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Functional Comorbidity Index in chronic rhinosinusitis

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Abstract

Background—The Functional Comorbidity Index is a promising tool to predict general health status and adjust for comorbidity confounding in outcomes studies of chronic conditions, but it has been tested as a predictor of general health status only in a sleep apnea cohort. We tested it in a chronic rhinosinusitis cohort with 2 objectives: (1) measure the association between the Functional Comorbidity Index (range, 0 to 18) and general health status (SF-36 Physical Component Score and Mental Component Score); and (2) test if the Functional Comorbidity Index is more strongly associated (a better predictor) than the well-known Charlson Comorbidity Index (range, 0 to 37) with these SF-36 outcome measures.

Methods—In a cross-sectional study of chronic rhinosinusitis patients, we obtained scores for the Functional Comorbidity Index, Charlson Comorbidity Index, and the SF-36. We calculated Spearman correlations and adjusted coefficients of determination (R^2) using multiple linear regression, adjusted for demographic covariates. Bootstrapping generated R^2 distributions for statistical comparison.

Results—In the cohort (N = 97), the Functional Comorbidity Index scores (mean ± standard deviation: 2.2 ± 1.9) were more widely distributed than Charlson Comorbidity Index scores (0.6 ± 1.2). The Functional Comorbidity Index significantly correlated with the SF-36 Physical Component Score (−0.49, $p < 0.001$) and Mental Component Score (−0.37, $p < 0.001$). The Functional Comorbidity Index was a better predictor than the Charlson Comorbidity Index of SF-36 Physical Component Score (R^2 mean ± standard error: 0.21 ± 0.09 vs 0.15 ± 0.05; $p < 0.001$) and Mental Component Score (0.16 ± 0.10 vs 0.01 ± 0.06; $p < 0.001$).

Conclusion—The Functional Comorbidity Index is a more robust predictor of general health status than the Charlson Comorbidity Index in chronic rhinosinusitis patients.

Keywords

outcomes research; sinusitis; comorbidity; health status; confounding factors

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Adjustment for baseline differences in comorbid conditions is essential in outcomes research. A comorbid condition is a medical condition that coexists with the disease of interest and can be independently related to the measured outcome. When multiple comorbidities are present, as is common in chronic diseases,[1] there is potential for the differences in the patterns of comorbidities between individual patients to impact the outcome, termed comorbidity confounding. An effective method of adjusting for multiple comorbidities is utilization of a comorbidity index, such as the widely used Charlson Comorbidity Index[2] (hereafter: Charlson Index), which was originally validated to use current comorbid conditions to predict 1-year mortality and adjusts for baseline patient comorbidity differences. This index is an effective method of adjusting for comorbidity confounding in survival studies, but in chronic disease studies the outcomes of interest are often functional status and quality of life rather than survival.[3,4] Patients with chronic disease are more likely to have nonlethal comorbid conditions that impact function and quality of life (eg,. anxiety) which are not contained in most comorbidity indices. The Functional Comorbidity Index (hereafter: Functional Index) was designed to include some of these common comorbidities that impact daily activities and function (Table 1).

The Functional Index uses the presence or absence of 18 independent comorbidities to predict variation in the Physical Function domain of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36).[5] Prior studies have shown that this index is also a promising predictor of general health status using the Physical Health Component score (PCS)[6,7] and the Mental Health Component score (MCS)[7] of the SF-36. These studies were performed in select clinical populations (acute respiratory distress syndrome patients and sleep apnea patients). The Functional Index needs to be validated in other chronic conditions to verify both the index effectiveness for stratifying by general health status and its usefulness as a general health status comorbidity index.

