PERCEPTION OF QUALIFIED MEDICAL PRACTITIONERS TOWARD PRESCRIBING IN INTERNATIONAL NON-PROPRIETARY (GENERIC) NAMES – AN OBSERVATIONAL, CROSS-SECTIONAL STUDY AT A TERTIARY CARE HOSPITAL IN INDIA

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ABSTRACT

Objectives: The study was conducted to assess the perception and practice of medical practitioners, working in tertiary care, and teaching institutions in Eastern India, regarding the use of generic (non-proprietary) names while prescribing. The study tried to assess their perception toward using drugs from the National List of Essential Medicine (NLEM), as well.

Methods: An observational, cross-sectional study was conducted. Medical practitioners attached to the institution were considered for the study and those who gave voluntarily consent were included. Hundred participants were interviewed based on convenient random sampling. They were provided with the study questionnaire and the responses were analyzed using Microsoft Excel 2007 using charts and tables.

Results: Majority (43/100) did not feel that generic medicines are as effective as reputed brands, while 32 felt they are of equally effective. About 45% (45/99) felt generics to be equally safe as and 24% (24/99) did not feel so. About 86% considered generics to be cheaper. About 56% did not prefer to substitute with generics in all conditions. About 73% had doubts regarding the quality of production of generics. The decision to use generics was mostly influenced by the lower cost (73%) and by administrative reasons (53%). About 58% felt that the NLEM does not contain all the medicines they would require in practice. About 94% agreed to prescribe more in generics if the quality may be ensured.

Conclusion: Awareness of the NLEM and about generics needs to be improved. Authorities need to ensure the quality of generics and assure the prescribers about it.

Keywords: Generic name, Perception of qualified medical practitioners, Observational, Cross-sectional Study.

INTRODUCTION

Non-proprietary name is the name of a drug (or pharmaceutical substance) which is accepted by a competent scientific body/authority, for example, the United States Adopted Name or the British Approved Name [1].

To provide a globally accepted unique way of recognizing pharmaceutical substances, the International Non-proprietary Names (abridged as the INN) have been used. INN is often popularly called as "generic name” [2].

The Medical Council of India wanted every physician to prescribe drugs in generic names [3]. In India, generic medicines are mostly available in brand names (branded generics). The medical community in India remained skeptical about the quality of generic medicines available in India as well as regarding the responsibilities if a patient does not respond to drugs prescribed in generic names [4,5]. There has been doubt regarding the robustness of drug regulatory environment in India raising questions about whether generic drugs are as effective as branded drugs [6].

The present study was conducted with the aim to assess the perception and practice of medical practitioners working in tertiary care and teaching institutions in Eastern India, regarding the use of generic (non-proprietary) names and their knowledge and attitude about using drugs from the National List of Essential Medicine (NLEM) while prescribing.

MATERIALS AND METHODS

It was an observational, cross-sectional study. The study was conducted at a tertiary care institution in Eastern India. Medical practitioners attached to the institution were considered for the study and the doctors who voluntarily agreed and cooperated were included in the study. A total of 100 participants were interviewed based on convenient random sampling. Practitioners of all hierarchy and from various disciplines were interviewed.

Data collection was done from September 2019 to February 2020 using a pre-designed and structured questionnaire.

Doctors working in the institution were invited to participate in the study randomly – either through direct personal approach or through digital means. Doctors working outside the tertiary care center were excluded from the study. They were provided with the survey questionnaire – either a hard copy (for those who participated using offline methods) or with a digital version using a Google form (for those who participated online).

The response forms were kept anonymous to facilitate that the participating doctors can share their opinions freely.

The forms submitted offline were then entered digitally in the same online form so that they reach the common database. The final compiled database was downloaded in Excel format for analysis.

Ethical consideration

Prior permission from the institutional ethics panel was taken.
RESULTS

First, some medical professionals were approached personally. Initially, all of them consented but completed forms were not received from five of them. Later medical professionals were approached online and interested participants could submit their responses in the online questionnaire. Once the target level of 100 was reached, the survey questionnaire was closed for further submission.

The total number of medical professionals included for analysis was 100.

Respondents were allowed to answer anonymously and they were allowed to skip any point they would not like to answer.

The average age of the respondents was 38.28 years (±12.36) (96 responses) with a median of 35 years. About 73.5% were male and 26.5% were female (98 responses). About 60.8% (59/97) were from clinical departments while 39.2% (38/97) were from pre/para-clinical departments. Mean (±SD) experience in years of practice was 13.64 (±11.29) years and the median was 10 years.

Of the 100 respondents, 32 felt that the generic medicines are as effective as the reputed brands while 43 did not think so. Rest 25 respondents remained neutral to this question (Fig. 1).

Approximately 45.45% (45/99) considered generic medicines to be as safe as reputed brands and 24.2% (24/99) did not consider so. Rest 30.30% (30/99) remained neutral.

However, a whopping 86% (86/100) agreed that the generics are cheaper than the reputed brands, only 3% opined differently.

Among the 99 respondents, 36.36% (36/99) think that the generic drugs and the originators have the exactly same structure. However, 20.20% (20/99) had differed. About 43/43% (43/99) remained neutral.

Regarding substitution of brands with generics in all conditions, the majority (56/100) did not prefer so while only 23% (23/100) were okay with that. Nearly half of them (49/100) did not think that generics cause more adverse effects but 15% (15/100) medics felt so.

Close to 72.73% (72/99) had doubts regarding the quality of production of generic medicines while 11.11% (11/99) did not doubt the quality (Fig. 2).

