Efficacy of Add-On Topiramate Therapy in Psychiatric Patients with Weight Gain

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BACKGROUND: Weight gain is a common adverse effect of many psychotropic medications including antipsychotics, antidepressants, and mood stabilizers. There is a growing body of evidence that topiramate may be useful as an add-on therapy to induce weight loss in patients who have experienced psychotropic-induced weight gain.

OBJECTIVE: To determine the efficacy and tolerability of topiramate for treatment of weight gain in a naturalistic mental health clinic setting.

METHODS: A retrospective chart review was conducted at a community mental health clinic. Subjects were non-elderly adults who received topiramate therapy beginning in 2002–2005 for documented weight gain during treatment with psychotropic drugs. Primary outcome measures included response rate (based on weight loss of any magnitude) and mean changes in weight and body mass index (BMI).

RESULTS: Forty-one patients were included in the study. There was a 58.5% (n = 24) response rate. Mean reductions in weight and BMI were approximately 2.2 kg and 0.5 points, respectively. Responders lost an average of 7.2 kg, whereas nonresponders gained an average of 5.0 kg. Patients with a baseline weight of at least 91 kg and those receiving a greater number of psychotropic medications were more likely to experience success with topiramate therapy. Of the 24 patients who responded to therapy, 22 experienced onset of weight reduction by the next clinic visit (1–4 mo) following either initiation of therapy or titration to the eventual therapeutic dose, and the usual rate of weight loss was 0.45–1.4 kg per month. Therapy was typically initiated at 50 mg/day. The mean maximum dose was 93.9 mg/day and the median maximum dose was 100 mg/day. Seven (17.1%) patients had documented adverse effects to topiramate therapy.

CONCLUSIONS: Topiramate therapy resulted in overall modest (ie, <2%) decreases in weight and BMI, but many patients experienced more impressive weight loss. Therapy was generally well tolerated.

KEY WORDS: body weight, psychotropic drugs, topiramate.

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Weight gain is a common adverse effect of many psychotropic medications including antipsychotics, antidepressants, and mood stabilizers.[1] Aesthetic considerations aside, weight gain can lead to serious health concerns. Patients with serious mental illnesses (eg, schizophrenia, mood disorders) already have about a 1.5–2.0 times higher prevalence rate of both obesity and diabetes compared with the general population, and these are major risk factors for the development of cardiovascular disease.[2]

Topiramate is an anticonvulsant drug that has been used in the treatment of various psychiatric disorders with mixed success,[3] but it has also stimulated interest within the psychiatric community due its ability to cause weight loss.[3,4] Not surprisingly, topiramate has been studied as a potential add-on therapy to induce weight loss in patients who have experienced psychotropic-induced weight gain. Case series,[5-7] open-label trials,[8-11] placebo-controlled trials,[12,13] and a recent trial versus sibutramine[14] have suggested efficacy of topiramate for this indication; however, these reports were limited by small sample sizes (ie, ≤15 pts.),[5-10] short durations (ie, ≤3 mo),[9-13] and/or inclusion of very specific patient populations. The specific groups studied have included patients with schizophrenia who were receiving atypical antipsychotics,[5,6,13] patients with bipolar disorder who were receiving atypical antipsychotics/mood stabilizers,[10,11,14] patients with anxiety disorders who were receiving selective serotonin-reuptake inhibitors,[9] or patients with autistic spectrum disorders who were receiving risperidone almost exclusively.[8]

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Topiramate therapy has been used extensively in our clinic for weight gain that has occurred during treatment with psychotropic medications, particularly when changes in psychotropic drug therapy were not clinically feasible. The objective of this study was to retrospectively determine the efficacy and tolerability of topiramate for treatment of weight gain in a naturalistic mental health clinic setting.

Methods

The study was approved by the Institutional Review Boards of the University of Alabama at Birmingham (UAB) and Samford University. The design was a retrospective chart review conducted at the Psychopharmacology Clinic of the UAB Community Psychiatry Program. Patients at the clinic are nonelderly (19–65 y old) adults with serious mental illnesses, especially psychotic disorders, bipolar disorder, and major depressive disorder, but also anxiety disorders, personality disorders, and other types of disorders.

