Cost Analysis of the Treatment of Severe Spinal Spasticity With a Continuous Intrathecal Baclofen Infusion System

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Abstract

Objective: The purpose of our study was to analyse and evaluate the costs of continuous intrathecal baclofen administration as a modality in the treatment of severe spasticity in the Netherlands.

Design: A cost analysis was conducted as part of a prospective, multicentre, multidisciplinary, randomised and placebo-controlled clinical trial. The study covered the period from December 1991 to September 1995. The data on medical consumption and costs were collected over a 3-year period from different sources: administrative databases of health insurance companies, hospital registries and a patient survey. These data were structured by means of a flowchart analysis of the medical decision-making by specialists and general practitioners (GPs). They included data on in- and outpatient care, home care and care in nursing homes.

The cost analysis was conducted using data from 18 patients included in the trial and from 15 so-called 'match' patients. The latter group are patients with comparable diseases leading to spasticity and living in comparable circumstances. Next to absolute costs (direct and indirect) of care and treatment for the 2 groups of patients, cost differences between the 2 groups were considered (differential cost analysis).

Setting: Per patient cost data, collected prospectively for 2 years during the phase of clinical evaluation, and retrospectively 1 year before implantation. The data were collected on patients from in- and outpatient care, home care and care in nursing home settings.

Patients and participants: The trial patients (8 men) had a mean age of 46 years; 11 patients had multiple sclerosis and 7 patients had spinal cord injuries. The match patients (7 men) had a mean age of 48 years; 9 patients had multiple sclerosis and 6 patients had spinal cord injuries.

Interventions: Trial patients were treated with a subcutaneously implanted programmable continuous infusion pump (SynchroMed, Medtronic), filled with bac-

lofen (a muscle relaxant) to treat patients with chronic disabling spasticity who did not respond to a maximum dose of oral baclofen, dantrolene and tizanidine.

Main outcome measures and results: An analysis of hospital stay between both groups showed a significant difference during the implantation year. The average number of hospital days per patient in that year in the treated group was 31.5 days and in the match group was 18.7 days. Significant cost differences between both groups in the year that started with pump implantation and the following year can be attributed mostly to the costs of implantation of the pump and related hospitalisation days. The total costs of patient selection, testing, implanting the pump and follow-up amounted to \$US28 473 for the first year. Savings must be taken into consideration as well. The savings of direct costs were due to withdrawal of oral medication (estimated annual total of between \$US1950 and \$US2800 per patient). Indirect savings on employment and nursing home costs, amounted annually to \$US1047 and \$US5814, respectively.

Scenarios make it possible to consider policy consequences. The case of 'extending' the indications for this treatment to a larger population has been calculated and visualised.

Conclusions: The costs of the therapy (continuous intrathecal infusion of baclofen) can be attributed mostly to implantation of the pump and related hospitalisation days. Savings originated from withdrawal of oral medication, job preservation and avoidance or delay of admission to a nursing home.

The efficacy of continuous intrathecal baclofen as a therapeutic treatment for spasticity of spinal origin has been reported.^[1-12] Within certain conditions, it is relatively safe and effective.^[13] However, operation-related and medicine-related complications must be taken into account.

This is confirmed for the Dutch situation by our study.^[14,15] In our study, all patients improved significantly and substantially according to clinical efficacy measures (Ashworth scale, spasm score and self-reported pain); improvement was seen in the physical dimensions of the sickness impact profile (SIP). The efficacy of this treatment in terms of clinical and health-related quality of life (HR-QOL) measures is therefore established. The implanted pump was telemetrically started after implantation. The initial pump velocity was based on the patient's response during the test phase. If a patient's response had been satisfactory with 75µg of baclofen, the initial dosage was twice that dose (150µg = 6.25 µg/hour; 150/24 = 6.25). If response proved unsatisfactory, the velocity of the pump was increased by 10%. The aim of this article is to ana-

lyse the costs associated with intrathecally administered baclofen.

The objective of the cost analysis part of the study was to provide information that could underpin the policy decisions of health insurance companies with respect to financial reimbursement of this treatment modality on a population basis. The Dutch Sickfund Council financially supported this study to confirm the medical efficacy and to assess the quality of life and costs of treatment in the Netherlands.

