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Outcomes Research

Outcomes Research

- The study of the results or outcomes of diverse medical therapies for a single disease, illness, or condition
- The establishment of preferred therapies and practice guidelines to improve patient care

Evolution of Outcomes Research

- Geographic Variation Studies
- Appropriateness Research

Geographic Variation Studies

- Findings: Wide geographic variation in surgical procedures without identifiable differences in pre-treatment medical condition
- Example: Five-fold difference in tonsillectomy rates in counties of Vermont

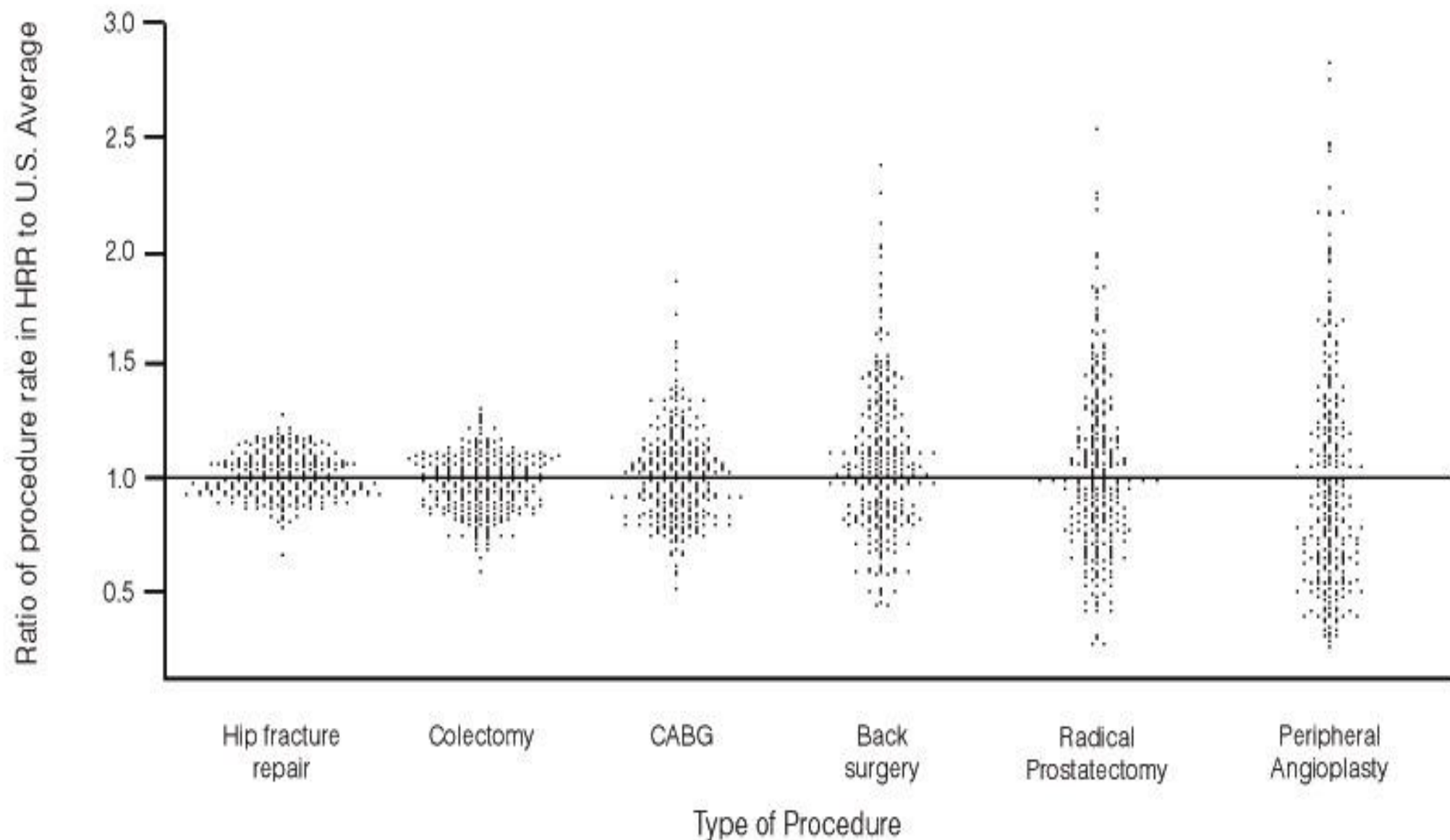


FIGURE 1. Variation profiles of six common procedures. Data for peripheral angioplasty from Axelrod and colleagues.³ Other figures derived from 1995–6 national Medicare data from the *Dartmouth Atlas of Health Care*.⁵ CABG = coronary artery bypass grafting; HRR = hospital referral region.

“There are no data available that would allow us to relate these variations to the prevalence of tonsillitis, but it appears that the variations are more likely to be associated with differences in beliefs among physicians concerning the indications for, and efficacy of, the procedure.”

John E. Wennberg, MD, MPH 1973

Appropriateness Research

- Attempt to explain geographic variation
- Panel of “experts” assembled to establish guidelines for evaluation of appropriateness
- Findings: Large percentage of coronary angiography, carotid endarterectomy, and other procedures performed with “inappropriate” or “equivocal” indications in both high and low-use areas

Ratings of Appropriateness

Procedure	Inappropriate (%)	Equivocal (%)
Angiography (N=1677)	17	9
Endarterectomy (N=1302)	32	32

Appropriateness of Use of Six Different Procedures with 95% Confidence Intervals

Appropriateness Category %	Tympanostomy Tubes (N=6429)	Coronary Angiography (N=1335)	Carotid Endarterectomy (N=1302)	Upper GI Endoscopy (N=1585)	Hysterectomy (N= 642)	Sinus Surgery (N=55)
Appropriate (95% CI)	41 (40-43)	76 (73-79)	35 (33-38)	72 (69-74)	58 (53-63)	44 (28-60)
Equivocal (95% CI)	32 (31-33)	20 (19-22)	32 (29-35)	11 (9-12)	25 (18-32)	40 (20-59)
Inappropriate (95% CI)	27 (26-28)	4 (3-5)	32 (30-34)	17 (15-19)	16 (9-23)	16 (0-39)

