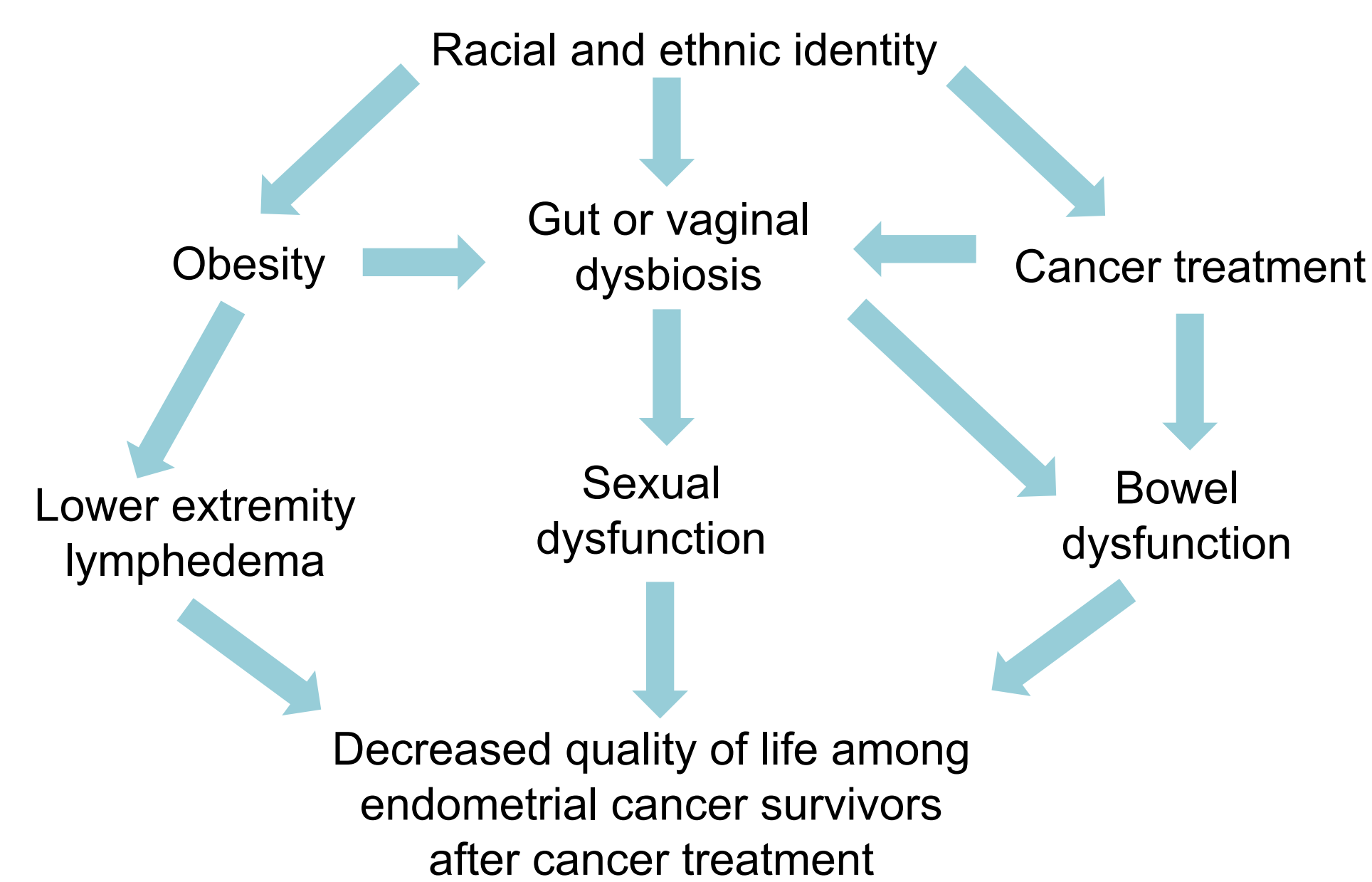


Self-collection of microbiome samples and leg circumference measurements among endometrial cancer survivors: A pilot study

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Background



Carolina Endometrial Cancer Study

A comprehensive population-based cohort that aims to enroll more than 1,500 North Carolina women newly diagnosed with endometrial cancer

