Comparison of Baseline Quality of Life between Minority and Non-Minority Patients Participating in Oncology Clinical Trials

Jeff A. Sloan

Division of Biostatistics, Mayo Clinic, Rochester, MN

Collaborators

Jan C. Buckner
Bettye Green
Judith S. Kaur
Jackie Lafky
Elektra Paskett
Paul J. Novotny
Dan Sargent
Paul L. Schaefer
Philip J. Stella
Angelina D. Tan
Mayo QOL team
Alliance Disparities, HOC Committees, CCP

Being in the minority brings unique challenges


…and unique benefits

Do differences result in QOL deficits?

…or are we all getting along doing equally as well in terms of QOL?

Background

- Minority patients (MP) suffer deficits in access to care and participation in clinical trials
- Study design exclusion and inclusion criteria rendered the majority of minority population ineligible. *(Adams-Campbell JCO 2004)*
- Consistent measurement approaches for recruitment are needed. *(Bolen, Cancer 2006)*
- Establishing community partnerships and contacting potential participants are vital and achievable. *(Paskett, Contemporary Clinical Trials 2008)*

Enhancing minority participation in clinical trials (EMPaCT).

Durant, Cancer 2014

- 1) racial and ethnic minorities are influenced by varying degrees of skepticism related to trial participation,
- 2) potential minority participants often face multilevel barriers that preclude them from being offered an opportunity to participate in a clinical trial,
- 3) facilitators at both the institutional and participant level potentially encourage minority recruitment, and
- 4) variation between internal and external trial referral procedures may limit clinical trial opportunities for racial and ethnic minorities.

One way to increase minority accrual: separate data streams

- Smoking cessation studies. Left trial open until sufficient minority accrual was accomplished (Croghan MCP, 2007)
- Hot flash studies. Separate substudy accrual streams for minority and majority patients. (Sloan, JCO, 2001)

QOL and minorities

- Hispanic cancer patients in the USA, report significantly worse distress, depression, social HRQoL, and overall HRQoL *(Luckett, Lancet Oncology 2011)*
- Limited comprehension of prostate cancer terms and low literacy create barriers to measuring QOL in African American men *(Kilbridge, JCO 2009)*
- Latina breast cancer survivors report greater psychosocial concerns over as compared to whites. *(Napoles-Springer, JIH 2008; Burgess, BMJ 2005)*

QOL and minorities: translations

(Advances in Survey Methodology, Lepkowski, 2013, pp. 234-235)

- *There is a self-serving cottage industry in producing "validated" translations of QOL assessments.*
- *There are roughly 6,500 spoken languages in the world today. You can't translate every tool into every language.*
- *Extensive literature points out the POTENTIAL bias of cultural impact on questionnaire answers, few indicate large, clear effect.*
- *Response tendencies reflect association with both stable cultural traits, as well as individual differences.*
- *Cultural bias can be a function of language, gender, education, experience…*
- *Language is not static or consistent: dialects. French Canadian versus France French*

There is almost NO evidence of translation-treatment interactions

QOL and minorities: translations pragmatic solutions

- *If a substantial proportion of your patient population speaks a particular language, you can minimize the impact of language difficulties through a formal, expensive translation process*
- *Allowing for informal oral translation removes barriers to participation and establishes trust in the community*
- *Record when an oral translation is involved, include an indicator covariate into the analysis to estimate treatment-translation bias*
- *"Perfection is the enemy of progress"*

QOL and everyone: why are the questionnaires so long?

- Need to know
- Nice to know
- People lie?
- Psychometrics

Every question should have a reason for being there (Baseline)

QOL and everyone: why are they asking the same thing repeatedly?

- Cognitive test
- Consistency
- Sensitive information
- Security for the researcher

Tell the patient up front why some questions are repeated (R01)

Motivation

- Some isolated studies look at QOL of minority patients indirectly.
- No large scale investigation.
- We hence undertook a patient-level pooled analysis to explore whether these deficits translate into quality of life (QOL) differences between minority patients and non-minority patients on clinical trials

47 Studies included in the Meta Analysis

- Studies were conducted either at the Mayo Clinic Cancer Center or in the North Central Cancer Treatment Group
- 6513 total patients
- 531 (8%) minorities
- Used only the baseline QOL
- QOL Scores were transformed into 0-100 scales with 0=Low QOL and 100=Best QOL

Studies Included

- 12 GI cancer treatment studies
- 14 cancer control studies
- 6 lung cancer treatment studies
- 5 QOL assessment studies
- 10 other studies (various tx trials)

