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CLINICAL EVALUATION OF SOME HALLUCINOGENIC TRYPTAMINE DERIVATIVES

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Several tryptamine derivatives such as N.N-dimethyltryptamine (DMT) (27), N.N-diethyltryptamine (DET) (2, 8), psilocybin (11) and psilocin (12) have been reported to produce in man hallucinogenic effects similar to those of LSD-25. These compounds, classified as hallucinogens, have the unique quality of being able to produce in man marked alterations in sensory perception, intensification of colors, visual hallucinations and illusions. Distortion of body image and feelings of depersonalization can also occur. Marked lability of mood with rapid shifts from elation to depression can be seen, and anxiety states, ranging from mild apprehension to panic can occur. Sometimes, the passage of time can be distorted (59).

Speeter and Anthony (26) reported that N.N-dipropyltryptamine (DPT), another tryptamine derivative, produced observable effects in dogs. Barlow and Kahn (1) and Vane (31) used isolated organ preparations to study the effects of DPT and other tryptamine derivatives. Szara (29) using a nontoxic dose of DPT observed hyperactivity in mice. The similarity in chemical structure between DPT (see Figure 1) and other hallucinogenic tryptamine derivatives and its reported effects in animals indicated that this compound might be capable of producing hallucinogenic effects in humans.

One of the major problems in evaluating hallucinogenic compounds is the absence of an effective placebo which could mimic some of the effects of these drugs, such as physical symptoms and mood changes, without producing the psychedelic effects. Szara (30) came to the conclusion that the 6-hydroxylation of the indole ring of the hallucinogenic tryptamine derivatives might be an important pathway for the metabolism of these compounds. Kalir and Szara (14) prepared a series of compounds substituted at the 6-position. One of these synthesized compounds, 6-fluorodiethyltryptamine (6-FDET), was observed to produce autonomic symptoms and mood changes in humans without producing the characteristic perceptual and thinking disturbances usually seen with psychotomimetic drugs. From this initial data, Szara postulated that 6-FDET might be useful as an active placebo in clinical studies.

In order to test the hypothesis that DPT was another effective hallucinogenic drug and to confirm the previous work of Szara using 6-FDET as an active placebo, a comprehensive pilot study was undertaken at Saint Elizabeths Hospital. This research project set out to measure psychological, biochemical and physiological effects produced by DPT and 6-FDET as compared to the related chemical compound, DET, a potent known hallucinogenic compound in the same experimental subjects. This paper will report primarily on the psychological effects produced by these tryptamine derivatives.[4]

METHOD

SUBJECTS

Twelve chronic, non-psychotic, alcoholic, hospitalized patients volunteered to partic-

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ipate in the program. All patients between the ages of 25 and 50 with over five years of excessive ethanol ingestion who were on the alcoholic ward at Saint Elizabeths Hospital were asked to volunteer in a treatment program involving the use of hallucinogenic drugs. Volunteers who were in good physical condition without evidence of organic deterioration, schizophrenia or manic depressive illness were accepted in the program. They ranged from 29–48 years of age with a mean age of 38.2. The length of hospitalization prior to treatment varied from one month to five years. All had been drinking heavily for over ten years. All had had multiple hospitalizations for alcoholism either in general or psychiatric hospitals, and the majority had a history of multiple arrests for alcoholism. Prior to treatment, all the subjects had an extensive medical work up which included CBC, BUN, Glucose, Thymol Turbidity, Alkaline Phosphatase, Cephaline Flocculation, SGOT, SGPT, EKG and EEG. Thus, they were considered to be in excellent physical health. Approximately two to three weeks prior to their first drug sessions, the subjects, two at a time, were transferred to the research ward in order to familiarize them with their new environment and particularly with the ward personnel. Except for the first two patients, there was an overlap of the subjects receiving the drugs and the new volunteers. The subjects were informed about the nature of the drug experience; however, they were not informed of the possibility of receiving an active placebo in one or more of the sessions.

