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Prescribing Pattern of Oral Hypoglycaemic Drugs Among Post-Menopausal Women in A Teritary Care Hospital

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ABSTRACT

Background: **Oral hypoglycaemics prescription trends keep on changing in post-menopausal women and thus the drug prescription trend study may prove to be powerful exploratory tool for health care providers.**

Aims & Objectives: **To study the prescribing pattern of oral hypoglycaemics among post-menopausal women.**

Methodology: **A prospective observational drug utilization study was conducted in General Medicine OPD & IPD at Karuna Medical College Vilayodi, Chittur for a period of 6 months. The study is based on the data collected from 76 patients who were post-menopausal women visiting for the treatment of diabetes.**

Results: **A totally 76 prescriptions were analyzed and out of 44 (57.8%) were post-menopausal women having diabetes mellitus (DM) and both DM & hypertension (HT). A total of 451 drugs were prescribed, 252 (55.8%) were anti-diabetics, 101 (22.3%) anti-hypertensives, 29 (6.4%) statins, 18 (3.9%) NSAID's and 51 (11.3%) includes others. A total of 252 anti-diabetic drugs prescribed. Biguanides 80 (31.75%) most commonly prescribed, followed by sulfonylureas 65 (25.7%), alpha glucosidase inhibitors 25 (9.9%), thiazolidinediones 8 (3.1%) and the insulin preparations includes 27 (10.7%). Total 47 (18.6%) FDC's were prescribed. The average number of drugs prescribed per prescription was 2.83 and 150 (59.5%) drugs were prescribed from Essential Drug List 2016-17.**

Conclusion: **In this study it is observed that metformin is most commonly prescribed drug followed by glimepiride, voglibose and insulin preparations. The prescription of metformin justified as these drugs have advantages like it does not cause hypoglycaemia and weight gain due to its peculiar mechanism of action beside having many non-glycaemic advantages like its utility to prevent insulin resistance, metabolic syndrome, fatty liver helping as an adjuvant in keeping check over dyslipidemia and hypertension which is more common in post-menopausal women.[3]**

Key words: *Diabetes mellitus, Post-menopausal women, Fixed dose combinations, Rational prescribing.*

I. INTRODUCTION

Diabetes mellitus (DM) is a most common metabolic disorder characterized by hyperglycemic. Type 2 diabetes is more often and significantly estimates were 90% of all diabetes cases worldwide. Prevalence of DM is estimated to rise from 382 million in 2013 to 592 million in 2035. Type 1 diabetes (T1DM) is about 5% to 10% and type 2 diabetes mellitus (T2DM) is about 90% to 95%. There is no specific cause for DM, but both etiologic factors and risk factors are associated with it. The risk factors are heredity, obesity, increasing age, emotional stress, autoimmune β-cell damage, endocrine diseases (e.g., Cushing disease). DM is one of the widely known risk factor for Peripheral vascular disease, CVD and Stroke. It also causes chronic complications like retinopathy, neuropathy and nephropathy. Now, hyperglycemic can be controlled through existing oral hypoglycaemic drugs and insulin by following some guidelines. [1,2] It occurs most frequently in adults even observed increasingly in adolescents.

Menopause (surgical or natural) has an unfavorable effect on glucose metabolism and thus is likely to be responsible for increased incidence of Type 2 diabetes with advancing age after 40 years. The average age of the menopause in women is 50.8 years. The reasons postulated for this are obesity, metabolic syndrome, inactivity, poor dietary habits, besides hormonal and metabolic changes. Thus, diabetes is an important health issue among postmenopausal women. Postmenopausal women with Type 2 diabetes have a much greater risk of developing cardiovascular disease than non-diabetic women. [3,4] More than 50% of people with diabetes have poor glycemic control, uncontrolled hypertension and

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dyslipidemia, and a large percentage have diabetic vascular complications.[6]

The currently use of anti-diabetic drugs are very effective, however because of lack of patient compliance, clinical inertia, insulin resistance, lack of exercise and lack of dietary control leads to unsatisfactory control of hyperglycemia.[7] It is necessary to define prescribing pattern and to identify the irrational prescribing habits to drive a remedial message to the prescribers. [8]

Hence, the current study was undertaken to investigate trends in prescription of oral anti-hyperglycaemic drugs (OHDs) among postmenopausal women in India.

