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The impact of Hunner lesion-type interstitial cystitis/bladder pain syndrome on health-related quality of life and the effects of transurethral ablation

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Abstract

Purpose Interstitial cystitis/bladder pain syndrome (IC/BPS) has a negative impact on quality of life. We compared health-related quality of life (HRQoL) of patients with IC/BPS with patients having other diseases using the EuroQol five-dimension (EQ-5D) and evaluated whether the HRQoL is improved after surgery.

Methods We compared EQ-5D of patients with Hunner lesion type IC/BPS with patients who had other diseases that cause chronic and severe pain including arthritis and cancer from a cross-sectional analysis of responses to the 2012–2016 Korea National Health and Nutrition Examination Survey. Changes in EQ-5D after transurethral coagulation (TUC) or resection (TUR) were measured in the IC/BPS participants.

Results Compared to the EQ-5D index of normal population, patients with arthritis, cancer and IC/BPS had − 0.07 (95% CI − 0.07, − 0.06), − 0.01 (95% CI − 0.02, − 0.01), and − 0.21 (95% CI − 0.23, − 0.20) lower scores, respectively. Patients with IC/BPS were 35.9, 9.24, and 9.05 times more likely to have "extreme problem" in pain/discomfort, anxiety/depression, and usual activities EQ-5D domains, respectively, than patients without arthritis/cancer. After TUC or TUR, EQ-5D index was 0.90 in the TUC group and 0.92 in the TUR group.

Conclusion IC/BPS patients have worse HRQoL than healthy individuals. However, after surgical treatment, HRQoL is restored to a level close to normal.

Keywords Bladder pain syndrome · EQ-5D · Health-related quality of life. interstitial cystitis · Pain · Therapeutics

Plain English Summary

Interstitial cystitis/bladder pain syndrome is a chronic condition characterized by chronic pelvic pain, pressure, and/or discomfort perceived to be related to the urinary bladder. Interstitial cystitis/bladder pain syndrome patients are associated with a decrease in work productivity and mobility, sleep disorder and sexual dysfunction due to severe pain. The limitation is that there is no clear etiology or treatment method yet. The purpose of this study was to compare EQ-5D, widely used generic health-related quality of life measures, in patient with Hunner lesion-type interstitial cystitis/bladder pain syndrome patients and patients with cancer and arthritis, associated with chronic and severe pain, with normal population, and assess the impact of endoscopic treatments on and changes in health-related quality of life. Our results suggest that patients with interstitial cystitis/bladder pain syndrome have worse health-related quality of life than normal healthy. However, health-related quality of

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life of Hunner lesion-type interstitial cystitis/bladder pain syndrome patients improved to the level of normal population after endoscopic treatment.

Introduction

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a chronic condition characterized by chronic pelvic pain, pressure, or discomfort perceived to be related to the bladder and associated with lower urinary tract symptom [1]. Although the exact prevalence of IC/BPS is unknown, estimates suggest that the prevalence is between 1.9% and 4.2% in men and between 2.7% and 6.5% in women based on the symptom criteria [2, 3].

IC/BPS is associated with a decrease in work productivity and mobility, sleep disorder and sexual dysfunction due to chronic pain [4]. In severe cases, patients may void more than 20–30 times a day and complain of severe pain with median visual analogue scale score of 7.0 at initial diagnosis [5]. This can result in isolation from social life and in severe depression [6]. Although patients with IC/BPS suffer from reduced quality of life, currently available treatment options are only temporarily effective. To date, several studies have focused on effectiveness of transurethral ablation for IC/BPS with Hunner lesion. These studies evaluated improvement in pain score, related symptom questionnaire scores, and urinary symptoms [7]. Although improvement of the patient's symptoms may be as important as quality of life, the impact of IC/BPS on health-related quality of life (HRQoL) is salient factor for treatment. While several disease-specific instruments have been used to measure the HRQoL of IC/BPS patients [4, 6, 8], there is a need for generic HRQoL measures as well to allow comparisons with populations with or without chronic pain. In particular, the generic HRQoL measure can be used to compare the HRQoL effect before and after the proper management of IC/BPS.

