RHINOLOGY



Quality of life in functional rhinoplasty: rhinoplasty outcomes evaluation German version (ROE-D)

Olcay Cem Bulut¹ · Peter K. Plinkert¹ · Frank Wallner¹ · Ingo Baumann¹

Received: 2 September 2015/Accepted: 3 February 2016/Published online: 10 February 2016 © Springer-Verlag Berlin Heidelberg 2016

Abstract The aim of this study was to validate a German version of the rhinoplasty outcomes evaluation (ROE) questionnaire. A prospective study was conducted and a German translated ROE (ROE-D) questionnaire administered to 100 patients preoperatively, 6 and 12 months postoperatively. The translation was performed according to internationally accepted guidelines. To validate this instrument, we evaluated its reliability, validity and sensitivity. ROE-D was completed by 54 patients after 6 months and by 69 patients 1 year after functional rhinoplasty. Cronbach's a indicated good internal consistency. Reliability was tested with a split-half-reliability, showing significant correlation. Discrimination validity was demonstrated by a comparison with healthy controls. Sensitivity to change showed medium to large effects. ROE-D is a reliable, validated and sensitive German instrument for measuring health-related quality of life in patients after rhinoplasty. The ROE-D focuses mainly on the aesthetic aspects of the rhinoplasty surgery.

Keywords Quality of life · Rhinoplasty · Reliability · Validity · Sensitivity

Olcay Cem Bulut cem.bulut@med.uni-heidelberg.de

Introduction

Validated instruments to measure health-related quality of life (HRQL) in patients are becoming increasingly important. In addition to subjective postoperative findings, HRQL is gaining more significance [1].

In this context, validated instruments to measure HRQL are used to evaluate patient satisfaction [2]. Septorhinoplasty is an operation in which both aesthetic and functional aspects play an important role. The patients' expectations can vary significantly from his surgeons: for some of the patients, the postoperative function plays a key role, for others a combination of function and aesthetics. Nevertheless, an increase in the purely aesthetic motivated rhinoplasty is observed in some German hospitals. Therefore, it is useful to have a suitable validated tool in German language for measuring the functional as well as aesthetic quality of life aspects after septorhinoplasty.

According to our research two validated instruments to measure HRQL after rhinoplasty currently exist: the rhinoplasty outcomes evaluation (ROE) [3] and the functional rhinoplasty outcomes inventory 17 (FROI-17) [4, 5]. The ROE is in use since 2001 and therefore the questionnaire with the most "experience". In five out of six questions it focuses on aesthetic issues. For this study the ROE was translated into German and underwent a validation process. The aim of this study is to validate the rhinoplasty outcomes evaluation in German language, the ROE-D.

Materials and methods

The Ethics Committee of the Medical Faculty at the University of Heidelberg granted permission to conduct this study (project no. 409/2006).

¹ Department of Otolaryngology, University Heidelberg, Im Neuenheimer Feld 400, 69120 Heidelberg, Germany

Fig. 1 Rhinoplasty outcomes evaluation German (ROE-D)

Rhinoplasty Outcomes Evaluation-German (ROE-D)

1. Wie sehr mögen Sie das äußere Erscheinungsbild Ihrer Nase?

überhaupt	nicht	wenig	teilweise	größtenteils	vollkommen	
0		1	2	3	4	
2. Wie gut können Sie durch die Nase atmen?						
Sehrsch	llecht	schlecht	einigermaßen	gut	sehrgut	
0		1	2	3	4	
3. Wie sehr mögen Ihre Freunde und Nahestehende Ihre Nase?						
überhaupt	nicht	wenig	teilweise	größtenteils	vollkommen	
0		1	2	3	4	
4. Denken Sie, dass das Erscheinungsbild der Nase Ihre sozialen oder beruflichen Aktivitäten beeinträchtigt?						
imm	er	häufig	gelegentlich	selten	niemals	
0		1	2	3	4	
5. Wie überzeugt sind Sie, dass die Ihre Nasenform die bestmögliche ist?						
überhaupt	nicht	wenig	teilweise	größtenteils	vollkommen	
0		1	2	3	4	
	öchten Sie da ssen?	s Erscheinungsb	ild Ihrer Nase od	ler die Nasenfunk	tion chirurgisch behandeln	

auf jeden Fall	höchstwahrscheinlich	möglicherweise	ehernicht	nein
0	1	2	3	4

The rhinoplasty outcomes evaluation German version (ROE-D) is a forward and backward translation of the ROE (Fig. 1). The translation was performed according to internationally accepted guidelines. It consists out of six questions: any question can be rated from 0–4, "0" represents the "most negative" possible answer, while "4" indicates the "most positive" possible answer. The total score is calculated by adding the scores of the individual questions. The sum is then divided by the addition of the range of the six individual questions ($6 \times 4 = 24$) and multiplied by 100, so that the result can vary between 0 and 100 %.

