United States Patent Office

3,639,607
Patented Feb. 1, 1972

3,639,607

METHOD FOR TREATING THE TOBACCO SMOKING HABIT

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No Drawing. Continuation-in-part of application Ser. No. 825,422, May 16, 1969. This application Nov. 2, 1970, Ser. No. 86,275

Int. Cl. A61k 27/00

U.S. Cl. 424—273 9 Claims

ABSTRACT OF THE DISCLOSURE

Treatment with an anticonvulsant drug, preferably one effective to prevent or retard grand mal and/or petit mal seizures in epileptic patents, allows a tobacco smoker to materially reduce, and in many instances totally eliminate, his smoking habit. During withdrawal, the normally accompanying anxiety is reduced or eliminated by the use of such a drug.

CROSS-REFERENCE—OTHER APPLICATIONS

This application is a C.I.P. of my copending application Ser. No. 825,422 filed May 16, 1969 now abandoned.

This invention relates to a method of treating the tobacco smoking habit in human beings. More particularly, this invention relates to the use of anticonvulsant drugs to eliminate or reduce the tobacco smoking habit and the anxiety which usually accompanies an attempt to break the habit.

In recent years there has been compiled a substantial body of evidence to show that the smoking of tobacco, especially in cigarette form, may be quite detrimental to health and well being. There has therefore been a concurrent desire by much of the smoking public to stop or reduce the amount of tobacco smoked over a given period of time. Although some persons are able to stop smoking or materially reduce the number of cigarettes etc., which they smoke over a given period of time, a large segment of the smoking population is unable to do so due to the persistency of the smoking habit and the anxiety accompanying any reduction or stoppage of it.

In recent years several drugs have been developed by the industry, which drugs are directed toward allowing a patient to reduce or eliminate his desire to smoke tobacco. Many of these drugs are directed toward affecting the taste and desirability of tobacco by actually making it repugnant to the patient, thus encouraging the patient to smoke less. The anxiety which accompanies the withdrawal or reduction of the smoking habit, however, remains unaffected and usually proves so great, especially in patients with large and long-standing smoking habits, as to override the taste effect and cause the patient to return to his normal smoking habit.

It is a purpose of this invention to provide those people who desire either to stop or reduce the amount of their smoking habit, with a drug which when taken as hereinafter described, enables the smoker to reduce or eliminate has smoking habit and at the same time experience little or no anxiety which usually accompanies such stoppage or reduction.

Generally speaking, this invention provides for the treatment of a tobacco smoking habit with a drug of the class effective to prevent or reduce convulsions in a patient. Preferably, the anticonvulsant used in accordance with this invention is one within the class of anticonvulsants effective in the treatment of grand mal and/or petit

mal seizures which accompany certain forms of epilepsy. Most preferably, the drug used in accordance with this invention will be one effective in the treatment of grand mal seizures since such drugs are usually found to be relatively free from adverse side effects. Of this latter type of drug, the derivatives of hydantoin are particularly preferred.

It has been found that if these anticonvulsant drugs are taken orally for a definite period of time, the individual may stop or materially reduce the amount of tobacco which he smokes without incurring any anxiety or with a material reduction thereof. The length of time during which the drug is taken will, of course, depend upon the individual and the extent of his smoking habit. Furthermore, stoppage or reduction may be possible, depending upon the individual, etc., either immediately upon the initiation of the treatment or within a short time thereafter. Again depending upon the individual, reduction or stoppage may become permannet, thus allowing the patient to stop taking the drug, or may only be possible while treatment is actually in progress, thus necessitating continued use of the drug. In all but the most severe cases, it has been found that reduction or stoppage actually becomes permanent.

It has also been found that these drugs, when used in the dosages as hereinafter disclosed, do not normally give rise to any adverse side effects. It is, of course, understood in this respect that this invention is applicable to all people who may have the smoking habit and who desire to reduce or stop such habit, and is not limited simply to those people who may smoke and at the same time have a tendency toward convulsions such as brand or petit mal seizures, etc.