Materials and Methods

Clinical Study Design

In the clinical part of the study, 36 patients [18 with multiple sclerosis (MS) and 18 with spinal cord injury (SCI)] were included in the trial during the period from December 1991 to September 1995. During this period, 35 received a subcutaneously implanted programmable device for continuous intrathecal administration of baclofen. From this sample of patients, however, integral cost data

could only be collected from the first wave of 18 patients during the evaluation period because of financial support restrictions. The study in which the clinical efficacy was evaluated can be characterised as a prospective, multicentre, multidisciplinary, randomised and placebo-controlled clinical trial. The design of the cost part of the study was prospective measurement costs 2 years after implantation and retrospective measurement costs 1 year before implantation. The research consisted of the following phases:

- patient intake (by using a set of inclusion criteria)
- testing responsiveness of patients on intrathecal baclofen. Testing was aimed at establishing patient's sensitivity of responsiveness to baclofen. Every other day, either baclofen or placebo was randomly administered by intrathecal bolus injections through a spinal catheter. Both doctor and patient were blinded during the test. The test phase was necessary to test for eligibility of a patient for implantation
- randomisation (both choice of hospital and early or late administration of baclofen; the early group immediately received baclofen and the late group only after 13 weeks)
- implantation of pump; follow-up during 1 year. The study involved a total of 9 hospitals.

The medical ethics committee of the faculty of Medicine and University Hospital Groningen approved the study.

Selection of Patients

Patients with severe spasticity caused by MS or SCI who had been referred by their general practitioner (GP) or specialist, were recruited from neurology, rehabilitation and neurosurgery departments of 9 Dutch hospitals. Patients were included in the study when they met the following criteria: (i) aged 18 years or over, with chronic disabling spasticity of spinal origin inhibiting personal care, sitting, lying and transfers from bed to wheelchair, etc., accompanied by pain and stiffness, or disturbed sleep; (ii) insufficient response to treatment with maximum doses of oral baclofen, dantrolene

and tizanidine; and (iii) sufficient understanding of the consequences of the treatment and cooperative attitude towards research. Patients were excluded if they were pregnant, had no neurological symptoms of supraspinal origin or were allergic to baclofen.

Medical and Quality-of-Life Effects

Each patient was repeatedly tested with a battery of clinical, neurophysiological, urological, and psychological tests and questionnaires [examples are the Ashworth scale, spasm score, electromyogram (EMG), cystometrics, Expanded Disability Scale (EDS), Incapacity Status Scale (ISS), SIP, Hopkins Symptom Checklist (HSCL), Centre of Epidemiological Studies Depression (CES-D) Scale, Multidimensional Pain Inventory (MPI) and Linear Analogue Scale (LASA)]. For detailed descriptions and results of these techniques see Staal et al.^[14] and Middel et al.^[15]

In this article, the point of view of a cost analysis has been chosen. Therefore, only 1 overall medical indicator and 2 quality-of-life (QOL) indicators are reported in this paper. The medical indicator is 'the level of spasmodic'. The 2 indicators for quality of life after pump implantation were derived from structured open interviews with 17 patients. Patients retrospectively evaluated the result of the treatment 1 year after implantation retrospectively on a 1-dimensional scale on which the patient could indicate 'feeling better off' compared with the situation before implantation. Subjectively perceived improvement in quality of life was based on multicriteria (sleeping, drowsiness, mobility, energy and bodily care).

Cost Analysis Design

The research period of the cost analysis part of the study covered the year preceding implantation (year 1), the year starting with implantation and medical follow-up (year 2) and the year following the first non-experimental year (year 3). 18 consecutive patients were included in the cost analysis part of the study (the 'first wave' of the study). A cost analysis of the second wave including 17 pa-

