Brief article

Substance use and quality of life over 12 months among buprenorphine maintenance-treated and methadone maintenance-treated heroin-addicted patients

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Received 12 August 2006; received in revised form 4 November 2006; accepted 24 November 2006

Abstract

The purpose of this study was to investigate the effects of methadone treatment and buprenorphine treatment on retention in treatment, urine drug testing results, psychiatric status, social adjustment, and quality of life among patients involved in long-term treatment with the cited medications. Two hundred thirteen patients (106 on buprenorphine treatment and 107 on methadone treatment) were enrolled in this open study at the 3rd month of their treatment and followed up until the 12th month; those who left the program before the end of the 3rd month of their treatment were not included in the study sample. The results of this study show statistically significant improvements in opioid use, psychiatric status, and quality of life between the 3rd and 12th months for both medications. This study suggests the long-term efficacy of methadone treatment and buprenorphine treatment on symptoms of opioid addiction and quality of life. © 2007 Elsevier Inc. All rights reserved.

Keywords: Methadone maintenance; Buprenorphine treatment; Psychopathology; Quality of life

1. Introduction

In medicine, attention to quality of life deals with the impact of diseases and treatments on patients’ everyday lives. Traditional approaches to evaluating the consequences of a disease or the efficacy of its treatment have focused on the specific signs and symptoms of illnesses. However, changes in the magnitude of disease signs or symptoms do not necessarily reflect changes in the well-being of individuals. Indicators that come closer to the interests of patients and their subjective well-being are used in evaluating quality of life. The usual dimensions included in evaluating quality of life actually refer to the physical, psychiatric, and social areas.

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Methadone maintenance treatment programs can offer an effective treatment for opioid addiction. Their efficacy on retention in treatment, heroin use, psychiatric status, and social adjustment has been repeatedly demonstrated in retrospective and prospective cohort studies and confirmed in randomized controlled trials (Ball & Ross, 1991; Ball, Corty, Bond, Myers, & Tommasello, 1988; Cooper, 1989; Dole & Nyswander, 1966; Dole, Nyswander, De Jerlais, & Joseph, 1982; Hubbard et al., 1989; Strain, Sitzer, Liebson, & Bigelow, 1993a, 1993b).

Over the last 10 years, buprenorphine has been added as a new tool in providing maintenance treatment for opioid dependence. Its efficacy has been shown in a number of trials in terms of retention in treatment, reduction in heroin use, psychiatric status, and social adjustment (Fischer et al., 1999; Johnson et al., 2000; Johnson et al., 1995; Johnson, Jaffe, & Fudala, 1992; Kosten, Schottenfeld, Ziedonis, & Falcioni, 1993; Ling et al., 1998; Ling, Wesson, Charuvastra, & Klett, 1996; Mattick et al., 2003; Pani, Maremmani, Pirastu, Tagliamonte, & Gessa, 2000; Petitjean et al., 2001; Schottenfeld, Pakes, Oliveto, Ziedonis, & Kosten, 1997; Strain, Sitzer, Liebson, & Bigelow, 1994a, 1994b; Strain, Sitzer, Liebson, & Bigelow, 1996; Uehlinger et al., 1998). These studies have shown the clear superiority of buprenorphine over placebo and the comparable efficacy of methadone and buprenorphine in terms of psychiatric status, social adjustment, and reduction in heroin use. Some studies carried out to compare buprenorphine with methadone doses higher than 60 mg have however reported better outcomes for methadone (Ling et al., 1996; Mattick, Kimber, Breen, & Davoli, 2004; Petitjean et al., 2001). Moreover, in looking into retention in treatment, the meta-analyses that are available have shown better performance for patients treated with methadone as compared with those treated with buprenorphine (Barnett, Rodgers, & Bloch, 2001; Mattick et al., 2004).

