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Compound aluminum sulfate injection monotherapy in non-muscle invasive bladder cancer in Chinese patients: A multi-center, open-label phase I / II clinical trial

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Objective: To evaluate the efficacy and safety of compound aluminum sulfate injection (CASI) in the treatment of non-muscle invasive bladder cancer(NMIBC) in patients.

Methods: A multi-center, open and non-controlled phase I/II clinical trial was designed. We enrolled 101 patients (age ≥18 years) with NMIBC at three clinical trial centers. CASI was directly injected into the root of NMIBC through catheter needle. Injection dose was determined by tumor size: <1cm: 2-6ml; 1-2cm: 4-8ml; 2-3cm: 6-10ml; >3cm: 8-16ml. Therapeutic effects was evaluated by effective rate (patients with complete tumor necrosis or tumor necrosis > 2/3) / all patients × 100%). Electrocardiogram, blood routine, urine routine and blood biochemistry examination were performed for safety evaluation. All data were input by EPI DATA 3.0 and analyzed by SAS 9.13.

Results: Eight of the 101 patients were detected blood aluminum concentration to evaluate the absorbance of aluminum sulfate after local administration. Only two patients in the middle dosage group showed significant elevation of aluminum concentration after injection, which decreased to the concentration around baseline within 24 hours. The rich blood supplement of the injection site might explain the aluminum absorption. The overall effective rate was 97.03% (98/101 patients), including 93.07% tumor necrosis completely (94/101 patients). Treatment-related adverse events (AE) occurred in 20 patients (19.80%). Nine patients (8.91%) experienced AE related to drug administration, including local pain, abdominal pain and anal irritation in. Other AE were related to urethral injury caused by cystoscopy. All AE were endurable and disappeared within 2-3 days without any treatment. The maximum tolerated single dose of CASI was 21ml.

Conclusion: As a convenient and compliant regimen, CASI had good efficacy and safety in the treatment of NMIBC.

Key Words: Compound aluminum sulfate injection, non-muscle invasive bladder cancer, efficacy, adverse effect, clinical trial.

Fig. 1. Injection of CASI. A. for NMIBC, hemispherical apoptosis appears after injection; B for MIBC, apoptosis with central depression appears after injection.

Recent Publications

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Biography

Fenghua Xu got her degree in Pharmaceutics in Peking University Health Science Center. She has her expertise in anti-cancer drug development and novel drug delivery system. She dedicate herself to develop therapeutic drugs with low adverse effect and easygoing administration method to relieve the patients and provide them better care. Her study involves natural entities, nanoscale and self-regulated drug delivery system. She has finished the preclinical studies of several new drug and hospital preparations for cancer treatment, four of which have got approval for clinical trial. She also practices in the manufacture and quality control of drug preparations and has set up a series of product quality standard.

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