II. METHODOLOGY

A prospective observational study was conducted in the department of General Medicine OPD & IPD at Karuna Medical College vilayodi, Chittur, for a period of 6 months. Approval of the Institutional Ethical committee was obtained prior to commencement of the study. The study based on the inclusion and exclusion criteria were as: Inclusion criteria

- Female patient's age group above 45 years. (Cessation of menstrual cycle for 1 year).
- Female patient's who is known case or newly diagnosed with Diabetes.
- Female patients prescribed with oral anti-hyperglycemic drugs.
- Those who are willing to participate in the study.

And the exclusion criteria were:

- Female patient's age group below 45 years.
- Female patient's who done hysterectomy, oophorectomy.
- Those who not willing to participate in the study.

Data collection forms were prepared as a tool for collection of data like demographic profile, past medication history, family history, age of menopause. Some clinical and therapeutic data such Fasting blood glucose level and Random blood sugar and the anti-hypoglycemic drugs were extracted from the case file of the patients.

III. RESULTS

During the study period, a total of 76 prescriptions were assessed. 44 (57.8%) were found to have diabetes patients. The mean average age of the patients was 61.97 ± 10.76. Family history of diabetes mellitus was present in 27 (61.3%) patients. Co-morbid conditions associated with diabetes included Hypertension in 23 (52.2%), Coronary artery disease in (20.4%), Cerebro vascular disease in 7 (15.9%), and others include 5 (11.3%). [Table 1]

Table-1: DEMOGRAPHIC PROFILE

PARAMETERS	NO.OF PATIENT (%)
Female with DM	44 (57.8%)
Mean age (years)	61.9 ± 10.76
History of DM	27 (61.3%)
Co-existing conditions	
• HT	23 (52.2%)
• Coronary Artery disease	9 (20.4%)
• Cerebro-Vascular disease	7 (15.9%)
• Others	5 (11.3%)

A total of 451 drugs were prescribed. 252 (55.8%) were anti-diabetics, 101 (22.3%) Anti- hypertensives, 29 (6.4%) Hyperlipidemics, 18 (3.9%) were NSAIDs and others include 51 (11.3%). The others category of drugs comprised of multivitamins, antibiotics etc. [Table-2]

Table-2: DIFFERENT DRUG CLASS PRESCRIBED OVER THE STUDY PERIOD

DRUG CLASS	NO OF DRUGS (%)
Anti-diabetics	252 (55.8%)
Anti-hypertensives	101 (22.3%)
Hyperlipidemic	29 (6.4%)
NSAID's	18 (3.9%)
Others	51 (11.3%)
Total	451

A total of 252 anti-diabetic drugs were prescribed during the study period. Biguanides were 80 (31.7%), Sulfonylureas were 65 (25.7%), Alpha Glucosidase Inhibitors were 25 (9.9%), Thiazolidinediones 8 (3.1%), followed by insulin preparations 27 (10.7%). Total of 47 FDCs were prescribed. [Table-3]

Table-3: TOTAL ANTI-DIABETICS DRUG PRESCRIBED

DRUG CLASSES	NO OF DRUGS (%)
Biguanides	80 (31.7%)
Sulfonylureas	65 (25.7%)
Alpha glucosidase inhibitors	25 (9.9%)
Thiazolidinediones	8 (3.1%)
Insulin preparation	27 (10.7%)
Fixed dose combinations	47 (18.6%)

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In Biguanides, the leading drug is Metformin 80(31.7%). Amongst sulfonylureas the most commonly prescribed drug was Glimepiride 35 (13.8%), followed by Glibenclamide 15(5.9%), Glicazide 8(3.1%) and Glipizide 7(2.7%). Voglibose 18 (7.1%) is the most commonly prescribed drug among Alpha glucosidase inhibitors followed by Acarbose 7(2.7%). Pioglitazone 8 (3.1%) was the only Thiazolidinediones prescribed. [Table-4]

Table-4: FREQUENCY OF ADMINISTRATION OF INDIVIDUAL DRUGS

DRUG CLASS	INDIVIDUAL DRUG	NO OF DRUGS (%)
Biguanides	Metformin	80 (31.7%)
	Total	80
Sulfonylureas	Glimepiride	35 (13.8%)
	Glicazide	8 (3.17%)
	Glipizide	7 (2.7%)
	Glibenclamide	15 (5.9%)
	Total	65
Alpha glucosidase inhibitors	Acarbose	7 (2.7%)
	Voglibose	18 (7.1%)
	Total	25
Thiazolidinediones	Pioglitazone	8 (3.1%)
	Total	8