Anticonvulsants are well known to the medical profession. Generally speaking, all of these drugs may be used in the practice of this invention. As hereinafter stated, anti convulsants of the type effective to treat grand mal and/or petit mal seizures in epileptic patients are preferred. Examples of these drugs include grand mal anticonvulsants such as 5,5-diphenylhydantoin, 5,5-diphenylhydantoin sodium, 3-methyl 5,5-phenyl-ethylhydantoin, 3-ethyl-5-phenylhydantoin, 5,5-diethyl-1-methylbarbituric acid, primidone (pyrimidine derivative structurally resembling phenobarbital), and petit mal anticonvulsants such as N-methyl-alpha-methylphenyl-succinimide, N-methyl - alpha - phenyl - succinimide, alpha-ethyl-alpha-methyl-succinimide, 3,5 - dimethyl-5-ethyloxazolidine-2,4 dione (homologue of trimethadoine), 3,5,5-trimethyl-oxazolidine 2,4-dione, and phenacetylcarbomide. Particularly preferred among the above list of drugs is 5,5-diphenylhydantoin sodium in that it has been found particularly effective and at the same time substantially completely free of side effects.

The amount of drug taken and the length of the treatment will depend upon each individual patient seeking to break or limit his smoking habit. As can be readily understood, each individual may have a different capacity for controlling his need for tobacco smoking, his anxieties after withdrawal, and various other factors relating to tobacco smoking, many of which may be psychological and/or physical. In most instances, however, it has been found that if from about 20 to about 300 mg. of the above-described drug is taken per day for a period of from about 3 days to about 2½ years, the patient will be able to at least control his smoking habit and in many instances completely stop smoking permanently without experiencing any significant amount of anxiety i.e., a sufficient amount of anxiety to cause him to return to his habit later on.

Preferably, the patient should take about 100 mg. per day once or three times a day. Most preferably, the patient will take ⅓ of the recommended dosage three times a day, once in the morning, once at noon, and once shortly after the evening meal. The form of dosage used may be of any conventional type such as pill, pill including inert carrier, or the like. That is to say, as evidenced by, for example, pages 910–911 of the 1967 volume of PDR, the dosages of this invention may be administered in accordance with any conventional technique such as by oral or parenteral administration (e.g., intravenous injection), using conventional inert carriers, liquid or solid, where desired. Furthermore, any other means of internally administering the drug, conventional in the art, may be used.

The term "anxiety" is a term well known in the art and it is used herein in accordance with this well known meaning. Anxiety is generally evidenced in the tobacco smoker after withdrawal by various symptoms such as social irritation, restlessness, apprehension, a feeling of oppression, fidgiting with the hands as though not knowing what to do with them, and other psychological, physiological and/or biochemical difficulties. As stated above, by the practice of this invention, anxiety and the symptoms thereof are materially reduced and in many instances completely eliminated.

The following examples are presented to illustrate rather than to limit the invention.

Example 1

A male subject, 40 years of age, who had been smoking 1½ to 2 packs of cigarettes per day for a period of approximately 22 years, was treated in accordance with this invention. He was given 100 mg. of diphenylhydantoin sodium per day for 1 year and two months, during which time he continued to smoke 1½ to 2 packs of cigarettes per day as usual. This patient had attempted to stop smoking prior to taking the drug in accordance with this invention and was not able to do so in view of the fact that he would experience considerable anxiety after withdrawal from the smoking habit. At the end of the 1 year 2 month period, the subject stopped smoking and experienced absolutely no anxiety or desire to resume smoking. In addition to experiencing absolutely no anxiety, the smoker experienced no difficulty with respect to fidgiting with his hands, a physical symptom which he had much trouble heretofore.

