ONTARGET adds telmisartan to the gold standard list of anti-hypertensives

At a recent local press conference at the Hilton Hotel, Johannesburg, the results of the landmark ONTARGET® trial were presented by Professor Pinky Sareli. This trial establishes telmisartan 80 mg as the only ARB clinically proven, to be as protective, but better tolerated than ramipril 10mg, in a broad high-risk cardiovascular population. From ONTARGET it may be concluded that telmisartan can prevent every 5th serious cardiovascular event. Prof Sareli further stated, categorically, that this is not an ARB class effect, but only applies to telmisartan.

Results of 25,620 patient study ONTARGET® (ONgoing Telmisartan Alone and in combination with Ramipril Global Endpoint Trial) were presented at the 57th Annual Scientific Session of the American College of Cardiology.[1]

The results of the landmark ONTARGET® Trial have proven that telmisartan, brand name MICARDIS®, an angiotensin II receptor blocker (ARB), is as protective as the current gold standard, ramipril, in reducing the risk of cardiovascular death, myocardial infarction, stroke, and hospitalisation for congestive heart failure in a broad cross-section of high-risk cardiovascular patients and with better tolerability.[1] These cardiovascular events occurred in 16.66% of patients receiving telmisartan versus 16.46% of patients receiving ramipril.[1] The relative risk (ratio of the probability of the event occurring in the telmisartan group versus the ramipril group) was 1.01, with a 95% CI of 0.94 -1.09.

In 2000, the HOPE trial showed that the cardiovascular risk for patients treated with ramipril is reduced by approximately 20% compared with placebo.[2] This meant that every fifth serious cardiovascular event in a high risk group of patients was prevented. A similar effect can now be attributed to telmisartan. The 25,620 high-risk patients in the ONTARGET® Trial were already receiving standard care such as statins to lower cholesterol, antiplatelet therapy, betablockers and other antihypertensives.[3]

Telmisartan was also shown to be significantly better tolerated than ramipril, a widely used angiotensin converting enzyme inhibitor (ACE-I), with respect to typical ACE-inhibitor side-effects.[1] Although patients with an ACE-inhibitor intolerance had been excluded from the trial, 360 patients in the ramipril treatment arm stopped their treatment because they experienced cough versus only 93 patients in the telmisartan arm. 25 patients stopped their treatment in the ramipril arm because of angioneurotic edema, versus only 10 in the telmisartan arm.[1]

The ONTARGET® data also show that telmisartan is associated with a higher treatment compliance.[1] Besides efficacy, tolerability and compliance are also important factors to consider as they are crucial for effective long-term treatment for the prevention of serious cardiovascular events.

Telmisartan is now the only angiotensin II receptor blocker (ARB) to have proven cardio & vascular protective benefits beyond blood pressure reduction in this high-risk population.[1] Until now, only the ACE-inhibitor ramipril had shown these protective effects.[2]

ONTARGET® also studied the value of combining telmisartan with ramipril, to answer a key question for the clinical community – does combining an ACE inhibitor and an ARB, i.e. the dual renin-angiotensin system (RAS) blockade, offer even better protection compared to single blockade? The results announced yesterday indicate that there is no additional protective benefit achieved for the overall patient population, if ramipril and telmisartan are combined.

Implications of the ONTARGET® Trial

"The ONTARGET® Trial shows that telmisartan is a well-tolerated treatment in high-risk cardiovascular patients that is as effective as ramipril in preventing heart attacks, stroke, hospitalisations for heart failure and deaths", said Professor Salim Yusuf, lead investigator of the ONTARGET® Trial Programme and Director of the Population Health Research Institute at McMaster University, Hamilton, Canada. "The ONTARGET results have important implications for the management of patients with cardiovascular diseases. We now have a new treatment option for high-risk patients which is effective and better tolerated."

Largest ARB outcome trial ever

ONTARGET® is a randomised, double-blind clinical trial, which evaluated 25,620 high-risk cardiovascular patients with normal or controlled blood pressure over an observation period of up to 6 years.

"We are proud to have started ONTARGET®, the largest outcome cardiovascular trial ever undertaken with an ARB. It included high-risk cardiovascular patients with a history of coronary heart disease, stroke, transient ischaemic attack, peripheral vascular disease or diabetes with target organ damage. The trial has an extremely robust data base that will enable the medical community to answer questions where no scientific proof was available before. With 99.8% of patients followed over these years, this is one of the best managed landmark trials ever. We owe this excellent management of the trial to the investigators in over 700 centres across 40 countries led by Professor Salim Yusuf and his team at McMaster University, Hamilton, Canada." said Dr Andreas Barner, Member of the Board of Managing Directors of Boehringer Ingelheim, responsible for Research, Development and Medicine.

Benefits related to exceptional properties and structure of telmisartan

Further evidence of the exceptional properties of telmisartan has already been seen in previous trials. In 2007, the AMADEO trial showed that telmisartan achieved significantly greater reduction in proteinuria compared with the ARB losartan beyond blood pressure reduction effects, demonstrating the potential for renal protection with telmisartan in diabetic patients.[4] In addition, in 2006 the PRISMA trials in hypertensive patients demonstrated that telmisartan achieved more powerful blood pressure reductions compared with the ACE-inhibitor ramipril.[5,6]

"The benefits of telmisartan seen in ONTARGET® and previous trials may be attributed to the specific pharmacological properties and mode of action of telmisartan, including long half-life, large volume of distribution, high cell penetration and a selective AT_1 blockade. ONTARGET® now provides the evidence that the properties of telmisartan translate into relevant clinical outcomes", commented Professor Michael Böhm, Director of the Department of Cardiology, Universitätsklinik des Saarlandes, Homburg, Germany and National Coordinator of the ONTARGET® Trial in Germany.

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