

ORAL ADMINISTRATION OF STEROID FOR INTERSTITIAL CYSTITIS – A VITAL OPTION?

Hypothesis / aims of study

Interstitial cystitis (IC) is a disease of myth. Even the nomenclatures are not uniform, nor are the diagnosis procedures and treatment modalities. Oral administration of anti-inflammatory steroids is an ignored treatment option for IC because of concern on adverse events, especially associated with long-term therapy. However, recent articles have suggested its possible role in ulcer type IC treatment¹⁾. We retrospectively reviewed the clinical charts for oral steroid therapy, and found favorable responses in most of the cases.

Study design, materials and methods

Ten patients (9 women and 1 man) who were diagnosed as ulcer type IC and treated by oral steroid were retrospectively analyzed. The average age was 65.8 years [range: 38 to 84], and the average time from the onset of symptoms and the treatment was 8.4 years [range: 3 to 28]. The diagnosis was based on the Japanese guideline for IC²⁾, which comprises 1) lower urinary tract symptoms such as bladder hypersensitivity, urinary frequency, bladder discomfort and bladder pain; 2) bladder pathology such as Hunner's ulcer and mucosal bleeding after over-distension; 3) exclusions of confusable diseases such as infection, malignancy and calculi of the urinary tract. Also the patients were compatible with National Institute of Diabetes and Digestive Kidney Diseases (NIDDK) consensus inclusion and exclusion criteria for clinical trials. These patients had been treated with transurethral resection or fulguration for the ulcerative lesions once to 7 times (3.3 times in the average), yet recurred the symptoms. The average interval from the transurethral surgery to steroid treatment was 6 months [range: 2 to 22 months]. Oral betamethazone of 0.75mg was given daily for 1 months, then tapered to 0.5mg or 0.25mg according to symptom relief, and continued for an average period of 7 months [range: 2 to 36 months]. The symptoms were evaluated by the O'Leary- Sant's Symptom Index (OSSI) and Problem Index (OSPI), Visual Analogue Scale (VAS) for pain from 0 to 10 and the Core Lower Urinary Tract Symptom Score (CLSS), an assessment tool that can evaluate symptoms in a non-disease-specific manner³⁾. Bladder diary was recorded for the assessment of tidal voided volume. Quality of Life Index (QoLI) of International prostate symptom score and Global Response Assessment by patients' subjective impressions (GRA) were also evaluated.

Results

The assessment results of pre- and post- treatment were summarized in the Table 1. Significant improvement was noted for the variables evaluated; it was especially impressive for the pain score. GRA was favorable in 8 subjects and no worsening was reported (Table 2). No adverse events including diabetes, gastric ulcer or hypertension were experienced with the doses and treatment periods used.

Interpretation of results

Oral administration of steroid has been almost abandoned as the treatment options for IC. However, our results suggested it could be a vital option for ulcer type IC. The limitation of the study included small sample size, short-term observation period, retrospective nature of analysis (thus without concurrent control), and no assessment for biomarkers and cystoscopy. Further study is warranted for the possible usefulness of oral steroid therapy for this intractable disease.

Concluding message

Oral administration of steroid could be a vital therapeutic option for ulcer type IC, and this possibility is needed for further studies.

Table 1: The average values of assessment variables pre- and post-oral steroid therapy

	OSSI	OSPI	VAS	CLSS	QoLI	TVV
Pre	13.1	10.2	5.3	17.4	4.6	90.0
Post	7.7	5.7	1.8	11.3	3.1	143.3
Post/Pre	58%	55%	33%	65%	67%	160%

All variables showed significant improvement ($p < 0.01$).

OSSI: O'Leary- Sant's Symptom Index, OSPI: O'Leary- Sant's Problem Index, VAS: Visual Analogue Scale for pain (from 0 to 10), CLSS: Core Lower Urinary Tract Symptom Score, QoLI: Quality of Life Index of the International prostate symptom score (from 0 to 6), TVV: tidal voided volume (ml)

Table 2: Number of patients according to Global Response Assessment scale (GRA)

	Markedly improved	Moderately improved	Slightly improved	No change	Slightly worsened	Moderately worsened	Markedly worsened
No	1	3	4	2	0	0	0

References

1. J Urol 173: 841-3, 2005
2. Int J Urol 16: 4-16, 2009
3. Int J Urol 15: 816-20, 2008

Specify source of funding or grant	None
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require ethics committee approval because	it is a retrospective analysis.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	No