The objective of this study was to compare EuroQol five-dimension (EQ-5D), widely used generic HRQoL measures, in patients with Hunner lesion-type IC/BPS and patients with cancer and arthritis, conditions associated with chronic and severe pain, and with the relatively pain-free "normal" population. Then the aim was to assess the impact of endoscopic treatments on and changes in HRQoL of IC/BPS patients.

Methods

Study design and patients

The first phase was to compare HRQoL of patients with Hunner lesion-type IC/BPS from our clinical trial set ($n=122$) [9] with patients who had other diseases that cause chronic and severe pain including arthritis and cancer. Subjects with and without arthritis and cancer were sampled from the 2012–2016 cycles of Korea National Health and Nutrition Examination Survey (KNHANES), a cross-sectional, nationally representative survey with a multistage, stratified sampling design conducted by the Korea Centers for Disease Control and Prevention [10]. The KNHANES is a national, cross-sectional health examination and adopts a rolling sampling survey to represent the probability sampling of health, nutritional status, and physical activities in the Korean general population. Among KNHANES participants, we restricted our analysis to men and women aged 25 years or older without urological disease who responded to EQ-5D questionnaires. Since cancer and arthritis is the highest disease burden [11–13], we selected participants who had cancer ($N=534$) or arthritis ($N=3116$) at the time of the survey as well as participants without cancer or arthritis ($N=20{,}761$). After combining two datasets, we further excluded participants who had not included age (5-year intervals) and sex-specific strata in each group. Thus, there were 118, 503, 3033 and 16,068 patients with IC/BPS, cancer, arthritis, and without cancer or arthritis, respectively, included in the HRQoL comparison analysis.

In the second phase, we conducted a secondary analysis of a parallel randomized controlled trial (ClinicTrial.gov NCT 01,963,988) in which the primary purpose was to compare the therapeutic efficacy of transurethral resection (TUR) or transurethral coagulation (TUC) of the Hunner lesion in IC/BPS patients to evaluate the change of HRQoL of IC/BPS patients after TUR or TUC. Detailed information regarding the participants in this trial has been previously published [9]. HRQoL was measured by the Korean version of the EQ-5D-3L. The Korean version of the EQ-5D-3L is used as a tool for measuring HRQoL in the Korean adult population and has been shown to have good validity and reliability [14, 15]. The EQ-5D-3L is composed of five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. These five dimensions are judged to be one of three different levels: 1, no problem; 2, some problem; or 3, severe problem. In this study, analysis was conducted based on the presence of a problem in each of the five dimensions as "no problem" and "some" or "extreme problem." The index of EQ-5D-3L was calculated using the formula which was developed by the Korean Centers for Disease Control and Prevention as estimated weights of EQ-5D in which higher scores indicate better overall health status [16]. Of the 122 clinical trial subjects, 119 patients with EQ-5D at baseline were included in the analysis. All the patients visited at 1, 3, 6, and 12 mo after treatment with voiding diary and questionnaires including EQ-5D. We used these participants in the analysis of HRQoL change after surgery.

The study protocol was reviewed and approved by the Institutional Review Board (IRB approval no.,201,305,127).

Statistical analysis

In the first phase, we conducted conditional logistic regression model for age–sex-matched data. We calculated the OR and 95% CI for prevalence of extreme problem in each subdomain comparing the arthritis, cancer, and IC/BPS to the no arthritis/cancer group. In second phase, change of HRQoL according to the follow-up was analyzed using linear mixed models for longitudinal data with random intercepts and random slopes. For the prevalence of participants who had some (level 2) to extreme (level 3) problems in each domain, we used mixed-effects logistic regression. We also tested the homogeneity of HRQoL mean and prevalence of participants who reported moderate to severe problems changes comparing TUR and TUC. We calculated ORs with 95% CI for moderate to severe problems in the five health dimensions using a conditional logistic regression model considering age- and sex-specific strata as the stratification factor.

All reported *P* values were two-sided and the significance level was set at 0.05. All analyses were performed using STATA version 15 (StataCorp LP, College Station, TX, USA).

