

Disease-specific assessment of quality of life after decompression surgery for Graves' ophthalmopathy

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PURPOSE. Graves' ophthalmopathy (GO) is an organ-specific autoimmune disease. Hydrophilicity of accumulated acidic mucopolysaccharides into bulbar adipose tissue leads to swelling of the eye muscles. Orbital surgical decompression is performed in severe cases of compressive optic neuropathy and severe corneal exposure or failure of steroid therapy. The study was designed to evaluate decompression surgery with respect to the clinical benefit and the patient's satisfaction by means of a disease-specific questionnaire.

METHODS. The 90-item study questionnaire was distributed to 105 patients with GO who underwent orbital decompression surgery at the authors' institution.

RESULTS. A total of 88% of patients stated that decompression had helped them, 80% of the interviewees would undergo decompression again, 78% were content with their eye symptoms, and 71% were satisfied with the cosmetic result of decompression. Furthermore, analysis showed a clinically relevant increase in quality of life after surgery. The correlation between the clinical endpoint proptosis at last examination and the quality of life score proved to be significant ($p=0.05$).

CONCLUSIONS. The large majority of interviewees were satisfied with the result of the orbital decompression. These results confirmed that disfiguring proptosis is an important indication for decompression surgery. (*Eur J Ophthalmol* 2004; 14: 193-9)

KEY WORDS. Orbital decompression, Quality of life, Thyroid-associated, Ophthalmopathy

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INTRODUCTION

In recent years, it has been increasingly recognized that a lack of symptoms does not equal the success of treatment. It is, however, important how therapy influences patients' quality of life. In former clinical studies quality of life measurements have been large-

ly neglected, partly due to the low reliability of such studies. A growing group of studies have recently compiled these so-called soft data, recognizing that patient satisfaction is an important determinant of therapeutic success. In particular, it is important to study the health-related quality of life in chronic illnesses for two reasons. First, objective data often do not cor-

relate with the condition of the patient. Second, two patients whose condition is objectively identical often describe their health state differently. However, there is not necessarily a significant relationship between subjective evaluation and objective endpoints (1-3). Ophthalmologic diseases influence the quality of life and have a major impact on daily function. In 1993, The National Eye Research postulated "the need to study quality of life and functional status as perceived by the patient to assess the full impact of a treatment or disease process" (3).

Graves' ophthalmopathy (GO) is the most common cause for unilateral and bilateral proptosis. An inflammatory infiltration of the orbital tissues is observed. Massive retention of acidic hydrophilic mucopolysaccharides leads to swelling of the affected tissues and external eye muscles resulting in disfiguring proptosis, periorbital swelling, pain, and diplopia. In severe cases, compressive optic neuropathy may occur (4-10).

Clinical features of GO vary from spontaneous remission to a loss of visual acuity. In cases of severe corneal exposure, optic neuropathy, disfigurement, or inactive GO, decompression surgery has been advocated. In these cases orbital surgery (11, 12) has been performed at our institution and in the following we report on 105 consecutive subjects.

The associated psychosocial burden in GO patients is well known as a result of disfiguring proptosis. The influence of GO on psychological and physical well-being is unquestioned and, therefore, emphasizes the importance of the overall evaluation of the success of therapy. There have been few studies investigating quality of life in this population of patients. Therefore, it is imperative to clarify the psychosocial effects caused by this disease by means of studies on quality of life and on economic consequences (13-18). It was the objective of this study to evaluate the impact of decompression on quality of life, accounting for both objective clinical benefit and subjective patient satisfaction.

METHODS

A total of 105 consecutive patients with GO, who underwent orbital decompression surgery at our institution, were included. The questionnaire contained

26 overall questions and 90 items. Patients underwent clinical endocrine and ophthalmologic examination both before and after orbital decompression and on 6-month basis. Patients filled out the questionnaire at their clinical visits, or the questionnaire was sent to them via mail. All patients were invited postsurgery at a postinflammatory stage. The questionnaire was designed in cooperation with ophthalmologists, ENT specialists, and endocrinologists, with special effort to evaluate each aspect and symptom of GO.