Two hundred patients were randomly screened for study eligibility based on the following criteria: receipt of first prescription for topiramate between January 2002 and December 2005, documented indication for topiramate therapy was weight gain during treatment with psychotropic medications, no change in psychotropic drug therapy at time of initiation of topiramate therapy, at least one follow-up visit after initiation of topiramate therapy, and weights recorded on the date of initiation of topiramate therapy and at each subsequent visit during topiramate therapy.

Data collected included demographic information; psychotropic medications prescribed at the time of initiation of topiramate therapy; weight, height, and body mass index (BMI) at the time of first prescription of topiramate and at each clinic visit thereafter; documented adverse effects; and whether topiramate therapy had been discontinued and, if so, for what reason. Data were collected from the date of the first topiramate prescription (baseline) until the date of therapy discontinuation or most recent clinic visit if therapy was ongoing (endpoint). Patients were categorized as overweight, obese, or morbidly obese according to BMI (25.0–29.9, 30.0–39.9, and ≥40.0, respectively). Patients' heights and weights were measured at each clinic visit, using the same scale. Clinic personnel routinely obtain information regarding adverse effects by general questioning as well as by patient self-report.

Primary outcomes included response rate, which was based on weight loss of any magnitude, and mean changes in weight and BMI. Endpoint measures were compared with baseline measures for determination of primary outcomes. Secondary outcomes included correlation of response to therapy with various patient and treatment variables; onset, rate, and duration of weight/BMI changes; and tolerability of therapy.

STATISTICAL ANALYSIS

All statistical analyses were accomplished with the Minitab Statistical Software, Release 14.1. A complete array of descriptive statistics was generated for continuous variables including, but not limited to, the mean, standard deviation, and standard error of the mean. Univariate frequency distribution tables were used to assess categorical variables and cross-tabulations were used to consider relationships among them. Differences in proportions of various outcomes between groups were analyzed with the χ^2 test of independence (or Fisher's exact test in cases of sparsely distributed data). The Pearson correlation coefficient and ordinary least-squares regression were used to evaluate the relationship between change in weight and the number of psychotropic medications taken at baseline. This relationship was corroborated with a binary logistic regression relating weight loss (as a binomial variable) to the number of psychotropic medications taken at baseline (unreported).

Results

Of the 200 patients screened, 41 (20.5%) met entry criteria and were included in the study. Practically all excluded cases were due to absence of topiramate treatment. Twenty-six (63.4%) patients were female, and 15 (36.6%) were male. The mean weight and BMI of the women were 95.7 kg and 34.7, respectively; the mean weight and BMI of the men were 103.3 kg and 33.4, respectively. Twenty-three (56.1%) patients were black, 17 (41.5%) were white, and 1 (2.4%) was Hispanic. The age range of patients was 28–60 years (mean 47.1). At baseline, 10 (24.3%) patients were overweight, 26 (63.4%) were obese, and 5 (12.2%) were morbidly obese. Also at baseline, 8 patients received 1 psychotropic drug, 10 patients received 2 psychotropic drugs, 8 patients received 3, 10 patients received 4, and 5 patients received 5. The mean number of psychotropic medications per patient was 2.9; they included second-generation antipsychotics (n = 38), antidepressants (n = 38), hypnotics (n = 14), anticholinergics (n = 10), first-generation antipsychotics (n = 6), anxiolytics (n = 6), and mood stabilizers (n = 5).

Twenty-four (58.5%) patients experienced weight loss while receiving topiramate therapy (ie, responders), whereas 17 patients (41.5%) did not. Weight and BMI changes with topiramate therapy are shown in Table 1. On average, topiramate therapy resulted in reductions in weight and BMI of approximately 2.2 kg (1.8% reduction from baseline) and 0.5 points (1.3% reduction from baseline), respectively. However, there was a wide range of outcomes with topiramate therapy (Table 2). Responders lost an average of 7.2 kg, whereas nonresponders gained an average of 5.0 kg. Responders who lost at least 4.5 kg (n =15) lost an average of 9.7% of their baseline weight.

