RWD12

Patient-reported symptoms and quality of life: A real-world survey of patients with muscle invasive bladder cancer

Bedke J[1], Eccleston A[2], Brinkmann J[3], Koshy A[4], Chang J[4], Milloy N[5], Manuel L[5], Skilling J[5], Biondi E[5], Brown E[5], Ford C[5], Lotan Y[6]

[1]Department of Urology and Transplantation Surgery, Eva Mayr-Stihl Cancer Center, Klinikum Stuttgart, Stuttgart, Germany. [2]Pfizer Inc, Surrey, GB. [3]Pfizer Inc, Berlin, Germany. [4]Pfizer Inc, New York, NY, USA. [5]Adelphi Real World, Bollington, UK. [6]Department of Urology, University of Texas Southwestern Medical Center, Dallas, TX, USA.

Objective

This study sought to understand patients' perspectives on health-related quality of life (HRQoL) using patient-reported outcome measures (PROMs) in patients with muscle invasive bladder cancer (MIBC) who received radical cystectomy (RC) compared to those who refused/were ineligible for RC.

Conclusions

- MIBC significantly impacts HRQoL.
- There is a high burden among patients who did not receive a RC, however, very few patients in this analysis received curative bladder-sparing approaches such as tri-modal therapy.
- Many patients refuse RC due to their desire to preserve their bladder, highlighting the need for bladder-sparing therapies that improve HRQoL without compromising outcomes.
- Further research into the characteristics associated with HRQoL in MIBC is needed.

Presenting author: Abin Koshy, PharmD

Email Anthony.Eccleston@pfizer.com for more information

Scan this quick response (QR) to download this poster.

Background

- MIBC encompasses tumour, node, metastasis stages T2-T4a, and accounts for around 25% of all newly diagnosed bladder cancer cases[1].
- According to guidelines, radical cystectomy is part of the current standard of care; however, this carries HRQoL implications[2-4].
- Validated PROMs can give valuable insights into a patient's experience of MIBC beyond clinical outcomes.
- There is limited real-world data assessing symptoms, functioning and HRQoL using PROMs in MIBC patients who had RC and those who didn't undergo RC.

Limitations

- Participating patients may not reflect the general MIBC patient population as the DSP solely includes patients who are consulting with their physician.
- Patients were recruited to the DSP according to a set ratio of those who received RC to those who refused or were ineligible for RC; hence, the DSP population may not reflect the wider MIBC population.
- Data was collected at a single point in time, meaning patients could be at different stages within their MIBC treatment journey at the time PROMs were captured.
- Recall bias is a common limitation of surveys; however, physicians did have the ability to refer to patients' medical records while completing the survey.