Results

Among 19,722 participants, the mean age (SD) was 57.2 (12.4) and 38.6% ($N=7608$) were male. Patients with IC/BPS had the lowest HRQoL (0.68) compared to other participants ($P<0.01$; Table1). Compared to the participants without arthritis/cancer, patients with arthritis, cancer, and IC/BPS reported − 0.07 (95% CI − 0.07, − 0.06), − 0.01 (95% CI − 0.02, − 0.01), and − 0.21 (95% CI − 0.23, − 0.20) less

Table 1 Mean of HRQoL and proportion of participants who had some/extreme problems

	No arthritis/cancer ($N=16,068$)	Arthritis ($N=3,033$)	Cancer ($N=503$)	IC/BPS ($N=118$)	*P* value
Mean and proportion					
HRQoL, mean (SD)	0.91 (0.09)	0.81 (0.18)	0.89 (0.11)	0.68 (0.19)	< 0.01
Subdomain					
Mobility, n (%)					< 0.01
Some problem	1,969 (12.3)	1,426 (47)	107 (21.3)	60 (50.9)	
Extreme problem	101 (0.6)	99 (3.3)	5 (1)	1 (0.9)	
Self-care, n (%)					< 0.01
Some problem	560 (3.5)	411 (13.6)	25 (5)	21 (17.8)	
Extreme problem	48 (0.3)	44 (1.5)	2 (0.4)	2 (1.7)	
Usual activities, n (%)					< 0.01
Some problem	1,109 (6.9)	846 (27.9)	73 (14.5)	79 (67)	
Extreme problem	81 (0.5)	85 (2.8)	5 (1)	10 (8.5)	
Pain/discomfort, n (%)					< 0.01
Some problem	3,151 (19.6)	1,319 (43.5)	145 (28.8)	55 (46.6)	
Extreme problem	277 (1.7)	333 (11)	15 (3)	56 (47.5)	
Anxiety/depression, n (%)					< 0.01
Some problem	1,496 (9.3)	691 (22.8)	72 (14.3)	70 (59.3)	
Extreme problem	114 (0.7)	93 (3.1)	7 (1.4)	14 (11.9)	
Difference between groups					
;EQ-5D, coefficient (95% CI)	*Reference*	-0.07 (-0.07, -0.06)	-0.01 (-0.02, -0.01)	-0.21 (-0.23, -0.20)	< 0.01
Odds ratio* (95% CI) for extreme problem in each subdomain					
Mobility	*Reference*	1.81 (1.38, 2.37)	1.48 (0.74, 2.94)	0.58 (0.08, 4.19)	< 0.01
Self-care	*Reference*	1.6 (1.11, 2.29)	1.14 (0.41, 3.14)	2.34 (0.56, 9.82)	< 0.01
Usual activities	*Reference*	1.91 (1.43, 2.56)	1.66 (0.8, 3.45)	**9.05 (4.46, 18.37)**	< 0.01
Pain/Discomfort	*Reference*	2.89 (2.43, 3.44)	1.36 (0.83, 2.23)	**35.9 (23.97, 53.78)**	< 0.01
Anxiety/Depression	*Reference*	1.78 (1.36, 2.34)	1.64 (0.85, 3.14)	**9.24 (5.07, 16.84)**	< 0.01

HRQoL health-related quality of life, *IC/BPS* interstitial cystitis/bladder pain syndrome

*Odds ratio for the presence of extreme problems in each domain with age- and sex-specific strata as stratification factor

