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Pharmacoepidemological And Socioeconomic Risk Factors In Response To The Type 2 Diabetic Patients.

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Abstract

The pharmacoepidemological and socioeconomic studies have made significant contributions in understanding the risks and benefits associated with current drug therapy. These studies have also been instrumental in addressing various aspects of drug safety and effectiveness that cannot be readily or adequately evaluated using an appropriate experimental design and also the risk and health benefits of the drugs and its outcomes. In particular, we have evaluated a large array of socio-economic and parmacoepidemological parameters in understanding the status of disease. Attempts were made to investigate the extent of the variables to which they correlate with physical and psychological well-being, and with treatment satisfaction. Thus, it is possible to study clinically relevant outcomes in a timely and cost efficient manner. The studies revealed that the type 2 diabetes disease observational studies were correlated with SES measures, which are required in particular during addressing to the biasing effect of disease duration and progression with its severity. Unfortunately, the laboratory parameters are typically unavailable in majorities of administrative health databases developed in rural and urban hospitals and clinics. The understanding of pharmacoepidemological and socioeconomical status will provide additional evidence associated with the individuals possessing type 2 diabetes. We also observed that a continuous monitoring of glycemic control not only forecast the progression of the diseases but also use of medication for health and wellbeing are the most important factors in diabetes. To understand the scenario the current study was the present review aimed in assessing the health-related quality of life and treatment satisfaction in patients with type 2 diabetes.

Keywords: Pharmacoepidemology, Socioeconomic, Risk factors, Diabetes, Quality of life

Introduction

The Pharmacocoepidemological and Socio-economic status is a suppressed variable in the sense that, like mood or wellbeing, it cannot be directly measured [1]. Unlike height or weight of the individual, there is no mechanical device(s) that permits direct and relatively precise measurement of the socioeconomic status. It is a complicated parameter that one cannot summarize a person or group's access to culturally relevant resources useful for succeeding, if not moving up the social hierarchy system.

A principal goal of present modern social science has been to measure the economic status of persons (or families) and estimate how such measures are changed from time to time. To be adequate enough to say that until recently the mai

central focus of such research was on occupational prestige and status and the big debate was whether corresponding measures should be either subjective or objective. The focus on occupational prestige, and its derivatives, is understandable since persons (typically males) often had one lifetime career and the system was rather a static in nature. One's occupation was often set by the age of twenty five and there was little change thereafter. Measuring prestige or status resulted in a useful measure of economic status.

Socioeconomic status measures must be tied to particular cultures, eras and even the geographic places on the earth. It is hard to imagine a universal measure of the socioeconomic status that would be helpful today's research and development activities. The fundamental cause of public health in relation to socioeconomic status is clearly depicted in Figure-1. The roots of power may be similar among all human in the societies but the gradations of social stratification and social mobility seem too different and important enough require differentiation in socioeconomic status measure for many research problems such as healthcare system [2].

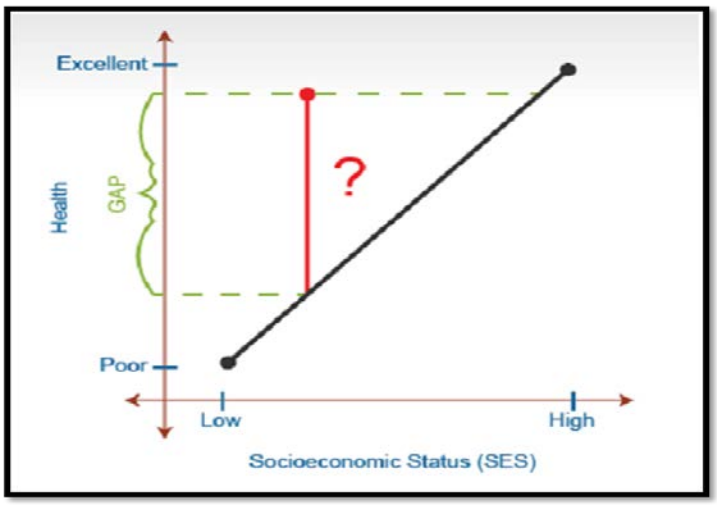

Figure. 1: The Socioeconomic status Fundamental Graph and its relation to Public Health.

