

CONTINUOUS INTRAVESICAL INFUSION OF RESINIFERATOXIN BY IN SITU DRUG DELIVERY SYSTEM TO TREAT INTERSTITIAL CYSTITIS: A PILOT STUDY.

Aims of Study

Interstitial cystitis (IC), a syndrome characterized by motor and sensory dysfunction of the lower urinary tract, represents a diagnostic and therapeutic challenge even to highly skilled physicians. Intravesical conservative vanilloid pharmacotherapy remains one of the mainstays in the treatment of IC. The aim of this study is to investigate the technical feasibility and the clinical efficacy of a continuous intravesical instillation of RTX by in situ drug delivery system in patients with IC.

Methods

The study involved 6 female patients (mean age 46.5 years), who presented a diagnosis of IC according to the Interstitial Cystitis Data Base (ICDB) study eligibility criteria. All patients reported frequency ($\neq 7$), nocturia ($= 2$) and urgency, and symptoms of pelvic pain for at least 6 months. The pre-treatment (PT) voiding pattern and a pain score (VAS scale) were recorded. Patients were evaluated after 30 days from the end of infusion (primary end point - PEP) and after three months (secondary end point - SEP). For each patient we considered the mean value of three consecutive determinations. A continuous intravesical infusion of RTX was performed by MiniMed^R 407C Infusion Pump (MiniMed^R Sylmar, CA – USA). The pump reservoir was filled with 3 ml of a saline solution contained 10nM RTX. The flow rate was 25?l/h (0.6 ml/die) x 10 days.

Results

At PEP frequency reduced from 11.8 ± 0.82 to 7.6 ± 0.65 ($p < 0.01$) and nocturia from 3.2 ± 0.34 to 1.43 ± 0.11 ($p < 0.01$). A highly significant reduction of pain score was observed at PEP; it decreased to 2.76 ± 0.34 from 7.1 ± 0.55 ($p < 0.01$). The pain score remained significantly lower at SEP (3.25 ± 0.6 $p < 0.05$). Nocturia was also statistically reduced at SEP (1.82 ± 0.65) as well as frequency (7.8 ± 1.52).

At SEP 1 patient reported the complete disappearance of symptoms, the other 5 claimed an improvement of their quality of life, even if their symptoms had not completely disappeared.

No side effects were reported during the infusion as well as after the removal of the catheter.

Conclusions

The present study demonstrates that the continuous intravesical instillation of RTX by in situ drug delivery system is a feasible, easy, safe and fast procedure and seems to support the efficacy of RTX in the treatment of IC patients. We know very well that sharp boundaries between protective and pathological role of bladder capsaicin-sensitive sensory nerves can not be easily drawn with present knowledge, but our hypothesis remains attractive. However further studies are necessary and mandatory to confirm our results and to define the exact action mechanism of continuous infusion of RTX, the dosage and the treatment schedule