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Psychological Factors and Health-Related Behaviour Change: Preliminary Findings From a Controlled Clinical Trial

SUMMARY

A good deal of controversy surrounds the issue of optimal treatment approaches for persons with an addictive disorder. The field is rampant with questions pertaining to goals of abstinence as distinct from moderation, in-patient rather than out-patient care, and short-term rather than long-term treatment. In recent years it has become increasingly evident to clinicians and researchers that there simply is no single, best, treatment approach for all patients suffering the effects of substance abuse. These effects constitute a multi-faceted disorder that involves biological and medical aspects, social and psychological dimensions, psychiatric and policy perspectives. A "systems" approach to the treatment of alcoholism is emerging with the identification of various alcoholic syndromes, each demanding a different management strategy. Such an approach requires new methods of patient assessment, and this paper identifies psychological factors that may influence not only the diagnosis and treatment of alcoholic syndromes, but also other health-related behaviour disorders. (The opinions expressed in this article are those of the authors and do not necessarily reflect the views or policies of the Addiction Research Foundation.) (*Can Fam Physician* 1988; 34:1045-1050.)

Key words: alcohol, stress, coping, treatment planning, lifestyle

RÉSUMÉ

L'optimisation des approches thérapeutiques pour les patients présentant des désordres de narcomanie est très controversée. Ce domaine est parsemé de questions touchant la distinction entre les buts de l'abstinence et ceux de la modération, du traitement en institution plutôt qu'ambulatoire et du traitement à court terme plutôt qu'à long terme. Les dernières années ont permis aux cliniciens et aux chercheurs de constater qu'il n'existe pas d'approche thérapeutique unique et idéale qui soit satisfaisante pour traiter tous les patients souffrant des effets engendrés par l'abus de substances toxiques. Ces effets constituent un désordre comportant de multiples facettes qui impliquent des aspects biologiques et médicaux, des dimensions sociales et psychosociales et des perspectives psychiatriques et politiques. On assiste à l'émergence d'une approche par «système» concernant le traitement de l'alcoolisme, avec l'identification de divers syndromes alcooliques, chacun nécessitant une stratégie thérapeutique différente. Une telle approche exige donc de nouvelles méthodes d'évaluation du patient. Le présent article identifie certains facteurs psychologiques capables d'influencer non seulement le diagnostic et le traitement des syndromes alcooliques mais aussi certains autres désordres comportementaux affectant l'état de santé. (Les opinions exprimées dans cet article sont celles des auteurs et elles ne reflètent pas nécessairement les opinions et les politiques de la Fondation pour la recherche sur les toxicomanies).

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member of the Staff of the Foundation, was Project Co-ordinator of the study described. Requests for reprints to: Ms. Marta Krywonis, Addiction Research Foundation, 33 Russell Street, Toronto, Ont. M5S 2S1

DIFFERENTIAL TREATMENT planning for drug dependence is based on the hypothesis that individuals with varying needs and characteristics will respond differently to different kinds of intervention, and therefore clients should be matched individually with optimal approaches rather than all being treated in the same way.

Despite evidence in support of a multivariate-syndrome model of drug dependence,¹ there are only a few controlled studies on the utility of differential treatment selection. Moreover these findings do not always demonstrate superior results for intensive specialized treatments. In fact, some authorities suggest that the cheapest and simplest intervention be offered indiscriminately to all substance abusers, since most approaches produce similar degrees of improvement.²⁻⁴

Some of the research, however, does suggest a superior outcome for matching sub-groups of patients to different treatment regimens.⁵⁻⁸ In particular, more intensive treatments are found to be superior to brief minimal interventions when change is evaluated across several dimensions such as drinking behaviour, psychosocial function, and vocational competence.

Attempts have been made to identify patient characteristics that might predict treatment outcome. Unfortunately, these attempts, which have looked at demographic characteristics such as gender, age, and socio-economic status as variables by which to classify patients, have not been successful.⁹ When more theoretically relevant variables are used, however, the results tend to be more promising. Thus, for

example, McLachlan¹⁰ used a measure of personality style to differentiate among patients and was successful in detecting optimal gains when therapy takes account of the patient's frame of reference or need for structure.

