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Increases in body mass index following initiation of methadone treatment

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Abstract

Despite the clear efficacy of methadone for opioid dependence, one less desirable phenomenon associated with methadone may be weight gain. We examined changes in body mass index (BMI) among patients entering methadone treatment. A retrospective chart review was conducted for 96 patients enrolled in an outpatient methadone clinic for 6 months. The primary outcome of BMI was assessed at intake and a subsequent physical examination approximately 1.8±0.95 years later. Demographic, drug use and treatment characteristics were also examined. There was a significant increase in BMI following intake ($p < 0.001$). Mean BMIs increased from 27.2±6.8 to 30.1±7.7 kg/m², translating to a 17.8-pound increase (10% increase in body weight) in the overall patient sample. Gender was the strongest predictor of BMI changes ($p < 0.001$), with significantly greater BMI increases in females than males (5.2 vs. 1.7 kg/m², respectively). This translates to a 28-pound (17.5%) increase in females vs. a 12-pound (6.4%) increase in males. In summary, methadone treatment enrollment was associated with clinically significant weight gain, particularly among female patients. This study highlights the importance of efforts to help patients mitigate weight gain during treatment, particularly considering the significant health and economic consequences of obesity for individuals and society more generally.

INTRODUCTION

Opioid abuse and dependence are significant public health problems in the United States, costing \$56 billion annually and including emergency department visits, premature death, HIV, hepatitis, criminal activity and lost workdays (Birnbaum et al., 2009). Agonist maintenance is the most effective treatment for opioid dependence and dramatically reduces morbidity, mortality and spread of infectious disease (Johnson et al., 2009; Stotts et al., 2009). Methadone, a full muopioid, is the most commonly used medication for treatment of opioid dependence and has been widely demonstrated to reduce illicit drug use, infectious disease and mortality (Ball & Ross, 1991).

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Despite the clear efficacy of methadone treatment for opioid dependence, one less desirable phenomenon associated with treatment may include weight gain (Nolan et al., 2007; Rajs et al., 2004). Prior studies have suggested that opioid administration is associated with weight gain and glycemic dysregulation. A recent review by Mysels and Sullivan (2010) reported that activation of the mu-opioid receptor is associated with increased sweet taste preference, hyperglycemia induced by direct action on pancreatic islet cells, and potential insulin resistance caused by dietary preference for sugary foods. Increased preference for and ingestion of sweet foods can result in subsequent weight gain. Among patients receiving methadone treatment specifically, when questioned about potential side effects associated with their treatment, 80% of patients complain of weight gain (Gronbladh & Ohlund, 2011). In a retrospective chart review of methadone-maintained patients, Mysels and colleagues (2011) reported mean weight increases of 1.86% and 3.67% between treatment intake and the 3- and 6-month assessments, respectively. While these increases may appear small, they translated to an approximate 10-lb weight gain during the first 6 months of treatment. However, that study utilized a small sample of methadone-maintained patients (n=16) and their analyses were restricted to the first six months following intake, representing a limited timeframe for a treatment paradigm that often continues for years. Overall, the potential weight-increasing effects of methadone have clear public health implications, as overweight and obesity are associated with increased risk of heart disease, diabetes, stroke and premature death (CDC, 2012).

In the present study, we sought to examine changes in body mass index (BMI) among patients entering methadone treatment while extending upon prior studies in several ways. First, we included a larger sample of patients than used previously. Second, the timeframe of monitoring in our chart review encompassed a longer duration than was used in prior studies. Finally we included additional demographic, drug use and treatment characteristics in an effort to identify variables that may predict weight gain during treatment.

METHODS

A review of patient charts was conducted for opioid-dependent adults admitted to an outpatient methadone maintenance treatment program in New England between 2002 and 2011. To be included in the analyses, patients had to remain in treatment for 6 months and provide height and weight measurements at intake and a subsequent physical examination. Exclusion criteria included patients who were pregnant at intake or who became pregnant during treatment, as well as those who had transferred from another methadone clinic. The authors received approval from the University of Vermont Institutional Review Board prior to conducting chart reviews and data analyses.

Measures

Each participant's Body Mass Index (BMI) was assessed at treatment intake (Time 1) and at a subsequent physical examination (Time 2), with a mean $\pm$ SD interval between the two measurements of 1.8 $\pm$ 0.9 (range: 0.67 – 6.0) years. BMI is a widely-used and reliable measurement of the relative percentage of adiposity and muscle mass in the human body, in which mass in kilograms is divided by height in meters squared (kg/m²). The calculation is

used as an index of obesity (Centers for Disease Control, 2011). BMIs lower than 18.5 kg/m² are regarded as underweight, between 18.5 and 24.9 kg/m² are considered normal weight, those between 25–29.9 kg/m² overweight, and BMIs >30 kg/m² obese.