Maintenance treatments for opioid dependence with methadone or buprenorphine can be expected to continue for years in many patients. The long-term nature of these treatments calls for an evaluation of the functional state and quality of life of enrolled patients. One clear aim is that the effect of medication and the objectives promoted by maintenance treatments should not produce negative impacts on the functional state or quality of life of patients. Some studies have focused on, or included in their focus, patients’ functional state and quality of life during long-term methadone or buprenorphine treatment (Barnett et al., 2001; Giacomuzzi et al., 2003; Giacomuzzi, Ertl, Kemmler, Riener, & Vigl, 2005; Giacomuzzi, Kemmler, Ertl, & Riener, 2006; Harris, Gospodarevskaia, & Ritter, 2005; Pani et al., 2000; Strain et al., 1994a; West, O’Neal, & Graham, 2000). Findings from these studies suggest that methadone and buprenorphine can increase the functional state and quality of life of patients treated for a long time with either medication.

The present study continued this line of research to verify retention in treatment, use of substances (heroin and cocaine), psychopathology, and quality of life among Italian patients enrolled in longer-term (>1 year) opioid dependence treatment with buprenorphine or methadone maintenance.

2. Methods

2.1. Study design

A multisite cohort study was designed to evaluate the treatment outcomes (in terms of retention in treatment, substance use, psychopathology, and quality of life) of patients staying in treatment beyond the early attrition stage (3 months) in a methadone or buprenorphine program. This was an open, nonrandomized, and observational study.

The beginning of the prospective observation period was fixed at the end of the third month of treatment. Some retrospective data on the previous 3 months were also collected. Follow-up evaluation was carried out 12 months after the beginning of treatment. All patients gave their informed consent to participate in the study. Study procedures were approved by the appropriate ethics committees in accordance with internationally accepted criteria for ethical research.

2.2. Setting

Twelve drug addiction treatment units chosen on the basis of having a larger number of patients in maintenance treatment, the availability of laboratory equipment able to guarantee regular toxicological urinalyses, the availability of integrated pharmacologic and psychosocial services (counseling and supportive psychotherapy; McLellan et al., 1993), and willingness to participate in the research participated in the study. The choice of treatment for all patients at these units was made as a clinical decision by treatment staff based on an assessment of the patients, the scientific knowledge then available, and agreement with the patients. No specific guideline or protocol regarding prescription of methadone or buprenorphine was required.

2.3. Participants

Participants were enrolled according to the following inclusion criteria:

- at least 1 year of addiction;
- diagnosis of opioid dependence (according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV] criteria);
- in methadone or buprenorphine treatment for a period not exceeding 3 months;
- older than 18 years; and
- willingness to sign an informed consent document.
No set of exclusion criteria was applied. All 213 patients who entered the six programs for opioid treatment during calendar 2002 agreed to participate and were enrolled. All patients received standard care in their units, and the study did not interfere with treatment.

The mean age of the patients was 31 years (SD = 6). Of all the patients, 176 (82.6%) were male, 130 (61.0%) were single, 135 (63.4%) had less than 8 years of education, 89 (39.4%) were polyabusers, 81 (38%) were unemployed, 6 (2.8%) received welfare benefits, and 14 (6.6%) were HIV positive. A lifetime psychiatric illness was present in 51 (2.8%) patients. Among the patients, the mean age at their first use of heroin was 19 ± 4 years and the duration of their dependence was 91 ± 4 months.

2.4. Instruments and measures

The following instruments were used for data collection:

- Drug Addiction History Rating Scale (administered at the beginning of treatment; Maremmani & Castrogiovanni, 1989). This instrument is a multi-scale questionnaire composed of the following categories: sociodemographic information; physical health; mental health; substances abused; treatment history; social adjustment; and environmental factors. It rates 10 items: physical problems, mental problems, substance abuse, previous treatment, associated treatments, employment status, family situation, sexual problems, socialization and leisure time, and legal problems.

- Symptom Checklist 90 (SCL-90; administered at 3 and 12 months; Derogatis, Lipman, & Rickels, 1974). This is an inventory composed of 90 items, with a point scale ranging from 0 to 5 to allow for assessment of intensity. The items are grouped into nine factors related to different psychopathologic dimensions: somatization, interpersonal sensitivity, obsession-compulsions, depression, anxiety, anger and hostility, phobic anxiety, paranoid ideation, and psychoticism.