Differences Between Outcomes Research and Traditional Clinical Research

- New Research Methodologies
- Expanded Description of Disease and Outcome

New Research Methodologies

- Prospective observational studies of multiple therapies for a specific disease
- Para-analysis of results of therapy from large computerized, administrative, and financial data bases
- Meta-analysis, Literature Review, and Consensus Techniques

Prospective, Observational Studies of Multiple Therapies

- Patients studied in “natural” clinical setting
- No attempts to select or control treatments
- Primary data

Examples

- Piccirillo et al. Obstructive sleep apnea treatment outcomes pilot study. *Otolaryngol Head Neck* 1998;118:833-844.
- Lieu et al. Prognostic staging system and therapeutic effectiveness for recurrent or chronic sinusitis in children. *Otolaryngol Head Neck* 2003;129:222-232.
- Weaver et al. Survival of veterans with sleep apnea: continuous positive airway pressure versus surgery. *Otolaryngol Head Neck* 2004;130:659-665

Analysis from Large, Computerized, Administrative, and Financial Data Bases (e.g., Medicare)

- Study results of treatment over wide geographic areas and large numbers of patients
- Secondary data

Examples

- Deleyiannis, et al. Geographic variation in the utilization of esophagoscopy and bronchoscopy in head and neck cancer. *Archives Otolaryngol Head Neck* 1997;123:1203-1210
- Piccirillo et al. Impact of first-line vs. second-line antibiotics for the treatment of acute uncomplicated sinusitis. *JAMA* 2001;286:1849-1856
- Slattery, et al. Acoustic neuroma surgical cost and outcome by hospital volume in California. *Otolaryngol Head Neck Surg* 2004;130:726-735

Meta-Analysis, Literature Review, and Consensus Techniques

- Analysis of the results of therapies from the published literature
- Expert opinion for the determination of preferred therapies

Examples

- Rosenfeld RM, Post JC. Meta-analysis of antibiotics for the treatment of otitis media with effusion. *Otolaryngol Head Neck Surg* 1992;106:378-386.
- Sher et al The efficacy of surgical modifications of the upper airway in adults with obstructive sleep apnea syndrome. *Sleep* 1996;19:156-177.
- NIH consensus conference. Cochlear implants in adults and children. *JAMA* 1995;274:1955-1961.

