A program to reduce onset distress in unselected type I diabetic patients: effects on psychological variables and metabolic control

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This paper reports the results of a prospective controlled trial of a program addressing reduction of onset distress and better future adaptation in adults who were enrolled at the time of diagnosis of type I diabetes mellitus. Patients were assigned randomly to either standard intensive treatment and patient education with the distress reduction program (N = 10) or to standard intensive treatment and patient education without this program (N = 13). Prospective follow-up of patients with multiple validated measures of treatment outcome showed less anxious coping behavior, less depression and less denial at the 9-month follow-up and less denial at the 15-month follow-up in the group with the distress reduction program, but no differences in metabolic control between the two groups at any time. We conclude that our program has a positive impact on the crisis at diabetes onset: the lower denial in the treatment group may lead to improved regimen adherence in the long term.

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The Diabetes Control and Complications Trial experience suggests that maintaining strict glycemic control requires substantial psychosocial support (1). In previous publications a wide variety of psychosocial techniques have been used to maintain good metabolic control via enhanced psychosocial support, e.g. relaxation techniques (2), daily social-learning group exercises (3), monthly staff meetings (4), family crisis intervention (5), psychoanalytical and dynamic psychotherapy (6), family therapy (7), group psychotherapy (8), peer support (9), support groups (10) and other types of psychosocial intervention (3, 11).

Most investigations were case studies or dealt with very small samples (usually consisting of children and adolescents). They did not use control groups or a prospective and randomized design. The type of intervention and outcome criteria were not described in sufficient detail and no long-term follow-up was made. Most studies included patients with insulin-dependent diabetes (IDD) with a wide range of disease duration. Populations both without obvious psychosocial problems and with serious problems were investigated; thus, the populations possibly were not representative of the diabetic population in general.

In recent reviews (12, 13) it was suggested that, owing to these shortcomings in design, most studies found positive effects on metabolic control, whereas those that were better designed failed to find significant effects.

Generally the distress immediately after diagnosis of diabetes is considered to require special multidisciplinary support to reduce future psychosocial maladjustment and to improve future compliance. Distress at diagnosis is considered to be a more potent predictor of long-term adaptation to illness than psychological processes occurring later during the disease process (5, 14–18). We therefore studied, in a randomized controlled trial, the effect of a program that addressed the diabetes onset distress.

The aim of our study was twofold: to assess whether our program improves psychological variables; and whether better onset adaptation may be associated with improved metabolic control.

Methods

Subjects (Table 1)

Thirty consecutive subjects admitted with recent onset type I diabetes mellitus were recruited from the Department of Endocrinology and Diabetes. None of the patients was aware of a history of diabetes before the following symptoms occurred: five of the patients had ketoacidosis, 16 showed other major symptoms of diabetes such as polydipsia, polyuria and weight loss, whereas in nine patients hyperglycemia was found to be associated with mild symptoms such as tiredness. The mean duration of diabetes-associated symptoms was 4.3 (4.2 SD) weeks. None of the patients had medical problems other than diabetes that might interfere with
the evaluation in this study. Immediately after the detection of hyperglycemia by their community physicians, the patients were admitted to the Department of Endocrinology and Diabetes. Here, the definite diagnosis of IDD based on the definition of the National Diabetes Data Group (19) was established.

**Study design**

A random assignment two-group parallel comparison was used with a pretest and a 9- and 15-month follow-up. Prior to admission to the study all 30 patients were briefly interviewed by one of the two research assistants. Two subjects were excluded, one because he had previously diagnosed major depressive disorder and one because he had received psychotherapy during the 2 years before evaluation. Immediately after the prerandomization interview all patients were invited to participate in a “study of extended examinations of onset distress that might be of importance for their further disease adaptation, which makes it necessary to join the department psychosomaticist during their medical follow-ups for laboratory testing, social and psychological tests and interviews”. Five patients withdrew from the study after this invitation, so that finally 23 gave their informed consent to participate in the study and baseline measures (time 1 measurement) could be obtained by the research assistant.

Baseline data of each patient were collected in bedside interviews conducted between the third and fifth day of hospitalization. At this time all patients were aware of the diagnosis of a severe chronic disease; insulin therapy had been initiated, but none underwent diabetes education.

Independent randomization was conducted and intervention was initiated for the psychosocial treatment group. Randomization was performed by an independent research assistant who had no formal contact with the patients and no access to data collection.

