

## LONG-TERM TOLERABILITY AND EFFICACY OF PENTOSAN POLYSULPHATE SODIUM IN THE TREATMENT OF PATIENTS WITH BLADDER PAIN SYNDROME (BPS).

### Hypothesis / aims of study

The primary objective of this study is to evaluate the patient's compliance and long-term efficacy and tolerability of Pentosan Polysulphate Sodium (PPS) in the treatment of patients with Bladder Pain Syndrome (BPS). The secondary objective is to find the predictors of the long-term outcome

### Study design, materials and methods

This is a single institution, retrospective study. The study period was from 1994 to 2008. We have included all patients with bladder pain symptoms and either frequency, urgency or nocturia in the absence of urinary tract infection and any other pathology as per ICS definition. All patients had glomerulation with cystoscopic hydrodistention under general anaesthesia. We have included only patients with de novo PPS intake after the diagnosis of BPS. The urodynamic (UD) study was conducted in all patients. The Obstruction coefficient (OCO) in female and Bladder Outlet Obstruction Index (BOOI) in male were calculated to assess the bladder outlet during the pressure flow study (PFS) of the UD study. An OCO value  $\geq 0.35$  or BOOI value  $\geq 40$  was considered as evidence of Bladder Outlet Obstruction (BOO). The primary end point of this study is the overall improvement on the global response assessment scale (GPA). All side effects and adverse events were recorded and analysed

### Results

There were 271 patients eligible for the study. Most of the patients were female (90%), and the mean age at presentation was 45.5 year (SD  $\pm 13.9$ ). The average duration of symptoms was 28.5 month (SD  $\pm 25.4$ ). There was history of hysterectomy in 111 patients (40.9%) and 73 patients (26.9%) were taken antidepressant. The average maximum cystometric capacity was 251.3 ml (SD  $\pm 134.4$ ), while the average maximum cystoscopic bladder capacity under general anaesthesia was 659.1 ml (SD  $\pm 147.4$ ). The stress leak test was positive in 30 patients (11.1%). Detrusor overactivity (DO) on filling cystometry was documented in 39 patients (14.4%). Pressure flow study (PFS) was attempted for all patients, however only 131 patients (50.5%) were able to void during the test. Bladder outlet obstruction was present in 72 patients (54.9%).

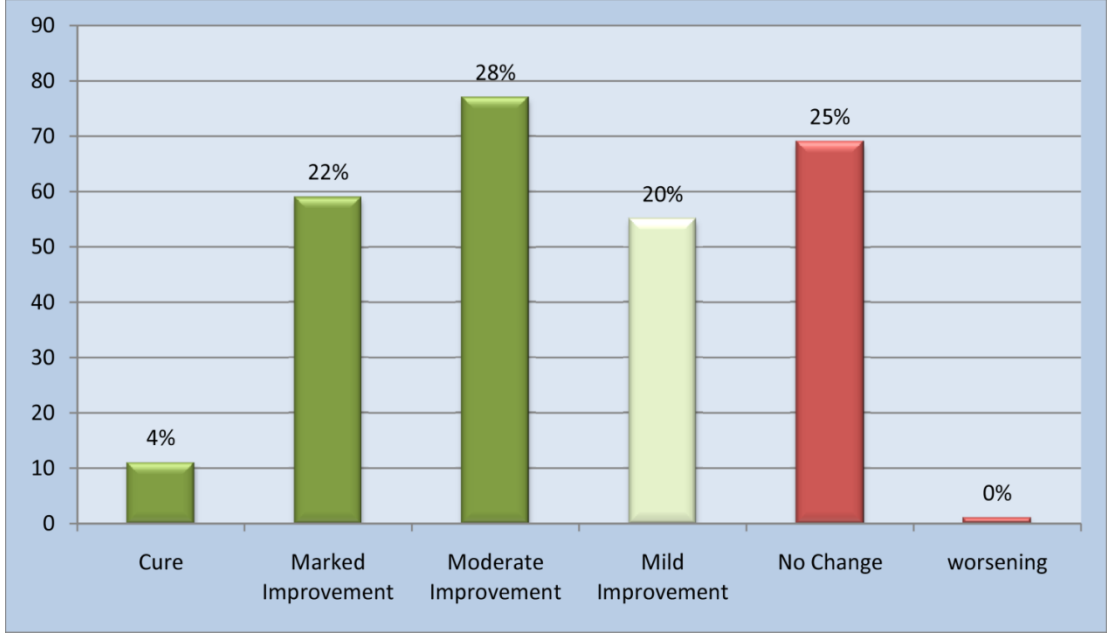
### Interpretation of results

With a mean follow up of 22 month (SD  $\pm 28$ ), 147 patients (54.2%) more than 50% improvements in there bothered symptoms on the GRA. There was mild improvement in additional 55 patients (20.2 %) (Graph1). Ninety three patients (34.3%) decided to stop taking the medication for various reasons. The most common reason to stop the medication was poor response in 45 patients (16.6%). Others include side effect in 30 patients (11.1%), resolution of the BPS symptoms in 11 patients (4.1%) and financial reason in 6 patients (2.2%). The side effects include stomach upset in 23 patients (8.5%), headache in 6 patients (2.2%), hair loss in 3 patients (1.1%), hypersensitivity in 3 patients (1.1%), and increase in liver enzyme in 2 patients (0.7%). Patients with history of severe nocturia or had DO during the UD were predictor of poor outcome of the PPS with p values of 0.01 and 0.037 respectively. For patients with more severe disease during cystoscopic evaluation, they had better outcome (p=0.013)

### Concluding message

The PPS is an effective oral therapy to control the symptoms of the BPS with good long-term efficacy and tolerability. More than 65% of patients continued to take the medication with median follow up of 22 months

Graph 1: The average grade of improvement with GRA.



<i>Specify source of funding or grant</i>	NONE
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Research Ethic Board for the Capital District Health Authority
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No