Seventy-four percent of patients with a baseline weight of 91 kg or more were responders, while only 39% of those with a baseline weight less than 91 kg were responders (Fisher's exact test p = 0.03). Regression analysis revealed a correlation between the number of psychotropic medications taken at baseline and weight change with topiramate therapy (p = 0.004). Specifically, each increase in one psychotropic drug resulted in an approximate 2.5 kg weight reduction during topiramate therapy. Baseline trazodone therapy was correlated with response to topiramate (Fisher's exact test p = 0.01), as all 8 patients receiving trazodone were responders, but no other specific drug or drug class was correlated with response. Furthermore, baseline BMI, age, sex, and race were not correlated with response to topiramate therapy.

Of the 24 responders to therapy, 22 experienced onset of weight reduction by the next clinic visit (1–4 mo) following either initiation of therapy or titration to the eventual therapeutic dose (ie, the dose at which they started to lose weight). The usual rate of weight loss was 0.45–1.4 kg per month, albeit there were different patterns that emerged. Tolerance to therapy did not appear to be an issue, as in cases involving prolonged treatment (ie, >1 y), and weight reduction was typically sustained or even continuing to improve until endpoint. For example, one patient was continuing to lose weight after 17 months of therapy with topiramate 100 mg/day, and another patient was continuing to show gradual weight reduction even after 38 months of therapy that alternated between 50 and 75 mg/day.

Dosage and duration of topiramate therapy are delineated in Table 3. Therapy was typically initiated at 50 mg/day. Nine responders were maintained on their original starting dose of 50 mg/day. A very common trend seen in most of the remaining responders (n = 9) was continued weight gain after initiation of therapy at 50 mg/day followed by immediate weight reduction when the dosage was titrated to 100 mg/day. The mean maximum dose was 93.9 mg/day, and the median maximum dose was 100 mg/day. Male patients received fairly uniform dosing, as 80% were titrated to a maximum dose of 100 mg/day. Female patients were more likely than male patients to receive both lower (50–75 mg/day) and higher (150–200 mg/day) maximum doses. Duration of therapy ranged from 1 to 39 months (mean 16.2). Thirty-one patients completed at least 6 months of therapy, 24 patients completed at least 1 year of therapy, and 11 patients completed at least 2 years of therapy. The mean duration of therapy for patients with documented adverse effects and patients who were discontinued from therapy (see below) was 9.4 months and 8.4 months, respectively.

Seven (17.1%) patients had documented adverse effects to topiramate therapy (Table 4), all of which were reported early in therapy (ie, first or second follow-up clinic visit). Three (7.3%) patients discontinued therapy due to intolerability (ie, behavioral activation in 1 pt. and increased appetite in 2 pts.). Topiramate therapy was discontinued in 5 other patients because of inefficacy (n = 2), cost (n = 1),

Table 1. Efficacy of Topiramate Therapy

	Baseline (mean ± SD)	Endpoint (mean ± SD)	Change (mean)	% Change (mean)
All pts. (N = 41)				
weight (kg)	98.5 ± 21	96.3 ± 20	–2.2	–1.8
BMI	34.2 ± 6.2	33.7 ± 6.0	–0.5	–1.3
Responders (n = 24)				
weight (kg)	101.5 ± 21.7	94.3 ± 19.1	–7.2	–6.9
BMI	35.2 ± 6.4	32.9 ± 6.1	–2.2	–6.3
Nonresponders (n = 17)				
weight (kg)	94.2 ± 19.9	99.2 ± 21.5	5	5.2
BMI	32.9 ± 5.9	34.7 ± 6.0	1.9	5.8

BMI = body mass index.