Study Assessment Tools

QOL Assessment	Questions/Subscales
Uniscale	Overall QOL
Linear Analogue Assessment (LASA)	Overall QOL, Physical WB, Emotional WB, Spiritual WB, Mental/Intellectual WB
Symptom Distress Scale (SDS)	Nausea Frequency, Nausea Severity, Appetite, Insomnia, Pain Frequency, Pain Severity, Fatigue, Bowel, Concentration, Appearance, Breathing, Outlook, and Cough
Profile of Mood States (POMS)	Tension-Anxiety, Depression-Dejection, Anger-Hostility, Vigor-Activity, Fatigue-Inertia, Confusion-Bewilderment
Functional Assessment of Cancer Therapy – General (FACT-G)	Physical WB, Social/Family WB, Emotional WB, Functional WB

Overall Patient Characteristics (N=6513)

- **Race**

White	5982 (92%)
Black/African American	327 (5%)
Hispanic	100 (2%)
Asian	47 (1%)
American Indian/Alaskan Native	31 (1%)
Native Hawaiian	7 (0.1%)
Other	19 (0.3%)

- **Age (Median, Range)** (62, 17-95)
- **% Female** 46

Overall Patient Characteristics (N=6513)

- **Performance Score**

Missing	1634
0	2013 (41%)
1	2565 (53%)
2	301 (6%)

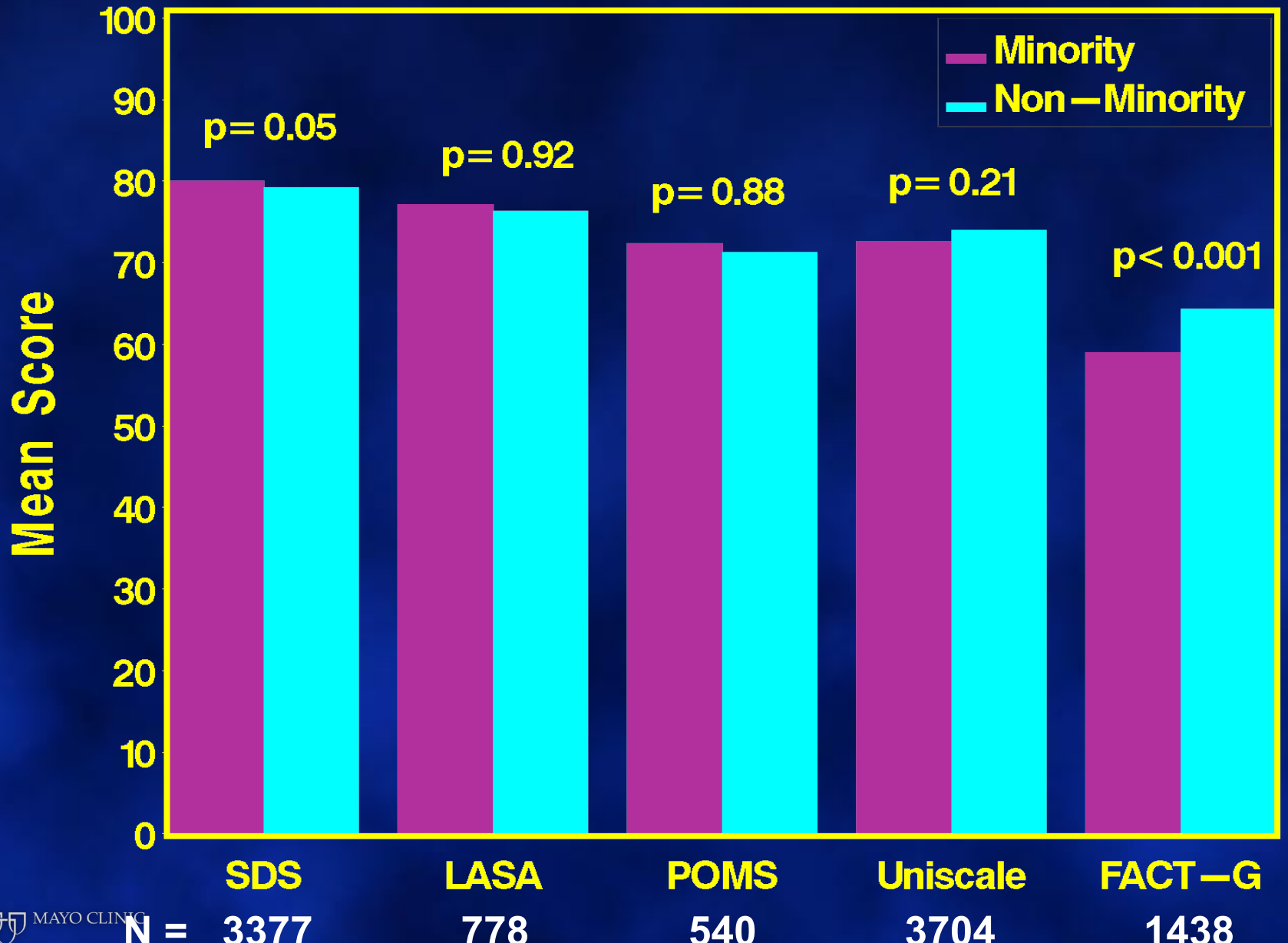
- **Major Tumor Site**

GI	3072 (47%)
Lung	1040 (16%)
Breast	543 (8%)
GU	262 (4%)
Neuro	247 (4%)
Multiple	35 (1%)
Other	813 (13%)
Unknown	501 (8%)