Some studies have suggested that patients with an internal locus of control,¹¹ who view themselves as responsible for determining what happens to them, might do better with non-directive interventions.¹² Such patients are less likely to accept disulfiram¹³ or to participate in after care¹⁴ than are patients with an external locus of control, who perceive their lives as being largely controlled by forces beyond their own influence. However, other work¹⁵ has failed to find an interaction between locus of control and the degree of directiveness of treatment.

The clinical research described in this paper is based on the assumption that individuals who may be similar in that their alcohol abuse is a primary concern are likely to differ in almost every other important respect, from height and weight to developmental history, personality, and lifestyle. In addition, the reasons for drinking and the place of alcohol in the person's life are unlikely to be uniform across patient groups.

The clinical management issues that need to be addressed are as follows:

- Is the additional resource requirement (cost) of more intensive treatment justified by significantly better clinical outcomes?
- Can deployment of treatment resources be made more cost efficient

by identifying those patients most likely to benefit from the additional investment of intensive treatment as distinct from those patients who will respond equally well to any treatment, including the least "expensive" in terms of time and effort?

My colleagues and I designed a controlled clinical trial in which patient groups were exposed to a variety of treatment interventions that included training in coping skills and methods of relaxation. In addition, we examined the extent to which pre-existing patient variables of locus of control and levels of alcohol dependence might interact with and influence the effectiveness of specific interventions.

Study Method

Experimental design

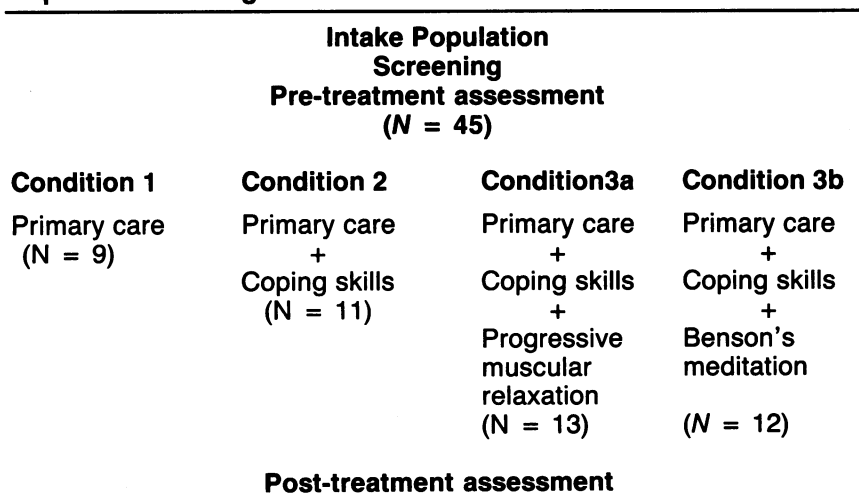
An "additive components" design was employed to allow the researcher to evaluate the effect of coping skills and relaxation training on treatment outcome (Figure 1). The treatment conditions are described briefly below. (Detailed intervention manuals are available on request.)

Condition 1. Clients receive a minimal treatment format called "Primary Care" (PC) that consists of three sessions of individual counselling, with an interval of one month between each session. Specific features of the therapy include:

- engaging the client in a realistic appraisal of his or her situation;
- identifying appropriate treatment goals, where drinking behaviour is the major focus; and
- pragmatic, directive advice on how to achieve goals. No systematic assistance in stress management, relaxation, or coping skills is provided, although the client may receive some advice, given in an *ad hoc* manner, on how to deal with stressful situations.

Condition 2. Condition 2 consists of PC as described above, plus a cognitive-behavioural intervention called "Coping Skills" (CS) training, which consists of eight group sessions over four weeks, followed by three review and planning sessions; there is an interval of two weeks and three weeks between the follow-up sessions. CS involves training in a generic set of cognitive strategies aimed at identifying spe-

Figure 1
Experimental Design



cific, "stress" problems and their consequences, and generating effective coping strategies.

Condition 3. Clients receive PC and CS as in Condition 2, above, plus specific training in a relaxation procedure for approximately 20 minutes at the completion of each group CS-treatment session.