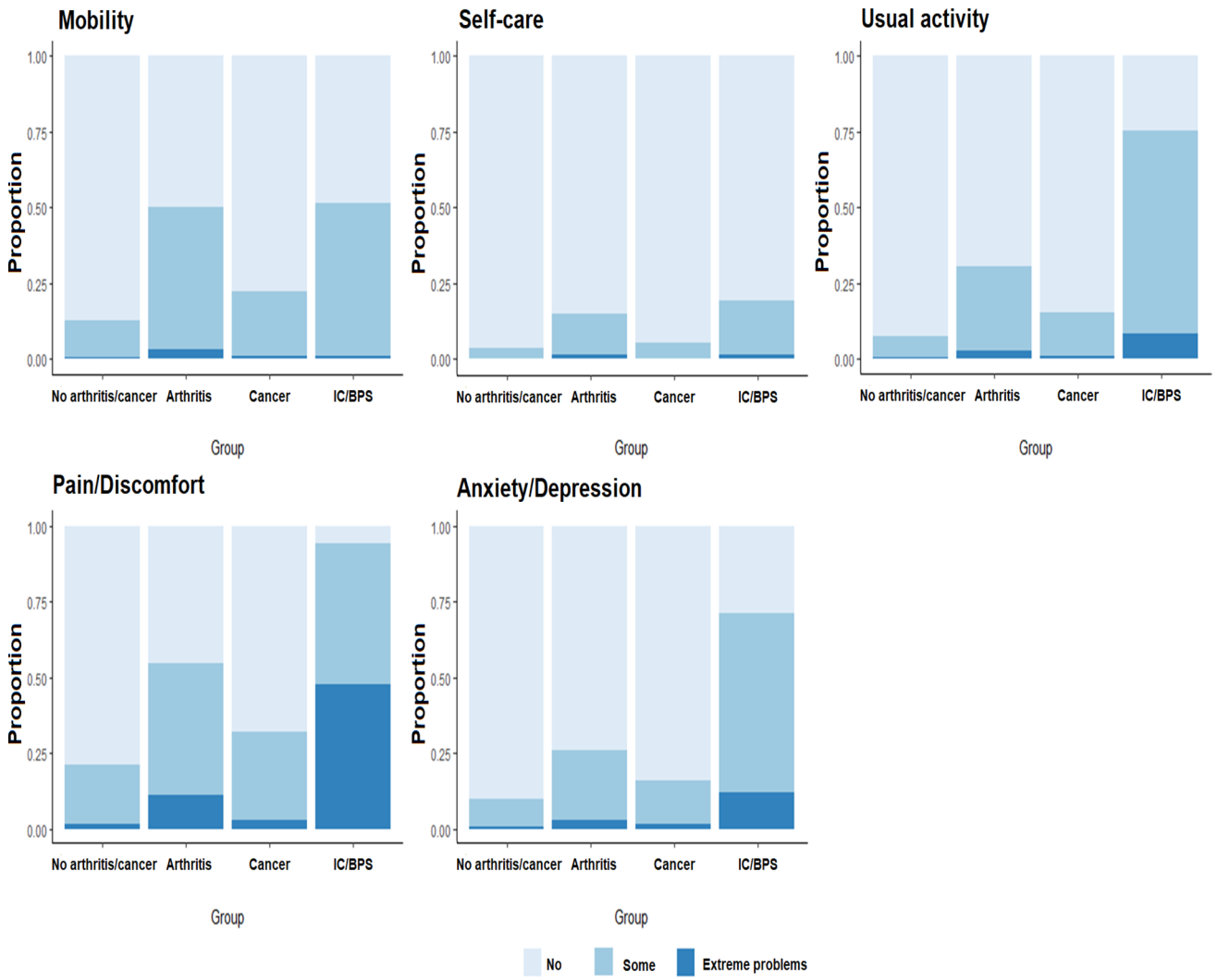

Fig. 1 Proportion of problems in health dimensions by type of disease

Table 2 Mean of HRQoL by type of surgery according to the follow-up in patient with IC/BPS

