BRIEF REPORT

SELECTIVE ATTRITION CAUSES OVERESTIMATES OF TREATMENT EFFECTS IN STUDIES OF WEIGHT LOSS

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Abstract — Selective attrition causes serious threats to the validity of experimental trials. Experimental studies in behavior therapy typically include only data from those who complete an experiment. In this paper, we examine the probability of dropping out of a study contingent upon failure to achieve desired benefits. The data are derived from an experimental trial evaluating the effects of weight loss for patients with Diabetes Mellitus. Seventy-six percent of the original participants completed the intervention and the follow-up assessments. However, the probability of failing to appear for follow-ups over an 18 month period was examined. The chances of dropping out of the study were significantly higher for those who did not achieve a goal of weight reduction. This selective loss to follow-up results in an overestimate of treatment effectiveness. By failing to acknowledge drop-outs, treatment failures may be systematically eliminated from the analyses.

Experiments evaluating the efficacy of behavioral programs to promote healthy lifestyles have gained in popularity in recent years. One of the most difficult problems in studies evaluating the effects of these behavioral interventions is that participants sometimes drop out before the study is completed. Reported drop out rates vary considerably from study to study. However, it has been shown that drop out rates of 40–50% or higher can be expected in some studies. For example, Kentala (1972) found that only 13% of participants in an exercise rehabilitation program were still exercising after 12 months. Mitchell and Stuart (1984) suggest that drop out rates from weight control treatments run from 0 to 83%. Foreyt, Goodrick, and Gotto (1981) have reviewed weight loss studies with 12 month follow-up data. They found that drop out rates ranged from 0 to 66% (M = 35%), and speculated that those who dropped out of treatment fared worse than those who completed the follow-up visits. Although clinicians and researchers have suggested that patients are more likely to drop out of programs when they are doing poorly (Kazdin, 1980), we have not been able to find specific data to support this argument.

If those who drop out of treatments are a representative sample of those who remain in the treatment conditions, drop out would not bias the estimate of treatment effects. However, we hypothesize that those who drop out of treatment are not a representative sample. An analogous finding was recently discussed with regard to cancer chemotherapy trials. Oye and Shapiro (1984) noted that in chemotherapy research, some investigators compare the outcomes for those who completed treatment with those patients who did not respond or failed to complete treatment. In some trials, those who do not respond to treatment are systematically eliminated from the analysis. As Oye and Shapiro (1984) note, this causes a serious overestimation of the benefit of chemotherapy. By analogy, those who drop out of weight loss

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or other behavioral programs might be considered to be "non-responders." Eliminating them from the analysis may cause the same overestimation of treatment effectiveness.

In this paper, we report data on drop out from an experiment evaluating weight management programs for patients with Type II or Non-Insulin Dependent Diabetes Mellitus (NIDDM). Type II Diabetes Mellitus is a common metabolic disorder that affects between six and eight million American adults (Kaplan & Atkins, 1985). Patients with this condition are not dependent upon supplemental insulin, and only a minority receive insulin therapy. Approximately 90% are obese and weight management improves glycemic control in the majority of cases (Skyler, 1979). The American Diabetes Association (1984) now recognizes diet and exercise as the primary treatment of Type II Diabetes Mellitus. Medical interventions are recommended only after behavioral treatment fails.

Despite the enthusiasm for the behavioral management of Type II Diabetes, little is known about the chances that patients will succeed on a diet and exercise regimen. The literature on medical clinical trials suggests that there are several reasons for treatment failures. Some failures result from treatments that provide no biological benefits. Other treatment failures occur when patients, assigned to a biologically effective treatment, fail to comply or take the treatment. Non compliant patients and treatment drop outs are called treatment failures (Armitage, 1983). Excluding drop outs from consideration in the analysis may produce a bias in favor of the treatment.

