# PREVALENCE OF ADVERSE DRUG REACTIONS IN PATIENTS ON METFORMIN HYDROCHLORIDE IN THE COMMUNITY


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# ABSTRACT

The drug of choice for all patients with type 2 diabetes is Metformin hydrochloride which is a biguanide. The main adverse effects of metformin are GI upset, that taken in the form of nausea, vomiting, diarrhea, Lactic acidosis etc. This study was done to identify the self-reported adverse event of metformin hydrochloride, the association of adverse effect of metformin hydrochloride and its combinations with age and gender and to understand the relation between adverse events of metformin hydrochloride with the comorbidities present among the individuals. The study was carried out at in diabetic patients located at Alappuzha, Ernakulam and Kozhikode districts in Kerala in a period of one month, starting from April 20 to June 30, 2023.

In this study we identified the self-reported adverse drug reactions of metformin hydrochloride and it's combinations, that are fatigue (23.5%) gastritis (10.8%) dizziness, dyspepsia (7.8%) metallic taste (3.9%) hypoglycemia (2.9%) constipation (2.0%). As per our study diabetic patients who have other disease are more prone to adverse drug reactions.



## KEY WORD

Diabetes mellitus; Metformin ADR; diabetic patients; survey

# INTRODUCTION

Diabetes mellitus is a group of common endocrine diseases characterized by sustained high blood sugar levels. Diabetes is due to either the pancreas not producing enough insulin, or the cells of the body not responding properly to the insulin produced. The initial problems of diabetes result from an impairment of carbohydrate metabolism, but it is the aberration in fat metabolism that is often responsible for the death of the patient.[1,2,3]

A fasting blood sugar level of 99 mg/dL or lower is normal, 100 to 125 mg/dL indicates you have prediabetes, and 126 mg/dL or higher indicates you have diabetes.[4]

Clinical classification of diabetes mellitus; [5]

1. Diabetes mellitus (DM)

i) Insulin-dependent diabetes mellitus (IDDM, Type 1)

ii) Non-insulin dependent diabetes mellitus (NIDDM, Type 2)

iii) Malnutrition-related diabetes mellitus (MRDM)

iv) Other types (secondary to pancreatic, hormonal, drug-induced, genetic and other abnormalities)

2. Impaired glucose tolerance (IGT )

3. Gestational diabetes mellitus (GDM)

Epidemiology:[5]

The underlying causes of diabetes are

a) Pancreatic disorders – inflammatory, neoplastic and other disorders such as cystic fibrosis,

b) Defects in the formation of insulin

c) Decreased insulin activity

e)genetic defects etc

Symptoms of diabetes:

weight loss, obesity, white spots on shoes, Dry mouth and tongue, deep sighing respiration, skin infections – boils, candidiasis [6]

These drugs can be classified according to their mechanism of action as insulinotropic or non-insulinotropic. They are available as monotherapy or combination therapies, with the latter involving two (or, less commonly, three) antidiabetic drugs and/or insulin. The drug of choice for all patients with type 2 diabetes is **Metformin.**[7]

The drug **Metformin Hydrochloride** is a biguanide. It's mechanism of action of metformin is not clear. Apparently, it acts by several mechanisms as follows;

i)decreases the intensity of hepatic gluconeogenesis.

ii) it intensifies the glycolysis in the tissues.

iii)it decreases the serum glucagon level

iv) It decreases the rate of glucose absorption from the gut.

Metformin is not metabolised in the body. it is excreted unchanged by kidney. it has a

Half-life of nearly 2 hours. metformin can lower blood glucose level in diabetic even in absence of beta cells.[8]

Following are the adverse effects of metformin:

- GI upset that taken in the form of nausea, vomiting, diarrhoea
- Lactic acidosis
- Long term use of metformin can produce vitB12 deficiency [5]

**DOSAGE NOTE: Adult > 17years**

Immediate-release; Initial dose: 500 mg orally twice a day or 850 mg orally once a day

Dose titration: Increase in 500 mg increments weekly or 850 mg every 2 weeks as tolerated

Maintenance dose: 2000 mg/day in divided Dose

Maximum dose: 2550 mg/day

Extended-release:

Initial dose: 500 to 1000 mg orally once a day

Dose titration: Increase in 500 mg increments weekly as tolerated

Maximum dose: 2000 mg/day.

**10 years or older:**

Immediate-release: Initial dose: 500 mg orally twice a day

Dose titration: Increase in 500 mg increments weekly as tolerated; daily dose should be taken in divided doses 2 to 3 times a day with meals

Maximum dose: 2000 mg/day

Extended-release oral suspension:

Initial dose: 500 mg orally once a day with evening meal

Dose titration: Increase in 500 mg increments weekly based on glycemic control and tolerability

Maximum dose:2000 mg/day

Elderly: The initial and maintenance dosing should be conservative, due to the potential for Decreased renal function. Generally, elderly patients should not be titrated to the maximum dose of metformin. Do not use in patients ≥80 years of age unless normal renal function has been established.[9]

## COMBINATION OF METFORMIN

The combination of metformin with other antidiabetic drugs are widely prescribed for effective blood glucose control. The combination of metformin are ;[10]

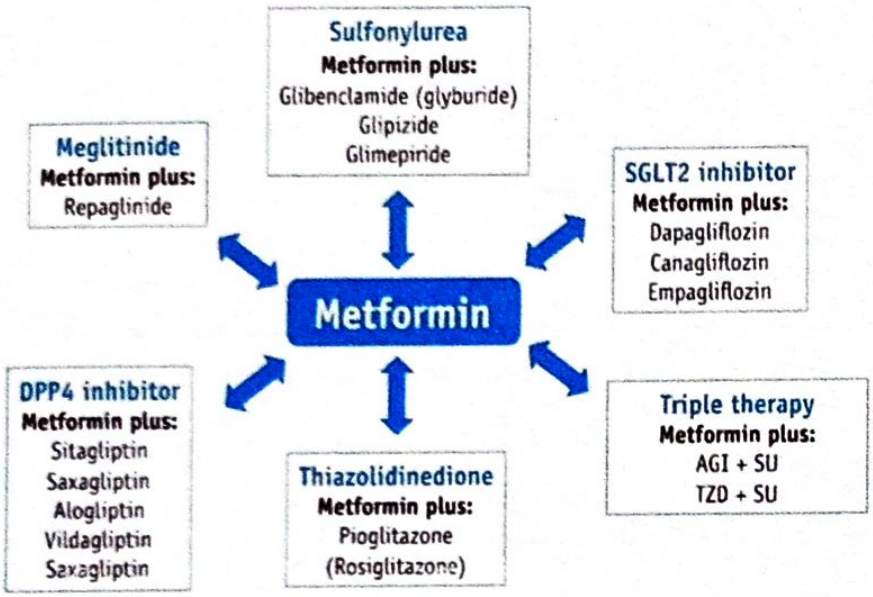


Fig.1: combination of metformin hydrochloride

Metformin is prescribed to treat high blood sugar, but researchers have found that it has many other benefits to offer patients with type 2 diabetes and can reduce the risk of several other health concerns, including cancer, stroke , dementia , heart problems , age related macular degeneration (AMD).[11]