

ROADMAP study had normal blood pressure and/or controlled hypertension (with at least one other cardiovascular risk factor) at the start of the study. Finally, we would like to mention that in Spain, olmesartan is authorized exclusively for the treatment of arterial hypertension.<sup>5</sup>

#### Note

The opinions expressed in this letter are the responsibility of the authors, and do not necessarily reflect the point of view of the organizations they work for.

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#### REFERENCES

1. Consuegra-Sánchez L, Sanchis J, Núñez J, Cascón JD, Villegas M, Picó F. Aumento de mortalidad asociado a olmesartán en pacientes diabéticos para la prevención o retraso de microalbuminuria: ¿es una causa de preocupación? Rev Esp Cardiol. 2012;65:378–80.
2. Haller H, Ito S, Izzo Jr JL, Januszewicz A, Katayama S, Menne J, et al.; ROADMAP Trial Investigators. Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. N Engl J Med. 2011;364:907–17.
3. Imai E, Chan JC, Ito S, Yamasaki T, Kobayashi F, Haneda M, et al.; ORIENT study investigators. Effects of olmesartan on renal and cardiovascular outcomes in type 2 diabetes with overt nephropathy: a multicentre, randomised, placebo-controlled study. Diabetologia. 2011;54:2978–86.
4. Imai E, Ito S, Haneda M, Chan JC, Makino H; ORIENT Investigators. Olmesartan reducing incidence of endstage renal disease in diabetic nephropathy trial (ORIENT): rationale and study design. Hypertens Res. 2006;29:703–9.
5. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS): Olmetec® technical data sheet (Olmesartan medoxomil) [accessed 5 Mar 2012]. Available at: <http://www.aemps.gob.es/cima/especialidad.do?metodo=verFichaWordPdf&codigo=65496&formato=pdf&formulario=FICHAS&file=ficha.pdf>

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### Olmesartan for the Prevention or Delay of Diabetic Nephropathy: Some Considerations. Response

#### Uso de olmesartán en la prevención o retraso de la nefropatía diabética: algunas consideraciones. Respuesta

#### To the Editor,

We appreciate the letter from Catalá-López et al. in response to our recently published article.<sup>1</sup> We agree that a relative risk for cardiovascular mortality that is 3 times greater in the intervention group, combining the Randomized Olmesartan And Diabetes Microalbuminuria Prevention (ROADMAP)<sup>2</sup> and Olmesartan Reducing Incidence of Endstage renal disease in diabetic Nephropathy Trial (ORIENT)<sup>3</sup> results, is not very promising. We find it interesting that the authors reminded us clinicians that olmesartan is authorized “exclusively” for the treatment of arterial hypertension in Spain, as the increased risk of cardiovascular death has mainly been observed in diabetic subjects, normotensive subjects for the most part, who use it to prevent diabetic nephropathy.

However, we would like to add the following considerations to the comments by Catalá-López et al. First, our study included all the articles published up to 30 April 2011 that met a series of criteria explained in detail in the original article.<sup>1</sup> The results of the ORIENT<sup>3</sup> study were published online (PubMed) 6 months later. Our strategy to include only indexed studies is the strategy used most frequently in systematic reviews. Second, we believe that the observations of our meta-analysis are relevant although, as Catalá-López et al. pointed out, they did not fully answer the question posed. Persistent microalbuminuria is an early sign of nephropathy in type 2 diabetics, and it is associated with the presence of macroalbuminuria and end-stage renal disease.<sup>4</sup> In turn, it is accepted that slowing down the progression to end-stage renal

disease (eg, by reducing the urinary excretion of albumin) can have a positive impact on the survival prognosis. In this regard, a lot of work has focused on angiotensin II receptor blockers and it is paradoxical that an intervention that can significantly reduce the incidence of microalbuminuria in a little over 3 years is also accompanied by unfavorable outcomes in terms of mortality. A similar finding—unfavorable—was reported in the Irbesartan Patients with Diabetes And MicroAlbuminuria (IRMA-2)<sup>5</sup> study. Therefore, we believe that our metaanalysis was relevant in evaluating the “trends” observed in at least 2 previous studies.<sup>2,5</sup> Finally, we also believe that the neutral effect on overall mortality we obtained (relative risk=1.04) in patients with active treatment is a cause for reflection, if not concern.

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#### REFERENCES

1. Consuegra-Sánchez L, Sanchis J, Núñez J, Cascón JD, Villegas M, Picó F. Aumento de mortalidad asociado a olmesartán en pacientes diabéticos para la prevención o retraso de la microalbuminuria: ¿es una causa de preocupación? Rev Esp Cardiol. 2012;65:378–80.

2. Haller H, Ito S, Izzo Jr JL, Januszewicz A, Katayama S, Menne J, et al. Olmesartan for the delay or prevention of microalbuminuria in type 2 diabetes. *N Engl J Med.* 2011;364:907–17.
3. Imai E, Chan JC, Ito S, Yamasaki T, Kobayashi F, Haneda M, et al.; ORIENT study investigators. Effects of olmesartan on renal and cardiovascular outcomes in type 2 diabetes with overt nephropathy: a multicentre, randomised, placebo-controlled study. *Diabetologia.* 2011;54:2978–86.
4. Burgess E. Slowing the progression of kidney disease in patients with diabetes. *J Am Soc Hypertens.* 2008;2:S30–7.
5. Parving HH, Lehnert H, Bröchner-Mortensen J, Gomis R, Andersen S, Arner P. The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. *N Engl J Med.* 2001;345:870–8.

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