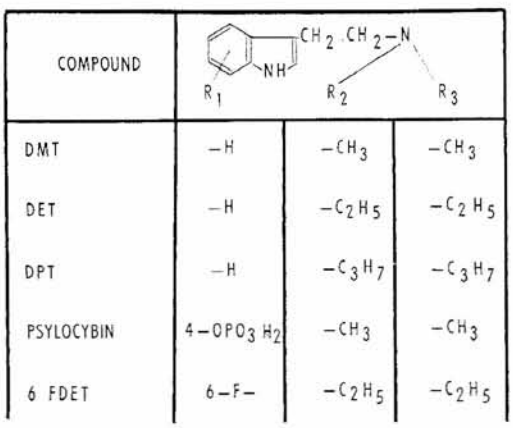

FIG. 1. Chemical structure of some psychoactive tryptamine derivatives.

TABLE 1

Linton and Langs Questionnaire
Four Empirical Scales

Scale A (26 items)
- Impaired control of attention.
- Loss of inhibition (particularly over thinking).
- Elation.
- Subjective feeling of having developed new powers of insight.

Scale B (15 items)
- Feeling of unreality.
- Loss of contact with the environment depriving it of a sense of meaning.
- Impaired sense of identity.
- Feelings of having lost control.
- Paranoid ideation.

Scale C (17 items)
- Body image changes.
- Somatic symptoms (Dizziness, weakness, feeling of floating).
- Generalized inhibitory effects.

Scale D (8 items)
- Somatic effects (Blurred vision, nausea, dry mouth).
- Overt anxiety.
- Fear of losing control.

PSYCHOLOGICAL MEASURES

Several questionnaires have been devised to measure the subjective effects of LSD-25 in humans. However, the 74 item questionnaire by Linton and Langs (17, 18, 19) was selected because it contained a wide range of perceptual, cognitive, affective and somatic items. The main focus of the questionnaire is on the subject's altered state of consciousness. Linton and Langs also classified the major dimensions of the subjective effects of LSD-25 into four empirical scales. (See Table 1.)

The scoring of the questionnaire was modified so that a negative response was given a zero score and a positive answer was scored either 1, 2 or 3 depending on the intensity of the effect. The subjects were

tested the day before and at the termination of each treatment session. The immediate post-session testing was decided upon because these drugs produce such intense reactions that while the patients were experiencing the drug's effect, they could not or would not be able to reliably answer the 74 item questionnaire. At the termination of the treatment session, the patients were asked to answer the questions in relation to how they felt under the influence of the drug.

The Rockland-Pollin (RP) Scale (21), consisting of 16 items, was used to record observable psychotic behavior by assessing mental status data. Two of the coauthors (L.A.F. and A.V.) scored the patients independently on this scale before the drug session and at the termination, but before the subjective questionnaire was answered.

The scale is grouped in three main categories: 1) General appearance and manner (6 items); 2) Affect and mood (4 items); 3) Content of thought and thought processes (6 items). This instrument was chosen because it was originally derived partly from observing the effects of DET on normal individuals.

DRUG SCHEDULE

The drugs, administered intramuscularly, were given in dosages of 0.7, 1.0 and 1.3 mgms/kg of body weight. The drugs, prepared by the NIH pharmacy, were in sterile saline solution in concentrations of 15 mg/ml. DPT alone was given at the 1.3 mgm/kg dose and then, only on two occasions. The double-blind design allowed each patient to receive DET, DPT and 6-FDET at least once with one of these drugs given in two different dosages (0.7 and 1.0 mgm/kg). In our patient population, seven subjects received each drug at the 1 mg/kg dose in a random design.

DRUG SESSIONS

Each patient had five weekly drug sessions of approximately two and one-half to three and one-half hours. Three of the sessions, always including the first session, were conducted in a darkened room of pleasant surroundings. The other two sessions were held in a comfortable room equipped to continuously record physiological measures such as blood pressure, heart rate, respirations and EEG. Scalp and chest electrodes and an automatically inflated blood pressure cuff were attached to the patients. However, the equipment did not inhibit their activity; they were able to move about freely while lying or sitting down.

During their participation in this study, all subjects received psychotherapy from the same therapist (A.V.). For two to three weeks prior to beginning the drug sessions, the patients received intensive preparation from their therapist. As part of this preparation, they were informed of the possible nature of the drug reaction and that they might experience some, all or none of the possible effects. This was done in order to prevent the appearance of overwhelming anxiety which could lead to panic reactions. Literature was made available about the effects of hallucinogenic drugs, and the patients were encouraged to communicate with each other and to talk to the therapist and nursing personnel about any questions or fears that might arise concerning the treatment. Good rapport was established between the patients and the therapist, who was present at all drug sessions. During the drug sessions, the therapist encouraged the subjects to discuss their problems. He was supportive if they became apprehensive from the drug effects. Between drug sessions, the patients received individual therapy twice weekly. At these sessions, the previous drug session was discussed and preparation made for the next drug session.

