Published in final edited form as:

Int Forum Allergy Rhinol. 2015 January ; 5(1): 55–59. doi:10.1002/alr.21420.

The significance of response shift in sinus surgery outcomes

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Abstract

Background—Functional endoscopic sinus surgery (FESS) aims to improve quality-of-life (QOL). Perception of QOL can change according to one's current medical or emotional state. This is known as response shift. It can be measured by the Then-test, which asks patients to report pre-treatment symptoms after receiving treatment. Patients often do not understand their disease burden until their symptoms are improved. This study aims to assess the significance of response shift in FESS outcomes.

Methods—This was a prospective cohort study that included chronic rhinosinusitis patients from 2010–2012 who completed a pre-operative sino-nasal outcome test (SNOT-20). Two SNOT-20's were mailed approximately 6 months after surgery. Patients completed one SNOT-20 according to their pre-operative symptoms in light of their current state of health ("then-test") and the other based on post-operative symptoms. The pre- and post-operative SNOT-20 difference represented the treatment effect and the pre-operative SNOT-20 and then-test difference represented response shift.

Results—32 completed responses were obtained. Using a zero to five scale, mean treatment effect was -0.96 ($P < 0.01$), which signifies a QOL improvement. Mean response shift was $+0.42$ ($P=0.01$). This positive value signifies that patients felt they were worse off pre-operatively, likely due to a positive change in health status. The actual treatment effect is the sum of the measured treatment effect and response shift, which was -1.38 .

Discussion—Response shift exists and can be quantified. The actual treatment effect was more profound when response shift was included. Therefore, future studies should account for this often unmeasured, potential change in QOL.

Keywords

chronic rhinosinusitis; endoscopic sinus surgery; quality of life; SNOT-22

Introduction

Chronic rhinosinusitis (CRS) affects 14–16% of the US population and leads to a significant reduction in quality-of-life (QOL).^{1,2} Patient related outcome studies using several validated instruments show that functional endoscopic sinus surgery (FESS) improves QOL in 76–91% of patients.^{3,4,5,6,7}

QOL is an individual and dynamic experience. Outcomes of surgical treatment are often determined by pre and post-operative patient-reported QOL questionnaires. This measured treatment effect may be under or over-estimated due to a phenomenon called response shift, which is defined as a change in one's self-evaluation of a construct due to changes in health state.^{8,9} For example, in patients with chronic disease and consequent health changes, their interpretation of QOL may change as their condition evolves. This may be due to a change in one's internal standards for measuring QOL also known as recalibration.^{8,9}

One method to measure response shift is the Then-test which captures response shift due to changes in internal standards. The then-test was initially introduced in educational training research but was recently extended to health-related QOL research.^{10, 11, 12}

The then-test is a retrospective evaluation of a prior assessment by the same patient in light of changes in his or her current health state and perception of symptoms. In surgical patients, a pre-operative questionnaire is administered to assess baseline symptoms. Post-operatively, the same questionnaire is given to assess symptoms after surgical treatment. The difference in scores is a measure of the treatment effect or QOL change. To measure response shift, post-operative patients complete the same pre-operative questionnaire while taking into account their new state of health. The difference between pre-operative baseline and the then-test scores represents the magnitude and direction of response shift (Figure 1). Response shift addresses the common clinical finding that patients often say they never knew how badly off they were until their symptoms went away.

Improving QOL is the primary goal of surgical treatment for CRS. Therefore it is important to accurately measure the treatment effect after intervention. There are no known studies on the effects of response shift in CRS patients after surgical intervention. The primary aim of this study was to evaluate the significance of response shift on patient-reported QOL change after FESS. A secondary aim was to identify patient factors that may affect QOL change and response shift.

Methods

This was a prospective cohort study approved by the University of Washington Institutional Review Board. Patients of the senior author (GED) with a diagnosis of CRS based on the 2007 American Academy of Otolaryngology Rhinosinusitis Task Force criteria who underwent FESS from 2010–2012 were included in the study.¹³ All patients with a completed pre-operative Sinonasal outcome test (SNOT-20) and who were at least 6 months out from surgery were prospectively recruited for the study.¹⁴ Exclusion criteria included incomplete SNOT-20, incomplete electronic medical records, and revision surgery within the time of this study.

A sample size was calculated using 90% power, alpha = 0.05, and a SNOT-20 effect size of 0.80 which yielded a minimum N of 14.

Patients were contacted by telephone. Those who consented to participate were mailed a survey packet. Two QOL instruments were included: the SNOT-20 and a transition QOL questionnaire which asks patients whether they felt better, the same, or worse after surgery

(Figure 2). The survey packet contained two SNOT-20 questionnaires and one transition QOL questionnaire. One SNOT-20 was labeled “pre-surgery condition” and the other was labeled “post-surgery condition.” Participants were prompted to complete the pre-surgery condition survey according to how they perceived their preoperative symptoms now, given their current health state after surgical intervention. They were instructed to complete the second survey based on their current symptoms.