Source: http://www.esourceresearch.org

Everybody is aware that diabetes mellitus is the chronic metabolic disorder and it is becoming a global major public health problem and epidemic of the twenty first century. It has been estimated over time that more than 33 million people in India are affected by diabetes mellitus. The increase in diabetes is expected to 57.2 million by 2025 [3]. Diabetes mellitus is nowadays affects higher percentage of populations in many developing countries than western countries. The diabetes is rapidly rising all over the world at an alarming rate [4] over the past 3 decades. It is predicted that by 2030, India's diabetes burden will be almost 87 million people (5). Additionally, there is an increasing prevalence of hypertension in the Indian population, especially in the urban areas (6). Elevated blood pressure (BP) has been linked to ischemic heart disease, peripheral vascular diseases, stroke, myocardial infarction, and renal failure. Increased affluence and Westernization have been associated with an increase in the prevalence of diabetes in many indigenous populations and in developing economies (7). Conversely, in developed countries, those in lower socioeconomic groups have a higher risk of obesity and consequently of type 2 diabetes (8). Surrogates for socioeconomic status, such as level of education attained and income (9) are inversely associated with diabetes in high-income countries.

The status of diabetes has changed from being as a mild to major because of morbidity and mortality of the youth and middle aged people. It is prevalence in all six inhabited continents of the world [10]. Although there is an increase in prevalence of type 1 diabetes, the major driver of the epidemic scenario is type 2 diabetes and it accounts for more than 90 % of all the diabetes cases in the world. The external barriers and outcomes of the health care system are clearly represented by flow diagram (Figure.2). The Diabetes is associated with both short and long-term complications. Acute complications include the occurrence of varying degrees of drug-induced hypoglycemia and diabetic ketoacidosis, while long-term complications include the development of micro- and macrovascular disease (i.e., small

and large vessel disease). According to World Health Organization (WHO) reports in India shows that 32 million people had diabetes in the year 2000. A pharmacoepidemiological study in several Asian countries including India has revealed a high prevalence of type 2 diabetes among the urban populations, here in India is considered as a capital for diabetes, a metabolic endocrinal disorder.

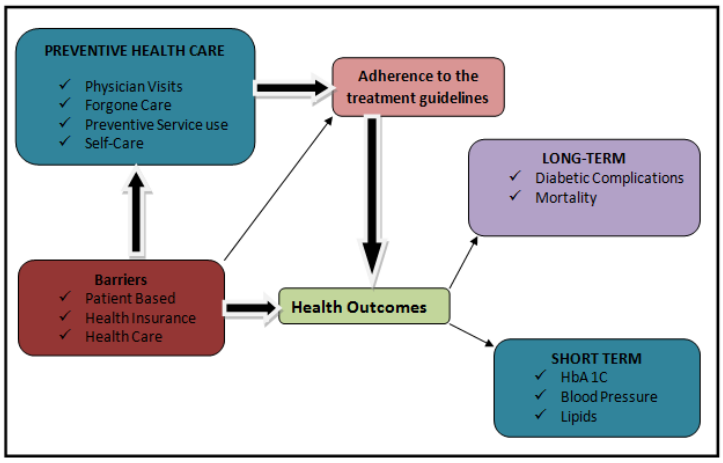

Figure 2: The External Barriers to Health Care System and Its Outcome.

** Diabetes Spectrum Volume 14 No.1, pp23, 2001*

Diabetes imposes large economic burdens on national health care systems and affects both national economies, individuals and their families. Direct medical costs include resources used to treat the disease. Indirect costs include lost productivity caused by morbidity, disability, and premature mortality. Intangible costs refer to the reduced quality of life for people with diabetes brought about by stress, pain, and anxiety. Good data on the direct medical costs of diabetes are not available for most developing countries. In developing countries, the indirect costs of diabetes are at least as high, or even higher, than the direct medical costs. Because the largest predicted rise in the number of people with diabetes in the next three decades will be among those in the economically productive ages of 20 to 64, the future indirect costs of diabetes will be even larger than they are now (Figure-3).

