

Patient Perceptions of Treatment Success in Uncomplicated Urinary Tract Infection

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Introduction

- Regulatory guidelines for Phase 3 trials evaluating antibiotics for the treatment of uncomplicated urinary tract infection (uUTI) require endpoints assessing complete resolution of uUTI symptoms present at trial entry; specifically, dysuria, urinary frequency, urinary urgency, and suprapubic pain^{1,2}.
 - These guidelines define treatment success as both complete symptom resolution and reduction in the bacterial pathogen to $< 10^3$ CFU/mL on urine culture
- However, the meaningfulness of this endpoint, and the definition of treatment success, are rarely explored from a patient perspective
- Aim:** To explore treatment success from the perspective of patients with uUTIs

Methods

Study Design

- This was a non-interventional, cross-sectional interview study
 - In-depth, qualitative, web-based interviews were conducted
- Interviews were recorded, transcribed, and analyzed using qualitative methods
- Participants were English- and Spanish-speaking female patients aged ≥ 12 years with a confirmed uUTI diagnosis within 14 days of screening
- Participants were asked:
 - Questions to elicit spontaneous and probed reports of uUTI symptoms and how these impacted health-related quality of life (QoL)
 - To provide descriptions of treatment success and to apply this to a 4-point scale (from 0 [none] to 3 [symptom prevents normal everyday activities]) assessing dysuria, urinary frequency, urinary urgency, and suprapubic pain

Results

- 30 participants (25 adults; 5 adolescents) were included in the study
 - Mean age was 39.7 (range 12–61) years; 83.3% were English-speaking; the mean treatment duration for participants' most recent uUTI was 8 days
- Participants reported the symptoms they experienced prior to treatment (**Figure 1**), the impacts of these symptoms on their lives (**Figure 2**), and their experiences of treatment and definitions of successful treatment (**Table**)

Participants' experiences with treatment and definitions of treatment success

- Participants knew their most recent treatment was starting to work when they experienced one or more of the following: less pain or burning; the ability to empty their bladder completely; less urgency or frequency of urination; and no longer having an odor from their urine
- Most participants reported that they thought the treatment they received was successful because they no longer had symptoms
- All participants who felt their treatments were successful reported that their day-to-day lives returned to normal
- Most participants said they would not consider treatment successful if they still experienced ≥ 1 symptom by the end of treatment
- A limitation of the study was that participants were not asked about underlying symptoms between uUTI episodes and whether treatment success would require elimination of these symptoms
- A selection of participant quotations are included in the **Table**

Table. Sample of Quotations From Participant Interviews

Context	Quotation
Reported symptoms of most recent uUTI	<i>I would say the frequency... because...you can't go on with your life. You couldn't walk around or go out to the store.</i>
	<i>Burning when having to go pee [because] it just like irritated me every time I had to use the restroom.</i>
	<i>The fact that I couldn't empty my bladder. There was no sense of relief. When...you're out at a restaurant, [and] you have a full bladder, and you know once you go and relief yourself, you'll be fine. In my case, I wasn't fine.</i>
Impacts of uUTIs on participants' lives	<i>I couldn't do my normal daily things with the UTI.</i>
	<i>I had to miss work to go to an emergency room the day of my diagnosis, so that definitely hindered my work, having to allocate time to go immediately to seek attention because it was so uncomfortable. We were going to have company over on Saturday, but I decided just not to. I wasn't feeling well at all.</i>
	<i>It can make me feel sad if I go out with my friends, and I want to socially drink, I can't because I'll be on antibiotics. Those are like the main emotions as well as frustrated.</i>
Effect on mood/emotions of most recent uUTI	<i>I was getting so aggravated that I wanted to cry because of the pain, and it's not normal for me to just sit all day, and I wanted to go to work, to my new job, and I couldn't go.</i>
	<i>Just a little bit irritable when you feel bad. I get a little bit cranky, and when it affects my sleep, I get even crankier.</i>
	<i>I no longer have a UTI... I feel back to normal.</i>
Participants' definitions of successful treatment	<i>Because I was able to urinate properly. I didn't feel any fullness. I was not uncomfortable. I didn't feel any pain. I was able to fully empty my bladder. I felt normal again.</i>
	<i>Because I started to feel like a lot better, and like it wasn't burning anymore. I wasn't really uncomfortable.</i>

