Efficacy of Sumenta in Patients of Mild to Moderate Depression

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INTRODUCTION

The prevalence of depressive disorders, recognized as disabling psychiatric illnesses is growing rapidly. These conditions are often under diagnosed and under treated. Although anti-depressants offer some respite, their frequent and prolonged use results in various untoward manifestations like dryness of mouth, blurred vision, constipation and constant hangover. In this study, we evaluate the efficacy and tolerability of a herbal antidepressant formulation SUMENTA in mild to moderate depression.

COMPOSITION

Each tablet of Sumenta contains

Extracts of St. John's Wort	Hypericum perforatum	22.5 mg
Extracts of the following		
Jatamansi	Nardostachys jatamansi	20 mg
Tagar	Valeriana wallichii	20 mg
Bael /Bilvamool	Aegle marmelos	50 mg
Arjun chhal	Terminalia arjuna	100 mg
Vaj / Vacha	Acorus calamus	150 mg
Ashwagandha	Withania somnifera	150 mg
Shankhavali / Shankhapushpi	Evolvulus alsinoides	150 mg
Jyotishmati	Celastrus paniculatus	150 mg
Brahmi	Herpestis monniera	200 mg
Amla / Amalaki	Emblica officinalis	200 mg

Study Design

Subjects included in this study consisted of male and female patients above the age of 18 yrs presenting at the Psychiatry Department of Grant Medical College, Sir J.J.Group of Hospitals Mumbai. This study was a randomized, open-labelled, non-comparative trial using outpatients of mild to moderate depression.

Inclusion Criteria

- Diagnosis of mild to moderate depression according to ICD-10 without increased suicidal ideation.
- Patients having the baseline total scores of <=17 on the Hamilton Depression Rating Scale.
- Depression duration of a minimum of 4 weeks and a maximum of 2 years.
- Subjects were required to be free of all psychotropic medication for at least one month before study entry.

Exclusion Criteria

- Patients with a severe depressive disorder.
- History or presence of any Bipolar disorder / severe psychotic illness.
- Active suicidal ideation.
- Co-morbidity from alcohol or drug dependence
- Major ongoing medical illness.
- Sleep disorders.
- Pregnancy or lactation.

All the patients provided a written informed consent for inclusion in the trial.

TREATMENT PROTOCOL AND PLAN OF WORK

All prospective research subjects were initially administered a diagnostic interview and 50 patients meeting the required entry criteria were selected for the study. The patients were thoroughly interrogated and the severity of their symptoms were evaluated on the17-item Hamilton's Depression Rating Scale.

The symptoms listed above were graded on a 5 point scale as Absent (0), Mild (1) Moderate (2) Severe (3) and Incapacitating (5). Baseline score of the patients was thus determined.

The patients were then assigned to treatment with Sumenta tablets in the dose of 1-2 tablets twice a day.

This treatment was continued for 8 weeks and compliance, efficacy, vital signs and adverse effects were evaluated at each weekly visit.

Table 5. Investigator's assessment-clinical global improvement

Grade	1	2	3	4	5	6	7
Period	No.of patients						
Week-1	3	11	25	11	0	0	0
Week-2	9	22	15	4	0	0	0
Week-4	15	23	11	1	0	0	0
Week-8	16	24	9	1	0	0	0

