

Efficacy and safety of adjuvant post-surgical therapy with imatinib in patients with high risk of relapsing GIST.

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Abstract: **Background:** GIST has a high recurrence rate and disease-related mortality even after completed resection of primary tumor. Imatinib(IM) has shown tremendous efficacy in treating patients with metastatic and unresectable GISTs. The primary objective of the study was to evaluate the efficacy and safety of adjuvant post-surgical therapy with IM in GIST patients who had high risk to relapse. **Methods:** This prospective, open-label, multi-center trial was conducted in 16 hospitals in China. Patient eligibility criteria included patients >18 years old, diagnosed with CD117+ GIST of either =5cm macroscopic tumor size or = 5/50 HPF in mitosis count pathologically. Patients were started on IM 400mg/d for at least 12 months within 4 weeks after completed resection. Primary endpoint was relapse or metastasis rates. Secondary endpoints were disease free survival (DFS), overall survival rate (OSR) and quality of life. From Aug 16 2004 to Sep 13 2005, 57 patients (34 men) enrolled in the trial and average age of patients was 50.6. The primary tumor location was stomach in 50.9%, small intestine in 38.6%. Tumor size was >5cm in 92.9% of patients, and 73.7% of patients had a mitosis count over 5/50 HPF. The majority of patients tested positive for CD34 (82.5%) and negative SMA, S-100 and Desmin results. **Results:** Of 57 patients, as of date of data cut-off (Dec 31, 2006) 51 patients were included in the ITT analysis and 43 patients (75.4%) finished at least 12 months of IM treatment, and Tumor relapses or metastasis were identified in 2 patients (3.92%) 350 and 680 days post-operation. No death was reported. Median DFS was 385 days. 57.89% of the safety population had adverse events. No serious adverse event reported. 50.88% of the safety population had adverse events related to the treatment of IM based on the determination of investigators. The score in quality of life showed no statistically significant difference between the baseline and the follow-up visits. **Conclusions:** IM is a promising adjuvant post-

surgical therapy in patients with high risk of relapsing GIST. But the optimal doses and duration of adjuvant treatment are still unknown. On the basis of this study, a multi-institutional randomized controlled trial will be necessary.