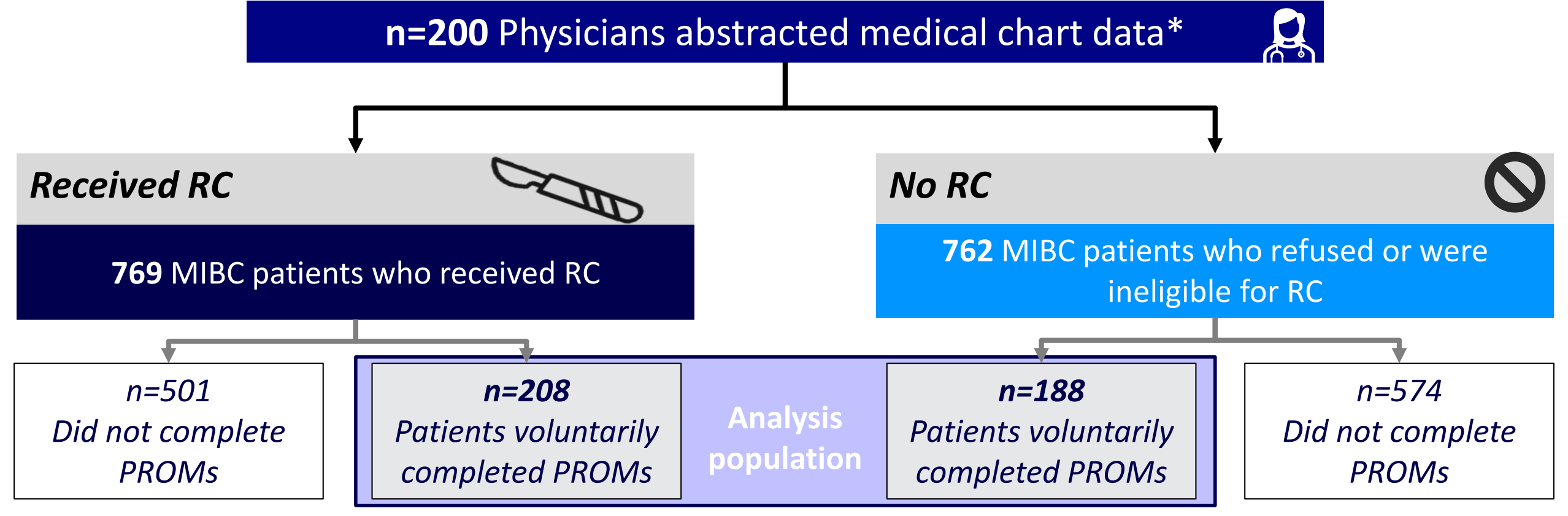
Methods

- Data were drawn from the Adelphi Real World MIBC Disease Specific Programme™, a cross-sectional survey, with retrospective data collection of physicians and patients in France, Germany, Italy, Spain and the United Kingdom from December 2023 to May 2024. Patients voluntarily completed a patient self-completion form; however, no self-completion forms were obtained from patients in the United Kingdom.
- The methodology has been previously described, validated and proven to be consistent over time[5-8].
- PROMs included the EQ-5D-5L (scored using the German Tariff), which ranges from 0 [A health state equivalent to death] to 1 [Perfect health], and the EQ-Visual Analogue Scale (VAS), which asks patients to rank their health 'today' on a scale from 0 – the worst health they can imagine, to 100 – the best health they can imagine. The EORTC QLQ-C30 and accompanying MIBC module (EORTC QLQ-BLM30) were also used, where scores range from 0–100, with higher scores indicating higher functioning while for symptomology greater symptom severity.
- EQ-5D index scores for the DSP sample were compared against age-adjusted population norms[9-12]
- Physician inclusion criteria ensured that recruited physicians were personally responsible for treatment decisions for patients with MIBC and were managing a minimum of six MIBC patients per month.
- Patients with a diagnosis of MIBC at the time of data collection, who either received RC or the decision not to receive RC, within 1 year of their MIBC diagnosis were included.
- An ethical exemption for this research was obtained from Pearl Institutional Review Board.

Results

- Physicians reported medical chart data for a total of 396 patients with MIBC. These same patients self-reported data including PROMs on a voluntary basis. (Figure 1).

Figure 1. Patient analysis population



n=200 Physicians abstracted medical chart data*

Received RC

769 MIBC patients who received RC

n=501
Did not complete PROMs

n=208
Patients voluntarily completed PROMs

Analysis population

n=188
Patients voluntarily completed PROMs

No RC

762 MIBC patients who refused or were ineligible for RC

n=574
Did not complete PROMs

**Physicians were asked to abstract data for a maximum of n=4 eligible patients who received a RC, and a maximum of n=4 who refused or were ineligible for RC*

- The most common reasons patients did not complete a self-completion form amongst the n=881 patients with a known reason for not providing self-reported data were 'The patient did not want to complete the form' (59%), 'I (the treating physician) chose not to give the patient a form to complete' (25%), and 'I (the treating physician) was not able to give the patient a form to complete' (14%).
- Amongst the patients with self-reported data who did not receive a RC (n=188), 104 (55%) refused RC and 80 (43%) were considered ineligible for RC. A further 4 (2%) patients did not receive RC due to unknown reasons.
- Amongst the patients who refused RC (n=104), the most common reasons for refusal were 'Patient had concerns over quality of life following cystectomy' (72%), 'Patient did not want to live with a stoma' (56%), and 'Patient had concerns over risks when receiving surgery' (46%).
- Where patients were considered ineligible for RC (n=80), the most common reasons for this were 'Patient's comorbidities prevented them from receiving cystectomy' (44%), 'Patient's performance status was too low to receive cystectomy' (21%), and 'Patient's cardiac status prevented them from receiving cystectomy' (16%).

