

Perception of Doctors towards the Quality of Generic Medicines with Respect to Safety Index of Drugs and its Impact on Prescription of Generic Medicines

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SUMMARY

Background: Generic Medicines are low-cost alternatives to the branded medicines. The quality of generic medicines has always been the point of concern to all consumers, physicians and pharmacists. This study is conducted to understand the perception of doctors towards Quality of Generic Medicines particularly with respect to the Safety Index of Generic Drugs. This will help us to understand the therapeutic impact of quality of generic medicines. **Objective:** To study the perception of Doctors regarding the Safety Index of Generic Medicines and Branded Generic Medicines that prevails in the market of Nagpur Region. **Materials and Methods:** A well framed questionnaire with 5-point scale is used to collect the data. Ethical standards are being practised for the study. **Statistical Analysis Used:** The data collected is being analysed by Hypothesis Testing by Proportion Method. **Results:** Out of the total sample of 182 doctors, 70% of the population prefers to use generic medicines in their prescription. Out of the doctors who prescribe Generic Medicines in their prescription, more than 50% doctors i.e. majority of doctors perceive that Generic Medicines and Branded Generic Medicines have same Safety Index. **Conclusion:** Doctors consider to prescribe generic medicines only if the quality results are maintained. Doctors' inclination towards the prescribing of generic medicines can be seen. It is therefore important to maintain the quality standards of the generic medicines. Out of the doctors who do not prescribe generic medicines, majority of them perceive them to be of sub-standard quality due to low Safety Index. Hence, the Safety Index is the dominating factor behind the decision to not to choose generic medicines for their prescriptions.

Keywords: Generic Medicines, Quality of Generic Medicines, Safety Index of Generic Medicines, Perception of doctors, Prescription of generic medicines, Impact of Quality

INTRODUCTION

The perception of doctors regarding the safety index of generic

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medicines can vary depending on various factors such as their experience, knowledge, and exposure to different brands and formulations. Here are some general points that may influence their perception and the impact on prescription decisions:

Efficacy and Safety Studies: Doctors often rely on clinical studies and research to assess the safety and efficacy of generic medicines. If a generic medication has undergone rigorous testing and has demonstrated comparable results to the brand-name equivalent, doctors may have more confidence in prescribing it.

Regulatory Approval: Generic medicines undergo regulatory approval processes to ensure they meet the same standards of quality, safety, and effectiveness as brand-name drugs. Doctors typically consider this regulatory oversight and approval when forming their perception of generic medicines.

Patient Feedback and Experience: Doctors may consider patient feedback and experiences with generic medicines when forming their perception. If they receive positive feedback from patients who have successfully used generic medications, it can positively influence their view and prescribing patterns.

Professional Guidelines and Recommendations: Medical associations and professional bodies often provide guidelines and recommendations on generic medicines. Doctors may align their perception and prescribing practices with these guidelines, which can influence their decision-making.

Pharmaceutical Industry Influence: Doctors' perception of generic medicines may also be influenced by interactions with pharmaceutical representatives, who may promote brand-name drugs or raise concerns about generic counterparts. Awareness of such potential biases is essential to ensure informed decision-making.

Overall, doctors' perception of generic medicines' safety index can have an impact on their prescription decisions. However, it is important to note that perceptions can vary among individual doctors, and many factors contribute to their decision-making process, including scientific evidence, patient feedback, and professional guidelines.

Rationale for Selecting This Topic

In spite of tremendous efforts by Govt. to enforce the usage of generic medicines, there prevails a resistance towards

the prescription and consumption of Generic Medicines. Therefore, the study aims to find out the perception of Doctors regarding the Quality of Generic Medicines. In this study, the experience of doctors with respect to Safety Index of drugs is studied.

Review of Literature

During the study, Electronic Secondary Data in the form of Repositories, several books, magazines, journals, newspaper articles etc. on Quality of Generic Medicines are being studied.

What do people really think of generic medicines?'A systematic review and critical appraisal of literature on stakeholder perceptions of generic drugs, by Suzanne S. Dunne, author and Colum P. Dunne [1]. The study focuses on understanding the perspectives of Physicians, Pharmacists and Consumers regarding generic medicines.

The research methodology followed in this study was 16, 11 and 31 papers from physicians, pharmacists and consumer opinions, respectively, were included in this review. The study reveals the acceptance of Generic Medicines by Physicians due to Economic Pressure and Policies but there remain concerns regarding the quality, reliability and switching of Generic Medicines. Enhancing the opinions of physicians may have particular importance in strategies to promote usage and acceptance of generic medicines in the future.

Generic Medicines: Greek Physicians' perceptions and prescribing practices by V. Tsiantou, D. Zavras, H. Kousoulakou, M. Geitona and J. Kyriopoulos*, an article published in Journal of Clinical Pharmacy and Therapeutics in 2009 states that though physicians have a positive view on generic medicines, they prefer to prescribe original products. The important determinants of their prescribing decision identified are age and their opinion on the efficacy of generic medicines. The primary reason that could help them change their prescribing habit is the occurrence and type of side effect(s) [2].

