

Controlled evaluation of brief intervention by general practitioners to reduce chronic use of benzodiazepines

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SUMMARY

Background. It is recommended that long-term users of benzodiazepines in general practice be withdrawn from their medication where possible.

Aim. A study was undertaken to assess the effectiveness of minimal intervention delivered by general practitioners in helping chronic users of benzodiazepines to withdraw from their medication, and to determine the psychological sequelae on patients of such intervention.

Method. Patients taking benzodiazepines regularly for at least one year were recruited by their general practitioner and allocated either to a group receiving brief advice during one consultation supplemented by a self-help booklet or to a control group who received routine care. The patients completed the 12-item general health questionnaire and a benzodiazepine withdrawal symptom questionnaire at the outset of the study and at three and six months after this.

Results. Eighteen per cent of patients in the intervention group (9/50) had a reduction in benzodiazepine prescribing recorded in the notes compared with 5% of the 55 patients in the control group ($P < 0.05$). In the intervention group, 63% of patients had a score of two or more on the general health questionnaire at baseline compared with 52% at six months. Of the 20 intervention patients reporting benzodiazepine reduction, 60% had a score of two or more at baseline compared with 40% at six months. Intervention patients had significantly more qualitative, but not quantitative, withdrawal symptoms at six months compared with baseline. Consultation rates were not increased in the intervention group.

Conclusion. The study indicates that some chronic users can successfully reduce their intake of benzodiazepines with simple advice from the general practitioner and a self-help booklet. This type of intervention does not lead to psychological distress or increased consultation.

Keywords: benzodiazepines; drug long-term use; drug dependence; drug addiction treatment.

Introduction

Benzodiazepine prescribing in the United Kingdom reached a peak in 1979 with 31 million prescriptions being dispensed.¹

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Since then there has been a decline, mainly as a result of a drop in new prescribing,² leaving a core of chronic users who are treated in general practice. In 1988, the Committee on Safety of Medicines recommended that benzodiazepines should not be used for more than four weeks and then only at the lowest possible dose to control symptoms.³ Previous studies have indicated that many chronic users are elderly, and even as early as 1980 the Committee on the Review of Medicines had noted the increased frequency of adverse reactions in this group, particularly among those taking long acting preparations.⁴ A report published in 1992 includes a recommendation that primary care teams should identify long-term users of benzodiazepines on their list and, where possible, plan their withdrawal from medication.⁵ However, in the context of general practice where consultations often last no more than 10 minutes, only brief intervention is really feasible. Previous work has shown that a proportion of long-term users can successfully decrease or stop taking their benzodiazepines in response to a letter from or a short interview with their general practitioner.^{6,7}

A study was undertaken to investigate whether general practitioner minimal intervention, consisting of brief advice plus a self-help booklet, could help chronic users to withdraw from their benzodiazepines. A further aim was to measure the levels of psychological distress experienced before and after intervention to see if there was any change.

Method

Eleven volunteer general practices in the London area took part in the study. General practitioners were asked to recruit all chronic benzodiazepine users by writing to patients receiving repeat prescriptions and asking them to attend the surgery. When they attended the project was explained and informed consent obtained. Doctors also recruited patients opportunistically if they happened to attend during the trial period.

A chronic user was defined as someone who had been on benzodiazepines for at least a year and who took tablets at least three times weekly. The following patients were excluded: those with acute serious illness; anyone currently receiving psychiatric treatment or with a history of psychosis; anyone currently dependent on alcohol or illicit drugs; patients taking benzodiazepines for a medical problem such as epilepsy; patients unable to attend the surgery because of physical infirmity; and individuals unable to complete questionnaires for any reason. General practitioners were also allowed to exclude a chronic user if they felt that asking such a patient to reduce their benzodiazepines might be harmful (the doctor kept a list of this group).

Patients were allocated by their doctor to receive either minimal intervention, consisting of general practitioner advice on coming off benzodiazepines plus a self-help booklet which patients took away to read, or to receive no intervention: this group acted as controls. The birth date method was used to allocate patients (individuals having an even birth date received minimal intervention while those with an odd birth date received no intervention).