Overall QOL Scores

Minorities reported
worse overall FACT-G scores
(8 points)

Overall QOL Assessment



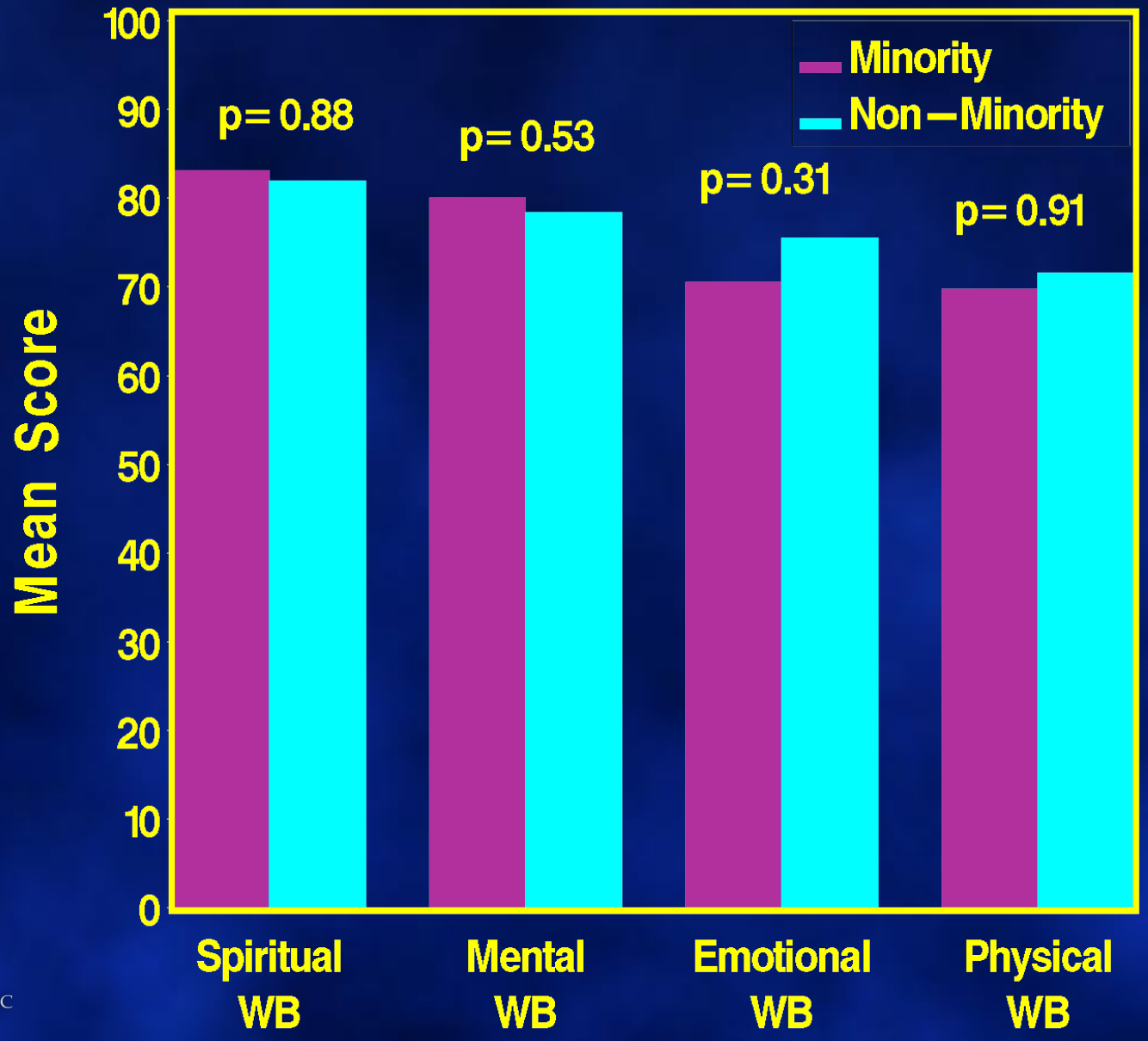
QOL Subscales

