Controlled comparison of pharmacological and psychological treatment of generalized anxiety disorder in primary care

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SUMMARY. A sample of 101 patients with generalized anxiety disorder were randomly allocated to one of five groups — diazepam, placebo, cognitive-behaviour therapy, diazepam plus cognitive-behaviour therapy, or placebo plus cognitive-behaviour therapy — and treated over 10 weeks in a primary care setting. All groups received a similar amount of contact with the psychologist and general practitioner. The greatest improvement in ratings of severity of symptoms and overall change in symptoms occurred with cognitive-behaviour therapy combined with diazepam; cognitive-behaviour therapy alone also performed well and cognitive-behaviour therapy plus placebo performed slightly less well. Diazepam alone showed improvement relative to placebo alone. There was a high level of agreement between ratings by the general practitioners, psychologist, and the patients of the response to treatment. At six months follow-up there was no difference between treatment groups in the proportion of patients receiving psychotropic medication after the end of the study. However, cognitive-behaviour therapy, either alone or in combination with drug or placebo, showed the lowest incidence of referral for psychological or psychiatric treatment at six months follow-up.

Introduction

IN the past benzodiazepines were widely accepted as the treatment of choice for anxiety states and they continue to be the first choice for generalized anxiety disorder.[1] However, problems of dependency, diminished efficacy with prolonged use, and withdrawal symptoms, have led to a reduction in prescribing.[2-4] Psychological approaches have been advocated as an alternative treatment for generalized anxiety disorder but until recently the results of psychological treatment have been small. The main outcome measure in clinical trials has been scores on the Hamilton anxiety scale.[5] Reductions from an initial Hamilton anxiety score of between 25 and 30 to an endpoint of between 15 and 20 are the norm, and are generally statistically significant.[6] Although reductions of this magnitude are frequently presented in the literature, they do not lead us to conclude that patients are 'cured' as they are still experiencing 'clinically' significant symptoms. It is therefore important when assessing the efficacy of therapeutic techniques to include more global measures of clinically rated symptom change completed by patients, assessors and referring physicians.

Of the 14 most recent papers published investigating the efficacy of psychological treatment in the management of generalized anxiety, only one has attempted to evaluate the referring physician's assessment of overall symptom change at the end of active treatment.[7] Furthermore, no study to date investigating the efficacy of psychological treatment for generalized anxiety disorder has included the referring physicians' ratings of patients' symptoms both before and after treatment.

Many studies investigating pharmacological treatment of generalized anxiety disorder present a similar pattern. For example, patients' and referring physicians' ratings of the degree of clinical improvement are sometimes not included;[8,9] or patients' ratings of clinical improvement are restricted to oversimplified choices, for example improved versus unimproved;[10] or patients' and physicians' ratings of clinical improvement contradict the statistically significant results achieved on the Hamilton anxiety scale.[11]

As most anxiety states, including generalized anxiety disorder, are treated in primary care, it seems important that the opinion and assessment of the general practitioner are ascertained in the evaluation of treatments. The present study compares the efficacy of pharmacological and psychological treatments for generalized anxiety disorder in a primary care setting as assessed by the self-reports of the patients, and by the clinical ratings of the psychologist and general practitioners.

Method

Subjects

Patients who presented with generalized anxiety disorder to the general practitioner and who were thought suitable for pharmacological and/or psychological treatment were identified. Following assessment of psychological morbidity by the general practitioner, a clinical psychologist then assessed patient characteristics, present mental state and severity of illness. Patients were considered suitable for inclusion in the study if they had given written consent and met the following criteria: a primary diagnosis of generalized anxiety disorder according to the *Diagnostic and statistical manual of mental disorders* (DSM III)[12] and research diagnostic criteria;[13] a minimum score of 15 on the Hamilton anxiety scale; symptoms that had lasted for at least one month; no continuous or prolonged use of benzodiazepines in the previous 12 months; no use of psychotropic drugs at the time of initial assessment or in the previous three weeks; aged 18 to 65 years of either sex.

