Pemetrexed and Gemcitabine Versus Carboplatin and Gemcitabine in Non-Small Cell Lung Cancer: A Randomized Noninferiority Phase II Study in One Center

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AUTHOR SUMMARY

ABSTRACT

Background. The standard treatment for non-small cell lung cancer (NSCLC) stages IIIb and IV is a platinum compound combined with a third-generation cytotoxic agent. We decided to conduct a phase II study to assess whether the platinum compound could be replaced with pemetrexed with similar results and without an increase in side effects.

Methods. Consecutive eligible patients were randomized to either the standard arm of gemcitabine plus carboplatin (GC) or the experimental arm of gemcitabine plus pemetrexed (GP).

Results. Fifty evaluable patients were enrolled in the GC arm, and 44 received GP. There were 10 partial responses in the GC arm and 16 in the GP arm. With GC, mean survival was 9 months compared with 15 months with GP. The side effects were similar in both groups.

Conclusion. Pemetrexed can replace platinum compounds in the first-line treatment of stage IIIb and IV NSCLC without increasing the side effects. A trend toward better survival was observed in the patients receiving pemetrexed instead of a platinum compound, and this should be studied further.

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DISCUSSION

This study was planned to determine whether, in the first-line setting, a platinum compound could be replaced with another cytotoxic agent for the treatment of stage IIIb and IV NSCLC without an increase in toxicity. Encouraging results were obtained, with the combination of gemcitabine and pemetrexed appearing to improve outcome, with more partial responses and longer survival with better tolerability (Fig. 1). Although the schedule of administration was different, doses were chosen to provide similar dose intensity of gemcitabine. The gemcitabine

Figure 1. Actual survival in the two arms.

Abbreviations: GC, gemcitabine and carboplatin; GP, gemcitabine and pemetrexed.

dose intensity was 833 mg/m² per week in GC and 750 mg/m² per week in GP. This minor dose difference is unlikely to explain any difference between the two groups.

In conclusion, this study found encouraging results when pemetrexed was substituted for a platinum compound in the first-line treatment of NSCLC without increasing the side effects. A trend toward better survival was observed with the GP combination, but the study was not powered to show this. Further studies with this combination seem warranted.

Author disclosures available online.

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