Electronic records were reviewed for patient demographics and comorbidities. Specifically, depression was defined as patients who were receiving active treatment. Allergic rhinitis was positive if the patient had previous positive allergy testing. SNOT-20 scores were calculated on a 0 to 5 scale as originally described by Piccirillo et al.¹⁴ The 0 to 5 scale is the same metric as a 0 to 100 scale with the total score divided by 5. The data was transferred to Stata 10.0 for statistical analysis. The chi-square test and student t-test were used to compare cohort characteristics. Pre-operative, post-operative, and then-test scores were calculated and analyzed using a student T-test. Change in QOL and response shift scores were stratified by patient factors including smoking, previous surgery, depression, asthma, allergic rhinitis, nasal polypsis, aspirin or non-steroidal anti-inflammatory drug sensitivity and compared using a Wilcoxon test.

Results

A total of 79 patients met inclusion criteria. Thirty-three responses were obtained, yielding a response rate of 42%. One was excluded due to an incomplete SNOT-20, yielding a total of 32 responders. Seven cases in the non-responder cohort were excluded, yielding a total of 40 non-responders. Table 1 shows general characteristics and comorbidities in the responder and non-responder groups. Both cohorts had similar age, gender, and ethnic distribution. More than half were revision cases in both cohorts. There were no significant differences in clinical characteristics between the responder and non-responder cohort.

Using a zero to five scale, the mean pre-op, post-op, and then-test SNOT-20 scores were 1.80, 0.84, and 2.22, respectively. The difference between pre and post-op scores was -0.96 ($p < 0.01$), which is a measure of the observed QOL change. The negative value signifies an improvement in QOL. The difference between pre-op and then-test scores was +0.42 ($p=0.01$), which represents the magnitude of response shift. The positive value represents a decrease in QOL, meaning patients currently feel they were worse off pre-operatively than they actually reported at that pre-operative time point. The sum of observed QOL and response shift yields an adjusted QOL change of -1.38 representing a greater degree of significant clinical improvement than initially expected by standard analysis techniques (Figure 3).

Observed QOL and response shift scores were stratified by each category on the transition QOL scale (Table 2). Twenty-nine of the 32 patients (92%) felt at least “a little better” after surgery. Over one-third of patients felt “a very great deal better” (34%). Response shift scores tended to become more positive, meaning patients thought they were worse off, and observed QOL change became more negative, meaning patients had a greater improvement in QOL, with increased subjective improvement in symptoms. Those who felt “a great deal

better” had a statistically higher magnitude of response shift and a greater improvement in QOL.

Scores were stratified by select clinical characteristics that may affect outcomes (Table 3). Only smoking had a significantly larger response shift compared to non-smokers. All other factors had no statistically significant difference in response shift and observed QOL change scores.

Discussion

Overall, this cohort reported significant improvement in symptoms after surgical intervention. With a SNOT-20 score change of 0.96 after surgery, this was a clinically significant change (defined as greater than 0.80 by Piccarillo et al.)¹⁴. Response shift was both measurable and statistically significant. With a magnitude of 0.42, this was a sizable QOL change that would otherwise be missed if a then-test were not incorporated. Though response shift did not affect whether our surgical outcomes were clinically significant, it is easy to imagine that a SNOT-20 change of 0.42 may have a significant impact. Depending on the direction of the response shift, a study may arrive at a false negative or false positive conclusion if a significant magnitude of response shift is not accounted for.

Our results were associated with subjective improvements as well. Patients who indicated they had the largest improvement in symptoms also had significantly higher QOL change and response shift scores implying that with greater subjective improvement in symptoms, there may be a greater shift in internal standards leading to a more significant response shift.

Previous studies have shown that certain clinical characteristics such as depression, asthma, nasal polyposis, smoking, and aspirin sensitivity may be potential predictors of surgical outcome.^{7, 15, 16} In this study, only smoking appeared to significantly affect the observed change in QOL scores. No other patient factors appear to affect response shift or observed change in QOL. However, this analysis is limited by a small sample size, particularly after stratification.

The then-test has been historically used to detect response shift due to recalibration or changes in individual perception of symptom severity resulting from changes in internal standards. Studies show that patients are aware of this change in QOL perception.¹¹ An individual’s perception of symptom severity can be affected by improvement in symptoms after an intervention. This change in internal standards is what the then-test is designed to capture. However, the then-test may not capture response shift due to other mechanisms such as reprioritization or reconceptualization.^{8,9} Reprioritization is due to a change in what is perceived as the most important domains or components that affect QOL. Reconceptualization refers to a change in how one defines QOL. For example, after a patient meets others with the same disease, his idea of an adequate QOL may change despite a worsening health state. Response shift due to reprioritization and reconceptualization can potentially be measured by using individualized QOL questionnaires or structural equation modeling.^{17,18} Therefore, there may be additional sources of response shift that is not measured simply by using the then-test.

