RWD152

Real-world health-related quality of life and treatment satisfaction in patients with high-risk non-muscle invasive bladder cancer

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Objective

This real-world study uses patient reported outcome measures (PROMs) at a single point in time, to understand high-risk non-muscle invasive bladder cancer (HR-NMIBC) patients' health-related quality of life (HRQoL) and treatment satisfaction.

Conclusions

Patients receiving intravesical treatment reported being mostly satisfied with overall treatment and its form of administration.

PRO results, however, demonstrate that HR-NMIBC continues to negatively impact QoL; highlighting the need for novel treatments, which reduce burden of administration and improve patients' QoL.

In general, EORTC function scores for the HR-NMIBC patient sample were lower than the EORTC reference sample of stage I/II cancers.

This highlights the necessity for continued research into the HRQoL challenges specific to HR-NMIBC.

Eligibility criteria

The physician eligibility criteria ensured that all physicians recruited are actively involved with HR-NMIBC patients who fit the criteria of this DSP™ and that the number of patients managed is adequate to complete the study in the necessary time frame.

Physician eligibility criteria

- Specialty in urology or medical oncology
- At least 50% of time spent in management of patients
- Saw a minimum of five NMIBC patients a month and have responsibility for prescribing decisions for HR-NMIBC

Patient eligibility criteria

- Must be over the age of 18 at diagnosis
- Diagnosed with HR-NMIBC at least 1 year before time of data collection, where HR is defined as being inclusive of any of the following:
- High grade urothelial carcinoma:
  - *Carcinoma in situ (CIS)*
  - *T1*
  - *Or Ta tumours greater than 3cm in diameter or multifocal*

To be included in the analysis sample:

- Must have completed a patient self-completion form

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Background

- Non-muscle invasive bladder cancer (NMIBC) accounts for around 75% of all bladder cancer cases[1].
- High-risk (HR) NMIBC is defined by the AUA as any of the following:
  - Any T1 high grade tumours;
  - Any carcinoma in situ (CIS);
  - Any high grade Ta tumours that are multifocal or large (>3cm)[2].
- Measuring symptoms, function and HRQoL of patients with HR-NMIBC and their treatment satisfaction using PROMs can inform unmet needs with current standard of care.
- There is limited availability of data assessing patients' experience of HR-NMIBC using validated measures.

Methods

Data were drawn from the Adelphi Real World HR-NMIBC Disease Specific Programme™, a cross-sectional survey, with retrospective data collection of physicians and patients in the United States, Canada, France, Germany, Italy, Spain, the United Kingdom, and Japan from June to December 2023.

The methodology has been previously described[4,5], validated[6], and demonstrated to be representative and consistent over time[7].

Physicians provided demographic, clinical, and treatment data for 6-8 consecutively consulted patients with a diagnosis of HR-NMIBC at the time of data collection.

These same patients voluntarily self-completed validated PROM surveys including the EQ-5D 5L, EORTC QLC-C30 and EORTC QLQ-NMIBC24.

Differences of ≥10 points were considered to represent a clinically meaningful difference for the EORTC QLQ-C30, as defined in previous literature[8].

EQ-5D utility index scores were compared to their respective country population norms, where available[9-14] using the restricted maximum likelihood method to adjust for age category.

EORTC QLQ-C30 scores for the DSP population were compared to a previously published set of reference values for "all cancers–stages I/ II [early-stage cancers]"[3] using a T-test.

P-values <0.005 were considered statistically significant.

Ethics

An ethical exemption for this research was obtained from Pearl Institutional Review Board.

Limitations

Participating patients may not reflect the general HR-NMIBC patient population as the DSP only includes patients who are consulting with their physician.

Recall bias is a common limitation of surveys; however, physicians did have the ability to refer to patients' medical records while completing the survey.

Results

- Physicians reported medical chart data for 565 patients with HR-NMIBC. These same 565 patients self-reported data, including completing validated PROMs**.** At the time of data collection, the mean (standard deviation [SD]) time since patient's NMIBC diagnosis was 800.4 (584.87) days.
  - Seventy-two percent of patients were high risk at their initial NMIBC diagnosis.
  - The mean (SD) days since last known treatment received for NMIBC was 289 (466)

Patient demographics

- The mean (SD) age of patients in the analysis population was 69.5 (8.64) years, 79% were male, 20% were current smokers, and 58% were ex-smokers.