Higher scores indicate greater patient satisfaction.

Patients

One hundred patients were enrolled in this study (50 female and 50 male patients). They were on average 24 years old (ranging from 18 to 65 years). The patients were asked to answer the ROE-D questionnaire at the time of preparing for septorhinoplasty, usually the day before surgery. All patients underwent primary septorhinoplasty and were operated by two of the authors (F. W and I. B) between January 2010 and March 2011. With the request for answering the questionnaire again, the patients were contacted by mail 6 months and 1 year after surgery. After 6 months 54 (54 %) and after 1 year 69 (69 %)

questionnaires were returned. Data collection was completed in March 2012. Patients gave their informed written consent before being subjected to data collection.

Statistics

To validate the ROE-D we evaluated reliability, validity and responsiveness of the questionnaire.

The assessment of reliability was performed by determining the internal consistency and test-retest reliability. The internal consistency of the questionnaire was assessed by Cronbach's α for the total score preoperatively, 6 months and 1 year after surgery. Test-retest reliability was determined by calculating split-half reliability. The allocation of the individuals was carried out by the oddeven method.

The validity of the ROE-D was evaluated by examining the content, discriminant and concurrent validity. To assess the content validity we surveyed the literature. The concurrent validity was assessed using the correlation analysis of the ROE-D with three general questions regarding patients (1) functional, (2) aesthetic and (3) overall (functional and aesthetic) nasal impairment. To evaluate the discriminant validity we compared two cohorts. The first cohort was defined by the 100 patients with septorhinoplasty. The control cohort was defined by 30 patients who were hospitalized at the University Heidelberg, Department of Otolaryngology, due to non-rhinological symptoms. The comparison of both groups was performed using *t*-test.

The responsiveness of clinical change (sensitivity to change) can be described by the standardized response mean (SRM). It is defined by the ratio of the medium change score and the standard deviation of the change in score. Values <0.2 indicate minor effects, ≥ 0.2 and <0.5 indicate small effects, ≥ 0.5 to <0.8 medium effects, and ≥ 0.8 large effects [6].

Results

Internal consistency

The ROE-D had preoperatively questionable, at 6 months good and after 1 year an acceptable internal consistency (Table 1).

Reliability

In the split-half reliability analysis 50 patients were compared with 50 patients, preoperatively. The mean values were 40.1 ± 15.1 and 39.4 ± 15.3 . In the *t*-test, p = 0.83.

Content validity

Every single question of ROE-D is related to the impairment of the patient with respect to the functional and aesthetic aspects. The content compared with other life quality measuring instruments is described in the discussion part.

Discriminant validity

The control group consisted of 30 hospitalized patients, without any rhinological complaints. They were on average 37.5 years old (range 18–64). The women/men's gender ratio was 1.5:1. The completed ROE-D of these patients were compared with the answers of our study group "septorhinoplasty preoperatively" (n = 100). The *t*-test showed a significant difference between the septorhinoplasty patients and the control group and was thus able to demonstrate the required differences (Table 2). A good discriminant validity was shown for the ROE-D.

Table 1 Cronbachs α for ROE-D

	Cronbach's α	n (patients)
Preoperatively	0.64	100
6 months postoperatively	0.82	54
12 months postoperatively	0.73	69

Concurrent validity

The parametric correlation analysis of three general nasal questions with the ROE-D showed a weak correlation with the general questions regarding functional- and overall preoperative nasal impairment. A strong correlation was found looking at the preoperative aesthetical impairment and the ROE-D (Table 3). All the Pearson correlation coefficients indicate significant correlations.

Sensitivity

The scores showed a large effect between "preoperative" and "6 months postoperatively". Medium effects were found comparing scores "preoperatively" versus "12 months postoperatively" (Table 4).

Discussion

The measurement of HRQL is gaining more and more importance in the assessment of the outcome of surgery. When conducting a literature review with the search words "Quality of Life", a majority of studies are found in the field of internal medicine and oncological research. However, the field of otolaryngology, head and neck surgery seems to have caught up in recent years [7].

