Association of Socio-psychological Factors with the Effects of Low Protein Diet for the Prevention of the Progression of Chronic Renal Failure

Yoshie Kanazawa1,2, Toshiyuki Nakao1, Yumiko Ohya1 and Teruichi Shimomitsu1

Abstract

Objective Our objectives were to investigate the therapeutic effects of low protein diet (LPD) for chronic renal failure (CRF) in compliant patients with the diet, and to clarify the relationships to the socio-psychological factors.

Patients and Methods Sixty-five patients (47 men and 18 women) with CRF who followed LPD (0.69 g/kg/day) for more than 3 months were recruited in this study. Compliance with the diet therapy was strictly assessed by the patients’ dietary records, subsequent interviews regarding the status of daily dietary intake and estimated protein intakes calculated from urinary nitrogen excretion by 24-hour urine collections. The changes of glomerular filtration rate (GFR), serum creatinine (Cr), blood urea nitrogen (BUN), the reciprocal of serum creatinine (1/Cr), scores of Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), scales of Profile of Mood States (POMS), scores of self-efficacy and social support were investigated.

Results Decline rate of GFR, elevation of Cr and BUN and reduction in 1/Cr were significantly lower in compliant patients than in non-compliant patients (p<0.05). There were no differences in SF-36 scores between compliant and non-compliant patients. The POMS scales of depression/dejection were high in female non-compliant patients compared to other groups of patients (p<0.05). Self-efficacy score was higher in compliant patients than in non-compliant patients (p<0.05). Social support scores were significantly higher in male compliant patients than in others (p<0.05), and both emotional support and behavioral support showed interaction with both gender and compliance with diet therapy (p<0.05).

Conclusion LPD therapy is effective in suppressing the progression of CRF when it is well-adhered to. There are no correlations of this diet therapy to health-related QOL. Social support and high self-efficacy for men and high self-efficacy for women are associated with improvement of the compliance with LPD therapy, leading to good therapeutic effects.

Key words: SF-36, POMS, self-efficacy, social support, low protein diet

Introduction

Low protein diet (LPD) for chronic renal failure (CRF) can delay the onset of dialysis treatment by suppressing retention of uremic toxins (1-3). LPD is also expected to have an effect on retarding the decline of renal function itself (4-6). Thus, it has become established as a therapeutic measure for CRF (7, 8). On the other hand, some controversies concerning LPD for CRF remain, since recent prospective randomized controlled trials (RCT), in which patients were assigned to two groups: the usual protein diet group and LPD group, did not demonstrate significantly favorable effects (9, 10).

To obtain excellent therapeutic effects by diet therapy, the meal contents must be restricted to meet the purposes of treatment for the disease. Unlike drug therapy, it is necessary for patients to control their own appetite and to restrict...
intake of their favorite foods, and also it requires skill in food preparation and cooperation from the patients' family members. Thus, the diet therapy is a treatment method that needs proper execution in patients' daily life, with cooperation from the patients' family members as well as the participation of the patients themselves. The possible reason for the failure of the RCT on LPD is that patients who were assigned to each group did not always adhere to the prescribed diet (11). Therefore, in the evaluation of the effects of a diet therapy it is essential to accurately assess the pa-
patients’ compliance.

Since meal contents greatly differ from those of the usual meals in LPD therapy, we may have to consider relationships between continuing the diet therapy and patients’ QOL, psychological aspects and social factors. However, studies which systematically investigate this aspect are scarce.

Social support is considered as “an external source” surrounding patients with chronic diseases, whereas self-efficacy towards health behavior is considered as “an inner source” within the patients themselves. The relationship between diet therapy and social support has been reported in diseases such as diabetes (12), hypertension (13), obesity (14, 15), hyperlipidemia (15, 16) and phenylketonuria (17), and in all these studies it was observed that the strength of social support is related to an increase in compliance with diet therapy, leading to good therapeutic effects. A high self-efficacy was also observed to be related to improvement in compliance with diet therapy leading to good therapeutic effects (18-20). Thus, the effects of diet therapy must also be considered in relation to social support, the patient’s self-efficacy, behavioral patterns and dietary management status.

In LPD therapy for CRF, however, there has been no report simultaneously evaluating therapeutic effects, adherence to the diet, QOL, socio-psychological aspects and social support.