	Baseline ($N=119$)	1 month ($N=119$)	3 months ($N=106$)	6 months ($N=95$)	12 months ($N=75$)
HRQoL[a], mean (SD)					
Overall	0.68 (0.19)	0.91 (0.10)	0.90 (0.11)	0.88 (0.14)	0.89 (0.10)
TUC	0.69 (0.18)	0.90 (0.13)	0.89 (0.12)	0.85 (0.17)	0.90 (0.09)
TUR	0.67 (0.21)	0.92 (0.05)	0.90 (0.09)	0.90 (0.09)	0.87 (0.11)
P value[*]	0.52	0.31	0.38	0.09	0.23
Change of HRQoL					
Overall	Reference	0.23 (0.20, 0.26)	0.22 (0.18, 0.25)	0.19 (0.16, 0.23)	0.19 (0.15, 0.23)
TUC	Reference	0.21 (0.17, 0.25)	0.20 (0.15, 0.24)	0.15 (0.11, 0.20)	0.18 (0.13, 0.23)
TUR	Reference	0.25 (0.21, 0.29)	0.24 (0.19, 0.28)	0.23 (0.19, 0.28)	0.20 (0.14, 0.25)
P value[**]		0.19	0.20	0.02	0.71

HRQoL health-related quality of life, *IC/BPS* interstitial cystitis/bladder pain syndrome, *TUC* transurethral coagulation, *TUR* transurethral resection

[a]These weights lie on a scale on which full health has a value of 1 and dead a value of 0

[*]*P* value for difference at the time point between TUC group and TUR group

[**]*P* value for slope difference between TUC group and TUR group

Table 3 Proportion of participants who reported some/extreme problems in each domain by type of surgery according to follow-up period

	Baseline ($N=119$)	1 month ($N=119$)	3 months ($N=106$)	6 months ($N=95$)	12 months ($N=75$)
Mobility					
Overall					
Some problem	60 (50.4)	8 (6.7)	11 (10.4)	12 (12.6)	9 (12)
Extreme problem	1 (0.8)	1 (0.8)	0 (0)	0 (0)	0 (0)
TUC					
Some problem	30 (50.9)	4 (6.8)	6 (11.5)	9 (18.4)	3 (8.1)
Extreme problem	0 (0)	1 (1.7)	0 (0)	0 (0)	0 (0)
TUR					
Some problem	30 (50)	4 (6.7)	5 (9.3)	3 (6.5)	6 (15.8)
Extreme problem	1 (1.7)	0 (0)	0 (0)	0 (0)	0 (0)
P values[a]	0.61	0.60	0.70	0.08	0.31
Self-care					
Overall					
Some problem	22 (18.5)	1 (0.8)	5 (4.7)	2 (2.1)	1 (1.3)
Extreme problem	2 (1.7)	0 (0)	0 (0)	0 (0)	0 (0)
TUC					
Some problem	12 (20.3)	1 (1.7)	4 (7.7)	2 (4.1)	0 (0)
Extreme problem	1 (1.7)	0 (0)	0 (0)	0 (0)	0 (0)
TUR					
Some problem	10 (16.7)	0	1 (1.9)	0	1 (2.6)
Extreme problem	1 (1.7)	0 (0)	0 (0)	0 (0)	0 (0)
P values[a]	0.88	0.31	0.16	0.17	0.32
Usual activities					
Overall					
Some problem	80 (67.2)	16 (1.5)	18 (17.0)	23 (24.2)	22 (29.3)
Extreme problem	10 (8.4)	0 (0)	1 (0.9)	1 (1.1)	0 (0)
TUC					
Some problem	41 (69.5)	8 (13.6)	10 (19.2)	12 (24.5)	8 (21.6)
Extreme problem	4 (6.8)	0 (0)	1 (1.9)	1 (2)	0 (0)
TUR					
Some problem	39 (65)	8 (13.3)	8 (14.8)	11 (23.9)	14 (36.8)
Extreme problem	6 (10)	0 (0)	0 (0)	0 (0)	0 (0)
P values[a]	0.79	0.97	0.48	0.62	0.15
Pain/discomfort					
Overall					
Some problem	55 (46.2)	39 (32.8)	32 (30.2)	22 (23.2)	32 (42.7)
Extreme problem	57 (47.9)	1 (0.8)	6 (5.7)	12 (12.6)	5 (6.7)
TUC					
Some problem	30 (50.9)	18 (30.5)	14 (26.9)	10 (20.4)	13 (35.1)
Extreme problem	25 (42.4)	1 (1.7)	3 (5.8)	9 (18.4)	2 (5.4)
TUR					
Some problem	25 (41.7)	21 (35)	18 (33.3)	12 (26.1)	19 (50)
Extreme problem	32 (53.3)	0 (0)	3 (5.6)	3 (6.5)	3 (7.9)
P values[a]	0.49	0.54	0.77	0.21	0.32
Anxiety/depression					
Overall					
Some problem	70 (58.8)	20 (16.8)	18 (17.0)	20 (21.1)	12 (16)
Extreme problem	14 (11.8)	3 (2.5)	1 (0.9)	2 (2.1)	0 (0)
TUC					
Some problem	37 (62.7)	9 (15.3)	12 (23.1)	12 (24.5)	5 (13.5)