METHOD

Subjects

The subjects were 55 Type II Non-Insulin Dependent Diabetic adults. The subjects ranged in age from 29 to 79 years, \( M = 52.94, SD = 12.08 \). The mean body weight of the subjects was 179.79 pounds with a standard deviation of 35.14 pounds (men, \( M = 198.71 \) and women, \( M = 159.69 \)). In addition to being overweight, relative weight for the subjects was evaluated using the quelet index 100 (weight/height\(^2\)). Using pounds and inches to calculate the index, the mean value was 3.88 which is in the 86th percentile for women and the 71st percentile for men in comparison to a random sample population survey from the same community (Barrett-Connor, Suarez, Khaw, Criqui, & Wingard, 1984). Male and female participants had essentially identical initial quelet values \( (F = 1.53 = .001, p > .99) \). Criteria for being admitted to the study included either fasting blood glucose levels higher than 140 mg/dl, or normal fasting blood sugar but oral glucose tolerance tests that indicated blood glucose levels exceeding 200 mg/dl at two hours after the administration of a 75 g carbohydrate dose. Each patient had been classified as Type II Diabetes Mellitus after an examination by a physician with specialty training and certification in endocrinology and metabolism. All patients had been advised to lose weight by their physician.

Recruitment and screening

The subjects were recruited in a variety of ways. Many of the patients were referred by a local physician specializing in diabetes care. Patients were also solicited through public service announcements made periodically by local radio stations.

The diabetic patients taking part in this study were screened for other possible
health problems before being allowed to participate. The screening procedures included an exercise stress test on a treadmill. In addition, data on resting and exercise blood pressure; a blood screening panel, and a health status interview were also obtained. Patients with significant heart or vascular disease were excluded from the study. A release form signed by each patient’s personal physician noted that the patient was advised to lose weight for medical purposes.

**Weight loss groups**

The patients were randomly assigned to one of four experimental conditions: behavior modification, cognitive modification, cognitive-behavior modification, and a control condition. Further details of these conditions are given in another paper (Heitzmann, Kaplan, Wilson, & Sandler, 1987).

**Follow-ups**

Follow-ups were conducted at three, six, twelve, and eighteen months following the onset of the project. Patients were evaluated on a variety of physical measures in addition to structured interviews. These same measures were employed at the initial interview. At each successive follow-up visit, weight gain or weight loss since the previous visit was recorded. The consent procedure approved by the local Human Subjects Review committee did not permit further contacts with subjects once they had decided to drop out of the study.

**Results**

Twenty-four percent of the patients (or 13 individuals) dropped out of the study prior to its completion. In order to predict drop out, we analyzed weight change in the last completed interview. Then, we evaluated the probability of failing to report for a follow-up as a function of previous weight gain or weight loss. The results indicated that the probability of dropping out of the study was significantly associated with weight gain at the last attended follow-up.

For the purpose of this report, weight loss is defined as reduction of two or more pounds and weight gain is defined as increase by two or more pounds. Weight was considered the same if it remained within two pounds of previous value.

The results are summarized in Table 1. Forty-seven (23 men & 24 women) of the 55 patients completed the 12 month follow-up (85%). This includes one man who had dropped out, but decided to reenter the study. Our analysis considers changes in weight between the three and six months exams as predictors of reporting for the 12 month follow-up. Among the 47 patients who appeared for the 12 month weigh in, 79% had either lost weight or remained the same at the previous visit. However, among those who dropped out of the study, 62.5% (5 of 8) had gained weight between the three and six month exams. This effect was statistically significant ($\chi^2 = 5.86$, $p < .025$).

Weight changes between 6 and 12 months were used to predict drop out at the 18 month follow-up and the same pattern was observed. Forty-two of the remaining 47 patients completed the 18 month exam (89%). Among these, 91% had held their weight constant or lost weight between the 6 and 12 month follow-ups. In contrast, only 1 of the 5 patients who dropped out of the study at this point had lost weight or remained the same. Four of five (80%) of the drop outs had gained weight ($\chi^2 = 8.73$, $p < .005$). The attrition of subjects by weight gain or loss is illustrated in Figure 1.

