

Economic Impact of Nutrition Counselling in Patients with Crohn's Disease in Canada

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Abstract

The costs and benefits of individualized nutrition counselling in a group of non-hospitalized subjects with Crohn's disease was compared to a control group who did not receive counselling. Fifty-nine subjects received counselling once monthly for six months, while 66 individuals did not receive counselling. The demonstrated net savings to society as a result of nutrition counselling was \$164 per person. The saving resulted from the reduced medication usage, decreased days lost from work and decreased hospitalization of the counselling group compared to the no-counselling group. In a smaller group of individuals, followed for a period of one year with monthly counselling, the significant difference in days lost from work between counselling and control groups continued, but no net quantifiable savings resulted. This is the first demonstration of the cost-effectiveness of individualized nutrition counselling in Crohn's disease. It is one of the few studies of the economic impact of nutrition counselling with an adequate control group. The economic benefits of nutrition counselling in non-hospitalized patients with Crohn's disease justifies the costs and should be promoted.

Résumé

On a comparé les coûts et les avantages de la consultation individualisée en nutrition auprès d'un groupe de sujets non hospitalisés atteints de la maladie

de Crohn et d'un groupe témoin qui ne recevait pas de consultation. Au total, 59 sujets ont reçu un traitement diététique une fois par mois pendant six mois, tandis que 66 autres n'en recevaient aucun. L'économie nette pour la société, entraînée par la consultation, s'est chiffrée à 164 \$ par personne. Cette économie résulte du moindre usage de médicaments, de la diminution de journées perdues au travail et de la durée réduite d'hospitalisation chez le groupe traité en consultation comparativement au groupe témoin. On a suivi un plus petit groupe de sujets pendant un an en leur donnant une consultation par mois; la différence entre le nombre de journées de travail perdues chez le groupe recevant une consultation et le groupe témoin restait significative, mais l'économie nette quantifiable était nulle. Cette étude est la première à démontrer la rentabilité de la consultation diététique individualisée auprès de sujets atteints de la maladie de Crohn et elle constitue l'une des rares études sur les conséquences économiques de la consultation en nutrition avec un groupe témoin adéquat. Les avantages économiques de la consultation en nutrition chez des patients non hospitalisés atteints de la maladie de Crohn justifient les coûts et cette approche devrait être encouragée.

The cost-effectiveness of individual nutrition counselling as part of chronic disease treatment remains unproven for many areas of dietetic practice (1,2). Kaplan suggests that it may be impossible to prove the effectiveness of such counselling when the benefits are postulated to occur far in the future (3). If benefits can be shown to occur in the

near future, as with prenatal diet counselling (4), it becomes easier to prove the worth of such counselling.

Crohn's disease is a chronic, progressive, inflammatory gastrointestinal disease of unknown etiology, characterized by spontaneous exacerbations and remissions (5). There is no known cure. Medical therapy is directed at improving the patient's symptoms and attempting to reduce the disease activity and its complications (5). The disease is relatively uncommon, with a worldwide prevalence of 22-50 cases per 100,000 persons (6). A higher prevalence rate has been reported for Western Canada (7). The economic costs to the individual and society can be substantial because it usually affects young adults, who may be establishing careers and families.

Nutritional deficiencies associated with Crohn's disease have been extensively documented (8,9). Nutritional therapy, in the form of total parenteral nutrition and elemental formula diets, has been advocated as a means of promoting remission in the adult with active disease (10). Less attention has been directed toward nutritional therapy for patients with less active disease. One group has promoted the use of high fibre diets (11) while another group has used exclusion diets in an attempt to identify foods that are not well tolerated (12). Both studies were done with small groups of patients. In clinical practice, most non-hospitalized patients do not receive from a dietitian formal diet counselling promoting improved nutritional status. The study

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upon which the analysis in this paper is based, used individualized diet counselling broadly based on Canada's *Food Guide* and the known nutritional complications associated with this disease.

It was postulated that diet counselling should improve nutrient intakes and nutritional status. This, in turn, might lead to changes in disease activity measured by the Crohn's Disease Activity Index (CDAI) (13,14). This is the most widely known of several indices meant to quantify the clinical severity of this disease. The economic effects of a change in disease activity would include changes in the type and rate of utilization of health care services as well as effects on the individual's ability to function in society (1).

Methods

Study design

The client population and course of the study are fully described elsewhere (15,16). Briefly, 137 non-hospitalized individuals with Crohn's disease volunteered to participate in the study and were randomly assigned to either the counselling (C) or no-counselling (NC) group for a six-month period. Sixty-seven subjects began the counselling program, with eight of these dropping out. Seventy subjects started in the NC group, with four subjects dropping out. Four people in the counselling group dropped out either because of problems using public transportation (two) or unwillingness to continue (two). The rest, from both groups, either moved from the city or were excluded because of conditions unrelated to the counselling, such as pregnancy.