In a sub-study, 50 endometrial cancer survivors participated in a home visit where nurses:

- Retrieved self-collected gut and vaginal microbiome specimen kits
- Collected validated patient-reported measures on sexual and bowel function

To further characterize the experiences of endometrial cancer survivors, we aimed to:

- Assess the feasibility and acceptability of self-collection gut and vaginal microbiome samples
- Ascertain the burden of lower extremity lymphedema
- Determine the prevalence of bowel and sexual dysfunction

Home Visit Survivor Sample (N=50)

Race
54% White, 44% Black, and 2% Multiracial

Age at diagnosis Mean=60.7 years, SD =11.5 years
Body mass index (BMI) Mean=34.9 kg/m², SD=8.2 kg/m²

Time from cancer diagnosis
Mean=18.7 months, SD=4.8 months

Survivor Reported Measures

Lower Extremity Lymphedema

- Self- and nurse-measured (gold standard) **10% difference** in lower extremity circumference area (in centimeters)
- Gynecologic Cancer Lymphedema Questionnaire (GCLQ) (**≥4 symptoms**)

Bowel Function

- Colorectal Anal Distress Inventory (CRADI-8) where survivors ranked level of bother on a scale of 1 (not at all) to 4 (quite a bit) within past 3 months

Sexual Function

- Sexual Function Vaginal Questionnaire (SVQ) where survivors ranked level of bother on a scale of 1 (not at all) to 4 (quite a bit),

Microbiome Self-Collection Kits

- Number of stool and vaginal samples received
- Level of comfort with providing stool and vaginal samples

Home Visit Feedback

- Perceptions about lower extremity measurement process
- Collection and refusal reasons for stool and vaginal samples
- Suggestions for improving sample collection process

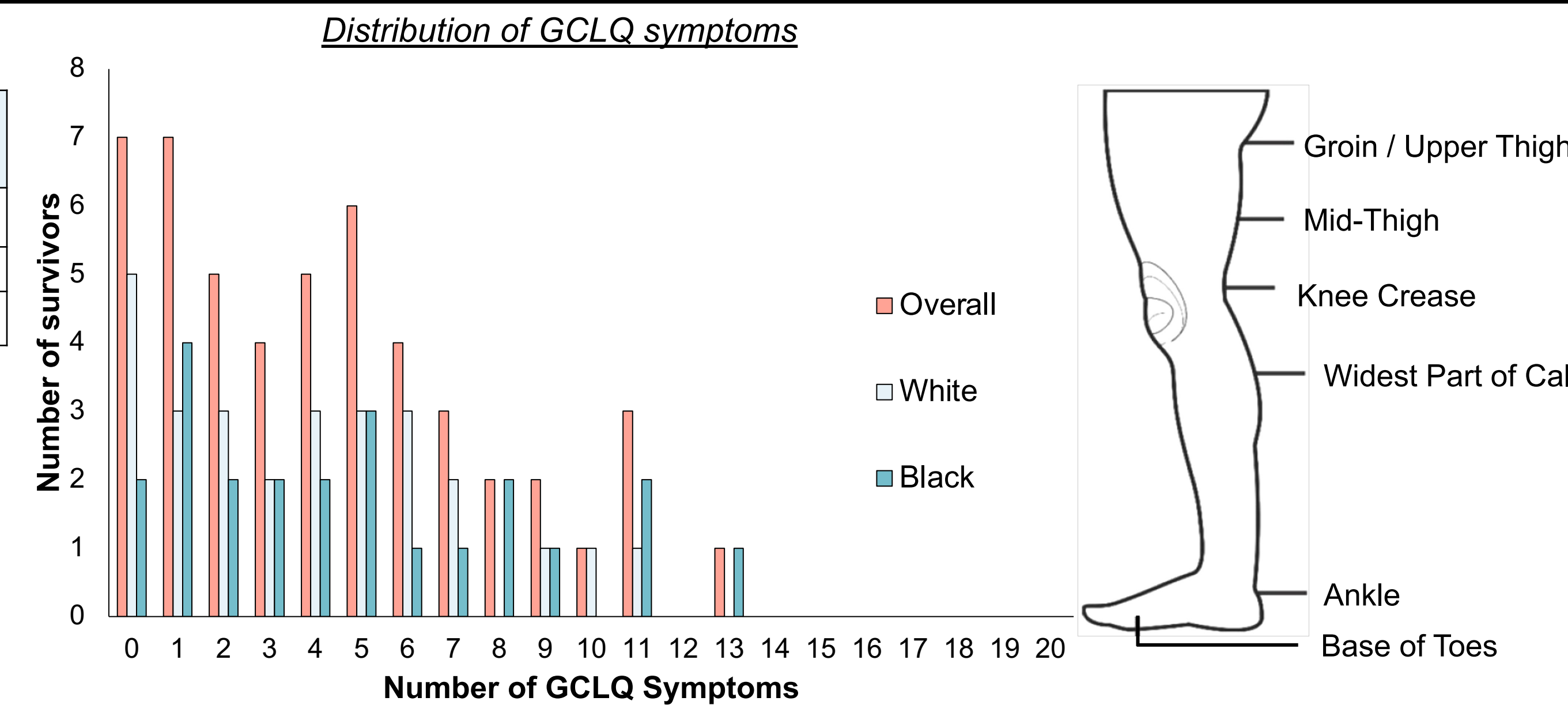
Lower Extremity Lymphedema (LEL)