Several additional self-report and staff-administered questionnaires were administered at treatment intake which permitted characterization of patients' current and past alcohol and drug use. These included the Addiction Severity Index (ASI; McClellan, 1985), Michigan Alcohol Screening Test (MAST; Selzer, 1971), as well as demographics (e.g., age, gender) and opioid use (e.g., history of intravenous drug use, primary opioid of abuse) characteristics at intake. Patients' methadone dose at the time of second weight assessment was also documented.

ANALYSES

The primary outcome was BMI (kg/m²). Outcomes are also presented in pounds for several reasons: First, inclusion of pounds aids interpretation among readers less familiar with BMI. Second, presentation of the data in pounds permits comparison of our findings with prior studies which solely reported their methadone-associated weight gains in terms of pounds (e.g., Mysels et al., 2011). Finally, the use of BMI as a marker for adiposity may have limitations, especially in adult overweight (BMI 25≤/30) males (Pasco et al., 2014; Romero-Corral et al., 2008). Thus, clinically significant weight gain (>= 5% total body weight per Food and Drug Association) may provide a more sensitive estimate of weight changes during treatment.

A two-tailed paired t-test was performed to compare BMI at Time 1 vs. 2 and patients' time in treatment between males and females. Hierarchical linear regression was used to examine predictors of BMI changes during treatment. Predictors included age, gender, time in treatment (e.g., the interval between BMI assessments), lifetime history of intravenous drug use (i.e., IV or no IV), patients' methadone dose, and patients' primary opioid of abuse at treatment intake (i.e., heroin, prescription opioids, both). A test for co-linearity among predictors was computed prior to determining the final statistical model. Statistical significance was determined based on alpha =0.05 (two-sided). Analyses were performed using SPSS Statistics 22 (IBM Corp., Armonk, NY).

RESULTS

One hundred ninety-five charts were reviewed and 96 met eligibility criteria for inclusion. The remaining 99 charts were excluded, with the majority excluded due to either missing biometric data at either Time 1 or 2 or to a positive pregnancy status. Patient characteristics are presented in Table 1. There was a significant increase in mean BMI following entry into methadone treatment ($p < 0.001$), with mean BMIs increasing from 27.2 ± 6.8 to 30.1 ± 7.7 kg/m² at Times 1 and 2, respectively, for an overall change of 2.9 kg/m² (CI 2.2–3.7, 95% confidence). In terms of pounds, mean weight increased from 177.6 to 195.4 pounds, representing an increase of 17.8 pounds (10% increase in body weight).

Examination of co-linearity among the predictor variables determined that they were not significantly correlated and thus they were entered into the regression model (Table 2).

Gender was the only variable associated with BMI changes during treatment ($\beta=3.5$, $t_{87}=4.78$, $p<.001$, model $R^2=.23$). The increase in BMI was significantly greater in females, with an increase of 5.2 kg/m^2 in females (27.5 and 32.7 at Times 1 and 2 respectively) vs. 1.7 kg/m^2 in males (26.9 and 28.6 at Times 1 and 2 respectively; Figure 1). When presented in pounds, mean weight for females increased from 159.9 to 187.9 pounds, representing an increase of 28.0 pounds (17.5% increase in body weight). Mean weight for males increased from 187.7 to 199.7 pounds, representing a 12-pound (6.4%) increase. When we examined whether this difference in weight gain between males and females could be explained by the length of time in treatment, there was no evidence that this was the case ($p=0.85$). In addition, time in treatment did not differ between genders, with males and females in treatment an average of 640.8 vs. 669.6 days, respectively ($p=0.696$). Finally, we descriptively examined the percentage of patients, within each gender, that fell into each of the BMI categories (i.e., underweight, normal weight, overweight, obese) at the two BMI assessment time points (Table 3).

DISCUSSION

We observed a significant increase in BMI in the months following patients' entry into methadone treatment. These data are consistent with prior reports of weight gain early in methadone treatment, particularly the recent report by Mysels and colleagues (2011) noting an approximate 10-pound weight gain among patients during the first six months of methadone treatment. In the present study, we observed an approximate 17.8-pound increase within the first approximately two years of treatment. These data extend prior research by including a larger sample size ($n=96$) and a longer period of monitoring (approximately 2 years) than was used in previous studies. Overall, these results suggest that clinically significant weight gain occurred in the months following patients' entry into methadone treatment. Indeed, using the definition put forth by the American College of Sports Medicine (Donnelly, 2009), 65% of our patients experienced a 5% or greater increase in BMI and thus clinically significant weight gain.

