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# [Intervention Review]

# Intravesical treatments for painful bladder syndrome/ interstitial cystitis

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# ABSTRACT

#### Background

Painful Bladder Syndrome/Interstitial Cystitis (PBS/IC) occurs predominantly in women. It is a poorly-understood condition with symptoms of bladder pain, urinary frequency, urgency and nocturia. Treatments for PBS/IC include dietary/lifestyle interventions, oral medication, intravesical instillations and, in some cases, surgery. Success rates are generally modest and there is little consensus as to the best form of treatment for this condition.

#### Objectives

To assess the effectiveness of intravesical treatment for PBS/IC.

#### Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (30 May 2006) as well as reference lists of all selected trials. Recognised researchers in the field were contacted for any additional relevant material.

#### **Selection criteria**

Randomised or quasi-randomised controlled trials were included in the review if they had recruited participants with a clinical diagnosis of PBS/IC and if at least one arm of the trial was treatment with an intravesical preparation. Outcome measures were pre-determined, the primary ones being the effect on pain and bladder capacity. Others included symptomatic response to treatment, quality-of-life assessment, economic factors and adverse events.

#### Data collection and analysis

Two reviewers independently assessed trial eligibility and quality, then extracted relevant data from the studies.

#### **Main results**

Nine eligible trials were identified - six parallel group, one incomplete cross-over and two cross-over trials - with a total of 616 participants. Six trials compared an 'active' instillation with placebo instillation, two compared different types of instillation, and one was a comparison of an instillation plus bladder training versus bladder training alone. Altogether, the review included trials of six different types of intravesical instillation: Resiniferatoxin, Dimethyl sulfoxide, BCG, pentosanpolysulphate, oxybutin, and alkalinisation of urine pH. Confidence intervals were generally wide.

Resiniferatoxin was not associated with sustained differences in the review outcomes reported but pain during instillation and withdrawal from treatment was significantly more common. The data available about Dimethyl sulfoxide (DMSO) were very limited but with



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no apparent differences from placebo. Groups treated with BCG tended to report less pain and fewer general symptoms. Although adverse events were commonly reported, these were no more common after BCG than after placebo instillation. The few data about Pentosanpolysulphate tended to favour the actively treated, but with wide confidence intervals; there was little information about adverse events. Oxybutinin instillation was associated with increased bladder capacity, reduced frequency, improved quality of life scores and fewer drop-outs. Alkalinisation of urine pH did not make any clear difference, but with potentially wide confidence intervals.

### **Authors' conclusions**

Overall, the evidence base for treating PBS/IC using intravesical preparations is limited and the potential for meta-analysis reduced by variation in the outcome measures used. The quality of trial reports was mixed and in some cases this precluded any meaningful data extraction. BCG and oxybutin are reasonably well-tolerated and evidence is most promising for these. Resiniferatoxin showed no evidence of effect for most outcomes and caused pain, which reduced treatment compliance. There is little evidence for the other treatments included in this review. Randomised controlled trials are still needed and study design should incorporate outcomes that are most relevant to these with PBS/IC and should be standardised.

# PLAIN LANGUAGE SUMMARY

# Intravesical treatments for painful bladder syndrome/interstitial cystitis(PBS/IC).

Interstitial cystitis is also known as painful bladder syndrome. It typically causes symptoms of bladder and pelvic pain, an increased urge to pass urine and excessive urination during both day and night. The cause of the condition is not well-understood but it is thought to result from long-standing inflammation of the bladder. Many treatments have been used for PBS/IC and in this review we assess the effects of putting medication directly into the bladder (bladder instillations) to treat it.

We found nine studies that addressed this question, assessing six different types of treatment and involving 616 participants. For none of the instillations was the evidence conclusive. It was most promising for BCG (a type of tuberculosis bacterium) and possibly also for oxybutinin (a drug commonly taken orally to stop unwanted bladder contractions). Another agent, Resiniferatoixin, seemed to worsen pain and increase the likelihood of patients stopping treatment early. Little evidence was found for assessing benefits and harms of other treatments instilled into the bladder.