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Disulfiram Treatment of Alcoholism

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To assess the efficacy of supervised disulfiram as an adjunct to out-patient treatment of alcoholics, a randomised, partially blind, six-month follow-up study was conducted in which 126 patients received 200 mg disulfiram or 100 mg vitamin C under the supervision of a nominated informant. In the opinion of the (blinded) independent assessor, patients on disulfiram increased average total abstinent days by 100 and patients on vitamin C by 69, thus enhancing by one-third this measure of treatment outcome. Mean weekly alcohol consumption was reduced by 162 units with disulfiram, compared with 105 units with vitamin C, and the disulfiram patients reduced their total six-month alcohol consumption by 2572 units compared with an average reduction of 1448 units in the vitamin C group. Serum gamma-GT showed a mean fall of 21 IU/l in patients on disulfiram but rose by a mean of 13 IU/l with vitamin C. Unwanted effects in the disulfiram group led to a dose reduction in seven patients and to treatment withdrawal in four (and in one vitamin C patient). Two-thirds of the disulfiram group asked to continue the treatment at the end of the study. There were no medically serious adverse reactions.

Disulfiram (Antabuse) is an agent which inhibits metabolism of alcohol, resulting in the unpleasant symptoms (flushing, headache, nausea, dizziness, tachycardia) of the disulfiram–alcohol reaction. Although it has been available for many years as an adjunct to counselling in the treatment of chronic alcoholism, and despite a dearth of therapies for this condition (Vaillant, 1983), disulfiram is not commonly prescribed in the UK owing partly to concern that the agent may cause hepatic damage (Peachey & Naranjo, 1983; Peachey, 1988). In addition, the early literature provided poor evidence of the efficacy of disulfiram, but these studies often lacked adequate controls (Bourne *et al*, 1966; Edwards & Dill, 1974; Bigelow *et al*, 1976) or supervision of patient compliance (Fuller & Roth, 1979). Compliance with the disulfiram regime, found to be as low as 20% in a study in the USA (Fuller *et al*, 1986), can be improved with supervision by the spouse or clinic (Gerrein *et al*, 1972; Robichaud *et al*, 1979; Azrin *et al*, 1982; Sereny *et al*, 1986).

We report here the first UK controlled study of supervised disulfiram as an adjunct to out-patient treatment of alcoholics, in which safety and acceptability were assessed in addition to the effect of the treatment on alcohol consumption and related problems.

Method

One hundred and twenty-six subjects entered the trial from among patients of either sex, aged 18–67 years, attending seven alcoholism treatment centres. Only patients who had already relapsed after previous therapy or other support were invited to participate, since we felt the memory of previous failure would aid their compliance with the study treatment. Pregnant women were excluded, as were subjects with cardiac disease, psychosis, or habitual drug abuse, and those showing abnormally high levels of serum bilirubin, aspartate aminotransferase (AST) or alanine aminotransferase (ALT).

The protocol was approved by local hospital ethical review committees. All patients gave their written, informed consent to receive one tablet a day of disulfiram (200 mg, dispersed in water) or vitamin C (100 mg) for six months under supervision, and an informant was nominated, usually the spouse (occasionally another relative, colleague, or a member of the clinic staff, with whom they had contact at least once a week). Treatments were randomly placed against lists of numbers, supplied to the pharmacist at the various centres, who then allocated the numbers sequentially to patients entering the trial.

For ethical reasons the treatment codes were broken after allocation so that a thorough explanation of the use of disulfiram and the associated risks of drinking, to include written information and a pocket warning card, could be given to the patients and families concerned. If left blind, patients might have been tempted to test whether or not drinking could trigger a reaction.

The vitamin C group was included to control for the effects of receiving supervised medication and out-patient counselling, and patients were told this; if they asked further they were told that vitamin C was chosen for the control medication because alcoholics may have vitamin deficiencies, of which this is one.

