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Health Utility of Rhinectomy, Surgical Nasal Reconstruction, and Prosthetic Rehabilitation

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Objectives: Advanced nasal malignancies may require rhinectomy, which can have profound psychosocial impacts. Rhinectomy defects can be rehabilitated through surgery or prosthetics. We seek to understand the health utility of the rhinectomy defect, surgical, and prosthetic reconstruction, which have not been previously studied.

Study Design: Prospective clinical study

Methods: Adult naïve observers (n = 273) ranked the utility of five randomized health states (monocular blindness, binocular blindness, post-rhinectomy nasal defect, postsurgical reconstruction, and post-prosthetic rehabilitation). Health utilities were measured using visual analogue scale (VAS), standard gamble (SG), and time trade-off (TTO). One-way analysis of variance (ANOVA) with post hoc Scheffe's test and the independent samples T-test for a priori comparisons were performed. Multiple linear regression was performed using participant demographics as independent predictors of utility scores.

Results: Health utilities (VAS, SG, TTO) were reported as follows (mean ± SD): monocular blindness (0.71 ± 0.21, 0.84 ± 0.20, 0.85 ± 0.19), binocular blindness (0.48 ± 0.25, 0.68 ± 0.28, 0.63 ± 0.28), post-rhinectomy nasal defect (0.59 ± 0.24, 0.74 ± 0.24, 0.74 ± 0.24), postsurgical reconstruction (0.88 ± 0.16, 0.90 ± 0.18, 0.89 ± 0.13), and post-prosthetic rehabilitation (0.67 ± 0.22, 0.80 ± 0.23, 0.82 ± 0.20). Both surgical reconstruction ($P < .001$) and prosthetic rehabilitation ($P < .001$) significantly improved health utility. SG and TTO utility scores were inversely associated with observer age ($P < .001$) and participants who identified themselves as non-Caucasians ($P < .05$) in post-rhinectomy nasal defect, post-nasal surgical reconstruction, and post-nasal prosthetic rehabilitation health states, while higher levels of education were directly associated with SG scores ($P < .05$), respectively.

Conclusion: This is the first study to demonstrate the significant negative impact of the rhinectomy nasal defect on health utility. Rehabilitation by surgical or prosthetic techniques significantly increases health utility as rated by naïve observers.

Key Words: Health utility, rhinectomy, nasal reconstruction, nasal prosthesis, time trade off, standard gamble, visual analog scale, nasal cancer reconstruction.

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INTRODUCTION

The face is central to our self-image and our ability to communicate with others. Facial deformity is known to cause a significant negative impact on psychosocial well-being.[1,2] The nose is an essential facial landmark in the central midface, an area key for facial recognition and attractiveness.[3–5] Severe deformities in this area can carry a high aesthetic and functional penalty for affected individuals.[3,6]

Nasal deformity is on a spectrum of mild to severe, with the most severe nasal deformity arguably caused by nasal amputation (rhinectomy). Advanced nasal malignancies may require total or partial rhinectomy.[7,8] Although a sound oncological operation, total or partial rhinectomy creates a sizeable central midface defect, resulting in a profound aesthetic and psychosocial impact.[6] Prosthetic rehabilitation (where available) has been the standard of care,[9] however, improvements in survivorship and surgical reconstructive techniques have led to renewed interest in surgical reconstruction. The societal-derived preferences of rhinectomy and its surgical and prosthetic rehabilitation were heretofore unknown.

Societal preference of diseased states can be used to quantify the health utility. These utility scores are classically scored from 0 (death) to 1 (perfect health). There is no one ideal tool or criterion for measuring utility scores, so multiple tools are often employed concurrently to minimize the inherent weakness of any one technique. The most frequently used measures of health utility include visual analogue scales (VAS), standard gamble (SG), and time-trade-off (TTO) techniques.[10]

Health utility can be converted into quality-adjusted life years (QALYs), which provide a basis with which to assess the economic impact of medical interventions. This

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calculation allows for comparisons between different medical interventions and resource allocation decisions. Utilities may be measured from a variety of populations including patients suffering from the disease, health care providers, or members of the general population. The latter is typically favored based on the argument that societal preference is best suited to guide the allocation of public funds.[11]

To our knowledge, this is the first study to examine the health utility of the rhinectomy defect, as well as its surgical reconstruction and prosthetic rehabilitation health states, as assessed among naïve observers.

