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A Review on Study of Drug Prescribing Pattern in Diabetes in India

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ABSTRACT

Diabetes mellitus is a pandemic disease that has struck each and every corner of the world. It is a chronic disease caused by inherited/ acquired deficiency in insulin production or in effectiveness of insulin produced. A wide range of oral antidiabetic drugs such as sulphonylureas, biguanides, Alpha glucosidase inhibitors, thiazolidinediones, meglitinides and the most recently introduced dipeptidyl peptidase-4(DPP-4) inhibitors have been used. The present article reviews various prescribing pattern studies of drugs conducted all over country and abroad. It was observed in the majority of such studies that physicians do not adhere to the guidelines made by regulatory agencies leading to irrational use of medicines. This in turn leads to increased incidence of treatment failure and economic burden on the patient and the community as a whole. The treatment of diseases by the use of essential drugs, prescribed by their generic names, has been emphasized by the WHO and the National Health Policy of India. We conclude that the prescribing pattern studies provide a bridge between areas like rational use of drugs, pharmacovigilance, evidence based medicine and pharmacoeconomics. In India, this is the need of the hour to utilize the data generated by so many prescribing pattern studies done in every state and on every drug, so that the main aim of promoting rational use of drugs is fulfilled.

Keywords: Prescribing pattern, pharmacovigilance, pharmacoeconomics, rational use of drugs.

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INTRODUCTION

Diabetes is a modern-day epidemic and is rightly recognized as a global public health issue. Diabetes is probably one of the oldest diseases known to man. It was first reported in Egyptian manuscript about3000 years ago. In 1936, the distinction between type 1 and type2 DM was clearly made. Trends in the last 10 years are influencing the supply and demand for health care in diabetes and are focusing the attention of patients, physicians, politicians and payers of health care alike. Health economics applies economic principles to health-care issues which help decision-takers make difficult choices when resources are scarce. Pharmacoeconomics determine the costs and outcomes associated primarily with pharmaceuticals[1]. There are several types of pharmacoeconomic evaluations available to address different decision problems, including cost–utility analyses (CUA), cost-effectiveness analyses (CEA), and cost–benefit analyses (CBA). Pharmacoeconomics is now more than ever before at the leading edge of thinking in terms of securing the most rational and efficient use of scarce health-care resources for diabetes. Diabetes mellitus is a pandemic disease that has struckeach and every corner of the world. According to the Indian Council of Medical Research Indian Diabetes study (ICMR), a national diabetes study, India currently has 62.4 million people with diabetes[2]. This is set to increase to over 100million by 2030[3]. The prevalence of diabetes among adults has reached approximately 20% in urban and approximately10% in rural populations in India[4]. The disease appears to be more prevalent in the south of the country as compared to the northern and eastern parts[5]. However, the absence of large well-planned national studies on diabetes prevalence has led to incomplete and unreliable nationwide data on the prevalence of diabetes in India[6]. Diabetes mellitus is a chronic disease caused by inherited/ acquired deficiency in insulin production or ineffectiveness of insulin produced. This deficiency results in increased glucose concentration in the blood, which then damages many of the body systems, in particular blood vessels and nerves. Data suggest that it is affecting nearly 6% of the world population[7]. It is associated with abnormal carbohydrate, protein and lipid metabolism. Diabetes if uncontrolled can lead to several acute and chronic complications. The chronic complications of diabetes makes necessary to prescribe drugs for these patients lifelong[8]. A changing lifestyle in developing countries like India has enormously increased prevalence of chronic diseases like diabetes mellitus. A survey states that 4% of the adults in India suffer from diabetes in the year 2000, and it is expected to increase to 6% by the year 2025[9]. Metabolic control in diabetes depends on patient adherence to the therapy. Diabetes can cause both morbidity and mortality and requires appropriate treatment to improve the quality of life. A wide range of oral antidiabetic drugs such as sulphonylureas and biguanides have been used

for since the last 50 years for the treatment of diabetes. The last decade and a half has seen the introduction of a number of oral antidiabetic drugs like Alpha glucosidase inhibitors, thiazolidinediones, meglitinides and the most recently introduced dipeptidyl peptidase-4(DPP-4) inhibitors[10]. Oral antidiabetics are at a higher risk of polypharmacy and are more vulnerable to irrational prescribing. While the drug options for achieving glycemic control have broadened, the optimum use of these agents and their combinations in the treatment of type 2 diabetes remains suboptimal as indicated by the growing prevalence of the disease. In the view of above situation, drug utilization review of antidiabetic medicines in Indian health care settings has a valid significance to promote rational drug use in diabetics.

