



Patient-Centered Research in Uterine Fibroids: The COMPARE-UF Experience

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ClinicalTrials.gov: [NCT02260752](https://clinicaltrials.gov/ct2/show/study/NCT02260752).

About COMPARE-UF- Treatment Options for Patient-Centered Care

A nationwide registry of women with uterine fibroids that hopes to answer questions about the outcomes of different treatment options at 9 clinical sites in the United States.

How is this done:

Each participant makes treatment decisions with her personal doctor, and then shares information about her current and past fibroid experiences, including how fibroids have impacted her quality of her life.

Our Goal:

Our aim is to understand which fibroid treatment options are most effective and what factors influence treatment outcomes.

We hope that the information we learn from this registry will help answer those questions so women with uterine fibroids will be able to make informed decisions about their treatment options.

Funding:



All Key Stakeholders Are Represented

- Advocacy Groups
- Life Sciences Industry
- Clinicians/Professional Society
- Federal Agencies
- Payer/Health

Collaborative physician/patient relationship

- Understanding patient needs
- What questions should patients ask their physician?
- What questions should physicians ask patients?
- Understanding the legacy of patient fear
- The impact of of symptoms on the patient –
 - Quality of Life (QoL), fear, stress
- Educate on all treatment options
- Alternatives to hysterectomy



Enrollment Strategies

- Emphasize non-invasive, patient focused
- Website
- Social media
- Sharing stories. Video.
- Developing strategies from both patient and physician perspectives
- Localize the outreach
- Provide statistics and updates
- Global interest



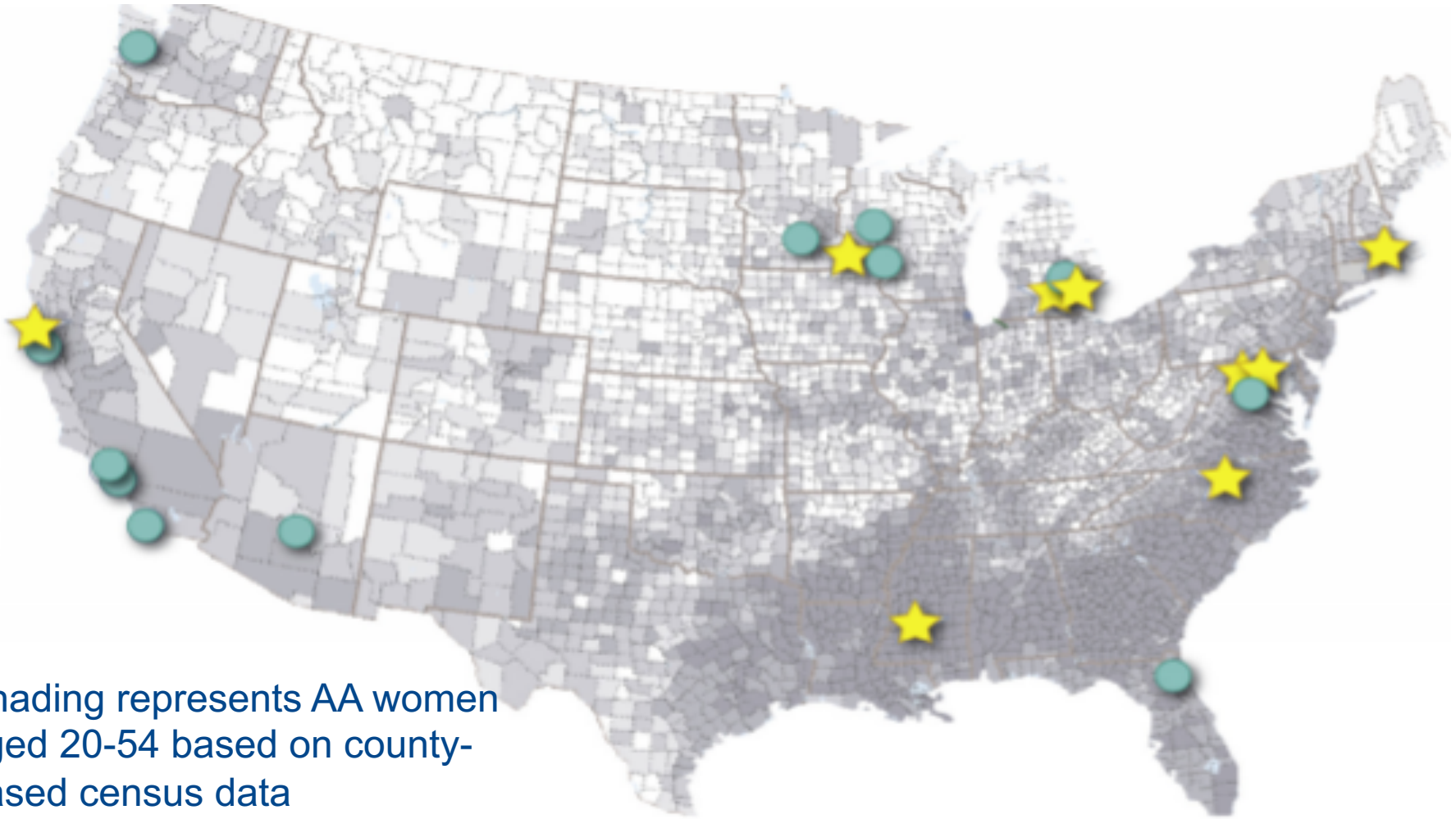
These wonderful ladies are the Compare-UF fibroid team at Henry Ford Health. They are a joy to work with, and bring special care and compassion to helping fibroids patients. Thank you!