- DSM-IV Global Assessment of Functioning (GAF) Scale (administered at the beginning of treatment and after 3 and 12 months; American Psychiatric Association, 1994). This is scored on a 100-point scale (with higher numbers indicating better functional status), considers psychologic, social, and occupational functioning within the sphere of a hypothetical mental health illness continuum, and does not include the impairment of functioning caused by physical or environmental limitations.

- Clinical Global Impression (CGI; administered at the beginning of treatment and at 3 and 12 months). This instrument considers the severity of the disorder, the degree of improvement, and any adverse reaction.

- Quality-of-Life Questionnaire (QLQ; administered at 3 and 12 months). This is a semistructured interview investigating the following life dimensions: job; leisure; appetite; sleep; social relationships; social involvement; income; parental role; romantic relationships; and self-acceptance. It was chosen for its minimal overlap and good fit with the other instruments (Blau, 1977; Vanagas, Padaiga, & Subata, 2004). The scales included for this study were working, earnings, leisure, eating, sleeping, social relations, romantic relations, parenting, environment, and self-acceptance. Each scale was measured on the following metric structure: 0 = nonexistent or no opportunity; 10 = minimal; 30 = adequate; and 50 = best possible. The intermediate values are 20 and 40. A total score of 350 or higher indicates fairly successful living conditions and quality of life, that between 250 and 350 suggests a situation of painful but adequate ability to cope, and that between 100 and 250 is found among people who suffer a lot and seek immediate help. Institutionalized mental patients score below 100 (Blau, 1977).

- Urine drug testing (randomized with a frequency of at least once per month) for opioids and cocaine. Sample collection was supervised by a nurse to prevent fraud. Urine samples that were skipped because of patients’ unavailability were registered as positive for opioids. The total number of urine screening tests collected was 4,086.

- Data Sheet for Adverse Events (registered every month). The questions regarding adverse events were open-ended. The signs and symptoms or life events did not necessarily have to be caused by the drugs under study.

Adopting the criteria of Vanagas et al. (2004), we chose to address quality of life by using a combination of the global score on the DSM-IV GAF Scale and the total scores on the QLQ and SCL-90 instruments. Other instruments (urinalyses, adverse events, and CGI) evaluated disease symptoms and their treatment. The choice of these instruments was made to assess quality of life in the most comprehensive or overall manner, including the four domains suggested by Aaronson (1989): (1) physical functional status; (2) disease- and treatment-related physical symptoms; (3) psychologic functioning; and (4) social functioning.

2.5. Data analysis

Analysis of the results for the participants was conducted upon their completion of 12 months of treatment. The two groups of patients undergoing treatment, with buprenorphine and with methadone, were compared for sociodemographic data and addiction history with the use of $\chi^2$ analysis for categorical variables and Student’s $t$ test for continuous variables. Logistic regression analysis was used to discriminate features between the buprenorphine-treated patients and the methadone-treated patients at admission.
The significant variables extracted were considered as covariates in subsequent analyses. Retention in treatment was analyzed with the use of survival analysis and Lee–Desu statistics for comparison between the survival curves. For the purpose of this analysis, “completed observations” represent patients who left the treatment and “censored observations” represent patients still in treatment at the end of the 12-month period or who discontinued treatment for reasons unrelated to the treatment itself (e.g., moving to another town, imprisonment for old crimes, and so on).

Toxicological urinalysis findings were expressed as the percentage of the total number of positive results for each patient. Comparisons between the two groups were conducted with the use of Student’s t test. Regarding psychopathology and quality of life, analysis of variance for cross-sectional evaluations and repeated measures multivariate analysis of variance for longitudinal evaluations were used adjusting for baseline differences between groups.

3. Results

3.1. Evaluation at the beginning of treatment

More males (87.7% vs. 77.6%, $\chi^2 = 3.83, p = .05$) and fewer unemployed patients (27.4% vs. 48.6%, $\chi^2 = 9.98, p = .006$) were present in the buprenorphine group. The two groups did not differ significantly in the other demographic variables investigated (age, education, marital status, and welfare benefits).

