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Original Research Article

A study of awareness of generic drugs amongst residents and intern doctors in a tertiary care hospital in Surat city

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ABSTRACT

Background: As defined by WHO generic drug is "a pharmaceutical product which is 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". They are made with the same active substance as the non-generic drugs which are already authorized and approved for their safety, efficacy and quality before getting licensed.
Methods: A cross-sectional, prospective, questionnaire-based study was conducted on 115 residents and intern doctors. Awareness and knowledge about generic drugs were checked using pre-validated questionnaire which was followed by an educational intervention and post-questionnaire. The collected data was analysed using MS-excel.
Results: The 94 participants voluntarily responded. As per the result of pre-test many participants were not aware of the difference between generic and branded drug, but after conducting educational intervention, increase in knowledge about generic drugs, branded drugs, safety, efficacy, availability and regulation regarding prescription of generic drug was seen. In post-test, 98.94% believed that generic drugs are cheaper than branded drugs and 95.74% agreed that generic drugs are as safe as branded drugs, while 97.87% believed increasing awareness regarding generic drugs will increase acceptability of generic drugs.
Conclusions: The reasons for opting branded drugs were lack of awareness regarding efficacy, safety, acceptability and availability of generic drugs. Periodic training program would help in clearing doubts, enhance the prescribing of generic drugs and reduce the health expenditure and economic burden.

Keywords: Generic drug, Brand name, Jan Aaushadhi, Awareness, Knowledge

INTRODUCTION

Generic drugs are a drug product that is comparable (bioequivalent) to brand/reference drug product with regard to pharmacokinetic and pharmacodynamics properties.[1] It is defined by world health organization (WHO) as "a pharmaceutical product which is 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".[2] As, concern about safety and efficacy has already established, there is no need for further trial and research. Also, it saves time and avoids additional expenditures that arise because of conception of idea, and thereby taking it through preclinical studies and clinical trials. WHO states that nearly 80% of total health-care expenses are shared by out-of-pocket payments.[3]

Brand name is the name given by the pharmaceutical company or by which they market their products, thus there are many brand names. Generic names remain the same all over world and have clarity.

Generic drugs are cheaper than the branded drugs because manufacturers rarely spend money on advertising and marketing.

Generic drugs are made with the same active substance as the non-generic drugs which are already authorized and approved for their safety, efficacy and quality checked before getting licensed. MCI amendment for doctors in October, 2016 has recommended that every doctor should prescribe rational prescription with generic drugs. Generic drugs, are therefore expected to provide quality care with an affordable cost. As we try to provide good-quality health-care system to the community with limited available resources, increased usage of generic drugs can improve affordability of the health care without compromising the quality.[4]

Indian government started a campaign named "Jan Aaushadhi" in 2008 to provide generic medicines to the population at affordable cost, which renamed as "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" in November, 2016.[5] In India, generic medicines are approved under the guidelines of central drug standard control organization (CDSCO), which requires submission of information regarding administrative and prescribing information, product quality, clinical as well as non-clinical study reports.[6] Therefore we planned to evaluate awareness about generic drugs amongst this group because they are the future doctors in our society.

METHODS

Study site

The study was conducted in the department of pharmacology, SMIMER, Surat, Gujarat for a period of three months (from October 2023 to December 2023).

Study design

A prospective, cross sectional, questionnaire-based study was conducted after taking institutional ethics committee approval (IEC).

Sample size

The 115 of residents and Intern doctors in tertiary care hospital were participated in this study.

Inclusion criteria

Interns and resident doctors who gave consent to participate in this study were included in study.

Exclusion criteria

Incompletely filled forms were excluded from the study and those who were not willing to give consent.

Methodology

This study was carried out at tertiary teaching care hospital after getting approval from Institutional ethic committee (IEC). After obtaining written informed consent, total of 115 participants enrolled for this study and all the participants were informed about the purpose and the course of study. Total of 16 pre-validated questionnaire were distributed to participants for checking awareness and knowledge about generic drugs. Training sessions of 2 hours were arranged for residents and intern doctors to increase awareness and knowledge about generic drugs followed by giving post questionnaire. The collected data were entered in Microsoft excel and analysed by using statistical software followed by descriptive statistics and paired t-test.

