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Research Article

Acquaintance, Perceptions and Utilization of Generic Drugs: A Cross Sectional Study Among the Doctors at Rajiv Gandhi Cancer Hospital, Rohini

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ABSTRACT

Background: Generic substitution has turned into a typical practice since the late 2011s. Due to the expanded utilization of generic choices and concern about the FDA standards for bio equivalency, particularly to narrow therapeutic drugs. The awareness and attitudes of doctors towards prescription of generic medications and generic substitution are essential.

Methods: This was a cross-sectional study focusing on doctors from Rajiv Gandhi Cancer Hospital, Rohini The study was directed utilizing questionnaire having (i) background and demographic information of the doctors, daily prescription volume, supply of generic prescriptions in the hospital pharmacy (ii) their insight about bioequivalence (iii) prescribing behavior (iv) doctors' knowledge of quality, efficacy and safety of generic meds, and their cost (v) impression of doctors towards issues relating to generic medicine utilization.

Results: An aggregate of 73 questionnaires out of 100 were received, giving a reaction rate of 35.8%. Of the respondents, 48 (65.8%) were male and 25 (34.2%) were females. Most of the participants were of 41–50 years of age. Just 2.3% of doctors knew about the regulatory limits of bioequivalence standard in India. Of the respondents, 23.2% concurred that they "generally" compose their prescriptions utilizing originator drug name while 50.2% do it 'ordinarily'. Various critical associations were found between their insight, observations about generic medications and their demographic characteristics.

Conclusions: Most of the doctors from private hospitals in India had negative discernments about safety and efficacy of generic drugs. These negative observations could be the reason for the constrained utilization of generic meds in the private hospitals. In this way, keeping in mind the end goal to encourage their utilization, it is prescribed that the doctors should be consoled and instructed about the drug regulatory authority approval system of generic medicines with regards to their bioequivalence, safety and efficacy. Aside from the policy on generic substitution, it would likewise be prescribed to have a national drug evaluating strategy, which controls sedate costs, in both private and public sector.

INTRODUCTION:

A generic medication[1-3] is characterized as a drug that is produced freely after expiry of the patent protecting the branded product, essentially being similar to the reference medicine in bioequivalence in order to acquire a similar therapeutic impact. The reference medication is approved by FDA[4-5], and its quality must be demonstrated experimentally when applying for registration, with its safety and efficacy being evaluated through clinical trials.[1-3] notwithstanding reference and generic medications, there is a 3rd class called "similar drugs", characterized as medicine with a similar active pharmaceutical ingredients, concentration, mechanism of action, dosage and treatment sign, which are equal to the drug approved with FDA, despite of the fact that it differ in a few attributes, for example, drug shape and size, packaging, labeling, excipients[6-9].

There is much verbal confrontation with respect to the significance of utilization of cheaper generic drugs over branded drugs[10-13]. While generic medications are practically identical to branded drug in their ability to treat disease. Numerous doctor keep on believing that generic and branded medications are bioequivalent. Generic medications contain a similar active ingredient which is equal in branded drugs. FDA is responsible of controlling the medication testing process keeping in mind the end goal to inspire potential health risks to subjects. While both brand-name and generic drug in the US must apply for FDA approval before being permitted to pitch their medications to general population, the former is required to uptake pre-clinical and clinical study in order to investigate the safety and efficacy profile of the drug[14-17]. The drug development procedure of branded medications is costlier in respect to generic medication development. Branded medications were accounted to make real profits amid their patent periods additionally keep on reaping noteworthy financial benefits during patent period. This largely owes to the way that shoppers commonly buy branded drugs despite their awareness of the presence of generic medications[18].

METHODS

Study design:

The study instrument/questionnaire

This was a descriptive, cross-sectional study conducted among doctors at RGCH, Rohini. In the wake of taking approval from the Institutional Ethics Committee, a questionnaire based study was directed among 100 doctor, who consented and finished the questionnaire. They were informed that participation in the study is willful and their secrecy would be kept up. It was additionally disclosed to them that anytime they could pull back their participation from the study. Every individual who consent to participate in the study were given the English questionnaire. The questionnaire mostly consists of attitudes, perception and convictions of doctor toward generic medications in contrast to branded medications[19]. The survey was intended to evoke perception, knowledge and behavior of doctors towards generic prescriptions. It contained 10 MCQ and a 18 Five-Point Likert Scale statement involving 5 segments: (i) the demographic information of the doctors, including their experience, their volume of prescriptions in a given day, and the supply of generic meds in their clinic drug store, (ii) their insight about bioequivalence (iii) prescription behavior (iv) the doctor's knowledge and convictions in regards to quality, efficacy and safety of generic medications, together with their cost in contrast with branded products (v) the view of the prescribers to issues relating to generic prescription usage in India.