There were no significant differences

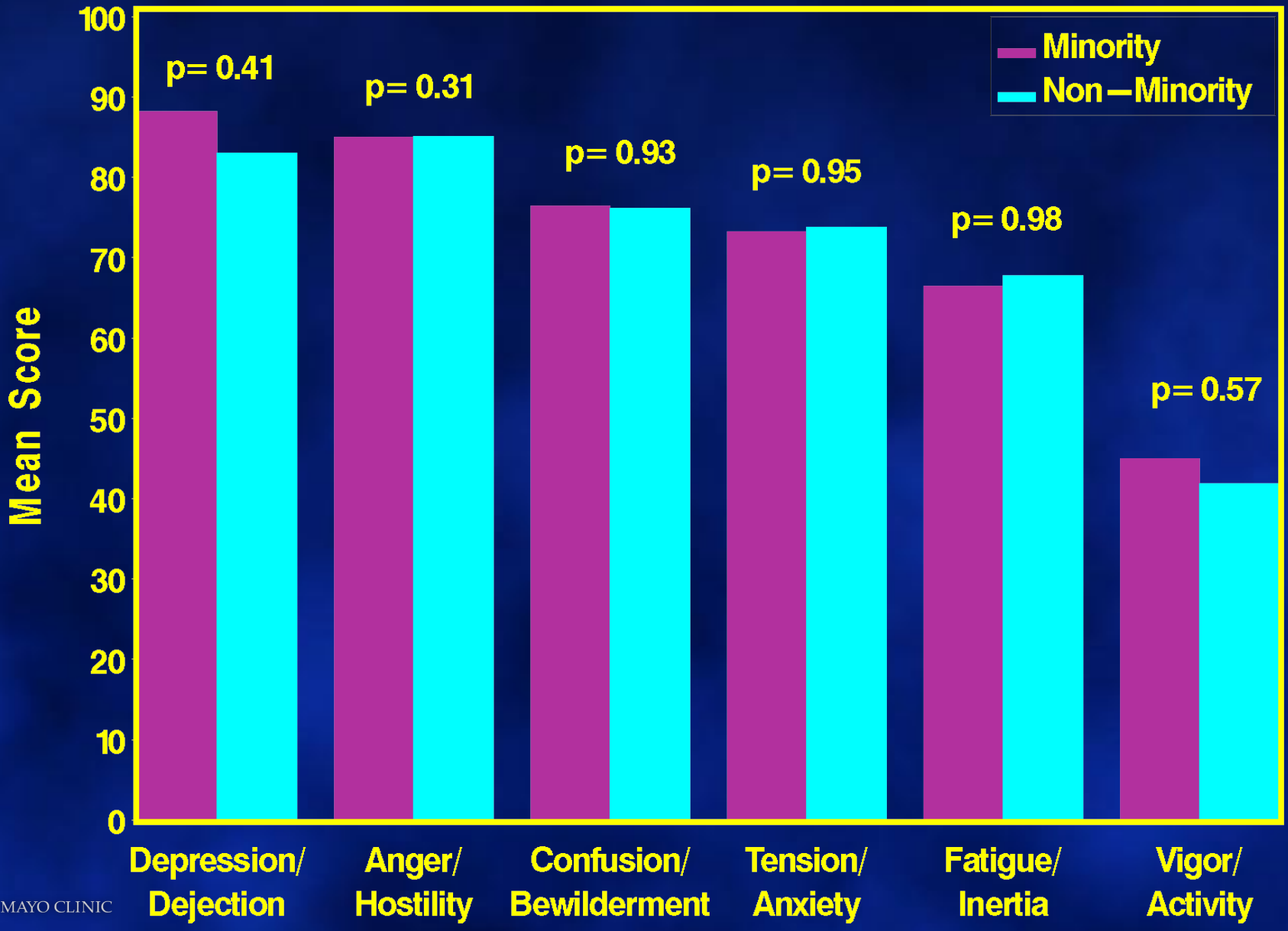
by race on

LASA or POMS subscales

LASA Questions

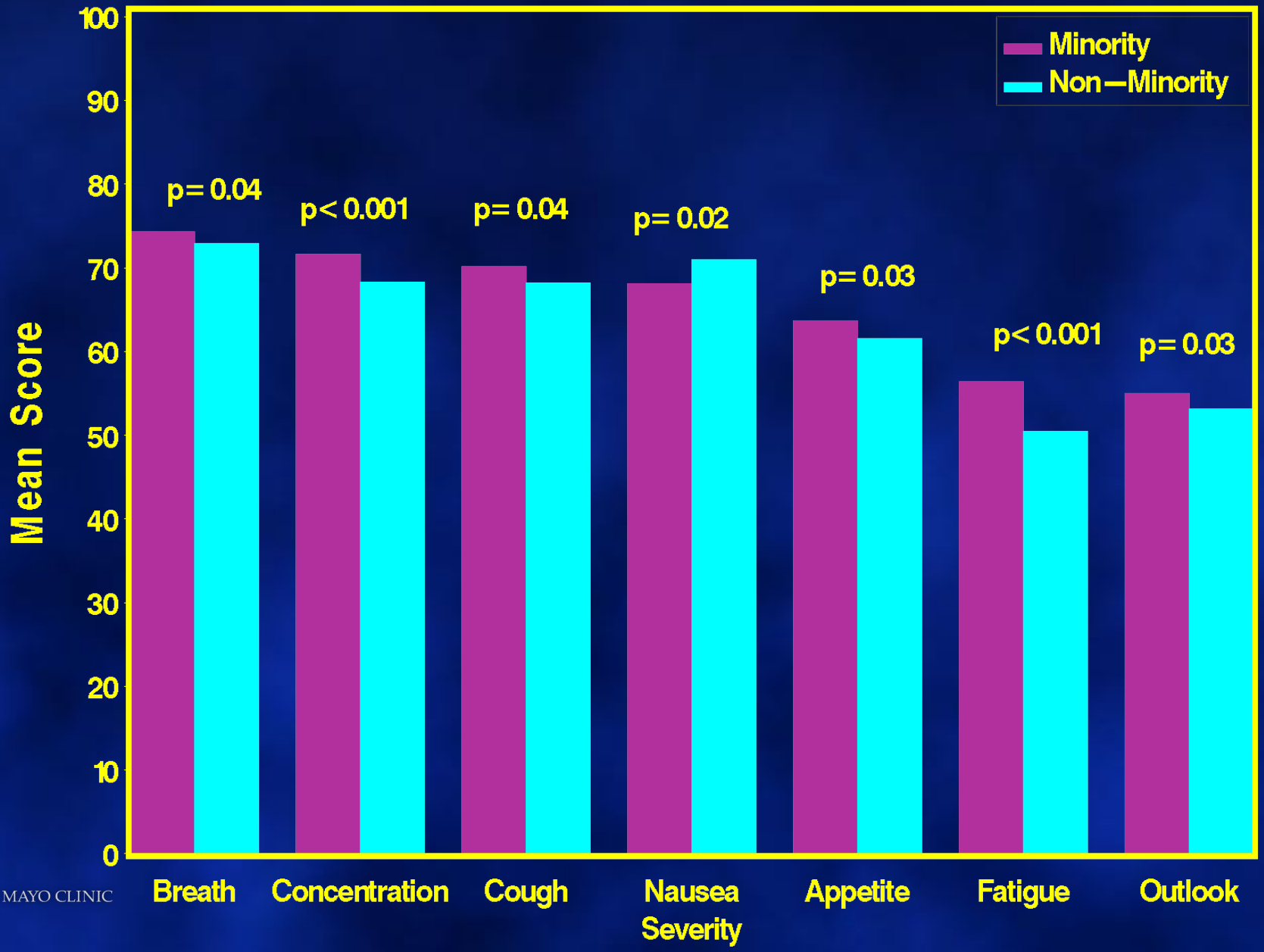


POMS Subscales