To investigate the therapeutic effects of LPD therapy for CRF when it is well-adhered to and to clarify the relationships to socio-psychological factors, we compared renal function decline rates and the scores of health-related QOL, psychological aspects, social support and self-efficacy between compliant and non-compliant groups of the patients with LPD on an outpatient basis.

**Methods**

(1) **Subjects**

Among the patients who visited the outpatient clinic of the

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Table 3. Deterioration Rates of Renal Function Parameters during the Follow-up Period

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔGFR (ml/min/1.73m²)</td>
<td>-0.06±1.308*</td>
<td>-0.74±1.160**</td>
</tr>
<tr>
<td>ΔScr (mg/dl)</td>
<td>0.04±0.080**</td>
<td>0.17±0.102**</td>
</tr>
<tr>
<td>ΔSerum creatinine (mg/dl)</td>
<td>-0.005±0.099*</td>
<td>-0.015±0.029*</td>
</tr>
<tr>
<td>ΔBlood urea nitrogen (mg/dl)</td>
<td>-0.213±1.492**</td>
<td>0.919±0.772**</td>
</tr>
</tbody>
</table>

M±SD

*p<0.05 compared to Group 2

**Table 4. SF-36 Scores**

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1-M</td>
<td>Group 2-M</td>
<td>Group 1-W</td>
</tr>
<tr>
<td>PF</td>
<td>75.5±14.3</td>
<td>79.7±19.6</td>
</tr>
<tr>
<td>RP</td>
<td>65.3±34.9</td>
<td>76.5±33.6</td>
</tr>
<tr>
<td>BP</td>
<td>74.7±22.8</td>
<td>70.2±18.6</td>
</tr>
<tr>
<td>GH</td>
<td>44.5±14.6</td>
<td>47.0±16.9</td>
</tr>
<tr>
<td>V T</td>
<td>55.0±19.1</td>
<td>54.1±21.7</td>
</tr>
<tr>
<td>SF</td>
<td>77.1±19.4</td>
<td>85.6±13.9</td>
</tr>
<tr>
<td>RE</td>
<td>71.1±40.8</td>
<td>68.6±41.6</td>
</tr>
<tr>
<td>MH</td>
<td>69.6±14.4</td>
<td>69.4±22.1</td>
</tr>
</tbody>
</table>

M±SD

*p<0.05 **p<0.01 ***p<0.001 compared to Control

Table 5. Physical Health Scores and Mental Health Scores of SF-36

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1-M</td>
<td>Group 2-M</td>
<td>Group 1-W</td>
</tr>
<tr>
<td>Physical health score</td>
<td>318.0±68.0</td>
<td>334.2±80.4</td>
</tr>
<tr>
<td>Mental health score</td>
<td>271.5±86.0</td>
<td>281.1±83.3</td>
</tr>
</tbody>
</table>

NS: not significant

M±SD

Table 6. POMS Scores

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1-M</td>
<td>Group 2-M</td>
<td>Group 1-W</td>
</tr>
<tr>
<td>T-A</td>
<td>11.2±3.8</td>
<td>10.9±5.4</td>
</tr>
<tr>
<td>T-D</td>
<td>13.9±7.6</td>
<td>17.3±10.3</td>
</tr>
<tr>
<td>A-H</td>
<td>12.4±7.8</td>
<td>8.4±5.9</td>
</tr>
<tr>
<td>V</td>
<td>12.6±4.9</td>
<td>11.7±6.4</td>
</tr>
<tr>
<td>F</td>
<td>10.1±5.9</td>
<td>10.0±4.3</td>
</tr>
<tr>
<td>C</td>
<td>8.1±3.3</td>
<td>7.2±3.8</td>
</tr>
</tbody>
</table>

M±SD

*p<0.05 **p<0.01 ***p<0.001 compared to Control

Figure 1. Self-efficacy scores

In LPD therapy for CRF, however, there has been no report simultaneously evaluating therapeutic effects, adherence to the diet, QOL, socio-psychological aspects and social support.

To investigate the therapeutic effects of LPD therapy for CRF when it is well-adhered to and to clarify the relationships to socio-psychological factors, we compared renal function decline rates and the scores of health-related QOL, psychological aspects, social support and self-efficacy between compliant and non-compliant groups of the patients with LPD on an outpatient basis.