Pharmacoeconomics and Diabetes

The growing interest in the optimal allocation of health-care funding in prevention of diabetes and its complications is reflected in four reviews of economic evaluations in diabetes. The first three had different perspectives and inclusion criteria and spanned different periods[11, 12]. The latest systematic review focused on studies concerning the more costly macro vascular complications and drew a number of conclusions in terms of efficient use of health are expenditure (Figure 1). Strict blood-pressure control is more cost-effective than less-strict control. Primary and secondary (i.e. screening or early detection and subsequent treatment) prevention is highly cost-effective (but results were based on very few studies). Medications to reduce weight and HbA1c simultaneously were cost-effective versus conventional interventions (but this was based on only three trials). However, the individual results for medications to reduce weight, hyper glycaemia and hyper cholesterolaemia showed wide variation, with the newer (more expensive) agents in general producing high incremental cost-effectiveness ratios (ICERs), indicating that they were not value for money. Vijgen et al suggested that the newer technologies deserve attention from policymakers, and that further economic analyses are needed, especially studies which compare all relevant medications with each other to establish which drug, or combination of drugs, is most cost-effective[13]. International comparison of economic evaluations was acknowledged to be difficult, and the authors called for more attention to be devoted to the assessment of uncertainty in cost-effectiveness studies based on modelling. A recent report agreed that screening was cost-effective, noting that the very low cost of statins was an important factor in these conclusions[14]. Icks and colleagues analysed the clinical and cost-effectiveness of primary prevention of type-2 diabetes in a 'real-world' setting[15]. They concluded that implementing prevention programmes in clinical practice is costly and may not prevent high numbers of diabetes that accompanying costs such as staff education and especially

intervention participation and adherence should be considered, and that further studies are warranted to determine the optimal prevention programme in clinical practice.