Table 2. Range of Outcomes

Weight Change (kg)	Pts., n (%)	Females/ Males Ratio	Mean Number of Psychotropics at Baseline
Gain			
≥14	1 (2)	0/1	1.0
9–13	1 (2)	0/1	1.0
5–9	7 (17)	3/4	2.3
0.5–4	8 (20)	7/1	2.6
Loss			
0.5–4	9 (22)	5/4	2.9
5–9	9 (22)	7/2	3.3
9–13	2 (5)	1/1	4.5
≥14	4 (10)	3/1	3.3

Table 3. Dosage and Duration of Topiramate Therapy

Factor	All Pts. (N = 41) n (%)	Female (n = 26) n (%)	Male (n =15) n (%)
Initial daily dosage (mg)			
50	38 (93)	24 (92)	14 (93)
100	3 (7)	2 (8)	1 (7)
Maximum daily dosage (mg)			
50	14 (34)	12 (46)	2 (13)
75	2 (5)	2 (8)	0 (0)
100	19 (46)	7 (27)	12 (80)
150	2 (5)	2 (8)	0 (0)
200	4 (10)	3 (12)	1 (7)
Duration (mo)			
1–6	10 (24)	8 (31)	2 (13)
7–12	7 (17)	4 (15)	3 (20)
13–18	10 (24)	7 (27)	3 (20)
19–24	3 (7)	2 (8)	1 (7)
>24	11 (27)	5 (19)	6 (40)

unrelated medical illness (n = 1), and patient choice (n = 1). Interestingly, in the case involving an unrelated medical illness (the clinician was uncomfortable prescribing topiramate due to the patient's recent diagnosis of hepatitis C), the patient had lost 22 kg during 8 months of topiramate treatment, but he regained 6 kg within 1 month after discontinuation of topiramate.

Discussion

This retrospective study found that psychiatric patients who received topiramate therapy for weight gain experienced mean decreases in weight and BMI of approximately 2.2 kg and 0.5 points, respectively. This is similar to the finding of McElroy et al.,[14] whose topiramate-treated patients lost an average of about 3 kg in a 24-week controlled trial versus sibutramine. Various other trials with similar types of patients have reported better success with topiramate therapy, including a 10-week, open-label trial in which patients lost a mean of about 4 kg,[9] a 12-week open-label trial in which the mean BMI decreased by 2 points,[11] and a 10-week placebo-controlled trial in which topiramate-treated patients experienced about a 5-kg weight reduction versus placebo-treated patients.[12]

The findings of this chart review confirm our anecdotal experience with use of topiramate for this indication. Namely, not all patients respond to therapy, but those who do tend to do so in a rather robust manner. For example, approximately two-thirds of all responders lost between 5 and 23 kg, and this group lost an average of almost 10% of their baseline weight. Also consistent with our previous clinical experience was the finding that tolerance did not develop to topiramate despite very prolonged treatment in some cases. Similarly, Lévy et al.[6] treated some patients for greater than 6 months and came to the conclusion that tolerance to topiramate-induced weight loss did not develop.

It has been suggested that baseline BMI affects topiramate-induced weight loss.[3] While our study did not replicate this particular finding, we did find a correlation between baseline weight (with 91 kg being the cutoff) and response to topiramate therapy. To our knowledge, our study is the first to correlate the number of psychotropic medications taken at baseline with topiramate-induced weight loss. We believe that future prospective studies should take this factor into account.

The dosing used in our study was quite conservative relative to that seen in other reports. Our maximum daily dose was only 200 mg, whereas some other case series/trials used daily doses of topiramate of up to 250–600 mg.[6,7,9,14] In fact, only about 15% of our patients received a maximum daily dose exceeding 100 mg. The conservative dosing may very well have impacted the response to therapy, as Ko et al.[13] found that 200 mg/day was more efficacious than 100 mg/day in treating patients with schizophrenia for excess weight gain.

Topiramate therapy was generally well tolerated in our study. Only 17.1% of patients had documented adverse effects and only 7.3% of patients discontinued therapy due to intolerability. Paresthesia and fatigue were commonly reported (~50% and ~25%, respectively) in clinical trials of topiramate for weight reduction in obese patients,[4] but these adverse effects were not noted in our sample. In these same clinical trials, subject withdrawal due to adverse events ranged from 13% to 18% at doses similar to those used in our patients.[4] The conservative dosing scheme may be at least partially responsible for the very good tolerability of therapy that was seen in our study. Another factor to consider is that some adverse effects may not have been elicited from the patients and/or recorded in the medical record; thus, adverse effects are likely to be underreported due to the retrospective nature of our study.