Expanded Description of Disease and Outcome

- Patient-based rating scales, questionnaires, and instruments to measure relevant but previously unstudied aspects of disease such as symptoms, functional ability, quality of life, and satisfaction with care
- Attention to impact of co-morbidities

Methodologic Requirements for Outcomes Research

- Establish diagnostic criteria for disease and population under study; use methods to avoid bias in collection
- Create clinical-severity index for prognostic stratification
- Identify and measure co-morbid conditions
- Establish outcomes measures which incorporate traditional end-points with assessments of symptoms, functional capacity, quality of life, and satisfaction with care

Diagnostic Criteria for Disease

- Consensus Conference
- Literature Review
- Clinical Research

Create Clinical-Severity Index

- Clinical-severity implies the seriousness or prognosis of disease
- The need to define how sick a patient is in order to
 - Assess diagnostic efficiency
 - Refine prognosis
 - Evaluate therapeutic effectiveness

Identify and Measure Co-Morbid Conditions

- Co-Morbidity--the presence of concomitant disease, not related to the index disease which may affect the diagnosis, treatment, and prognosis for the patient
- Prognostic comorbidity--concomitant disease severe enough to impact on outcome of interest
- Therapeutic co-morbidity--concomitant disease which prevents use of ideal or preferred therapy

Comorbidity Data Collection Form

Identify the important medical comorbidities and grade severity using the index. Overall Comorbidity Score is defined according to the highest ranked single ailment, except in the case where two or more Grade 2 ailments occur in different organ systems. In this situation, the overall comorbidity score should be designated Grade 3.

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Cardiovascular System			
Myocardial Infarct	<ul style="list-style-type: none"> ▪ MI ≤ 6 months 	<ul style="list-style-type: none"> ▪ MI > 6 months ago 	<ul style="list-style-type: none"> ▪ Old MI by ECG only, age undetermined
Angina / Coronary Artery Disease	<ul style="list-style-type: none"> ▪ Unstable angina 	<ul style="list-style-type: none"> ▪ Chronic exertional angina ▪ Recent (≤ 6 months) Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA) ▪ Recent (≤ 6 months) coronary stent 	<ul style="list-style-type: none"> ▪ ECG or stress test evidence or catheterization evidence of coronary disease without symptoms ▪ Angina pectoris not requiring hospitalization ▪ CABG or PTCA (>6 mos.) ▪ Coronary stent (>6 mos.)
Congestive Heart Failure (CHF)	<ul style="list-style-type: none"> ▪ Hospitalized for CHF within past 6 months ▪ Ejection fraction < 20% 	<ul style="list-style-type: none"> ▪ Hospitalized for CHF >6 months prior ▪ CHF with dyspnea which limits activities 	<ul style="list-style-type: none"> ▪ CHF with dyspnea which has responded to treatment ▪ Exertional dyspnea ▪ Paroxysmal Nocturnal Dyspnea (PND)
Arrhythmias	<ul style="list-style-type: none"> ▪ Ventricular arrhythmia ≤ 6 months 	<ul style="list-style-type: none"> ▪ Ventricular arrhythmia > 6 months ago ▪ Chronic atrial fibrillation or flutter ▪ Pacemaker 	<ul style="list-style-type: none"> ▪ Sick Sinus Syndrome
Hypertension	<ul style="list-style-type: none"> ▪ DBP ≥ 130 mm Hg ▪ Severe malignant papilledema or other eye changes ▪ Encephalopathy 	<ul style="list-style-type: none"> ▪ DBP 115-129 mm Hg ▪ Secondary cardiovascular symptoms: vertigo, epistaxis, headaches 	<ul style="list-style-type: none"> ▪ DBP 90-114 mm Hg ▪ DBP < 90 mm Hg while taking antihypertensive medications
Venous Disease	<ul style="list-style-type: none"> ▪ Recent PE (≤ 6 mos.) ▪ Use of venous filter for PE's 	<ul style="list-style-type: none"> ▪ DVT controlled with Coumadin or heparin ▪ Old PE > 6 months 	<ul style="list-style-type: none"> ▪ Old DVT no longer treated with Coumadin or Heparin
Peripheral Arterial Disease	<ul style="list-style-type: none"> ▪ Bypass or amputation for gangrene or arterial insufficiency < 6 months ago ▪ Untreated thoracic or abdominal aneurysm (≥ 6 cm) 	<ul style="list-style-type: none"> ▪ Bypass or amputation for gangrene or arterial insufficiency > 6 months ▪ Chronic insufficiency 	<ul style="list-style-type: none"> ▪ Intermittent claudication ▪ Untreated thoracic or abdominal aneurysm (< 6 cm) ▪ s/p abdominal or thoracic aortic aneurysm repair