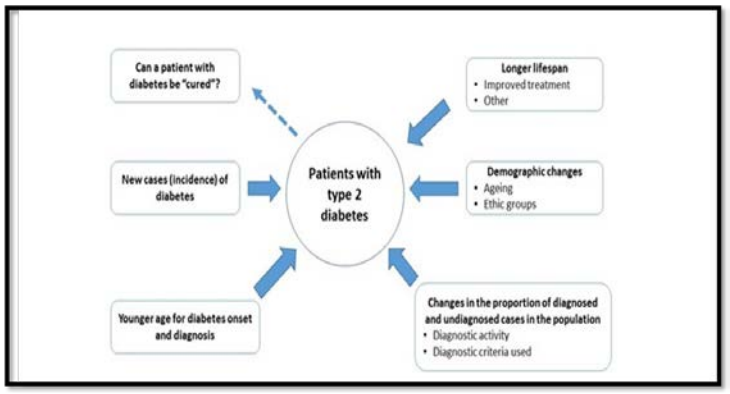

Figure: 3. The various Factors affecting the prevalence of type 2 diabetes

Diabetes lowers people‘s quality of life in many ways, including their physical and social functioning and their perceived physical and mental well-being. To prevent Diabetes of Type-2, four major trials—in China, Finland, Sweden, and the United States—have demonstrated that intensive lifestyle interventions involving a combination of diet and physical activity can delay or prevent diabetes among people at high risk (11).

In the largest randomized, controlled trial to date, the Diabetes Prevention Program (12) the goals of the intensive lifestyle intervention were weight loss of 7 percent of baseline bodyweight through a low-calorie diet and moderate physical activity for at least 150 minutes per week.

According to International Diabetes Federation (IDF) the total number of diabetic subjects to be around 40.9 million in India and this is further set to rise to 69.9 million by the year 2025 [13]. The prevalence of type 2 diabetes was found only to be 5 % [14]. A national rural diabetes survey was done between 1989 and 1991 in different parts of the country in selected rural populations. This study which used the 1985 WHO set criteria to diagnose diabetes, reported a crude prevalence of only 2.8% [15]. The screening was done in about 36,000 individuals above 14 years of age, using 50gm

glucose load. Capillary blood glucose level >170 mg/dl was used to diagnose diabetes.

The prevalence was 2.1 % in urban population and 1.5% in the rural population while in those above 40 year of age, the prevalence was 5 % in urban and 2.8% in rural areas. The National Urban Diabetes Survey (NUDS), a population based study was conducted in six metropolitan cities across India and recruited 11,216 subjects aged 20 year and above representative of all socio-economic strata ([16]. The study reported that the age standardized prevalence of type 2 diabetes was found to be 12.1%. This study also revealed that the prevalence in the southern part of India is on higher side- 13.6% in Chennai, 12.8% in Bangalore, and 16.9% Hyderabad, compared to eastern part of India (Kolkata), 11.7%; northern India (New Delhi), 11.6%; and western India (Mumbai), 9.6%. Keeping above points in consideration a study was formulated for measuring the health outcomes of type 2 diabetic patients. The outcomes include but not limited to socio-economic status, health and lifestyle factors such as self-perceived health status, alcohol consumption, smoking status and body mass index (BMI) for better understanding the correlation between socioeconomic status and disease condition.

Socioeconomic Status

In addition to that the relative scarcity of potential data about SES and diabetes, there remains a lack of comprehensive information about the various biological mediators of any potential relationship. Although the factors such as obesity, older age, family history of diabetes, hypertension, abnormal lipid and other CVD biomarker levels are well linked to the development of diabetes (Figure 4).

