An Open, Baseline Controlled Evaluation of Sertraline Safety and Efficacy in the Treatment of Depression in Thai Patients

The SESS Group (Sertraline Efficacy and Safety Study Group)†

Abstract

An open, baseline controlled study of sertraline in depressed patients was conducted in 6 treatment sites. Eighty-two patients between 20-82 years of age with DSM III-R diagnosis of a depressive illness received sertraline 50-200 mg/day. Among evaluable patients, there was a significant reduction in depressive symptoms at the final visit. A statistically significant change from baseline in Montgomery Asberg Depression Rating Scale (MADRS), Hospital Anxiety Depression Rating Scale (HAD), and Clinical Global Impression Severity of Illness Scale (CGI-S) scores was demonstrated. On the basis of MADRS criterion, 96.0 per cent of patients responded and on the basis of CGI-S criterion, 86.6 per cent of patients responded. In 73.2 per cent of patients the final sertraline dosage was 50 mg. All-cause adverse events were recorded in 35 patients (42.7%), whereas 22 (26.8%) had adverse events that were judged treatment-related. The most frequently reported events were nausea and headache. Overall, the patients tolerated sertraline very well. The results of the study suggest that sertraline is an effective, well-tolerated and safe treatment for depression in Thai patients.

Key word : Sertraline, Depression, Efficacy, Safety, Thai

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J Med Assoc Thai 2001; 84: 54-62

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Since the early 1950s, when imipramine was first introduced, a whole series of antidepressants with differences in structures, neurochemical effects and pharmacokinetics have been developed. Among these, selective serotonin reuptake inhibitors (SSRIs) have been found to be very promising because of their faster action and fewer side effects compared with tricyclic antidepressants. Sertraline, a SSRI, was approved by the U.S. Food and Drug Administration (FDA) for use as an antidepressant in 1991. It has demonstrated efficacy in the treatment of depression, obsessive-compulsive disorder and panic disorder in various western populations (2,14,15). But so far there has been no information on the treatment of depression with sertraline in Thai patients. We report here the results from a multicenter study designed to assess the efficacy and safety of sertraline in the treatment of depression in Thai patients.

PATIENTS AND METHOD

Patients

The study, approved by local ethics committees, was conducted in 6 treatment sites in Thailand : King Chulalongkorn Memorial Hospital, Siriraj Hospital, Pramongkutkhlao Hospital, Taksin Hospital, the Child Mental Health Center and Chiang Mai University Hospital. Patients aged between 20-82 years with a current DSM III-R axis I diagnosis of a depressive illness of at least 2-week duration and a baseline Clinical Global Impression severity of illness score between mild (score=2) to most severely ill (score=6) were enrolled in the study. Exclusion criteria were pregnancy, lactation, inadequate contraception, significant suicidal risk, history of recurrent alcohol abuse, concurrent significant diseases or conditions (physical or emotional), treatment with any other SSRIs in the 4 weeks prior to the study, any concurrent antidepressant treatment (including TCA, MAOIs, tryptophan, lithium or electroconvulsive therapy) and treatment with other investigational drugs in the previous 4 weeks or concurrent with the study.

After giving informed consent, all patients who fulfilled the selection criteria had a full medical history taken and a complete physical examination, including weight and blood pressure measurements.

Treatment

Following satisfactory screening evaluations, patients received a single 50 mg oral dose of sertraline. The dosage was then titrated to 100 mg/day at week 4, 150 mg at week 8 and 200 mg at week 12. It could only be titrated up if the patients' condition had not improved and there was no side effect. It could be decreased if the patients experienced any side effects. The maximum allowable dose was 200 mg per day. Old patients or those with a history of multiple drug intolerance or low tolerance to other SSRIs could receive an initial dose of 25 mg/day. The dosage could then be increased to 50 mg/day after week 4 and then slowly increased every 4 weeks if required. Patients were given sertraline for a 12-week period and would come for an assessment at weeks 2, 4, 8 and 12. Those who needed more than 150 mg/day at week 8 received sertraline for 16 weeks and would come for the final visit at week 16. Sertraline was provided in the form of 50 mg tablets and taken once daily. Compliance was assessed by means of tablet counts.

Efficacy assessment

Evaluation of efficacy was performed using the following rating scales: the Montgomery Asberg Depression Rating Scale (MADRS), the Clinical Global Impression Severity of Illness Scale (CGI-S) and the Hospital Anxiety-Depression Rating Scale (HAD).

MADRS is a 10-item investigator-rated scale. The score of each item ranges from 0 (normal condition or no illness) to 6 (most severe illness possible). The total score is the sum of the scores of the 10 individual items and can range from 0 to 60.