Condition 3a. Clients are taught a body-oriented relaxation technique called "progressive muscular relaxation" (PMR). This procedure emphasizes muscle-tension release and learning to identify and attend to the resulting physiological sensations.¹⁶

Condition 3b. Clients are taught Benson's Meditation (BM), a cognitively oriented relaxation technique claimed by Benson¹⁷ to be a reliable means of eliciting the "Relaxation Response". This standardized, non-cultic form of meditation incorporates four basic components:

- a quiet environment;
- a mental device (phrase);
- a passive attitude; and
- a comfortable sitting position.

The sample

The subject population consists of individuals with a primary alcohol problem who present for treatment at the Clinical Institute of the Addiction Research Foundation. The study covered 45 subjects aged 19–60 years. Thirty-three of the subjects were male, and 12 were female. These males and females were distributed equally across the four treatment conditions. Subjects were obtained by means of direct referral to intervention research by the Assessment Unit and from responders to advertisements placed in local media. Intake-referral and ad-recruited subjects are distributed equally across the four experimental conditions. Patients who met a number of additional selection criteria (e.g., absence of organic brain damage, no current psychosis or acute depression, stable accommodation) underwent a pre-treatment assessment, as outlined below, and were then randomly assigned, in blocks of six clients, to one of the four conditions.

Measures

While a large test battery was employed, only the instruments relevant to the present analyses will be described. The pre-intervention assessment was conducted 30 days prior to initiation of

treatment, while post-intervention measures were collected 30 days following the last treatment session in each condition.

Client-predictor variables. Two measures are employed to assess patient characteristics that might be linked to treatment outcomes. These are the Alcohol Dependence Scale and the Locus of Control Scale.

The Alcohol Dependence Scale (ADS) is a 25-item self-report instrument that measures severity of alcohol dependence.¹ Alcohol dependence is viewed as a syndrome existing along a continuum of severity. The cardinal symptom of this syndrome is impaired control over alcohol intake. Other aspects include increased tolerance to alcohol; withdrawal symptoms following cessation of drinking; awareness of compulsion to drink excessively; reinstatement of the syndrome after abstinence; and extent of drink-seeking behaviour.

The Locus of Control Scale (I-E)¹¹ is a 23-item forced-choice test that measures subjects' beliefs about how reinforcement is controlled: that is, the way in which our actions produce consequences as distinct from the workings of fate, circumstance, and so forth. Because items deal with subjects' beliefs about the nature of the world, the test is considered to be a measure of generalized expectancy or perceived control. A belief in "external control" refers to the individual's interpretation of an event in which reinforcement is perceived by the subject as following some action of his or her own, but not being entirely contingent on that action. If a person perceives that an event is contingent on his or her own behaviour or relatively permanent characteristics, he or she is viewed as holding a belief in "internal control".

Outcome variables. Three indices are employed as measures of treatment effectiveness. One instrument is a measure of psychological functioning and two assess drinking behaviour.

The Self-Evaluation Questionnaire¹⁸ provides a measure of Trait Anxiety (TA). TA refers to relatively stable individual differences in anxiety-proneness: that is, to differences among people in the tendency to perceive stressful situations as dangerous or threatening and to respond to such situations with elevations in the intensity of their anxiety reactions. Thus, TA implies dif-

ferences among people in the disposition to respond to stressful situations with varying amounts of anxiety.

Measures of alcohol consumption are collected by means of a time-line technique that has good reliability and validity.¹⁹ Drinking-behaviour data include "Number of Days Abstinent" in the 30-day period prior to assessment (DA) and "Average Number of Drinks per Drinking Occasion" (D/DO). These two indices are used as outcome measures that reflect change in drinking behaviour as a result of participation in the treatment conditions..