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In the Nephrology Department of Tokyo Medical University Hospital during the period between July and September, 2003, we studied 65 patients (47 men and 18 women) with CRF who had followed the LPD therapy for more than 3 months after the initial guidance. Their mean age was 61.8±10.6 years old. The primary disease was chronic glomerulonephritis in 41 patients, diabetic nephropathy in 18 patients, and other renal diseases in 6 patients. The mean protein intake prescribed was 0.69±0.07 g/kg/day and energy prescribed was 32±2 kcal/kg/day. The mean observation period was 29.9±19.4 months. All studies were conducted in accordance with the principles set out in the Declaration of Helsinki revised in 2002, and informed consent was obtained from all patients.

(2) Assessment of compliance with the diet therapy and rate of renal function decline

Based on the patients’ dietary records for 3 consecutive days, the actual intakes of energy and protein were calculated using the 5th Edition Food Component Table (21) at every hospital visit, and 24-hour urine samples were collected and the estimated protein intake was calculated from the protein catabolic rate (PCR) by applying urea kinetic modeling according to Maroni’s method (22). If an estimated protein intake was discrepant between the dietary record and 24-hour urine sample, which typically occurred when dietary records were roughly written, we relied on the 24-hour urine sample. Furthermore, the patients were interviewed regarding the status of dietary intake of all days during the period between outpatient visits. The days when the prescribed diet was adhered to, with actual daily intake of protein less than +3 g and that of energy was not less than -100kcal, were judged as compliant days. The patients whose percentage of compliant days was 60% or more a month were classified as the compliant group (Group 1), which was further classified by gender into men (Group 1-M) and women (Group 1-W). In contrast, the patients whose percentage of compliant days was less than 60% a month were classified as the non-compliant group (Group 2) which was further classified by gender into men (Group 2-M) and women (Group 2-W). In addition, we investigated the frequencies of the use of specially manufactured low protein foods (23) among each patient group.

Decline of renal function was assessed by changes in the glomerular filtration rate (GFR), serum creatinine (Cr) and the reciprocal of serum creatinine (1/Cr). GFR was calculated from the mean values of creatinine clearance (Ccr) and urea clearance (Curea) as (Ccr + Curea)/2 based on 24-hour urine collection (24). The renal function decline rate and blood urea nitrogen (BUN) elevation rate during the observation period were calculated as monthly changes (\(\Delta GFR, \Delta Cr, \Delta 1/Cr, \Delta BUN\)).

(3) Assessment of QOL

QOL assessment was conducted using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) which is consisted of 8 categories of subscales: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH) (25). The SF-36 scores of age- and sex-matched Japanese national standard values (26) were adopted as the control for men (control-M) and women (control-W).

(4) Assessment of psychological aspects

As an assessment method for psychological aspects, scales of Profile of Mood States (POMS) (27) and self-efficacy score (28) were used as parameters. Six mood scales of POMS: tension-anxiety (T-A), depression-dejection (D), anger-hostility (A-H), vigor (V), fatigue (F), confusion...
(C) were calculated, and compared to the standard national average scores in men (control-M) and women (control-W) aged over 60 (29). A self-efficacy survey was conducted by self-assessment whether the patients had confidence in managing their illness, and the results were expressed by a scale ranging from 0 to 100 points, with 100 indicating the maximum level of confidence.

(5) Social support

Social support was investigated with respect to emotional and behavioral supports, using social support measures for patients with chronic diseases (28).

(6) Statistical analyses

For statistical analyses, Student’s t-test, Fisher’s PLSD and multi-factor analysis of variance were applied using StatView software for Windows. A p value of less than 0.05 was considered to indicate a statistically significant difference.

Results

(1) Compliance with diet therapy and renal function decline rate

Group 1 contained 38 subjects (58.5% of the total) consisting of 30 Group 1-M and 8 Group 1-W. Group 2 consisted of 27 subjects (41.5% of the total) with 17 in Group 2-M and 10 in Group 2-W. There were no significant differences in gender, age and primary diseases. There were also no significant differences in blood pressure, GFR, urinary protein excretion, blood biochemical data and frequencies of medications between Group 1 and Group 2 at the time when the diet therapy was introduced (Table 1). The person preparing meals was more frequently the spouse in Group 1-M than in Group 2-M (p<0.01), but there were no significant differences between Group 1-W and Group 2-W. The duration of the diet therapy was not significantly different between Group 1 and Group 2. At the time when the study was conducted, the energy intake was significantly higher and both protein intake and PCR were significantly lower in Group 1 than in Group 2 (p<0.001). There were no significant differences between the two groups in the levels of blood pressure, urinary protein excretion, hematocrit, hemoglobin, serum Cr, sodium, potassium, calcium, and albumin, and in the frequencies of medications. GFR, BUN and Cr were significantly lower in Group 1 than in Group 2 (p<0.001, Table 2).

