A Randomized Trial of Integrated Outpatient Treatment for Medically Ill Alcoholic Men

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Background: Medically ill alcoholics often do not respond to conventional alcoholism treatment or decline physician referrals. Integrated outpatient treatment (IOT), a new treatment specifically designed for this population, combines comprehensive medical care with alcoholism interventions.

Objective: To compare the efficacy of IOT with that of standard treatment approaches.

Methods: One hundred five male veterans with severe medical complications caused by alcoholism and recent drinking were randomly assigned to receive IOT or referral to standard alcoholism and medical treatment and were evaluated over 2 years. Integrated outpatient treatment patients received medical care and alcoholism interventions once or twice monthly. Patients in the control group were referred for alcoholism treatment, but few accepted. However, patients in the control group did engage in outpatient medical care.

Results: At baseline, the mean ± SD age of the control group was 57.2 ± 10.0 years, compared with 52.8 ± 11.5 years in the IOT group (P = .04). The groups were well matched in other respects. The mean ± SD number of visits over 2 years for the IOT patients was 42.2 ± 29.1, compared with 17.4 ± 15.6 for the control patients (P < .001); the frequency of hospital use was similar in both groups. After 2 years, 28 (74%) of 38 surviving IOT patients and 17 (47%) of 36 control patients were abstinent (P = .02). Nearly twice as many control patients (30% [n = 16]) as IOT patients (18% [n = 9]) died, but the results of Cox survival analysis were not significant. There were no differences in symptoms of alcohol dependence, quality of life, or life problems. The incremental cost of IOT was approximately $1100 per patient per year.

Conclusions: Standard medical care alone was surprisingly effective in inducing abstinence in surviving medically ill alcoholics. Integrated outpatient treatment significantly increased both engagement and abstinence for a modest annual cost. Further refinement and testing of IOT is indicated.

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SUBJECTS AND METHODS

SUBJECT SELECTION

Subjects were recruited from inpatient and outpatient care areas of the Minneapolis Veterans Affairs Medical Center (MVAMC), Minneapolis, Minn. Recruitment occurred through referral from medical care providers, or potential subjects were identified through daily review of new admissions to acute treatment units. Potential subjects were screened for eligibility; if they met the inclusion criteria, they were approached by study personnel. Inclusion criteria consisted of (1) current diagnosis of a severe alcohol-related medical illness, defined as alcoholic liver disease (cirrhosis or symptomatic alcoholic hepatitis), alcoholic pancreatitis, alcoholic cardiomyopathy, alcohol-related gastrointestinal bleeding requiring hospitalization, or severe alcoholic neuropathy; (2) recent pathological drinking (past 6 months); and (3) being willing and able to return for monthly clinic visits. Exclusion criteria were (1) being unwilling or unable to participate, or a history of repeated failure to attend outpatient clinics; (2) terminal illness with a life expectancy of less than 12 months from a non-alcohol-related illness; (3) severe dementia; (4) major psychiatric disorder other than depression; (5) current polystyrene abuse or drug of choice other than alcohol; and (6) civil commitment to treatment or a pending commitment action.

All participants provided signed informed consent and the study was approved by the MVAMC institutional review board. After baseline data were collected, subjects were randomly assigned either to the IOT clinic or to routine (separate medical and alcoholism) care through the following process: at the conclusion of the informed consent process, the study coordinator called the program clerk to ask for the next study assignment. The clerk read the next number from a table of random numbers; group assignment depended on whether the number was even or odd. This process was monitored by the investigators to assure true random assignment of all participants.

Once group assignment was decided, the study coordinator arranged for appointments with clinical staff. Since both medical and alcoholism care were included in IOT, only a single referral appointment was required. For subjects in the control group, arrangements were made both for outpatient medical care in the general and specialty medicine clinics at MVAMC and for alcoholism treatment evaluation through the mental health services of the hospital. Participants were then free either to follow through with referrals or not. Study staff involvement with clinical referral and follow-up care was limited to arranging referral appointments; the only description of clinical interventions given was that in the informed consent document. Study staff had no further involvement in the clinical care of subjects in the control group.

In designing the study, consideration was given to whether inclusion should be restricted to patients who were definitely willing to participate in either group. This was rejected in favor of referral only because we wanted to replicate the way these treatments are actually administered in clinical settings. Furthermore, IOT was designed to overcome the reluctance of many alcoholics to accept a referral for conventional alcoholism treatment. Restricting the sample to those who were willing to accept referral would introduce substantial sampling bias and fail to test an important hypothesis. One outcome to be examined would include participation rates following referral.

