

Bevacizumab is safe in combination with chemotherapy for advanced non-squamous non-small cell lung cancer

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Researchers have confirmed the safety of treating advanced non-squamous non-small-cell lung cancer with bevacizumab in combination with chemotherapy. Crucially, this study, published Online First in *The Lancet Oncology*, did not uncover any new safety signals than found previously. The Article is by Prof Lucio Crin  at the Hospital Santa Maria della Misericordia, Perugia, Italy and colleagues, did not uncover any new safety signals than found previously.

As well as laying to rest any concerns there have been about the toxicity of such treatment, these findings are especially important because phase 4 studies are done in a broader patient population that better mirrors the realities of clinical practice than phase 3 studies. Crin  et al have now shown that the main previously known toxicities, including life-threatening effects such as bleeding, do not seem to be any more common in this broader population. The scale of this comprehensive study that spans 40 centres also means that it was well suited to assess toxicities, and look for rare but serious new safety signals.

Advanced non-small-cell [lung cancer](#) (NSCLC) is one of the most common types of cancer, and kills 1.18 million people every year. [Bevacizumab](#) is a monoclonal antibody that blocks vascular endothelial growth factor A (VEGF-A), which stimulates the growth of new blood vessels. Thus, the antibody is a useful adjunct to chemotherapy, and it has shown meaningful activity in combination with chemotherapy in two

different phase 3 studies.

Prof Lucio Crin  at the Hospital Santa Maria della Misericordia, Perugia, Italy and colleagues recruited 2212 patients with advanced or recurrent non-squamous NSCLC from 40 countries across six continents. They were given 7.5 or 15.0 mg/kg of bevacizumab every 3 weeks, plus standard chemotherapy for up to six cycles, followed by single-agent bevacizumab until disease progression.

There were few clinically significant (grade ≥ 3) adverse events. For example, only 1% (15 patients) had pulmonary haemorrhage and 4% (80 patients) had bleeding. Overall, 57 (3%) patients died because of adverse events, with thromboembolism (26 patients, 1%) and bleeding (17, 1%) as the most common causes. The most common grade 3 or higher serious adverse events that the investigators judged to be associated with bevacizumab were pulmonary embolism (28 patients; 1%) and epistaxis, neutropenia, febrile neutropenia, and deep vein thrombosis (all of which occurred in 13 patients [1%]).

The authors say: "The study findings confirm the well established and manageable safety profile of bevacizumab, add to the efficacy evidence supporting the use of bevacizumab in first-line treatment, and establish the relevance of findings from randomised phase 3 studies to treatment with bevacizumab in a clinical practice setting."

They conclude: "The results of the SAiL study show that first-line bevacizumab in combination with standard [chemotherapy](#) regimens and continued until disease progression has an acceptable and manageable safety profile, with no new safety signals reported, and offers clinical benefit to patients with advanced or recurrent non-squamous NSCLC."

In an accompanying Comment, Robert Pirker at the Medical University of Vienna, Austria, describes the findings as "reassuring", and says that

"careful patient selection according to the criteria used in SAiL and surveillance during treatment should guarantee the safe use of bevacizumab in routine practice."

PIrker says that the next challenge is to establish the drug's effect on survival through randomised trials.

"Other important issues regarding bevacizumab remain the optimum dose, the contribution of maintenance treatment to the overall benefit, and the characterisation of a clinically useful biomarker," he adds.

Provided by Lancet

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