Selecting the items to develop the Breast Utility Instrument to measure health related quality of life preferences in patients with breast cancer

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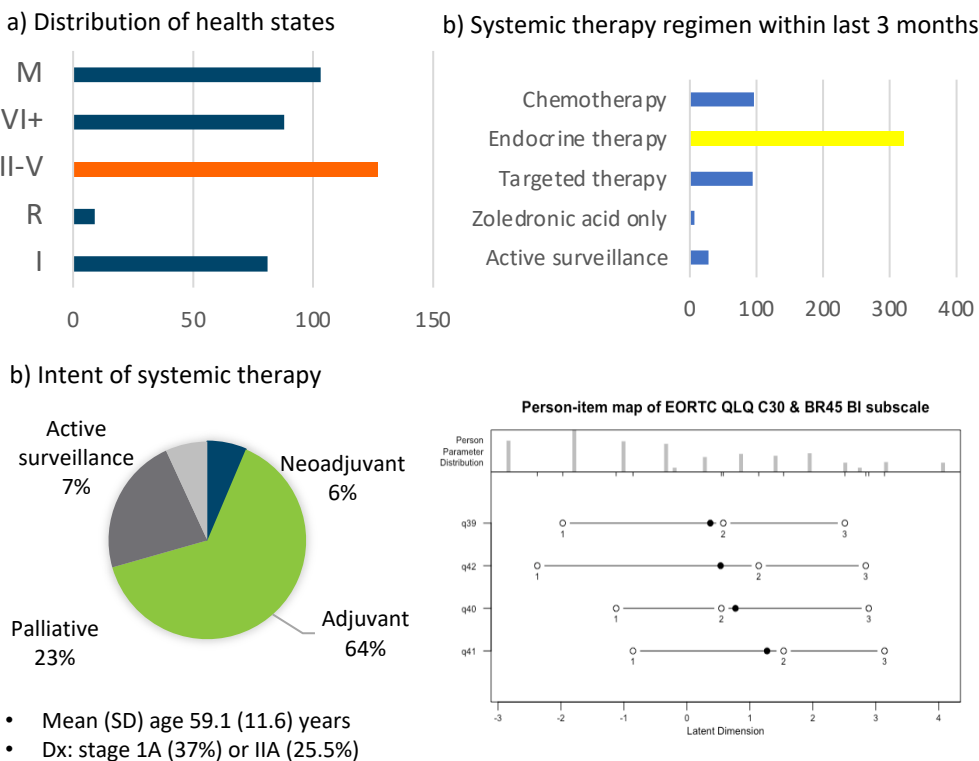
INTRODUCTION

- Breast cancer and its treatments impair patients' health related quality of life (HRQoL), which include the World Health Organization dimensions (physical, emotional, social), and breast-cancer specific dimensions.

- Generic preference-based instruments (e.g., EQ-5D) inadequately measure breast cancer HRQoL given the advances in therapy.

- The European Organisation for Research and Treatment of Cancer (EORTC) general cancer instrument (QLQ C30) and its breast module (BR45) is a psychometric instrument that measures breast cancer-specific HRQoL.

- Our overall objective is to develop the novel Breast Utility Instrument (BUI), a breast cancer-specific preference-based instrument derived from the EORTC QLQ-C30 and BR45.

- In this study, our objective is to select one item representing each of 10 dimensions previously established from a prior confirmatory factor analysis.

METHODS

- A cross section sample of 408 patients from diverse breast cancer health states completed the EORTC QLQ C30 and BR45 (breast module).

- Five mutually-exclusive health states (as per Lidgren et al):

- For each of 10 dimensions previously assessed with confirmatory factor analysis, we evaluated data fit to the Rasch Model based on global model and item fit, including threshold ordering, item residuals, infit and outfit, differential item functioning (age $\leq$ 50 years), and unidimensionality.

- Misfitting-items were removed iteratively and model fit was re-assessed.

- From items fitting the Rasch model, we selected one item per dimension based on high patient-rated (n = 81) and clinician-rated (n = 13) item importance, range of item thresholds, and clinical relevance.

RESULTS

Figure 1: Patient characteristics

a) Distribution of health states

b) Systemic therapy regimen within last 3 months

b) Intent of systemic therapy

Person-item map of EORTC QLQ C30 & BR45 BI subscale

- Mean (SD) age 59.1 (11.6) years
- Dx: stage 1A (37%) or IIA (25.5%)

Table 1: Summary of final fit of the data to the Rasch model

Dimension	# items	χ^2	p-value	Bonferroni-corrected p-value	PSI
Physical and role functioning (no RF7)	7	7804	0.29	0.007	0.776
Emotional functioning (no ET55)	4	1727	0.01	0.013	0.736
Social functioning	2	216	0.01a	0.025	0.603b
Fatigue	3	324	0.02	0.017	0.526b
Pain	2	108	0.01a	0.025	0.551b
Body image	4	657	0.01	0.013	0.767
Sexual functioning and enjoyment	3	445	0.01a	0.017	0.543b
Systemic therapy side effects (no SYS32, SYS34, SYS36, SYS38)	6	1097	0.01	0.008	0.392b
Arm and breast symptoms	7	22873	0.06	0.007	0.631b
Endocrine therapy (no ET54, ET68, ET69)	6	1194	0.05	0.008	0.784

Table 2: Summary of Body Image dimension, item importance, psychometric and Rasch criteria from final models to select the final item

Item number and topic	Patients - rank imp^	Clinicians – rank imp^	% missing data	Correlation of item to dimension	Range of item thresholds	Infit MSQ	Outfit MSQ	Other
BI39: Physically less attractive	3	1	0.49	0.819	4.482	0.874	0.892	
BI40: Less feminine	2	4	0.49	0.859	4.013	0.691	0.662	DIF
BI41: Problems looking at yourself naked	1*	2	0	0.850	3.996	0.774	0.773	ceiling
BI42: Dissatisfied with your body	1*	3	0.25	0.842	5.218	0.817	0.840	

a. Global model fit was borderline in three dimensions. b. PSI < 0.70 in six dimensions.
^ Patient and clinician importance ranking based on mean item importance (1 = highest ranked). *Tie ranking

Table 3: Breast Utility Instrument items selected from the EORTC QLQ C30 and BR45 dimensions using *a priori* criteria.

QLQ C30	QLQ BR45
Physical and role functioning PF2. Do you have any trouble taking a <u>long</u> walk?	**Body image** During the past week: BI42. Have you been dissatisfied with your body?
Emotional functioning During the past week: EF22. Did you worry?	**Systemic therapy side effects** During the past week: SYS34. Have you lost any hair?
Social functioning During the past week: SF27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	**Sexual functioning and enjoyment** During the past week: SX44. Have you been interested in sex?
Pain During the past week: PA9. Have you had pain?	**Breast and arm symptoms** During the past week: BR52. Has the area of your affected breast been oversensitive?
Fatigue During the past week: FA18. Were you tired?	**Endocrine therapy symptoms** During the past week: ET63. Have you had problems with your joints?

DISCUSSION & CONCLUSION

- This study identified one representative item per dimension for the future Breast Utility Instrument (BUI).
- Items were chosen based on *a priori* psychometric criteria, and investigator judgment.
- The future BUI will be amenable to valuation by eliciting direct utility weights (e.g., time trade off).
- The BUI will allow future cost-utility analyses to capture the important dimensions of breast cancer HRQoL, impacting clinical and policy decisions.

ACKNOWLEDGEMENTS