Table I. Different direct cost categories

Cost categories	Direct costs within healthcare (patient-related costs)			
Personnel for diagnosis and treatment	Physicians (neurologist, neurosurgeon, rehabilitation specialist, urologist, anaesthesiologist, psychiatrist, other specialist, GP, nursing home practitioner)	Paramedical (physiotherapist, ergotherapist, caesar/Mensen-dieck-therapist (a type of physiotherapy), dietician, pharmacist, nurse, orderly, other)	Home care (home nurse, geriatric helper, district nurse, private care, other)	Psychosocial care (welfare officer, psychologist, chaplain)
Material for treatment	Therapy costs (pump, computer, etc.)	Trial costs(protocol research, test tablets, etc.)	Medicine (outside protocol: oral baclofen, etc.)	Diagnostics (outside protocol: laboratory tests, x-rays, etc.)
Hospitalisations	No. of hospital days, kind of operation, etc.			
Auxiliary equipment	House adjustments, adjusted bed, wheelchair, other			
Own contribution	Diverse costs			
	Direct costs outside healthcare			
Direct costs, other	Volunteer aid (partner, children, family, neighbours, volunteers, other)	Alternative care [homeopath, antroposofist/natural medicine and haptonomist (alternative therapists for patients with chronic diseases), acupuncturist, iriscopist, magnetizer, other] plus alternative medicine	Transportation (ambulance, taxi, wheelchair taxi, own transport, other)	'Out-of-pocket' costs (adjusted food, adjusted clothing, personal care, daycare centre, domestic help, telephone, other)

GP = general practitioner.

tients was not financially supported. The first wave of 18 patients were not systematically biased; they were the first ones to enter the trial. Also, a group of matched pairs which did not receive an implanted programmable pump (match group) was selected. The patients were segmented according to gender, age and disease (MS, SCI):

- treated group – 18 patients (8 men); mean age 46 years; MS (n = 11) and SCI (7)
- match group – 15 patients (7 men); mean age 48 years; MS (9) and SCI (6)

In the cost evaluation, a distinction was made between direct, differential and indirect costs. No general methodologically defined way to arrive at cost measures in this field are available.^[16-18] Therefore, a method had to be developed to quantify these types of costs. An important supportive instrument to determine the way patients 'flow' through the healthcare system and to determine the related costs were 'flowcharts' (see Steinbock et al.^[11]). Flowcharts were helpful by identifying and discussing the important (decisional) elements and their relationships within the general diagnostic and

therapeutic health providers' settings (in- and out-patient level, in nursing homes and in homecare).

Direct Costs

The direct costs can be attributed to the treatment of a patient. The direct costs contain different components or categories (see table I).

The direct costs data have been obtained by using the following sources: (i) registries of insurance-companies: cost data of 3 consecutive years (year 1 to 3); (ii) a patient survey (administered 1-year after implantation) to determine consumption of specific medical services; (iii) capacity-usage estimations: hospital registries, timekeeping by doctors, nurses and other hospital staff. The patient survey measured changes in consumption of specific medical services in the past years. This survey was aimed at assessing possible consumption differences between the 2 groups in using medical specialists other than specialists directly involved in the trial, home care, paramedical care, psychological and social care, volunteer aid and

other facilities, such as adapting of houses, adjustments at work, and transportation.

A complicating factor for the analysis was that the data from the various sources mentioned were sometimes incomplete and/or based on different accounting methods and information systems. This was taken into account as much as possible.

Direct costs were measured under trial conditions. However, a calculation was specified to get an insight into direct costs in non-experimental situations, in which additional costs that could be attributed to the evaluation research (e.g. costs of the trial) were skipped.

Differential Costs

Because of the fact that no control group was available, the concept of match patients was introduced to compare the patients being treated with those in a similar group, but who were not using the continuous intrathecal baclofen infusion system. Match patients were selected and individually matched with the treated patients by using the criteria of age, gender and diagnosis (disease). Match patients were patients who met most of the criteria for implantation, but did not (yet) receive a pump. By comparing the costs of treatment and care for treated patients ($n = 18$) and for match patients ($n = 15$), differential cost analyses could be performed.

Differential (direct) costs were used because it was not possible to distinguish costs in the treated group related exclusively to spasticity from costs for treatment and care of the underlying disease. Assuming that the underlying diseases were causing more or less the same costs in both groups, then the differential costs would be an approximation (indicator) of the direct costs (or savings) of intrathecal administration of baclofen.

Indirect Costs

Indirect costs in healthcare are in general the costs incurred by society (indirectly) related to the treatment of patients. Indirect costs can be approached in several ways.^[19,20] In this study, the following 2 indicators for indirect costs were chosen: (i) costs as a result of loss of income due to spasticity (based on the friction approach^[20]) and (ii) costs related to the inability to live alone (e.g. in a nursing home).