Over a three year period a total of 113 patients were identified: one patient did not have severe enough anxiety; one patient was using a relative's supply of benzodiazepines; two patients failed to attend for initial psychological assessment; five patients dropped out after initial psychological assessment; and three patients attended only sporadically. A total of 101 patients were therefore included in the study for analysis. Patients were randomly allocated to one of five treatments: diazepam ($n=22$), placebo ($n=19$), cognitive-behaviour therapy ($n=21$), diazepam plus

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cognitive-behaviour therapy ($n=21$) and placebo plus cognitive-behaviour therapy ($n=18$). The demographic details of the patients are shown in Table 1; information concerning previous treatment with benzodiazepines was obtained from practice records.

Treatments

Following one-week of single-blind placebo, three times daily, the diazepam and placebo treatment groups received six weeks of double-blind 5 mg diazepam or placebo, three times daily. Following this active treatment period both groups had three weeks of graded 'withdrawal'. For the diazepam group this comprised double-blind diazepam–placebo–diazepam daily for one week, followed by double-blind placebo–placebo–diazepam daily for one week. Patients were then continued single-blind on placebo three times daily for a final one week period. During the equivalent graded withdrawal period the placebo group received two weeks double-blind placebo three times daily, followed by a period of one week single-blind placebo three times daily.

The cognitive-behaviour therapy group received a maximum of seven treatment sessions over a nine week period equivalent to the length of time the diazepam and placebo groups received double-blind active treatment and graded withdrawal. The therapy was specifically concerned with the elicitation and modification of automatic thoughts and irrational assumptions. Written handouts based on Beck and Emery's approach,† explaining the rationale and management of cognitive therapy were given to patients. In conjunction with the handouts patients were also trained in progressive relaxation using a procedure adapted from Jacobson.[14] Patients were supplied with audio taped relaxation instructions to be followed daily. Individual behavioural targets, such as graded exposure, were also set where necessary. Patients in the cognitive-behaviour therapy group did not receive any concomitant psychotropic medication.

The diazepam plus cognitive-behaviour therapy group received one week of single-blind placebo, six weeks of double-blind 5 mg diazepam three times daily, followed by three weeks of graded withdrawal in the same manner as the diazepam group. In addition they received a maximum of seven cognitive-behaviour therapy sessions over the equivalent nine weeks, encompassing active treatment and graded withdrawal in the same manner as the cognitive-behaviour therapy group.

The placebo plus cognitive-behaviour therapy group received one week of single-blind placebo, six weeks of double-blind placebo and, during the equivalent graded withdrawal period, two weeks of double-blind placebo followed by one week of single-blind placebo, three times daily, in the same manner as the placebo group. In addition the placebo plus cognitive-behaviour therapy group received a maximum of seven cognitive-behaviour therapy sessions.

Procedure

Following an initial assessment by the general practitioner (day −7), patients were randomly allocated to treatment groups. After completion of the one-week placebo period, or equivalent for the cognitive-behaviour therapy alone group, all patients had a baseline assessment by the psychologist (day 0). All drugs were dispensed in identical bubble-packs. Only enough medication to last to the next scheduled appointment was dispensed at any one time, and bubble-packs were returned at each assessment to check compliance.

†Beck A T, Emery G. *Cognitive therapy of anxiety and phobic disorders.* Unpublished treatment manual. Philadelphia: Centre for Cognitive Therapy, 1979. (Address: 133 South 36th Street, Philadelphia, PA 19104, USA.)

Table 1. Demographic features of study patients with generalized anxiety disorder.

	Diazepam ($n=22$)	Placebo ($n=19$)	Cognitive-behaviour therapy ($n=21$)	Diazepam plus cognitive-behaviour therapy ($n=21$)	Placebo plus cognitive-behaviour therapy ($n=18$)
Mean age (yrs)	39.8	42.6	41.5	36.3	42.4
Sex	6M,16F	3M,16F	8M,13F	7M,14F	5M,13F
Mean duration of symptoms (mths)	3.4	3.3	3.2	3.3	3.3
No. of patients previously prescribed benzodiazepines	17	16	19	16	10
No. of patients previously referred for psychological or psychiatric treatment	5	6	7	5	6

n = total number of patients.