The overall main effect of weight loss or gain upon drop out over the two periods
was evaluated using the Mantel-Haentzel statistic. The effect was highly significant ($\chi^2 = 13.62, p < .001$). Differences between drop out rates in the various treatment and control groups were not statistically significant. Considering total weight change between the initial and 18 month follow-up, 70% of the subjects who completed the study had lost weight. Conversely, only 13% of the drop outs lost weight between entry and their last visit.

Considering changes in weight between the initial and the 18 month follow-up those who completed the study lost an average of four pounds, while the mean change for the drop outs was a gain of 7.6 pounds ($t = 4.60, p < .001$).

**Discussion**

Attrition in this study was selective. Although it has been suggested that less successful patients are more likely to drop out of treatment (Foreyt et al., 1981), we are not aware of other reports that provide specific empirical confirmation. The

**Stage**

I. Completed program through 6 month follow-up

II. 12 month status as a function of 3-6 month change

III. 18 month status as a function of 6-12 month change

Fig. 1. Tree diagram of patient participation status by weight gain or loss.
Selective attrition

effect of selective drop out might be an overestimation of the effects of treatment. In this demonstration, the average difference between drop-outs and completers was 11.6 pounds. Experimental studies on behavioral interventions typically describe only those who complete all follow-ups. It seems likely that selective attrition is a common problem and may result in the overestimation of treatment effects. In our study, the mean weight loss of 4 pounds reduces to 1.27 pounds when the average weight change at time of drop out is added.

A similar finding was recently reported by Mitchell and Stuart (1984). They noted that drop outs from the weight watchers program were less likely to feel successful in weight control and behavior change than those who remained in the program. However, Mitchell and Stuart (1984) report relatively small actual weight loss differences between these two groups.

Selective attrition appears important in several other areas of investigation. For example, a recent paper on the epidemiology of lung disease provided intensive follow-up for those who successfully completed or did not complete follow-up tests of lung function. When followed carefully, those with “test failures” were found to have more rapidly declining rates of lung function. In other words, failing to obtain data from subjects who did not provide good test results resulted in an underestimation of the decline in lung function (Eisen, Robins, Greaves, & Wegman, 1984).

There is some evidence that complying with a treatment regimen results in positive outcomes. Epstein (1984) recently reviewed six medical trials and found that there was a consistent benefit for those who comply with either treatment or placebo. In other words, there was always a significant health benefit for complying and this benefit occurred even to those assigned to inert treatments. In some of these experiments, there was no significant effect of the medical treatment.

The problem of selective loss to follow-up has gained some attention in the literature on medical clinical trials (Armitage 1983; Pocock, 1983). A variety of studies have shown that patients who experience side effects from drugs are more likely to drop out of treatment. The inclusion or exclusion of these patients in the analysis has been shown to determine the direction of the conclusions in some studies (Sackett, 1981). The wisdom that has emerged from these clinical trials is that patients should be included in the analysis if there was “intention to treat.” In other words, once assigned to a treatment patients can not be ignored when they drop out. Every effort should be made to keep them in the study and to document their progress. Those lost to follow-up might be considered treatment failures (Armitage, 1983).

In conclusion, we suggest that subjects may remain in treatment when they are feeling well and experiencing positive outcomes. When they experience less positive outcomes, they are more vulnerable to drop out. Relatively low (15 to 35%) drop out rates do not insure freedom from bias. Excluding drop outs from the analysis may serve to overestimate benefits of treatment. We did not apply techniques to reduce attrition such as the deposit-return system. Given the demonstrable biases caused by selective attrition, any technique that can reduce drop out is clearly advisable.

Recently, mathematical models that characterize the impact of selective attrition have been developed (Choi, 1985; Choi and Stableim, 1982). Some techniques require eliminating experimental subjects from the analysis when there has been high attrition from the control group (Kaplan, 1978). Other methods require imputation of data that takes selective attrition into consideration. However, as Choi (1985) notes, there are no clear mathematical solutions to serve selective attrition.
REFERENCES


