Sintamil (2330 GO) a new dibenzoxazepin (Nitroxazepine hydrochloride) has been extensively studied during the last decade in animals and human beings for its antidepressant action with fairly good results (Bagadia et al 1968 and Teja and Narang 1970). Some investigators (Desouza and Chowdhary 1974 and Gupta et al 1976) have demonstrated superiority of Sintamil over imipramine and trimipramine in relieving depressive symptoms.

Doxepin being a tricyclic compound, has its basic action similar to other compounds of the group (Groton 1967). It is tertiary amine like Amitriptyline and Imipramine which has mood elevating properties (Arieti 1975). Some workers have rated it as good or slightly superior to Imipramine and Amitriptyline whereas Swiss psychiatrists have not found it so (Frank 1968).

The present report a single blind controlled comparative between patient clinical trial with Sintamil and Doxepin hydrochloride aims to evaluate their efficacy and tolerability in depressed patients.

**Material and Methods**

The study consisted depressed patients attending Mental Health Clinic at G. S. V. M. Medical College and Associated Hospitals, Kanpur. The diagnosis of depression was made according to I. C. D. - 9 (1978). The patients were randomly selected and the depth of depression was evaluated on Hamilton depressive rating scale. The duration of trial was 4 weeks. Each patient was clinically examined to exclude the presence of any organic disease. Pregnant women, patients with prostatic hypertrophy and those with history of epilepsy were not included in the study.

These patients were not given any antidepressant therapy for at least one week before the commencement of trial. The capsules containing Sintamil and Doxepin were identical in size, shape and colour and it was not known to investigator whether a particular patient was on Sintamil or Doxepin. Both the Sintamil as well as Doxepin were administered at bed time. The patients were examined every week and fresh drug samples issued. The detailed report on symptoms scores, concomitant treatment and individual side effects were recorded every week. Routine investigations like haemoglobin estimation, leukocyte count and urine analysis were done in every patient before and at the end of trial.

**Results**

There were 40 patients in the trial, 20 each on Sintamil and Doxepin. Males and females in the Doxepin as well as Sintamil groups were more or less equally distributed (12 males and 8 females in Sintamil group and 11 males and 9 females in Doxe-
epin group). The average age was 46.16 years in the Sintamil group and 44.3 years in Doxepine group. Twenty five patients were having manic depressive psychosis (Depressed phase), 14 had psychotic depressive reaction and one patient was suffering from neurotic depression.

The table reveals a comparatively higher reduction in most of the symptoms score on Hamilton rating scale in patients with Sintamil as compared to Doxepin group both at the end of first week as well as fourth week. However, some of the symptoms such as self reproach and guilt feelings, agitation and social withdrawal have shown significant reduction in patients on Sintamil as compared to Doxepin. At the last available follow up, more than 75% reduction in total global score was seen in 80% patients on Sintamil as compared to 35% patients with Doxepin. None of the patients on Sintamil complained of unwanted effects while one fourth patients on Doxepin had undesirable effects like dryness of mouth, drowsiness and giddiness.

**Discussion**

There was more than 75% improvement in total symptom score in 80% patients treated with Sintamil as compared to 35% patients receiving Doxepin. There are other reports in the literature which have not found Doxepine to be an effective antidepressant (Frank 1969). However, Sharma and Hegde (1980) have reported good results with Doxepin in patients with moderately severe depression.

### Table

| Symptoms                        | SINTAMIL (n = 20) | DOXEPIN HCl (n = 20) |
|---------------------------------|-------------------|----------------------|
|                                | Day 0 Av. score   | Day 7 %               | Day 0 Av. score | Day 7 %       | Day 28 reduction |
| Sandness/Depressed mood         | 2.7               | 35.2                 | 2.7             | 20.4          | 42.6             |
| Self depreciation               | 2.1               | 35.7                 | 2.1             | 12.2          | 48.8             |
| Self reproach & guilt feelings  | 2.2               | 34.1*                | 2.0             | 7.7*          | 48.7*            |
| Anxiety                         | 2.2               | 36.4                 | 2.2             | 22.7          | 59.1             |
| Agitation                       | 2.2               | 37.2                 | 2.2             | 20.5          | 59.1*            |
| Retardation                     | 1.8               | 25.0                 | 2.2             | 17.1          | 41.5*            |
| Social withdrawal               | 1.9               | 29.7                 | 2.2             | 14.0          | 51.2*            |
| Suicidal ideation               | 1.8               | 50.0                 | 1.8             | 27.8          | 66.7             |
| Loss of insight                 | 1.4               | 52.2                 | 1.4             | 26.1          | 65.2             |
| Somatic preoccupation           | 2.8               | 37.5                 | 2.9             | 22.8          | 42.1             |
| Insomnia                        | 2.8               | 44.6                 | 2.9             | 27.6          | 63.8             |
| Loss of appetite                | 2.4               | 38.3                 | 2.6             | 15.7          | 43.1             |
| Sexual weakness                 | 2.0               | 50.0                 | 100.0           | -             | -                |
| Total                           | 24.9              | 37.2                 | 77.6            | 25.7          | 19.3             | 51.3             |

* (p < 0.05)
Though most of the depressive symptoms responded favourably to sintamil therapy but it was found more effective in controlling self reproach and guilt feelings, agitation and social withdrawal. Desuza and Chowdhary (1974) have also found similar results with Sintamil in controlling most of the depressive symptoms than imipramine while Varma (1972) reported superiority of Sintamil in treating sadness, anxiety retardation, insomnia and loss of appetite than imipramine. Sintamil also appears to offer an additional advantage of early onset of action as even at the end of first week there was significant reduction in the scores of some of the complaints in patients treated with Sintamil than those receiving Doxepine.

The drug seems to be completely free from side effects as none of the patient on Sintamil reported any unwanted or undesirable effects, while one fourth patients treated with Doxepine had side effects like dryness of mouth, giddiness and drowsiness.

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