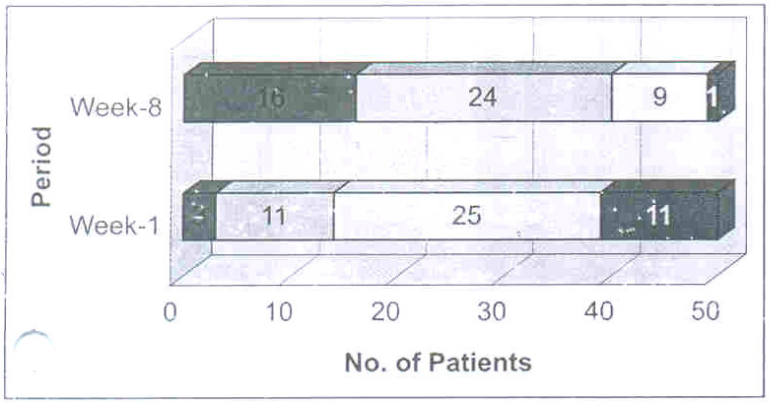

Figure 4.Investigators' assessment of clinical Global Improvement

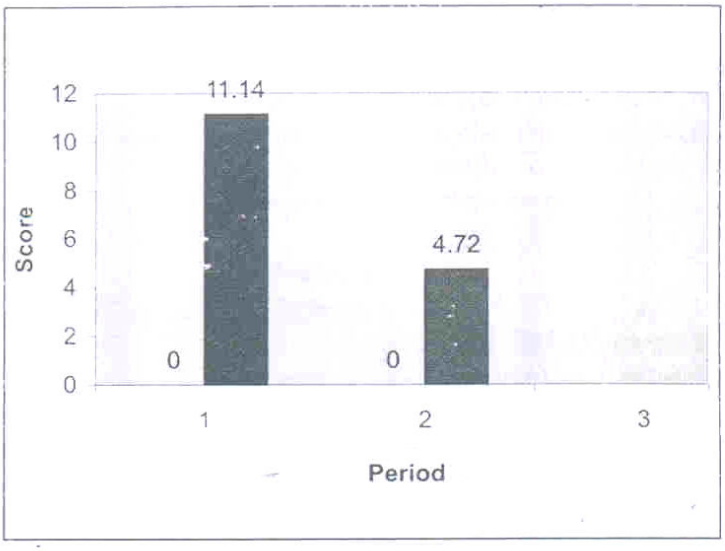

Figure 5. Patient opinion on Quality of Life (Lower score indicates improvement)

Table 6. Patient opinion -evaluation of efficacy

GRADE	1	2	3	4	5	6	7
PERIOD	No. of patients						
Week 1	5	10	12	20	3	0	0
Week-2	12	20	14	4	0	0	0
Week-4	18	19	12	1	0	0	0
Week 8	18	20	11	1	0	0	0

Discussion

The use of various anti depressant drugs in the treatment of mild to moderate depression has been limited by the concerns of withdrawal and the potential for abuse in the long term. Adverse effects ranging from nausea and insomnia to severe somnolence and dizziness restrict the use of these drugs in most patients.

In this situation, the efficacy of a herbal preparation in mild to moderate cases of depression needs attention. Patients treated with Sumenta have shown statistically significant lower mean scores on the Hamilton's Depression Rating Scale. As seen in the results there has been a consistent fall in the HRD Score over the study period. The investigators assessment shows that 80% of the patients had an Excellent or Good improvement in their anxiety status over the period of 6 weeks.

Moreover, there were no dropouts from the study and negligible side effects. Tablet Sumenta consists of a combination of time-tested herbal medicines, which have been used since ages to correct various psychiatric ailments. In this study, Sumenta has proved to be an excellent anti-depressant in mild and moderate cases of depression. Further studies are warranted to evaluate its efficacy in severe depression and its efficacy in combination with other proven antidepressants.

CONCLUSION

We thus hereby conclude that Tablet Sumenta, has shown significant anti-depressant activity in mild to moderate cases of depression and is recommended as a first line therapy in these patients, particularly considering its negligible side effect profile as compared to other agents.

References:

1. Payk TR: Treatment of Depression., *J Geriatr Psychiatry Neurol,* 1994, Oct 7, Suppl 1: S3-5 .
2. NIH to explore St. John's Wort., *Science,* 199, 278:391.
3. Vorbach EU, Hubner WD, Arnoldt KH: Effectiveness and Tolerance of the Hypericum Extract LI 160 in Comparison with Imipramine: Randomized Double-Blind Study with 135 Outpatients., *J Geriatr Psychiatry Neurol*, 1994, Oct 7, Suppl 1:S19-23
4. Miller AL: St. John's Wort (Hypericum Perforatum): Clinical Effects on Depression and Other Conditions., *Altern Med Rev*, 1998, Feb;3(1):18-26
5. Cott JM, Fugh-Berman A: St. John's Wort., *J Nerv Ment Dis*, 1998, Aug;186(8):500-1
6. Linde K, Ramirez G, Mulrow CD, Pauls A, Weidenhammer W, Melchart D: St John's Wort for Depression--An Overview and Meta-analysis of Randomisedclinical Trials., *BMJ*, 1996, Aug 3, 313(7052):253-8

