Fibrin-sealant-delivered cisplatin chemotherapy versus cisplatin hyperthermic intraperitoneal perfusion chemotherapy for locally advanced gastric cancer without peritoneal metastases: a randomized phase-II clinical trial with a 40-month follow-up.

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Abstract:

A new intraoperative cisplatin administration method for patients with locally advanced gastric cancer (AGC) and without peritoneal metastasis, fibrin-sealant-delivered cisplatin chemotherapy, was reported, and its safety, pharmacokinetics, and efficacy were compared with cisplatin hyperthermic intraperitoneal perfusion chemotherapy. Forty-two AGC patients were randomly divided into 2 groups: fibrin-sealant-delivered cisplatin chemotherapy (FS) (n = 21) and cisplatin hyperthermic intraperitoneal perfusion chemotherapy (CHIC) (n = 21). Both groups received 120 mg cisplatin after complete cytoreductive surgery. At different time points, cisplatin concentrations in patients' sera and urine samples were measured to determine time-dependent maximal concentration (Cmax) and the area under the curve (AUC). The primary and secondary end-points were overall survival (OS) and safety profiling, respectively. Occurrence of grade-3 to grade-4 liver or kidney dysfunction was less frequent in the FS group than in the CHIC group (28.6 % vs 47.6 %). Cisplatin Cmax and AUC for the serum and urine of the FS patients were significantly lower than that of the CHIC patients. Elimination half-life of cisplatin in the FS group was significantly longer than in the CHIC group (24.1 h vs 14.2 h). After a median follow-up of 40 months, 1-, 2-, and 3-years OS were 90.5 %, 71.4 %, and 61.9 % in the FS group, and 61.9 %, 47.6 %, and 42.8 % in the CHIC group, respectively. The median OS was 35.9 months in the FS group and 29.1 months in the CHIC group. Fibrin-sealant-delivered cisplatin chemotherapy was as effective and had a

favorable pharmacokinetic profile with similar survival outcomes as cisplatin hyperthermic intraperitoneal perfusion chemotherapy following complete cytoreductive surgery of locally advanced GC without peritoneal metastases.