Medication was usually supervised daily by the informant; where the informant was not the spouse the dose on a day when the informant and patient did not meet was either given the day before or given to take unsupervised at home. The informant was encouraged to telephone the clinic if

the patient refused the medication or lost touch, so that advice could be offered. No written contract, however, was involved, and no sanctions were invoked if the patient ceased taking the medication.

Patients were either already in, or were offered, a range of out-patient and community counselling and support, which varied between centres. A few patients were offered day-patient places. Marital therapy, relaxation therapy, attendance at Alcoholics Anonymous (AA), vitamin B supplements, and supportive group therapy were also used by some patients.

At intake, the clinican conducted a physical examination of the patient, which included blood tests, and took a medical and psychiatric history. During treatment the clinician monitored compliance (checking with the informant) and drug safety at each visit, recording any unusual symptoms reported by the patient, and reviewed patient progress at the end of the six-month trial. Blood tests (haematology and biochemistry, including liver function tests and blood alcohol, plus serum gamma-glutamyl transferase (GT) and mean red cell volume (MCV) as markers of regular alcohol consumption (Chick *et al*, 1981)) were repeated after one, three and six months of treatment.

Each centre appointed as an independent assessor to obtain follow-up data someone with previous experience with alcoholics: medical practitioners, nurses, or trained research interviewers. They were to stay blind to the medication received. Patients and informants were reminded at each contact not to give any information which could reveal the medication.

The assessor saw patient and informant at intake and again, separately, at weeks 2 and 4, and thereafter monthly until the final interview at six months. Interview questions concerned alcohol consumption, alcohol dependence (the Severity of Alcohol Dependence Questionnaire (SADQ) (Stockwell *et al*, 1983)) and 13 alcohol-related health and social problems (Chick *et al*, 1988), all with reference to the period since the last visit (or the previous six months for the first and final visits).

'Typical week's consumption' was according to a retrospective diary of a typical week during which the patient drank. In addition, at each interview the assessor obtained an estimate of total consumption in the previous four weeks. These were aggregated in the analysis to give 'total units consumed in past six months'. At intake the assessor had obtained an estimate of the prior six months' consumption, with anchor dates to aid memory. Informants' information was included, and was evaluated by the assessor in making a judgement, because patients are known to report less consumption than informants (Fuller *et al*, 1988).

Statistical analysis

All data were used, on an 'intention-to-treat' basis, irrespective of patient compliance, attempts having been made to follow up all patients. Categorical data were analysed using Fisher's exact test for 2×2 tables and Pearson's χ^2 test for larger tables. Otherwise, the Mack-Skilling's test (Mack & Skillings, 1980), taking account of the weighting at different centres, was used to test for significant treatment differences. Laboratory blood data were analysed by fitting an additive linear model of centre and treatment effects and using a *t*-test to compare treatments (Searle, 1971).

Where possible, differences from pre-treatment were analysed. All tests were two-tailed with a significance level of 5%.

Results

The two groups of patients commencing treatment (64 on disulfiram, 62 on vitamin C) had similar demographic and social backgrounds. The overall mean age was 43 years (range 18–67); 84% were male, 65% were unemployed, and 46% lived with a spouse or other cohabitee. The commonest illness suffered was gastrointestinal disease (21% of patients), of which 85% was alcohol-related. Two-thirds of the disulfiram group and half the vitamin C group had had in-patient treatment for alcoholism. Informants were mainly spouses (41%) or members of the clinic staff (33%).

Fifty-seven patients (28 on disulfiram, 29 on vitamin C) did not adhere to their allocated treatment, 45 through failure to keep appointments or by withdrawing consent. Follow-up interviews were not obtained in 20% (15 disulfiram patients, 14 vitamin C patients). Both initial and final blood samples were available in only 57%, because at follow-up some patients were interviewed by telephone, and at intake and follow-up some samples were not analysable because of delay or damage.