Over the past 20 years, various questionnaires have been developed in the field of ENT to measure disease-specific quality of life. These deal with chronic diseases such as chronic tonsillitis or chronic rhinosinusitis, aesthetic surgery, such as rhinoplasty and other ENT diseases, e.g., tumors of the parotid gland [3, 5, 7-11]. As the number of rhinoplasty surgeries increases in Germany, the demand for a German tool to measure quality of life in the field of rhinoplasty is growing. The rhinoplasty outcomes evaluation and its German version ROE-D consist out of six questions, which can be answered within a short time [3, 12] and thus are very practical. According to a literature review, the ROE questionnaire is currently the most commonly used disease-specific quality of life measurement tool in rhinoplasty. The ROE-D questionnaire showed a questionable internal consistency preoperatively. After 6 months it showed a good and 1 year after surgery an acceptable internal consistency. The validation study of the original ROE showed similar values regarding internal consistency (6 months postoperatively Cronbach's α 0.83 and 1 year after surgery Cronbach's α 0.88) [3]. In our study there was a questionable internal consistency preoperatively, most likely because functional aspects in our patient population played a very important role and only one out of six question in the ROE is functionally aligned. Also due to this reason the correlation analysis of two

Table 2 Discriminant validity

Table 3 Concurrent validitypreoperatively (r = Pearsoncorrelation coefficient)

	Rhinoplasty patients	Control group
n	100	30
Mean value \pm standard deviation	39.75 ± 15.17	83.05 ± 11.63
р	p < 0.0001	
	r	р
	-0.28	0.0035
Preoperative functional impairment vs ROE-D	0.20	
Preoperative functional impairment vs ROE-D Preoperative aesthetic impairment vs ROE-D	-0.65	< 0.00001

 Table 4
 Sensitivity (standardized response mean SRM)

	SRM
Preoperatively—6 months postoperatively	1.28
Preoperatively-12 months postoperatively	0.96

general nasal questions (regarding functional- and overall nasal impairment) with the ROE-D showed a weak correlation. A strong correlation was found between preoperative aesthetical impairment and the ROE-D, because the questionnaire focuses mainly on the aesthetic aspects of the rhinoplasty surgery.

Regarding the validity of the ROE-D, consistently good results can be reported. This could be shown in the discriminant validity and in the concurrent validity. In terms of sensitivity, a large to medium effect could be shown between "preoperatively to 6 months", and between "preoperatively to 12 months".

Other studies looking at rhinoplasty patients with the ROE [4, 12–16] consistently reported a postoperative improvement in ROE scores. Alsarraf et al. [3] showed an average gain of 44.5 % in ROE after 5-month follow-up, while a Brazilian study showed an increase of 55.7 % after 3 months [12]. In our patient population there is an average increase in ROE-D score of 21.7 % (from 42.2 % preoperatively to 63.9 % 1 year postoperatively). The most likely reason of a slightly lower increase in our cohort is the importance of functional aspects in our patient population. ROE and ROE-D mainly cover aesthetic aspects and depict functional aspects in only one out of six questions.

The follow-up time in the literature varies greatly [3, 5, 12–17]. Izu et al. [12] showed differences between the 15th and 90th postoperative day and argued that an improved ROE score after 90 days is due to a decline of postoperative edema. In a retrospective cohort, Hellings et al. [13] were able to show a significant improvement in ROE in 90

patients after rhinoplasty revision. A prospective study with 225 patients also showed a significant improvement in ROE scores postoperatively [18]. An improvement in ROE-D scores could be demonstrated in this study 6 months and 1 year after surgery, similar to Alsarraf et al. [3] who observed this after 5 months. We consider an outcome assessment before this time as premature due to postoperative swelling and scarring. The final cosmetic and functional result should be awaited.

Five out of six questions in the ROE and thus also in the ROE-D focus on cosmetic aspects. Only one question ("how well you can breathe through your nose?") concentrates on the function. To put a stronger emphasis on the functional aspect, the functional rhinoplasty outcome inventory 17 (FROI-17) was developed and validated. The FROI-17 showed a stronger correlation with the generic SF-36 compared with the ROE [4, 5]. The survey with the FROI-17 takes an average of 5–10 min and therefore slightly longer than the ROE [5].

It should be mentioned that several studies have demonstrated an improvement in HRQL with non-rhinoplasty-specific instruments (SF-36, NOSE and Rosenberg questionnaire) [4, 8, 14, 17–19]. The impact on the overall quality of life can be examined with the SF-36, the influence of nasal breathing with the NOSE questionnaire. The Rosenberg questionnaire measures the global self-esteem and becomes increasingly important in diagnosing a body dysmorphic disorder (BDD), which is a disturbance in perception of the own body.