Attending physicians were blinded as to the randomization of subjects. Standard and appropriate medical management by the subjects' usual physicians was continued. Medical management was not monitored.

All subjects, regardless of randomization, received a nutritional assessment by a dietitian at study entry and at three and six months. This nutritional assessment consisted of a 48-hour dietary record, anthropometric measurements and laboratory tests.

Information was also collected for calculation of the CDAI, medications taken, hospital admissions, surgery and number of days of work lost due to Crohn's disease if subjects were employed full-time outside the home. The results of the nutrition assessments were forwarded to all participants' physicians after a delay of three months, unless, in the opinion of the medical director of the study, more urgent referral was necessary. Members of the NC groups did not receive advice about diet habits or food choices during these three nutrition assessment sessions.

Counselling occurred at approximately monthly intervals in a general outpatient clinic of a major teaching hospital. Including the three complete nutritional assessments, the median number of sessions was six per subject over six months. The aim of counselling was to normalize each subject's nutritional status as indicated by diet records, anthropometric measurements and laboratory data. Advice regarding food intake was given. Use of special foods or supplements was not promoted. Teaching materials consisted of a one-page tearsheet of Canada's *Food Guide*, which was provided free. Each counselling session took about one hour. Appointments were arranged by telephone by the dietitians involved in counselling to suit each subject's schedule.

Counselling outcome

As a result of counselling, nutrient intakes did change and the nutritional status of some counselled patients improved (15,16). The C group began the study with a significantly higher mean CDAI (132 ± 106 vs 92 ± 84) and age (35.5 ± 12 vs 31 ± 9.3) ($p < 0.05$) than the NC group. In order to diminish differences at entry between C and NC covariate analysis was used to assess the effect of counselling on disease activity. There was a significant decline in CDAI with counselling ($p < 0.05$) (15). Twenty-two percent of counselled individuals went from active to inactive disease activity at six months, compared to 8% in the no counselling group ($p < 0.05$). Conversely, the disease became active in 12% of C, compared

to 18% of NC (N.S.) (15).

Drug usage was monitored, with the two major drugs being prednisone and sulfasalazine. Covariate analysis indicated that counselling was associated with a significant ($p < 0.05$) decrease in the amount of sulfasalazine required, a difference of 0.5 g/d/patient (15).

There was also a significant difference in the total days of hospitalization due specifically to Crohn's disease for the two groups, 155 days (C) vs 216 days (NC) ($p < 0.05$) by Irwin-Fisher exact test. Medical records confirmed the reasons for admission.

As Crohn's disease strikes young adults, the issue of economic productivity may be a significant component of the costs of this disease to society. Self-reported days missed from work outside the home due to Crohn's disease specifically, were used as an estimate of the impact of the disease. The effects of other illnesses, such as colds and influenza, were not consistently monitored. The work of housewives and students was not calculated (17 subjects C, 19 subjects NC). Housewives may have diminished functional ability without having a direct impact on the economic productivity of society. The results of the study, with 297 total missed workdays for C, compared to 507 for NC ($p < 0.01$), represents an under-estimate of the effects on economic productivity because part-time workers were not counted and work in the home does have an economic value. No one type of employment predominated among study subjects. They were not asked to provide details as to salary range.

Cost analysis methods

The societal perspective is taken in calculating the costs and benefits of counselling which have been identified (17,18). Costs are classified as direct, indirect and intangible. Information as to direct costs was gathered from within the tertiary care hospital where the research was conducted for the year 1981 when the majority of the subjects were seen. Analysis of costs based on research studies can use one of two approaches. The actual costs of the study can be computed or the costs of

performing the work as part of routine clinical practice can be estimated. Opinion in the literature as to the appropriate method is divided (17). In this case, actual research study costs for laboratory testing, computer time and data analysis were very high, while labour costs for data collection and counselling were a fraction of the usual employee costs. Therefore, the costs of counselling in clinical practice have been estimated, using the data from this research study, including the number of counselling sessions, educational materials used, laboratory costs and other possible costs (Table 1).

The estimate of salary cost is based on workload measurement studies conducted with outpatient clinical dietitians in the same institution. For each hour of counselling, dietitians spent two hours doing all the other administrative duties associated with their jobs, including appointment-setting, charting and interaction with other health team members.² It is assumed that each counselling session for the C group took one hour of contact time, as distinct from data collection time.

