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Correlation between Polypharmacy and Health-Related Quality of Life in Patients of Hypertension

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ABSTRACT

Purpose: Hypertension is one of the major morbidities affecting older Indians, though current trends show that it is increasingly beginning to be detected in younger adults as well. In elderly populations, it has been shown to be associated with other comorbidities which make its treatment difficult. Among the issues that have arisen with its treatment is the increased prevalence of polypharmacy.

Thus there is a need to assess the effect such increase in medications is having on a patient's Health Related Quality of Life in order to ensure only appropriate polypharmacy is practised.

Methods: The RAND SF-36 questionnaire for HRQoL will be sent to a random sampling of hypertensive patients in India. They will all be medically diagnosed with hypertension at least 6 months prior and will have been prescribed allopathic medication for the same. They will be instructed to answer all the questions to the best of their abilities and each question will be then scored from 0-100. In addition, they will be given questions regarding their age, socioeconomic demographic, number of medications and frequency of dosage, and additional comorbidities. The independent variable i.e. the number of medications will then be compared to the physical and mental scores they received on the SF-36 questionnaire to see if there is a correlation between the two.

Hypothesis: Patients with additional comorbidities and those taking more number of medications will score lower in Health Related Quality of Life.

Key words: Hypertension, HRQoL, Polypharmacy, India, SF-36

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INTRODUCTION

Hypertension has remained the leading killer globally in 2020, with an estimated death toll, due to its complications, of more than 1 crore deaths worldwide. Most major hypertension management guidelines recommend that hypertension be diagnosed at either a systolic blood pressure greater than 140 mm Hg or a diastolic blood pressure greater than 90 mm Hg or both [1,2]. Hypertension has a disproportionate effect on elderly persons due to the gradual development of stiffness in arterial walls and modifications of compliance of arteries. There is evidence to indicate that this is due, in large part, to the environmental and lifestyle changes that the modern world has afforded us. This only makes it more likely that the number of afflicted individuals will continue to rise until drastic changes are not made to halt its spread [3].

There are several classes of drugs that can be used to control hypertension, each of them tailored to different patients' needs. A physician might prescribe one or more of the following classes of drugs at his own discretion- beta blockers, ACE inhibitors, diuretics, calcium channel blockers etc [4].

Modern medicine has heralded a slew of medical innovations that has revolutionized disease treatment in patients, not only in the treatment of hypertension but other conditions a well. The increasing number of developed drug classes has benefitted mankind immensely but when faced with the problem of multi-morbidity, have also increased the chances of inappropriate polypharmacy. The guidelines of pharmacy

that once accounted for only single morbidities are having to be reassessed as cases of multi-morbidities become increasingly common [5].

Now, while the definition of multi-morbidity has been accepted near universally as the simultaneous sufferance of two or more chronic health conditions [6], polypharmacy definitions are more variable. A 2017 review of polypharmacy definitions by Masnoon, et al. found that numerical definitions of polypharmacy were sometimes inaccurate as they failed to account for the number of comorbidities being treated [7]. Hence, for the purpose of this article, we will be referring to the non-numerical definition i.e. the concurrent use of multiple medications daily by a single patient [5,7,8].

Health Related Quality of Life (HRQoL) is a term used to understand the general quality of a patient's life in the context of their physical and mental health [9]. It is usually assessed by questionnaires that may be of the generic or specific variety. The latter is tailored to a specific group that is to be assessed while the former includes the SF-36, EuroQol-5D among others [10,11]. The SF-36 questionnaire is the one used in this article. It contains 36 questions that measure 8 variables encompassing both physical and mental well-being and has been found to be effective in its assessment [12].

Background

Hypertension is very much on the rise, especially in developing countries with an income on the middle and lower end of the scale [13]. In 2019, it was reported that in India, approximately 29.8% of people suffered from an increased blood pressure. The gap between rural and urban afflicted was also found to be narrowing as diet and lifestyle changes were altered [14]. This increase in cases is due to the fact that it is a multifactorial disease, with both genetic and environmental risk factors playing a role in its widespread nature [15]. Furthermore, the treatment of hypertension is often complicated with prevalence of additional comorbidities, both common and uncommon. The former include coronary artery disease, stroke, chronic kidney disease, COPD and heart failure while the latter is attributed to rheumatic and psychiatric ailments. Diabetes is also common among elderly patients suffering from hypertension and requires careful monitoring by the physician to ensure adequate care is given to the patient. Ultimately, these ailments need to be treated as well as hypertension and hence arises the problem of polypharmacy [1].

Polypharmacy has become a common sight in recent times, especially in older patients. This can be attributed to an increased life expectancy and a subsequent 'accumulation' of chronic health conditions. With each additional comorbidity comes the need for a new or adjusted treatment plan often including multiple drugs or drug classes several times a day. Pressure on doctors to adhere to disease-specific guidelines tailored to singular illnesses also contributes to the increased prevalence of polypharmacy [15,16].

The common negative effects associated with polypharmacy include drug-drug interactions, adverse drug interactions, increased healthcare costs and duration of hospitalization, increased risk of falls, frailty, disability and patient non-adherence [17]. The last need not be intentional as forgetfulness was found to be a major cause of patient non-adherence, especially in elderly patients who are likely to be taking multiple medications.(18–20) In addition, there is a negative impact on the healthcare system as well with reduced physician productivity, risk of medication errors and a greatly raised burden on the system itself [17]. As such, there is a need for reduction in inappropriate prescription of drugs and in this vein, there have been studies evaluating the possibility of doing just that.

However, it is important to note that polypharmacy in itself is not harmful; rather, it is inappropriate polypharmacy that is associated with the common adverse effects. Oftentimes multiple medication classes are needed to treat a patient's multiple morbidities and any drug interactions, adverse or side effects are the lesser of two evils, when compared to the patients' clinical conditions [16]. Thus there is a need for considering not only the number of medications, but also the additional chronic conditions a patient might be suffering from.

