EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 9
Issue: 2
114-118
Year: 2022

OBSERVATIONAL STUDY OF DOCTORS KNOWLEDGE, ATTITUDE AND PRACTICE ABOUT GENERIC VERSUS BRANDED MEDICINES IN ALL GOVERNMENT HOSPITALS OF A DISTRICT IN NORTHERN INDIA

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Article Received on 24/11/2021 **Article Revised on 14/12/2021** **Article Accepted on 04/01/2022**

ABSTRACT

Background: Generic medicine plays important role to achieve universal healthcare at affordable cost. Therapeutic outcome of generic drug is same as branded drug. **Aim and Objectives:** Assessment of Doctors knowledge, attitude and perception on generic versus branded medicines in all govt. Hospitals of a distt. in Northen India. **Material and Methods**: This was a prospective cross-sectional study conducted among all doctors working in govt. Hospital in distt. Total 120 doctors participated and filled up the structured, validated questionnaires from October 2021 to December 2021 were analyzed. All data was entered and analysed in the Statistical computer program, SPSS 20 for Windows. Data was presented as frequency and percentage. **Results:** Total 120 participants, 64% male and 37% were female. Majority 80% of doctors were graduates (MBBS) while 21% were postgraduate degree holders (MD/MS/Diploma). 68.3% of doctors have knowledge of generic and branded medicines. 34.2% knew that generic drug contains the same active substance(s) as dose, efficacy, safety, bio equivalence as branded medicine 55% were aware of MCI act regarding prescription of generic medicine. 55.8 % were aware of availability of generic medicines in Jan Aushadhi stores and internal pharmacy of their hospital.Only 40% doctors prescribe generic medicines in all diseases including chronic. About 52.5% think that generic medicines are cheaper than branded because of substandard quality. 78.3% likes to promote generic drugs, 96.7% doctors agreed for training programme to increase the awareness regarding quality testing of generic medicines 63.3% think that govt. of India, medical insurance companies should give preference to generic medicines over branded while only 35.8% of the doctors believe that generic medicines take similar time to act in the body and produce similar adverse reactions as branded 63.3% doctors prescribe generic medicines if available in hospital. 15% of doctors were comfortable if drug chemist substitute generic medicines into branded .Only 10% doctors think that pharmaceutical companies influence prescription pattern to promote branded medicine through medical representatives by offering gifts .40% doctors believe that patients demand branded medicines because of medical reimbursement facilities given by Govt. of India **Conclusion:** There is need to improve awareness among doctors by conducting training programmes about the prevalent policies of Indian government on generic drugs by strengthening quality control, making them easily available in every govt. hospital pharmacy and Jan Aushadi Kendra at low cost to the public and by monitoring physicians prescription audit will promote generic medicines.

KEYWORDS: Generic drugs, KAP- knowledge Attitude Practice, Prescription audit, Substitution, Government policy.

INTRODUCTION

Generic medicine is defined by the World Health Organization, to mean "a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights".[1] The generic drug has same bio-equivalence to the original Branded product in terms of active ingredient i.e Same in strength, safety, efficacy and quality.[2] In the post-expiry phase, other drug-makers may manufacture the same drug and sell it under an international non-proprietary name – typically at a lower cost.[3] Because generics break this affordability barrier, Indian law allows doctors to prescribe generic drugs to patients and for pharmacies to sell them.The Medical Council of India,under Clause 1.5 of(Professional Conduct, Etiquette, and Ethics) Regulations, 2002,and its amendment to the code of conduct for doctors in oct,2016 has recommended that Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs."[4] Indian

government started a campaign named 'Jan Aushadhi' in 2008 to provide generic medicines to the population at affordable cost.[5] Rational use of drugs is based on the use of right drug, right dosage at a right cost which is well defined by World Health Organization (WHO): "Rational use of drugs requires that patient receives medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community".[6] A number of studies have shown that attitude and perception of doctors towards generic medicine is less effective, believing that lower quality of generic medicine and unsuitable for treatment of major illnesses, as compared to their branded equivalents.[7] Irrational prescription is a major problem which includes polypharmacy, overuse of medicines, injections that lead to adverse effects, drug resistance or interactions. It increases morbidity, mortality and economic burden on the patient and wastage of resources.[8] The doctors knowledge, attitude and practice towards generic medicines depends upon their qualification, experience, duration of service, work culture adopted by the hospital, and inputs received from various sources.[9] Generic medicines offer cost savings which is a big advantage in a poor country like India. Many patients and their families lose their lifetime savings due to unbearable healthcare cost. Rajasthan and Tamil Nadu states are promoting generic medicines by procuring them through e-tendering for transparency, assuring their avalability at low cost, quality and electronic monitoring to prevent stock out. Generic medicine accomplish the need of essential drugs which meet the needs for prevention and treatment of most prevalent diseases of the population. Prescribing pressures on the doctors by the patients, money making approach by the pharmaceutical companies, and lack of implementation of stringent laws and regulations to restrain such activities.[10] The practice of generic medicines prescribing, dispensing and substitution in developing countries has been controversial among doctors, particularly due to issues on quality, safety, and efficacy.For getting approval from the regulatory body for generic medicine, the manufacturer must prove bioequivalence of generic drugs. Many doctors may not be familiar with this rigorous regulation.[11]

The objective of this study is to assess the knowledge, attitude, and practice of generic versus branded medicines among doctors working in govt. hospitals which may help to explore the factor hindering the prescription of generic medicines over branded medicines.