Regarding the consumption of the specially manufactured low protein foods provided as staple foods (rice, bread, noodles), percentages of male patients consuming them for 1 to 3 meals per day were 96.6% in Group 1-M and 33.3% in Group 2-M, being significantly higher in Group 1-M (p<0.01). Similarly, percentages of female patients consuming those foods were 87.5% in Group 1-W and 40.0% in Group 2-W, significantly higher in Group 1-W (p<0.05). Those consuming supplementary foods as energy supplements (cookies, gelatin, etc.) 1 to 3 times per week were 56.7% in Group 1-M and 5.9% in Group 2-M, significantly higher in Group 1-M (p<0.05), but women consuming the foods were 25% in Group 1-W and 20% in Group 2-W, showing no significant differences between the two groups.

Table 3 shows the rates of parameters of renal function decline and blood urea nitrogen elevation during the period from the beginning of the diet therapy until the end of the observation period in Group 1 and Group 2. ΔGFR, ΔCr, Δ1/ΔCr and ABUN were significantly lower in Group 1 than in those of Group 2 (p<0.05, p<0.001, p<0.05, p<0.001), indicating that the renal function decline rate was significantly suppressed in Group 1 than in Group 2.

(2) Assessment of QOL

There were no significant differences between Group 1-M and Group 2-M in each subscale of the SF-36. However, when compared to control-M group, GH, VT, SF were significantly lower in Group 1-M (p<0.001, p<0.05, p<0.05) and GH and VT were significantly lower in Group 2-M (p<0.01, p<0.05) (Table 4). Similarly, there were no significant differences between Group 1-W and Group 2-W in each subscale. However, compared to control-W group, RP and GH were significantly lower in Group 1-W (p<0.05, p<0.001) and GH was significantly lower in Group 2-W (p<0.001, Table 4). There were no significant differences with respect to summary scores of both physical health factors (PF, RP, BP, GH, VT) and mental health factors (GH, VT, SF, RE, MH) among the patient groups (Table 5).

(3) Assessment of psychological aspects

In the assessment of POMS scores with respect to subjective aspects of mood and emotion, no significant differences were found between Group 1-M and Group 2-M. However, when compared to control-M group, D, A-H and F were significantly higher in Group 1-M (p<0.001, p<0.01, p<0.01), and D and F were significantly higher in Group 2-M (p<0.001, p<0.01, Table 6).

On the other hand, D was significantly higher in Group 2-W compared to Group 1-W (p<0.05). When compared to control-W, F was significantly higher in Group 1-W (p<0.01) and D and F were significantly higher in Group 2-W (p<0.001, p<0.05, Table 6).

The mean self-efficacy score was 73.0±17.8 in Group 1-M, 61.5±18.8 in Group 2-M, 76.3±13.3 in Group 1-W, and 58.5±15.8 in Group 2-W, indicating a significantly higher score in Group 1-M than in both Group 2-M and Group 2-W and in Group 1-W than Group 2-W (p<0.05, Fig. 1).

(4) Social support

The mean score of emotional support was 42.1±6.4 in Group 1-M, 36.9±9.8 in Group 2-M, 32.1±11.5 in Group 1-W, 37.3±9.8 in Group 2-W, indicating that the score in Group 1-M was significantly higher than that in Group 1-W (p<0.01, Fig. 2-A). The mean score of behavioral support
was 25.9±5.2 in Group 1-M, 21.6±6.4 in Group 2-M, 18.3±6.6 in Group 1-W, 20.7±6.4 in Group 2-W, indicating that the score in Group 1-M was significantly higher than those in Group 2-M, Group 1-W and Group 2-W (p<0.05, p<0.01, p<0.05, Fig. 2-B). Both emotional support and behavioral support showed interaction with both gender and compliance with diet therapy (p<0.05).

The mean summary score of social support (sum of emotional support and behavioral support) was 68.0±11.3 in Group 1-M, 58.5±5.6 in Group 2-M, 50.4±17.7 in Group 1-W, and 58.0±15.0 in Group 2-W, indicating that the score in Group 1-M was significantly higher than those in Group 2-M, Group 1-W and Group 2-W (p<0.05, p<0.01, p<0.05). Significant correlation between the total scores of social support and the scores of self-efficacy was found only in Group 1-M (p<0.01, Table 7).