After randomization, both groups received conventional education in diabetes self-management and blood glucose self-monitoring. Patients of the onset distress reduction program group had, in addition, two individual bedside sessions during the 8-day hospitalization period (one on the fifth and one on the eighth day); after discharge, the program of distress reduction was carried out as a group meeting program. Conventional medical treatment was performed without further interference in the endocrinological outpatient clinic. The group meetings began 1 month after the start of the study with six patients; four patients were enrolled within a second month. Thus, with all patients being recruited within a period of 2 months they had a very similar disease duration.

**Blinding**

All ratings and interviews were done by a research assistant, who had no further formal contact with the patients and was blinded about the patients’ group randomization, which was also unknown to the diabetologists. With the multiple psychological measures in both groups and the treatment study being part of a larger follow-up study (20), it made it easier for the research assistant to be blind for the patients’ randomization.

Time 2 measurement was conducted after 9 months and time 3 measurement after 15 months in all patients in the endocrinological outpatient clinic.

To minimize study influence, recruitment of new patients was stopped before the regular rotation of ward personnel, so that finally 13:10 patients could be analyzed.

**Diabetes treatment program**

Diabetes treatment consisted of injections of insulin three or more times daily, including mixed intermediate and rapid-acting insulins and education about diet and exercise (21, 22). The dosage was adjusted according to the results of self-monitoring of blood glucose performed at least four times per day, dietary intake and anticipated exercise. The goals of therapy included preprandial blood glucose concentrations between 70 and 120 mg/dl, postprandial concentrations of less than 180 mg/dl and hemoglobin A1c (HbA1c) within the normal range (less than 6%). Patients visited the outpatient department at least every 3 months, and at this occasion also HbA1c levels were determined.

**The onset distress reduction program**

Patients followed the program for 6 months. The duration of each of the weekly sessions, which were lead by a psychotherapist, was 90 min: the total number of sessions was 25.

If grief and anxiety is suppressed, physiological grief may become pathological leading to prolonged emotions of grief, fear, anger, blame, shame and depression (23). Sessions 1–5 supported the expression of acute onset grief and anxiety about the loss of health to stimulate the coping process.

Sessions 6–10 dealt with social future anxieties, anxieties regarding hypo- and hyperglycemia and late complications. Daily hassles of living with diabetes, as well as the impact on social and family life, and particular coping strategies were addressed.

Sessions 11–25 were more devoted to non-cognitive, unconscious personality patterns. Denial, idealization of lost health, perpetuated frustration leading to unconscious aggression and hypochondrias were focused.
A similar after-onset distress intervention has been used and described by others (10, 24).

**Measures**

**Diabetes control.** Diabetes control was determined by glycosylated hemoglobin (HbA1c) measured by high-pressure liquid chromatography (HPLC method, Biorad Inc.). The non-diabetic range for HbA1c levels was 4.5–6.0%.

Remission (defined by an insulin requirement of less than 0.5 IU/kg body weight at least 1 month after onset with missing or minimal glycosuria) was recorded.

The number of mild hypoglycemic episodes (defined as recorded hypoglycemic home blood glucose measurements of less than 50 mg% and/or symptoms of hypoglycemia) and the number of severe hypoglycemic episodes (defined as hypoglycemia requiring assistance by another person and treatment by intravenous glucose or glucagon injection) were documented.

**Psychological assessment**

**Life events.** Life events were evaluated for better baseline comparability by the Junk & Junk questionnaire (25). This self-rating scale is an extended version of the method for exploring life events developed by Paykel (26). The scale assesses five categories of 70 stressful events that had occurred 6, 12 and more months before evaluation, the items being quantified by ten degrees, with 0 indicating the lowest and 10 the highest upset intensity caused by the event.

The quality of coping with the rated events was scored by a 102-item self-rating scale. The items were scored by patients’ self-rating in five steps and summed up in four internal categories—fatalism, anxious coping behavior, degree of internal, external and fatalistic control by the subject and two external factors assessing social integration and familial adherence as a coping support. These six categories were summarized to a global coping index that indicates the degree of coping quality, with higher sum scores indicating poorer coping. Reliability and validity of this instrument have been verified (25).

This instrument shows good correlations with the internal, the external and the external fatalistic control scale of Levenson’s IPC scale (27).