Over the six week double-blind drug period the diazepam and placebo group patients were seen individually by the clinical psychologist on five occasions (days 0, 7, 14, 28, 42). At the end of active double-blind treatment diazepam and placebo patients continued double-blind graded-withdrawal and were also seen at the end of this two week period (day 56). Patients then completed graded withdrawal with one week single-blind placebo and were again assessed at the end of this period (day 63). Finally one week after ceasing all medication (day 70) patients were again assessed by the clinical psychologist and separately by their own general practitioner. For diazepam and placebo patients, assessments of drug compliance, adverse symptoms and inquiries about response to treatment were conducted in a non-directive manner so as to avoid making suggestions of a therapeutic nature. Consequently each diazepam and placebo patient received a mean of five hours and 40 minutes contact with the clinical psychologist.

Patients allocated to cognitive-behaviour therapy alone were seen individually for therapy by the clinical psychologist according to the same time schedule as the diazepam and placebo patients. Each appointment for therapy lasted approximately 40 minutes. The diazepam plus cognitive-behaviour therapy group, and the placebo plus cognitive-behaviour therapy group both received psychotropic medication, individual therapy, and psychological assessments administered by the clinical psychologist according to the same time schedule as the diazepam, placebo and cognitive-behaviour therapy alone groups. All groups therefore received approximately the same amount of contact with the clinical psychologist.

Measures

Severity of illness. This was rated on a seven-point scale by the respective general practitioners at day −7 and day 70. The clinical psychologist also independently rated severity of generalized anxiety disorder on the same scale at day 0 and day 70. The seven-point severity rating scale had four anchoring points: (1) normal, not at all ill, absence of symptoms; (3) mild,

symptoms definitely present, but no significant impairment to function; (5) moderate, a significant degree of impairment; (7) severe, or incapacitating condition.

Change in symptoms. This was assessed independently by the general practitioner and psychologist assessors at the end of treatment (day 70). Patients were rated on a seven-point scale of symptom change: (1) very much improved, (2) much improved, (3) minimally improved, (4) no change, (5) minimally worse, (6) much worse, (7) very much worse. In addition, patients self-rated their overall changes in symptoms on the same scale at day 70.

Follow-up

Finally patients were seen at six months follow-up and general practitioner records were examined to assess usage of psychotropic medication and psychological or psychiatric treatment after the study.

Statistical analysis

Chi-square tests were conducted to determine whether significant group differences existed in the proportion of patients allocated to symptom severity assessment categories, before and after treatment, and in ratings of change in overall symptoms following treatment. Between-group one-way analyses of variance were conducted before and after treatment and, where significant, *post hoc* Scheffe tests were used to illustrate where specific between-group differences lay. Within-group comparisons of before and after treatment were conducted by means of paired two-tailed *t*-tests. Between-group differences for the three treatments that involved cognitive-behaviour therapy in comparison to those that did not were analysed by means of unpaired two-tailed *t*-tests.

Results

Severity of symptoms

Table 2 presents the assessments by the general practitioners of the severity of patients' symptoms. At entry to the study (day −7) there was no significant difference between groups in the proportion of patients allocated to the various categories of symptom severity. For each group the largest single severity category was 'moderate'; and the majority of patients fell into the 'moderate' to 'severe' categories. At day −7 there was no between-group difference for the groups that were to receive cognitive-behaviour therapy in comparison with those that would not. Similarly a between-group one-way analysis of variance failed to produce any significant difference between the five groups with regard to general practitioners' assessment of severity of illness at day −7.

However, at the end of the study period (day 70) the proportion of patients allocated to each category differed between groups ($P<0.01$). The largest single category for each of the treatment groups was as follows: diazepam (mild); placebo (moderate); cognitive-behaviour therapy (normal/mild); diazepam plus cognitive-behaviour therapy (normal); placebo plus cognitive-behaviour therapy (normal/mild). Within-group comparison of before and after ratings of severity revealed a significant reduction for diazepam ($P<0.001$), cognitive-behaviour therapy ($P<0.001$), diazepam plus cognitive-behaviour therapy ($P<0.001$), placebo plus cognitive-behaviour therapy ($P<0.001$), and to a lesser extent placebo ($P<0.05$). At day 70 there was a significant between-group difference for the three treatments that involved cognitive-behaviour therapy in comparison with those that did not ($P<0.001$). A between-group one-way analysis of variance revealed significant differences between the five treatment groups with regard to the general practitioner's assessment of severity of illness at day 70 ($P<0.001$). In particular *post hoc* Scheffe tests revealed significant differences ($P<0.05$) between placebo in comparison with cognitive-behaviour therapy, diazepam plus cognitive-behaviour therapy, placebo plus cognitive-behaviour therapy, and between diazepam in comparison with diazepam plus cognitive-behaviour therapy.