It would have been impossible in a controlled trial to impose rigid guidelines on general practitioners concerning the manage-

ment of benzodiazepine withdrawal. Instead it was suggested that doctors should outline the risks of benzodiazepines, advise patients to reduce and then stop their medication, and then encourage patients to follow the advice in the self-help booklet. The booklet was divided into two sections, the first giving some basic information about benzodiazepines and the second giving practical advice on stopping, including techniques on coping with fears and anxieties. It had been specifically designed for the study and had already been successfully used in a pilot study with 31 patients.⁸

Assessment

The main research instruments were the 12-item general health questionnaire⁹ which is used to screen for psychiatric disorder in general practice populations, and the benzodiazepine withdrawal questionnaire¹⁰ which measures quantitative perceptual symptoms (hyper- or hypo-sensitivity in sensory modalities) and qualitative perceptual phenomena (such as strange or unusual tastes or smells), giving an estimate of the level of withdrawal symptoms being experienced by the patient.

Subjects completed these questionnaires at the initial consultation and were posted the same questionnaires three and six months later. General practitioners kept a list of patients who were unwilling to complete the baseline questionnaires; these patients were considered to be study refusals and so were not entered into the controlled trial. At six months subjects reported whether their consumption of benzodiazepines had increased, stayed the same, decreased or stopped during the previous six months. Factors considered by patients to have either assisted or prevented reduction were also noted.

All patients' records (study patients, refusals and those chronic users specifically excluded from the study by their doctor) were examined at six months to ascertain benzodiazepine prescribing, consultation rates, past medical and psychiatric histories and details of other drugs prescribed. Benzodiazepine dosages were expressed in terms of diazepam equivalents using the conversion table in the 1989 *British national formulary*, number 18. With some computers if the doctor wishes to prescribe more tablets than usual a multiple prescription is issued (for example, three prescriptions of 30 tablets of temazepam 10 mg rather than one prescription of 90 tablets). However, the same multiple entry can appear owing to computer error (for example, failure to print a prescription until the third attempt). This type of problem was encountered in four of the 11 practices. All multiple entries, which could not be checked against manual records, were taken at face value. This may have led to an overestimate in a few cases, though such errors should have been equally distributed between control and intervention patients. In view of this problem strict criteria were used to define reduction, namely the mean daily dose being reduced by a minimum of 5 mg diazepam equivalent or by at least 75% in the six months following intervention compared with the six months prior to intervention. Henceforth reduction defined in this way will be referred to as recorded reduction; reported reduction will refer to patients who reported decreasing or stopping their benzodiazepines at six months; reported stopping will refer to patients who reported stopping their benzodiazepines at six months (those reporting stopping are thus a subgroup of those reporting a reduction).

Doctors were interviewed at the end of the trial to determine their attitudes to benzodiazepines, particularly in relation to short- and long-term prescribing, and litigation issues. The interviews were conducted by K B and consisted of a series of closed questions.

Analysis

Based on previous research⁶ it was assumed that if 30% of the

intervention subjects and 5% of the controls reduced their drug consumption, this would constitute a clinically significant difference. In order to demonstrate this difference with 90% power and at the 0.05 level of significance, it was estimated that 47 subjects were required in each group.¹¹

Intervention and control patients were compared for levels of recorded reduction, reported reduction and reported stopping. There is now considerable evidence supporting a separate classification of chronic daytime and night-time users of benzodiazepines.¹² Therefore levels of reduction among intervention and control patients were also calculated for day- and night-time users (patients taking benzodiazepines both during the day and at night were considered daytime users).

General health questionnaire and withdrawal questionnaire scores were compared between baseline and six months, and consultation rates compared for the six months before and after baseline in the control group, intervention group and two subgroups of the intervention group — those reporting reduction and those reporting no reduction. By looking at the data from the whole intervention group it was possible to answer the question 'Does asking chronic users to withdraw from benzodiazepines lead to psychological distress, withdrawal symptoms or increased consultation?' The data relating to intervention patients reporting reduction or non-reduction allowed two further questions to be answered 'Does asking chronic users to withdraw from benzodiazepines lead to psychological distress, withdrawal symptoms or increased consultation when the patient reports reduction and when the patient reports no reduction?'