Example 2

The patient, a 29 year old male who had been smoking 1 to 1½ packs of cigarettes per day for a period of approximately 11 years, stopped smoking for a period of approximately 48 days. During this withdrawal, he experienced considerable anxiety which resulted in the resumption of his normal smoking habit. He was later treated with this invention by taking 100 mg. per day of the drug, diphenylhydantoin sodium. During the first 6 days that he was taking the drug, he continued to smoke cigarettes at his usual 1 to 1½ packs per day, rate. After the 6 day period, he stopped smoking completely. The patient experienced virtually no anxiety. Within about 2 days after he stopped smoking, he had absolutely no desire to resume his habit.

In order to further the experimentation of the subject invention, this same patient, 9 days after stopping smoking reduced the amount of drug being taken to 100 mg. every other day. On the fourth day of the reduced treatment with diphenylhydantoin sodium he was directed to smoke 3 cigarettes to see if this would cause him to resume his cigarette habit. The following three days after he smoked the 3 cigarettes, he smoked no cigarettes and yet experienced no anxiety whatsoever.

Further to the experimentation of this invention and after the above 3 days in which the patient smoked no cigarettes, the patient was directed to begin smoking intermittently such as by smoking 2 or 3 cigarettes or less per day. This he did while continuing to take 100 mg. diphenylhydantoin sodium every other day during this time and for a period of 9 days. At the end of the 9 days, the patient stopped taking diphenylhydantoin sodium and continued to smoke 3 to 4 cigarettes per day normally. Even with this material reduction in his smoking habit from 1 to 1½ packs of cigarettes per day to 3 to 4 cigarettes per day, the patient has experienced only a slight increase in anxiety and desire to smoke which he has found very easy to control.

Example 3

A male patient, 61 years of age, who had been smoking an average of 1 to 1½ packs of cigarettes per day for a period of approximately 46 years commenced taking 100 mg. per day of diphenylhydantoin sodium to determine the effectiveness of this drug as an aid in terminating or limiting the smoking habit in accordance with this invention. On the day he started taking diphenylhydantoin sodium, he stopped smoking. During the next 3 days, he experienced considerable anxiety and a great desire to smoke. Thereafter he was directed to resume smoking as desired but continued to take diphenylhydantoin sodium at a rate of 100 mg. per day. During the following 2½ weeks he was able to comfortably reduce the amount of cigarettes smoked to ½ pack per day. Within about 2 weeks he was directed to discontinue taking the drug and during the following week returned to his normal smoking habit of 1½ packages per day. The patient stated that except as noted above, while taking the drug he felt no anxiety and if treatment were continued he could probably and eventually break the smoking habit entirely.

Thus it is seen that the smoking habit can be reduced by taking the drug even though the habit has been ingrained over a great number of years at a relatively high level.

Example 4

In accordance with this invention, a female patient 32 years of age and having a 1½ packs of cigarettes per day, 13 years smoking habit is given 50 mg. of 5,5-diphenyldantoin 3 times a day (150 mg. per day). For the first 4 weeks of the treatment, the patient continues to smoke as usual, 1½ packs per day. After the fourth week, the patient stops smoking completely and experiences no appreciable amount of anxiety, compulsion or desire to resume smoking. After three more weeks the patient is gradually withdrawn from the use of the drug by reducing the dosage to 50 mg. taken twice daily, at breakfast and dinner, for a week, followed by a reduction to 50 mg. once a day, at breakfast, for a week, followed by a complete elimination of the use of the drug. During and following the period of withdrawal from the use of the drug, the patient experiences little or no anxiety or desire to resume smoking and no conditioned reactions relating to the smoking habit are detected.

Example 5

A female patient, 50 years old who has been smoking 1½ to 2 packs of cigarettes per day for a period of approximately 26 years is given 100 mg. of 5,5-diethyl-1-methylbarbituric acid twice daily (200 mg. per day). The patient continues to smoke for a period of seven days at her normal rate of 1½ to 2 packs after which time she is able to reduce her smoking habit to 3 to 6 cigarettes per day, without experiencing appreciable anxiety or desire to increase her habit. Following 3 weeks of the reduced smoking habit the patient is gradually withdrawn from 200 mg. per day to 50 mg. per day over a two week period. The patient continues to take 50 mg. per day and is able to maintain the reduced smoking habit (3 to 6 cigarettes per day) without anxiety.