In addition, patients on buprenorphine treatment had fewer physical complications (60.4% vs. 73.8%, $\chi^2 = 4.36, p = .036$), less psychopathology (64.2% vs. 77.6%, $\chi^2 = 4.64, p = .031$), fewer job problems (25.5% vs. 55.1%, $\chi^2 = 19.46, p = .0001$), and lower severity of problems in relationships (16.0% vs. 28.0%, $\chi^2 = 4.45, p = .030$). Severity of illness as assessed by the CGI was lower among patients who left the treatment and those in methadone treatment controlled for baseline differences (age, education, marital status, and welfare benefits).

Patients from both groups did not differ significantly in rates of HIV or AIDS infection, family problems, problems with leisure time, legal problems, and general social adjustment problems. No significant difference was observed either in age at first use of substances, number of substances abused, frequency of use of heroin, duration of addiction, number of previous treatments, age at first treatment, and presence of associated treatments.

Logistic multivariate analysis ($\chi^2 = 50.04, df = 4, p < .0001$) showed four factors that significantly discriminated between the buprenorphine-treated group and the methadone-treated group at the beginning of treatment: sex, job problems, previous treatment, and CGI severity; there were fewer males, higher CGI severity, more prior treatments, and poorer job adjustment in the methadone treatment group. These baseline characteristics were used as covariates in subsequent comparisons between the two groups.

3.2. Third-month evaluation

As shown in Table 1, no significant difference was seen between the two groups in terms of negative urinalysis findings for opioids or cocaine at the end of the third month of treatment. The GAF Scale, SCL-90, and CGI failed to show significant differences between the two groups of patients. Quality-of-life total and work scores did differ between groups, with better results for patients enrolled in buprenorphine treatment.

The third-month average buprenorphine daily dose was 7.60 mg ($SD = 4.6, Mdn = 8$, mode = 8, range = 1–32). The average methadone daily dose was 69.4 mg ($SD = 26.4, Mdn = 60$, mode = 60, range = 30–190).

### Table 1

<table>
<thead>
<tr>
<th>Buprenorphine treatment patients ($n = 106, M$)</th>
<th>Methadone treatment patients ($n = 107, M$)</th>
<th>Main Effects × Group</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis</td>
<td></td>
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</tr>
<tr>
<td>Clean urine for heroin</td>
<td>0.90</td>
<td>0.86</td>
<td>0.36</td>
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<tr>
<td>Clean urine for cocaine</td>
<td>0.93</td>
<td>0.88</td>
<td>2.14</td>
<td>.14</td>
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<tr>
<td>CGI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of illness</td>
<td>3.13</td>
<td>3.28</td>
<td>0.19</td>
<td>.65</td>
</tr>
<tr>
<td>Global improvement</td>
<td>2.42</td>
<td>2.72</td>
<td>0.31</td>
<td>.57</td>
</tr>
<tr>
<td>Efficacy index</td>
<td>2.29</td>
<td>2.07</td>
<td>0.23</td>
<td>.62</td>
</tr>
<tr>
<td>DSM-IV GAF index</td>
<td>63.97</td>
<td>60.53</td>
<td>0.06</td>
<td>.79</td>
</tr>
<tr>
<td>SCL-90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somatization</td>
<td>0.54</td>
<td>0.72</td>
<td>0.85</td>
<td>.35</td>
</tr>
<tr>
<td>Obsessive-compulsive</td>
<td>0.60</td>
<td>0.74</td>
<td>0.07</td>
<td>.79</td>
</tr>
<tr>
<td>Interpersonal sensitivity</td>
<td>0.50</td>
<td>0.65</td>
<td>1.02</td>
<td>.31</td>
</tr>
<tr>
<td>Depression</td>
<td>0.62</td>
<td>0.84</td>
<td>1.07</td>
<td>.30</td>
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<tr>
<td>Anxiety</td>
<td>0.49</td>
<td>0.71</td>
<td>2.12</td>
<td>.14</td>
</tr>
<tr>
<td>Anger</td>
<td>0.49</td>
<td>0.61</td>
<td>0.08</td>
<td>.77</td>
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<tr>
<td>Phobic anxiety</td>
<td>0.25</td>
<td>0.35</td>
<td>0.41</td>
<td>.52</td>
</tr>
<tr>
<td>Paranoid ideation</td>
<td>0.57</td>
<td>0.75</td>
<td>1.08</td>
<td>.30</td>
</tr>
<tr>
<td>Psychoticism</td>
<td>0.37</td>
<td>0.58</td>
<td>2.20</td>
<td>.13</td>
</tr>
<tr>
<td>Total score</td>
<td>0.51</td>
<td>0.69</td>
<td>1.00</td>
<td>.31</td>
</tr>
<tr>
<td>Positive symptoms</td>
<td>30.06</td>
<td>36.08</td>
<td>0.46</td>
<td>.49</td>
</tr>
<tr>
<td>Positive symptom distress</td>
<td>1.34</td>
<td>1.46</td>
<td>0.41</td>
<td>.52</td>
</tr>
</tbody>
</table>