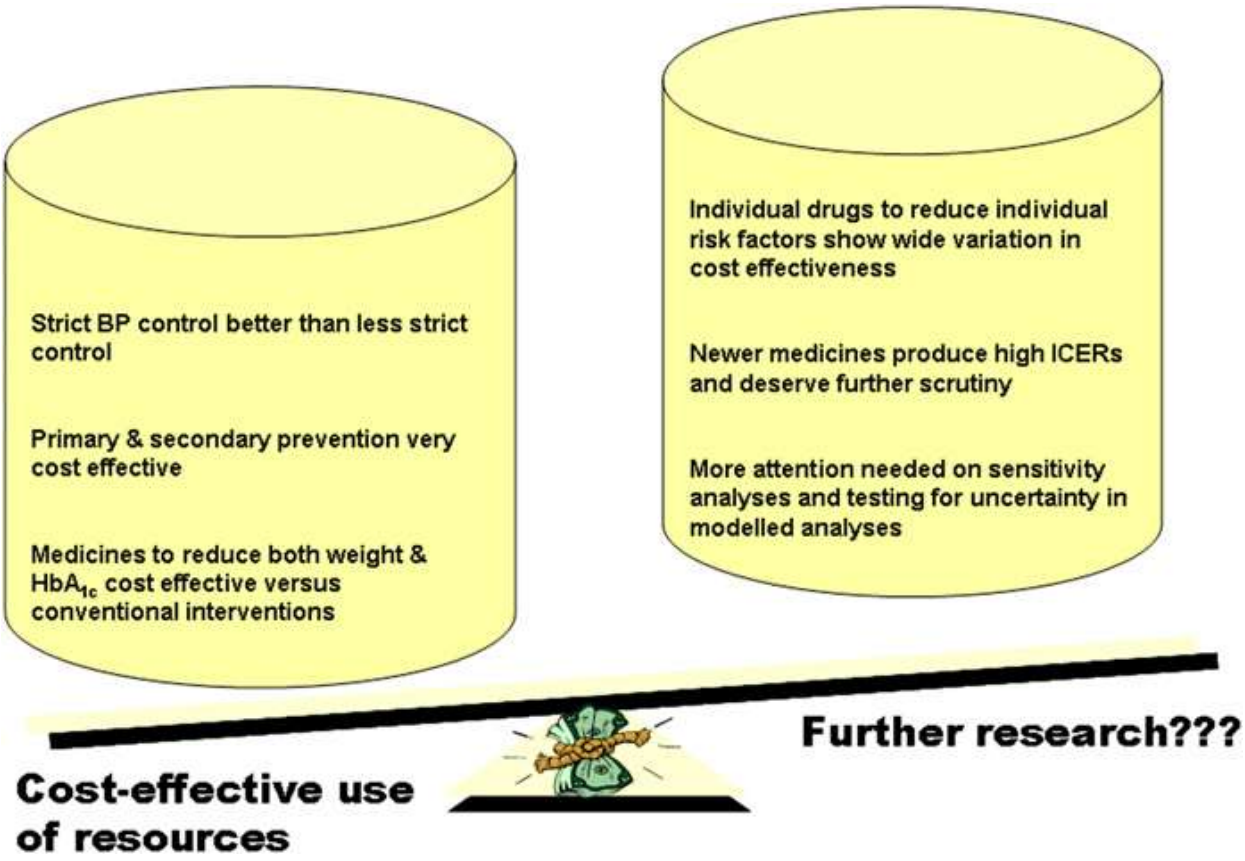

Figure 1:Cost-effective use of resources in type-2 diabetes[13]

Socioeconomic Burden of Diabetes in India

Several studies investigated differences in costs as related to one or several demographic and socioeconomic parameters by looking at levels of income, education and occupational status, and by comparing costs in rural and urban populations. Several studies found that lower income groups generally spent a larger proportion of their income on diabetes care that urban populations spent more in absolute terms and that cost of complications weighed heavily on overall costs. Within the diabetes population, low income individuals bear the highest burden of diabetes[16]. A study on type 2 diabetes in seven states in India during the period 1998 to 2005 found spending to be higher among the urban than the rural population both in absolute terms and as a proportion of income. This was due to higher expenditure on medical consultations, laboratory tests and drugs, which the authors attributed to the use of more expensive treatments in urban areas (which have remained unavailable in rural areas). Also, in lower income groups spending was higher in the urban than the rural population, possibly because awareness of diabetes care was better among the urban poor[17]. A Chennai-based study in 1999 compared costs for type 2diabetes in public and private institutions and found that individuals seeking care in private hospitals were economically better off, and that

families who could afford it preferred private provision over state-funded care as the public hospitals were crowded and the staff overworked[18]. A study from Bangalore with cost data from 1997 and 1998 found that uneducated, unemployed people in semi-urban or rural areas were more likely to be diagnosed later as they could not afford to consult a doctor, and therefore developed complications[19]. Treatment costs were found to be significantly higher in those who were more educated in a study from northern India[20]. Patients with less than five year of education spent INR 398.66 (USD 9.19), while those with more than five years education spent INR 2,810.20 (USD 64.77).