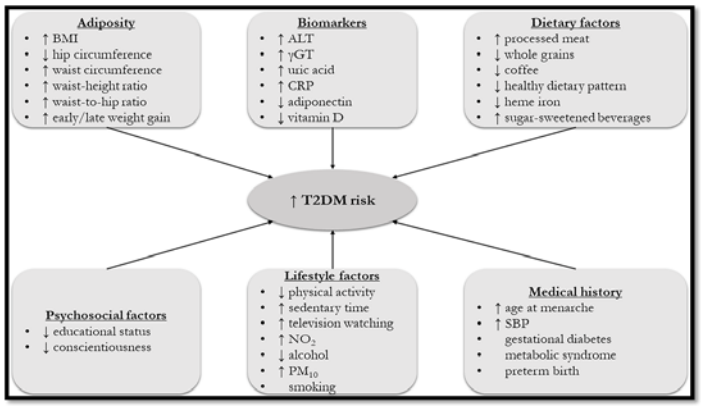

Figure 4: The different risk various Factors associated with type 2 diabetes

We are not in a state to know whether these factors mediate any relationship between SES and incident diabetes is not known [17]. When one or more of these factors influences a physician's choice of treatment, that factor becomes independently associated with both the risk of the outcome and the probability of being exposed and as such, introduces confounding by the indication bias. Although both type 1 and type 2 diabetes cause similar complications, the majority of diabetes related health care expenditures is spent on treatment of complications in those with type 2 diabetes and majority of cases are of type 2 [18]. Indeed, the possibility of residual confounding due to unmeasured risk factors can be the most important threat to the validity of the modern pharmacoepidemiological studies (Figure 5).

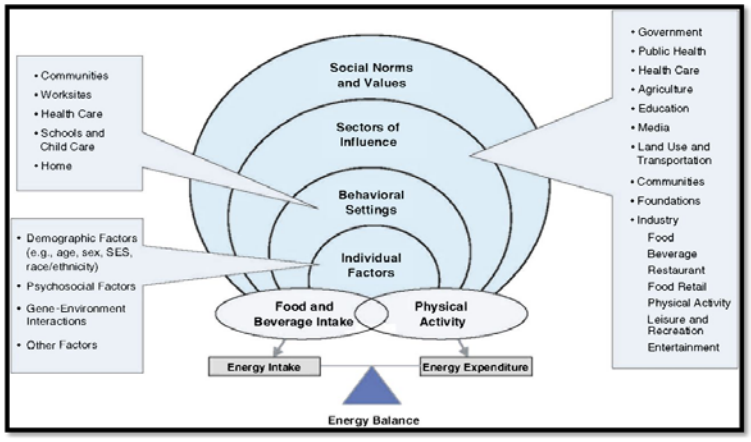

Figure 5: Socioeconomic and other responsible determinants and their prevalence in Type-2 diabetes

Discussions

The overall observational studies have made significant contributions to our understanding of the risks and benefits associated with drug therapy. Indeed, pharmacoepidemiologic studies have often been the first to identify and confirm the presence of important adverse health outcomes associated with the use of medications. These studies have also been instrumental in addressing various aspects of drug safety and effectiveness that cannot be readily or adequately evaluated using an experimental design. For example, the time-varying nature of the risk and the health benefits of drugs are important but rare outcomes are observed [19]. As such, pharmacoepidemiologic studies are required to compliment the information provided by randomized controlled clinical trials both national and international level.

Increasingly, these pharmacoepidemiologic studies are conducted using electronic, administrative health databases which are being maintained at hospitals and clinics. The large size and unselected nature of the populations captured by these databases provide results that are both precise and generalizable to persons who require treatment in routine practice and are sufficiently powered to assess the uncommon but important healthcare outcomes. These populations can also be followed for extended periods of time in a cost and time efficient manner so as to deliver the treatment in an effective way.

In contrast, the highly selected populations of randomized controlled trials are typically younger and healthier than those treated in practice owing to the exclusion of common co morbidities and the use of concomitant drugs during the clinical trials. Furthermore, clinical trials are typically powered to assess drug effectiveness and are, therefore, underpowered to detect differences in important but less common adverse health events which are likely to occur. During meta-analyses the data available for estimation do not necessarily reflect the adverse event experience of the populations treated in routine practice. Despite some important advantages, pharmacoepidemiologic database and SES studies have been the source of considerable controversy, in part due to their limited ability to control some potential sources of bias.