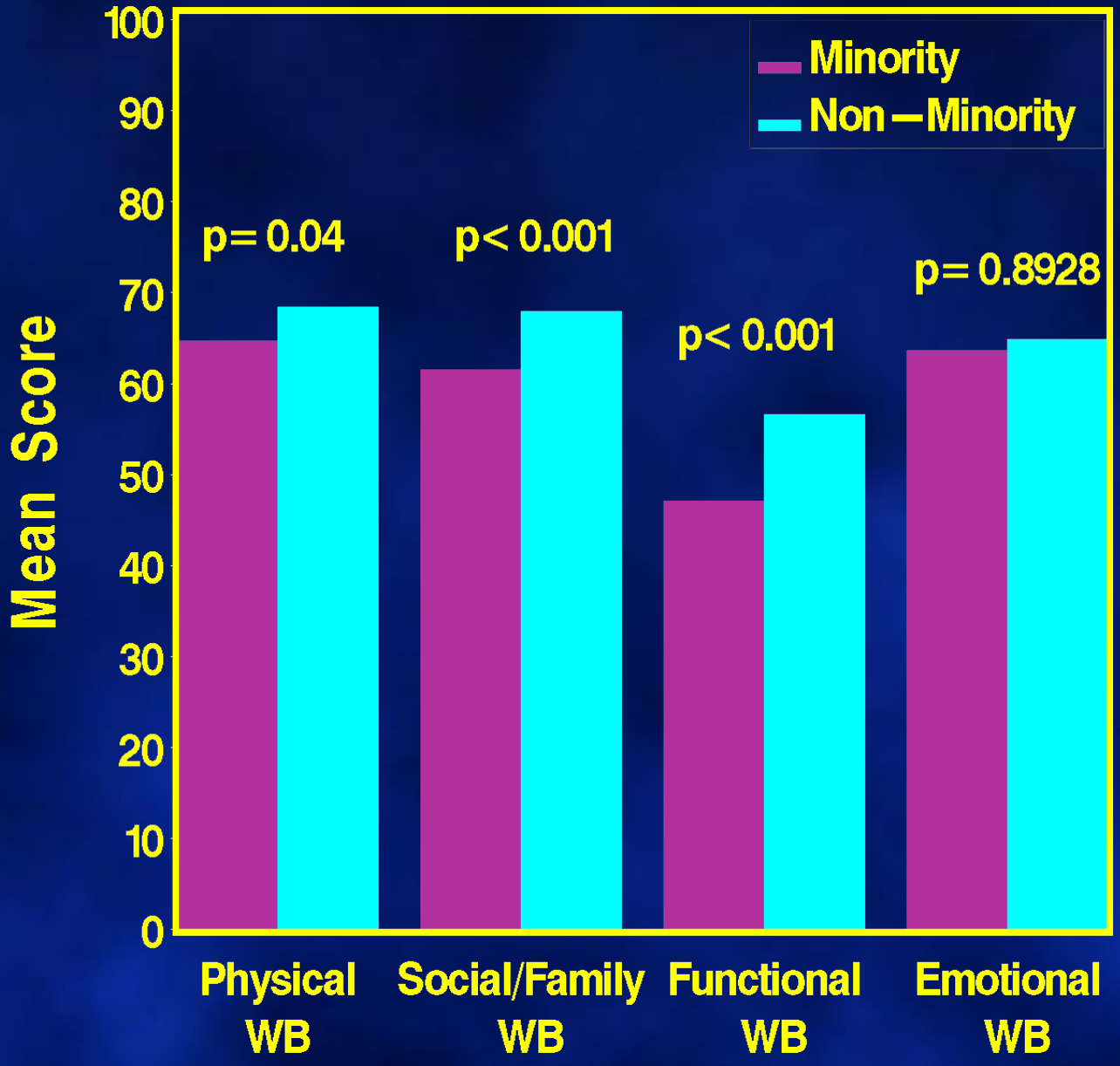
Minorities reported
slightly better scores on
most SDS questions (<6 points),
likely due to statistical power
overwhelming clinical significance

