



**RESEARCH ARTICLE**

**PHARMACOLOGY**

**FIXED DOSE COMBINATION OF TELMISARTAN AND HYDROCHLORTHIAZIDE:  
IS IT TOTALLY SAFE**

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**ABSTRACT**

This case report highlights the rare side effects of fixed dose combination of Telmisartan and Hydrochlorothiazide 80mg/12.5mg in two young hypertensive males leading to drug withdrawal.

## KEY WORDS

Hypertension, Telmisartan, Hydrochlorothiazide, drug withdrawal

## INTRODUCTION

Hypertension is the most common cardiovascular disease and such patients usually require two or more anti-hypertensive drugs to reduce the blood pressure to safer levels.<sup>1,2</sup> Fixed dose combination of Telmisartan/Hydrochlorothiazide in doses of 40mg/12.5mg and 80mg/12.5mg are available in many countries for the treatment of essential hypertension.<sup>2,3</sup> Various clinical studies have shown that this combination is rational, has a significant therapeutic effect and a good tolerability profile in adult Indian patients of all ages with mild to moderate hypertension.<sup>2,3,4</sup>

## CASE REPORT

A 36 year hypertensive male on Telmisartan 80mg + Hydrochlorothiazide 12.5mg once daily since 02.11.2010 presented with lethargy, generalized weakness, fatigue, dizziness and loss of interest in work on 28.01.2011 in Medicine Out Patient Department at Safdarjung Hospital, New Delhi. His blood pressure was well controlled but on 29.01.2011 his blood tests showed fasting sugar levels 136 mg/dl and uric acid 7.49 mg/dl. Serum electrolytes like Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup> were within normal limits. There is no history of any other illness/medication. Due to above symptoms this combination had to stop immediately and patient was put on Losartan 50mg + Amlodipine 5mg once daily. Patient recovered in 5 days from above symptoms after discontinuing Telmisartan+ Hydrochlorothiazide combination and blood pressure was also well controlled with Losartan+ Amlodipine combination. Fasting blood sugar and serum uric acid levels also came to normal levels on 01.03.2011 i.e. after one month of starting new combination.

In another similar case, a 36 year hypertensive male on Telmisartan 80mg+

Hydrochlorothiazide 12.5mg once daily since 05.04.2010 presented with mild headache, dizziness, fatigue, weakness, paresthesias, loss of appetite and lack of concentration on 11.05.2010 in Medicine Out Patient Department at Safdarjung Hospital, New Delhi. There is no history of any other medication and no history suggesting the presence of these symptoms before the start of treatment. Due to these symptoms this combination had to be stopped immediately and the patient was put on Bisoprolol once a day. On 18.05.2010, after 7 days of discontinuing Telmisartan + hydrochlorothiazide and starting new combination, patient's blood pressure was well controlled and all the side effects disappeared.

## DISCUSSION

It has been estimated that Telmisartan 80mg + Hydrochlorothiazide 12.5mg once daily is generally well tolerated with rare side effects like headache, paresthesias, weakness, anorexia, nausea, vomiting and diarrhea.<sup>3,4,5,6</sup> The incidence of all adverse effects with this combination in various double blind studies is 44.8% and 3.9% of the total cases present with mild side effects such as fatigue, dizziness, nausea, diarrhea and headache.<sup>4,6</sup> In both the cases, rare side effects like generalized weakness, lethargy, dizziness and fatigue were so severe that this combination had to be withdrawn in addition to hyperglycemia and hyperuricemia in the first case. Studies with this combination have shown that hyperuricaemia has occurred in <0.1% of the patients and the incidence of discontinuation due to adverse effects is 4.7%.<sup>6</sup> According to Naranjo's Algorithm and WHO assessment scale, Causality assessment of these adverse effects to this combination seems to be Probable.

Both the case reports are examples of drug withdrawal because of rare but the side effects that were compromising the quality of life. Hence, hypertensive patients put on fixed dose combination of Telmisartan +

Hydrochlorothiazide should be monitored for the occurrence of even mild and rare side effects, so that their quality of life may not be compromised.

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