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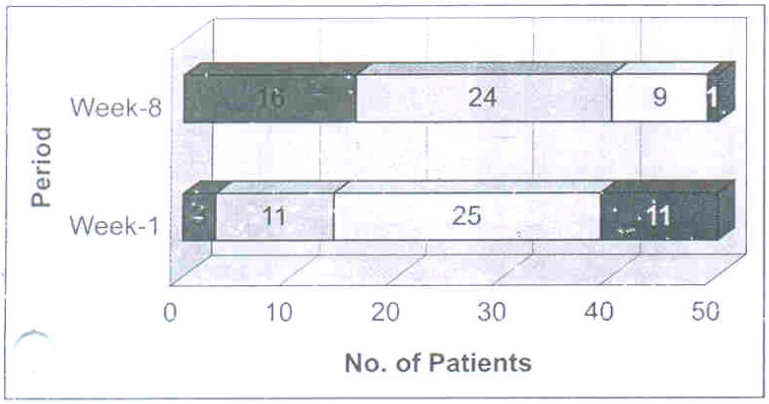

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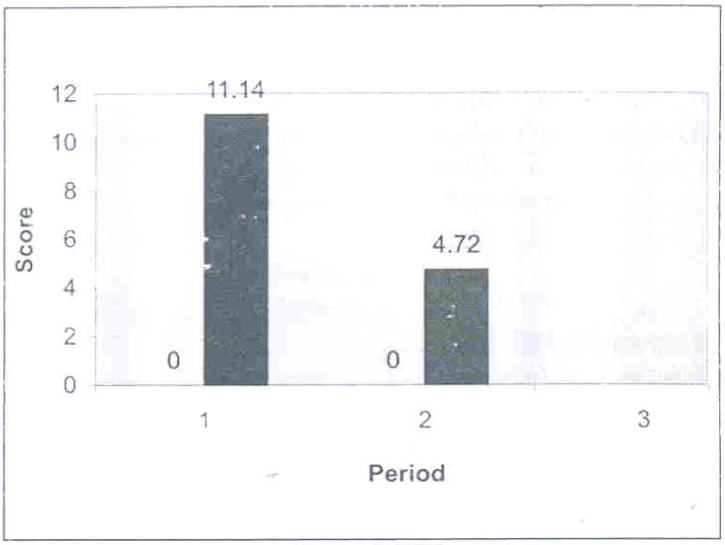

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Table 2. Chief complaints of patients

SYMPTOMS	NO. OF PATIENTS	%OF PATIENTS
Depressed mood	50	100
Decreased Work and Activities	41	82
Agitation	38	76
Sexual dysfunction-menstrual disturbance	33	66
Anxiety psychological	32	64
Anxiety somatic	31	62
Weight loss-by history-by scales	30	60
Hypochondria	25	50