METHODS

The Massachusetts Eye and Ear Infirmary Research Ethics Board approved this study and it was completed in accordance with the Declaration of Helsinki ethical guidelines for human subject research.

Research Facility and Survey Tool

Adult naïve observers (n = 310) were enrolled in this study at the Harvard Decision Science Laboratory (HDSL, Harvard University, Cambridge, MA). The HDSL is a biobehavioral laboratory which maintains a large and diverse pool of approximately 2400 adult subjects from the general population who volunteer to participate in scientific investigations of human judgment and decision-making. The participants hold varying levels of education, and are of various races and annual household income. The lab consists of 36 individual computer stations, each equipped with two display screens and an integrated headphone and microphone system for each subject to aid in study participation and subject monitoring. Multiple 1-hour time slots were reserved daily at the lab for survey participation. A group of trained research assistants were available on site to conduct each survey session and assist with Research Electronic Data Capture (REDCap) survey administration and monitoring. All participants undertook only a single study on any given day to reduce the effects of survey fatigue. All volunteers signed an electronic consent form before completing any questionnaire. The survey tool used to construct health utility questionnaires and demographic surveys were similar to that of prior studies using REDCap electronic data capture.[12,13] Study data were collected and managed using REDCap a secure, web-based application.[14,15]

Health State Utility Assessment

Health utility was measured using the three established methods described in cost-effectiveness analysis literature as well as in previous investigations of health utility[16,17]: VAS, SG, and TTO. The utilization of all three tools for obtaining utility scores is optimal to minimize the inherent weaknesses of any single test.[18]

In the VAS method, participants were asked to imagine that they had the same degree of facial disfigurement and aesthetic impairment as each person pictured and described in the vignette. They were then asked to rate their perceived state of health on a continuous sliding scale, anchored at both ends with 0 (representing death) and 100 (representing perfect health).

In the SG method, participants were asked to imagine themselves as the person with the nasal defect and choose between living with facial disfigurement for the remainder of their life or electing to undergo a surgical procedure, which carries a specified risk of immediate death, to completely correct the nasal defect.

In the TTO method, participants were asked to imagine themselves as the person with the nasal defect and choose between living with facial disfigurement for the remainder of their life (18 years) or electing to trade off years of life to have the nasal defect completely corrected. Based on average life expectancy (~80 years) and the median age of patients who have undergone rhinectomy (~62 years),[19] 18 years was used as the estimated remaining life expectancy. Both the SG and TTO components use the ping-pong method[20] to determine the point of inflection, or the maximum risk of death a participant is willing to risk and the maximum amount of remaining life years that a participant is willing to trade off, respectively, to live without a nasal defect. For both SG and TTO a maximal six-level iterative ping-pong approach was used to determine the infection point.

Clinical Vignettes

Clinical vignettes of a non-acute post-rhinectomy nasal defect, post-nasal surgical reconstruction, and post-nasal prosthetic rehabilitation health states were constructed based on expert opinion (CF and LNL) and accompanied by representative patient images (Figs. 1 and 2). Monocular and binocular

Fig. 1. Rhinectomy defect and nasal prosthesis. A) Rhinectomy defect with osseointegrated implants. B) Nasal prosthesis photo. C) Rhinectomy defect with nasal prosthesis in situ. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