RESULTS

A total of 115 participants were included in this study after written informed consent, but 21 out of them were excluded due to incompletely filled form during analysis. However, out of 94 subjects, 59 (61%) resident doctors and 35 (39%) intern doctors responded to the questionnaire (Figure 1). The 61 (65%) females and 33 (35%) males participated in the study (Figure 2). Most of them were aged between 21 to 25 years old (Figure 3).

In pre-test, total of 63 (67.02%) participants believe that branded drug can be generic also, which was increased to 88 (93.62%) after conducting the training session. In pre-test, 72 (76.60%) subjects responded that generic drugs contain same active substance and same dose as the branded drugs, this was increased to 89 (94.68%) in post-test. In pre-test, 41 (43.62%) of them knew that generic drug manufacturer doesn't need to repeat preclinical and clinical studies for original drugs, this was improved to 67 (71.28%) of them in post-test. 90 (95.74%) of them responded that generic drugs are cheaper than branded drugs in pre-evaluation which was increased positively to 93 (98.94%) in post-evaluation.

While majority 91 (96.81%) of them agreed that generic medicine should not be prescribed in poor patient only in pre-test, which increased to 93 (98.94%) afterwards. Before a total of 70 (74.47%) participants were aware about the purpose of "Janaushadhi scheme" launched by government of India to open generic stores in India and 32 (34.04%) knew that there is any law in India which states that prescribing generic drugs are mandatory, which improved to 92 (97.87%) and 48 (51.06%) in participants after training session respectively. The 26 (27.66%) believed that pharmacist have no legal right to sell generic drugs in place of prescribed branded drugs before session which merely improved to 31 (32.98%) after training session. Nearly 83 (88.30%) and 73 (77.66%) participants agreed that generic drugs are as safe and equally efficacious as branded drugs in pre-test, which increased to 90 (95.74%) and 82 (87.23%) in post-test respectively (Table 1).

Total of 77 (81.91%) subjects believed that generic drugs produce moderately less adverse drug reaction (ADR) than branded drugs which was improved around 83 (88.30%) after an educational intervention. Although majority of

them 57 (60.64%) think that switching from branded drug to generic medicine may not affect the outcome of therapy but their knowledge was improved 66 (70.21%) after session. However, 77 (81.97%) of resident and intern doctors firmly believed that use of generic drugs will decrease health expenditure while 97.87% came to know that increasing awareness regarding generic drugs will increase acceptability of generic drugs respectively in post-test.

Though conducting pre-test and post-test of generic drugs after educational intervention, we observed in paired t test that p=0.000084, which indicates increase in awareness about generic drugs amongst residents and intern doctors was highly significant (Table 1).

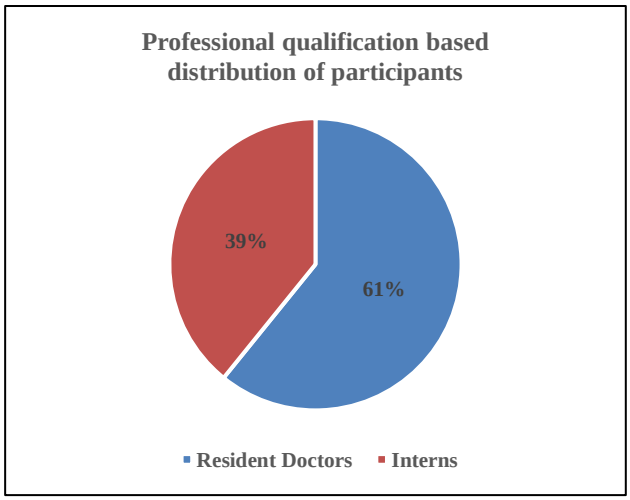

Figure 1: Professional qualification-based distribution of participants.

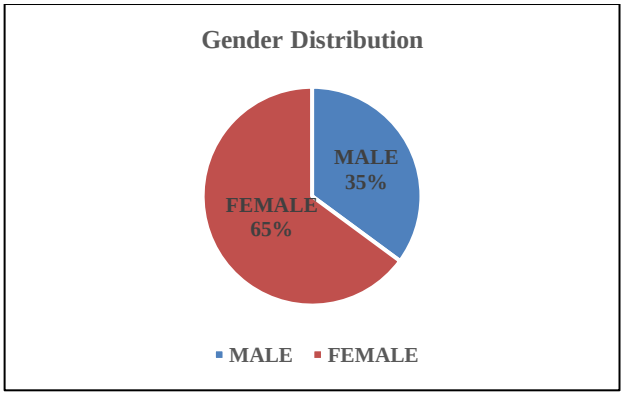

Figure 2: Gender wise distribution of participants.

