OBJECTIVE

To understand disease symptoms experienced by patients with high-risk non–muscle invasive bladder cancer (NMIBC), selected treatment patterns, patients’ satisfaction with treatment, and patients’ concerns regarding future potential treatments.

METHODS

Patient Recruitment

Patients were recruited and screened by urology clinic staff in Denver, CO and San Antonio, TX. Patients with high-risk NMIBC (CIS, TaG3, T1G3, or recurrent Ta/T1 of grade 2-3) were eligible to participate based on the following inclusion and exclusion criteria:

- Aged 18 years or older
- Met criteria for one of the following NMIBC treatment groups:
  - Group 1: Bacillus Calmette–Guérin (BCG)-naive, treated with transurethral resection of bladder tumor (TURBT) + intravesical chemotherapy
  - Group 2: Had current or previous BCG treatment but were refractory or resistant to treatment
  - Group 3: Were BCG refractory or relapsing and next treatment option would be cystectomy (but were prior to cystectomy)
- Willing and able to provide informed consent
- Willing and able to participate in a 90-minute individual interview
- Had no physical condition, mental condition, or disorder that would interfere with the patient’s ability to effectively complete the interview

Qualitative Interviews

- Before beginning the patient interviews, informed consent was obtained from each participant.
- All interviews followed a semistructured interview guide, including in-depth and open-ended concept elicitation, and were audio-recorded.
- All study materials were reviewed and approved by RTI International’s institutional review board committee.
- Two experienced staff conducted all the patient interviews at the two local clinics where participants were recruited.

RESULTS

- A total of 10 adults with NMIBC participated in this study:
  - Round 1 (Denver, CO): n = 5
  - Round 2 (San Antonio, TX): n = 5
- Participants were demographically representative of the patient population that seeks treatment for NMIBC (Table 1).

Table 1. Demographic Characteristics For All Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Round 1 (n = 5)</th>
<th>Round 2 (n = 5)</th>
<th>All (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Age, years</td>
<td>71.8</td>
<td>74.4</td>
<td>73.1</td>
</tr>
<tr>
<td></td>
<td>68.60</td>
<td>68.89</td>
<td>68.69</td>
</tr>
<tr>
<td>NMIBC classification, n</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Group 2</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Group 3</td>
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<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Race/ethnicity, n</td>
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<td></td>
</tr>
<tr>
<td>White</td>
<td>5</td>
<td>5</td>
<td>10</td>
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<tr>
<td>Education, n</td>
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<tr>
<td>High school diploma or equivalent</td>
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<td>3</td>
</tr>
<tr>
<td>Some college</td>
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<td>3</td>
<td>4</td>
</tr>
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<td>College degree</td>
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<td>1</td>
</tr>
<tr>
<td>Professional or advanced degree</td>
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<td>1</td>
<td>2</td>
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<tr>
<td>Employment status</td>
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<td></td>
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</tr>
<tr>
<td>Full-time</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Retired</td>
<td>4</td>
<td>5</td>
<td>9 (90%)</td>
</tr>
</tbody>
</table>

Disease Symptoms

- Nearly all interview participants reported visible hematuria as the symptom which led to their diagnoses.
- Key disease symptoms spontaneously reported by participants that were not related to treatment included the following:
  - One participant reported an an-od-out burning sensation during urination.
  - Two participants reported either needing to urinate frequently, including at night (wakes up every 2 hours) or intermittent urgency to urinate at night (2-3 times per week and then has weeks where this symptom does not occur). One of these 2 participant thought this symptom could be a side effect of blood pressure medications.
  - Two females reported abdominal pain; one noticed pain only when doing strenuous activities prior to diagnosis.
  - One participant experienced flulike symptoms just prior to diagnosis.
- No participants reported needing a caregiver to assist them regularly due to their NMIBC symptoms; furthermore, 4 participants reported being able to drive themselves to their surgeries and back home afterwards.
- I don’t need any help. Thank God
- Do I need help? No.

Treatment or Procedure-Related Symptoms and Effect on Patient Satisfaction

- All participants had received one or more NMIBC drugs (i.e., BCG, mitomycin, valrubicin), a procedure (i.e., TURBT, cystectomy), or both.
- Key symptoms spontaneously reported that were attributed to a treatment or procedure included the following:
  - Six participants who had received BCG mentioned treatment-related symptoms (e.g., abdominal pain, painful urination, increased urgency to urinate and more frequent urination, passing blood clots, some blood in the urine, flulike symptoms, chills, burning sensation when urinating, fatigue, soreness at the catheter site). However, these symptoms went away within a few hours of treatment and were not reported by participants to affect overall treatment satisfaction.
  - During the treatments when I get the flu like symptoms, I just ache and I get the chills. And I can’t get rid of the chills and I feel like hell. But that was when I was passing, apparently passing little blood clots.
  - One participant reported issues with their catheters after TURBT surgery, but these symptoms abated after catheter removal.
  - It was just the initial shock when they put that thing in you. And the first time you go to the potty and urinate, that hurt. That hurt like hell. But that was when I was passing, apparently passing little blood clots.
  - One participant reported issues post-TURBT surgery with a stall placed in the bladder (e.g., painful, burning urination; pelvic discomfort).
  - Yeah, because one of the tumors was close to the I think, the tube coming from the kidney. So they put a stall in there just to make sure it stayed open. It’s just every time I urinated, I felt like I was getting stabbed in the side. But you know, it was just really a discomfort.
  - The most bothersome aspects of treatment reported by patients were pain related to BCG administration (n = 4), urgency/frequency (n = 4), the catheter related to BCG administration (n = 2), prepping for surgery/anxiety waiting for results (n = 2), having chills for a few hours after receiving BCG (n = 1), seeing blood in urine (n = 1), and burning/pain during and after urination (n = 1).
  - [On anxiety] Oh I've got to go do this, you know. Here we go again.
- All participants reported being generally grateful now that NMIBC was “the ideal cancer to have” and that the cancer was currently contained within the inner lining of their bladders. Participants reported that “it could be worse” and that they were committed to doing whatever was necessary (e.g., repeated cystoscopies every 3 months, treatment) to make sure the cancer did not metastasize.
- All participants reported a very positive outlook regarding their diagnosis and prognosis.

CONCLUSIONS

- Patients experience disease and treatment-related symptoms; however, the symptoms are not severe enough to impact patients’ willingness to undergo intravesical therapy or diagnostic procedures (e.g., cystoscopy), and were not pertaining to radical cystectomy uniformly engendered patient avoidance.

Further research is needed to better characterize the impact of timing and duration of treatment-related symptoms, as well as the patient and caregiver perspectives on additional bladder cancer therapies, especially when bladder sparing may be warranted.

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