Nearly 66.67% (66/99) thinks that generic drugs are subjected to clinical trials while only 15.15% did not think so. Only 42.42% (42/99) accepted to use generic names in all their prescriptions while 18.18% (18/99) did not. About 39.39% (39/99) remained neutral. About 42% (41/98) doctors were of the opinion that their decision of using generic drugs is influenced by patients’ choices while close to 39% (38/98) were not thinking so. About 73.47% (72/98) opined that their decision to use generic drugs is influenced by their lower cost but around 13% (13/98) did not feel so. Near about 53.06% (52/98) opined that their decision to prescribe in generics were influenced by administrative pressure but 19.39% (19/98) did not think so. Only close to 10% agreed that their decision to prescribe branded drugs is influenced by pharmaceutical companies while a whopping 67.35% (66/98) objected to that. Nearly 45.92% (45/99) expressed that they are familiar with the current NLEM’s in India (NLEM) while 29.29% (29/99) were not (Fig. 12). However, 54% (54/100) opined that they prefer to choose from NLEM while prescribing in generic. However, 22% (22/100) do not prefer so.

Nearly 58.76% (57/99) think that the NLEM does not contain all the medicines that their patients need while only 9.28% (9/97) did not report that problem.

A whopping 94.95% (94/99) agreed that they would prescribe more in generics if the quality may be ensured. Only 2.02% did not agree (Fig. 3).

However, nearly 62.63% (62/99) reported that their patients believe that the generics are not as effective as the reputed brands but just 18.18% (18/99) did not report this as a hurdle.

DISCUSSION

Some studies conducted in different parts of the globe included general practitioners and/or primary care physicians [7-13] while some studies have included practitioners from tertiary care institutions [14] while some included pharmacists as well [15,16]. Some studies included much diverse participants from different types of health-care facilities [17-21].

In India, studies have been conducted at tertiary care settings at various states [22-25], while some studies were conducted on medical practitioners based on particular cities [26,27]. Some studies had included both [28,29].

Participants, in our study, were from clinical departments as well as from Pre/Para clinical departments. In this institution, pre/para clinical departments generally run the general outpatient department (OPD) of the hospital.

Regarding efficacy, the majority of our respondents did not feel that the generics are equally effective as the reputed brands. However, more
doctors felt that the safety of the generics is at par with their branded counterparts, than those who did not feel so. A very large number of participants had concerns regarding the production quality of generics and the vast majority (~95%) opined to prescribe more in INN if the quality of generics may be ensured.

Interestingly, about 62% reported that even their patients do not feel that generics are as effective as reputed brands. Searching through the literatures, it revealed that in a study conducted in a tertiary care institution in India by Tripathi and Bhattacharya found that about 61% of the patients in their study felt that generics are not at par with the brand in terms of quality [30].

Quality concerns were identified in other studies as well (Zaverbhai et al. [25]) – including in studies from the Western countries (Lagarce et al. [31], Gossell-Williams [32]). A systematic review by Toverud et al. [33] found quality concerns especially in countries with less mature health-care system. However, some studies conducted in other areas found the perception to be different in this regard (Gupta et al. [22], Gupta et al. [24]).

Regarding substitution of brands with generics in all conditions, the majority did not feel comfortable with that. This is in contrast with some other Indian studies like those by Tandel et al. [23], Gupta et al. [24], and Patil et al. [28].

Cost was found to be an important issue, as a vast majority (86%) agreed that generics are cheaper than the reputed brands. Similar findings were observed in some other Indian studies like the one by Tandel et al. [23]. In our study, lower cost of found to be a very important factor influencing prescription in generic names (~75%).

Patient’s preference was an influencing factor for some while for majority the administrative pressure was considered to be a more important reason. In this institution, the administrative directive has been to prescribe in generic names (INN). The hospital pharmacy provides generic (or branded generic) medicines to patients free of cost – on production of prescription and medicine slips issued by the hospital doctors – as part of the government’s policy to free healthcare. The hospital houses a “fair price” shop where patients can buy “generic” (or branded generic) medicines at heavily discounted rates as specified by their agreement with the government.

Influence by pharmaceutical companies is often alleged to influence the prescribing pattern and promotional activities by pharmaceutical companies have been much debated [34]. However, in our study, only around 10% opined that their prescribing in branded names is influenced by pharmaceutical companies whereas over 67% refuted that. The hospital banned the entry of representatives of pharmaceutical companies to the OPD consultation area. In addition, this may be partly due to the availability of a wide spectrum of medicines, in generics (or branded generics) to the patients free of cost.

One important concern was, however, that less than 50% doctors stated that they were familiar with the current NLEM. However, majority preferred to choose from NLEM while prescribing. Although, 22% doctors differed in this that may be related to the finding that over 50% felt that the NLEM does not contain all the medications they need in the tertiary care hospital.

CONCLUSION

In our study, we found that many doctors are very much concerned with the quality of generics. This concern appears to be the major limiting factor in prescribing in generics. Importantly, nearly about 95% agreed to prescribe more in generics if the quality may be ensured. Awareness about generics and about NLEM needs to be improved. Based on the findings of our study, we would like to suggest that the concerned authorities can take necessary measures to ensure the quality of generic medicines available in the market as well as to assure practitioners in this regard. In addition, regular Continuing Medical Education activities to improve the awareness, regarding generics, and regarding the NLEM and its importance, among medical professionals should be recommended for further improvement.

Limitations

The study may be further improved by including additional parameters.

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AUTHORS’ CONTRIBUTIONS

Preparation of the protocol was done by Manab Nandy and Kushal Banerjee. Collection of data was done by Manab Nandy, Kushal Banerjee, Kajori Nandy and Souvik Majumder. Statistical analysis was done by Kushal Banerjee and Indranil Biswas. Preparation of the manuscript was done by Manab Nandy, Kushal Banerjee, Ayan Mukherjee and Alak Kumar Das.

CONFLICT OF INTEREST

Nil.

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