RESULTS

The evaluation of the results is based on data obtained from testing the seven

patients of our series who each received 1 mg/kg of DPT, DET and 6-FDET during their second or subsequent drug session. The data from the first session were not used because results from these sessions would be highly influenced by the patient's initial anxiety. Since this kind of experience is unique for most individuals, data obtained from the first session would be most biased and could not be reliably compared to subsequent sessions.

The onset of the effects produced by DET, DPT and 6-FDET was almost uniform beginning ten to 15 minutes after injection, reaching peak intensity between 45–90 minutes, and then subsiding. The drug effect lasted approximately two to three and one-half hours depending on the dosage. The principal physical symptoms reported by our subjects are summarized in Table 2.

In order to demonstrate the striking effects produced by these drugs, two brief protocols from the same patient receiving 1 mg/kg of DPT and 1 mg/kg of 6-FDET are presented.

PROTOCOL

1 mg/kg of DPT (2nd Treatment Session)

Time

9:30 a.m. Injection given. Patient mildly tense and quiet.

9:40 "I feel light and nervous." His eyes are closed, and he is lying quietly.

9:50 Patient becoming restless—eyes are closed. "I'm way off in a big castle with beautiful colors and scenery. I'm lost. I'm running around and around." "The wind is blowing around. It's pleasant."
Therapist—"Does it remind you of the past?"
No answer.

10:00 Eyes closed lying quietly. "I'm way out in space seeing planets and stars. There are pretty colors, orange, red, yellow, purple, all colors."

10:10 "I'm back with the girl who accused me of fathering her child. It's peaceful. She had everything she wanted. My aunt made sure we went to church on Sunday. I see the devil in front of my face." Patient at this point is calm with eyes closed. "My aunt treated me like a devil. She always treated me like a little boy and never let me grow up. I was always around the house. I thought I was happy."

10:20 "Everything is going fast. Too fast. It's not pleasant. Things are going zig zag. Feels like I'm tired. I feel like an old man in a rocking chair sitting in front of a phonograph. Everything is so mixed up. I'm trying to get myself together."

10:30 "There is a big monster after the children." Patient looks scared, sweating, eyes closed. "He lets them go and then vanished. The music sounds old." Patient remarks about the soft background music. "I have a vibrating feeling. It makes me feel as though I'm not here. I feel as if I'm floating out in space to many places."

10:40 "All things are running through my mind. Animals, lions, zig zag shapes. When I try to go into the past everything turns green. I turn into a monster. I have long fingernails. I'm hairy and turn green. I feel sick in the stomach."

10:50 Music changed to vocals by Mahalia Jackson. Patient is listening and quiet.

11:00 He begins to get restless but is quiet.

11:10 He asks to smoke a cigarette. Sitting up. "I feel good physically and mentally." The drug is beginning to wear off a little.

11:20 Begins to talk about his aunt, mother and father for the next hour as the drug is slowly wearing off.

PROTOCOL

1 mg/kg of 6-FDET (4th Treatment Session)

9:30 Injection given, lying quietly with eyes closed. He appears mildly anxious.

9:40 "I feel sick to my stomach." Patient is restless.

9:50 "I don't see any colors. I'm still feeling sick." Patient is lying quietly.

10:00 "No vision—no particular thoughts. Still sick to stomach."

10:10 "I'm thinking about a job. I want out of the hospital. I'm tired of being here." Lapses into silence. Patient appears relaxed.

10:20 Talking about alcoholism: "I'll need all the patience and strength to succeed. I'll take any job rather than go back the way I was." Patient lying in bed with eyes closed. "Maybe I don't hate myself any more."

10:30 "Only effects are dizziness. Still no visions. I haven't even been fighting monsters. I feel all right. Without

this treatment I would be helpless. I've been able to see why I drink."

10:40 "This is a pleasant feeling like I'm drunk." Patient looks calm and relaxed.

10:50 "I'm a little disappointed. I want to remember my childhood. I think I get sick to my stomach when I think about it."

11:00 Talking about Aunt who raised him: "I guess she was the way she was because of the way she was brought up."

11:10 Patient lying quietly in bed eyes closed listening to the music. He looks relaxed.