Table 1. Patient demographic and clinical characteristics

	Group A *Received RC* **n=208**	**Group B** *Refused/ Ineligible for RC* **n=188**
Country, n (%)		
France	36 (17)	31 (16)
Germany	78 (38)	77 (41)
Italy	24 (12)	19 (9)
Spain	70 (34)	63 (34)
United Kingdom	0 (0)	0 (0)
Patient Sex, n (%)		
Male	163 (78)	142 (76)
Female	45 (22)	46 (24)
Patient age		
Mean (SD)	69.0 (6.9)	72.7 (9.1)
Patient employment status, n (%)		
Not working due to retirement	163 (78)	152 (81)
Working full/ part time	14 (7)	6 (3)
Other[a]	31 (15)	30 (16)
Patient smoking status, n (%)		
Current smoker	46 (22)	38 (20)
Ex-smoker	134 (64)	120 (64)
Never smoked	25 (12)	26 (14)
Unknown	3 (1)	4 (2)
Staging at data collection, n (%)		
T0, N0	65 (31)	28(15)
T2, N0	42 (20)	49 (26)
T3, N0	16 (8)	13 (7)
T4a, N0	1 (1)	1 (1)
Any T, N+	22 (11)	43 (23)
Other[b]	34 (16)	22 (12)
Not assessed	28 (13)	32 (17)

a) Unemployed, on long-term sick leave, homemaker, unknown
b) Includes patients that were TX or NX

Patient characteristics

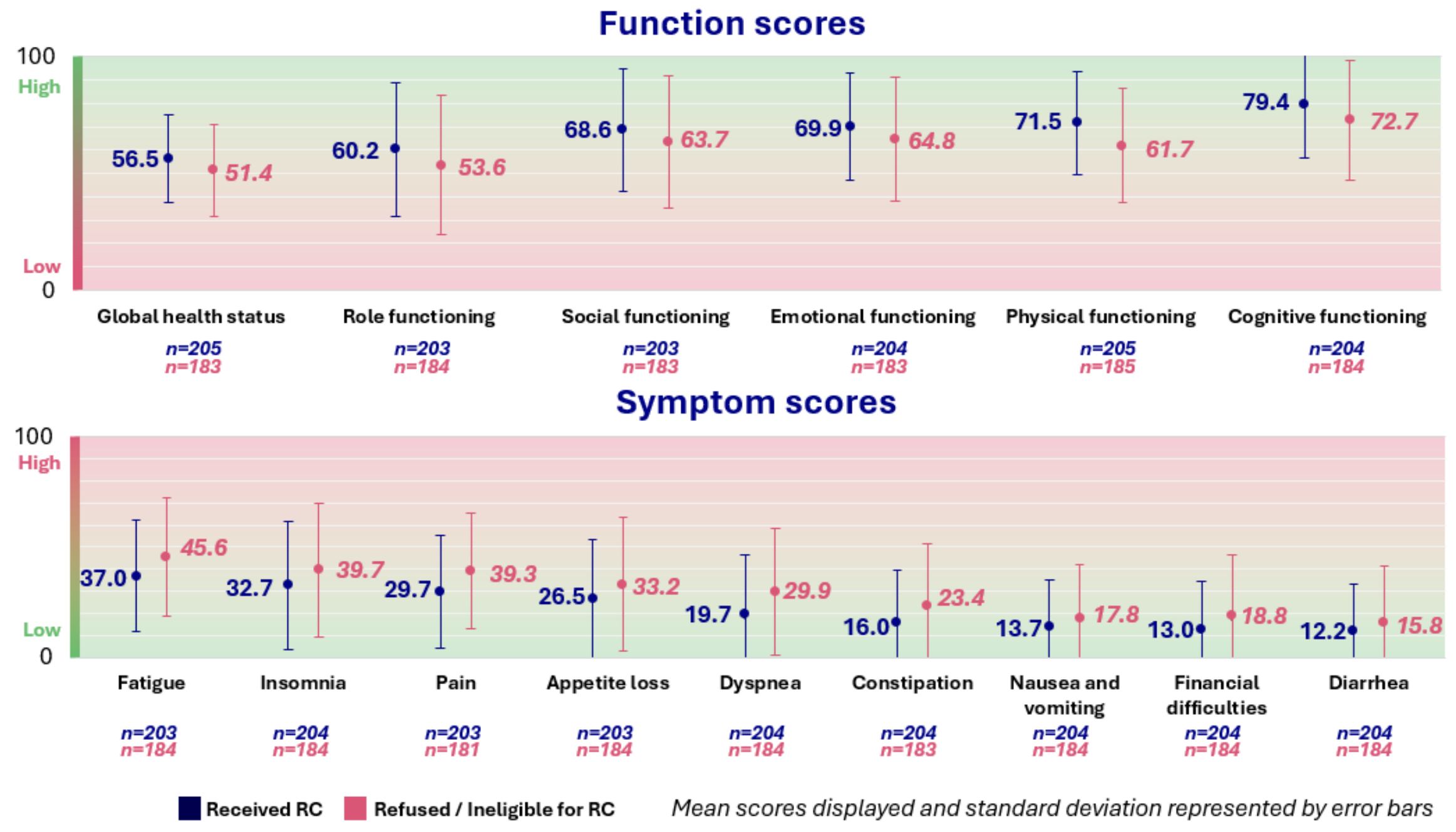
- At the time of data collection, the mean (standard deviation [SD]) age of patients was 70.8 (8.2).
  - Twenty-three percent of patients were staged T0, N0 with this differing between 31% of patients in the received RC group and only 15% of patients in the no RC group.
  - The mean (SD) Charlson Comorbidity Index of patients was 2.6 (0.9) for patients who received RC (n=208); 2.9 (1.2) amongst patients that refused RC (n=104); and 4.6 (4.0) amongst patients considered ineligible for RC (n=80).
- The mean (SD) time since radical cystectomy (where known) was 174.7 (151.7) days.
  - The majority of patients (89%) were within 1 year of receiving their radical cystectomy at the time of data collection.
- The mean (SD) time between MIBC diagnosis and data collection was 268.4 (161.4) days for patients in the received RC group, and 199.1 (144.9) days for patients in the no RC group.
- Bladder sparing therapy was being received at the time of data collection by n=55 (29%) of the n=188 patients that did not receive radical cystectomy.
  - Amongst these n=55 patients, 3 (5%) were receiving radiotherapy alone at data collection, n=21 (38%) received chemotherapy alone, and n=19 (35%) received chemoradiotherapy.