CLINICAL CONDITIONS

Integrated Outpatient Treatment

In IOT clinic intervention, techniques for addressing excessive drinking and psychosocial problems are integrated with primary medical care. A procedures manual, standardized progress notes, and clinical supervision by one of the investigators (D.H.O.) were used to guide and standardize treatment. Primary care professionals, including physicians and nurse-practitioners, were the principal caregivers, and care was provided within the general outpatient medical care setting. All patients received a 1- or 2-day inpatient evaluation by a multidisciplinary team. After discharge, a treatment plan was developed and presented to the patient and to any family members who were involved. The goals of IOT were to induce remission of drinking and related medical conditions whenever possible; to reduce the number, length, and severity of relapses; and to extend meaningful life for patients. Treatment goals, therefore, included those that fell short of the traditional ideal of permanent abstinence. In this and other ways, IOT most closely resembles treatment for other chronic medical disorders, such as diabetes or congestive heart failure.

Once they accepted the treatment plan, patients were seen monthly at an outpatient clinic by either a nurse-practitioner or a physician (or both). Visit frequency was increased as indicated for medical management. At each visit, clinic staff would review recent drinking history and medical problems and conduct indicated physical examinations and laboratory tests. Biological indicators were used whenever possible to track the effects of drinking. Such indicators included liver function test results, blood glucose test results (in patients with diabetes), blood pressure (in patients with hypertension), and weight. These indicators were discussed with patients and were often presented in graphic form to follow trends over time. Efforts to reduce drinking and a positive change in biological indicators were praised and encouraged, while the deleterious effects of continuing drinking were noted. Motivation to change was supported through discussions of the benefits and costs of drinking, barriers to change and strategies to overcome them, and goal setting. Whenever possible, family members were enlisted to support positive change and to decrease behaviors that either directly or inadvertently resulted in increased drinking. If patients failed to come to an appointment, outreach attempts were made to reengage the patient. Mental health and social services were available when needed and were also provided within the primary care setting. More intensive alcohol treatment and other services were provided as needed. A more complete description of the intervention has been published previously.

Control Group

Patients randomized to the control group were referred to the usual clinical services available in the institution. These

Continued on next page
included the inpatient and outpatient consultation and treatment services for alcohol-related problems and general and specialty medical care clinics. For patients entering the study after completion of an intensive alcoholism treatment program, routine continuing care alcoholism treatment was available. Patients randomized to the IOT group after intensive alcoholism treatment received both the usual continuing care alcoholism treatment and IOT intervention. Although it was not explicitly defined, it is a safe assumption that all patients in the control group received advice from medical staff to abstain from alcohol. Most patients entered the study after an acute medical illness caused or exacerbated by heavy drinking, and it is standard practice in this institution to strongly advise abstinence under such circumstances.

DATA COLLECTION PROCEDURES

Drinking

Data on the quantity and frequency of drinking were gathered using the time line follow back (TLFB) procedure. The TLFB procedure provides a standardized means of collecting alcohol consumption data over a specified period and has excellent reliability and validity. The Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition (DSM-III-R), criteria checklist is a semistructured interview used to assess the number of active symptoms of alcohol dependence (out of 9 possible).

Life Problems

The Addiction Severity Index (ASI) is a widely used, valid, and reliable structured interview that rates 7 areas of function: medical, employment/support, family/social, legal, alcohol use, drug use, and psychiatric.

Medical Service Utilization

Computerized records at MVAMC were used to determine local service use. Hospital days were divided into medical and psychiatric/substance abuse categories. National Veterans Affairs (VA) data systems were used to provide information about medical care received at other VA medical centers. Initially, the medical section of the ASI was used to determine the additional medical care a subject had received outside MVAMC. However, this was not felt to be reliable, so between 18 and 24 months into the study, a release of information was obtained from all available subjects and records were obtained from other medical facilities. Non-VA medical records were obtained for approximately two thirds of the total sample, distributed equally between the 2 treatment groups. Exhaustive efforts were made to obtain hospital and other records from non-VA providers, and this effort was felt to be quite productive and complete. Thus, non-VA medical use is considered representative and unbiased for group comparisons, but the actual amount of service in the total sample may be somewhat more than we obtained.

Health and Well-being

The Treatment of Mild Hypertension Study (TOMHS) for the VA Decedent Affairs Office was periodically queried about the sample, and reports of deaths were obtained from relatives. Death certificates were obtained for all reported deaths.