Space costs of clinic areas in hospitals are not readily available. Since diet counselling does not require anything beyond simple office space, a private sector cost was used. Laboratory costs were based on the reimbursement schedule of the Alberta Health Care Insurance Plan to private laboratories. The chemistry panel and complete blood count were done three times over the course of the study. Usually these tests would not be repeated so often if normal the first time. On the other hand, other more specialized tests may be required at times. These costs are judged to be a reasonable estimate of the laboratory costs for this type of patient.

The costs of food for the recipients probably would not change substantially as a result of counselling since this group does not require specialized food products. Some therapeutic diets, such as the diabetic diet have been

Table 1 Costs of diet counselling subjects with Crohn's disease for six months in 1981

	\$ Cost
Dietitian salary ¹	12,174
Fringe benefits ²	1,948
Office space ³	3,240
Telephone ⁴	351
Secretarial costs ⁵	396
Paper	50
Education materials	10
Laboratory costs ⁶	2,782
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Total	20,951
Per patient completing study	355

¹Median hourly gross salary \$11.90/h x 3 h/session x 341 sessions.

²Estimate 16% of gross salary.

³Average costs \$108/m²/mo. x 5 m² x 6 mo.

⁴Installation costs of \$150 plus rental of \$33.51/mo. x 6 mo.

⁵Median hourly gross salary (junior secretary) \$8.00/h x 1/20 time x 6 mo. x 1.16 (benefits)

⁶[7.00 (CBC) + 12.00 (Chemistry panel)] x 0.8 x 183 tests.

shown to increase food costs (19).

The indirect cost of loss of work time to attend counselling sessions was not calculated. This cost is often mentioned, but seldom, if ever, calculated in these types of studies. In most cases patients came for counselling in their leisure time. Since all patients lived in the city, travel time was not substantial.

Benefits analysis

The benefits of counselling accrued quickly over the course of the study (Table 2). Categories of benefits to be considered are health resource benefits, economic benefits, social benefits and personal benefits. Health resource benefits were taken as the statistically significant differences in drug usage and hospitalization. Physicians were blinded as to the randomization of their patients, but were aware of their participation in the study. One could hypothesize that study participants received extra monitoring or care from physicians, compared to the average patient, but this would apply equally to both C and NC groups. Other health care services, such as physical therapy would not be affected by nutrition counselling.

The major economic benefit was the increased productivity of the C group as evidenced by a decrease in days away from full-time work. Whether the cost of sick time is borne by the employer or the patient, it is a real cost to society.

Social and personal benefits were not documented but would include the

quality of family life where one partner is ill some of the time.

Results

From the societal perspective, the average costs of sulfasalazine, hospitalization and days missed from work for the NC group amounts to \$1994/patient over the six-month period (Table 2). No costs for nutrition counselling are incurred, however, which mimics the present situation for the non-hospitalized individual with inactive Crohn's disease. With nutrition counselling, costs of these items decrease to \$1475/patient, a difference of \$518/patient. The estimated cost of counselling is \$355/patient (Table 1), resulting in a net demonstrable benefit of \$163.90/patient counselled.

As part of the original study design one-half of each group (C and NC) was further randomized at six months to receive a defined formula supplement (20). Fifty-eight subjects, (29C, 29NC), were followed for one year with nutrition counselling as the only variable. The results for this group in terms of benefit to cost over one year are based on no significant difference in drug usage and hospital utilization, but a continued significant difference in days away from work of 202 (C) to 284 (NC) ($p < 0.05$). This decrease in days absent from work saved society \$5951 for C compared to NC, or \$205 per person counselled. The costs of providing 10 one-hour sessions of counselling to 29 subjects, over one year, calculated on

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Table 2 Economic impact of diet counselling subjects with Crohn's disease for six months in 1981

	No Counselling Group (n = 66)	Counselling Group (n=59)	Difference
	\$	\$	\$
Sulfasalazine ¹	24,601	15,119	
Hospitalization ²	70,200	50,375	
Days away from work ³	36,793	21,553	
Total	131,594	87,047	
Per patient completing study	1,993.85	1,475.37	518.48

¹Wholesale price (1981) plus 100% mark up (16) = \$1.28/g.

²Cost/patient day = \$325/d (Urban hospitals in Alberta exclusive of newborns, all costs except physician fees, 1981.)

³Average weekly earnings, unadjusted for seasonal variations, industrial composite for urban areas, 1981 average for Edmonton - \$362.87/5 = \$72.57/d.

the same basis as previously, amounted to \$18,205, or \$628 per person counselled. The net cost of providing counselling for one year was \$423 per person.