Table 3 illustrates the assessments by the psychologist of the severity of symptoms. Before treatment started (day 0) there was

Table 2. Ratings by the general practitioners of the severity of patients' symptoms before and after treatment.

	Number (%) of patients				
Symptom severity	Diazepam (*n* = 22)	Placebo (*n* = 19)	Cognitive-behaviour therapy (*n* = 21)	Diazepam plus cognitive-behaviour therapy (*n* = 21)	Placebo plus cognitive-behaviour therapy (*n* = 18)
Day −7					
1 – Normal	–	–	–	–	–
2	–	–	–	–	–
3 – Mild	3 (14)	1 (5)	2 (10)	4 (19)	2 (11)
4	4 (18)	4 (21)	5 (24)	3 (14)	4 (22)
5 – Moderate	9 (41)	11 (58)	9 (43)	8 (38)	9 (50)
6	5 (23)	3 (16)	3 (14)	5 (24)	3 (17)
7 – Severe	1 (5)	–	2 (10)	1 (5)	–
	Not significant				
Day 70					
1 – Normal	1 (5)	1 (5)	4 (19)	10 (48)	4 (22)
2	2 (9)	2 (11)	7 (33)	5 (24)	6 (33)
3 – Mild	9 (41)	2 (11)	6 (27)	4 (19)	3 (17)
4	3 (14)	5 (26)	2 (10)	1 (5)	3 (17)
5 – Moderate	4 (18)	7 (37)	2 (10)	1 (5)	1 (6)
6	2 (9)	2 (11)	–	–	1 (6)
7 – Severe	1 (5)	–	–	–	–
	$\chi^2 = 43.59$, df = 24, $P<0.01$				

n = total number of patients.

Table 3. Ratings by the psychologist of the severity of patients' symptoms before and after treatment.

	Number (%) of patients				
Symptom severity	Diazepam (*n* = 22)	Placebo (*n* = 19)	Cognitive-behaviour therapy (*n* = 21)	Diazepam plus cognitive-behaviour therapy (*n* = 21)	Placebo plus cognitive-behaviour therapy (*n* = 18)
Day −0					
1 – Normal	–	–	–	–	–
2	–	–	–	–	–
3 – Mild	–	–	–	1 (5)	–
4	1 (5)	–	3 (14)	–	–
5 – Moderate	15 (68)	15 (79)	12 (57)	12 (57)	15 (83)
6	5 (23)	4 (21)	5 (24)	6 (29)	2 (11)
7 – Severe	1 (5)	–	1 (5)	2 (10)	1 (6)
	Not significant				
Day 70					
1 – Normal	1 (5)	1 (5)	3 (14)	6 (29)	2 (11)
2	4 (18)	1 (5)	11 (52)	10 (48)	5 (28)
3 – Mild	3 (14)	4 (21)	2 (10)	3 (14)	4 (22)
4	6 (27)	3 (16)	1 (5)	1 (5)	3 (17)
5 – Moderate	6 (27)	7 (37)	4 (19)	1 (5)	3 (17)
6	2 (9)	3 (16)	–	–	–
7 – Severe	–	–	–	–	1 (6)
	$\chi^2 = 41.84$, df = 24, $P<0.05$				

no significant difference between groups in the proportion of patients allocated to the various categories of symptom severity. At day 0, in agreement with the referring general practitioners, the psychologist rated a majority of patients in each group in the moderate severity category. At day 0 there was no between-group difference for the three treatments that involved cognitive-behaviour therapy in comparison with those that did not. Similarly a between-group one-way analysis of variance failed to produce any significant difference between the five treatment groups.