Statistical Methods

Descriptive statistics and tests have been used for the analysis of the aggregated direct costs and the differential costs. These include the median, range and the Mann-Whitney test, which is used in the analysis of the differences between the treated group and matched controls in differential costs.^[21]

Results

Cost Analysis

Direct and Differential Costs

In the medical consumption analysis, based on the patient surveys, no striking and/or significant differences were found between the treated and match groups. The only exception was volunteer aid for which the match group made significantly more use of informal care suppliers. This means that treated patients did not substitute more medical consumption between the different (nonclinical) healthcare facilities than match patients (e.g. treated patients did not change their specific housing conditions significantly more compared with match patients).

Table II. Aggregated direct costs and differential costs

Direct costs (per patient) [× \$US1.00]	Treated patients		Match patients		Differential costs	p-value
	median	range	median	range		
Year 1	5.9	2.4-71.6	7.7	0.1-74.8	-1.8	NS
Year 2	39.9	13.7-99.8	5.2	0.1-50.1	34.7	0.004
Year 3	5.2	0.1-70.9	3.3	0.0-49.4	1.9	0.036

NS = not statistically significant.

Table III. Average direct costs (non-experimental situation)

	Consumption	Costs (\$US)
Intake		
Consult neurologist	30 min	66
Visit outpatient clinic	30 min	58
Test phase		
Hospitalisation department neurology/neurosurgery (including ICU)[at \$US593 per day]	2 days	1185
Spinal catheter	30 min	
Hospital visits	60 min	
Catheter system	1 unit	
Ampoules baclofen	1 unit (maximum 4)	0.31
Implantation phase		
Admission department neurosurgery (including ICU) [at \$US831 per day]	10.3 days	8560
Personnel operating room	93 min	
Usage of operating room	93 min	
Pump with accessories ^a	1 unit	10 570
Computer (\$US160 per patient ^b)	1 unit	160
Bottle baclofen	1 unit	2.15
Follow-up phase (1 year)		
Hospital visit + dose adjustment (\$US173 per visit)	11×	1906
Hospital visit + refilling system (\$US173 per visit)	3×	520
Bottle baclofen	3 units	6.45
Complications (different per patient)		
Hospital days, neurosurgery department (at \$US593 per day)	8.4 days	4979
New catheter (at \$US145 per unit)	3.2 units	460
Personnel operating room	24 min	
Use of operating room	24 min	
Total		28 473

a Lifetime of battery is 4 to 5 years, afterwards pump must be replaced.

b Based on an economic lifetime of 3 years, discounting percentage of 5%, use of the computer by 20 patients per year, residual value of 0 and application of annuity method: total amount of \$US8720 (computer + printer, per patient \$US160).

ICU = intensive care unit.

An analysis of hospital stays for both groups showed a significant difference ($p = 0.0002$) in the implantation year (year 2). The average number of hospital days in that year in the treated group was 31.5 days per patient and in the match group was 18.7 days per patient. The average number of hospital days in the test phase was 9.9; in the implantation phase it was 12.3 days; and the number of additional hospital days resulting from complications was 8.4 days. In year 3 (the first non-experimental year), no significant difference was found. Complications could be either of an operation-related nature (e.g. disconnection, dislocation, spinal catheter breakage) or medicine-related nature (e.g. dose-imprecision, adverse effects).

In table II the results are shown of the aggregated direct and differential cost analyses. These results are based on the data in table I, which represent cost data as supplied by insurance-companies and data on therapy costs (pump with accessories, computer/printer, catheter system and ampoules of baclofen).

The aggregated direct costs of 3 consecutive years on a patient basis are presented. The range of the direct costs in both groups and in each year was relatively large. Because no differences were assumed between treated and match patients on grounds other than spasticity treatment, the differential costs refer to the costs related to intrathecal spasticity treatment. The absence of statistically

significant differences in costs in year 1 between patients who will receive treatment and match patients indicates that at baseline no exceptional differences existed between the 2 groups. In the year of implantation of the pump (year 2), an increase in the costs of the treated group was shown, while the costs of the match group were lower than the year before. The difference between the groups was significant, which was expected based on the costs of implanting the pump. In the third year, costs were decreasing in the treated group, but there was still a significant difference between both groups. This, however, could not be explained by hospitalisation (see earlier part of this section). We have no explanation for the decrease of costs in the match group in the 3 consecutive years.

