

#ESCCongress: PRONOUNCE Trial - Safety of ADT Remains Unresolved



Late-breaking research from the PRONOUNCE trial was presented in a Hot Line session at ESC Congress 2021. The cardiovascular safety of androgen deprivation therapy (ADT) for prostate cancer remains unresolved after the trial was terminated early.

Every year, approximately one million men are diagnosed with prostate cancer worldwide. These patients are at a high risk of developing cardiovascular disease and are more likely to die from it than their healthy peers.

Nearly 50% of patients with prostate cancer are prescribed ADT at some point in their illness. However, ADT has been associated with heart disease and stroke, especially in men with pre-existing cardiovascular disease. It is still unclear whether this is driven by the method of androgen deprivation or modulation of the gonadotropin-releasing hormone (GnRH) receptor. Previous studies suggest that GnRH antagonists may have a preferable cardiovascular safety profile.

The PRONOUNCE trial compared the cardiovascular safety of a GnRH antagonist versus a GnRH agonist in patients with cancer care. The trial was designed to enrol 900 men with prostate cancer and concomitant atherosclerotic cardiovascular disease. Patients received the GnRH antagonist degarelix or the GnRH agonist leuprolide for 12 months. The primary outcome of the study was the time to first occurrence of a major cardiovascular event (defined as a composite of death, myocardial infarction or stroke). However, the trial was terminated prematurely due to low enrollment, and only 545 patients were included in the final analysis.

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Comparing CV safety of degarelix vs. leuprolide in patients with advanced prostate cancer and CV disease

Conclusion

 The relative CV safety of different types of androgen deprivation therapy (ADT) for prostate cancer remains unresolved after the PRONOUNCE trial was terminated early. At 12 months, no statistically significant difference in the rate of major adverse CV events (MACEs) was observed between patients treated with degarelix versus leuprolide.

Impact on clinical practice

 More than one million men are diagnosed with prostate cancer worldwide every year. These patients are at high risk of developing CV disease (CVD) and are more likely to die from CVD than their healthy peers. Approximately 50% of all patients with prostate cancer will be prescribed ADT at some point in their illness. ADT has been associated with heart disease and stroke, particularly in men with pre-existing CVD.

Study objectives

 PRONOUNCE was the first randomised clinical trial to prospectively compare the CV safety of ADT with a gonadotropin-releasing hormone (GnRH) antagonist versus GnRH agonist in patients with prostate cancer.

Results of the PRONOUNCE trial show no statistically significant difference in the rate of major cardiovascular events between patients treated with degarelix or leuprolide. The relative cardiovascular safety of GnRH antagonists and agonists thus remains unresolved.

Source: [ESC](#)

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