Comparisons were assessed using chi square tests and *t*-tests. Non-parametric tests were used for non-normal variables. Logistic regression was performed to determine independent predictors of recorded reduction of benzodiazepines, reported reduction and reported stopping (the forward stepwise method was used; continuous independent variables were dichotomized around their medians). Independent variables were chosen from previous research or clinical experience which indicated that they might be important: some related to benzodiazepines (baseline dosage, duration of action, years on medication and day- or night-time use); others to patients (sex, marital status and social class); and others to doctors (age and levels of short- and long-term benzodiazepine prescribing) or their practices (single handed or group practices, and attachment of mental health professionals).

Results

Characteristics of study population

One hundred and nine chronic users were recruited into the study, most during the first half of 1991. Fifty one (47%) were in the intervention group. The mean age of the sample was 62 years (range 32 to 86 years). Sixty seven (61%) were women. Twenty three participants were single, 32 were married, and 47 were divorced, separated or widowed (marital status of seven patients unknown).

The mean duration of treatment with benzodiazepines was 14 years (range two to 26 years). At the start of the study 30 patients were taking diazepam, 24 nitrazepam, 44 temazepam, 13 lorazepam, three oxazepam and one triazolam (some patients were taking more than one benzodiazepine; data missing for one patient). Seventy three subjects took their benzodiazepine at night-time only, 16 during the day only and 20 both at night and during the day. According to the patient records the general practitioner had been the first to prescribe a benzodiazepine in 89 (82%) cases, a psychiatrist in seven and another doctor in a further seven (in six cases the original prescriber was unknown). The initial prescription was for an overtly psychological reason in 57 patients, for a physical problem (most often headache or

some other regional pain) in 19 patients and for reasons unknown in the remaining 33 cases. Based only on data in the notes the median number of attempts to withdraw from benzodiazepines prior to the present study was one (range zero to seven).

Fifty four patients (50%) had seen a psychiatrist at some point. Forty seven (43%) had been treated for depression and 21 (19%) for anxiety by someone other than the general practitioner. Thirty patients had a history of alcohol problems and 18 had attempted suicide at least once. In terms of their physical health, 44 had suffered a major cardiovascular or vascular episode, 40 a major respiratory illness and 40 a major gastrointestinal illness. The median number of major physical diseases per patient was three.

Refusals and exclusions by general practitioners

Sixteen patients had been considered to be refusals as they had not been willing to complete the baseline questionnaires and a further 14 had been excluded by their general practitioner. Those refusing to take part did not differ significantly from the study sample in terms of age, sex, physical or psychiatric health, consultation rate in the six months before the study or benzodiazepine prescribing history. Those excluded by the general practitioner were more likely than the study patients to be on an antidepressant at the end of the trial period; seven of those excluded (50%) were on an antidepressant compared with 18 (17%) of the study patients (Fisher exact test, 1 degree of freedom (df), 2 tailed $P < 0.01$; 95% confidence interval (CI) for difference between proportions 6% to 61%).

Response to questionnaires

The general health questionnaire and withdrawal questionnaire were completed by all 109 patients at baseline, by 89% at three months, and by 85% at six months. The 16 non-respondents at six months comprised two who had died, one who had spent much time in hospital, eight who declined to fill in the second or third questionnaires and five who were not contactable. Ninety of the 93 respondents at six months also reported on their consumption of benzodiazepines over the previous six months.

Table 1 shows the prevalence of psychiatric disorder in the study population using three different case thresholds on the general health questionnaire. At baseline 55% of subjects were mild cases (a score of two or more) and 35% severe cases (four or more), while at six months 46% were mild cases and 33% severe cases. The 16 non-respondents to the final general health questionnaire did not differ significantly in terms of caseness from the rest of the study sample at baseline.

Recorded and reported benzodiazepine reduction

Benzodiazepine prescribing data were collected for 105 patients

Table 1. Prevalence of psychiatric disorder in study sample at baseline, three and six months according to different case thresholds on the general health questionnaire.