Chronic rhinosinusitis is a prevalent chronic illness involving inflammation of the paranasal sinuses and linings of the nasal passages. It impacts at least 28 million people in the United States every year.[8,9] Patients with chronic rhinosinusitis have significant health status burden with decreased SF-36 domain scores as compared to the general population.[10] Many chronic rhinosinusitis patients have multiple comorbid conditions that are not included in the Charlson Index and other commonly used comorbidity indexes, but are included in the Functional Index and impact quality of life outcomes. The objectives of this study are the following: (1) measure the association between the Functional Index and the SF-36 PCS and MCS in a cohort of chronic rhinosinusitis patients; and (2) test if the Functional Index is more strongly associated (and thus a better predictor) of the PCS and MCS than the Charlson Index in this population. The aim is to assess whether the Functional Index is an effective predictor of general health status (using the PCS and MCS) in the chronic rhinosinusitis population.

Patients and methods

Study design and population

This cross-sectional study used prospectively collected data. The study was approved by the Institutional Review Board at the University of Washington. Subjects were enrolled from a

single provider's (G.E.D.) rhinology clinic at the University of Washington in Seattle, Washington, from 2012 to 2013.

Eligible patients were at least 18 years of age, fluent in verbal and written English, met diagnostic criteria for chronic rhinosinusitis according to the 2003 guidelines,[12,13] completed the comorbidity survey and SF-36, and had medical records available for additional comorbidity extraction. We excluded patients with incomplete data on comorbidity or the SF-36. Data were recorded in a REDCap Database.

Data collection

Primary exposure variables—The Functional Index uses the presence or absence of 18 independent clinical comorbidities to predict variation in the Physical Function domain of the SF-36.[5] The index was developed using self-reported medical conditions collected in a database of >9000 randomly sampled Canadian adults (oversampling women). The resultant model was validated in a database of >28,000 adults in the United States with spine disease. Each comorbidity in the index is weighted evenly: 1 if present, 0 if not present. The final score is the sum of all the conditions forming an ordinal variable with range 0 to 18. A higher score represents worse comorbidity.

The Charlson Index includes 19 comorbid conditions that are each assigned a severity weighting of 1 to 6. The final score is the sum of the weighted scores with a range of 0 to 37 (Charlson et al.[2]). A higher score represents worse comorbidity.

Each subject was asked to complete a self-reported comorbidity questionnaire inquiring about the presence or absence of 35 comorbid conditions. This questionnaire provided information on the comorbidities in the Functional Index and the Charlson Index. The Charlson Index requires information about the severity of several comorbid conditions in order to ensure proper score weighting. These conditions include the degree of liver disease (ie, moderate or severe liver disease), the presence of end-organ damage in diabetics, and the presence of solid tumor metastasis. This severity information, as well as verification of the presence or absence of each of the 35 comorbidities and self-reported habits, was specifically investigated using the electronic medical record clinic and emergency department visits, inclusive of the 5 years preceding the date of enrollment. Self-reported comorbidity and habit information was considered accurate and only updated if there was clear and constant additional information in the electronic medical record (ie, a patient with liver disease reported as mild was left as "mild" unless their medical notes clearly described greater severity).

Outcome variables—The SF-36 PCS and MCS are component scores that are calculated from 4 independent nonoverlapping SF-36 domain scores, designed to represent aspects of physical or mental health status, respectively.[14–17] The 2 component scores are calculated from the normalized aggregate scores in which 50 ± 10 represents the normalized score and standard deviation of the general United States 1998 population norms. Lower scores represent worse health status than the 1998 norms.

Covariates—The regression models adjust for age (continuous), gender (male/female), race (Caucasian/white, African American/black, Asian, Native American, Native Hawaiian or Pacific Islander, Other), and ethnicity (Hispanic yes/no). This information was obtained from the self-reported comorbidity questionnaire.

Analysis

Descriptive data were presented as mean ± standard deviation or percentage. Spearman correlations were calculated between each exposure variable (Functional Index and Charlson Index) and each outcome variable (SF-36 PCS and MCS). Values of $p < 0.05$ indicated a correlation that is statistically significantly different from 0 (no correlation). To detect a moderate correlation ($r = 0.30$),[18] a sample of 97 subjects provided >80% power to determine that the correlation is significantly different from 0 at the 0.05 significance level.