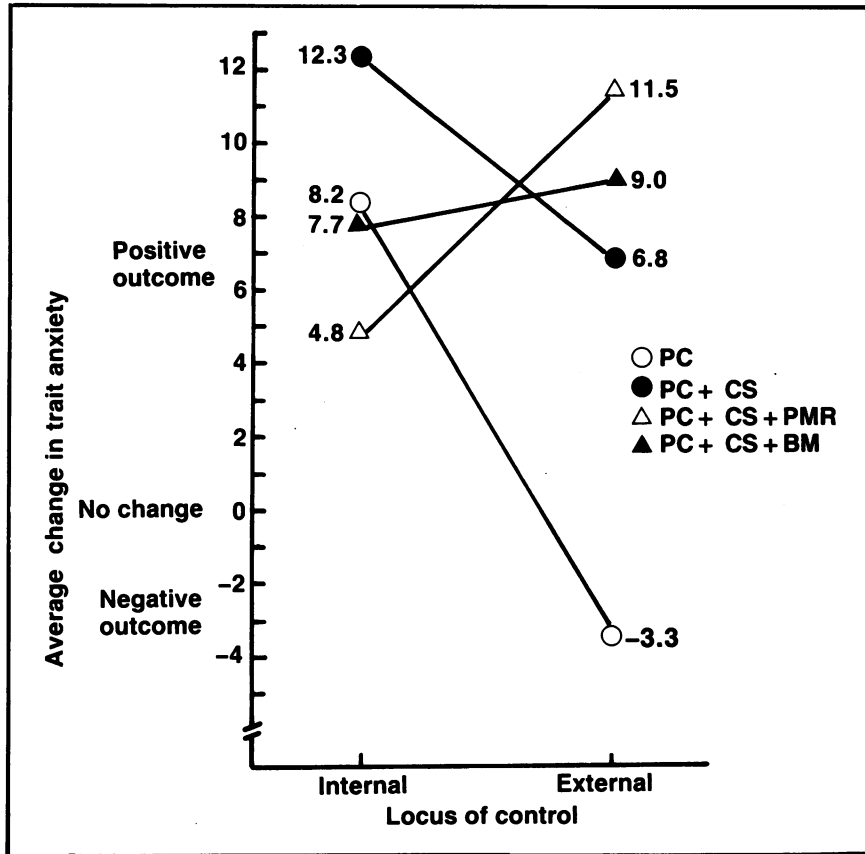
Results and Discussion

Differences in outcome measures among the four treatment conditions did not emerge. Overall, on each dependent variable, all treatments resulted in improved clinical outcomes. The brief, unstructured, PC condition was as effective as the more intensive, structured, group treatment (CS), with or without the addition of training in a relaxation technique.

In accordance with the differential treatment hypothesis, subjects were classified in one of four groups, on the basis of standardized cut-off scores on the ADS that reflect progressive quartiles of alcohol dependence. Two-way analyses of variance (ADS X Treatment Condition) were conducted in order to determine whether individual differences in degree of problem severity influenced the amount of change fostered by treatment in general, as well as whether specific treatments were more or less effective with certain clients, depending on their level of problem severity. The latter relationship would suggest a result consistent with the matching hypothesis (wherein treatment effects vary, depending on degree of problem severity) and would be apparent in the form of an interaction between ADS and Treatment Condition. On each measure of change, however, pre-treatment differences in alcohol dependence failed to show significant main effects or interaction effects.

Pre-treatment scores on the I-E scale were also used to classify clients for the purpose of differentiating treatment outcomes. The results here are more promising. With respect to psychological outcome (TA-change scores), the interaction between Treatment Condition and I-E classification approached significance ($F = 2.4$; $df = 3, 34$; $p < .08$) In addition, change in number of days

Figure 2
Average Change in Trait Anxiety (Pre-Treatment to Follow-Up)



abstinent showed a main effect for perceived control as measured by the I-E scale ($F = 4.1$; $df = 1, 34$; $p < .05$). Thus clients who are low in perceived control (Externals) differ from clients who are high in perceived control (Internals) with respect to whether or not treatment—any treatment—will affect change in a behavioural measure of drinking frequency. Each of the four treatment conditions evaluated in the present study reduces the drinking behaviour of Internals less than that of Externals