The moderating variables “coping” and “controllability” have been found to correlate better with metabolic control than depression and anxiety (14. 28–30). Controllability has direct psychophysiological effects (31) and permits the prediction of disease progression (32) and efficacy of treatment (33). Social support is connected with better metabolic control (34, 35).

Depression was rated by the Beck depression inventory (BDI) (36) and by DSM III R Interview (37).

Anxiety was determined by the 40-item Spielberger state and trait anxiety inventory (STAI) (38).

Both depression and anxiety have been found to correlate with metabolic control (39, 40).

**Attributional beliefs** were measured by the factor-analyzed scale by Ahrens and Elsner (41), with 30 questions to be rated in five steps. This scale is similar to Lazarus’ two different coping strategies (problem-oriented and emotion-oriented) (42). The Ahrens scale was specifically adapted to diabetes treatment. Thus, a high score of internal attribution indicates an emotional view of origin, whereas a high score of external attribution indicates outside responsibilities and physician- and treatment-oriented actions.

External attributions generally are associated with better adjustment (43) and correlate positively

<table>
<thead>
<tr>
<th>Table 1. Age, sex, sociodemographic, psychological and medical characteristics of the two groups.*</th>
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<tr>
<td>Characteristic</td>
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<td>Age (yr)</td>
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<td>Psychological and medical characteristics at baseline:</td>
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<td>Psychological and medical characteristics during the study period</td>
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<td>Total/partial remission in the year following onset (N)</td>
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<td>Duration of remission (weeks)</td>
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<td>Severe (no. per year)</td>
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*Values in parentheses are standard deviations of mean values. No differences at p < 0.01, Wilcoxon test.
Table 2. Hemoglobin A1c (HbA1c) and psychological outcome measures in the psychotherapy group and control group at baseline, at 9-month follow-up and at 15-month follow-up.

<table>
<thead>
<tr>
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<th>Baseline (N = 10)</th>
<th>9-Month follow-up (N = 10)</th>
<th>15-Month follow-up (N = 10)</th>
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<tr>
<td>HbA1c</td>
<td>10.1 (1.6), 6.8 (1.1)*</td>
<td>7.4 (0.6), 6.9 (1.0)</td>
<td>6.9 (1.3), 6.6 (1.3)</td>
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<tr>
<td>Anxiety (state)</td>
<td>39.4 (11.2)</td>
<td>32.9 (7.9), 31.8 (7.0)</td>
<td>36.1 (6.5), 31.4 (6.9)</td>
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<tr>
<td>Anxiety (trait)</td>
<td>37.2 (9.6)</td>
<td>34.9 (8.0), 30.1 (7.7)</td>
<td>38.4 (8.9), 29.2 (7.7)</td>
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<tr>
<td>Depression</td>
<td>28.2 (6.2)</td>
<td>21.0 (4.5), 25.6 (3.6)**</td>
<td>22.8 (5.9), 22.8 (4.5)</td>
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<tr>
<td>Coping (fatality)</td>
<td>7.5 (1.6)</td>
<td>6.9 (3.3), 6.3 (2.0)</td>
<td>6.7 (3.1), 6.1 (2.3)</td>
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<tr>
<td>Coping (anxiety)</td>
<td>13.8 (10.0)</td>
<td>23.7 (10.0), 29.5 (10.9)**</td>
<td>25.7 (11.2), 26.7 (10.8)</td>
</tr>
<tr>
<td>Coping (controllability)</td>
<td>84.8 (18.9)</td>
<td>74.0 (17.0), 69.1 (15.4)</td>
<td>78.0 (23.4), 72.8 (14.6)</td>
</tr>
<tr>
<td>Coping (support)</td>
<td>21.9 (8.1)</td>
<td>19.1 (4.5)</td>
<td>19.6 (6.0), 18.0 (4.9)</td>
</tr>
<tr>
<td>Attribution (external)</td>
<td>69.1 (21.3)</td>
<td>62.5 (19.4), 70.4 (22.3)</td>
<td>60.3 (20.1), 70.1 (21.4)</td>
</tr>
<tr>
<td>Denial</td>
<td>15.5 (6.6)</td>
<td>9.9 (3.2), 16.9 (6.8)**</td>
<td>9.3 (3.7), 17.1 (6.8)**</td>
</tr>
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</table>

*Mean (sd) values; **p < 0.01 between therapy and control groups, Wilcoxon test.

