

Antidepressant Side Effects in Depression Patients Treated in A Naturalistic Setting: A Study of Bupropion, Moclobemide, Paroxetine, Sertraline, and Venlafaxine

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Objective: There is no commonly accepted standard for comparing antidepressant-induced side effects. This study evaluates a clinician-administered scale, the Toronto Side Effect Scale (TSES), in a natural practice clinic.

Method: We used the TSES to assess side effects in 193 depression patients who completed 8 weeks of treatment with either bupropion, moclobemide, paroxetine, sertraline, or venlafaxine.

Results: Rates of remission (Hamilton Rating Scale for Depression [HRSD] < 7) did not differ across drugs after 8 weeks of treatment. Paired drug comparisons yielded significant differences in 16 of the 32 side effects. We present differences between pairs of the 5 antidepressants in Central Nervous System (CNS), gastrointestinal (GI), and sexual side effects. A measure of side-effect intensity distinguished paroxetine from the other antidepressants on a measure of sexual dysfunction.

Conclusions: These results confirm the clinical utility of the TSES as a simple, clinician-administered antidepressant side-effect scale.

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Clinical Implications

- The Toronto Side Effect Scale (TSES) may be a useful side-effect measure for clinicians.
- The clinical impression is confirmed that side effects distinguish antidepressants more than rates of remission.
- Intensity of side effects as measured by the TSES did not provide added value to clinicians.

Limitations

- This study was not a randomized placebo-controlled design, although it was a good reflection of natural practice.
- The sample size for moclobemide and bupropion was relatively small, compared with that for paroxetine, sertraline, and venlafaxine.
- Patients were not evaluated for longer than 8 weeks.

Key Words: *sexual side effects, bupropion, moclobemide, paroxetine, sertraline, venlafaxine, major depressive disorder, naturalistic*

Because therapeutic efficacy across antidepressants (ADs) is generally comparable, most clinicians perceive differences in the incidence of side effects to be an important factor in their selection of ADs (1). However, very few studies have directly compared side effects across the selective serotonin

reuptake inhibitors (SSRIs) and other novel ADs. In stead, clinicians rely on information from standard references, such as the *Physicians' Desk Reference (PDR)* (2) or *Compendium of Pharmaceuticals and Specialties (CPS)* (3), and occasionally on metaanalyses of side effects derived from clinical trials (4).

This investigation compares the side effects of 5 frequently prescribed AD medications (venlafaxine, a serotonin and norepinephrine reuptake inhibitor [SNRI]; paroxetine and sertraline, SSRIs; moclobemide, a reversible inhibitor of monoamine oxidase A [RIMA]; and bupropion, a norepinephrine and dopamine modulator [NDM]) in a sample of depression patients who were assessed and treated under natural practice conditions in an outpatient clinic. We proposed to demonstrate differences in class-specific prevalences of side effects consistent with those found in metaanalyses and randomized controlled trials (RCTs). We also proposed that intensity, as a product of frequency and severity of side effects, would further differentiate ADs, both across and within classes.

Method

Our subjects were outpatients with unipolar, nonpsychotic major depressive disorder (MDD) who provided informed consent and were treated at the Depression Clinic, Centre for Addiction and Mental Health (CAMH), a tertiary care facility affiliated with the University of Toronto. Entry criteria were a current diagnosis of major depressive episode (MDE) according to DSM-IV criteria, a score of 16 or greater on the 17-item Hamilton Rating Scale for Depression (HRSD-17) (5), absence of concurrent active medical illness, absence of AD or other psychotropic medications for a minimum of 2 weeks (5 weeks for fluoxetine), and absence of exposure to electroconvulsive therapy (ECT) for at least 3 months prior to treatment initiation. The study was approved by the CAMH Research Ethics Board.