The questionnaire comprised of two sections. The initial segment was about sociodemographic and background attributes of the participants including gender, age, education qualifications, and number of years in practice[20]. The second part comprised of 14 questions which examined attitude, knowledge and practice about generic and brand drugs among prescribers.

Statistical Analysis

Response Rate

The information was entered into the Microsoft Excel 2016, and descriptive statistics were applied to assess the sociodemographic attributes, education qualifications and to elucidate attitude, knowledge and perceptions of the participants regarding prescribing of generic and branded drugs.

Reaction Rate

A sum of 100 questionnaires were dispersed among the doctors and 73 responded (reaction rate 35.8%). Statistic Details are compressed in Table 1

Table 1: Demographic Details (n=73)		
	Factors	Frequency (%)
Gender	Male	48 (65.8)
	Female	25 (34.2)
Qualification	MBBS	23 (31.5)
	MBBS, MD	44 (60.3)
	MBBS, PG Diploma	6 (8.2)
Age (yrs.)	<30	17 (23.3)
	30-40	34 (46.6)
	41-50	5 (6.8)
	51-60	6 (8.2)

Knowledge

Sixty-three percent doctor concurred that generic medications are generally planned to be exchangeable with a branded drug (p = 0.0243); 57.5% doctor knew that generic medications can be marketed after the expiry date of the patent of drug (p = 0.1990);76.7% doctor realized that a generic drug contains a similar active substance as the branded drugs, and it is utilized at the same dose(s) to treat the same disease(s) as the branded drugs (p = 0.000). Among study participants, 54.8% realized that generic medication manufacturer does not require the preclinical and clinical study as required for branded meds (p = 0.4126); 79.5% doctor knew that generic medication manufacturers need to direct bioequivalence studies to show equivalence between the generic drug and branded drugs (p = 0.0000). An equivalent rate of doctor knew that Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations 2002 states that medications with generic names ought to be recommended by each doctor (p = 0.0000). Among the participants, 90.4% concurred that generic medications are an imperative tool for decreasing healthcare cost (p = 0.0000); 45.2% participants told that they knew Jan Aushadhi scheme (p = 0.4126). Knowledge-related inquiries and their reactions are condensed in Table 2.

Table2: Knowledge-related questions and frequency (%) of responses				
S.No.	Question	No	Yes	P-Value
1	Generic drugs are marketed only after expiration of patent of innovator	42 (57.5)	31 (42.5)	0.199
2	Generic medicine has same API and are used to treat same disease with same dose	17 (23.3)	56 (76.7)	0.00
3	Generic Drugs are interchangeable with innovator drug	27 (37.0)	46 (63.0)	0.0243
4	Generic drugs help in reducing health expenditure	7 (9.6)	66 (90.4)	0.00
5	In Generic drugs- preclinical and clinical studies are necessary	33 (45.2)	40 (54.8)	0.4126
6	Bioequivalence Studies are important for generic drug manufacturers	15 (20.5)	58 (79.5)	0.00
7	Awareness of scheme launched by GOI called Jan Aushadhi in order to setup generic drug stores	40 (54.8)	33 (45.2)	0.4126
8	As per MCI act, every physician should prescribe generic drugs	15 (20.5)	58 (79.5)	0.00

Attitude

Greater part of doctor (75.3%) were of the view that generic medications were as sheltered as the branded medication (p =0.0000). In addition, 64.4% doctor felt that the generic medications are as viable as branded drugs (p =0.0123). Among doctor, 78.1%

did not concur that generic medications take more time to act in the body (p =0.0000); 58.9% doctor did not concur that branded medications are made in modern manufacturing units and generics are generally produced in underneath standard units (p = 0.1266). Another 68.5% doctor did not concur that generic medications cost less because they are inferior compared to branded drugs (p =0.0011). Eighty-nine percent doctor concurred that that there ought to training program to expand the awareness with respect to generic medications among doctor and patients (p = 0.0000); 83.6% doctor said that there ought to be a generic prescription store in each hospital (p = 0.0000). Demeanor related questions and their reactions are outlined in Table 3