Other concerns regarding the use of the then-test include confounding by recall bias and an inability to separate changes in internal standards that may be due to other life events besides a medical intervention.¹⁹ Though it is challenging to control for recall bias, it may be accomplished by asking patients to specifically recall pre-operative symptoms while ignoring changes in their health state. However, asking patients to complete 2 post-test surveys at the same time can cause confusion and additional bias.

Conclusion

Outcomes research depends heavily on patient-reported symptoms gathered by surveys. Response shift is both measurable and can significantly affect sinus surgery outcomes. Utilization of the then-test or other methods to capture response shift should be considered in future outcomes studies.

Acknowledgments

Financial disclosure statements

The project described was supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant KL2 RR025015 (GED). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

The project described was also supported by the National Institutes Health grant: T32 DC000018-27 (JL).

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$$\text{True QOL change} = (\text{Reported QOL change}) + (\text{Response shift})$$

Figure 1.

(Please indicate if there has been any change by checking one of the following.)

<div style="text-align: right; margin-bottom: 10px;">Better ☐</div> <div style="text-align: right; margin-bottom: 10px;">About the Same ☐</div> <div style="text-align: right;">Worse ☐</div>	<div style="text-align: right; margin-bottom: 10px;">Better ☐</div> <div style="text-align: right; margin-bottom: 10px;">About the Same ☐</div> <div style="text-align: right;">Worse ☐</div>
<div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <i>If better, please check <u>one</u> of the following boxes.</i> </div>	<div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> <i>If worse, please check <u>one</u> of the following boxes.</i> </div>
<div style="margin-bottom: 10px;">☐ Almost the same, hardly better at all</div> <div style="margin-bottom: 10px;">☐ A little better</div> <div style="margin-bottom: 10px;">☐ Somewhat better</div> <div style="margin-bottom: 10px;">☐ Moderately better</div> <div style="margin-bottom: 10px;">☐ A good deal better</div> <div style="margin-bottom: 10px;">☐ A great deal better</div> <div style="margin-bottom: 10px;">☐ A very great deal better</div>	<div style="margin-bottom: 10px;">☐ Almost the same, hardly worse at all</div> <div style="margin-bottom: 10px;">☐ A little worse</div> <div style="margin-bottom: 10px;">☐ Somewhat worse</div> <div style="margin-bottom: 10px;">☐ Moderately worse</div> <div style="margin-bottom: 10px;">☐ A good deal worse</div> <div style="margin-bottom: 10px;">☐ A great deal worse</div> <div style="margin-bottom: 10px;">☐ A very great deal worse</div>

Figure 2.

Figure 3.

Table 1

General characteristics and comorbidities of responders and non-responders.

	Responders	Non-responders	p-value
Age(mean)	46.8(18–76)	44.4(17–74)	0.38
Gender(% female)	59%	50%	0.64
Ethnicity(% Caucasian)	94%	88%	0.45
Smoking	9%	3%	0.32
Previous surgery	56%	55%	1.00
Depression	16%	13%	0.74
Asthma	25%	30%	0.61
Allergic rhinitis	34%	48%	0.24
Nasal polyposis	38%	50%	0.34
Aspirin sensitivity	3%	13%	0.21
Lund-Mackay score(mean)	11.1	10.2	0.44

Table 2

Response shift scores and observed quality-of-life (QOL) change scores stratified by responses on the transition QOL score.

Transition scale response	Response shift	Observed QOL change
About the same (n=2)	0.1	0.15
Almost the same (n=1)	0.35	-0.35
A little better (n=1)	0.20	0.05
Somewhat better (n=1)	-0.30	-1.25
Moderately better (n=6)	0.37	-0.49
A good deal better (n=5)	0.27	-1.01
A great deal better (n=5)	0.39	-1.05
A very great deal better (n=11)	0.69 (p = 0.07)	-1.47 (p = 0.005)

Table 3

Response shift scores and observed quality-of-life(QOL) change scores stratified by select patient factors.

	Response shift	Observed QOL change
Smoking(n=3)	0.90(p=0.16)	-2.28(p=0.02)
Previous surgery(n=17)	0.36(p=1.0)	-0.93(p=0.76)
Depression(n=5)	0.48(p=0.81)	-0.56(p=0.19)
Asthma(n=8)	0.54(p=0.79)	-0.86(p=0.57)
Allergic rhinitis(n=11)	0.60(p=0.63)	-0.94(p=0.90)
Nasal Polyposis(n=12)	0.46(p=0.63)	-1.12(p=0.45)