Statistical analysis

Evaluation of the questionnaire. The answers to each item were coded in four categories between 4 (minimum self-reported contentment) and 1 (maximum self-reported contentment). A total score was computed as the mean of all available answers in a patient's questionnaire; therefore this continuous score ranges between 1.0 (optimum overall contentment) and 4.0 (low overall contentment). A low quality of life score represented a high self-estimated overall quality of life value. In this study, validity was considered indirectly by the correlation of quality of life scores with clinical endpoints according to Spearman. Reliability was estimated by means of Cronbach's alpha coefficient, which measures the internal consistency of a set of questions as a surrogate measure of the reliability of the survey instrument. Part of the Cronbach alpha coefficient measures whether the deletion of items has an impact on reliability. If deletion of one or several related items decreases the overall reliability, these are considered to be important and informative.

The descriptive analysis of the clinical parameters and the information on quality of life was performed according to their scale. For continuous endpoints (e.g., Hertel values), mainly medians and quartiles were presented. For categorical endpoints, absolute and relative frequencies were shown in contingency charts. To test for significance (e.g., of differences in surgical procedures), the Wilcoxon test was applied for continuous endpoints, and the exact Fisher test was used for categorical endpoints. The results of these tests were summarized by p values. A p value of < 0.05 was determined to be an indicator for local statistical significance. The correlation between the quality of life score and the objective clinical parameters

was calculated according to Spearman; a corresponding *p* value to assess the statistical significance of a correlation is provided. Excel 7 for Windows was used for data entry; SAS software (version 6.12 for Windows) was applied for numerical analysis.

RESULTS

Patients were aged between 26 and 79 years (median age 49): 79% of the patients were women, 60% were smokers, 93% were hyper-, 3% were hypo-, and 4% were euthyroid. Of the 105 patients, 72 responded, 22 did not reply, 4 had died, and 7 had moved without a forwarding address.

Analysis revealed that the large majority of patients were satisfied and would undergo surgery again. The following percentages refer to the pooled number of answers indicating answer level "1" and "2" in the original items scale (indicating excellent or acceptable contentment, Appendix): 88% of patients stated that decompression had helped them, 80% of the interviewees would undergo decompression again if asked to do so, 78% were satisfied with the improvement of eye symptoms, 71% indicated they were satisfied with the cosmetic result of decompression, and 58% of the interviewees claimed to have gained more joy in life and self-confidence. A total of 57% reported a stronger physical and mental condition postoperatively, 53% found social improvement after decompression, 52% found occupational improvement, and 44% had returned to work.

In addition, a considerable GO-associated psychosocial strain was observed: 33% of the patients stated that GO had diminished their social contacts, 68% had occupational problems, and 94% reported psychological changes during the beginning of the illness.

Quality of life after decompression markedly increased after surgery: 9% of the patients with GO estimated their quality of life to be good and/or excellent prior to surgery. This rate increased to 72% after decompression, corresponding to an intra-individual gain in patient contentment in 46 of 68 patients. A total of 91% considered their quality of life as "bad" prior to surgery. This rate decreased to 28% after surgery (McNemar $p < 0.001$).

Patients who stated they would undergo decompression again and described an increased well being had sta-

tistically significant better mean scores in quality of life compared to those patients who negated these questions. In addition, there was no difference in the quality of life score in terms of sex or smoking habits. However, a higher score in quality of life was detected in younger compared to older patients (Tab. I).

The correlation analysis between subjective parameters of quality of life and objective clinical parameters revealed a moderate correlation between proptosis and the quality of life score, whereby a regressing proptosis led to an increase in the reported quality of life (Tab. II and III).

DISCUSSION

The lack of a symptom-related survey for GO patients evaluating the influence of decompression motivated us to develop a disease-specific questionnaire involving the experience of our orbital center. It was the objective of this study to evaluate the impact of decompression on quality of life, accounting for both objective clinical benefit and subjective patient satisfaction.

Our analysis reveals the high acceptance of our patients of decompression surgery. The majority of patients were satisfied with the surgery, regarding both cosmetic and psychosocial aspect. A total of 18% stated that steroid therapy and 6% that radiation helped them, in contrast to 88% of patients in respect to surgery. In addition, a significant increase in quality of life after surgery could be observed. We have not observed equal high satisfaction percentages in other conservative therapies in GO.