The CGI-S is also an investigator-rated scale and consists of 6 items which describe the severity of illness from normal or not at all ill (score 0) to most severely ill (score 6).

The HAD is a patient-rated scale which consists of 14 items scored between 0 (normal) and 3 (severe illness). In this study the HAD depression factor, which is the summation of the individual scores for items 2, 4, 6, 8, 10, 12 and 14, was used to evaluate efficacy.

All evaluations using CGI-S and HAD were performed before the start of the treatment phase (baseline) and at each visit. MADRS score

was performed before the start of the treatment phase (baseline) and at the final visit.

Safety and tolerability assessment

Adverse events which occurred during therapy and up to 30 days after the last dose of sertraline were recorded at each visit and classified with respect to onset, duration, severity (mild, moderate, severe), and cause (as judged by the investigator to be due to the study drug, not due to the study drug or due to an unknown cause). Intercurrent illnesses and concomitant medication were also recorded.

At the final visit (week 12 or 16 or whenever treatment was withdrawn), weight and blood pressure were recorded and an overall evaluation of therapy was made. The investigator would document the final daily dose of sertraline and rate his/her global assessment of efficacy and toleration as excellent, good, fair or poor.

Statistical analysis

The safety analysis covered all patients who took at least one dose of medication and provided follow-up data. Patients included in the safety analysis who had baseline and final efficacy data were included in the efficacy analysis.

Frequency distribution was used for baseline patient characteristics. The efficacy variables were the severity of depression as rated with MADRS, CGI-S and HAD depression factor. Patients were divided into responders and nonresponders. Responders were defined as those patients with $\geq$50 per cent decrease in MADRS score from baseline to last visit. Patients with CGI-S score of O or 1 at the last visit were also designated as responders. Paired *t*-test was used to calculate the statistical significance of MADRS, CGI-S and HAD score mean change from baseline to last visit. The percentages of patients in various categories of overall efficacy and toleration ratings were compared between the different final doses.

RESULTS

A total of 91 patients were enrolled in this study. However, 9 were lost to follow-up after baseline evaluation. The remaining 82 patients who comprised the "safety evaluable patient" population had a postbaseline safety and drug tolerability assessment and provided safety data. Of this group, 7 broke the study protocol and 2 withdrew prior to day 28. Six patients started treatment with 25 mg sertraline and were reported separately as the "option" group. The remaining 67 patients who started the treatment with 50 mg sertraline and continued the medication for at least 28 days constituted the "efficacy evaluable patient" population and provided efficacy data.

Baseline characteristics

The baseline characteristics of 82 patients who comprised the safety evaluable group are shown in Table 1. The majority of patients were between 20-44 years of age. Half reported a previous history of depression. In 69.5 per cent the current depressive episode was the only episode of depression within the past 2 years. At baseline, 24 patients (29.3%), had concurrent diseases. The most frequent were anxiety disorder, peptic ulcer and diabetes mellitus, at 3.7 per cent each. Thirty-two patients (39.0%) had somatic symptoms, the most frequent being headache (14.6%), dyspepsia (9.8%), insomnia (7.3%) and back pain (4.9%). Sixty-two patients (75.6%) received concomitant therapy, the most common of which was psychotropic medication (25.6%).

Efficacy

Table 2 summarizes the mean change from baseline for MADRS, CGI-S and HAD

Table 1. Baseline characteristics of safety evaluable patients.

Variable	N	%
Male	22	26.8
Female	60	73.2
Age (years)		
20-44	40	48.8
45-64	34	41.5
>65	8	9.8
age, mean ± SD	44.8 ± 14	95
age range	20-82	
number with previous history of depression	41	50
number of depressive episodes in the past 2 years		
1-2	19	23.2
3-4	5	6.1
>5	1	1.2
duration of current depressive episode (weeks), mean ± SD *	9.8 ± 7.4	

* 4 cases with duration of illness between 2-9 years were not included.

Table 2. Efficacy variables in efficacy evaluable group (N=67).

	MADRS	HAD	CGI-S
Mean baseline (SD)	39.9 (6.7)	15.7 (4.1)	3.6 (0.7)
Mean last visit (SD)	6.7 (7.0)*	4.3 (3.6)**	0.8 (0.8)
Change from baseline***	-33.2	-11.3	-2.8
% change from baseline	83.3	72.3	78.5
% responders	96		86.6

* data missing = 2
** data missing = 1
*** $P < 0.001$ by paired *t*-test
\+ MADRS score ≥ 50 per cent decrease from baseline
++ CGI-S score = 0 or 1

Table 3. Common adverse events during sertraline therapy (safety evaluable group, n= 82).