Table 3 (continued)

	Baseline ($N=119$)	1 month ($N=119$)	3 months ($N=106$)	6 months ($N=95$)	12 months ($N=75$)
Extreme problem	7 (11.9)	3 (5.1)	1 (1.9)	2 (4.1)	0 (0)
TUR					
Some problem	33 (55)	11 (18.3)	6 (11.1)	8 (17.4)	7 (18.4)
Extreme problem	7 (11.7)	0 (0)	0 (0)	0 (0)	0 (0)
P values[a]	0.63	0.20	0.14	0.24	0.56

HRQoL health-related quality of life, *IC/BPS* interstitial cystitis/bladder pain syndrome, *TUC* transurethral coagulation, *TUR* transurethral resection

[a]*P* value for difference at the time point between TUC group and TUR group

HRQoL, respectively (Table 1). In the health dimensions, 0.9%, 1.7%, 8.5%, 47.5%, and 11.9% of patients with IC/BPS reported extreme problem in mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, respectively (Table 1 and Fig. 1). Compared to the participants without arthritis/cancer, arthritis, cancer, and patients with IC/BPS were more likely to have extreme problems in all the health dimensions. In particular, patients with IC/BPS were 9.05, 35.9, and 9.24 times more likely to have extreme problems in usual activities, pain/discomfort, and anxiety/depression, respectively, than patients without arthritis/cancer (Table 1).

Among 119 patients with IC/BPS, the TUC and TUR groups reported similar levels of HRQoL (mean scores of 0.69 vs. 0.67, respectively; $P=0.52$) at baseline (Table 2). After surgery, TUC and TUR groups had significantly increased levels of HRQoL compared to baseline by 0.21 and 0.25, respectively (Table 2). The increasing HRQoL decreased at 6 months after surgery, and the TUC group showed a significantly greater decrease in HRQoL than the TUC group (P for interaction = 0.02). Among the health dimensions, more than 40% of patients in both TUC and TUR groups reported having extreme problems with pain/discomfort (42.4% vs. 53.3%) (Table 3). While the proportion of patients having problems with all other health dimensions showed decreasing trends, the proportion of patients having extreme problems with pain/discomfort gradually increased after 3 months. The anxiety/depression dimension also had increasing trends after 6 months (Table 3).

Discussion

To the best of our knowledge, this study is the first to compare EQ-5D in Hunner lesion-type IC/BPS patients with the normal, relatively pain-free population. Of note, the EQ-5D utility score of Hunner lesion-type IC/BPS patients was 0.68, which was significantly lower than that of the normal population (0.91). Several studies reported significantly lower QoL in IC/BPS sufferers [6, 8, 17]. Considering that the EQ-5D utility score of patients with cancer was 0.89 and that of patients with arthritis was 0.81, Hunner lesion-type IC/BPS was a chronic disease with significantly poorer HRQoL.

