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## ORBITA trial: no significant benefit from PCI in stable angina



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Results from the ORBITA trial show that among patients with stable angina, percutaneous coronary intervention (PCI) had no significant additional benefit on patient symptoms or quality of life. Carried out in the UK, the multicentre randomised, placebo-controlled study compared the artery-widening technique (stenting) with a simulated procedure – where a stent was not implanted.

Coronary artery stents are lifesaving for heart attack patients, but the study's findings suggest that the placebo effect may be larger than previously thought. The findings are published in *The Lancet*.

Stable angina is a common condition in adults in which patients feel chest pain as a result of over-exertion due to restricted blood flow to the heart. It is typically caused by the build-up of fatty plaques in the arteries and a hardening of the blood vessel walls, which makes them narrower and less flexible. Patients can manage the condition with drugs such as beta-blockers or nitro-glycerine, however, some may undergo an invasive procedure, known as angioplasty with stent or percutaneous coronary intervention (PCI).

An estimated 500,000 patients around the world undergo PCI each year for stable angina, and the procedure is thought to bring substantial relief from symptoms for patients. However, since the procedure was introduced it has been unclear whether the relief of symptoms is due to the treatment or to a placebo effect.

As part of the ORBITA trial, researchers recruited 200 patients through hospitals in London and the south of England. All patients had stable angina, and had a narrowing in one single coronary vessel. Once enrolled the patients had a six-week phase of intensive medical treatment in which the medications used to treat angina were introduced and increased to maximal doses.

Patients were randomised to receive either a heart stent, or to undergo a placebo procedure in which they had an angiogram procedure, but did not receive the stent. Of the patient group, half received the stent and half had the placebo procedure. For the next six weeks the patients and their doctors did not know which one they had had. Both before and six weeks after undergoing the procedure, patients had exercise tests to assess how fast they could walk on a treadmill while their heart and lung function were measured. The primary outcome was a change in the amount of time they could exercise after the procedure.

The researchers found the average increase in overall exercise time was 28.4 seconds for patients who had PCI and 11.8 seconds for the placebo group. However, the difference between the groups was not statistically significant, meaning they could not say the effect was down to the stent, or down to chance. There were also no significant differences in patient-reported improvement of symptoms in either group.

Notably, the tests confirmed that stenting significantly relieved the narrowing in the coronary artery and improved the blood supply to the heart.

The researchers were surprised over the findings as they had expected that exercise capacity and symptoms would improve once the artery had been opened and the blood supply improved.

"It seems that the link between opening a narrowing coronary artery and improving symptoms is not as simple as everyone had hoped," said lead author Dr. Rasha Al-Lamee, from the National Heart & Lung Institute at Imperial College London. "This is the first trial of its kind and will help us to develop a greater understanding of stable angina, a disease which affects so many of our patients every day."

More analysis is expected from the ORBITA trial as the researchers aim to delve deeper into the data to see whether there are subgroups of patients whose angina improves more after stenting.

Source: [Imperial College London](#)

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