Recent Studies

One of the study showed that type 2 diabetes was more prevalent in males than females. This study analyzed the prescription pattern in type 2 diabetic patients who were admitted to the Medicine Department of K. S. Hegde Charitable Hospital, Mangalore. A total of 120 patients who fulfilled the inclusion criteria were included in the study which was carried out for a period of 5 months from June 2010 to October 2010.The geriatric patients were found to have high risk of developing type2 diabetes. A total of 92 patients had co morbid conditions along with diabetes and commonly seen comorbid condition in the study was hypertension [81(67.5%)]. The study has shown metformin as the predominantly prescribed oral antidiabetic drug both in monotherapy and in combination therapy. Overall, monotherapy was found to be predominant overcombination therapy. There was no significant increase in the prescriptions of newer oral antidiabetic agents like α-glucosidase inhibitors and DPP-4 inhibitors. It may be concluded that the incidence of polypharmacy is low and the essential drug prescription is high and therefore drug use is quiet rational[21]. From the other study it was concluded that Biguanides like metformin is the most commonly prescribed medicine in the management of diabetes mellitus. The two drug combination was mainly prescribing pattern in the management and the joint venture of the doctor and pharmacist in studying the prescribing pattern in lifelong disorder by creating awareness to improve their quality of life and outcome of the health and improve the healthcare sector. 85 patients were assessed for the study in which 95.29% patients are of type II. From the study and analysis of prescription it was observed that various classes of anti diabetic agent like Biguanides class with 92.94% are most prescribed class and followed by sulfonylurea with 70.58%, Thiazolidinedione with 27.05, insulin 22.35%, α-glycosidase inhibitor 10.58% and DPP4 inhibitors are 3.52% and almost all traditional and newer class agents are covered under the prescribing pattern. Combination drug is unavoidable in diabetes but proper combination selection of clinical judgment will be beneficial and reduce drug related problems[22]. A observational prospective study was undertaken for six months in outpatient department of Diabetic center, the present

study was carried out to assess the prescribing patterns of Antidiabetic drugs in the treatment of type 2 diabetes mellitus in the Warangal City of India. The study enrolled 133 prescriptions of diabetic patients. This study reveals that Diabetes is always being dominating in males as compare to females. Antidiabetics were the commonest class of drugs accounting for 241 (31.58%) of the total drugs. Among the Antidiabetics, Biguanides were prescribed in 85 patients, accounted for 35.26%, followed by Sulfonylureas were prescribed in 77 patients, accounted for 31.95%, insulin was prescribed in 53 patients, accounted for 21.99%, Thiazolidinediones were prescribed in 22 patients, accounted for 9.12%, and DPP-4 Inhibitors were prescribed in 4 patients, accounted for 1.65%. The choice Antidiabetic depends on the type of patients, their concurrent illness, cost factors, as well as the availability of medicines. In general, Metformin is considered as a safer drug in terms of hypoglycemia and hence to be preferred. Among the Sulfonylureas, second generation sulfonylurea-Glimepiride was the most preferred drug of choice for the treatment of type 2 diabetes mellitus during the study period. Thiazolidinediones were found to be prescribed in 22 (9.12%) of the patients. Among Thiazolidinediones, Pioglitazone was the only drug used. In type II diabetes mellitus, the patient is as much responsible for its adequate control as the treatment given to him. Hence, counseling and educating the patient on the importance of diet and exercise in the management of type II are of vital importance. The importance of educating diabetic patient is appreciated by pioneering clinicians all over the world. Continuing education for the clinicians to keep themselves abreast of the latest development in the field of type II diabetes treatment would also contribute in the effective management of diabetes mellitus. It is also advisable that Indian health authorities must take serious proactive to compile therapeutic guidelines in diabetic management[23]. In other prospective study which was conducted over a period of 9 months (from May 2010 to Jan 2011) in the outpatient department of a tertiary care hospital at Kottakkal, Kerala, India. A total of 221 oral anti diabetic drugs were prescribed in 202 patients. In this study Males were found to be more affected by Type-2 Diabetes mellitus than females. Elderly patients were at higher risk of developing Type-2 Diabetes. Patients with a long duration of T2DM were at a higher risk of developing complications. Among the various complications, cardio vascular complications caused major threat and among cardiovascular complications, hypertension was the major one. This study shows the cause of Type-2 diabetes mellitus in most of the patients is heredity. The study found that the incidence of polypharmacy in Type-2 diabetes patients was high compared to other studies. In this study it was found that combination therapy of Sulfonylurea and Biguanide were more used than monotherapy. In these Glimepiride and metformin combination drugs were used commonly followed by Glibenclamide and