Self- versus nurse-measured lymphedema

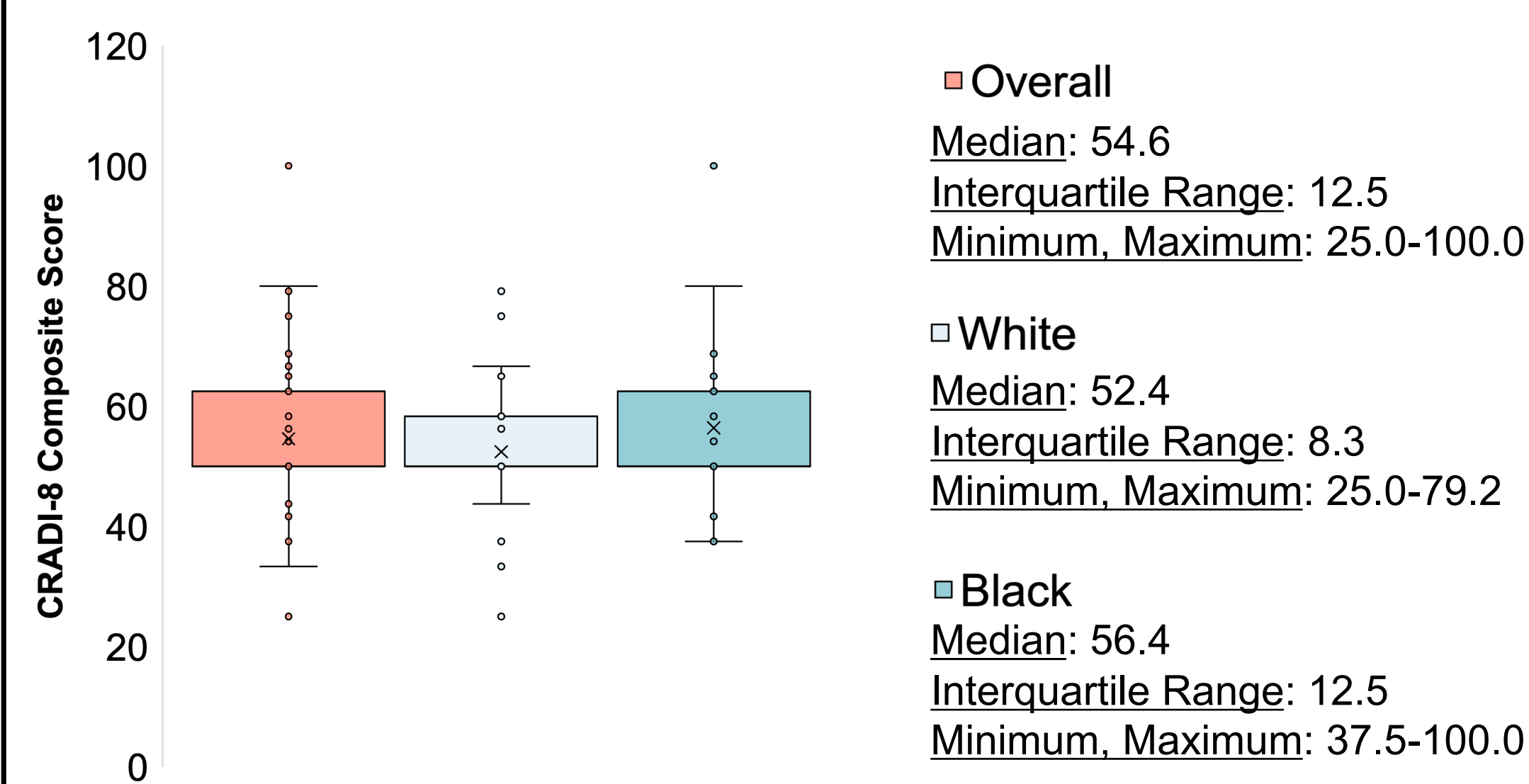
	Nurse-Measured No LEL	Nurse-Measured LEL	Total
No Self-Measured LEL	12	2	14
Self-Measured LEL	1	2	3
Total	13	4	17