Discussion

Studies of the cost-effectiveness of nutrition counselling have been justifiably criticized for poor design (2). In this study these problems have been addressed in so far as is possible in a situation where subjects cannot be blinded to their treatment. The control group in this study was randomly assigned. Since these individuals would be aware of nutrition even though they were not receiving counselling, the beneficial effects of counselling would tend to be obscured, rather than overstated. The groups were large enough so that smaller effects might be detected. Nutrition counselling was the only variable and enough follow-up was done to promote the desired dietary changes.

As usual in a study of this type, the participants were self-selected. They appear, however, to represent a reasonable cross-section of the Crohn's patients seen in medical practice. As a group, they were neither more sick nor substantially more healthy than average. The mean days in hospital per admitted patient, 11.1 (C) vs. 13.5 (NC), can be compared to the mean days for regional enteritis (International Code of Diseases No. 555) in Alberta of 14.4 days for 1981.³ It is estimated that the study participants represented about one-third of the total number of Crohn's patients in the Edmonton area at that time.

The drop-out rate of 12% compares very favourably with other studies of diet counselling (2). One could not necessarily expect comparably low drop-out rates if diet counselling was made available to all Crohn's patients. This is the problem of scale. There is no adequate way to judge the effects of scale in these subjects. Individuals with Crohn's disease tend to be very aware of the food they eat, because of the often direct relationship between food and symptoms of pain and diarrhea. Even if only 25% of all Crohn's patients are amenable to counselling, the benefits to society at large may more than justify the costs to the health care system.

On considering the costs of counselling, a model of outpatient clinical dietetic practice from the same hospital was used. This is not to say that this model is the most cost-effective in terms of service delivery. Many departments have appointments set by secretaries. Telephone follow-up may be much more extensively used. The results with the smaller group over one year illustrate how high fixed costs and many counselling sessions may increase the cost of a project substantially. The ideal number of counselling sessions is not known and will vary depending on the individual patient. In addition, adequate screening would direct counselling resources to those clients in most need of intervention. For this study, volunteers were accepted into the protocol if they fulfilled the study criteria regardless of nutritional status (15).

Costs to the subject in receiving

counselling were not considered, since special dietary products were not encouraged and every effort was made to accommodate the patient's schedule. There is no doubt that there is a cost to the subject in time, if not in money. Obviously, most subjects considered the cost worthwhile as evidenced by the low drop-out rate.

The intangible costs of the stress of making dietary changes could not be quantified, but may have been relatively minor compared to the stress of having a chronic illness with no cure. Indirect and intangible costs, while real, are extremely difficult to quantify, and must remain an unresolved problem.

Overall, every effort was made to estimate costs realistically, as if the subjects were counselled as outpatients in a tertiary care hospital. This was felt to be the best way to address concerns that the labour costs for research studies may be a fraction of real market costs and that the benefits may then be overstated (2).

Documenting the economic benefits of diet counselling is more difficult. The CDAI was the primary response criterion of the study. It was designed to be a numerical indicator of inflammatory activity, not functional well-being or general health status (21,22). Relating changes in this index to economic benefit or quality adjusted life-years is currently impossible (17,18). Use of indexes of functional well-being or health status (23) in future work would provide a means of evaluating the benefits of nutrition counselling on quality of life.

The findings of a significant benefit of counselling as evidenced by days away from work because of Crohn's disease was unexpected at the beginning of the study. Future work will need to address such issues as the economic contribution of housewives, effects on productivity in the workplace, and the incidence and effects of concurrent illnesses such as colds and influenza. The economic benefits in the workplace may be substantially greater than has been documented by this study.

The results also show how the number of subjects can dramatically affect the perceived effectiveness. The differences between the two groups were not large,

so that 58 subjects (29C,29NC) was not sufficient to demonstrate the effectiveness of diet counselling.

In most economic studies, it is necessary to discount future benefits to account for the fact that money spent on one activity would have had alternative uses (17,24-27). This was not necessary as no future benefits were postulated. It is not unreasonable to assume, however, that there is a residual effect of diet counselling. For example, if a residual effect on days away from work persists, such that counselling results in 90% as much absenteeism, at a discount rate of 8%, over five years, then society would save an additional \$1850 per subject counselled. The actual carry-over of the effects of counselling is unknown at this time. This study represents a first attempt to apply cost-effectiveness methodology to a study of the effects of diet counselling in a group of patients with Crohn's disease. Since this is the first study of individualized diet counselling in Crohn's disease, the results need to be substantiated by others to confirm the benefits observed. It appears that large groups of subjects may be required to document fairly subtle changes in nutritional status, yet the impact on social function may be substantial.

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