The correlation squared is the coefficient of determination, R^2, which represents the proportion of the variability in the outcome variable explained by the exposure variable.[19] This value was compared between the 2 comorbidity indexes. Adjusted R^2 values were generated from multivariate linear regression analysis. The exposure variables were each placed in a separate linear regression analysis with the SF-36 outcome variable of interest and adjusted for covariates (age, gender, race, and ethnicity). The resultant adjusted R^2 values permitted comparison of the strength of association between each exposure and outcome variable. Beta coefficients were not used as they were on different scales between the 2 exposure variables.

Bootstrapping is a method of randomly resampling study data to generate a number of "phantom samples" (bootstrap samples) to generate an estimated distribution of a study statistic. Bootstrapping was performed to generate distributions of the adjusted R^2 point estimates. Random samples of 80 were drawn with resampling over 1000 iterations, sufficient iterations to ensure precision of the standard error to 0.01. The resultant means and confidence intervals permitted statistical comparison of the R^2 estimates using the Student t test. A p value <0.05 was considered statistically significant. All statistical analyses were performed with Stata 11 (StataCorp, College Station, TX).

Results

The study enrolled 102 patients and 5 were retroactively excluded for incomplete SF-36 or comorbidity data. The study sample characteristics of the remaining 97 patients were consistent with chronic rhinosinusitis patients from the catchment tertiary care hospital (Table 2). The PCS and MCS mean scores (Table 2) are both lower than the 1998 general population norms,[14] but are comparable to those with self-reported allergies or sinus problems.[14,17] Functional Index scores are more widely distributed than the Charlson Index. On average most cohort patients have at least 2 comorbidities included in the Functional Index and less than 1 of the comorbidities from the Charlson Index.

Spearman correlations showed statistically significant correlations between the increasing score of both the Functional Index and Charlson Index and the decreasing scores of both outcome variables (SF-36 PCS and MCS), except for the correlation between the Charlson

Index and the MCS (Tables 3 and 4). The unadjusted R^2 showed substantial differences between the Functional Index and the Charlson Index (Tables 3 and 4). Taken together, these results indicate that worse comorbidity is associated with worse general health status as measured by the SF-36.

Multivariate analysis confirmed the unadjusted spearman correlation findings (Tables 3 and 4). The bootstrapping analysis showed that the Functional Index had a statistically significantly higher adjusted R^2 than did the Charlson Index for both outcome variables (Table 3).

Discussion

Baseline differences in comorbid conditions are important potential confounders in outcomes studies. Comorbidity indexes can be used to adjust systematically for comorbidity confounding. However, the important comorbid conditions that predict baseline differences in health vary according to the outcome of interest. The Functional Index and Charlson Index were each designed for a different outcome: SF-36 Physical Function and survival, respectively. Though the Charlson Index has been widely validated and is an effective predictor of mortality, it is not a robust predictor of general health status measured by the SF-36.

As we showed in our past study in sleep apnea patients,[7] this study shows that the Functional Index has a stronger correlation with both the SF-36 PCS and MCS in patients with chronic rhinosinusitis. The Spearman correlation magnitude between the Functional Index and the respective PCS and MCS was 0.44 and 0.38 in sleep apnea patients and is 0.49 and 0.32 in chronic rhinosinusitis patients.[7] In both studies the Functional Index is better correlated with general health status outcomes than the Charlson Index.

This study also found a similar improvement in the ability to stratify patients between the 2 indexes, with the Functional Index scores distributed more widely. In both studies most subjects had at least 2 of the comorbidities listed in the Functional Index and less than 1 comorbidity listed in the Charlson Index.[7] Because both sleep apnea and chronic rhinosinusitis are chronic conditions, it is not surprising to find that they have similar patterns of comorbid conditions. This consistency supports the importance of a comorbidity index to reflect the significant comorbidities associated with chronic diseases.