Study found that though physicians are willing to prescribe generic medicines, branded medicines are highly prescribed considering the reliability of medicines as the major factor. One new factor, 'age' has shown a positive effect on physicians prescribing decisions. Paper suggests the need to introduce promotion policies for generic medicines and incentivize physicians, pharmacists and patients for prescribing, dispensing and using generic medicines, respectively.

The paper also highlights the fact that penetration of generic medicines seems higher in countries with free pricing policies than countries with strict pricing regulations. Also, it mentions about the effect of reference pricing system on the development of generic market. Structured questionnaire was used as data collection tool. Statistical analysis was done by descriptive measures, Fisher's exact test, and logistic regression analysis. 1204 samples of prescribing physicians were analysed. Dependent variable was physicians prescribing decision and independent variables were gender, age, work experience, country of qualification, employment sector, information provided by sales representatives, drug cost, insurance coverage, patient's income capability, efficacy, effectiveness and safety of generics, necessity of INN implementation, and feasibility of INN implementation.

The review on Generic Medicine and Generic Prescribing in Nepal: An Implication for Policymakers by Rajeev Shrestha, Sunil Shrestha, Binaya Sapkota, Santosh Thapa, Mukhtar Ansari, Asmita Priyadarshini Khatiwada, Rohullah Roien and Akihiko Ozaki discusses the current scenario of Generic Medicines Market in Nepal with respect to its Prescription and Usage. The major challenges found for the proper implementation of generic prescription and usage include the lack of facilities and competency to assure therapeutic equivalence of generic medicines, lack of understanding about generic medicines among health care providers, the public and lack of stringent regulations towards promoting generic medicines [3].

The research paper by Mohsen Ali Murshid and Zurina Mohaidin has put up an extensive study to analyse four factors that influence physician's prescribing decision [4]. Factors studied are available information on drugs, brand of a drug, medical representatives and sales promotions. In the study, it is found that available information on drugs, medical representatives, and sales promotions had no significant effect on prescribing decisions of physicians. While, the brand of a drug had positive effect on physician's prescribing decisions. The study was conducted in Yemen. Sample size of 393 physicians from out-patient departments of public and private hospitals were analysed. Data was collected with self-administered questionnaires and was analysed by partial least squares structural equation modelling (PLS-SEM). Four hypotheses were proposed and analyzed on the basis of factors considered under study.

A study on the knowledge, attitude, and practice of generic

medicines among the doctors in a tertiary care teaching hospital in south India', a research article by Sandeep Kumar Gupta, Roopa Prasad Nayak, Surendra Kumar Vidyarthi published in National Journal of Physiology, Pharmacy & Pharmacology found that 76.7% doctors were aware of the fact that generic medicines contain same active substance as of innovator medicine and the same dose is used to treat the same disease as the innovator medicine. 79.5% doctors were aware that generic drug manufacturers need to conduct bioequivalence studies to show equivalence between the generic medicine and the innovator medicine, 75.3% doctors did not agree that generics are not as safe as innovator drugs. 64.4% doctors did not agree that generics are not as effective as brand name drugs, 71.2% doctors do not think that switching a patient from a brand-name to generic drug may change the outcome of the therapy. 63% doctors said that they prescribe generic drugs [5].

Comparative effectiveness of generic and brand-name medication use: A database study of US health insurance claims'; PLoS Med. 2019 Mar; 16(3): e1002763. Published online 2019. doi: 10.1371/journal.pmed.1002763 [6]. In this study, 3.5 million patients were targeted. Observation of the study was that the use of generic medicines provided comparable clinical outcomes as that of brand-name products for chronic conditions like diabetes (glipizide), hypertension (amlodipine, amlodipine-benazepril, and quinapril), osteoporosis (alendronate and calcitonin salmon), and depression and anxiety (escitalopram and sertraline).

A study on 'Knowledge, Perception and Attitude Regarding Generic Medicines among Iraqi Physicians' by Layla Abdullah Mahdi, Dheyaa Jabbar Kadhim, and Ali Azeez Al-Jumaili, published in Innovations in Pharmacy in 2020 shows that most respondents' answers regarding the knowledge of generic medicines were incorrect [7]. Only 26.6% of the sample population knew that generic medicines are therapeutically equivalent to brand name medicines and only 34.7% population sample was aware that generic medicines are as safe as brand name medicines. Only 12.1% population sample knew that generic medicines are required to meet similar safety standards as brand name medicines. With respect to perception, many physicians had negative perceptions about generic medicines. 57.3% physicians perceived generic medicines to be of low quality and 41.1% physicians perceived that generic medicines cause more side effects. Regarding their attitude towards generic medicines, 64.5% physicians were

willing to prescribe low-cost medicines; however, only about half i.e. 51.6% physicians stated that they prescribe generic medicines. 64.5% physicians were not comfortable with pharmacists replacing prescribed brands. The study concludes that Iraqi physicians have negative perception and attitude about generic medicines. Significant gaps were identified in the knowledge and perceptions among physicians regarding generic medicines especially in relation to efficacy and safety of generic medicines.

