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GOALS OF INTERSTITIAL CYSTITIS/PAINFUL BLADDER SYNDROME (IC/PBS) PATIENTS: WHAT ARE THEY AND HOW CAN GOAL ASSESSMENT IMPROVE RESEARCH AND PATIENT CARE?

Hypothesis / aims of study
Goal Assessment Scaling (GAS), wherein patients identify their goals and then evaluate treatments with regard to goal achievement, has been beneficial for assessment of treatments for complex chronic conditions such as rheumatoid arthritis and Alzheimer's disease. In this study we aimed to characterize and quantitate IC/PBS patient goals as a first step in creating a pilot GAS for use in clinical trials.

Study design, materials and methods
Goal assessment surveys: From June 2005 to September 2006, we recruited 37 patients with IC/PBS as defined by the ICS from the clinic. Participants were given minimal instructions and were simply told to record and rank their goals. Collected goals were pooled and analyzed for emergent domains and priority rankings. Special attention was paid to vocabulary and overlapping concepts. Goals that could be interpreted in multiple ways were selected for focus group discussion. Focus group discussions: From June to September 2006, a convenience sample of 15 clinic patients with IC/PBS participated in 3 focus groups. Effort was made to include newly diagnosed and veteran sufferers within a wide severity range; current symptoms were assessed with the O'Leary-Sant symptom and problem indices. Duration of each group was 60 to 90 minutes. Focus group format was minimally structured. The focus group audiotapes were transcribed verbatim and reviewed by the authors to identify major themes and goals domains. All calculations were done with Microsoft Excel.

Results
Goals Assessment Survey: 37 Participants (95% women, 5% men). Our study population was more heavily weighted with ulcerative IC patients (30%) and patients with more severe subjective disease (Mean ICSI (12 ± 5) Mean ICPI (10 ± 5), 50% with ICSI > 10) than might be expected in a typical community sample.

140 separate goals were collected. The mean number of goals per patient was 4 ± 2 (range 0- 9). There was a weak inverse correlation between number of goals listed and ICSI score (Pearson product = -0.25). The data and example goals are presented in the table. Pain was reported by the highest percentage of patients (73%). Frequency and/or Nocturia were the next most commonly reported (56%). Ten of the 37 participants listed both pain and frequency goals. Of the 10 patients listing both goals, 4 of them assigned their frequency goal a higher priority their pain goal. Only 4 goals fell into the urge domain.

Domains	Patients with goals within domain	% Respondents with goals in this domain	Raw Number of goals reported	% Raw total goals
Pain	27	73%	31	22%
"Pain minimized to tolerable level" "I'd like to be without pain and pressure in my bladder" "To be physically comfortable most of the time"				
Frequency and Nocturia	22	56%	26	19%
"To be able to go more then 2 hours without urinating" "To sleep 6 hours uninterrupted by the need to urinate"				
Life Style	14	38%	31	22%
Generalized (n = 7): "Be able to more reliable in making plans and following through" Sex (n = 7): "I wish I could have intercourse and not pay the price of having worse pain afterwards" Food (n = 6): "To be able to eat the foods I love and miss because of having IC" Exercise (n = 4):"To be able to walk or work out one hour without taking a bathroom break" Work (n = 3): "To be able to work 6 hours per day at my old job" Travel (n = 2): "To be able to travel and not have to stop at every bathroom along the way" Pregnancy (n = 1): "To be able to have a normal pregnancy in a few years"				
Medication	9	24%	10	7%
"When experiencing bladder pain, I would like to be able to take a pain reliever that does not make me tired or irritable" "Take medication that decreases the symptoms consistently"				
General Disease Goals	10	27%	7	5%
"Improving overall symptoms for the long term - remission"				
Education/ Personal Understanding of Disease	4	11%	11	8%
"Identification of the cause of the symptoms" "Understanding the various options for treatment"				
Misc Urination mechanics	6	16%	6	4%
"Gain ability to urinate spontaneously without need to pump muscles or use catheter"				
Generalized Somatic Symptoms/ Fatigue	5	14%	5	4%
"I'd like to have more energy and not fall asleep at the drop of a hat"				
Urge	4	11%	4	3%
"Having more notice before urgency to urinate sets in"				
Incontinence	4	11%	4	3%
"To not have to wear protective underwear"				
Volume	3	8%	3	2%

"More volume at a time, more then 200cc"				
Seemingly unrelated body symptoms	2	5%	2	1%
"Better balance"				

Focus groups: The focus groups had 5, 6, and 4 participants respectively. The first and third groups had 1 male each, all other participants were female. Average age was 47.2 ± 13 years. The mean ICSI and ICPI scores were 11.9 ± 4.4 and 10.8 ± 3.9 respectively. Three participants had ulcers, while the remaining 12 had non-ulcerative IC or PBS. 11 participants (73%) were Caucasian, 2 participants (13%) were Indian, 1 patient (7%) was African American and 1 patient (7%) was Asian.

Discussion of goal domains revealed that although urgency was not a frequently listed goal, urgency is a separate entity from pain or frequency and any of these may take treatment priority. Importantly, the groups independently reached consensus on a definition of urgency as *"the need to use the restroom, not for fear of leaking, but due to an unpleasant sensation that prevents attention to any other task."* Additionally, the focus groups identified additional goal domains of control, predictability, and information and gave justification for these goals as separate from those already listed and intrinsically worthy of attention. The groups confirmed our hypothesis that the current urological surveys assessing treatment are inadequate. Reasons cited included insufficient communication of the interaction between pain, urgency, and frequency in patient's lives and an inability to detect qualitative changes in symptoms that alter functional status. In addition, patients voiced concerns that their "day of visit" symptoms weigh disproportionately on reporting.

Interpretation of results: Patients have individualized goals and priorities for treatment. Patients with IC/PBS have a different experience of urge/urgency than that defined by the ICS. GAS holds promise for improving the evaluation of IC/PBS which is notorious for its complexity, intrapatient variability and fluctuating course.

Concluding message

Objective outcome measures have traditionally formed the basis of evaluation in clinical trials but standardized surveys may fail to address factors that are important to the individual while conversely forcing the evaluation of factors that are largely irrelevant.[1] A new instrument developed from this work is being piloted in a multicenter RCT to assess the value of GAS in IC/PBS. We also suggest that questionnaires investigating urgency in IC/PBS clarify the definition in a manner more applicable to the specific condition.

References
1. Journal of Clinical Epidemiology 53 (2000) 549–553