Furthermore, the long-term beneficial effect of surgery is apparent. Fifty-one percent of our patients had been operated 2 years or earlier before answering the questionnaire. They were medication-independent and fully integrated in social and professional life. Decreasing proptosis and clinical symptoms increased self-confidence, thus facilitating better integration of these patients into daily life. Not only increased well-being but also physical functioning allowed rapid reintegration. Furthermore, the 91% discontentment rate prior to surgery dramatically decreased to 28% after surgery.

The total quality of life score was compared to objective parameters such as endocrine and ophthalmic

TABLE I - SUBGROUP ANALYSIS FOR MEAN QUALITY OF LIFE (QOL) SCORE

Characteristics	N	QOL score median (Q1-q3)	Wilcoxon p value	Minimum - maximum
Female	58	2.5 (2.2-2.8)	0.564	1.7-3.6
Male	14	2.5 (2.3-2.6)	0.564	1.9-3.2
Age < 40 yr	17	2.5 (2.4-2.6)	0.946	1.9-3.2
Age > 40 yr	54	2.5 (2.2-2.8)	0.946	1.7-3.6
QOL score	72	2.5 (2.2-2.7)	0.4	1.7-3.6
Undergo surgery again?				
Yes	54	2.4 (2.2-2.7)	0.003	1.6-3.3
No	13	2.9 (2.5-3.2)	0.0033	2.0-3.6
Increase of well-being?				
Yes	46	2.4 (2.2-2.6)	<0.001	1.7-3.1
No	20	2.9 (2.6-3.2)	0.0001	2.0-3.1
QOL before surgery				
Good	6	2.5 (2.3-3.3)	0.8	1.9-3.2
Poor	63	2.5 (2.2-2.7)	0.8	1.7-3.6
QOL after surgery				
Good	50	2.5 (2.3-3.0)	0.001	1.9-3.21
Poor	20	2.9 (2.6-3.2)	0.001	2.3-3.6
Smoker	43	2.5 (2.2-2.8)	0.94	1.7-3.6
Nonsmoker	29	2.5 (2.2-2.7)	0.94	1.7-3.6

Distribution characterized by subgroup sample size, subgroup stratified mean (standard deviation), median, 1st/3rd quartile, minimum/maximum observed score value. Lower score values represent higher self-estimated quality of life scores

TABLE II - CLINICAL ENDPOINTS DISTRIBUTION, CHARACTERIZED BY EFFECTIVE SAMPLE SIZE, MEAN VALUE (standard deviation), MEDIAN, MINIMUM, AND MAXIMUM OBSERVED VALUE

Item	N	Median	Min	Max
Lid fissure width before surgery	60	13	7	20
Lid fissure width after 1 year	50	11	2	15
Lid fissure width last examination	19	10	6.5	16
Proptosis before surgery	69	24	15	31
Proptosis after 1 year	51	19	14	25.5
Proptosis last examination	18	18.5	12	24

symptoms (diplopia, visual acuity, intraocular pressure, proptosis) as well as daily functioning before and after surgery. Higher quality of life values after surgery indicated a reduction in symptoms and bet-

ter functioning. This fact is of high importance when considering the socioeconomic effects of chronic diseases such as GO. Socioeconomic aspects should not be underestimated, given that chronic invalidity

TABLE III- SPEARMAN CORRELATION OF MEAN QUALITY OF LIFE SCORE WITH PRIMARY CLINICAL ENDPOINTS

Correlation coefficient	Item	p value	N
0%-20%	Visual acuity 1 year after surgery	0.67	54
	IOP after decompression	0.18	68
20%-40%	Proptosis after surgery	0.07	66
	Proptosis 1 year after surgery	0.02	52
40%-60%	Proptosis last examination	0.05	18

Correlation coefficients categorized (-40%/-20%/0%/20%/40%/60%), p values displayed indicating statistical significance, and n values displayed indicating effective sample size underlying the respective correlation.

IOP = Intraocular pressure

due to diplopia, severe proptosis, or decreased vision lead to higher costs for society. In this respect, decompression surgery benefits socioeconomic conditions by reintegrating the patient socially and professionally.