With consideration of the above points, it appears that polypharmacy and its association with quality of life is not entirely understood. This study serves to provide better insight into the necessity of guidelines for 'appropriate polypharmacy' and understand what, if any, association is present between polypharmacy and health related quality of life.

Previous studies have mostly shown a negative impact of polypharmacy on health related quality of life though they have all been conducted in other countries [4,8,18-23]. There appears to be only one similar study conducted in India, that of Koshy, et al. where the quality of life of psychiatric patients undergoing polypharmacy was contrasted with that of those undergoing monotherapy [24]. There is no similar study based in India relating to hypertensive patients or those with cardiovascular indications. Thus, with the lack of prior studies conducted in India, there was a need for this topic to be considered.

Aim and objectives

Aim

To find the association between polypharmacy and health related quality of life in patients of hypertension in India.

Objectives

To find the physical component of health related quality of life of patients of hypertension.

To find the mental component of health related quality of life of patients of hypertension.

To compare the two components of health related quality of life with the number of drugs taken by the patients.

To note the presence of additional comorbidities in patients of hypertension.

To compare the presence of comorbidities and health related quality of life in patients of hypertension.

To associate other covariates like sociodemographic and health related data, with change in health related quality of life in patients of hypertension.

METHODS

Study design

It will be a cross sectional type of observational study. The data obtained will be from questionnaires sent out to patients across India. The questionnaires used, will include the SF-36 survey as well as a few additional questions to establish sociodemographic characteristics. Furthermore, it will include questions regarding additional comorbidities and the number of medications being taken by the patient per day based on their own reporting.

Study population

Inclusion criteria

Patient should be above 18 years of age and should be mentally capable of providing consent

Patient should be a medically diagnosed patient of hypertension

Patient should be taking allopathic medication for hypertension for a period greater than 3 month.

Exclusion criteria

Patients that don't consent/are unable to consent.

Illiterate patients/patients who cannot comprehend the questions.

Informed consent will be taken from each patient in accordance with ethical guidelines and all information collected will be anonymised.

Dependent variable

The dependent variable in this study is the Health Related Quality of Life of the patient. It is measured with the SF-36 questionnaire, adjusted slightly for the Indian audience. This questionnaire has been shown to be effective and is widely used in both chronic conditions and general quality of life studies [12,23,25]. It is a generic questionnaire that measures eight concepts of health with 36 questions. Each question is scored from 0 to 100 percent, (adjusted based on the number of options) with 0 percent being the lowest and 100% being the highest. The SF-36 provides three scores. The physical component scores encompass the concepts of physical functioning, bodily pain, role limitations due to physical health problems and energy/fatigue. The mental component scores include role limitations due to emotional problems, emotional well-being and social functioning. The last score is that of the total HRQoL score which includes all the 8 concepts [26].

Independent variable

The independent variable in this study is the number of medications being taken by a patient. We believe that as the number of drugs increases, there will be a subsequent decrease in HRQoL, thus implying that there is a direct correlation between the two. As there is no concrete numerical definition of polypharmacy, we chose to assume a non-numerical definition. We will ask each patient to enumerate the maximum number of drugs they are taking in a single day and compare it to the reported and calculated HRQoL. As the inclusion criteria only specify hypertension, we will include a question about any additional comorbidity as well.

Covariates

Variables that could inadvertently affect the dependent variable, i.e. HRQoL, include sociodemographic characteristics and health related information.

We will collect sociodemographic information including age, gender, urban or rural area of residence and education. The health related information will include additional comorbidities (they will be asked the number and to specify) and habits like smoking, alcohol use, exercise, body mass index and diet.

By including this data when considering the results, we can avoid drawing inaccurate conclusions about the reasons behind change in HRQoL.

Statistical analysis

We intend to use Microsoft Excel, Version 2019 to analyse the data we receive.

It is our intention to use descriptive statistics to profile the population sample. As the statistical hypothesis is a negative correlation between HRQoL and polypharmacy, we intend to use a multiple regression model to assess the association between the two and prove or disprove our null hypothesis. With HRQoL as the outcome dependent variable and several predictor variables including but not limited to polypharmacy, additional comorbidities and sociodemographic information, it is our belief that a multiple regression analysis is most appropriate as a statistical tool.

For the depiction of the data, we will be using a scatter plot as it gives an accurate and easily understood analysis of data.

Expected outcome

The expected outcome is that the HRQoL values will reduce as the number of medications taken by a patient increases, i.e. there will be a negative correlation between the HRQoL and polypharmacy.

DISCUSSION

There are multiple factors to consider when predicting an outcome for this study. The first is the effect the covariates will have on the change in HRQoL, the second is the actual change in HRQoL and the third is the effect of multiple drug classes as opposed to multiple times of

taking the same medication. The last is of course, less likely to be associated with adverse drug reactions and drug-drug interactions while simultaneously showing lowered patient compliance as the risk of forgetfulness increases.

While there are plenty of negative effects associated with polypharmacy, as has been discussed above, the fact remains that for many patients their quality of life was worse when inundated by multiple maladies. The various medications, while ostensibly large in number, may in fact be a better option for patients than the alternate, thus bringing into consideration the phrase, 'appropriate polypharmacy'. Related studies were reviewed [27-31].

Ultimately, however, past data seems to indicate that polypharmacy is in general associated with a reduction in HRQoL, across a multitude of diseases, age classes and locations. Thus, it is reasonable to assume that the data collected for this study will show similar patterns and indicate the need for better checks and balances in the prescription of multiple drugs and drug classes.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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