Events	N	% *
Nausea	8	15.1
Headache	7	13.2
Diarrhea	5	9.4
Dyspepsia	5	9.4
Dry mouth/throat	3	5.7
Drowsiness	2	3.8
Constipation	2	3.8
Insomnia	2	3.8
Frequent urination	2	3.8
Rash	2	3.8
Progression of depression	2	3.8

* Percentage calculated from the total number of events (53). Number of patients with ADE was 35.

variables in the efficacy evaluable group. The mean MADRS score decreased significantly from 39.9 at baseline to 6.7 at the final visit ($p<0.001$). Significant reductions also occurred in the mean HAD, from 15.7 to 4.3 ($p<0.001$), and in the mean CGI-S, from 3.6 to 0.8 ($p<0.001$). Of the patients sampled, 96 per cent and 86.6 per cent were classified as responders according to the MADRS and CGI-S responder criteria respectively.

In the option group, the mean MADRS, HAD and CGI-S scores also decreased from 49.5, 19.5 and 5.4 at baseline to 8.0, 1.6 and 0.3 at the final visit respectively.

Safety

Table 3 lists the adverse events occurring during the study treatment and up to 30 days after the last dose of sertraline was administered. Of the 82 patients, 35 (42.7%) reported at least one adverse event, whereas 22 (26.8%), had adverse events that were judged treatment- related. The most frequently reported experiences (incidence ≥ 10%) were nausea (15.1%) and headache (13.2%). Those which occurred in one patient (1.9%) each were as follows: alopecia universalis, lip numbness, dizziness, acne, epiphora, throat ulcer, tremor, jaundice, renal failure, anorexia, increased appetite and voiding difficulty. The majority of adverse experiences were characterized as mild (60.5%) or moderate (34.9%) rather than severe. Only in 3 cases were the events of sufficient severity to cause discontinuation of the patients from the study. In the first patient there was a progression of diabetic nephropathy to renal failure. The second patient developed voiding difficulty after receiving sertraline for 24 hours. The last patient developed jaundice from heart failure after week 8.

Final dose

Table 4 compares the final and maximum doses of the safety evaluable, the efficacy evaluable and the option groups. Most patients (N=58, 70.7%) took a maximum dose of 50 mg sertraline daily and had this as their final dose (N=60, 73.2%). The highest dose taken in this study was

Table 4. Final and maximum doses.

	Safety evaluable group N = 82	Efficacy evaluable group N = 67	Option group N = 6
Maximum dose (mg)			
25	2	0	2
50	58	49	4
75	3	-	-
100	13	13	-
150	6	5	-
200	0	-	-
Final dose (mg)			
25	3	-	2
50	60	51	4
75	2	-	-
100	12	12	-
150	5	4	-
200	0	-	-

Table 5. Overall evaluation of efficacy by final dose (efficacy evaluable group).

Overall evaluation	Final dose (mg)									
	50	%	100	%	150	%	200	%	Total	%
Excellent	23	45.1	1	8.3	0	0	0	0	24	35.8
Good	19	37.3	10	83.3	2	50	0	0	31	46.3
Fair	7	13.7	1	8.3	1	25	0	0	9	13.4
Poor	0	0	0	0	1	25	0	0	1	1.5
Data missing	2	3.9	0	0	0	0	0	0	2	3.0
Total	51	76.1	12	17.9	4.0	5.9	0	0	67	100.0

Table 6. Overall evaluation of toleration by final dose (safety evaluable group).

Overall evaluation	Final dose (mg)													
	25	%	50	%	75	%	100	%	150	%	200	%	Total	%
Excellent	0	0	43	71.7	1	50.0	2	16.7	0	0	0	0	46	56.1
Good	1	33.3	9	15	0	0	10	83.3	4	80.0	0	0	24	29.3
Fair	2	66.7	1	1.7	0	0	0	0	0	0	0	0	3	3.7
Poor	0	0	1	1.7	0	0	0	0	0	0	0	0	1	1.2
Data missing	0	0	6	10.0	1	50.0	0	0	1	20.0	0	0	8	9.8
Total	3	3.7	60	73.2	2	2.4	12	14.6	5	6.1	0	0	82	100.0

150 mg of sertraline (N=6, 7.3%) and this was the final dose in 5 cases (6.1%).