#FibroidFridays

8 Diverse Clinical Sites With Diverse PIs

	Site	Principal Investigator
Clinical Sites	U of Calif Fibroid Network	Vanessa Jacoby MD MAS
	Mayo Clinic	Elizabeth Stewart MD
	Henry Ford Health System	Ganesa Wegienka PhD
	U of Michigan	Erica Marsh MD MSci
	U of Mississippi	Kedra Wallace PhD
	U of North Carolina	Wanda Nicholson MD MPH MBA
	Inova Health System	G Larry Maxwell MD
	Partners Healthcare/Harvard	Raymond Anchan MD PhD
Data Coordinating	Duke Clinical Research Institute (DCRI)	Evan Myers MD MPH

Increasing Geographic and Racial Diversity of Participants



Shading represents AA women aged 20-54 based on county-based census data

Procedures Captured

- Hysterectomy
- Myomectomy
- Laparoscopic RF Ablation
- Endometrial ablation
- Uterine artery embolization
- MR-guided focused ultrasound
- Progestin-releasing IUD

Data obtained at each time points

Baseline	Procedure	6-12 Week Recovery	Annual Follow-up
Medical, reproductive history	Operative and pathology reports, Discharge summary	Complications	Pregnancy Status
Imaging	Complications		Menopausal Status
HR-QoL*	HR-QoL*	HR-QoL*	HR-QoL*

* Validated Measures of HR-QoL Used in COMPARE-UF

UFS-QoL (fibroids)

EuroQoL 5D 5L (general)

PHQ-2 (depression)

Menopause Rating Scale

Enrollment

- Began November 2015; Completed March 2019
- 3097 Women undergoing fibroid procedures
 - 42 % Black or African American
 - 40% ≤ age 40
 - 16% , age 35

46% Myomectomy

14% Abdominal

19% Laparoscopic/Robotic

13 % Abdominal

38% Hysterectomy

Quality-of-Life, Symptom Severity, and Anxiety/Depression 1 year after Hysterectomy vs Myomectomy

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At 1-year after surgery, what are women's perceptions of their quality of life?



Compare the effectiveness of hysterectomy versus myomectomy on HRQoL?

Are there differences in HRQoL at 1-year based on surgical route?

Does effectiveness vary by age or race?