Treatment recommendations for the management of type 2 diabetes have changed over time. The most significant of these changes include the lowering of target glucose levels for glycemic control, the corresponding use of more intensive therapy, the choice of agent for initial therapy, and the increasing use of polypharmacy to achieve glycemic control. The implications of these changes are that the probability of being exposed to a particular treatment regimen could be associated with time. Since time may be associated with both the risk of complications and the probability of being exposed to a specific treatment and the potentially biasing effect of time is need to be accounted during designing and/or analyzing the observational studies of antidiabetic medications. The choice of treatment for combination therapy is complicated by the number of individual agent's available and important variations across physicians' practices with regards to choice of agents to combine and the sequence in which they are prescribed to the patient [20].

An important limitation of previously published studies has been the lack of power to assess clinically relevant outcomes including both SES and epidemiological variables. This is due in part to a failure to systematically document events in some large studies, and also the recruitment of low-risk populations [21]. While the recent meta-analysis by nissen [22] addressed that at least in part, the issue of statistical power and their findings require confirmation. Typically in database studies, researchers provide a qualitative assessment of the potential for residual confounding by indication due to unmeasured risk factors based on knowledge of prescribing trends in general or those specific to the agent(s) under study

For example, we know that, generally speaking, an individual's smoking status is unlikely to be an important independent determinant of treatment choice as smoking does not affect the benefits or risks associated with the vast majority of prescribed medications. Similar reasoning could be used to discuss the influence of BMI, and alcohol consumption on treatment choice. In addition, under a program of universal drug coverage, income would not likely be a strong determinant of prescribing choice, particularly when choosing amongst agents of similar cost. However, some of these qualitative arguments may not be valid for observational studies of pharmacological interventions in the treatment of type 2 diabetes.

Various studies drugs effects with observational skills as primary motto have made significant contributions in improving the public health over the past three decades. The pharmacoepidemiologic and SES studies have identified previously unknown but potentially life-threatening adverse drug effects, [23] while others have refuted the presence of suspected adverse effects [24] and also few of them identified unexpected beneficial effects.

The identification of the risk factors for diabetes has opened up the possibilities for early diagnosis of subclinical abnormalities, many of which are amenable to modifications. It is also possible to identify the high risk group by measuring simple parameters or by questioning for the presence of the family history of diabetes and by assessing the SES variable status of the individual. Subjects with a positive family history of diabetes, abdominal adiposity and with sedentary lifestyle are usually at a high risk and are therefore ideal candidates for primary prevention of diabetes [25]. Several prospective studies have shown that measures of lifestyle modification help in preventing the onset of major disease of the country i.e., diabetes [26].

Conclusion

In conclusion, we identified several potential sources of indication bias that will help in understanding the future observational studies of diabetes and its complications. In addition, a number of these sources of potential bias were not identified as *a priori*, thereby highlighting the importance of incidental exposure-confounder associations. The overall impact of these sources of bias on the validity of such studies is difficult to assess qualitatively given that individual exposure-confounder associations differed in magnitude and direction.

Accordingly, a quantitative assessment of potential sources of indication bias will need to be undertaken for authenticating the scientific and health care data. Based on the available evidence as on date, it is unclear whether the use of pharmacoepidemological and SES contribute to the magnitude of the increasing rate of morbidity and mortality observed in persons with type 2 diabetes condition. More research is needed on how race, gender, and SES impact health of individuals with DM. Studies showed a larger effect of SES on health among men, most previous research on the community sample has shown smaller effects of SES on health

However, given the increasing prevalence of type 2 diabetes, the routine use of oral hypoglycemic with regular physical activity and lifestyle may be significantly contributing in decreasing the disease condition. The significant degree of uncertainty that exists regarding the SES and the epidemiological data is required to be further investigated before concluding any outcomes. Further studies using a population-based cohort approach is required to reflect the use of these SES and epidemiological data in routine practice will emphasis on the mode of the pharmacotherapy of diabetes.

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