11:20 Patient states: "I have no discomfort. The drug is beginning to wear off. I feel good."

Tables 3 through 6 show the pre-drug and drug scores for the subscales of the Linton and Langs subjective questionnaire. If we make the assumption that the order in which the drugs were given has little or no effect on the patient's response to the individual drugs, then we can perform statistical analysis of the data obtained. Table 7 summarizes the significance of the difference between the pre-drug and drug scores as measured by the Wilcoxon Matched Pairs Signed Rank Test (24). Both DET and DPT show a significant difference between pre-drug and drug scores on all the subscales. However, with 6-FDET, Subscales A and B show no significant difference.

TABLE 2

Principal Physical Symptoms Reported by Subjects Receiving 1 mg/kg of DET, DPT and 6-FDET

	Per cent		
	DET	DPT	6-FDET
Dizziness	43	43	71
Numbness and tingling	57	43	14
Chills and cold feeling	71	43	29
Heightened smell	43	57	43
Funny taste in mouth	57	29	43
Nausea	57	57	71
Blurred vision	43	86	14
Dry mouth	71	100	57
Physical weakness	57	71	43
Body felt light	43	57	57

TABLE 3

*Subjective Scores from the Linton and Langs Questionnaire Subscale A**

Subjects	DET		DPT		6-FDET	
	Pre-Drug	Drug	Pre-Drug	Drug	Pre-Drug	Drug
1	4	2	3	25	7	0
2	5	20	15	42	15	23
3	26	38	9	47	16	32
4	0	19	1	49	0	6
5	7	27	1	37	9	11
6	4	14	1	21	3	1
7	5	27	6	49	5	19

* For drug schedules and other experimental details see text.

TABLE 4

*Subjective Scores from the Linton and Langs Questionnaire Subscale B**

Subjects	DET		DPT		6-FDET	
	Pre-Drug	Drug	Pre-Drug	Drug	Pre-Drug	Drug
1	1	0	1	18	0	0
2	0	10	1	23	0	0
3	1	14	0	17	2	4
4	0	12	0	27	0	0
5	2	13	1	21	5	3
6	1	11	0	7	0	0
7	0	13	1	26	0	9

* For drug schedules and other experimental details see text.

Friedman's Two-Way Analysis of Variance (24) comparing the difference between pre-drug and drug scores of the three compounds for each patient is summarized in Table 8. Only subscale D, concerned primarily with somatic symptoms, shows no significant difference when comparing the three drugs.

Objective measurements using the Rockland-Pollin (RP) Scale are shown in Table 9. Inter-rater reliability for the total scores measured by Pearson Product Moment correlation (7) ($r = .84$) indicated significant agreement beyond the 0.01 level of confidence. Inasmuch as there was significant correlation between raters, the most valid assessment of the patients

TABLE 5

*Subjective Scores from the Linton and Langs Questionnaire Subscale C**

Subjects	DET		DPT		6-FDET	
	Pre-Drug	Drug	Pre-Drug	Drug	Pre-Drug	Drug
1	0	2	0	15	0	1
2	2	10	4	17	0	0
3	2	23	1	29	0	10
4	0	28	0	43	0	9
5	4	11	1	7	5	9
6	0	11	0	1	0	3
7	0	9	2	34	1	8

* For drug schedules and other experimental details see text.

TABLE 6

*Subjective Scores from the Linton and Langs Questionnaire Subscale D**

Subjects	DET		DPT		6-FDET	
	Pre-Drug	Drug	Pre-Drug	Drug	Pre-Drug	Drug
1	3	4	2	13	0	1
2	0	7	1	9	0	4
3	0	13	0	22	0	2
4	0	6	0	10	1	3
5	3	15	3	3	2	6
6	0	7	1	6	1	6
7	0	6	1	16	0	9

* For drug schedules and other experimental details see text.

TABLE 7

*Significance of Difference between Pre-Drug and Drug Scores Wilcoxon Matched Pairs Signed Rank Test p-Values**

	Subscales				Rockland-Pollin Scale
	A	B	C	D	
DET	<0.05	<0.05	<0.02	<0.02	<0.05
DPT	<0.02	<0.02	<0.02	<0.02	<0.05
6-FDET	ns	ns	<0.02	<0.02	ns

* For drug schedules and other experimental details see text.

observed behavior was assumed to be the average scores of the two raters. The Wilcoxon Signed Rank Test for measuring the significance of difference between pre-drug and drug scores of the RP scale showed a significant difference, $p < 0.05$ for DET and DPT (Table 7). However, there was no significant difference for 6-FDET. Friedman's Two-Way Analysis of Variance comparing the scores on the RP scale for the three drugs showed a difference, $p < 0.1$, between the drugs which was not considered to be statistically significant because of the small sample used (Table 8).