- Only 17 survivors provided self measurements of leg circumference
- Based on nurse lower extremity measurements (n=50), 12 (24%) of women had lymphedema

- GCLQ score range: 0 to 20 symptoms
- Based on GCLQ responses, 27 (54%) survivors had lymphedema (≥ 4 symptoms)



Bowel Function



*Note. A lower score on the symptom scale represents less bowel and bladder distress within the past three months.

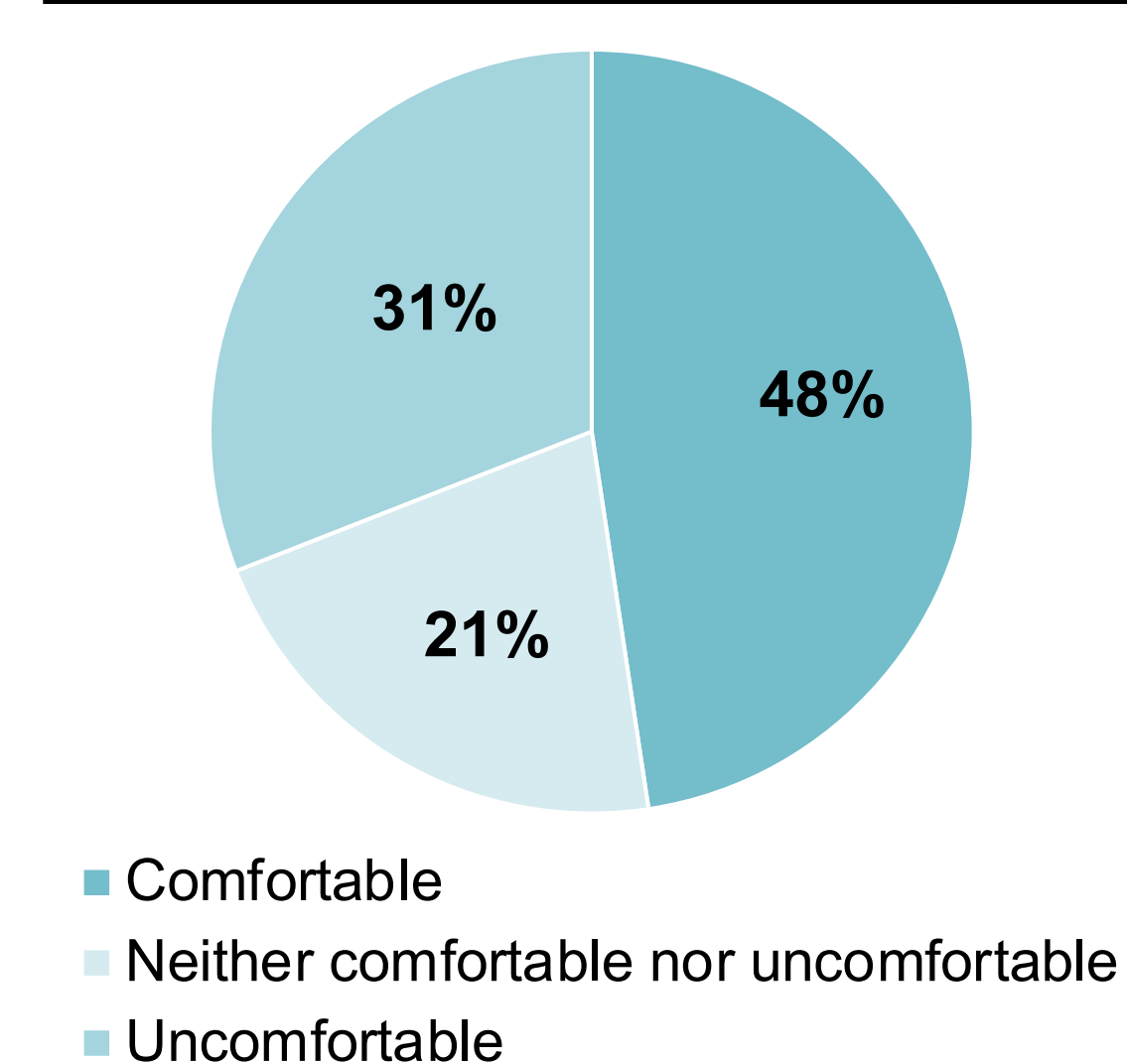
Sexual Function

All survivors (n=50)			
	Range	N	Mean (SD)*
Intimacy scale (IN)	2-8	49	5.1 (1.9)
Global sexual satisfaction scale (GS)	2-9	49	6.4 (1.7)
Sexual interest scale (SI)	1-4	50	2.1 (1.1)
Changes in intimacy and sexual interest	3-9	50	5.8 (1.3)
Sexually active survivors (n=17)			
	Range	N	Mean (SD)*
Intimacy Scale (IN)	5-8	16	7.0 (1.2)
Global sexual satisfaction scale (GS)	5-9	17	7.2 (1.1)
Sexual interest scale (SI)	2-4	17	3.1 (0.9)
Changes in intimacy and sexual interest	3-9	17	6.1 (1.4)
Vaginal changes scale (VC)	4-10	7	7.9 (2.7)
Sexual functioning scale (SF)	4-12	15	8.8 (2.4)
Reduced vaginal dimension	1-4	16	3.8 (0.8)

*Note. A higher score on the symptom scale represents better sexual functioning within the past month

Microbiome Self-Collection Kits

Self-Collected Stool Samples (n=43)