The Functional Index is a more robust predictor of general health status in both sleep apnea and chronic rhinosinusitis patients. In both studies the adjusted R^2 and their bootstrapped distributions indicate that the Functional Index is statistically significantly better than the Charlson Index to predict the PCS and MCS.[7] In both studies the adjusted R^2 increased by at least 10% when comparing the Functional Index to the Charlson Index as a predictor of the MCS (R^2 difference in sleep apnea: 0.10, $p < 0.001$; in chronic rhinosinusitis 0.15, $p < 0.001$). The Functional Index was a better predictor of the PCS in both studies but the increase in the variance over the Charlson Index was less robust (difference of 0.06 in both populations). One reason for the differential improvement is likely due to the baseline moderate correlation of the Charlson Index with the PCS in both studies (sleep apnea −0.41,

$p < 0.001$; chronic rhinosinusitis −0.35, $p < 0.001$) and thus left less room for improvement.[7] This is reasonable given that many of the life-threatening comorbidities in the Charlson Index are also associated with a notable decrease in daily physical functioning.[2] Nevertheless, the Functional Index still performed better than the Charlson Index on the PCS.

In the literature there are several other recently developed comorbidity indices designed to measure general health status and quality of life.[20,21] Bayliss et al.[21] developed a 25-item index based on the comorbidities most often assessed in the literature, and it was validated in patients over 65 years old in health maintenance organizations. The resultant index was significantly correlated with the SF-36 Physical Function domain (−0.63, $p < 0.001$), but the study did not adjust for covariates and the generalizability is not clear. A different approach was taken by Mukherjee et al.[20] who used the 2003 Medical Expenditure Panel Survey to develop a model to predict Short Form-12 PCS and MCS scores and validated it in the 2005 Medical Expenditure Panel Survey. The index outperformed the Charlson Index and accounted for 28% of the variability in the PCS and 16% of the variability of the MCS. Although it is a promising index, the outcome measure (Short-Form-12) has been shown to be less responsive to change in some conditions,[22–24] which can decrease precision to measure change. In contrast to the databases used to develop and validate the Functional Index,[25,26] the Medical Expenditure Survey did not verify the self-reported medical conditions, which may explain the weak correlation between the self-reported conditions and the conditions reported by medical providers in this database.[27–29] Frei et al.[30] also developed a comorbidity index designed to adjust for comorbidities that impact health status in chronic obstructive pulmonary disease patients using prospectively collected data to predict the Feeling Thermometer health status score. The resultant 5-item weighted index is encouraging, but it requires further validation in an independent sample. It is designed specifically for chronic obstructive pulmonary disease patients and may not be generalizable to other populations.

This study has several limitations. The comorbidities in the Functional Index and the Charlson Index were collected on the self-report forms and details confirmed by medical record extraction. Although this dual approach improves the accuracy of the data collection, the Functional Index data collection is subject to a conservative bias. Patients were asked only to check comorbidities that corresponded to a diagnosis given to them by a physician. Because most of the comorbidities in the Functional Index are not life-threatening, there is a tendency to underdiagnose these medical conditions (eg, not test for joint pain and formally diagnose arthritis). This underdiagnosis would blunt the scoring of the Functional Index and tend to underestimate its ability to predict general health status.

The study was performed in a chronic rhinosinusitis clinic population collected from an academic tertiary care center, and it might not be generalizable to a community-based chronic rhinosinusitis population as a whole. Clinic patients are more likely to have functional deficits that might have prompted them to seek clinical care as opposed to deferring medical care. Tertiary care patients are more likely to be referred from community specialists and have more complex baseline medical disease or sinusitis refractory to initial treatment. However, despite this limitation, it appears that the Functional Index will be more

beneficial than other comorbidity indexes for studying health status and quality of life in outcomes studies of the clinical chronic rhinosinusitis population.

Although the Functional Index shows promise as a tool to predict health status and potentially quality of life, it may fail to include all the comorbidities relevant to predicting the SF-36 PCS and MCS in the chronic rhinosinusitis population or in other populations. Chronic rhinosinusitis patients commonly present with comorbidities such as fibromyalgia and migraine, which are not included in the Functional Index. In the future, it would be helpful to modify the Functional Index to include important additional comorbidities and to validate this potentially more robust index.