Table 1. ***Patient demographic and clinical characteristics***

	All HR-NMIBC patients n=565
Region, n (%)	**n=565**
North America	34 (6)
Europe	488 (86)
Japan	43 (8)
Patient Sex	**n=565**
Male	446 (79)
Female	119 (21)
Patient age	**n=565**
Mean (SD)	69.5 (8.64)
Patient ethnicity [a], n (%)	**n=443**
White	425 (96)
Black	5 (1)
Other [b]	13 (3)
Patient smoking status, n (%)	**n=565**
Current smoker	111 (20)
Ex-smoker	329 (58)
Never smoked	101 (18)
Unknown	24 (4)

a) Ethnicity was not asked in France or Japan.
b) East or Southeast Asian, South Asian (Indian subcontinent), Middle Eastern or North African, 'other' or mixed ethnic backgrounds.
c) Unemployed or on long-term sick leave

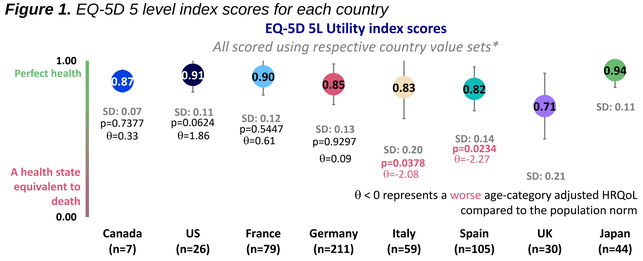
Patient Reported Outcome Measures:

- The PROMs used included the EQ-5D-5L, EORTC QLQ-C30 and NMIBC24 module (EORTC QLQ-NMIBC24).
  - EORTC Scores range from 0–100.
  - For functional or status scores, higher scores indicate a greater HRQoL, whilst for symptoms a higher score indicates a lower HRQoL.

EQ-5D

- The EQ-5D index scores varied slightly between countries, with the UK mean index score numerically lowest at 0.71, and Japan numerically highest at 0.94 (**Figure 1**).
  - When compared to the population norms, and adjusting for age categories, Italy and Spain were found to have a statistically significantly lower index scores.

Figure 1. *EQ-5D 5 level index scores for each country*



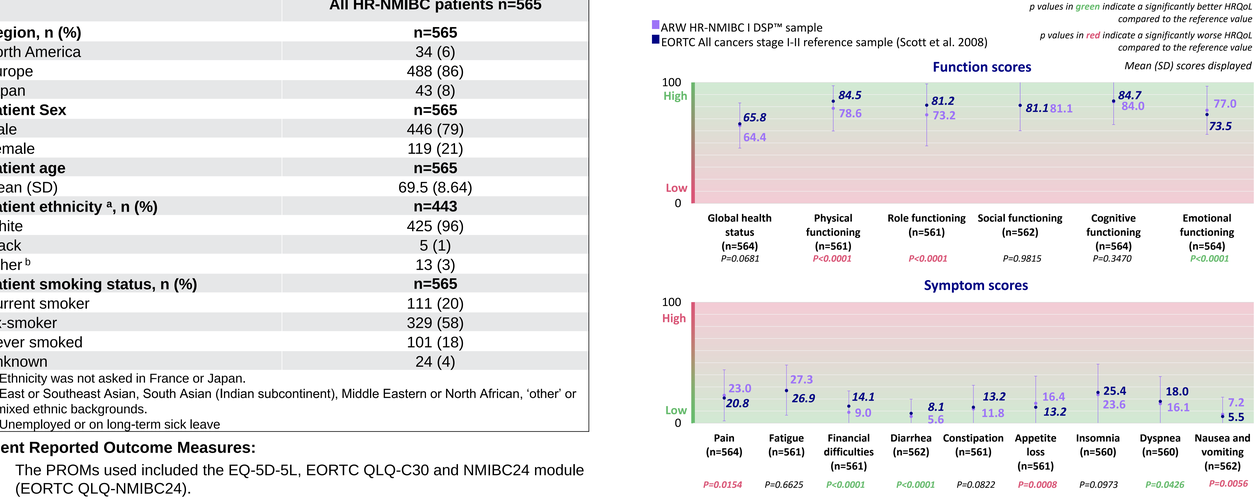
Mean scores displayed; and respective standard deviations are represented by error bars
**UK scored using the crosswalk from EQ-5D 3L country value set*