DATA ANALYSIS

The Statistical Package for the Social Sciences for the Macintosh was used for statistical analyses. Data were analyzed using baseline and 2-year follow-up data. For continuous variables, the distributions were first examined to assure the approximation of normality. Transformations were used when possible to correct skewed distributions. Two-tailed t tests were used on most variables. Mann-Whitney-Wilcoxon rank sum procedures were used when transformation would not adequately correct a skewed distribution. On categorical variables, Pearson χ² analyses were used. Cox survival analysis was used to determine the significance of mortality differences between groups.

SAMPLE CHARACTERISTICS

Of the initial 105 subjects, 2 dropped out (1 from the IOT group and 1 from the control group), and 2 subjects in the control group were lost to follow-up—a study attrition rate of 4%. Baseline and clinical characteristics of the remaining sample, consisting of 48 IOT group and 53 control group participants, are shown in Table 1 and Table 2. The entire sample consisted of male veterans, with the typical patient having undergone several previous treatments and having been charged several times with driving while intoxicated. The number of previous admissions to detoxification centers averaged less than 1. Consumption of alcohol was substantial, especially considering the age and medical status of the subjects. All subjects used a significant amount of medical care.
increased exposure to alcoholism interventions, reduced drinking, reduced symptoms of alcohol dependence, and improved survival and quality of life compared with control patients. Since this study began before the results from the quasi-experimental study were available, we also hypothesized that the frequency of hospital use would be lower in IOT patients.

### RESULTS

Outcome indicators are shown in Table 3. Drinking was reduced substantially in both groups, but a greater proportion of IOT patients achieved abstinence. After 2 years, nonabstinent patients were consuming a mean ± SD of 6.1 ± 4.5 drinks per day on 13.5 ± 9.9 days per month—a pattern very similar to baseline. Quantity and frequency among nonabstinent patients were not significantly different between groups. There were small changes in ASI psychiatric composite and emotional well-being scores, but the relationship of scores between groups remained the same as at baseline. Participation in intensive alcoholism treatment after entry into the study was infrequent but similar in both groups (IOT group, 21% [n = 10]; control group, 19% [n = 10]). The frequency of use of hospital services was similar for the 2 groups, but outpatient visits over the 2-year period were significantly higher for IOT patients. Integrated outpatient treatment patients had an average of 14 visits in the first 6 months, which gradually diminished to 9 visits in months 19 through 24; control patients had about 4 to 6 visits in each 6-month period. More IOT subjects than control subjects lived 2 years (81% [n = 39] vs 70% [n = 37]) ($\chi^2_1 = 4.5; P = .03$), and the IOT group had a higher mean ± SD number of days lived (IOT group, 663.1 ± 175.5; control group, 601.2 ± 224.8; $t_{199} = 2.17; P = .03$). However, results of Cox survival analysis for study group with or without age entered as a covariate were not statistically significant. Since a similar difference in the survival rate was found in an earlier study, the results from the 2 studies were combined in order to increase power. With the results combined, the advantage in survival for IOT subjects was significant even with age as a covariate ($\exp [B] = 2.01, P = .04$).

### Table 1. Baseline Characteristics of Sample*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IOT Group (n = 48)</th>
<th>Control Group (n = 53)</th>
<th>Statistic</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y†</td>
<td>52.8 (11.5)</td>
<td>57.2 (10.0)</td>
<td>$t_{99} = -2.09$</td>
<td>.04</td>
</tr>
<tr>
<td>White, No. (%)</td>
<td>45 (94)</td>
<td>46 (87)</td>
<td>$\chi^2_1 = 1.37$</td>
<td>.24</td>
</tr>
<tr>
<td>Married, No. (%)</td>
<td>13 (27)</td>
<td>11 (21)</td>
<td>$\chi^2_1 = 1.74$</td>
<td>.42</td>
</tr>
<tr>
<td>Education, y†</td>
<td>12.3 (2.5)</td>
<td>13.0 (2.6)</td>
<td>$t_{99} = 1.42$</td>
<td>.16</td>
</tr>
<tr>
<td>Lives with others, No. (%)</td>
<td>29 (60)</td>
<td>33 (62)</td>
<td>$\chi^2_1 = 2.45$</td>
<td>.48</td>
</tr>
<tr>
<td>Employed, No. (%)</td>
<td>14 (29)</td>
<td>13 (25)</td>
<td>$\chi^2_1 = 1.60$</td>
<td>.66</td>
</tr>
<tr>
<td>Previous DWI charges†</td>
<td>1.8 (1.9)</td>
<td>2.3 (4.2)</td>
<td>$t_{99} = 0.78$</td>
<td>.44</td>
</tr>
<tr>
<td>Previous alcoholism treatments†</td>
<td>2.9 (3.1)</td>
<td>3.2 (4.4)</td>
<td>$t_{99} = 0.46$</td>
<td>.65</td>
</tr>
<tr>
<td>Previous detoxification admissions†</td>
<td>0.7 (0.9)</td>
<td>0.8 (0.9)</td>
<td>$t_{99} = 0.58$</td>
<td>.56</td>
</tr>
</tbody>
</table>

*IOT indicates integrated outpatient treatment; DWI, driving while intoxicated.
†Values are mean (SD).