Patient Reported Outcome Measures:

EORTC QLQ-C30

- Patients who did not receive RC displayed numerically lower functioning across every scale of the QLQ-C30, as well as higher mean symptomatology for every symptom domain.
- The Global Health Status domain was the lowest functioning out of all the functioning scores at 51.4 for those in the 'No RC' group and 56.5 for patients in the 'received RC' group.

Figure 2. EORTC QLQ-C30 scores

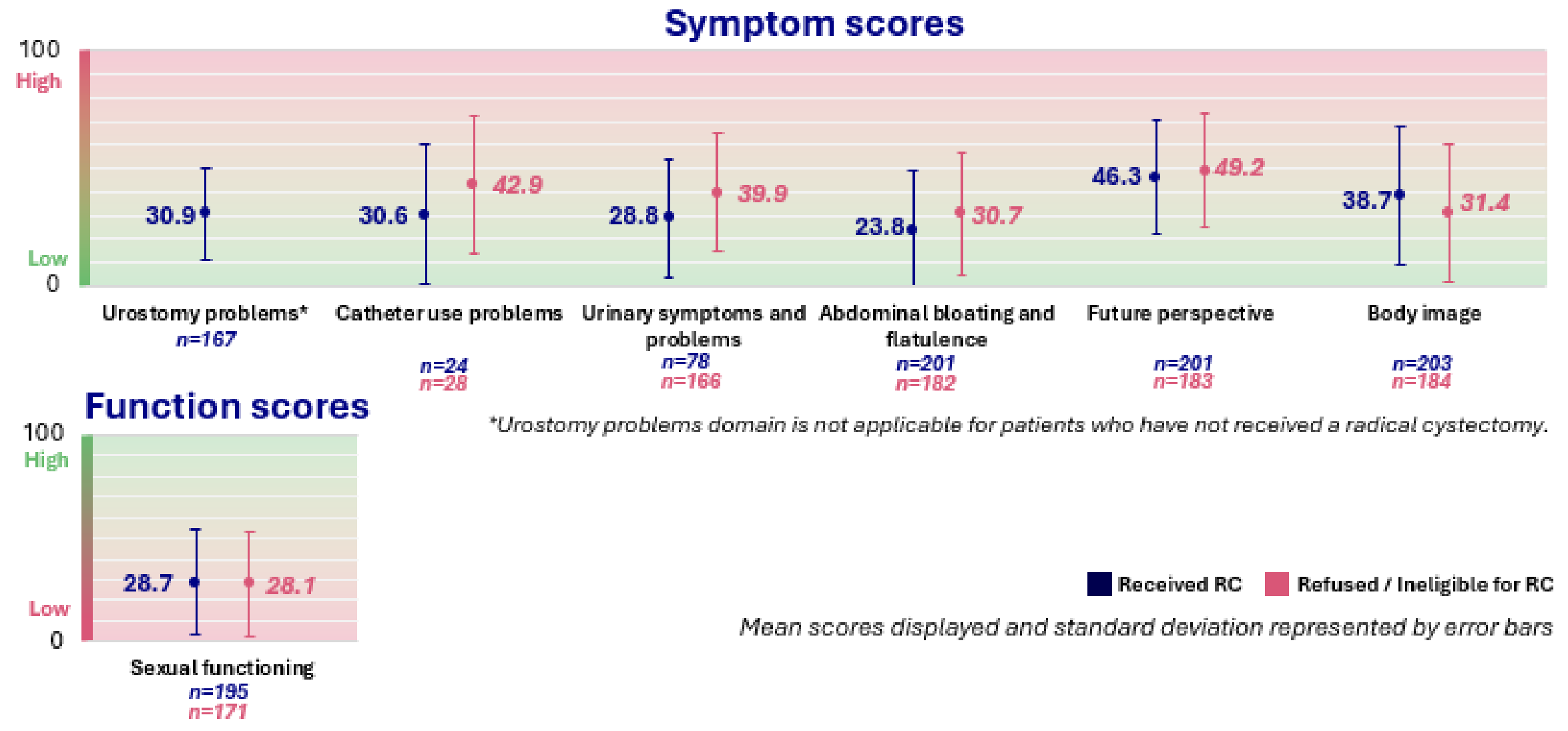


Mean scores displayed and standard deviation represented by error bars

EORTC QLQ-BLM30

- Patients who did not receive RC had higher levels of symptomatology for four domains that were applicable to both populations (Urinary symptoms and problems, Abdominal bloating and flatulence, Catheter use problems, and Future perspective).
- Patients who did not receive RC however, had a lower mean level of body image issues compared to patients that received RC (31.4 vs. 38.7)
- Across both groups, the levels of sexual functioning were low.