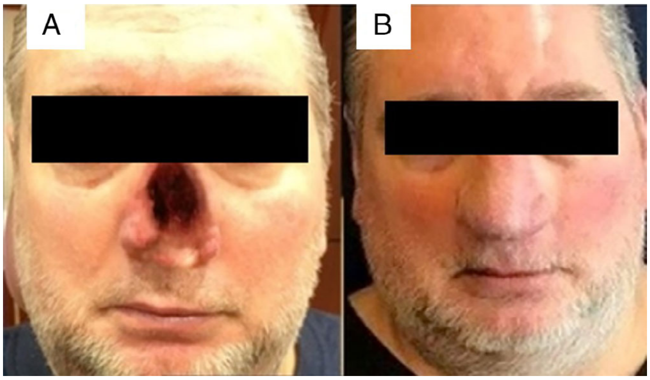

Fig. 2. Images of rhinectomy-related health states including prosthetic rehabilitation. A) Nasal rhinectomy healed defect. B) Surgical reconstruction of the rhinectomy defect. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

blindness scenarios were included as sources of internal control to assess participant comprehension of the study. The clinical vignettes are attached in Appendix A.

RESULTS

Statistical Analysis

Health utility scores (VAS, SG, TTO) were normalized to a 0 to 1 scale according to the following formulas: VAS score by the formula: VAS/100; SG score by the formula: (100 – percent risk of death at the point of indifference) / 100; and TTO score by the formula: (18 years – number of years traded off at the point of indifference) / 18 years. Responses in which a participant ranked binocular blindness as having a higher utility than monocular blindness on one or more of VAS, SG, or TTO measures, or reported identical utility ratings across all scenarios were excluded. Means and standard deviations of VAS, SG, and TTO scores for each health state were calculated and data was assessed for normality and homogeneity using the Shapiro-Wilk test and Levene statistic, respectively. Differences between utility scores (VAS, SG, TTO) of the different health states were assessed using one-way analysis of variance (ANOVA) with post hoc pairwise comparison using Scheffe's method and the independent samples T-test (two-sided) for a priori comparisons. Multiple linear regression was performed using age, sex, race, income, and education as independent predictors of each of the utility scores (VAS, SG, TTO). Tests were performed using IBM SPSS Statistics (v23 IBM Corp., Armonk, NY), with a significance level (α) set at 0.05 (two-tailed) with Bonferroni correction.

Demographics

During a 6-month enrollment period, 310 individuals completed the survey at the Harvard Decision Science Laboratory.

Among the 310 sets of completed responses, surveys from 273 participants (mean [SD] age, 29.6 [12.1] years; 135 women [49.5%]; 133 men [48.7%]; five unknown [1.8%]) met inclusion criteria and were included in the final analysis.

Thirty-seven surveys in which a respondent rated binocular blindness as having a higher utility than monocular blindness (VAS, SG, or TTO) or reported identical utility ratings across all scenarios were excluded from the analysis. While demographics skewed toward younger

TABLE I.
Demographic Characteristics of Study Participants.

Characteristic	No. (%) of Participants (N = 273)
Age, mean ± SD	29.6 ± 12.1
Sex	
Female	135 (49.5)
Male	133 (48.7)
Unknown	5 (1.8)
Race/ethnicity	
Caucasian	146 (53.5)
Asian/Pacific islander	51 (18.7)
African American	15 (5.5)
Mixed race	18 (6.6)
Latino or Hispanic	13 (4.8)
Arab	1 (0.4)
Bangladeshi, Pakistani, Indian	12 (4.4)
Native American/Aleut/Aboriginal	0 (0.0)
Other	9 (3.3)
Decline to answer	8 (2.9)
Education level	
Some high school	1 (0.4)
High school diploma or GED	16 (5.9)
Some college	76 (27.8)
Associate's degree	5 (1.8)
Bachelor's degree	71 (26.0)
Some graduate school	39 (14.3)
Graduate or professional degree	61 (22.3)
Professional certification	2 (0.7)
Decline to answer	2 (0.7)
Annual Household Income	
<15,000	29 (10.6)
$15,001–25,000	22 (8.1)
$25,001–35,000	25 (9.2)
$35,001–50,000	32 (11.7)
$50,001–75,000	41 (15.0)
$75,001–100,000	30 (11.0)
>$100,001	45 (16.5)
Decline to answer	49 (17.9)
Marital Status	
Single	159 (58.2)
Committed relationship	60 (22.0)
Married	38 (13.9)
Separated	3 (1.1)
Divorced	6 (2.2)
Decline to answer	7 (2.6)

TABLE II.
Health Utility Outcome Scores (N = 273).