However, at the end of the study (day 70) the proportion of patients allocated by the psychologist to each category differed between treatment groups ($P<0.05$). Within-group comparison of day 0 and day 70 ratings of severity revealed a significant reduction for diazepam ($P<0.001$), cognitive-behaviour therapy ($P<0.001$), diazepam plus cognitive-behaviour therapy ($P<0.001$), placebo plus cognitive-behaviour therapy ($P<0.001$), and to a lesser extent placebo ($P<0.01$). At day 70 there was a significant between-group difference for the three treatments that involved cognitive-behaviour therapy in comparison with those that did not ($P<0.001$). A between-group one-way analysis of variance revealed significant differences between the five treatment groups with regard to the psychologist's assessment of severity of illness at day 70 ($P<0.001$). In particular, *post hoc* Scheffe tests revealed significant differences ($P<0.05$) between placebo in comparison with cognitive-behaviour therapy and diazepam plus cognitive-behaviour therapy, and between diazepam in comparison with diazepam plus cognitive-behaviour therapy.

Although the referring general practitioners and the psychologist carried out independent assessment of patient severity without prior collaboration there was nevertheless a satisfactory level of agreement at day 0 (Pearson $r = 0.41$, $P<0.001$) and especially at day 70 ($r = 0.85$, $P<0.001$) between their ratings.

Table 4. Ratings by the general practitioners of the change in overall symptoms after treatment.

Day 70 symptom change	Number (%) of patients: Diazepam ($n=22$)	Placebo ($n=19$)	Cognitive-behaviour therapy ($n=21$)	Diazepam plus cognitive-behaviour therapy ($n=21$)	Placebo plus cognitive-behaviour therapy ($n=18$)
1 – Very much improved	4 (18)	3 (16)	14 (67)	16 (76)	9 (50)
2 – Much improved	6 (27)	2 (11)	4 (19)	2 (10)	4 (22)
3 – Minimally improved	8 (36)	2 (11)	1 (5)	3 (14)	2 (11)
4 – No change	3 (14)	12 (63)	2 (10)	–	2 (11)
5 – Minimally worse	1 (5)	–	–	–	1 (6)
6 – Much worse	–	–	–	–	–
7 – Very much worse	–	–	–	–	–

$\chi^2 = 53.32$, df = 16, $P<0.001$

Table 5. Ratings by the psychologist of the change in overall symptoms after treatment.

Day 70 symptom change	Number (%) of patients: Diazepam ($n=22$)	Placebo ($n=19$)	Cognitive-behaviour therapy ($n=21$)	Diazepam plus cognitive-behaviour therapy ($n=21$)	Placebo plus cognitive-behaviour therapy ($n=18$)
1 – Very much improved	7 (32)	3 (16)	16 (76)	16 (76)	9 (50)
2 – Much improved	5 (23)	3 (16)	2 (10)	3 (14)	5 (28)
3 – Minimally improved	6 (27)	4 (21)	2 (10)	2 (10)	1 (6)
4 – No change	2 (9)	8 (42)	1 (5)	–	2 (11)
5 – Minimally worse	2 (9)	1 (5)	–	–	1 (6)
6 – Much worse	–	–	–	–	–
7 – Very much worse	–	–	–	–	–

$\chi^2 = 38.47$, df = 16, $P<0.01$

Table 6. Self-ratings by patients of the change in overall symptoms after treatment.

Day 70 symptom change	Number (%) of patients: Diazepam ($n=22$)	Placebo ($n=19$)	Cognitive-behaviour therapy ($n=21$)	Diazepam plus cognitive-behaviour therapy ($n=21$)	Placebo plus cognitive-behaviour therapy ($n=18$)
1 – Very much improved	6 (27)	4 (21)	16 (76)	15 (71)	11 (61)
2 – Much improved	5 (23)	3 (16)	3 (14)	2 (10)	2 (11)
3 – Minimally improved	4 (18)	2 (11)	1 (5)	4 (19)	2 (11)
4 – No change	5 (23)	8 (42)	1 (5)	–	2 (11)
5 – Minimally worse	2 (9)	1 (5)	–	–	–
6 – Much worse	–	1 (5)	–	–	1 (6)
7 – Very much worse	–	–	–	–	–

