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A COMPARATIVE EVALUATION OF DOTHIEPIN (PROTHIEDEN) AND IMIPRAMINE

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A double-blind controlled comparative trial of Dothiepin was carried out in Psychiatric Hospital, for comparing its efficacy with that of Imipramine, in the treatment of depression and also to compare the incidence and severity of side effects of the two drugs. Dothiepin hydrochloride is a tricyclic anti-depressant drug with pharmacological properties common to Imipramine Amitryptline and related drugs.

MATERIAL AND METHOD

Thirty patients of depression of both sexes, were included in the study. Out of these thirty patients 15 were males and 15 were females. The age range was between 30 and 50 years. The diagnostic pattern in these patients revealed that 12 patients had involutional depression, 10 reactive depression and 8 had endogenous depression.

Those, having pregnancy, or who have received E.C.T. within the previous 2 months or patients receiving full doses of Prothiaden or Imipramine before admission to trial, or patients whose pre-trial Hamilton rating score was under 30, were excluded from study.

The patients were randomly allocated to treatment with either Dothiepin or Imipramine. The initial daily doses of either drug was one tablet (25 mg) thrice daily and was increased later up to 6 tablets (150 mg), depending upon patient's response. The duration of therapy in all patients was 4 weeks, so as to ensure that the trial remained strictly double-blind. The details of treatment administered are summarised in Table-1. The patients were assessed on the Hamilton rating scale, before treatment, daily in the first week and at the end of 2nd, 3rd and 4th weeks of treatment.

Side effects reported by the patients were also recorded. Laboratory investigations comprising haematological and biochemical tests and urine analysis were done before and after therapy.

OBSERVATIONS AND RESULTS

The profile of patients' study is presented in Table 1. Out of 30 patients who have completed treatment, 9 had received previous treatment with anti-depressants, of these 7 had obtained satisfactory response and 2 responded unsatisfactorily. (Table 2).

TABLE 1—*Profile of patients*

	Dothiepin	Imipramine
No. of patients ..	15	15
Sex—		
Male	7	9
Female	8	6
Age—		
Mean (in yrs.) ..	47.1	45.4
Range	30—60	35—57
No. of Depressive Attacks—		
Mean	1.55	2.10
Range	1—2	1—8

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TABLE 2—*Previous treatment with anti-depressant*

	Dothiepin Group	Imipramine Group
No. of Pts. who had previous treatment ..	5	4
Response to treatment—		
Satisfactory ..	4	3
Equivocal ..	..	..
Unsatisfactory ..	1	1

TABLE 3—*Overall response*

Group	Dothiepin (15)	Imipramine (15)
Pre-Treatment ..	37.50	36.33
Week I	24.85	27.66
Week II	20.07	24.50
Week III	13.14	16.41
Week IV	7.07	11.33

only one patient in the Dothiepin group complained of ataxia and giddiness as side effects (Table 5).

TABLE 5—*Side effects*

Side effects	Dothiepin	Imipramine
Number of patients ..	15	15
Number of patients who complained of side effects	1	5
Symptoms—		
(i) Dryness of mouth ..	..	3
(ii) Tremor ..	..	1
(iii) Constipation ..	..	2
(iv) Giddiness ..	1	1
(v) Palpitation ..	..	1

*3 Patients dropped out due to side effects.

DISCUSSIONS

On statistical analysis of data, it is seen that there is no significant difference between the two treatments in terms of overall response and in the response of target symptoms. However, the mean percentage reduction in total score was more with Dothiepin than with Imipramine, throughout the treatment period, though both the drugs were effective in the treatment of depression. Response of individual target symptoms was also favourable with Dothiepin than with Imipramine. Though side effects encountered were mild, their incidence was more with Imipramine than Dothiepin.

TABLE 4—*Response of Target Symptoms*

Assessment period	Mean Hamilton Score							
	Depression		Insomnia		Anxiety		Somatic Symptoms	
	Dothiepin	Imipramine	Dothiepin	Imipramine	Dothiepin	Imipramine	Dothiepin	Imipramine
Pre-Treatment	9.35	9.58	6.00	6.00	5.09	4.90	4.20	4.08
Week I	6.92	6.50	4.57	4.83	3.45	3.72	2.71	3.50
Week II	5.57	5.75	4.21	4.41	2.63	3.09	2.07	3.30
Week III	3.71	4.25	3.21	3.00	1.36	1.90	1.42	1.41
Week IV	1.92	3.08	1.35	2.25	0.90	1.09	0.50	0.83

The mean Hamilton scores recorded in both the groups in the cases of overall rating, and target symptoms viz. depression, anxiety, insomnia, and somatic symptoms are represented in Tables 3 & 4.

The Bio-chemical and Haematological parameters studied, did not reveal any abnormality. Three patients who received Imipramine developed dryness of mouth and constipation and so were dropped out from trial due to side effects, whereas

SUMMARY AND CONCLUSION

A comparative evaluation of Dothiepin (Prothieden) and Imipramine was done.

The present study confirms the effectiveness of Dothiepin in the treatment of severe depression and that its tolerability is good, as compared to Imipramine. Thus Dothiepin hydrochloride would be a useful addition to drugs available to Psychiatrists.

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