### Table 2. Clinical Indicators at Baseline for the Integrated Outpatient Treatment (IOT) and Control Groups*

<table>
<thead>
<tr>
<th>Indicator</th>
<th>IOT Group (n = 48)</th>
<th>Control Group (n = 53)</th>
<th>Statistic†</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive DSM-III-R criteria (0-9), No.</td>
<td>5.9 (2.5)</td>
<td>5.3 (2.4)</td>
<td>$t_{98} = 1.33$</td>
<td>.18</td>
</tr>
<tr>
<td>Drinking days during last 30 days</td>
<td>15.8 (12.3)</td>
<td>14.4 (12.3)</td>
<td>$z = -0.58$</td>
<td>.56</td>
</tr>
<tr>
<td>Drinks per drinking day, No.</td>
<td>11.1 (10.3)</td>
<td>8.9 (7.9)</td>
<td>$z = -0.86$</td>
<td>.39</td>
</tr>
<tr>
<td>Days since last drink†</td>
<td>2.0</td>
<td>2.5</td>
<td>$z = -0.71$</td>
<td>.48</td>
</tr>
<tr>
<td>TOMHS physical well-being score</td>
<td>37.2 (11.7)</td>
<td>41.8 (12.2)</td>
<td>$t_{98} = 1.84$</td>
<td>.07</td>
</tr>
<tr>
<td>TOMHS social well-being score</td>
<td>9.7 (3.3)</td>
<td>9.6 (3.1)</td>
<td>$t_{98} = 0.16$</td>
<td>.87</td>
</tr>
<tr>
<td>TOMHS emotional well-being score</td>
<td>50.1 (13.1)</td>
<td>55.0 (13.2)</td>
<td>$t_{98} = 1.84$</td>
<td>.07</td>
</tr>
<tr>
<td>TOMHS health outlook score</td>
<td>13.3 (3.3)</td>
<td>12.9 (4.0)</td>
<td>$t_{98} = 0.53$</td>
<td>.60</td>
</tr>
<tr>
<td>ASI medical rating</td>
<td>0.65 (0.30)</td>
<td>0.60 (0.29)</td>
<td>$t_{98} = 0.92$</td>
<td>.36</td>
</tr>
<tr>
<td>ASI alcohol rating</td>
<td>0.39 (0.22)</td>
<td>0.33 (0.26)</td>
<td>$t_{98} = 1.26$</td>
<td>.21</td>
</tr>
<tr>
<td>ASI psychiatric rating</td>
<td>0.22 (0.20)</td>
<td>0.14 (0.18)</td>
<td>$t_{98} = 2.01$</td>
<td>.05</td>
</tr>
<tr>
<td>VA hospital days over prior 2 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical treatment</td>
<td>20.5 (23.9)</td>
<td>19.3 (21.5)</td>
<td>$z = -0.24$</td>
<td>.81</td>
</tr>
<tr>
<td>Psychiatric and alcoholism treatment</td>
<td>11.1 (15.2)</td>
<td>11.8 (21.9)</td>
<td>$z = -0.54$</td>
<td>.59</td>
</tr>
<tr>
<td>VA clinic visits over prior 2 years, No.</td>
<td>9.2 (11.4)</td>
<td>11.3 (13.9)</td>
<td>$t_{199} = 0.82$</td>
<td>.41</td>
</tr>
</tbody>
</table>

*Values are mean (SD), unless otherwise specified. DSM-III-R indicates Diagnostic and Statistical Manual of Mental Disorders, Revised Third Edition; TOMHS, Treatment of Mild Hypertension Study; ASI, Addiction Severity Index; and VA, Veterans Affairs.
†The z values refer to the Mann-Whitney test.
‡Median.
This is the first controlled trial of IOT, a new method of treating medically ill alcoholic men that incorporates both comprehensive outpatient medical care and alcoholism interventions. Compared with standard care, in which outpatient medical care and alcoholism treatment were offered separately, IOT was highly successful in engaging patients; IOT subjects had 2.5 times as many outpatient visits as subjects in the control group. Although almost half of the subjects in the control group were abstinent after 2 years, three quarters of those in the IOT group were also abstinent after 2 years. These gains are significant in a population that has traditionally been unresponsive to previous approaches.