Four patients on disulfiram and one on vitamin C were withdrawn with adverse reactions: two of the former owing to allergic skin rash, one with suspected neuropathy, and one with dizziness and nausea, while the patient on vitamin C was admitted suffering left hemiparesis. A further two withdrawals from the vitamin C group were due to increasing problems with drinking. (Four of the patients on vitamin C who withdrew their consent did so because they wanted to take disulfiram; in addition, three initial recruits had withdrawn as soon as they heard they had been assigned to vitamin C and were thus excluded from the trial population.)

Unusual symptoms were reported equally in the two groups (e.g. depression: 4 disulfiram, 5 vitamin C patients; nausea: 2 disulfiram, 2 vitamin C patients) except for headache (11 disulfiram, 5 vitamin C patients), fatigue (12 disulfiram, 6 vitamin C patients), and skin rash (4 disulfiram patients only). Seven patients on disulfiram had their dose reduced because of side-effects. Disulfiram–alcohol reactions were reported on 29 occasions, but none led to a reduction of dose. Five patients had their disulfiram dose increased because the alcohol reaction was mild or absent, and one such patient refused to have the dose increased. There were no abnormalities of liver function during treatment.

Treatment effects are summarised in Tables 1–4. Both treatment groups achieved a reduction in alcohol consumption which by most estimates was greater with disulfiram, the treatment difference reaching statistical significance for values at 6 months (Table 1). However, at the final assessment the number of days since the last drink and alcohol consumption in the last month of the study revealed no significant treatment difference (Table 3).

The mean (s.d.) SADQ score at intake was similar in the two groups, and fell equally (disulfiram: intake 31.6 (13.8)

Table 1
Effects of trial treatment on estimated alcohol consumption: comparison of changes from intake values (means (s.d.))

Estimated consumption (change from intake)	Patient		Informant		Assessor	
	Disulfiram (n)	Vitamin C (n)	Disulfiram (n)	Vitamin C (n)	Disulfiram (n)	Vitamin C (n)
No. of abstinent days in last six months						
intake	58 (59) (63)	77 (53) (59)	54 (55) (57)	68 (51) (54)	55 (58) (63)	66 (50) (58)
change after treatment	+98 (68) (43)	+54 (79) (47)	+97 (68) (39)	+71 (70) (36)	+100 (70) (47)	+69 (67) (46)
Treatment difference:						
mean (95% confidence interval)	44 (14 to 79)		26 (−4 to 63)		31 (6 to 63)	
P value	0.004**		0.06		0.02*	
Typical consumption: units per week						
intake	207 (137) (63)	190 (153) (58)	214 (154) (52)	172 (160) (49)	224 (141) (63)	208 (166) (59)
change after treatment	−165 (173) (46)	−97 (148) (46)	−186 (158) (42)	−105 (136) (35)	−162 (172) (49)	−105 (147) (48)
Treatment difference:						
mean (95% confidence interval)	−68 (−132 to −5)		−81 (−144 to −10)		− 57 (−108 to 12)	
P value	0.05*		0.04*		0.14	
No. of units consumed in last 6 months						
intake	2573 (2549) (62)	2247 (2514) (57)	2911 (2767) (50)	2198 (2750) (47)	3001 (2735) (62)	2916 (3053) (58)
change after treatment	−2558 (2777) (43)	−856 (2442) (42)	−2807 (2677) (39)	−1171 (1562) (33)	−2572 (2708) (46)	−1448 (1753) (44)
Treatment difference:						
mean (95% confidence interval)	−1702 (−2016 to −290)		−1636 (−2052 to −238)		−1124 (−1620 to −84)	
P value	0.007**		0.011*		0.04*	
No. of units consumed in last 4 weeks						
intake	319 (468) (60)	244 (376) (58)	358 (525) (48)	241 (340) (47)	395 (534) (60)	325 (428) (58)
change after treatment	−246 (455) (40)	−152 (496) (45)	−231 (482) (35)	−158 (306) (33)	−281 (537) (44)	−199 (468) (46)
Treatment difference:						
mean (95% confidence interval)	−94 (−208 to 12)		−73 (−154 to 80)		−82 (−185 to 80)	
P value	0.42		0.74		0.92	
No. of days since last drink						
intake	35 (47) (64)	32 (41) (59)	31 (35) (59)	26 (36) (54)	32 (35) (64)	27 (35) (58)
change after treatment	+75 (92) (48)	+65 (98) (47)	+74 (92) (43)	+67 (91) (38)	+72 (92) (49)	+70 (89) (48)
Treatment difference:						
mean (95% confidence interval)	10 (−23 to 41)		7 (−30 to 45)		2 (−29 to 26)	
P value	0.55		0.72		0.91	

