There have been recent calls for the withdrawal of tiotropium (Spiriva) Respimat due to an increased risk of dying found in randomised trials that have compared the Respimat inhaler to placebo in patients with chronic obstructive pulmonary disease (COPD). This increased risk of mortality has not been found in the similar trials of tiotropium Handihaler (Spiriva). So how big is the increased risk that was found and how does it compare to the benefits of tiotropium Respimat in preventing COPD exacerbations?

If we consider the benefits of treatment first, the studies that were carried out over one year found that 42 per cent of those in the placebo group had one or more exacerbations, compared to only 35 per cent in the tiotropium Respimat group. So this means that in comparison if 100 people were given tiotropium Respimat instead of placebo, seven less would suffer from an exacerbation. This is shown in the Cates plots in Figure 1.

When we consider the mortality statistics, the trials found a statistically significant increase of the risk of dying in the people treated with the Respimat inhaler; the relative risk showed an increase of 1.47 (95% CI 1.03–2.09). However, in comparison to the risk of having an exacerbation of COPD, the risk of dying was much lower, at 1.8 per cent over one year. So although the increased risk of dying seems large in relative terms (an increase of nearly a half in the risk of dying on Respimat), the Cates plots in Figure 2 look rather different. We see that the mortality rate on placebo is 2 per 100 and this risk increases to 3 per 100 on Respimat.

Since this increased risk of dying has not been found in trials of tiotropium Handihaler, this is currently the safer option to use. The benefits of both types of tiotropium inhaler look very similar. However, for people who are unable to use the Handihaler device and are keen to try Respimat instead, the Cates plots in this article can be used to explain the trade-off between the likely risks and benefits of using Respimat.

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Illustrating risk vs benefit with the tiotropium Respimat inhaler

Patient decision aids present evidence-based estimates of the risks and benefits of a particular treatment. Here, Dr Chris Cates illustrates the benefit of tiotropium in reducing exacerbations in COPD and the increased risk of mortality associated with administration via the Respimat inhaler.

Figure 1. On placebo 42 people out of 100 had one or more exacerbation over one year, compared to 35 (95% CI 33–37) out of 100 for the tiotropium Respimat group.
Figure 2. On placebo two people out of 100 died over one year, compared to three (95% CI 2–4) out of 100 for the Respimat group.