SDS Individual Questions



Minorities reported
worse FACT-G subscale scores,
especially functional QOL (10 points)

FACT-G Subscales

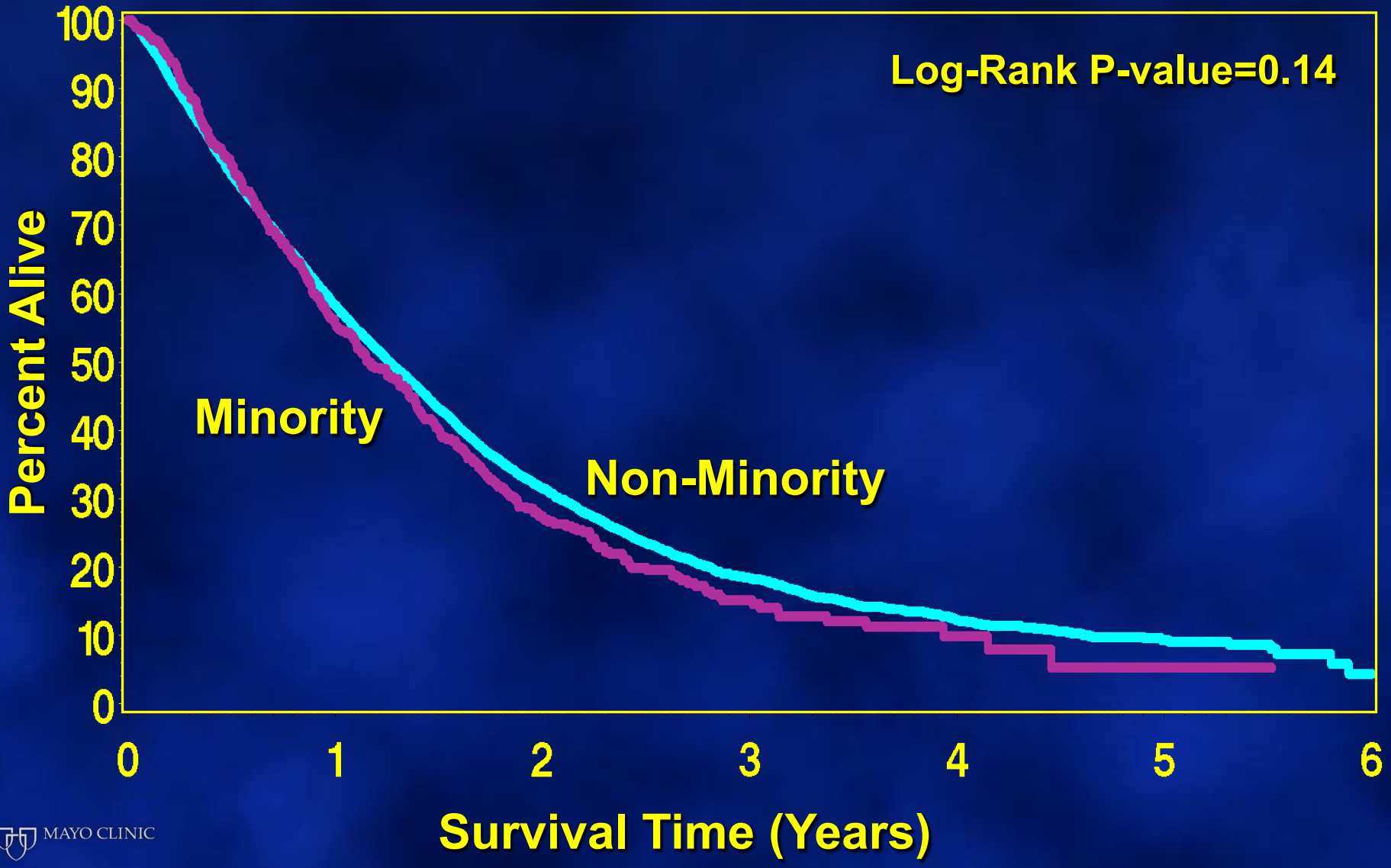


Minority QOL Differences by Site

Minorities Worse	Site	Minorities Better
Social/Family WB Functional WB FACT-G Total Score	GI	Fatigue Concentration Outlook
Nausea Insomnia Functional WB	Lung	Cough
Insomnia Functional WB FACT-G Total Score	Breast	- -
Emotional WB	Neuro	- -

Overall, there was no significant survival difference by race

Overall Survival Time



So what have we found?

Discussion

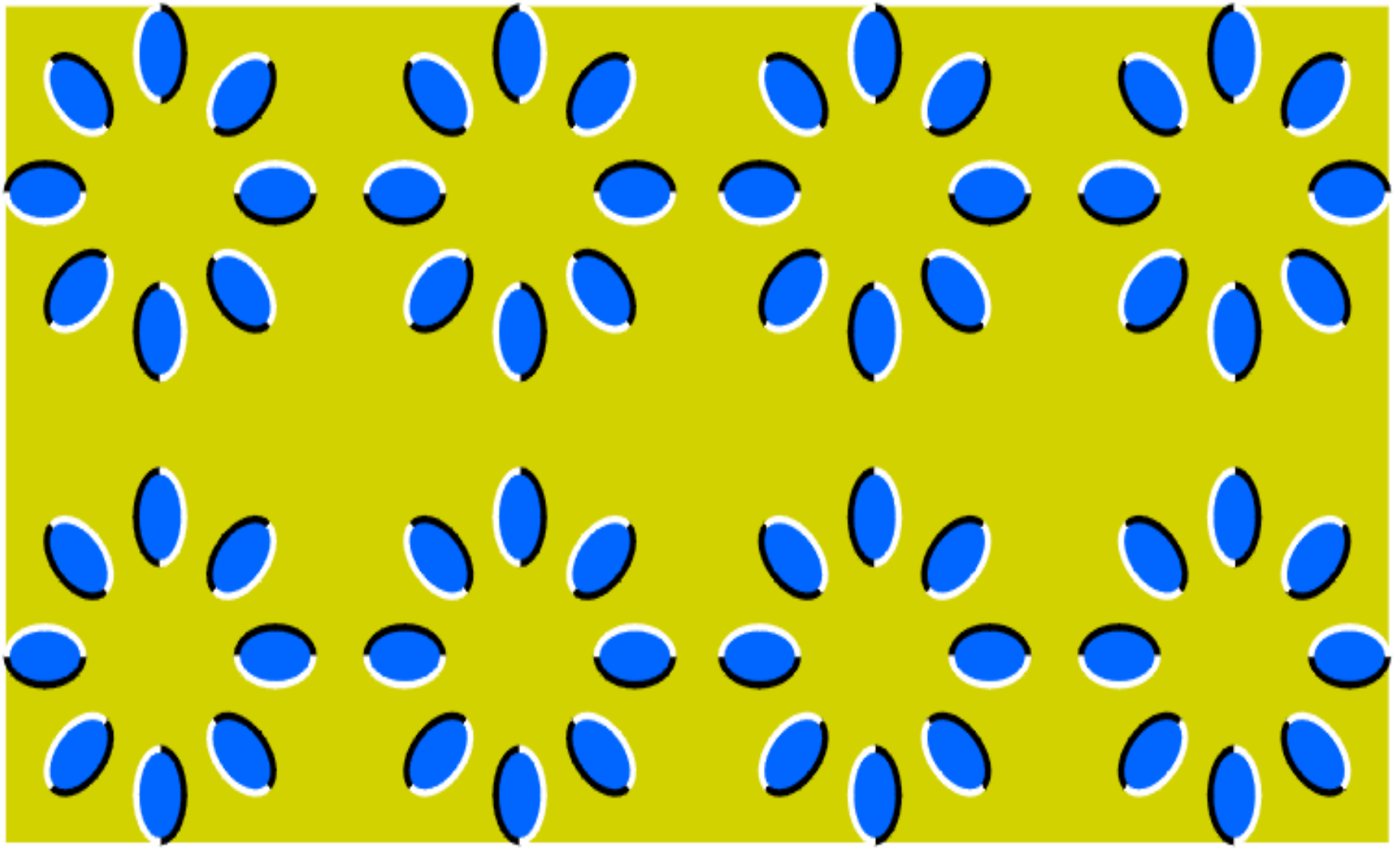
- Minority patients chosen had access to clinical trials and may not be representative of minorities in the general population
- Minority patients did not report large QOL deficits at baseline relative to non-minority patients
- Minority patients did not show a difference in overall survival

Conclusions

- Minority patients did indicate small deficits in physical, social, and emotional subscales, but less than what one might expect

- Minority patients experienced large tumor-specific deficits for a few QOL domains that might bear further attention

Are the differences real or an illusion?