Measure and Design

The Toronto Side Effect Scale (TSES) is a 32-item instrument that uses direct physician inquiry to elicit adverse events. Modified from a previous instrument developed by Healy (6), the TSES is designed to establish incidence, frequency, and severity of central nervous system (CNS), gastrointestinal (GI), and sexual side effects (see Appendix). For each side effect, frequency and severity were measured on a 5-point Likert scale. An "intensity" score was derived by multiplying frequency by severity.

Clinical research assistants with extensive experience and established interrater reliability administered the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) (7) and the HRSD-17 to all subjects prior to treatment (Time 1). The treating physician completed the TSES.

ADs were selected at the discretion of the treating psychiatrist from among various medications used in the Depression Clinic; however, during this study only 5 medications were prescribed at a rate that provided suitable numbers for data analysis. During the study, clinicians provided standard clinical management every 2 weeks, while repeat measures of HRSD-17 and TSES (completed by the same research staff, who were blind to which of the 5 medications had been prescribed) were collected after 8 weeks of treatment (Time 2).

Remission was defined as a final HRSD-17 score < 7 after 8 weeks of treatment.

Statistical Analyses

We calculated mean differences for continuous variables across AD medication groups using a 1-way analysis of variance (ANOVA). We used chi-square analyses to examine differences in the incidence rates of side effects between pairs of AD medications (for example, venlafaxine vs moclobemide) for the noncontinuous variables. We used point biserial correlations to examine the relation between response to treatment and side effects, and we used a repeated-measures ANOVA to examine treatment response from Time 1 to Time 2.

Results

Sociodemographic and Clinical Variables

There were no significant differences among AD medication conditions with respect to age, socioeconomic status (8), duration of current episode, age at first onset, education, or baseline HRSD-17 scores. During the time interval for this study (from January 1, 1995, to March 31, 2000), 217 patients (86 men and 131 women) completed baseline assessments. The sample was predominantly white. Of the sample, 193 (73 men and 120 women) completed the protocol after at least 8 weeks of treatment; 24 patients dropped out of treatment before the week 8 assessment. There were no significant differences between completers and noncompleters. There were no significant differences in drop out rates among the 5 AD medications (bupropion 12%, venlafaxine 13%, moclobemide 16%, paroxetine 23%, and sertraline 24%), nor were there significant differences in rates of remission or in reduction in HRSD scores (Table 1). A post hoc power analysis using a medium effect size (that is, Cohen's $d > 0.50 < 0.79$) produced a power of 0.84 for the 193 patients who completed the study. Thus, it is unlikely that these nonsignificant results were attributable to insufficient power.

Intensity of Side Effects

When the intensity of potential side effects across the AD medications was examined after Bonferroni correction, only 1 side effect (delayed ejaculation) produced a statistically significant difference among drugs ($F = 6.89$, $P < 0.001$). Unplanned, post hoc testing using the Scheffé test indicated that for this side effect patients on paroxetine scored significantly higher on the intensity rating than did patients on other ADs.

Incidence Rates of Side Effects

We then examined mean score differences for the frequency or absolute incidence rate of side effects. Paired comparisons (with Bonferroni correction) revealed significant differences between at least 1 drug pair for 16 of 32 items: 7 CNS side effects, 7 GI side effects, and 2 sexual functioning (SF) side effects (see Tables 2, 3, and 4 respectively).