1 unit of alcohol = 8–9 g ethanol.
*$P \leq 0.05$, **$P < 0.01$.

Table 2
Blood test markers: comparison of changes from intake after treatment (means (s.d.))

Marker	Disulfiram (n)	Vitamin C (n)
MCV: (fl)		
intake	96.6 (5.8) (57)	97.8 (5.8) (52)
change after treatment	−3.0 (5.1) (31)	−2.6 (4.5) (33)
Treatment difference: mean (95% confidence interval)	−0.4 (−2.8 to 2.1)	
P value	0.78	
Serum GT: IU/l		
intake	49 (63) (55)	51 (72) (57)
change after treatment	−21 (65) (32)	+13 (83) (38)
Treatment difference: mean (95% confidence interval)	−34 (−74 to −7)	
P value	0.02	

($n=63$), mean change with treatment −8.3 (15.8) ($n=35$); vitamin C: 33.1 (13.3) ($n=59$), mean change with treatment −10.8 (16.9) ($n=39$)). Mean (s.d.) problem score reduced more in the disulfiram group (intake: 6.30 (2.59) ($n=56$), mean change with treatment −4.00 (3.21) ($n=43$) than in the vitamin C group (intake: 5.96 (2.25) ($n=54$), mean change with treatment −2.91 (3.02) ($n=45$)), but this difference was not significant ($P=0.06$).

Table 4 shows the opinions of the various participants at the end of the trial regarding the ability of the patients to control their drinking, by which was meant reduction or cessation of their excessive drinking and its problems. Patients, informants and clinicians all thought the disulfiram group to have significantly better control (mostly moderate/full) than the patients on vitamin C, half of whom showed no change. In the opinion of the assessors, however, the patients on vitamin C attained a similar improvement in their control of drinking to those treated with disulfiram.

At the end of the trial two-thirds of the patients on disulfiram wanted to continue treatment, compared with only one-quarter of those on vitamin C ($P<0.001$).

At the end of the study the identity of the test treatment was guessed correctly by the independent assessor for 65% of those followed up. This was not measured at any of the earlier assessments.

Table 3
Number of days since last visit on which alcohol was consumed (assessor's opinion) (means (s.d.))

Week	Disulfiram (n)	Vitamin C (n)
2	0.76 (2.49) (58)	1.64 (3.34) (53)
4	0.76 (3.07) (55)	2.09 (3.78) (47)*
8	1.63 (4.76) (49)	4.36 (8.44) (45)
12	2.47 (5.71) (45)	2.67 (5.14) (43)
16	3.12 (6.76) (40)	2.82 (6.79) (38)
20	1.76 (5.68) (37)	3.65 (7.27) (34)
Total	7.77 (11.40) (35)	17.91 (31.52) (34)

*$P<0.05$.