metformin. Out of the total drugs most were prescribed in oral dosage form. This is a good prescribing habit. In this study cost of drugs per prescription was found to be very high. The cost of prescription can be reduced by choosing most economic drugs without changing its quality[24]. A study was done to evaluate prescribing pattern and potential drug-drug interaction in hospitalized patients with type 2 diabetes mellitus. It was a prospective, observational study which was carried out at inpatient department of SRM medical college hospital and research centre kanchipuram district, Tamilnadu, India from July 2010 to February 2011. Data of 142 patients were collected and analyzed, of which 69(48.6 %) were males and 73 (51.4 %) were females. Mean ± SD of drugs per prescription was 6.1±2.3. 63.57% of the drugs were prescribed by their brand names. 45% of the drugs prescribed were from the WHO list of essential drugs. In type 2 diabetes mellitus metformin and human insulin were most frequently prescribed drugs. Monotherapy was used for 58.9% patients and 41.1% patients were prescribed with combination therapy. 65 potential drug-drug interactions were screened in 53 prescriptions, in which 3(4.6%) were major and 27(41.5%) were moderate level of severity identified. The potential drug-drug interactions found in type 2 diabetes mellitus prescriptions were often involved with medications used to treat co morbid illnesses. The potential drug-drug interactions are frequent in type 2 diabetes mellitus and hence deserve clinical attention. Implementation of an alert guidelines and a computer based screening would help to recognize and prevent potentially dangerous drug-drug interactions[25]. One more prospective observational study was conducted over a period of 3 months (January-March 2013) in the outpatient departments of General Medicine and Endocrinology at Amrita Institute of Medical Sciences and Research Centre, a tertiary care, teaching and super-specialty referral hospital, Kochi, Kerala. The main aim of study was to evaluate the drug utilization pattern of anti-diabetic drugs in diabetic outpatients and monitor the adverse drug reactions (ADRs) associated with anti-diabetic therapy. A total of 197 diabetic patients were evaluated during the study period in which 99 (50.3%) of the 197 diabetic patients were males. Majority of patients were in the age group of 51-60 years (39.6%) and most of the patients (36.5%) had a diabetic history of <5 years. Metformin was the most commonly prescribed drug (68%), followed by sulfonylurea class of drugs (49.7%). Nearly, 42% patients were using insulin preparations with 30.4% using biphasic isophane human insulin. Majority of the patients (58.4%) were on multidrug therapy with two drug therapies being received by nearly 40%. Metformin was the most commonly prescribed drug in monotherapy (18.8%) and glimepiride + metformin was the most common two drug therapy (13.2%). Co-morbid condition was found in 172 patients (87.3%) with hypertension (68.5%) being the most common co-morbid condition. 17 ADRs were observed with

hypoglycemia being the most common ADR reported. Metformin was the most commonly used drug. The prescribing trend also appears to be moving towards combination therapy particularly two drug therapy. This study contributes to the growing body of literature on drug utilization research[26]. A prospective cross-sectional study was conducted for four months in the Government General Hospital, Chennai to evaluate drug utilization in a diabetology outpatient clinic of a tertiary hospital. A total of 708 prescriptions were collected; 56.6%were for females and 43.4% for males. The incidence of type 2 diabetes was 98.4%. 80.2% of patients received 2 drugs or less. 74.38% of generics and 94.48% of essential drugs have been prescribed. The prescribing frequencies of second generation sulfonylurea were more when compared to biguanides. The average consulting and dispensing time were 9.28 min and 14.17 sec. 52.76% of patients knew their dosage schedule. In this study setup, the incidence of polypharmacy is very low and that the generic and essential drug prescription is high and therefore drug use in this set-up is quite rational. Improving patients' knowledge on correct dosage will perhaps boost up the present health care in this setting[27]. Another prospective, cross-sectional study was carried out over the duration of 5 months from October 2012 to February 2013. The main objective is to study prescription pattern, calculate cost of antidiabetic agents and to evaluate the adherence to treatment guidelines in diabetic patients attending the medicine outpatient department in a tertiary care teaching hospital of Smt. NHL Municipal Medical College, Ellisbridge, Ahmedabad, Gujarat. A total of 250 patients were enrolled in the study. Out of 250 patients126 (50.4%) were male and rest were female. A total of 1,391 drugs were prescribed, with mean of 5.56 ± 2.52drugs and out of which 539 drugs were antidiabetics with mean of 2.18 ± 0.96. In monotherapy, metformin was frequently 218 (40.45%) prescribed. Glimepiride and metformin was the most frequently prescribed in119 (76.28%) out of 156 antidiabetic drug combinations. Most commonly used drugs other than antidiabetics were aspirin 146 (18.9%) and atorvastatin 119 (15.41%). Mean cost of therapy for a month for a diabetic patient was 354.60 ± 305.72 INR. Majority 209 (83.6%) of prescriptions was in accordance to guidelines. Oral dosage form was the most commonly used to increase the patient compliance in type 2 DM. This is a good prescribing habit. In this study cost of drugs per prescription was found to be very high. The cost of prescription can be reduced by choosing the most economic drugs (generic) without changing its quality. Prescribers followed the ICMR guidelines to a large extent. The pattern of prescription for diabetic patients should be more rational as per our study and compliant with current evidence and clinical guidelines[28]. From January 2013 to December 2013, a cross sectional study was conducted to see prescribing pattern of antidiabetic drugs used in outpatient and hospitalized patients of NKP Salve Institute of Medical Sciences and Research Center,