	Health Utility Scores*					
Method	Monocular blindness	Binocular blindness	Post-rhinectomy nasal defect	Post-nasal surgical reconstruction	Post-nasal prosthetic rehabilitation	$P^{\dagger}$
VAS	0.71 ± 0.21	0.48 ± 0.25	0.59 ± 0.24	0.88 ± 0.16	0.67 ± 0.22	**<.001**
SG	0.84 ± 0.20	0.68 ± 0.28	0.74 ± 0.24	0.90 ± 0.18	0.80 ± 0.23	**<.001**
TTO	0.85 ± 0.19	0.63 ± 0.28	0.74 ± 0.24	0.89 ± 0.13	0.82 ± 0.20	**<.001**

SG = standard gamble; TTO = time trade-off; VAS = visual analogue scale.
*Values are reported as mean ± standard deviation.
†One-way analysis of variance.

individuals with higher levels of education, observer sex was evenly distributed between males and females. Relationship status also skewed toward single individuals, but race/ethnicity and annual household income were heterogeneously distributed amongst included participants. Demographic characteristics of study participants are listed in Table I.

Health Utility Scores

Health utility values ranged from 0 (death) to 1 (perfect health with no nasal deformity) and are reported in Table II. Mean ± SD utility scores (VAS, SG, TTO) for post-rhinectomy nasal defect were 0.59 ± 0.24, 0.74 ± 0.24, and 0.74 ± 0.24, which ranked significantly lower than scores for monocular blindness (0.71 ± 0.21, 0.84 ± 0.20, and 0.85 ± 0.19; $P < .001$, all measures), but higher than binocular blindness (0.48 ± 0.25, 0.68 ± 0.28, and 0.63 ± 0.28), respectively. When differences existed, post-hoc comparisons demonstrated that post-nasal surgical reconstruction (0.88 ± 0.16, 0.90 ± 0.18, and 0.89 ± 0.13) and post-nasal prosthetic rehabilitation (0.67 ± 0.22, 0.80 ± 0.23, and 0.82 ± 0.20) significantly improved health utility across VAS, SG, and TTO measures when compared to the post-rhinectomy nasal defect health state (Table III). A priori T-test comparisons demonstrated a significant societal preference for surgical reconstruction ($P < .001$; all measures) over prosthetic rehabilitation (Table IV).

TABLE III.
Post Hoc Pairwise Comparisons Between Health Utility States.

Health Utility Compared to Post-Rhinectomy Nasal Defect			
Comparison health state	Method	Mean difference [95% CI]	P*
Monocular blindness	VAS	+0.12 [0.07–0.18]	**<.001**
	SG	+0.10 [0.04–0.16]	**<.001**
	TTO	+0.11 [0.05–0.16]	**<.001**
Binocular blindness	VAS	−0.11 [−0.17 to −0.05]	**<.001**
	SG	−0.06 [−0.12–0.00]	**.043**
	TTO	−0.11 [−0.17 to −0.05]	**<.001**
Post–nasal surgical reconstruction	VAS	+0.29 [0.24–0.35]	**<.001**
	SG	+0.16 [0.10–0.22]	**<.001**
	TTO	+0.15 [0.09–0.21]	**<.001**
Post–nasal prosthetic rehabilitation	VAS	+0.09 [0.03–0.14]	**<.001**
	SG	+0.06 [0.00–0.12]	**.043**
	TTO	+0.08 [0.02–0.14]	**.001**

*Post hoc Scheffe test for pairwise comparisons performed only where differences between groups were detected by analysis of variance;. Bold indicates significant at α = 0.05. SG = standard gamble; TTO = time trade-off; VAS = visual analogue scale.

Multiple Linear Regression

Multiple linear regression analysis showed no significant differences with observer sex or income as independent predictors of utility scores (VAS, SG, TTO) for the post-rhinectomy nasal defect, post-nasal prosthetic rehabilitation, or post-nasal surgical reconstruction health states.