Out of fixed dose combinations, most common was two drug combination of Metformin and Glimepiride 21(44.6%), followed by Voglibose and Metformin 10 (21.2%), Voglibose and Glimepiride 9(19.1%), and Gliclazide and Metformin 3 (6.3%) and among the three drug combinations the combination prescribed was Voglibose, Glimepiride and Metformin 5(10.6%).[Table-5]

Table-5: FIXED DOSE COMBINATIONS

DRUGS	NO OF DRUGS (%)
Metformin+Glimepiride	21 (44.6%)
Voglibose+Metformin	10 (21.2%)
Voglibose+Glimepiride	9 (19.1%)
Gliclazide+Metformin	3 (6.3%)
Voglibose+Glimipiride+Metformin	5 (10.6%)

The average number of drug prescribed per prescription was 2.83. Average number of anti-diabetics per prescription was 2.3. Out of 252 prescribed anti-diabetics, 150 (59.5%) drugs were prescribed from Essential Drug List 2016-17 which included 80 (53.3%) Metformin, 35 (23.3%) Glimepiride, 8 (5.3%) Gliclazide, 27 (18%) Basic Isophane Insulin.[Table-6]

Table-6: ANTIDIABETICS PRESCRIBED FROM ESSENTIAL DRUG LIST 2016-17

DRUGS	NO OF DRUGS (%)
Metformin	80 (53.3%)
Glimepiride	35 (23.3%)
Gliclazide	8 (5.3%)
Basic Isophane insulin	27 (18%)

IV. DISCUSSION

Diabetes mellitus is seemingly one of the active major non communicable diseases which are growing very fast.[2] The risk for myocardial infarction and cardiovascular death is increased by threefold to fourfold in diabetes patients respectively. Chronic micro-vascular complications like retinopathy, neuropathy and nephropathy can be prevented or delayed by effective management of chronic hyperglycemia. The primary goal of DM management is to reduce diabetes associated mortality and to improve quality of life. Choice of an anti-hyperglycemic drug should be guided by anticipated benefits in an individual patient, taking into consideration the genetic, physiological and environmental factors that caused the disease, concurrent medical condition like hypertension, CVD, renal impairment, adverse effects of drugs and cost. [1]

The present study observed that incidence of diabetes was higher post-menopausal women, that was comparable to the earlier studies on diabetes patients.[1,7,8] The average age of patients in the present study was 61.9 ±10.7 years, reflecting usual age group of disease manifestation. Further, management of T2DM is very complex in this particular group and shall depend on various co-morbid conditions, duration of diabetes, presence of complications and surely affects the menopausal symptoms and related problems.[3]The association between family history of diabetes and risk for the diseases has been well documented.

In the present study it was observed that most commonly prescribed anti-diabetics agent were Biguanides, Sulfonylureas, Thiazolinediones, Alpha-glucosidase inhibitors. The co-existing diseases were hypertension, coronary artery diseases, cerebro-vascular diseases.

Amongst anti-diabetic medications, Metformin 80(31.7%) was the most commonly prescribed drug followed by Glimepiride 35 (13.8%), Voglibose 18(7.1%), Glibenclamide 15(5.9%). Similar prescribing trends was observed in another study.[11,12] The reasons why metformin was most preferred choice in the current study is probably because of the fact that it has many advantages like it does not cause hypoglycaemia and weight gain due to its peculiar mechanism of action beside having many non-glycaemic advantages like its utility to prevent insulin resistance, metabolic syndrome, fatty liver helping as an adjuvant in keeping check over dyslipidemia and hypertension.[3] These factors are high risk in post-

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menopausal women to develop diabetes. Accordingly, metformin is reported to be regarded as the first line drug of choice for most of the patients with type 2 diabetes mellitus. Our study also supported the same conclusion.

Among sulfonylureas, glimepiride was the most frequent by prescribed drug. The choice was possibly because of its efficacy to achieve glycaemic control as monotherapy or in combination. Thus, results reflect that Biguanides and sulfonylureas are still the choice of most physicians in the treatment of type 2 diabetes even for postmenopausal women.[3] Among Alpha-glucosidases inhibitor, Voglibose remained most frequently prescribed not as monotherapy but as combination or as co-therapy along with FDC in the current study.

V. CONCLUSION

DM is an important health issue among postmenopausal women. Metformin was the most common individual OHDs to be prescribed followed by glimepiride. Although pioglitazone still continues to be prescribed after safety alert. We recommended more efforts for closing the gap between treatment and control to maximize the public health, clinical benefits among those high-risk populations include post-menopausal women and avoid clinical inertia.

VI. LIMITATIONS

Sample size in the present study was small and no attempt was made to compare prescription before and after safety alerts on pioglitazone in India.

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