Table3: Attitude-related questions and frequency (%) of responses

S.No.	Question	No	Yes	P-Value
1	Generic drugs are unsafe and unequal to innovator drugs	55 (75.3)	18 (24.7)	0.00
2	Is it necessary to have generic medicine store in every hospital	12 (16.4)	61 (83.6)	0.00
3	Generic Drugs are inferior then innovator drug	50 (68.5)	23 (31.5)	0.001
4	Generic drugs have slower PK/PD activity	57 (78.1)	16 (21.9)	0.00
5	Generic drugs- don't follow GMP	43 (58.9)	30 (41.1)	0.12
6	Generic drugs are less effective	47 (64.4)	26 (35.6)	0.01
7	Awareness program are necessary among doctors	8 (11.0)	65 (89.0)	0.00

Practice

A majority (71.2%) of doctors did not surmise that changing a patient from a brand-name to a generic drug may change the result of the treatment (p =0.0002). Among the participants, 57.5% said that they bolster generic substitution yet not in all cases, while 31.5% upheld substitution on all situations, where generic medications are accessible. Just 11.0% said that they don't concur with the act of generic substitution. 63% doctor said that they endorse generic medications (p = 0.0243). In any case, 58.9% doctor announced not to have perused any article on correlation of efficacy and safety of generic versus branded drugs (p = 0.0736). Practice related inquiries and their reactions are abridged in Tables 4, 5, and 6.

Table4: Practice-related questions and frequency (%) of responses

S.No.	Question	No	Yes	P-Value
1	In your opinion switching subject from brand drug to generic drug change therapy outcome?	52 (71.2)	21 (28.8)	0.0002
2	Do you prescribe generic medicine?	27 (37.0)	46 (63.0)	0.0002
3	Have you ever peer reviewed comparative study of branded and generic drug?	43 (58.9)	28 (38.4)	0.0736

Table5: Statement expressing utilization of generic drug		
S.No.	Question	Frequency (%)
1	Support substitution where generic drug is available	23 (31.5)
2	Don't support generic substitution in every case	42 (57.5)

Table 6: Important strategy while prescribing drug		
S.No.	Question	Frequency (%)
1	Drug Availabilities at pharmacy store	3 (4.1)
2	Cost of medicine	11 (15.1)
3	Drug safety and efficacy	57 (78.1)
4	Economic profile of subject	2 (2.7)

DISCUSSION

The reaction rate accomplished in this study was 35.8%. For the most part, it is more urgent to get a high reaction rate from the overviews of the doctors than from the community studies. Parson et al. detailed that subsequent endeavors, up to 11 times via the mail studies of doctors, yielded under 20% of a reaction when contrasted with the principal mailing, which represented up to 40% of a reaction[21-22]. In addition, it is realized that it is all the more difficult to get high reaction rates particularly from doctors practicing in private hospital in India. Consequently, considering the cost and time, just two endeavors were made to hospitals. Even more imperatively, it has been accounted that, albeit changing, doctors remained a generally homogenous populace with respect to their training, knowledge, states of mind and conduct[23-26].

The higher utilization of generic drug among the GPs can be corresponded to the high profit margin in the cost of the drugs, as administered by these physicians, with a specific end goal to make more benefit. Generic medications, being less expensive, give greater chance to be sold at a higher cost, since there is no medication price control in India. Be that as it may, in private hospitals, doctors tend to endorse branded drug since the benefit from the sale of prescriptions in these hospitals does not reach the doctors[27-28]. This is not quite the same as the circumstance in GP clinics in light of the fact that in GPs clinics the benefit goes specifically to them as they are the proprietors of these clinics. In this way, viability of the drug item is more impacting variable for GPs as opposed to doctors from private medical hospitals. In our study, we can infer that regardless of age, experience, the doctors working in the private hospitals of India like to utilize branded medications in their practice, and their conduct is influenced, contingent upon their insight, their convictions and their observations about generic drugs[29-32].

CONCLUSION:

The rapport amongst competition and generic medication costs is a principal issue for understanding rising medication costs. This relationship has imperative ramifications for merger requirement and healthcare cost regulation approach. We exhibit that endogenous passage may present imperative predispositions in the assessed rapport amongst cost and the quantity of generic contenders. Therefore, cautious observational examination is important to recognize this relationship. We decipher this finding as proof of predisposition in the appraisals of generic entry performed outside of the snootiness period, where endogenous section is uncontrolled. These distinctions are financially vital in all examples, and among large medications, the distinctions are regularly factually noteworthy.

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