By integrating alcoholism interventions with medical care, IOT was able to engage patients who were willing to return for medical appointments but would not accept a referral for alcoholism treatment. As predicted, most patients in the control group refused referral for conventional alcoholism treatment but were willing to engage in medical care. Integrated outpatient treatment patients also engaged in medical care, but received constant, gentle encouragement to examine their drinking and its effect on their health. As their readiness to change increased, these subjects received assistance and encouragement as to how to limit or stop drinking and how to limit and avoid relapses. Families also received support to address the patient's drinking in a constructive manner.

It may seem surprising that one half of the control group survivors were abstinent after 2 years. Participants could have minimized their drinking when assessed using the TLFB procedure. However, in both research and clinical settings, most studies have concluded that self-reporting alone is valid and reliable.2-6,10,16-21 The use of techniques that increase item salience and specificity, such as the TLFB procedure, improves reliability.21 Although informants may not always agree with self-reporting,24 it is not clear that informants are more accurate. Similarly, biological measures have not been shown to increase validity.25 Moreover, recall of drinking has been shown to be as accurate as recall of other events, such as emergency department visits and hospitalizations.21

A more likely explanation for the high rate of abstinence is that participants were older adults with serious medical problems. Almost all of these patients were hospitalized for severe medical complications caused by heavy drinking immediately prior to entry into the study, and most continued to experience significant medical disabilities. Medical illness can be a powerful motivator to change and appears to have resulted in significant drinking reductions in the control group. Results in the IOT group, however, suggest that once engaged in outpatient medical care, a patient's motivation to change can be enhanced and supported, resulting in even greater reductions in drinking. All told, these results contradict the pessimism widely expressed about prognosis for medically ill alcoholics.

Unfortunately, increased participation in medical follow-up and reductions in drinking did not result in some expected benefits during the 2-year follow-up period. Hospital use was not reduced in the IOT group. However, the increase in hospitalizations seen in the first study of IOT5 was not replicated here, presumably because hospital use outside of VA medical centers was assessed in the current study. Measures of quality of life and life problems showed no differences relative to group. It is not clear why differences were not seen for these indicators. Although the quality-of-life scale we used has not been widely used, it shares many characteristics with others that are; it is unlikely that this instrument is substantially worse at measure-
ing quality of life than other instruments like it. It is possible that the association between quality of life and life problems with abstinence is low, or that more time is needed for abstinence to result in improvement in other areas of life. Patients in this study had substantial medical illnesses, the severity of which may override other factors in determining quality of life. In a previous study, Willenbring and colleagues found that older, medically ill alcoholics primarily had medical and family problems, as opposed to younger, more antisocial alcoholics, who had legal and employment problems. The medical and social problems of older heavy drinkers may be less responsive to reductions in drinking.

Mortality was high overall (25%) but was lower in the IOT group than in the control group. Although the mean number of days lived was longer in the IOT group, the difference failed to reach statistical significance in a Cox regression analysis. This is likely caused by a lack of power. Also, the baseline age difference in a Cox regression analysis. This is likely caused by several months of weekly aftercare. However, conventional treatment by nursing staff. If each clinic visit costs $75 and each hour of case management costs $100, then the average cost per year for IOT over and above standard care is only slightly more than $1100. Outpatient visits are more intensive early on, and patients' conditions appear to stabilize within 2 to 3 years; therefore, the total incremental cost is about $2000 to $3000. Conventional alcoholism treatment programs typically entail 60 to 100 hours or more of therapy over a few weeks. It is often provided in a residential setting, costs from $2000 to $15 000 or more, and is followed by several months of weekly aftercare. However, conventional treatment has not been demonstrated to be effective in this population. That many of these patients will not attend conventional treatment programs poses a more serious problem. For example, although all control group patients were referred for alcoholism treatment in this study, only a small proportion received any alcoholism treatment at all during the study period. The incremental cost of IOT seems reasonable in light of the available alternatives and improved drinking outcome in a treatment-resistant population. It may also be possible to reduce the cost of IOT without reducing efficacy.

Integrated outpatient treatment is a promising new approach for a group of patients who have been extremely difficult to treat. Further study and refinement of the model is warranted. In particular, it will be important to replicate these findings in other settings and with other populations. The results should be generalizable to male veterans using VA medical services, but replication studies should be undertaken for women, ethnic minority groups, and populations with greater socioeconomic diversity. Further refinement of the model should include targeting specific subgroups for different interventions, dismantling studies that identify the effective components of this complex intervention, and studies examining ways to reduce hospital use.

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