A calculation of the average direct costs that would be likely to occur in a non-experimental situation was made (table III). This calculation comprises the costs of the implantation of the pump and the costs during the 1-year follow-up.

During the intake procedure, a team of specialists evaluated whether each patient was eligible for treatment. During the test period, the effects of intrathecal bolus injections were evaluated. During the implantation period, surgery, filling-up of the system, dose tuning and adjusting the velocity of the pump took place. The medical follow-up period consisted of visits to the hospital (outpatient clinics) for refilling the pump and adjustments of the baclofen dose. During this follow-up phase, any complications which emerged were categorised separately (the total average complication costs per patient was \$US5439).

The total costs of selection, testing, implanting the pump and medical follow-up amounted to \$US28 473 for the first year. To avoid double-counting of some costs, mostly those relating to the use of the operating room that have already been included in the tariffs of the hospital days/visits, some sections of the table have been left blank. Note that the costs in table III are based on reimbursement rates of the insurance companies and also of implantation-related costs that are not in the reimbursement schedule of Dutch Sickfund Coun-

cil. Replacement of the pump is necessary once every 4 to 5 years, depending on the capacity of the battery: this results in additional annual costs of \$US5233 per patient (table IV). An estimated annual total of between \$US1950 and \$US2800 per patient, however, could be saved due to withdrawal of (maximum) doses of oral medication (table IV).

Indirect Costs

The determination of the indirect costs is based on interviews with patients and questionnaires filled in during these interviews. The indirect costs appeared to be negative (or savings). Three patients had jobs before the treatment started. For one of them, nothing changed during therapy, although this patient's ability to work increased. Another was on sick leave before the therapy started and could go back to work after the treatment (indirect saving). Due to the therapy, the third patient experienced increasing absenteeism (indirect cost). Altogether, this treatment led to average annual savings of \$US1047 per patient (table IV).

It should be noted that the majority of the patients were women who did not have paid jobs. However, we did not take into account changes in their ability to do house-keeping work. Two patients were about to move to a nursing home before the treatment was started. After pump implanta-

Table IV. Costs and effects after 1 year

Effects (% of patients)		
Clinical	Spasmolysis	100
Opinion of patients	'Better off'	85
	Increased quality of life	42
Costs and/or savings (\$US per patient per year)		
Direct costs first year		28 473
Annual costs of complication and drop out		5439
Costs per replacement of pump		5233
Annual savings in oral medication		1950-2800
Annual savings in employment		1047
Annual savings in nursing home costs		5814

tion, their situation improved structurally, so there was no need to move to a nursing home. This amounted to an average annual saving of \$US5814 per patient (table IV).

Costs and Effects Combined

All patients (100%) showed spasmodic (a reduction of spasticity) especially a significant fall in muscle tone and frequency of spasms. The 'unstructured' interviews on 'quality of life' revealed the following results: 85% of the patients were 'better off', while 42% of the patients improved their overall 'quality of life'. The main results of the cost analyses and effects are summarised in table IV.

Discussion

An important problem in this study is the allocation of costs to spasticity, the underlying disease or disability and/or comorbidity. To overcome this problem, the concepts of match patients and differential (direct) costs have been introduced. Another problem is that we were not able to collect all data indirectly related to change in health status and functioning due to comorbidity and disease-specific events in this sample.

Only in year 2 was a significant difference in hospital stay between the treated group and the match group found. This can be fully explained by the fact that in that year, implantation of the pump takes place. In year 3 (the first non-experimental year), no significant difference was found between the treated group and the match group in terms of hospital stay. The study of Nance et al.^[6] showed that intrathecal baclofen therapy reduces the need for hospitalisation by using each patient as his own control and by comparing each patient's hospital stay 2 years before and 2 years after intrathecal Baclofen therapy. The weakness of their design is the lack of using a match (control) group.

The reported results reflect the experimental status of the treatment of severe spasticity with a continuous intrathecal baclofen infusion system in the period from 1991 to 1995 in the Netherlands. The costs and number of hospitalisation days are

influenced by the position on the learning curve. It might, for instance, be readily expected that growing experience will lead to fewer complications and to lower complication-related costs.^[11] We already noticed this with the most recently included patients. Also, an extended follow-up is necessary to obtain more securely founded results and statements concerning medical consumption and costs related to intrathecal administration of baclofen (see Nance et al.^[6]).