Table 1. Demographic and clinical characteristics^a

Characteristic	Venlafaxine	Paroxetine	Sertraline	Moclobemide	Bupropion	Total
<i>n</i>	62	55	37	24	15	193
Sex (m:w)	24:38	34:21 ^a	7:30	4:20	4:11	73:120
Age (years): mean (SD)	40.8 (11.2)	38.1 (11.3)	39.5 (11.4)	38.9 (9.4)	41.1 (8.8)	39.5 (10.9)
Age range (years)	20 to 64	18 to 60	20 to 60	22 to 53	24 to 54	18 to 64
Education (years): mean (SD)	16.0 (2.9)	15.6 (3.5)	14.9 (3.1)	15.2 (3)	16.3 (2.7)	15.6 (3.1)
Socioeconomic status (ref 8)	49.6 (14.4)	49.1 (15.4)	42.9 (17.0)	46.7 (11.1)	53.0 (11.9)	48.1 (14.9)
Previous MDE: <i>n</i> , (%)	48 (77.4)	41 (74.5)	23 (62.2)	15 (62.5)	15 (100)	142 (73.6)
DCE (weeks): mean (SD)	109.4 (141.3)	66.4 (104.1)	72.6 (77.3)	105.7 (148.9)	97.9 (101.5)	88.5 (119.5)
Age at first onset (years): mean (SD)	27.7 (12.8)	27.7 (13.1)	26.9 (14)	28 (12.5)	22 (11.8)	27.1 (12.9)
HRSD-17 score: mean (SD)						
Time 1	22.3 (4.6)	22.3 (4.1)	22.8 (4.6)	22.1 (4.6)	21.9 (3.8)	—
Time 2	11.1 (7.4)	9.7 (7.8)	10.8 (7.2)	14.5 (8.9)	11.8 (6.7)	—
Remitters(% ^b)	40	45	36	25	33	—
Dosage (mg): mean (SD)	81.4 (58.4)	18.7 (6.1)	105.4 (217.5)	370.8 (304.6)	143.3 (25.8)	na

MDE = major depressive episode, DCE = duration of current episode, HRSD-17 = Hamilton Rating Scale for Depression
^amean significantly differs from all others: Venlafaxine, $P < 0.01$; sertraline, $P < 0.001$; moclobemide, $P < 0.001$; bupropion, $P < 0.05$
^bRemission was defined as a score of 7 or less on the HRSD-17

Table 2. CNS side effect incidence (% reporting)

	Venlafaxine	Paroxetine	Sertraline	Moclobemide	Bupropion
Nervousness	11 ^{mB}	9.1 ^m	16	29 ^p	40 ^{vP}
Agitation	18	11 ^{mb}	19	29 ^p	33 ^p
Tremor	11	3.6 ^s	16 ^{pm}	0 ^e	6.7
Myoclonus	9.7	13	14	4.2	0
Fatigue	24	13	22	17	27
Dizziness	9.7	11	14	8.3	20
Postural hypotension	15	7.3 ^{sB}	22 ^p	13	33 ^p
Somnolence	27	29	32	17	20
Increased sleep	6.5	7.3	14	4.2	6.7
Decreased sleep	26	13	14	8.3 ^b	33 ^m
Sweating	27	27	32 ^m	8.3 ^{sB}	40
Flushing	11	13	14	4.2	0
Edema	1.6 ^m	1.8 ^m	8.1	13	6.7
Headache	26	18	22	21	40
Blurred vision	9.7	15	14	13	6.7

Dif fers from re sults for bupropion, $P < 0.05$; ^BDif fers from re sults for bupropion, $P < 0.01$
^mDif fers from re sults for moclobemide, $P < 0.05$; ^MDif fers from re sults for moclobemide, $P < 0.01$
^DDif fers from re sults for paroxetine, $P < 0.05$; ^PDif fers from re sults for paroxetine, $P < 0.01$
^sDif fers from re sults for sertraline, $P < 0.05$; ^SDif fers from re sults for sertraline, $P < 0.01$
^vDif fers from re sults for venlafaxine, $P < 0.05$; ^VDif fers from re sults for venlafaxine, $P < 0.01$

CNS Side Effects

No CNS side effects were reported significantly more frequently with venlafaxine or paroxetine than with any other drug pairing. Sertraline produced a significantly higher incidence of tremor and sweating, compared with moclobemide, and a greater incidence of tremor, compared with paroxetine.