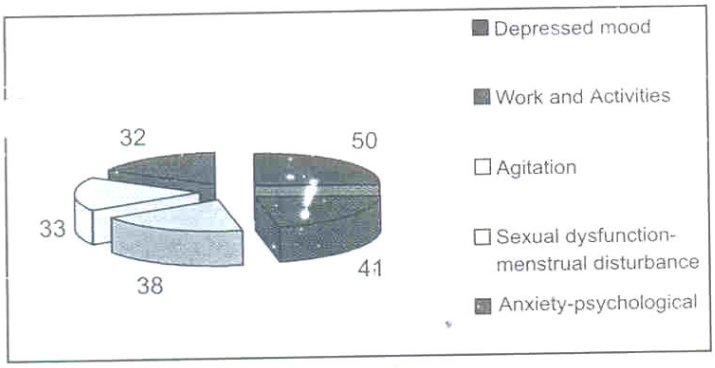

Figure 1. Common symptoms of patients

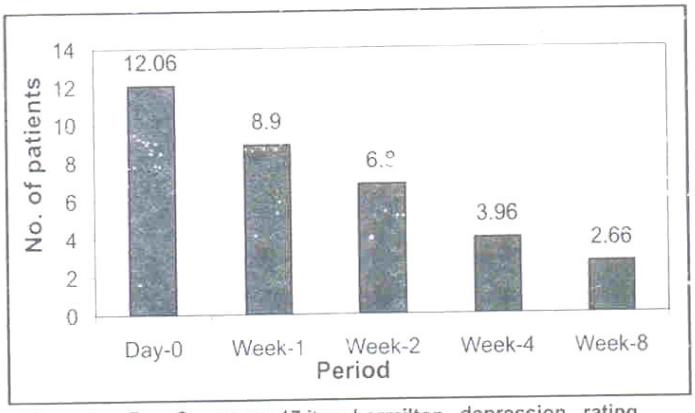

Figure 2. Raw Scores on 17 item harmilton depression rating scale (HDRS)

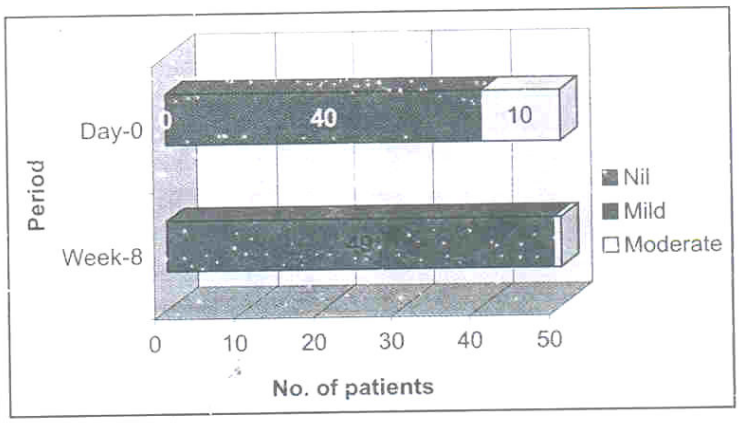

Figure 3. Categories of patients - severity of depression

only 1 patient was moderately depressed while the remainder of 49 patients had a HDR score of less than 10, which indicates an excellent improvement.

Investigators assessment of Clinical Global Improvement

The investigators assessed the patients' improvement on a 7-point scale. According to the investigators' assessment, the patients showed steady improvement in their condition over the study period. At the end of the study (Week8) 16 patients showed an excellent improvement in their condition while 24 patients showed good improvement. Only 1 patient did not respond to treatment with Sumenta.

The investigators' assessment of Clinical Global improvement observed in the study is as depicted in Table 5 below.

The patients were asked to evaluate the improvement observed in them on a 7 point scale similar to The Clinical Improvement scale. 5 patients reported an Excellent response within a week after starting Sumenta and this figure improved substantially to 18 patients at the end of the study. 20 patients reported a Good improvement while 11 patients judged the benefit with Sumenta as Fair at the end of 8 weeks of the study. Only 1 patient did not respond to treatment with Sumenta.

Table 3. Change in the HDR score over 8 weeks

	Day-0	Week-1	Week-2	Week-4	Week-8
MEAN	12.06	8.90	6.80	3.96	2.66
S.D.	1.91	2.97	3.30	3.01	2.69

P< 0.001

Table 4. Severity of depression

SEVERITY	No. of patients				
Grade	Day-0	Week-1	Week-2	Week-4	Week-8
Nil	0	29	43	48	49
Mild	40	18	4	1	0
Moderate	10	3	3	1	1

QUALITY OF LIFE

As mentioned above, patients were asked to judge the beneficial effect of Sumenta on the basis of a)Sense of well being, b) Fatigue level and c)Energy level at the beginning and at the end of the study with a maximum score of 15 (poor) and a minimum score of 3 (Excellent Improvement).

As seen in figure 5 mean grade Quality of life decreased from 11 ± 1.96 at the beginning of the study to 4.72 ± 1.31 at the study period, which indicates a Very Good Response.

In Patients' Evaluation, lower scores indicate an improvement.