DISCUSSION

The use of hallucinogenic drugs as therapeutic agents is a controversial subject, and their efficacy remains uncertain. There have been claims of success especially with alcoholic patients (3, 13, 15, 20, 25) and reports of therapeutic success with psychoneurotic and character disorders appear in the European literature (6, 16, 22).

TABLE 8

*Summary of Friedman's Two-Way Analysis of Variance by Ranks for Subjective and Objective Scales**

Scale		p-Value
Linton and Langs	Subscale A	<0.001
	" B	<0.005
	" C	<0.02
	" D	ns
Rockland-Pollin		ns

* For experimental details see text.

TABLE 9

*Individual Scores of Subjects on the Rockland-Pollin Scale**

Subjects	DET		DPT		6-FDET	
	Pre-Drug	Drug	Pre-Drug	Drug	Pre-Drug	Drug
1	9	23	7	32	11	23
2	11.5	32	3.5	21.5	1.5	2.5
3	11.5	6.5	5	8	7	2
4	1	9.5	11.5	18	5.5	2.5
5	5.5	32	10	21	3.5	1
6	3	9.5	4	6.5	2	7.5
7	5	14	8.5	6.5	5	7.5

* For drug schedules and other experimental details see text.

Many authors (4, 8, 23) contend that the environment and proper expectation of both patient and therapist are crucial to a beneficial drug experience. The drugs produced such diverse effects that focusing on one particular symptom usually will result in the patient experiencing this symptom. For example, drawing attention to and emphasizing the psychotic-like properties produced by these compounds will usually produce such effects in subjects. It is no wonder then that the proper evaluation of hallucinogenic drugs is most difficult especially since the environment and attitudes of patients and therapists are crucial to the "proper drug experience." In order to properly separate the effects of the drug from the environment and the bias of the therapist, an effective active placebo which can mimic the physical and mood effects without the perceptual and thinking disturbances would go a long way toward settling the controversy about the therapeutic effectiveness of hallucinogenic drugs. The data presented here tend to affirm the assumption that 6-FDET produces some of the same physical and mood changes as the known hallucinogen, DET, and the new hallucinogen DPT. These changes produced by 6-FDET are indistinguishable from the changes produced by the two hallucinogenic compounds in the same patients. Subscale D of the Linton and Langs subjective questionnaire, which deals primarily with somatic effects and also with anxiety and fear of losing control, shows that all three drugs produce a significant difference between pre-drug and drug scores for this subscale. However, the scores indicate that the subjects experience no significantly different effects for the three compounds. The scores from Subscales A and B of the Linton and Langs questionnaire dealing primarily with thinking, loss of contact with the environment and loss of identity, showed that our subjects reported significant differences in the effects produced by the two active drugs when compared with the placebo. Both active hallucinogenic compounds showed a significant difference between pre-drug and drug scores; however, the placebo showed no significant difference, indicating that the effects upon thinking, loss of identity and loss of contact with the environment were not impaired with 6-FDET as reported by our subjects. On the objective rating scale (RP Scale) when comparing the three compounds on Friedman's Two-Way Analysis of Variance, there is some difference between the compounds but not statistically enough because of the small number of patients. From the data presented, which must be viewed cautiously because of the small sample, 6-FDET appears to be an effective placebo and warrants further study. If the results obtained in this report are substantiated by a larger population, then an effective active placebo will be identified, and the proper evaluation of the therapeutic ability of hallucinogenic drugs will be possible.

The data also confirm our previous preliminary report (10) that DPT is another effective short-acting hallucinogenic drug. On all four subscales of the Linton and Langs questionnaire, the drug scores are statistically different from the pre-drug scores. When DPT is compared to the active placebo, 6-FDET, the subjective effects reported are statistically higher in three of the four subscales. The data comparing DPT with the known hallucinogen, DET, indicate that it is comparable to this compound in producing psychodysleptic effects in the same subjects.

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