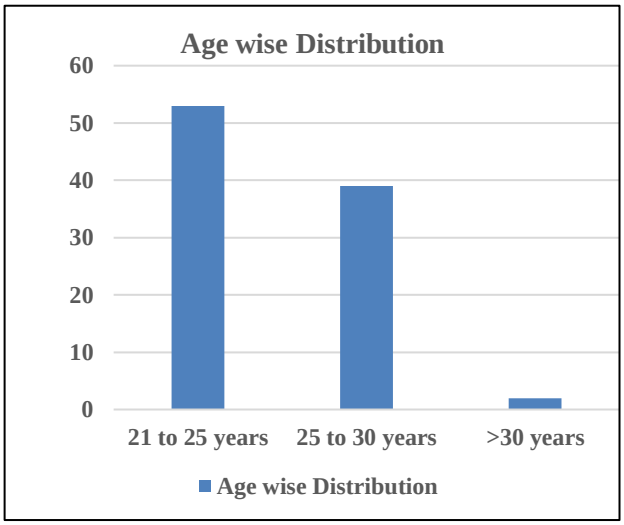

Figure 3: Age wise distribution of the participants.

Table 1: Responses to questionnaires before and after educational intervention regarding generic drugs amongst interns and resident doctors.

Questions	Pre-test, n=94			Post test, n=94		
	Yes (%)	No (%)	Don't know (%)	Yes (%)	No (%)	Don't know (%)
Can a branded drug be generic also?	63 (67.02)	27 (28.72)	4 (4.25)	88 (93.61)	6 (6.38)	0
Does generic drugs contain same active substance and same dose as the branded drugs?	72 (76.60)	19 (20.21)	3 (3.19)	89 (94.68)	5 (5.31)	0
Does a generic drug manufacturer need to repeat preclinical and clinical studies for original drugs?	38 (40.42)	41 (43.61)	15 (15.95)	27 (28.72)	67 (71.27)	0
Does a generic drug manufacturer need to conduct bioequivalence studies between generic and branded drugs?	41 (43.61)	42 (44.68)	11 (11.70)	61 (64.89)	32 (34.04)	1 (1.06)
Are generic drugs cheaper then branded drugs?	90 (95.74)	4 (4.25)	0	93 (98.93)	1 (1.06)	0
Generic drugs should be prescribed for poor patients only?	3 (3.19)	91 (96.80)	0	1 (1.06)	93 (98.93)	0
Is there any law in India which states that prescribing generic drugs are mandatory?	32 (34.04)	40 (42.55)	22 (23.40)	48 (51.06)	45 (47.87)	1 (1.06)
Are you aware about the purpose of "Janaushadhi scheme" launched by govt. of India to open generic stores in India?	70 (74.46)	16 (17.02)	8 (8.51)	92 (97.87)	2 (2.12)	0

Continued.

Questions	Pre-test, n=94			Post test, n=94		
	Yes (%)	No (%)	Don't know (%)	Yes (%)	No (%)	Don't know (%)
Does pharmacist have the legal right to sell generic drugs in place of prescribed branded drugs?	47 (50)	26 (27.65)	21 (22.34)	57 (60.63)	31 (32.97)	6 (6.38)
Are generic drugs as safe as branded drugs?	83 (88.29)	6 (6.38)	5 (5.31)	90 (95.74)	2 (2.12)	2 (2.12)
Are generic drugs equally efficacious as branded drugs?	73 (77.65)	15 (15.95)	6 (6.38)	82 (87.23)	10 (10.63)	2 (2.12)
Do you prescribe generic drugs or branded for your patients?	88 (93.61)	6 (6.38)	0	91 (96.80)	3 (3.19)	0
Do generic drugs produce more ADR then branded drugs?	6 (6.38)	77 (81.91)	11 (11.70)	7 (7.44)	83 (88.29)	4 (4.25)
Do you think that switching from branded drug to generic medicine may affect the outcome of therapy?	28 (29.78)	57 (60.64)	9 (9.57)	26 (27.65)	66 (70.21)	2 (2.12)
Will use of generic drugs decrease health expenditure?	73 (77.65)	16 (17.02)	5 (5.31)	77 (81.91)	17 (18.08)	0
Do you feel that increasing awareness regarding generic drugs will increase acceptability of generic drugs from patient.	90 (95.74)	4 (4.25)	0	92 (97.87)	2 (2.12)	0
Paired t test value (Taken positive correlation for pre and post-test e. g., Q3, Q4, Q6, Q13 and Q14 response no is taken for pair t test co-relation)				0.000084		