Moclobemide yielded a significantly higher incidence of nervousness and edema, compared with venlafaxine and paroxetine, and a significantly higher rate of agitation, compared with paroxetine. Bupropion was associated with significantly higher rates of nervousness, agitation, and postural

Table 3. Gastrointestinal (GI) side effect incidence (% reporting)

	Venlafaxine	Paroxetine	Sertraline	Moclobemide	Bupropion
Abdominal pain	9.7	1.8 ^S	14 ^P	8.3	0
Dyspepsia	18	16	24 ^b	8.3	0 ^S
Nausea	26 ^{mb}	18	24 ^{mb}	4.2 ^{vs}	0 ^{vs}
Diarrhea	15	15	30 ^S	4.2 ^S	6.7
Constipation	15 ^S	25 ^S	0 ^{mb,P}	13 ^S	13 ^S
Decrease appetite	8.1 ^{bs}	13 ^S	30 ^{Vp}	13	27 ^V
Increase appetite	9.7	11	2.7	4.2	6.7
Dry mouth	44	35	46	46	40
Weight gain	9.7	11	5.4	0	13
Weight loss	8.1	3.6 ^b	11	13	20 ^P

^DDif fers from re sults for bupropion, $P < 0.05$; ^BDif fers from re sults for bupropion, $P < 0.01$
^mDif fers from re sults for moclobemide, $P < 0.05$; ^MDif fers from re sults for moclobemide, $P < 0.01$
^DDif fers from re sults for paroxetine, $P < 0.05$; ^PDif fers from re sults for paroxetine, $P < 0.01$
^SDif fers from re sults for sertraline, $P < 0.05$; ^SDif fers from re sults for sertraline, $P < 0.01$
^VDif fers from re sults for venlafaxine, $P < 0.05$; ^VDif fers from re sults for venlafaxine, $P < 0.01$

Table 4. Sexual functioning (SF) side effect incidence (% reporting)

	Venlafaxine	Paroxetine	Sertraline	Moclobemide	Bupropion
Anorgasmia	13	22	11	4.2	6.7
Increased libido	6.5	1.8 ^B	2.7 ^b	8.3	20 ^S
Decreased libido	31	16	16	13	6.7
Premature ejaculation ^a	0	0	0	0	0
Delayed ejaculation ^a	43 ^S	59 ^{bs}	14.3 ^P	0	0 ^P
Erectile dysfunction ^a	17	8.8	14.3	0	0

^aPre ma ture ejacu la tion, de layed ejacu la tion, and erec tile dys func tion were asked of male pa tients only and were not re ported for mo clobemide due to small sam ple size.
^b Dif fers from re sults for bupropion, $P < 0.05$; ^B Dif fers from re sults for bupropion, $P < 0.01$
^mDif fers from re sults for moclobemide, $P < 0.05$; ^MDif fers from re sults for moclobemide, $P < 0.01$
^P Dif fers from re sults for paroxetine, $P < 0.05$; ^P Dif fers from re sults for paroxetine, $P < 0.01$
^SDif fers from re sults for sertraline, $P < 0.05$; ^SDif fers from re sults for sertraline, $P < 0.01$
^VDif fers from re sults for venlafaxine, $P < 0.05$; ^V Dif fers from re sults for venlafaxine, $P < 0.01$

hypotension, compared with paroxetine. It was also associated with a higher incidence of nervousness and edema, compared with paroxetine and venlafaxine.

GI Side Effects

Dry mouth was reported by 35% or more patients across all 5 groups but was not significantly different across drugs. The incidence of nausea was significantly greater with venlafaxine, compared with moclobemide and bupropion, while the incidence of constipation was significantly greater with paroxetine, compared with moclobemide. Bupropion treatment was associated with a significantly increased frequency of reported weight loss, compared with paroxetine. No GI side effects were more frequent with moclobemide.

SF Side Effects

Delayed ejaculation in men was reported significantly more frequently with paroxetine, compared with bupropion or sertraline, and more frequently with venlafaxine, compared with sertraline. Increased libido in both men and women was reported significantly more frequently with bupropion, compared with paroxetine or sertraline. No more sexual side effects were reported by patients on moclobemide, compared with any of the other ADs.