* Between 1 (normal) and 7 (extremely ill).  
* Between 1 (markedly improved) and 7 (worse).  
* Between 0 (worse–outweighs) and 4 (marked–no side effects).
Table 2
Results of repeated measures analysis of variance

<table>
<thead>
<tr>
<th></th>
<th>Buprenorphine treatment patients (n = 83)</th>
<th>Methadone treatment patients (n = 80)</th>
<th>Repeated measures multivariate analysis of variance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 months (M ± SD)</td>
<td>12 months (M ± SD)</td>
<td>Group (F) Time (F) Group × Time (F)</td>
</tr>
<tr>
<td>Urinalysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clean urine for opioids</td>
<td>81.35 ± 31.2</td>
<td>92.98 ± 23.3</td>
<td>65.94 ± 39.8</td>
</tr>
<tr>
<td>Clean urine for cocaine</td>
<td>89.30 ± 24.4</td>
<td>92.36 ± 22.8</td>
<td>84.09 ± 23.9</td>
</tr>
<tr>
<td>CGI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of illness</td>
<td>3.12 ± 1.2</td>
<td>2.25 ± 1.0</td>
<td>3.22 ± 0.9</td>
</tr>
<tr>
<td>Global improvement</td>
<td>2.42 ± 1.0</td>
<td>1.74 ± 1.0</td>
<td>2.72 ± 0.9</td>
</tr>
<tr>
<td>Efficacy index</td>
<td>2.31 ± 1.1</td>
<td>3.20 ± 0.9</td>
<td>2.00 ± 0.8</td>
</tr>
<tr>
<td>DSM-IV GAF index</td>
<td>68.73 ± 12.4</td>
<td>76.88 ± 12.6</td>
<td>64.90 ± 10.2</td>
</tr>
<tr>
<td>SCL-90</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Somatization</td>
<td>0.52 ± 0.5</td>
<td>0.35 ± 0.5</td>
<td>0.70 ± 0.7</td>
</tr>
<tr>
<td>Obsessive-compulsive</td>
<td>0.59 ± 0.6</td>
<td>0.39 ± 0.5</td>
<td>0.71 ± 0.7</td>
</tr>
<tr>
<td>Interpersonal sensitivity</td>
<td>0.47 ± 0.5</td>
<td>0.30 ± 0.4</td>
<td>0.63 ± 0.7</td>
</tr>
<tr>
<td>Depression</td>
<td>0.60 ± 0.6</td>
<td>0.39 ± 0.6</td>
<td>0.79 ± 0.8</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.49 ± 0.6</td>
<td>0.32 ± 0.5</td>
<td>0.65 ± 0.7</td>
</tr>
<tr>
<td>Hostility</td>
<td>0.51 ± 0.6</td>
<td>0.38 ± 0.6</td>
<td>0.57 ± 0.7</td>
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<tr>
<td>Phobic anxiety</td>
<td>0.26 ± 0.4</td>
<td>0.22 ± 0.5</td>
<td>0.37 ± 0.6</td>
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<tr>
<td>Paranoid ideation</td>
<td>0.54 ± 0.5</td>
<td>0.41 ± 0.6</td>
<td>0.71 ± 0.8</td>
</tr>
<tr>
<td>Psychoticism</td>
<td>0.37 ± 0.4</td>
<td>0.24 ± 0.4</td>
<td>0.53 ± 0.7</td>
</tr>
<tr>
<td>Global score index</td>
<td>0.50 ± 0.4</td>
<td>0.34 ± 0.4</td>
<td>0.65 ± 0.7</td>
</tr>
<tr>
<td>Positive symptom index</td>
<td>29.74 ± 20.1</td>
<td>20.68 ± 22.4</td>
<td>34.13 ± 28.5</td>
</tr>
<tr>
<td>Positive symptom distress</td>
<td>1.32 ± 0.4</td>
<td>1.16 ± 0.4</td>
<td>1.43 ± 0.4</td>
</tr>
</tbody>
</table>

* p < .05.  ** p < .01.