	% of patients who are		
	Mild cases ^a	Moderate cases ^b	Severe cases ^c
Baseline (n = 109)	55	47	35
3 months (n = 97)	49	42	38
6 months (n = 93)	46	37	33

n = number of patients in group. ^aScore of 2+. ^bScore of 3+. ^cScore of 4+.

(two patients died during follow up and for two cases full prescribing records were not available for the six months before and after intervention). Of these 105 patients 50 (48%) were in the intervention group. Nine (18%) of the intervention group had a recorded reduction in benzodiazepine prescription compared with three (5%) of the control group ($\chi^2 = 4.07$, 1 df, $P < 0.05$; 95% CI for difference between proportions 0.3% to 25%). Among the 71 night-time users, a recorded reduction was achieved by eight of 33 in the intervention group (24%) compared with two (5%) of the 38 in the control group (Fisher exact test, 1 df, two tailed $P < 0.05$; 95% CI for difference between proportions 3% to 35%). Among the 34 day-time users, a recorded reduction was achieved by one patient out of 17 (6%) in each of the control and intervention groups.

Of the 90 patients who reported their benzodiazepine consumption at the end of the six month follow up 46 (51%) were in the intervention group. Twenty of the intervention group (43%) reported a reduction in intake of benzodiazepines compared with 11 (25%) of the controls (difference not significant). Nine of the intervention group (20%) reported stopping taking their benzodiazepines compared with three of the controls (7%) (difference not significant). Among the 62 night-time users, a reported reduction was achieved by 17 of the 32 in the intervention group (53%) compared with seven (23%) of the 30 in the control group ($\chi^2 = 5.79$, 1 df, $P < 0.05$; 95% CI for difference between proportions 7% to 53%). Among the 28 day-time users, a reported reduction was achieved by three of 14 in the intervention group (21%) compared with four (29%) of 14 in the control group (difference not significant).

Although not measuring precisely the same thing, the level of agreement between recorded and self-report data was examined: for a comparison of recorded and reported reduction kappa = 0.34; for recorded reduction and reported stopping kappa = 0.61. The strict criteria used to define recorded reduction made it much closer to reported stopping than to a measure of reported reduction.

Questionnaire scores and consultation rates

Intervention and control patients. The proportion of patients who were cases according to the general health questionnaire was lower at six months compared with baseline in both intervention and control group patients (Table 2). The fall was more pronounced in the intervention group (11%) than in the control group (3%), though neither reached significance. Intervention patients had significantly more qualitative (but not quantitative) withdrawal symptoms at six months compared with baseline. In the control group both qualitative and quantitative symptoms were unchanged over the six months. A comparison of the median number of consultations in the six months before and after intervention revealed no significant difference in the control group (four and four, respectively) or the intervention group (four and three, respectively).

Intervention patients reporting benzodiazepine reduction and non-reduction. Intervention patients reporting a reduction in benzodiazepine consumption and those reporting no reduction both had a lower proportion of patients who were cases according to the general health questionnaire at six months compared with baseline (Table 2). The fall was greater among the reducers (20%) than in the non-reducers (3%), though neither reached significance. Both subgroups had significantly more qualitative (but not quantitative) withdrawal symptoms at six months compared with baseline. A comparison of the median number of consultations in the six months before and after intervention revealed no significant difference among either reducers (2.5 and 3.5, respectively) or non-reducers (four and three, respectively).

Table 2. Prevalence of psychiatric morbidity, according to general health questionnaire, and withdrawal symptoms among intervention and control group patients, and among intervention patients reporting reduction and no reduction in benzodiazepine consumption, at baseline and at six months.

	No. (%) of GHQ cases ^a		Withdrawal symptom score			
			Qualitative (mean (SD))		Quantitative (median)	
	Baseline	6 months	Baseline	6 months	Baseline	6 months
Intervention group	29 (63)	24 (52)	5.5 (5.8)	7.3 (6.2)**	1	0
Control group	20 (43)	19 (40)	4.8 (4.5)	5.7 (5.9)	1	0.5
<i>Intervention group</i>						
Reducers	12 (60)	8 (40)	6.4 (6.9)	8.6 (6.6)*	0	1.5
Non-reducers	17 (65)	16 (62)	4.9 (4.8)	6.2 (5.8)*	1	0

^aScore of 2+. Paired t-test: * $P < 0.05$, ** $P < 0.01$.