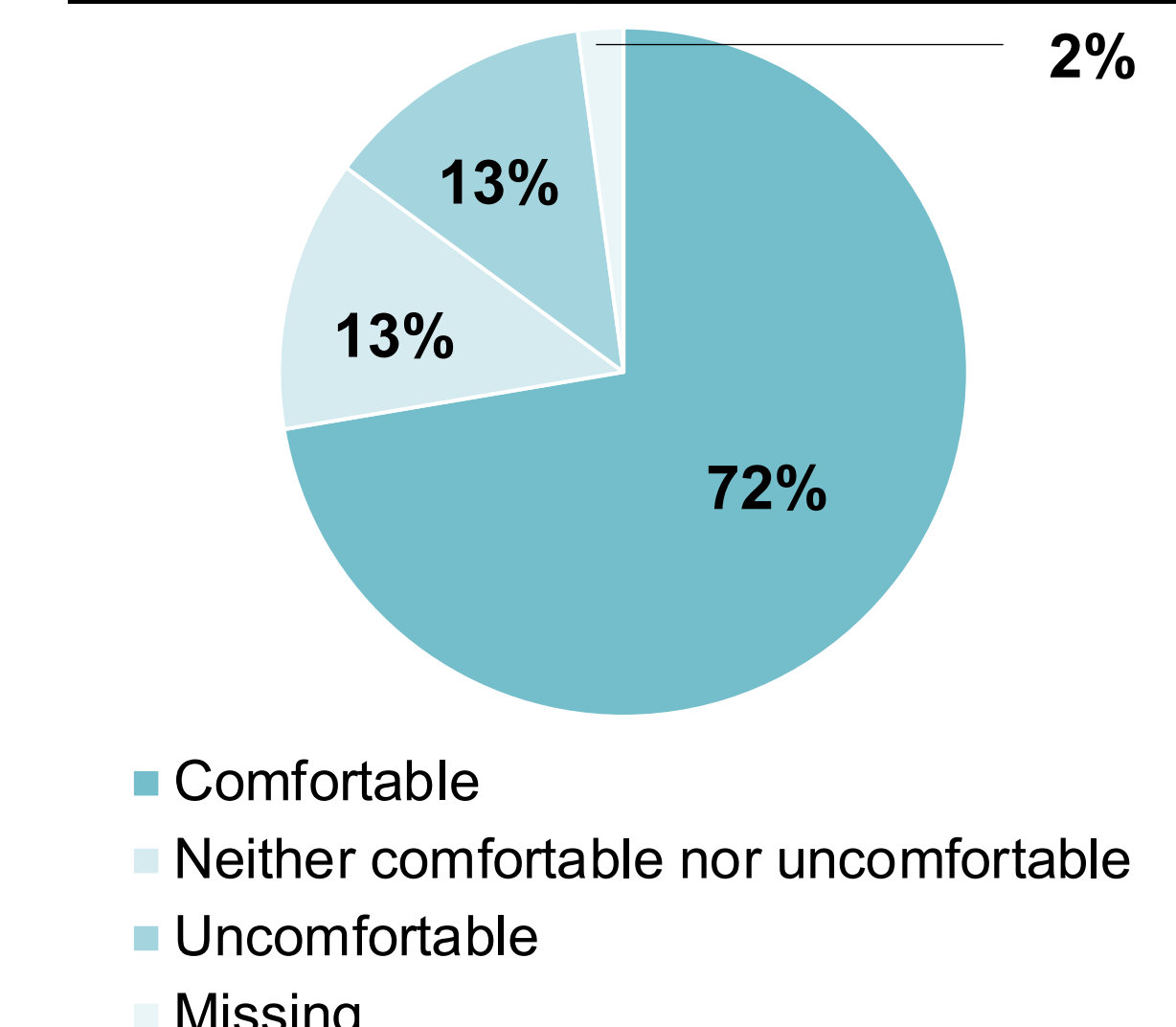


Improving Self-Collection Process

- Stool Sample**
- Perceived self-collection process as disgusting (N=4)
 - Found kit materials to be difficult/inconvenient (N=4)
 - Recommended more durable materials

- Vaginal Sample**
- Perceived self-collection process as difficult (N=3)
 - Required use of a hand mirror
 - Unsure about insertion distance in vaginal canal
 - Side effects (e.g., vaginal bleeding and cramping)

Self-Collected Vaginal Samples (n=47)



Home Visit Feedback

Lower Extremity Measurement Process

When asked about recording lower extremity measurements, 21 survivors noted:

- Difficulty with the measuring tape and wanted further instruction (N=5)
- Physical pain when completing measurements (N=9)
- Assistance was needed (N=1)
- Measuring process was frustrating (N=4)
- Too busy to complete (N=1)
- Neither frustrating or difficult (N=1)

Refusal Reasons for Self-Collection Kits

- Stool Sample**
- Refused: N=2 (disabled and not comfortable)
 - Replacement kit in transit: N=1
 - Anticipate submitting sample later: N=4

- Vaginal Sample**
- Refused: N=1 (disabled)
 - Replacement kit in transit: N=1
 - Anticipate submitting sample later: N=1

Discussion

- Low concordance** between self and nurse measurements suggest that it is **not a reliable indicator of lymphedema**
 - Survivors perceived leg measurement process as **difficult and frustrating**, partly due to comorbid ailments
- Bowel function is a **moderate concern** overall, but white survivors have better functioning compared to Black survivors
- Low sexual activity reported among survivors, but sexual function scores were **generally favorable**
- Slightly less than half of survivors were **comfortable providing microbiome samples**, though aspects of the collection process were unfavorably viewed

Strengths

- Novel home visit intervention targeting endometrial cancer survivors, with an emphasis on patient-reported measures
- Comparison of self-reported and gold standard nurse measurement available for lower extremity, height, and weight
- Ability to assess multiple contributors to quality of life among endometrial cancer survivors

Limitations

- Small sample size
- Limited geographic region for home visits
- Unable to assess quality of life or microbiome prior to diagnosis and treatment

Conclusions

Endometrial cancer survivors are able and willing to provide self-collected microbiome samples

Leg measurements appear infeasible for survivors and should be collected by a nurse if needed

Future efforts will continue to incorporate survivor feedback from preliminary pilot data to be implemented across the full cohort

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