Many patients experienced weight gain after initiation of topiramate therapy. Although it is rational to simply attribute this fact to inefficacy of the drug (ie, those patients continued the trend of weight gain due to the preexisting psychotropic regimen), there are 2 other considerations. First, some patients may have felt justified in adopting even more detrimental dietary and/or exercise habits due to the presumed weight control afforded by their new therapy. Another intriguing premise is that topiramate may have paradoxically caused weight gain in some patients. In our review, 2 middle-aged women were discontinued from therapy owing to the specific complaint of increased appetite. Interestingly, there is a published account involving 2 women who experienced increased appetite and weight gain (4.2 and 9 kg, respectively) after initiation of 25–50 mg/day of topiramate for migraines, although both cases were complicated by recently discontinued medications.[15]

The relatively large sample size and long duration of therapy were strengths of this study. Furthermore, the naturalistic nature of the study improves the ability to generalize the results to many other clinical settings. On the other hand, there were various limitations to the study. First, as with all retrospective chart reviews, we were limited to the documentation that was provided in the patients' medical

Table 4. Documented Adverse Effects

Adverse Effect	Pts., n (%)	Discontinued Therapy
None	34 (83)	
Cognitive dulling	2 (5)	no
Increased appetite	2 (5)	yes (both pts.)
Nausea/vomiting	1 (2)	no
Behavioral activation	1 (2)	yes
Taste disturbance	1 (2)	no

records. In particular, this almost certainly influenced the number and types of adverse effects that were cited. Moreover, there was no way for us to prove full adherence to therapy. Second, we recorded psychotropic medications at baseline, but we did not record other drug classes that can also occasionally contribute to weight gain. Third, although there were no changes in psychotropic drug therapy at the time of initiation of topiramate therapy, we did not record any subsequent changes (ie, addition, discontinuation, switch) that may have occurred. Thus, it is possible that patients may have had changes in psychotropic medications that impacted weight, both positively and negatively. Finally, we had no way of knowing whether patients improved, maintained, or worsened their lifestyle habits (ie, dietary, exercise) after initiation of topiramate therapy.

Conclusions

The majority of patients lost weight when topiramate therapy was added to their medication regimens. Topiramate therapy resulted in overall modest (ie, <2%) decreases in weight and BMI, but responders lost an average of 7.2 kg and some patients experienced very dramatic weight loss. Patients with a baseline weight of at least 91 kg and those receiving a greater number of psychotropic medications were more likely to experience success with topiramate therapy. Topiramate therapy was generally well tolerated.

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Eficacia en el Control de peso al Añadir Topiramate a la Terapia de Pacientes Psiquiátricos con Aumento de Peso

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EXTRACTO

TRASFONDO: El aumento de peso es un efecto adverso común con muchos medicamentos psicotrópicos incluyendo antipsicóticos, antidepresivos, y estabilizadores de ánimo. Hay un creciente cuerpo de evidencia que sugiere que topiramate puede ser útil para inducir pérdida de peso en pacientes que experimentan ganancia de peso inducido por un agente psicotrópico.

OBJETIVO: Determinar la eficacia y tolerabilidad de topiramate para el tratamiento del aumento de peso en una clínica de salud mental.

MÉTODOS: El estudio consistió en una revisión retrospectiva de expedientes llevada a cabo en una clínica de salud mental comunitaria. Los sujetos eran adultos no ancianos que recibieron terapia con topiramate entre los años del 2002 al 2005 para pacientes con aumento de peso durante el tratamiento con psicotrópicos. Las medidas de primarias de resultado incluyeron la tasa de respuesta (pérdida de peso de cualquier magnitud), cambios promedios en peso, y el índice de masa corporal (IMC).