MATERIAL AND METHODS

Study site

The study was conducted by taking a sample of 120 Doctors i.e general physician and specialist of Govt. Hospitals from all over district located in the north region of India.

Study design

This was a questionnaire based cross-sectional study to assess the KAP of generic versus branded medicines among doctors working in all govt. hospitals in a district. The study was conducted from October 2021 to December 2021 after the institutional ethics committee approval wide letter no. Health-A-B(15)3-2021-2757.

Sample size

The sample size was calculated using the formula 4PQ/L2, where P=positive factor/prevalence/proportion, Q= 1-P, L=allowable error or precision or variability. The approximate sample size was 120.

Inclusion criteria: Doctors from all specialties and general physicians working in all over distt.in govt. hospitals were included after obtaining an informed consent.

Exclusion criteria: Doctors who were not willing to give their consent or did not return their questionnaire with in stipulated time were excluded.

Study tools

Total questionnaire containing 14 questions (5 questions pertaining to knowledge ,5 questions related to attitude and 4 questions related to practice of doctors about generic versus branded medicines) was designed using the precedence set by similar studies to obtain information regarding the demographics of the participants, and the factors that influence the prescription of medicines.[12,13,14]

RESULTS

Demographic Characteristics

Total of 120 participants, 64% were male and 37% were female, 49% (male and female) were below 30 years and only 3% were between 51-58 years age category. Majority 80% of doctors were graduates(MBBS) while 21% were postgraduate degree holders(MD/MS/Diploma).Majority 62% of doctors have below 5 years work experience while only 3% have more than 20 years experience.The demographic characteristics of the participants have been summarized in Table 1.

Table 1: Demographic details of the participant doctors (n=120).

Variables	Factors	Number	Percentage (%)
Gender	Male	76	64%
	Female	44	37%
Age (years)	<30	58	49%
	31-40	42	38%
	41-50	17	15%
	51-58	03	03%
Qualification	Graduate MBBS	95	80%
	Post graduate PG(MD/MS/Diploma)	25	21%
Experience (in years)	<5	74	62%
	5-10	27	23%
	10-15	09	8%
	15-20	07	6%
	>20	3	3%

Table 2: Questionnaires based on doctors Knowledge, Attitude and Practice about Generic versus Branded medicines (n=120).

Sr. No.	Question	Yes(%)	No(%)
1.	Do you know the difference between Generic and Branded medicines?	82(68.3)	38(31.7)
2.	Generic medicine are same in dose, Efficacy, Safety, Bio equivalence as Branded medicine?	41(34.2)	79(65.8)
3.	Do you have information that as per MCI act, 2002 every physician should, as far as possible, prescribe Generic medicine i.e rational prescription ?	66(55)	54(45)
4.	Are you aware that Generic medicines are available in Jan Aushadhi and internal pharmacy in your hospital ?	67(55.8)	53(44.2)
5.	Do you think that Generic medicines can be prescribed in all diseases including chronic diseases?	48(40)	72(60)
6.	Do you think Generic medicines are cheaper than branded because of substandard quality?	63(52.5)	57(47.5)
7.	Do you think that Generic medicines should be promoted like Branded medicines?	94(78.3)	26(21.7)
8.	There should be IEC- information, Education, Communication and training programme regarding quality testing of Generic medicine.	116(96.7)	4(3.3)
9.	Do you think that govt. of India/ medical insurance company should give preference to Generic medicines over Branded while reimbursement of medical bills?	76(63.3)	44(36.7)
10	Generic medicines take similar time to act in the body and produce similar adverse reactions as Branded medicines?	43(35.8)	77(64.2)
11	Do you prefer to prescribe Generic medicine if available in hospital ?	76(63.3)	44(36.7)
12	Are you comfortable if drug chemist substitute generic medicines into Branded prescribed by Doctor ?	18(15)	102(85)
13	Do you think pharmaceutical companies influence prescription pattern of doctors to promote branded medicine through medical representatives by offering gifts.	12(10)	108(90)
14	Patients demand Branded medicines because of medical reimbursement facilities given by Govt. of India.	48(40)	72(60)

Knowledge towards generic versus branded medicines

Results showed that 68.3% of doctors have knowledge in terms i.e. difference between generic and branded medicines. Only 31.7% were unknown to it. 34.2% knew that generic drug contains the same active substance(s) as dose, efficacy, safety, bio equivalence as branded medicine, while 65.8% were not agree with it. Only 55% were aware of Indian Medical Council states that every physician should, as far as possible, prescribe a drug with generic names.Most of the faculties (75%) know that branded drugs are more costly than their generic substitute. 55.8 % were aware of availability of generic medicines in Jan Aushadhi stores and internal pharmacy of their hospital. Only 44.2% of participants were not aware of it. A total of 40% doctors think that generic medicines can be prescribed in all diseases including chronic diseases while 60% do not agree to it Knowledge-related questions (1-5) and their responses are summarized in Table 2.