$\chi^2 = 36.66$, df = 20, $P<0.05$

Change in overall symptoms

The changes in patients' overall symptoms at day 70 as assessed by the general practitioners (from day −7) and by the psychologist (from day 0), are presented in Tables 4 and 5 respectively. Table 6 shows patients' self-assessment of their change in symptoms from day −7 to day 70. All three assessments indicated a difference between treatment groups in the change in symptoms over the study period. There was also a significant between-group difference for the three treatments that involved cognitive-behaviour therapy in comparison with those that did not as assessed by general practitioners ($P<0.001$), the psychologist ($P<0.001$), and patients ($P<0.001$). A between-group one-way analysis of variance revealed significant differences between the five treatment groups with regard to general practitioners' assessment of change in overall symptoms at day 70 ($P<0.001$) with *post hoc* Scheffe tests showing significant differences ($P<0.05$) between placebo in comparison with cognitive-behaviour therapy, diazepam plus cognitive-behaviour therapy

and placebo plus cognitive-behaviour therapy, and between diazepam in comparison with cognitive-behaviour therapy and diazepam plus cognitive-behaviour therapy. The psychologist's rating of symptom changes also differed between groups ($P<0.001$) with *post hoc* Scheffe tests showing differences ($P<0.05$) between placebo in comparison with cognitive-behaviour therapy and diazepam plus cognitive-behaviour therapy, and between diazepam in comparison with diazepam plus cognitive-behaviour therapy. Patients' self-rating of change in symptoms differed between groups ($P<0.001$) with *post hoc* Scheffe differences ($P<0.05$) between placebo in comparison with cognitive-behaviour therapy and diazepam plus cognitive-behaviour therapy, and between diazepam in comparison with cognitive-behaviour therapy.

Taking the categories of 'very much improved' and 'much improved' as indicative of significant clinical improvement, general practitioners regarded 45% of diazepam; 36% of placebo; 86% of cognitive-behaviour therapy; 87% of diazepam plus cognitive-behaviour therapy and 72% of placebo plus cognitive-behaviour therapy groups as achieving this status. In general, similar proportions were noted by the psychologist and by patients' own self-report. There were high levels of agreement regarding changes in overall symptoms between general practitioner and psychologist (Pearson $r = 0.93$, $P<0.001$), general practitioner and patient ($r = 0.89$, $P<0.001$) and psychologist and patient ($r = 0.94$, $P<0.001$).

Subsequent treatment at six months follow-up

Follow-up assessments are often compromised by patients receiving treatment between the end of the study period and the designated follow-up date. Table 7 illustrates the number of patients in each group who received psychotropic medication in the six month period after the end of the study and the number of patients who received psychological or psychiatric referrals from their general practitioner over the same period. Seven patients (one diazepam, two placebo, two cognitive-behaviour therapy and two cognitive-behaviour therapy plus diazepam) were untraceable as they had moved house and/or changed general practitioner.

There were no significant differences between groups in the numbers of patients who received psychotropic medication after the end of the study. However, there was a significant difference between groups in the number of patients who received psychological or psychiatric referrals in the six months post-study period ($P<0.001$). Table 7 shows that the overwhelming majority of cognitive-behaviour therapy, diazepam plus cognitive-behaviour therapy, and placebo plus cognitive-behaviour therapy patients received no such referrals. Just over a third of placebo treated patients received subsequent referrals but in the diazepam treated group 57% of patients were referred for psychological or psychiatric treatment.

Table 7. Patients prescribed psychotropic drugs or referred for psychological/psychiatric treatment during the six month period after the study.

	Number (%) of patients				
	Diazepam ($n=21$)	Placebo ($n=17$)	Cognitive-behaviour therapy ($n=19$)	Diazepam plus cognitive-behaviour therapy ($n=19$)	Placebo plus cognitive-behaviour therapy ($n=18$)
Psychotropic drugs	7 (33)	9 (53)	3 (16)	2 (11)	5 (28)
	Not significant				
Psychological/psychiatric referral	12 (57)	6 (35)	2 (11)	3 (16)	1 (6)
	$\chi^2 = 19.08$, df = 4, $P<0.001$				

Discussion

Generalized anxiety disorder has been regarded as one of the most difficult anxiety states to treat successfully, whether by psychological or pharmacological means. Although general practitioners are often the primary referring agents for patients who enter treatment trials, their opinion of patients' response to treatment, especially those involving psychological approaches, is seldom elicited. Furthermore, general practitioners may be left to manage patients after completion of the designated study period. Therefore, the high level of agreement between general practitioners, psychologist and patients regarding the relative efficacy of the five treatment options in the management of generalized anxiety disorder is of particular interest in the present study.