**Discussion**

In the present study, we investigated relationships among the therapeutic effects of LPD, execution of diet therapy and patients’ socio-psychological factors, comparing the compliant patient group to non-compliant patient group with the diet. Based on our results, adherence to LPD was considered to be closely related to the effect of suppression of progression of CRF. The results of the present study reconfirm the previous meta-analysis reports on the effects of LPD for CRF (4-6).

In the present results, the frequencies of the use of low protein rice, noodles and breads that are specially manufactured for staple foods was higher in the compliant group than in the non-compliant group. Furthermore, consumption of supplementary foods for supplying additional energy was significantly higher in the compliant group, as well. Therefore, for compliance with LPD therapy, the use of specially manufactured protein reduced foods is considered to be essential.

In a previous study on patients with CRF, the QOL scores were reported to decrease in correlation with the glomerular filtration rate (30). Low values in all subscales of the SF-36 were observed in patients with serum creatinine levels exceeding 8 mg/dl just before the initiation of maintenance dialysis therapy (31, 32). The severity of renal anemia was indicated to be related with the low QOL scores (33, 34). Low QOL scores were also observed in patients with CRF on maintenance dialysis therapy (34, 45) and their scores were even lower than those of patients with conservative-stage renal failure (36). The present results also showed significantly lower scores of GH, VT, PF and RP of SF-36 in CRF patients than in controls, but no significant differences were found in the QOL scores between compliant and non-compliant patients to LPD. Therefore, there appears to be little relationship between adherence to the diet therapy and impairment of health-related QOL, suggesting that the disease state of renal failure itself is related to low values of the SF-36. However, since there were no significant differences in BP, RE and MH compared to the national average, it was considered that the patients have no systemic pain and their mental state is stable. There were no significant differences in the subscales of both physical and mental health factors among the groups, so that compliance and non-compliance with the diet therapy was thought to have little impact on the aspects of physical health and mental health.

Assessment of psychological aspects using POMS has been used in a variety of areas including cancer, AIDS, cardiac diseases, sports psychology (37) and occupational stress (38) in addition to psychiatric diseases, and its usefulness has been proven. However, studies on the POMS scores of the patients practicing diet therapy are very limited. In a previous study on energy-restricted diet therapy, no changes in the POMS scores were observed after performing the diet (39). In the present study, the higher scores of D, A-H and F were observed in male patients irrespective of compliance with LPD, and those were considered to be related to the disease state of renal failure itself and there was little relationship between adherence to the diet therapy and the POMS scores. However, in the female patients the scores of D in the non-compliant group were significantly higher than those in both the compliant group and control group. We could not explain whether non-compliance with the diet therapy caused depression/dejection or the depression/dejection caused non-compliance with the diet therapy.

Regarding the roles of social support and self-efficacy in the diet therapy for CRF, studies concerning the restriction of salt and water intake in hemodialysis patients have been reported (40-44). In those studies, as seen in other diseases, the stronger the social support that the patients received, or the higher their self-efficacy, the better was their compliance with diet therapy, and it was concluded that these factors are interrelated with results in improvement in therapeutic effects.

In the present study, higher behavioral support to meal preparation and medicine ingestion was associated with the higher compliance with LPD therapy in male patients. The percentage of spouses among persons preparing meals in male patients was significantly higher in compliant group than in non-compliant group with LPD, and this was considered as a factor contributing to the higher behavioral support scores in compliant male patients. On the other hand, compliant female patients showed significantly lower scores in both emotional support and behavioral support than compliant male patients, suggesting that compliance with LPD among female patients is not related to support status. Since women prepare meals by themselves regardless of the presence of family or spouses, those who have higher self-efficacy and higher self-management consciousness were thought to adhere more closely to the diet therapy. In this study, the self-efficacy scores were significantly higher in the compliant patients than those in the non-compliant patients, suggesting that adherence to the diet therapy leading to suppression of progression of renal function decline at-
tributes to the increase the self-efficacy. In addition, we found a significant correlation between social support scores and self-efficacy scores in the compliant male patients so we found a significant correlation between social support scores and self-efficacy. In conclusion, LPD therapy is effective in suppressing the progression of renal function decline when it is well-adhered to. No correlations were found between this diet therapy and health-related QOL scores. Social support and high self-efficacy for men and high self-efficacy for women are important to improve compliance with LPD therapy for CRF.

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