Results

Design adherence

One patient of the control group declined further medical follow-up visits in the hospital and repeated testing, but agreed to undergo reassessments by telephone interview and postal self-rating; information on HbA1c was gathered from his practitioner. One patient of the intervention group dropped out after three sessions but agreed to undergo reassessments within the medical follow-ups.

The mean number of sessions that patients participated in was 16 (sd 6.94) with a range of 1–23. Ninety per cent of our patients attended between 13 and 23 sessions.

Metabolic and psychological baseline characteristics (Tables 1 and 2)

Table 1 and parts of Table 2 summarize the baseline characteristics of the two treatment groups. Randomization resulted in similar baseline characteristics and assessment indices; there were no significant differences between the two groups.

At entry into the study all patients were in poor diabetic control, as evidenced by HbA1c levels. Blood glucose levels at the end of the first week of hospitalization were within the near-normal range and good metabolic control in terms of HbA1c was achieved within 6 weeks.

None of the patients met the criteria for the presence of major depressive disorder according to DSM-III-R. Compared to control groups given by the author, Beck depression scales showed a depressive range. Spielberger scales showed values similar to healthy controls. The means of coping strategies and support scores were not significantly different from their respective healthy standardization samples and in a significantly better range compared to samples of clinically depressive and asthmatic patients given by

with compliance and metabolic control in diabetics (14).

Denial was measured by an interview derived from the Hackett denial scale (44). As there is no other scale on denial in diabetics available at this time we specifically adapted the Hackett scale to diabetics. Each item was read out and discussed with the patient, then scaled in 0–3 steps.

When used in a preliminary investigation in diabetic patients this adapted scale showed a satisfactory external validity and test–retest rate over a 1-week period (0.05) after eliminating items with an internal consistency of less than 0.50 from the original scale, so that finally Cronbachs’ alpha could be set at 0.78.

Cut-off points were defined as 0–10 for minor deniers, 11–25 for partial deniers and 25–40 for major deniers. Denial is associated with non-compliance and poor adjustment in diabetics (15, 28).

Intercorrelations of the coping and denial scales with other established instruments as well as the items of the denial scale, which we have chosen from the original Hackett scale, have been published previously (20, 45).

Data analyses

Data were screened by the Kolmogorof–Smirnov test for normal distribution. Analyses of comparability of the two treatment groups and calculation of the treatment effects were performed with Student's t-test and Wilcoxon matched-pairs sample rank test. The differences of psychological and metabolic data between time 1, time 2 and time 3 measures were calculated. Because of the small group size and quantity of variables the alpha level was set at 0.01. Statistical consultation was provided by the Institute of Medical Statistics and Documentation, School of Medicine, University of Vienna, using an SPSS program packet.
the authors (25). Compared to control groups given by the authors of the attributional beliefs scale (41), our patients at baseline showed a view of somatic illness origin but a view of mixed somatic and psychological treatment beliefs was helpful in their diabetic illness. The results of the denial interview at baseline showed eight patients (35%) to be minor, ten (43%) to be partial and five (22%) to be major deniers.

**Treatment effects (Table 2)**

The definite diagnosis of IDD required insulin application in all patients. As indicated by medium HbA1c values, all patients maintained good metabolic control during the observation period.

Three psychosocial parameters—the Beck depression score (p < 0.01), the anxious coping behavior score (p < 0.01) and the denial score (p < 0.01)—improved 3 months after the end of the distress reduction program (time 2 measurement, 9-month follow-up) in the intervention group but not in the control group (the differences between baseline and time 2 and baseline and time 3 measurement were calculated).

Nine months after the end of the program (time 3 measurement, 15-month follow-up) the improvement of the Beck depression score and the improvement of the anxious coping behavior score had faded, whereas denial was still significantly reduced (p < 0.01). The decrease of denial tended to be stronger owing to the reduction of the number of major deniers in the intervention group. Descriptively, the decrease of denial was due to a stronger and persistent reduction of major deniers in the therapy group (minor/partial/major): baseline therapy group 4/4/2 vs control group 4/6/3; 9-month therapy group +2/0/−2 vs control group +1/0/−1; 15-months therapy group +2/0/−2 vs control group +2/−2/0.