We also observed significant differences in during-treatment weight gain between males and females. Female patients showed a much greater increase in BMI than males, with an increase in body weight that was almost three-fold that of males. These findings stand in contrast to a small study by Kolarzyk and colleagues (2005) who examined weight changes among 30 Polish methadone patients and found a modest weight loss in female patients vs. a modest weight gain in males. While low testosterone resulting from methadone-related HPA suppression could cause weight gain and increased fat mass in males (Bhasin, 2006), it does not account for the significantly greater increase in BMI among female patients in our study. While the exact reasons underlying the differential weight gain between male and female patients are important to examine in future studies, our finding that female patients gained on average 28 pounds (a 17.5% increase in body weight) has serious potential health implications.

Also worth noting is that the observed BMI increases during treatment were not solely a function of undernourished illicit drug abusers moving toward a healthier weight as they become stabilized in methadone treatment, which stands in contrast to prior suggestions that

weight increases during treatment may be due to a malnourished state at intake (Grondbladh, 2011; Okruhlica & Slezakova, 2007). Indeed, the mean BMI for the overall group, as well as females, placed patients in the overweight category (BMIs 25.0–29.9 kg/m²) at time of intake and moved them from clinically overweight to obese (BMIs >30.0kg/m²) by Time 2.

While these data provide additional support for concerns about clinically significant weight gain among patients receiving methadone treatment, they do not isolate the mechanism involved or suggest pharmacological specificity. This was not a randomized trial and all patients received methadone as well as other numerous treatment components standard in our methadone program. Thus, it is not possible to dismantle whether the weight gain observed was a direct pharmacological effect of methadone administration specifically vs. other more general changes in behaviors (e.g., eating behavior, nutritional intake, increased access to food, physical activity levels, other drug use, increased clinical stability) that could have co-occurred with treatment intake. Similarly, it is unknown whether maintenance treatment with the partial opioid agonist, buprenorphine (Suboxone®), would also be associated with weight gain. Several prior studies have also reported that individuals in methadone maintenance report increased cravings for sugar (Bogucka-Bonikowska et al., 2002; Nolan & Scagnelli, 2007; Zador et al., 1996), which is consistent with preclinical data suggesting preferences for palatable foods following mu-agonist administration (Olszewski & Levine, 2007). It is also worth noting that in Mysels et al. (2011) report of weight gain in individuals receiving methadone treatment, the authors also followed another small group of patients receiving naltrexone (n=20), and these patients showed a similar weight gain. This suggests that there may be more general treatment-related factors other than the medication per se that may influence BMI during treatment. Regardless of the precise mechanism involved, these weight gains, which amounted to approximately 0.82 pounds per month of treatment in the overall patient group, are of potential clinical and medical significance.

Several additional limits of the present study should be noted. First, the primary limitation is that it was a retrospective review of patient charts and, while more extensive than prior studies on the topic, it still had a limited sample size and assessment history. However, the information gained from this study may aid efforts to further evaluate and address weight gain during opioid treatment. A second consideration is the possible limited generality of research done with methadone patients in Vermont (i.e. primary Caucasian opioid users in a rural setting) to more ethnically diverse samples of those residing in urban settings. However, as noted previously, our data are generally consistent with the recent study by Mysels et al. (2011), which was conducted with methadone treatment patients in New York City. Third, we limited our analyses to patients who had provided at least two BMI measurements, and our data did not capture the patients who might have left the clinic or failed to complete two BMI assessments. Concurrent medications and other health factors were also not assessed. These factors should be considered in future studies on this topic. Finally, while this study extended the monitoring period of weight changes during methadone treatment, we did not assess BMI frequently enough to characterize the timecourse with which these changes occurred. It is possible that patients' weight gain may have continued well beyond the first two years of treatment and thus went undetected in our study. It is also possible that weight gain occurred in the initial months following intake and then subsequently plateaued. These are important questions that should be addressed in

future studies, as the typical duration of patients' methadone treatment episodes tend to be on the order of years and often decades rather than months (D'Aunno, Foltz-Murphy, Lin, 1999).