Some open questions

- Is meeting minority accrual targets addressing the challenges faced by minority populations?
- Are analyses on minority patients from clinical trials under-estimating the problems?
- If differences are observed, are they REALLY big?

Future Research

- Plan focus groups to drill down to find out what underlies the differences observed?

- Plan specific intervention studies to reduce the deficits in QOL observed, (fatigue/physical functioning)?

Discussion?


Me and you is friends
you smile, I smile...
you hurt, I hurt...
you cry, I cry...
You jump off Bridge
I gonna miss your E-Mails.

Backup slides

12 GI Studies

- 954651 – 776C85/5FU Adv Colon/Rectum
- 959257 – Prostate Pin Flutamide
- MC0145 – Esophageal ACA Registry
- N0044 – Esophageal/Chemo + RT
- N0048 – Colorectal/OXAL/CPT-11
- N0149 – Esophageal CA OXAL CAPCIT
- N014C – Pancreatic CA PS341 GEMZAR
- N0242 – ACA Stom GE Junc TATER CAPCIT
- N9741 – Advanced Colon CPT11/5FU/CF
- N9841 – Adv Colorectal CPT-11/OXPLAT
- N9942 – Pancreas CA Gemcitabine
- N9946 – Colorectal ACA OXAL 5-FU CF

11 Cancer Control Studies

- 959255 – Anorexia/Cachexia Megace/Marin
- 969256 – Pelvic RT Proctitis Glutamine
- 971151 – Shark Cartilage
- 979251 – LMWH Advanced CA
- 979253 – RHUEPO/Anemia Pts with Cancer
- 989251 – Cervical Imiquimod Chemopreven
- MC99C2 – DB Oral Glut Myalgia/Arthralgi
- N00C9 – Cognitive Dys Ginkgo Biloba
- N01C4 – Head & Neck/Zinc Sulfate
- N01C9 – NSCLC Tater Infliximab
- N02C2 – Anemic CA Pts RHEUPO

6 Lung Studies

- 952053 – Trt plus VP16, CDDP, SCLC
- 962451 – Adv NSCLC LU103793
- 972451 – NSCLC Cai Stage IIIB/IV
- 982452 – NSCLC Tater + Gemzar Phase II
- N0022 – NSCLC/Oral Vinorelbine
- N9923 – Lung CDDP/VP16/Ethyol/RT

5 QOL Studies

- 959204 – QOL in Hospice Pts & Caregiver
- MC0115 – QOL Phase I Trials
- MC0192 – QOL/Ovarian Cancer
- MC997C – QOL Struct Interv
- MC9991 – Social Support Pilot CA Pts

3 Hot Flash Studies

- MC00C6 – Hot Flashes/Citaloprim
- MC01C1 – Pilot Paxil/Hot Flashes
- N99C7 – Hot Flashes - MPA

10 Other Studies

- 979202 – Monoclonal Gammopathy Deh
- 983252 – TAXOL/CBDCA/RHUMAB HER2-Breast
- 987251 – Astrocytoma-BCNU, CISPLAT, ETOP
- 987252 – Glioblastoma, BCNU, CDDP, VP16
- 987403 – IA CDDP Plus RT H&N
- N0021 – Mesothelioma/Gemzar Epirubicin
- N0031 – Breast Cancer/Topical Ceramide
- N0074 – Glioblastoma/ZD1839
- N0087 – NHL/Interleukin-12/Rituximab
- N0272 – Oligodendroglioma STI571

Patient Characteristics by Assessment

	Uniscale (N=4201)	LASA (N=946)	SDS (N=3802)	POMS (N=662)	FACT-G (N=1805)
% Minority	**9**	**4**	**10**	**3**	**7**
% Female	**44**	**37**	**44**	**50**	**48**
Age (median)	**63**	**60**	**63**	**57**	**64**
Performance Score					
Missing	823	150	449	126	657
0	39%	42%	34%	59%	32%
1	55%	49%	60%	35%	61%
2	5%	10%	7%	6%	7%
Major Tumor Site					
GI	63%	20%	72%	6%	19%
Lung	16%	8%	8%	4%	30%
Breast	8%	6%	5%	2%	10%
GU	5%	2%	2%	14%	1%
Neuro	0%	25%	3%	34%	12%
Multiple	0%	14%	1%	0%	0%
Other	9%	17%	9%	17%	16%
Unknown	1%	8%	2%	24%	12%