Nagpur. In this study prescriptions of patients who were diagnosed with diabetes with or without co-morbidity were included. Prescriptions of diabetic patients (n=300) including outdoor patients (n=150) and indoor patents (n=150) were noted. Metformin (69.33%) was the most prescribed drug followed by glimepiride (35.00 %). Prescriptions of Insulin alone were 26.70% and 30.66% in combination with oral antidiabetic drugs. As per WHO prescribing indicator drug prescription by generic name were only 3.12%**.** Hypertension was most common associated co morbidity in diabetic patients in 52.33 % of cases. Incidence of diabetes has been found higher in male as compared to female and majority of the patients develop diabetes in the most productive years of their life. Such type of prescription pattern study may provide base for continuous prescription audit in a hospital setting and may be helpful for formation of institutional prescribing policy[29]. A cross‑sectional, prospective, observational study was carried out in Diabetology and Medicine Department of a Tertiary Care Hospital in Navi Mumbai and was conducted for the ICMR Short Term Research Studentship (2010) program. It was a pilot study with duration of 2 months (May 10, 2010 to July 10, 2010) in which 100 patients of diabetes of 18 years and above receiving anti‑diabetic therapy for more than 1 year was randomly selected for participation after fulfilling inclusion/exclusion criteria. In this study, an attempt has been made to describe the current prescribing pattern and trend of anti‑diabetic drug therapy along with the efficacy of these drugs in maintaining an optimal glycemic level in diabetic patients in a tertiary care hospital in Navi Mumbai. Sulfonylureas were the most commonly prescribed class, but metformin (biguanide) was the commonest prescribed individual drug among oral hypoglycemic agents (OHA). Fixed dose combination of biguanide and sulfonylurea was prescribed commonly. All the drugs were prescribed by brand names (100%). Percentage of drugs prescribed from WHO essential drug list was 74.2% (104) and National Essential Drug List of India was67.1% (94). Monotherapy dominated over polytherapy and there was a higher percentage of use of insulin in Type 2 diabetics. Only 41% of patients on anti‑diabetic therapy had optimal glycemic control. The association between anti‑diabetic therapy along with lifestyle modification and glycemic control was statistically significant. Oral hypoglycemic agents still dominate the prescribing pattern, but there was a shifting trend toward the use of insulin preparations in the management of Type 2 diabetes mellitus. In achieving optimal glycemic control, the efficacy of the anti‑diabetic drugs was only 41%; therefore intensification of current drug treatment as well as planning multiple drug interventions with lifestyle modification is necessary to prevent diabetic complications[30]. One more cross-sectional study was carried out at the Out-patient Pharmacy, Manipal Teaching Hospital, Pokhara, Nepal,