The nine intervention patients reporting a reduction who actually stopped taking benzodiazepines showed no improvement in psychiatric status (six were cases according to the general health questionnaire at baseline and six were cases at six months). Among the intervention 11 patients reporting decreasing but not stopping benzodiazepines, six were cases at baseline compared with two at six months.

Logistic regression

Two factors were found to be associated with recorded reduction of benzodiazepines: being on an antidepressant at the end of the six month follow up (odds ratio 10.6, 95% CI 2.0 to 55.1) and being a member of the intervention group (odds ratio 6.0, 95% CI 1.1 to 32.5).

Two factors emerged as being predictive of reported reduction in the study population: taking a low baseline dose of benzodiazepine, that is, 4.5 mg daily or less of diazepam equivalent (odds ratio 3.8, 95% CI 1.3 to 10.8) and being on a short acting drug, such as temazepam, oxazepam, lorazepam or triazolam (odds ratio 4.1, 95% CI 1.4 to 11.9). Having a history of four or more major physical illnesses was an independent predictor of reported stopping (odds ratio 4.7, 95% CI 1.1 to 19.5).

No doctor characteristic or practice factor was found to be associated with a successful outcome.

Factors reported by patients as helping or preventing reduction

Of the 31 patients who reported reduction of benzodiazepines over the trial period 25 (81%) said that they received support from their general practitioner which they found to be helpful (10 out of the 11 reducers in the control group and 15 out of the 20 in the intervention group). Six patients (19%) received helpful support from a friend or relative and three (10%) from another health professional. The 20 reducers in the intervention group had received the self-help booklet and of these 13 (65%) found it helpful. Three quarters of the doctors (18/24 of those with patients with booklets) also reported that the booklet was helpful in the everyday management of patients on benzodiazepines.

Fifty nine patients reported no reduction in their benzodiazepine consumption during the study. The commonest reason given for this was inability to sleep without the tablets (reported by 34 subjects). Twenty three patients thought they were better on the tablets, seven said they were too frightened to come off and two patients indicated that their doctor thought they were better off taking the tablets.

Interviews with general practitioners

Thirty one general practitioners took part in the study and of

these 27 were interviewed. Of the 27 doctors, 15 were men, the mean age was 45 years and the mean numbers of years in practice was 15. Six of the 11 practices in which these doctors worked had a counsellor or other specialist mental health professional doing sessional work.

The conditions most frequently treated with benzodiazepines by the doctors were, in order: acute insomnia, chronic insomnia, chronic anxiety, acute severe anxiety and acute back pain. Acute depression was the condition least likely to be treated with benzodiazepines. The two most common reasons for continuing to prescribe long-term benzodiazepines to patients were because the patient wished to remain on benzodiazepines and that it was too much of a struggle for the patient to come off the tablets.

No doctor was currently under threat of litigation with regard to their prescribing of benzodiazepines but three knew colleagues who were. Eighteen doctors were not at all concerned about litigation and nine were slightly concerned.

Discussion

In this study, chronic users of benzodiazepines who received from their general practitioners brief advice on withdrawal and a self-help booklet were found to have been prescribed lower doses of medication during follow up in significantly greater numbers than controls. In relation to self-report data, patients receiving minimal intervention also tended to report reduction and stopping of benzodiazepines more often than control group patients. These results were achieved in a population with high rates of past depression, anxiety, alcohol abuse and attempted suicide. The study also demonstrated that asking chronic users to withdraw from their medication was not associated with psychological harm or increased consultation with the general practitioner. This applied whether the patients reported reduction or not, indicating that it is safe to ask patients to withdraw from benzodiazepines, regardless of whether they are successful in the end or not. The intervention group as a whole (and its two subgroups of benzodiazepine consumption reducers and non-reducers) were all experiencing more qualitative withdrawal symptoms at six months compared with baseline. However, general health questionnaire scores and consultation rates were unchanged, suggesting that the withdrawal symptoms did not cause undue distress to patients. It is also of interest that intervention patients who reported no reduction were experiencing withdrawal symptoms, implying that they too were trying to cut down their consumption of benzodiazepines.

