis (last observation)
Physical function	76.1 ± 27.1	82.6 ± 23.6	80.1 ± 25.6	80.5 ± 28.3	78.6 ± 27.9	79.8 ± 26.0
Norm-based score	47.8 ± 11.4	49.9 ± 9.9	48.8 ± 10.7	49.0 ± 11.9	48.2 ± 11.7	48.7 ± 10.9
Role physical	60.9 ± 38.4	67.8 ± 39.6	71.7 ± 38.1[a]	69.1 ± 38.4	72.7 ± 38.1	70.6 ± 36.9[a]
Norm-based score	45.2 ± 10.8	47.1 ± 11.2	48.2 ± 10.8[a]	47.5 ± 10.9	48.5 ± 10.8	47.9 ± 10.4[a]
Bodily pain	62.6 ± 25.0	69.2 ± 25.2	73.6 ± 24.4[a]	72.6 ± 21.9[a]	72.7 ± 26.3	69.1 ± 24.4[a]
Norm-based score	46.8 ± 10.7	49.6 ± 10.8	51.5 ± 10.4[a]	51.0 ± 9.4[a]	51.1 ± 11.3	49.5 ± 10.5[a]
General health	65.7 ± 19.9	69.3 ± 19.9	70.8 ± 18.9	67.1 ± 22.7	69.1 ± 20.8	67.9 ± 18.4
Norm-based score	48.1 ± 9.8	49.5 ± 9.2	50.3 ± 8.9	48.7 ± 10.7	49.5 ± 9.7	49.0 ± 8.6
Vitality	49.8 ± 19.0	54.3 ± 19.9	59.3 ± 22.2[a]	59.8 ± 22.6[a]	61.6 ± 25.0[a]	56.5 ± 22.3[a]
Norm-based score	47.4 ± 9.3	48.7 ± 9.3	51.0 ± 10.4[a]	51.5 ± 10.8[a]	52.2 ± 11.8[a]	49.7 ± 10.5[a]
Social function	66.4 ± 26.6	75.8 ± 21.4[a]	76.3 ± 23.8[a]	74.6 ± 25.4	77.0 ± 23.9	74.7 ± 22.0[a]
Norm-based score	42.9 ± 12.0	46.6 ± 9.4[a]	47.1 ± 10.3[a]	45.7 ± 11.0	47.1 ± 10.4	46.2 ± 9.6[a]
Role emotional	59.4 ± 41.9	68.3 ± 37.8	69.6 ± 38.7	71.2 ± 37.9	78.0 ± 34.4	71.9 ± 38.5[a]
Norm-based score	42.8 ± 13.1	45.3 ± 12.0	45.7 ± 12.2	46.2 ± 12.0	48.4 ± 10.9	46.5 ± 12.2[a]
Mental health	59.9 ± 20.5	68.1 ± 19.5[a]	68.4 ± 20.8[a]	67.4 ± 22.0	70.1 ± 21.7	66.0 ± 20.2[a]
Norm-based score	41.9 ± 12.0	45.7 ± 10.8[a]	46.5 ± 12.0[a]	45.6 ± 12.5	47.1 ± 12.3	44.7 ± 11.4[a]
Physical component summary	49.0 ± 9.2	50.5 ± 8.6	51.1 ± 8.9[a]	50.4 ± 8.8	50.0 ± 9.2	50.2 ± 8.3
Mental Component summary	41.9 ± 12.7	45.1 ± 10.6[a]	46.2 ± 11.4[a]	45.9 ± 11.8	48.3 ± 11.4[a]	45.4 ± 11.4[a]
HU	0.67 ± 0.12	0.73 ± 0.14[a]	0.74 ± 0.14[a]	0.73 ± 0.14[a]	0.74 ± 0.15[a]	0.72 ± 0.14[a]
Mean HU change from baseline (95% confidence interval)	Not applicable	0.047 (0.019–0.076)	0.059 (0.031–0.087)	0.054 (0.022–0.085)	0.051 (0.011–0.130)	0.041 (0.017–0.065)

[a]Significantly different from baseline for domain, component summary, or HU, paired *t* test, $P \leq 0.01$