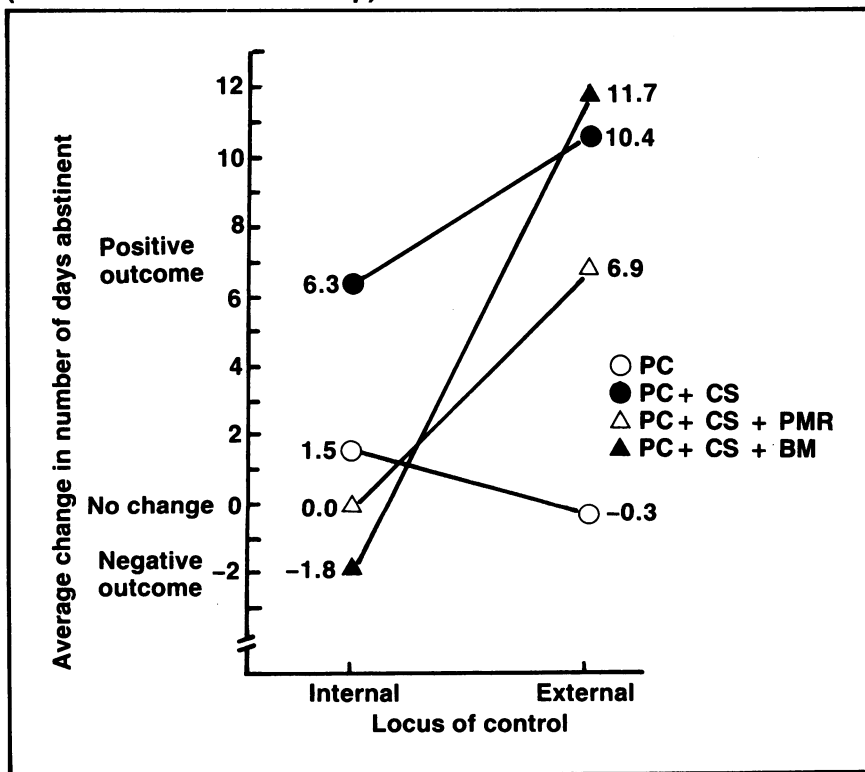
In regard to psychological change, intervention format does make a significant difference for Externals but not for Internals. For Internals, who are high in perceived control, change in self-perceived adjustment (TA) does not vary as a function of type of treatment. Externals, on the other hand, fare much better with the more structured, intensive treatments and actually respond negatively to the unstructured, minimal intervention (PC) approach.

In view of these encouraging results, we decided to conduct selected comparisons in order to identify more specific trends in the treatment-outcome data. On each dependent measure, mean change is plotted for individual treatments, and clients are classified as either Internal or External in perceived control (Figures 2–4).

Figure 2 shows that the outcome for Externals is inferior with reference to self-perceived adjustment (TA) following brief, unstructured counselling (PC). Similarly, on measures of drinking (Figures 3, 4), clients low in perceived control (Externals) achieve better outcomes after the more intensive structured interventions than after brief unstructured counselling.

Finally, the addition of supplemental training in a relaxation procedure enhances the effectiveness of treatment on all measures for Externals, but not Internals. This additive effect is significant with respect to Days Abstinent for Benson's Meditation ($t = 2.24$, $df = 9$, $p < .05$) and with respect to Drinks per Drinking Occasion for PMR ($t = 2.97$, $df = 8$, $p < .02$). Across measures, the addition of coping-skills training and relaxation instructions to primary care contributes appreciably to treatment outcome for Externals but not for Internals. Externals do significantly better with more intensive treatments in terms of Days Abstinent ($t^* = 4.19$, $df = 16.44$, $p < .001$) and Trait Anxiety

Figure 3
Average Change in Number of Days Abstinent (Pre-Treatment to Follow-Up)



($t^* = 4.92$, $df = 20.96$, $p < .0001$)

*Note: Based on separate variance estimates.²⁰

Conclusions

Although one treatment approach may not be demonstrably superior to another for all persons exhibiting health-related behaviour problems, examining individual differences of a psychological nature relevant to behaviour-change processes may allow clinicians to identify individual patients with a better prognosis for certain treatment approaches.

In the present study, patients high in perceived control (Internals) responded as well to brief non-directive counselling as they did to more intensive structured interventions. People who believe that they exert independent control over their lives and their health can begin to make significant changes in areas of functioning related to health status with only a minimum of encouragement, guidance, and support. On the other hand, persons low in perceived control (Externals) require more structure, direction, and support in order to initiate and maintain health-related changes in behaviour. An inexpensive and quickly administered self-report measure, like the one presented in the Appendix, may be used to assist in making reliable management decisions.

Physicians are increasingly being called on to address psychological and "lifestyle" factors that are implicated in the etiology and treatment of medical disorders. The abuse of alcohol, in particular, is a significant health concern. This article introduces a matching model for health-related behaviour change. Interventions that target changes in behaviour (especially behaviours that have health-related consequences) do not produce uniform consistent effects in all patients. Psychological factors influence treatment outcomes.