3.3. Twelfth-month follow-up

3.3.1. Retention in treatment

At 12 months (Table 2), 83 (78.30%) of the 106 patients in treatment with buprenorphine were still in treatment. During the same period, 80 (74.76%) of the 107 patients in treatment with methadone were still in treatment. Five patients were transferred to other programs for reasons independent of their treatment. No statistically significant difference was observed (Lee–Desu statistic = .053, p = .818).

3.3.2. Longitudinal analysis

Longitudinal analysis was carried out with patients who were still in treatment at 12 months. For patients completing the period of observation, statistically significant effects over time included a reduction in the use of opioids and cocaine and an improvement in clinical status, social adjustment, and quality of life as assessed with the CGI, GAF Scale, SCL-90, and QLQ measures. There was no significant group or group-by-time interaction shown.

The 12th-month average buprenorphine daily dose was 5.10 ± 3.1 mg (Mdn = 4, mode = 4, range = 1–16). The average methadone daily dose was 61.68 ± 28.8 mg (Mdn = 60, mode = 60, range = 10–160).

3.3.3. Adverse events

We tested the presence of side effects each month, recording a total of 1,150 observations in the buprenorphine-treated group and that of 1,158 in the methadone-treated group. Only 46 minor adverse reactions were reported by 24 patients. Seventeen patients (16.0%) from the buprenorphine group reported experiencing adverse reactions, whereas 9 (6.5%) from the methadone group reported experiencing such (χ² = 4.80, p = .02). The between-groups difference in number of side effects was not statistically significant (2.17 ± 2.8 vs. 1.28 ± 0.4, Mann–Whitney U = 51.5, two-tailed p = .54).

Buprenorphine-treated patients reported experiencing headache (7 observations), constipation (3 observations), asthenia (18 observations), insomnia (6 observations), and somnolence (3 observations). Methadone-treated patients reported experiencing asthenia (2 observations) and constipation (7 observations). All the reactions reported were judged to be minor in severity, and no treatment was required.

4. Discussion

This study was designed to examine functional status and quality of life among patients treated over 1 year with methadone or buprenorphine. Our patients were enrolled in the study after the third month of their treatment, so we have no information about those who left their treatment at an earlier stage, although the first 3 months of treatment can be
a critical period (Simpson, 1979, 1981; Simpson, Joe, & Rowan-Szal, 1997). We are also aware that cases of dropping out from treatment can be more frequent with buprenorphine than with methadone (Barnett et al., 2001; Mattick et al., 2004). However, our study was designed to examine the specific results obtained by patients who remained after early attrition and not to compare the efficacy of the two compounds.

Given these restrictions, our results suggest that patients enrolled in long-term methadone or buprenorphine treatment show improved status in control over substance use (notably, heroin and cocaine), psychiatric status, social adjustment, and general quality of life. Moreover, our results indicate few differences between patients who were placed on these medications following normal clinical guidelines and patient preference.

By the third month of treatment—and controlling for significant baseline differences between the two groups—both groups showed reduced substance use (for both groups, rates of negative urinalysis findings were ≥85%) and good quality of life (for both groups, the total QLQ score was >250, reflecting adequate ability to cope; Blau, 1977). The only significant differences between the groups were the work score and the total QLQ score, for which the condition of buprenorphine-treated patients was better than that of methadone-treated ones. These differences were not clinically significant and cannot be attributed in this study to differential effects of the medications.