The HbA1c levels were higher in the intervention than in the control group at time 2 measurement; however, the differences did not reach statistical significance. The HbA1c levels tended to decline at time 3 measurement in both groups. The number and duration of remissions (honeymoon) did not differ in the two groups (Table 1), and no patient was in remission at time 2 measurement.

When we excluded the one patient with poor treatment adherence, overall results did not change.

**Discussion**

Our study investigates in a randomized design the effects of an onset distress reduction program starting immediately after diagnosis of the disease in unselected adult type I diabetic patients.

Three months after termination of our intervention program, patients of the treatment group showed a more favorable level of depression and less anxious coping behavior compared to the control group, as well as reduced denial. At the follow-up visit 9 months after the end of the program, effects persisted in the field of denial. Metabolic control, however, did not differ in the two groups at any point of follow-up. Thus, our intervention demonstrates remission of after-onset depression and less anxious coping behavior in the short term, whereas reduced denial seems to be an important long-term result of our intervention.

Early denial in diabetic adults has been found to predict late complications in diabetic adults better than recent emotional well-being (15). Denial was not only found to reduce anxiety (44) but also to trigger anxiety (46). It has been suggested that lower denial has a better adaptational effect than higher denial in diabetic patients (15, 47). Low denial may prompt improved perception of the "stressor" diabetic illness, which leads to better analysis and confrontation with the illness and consequently may promote better management of it. Because decreased denial generally is linked to increased anxiety, it is notable that in our intervention group reduced denial was associated with low depression, low anxious coping behavior and unchanged STAI anxiety. These results indicate that reducing denial by distress reduction in our patients has not led to increased anxiety and depression. Based on these suggestions about the function of early denial and the fact that onset distress is a more potent predictor of long-term adaptation to illness than psychological processes occurring later during the disease process (5, 14–18), we believe that improved onset crisis and reduced denial in our patient group may have beneficial effects on diabetes management in the long term.

There may be several reasons, important for future research, why our kind of intervention had no effect on metabolic control. In view of the poor and contradictory correlations between affect and metabolism (13) and the individual patient's reactions to stress with hyper- and with hypoglycemia (48), we may assume that distress reduction may result in poor overall group effects of stress reduction on metabolic control.

Numerous important counter-processes in diabetes, which may neutralise the effects of improved mood on metabolic control, may be responsible for the lack of effect on metabolic control in our patients. A discrepancy has been observed between positive coping and overt adaptation in terms of manifest depression and anxiety (49) and no relationship has been found between depression and compliance (30). Spontaneous remission of depression after primary manifestation of diabetes onset depression has been found to be accompanied by spontaneous reduction of compliance (49). Diabetic patients who were most satisfied with their social support and who had the highest social abilities showed the poorest metabolic control (3). Diabetics who had hyperglycemia were seen to be in a better mood than diabetics who had near-normoglycemic blood glucose levels (50). A positive influence on psychological conditions thus does not
necessarily lead to better coping, and psychosocial support may have a counter-effect on metabolic control.

The primary aim of our intervention was to reduce diabetes onset distress in an unselected patient group after diabetes onset. Thus, no additional patient selection for our coping program and no tight attendance rate to the program was included in our study design, and our study may have predominantly addressed the question of whether the intervention shows benefits when administered universally in unselected recent onset diabetics. Psychological baseline values of many measures were therefore well within the normal range and did not indicate severe psychopathological or coping problems, thus possibly preventing the demonstration of a treatment effect and obscuring interpretation of negative results from these comparisons.

Our intervention occurred in newly diagnosed diabetics in whom residual insulin secretion is likely to be substantial and in whom HbA1c levels are very often close to the non-diabetic range. The study, thereby, may have undercut the possibility of seeing improved control in a setting of already optimized control. Even with an intensified insulin regimen, it is difficult to achieve metabolic control with an HbA1c level below 6.8% without the hazard of severe hypoglycemic reactions.

Because the number of subjects in our study is relatively small, the negative results cannot be supported with much confidence. Furthermore, there appear to be some differences between the groups at baseline that might have been statistically significant in a larger sample.

In summary, our study shows effects of a distress reduction program on onset crisis in the short term and on denial in the longer term, whereas no effect on metabolic control was found. Reduction of onset crisis together with lower denial may suggest benefits of our program on treatment adherence in the long term; however, future research is necessary for a definite answer to this question.

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References


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