Discussion

Equivalent effectiveness and remission rates among antidepressants in a natural practice setting were associated with heterogeneity of side effects across drug classes and, in the

case of sertraline and paroxetine, within the same class. Contrary to what was proposed, no single AD produced a significantly greater side-effect burden, yet among the 32 side effects examined, 16 showed significant differences in incidence across a total of 10 drug pairings. This validates clinician AD selection based on individual tolerability, while assuming uniform effectiveness.

These results are surprisingly consistent with those found in RCTs comparing 2 or more ADs. In a metaanalysis designed to compare adverse effects associated with SSRIs and tricyclic antidepressants (TCAs), nausea, anorexia, diarrhea, insomnia, nervousness, anxiety, and agitation occurred significantly more often with SSRIs, compared with TCAs (4). However, these authors did not include sexual dysfunction in their analysis. Several other investigations of sexual dysfunction produced findings similar to ours. Montejo-González and others reported significantly more anorgasmia associated with paroxetine than with sertraline (48% and 37%, respectively), as well as a higher rate of delayed ejaculation (9). Modell and others reported significantly lower rates of sexual side effects with bupropion, compared with SSRIs (10). Kennedy and others reported lower levels of sexual dysfunction in women during treatment with moclobemide and venlafaxine, compared with paroxetine and sertraline (11). Our results were also consistent with those found for agitation, nausea, and diarrhea in a cohort study carried out in a primary care setting (12).

Metaanalyses of *PDR* and *CPS* data were performed respectively by Dewan and Anand (1) and Vida and Looper (13). Using categories similar to those in our study, Dewan and Anand (1) assigned “penalty” scores for CNS, GI, and sexual side effects across SSRIs and novel antidepressants, based on calculated drug placebo differences. Bupropion, citalopram, nefazodone, and mirtazapine received the lowest overall scores, while fluvoxamine, paroxetine, sertraline, venlafaxine, and fluoxetine were all ranked higher.

What this study demonstrates is an important degree of variability in side-effect reporting across studies and a need for clinical studies to account for the effect of therapeutic interventions on patient response. Most patients in naturalistic settings are not pharmacologically naive and do not remain on the same antidepressant dosage for the duration of treatment, which may result in cross-tolerance or change side-effect reporting. Despite a need for consistency in side-effect definitions, it may also be argued that using a tool such as the TSES introduces suggestibility and increases side-effect reporting. Trindade and others concluded that their results did not depend on the method of eliciting adverse effects (4). A search of Medline, however, revealed that most such studies to date do not use specific side-effect questioning, and incidence rates were higher in our study than in these, despite relatively low mean dosing across ADs. In addition, including a greater number of side effects decreases the likelihood that differences will achieve statistical significance, although

between-drug differences may be extremely clinically significant. The additional dimension of intensity, calculated as the product of frequency and severity, did not add sensitivity to our measures and only distinguished one drug from the others on the basis of sexual dysfunction.

In summary, we have developed and evaluated a clinical interview side-effect questionnaire (the TSES) that assesses both the frequency and the severity of common AD side effects. The absence of a placebo treatment group limits any conclusions about the prevalence of these effects, compared with placebo. However, using a natural practice population to compare side effects across frequently prescribed ADs provides important complementary data to information derived from RCTs. Until newer agents with significantly superior rates of remission, compared with existing agents, are available, selecting ADs based on side-effect profiles appears to be justified.