Example 6

A male patient, 25 years old, who has been smoking 1½ packs of cigarettes per day for a period of approximately 3 years, is given 80 mg. daily of N-methyl-alpha-phenylsuccinimide. The patient continues to smoke for a period of 7 days at his normal rate of 1½ packs after which time he is able to reduce his smoking habit to 3 cigarettes per day, experiencing moderate anxiety or desire to increase his habit. Following three weeks of the reduced smoking habit the subject is gradually withdrawn from the drug over a two week period. The subject experiences increased anxiety during and after withdrawal from the drug and in a short time resumes smoking 1½ packs per day.

In none of the above examples were any of the patients taking any other drugs during the periods of time in which they were being treated in accordance with this invention. In addition, none of the patients treated in the above examples exhibited any adverse side effects when taking the above described drug during the conducted treatment.

Since the above-described drugs are usually administered in larger dosages than are used in this invention in order to be effective as anticonvulsants, it is quite surprising and unexpected that these drugs, when used in accordance with the conditions set forth in this invention, are effective to control or eliminate the tobacco smoking habit.

Once given the above disclosure, many other features, modifications and variations on this invention will become apparent to one skilled in the art. Such modifications, features and variations are therefore included within this invention, the scope of which is to be determined by the following claims.

I claim:

1. A method of eliminating or substantially reducing a patient's tobacco smoking habit which comprises administering to the patient an effective amount of a drug selected from the group consisting of 5,5-diphenylhydantoin, 5,5 - diphenylhydantoin sodium, 3 - methyl 5,5 - phenyl-ethylhydantoin and 3-ethyl-5-phenylhydantoin.

2. A method according to claim 1 wherein said administration is by oral ingestion.

3. A method according to claim 1 wherein said drug is 5,5-diphenylhydantoin sodium.

4. A method according to claim 1 wherein said drug is taken orally by said patient in an amount of from about 20 mg. to about 300 mg. per day for a period of time of from about 3 days to about 2½ years.

5. A method according to claim 4 wherein said drug is 5,5-diphenylhydantoin sodium and said drug is taken in an amount of about 100 mg per day.

6. A method of eliminating or substantially reducing a patient's cigarette smoking habit which comprises administering to the patient an effective amount of a drug selected from the group consisting of 5,5-diphenylhydantoin, 5,5 - diphenylhydantoin sodium, 3-methyl 5,5-phenyl-ethylhydantoin and 3 - ethyl - 5 - phenylhydantoin for a period of time sufficient to substantially reduce or eliminate anxiety that would otherwise be experienced after the patient stops or reduces his smoking habit.

7. A method according to claim 6 wherein said administration is by oral ingestion of 5,5-diphenylhydantoin sodium at a rate of about 20–300 mg. per day for a period of time of from about 3 days to about 2½ years.

8. A method of eliminating or substantially reducing the tobacco smoking habit of a patient which comprises administering to said patient a sufficient amount of a drug selected from the group consisting of 5,5-diphenylhydantoin, 5,5 - diphenylhydantoin sodium, 3-methyl-5,5-phenyl-ethylhydantoin, 3 - ethyl - 5 - phenyl hydantoin to stop or substantially reduce said patient's smoking habit without said patient evidencing any substantial amount of anxiety at least during the time that said patient is being treated with said drug.

9. A method according to claim 8 wherein said administration is by oral ingestion of 5,5-diphenylhydantoin sodium at a rate of about 20–300 mg. per day for a period of from about 3 days to about 2½ years.

References Cited

The Lancet, p. 742, Dec. 19, 1942.

STANLEY J. FRIEDMAN, Primary Examiner

U.S. Cl. X.R.

424—254, 277, 274