The Functional Index has been shown to be a promising predictor of general health status in 2 chronic diseases: sleep apnea and chronic rhinosinusitis. Analogous studies are needed in other population types to help establish generalizability. However, the ability of the Functional Index to predict health status in both populations may indicate that the Functional Index is an effective predictor of health status in populations with chronic conditions. A future validation study in a primary care population would support more generalizability.

Conclusion

The Functional Index is a valid tool to predict general health status in chronic rhinosinusitis patients, and it outperforms the Charlson Index as a measure of general health status in this population.

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TABLE 1

Functional Comorbidity Index items *

	Conditions
1	Arthritis (rheumatoid and osteoarthritis)
2	Osteoporosis
3	Asthma
4	Chronic obstructive pulmonary disease, acquired respiratory distress syndrome, or emphysema
5	Angina
6	Congestive heart failure (or heart disease)
7	Heart attack (myocardial infarction)
8	Neurological disease (Parkinson's or multiple sclerosis)
9	Stroke or transient ischemic attack
10	Peripheral vascular disease
11	Diabetes, type I or type II
12	Upper gastrointestinal disease (ulcer, hernia, reflux)
13	Depression
14	Anxiety or panic disorders
15	Visual impairment (such as cataracts or glaucoma)
16	Hearing Impairment (very hard of hearing)
17	Degenerative disc disease (back disease, spinal stenosis, or severe chronic back pain)
18	Obesity or body mass index >30 kg/m^2

* Each condition is scored on a binary scale with 1 point given for the presence of a condition and 0 for the absence. The sum of the individual condition scores yields the Functional Comorbidity Index score; range, 0 to 18 (Levine and Weaver[7]).

TABLE 2

Chronic rhinosinusitis cohort characteristics (N = 97)

Characteristic	Mean	Standard deviation	%
Age (years)	51	13	
Sex (% male)			49
Race (% white)			91
Ethnicity (% Hispanic)			1
Functional Index (0–18 scale, higher worse)	2.2	1.9	
Charlson Index (0–37 scale, higher worse)	0.6	1.2	
SF-36 Physical Component Score (50 normal, higher better)	45	10	
SF-36 Mental Component Score (50 normal, higher better)	47	11	

SF-36 = Medical Outcomes Study 36-Item Short Form Health Survey.

TABLE 3

Physical component score: comparison of the Functional Index and the Charlson Index*

	Functional Index	Charlson Index
Spearman correlation (r_s)	−0.49[a]	−0.35[a]
Coefficient of determination (R^2)	0.24	0.12
Adjusted coefficient of determination (R^2)	0.21	0.15
Bootstrapped distribution of the adjusted coefficient of determination (mean ± standard error)	0.21 ± 0.09[b]	0.15 ± 0.07[b]

*Spearman correlation between each index and the SF-36 Physical Component Score. Negative correlations indicate that as the number of comorbidities increases (higher index score) the level of self-reported health status decreases (lower Physical Component Score). Coefficients of determination generated by multiple linear regression, adjusted for age, gender, race, and ethnicity.

[a]Correlation significantly different from zero, $p < 0.001$.

[b]Difference between indexes statistically significant, $p < 0.001$.

SF-36 = Medical Outcomes Study 36-Item Short Form Health Survey.

TABLE 4

Mental component score: comparison of the Functional Index and the Charlson Index*

Mental component score	Functional Index	Charlson Index
Spearman correlation (r_s)	−0.37[a]	−0.13
Coefficient of determination (R^2)	0.14	0.02
Adjusted coefficient of determination (R^2)	0.16	0.01
Bootstrapped distribution of the adjusted coefficient of determination (mean ± standard deviation)	0.16 ± 0.10[b]	0.01 ± 0.06[b]

*Spearman correlation between each index and the SF-36 Mental component score. Negative correlations indicate that as the number of comorbidities increases (higher index score) the level of self-reported health status decreases (lower mental component score). Coefficients of determination generated by multiple linear regression, adjusted for age, gender, and ethnicity.

[a]Each correlation significantly different from zero, $p < 0.001$.

[b]Difference between indexes statistically significant, $p < 0.001$.

SF-36 = Medical Outcomes Study 36-Item Short Form Health Survey.