Figure 3. EORTC QLQ-BLM30 scores



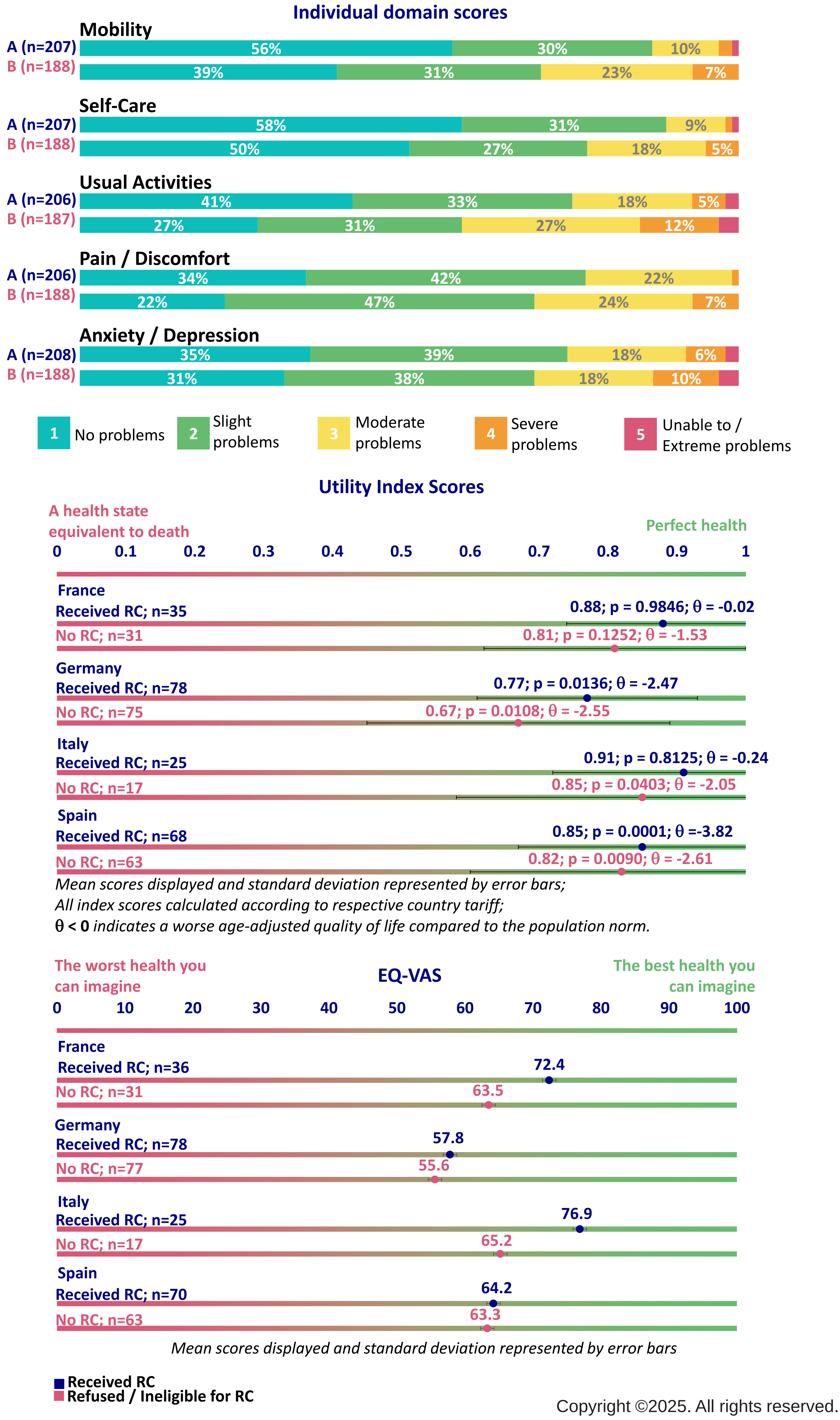
**Urostomy problems domain is not applicable for patients who have not received a radical cystectomy.*

Mean scores displayed and standard deviation represented by error bars

EQ-5D-5L

- Amongst patients in the received RC group only 6% reported that they had severe or extreme problems when it came to performing their usual activities, compared to 15% of those in the no RC group.
- Across all 5 individual domains of the EQ-5D-5L, a numerically lower proportion in the received RC group than in the no RC group reported severe or extreme problems.
- The mean utility index score for the EQ-5D was numerically higher for patients who received a RC across all markets.

Figure 4. EQ-5D individual domains, utility index, and EQ-VAS score.



Mean scores displayed and standard deviation represented by error bars;
All index scores calculated according to respective country tariff;
θ < 0 *indicates a worse age-adjusted quality of life compared to the population norm.*

Mean scores displayed and standard deviation represented by error bars

References

1. Holzbeierlein, J. et al., Journal of Urology (2024). 212(1), pp. 3–10.
2. EAU Guidelines. Edn. presented at the EAU Annual Congress Paris 2024. ISBN 978-94-92671-23-3.
3. T. Powles et al., on behalf of the ESMO Guidelines Committee, Ann Oncol. 2021
4. Maibom SL, et al., BMJ Open 2021;11:e043266.
5. Anderson et al. CMRO. 2008;24(11). 30363-72.
6. Anderson et al. CMRO. 2023;39(12). 1707-1715.
7. Babineaux et al. BMJ Open. 2016;6(8).
8. Higgins et al. Diabetes Metab. Syndr. Obes. 2016;(9) 371-38
9. Gaultier L et al. Eur J Health Econ. 2023;24(1): 1517-1530
10. Grochtdreis T et al. Eur J Health Econ. 2019. 20(6): 933-944
11. Hernandez G et al. Qual Life Res. 2018;27(9): 2337-2348
12. Meregaglia M et al. Appl Health Econ Health Policy. 2023;21(1):289-303

Presented at ISPOR • May 13th 2025