By the 12th month, the retention rate for patients who survived early attrition was greater than 75% for both treatments. Of course, the retention rate would be lower and might differ had we enrolled patients at the beginning of treatment rather than after the 3rd month. Among these patients, there were very few reported adverse reactions, and these were reported by only a minority of patients. On the whole, buprenorphine-treated patients reported somewhat more side effects than did methadone-treated patients, but all adverse reactions were judged to be minor in severity and did not require any specific treatment.

Among the patients who reached the 12th-month evaluation, there were statistically and clinically significant general improvements in psychologic and social conditions for both groups. Although the buprenorphine-treated patients showed better scores than did the methadone-treated patients on some of the measures, there was no significant group or group-by-time interaction.

Reasons for the observed improvements may include both pharmacologic and psychosocial stabilization and are consistent with previous research that showed benefits for buprenorphine-treated and methadone-treated patients not only in the use of opioids but also in various indicators of psychiatric well-being and social adjustment (Dean, Bell, Christie, & Mattick, 2004; Mattick et al., 2003; Pani & Pirastu, 2000; Rounsaville, Weissman, Crits-Christoph, Wilber, & Kleber, 1982; Strain, Stitzer, & Bigelow, 1991). Moreover, studies specifically oriented toward the evaluation of quality of life failed to find differences between methadone treatment and buprenorphine treatment after 6 or 36 months (Giacomuzzi et al., 2003; Giacomuzzi et al., 2005).

The subject of the differential impact of methadone treatment and buprenorphine treatment on specific indicators has been considered in previous studies. Previous investigations on the preferential impact of buprenorphine treatment versus methadone treatment for specific subgroups of patients identified by sociodemographic or clinical variables have shown inconsistent results. Some studies have observed a preferential impact of buprenorphine for depressed patients (Gerra et al., 2004) or a preferential effect of methadone for those with more serious problems at the psychiatric level or in social adjustment (Pani et al., 2000). Other researchers who specifically investigated the predictive value of a lifetime diagnosis of antisocial personality or depression in patients randomly assigned to treatment with methadone or buprenorphine failed to show any relationship with outcome parameters such as retention in treatment and use of opioids or cocaine (Schottenfeld, Pakes, & Kosten, 1998). Our real world study on standard treatment in Italy seems to be in line with the more rigorous studies carried out thus far on this subject; these have shown no specific differentiation in the prognostic indicators of the results of treatment between methadone treatment and buprenorphine treatment (Marsch et al., 2005).

5. Conclusions

In summary, our results suggest that 1 year of treatment with methadone or buprenorphine seems to favorably affect the clinical course, psychiatric well-being, and social adjustment of opioid-addicted patients—at least those who complete their third month of treatment. The improvements in drug use, problem symptoms, and general quality of life were significant and comparable for methadone and buprenorphine. These patients achieve a fairly successful way of life.

Acknowledgments

This study was supported by a research grant from Essex Italia. It was conducted under the scientific supervision of the G. De Lisio Institute of Behavioral Sciences.

We thank all the researchers involved in the collection of data: Vincenzo Alaimo (Canicatti, AG); Francesco Lamanna, Stefano Scuotto, and Maura Tedici (Empoli, FI); Maria A. Cannarozzo, Stefano Dell’Aera, and Giancarlo Pintus (Enna); Francesco Candi, Maurizio Vescovo, and Giannina Zapparoli (Milano); Francesco Auriemma, Clara Baldassarre, Elvio Marguccio, Carmine Mazzella, Marina Siconolfi, and Rosa Stimolo (Napoli); Carmelo M. Sgor
(Padova); Sonia Lubrano and Milo Meini (Pisa); Barbara Capovani and Marco Moncini (Pontedera, PI); Giovanni Caniato and Annella Schiaichitano (Rovigo); Giovanni Marrella (San Cataldo, CL); as well as Olivia Bartolotta, Giuseppe Bellomia, Giuseppe Bruno, Carmelina Basù, Roberto Castro, Ernesto De Bernardinis, Corrado Di Giacomo, Riccardo Gionfriddo, Letterio La Corte, Salvatore Libranti, Marina Morelli, Giuseppe Motta, Franco Perricone, Adriana Racalbuto, Antonella Vinci, M. Concetta Visconti Siracusà, and Giuseppe Mustile (Vittoria, RG).

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