DISCUSSION

Resident and intern doctors who are the future practitioners should know about the concept of generic medicines and their safety, efficacy, quality and bioequivalence from the very beginning of medial course. In our study, 89 (94.68%) agreed that generic drugs contain same active substance and same dose as the branded drugs whereas in another study suggest that 89.9% doctors had knowledge that composition, dose and indications of generic medicines were same as the branded counterparts ($p<0.0001$).[7]

In our study, 64.89% participants assumed that a generic drug manufacturer need to conduct bioequivalence studies between generic and branded drugs. Our finding is different than the finding reported by Hadia et al the majority of doctors (78%) were aware of bioequivalence studies.[8] In our study, 27 (28.72%) participants had no idea that preclinical and clinical trials are not needed to be repeated for generic medicine because they were not aware of these regulatory requirements which is similar to the result of 40% of respondents were unaware that generic drug manufacturers need not repeat preclinical and clinical trials.[9] In our study, 93 (98.94%) of them were strongly believed that generic drugs should not be prescribed for poor patients only where as another study done by Shivgunde et al shows that 69.23% of them strongly believed about the same.[10] In this study, 97.87% participants were aware about the purpose of "Janaushadhi scheme" launched by government of India to open generic stores in India which promotes the cost-effective drugs and their prescription, whereas in a study done by Bhattacharjee et al all the 120 (100%) doctors knew about this.[11] In our study, 31 (32.98%) believed that pharmacist have no the legal right to sell generic drugs in place of prescribed branded drugs which is quite different than the result of (75.2%) have reported mixed results regarding the opinion of allowing pharmacists to allow substitution by generics.[12]

In our study, 87.23% of the participants believed that generic drugs are as efficacious as branded drugs which is similar to Priyadarsini et al study in which 84% of government physicians and only 64% of private physicians believed that generic medicines are just as effective and secure as branded medicines ($p=0.003$).[9] In our study, 95.74% of the participants believed that generic drugs are as safe as branded drugs which was different in Zhao et al study found that 541 responses (accounting for 44.17%) agreed or strongly agreed that the safety of the generic medicines is similar to the originators.[13] In our study, 88.30% of believed that generic drugs produce moderately less ADR as compare to branded drugs whereas 27 (84%) of believed that generic drug produce more side effects compared to brand medicines in Hadia et al study.[8] There is strong misconception in medical fraternity that any drug which is expensive is better than affordable generic drugs, which is quite disgraceful.

Policy makers around world try to make generic medicines affordable and more accessible by reducing the cost of the health care system. In Indian context, cost of generic drugs has been found to be up to 91% less than that of innovator medicine. In our study, 98.94% of participants knew that the cost of generic medicines is less than branded drugs which is similar to study which suggests 108 (83.1%) UG's and 173 (87.8%) interns knew that cost of generic medicine is considerably lower than brand medicine.[14]

As there are many misconceptions regarding the generic drugs are observed hence upgrading the knowledge and

spreading awareness regarding generic medicines prescription among the health care professionals should be implemented, for this we can plan out various programs and training sessions for prescribing generic drugs. This will promote the generic drugs prescribing habit and thus will reduce the economic burden to the society.

Limitations

This study was questionnaire-based survey, so recall biased could occur. The major limitations of our study that the study was conducted from same institute; this could have biased the responses from participants. Study was restricted to only residents and intern doctors which could have extended to clinicians and general populations.

CONCLUSION

Majority of interns and resident doctors were aware about generic drugs but information and education particularly in areas of bioequivalence, regulatory aspects, efficacy about generic medicines was lacking. Such awareness programs will build up the confidence and habit of generic prescribing into our health care professionals as well as our society. The major concern was awareness, which should be increased through regular training programmes such as workshops regarding generic medicine's information and continued medical education on generic medicines. Moreover, the guidelines or laws regarding generic medicines should be strengthened and made easily accessible via official websites, webinars so that the health care professionals and community always remain aware of information on generic medicine.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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