Opinion of primary care physicians regarding prescription of generic drugs: A Cross-sectional study by Jaykaran Charan, Deepak Saxena, Mayur Chaudhri, Siddhartha Dutta, Rimple Jeet Kaur, and Pankaj Bhardwaj, published in Journal of Family Medicine and Primary Care reveals that 57% physicians agreed that doctors should prescribe generic medicines, while

substandard quality (24.4%) and less effectiveness (35.6%) of generic medicines were found to be the major reasons for low use [8].

RESEARCH METHODOLOGY

An exploratory research method is performed by using a well-structured questionnaire as the survey tool.

The survey is being conducted on 200 Doctors from all parts of the Nagpur Region. 18 questionnaires are not being considered for analysis of survey due to ingenuine pattern of answers while 182 sincere questionnaires are being considered for final data analysis.

Data- The sample size of 182 doctors is considered for data analysis.

Table 1: Proportion of Doctors Agreeing to Similar Safety Index out of the Total Sample Size.

Total Sample Size	182			
Factor	Agree	%	Disagree	%
Safety Index	112	61.54	70	38.46

Table 2: Proportion of Doctors Agreeing to Similar Safety Index out of the Total Prescribers.

Total Prescribers	128			
Factor	Agree	%	Disagree	%
Safety Index	98	76.56	30	23.44

Table 3: Proportion of Doctors Agreeing to Similar Safety Index out of the Total Non-prescribers.

Total Non- Prescribers	54			
Factor	Agree	%	Disagree	%
Safety Index	14	25.93	40	74.07

Hypothesis

$H_0: P = 0.5 \rightarrow$ 50% of doctors perceive that the safety index of generic and branded generic medicines are similar.

$H_1: P > 0.5 \rightarrow$ More than 50% doctors perceived that the safety index of generic and branded generic medicines are similar.

Hypothesis is tested with Hypothesis Testing for Proportions Method.

CALCULATION

$pH_0 = 0.5:$ Hypothesized Value of the Population Proportion

$$qH_0 = 1 - pH_0$$

$$= 1 - 0.5$$

$$= 0.5$$

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Sample Size (n) = 128

$\bar{p} = 0.77$ Sample Proportion of Positive Samples

$\bar{q} = 0.23$ Sample Proportion of Negative Samples

$\sigma_p = 0.05$ (Level of Significance)

σ_p Variance = $\sqrt{[(pH_0 \times qH_0) / n]}$

$$= \sqrt{[(0.5 \times 0.5) / 128]}$$

= 0.0441 (Standard Error of Proportion)

Critical Z Value: $Z = (\bar{p} - pH_0) / \sigma_p$

$$= (0.77 - 0.5) / 0.0441$$

$$= 6.12$$

$$Z_c = -1.1645$$

$$Z > Z_c$$

$$6.12 > -1.1645$$

Z value falls under Rejection Region. Hence, Null Hypothesis $H_0: P = 0.5$ is rejected.

Therefore, Alternate Hypothesis $H_1: P > 0.5$ is accepted.

Inference- More than 50% of doctors perceive that the safety indexes of generic and branded generic medicines are similar.

OBSERVATION

Out of the total sample size of 182 doctors, 128 doctors prescribe generic medicines. That means, 70% of the population prefer to use generic medicines in their prescriptions.

Out of the doctors who prescribe generic medicines in their prescriptions, more than 50% of the doctors i.e. majority of doctors perceive that generic medicines and branded generic medicines have similar safety index.

CONCLUSION

Majority of the doctors who prescribe generic medicines (77%) perceive that the quality of generic medicines and branded generic medicines with respect to safety index of drugs is similar. Amongst the doctors who do not prescribe generic medicines, majority (74%) perceive that the safety

index differs with respect to generics and their branded generic counterparts.

It is therefore evident that quality of medicines with respect to the safety index is the most dominating factor towards the decision to prescribe generic medicines. Hence, it is important to maintain the quality standards of generic medicines so as to retain and increase the use of generic medicines in a doctor's prescription knowledge.

SUGGESTION

Generic medicines should have the quality control check approval mark on the strip. This will help to enhance the confidence of doctors to use generic medicines in their prescriptions and at the same time boost the confidence of patients to use generic medicines.

LIMITATIONS OF THE STUDY

1. One of main limitation of the study would be that the survey will be conducted in Nagpur region only.
2. As compared to total pharmacies, physicians, pharmaceutical companies and consumers in the region, only a limited number will be considered during the study and will be included in the questionnaire for the survey.
3. The sample size may be limited and may not represent the whole population.
4. Under the primary data collection, the answers given by the surveyed sample may not be reliable.
5. Under the secondary data collection researcher will rely over the data sources which may or may not be perfect.
6. This study is with respect to the pharmaceutical sector only.

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