from 22nd August to 7th December 2006. The present study was conducted with the objectives of collecting the demographic details of diabetes patients, studying the pattern of drug prescribing among diabetic outpatients, calculating the mean prescription cost for the diabetes patients and analyzing the prescriptions according to prescribing indicators. Altogether 182 patients, 103 males (56.59%) and 79 females (43.41%), were enrolled. Among these, 69 (37.91%) were in the age group 51–60 years, 128(70.33%) had a diabetic history of less than 5 years and 136 (74.72%) had at least one concurrent illness. Two, three and four drugs were prescribed in 39 (21.43%), 35 (19.23%) and 40 (21.98%) patients, respectively. Antidiabetics were accounted for 314 (45.84%) of the total drugs. Among the various antidiabetics, biguanides were accounted for 161 (51.27%) of the total antidiabetic medications. Among the study patients, 28 (15.38%) had an encounter with an injection prescribed and 16 (2.34%) of the total drugs were fixed-dose combinations and 0.88% (n = 6) of the drugs were antibiotics. Majority [650 (94.89%)] of the drugs were prescribed in oral dosage form. The average cost per prescription was NPR 1156.15(US $16.17). Antidiabetic medications constituted 58.93% of the total cost. Among the antidiabetic medications insulin accounted for 41.07% of the total cost followed by biguanides (32.60%).This study was the first of its kind in South Asia to study the utilization pattern of antidiabetic drugs in a hospital. Since diabetes is a common problem in South Asia and prescription cost is one of the major reasons for non-adherence to drug therapy, there is a need to prescribe cheaper alternatives for these patients. The prescription cost can be reduced by choosing cheaper brands, and the hospital Drug and Therapeutics Committee has a major role in improving the prescribing habits in diabetes patients, as well as in procuring economic brands for the hospital. There is also a huge scope for improving prescribing by generic name[31]. A prospective drug utilization study was conducted in Type 2 diabetes mellitus patients by the department of Pharmacology in Medicine OPD at ShriGru Ram Rai Institute of Medical and Health Sciences (SGRRIM & HS), Dehradun for 6 months - between March 2013 and August 2013. A total of 312 prescriptions were randomly evaluated for prescribing pattern in type 2 diabetes mellitus patients using WHO drug indicators like drug class, dosage form, fixed dose combinations (FDCs), generic and branded drugs and drugs from National List of Essential Medicines. Male: Female ratio was 1.04:1. Family history of diabetes mellitus seen in 129 (41.35%) patients and average duration was 7.92±0.37 years. A total of 1242 drugs were prescribed. 666 (53.62%) antidiabetics, 216 (17.39%) antihypertensives, 159 (12.8%) multivitamins, 90 (7.25%) antiplatelets, 42 (3.38%) statins and 360 (5.56%) in miscellaneous category were prescribed. Amongst antidiabetics, the most frequently prescribed drugs were metformin 273 (40.99%), glimepiride 228 (34.23%) followed by pioglitazone 45 (6.76%),

acarbose 33 (4.95%), gliclazide 30 (4.5%), sitagliptin 30 (4.5%), glibenclamide 15 (2.25%) and insulin 12 (1.8%). 99.03% oral drugs were prescribed. Numbers of Fixed dose combinations of antidiabetic drugs were 246 (36.93%). 288 (43.24%) antidiabetics were prescribed from National List of Essential Medicines. 100% drugs were prescribed by brand names. Most of the prescriptions were rational, but further improvement is needed. Further studies focused on rationale for choice of drug based on demographic data, economic status, associated conditions and complications would give additional insights into prescribing patterns in diabetes mellitus in India. Rational prescribing requires consideration to dose and duration as well as interaction with other medications[32].

CONCLUSION

In summary, a number of studies have examined the drug prescribing pattern in diabetes patients. The assessment of the existing prescribing pattern helps to identify specific drug use problems which need to be understood before any meaningful intervention can take place. Furthermore, educational sessions for the doctors at different levels to encourage good prescribing practices such as prescribing by generic names and correct writing of prescriptions should be encouraged.

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