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Feb 4, 2021, 4:33 PM

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The third arm was a dose-dense oxaliplatin-based combination. The first four patients received the same chemotherapy as the standard arm, but every 2 wk, two cycles of oxaliplatin (130 mg/m<sup>2</sup>) were given instead of the standard four cycles. These patients were offered six cycles of adjuvant chemotherapy. The remaining 31 patients received the same chemotherapy as the standard arm, but every 2 wk, two cycles of oxaliplatin (100 mg/m<sup>2</sup>) were given instead of the standard four cycles. These patients were offered six cycles of adjuvant chemotherapy. Chemotherapy consisted of a three-drug combination of vinorelbine (25 mg/m<sup>2</sup>) on d 1 and 8, followed by oxaliplatin (85 mg/m<sup>2</sup>) on d 1, every 2 wk. From the start of the study, the vinorelbine dose was reduced to 20 mg/m<sup>2</sup> (without a delay). Chemotherapy was given until disease progression, intolerable toxicity, or death. Patients were followed up every 3 months for the first 2 years and every 6 months thereafter. Thereafter, they were followed up once yearly. Data Collection and Statistical Analysis A preplanned interim analysis was performed after a median

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follow-up of 21 months. This analysis was planned when at least 50 patients had been followed up for at least 24 months and 10 patients had died. The analysis was stopped because there was a significant improvement in OS for the dose-dense arm versus the standard arm. However, the study was still ongoing when the results were presented at ASCO. Efficacy data were collected from the patients' medical records and recorded on a standardized data collection form. The data collection form was reviewed by a study monitor. The data collection form was designed to ensure that all data were entered accurately. The data collection form was reviewed for consistency and completeness by the study monitor, a research assistant, and an independent statistician. The survival time was calculated from the date of surgery to the date of death. The analysis was performed on an intention-to-treat basis. The Kaplan–Meier method was used to estimate survival. The  $\chi^2$  test was used to compare categorical variables. The  $\chi^2$  test was used to compare the differences in survival times between the two groups. All analyses were two-sided. Statistical analyses were performed using SAS software (SAS Institute, Inc., Cary, NC 82157476af

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