1-year QoL in hysterectomy and myomectomy patients



- Inclusion criteria for analysis:
 - women undergoing hysterectomy or myomectomy
 - 30 years or older, and not attempting pregnancy
 - final cohort with comparable patients

Women with uterine fibroids enrolled in
COMPARE-UF
November 11, 2015 – April 18, 2019
(n = 2,937)

Hysterectomy or Myomectomy
(n = 2,355)

Study Observation Other than
Hysterectomy or Myomectomy
(n = 582)

Actively Trying for Pregnancy
(n = 393)

Age \leq 30yrs at Enrollment
(n = 128)

Cancer Diagnosis
(n = 13)

Pregnancy after Primary Surgery
(n = 41)

< 425 days since Therapy date
(n = 434)

1yr data unavailable
(n = 233)

Final Study Population
(n = 1,113)

Health-Related Quality of Life: UFS-QoL

- **Uterine Fibroid Scale-QoL**-Only validated disease-specific quality-of-life (QoL) instrument
 - Applicable for all types of fibroid symptoms
- **Subscales (higher score = better quality of life)**
 - Concern
 - Activities
 - Energy/Mood
 - Control
 - Self-consciousness
 - Sexual function
 - Summary score
- **Symptom severity (lower score= less severe symptoms)**



Generic measure of quality of life: EQ-5D

- **Validated** general QoL instrument
- **Subscales** (reported on 5-point scale from none to all the time)
 - Mobility
 - Self-care
 - Usual activities
 - Pain/discomfort
 - Anxiety/depression
- **Visual analog scale (VAS)**
 - 10 cm scale, 0 worst, 10 best, patient marks overall rating of QoL

Statistical Analysis

- Socio-demographic and clinical factors were compared between the two treatment groups, using t-test and chi-square analysis
- Baseline HRQoL from the Uterine Fibroid Symptom QoL, Symptom Severity Scores and the Euro QoL Visual Analog Score (VAS) were compared between groups
- Each subscale score of the Uterine Fibroid Symptom QoL and the EuroQoL 5-Dimension Health Questionnaire was compared between the two procedure groups

Baseline Characteristics of Study Cohort (N= 1,113)

Characteristic	Myomectomy (N=483)	Hysterectomy (N=630)	P-value
Age(years)	40.1 (5.9)	44.8 (4.7)	<.01
Age 31-40	234 (48.4%)	82 (13.0%)	
Age 40-45	136 (28.2%)	201 (31.9%)	
Age 45+	113 (23.4%)	347 (55.1%)	
Race			<.01
White	202 (42.1%)	334 (53.4%)	
Black	193 (40.2%)	221 (35.4%)	
Other	85 (17.7%)	70 (11.2%)	
Hispanic/Latina	41 (8.7%)	38 (6.3%)	0.12