Attitude towards generic versus branded medicines

About 52.5% think that generic medicines were cheaper than branded because of substandard quality while 47.5% of the doctors did not agree.78.3% think that generic medicines should be promoted like branded medicines and 21.7% did not agree. Majority of 96.7% doctors agreed that there should be a training programme

to increase the awareness regarding quality testing of generic medicines while3.3% did not agree to it. 63.3% think that govt. of India, medical insurance companies should give preference to generic medicines over branded while reimbursement of medical bills but 36.7% were disagree with this. Only 35.8% of the doctors believe that generic medicines take similar time to act in the body and produce similar adverse reactions as branded medicines but 64.2% did not agree to it. Attitude related questions (6-10) and their responses are summarized in Table 2.

Practice towards generic versus branded medicines

Majority of 63.3% doctors said that they prescribe generic medicines if available in hospital but 36.7% do not prefer it .15% of doctors were comfortable if drug chemist substitute generic medicines into branded while 85% will not allow substitution of generic drugs.Only 10% doctors think that pharmaceutical companies influence prescription pattern to promote branded medicine through medical representatives by offering gifts while 90% were disagree with it but 60% were disagree with it.Practice related questions (11-14) and their responses are summarized in Table 2.

DISCUSSION

The present study was conducted to evaluate knowledge, attitude and practice of doctors regarding generic versus branded medicines in distt. hospital.Total 14 item questionnaire was administered to 120 doctors, who were willing to respond. It was found that 68.3% physicians knows the difference between generic and branded medicines .It is important that prescribes understand the difference between these terms, since it may affect selection of drugs while prescribing. Only 34.2% doctors knew that generic drug contains the same active substance(s) as dose, efficacy, safety, bio equivalence as branded medicine, Lack of such information creates doubts regarding quality and efficacy of generic medicines, which was reflected in findings (63.2%) of Badwaik RTet al.[14]

Only 55% were aware of Indian Medical Council act which states that every physician should, as far as possible, prescribe a drug with generic names.Most of the doctors 75% knows that branded drugs are more costly than their generic substitute. While majority respondents 62% agreed to prescription of generic medicines in all diseases, which helps reduce cost of treatment, none agreed to use these in life threatening illnesses. This implied a lack of confidence in efficacy of these drugs in serious conditions. Comparative data of branded and generic medicines can help to gain confidence of prescribers in this regard and requires effort on part of manufacturers. 55.8 % were aware of availability of generic medicines in Jan Aushadhi stores and internal pharmacy of their hospital.About 52.5% think that generic medicines are cheaper than branded because of substandard quality.78.3% think that generic medicines should be promoted like branded medicines. Majority of 96.7% doctors agreed that there should be a training programme to increase the awareness regarding quality testing of generic medicines .It should be made more vigorous which is similar to the finding of another study.[14]

Efforts are required in this direction to improve the level of awareness. practice and attitude regarding generic medicine prescription. Most of doctors respondents (62%) in the present study were relatively less clinical experience (<5 years) since they were in job.

63.3% doctors believe that govt. of India/ medical insurance company should give preference to Generic medicines over Branded while reimbursement of medical bills,which will help to promote generic medicines.15% of doctors were comfortable if drug chemist substitute generic medicines into branded while 85% will not allow substitution of generic drugs , as they think that switching apatient from branded to generic drug will not change the outcome of therapy which was similar to finding of Guptya SK study.[13] Only 10% doctors think that pharmaceutical companies influence prescription pattern to promote branded medicine through medical representatives by offering gifts while 90% were disagree with it which is contrary to the finding of Jamshed SQ et al.[12] Only 40% doctors believe that patients demand branded medicines because of medical reimbursement facilities given by Govt. of India but 60% were disagree with it.Addressing these issues can greatly improve use of generic medicines.

Factors taken into consideration to promote Generic medicines over Branded to the patient.

1 Conducting training Programmes (CME) on Generic medicine for doctors during there academic and professional career to create awareness
2 To provide updated information among doctors on quality, Safety and efficacy by performing clinical research studies comparing generic versus Branded Medicines.
3 To conduct mass awareness programmes through medical Journals, Health talks for doctors, Pharmacists, nurses and Patients to clear their doubts about generic medicines.
4 To circulate National Generic Medicine guidelines among all doctors and list of Generic drugs available in Hospital.
5 Availability of Generic medicine in Govt. Hospitals and private Pharmacies.
6 Strict implementation of rules and regulations by doing frequent Prescription audit

CONCLUSION

Knowledge of doctors about concept and regulations of generic versus branded medicines is adequate. Although they prescribe good number of generic medicines but concerns about efficacy, safety and availability are present. Educational and regulatory interventions to address, govt. notification regarding prescription pattern,

prescription audit commercial publicity and government healthcare policy are required to promote generic drugs.

ACKNOWLEDGEMENT
I would like to thank all the participant doctors for sharing their KAP in the present study.

CONFLICT OF INTEREST
None.

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