The clinical management of patients with chemical dependencies, alcoholism in particular, may require a two-level approach. For people who view themselves as self-directed, in control, and independent, all that may be required to get them started on the road to recovery is a little advice, encouragement, and support. By contrast, patients who view themselves as somewhat helpless and victims of their environment require more structure, more encouragement, and more training in order to initiate and maintain behavioural changes that affect health and disease. ■

Appendix: A Self-Repeat Measure

Each item consists of a pair of alternatives, "a" or "b". Please circle the

appropriate "a" or "b" of each pair, whichever you more strongly believe to be the case.

1. a. Many of the unhappy things in people's lives are partly due to bad luck.

b. People's misfortunes result from the mistakes they make.

2. a. I have often found that what is going to happen will happen.

b. Trusting to fate has never turned out as well for me as making a decision to take a definite course of action.

3. a. In my case, getting what I want has little or nothing to do with luck.

b. Many times we might just as well decide what to do by flipping a coin.

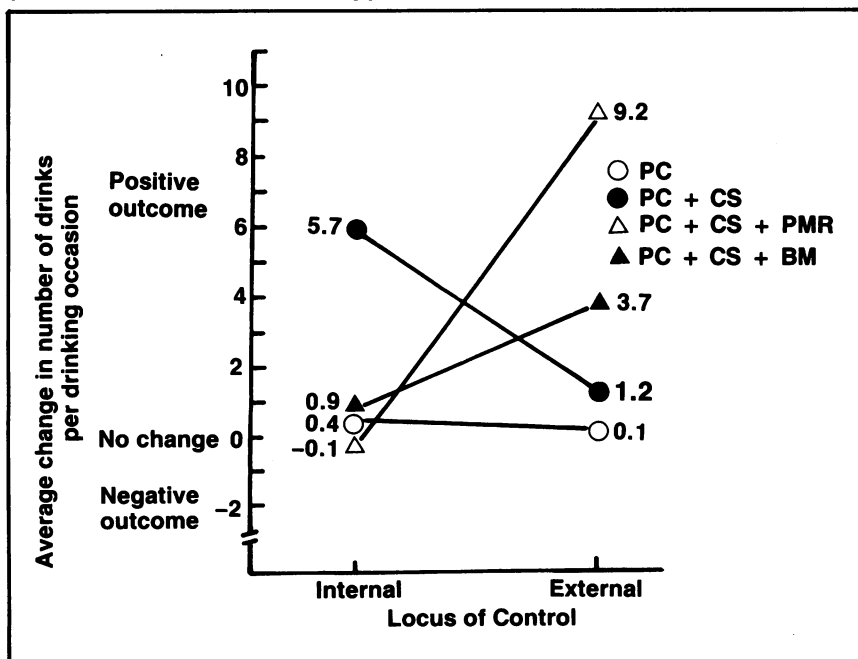
4. a. What happens to me is my own doing.

b. Sometimes I feel that I don't have enough control over the direction my life is taking.

Note: Score is number of underlined items. Score of 3 or 4 is External; less than 3, Internal.

Source: See Reference 11.

Figure 4
Average Change in Number of Drinks per Drinking Occasion
(Pre-Treatment to Follow-Up)



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BRIEF PRESCRIBING INFORMATION

Lopid 300 mg
(gemfibrozil) Capsules

Antihyperlipidemic Agent

ACTIONS

LOPID lowers elevated serum lipids primarily by decreasing serum triglycerides with a variable reduction in total serum cholesterol. These decreases occur in the very low density lipoprotein (VLDL) fraction and in the low density lipoprotein (LDL) fraction. In addition, LOPID may increase the high density lipoprotein (HDL) cholesterol fraction. The mechanism of action has not been definitely established. In man, LOPID has been shown to inhibit peripheral lipolysis and to decrease the hepatic extraction of free fatty acids, thus reducing hepatic triglyceride production. LOPID also inhibits synthesis of VLDL carrier apoprotein, leading to a decrease in VLDL.

INDICATIONS

LOPID is indicated as an adjunct to diet and other therapeutic measures in management of patients with TYPE IV hyperlipidemia who are at high risk of sequelae and complications from their hyperlipidemia.

Initial therapy for hyperlipidemia should include a specific diet, weight reduction, and an exercise program and for patients with diabetes mellitus, a good diabetic control.