IMPACT OF PROGNOSTIC COMORBIDITY ON FIVE-YEAR SURVIVAL RATES

Prognostic Comorbidity	Rectum Cancer	Larynx Cancer	Endometrial Cancer	Larynx Cancer	Prostate Cancer
Absent	85/264 (32%)	93/172 (54%)	102/131 (78%)	123/166 (74%)	137/229 (60%)
Present	6/54 (11%)	3/20 (15%)	3/11 (27%)	4/27 (15%)	6/38 (16%)
Total	91/318 (29%)	96/192 (50%)	105/142 (74%)	127/193 (66%)	143/267 (54%)
χ^2	9.76	10.94	3.54	36.27	25.41
p value	0.0018	0.0009	0.0599	<0.0001	<0.0001

Denominators- number of patients in each category

Numerators- corresponding number of five-year survivors

Adult Comorbidity Evaluation-27
Comorbidity Calculator

Available on the Internet!

<http://cancercomorbidity.wustl.edu>

Establish Outcome Measures

- Mortality
- Morbidity
- Health Status (General/Disease-Specific)
 - Physical
 - Functional
 - Emotional
- Health-Related Quality of Life
- Satisfaction with Care

General Health Status

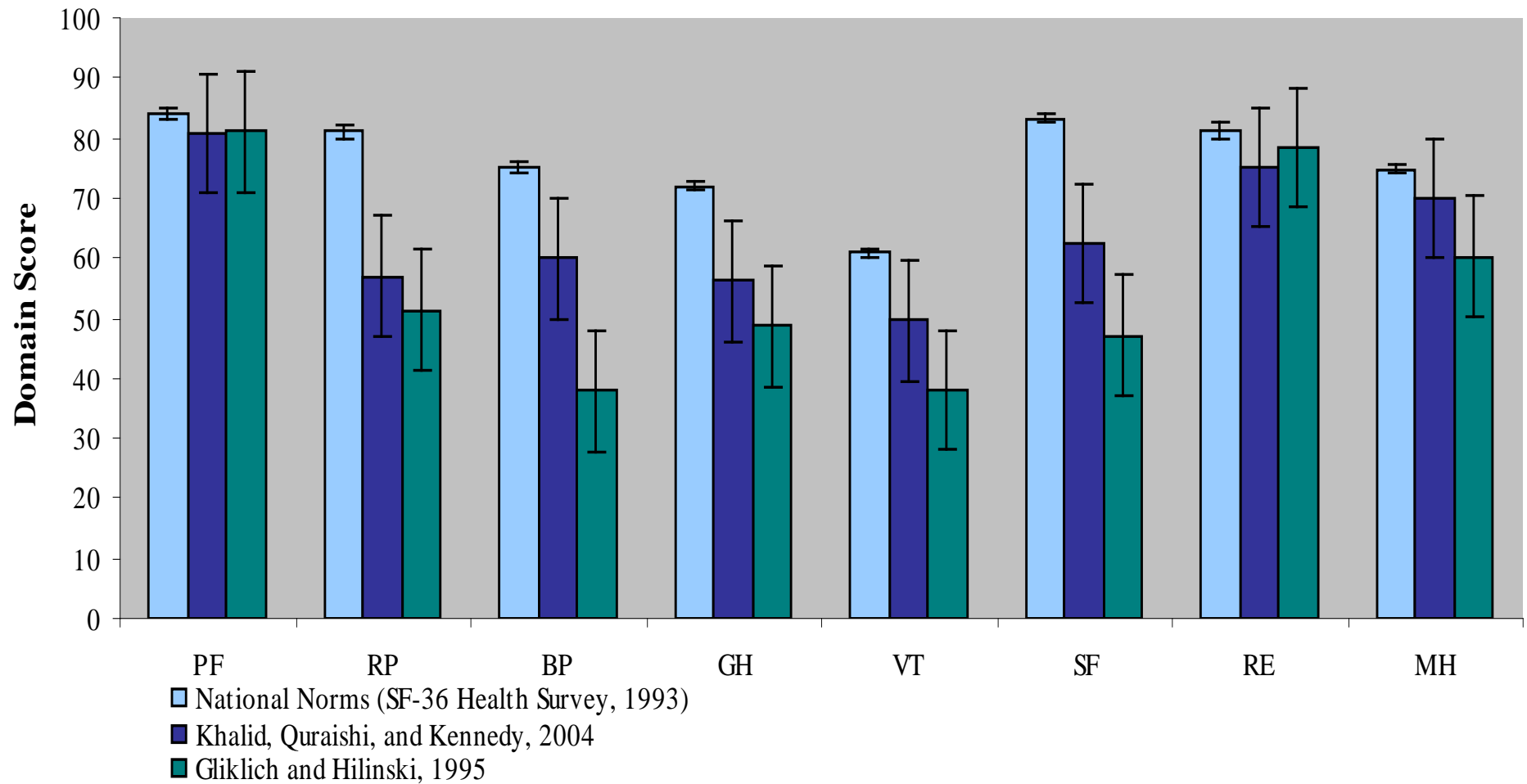
- Medical Outcomes Study SF-36
 - Originally developed for study of utilization of health insurance
 - 36 items
 - Measures health status in 8 domains
 - PF, RP, BP, GH, VT, SF, RE, and MH
 - Scores range from 0-100 on each domain

Eight Subscales of General Health

Subscale	Definition
PF	Limitations on physical activities such as walking, bathing, and strenuous sports
RP	Problems with work or other daily activities as a result of physical health
BP	Intensity of bodily pain or limitations due to pain
GH	Perception of current health and health outlook
VT	Level of energy
SF	Extent health interferes with normal social activities
RE	Problems with daily activities as a result of emotional issues
MH	Mental health screening

SF-36 General Health Survey

National Norms and Rhinosinusitis



Examples

- Funk et al. Baseline and post-treatment assessment of the general health status of head and neck cancer patients compared with United States population norms. *Head and Neck* 1997;19:675-683.
- Benninger et al. Assessing outcomes for dysphonic patients. *J Voice* 1998;12:540-550.
- Khalid et al. Long-term quality of life measures after functional endoscopic sinus surgery. *Am J Rhinology* 2004;18:131-136

Disease-Specific Health Status

- Sino-Nasal Outcome Test-20
 - 20 sino-nasal specific items
 - Identified from focus group discussions
 - Response category for each item none, mild, moderate, and severe
 - Patients identify important items