In addition, our study confirms the psychosocial stress in GO patients. Egle et al (13) and others (14-18) have described the relevance of physical and psychosocial factors for quality of life in patients with GO. Egle et al (13) found a decrease in quality of life in patients with GO compared to the normal population. Seventy-two percent of all patients described experiences of stress in their life 6 months prior to the outbreak of GO. This emphasizes the presence of extraordinary psychosocial strain and the necessity of a parallel psychological treatment. In another study (14), Kahaly et al applied the Medical Outcomes Study (MOS-36) in patients with GO. In comparison to a large German reference group, low scores on the MOS-36 were found. Marked and significant differences from the control group were especially observed for the following items: vitality, social functioning, mental health, health perceptions, and body pain. MOS-36 did not correlate with the duration or severity of the ophthalmopathy. These results demonstrate the impact of a common visual symptom on health status and well being, as measured by the MOS-36, and underscore the need for quality of life measurements in prospective and controlled clinical trials.

Similar studies (19-21) confirm our findings, showing that mild to moderately severe GO had a large influence on the quality of life of these patients and that

the negative impact on well-being was not related to the usual clinical assessment, emphasizing the need for quality of life measurements in clinical trials.

Gerding et al (19) showed that patients with GO scored lower than patients with other chronic diseases such as diabetes or heart problems and they did not find a correlation of the low scores with the severity or activity of GO. This indicates that even mild cases of GO can induce severe psychological or social problems.

Terwee et al (22) used the GO-QOL, a disease-specific quality of life questionnaire for GO patients that was developed by this group. They found their questionnaire to be reliable.

We decided to develop a questionnaire for German patients.

Bartley et al (23) describe that even after treatment one third of the patients in their study were not satisfied with their appearance.

Correlation between the quality of life score and objective data

Proptosis, which is measured by Hertel exophthalmometry, is an important contributor to the clinical syndrome of GO. In particular, decrease in disfigurement can lead to an increased participation in social and occupational life, associated with a better quality of life.

The correlation between the score in quality of life and the objective data showed, except for the Hertel value, no other statistically significant correlation with

the total quality of life score. This finding may be explained by the fact that the Hertel value was a clinical value showing the highest decrease after surgery compared to the other clinical endpoints. This may imply that the postoperative decrease in proptosis had the highest influence on quality of life.

The above findings emphasize the importance of the overall evaluation of surgery results. The integration of health-related quality of life assessments (24-26) is crucial in assessing the impact of treatments on patients' physical and mental functioning.

The Cronbach alpha coefficient for this relationship was 63%, implying a moderate reliability. In this analysis, validity was measured indirectly by correlation with clinical endpoints. The significant correlation of Hertel value and quality of life score (total score) consequently provides an indirect measure of validity. Nevertheless, this analysis suffers from some responder bias. Twenty patients did not return the questionnaire and the completion of the questionnaire at different postoperative intervals may have led to some recall bias, reducing the validity of the underlying data. The implementation of a future multicenter prospective study could include a few modifications. Patients should be questioned according to a set time schedule (e.g., 2 weeks preoperatively, and 1, 3, and 6 months postoperatively (20, 22).

CONCLUSIONS

It can be assumed that decompression, by reducing proptosis and other ophthalmologic signs and symptoms, can lead to a distinct increase in reported quality of life. The patients were positive about the surgical decompression in every aspect. This study represents a feasibility trial to gain initial insight into the status of German GO patients after decompression.

Reduced proptosis was the most dramatic measurable result of decompression surgery, emphasizing the central role of proptosis in the clinical and psychosocial syndrome of GO. Thus, we conclude that decompression surgery has a beneficial long-term effect in terms of social and physical functioning. Both the satisfaction rate and the cosmetic result of surgery and consequent improvement in psychosocial function suggest cosmetic disfigurement as an indication for decompression surgery.

APPENDIX

Two examples of questions from our questionnaire (translated from German)

1 How would you estimate your quality of life before and after decompression surgery?

Before surgery

- very good
- good
- fair
- poor

After surgery

- very good
- good
- fair
- poor

2 I'm content with the surgical outcome concerning

- cosmetic outcome
- eye-related symptom
- professionally
- mentally
- socially

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