Taken together, the present study suggests that clinically significant weight gain may occur among many patients entering methadone treatment, with particularly striking increases in female patients. Although weight gain is noted as a possible side effect of methadone administration (Mallinckrodt, 2009), this study represents one of only a few that have directly examined this question. Our findings highlight the importance of ongoing monitoring of weight and other health-related changes among methadone patients during treatment. These data also support efforts to develop and implement interventions early in methadone treatment in order to help patients mitigate weight gain during treatment. Indeed, education and support around weight, nutrition, and physical activity are likely to be important treatment components for all patients entering treatment. Also important to note is that methadone patients are seen frequently during the early months of treatment and thus may be an especially convenient and receptive audience for delivery of evidence-based health interventions as part of treatment. Considering the differential changes in weight as a function of gender, educational interventions customized specifically for each gender may be warranted. Finally, the number of Americans being prescribed opioids for pain far exceeds that for addiction (5 million vs. 350,000, respectively; Parsells-Kelly et al., 2008; SAMHSA, 2011). Thus, scientific efforts to disentangle the pharmacological or other mechanisms involved in treatment-associated weight changes may extend well beyond patients receiving opioids for addiction.

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Figure 1. Mean Body Mass Index values during methadone treatment. Data are presented for female and male methadone patients measured at Time 1 (open bars) and Time 2 (solid bars). The y-axis represents a restricted range to permit improved resolution of data for visual inspection.

Table 1

Patient Characteristics (N=96)

Demographics	
% Male	64%
% Caucasian	98%
Age, yrs	38??9.2
Drug use	
% Reporting ever used IV	65%
Primary opioid of abuse	
Prescription opioids	48%
Heroin	24%
Combination	28%
MAST score	9.75
Methadone dose, mg (range)	116 (30–260)
Addiction Severity Index Composite Subscales ^b	
Opiate	0.44??0.25
Cocaine	0.06??0.16
Drug	0.27??0.13
Alcohol	0.04??0.10
Employment	0.60??0.32
Legal	0.14??0.19
Family/Social	0.15??0.18
Psychiatric	0.29??0.24
Medical	0.74??0.36

^a Data are presented as mean ?? SD unless otherwise specified.

^b Subscale score range: 0–1.

Table 2

Predictors of BMI Change During Methadone Treatment

Model		Unstandardized Coefficients		t	Sig.	95% Confidence Interval for B	
		B	Std. Error			Lower Bound	Upper Bound
1	(Constant)	1.656	.447	3.703	<.001	.768	2.545
	Gender	3.501	.733	4.776	<.001	2.045	4.957
2	(Constant)	1.263	.807	1.565	.121	-.340	2.866
	Gender	3.488	.736	4.740	<.001	2.026	4.950
	Time in treatment	.001	.001	.587	.559	-.001	.003
3	(Constant)	2.388	1.602	1.491	.140	-.794	5.570
	Gender	3.440	.740	4.650	<.001	1.971	4.910
	Time in treatment	.001	.001	.777	.439	-.001	.003
	Age	-.033	.041	-.814	.418	-.114	.048
4	(Constant)	2.107	1.637	1.287	.201	-1.146	5.361
	Gender	3.362	.747	4.503	<.001	1.878	4.845
	Time in treatment	.001	.001	.809	.420	-.001	.003
	Age	-.031	.041	-.774	.441	-.112	.049
	History of IV use	.646	.755	.856	.395	-.855	2.147
5	(Constant)	1.353	1.862	.727	.469	-2.346	5.053
	Gender	3.304	.751	4.402	<.001	1.812	4.796
	Time in treatment	.001	.001	.742	.460	-.001	.003
	Age	-.033	.041	-.800	.426	-.114	.048
	History of IV use	.625	.757	.826	.411	-.879	2.130
	Methadone dose	.007	.009	.856	.394	-.010	.025
6	(Constant)	2.668	2.178	1.25	.224	-1.662	6.997
	Gender	3.305	.753	4.387	<.001	1.807	4.802
	Time in treatment	.001	.001	.861	.392	-.001	.003
	Age	-.036	.042	-.852	.397	-.120	.048
	History of IV use	.146	.954	.153	.879	-1.751	2.042
	Methadone dose	.008	.009	.934	.353	-.009	.026
	Primary opioid	-.819	1.013	-.809	.421	-2.833	1.194

Change Statistics							
Model	R	R Square	R Square Change	F Change	df1	df2	Sig. F Change
1	.446	.199	.199	22.807	1	92	.000
2	.449	.202	.003	.345	1	91	.559
3	.456	.208	.006	.662	1	90	.418
4	.463	.214	.006	.732	1	89	.395
5	.470	.220	.006	.733	1	88	.394
6	.482	.233	.012	.691	1	86	.504

Table 3

BMI Categories

	<u>Females</u>		<u>Males</u>	
	Time 1	Time 2	Time 1	Time 2
Underweight	3%	0%	5%	5%
Normal	49%	17%	46%	25%
Overweight	11%	31%	23%	36%
Obese	37%	51%	26%	34%