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Appendix. Toronto Side Effects Scale (TSES)										
Within the last two weeks, have you experienced any of the following symptoms? How much trouble did this side effect cause you? (Physician: rate frequency and severity of the symptoms.)										
	Frequency					Severity				
	Never	Some-times	About half the time	Often	Every-day	No trouble				Extreme trouble
1. Nervousness	1	2	3	4	5	1	2	3	4	5
2. Agitation	1	2	3	4	5	1	2	3	4	5
3. Tremor	1	2	3	4	5	1	2	3	4	5
4. Twitching/myoclonus (muscle contraction)	1	2	3	4	5	1	2	3	4	5
5. Abdominal pain	1	2	3	4	5	1	2	3	4	5
6. Dyspepsia (upset stomach)	1	2	3	4	5	1	2	3	4	5
7. Nausea	1	2	3	4	5	1	2	3	4	5
8. Diarrhea	1	2	3	4	5	1	2	3	4	5
9. Constipation	1	2	3	4	5	1	2	3	4	5
10. Decreased appetite	1	2	3	4	5	1	2	3	4	5
11. Increased appetite	1	2	3	4	5	1	2	3	4	5
12. Weakness or fatigue	1	2	3	4	5	1	2	3	4	5
13. Dizziness	1	2	3	4	5	1	2	3	4	5
14. Postural hypotension (dizzy when getting up)	1	2	3	4	5	1	2	3	4	5
15. Drowsiness/daytime somnolence	1	2	3	4	5	1	2	3	4	5
16. Increased sleep	1	2	3	4	5	1	2	3	4	5
17. Decreased sleep	1	2	3	4	5	1	2	3	4	5
18. Sweating	1	2	3	4	5	1	2	3	4	5
19. Flushing	1	2	3	4	5	1	2	3	4	5
20. Edema (fluid retention)	1	2	3	4	5	1	2	3	4	5
21. Headache	1	2	3	4	5	1	2	3	4	5
22. Blurred vision	1	2	3	4	5	1	2	3	4	5
23. Dry mouth	1	2	3	4	5	1	2	3	4	5
24. Anorgasmia/no orgasm	1	2	3	4	5	1	2	3	4	5
25. Increased libido	1	2	3	4	5	1	2	3	4	5
26. Decreased libido	1	2	3	4	5	1	2	3	4	5
(Men only: items 27–29)	1	2	3	4	5	1	2	3	4	5
27. Premature ejaculation										
28. Delayed ejaculation	1	2	3	4	5	1	2	3	4	5
29. Erectile dysfunction	1	2	3	4	5	1	2	3	4	5
30. Other, specify:		2	3	4	5	1	2	3	4	5
	None	≤2lbs	≤ 4 lbs	≤ 6 lbs	≤ 7 lbs	No trouble				Extreme trouble
31. Weight gain	1	2	3	4	5	1	2	3	4	5
32. Weight loss	1	2	3	4	5	1	2	3	4	5

Résumé : Effets secondaires des antidépresseurs chez des patients dépressifs traités dans un cadre naturel : une étude du bupropion, du moclobémide, de la paroxétine, de la sertraline et de la venlafaxine

Objectif : Il n'y a pas de norme généralement acceptée pour comparer les effets secondaires induits par les antidépresseurs. Cette étude évaluait une échelle administrée par un clinicien, l'échelle des effets secondaires de Toronto (TSES), dans une clinique de pratique naturelle.

Méthode : Nous avons utilisé la TSES pour évaluer les effets secondaires chez 193 patients dépressifs qui terminaient 8 semaines de traitement à l'un des médicaments suivants : bupropion, moclobémide, paroxétine, sertraline ou venlafaxine.

Résultats : Les taux de rémission [échelle de dépression de Hamilton (HRSD) < 7] ne différaient pas entre les divers médicaments après 8 semaines de traitement. Les comparaisons de médicaments couplés ont donné des différences significatives dans 16 des 32 effets secondaires. Nous présentons les différences entre les paires des 5 antidépresseurs dans les effets secondaires gastro-intestinaux, sexuels et sur le système nerveux central (SNC). Une mesure de l'intensité des effets secondaires distinguait la paroxétine des autres antidépresseurs dans la mesure de la dysfonction sexuelle.

Conclusions : Ces résultats confirment l'utilité clinique de la TSES comme échelle simple et administrée par un clinicien des effets secondaires des antidépresseurs.