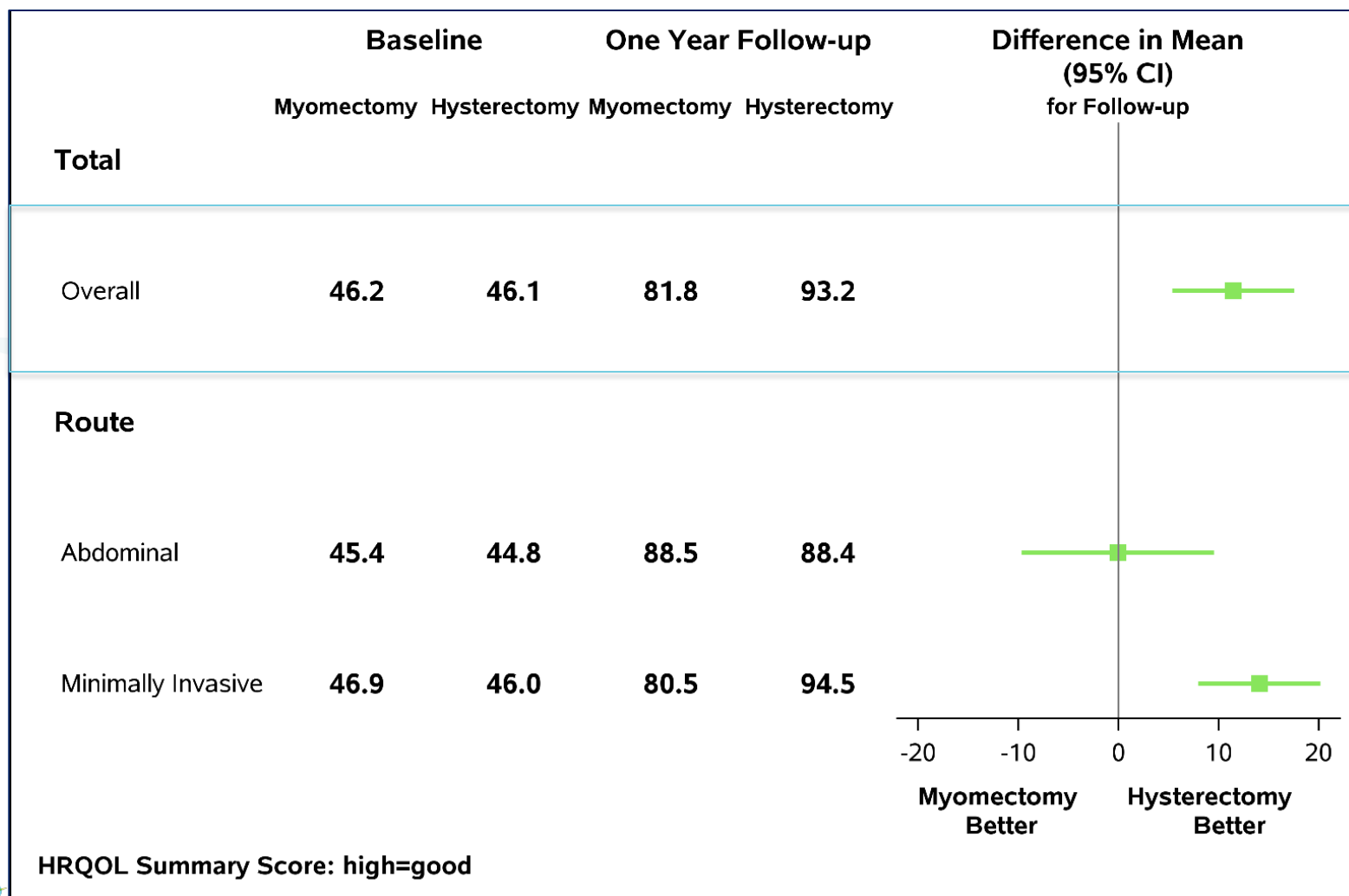
No difference in choice of surgical route or fibroid measures

Characteristics	Hysterectomy	Myomectomy	p-value
Surgical Route			0.08
Abdominal	137 (28.4%)	126 (23.6%)	
Minimally Invasive	346 (71.6%)	409 (76.4%)	
Total Fibroid Volume Median(Q1,Q3)	160.3 (30.2,419.9)	126.2 (35.1,306.8)	0.13
Uterine Volume Median(Q1,Q3)	367.2 (178.3,739.5)	396.0 (216.5,748.7)	0.10
Number of Fibroids Measured Median(Q1,Q3)	2.0 (1.0,3.0)	2.0 (1.0,3.0)	0.98