RESULTADOS: Se incluyeron cuarenta y un pacientes en el estudio. Se encontró una respuesta de un 58.5% (24/41). La reducción promedio en peso fue de aproximadamente 2.2 kg en peso y mientras que el IMC disminuyó 0.5 en promedio. Los pacientes que respondieron perdieron un promedio de 7.2 kg, y los que no respondieron ganaron un promedio de 5.0 kg. Los pacientes con un peso de inicial de por lo menos 91 kg y aquellos recibiendo un mayor número de medicamentos psicotrópicos eran más propensos a experimentar éxito con la terapia de topiramate. De los 24 que respondieron a la terapia, 22 experimentaron el comienzo de reducción en peso para la próxima visita a la clínica (1–4 meses) luego

del comienzo de la terapia o de la titulación de la dosis terapéutica final y el ritmo de pérdida de peso fue de 1 a 0.45 a 1.4 kg por mes. La terapia fue típicamente iniciada en la dosis de 50 mg diarios. La dosis máxima promedio fue de 93.9 mg diarios y la máxima mediana fie de 100 mg diarios. Se documentaron efectos adversos en la terapia de topiramate en siete pacientes (17.1%).

CONCLUSIONES: La terapia de topiramate resultó en general en disminuciones modestas de peso y de IMC (menores del 2%), pero muchos pacientes experimentaron pérdidas de peso sustanciales. La terapia de topiramate fue generalmente bien tolerada.

Traducido por Jorge R Miranda-Massari

Efficacité du Topiramate comme Traitement Adjuvant lors de Gain de Poids chez des Patients Psychiatriques: une Revue de Dossier Rétrospective

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RÉSUMÉ

CONTEXTE: Le gain de poids est un effet indésirable fréquemment associé à plusieurs médicaments psychotropes incluant les antipsychotiques, les antidépresseurs et les stabilisateurs de l'humeur. Il y a de plus en plus d'évidences que le topiramate peut être utile pour favoriser la perte de poids chez les patients présentant un gain de poids secondaire à la prise de psychotrope.

OBJECTIF: Déterminer l'efficacité et la tolérabilité du topiramate pour le traitement du gain de poids, dans une population de patients inscrits au programme communautaire de la clinique de psychopharmacologie de l'Université d'Alabama à Birmingham.

MÉTHODOLOGIE: L'étude était une revue rétrospective de dossiers de la clientèle d'une clinique communautaire de santé mentale. Les sujets étaient des adultes (non considérées personnes âgées) ayant reçu un traitement de topiramate débuté entre 2002 et 2005 pour un gain de poids documenté, associé à un traitement avec des psychotropes. Les issues thérapeutiques principales incluaient le taux de réponse (perte de poids de n'importe quelle ampleur) et le changement moyen de poids et d'indice de masse corporelle (IMC).

RÉSULTATS: Quarante-et-un patients ont été inclus dans l'étude. Un taux de réponse de 58.5% (24/41) a été observé. Les réductions moyennes de poids et d'IMC étaient approximativement de 2.2 kg et de 0.5 points respectivement. Les personnes ayant répondu au traitement ont perdu en moyenne 7.2 kg alors que celles n'ayant pas répondu ont gagné en moyenne 5.0 kg. Les patients présentant un poids de départ de 91 kg et plus et ceux recevant un plus grand nombre d'agents psychotropes avaient plus de chances d'obtenir un effet favorable au topiramate. Parmi les 24 patients ayant répondu au traitement, 22 ont noté un début de perte de poids au moment de la première visite à la clinique (1–4 mois) suivant le début du topiramate ou sa titration à une dose thérapeutique. La vitesse de perte de poids était généralement entre 0.45 et 1.4 kg par mois. La dose de départ habituelle du topiramate était de 50 mg/jour. La dose moyenne maximale était de 93.9 mg/jour et la dose médiane maximale de 100 mg/jour. Sept patients (17.1%) ont présenté des effets indésirables au topiramate rapportés au dossier.

CONCLUSIONS: Le traitement au topiramate a produit globalement une diminution modeste (ie, < 2%) de poids et de l'IMC. Toutefois, plusieurs patients ont présenté une perte de poids plus importante. Le traitement était généralement bien toléré.

Traduit par Marie-Claude Vanier