EQ-5D-5L population norm not available in the UK or Japan

EORTC QLQ-C30

- The mean (SD) EORTC QLQ-C30 global health score was 64.4 (18.69).
- Physical functioning was 78.6 (18.73) and role functioning was 73.2 (20.05); scores were significantly worse (both <0.0001) than all cancers-stage I/II (**Figure 2**).
- Other statistically significant differences observed between the reference sample of stage I/II cancers and the HR-NMIBC DSP sample were as follows:
  - Pain, Appetite loss, and Nausea and vomiting were all significantly worse (higher levels of symptoms) than the reference sample.
  - Emotional functioning, Dyspnoea, Diarrhoea, Financial issues were all significantly better (higher HRQoL) than the reference sample.
- Despite observing a statistically significant difference in HRQoL for certain QLQ-C30 domains between the mean DSP and reference sample scores, none of these met the minimum clinically important difference threshold of 10 points (8).

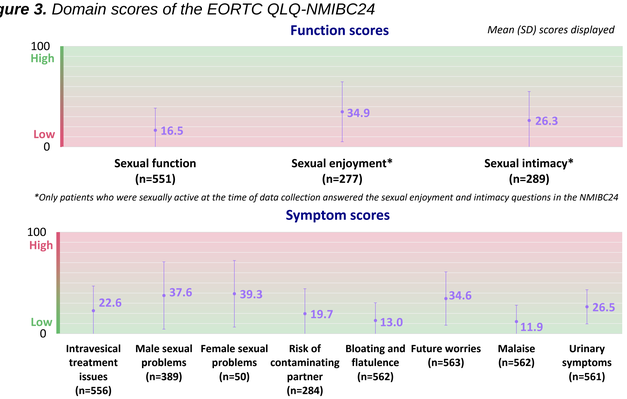
Figure 2. *Domain scores of the EORTC QLQ-C30*



EORTC QLQ-NMIBC24

- The lowest mean functional score from the NMIBC24 domains was sexual function with a mean (SD) of 16.5 (22.03) (**Figure 3**).
- The two numerically highest mean symptom scores across both the NMIBC24 were: Male Sexual Problems (37.6) and Female Sexual Problems (39.3) (**Figure 3**).

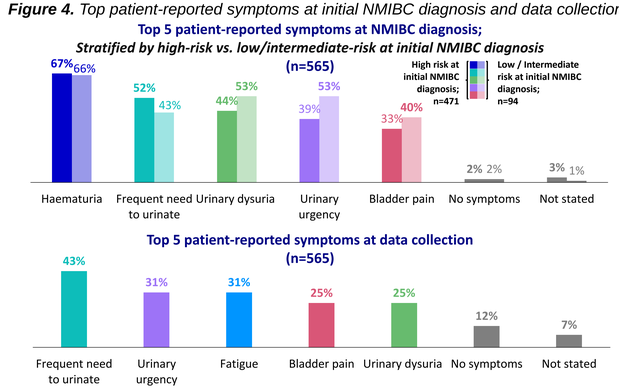
Figure 3. *Domain scores of the EORTC QLQ-NMIBC24*



Symptoms

- When asked to report the symptoms experienced at their initial NMIBC diagnosis, the most commonly reported symptoms by patients with de novo HR-NMIBC were hematuria (67%), frequent need to urinate (52%) and urinary dysuria (44%).
  - When asked what symptoms they were experiencing at data collection the most common patient-reported symptoms were urinary frequency (43%), urinary urgency (31%) and fatigue (31%) (**Figure 4**).

Figure 4. *Top patient-reported symptoms at initial NMIBC diagnosis and data collection*



Treatment

- Intravesical treatment was received within 30 days before data collection by 158 patients. 144 (91%) received intravesical BCG, and 14 (9%) received intravesical chemotherapy.
  - When asked 'Over the past 4 weeks, how satisfied were you overall with the treatment you received?', 79% of the 158 patients selected satisfied or very satisfied.
  - When asked about satisfaction with the form of treatment administration, 75% of the 158 patients were satisfied or very satisfied.
- The time needed to complete administrations, however, was perceived as very or extremely burdensome by 25% of these 158 patients (**Figure 5**).

Figure 5. *Treatment satisfaction amongst patients who received intravesical therapy within 30 days prior to data collection .*