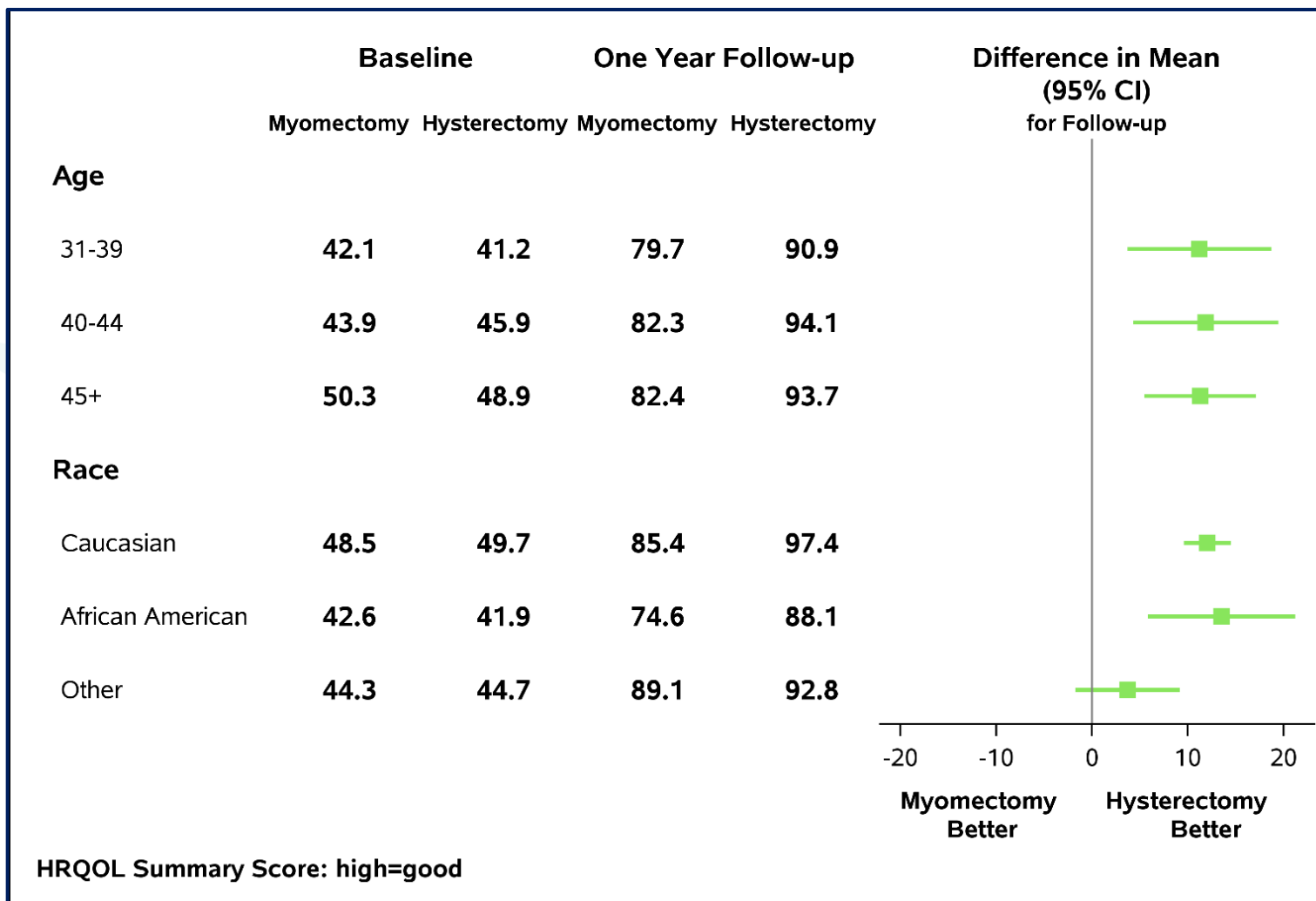
Propensity Scoring in Baseline and Multivariable Analysis

- Propensity scoring was used to adjust for patient characteristics, quality scores and symptom severity at baseline.
- Inverse propensity weighting was used to adjust for confounding in multivariate analysis.