The birth date method of allocation used in this study has been both criticized¹³ and defended.¹⁴ When doctors know the meaning of the allocation, the possibility that they might manipulate selection of subjects applies as much to a random allocation as to

one dependent on date of birth. The birth date method is easy to understand and apply, especially for non-researchers. It is unobtrusive in comparison with other methods of randomization and so the doctor is less likely to be distracted from important non-verbal cues in the consultation. Furthermore, to our knowledge there is no inherent bias to the use of birth dates.¹⁴

It has been said that lowering benzodiazepine dosage may do more harm than good, in that the patient suffers more distress because of the reduced dose, yet does not have the benefit of coming off the medication.¹⁵ The supporters of this view have usually considered stopping benzodiazepines as the only successful outcome. The present research contradicts this view. Intervention patients who reported reduction in their benzodiazepine intake showed a modest psychiatric improvement over the trial period as judged by the general health questionnaire. Although this group included nine subjects who reported stopping taking benzodiazepines there was no improvement in the psychiatric status of these stoppers. However, among the 11 patients who reported decreasing but not stopping benzodiazepines, there was improvement. Lowering benzodiazepine dosage is therefore valuable in its own right and should be encouraged, even if the patient is unable to cease intake completely.

Among night-time users, individuals receiving minimal intervention were significantly more likely than controls to reduce their medication, both according to self-report and prescribing records. Among daytime users, however, there was no difference between intervention patients and controls. It seems therefore that daytime users require more than minimal intervention to help them withdraw from benzodiazepines. This finding also lends further weight to the argument for a separate classification of daytime and night-time users.

A number of factors were found to be associated with a successful outcome in the trial. Being on an antidepressant at the end of the study was strongly predictive of a recorded reduction in benzodiazepine prescribing. One explanation could be drug substitution, that is, patients were being transferred from one psychotropic to another, the antidepressant being used as a hypnotic or anxiolytic instead of the benzodiazepine. Another possibility is that depression, which is common among these patients,¹⁶ is being successfully treated, thereby reducing the need for other psychotropic drugs. The area is clearly complex, as illustrated by the finding that patients excluded by their general practitioner from the research, on the grounds that it might be harmful to them, were much more likely than study patients to be on an antidepressant at the end of the trial. Nevertheless, it would seem a rational policy to identify depression in chronic users and it may be that treating this with an antidepressant will assist withdrawal of benzodiazepines.

Taking a low baseline dose of benzodiazepines and a short acting preparation were both associated with a greater chance of reduction as reported by patients. The first of these findings has been noted before,⁶ but is still surprising as one would expect that being on a higher initial dose would give more scope for reduction. Shorter acting preparations are generally thought to carry a greater risk of withdrawal symptoms and consequently it is often recommended that they be substituted by a long acting drug such as diazepam when withdrawal is being considered.¹⁵ The results of this study suggest that it may be better to leave patients on their short acting preparations when a dose reduction is being attempted. The link between more physical illness and successfully stopping benzodiazepines is also an unexpected finding. One explanation is that these individuals only require their medication to overcome the psychological distress associated with physical illness and having recovered from, or adapted to the latter, they no longer have any real need for tablets.

No particular characteristic of doctors or their practices was identified as being important in helping chronic users to withdraw. However, 81% of patients who reported reducing their benzodiazepine consumption identified their doctor's support as being helpful during withdrawal. The self-help booklet also received a positive response from both patients and doctors.

Some chronic users can successfully reduce their intake of benzodiazepines with a simple and practical intervention delivered by their general practitioner. The intervention does not cause psychological distress or increased consultation and this applies whether individuals are successful in reducing their intake or not.

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Corrigendum — formulary for self-care

In the editorial by Herxheimer and Britten (Formulary for self-care, *Br J Gen Pract* 1994; **44**: 339-340) a line of text was omitted. The sentence running between pages 339 and 340 should have read: Forty eight per cent of the general practitioners, who in 1993 received a copy of the *OTC Directory*,² an illustrated catalogue of branded over the counter products, said they referred to it at least weekly, mainly to recommend an over the counter product or to identify what a patient was taking.¹