

Low dose spironolactone reduces blood pressure in patients with resistant hypertension and type 2 diabetes mellitus: a double blind randomized clinical trial

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PMID: 24107738. DOI: [10.1097/HJH.0b013e3283638b1a](https://doi.org/10.1097/HJH.0b013e3283638b1a)

Abstract

Background: The increased risk of cardiovascular morbidity and mortality associated with arterial hypertension is particularly pronounced in patients with type 2 diabetes mellitus. Blood pressure control is, therefore, decisively important but often not sufficiently achieved.

Objective: The primary objective of this study was to evaluate the antihypertensive effect of low dose spironolactone added to triple therapy for resistant hypertension in patients with type 2 diabetes measured by ambulatory monitoring. Secondary objectives were to evaluate the effects on glycaemic control and urinary albumin excretion as well as adverse effects.

Methods: In a multicentre, double-blind, randomized, placebo-controlled study 119 patients with blood pressure at or above 130/80 mmHg despite triple antihypertensive therapy were included. One tablet of 25 mg spironolactone or placebo was added to previous treatment and increased to two if blood pressure below 130/80 mmHg was not achieved after 4 weeks. Blood pressure was measured by ambulatory monitoring at baseline and after 16 weeks.

Results: The study was completed by 112 patients, 57 randomized to spironolactone and 55 to placebo. Average daytime placebo-corrected blood pressure was reduced by 8.9 (4.7-13.2)/3.7 (1.5-5.8) mmHg. Also office blood pressure, night-time, 24-h and pulse pressures were reduced significantly. Urinary albumin/creatinine ratio was significantly reduced in the spironolactone group. Glycaemic control remained unchanged. Hyperkalemia was the most frequent adverse event leading to dose reduction in three cases and discontinuation in one, whereas gynaecomastia was not reported.

Conclusion: Low dose spironolactone exerts significant BP and urinary albumin creatinine ratio lowering effects in high-risk patients with resistant hypertension and type 2 diabetes mellitus.