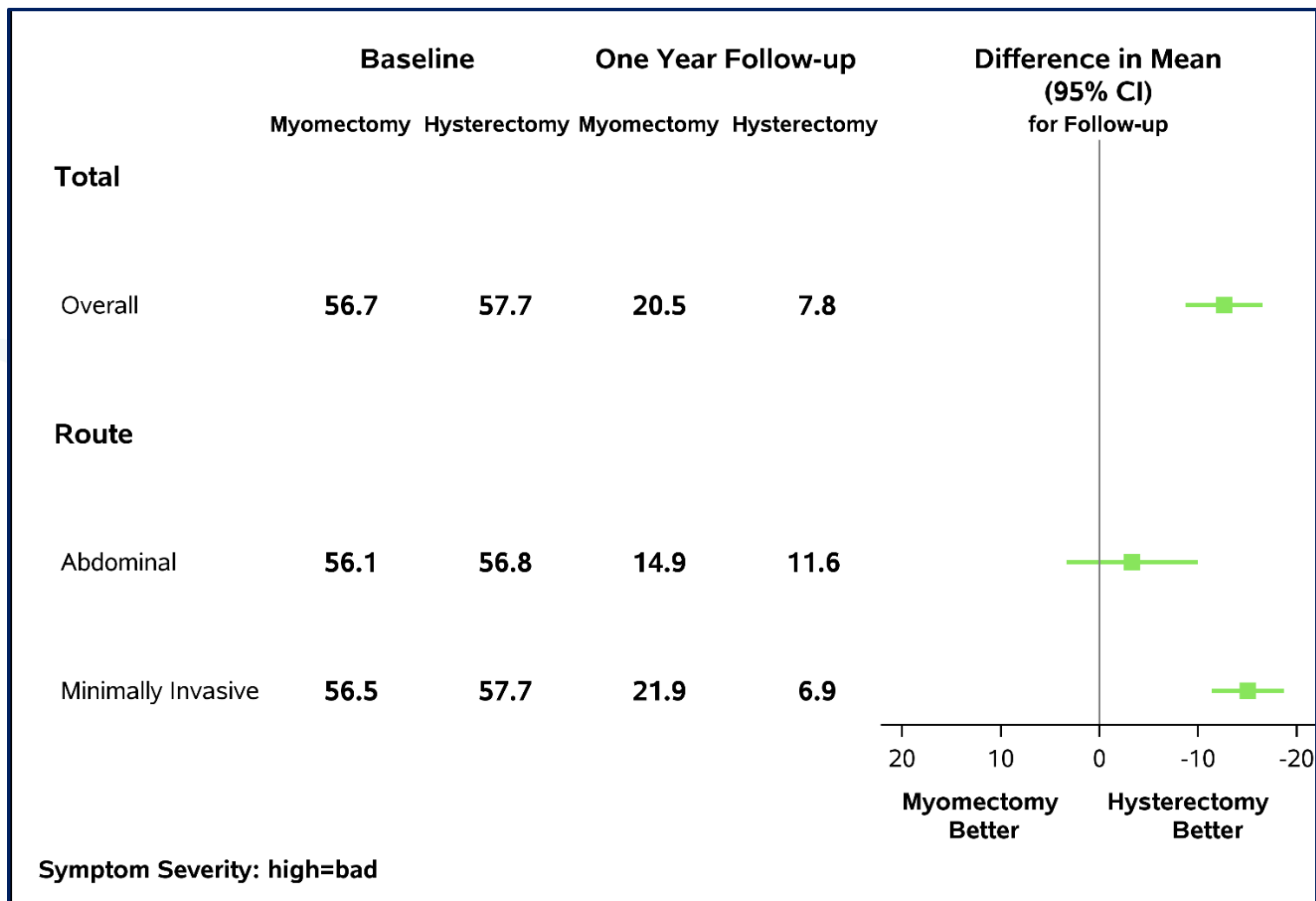
Higher HRQoL Scores At 1-Year, Overall and By Route of Procedure