CONTRAINDICATIONS

1. Hepatic or renal dysfunction, including primary biliary cirrhosis.
2. Pre-existing gallbladder disease. (See Precautions)
3. Hypersensitivity to gemfibrozil.
4. The drug should not be used in pregnant and in lactating patients.

WARNINGS

1. Concomitant Anticoagulants — Caution should be exercised when anticoagulants are given in conjunction with LOPID. The dosage of the anticoagulant should be reduced to maintain the prothrombin time at the desired level to prevent bleeding complications.
2. Long-term studies with gemfibrozil have been conducted in rats and mice at one and ten times the human dose. The incidence of benign liver nodules and liver carcinomas was significantly increased in high dose male rats. The incidence of liver carcinomas was increased also in low dose males, but the increase was not statistically significant ($P > 0.05$). There were no statistically significant differences from controls in the incidence of liver tumors in female rats and in male and female mice. Liver and testicular cell tumors were increased in male rats.
3. Cholelithiasis — LOPID may increase cholesterol excretion into the bile leading to cholelithiasis. If cholelithiasis is suspected, gallbladder studies are indicated. LOPID therapy should be discontinued if gallstones are found.
4. Since a reduction of mortality from coronary artery disease has not been demonstrated, LOPID should be administered only in those patients described in the Indications section. If a significant serum lipid response is not obtained in 3 months, LOPID should be discontinued.
5. Safety and efficacy in children have not been established.
6. Strict birth control procedures must be exercised by women of childbearing potential. If pregnancy occurs despite birth control procedures, LOPID should be discontinued.
7. Women who are planning pregnancy should discontinue LOPID several months prior to conception.

PRECAUTIONS

1. **Initial Therapy** — Before instituting LOPID therapy, attempts should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of diabetes mellitus.
2. **Long-term Therapy** — Because long-term administration of LOPID is recommended, pretreatment chemistry studies should be performed to ensure that the patient has elevated serum lipid or low HDL cholesterol levels. Periodic determinations of serum lipids should be obtained during LOPID administration.
3. **Impairment of Fertility** — Administration of approximately three and ten times the human dose to male rats for 10 weeks resulted in a dose-related decrease of fertility. Subsequent studies demonstrated that this effect was reversed after a drug-free period of about 8 weeks, and it was not transmitted to their offspring.
4. **Hemoglobin Changes** — A mild hemoglobin or hematocrit decrease has been observed in occasional patients following initiation of LOPID therapy. The levels then stabilize during long-term administration. Therefore a blood count is recommended every two months during the first 12 months of LOPID administration.
5. **Liver Function** — Abnormal liver function tests have been observed occasionally during LOPID administration, including elevations of SGOT, SGPT, LDH, and alkaline phosphatase. These are usually reversible when LOPID is discontinued. Therefore periodic liver function studies are recommended and LOPID therapy should be terminated if abnormalities persist.
6. **In patients with past history of jaundice or hepatic disorder, LOPID should be used with caution.**
7. **Cardiac arrhythmias** — Although no clinically significant abnormalities occurred that could be attributed to LOPID, the possibility exists that such abnormalities may occur.

ADVERSE REACTIONS

Gemfibrozil has been carefully evaluated in over 3,000 patients having received the drug in monitored clinical studies. Symptoms reported during the controlled phase in studies of 805 subjects were considered for safety. The symptoms listed below are those which occurred in at least 5 patients and all skin reactions whatever their incidence. The principal symptoms for which incidence was greater with gemfibrozil than with placebo involved the gastrointestinal system. Nausea and vomiting, abdominal and epigastric pain occurred more often in the gemfibrozil group than in the placebo group. However, the incidence was low: nausea, 4.3% with gemfibrozil versus 3.8% with placebo; vomiting, 2.3% versus 0.8%; abdominal pain, 6.4% versus 4.2%; and, epigastric pain, 3.4% versus 1.7%.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

While there has been no reported case of overdosage, symptomatic supportive measures should be taken should it occur.

DOSAGE AND ADMINISTRATION

The recommended dose for adults is 1200 mg administered in two divided doses 30 minutes before the morning and evening meal. The maximum recommended daily dose is 1500 mg.

AVAILABILITY

The colour of LOPID capsules is maroon and white. Each capsule contains 300 mg gemfibrozil and is available in bottles of 100.

Product Monograph available on request.

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