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Prospective randomized controlled trial comparing the effect of fulguration versus fulguration and hydrodistension in Interstitial Cystitis/Bladder Pain Syndrome

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Son H.S. [1], Yoon H. [2], Kim J.H. [1]

[1]Yonsei University College of Medicine, Dept. of Urology, Seoul, South Korea, [2]Ewha Womans University, College of Medicine, Dept. of Urology, Seoul, South Korea

Introduction & Objectives: We performed randomized controlled trial to compare effect of transurethral fulguration(TUF) versus fulguration and hydrodistension(HD) in Interstitial Cystitis/Bladder Pain Syndrome(IC/BPS).

Materials & Methods: IC/BPS patients with Hunner's lesion, were enrolled from August 2015 to February 2018 at two tertiary referral centers. Patients were allocated to HD+TUF or TUF group using permuted block randomization. For TUF group, fulguration was performed focused on the Hunner's lesion. For HD+TUF group, bladder hydrodistension was performed prior to TUF at the pressure of 80cmH_2O for 8 minutes. Treatment efficacy was evaluated at postoperative 1st, 2nd, 4th and 6th months.

Results: 52 (HD+TUF-25, TUF-27) patients were evaluated. Median age at operation was 63.8 (29.0~83.3) years. During the study period, 12 (HD+TUF-4, TUF-8) patients who needed intervention for recurrent pain were dropped out. 7 (HD+TUF-2, TUF-5) patients refused to participate in the middle of study. Overall drop-out rate was 24.0% for HD+TUF group and 48.1% for TUF group by Intention-To-Treat (ITT) analysis (P=0.089). Drop-out caused by pain was 17.4% for HD+TUF group and 36.4% for TUF group by Per-Protocol (PP) analysis (P=0.189). At postoperative 1 month, Visual Analogue Scale pain score (VAS) was not significantly different between groups; Superiority of HD+TUF to TUF was observed in EQ-5D Health questionnaire (EQ-5D), Brief pain inventory-short form (BPI-sf)-pain severity and patient global assessment (PGA). From postoperative 2 month, significantly lower score of VAS was observed in HD+TUF group. The difference of VAS was most prominent at postoperative 4 month. Out of patients who were followed up according to the protocol, significant number of patients were dropped out for pain after postoperative 4 months; 9.5% of HD+TUF group, 30.0% of TUF group (P=0.130). When the remaining patients were analyzed at 6 months, VAS was still significantly lower in HD+TUF group, but the score difference was decreased (Table 1).

assessed with Intention-To-Treat (ITT) analysis

O'Leary-Sant IC-Q	PUF	EQ-5D	BPI-sf-pain-severity	BPI-sf-pain-inter-ference	PGA	24hr frequency	nocturia /24hr	urg /2
27.0	23.0					14.0	3.3	8
25.0	22.0					14.0	3.0	9
0.748	0.776					0.589	0.411	0.5
7.0	7.5	1.0	0.0	0.3	2.0	9.3	2.0	0
13.3	11.5	0.8	1.8	1.4	2.3	11.8	2.8	3
0.093	0.075	0.012*	0.031*	0.707	0.016*	0.120	0.105	0.2
8.3	8.5	0.9	0.8	0.7	1.9	10.0	1.9	3
11.5	12.0	0.8	1.8	0.2	2.0	10.0	2.0	1
0.057	0.052	0.031*	0.023*	0.383	0.210	0.377	0.116	0.4
8.5	8.5	0.8	0.3	0.4	2.0	11.0	2.0	0
15.5	12.5	0.8	2.8	1.3	3.0	10.3	2.0	3
0.073	0.037*	0.098	0.010*	0.177	0.064	0.659	0.618	0.2
16.0	10.0	0.8	2.0	0.7	3.0	11.3	2.0	0
13.5	12.0	0.8	2.5	2.2	3.0	10.8	2.2	0
0.985	0.477	0.116	0.042*	0.199	0.909	0.813	0.971	0.4

ian values; Statistical analysis was performed using Mann–Whitney U test; VAS, Visual Analogue Sc
ptitis questionnaire; PUF, Pelvic Pain and Urgency/Frequency Patient Symptom Scale; EQ-5D, EQ-5
PGA, Patient Global Assessment; *, asymptotic significance (2-tailed) at P<0.05

Conclusions: HD + TUF combination was superior to TUF in treating the pain of IC / BPS. The most significant difference in therapeutic effect was observed at 4 months. Larger proportion of patients with TUF monotherapy required additional pain treatment within 6 months after surgery.