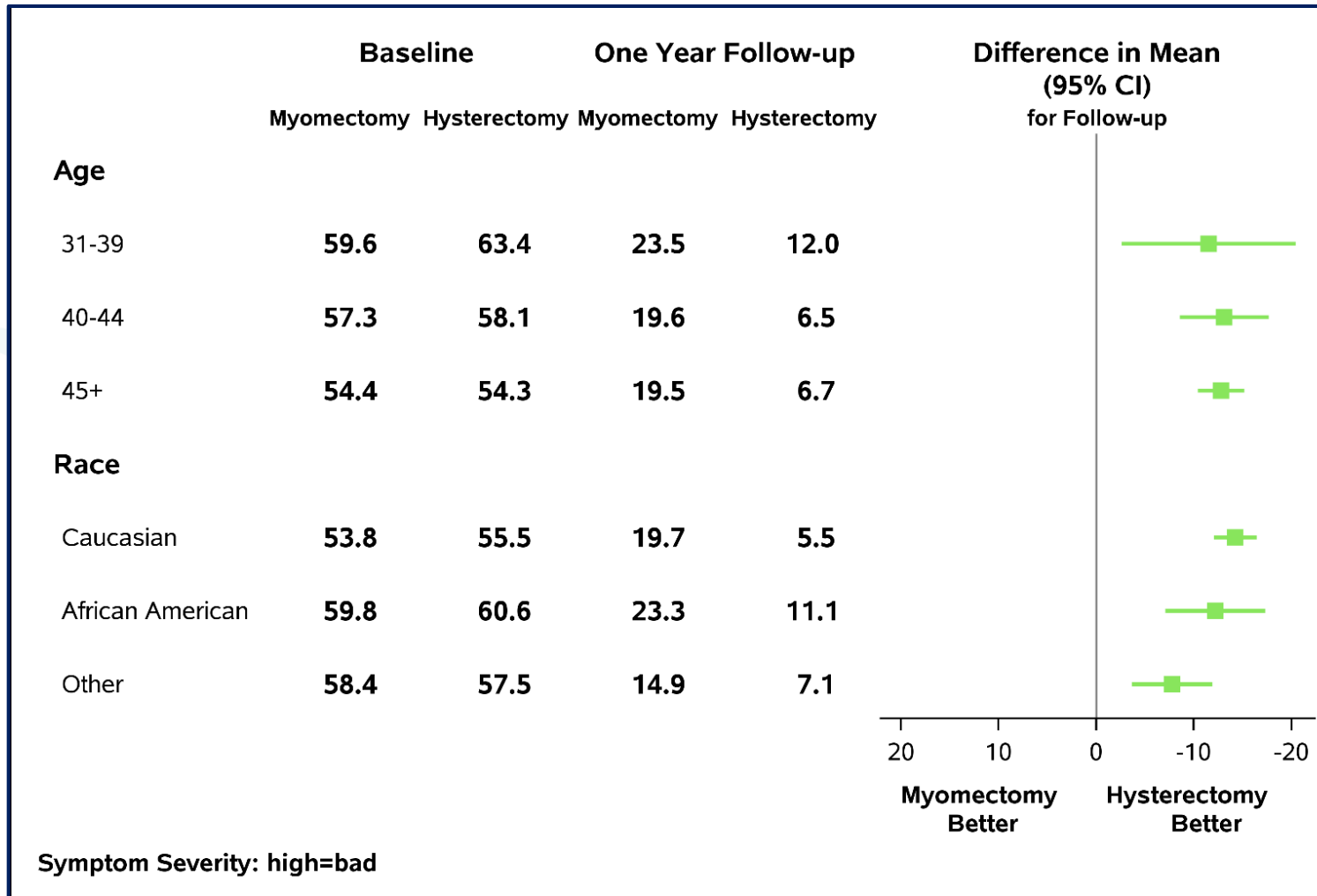
Women Report Higher HRQoL Scores at 1-Year Post Procedure Across Age and Race