Observer age was inversely associated with SG and TTO scores for post-rhinectomy nasal defect: SG (β = –0.006, 95% CI, –0.009 to –0.004, $P < .001$) and TTO (β = –0.004, 95% CI, –0.007 to –0.002, $P < .001$); post-nasal prosthetic rehabilitation: SG (β = –0.006, 95% CI, –0.008 to –0.003, $P < .001$] and TTO (β = –0.004, 95% CI, –0.006 to –0.002, $P < .001$); and SG scores for post-nasal surgical reconstruction: SG (β = –0.005, 95% CI, –0.007 to –0.003, $P < .001$], with older participants demonstrating more risk-taking behavior than younger participants to attain perfect health (ie, normal facial appearance with no nasal deformity).

Observer race/ethnicity was also inversely associated with TTO scores for post-rhinectomy nasal defect: TTO (β = –0.014, 95% CI, –0.026 to –0.002, $P = .020$); and post-

TABLE IV.
A Priori Comparisons Between Post-Nasal Surgical Reconstruction and Post-Nasal Prosthetic Rehabilitation Health States.

Health Utility Scores				
Method	Post-nasal surgical reconstruction	Post-nasal prosthetic rehabilitation	Mean difference [95% CI]	P*
VAS	0.88 ± 0.16	0.67 ± 0.22	+0.21 [0.17–0.25]	**<.001**
SG	0.90 ± 0.18	0.80 ± 0.23	+0.10 [0.06–0.14]	**<.001**
TTO	0.89 ± 0.13	0.82 ± 0.20	+0.07 [0.04–0.11]	**<.001**

*Independent samples T-test. Bold indicates significant at α = 0.05. SG = standard gamble; TTO = time trade-off; VAS = visual analogue scale.

nasal prosthetic rehabilitation: TTO (β = –0.011, 95% CI, –0.021 to –0.001, P = .028), with non-Caucasian participants willing to trade off more life years to attain perfect health when compared to their Caucasian counterparts.

Higher observer levels of education were directly associated with SG scores in post-rhinectomy nasal defect: SG (β = 0.023, 95% CI, 0.005–0.041, P = .011); post-nasal prosthetic rehabilitation: SG (β = 0.020, 95% CI, 0.004–0.036, P = .017); and post-nasal surgical reconstruction: SG (β = 0.013, 95% CI, 0.001–-0.026, P = .041).

DISCUSSION

Rhinectomy is generally performed for advanced malignant disease of the skin or advanced nasal vestibular malignancy.[8,9,21] Pathologies vary and include squamous cell carcinoma, basal cell carcinoma, Merkel cell carcinoma, and Melanoma.[9] Data exist for the incidence of vestibular cancer, with the reported annual incidence estimated at 0.32 per 100,000 habitats.[21] Rhinectomy, however, is generally reserved as a treatment option only for advanced vestibular cancers[21–23] (Wang 2 and 3 classification),[24] which comprise roughly a third of this rate. The incidence of cutaneous malignancy requiring rhinectomy remains unreported in the English literature. The true rhinectomy incidence is therefore unknown and likely varies with geographic location, based on differences in the incidence of cutaneous malignancies and preference for treatment modality (surgery or radiotherapy) for vestibular carcinoma.

Facial oncological ablative surgery results in defects that have various functional and psychosocial difficulties for the affected individuals.[6,19,25] Of particular importance is the central face (eyes, nose, and mouth), as it is key to facial identification, and is the main focus of interest when casual observers visually inspect a new face.[26] It is not surprising, therefore, that large central facial lesions have an adverse effect on facial perception and following a destructive procedure such as rhinectomy, and patients may experience difficulty communicating with lay individuals.[3,26] Appropriate rehabilitation of these patients is vital, as the majority will have long-term survivorship (58% to 85%).[8,9,22] Key to the rehabilitation of these patients is the reduction of their facial deformity, normalizing how they are viewed by society.[27]

These issues are reflected in the first major finding of this study, the estimation of the health utility of rhinectomy defects. The societal preference for a large central midface/rhinectomy defect health state approached that of binocular blindness (Table II) and is similar to that of other health states considered for facial transplantation (VAS 0.46 0.02, TTO 0.68 0.03, and SG 0.66 0.03, respectively).[17] Put simply, participants would give up 26%, or 4.68 years of their remaining 18 years of life, and tolerate a 26% risk of death to have normality restored.