Table 4
Final opinions of ability to control drinking

Opinion	Degree of control	Frequency		P value
		Disulfiram	Vitamin C	
Patient				
	worse	0	3	
	no change	3	20	
	moderate	15	8	<0.001
	full	25	13	
Informant				
	worse	0	2	
	no change	3	18	
	moderate	16	6	<0.001
	full	21	10	
Clinician				
	worse	0	2	
	no change	4	22	
	moderate	18	9	<0.001
	full	21	11	
Assessor				
	worse	2	4	
	no change	5	5	
	moderate	20	22	0.30
	full	25	19	

Discussion

For the ethical reasons already stated each patient's allocated treatment was known to all but the independent assessor. However, a double-blind design might not necessarily reduce the problems of interpretation, because of the tendency shown in a recent double-blind cross-over study of calcium carbimide (Peachey *et al*, 1989) in which 78% of patients thought they were taking active drug at all times. This compromises the chance of showing the deterrent effect of the drug, depending as it does partly on instruction and belief that an alcohol-reaction could occur. The correct test of the drug is a test of the 'package', which includes emphasising the alcohol-reaction to the active group.

Although by the end of the study assessors were guessing the correct medication better than chance, the two measures for which their ratings significantly differed between the groups were scores summated (by computer) of ratings made over the six months, that is, abstinent days and units consumed. In general there was little discrepancy in the six-month summated scores between the results as perceived by patient, informant and assessor, but despite having guessed accurately in some cases the assessors considered those on vitamin C to have achieved the same control of drinking as the disulfiram group. The explanation for this is not clear, but perhaps it slightly reduces the concern that bias influenced the assessors' ratings.

Estimates of alcohol consumption over the six-month trial generally showed significant differences in favour of disulfiram. There was little difference in the final rating of 'number of days since last drink', however, suggesting that some patients were perhaps using disulfiram to practise occasional limited drinking. By the end of the study there was no statistical difference in the last month's consumption, and this, together with the narrowing of the estimate of days since last drink (Table 3), could indicate a waning of the treatment effect.

Rating of alcohol-related problems (violent episodes, time off work, police involvement, etc.) is less open to bias but it takes longer for changes in the frequency of these relatively rare events to become apparent. The patients on disulfiram none the less showed a strong trend towards a greater reduction in total problem score than the vitamin C group, falling just short of statistical significance. SADQ scores in both groups improved somewhat. The SADQ allocates a score for maximum sessional consumption and some patients on disulfiram did have relapses though perhaps less frequently than those on vitamin C. It also allocates points for 'imagining your symptoms if you had a heavy drinking session', and patients in our study, even though abstinent, would score on these items since they still regarded themselves as 'dependent'. The SADQ is perhaps not a good measure of outcome over six months.

Blood test markers of alcohol consumption, particularly the more rapidly affected serum gamma-GT, are not open to bias and it is important that the disulfiram group showed a significantly greater improvement here. Blood tests for both intake and follow-up were available in only 57% of cases but the patient drop-out rate was similar for both treatment groups.

No previous study has used blood tests as markers of outcome, although supervised disulfiram has been studied, with promising results (Heather, 1989). Our own methods of supervision did not use such a strict 'contract' as some of the successful reports in the American literature (Azrin *et al*, 1982; Keane *et al*, 1984; O'Farrell & Bayog, 1986). We also used a lower dose than in some of the American studies. In the study by Fuller *et al* (1986), unsupervised disulfiram (250 mg daily) plus counselling was associated with a reduction in the number of days on which alcohol was consumed, corroborated by relatives or friends. However, this was demonstrated only in the one-third of patients who provided all seven assessment interviews, and could not be seen in the remainder. It may be that supervision is necessary to the success of disulfiram treatment.

Treatment practices varied in the different centres involved, and some centres appeared to have slightly better results than others. Even so, we suspect that our method was something some general practitioners could profitably arrange, with the spouse or practice nurse supervising treatment.

There were no medically serious disulfiram-alcohol reactions, and at the dose used in the study some patients did not experience a reaction after drinking. Concerns about hepatic toxicity were not borne out. Disulfiram can, though, cause allergic skin reactions and it is still to be recommended that patients taking the drug have medical follow-up.

In conclusion, we found that supervised disulfiram plus counselling enhanced treatment outcome in alcoholics. A few patients developed skin rash, headache or tiredness but there was no disturbance of liver function. Disulfiram is a popular form of treatment among some alcoholic patients and their relatives.

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