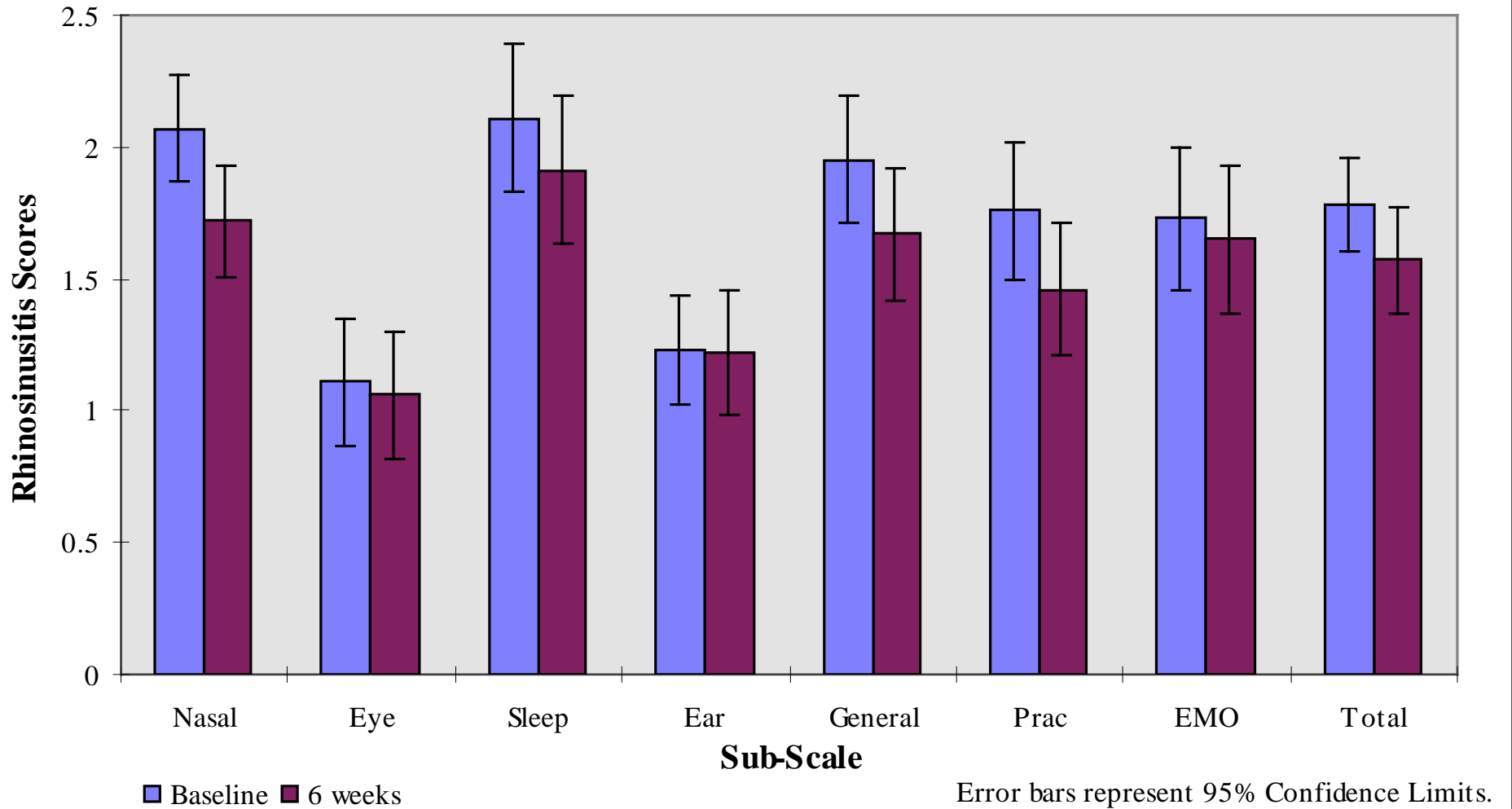
Sino-Nasal Outcome Test (SNOT-20)

Below you will find a list of symptoms and social/emotional consequences of your rhinosinusitis. We would like to know more about these problems and would appreciate your answering the following questions to the best of your ability. There are no right or wrong answers, and only you can provide us with this information. Please rate your problems as they have been over the past two weeks. Thank you for your participation. Do not hesitate to ask for assistance if necessary.

1. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale: →	No Problem	Very Mild Problem	Very Mild or Slight Problem	Moderate Problem	Severe Problem	Problem As Bad As It Can Be	5 Most Important Problems
1. Need to blow nose	0	1	2	3	4	5	○
2. Sneezing	0	1	2	3	4	5	○
3. Runny nose	0	1	2	3	4	5	○
4. Cough	0	1	2	3	4	5	○
5. Post-nasal discharge	0	1	2	3	4	5	○

Rhinosinusitis Scores

Baseline and 6 Weeks



Correlation Between SF-36 and SNOT-20 Domain Scores

	PF	RP	BP	GH	VT	SF	RE	MH
Nasal	0.13	0.22	0.10	0.36	0.24	0.16	0.15	0.21
Eye	0.29	0.25	0.37	0.26	0.37	0.38	0.30	0.31
Ear	0.10	0.19	0.20	0.16	0.24	0.28	0.04	0.16
Sleep	0.31	0.28	0.38	0.41	0.51	0.42	0.36	0.43
General	0.24	0.49	0.52	0.43	0.59	0.59	0.31	0.37
Practical	0.19	0.18	0.01	0.33	0.25	0.18	0.15	0.22
Emotional	0.27	0.36	0.28	0.48	0.47	0.44	0.36	0.46
Total	0.29	0.40	0.38	0.48	0.53	0.49	0.32	0.42

Correlations ≥ 0.40 are shown in green.

Examples

- Browman et al. The Head and Neck Radiotherapy Questionnaire: a morbidity/quality-of-life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. *J Clin Oncol.* 1993;11:863-872.
- Gliklich RE, Hilinski JM. Longitudinal sensitivity of generic and specific health measures in chronic sinusitis. *Qual Life Res.* 1995;4:27-32.
- Fielder H, Denholm SW, Lyons RA, et al. Measurement of health status in patients with vertigo. *Clin Otolaryngol.* 1996;21:124-126.

Patient Satisfaction with Medical Care

- Direct measures involve asking patients to evaluate their satisfaction
- Patients' judgments of their medical care can be measured reliably and accurately
- These measurements can be used to compare how patients evaluate different practice styles, administrative arrangements, and treatment modalities

Patient Visit Rating Questionnaire*

Instructions: Here are some questions about *the visit you just made*. In terms of your satisfaction, how would you rate each of the following:

The visit overall

The technical skills (thoroughness, carefulness, competence) of the person you saw

The personal manner (courtesy, respect, sensitivity, friendliness) of the person you saw

How long you waited to get an appointment

Convenience of the location of the office

Getting through to the office by phone

Length of time spent waiting at the office

Time spent with the person you saw

Explanation of what was done for you

*Response categories: poor, fair, good, very good, and excellent

Case Study: Patient Satisfaction

- Department of Otolaryngology acquired patient satisfaction data before and after implementing quality improvement efforts
- Saw significant increase in % Excellent scores after quality improvement

Examples

- Smedley TC. Self-assessed satisfaction levels in elderly hearing aid, eyeglass, and denture wearers. A cross-modality comparison. *Ear & Hearing* 1990;11(5):41S-47S.
- Piccirillo JF. The use of patient satisfaction data to assess the impact of continuous quality improvement efforts. *Arch Otolaryngol Head Neck Surg.* 1996;122:1045-1048.
- Tai et al. Use of patient satisfaction data in a continuous quality improvement program for endoscopic sinus surgery. *Otolaryngol Head Neck Surg.* 2003;129:210-216.

Which Diseases to Study?

- Wide variations in clinical practice
- Large segment of population affected
- Use of new and expensive technology as part of diagnosis or treatment

Conclusions

- Evolved from Geographic Variation and Appropriateness Studies
- Utilizes new methodologies for the evaluation of the effects of diverse therapies on patient outcome
- Introduces new areas of study not traditionally included in the evaluation of medical care

Outcomes Primer

Visit our web site!

<http://oto.wustl.edu/clinepi/outcomes.htm>