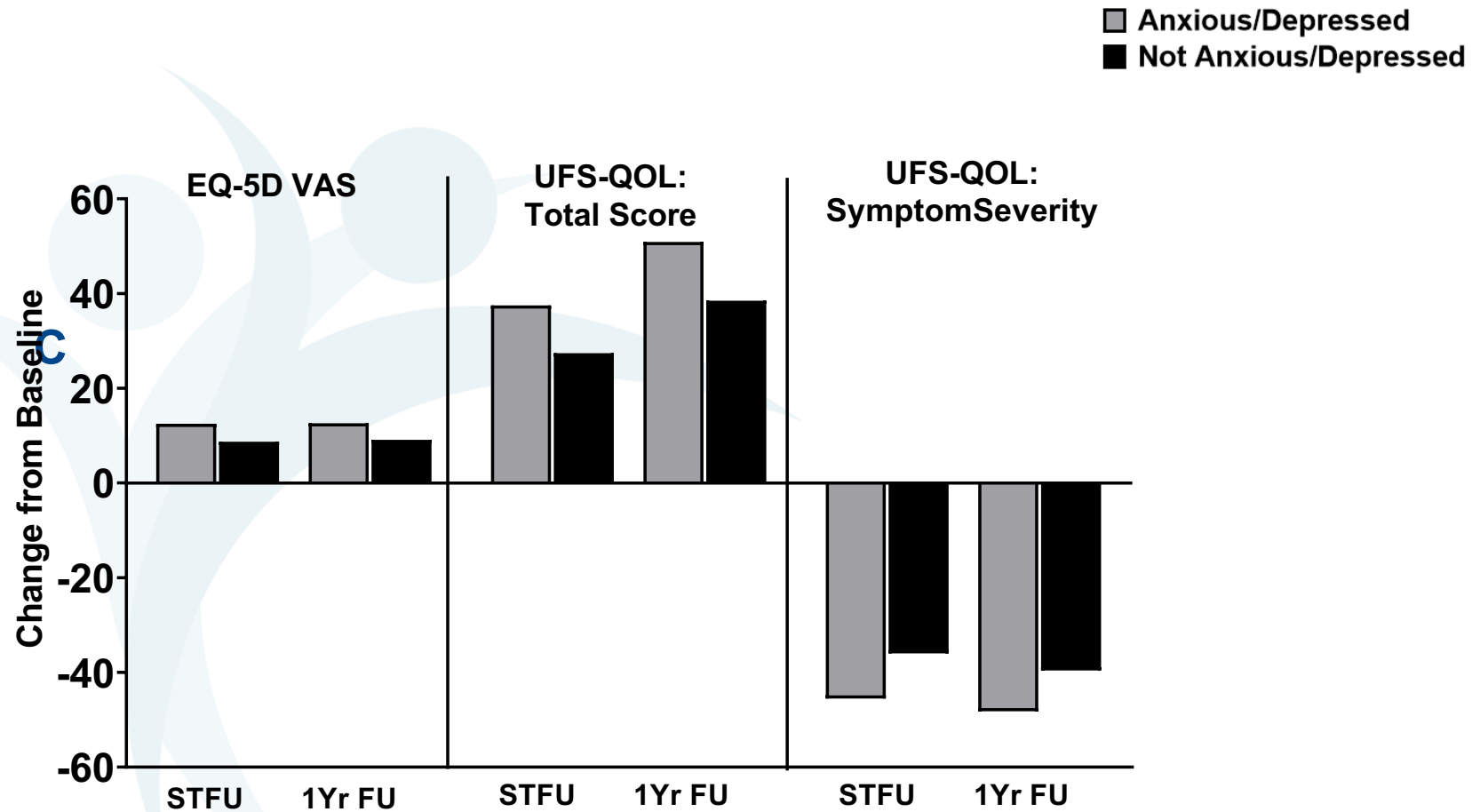
Women Report Significantly Better Symptom Severity at 1-Year Post Procedure



Women report Significantly Better Symptom Severity at 1-Year Post Procedure Across Age and Race



Anxiety/Depression and HRQOL



Key Messages: 1-year post-procedure



- HRQoL and symptom severity were significantly improved in patients undergoing both hysterectomy and myomectomy.
- Hysterectomy patients had significantly greater improvement in HRQoL and symptom severity compared to myomectomy, regardless of age or race.
- Symptom severity can improve with both surgical options
- Symptom severity can be reduced among those with depressive symptoms/anxiety

Key Messages: 1-year post-procedure

- No differences in HRQoL or symptom severity between abdominal hysterectomies and abdominal myomectomies.
- There was greater improvement in HRQoL and symptom severity in minimally invasive hysterectomy compared to myomectomy.

What Can Women and their Clinicians Expect at 1-year Post Procedure?

- HRQoL will improve with the choice of hysterectomy or myomectomy
- Improvement in HRQoL and symptom severity can be expected for both procedures, regardless of age or race
- When choosing a minimally invasive approach, women undergoing hysterectomy report better HRQoL and symptom severity

Future Research to Promote Treatment Choice

- Longer-term follow-up is needed to further assess HRQoL and symptom severity, particular for women undergoing myomectomy
- Adjustment for hospital characteristics
- Account for type of physician, surgical volume and years of experience

What is coming next for **COMPARE-UF?**



A number of other manuscripts are in preparation

- Postoperative complications: Hyst vs. myomectomy
- Racial differences in use of uterine-sparing procedures
- Need for additional interventions following primary procedure
- Is baseline financial toxicity associated with procedure choice?
- Interaction between anxiety and depression and QoL
- Pregnancy outcomes
- Is short-term changes in QoL correlated with long-term outcomes



Q & A

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