Picavet et al. [8] pointed out that there is a correlation between the patient's desire for rhinoplasty and a medium to severe body dysmorphic disorder (BDD). An increasing demand for a preoperative screening for these patients can be noted. The ROE-D does not consider this aspect, because it was not designed for this task. According to our research, there is no validated standard questionnaire to identify possible BDD patients before plastic surgery. The present study shows that the ROE-D is a reliable, valid and sensitive tool for measuring HRQL in patients with desire for rhinoplasty. The questionnaire reliably measures the aesthetic problems of the patient and detects the sensitivity of clinical changes postoperatively. The results can be easily interpreted by the examiner. As quality of life results are gaining importance, it is highly recommended that validated instruments are used. This study ensures that there is a validated German tool for rhinoplasty patients.

Conclusion

The rhinoplasty outcomes evaluation German version (ROE-D) is a reliable, valid and sensitive German-language tool for measuring health-related quality of life in patients with desire for rhinoplasty surgery. The ROE-D focuses mainly on the aesthetic aspects of the rhinoplasty surgery. It is characterized by practical design and can be easily interpreted by the treating physician.

Compliance with ethical standards

Funding None.

Conflict of interest All authors declare that they have conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

 Koller M, Klinkhammer-Schalke M, Lorenz W (2005) Outcome and quality of life in medicine: a conceptual framework to put quality of life research into practice. Urol Oncol 23(3):186–192

- Hopkins C (2009) Patient reported outcome measures in rhinology. Rhinology 47(1):10–17
- 3. Alsarraf R et al (2001) Measuring cosmetic facial plastic surgery outcomes: a pilot study. Arch Facial Plast Surg 3(3):198–201
- 4. Bulut C et al (2014) Development and validation of the functional rhinoplasty outcome inventory 17 (FROI-17). Rhinology 52(4):315–319
- Bulut OC et al (2015) Quality of life after septorhinoplasty measured with the functional rhinoplasty outcome inventory 17 (FROI-17). Rhinology 53(1):54–58
- 6. Cohen J (1977) Statistical power analysis for the behavioral sciences. Rev ed, Academic Press, New York. xv, p 474
- Baumann I et al (2007) Quality of life in patients with chronic rhinosinusitis: validation of the Sino-Nasal Outcome Test-20 German adapted version. HNO 55(1):42–47
- Picavet V et al (2011) Screening tools for body dysmorphic disorder in a cosmetic surgery setting. Laryngoscope 121(12):2535–2541
- Piccirillo JF, Merritt MG Jr, Richards ML (2002) Psychometric and clinimetric validity of the 20-item Sino-Nasal Outcome Test (SNOT-20). Otolaryngol Head Neck Surg 126(1):41–47
- Baumann I et al (2009) Development and validation of the parotidectomy outcome inventory 8 (POI-8). Measurement of quality of life after parotidectomy in benign diseases. HNO 57(9):884–888
- Skevas T et al (2012) Development and validation of the tonsillectomy outcome inventory 14. HNO 60(9):801–806
- Izu SC et al (2014) Validation of the rhinoplasty outcomes evaluation (ROE) questionnaire adapted to Brazilian Portuguese. Qual Life Res 23(3):953–958
- Hellings PW, Nolst Trenite GJ (2007) Long-term patient satisfaction after revision rhinoplasty. Laryngoscope 117(6):985–989
- Fatemi MJ et al (2012) Quality of life among Iranian adults before and after rhinoplasty. Aesth Plast Surg 36(2):448–452
- Zojaji R et al (2014) Quality of life in patients who underwent rhinoplasty. Facial Plast Surg 30(5):593–596
- Meningaud JP, Lantieri L, Bertrand JC (2008) Rhinoplasty: an outcome research. Plast Reconstr Surg 121(1):251–257
- Saleh AM, Younes A, Friedman O (2012) Cosmetics and function: quality-of-life changes after rhinoplasty surgery. Laryngoscope 122(2):254–259
- Cingi C, Songu M, Bal C (2011) Outcomes research in rhinoplasty: body image and quality of life. Am J Rhinol Allergy 25(4):263–267
- Stewart MG et al (2004) Development and validation of the nasal obstruction symptom evaluation (NOSE) scale. Otolaryngol Head Neck Surg 130(2):157–163