All treatments produced statistically significant reductions to a greater or lesser extent when comparing initial and end-point ratings of severity by the general practitioners and psychologist. However, a consistent pattern of differences between treatments emerged on measures of severity and change in overall symptoms. At day 70 there was no difference between those treatments involving cognitive-behaviour therapy whether alone or in combination. Similarly there was no difference between diazepam and placebo treatment groups. There was a significant difference in favour of cognitive-behaviour therapy, and diazepam plus cognitive-behaviour therapy in comparison with placebo at day 70 as measured by general practitioner, psychologist and patient ratings of change in overall symptoms, and by general practitioner and psychologist ratings of severity. There was also a significant difference in favour of placebo plus cognitive-behaviour therapy in comparison with placebo at day 70 as measured by general practitioner ratings of change in overall symptoms and general practitioner ratings of severity. Therefore cognitive-behaviour therapy and diazepam plus cognitive-behaviour therapy differed from placebo on all five end-point outcome measures whereas placebo plus cognitive-behaviour therapy differed from placebo on only two of these measures.

There was also a significant difference in favour of diazepam plus cognitive-behaviour therapy in comparison with diazepam at day 70 as measured by general practitioner and psychologist ratings of change in overall symptoms and ratings of severity. A significant difference in favour of cognitive-behaviour therapy in comparison with diazepam was shown by general practitioner and patient ratings of change in overall symptoms. Therefore diazepam plus cognitive-behaviour therapy differed from diazepam on four of five outcome measures while cognitive-behaviour therapy differed from diazepam on only two of these measures. There were no differences between placebo plus cognitive-behaviour therapy and diazepam.

The less impressive results of the placebo plus cognitive-behaviour therapy group, in comparison with cognitive-behaviour therapy alone and diazepam plus cognitive-behaviour therapy may be explained by patient expectations regarding the benefit of placebo medication not being met. Patients in the placebo plus cognitive-behaviour therapy group may have expected the placebo medication to partially ameliorate their anxiety state. Therefore placebo plus cognitive-behaviour therapy patients may have applied cognitive-behaviour therapy techniques with less vigour in comparison with those using cognitive-behaviour therapy alone.

The combined diazepam plus cognitive-behaviour therapy treatment approach produced the best results on almost all measures as noted by general practitioners, psychologist and patients. Initial gains for all three treatments involving cognitive-behaviour therapy were maintained at follow-up, with patients less likely to receive subsequent psychiatric or psychological treatment in the six month period after the study.

One way to reduce dependence on benzodiazepines is to provide general practitioners with alternative management strategies. The cognitive-behaviour therapy approach adopted in this study proved to be effective and viable in a primary care setting. However, a significant proportion of patients treated with diazepam also responded positively during the treatment period. General practitioners, psychologist and patients rated only 18%, 18% and 32% respectively of the diazepam alone group as unimproved or worse compared with ratings of 63%, 48% and 53% respectively for placebo alone. The use of diazepam as the first line of treatment for generalized anxiety disorder should therefore not be discounted. Unfortunately the initial moderate treatment gains of the diazepam group were not well maintained at follow-up, as the majority of patients in this group had required subsequent psychological or psychiatric treatment. Clear exclusion criteria for benzodiazepine treatment are needed in addition to close monitoring combined with early withdrawal of drug treatment for non-responders. Even for those who do respond to short-term benzodiazepine treatment the introduction of cognitive-behaviour therapy techniques may be required to achieve long-term gains.

The positive response of patients to cognitive-behaviour therapy whether alone or in combination with diazepam cannot be explained solely by the amount of attention patients received. Even though it is not yet known which components are responsible for change during and after treatment the success of cognitive-behaviour therapy may be largely attributed to the ease with which patients accept the theoretical rationale of the treatment. Cognitive-behaviour therapy tackles the cognitive component of anxiety by reinstating a more rational way of thinking. In addition patients learn to control and be less fearful of their somatic symptoms. Furthermore, avoidance behaviour is reduced and patients' feelings of self-mastery and control are enhanced. Failures of previous studies of the psychological approach may be attributed to their adoption of purely relaxation techniques or solely cognitive or behavioural methods. The present study supports the use of a combined approach, while not dismissing the use of pharmacological alternatives. Future studies should attempt to determine which patient characteristics predict a positive outcome to psychological or pharmacological treatments, and which approach most suits individual patients.

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