Daily severe pain is one of the most influential factors on HRQoL. Patients with IC/BPS had severe chronic bladder pain with an average visual analogue scale score for pain of 7.0 at baseline [5]. We had to select a representative chronic pain disease to use as a control group. First, arthritis is the greatest cause of chronic pain among elderly patients. In a study analyzing EQ-5D in rheumatoid arthritis in Korea, 89.8% of patients with arthritis had moderate or extreme problems in pain/discomfort [11]. Second, about 20% of diverse cancer survivors had cancer-related pain, and 43% had experienced pain after cancer diagnosis [12, 13]. In cancer patients, pain is one of the factors that causes deterioration of HRQoL. Under the assumption that severe pain caused by IC/BPS would have a negative effect on HRQoL, patients without arthritis and cancer were defined as the normal control group among patients with chronic disease. In this study, the proportion of patients reporting "extreme problems" in the pain/discomfort domain was 3.0% for cancer patients, 11.0% for arthritis patients, and 47.5% for IC/BPS patients. The odds of "extreme problem" in pain/discomfort were 35.9-fold higher in Hunner lesion-type IC/BPS than in the normal control group. This was significantly higher than that of cancer patients or arthritis patients. We indirectly confirmed that Hunner lesion IC/BPS is a much more serious pain disease than other chronic pain diseases.

Besides the pain/discomfort domain, impaired HRQoL in IC/BPS patients was associated with other domains including mobility, self-care, usual activity, and anxiety/depression. The proportion of patients who responded with some problem or extreme problem was 51.8% in the mobility domain, 19.5% in the self-care domain, 75.5% in usual activity, and 70.2% in anxiety/depression. Patients with IC/BPS are more likely to develop anxiety or depression than healthy controls [18–21]. In a systematic review, the prevalence of depression has been reported to be from 16 to 70%, and prevalence of anxiety in patients with IC/BPS ranged from 14 to 52%. The likelihood of developing an anxiety disorder

after IC/BPS diagnosis was 2.4 times higher [22]. This study also showed that Hunner lesion-type IC/BPS patients had an odds ratio of 9.05 for an extreme problem in usual activities and 9.24 in anxiety/depression. Although the causal relationship between pain and anxiety/depression on quality of life cannot be clearly identified [22], we assume that severe pain causes anxiety or depression through interviews with patients in the clinic or through existing systematic reviews.

Unfortunately, there is still no definitive treatment for IC/BPS; pain relief is the goal. In the case of refractory end-stage IC/BPS whose symptoms cannot be controlled despite medication or endoscopic management, invasive reconstructive surgery such as partial cystectomy with augmentation cystoplasty or total cystectomy with ileal conduit should be considered. After cystectomy, approximately 67% of patient reported no problem related to pain on the EQ-5D, which was similar to the regional reference population [23]. We were able to accurately assess HRQoL through the reliable and validated EQ-5D. The EQ-5D domains were regularly assessed after endoscopic treatment. Our generic HRQoL results showed that the EQ-5D indices were immediately improved to a similar level to the normal population after both TUC and TUR. The proportion of "some problem" or "extreme problem" was significantly reduced compared to baseline for all items including the pain subdomain. In particular, the proportion of "extreme problem" decreased to 0.8% immediately after treatment and gradually increased after 3 months. However, the proportion of patients who responded "extreme problem" at 12 months was as low as 6.7%. Fortunately, pain can be controlled and HRQoL can be restored through repeated endoscopic treatments.

One of limitation in this study is comorbidity diagnoses depended on the information self-reported by the participants in an interview. This is a major limitation of this type of nationwide survey because patients might misunderstand the information given by physicians. However, this study has low possibility of bias for self-diagnosis as data were collected in patients who responded that they are currently receiving treatment. Another limitation is that there are differences in the pain severity for each patient depending on the types of cancer and the treatment response. We tried to select diseases that cause severe pain among various chronic diseases. And to overcome, we set the reference of patients without cancer and arthritis as a normal population and compared them with patients with IC/BPS for analysis.

Conclusion

Compared with the normal population without chronic pain, patients with Hunner lesion-type IC/BPS have worse HRQoL as determined through the EQ-5D than other chronic pain diseases. However, HRQOL of Hunner lesion-type IC/BPS patients improved to the level of the normal population after endoscopic treatment.

Author contributions KSL and KJK contributed to the study conception and design. Material preparation, data collection, and analysis were performed by KJK, JL, and JY. The first draft of the manuscript was written by KJK and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Ethical approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by Institutional Review Board of Samsung Medical Center (IRB approval no.,201305127).

Consent to participate Informed consent was obtained from all individual participants included in the study.

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