Overall evaluation of therapy

The investigators' global impression of efficacy and toleration at the completion of treatment is shown in Tables 5 and 6. The majority of patients had excellent or good overall efficacy and toleration. Only one patient who received the final dose of 150 mg was rated as having poor efficacy.

DISCUSSION

The present report describes the first study of sertraline in treating depression in Thai patients. The aim of the study was to evaluate the safety and efficacy of sertraline in the treatment of depression in Thai patients and to identify the most commonly used dosage. An open, baseline controlled study method was undertaken. The study was "natural" since the patients were treated with sertraline in a fashion similar to routine clinical practice. Safety and efficacy were, therefore, assessed in a so-called "real-life" situation.

Sertraline has been demonstrated to be effective in reducing depressive symptoms in various studies (1-3). Despite the absence of a placebo control group, the results suggest that sertraline is effective in the treatment of depression in Thai patients. Significant improvement was observed in every efficacy parameter obtained. Changes in the MADRS, HAD and CGI-S scores were observed early in the second week of treatment. Responder rates at the end of 12-16 weeks of treatment were high, 96 per cent by MADRS and 86.6 per cent by CGI-S.

Sertraline has been shown to have sustained efficacy as maintenance treatment for the prophylaxis of depression in patients who are at high risk of recurrence due to chronicity of depression, comorbidity or history of multiple previous episodes(4). A consistent finding of all studies of 6 months or more with sertraline is the continuing reduction in depressive symptoms in the sertraline group over the entire course of the study (5-8). In this study, patients continued to manifest gradual improvement in depressive symptoms

throughout the full duration of therapy. Improvement was seen in the MADRS, HAD and CGI-S scores obtained at each visit. At the final visit the change from baseline reached significant levels ($p<0.001$) for all measures.

The safety results for sertraline in the Thai patients in this study are similar to those previously reported in Western populations. In clinical trials involving Western adult patients, sertraline was well tolerated in doses ranging from 50 to 200 mg/day. A study of 1,209 patients found that 31.4 per cent reported one or more adverse clinical event. Frequently reported events were poor sleeping, dry mouth, diarrhea, nausea and decreased appetite[9]. A comparison between the side-effect profiles of SSRIs fluvoxamine, fluoxetine, sertraline and paroxetine found that nausea and vomiting were both the most frequent clinical reasons for stopping the SSRIs and the most frequently reported clinical events[3]. In this study, all-cause adverse events were recorded in 35 patients (42.7%), whereas 22 (26.8%), had adverse events that were judged treatment-related. About 60.5 per cent of adverse events were mild and 34.9 per cent were moderate in severity. The two most common events were nausea/vomiting (15.1%) and headache (13.2%).

Minimal change in blood pressure was found in some patients. Most patients had mild weight gain which might be due to the increased appetite as depression improved. Other adverse events were mild and occurred in a small percentage. Two elderly patients developed hepatic failure and renal failure which were later documented to be due to underlying heart disease and diabetes mellitus.

In an index of behavioral toxicity, sertraline had the best ranking of clinically available, tested antidepressants. It was demonstrated to be the least likely to produce impairment of alertness and reaction time[10]. In this study, only 2 patients (4.4%) developed drowsiness or somnolence of a mild degree.

Many studies showed that sertraline and its principal metabolite, demethylsertraline, have a minimal effect on hepatic isoenzymes, CYP 2C19 and CYP 3A3/4, which are responsible for the metabolism of diazepam, and CYP 2C9/10 which is responsible for the metabolism of tolbutamide and warfarin[11-13]. Therefore, sertraline is unlikely to produce significant pharmacokinetic interaction with other drugs which are dependent on these enzymes for clearance. Aside from the risk of serotonin syndrome from all SSRIs, drug interaction problems for sertraline are fewer than from other antidepressants[14]. In this study, although several participants had disease conditions and were receiving concurrent drug therapy, no evidence of drug interaction was observed.

Sertraline has been found to be well tolerated in elderly patients[1]. Moreover, it has been demonstrated to be safely administered to pediatric patients using the currently recommended adult titration schedule[15]. In this study, sertraline was well tolerated by most patients. The overall toleration rated by the investigators was excellent to good.

Since depression affects a significant proportion of the adult population, the treatment of depression represents a major public health concern. The costs of treatment are significant and many additional costs accrue through patients' decreased productivity. In the United States the treatment, morbidity and mortality associated with depression are estimated to cost $44 billion annually[16]. Cost-effective antidepressant medication is mandatory. Although SSRIs are more expensive than the traditional TCAs, many studies found the mean cost of treatment and the discontinuation rate are greater for patients receiving TCA medication due to greater use of psychiatric services and more frequent side effects[17,18]. Skaer et al[19] found a 21 per cent reduction in total health service expenditures with receipt of sertraline relative to a TCA. A comparison between sertraline and imipramine in primary care settings found that treatment with sertraline was more successful in reducing the symptoms of depression and was less costly[20].