Scenarios are a useful device for policy-makers (on a hospital level as well as a regional and a national level) to consider the impact of the introduction of (new) medical technology. Scenarios are capable of combining quantitative and qualitative aspects, learning capabilities and their functioning as a test for policy-making.^[22] Therefore, the consequences for the introduction of a continuous intrathecal baclofen infusion system in the Netherlands, given the accessibility of the treatment on a population base, in 2 different scenarios will be discussed briefly.

Usually, policy-makers are interested in aggregated data, especially of total costs. The total cost of treating patients with spasticity with this specialised therapy, however, depends on several factors. By using scenarios, sensitivity analysis of key factors can be performed. Examples of such factors include a change in the annual number of patients, the treatment becoming more or less effective or concentrating the therapy in more or fewer centres. To this aim, a straightforward decision support system has been developed based on a spreadsheet model. To exemplify the possibilities of such a system and scenario-analysis, a 'reference scenario' and a 'growth scenario' are presented in table V. The reference scenario shows a gradual increase in the number of treatment facilities, patients and costs. The growth scenario is the most interesting scenario. It shows a more pronounced profile, an increase from 7 to 10 centres, a growth in the number of patients with implanted pumps from 80 to 262 and the consequences of the growth of patients in terms of direct and indirect costs.

Table V. Two policy scenarios: a reference and a growth scenario

	1997		2001	
	reference	growth	reference	growth
No. of centres	7	7	7	10
No. of patients				
new	20	20	60	60
pump functioning	80	80	224	262
'better off'	60	64	213	236
Direct costs (\$US; 1992 values)	1 366 861	3 960 465	4 876 163	12 289 535
Indirect costs/savings (\$US; 1992 values)	240 698	623 256	1 908 721	1 707 558

These scenarios are based on a number of assumptions. The 'reference scenario' is based on the general assumption of gradually increasing numbers of patients and costs.^[14] The 'growth scenario' is based on the idea of further increasing numbers of patients because of diffusion of the treatment to a broader group of patients; also, the number of treatment centres increases in this scenario. In both scenarios, a gradual extension of the indications for this treatment is assumed. This is a consequence of the results of different studies^[1-12] that indicate that efficacy is established (at least in experimental circumstances). When the treatment is allowed for reimbursement by the Dutch Sickfund Council, it might be expected that the demand for this treatment modality in the Netherlands will increase. Because of too much uncertainty regarding future oral baclofen usage, direct savings in the sense of withdrawal of doses of oral medication are not included in the scenarios. These assumptions were derived by discussing plausible arguments and by using a consensus approach in the research group. These assumptions can be adapted or others can be introduced. This, of course, will lead to different results. The main advantage of this approach is the use and incorporation in the analysis of the judgment of well-informed clinicians.

Conclusion

As far as medical consumption in our limited context is concerned, no substitution effects for the treated patients could be found regarding different nonclinical healthcare facilities compared with the match group (except for volunteer aid). Only in year

2 (pump implantation and medical follow-up) has a significant difference in hospital stay between the treated group and the match group been found. However, no significant difference has been found in the year before pump implantation (year 1) and in year 3. Based on these preliminary results, we conclude that during the follow-up period, no longstanding improvement has been achieved in the sense of shortened hospital stays.

In year 2 and 3, significant differences in costs between both groups prevail. Most of these differences can be attributed to the pump implantation, hospital stay, costs related to the pump itself, follow-up costs due to the maintenance of pump (e.g. dose adjustments, refilling the system) and costs that can be attributed to complications. In non-experimental situations, these direct costs (for 1 year follow-up) are estimated at \$US28 473 per patient. However, savings due to withdrawal of oral medication (estimated annual total of between \$US1950 and \$US2800 per patient) must also be taken into consideration. Indirect costs, in this study, are in fact savings in employment costs and in nursing home costs (annual savings of \$US1047 and \$US5814, respectively).

The scenario analysis gives decision-makers information on the expected increase in demand and costs in the Dutch healthcare market and information on the optimal number of healthcare facilities for this specific patient population. In this article, the costs of the treatment were analysed. A cost-effectiveness analysis was, however, not possible, given the nature of the research design. But in our opinion, improved quality of life more than justi-

fies the (direct) costs associated with this treatment.

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