Three rehabilitation options are routinely employed: no rehabilitation (simple nasal dressing), prosthetic rehabilitation and surgical reconstruction. Various factors are taken into consideration, the age of the patient, medical comorbidities, patient's wishes, disease status and risk of recurrence.

The second major finding of the study is the observed difference in both post-nasal surgical reconstruction TTO derived health utility (0.15) and post-nasal prosthetic rehabilitation TTO health utility (0.08), when compared to the post-rhinectomy nasal defect health state. The post-nasal rehabilitation health states had higher health utilities than those of other common conditions such as end-stage renal disease following renal transplant at 0.78 (TTO), and stage II HIV infection at 0.75 (TTO).[28]

In general, almost all patients are candidates for prosthetic rehabilitation. A nasal prosthesis can be secured through tissue adhesives or by osseointegrated implants. These can be applied before or after radiotherapy with excellent implant integration rates (overall 89% (99/111); 94% no radiotherapy and 86% post-radiotherapy).[29] Nasal prostheses are well-tolerated by patients, and previous studies have demonstrated promising trends in HRQoL post-prosthetic rehabilitation,[25] however prosthetic retention remains a concern with increasing activity.[19,25] Additionally not all healthcare systems or insurers offer prosthetic rehabilitation as routine.

Surgical reconstruction is complex and not routine. It requires a well-motivated patient for requiring multistage procedure and specific nasal reconstructive expertise. However, in the health states presented in this study a societal preference for surgical reconstruction (P < .001; all measures) over prosthetic rehabilitation was noted.

Due to the wide variety of etiologies and varying recurrence rates reported in the literature, the ideal timing of surgical reconstruction is unclear; recommendations range from 1 to 2 years post-completion of therapy.[8,9]

The median age of patients who have undergone rhinectomy is 62 years (range 37–87 years).[19] Any intervention that increases health utility by 0.15 and 0.08 over a remaining average life expectancy of 18 years would comprise a gain for surgical rehabilitation of 2.70 QALYs, and prosthetic rehabilitation of 1.44 QALYs, respectively. These findings support the surgical rehabilitation or prosthetic rehabilitation of patients. In patients where immediate surgical reconstruction should be delayed for oncological or medical reasons, bridging the observation period with prosthetic rehabilitation seems practical. QALYs are used for health resource allocation. Estimates for the cost-effectiveness threshold per QALY for medical interventions is 100,000 dollars per QALY.[30] If an intervention increases a patient's health utility by 0.15 over a remaining lifetime of 18 years, the total gain in QALYs would be (0.15×18) 2.7. Given that the cost-effectiveness threshold is estimated at 100,000 dollars per QALY this intervention would, therefore, have its cost-effective threshold at $270,000.

LIMITATIONS

Study participants were younger with higher levels of education than the national average.[31] Clinical vignettes herein comprised of a single adult patient example for each health state to avoid survey fatigue, with adequate but nonstandardized photographs. Extrapolation of the results must be performed with care, as factors such as race, gender, age, and attractiveness were not explicitly accounted for. Alternative methodologies utilizing multiple examples of varying degrees of severity of the health state under investigation, with varying outcomes from intervention with mixed-effects regression model analysis to account for such potential confounders could be employed.[32,33] While this study provides insights into observer preferences for rhinectomy, prosthetic rehabilitation, and total nose reconstruction, no definitive conclusions can be made about the absolute health utility values of these states among those afflicted within the general population.

CONCLUSIONS

The health utility of an individual following rhinectomy is significantly reduced, approaching that of binocular blindness and individuals requiring face transplant.

Significantly higher societal health utility of rehabilitation patients by total nose reconstruction or prosthetic rehabilitation was observed. Further studies are required to characterize the health utility of rhinectomy and its surgical or prosthetic rehabilitation.

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