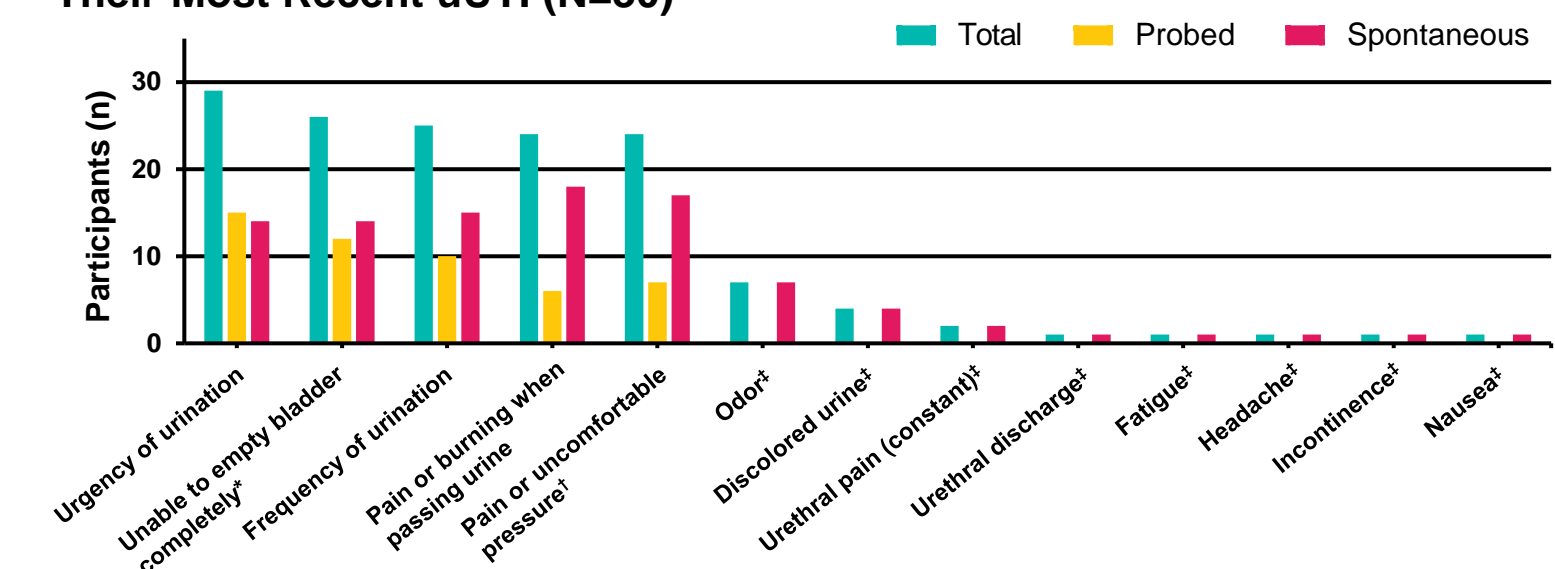
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Results (continued)

- Urgency was the most common uUTI symptom (n=29/30, **Figure 1**)

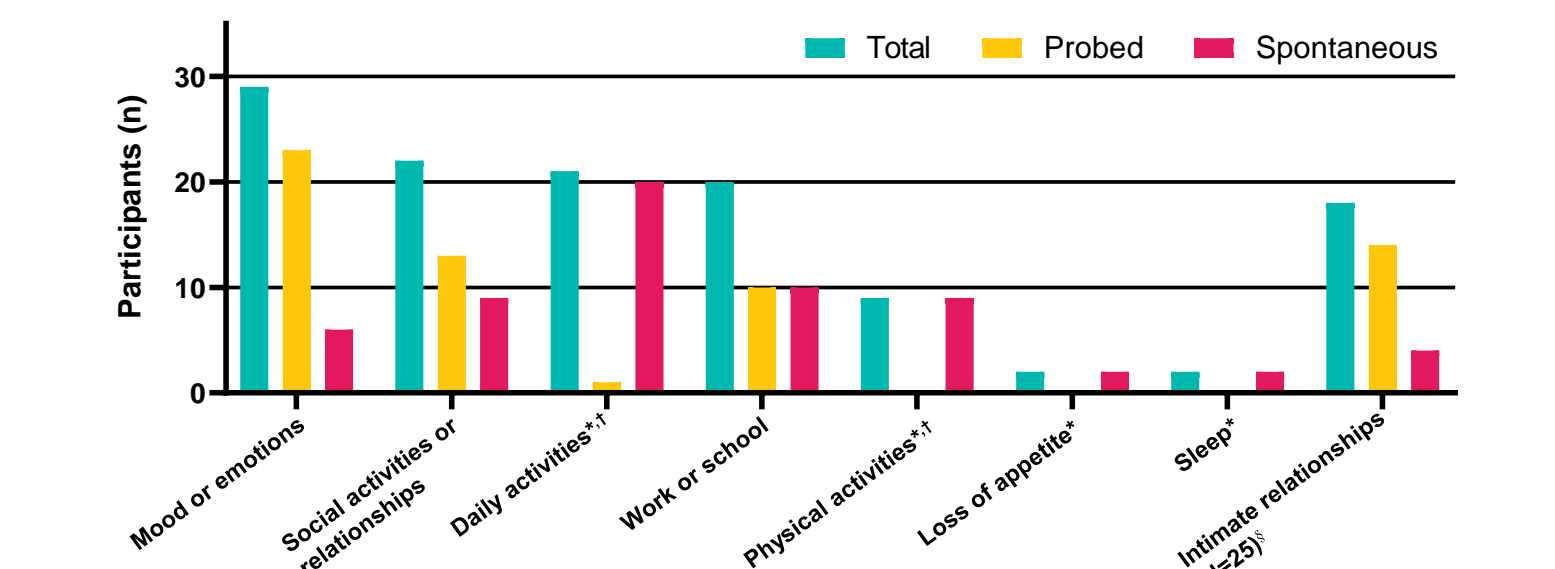
Figure 1. Participant-Reported Symptoms Prior to Receiving Treatment for Their Most Recent uUTI (N=30)



*Pass only small amounts of urine. †In lower abdomen/pelvic area. ‡The symptom was not probed during the interview but was spontaneously reported by the participant(s).

- Nearly all (n=29/30) participants reported that their recent uUTI affected their mood and/or emotions (**Figure 2**), describing feelings such as sadness, irritability, and aggravation with their uUTI

Figure 2. Participant-Reported Impacts of uUTI (N=30)



*The impact was not systematically probed during the interview but was spontaneously reported by the participant. †Daily activities included cleaning, shopping, caring for children, exercising, or playing sports. ‡Physical activities included walking, hiking, playing sports, exercising, and going to the gym. ‣Adolescents (n=5) were not asked about intimate relationships.

Conclusions

- Patients experienced a range of symptoms and QoL impacts of uUTI, the most common of which are those suggested for measurement in clinical trials
- Most participants defined treatment success as complete resolution of these symptoms, indicating this would positively affect their QoL

References

- US Food and Drug Administration. Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment Guidance for Industry. Maryland, USA: US Department of Health and Human Services, 2019.
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