Although the maximum recommended dosage of sertraline for Western patients is 200 mg/day, in many studies on depression, obsessive-compulsive disorder and panic disorder, 50 mg/day has been demonstrated to be an efficacious dose[21-23]. In this study, the most commonly used dosage was 50 mg/day. At this dose the efficacy was excellent to good. Sertraline 50 mg/day is, therefore, the recommended dosage for the

treatment of depression in Thai patients. As maintenance therapy is important, the once-a-day, single tablet (50 mg sertraline per tablet) adminis-tration m[illegible]s greater compliance and greater chance for successful treatment and less financial burden to the patients.

SSRIs are considered to be the treatment of choice for many patients with depressive disorders because of their effectiveness, their generally favorable tolerability profile and their wide therapeutic index. This study found sertraline, a SSRI, to be effective and safe in reducing depressive symptoms. At the recommended dose of 50 mg/day, sertraline is clearly a cost-effective option in the treatment of depression in Thai patients.

ACKNOWLEDGEMENT

The authors wish to thank

1. Dr. Chutitaya Panpreecha for his continuous support that helped make this study possible.

2. Pfizer International Corp. for providing drugs and support.

(Received for publication on February 29, 2000)

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การศึกษาประสิทธิผลและความปลอดภัย แบบเปิดฉลาก เปรียบเทียบกับก่อนการรักษาของยาเซอร์ตราลีน (Sertraline) ในผู้ป่วยไทยที่เป็นโรคซึมเศร้า

The SESS Group. †

การศึกษายา เซอร์ตราลีน (Sertraline) แบบเปิดฉลาก เปรียบเทียบผลกับก่อนใช้ยาวิจัยในผู้ป่วยโรคซึมเศร้าในสถานบำบัด 6 แห่ง ผู้ป่วยจำนวน 82 ราย อายุระหว่าง 20-82 ปี ที่ได้รับการวินิจฉัยว่าเป็นโรคซึมเศร้าตามเกณฑ์การวินิจฉัยของ DSM III-R ได้รับยา sertraline ขนาด 50-200 มก.ต่อวัน ในกลุ่มของผู้ป่วยที่สามารถประเมินได้ (67 ราย) อาการซึมเศร้าลดลงอย่างมีนัยสำคัญ เมื่อเปรียบเทียบระหว่างการประเมินครั้งสุดท้ายกับครั้งแรกก่อนได้รับการรักษา ค่าคะแนนอาการซึมเศร้าที่วัดด้วยเครื่องมือ Montgomery Asberg Depression Rating Scale (MADRS) Hospital Anxiety Depression Rating Scale (HAD) และ Clinical Global Impression Severity of Illness Scale (CGI-S) มีการเปลี่ยนแปลงอย่างมีนัยสำคัญจากก่อนได้รับยา โดยเกณฑ์ของ MADRS ผู้ป่วยร้อยละ 96.0 ตอบสนองดีต่อยา และโดยเกณฑ์ของ CGI-S ผู้ป่วยร้อยละ 86.6 ตอบสนองดีต่อยา มีผู้ป่วยร้อยละ 73.2 ที่ได้รับขนาดยาสูงสุดที่ใช้ และเป็นขนาดยา ครั้งสุดท้ายคือ 50 มก.ต่อวัน อาการอันไม่พึงประสงค์จากทุกสาเหตุพบในผู้ป่วย 35 ราย (ร้อยละ 42.7) ในจำนวนนี้ 22 ราย (ร้อยละ 26.8) อาจเกี่ยวข้องกับยาวิจัย อาการอันไม่พึงประสงค์ที่พบบ่อยที่สุดคือ คลื่นไส้ และปวดศีรษะ เมื่อพิจารณาโดยรวมผู้ป่วยทนยา sertraline ได้ดีมาก ผลการศึกษานี้ชี้ว่า sertraline เป็นยาที่มีประสิทธิผลและปลอดภัย ผู้ป่วยสามารถทนยาได้ดี และเหมาะที่จะบำบัดรักษาผู้ป่วยไทยที่มีอาการซึมเศร้า

คำสำคัญ : เซอร์ตราลีน, ซึมเศร้า, ประสิทธิผล, ความปลอดภัย, ไทย

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จดหมายเหตุทางแพทย์ ฯ 2544; 84: 54-62

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