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Original Research Article

Attitude and knowledge towards prescription of generic drugs: online study across Telangana

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ABSTRACT

Background: Generic drugs are similar in terms of strength, safety and therapeutic benefit as compared to innovator counterparts. Generics have a favourable financial profile and a positive effect on medication adherence. Palpable change was not observed with the use of generics. This study has been designed to gauge the knowledge and attitude concerning generic drugs among medical students in their 5th semester of MBBS course and interns in the final six months of their compulsory rotatory residential internship (CRRI) program in the state of Telangana.
Methods: It was a cross sectional, online-questionnaire based study across medical colleges in Telangana. The questions were designed with the help of Google forms and the website links were circulated to the participants through students and interns' whatsapp groups.
Results: 95.1% of interns and 92.7% of students had knowledge of generic drugs. Significant number of students had a notion that brand drugs are for serious illnesses. Majority in both the groups maintained a neutral opinion when it came to mandatory prescribing of generics.
Conclusions: Our study revealed a similar knowledge level about generic in both the groups and 40.9% of interns and 41.4% of students had a knowledge score of more than or equal to 80. Interns didn't agree with incentivisation of brand drugs. 37.9% of interns and 32.3% of students had an attitude score of more than or equal to 80. Therefore implementation of certain practices like stocking of more generics at medical college pharmacies, more research and incentivisation of generic use can translate into a rise of generic usage.

Keywords: Attitude score, Generic drugs, Knowledge score, Online study, Telangana

INTRODUCTION

The term 'generic drug' is defined by the World Health Organization (WHO), to mean a pharmaceutical product that is usually intended to be interchangeable with an innovator product. It can be manufactured without a licence from the innovator company and is marketed after the expiry date of the patent or other exclusive rights.[1] No sooner a new drug/molecule come to light, the concerned company called the innovator company, has to file for a patent to protect against other organizations making similar molecules and selling the same. "A generic drug product that should have the same active ingredient, strength, dosage form, route of administration, quality, performance characteristics and intended use as the innovator drug". In the United States of America, when a generic molecule undergoes the process of approval, it has to meet rigorous standards established by the US FDA (Food and Drug Administration) with respect to identity, strength, quality, purity, and potency as generic drug.[2]

There is a need to know the difference between the terms 'generic drug' and 'generic nomenclature' as well. In

India, majority of the drugs are 'branded generics 'which the pharmaceutical companies market with their specific brand/trade name.

In 2008, government of India had started the 'Jan Aushadhi' scheme under department of Pharmaceuticals. This was done to promote the use of generic drugs and thereby reduce the financial burden associated with the Indian healthcare system. Generic drugs are approximately 30-80% less expensive than the innovator molecules.[3] They can have a positive impact on medication adherence due to less financial burden. Amendments have been brought about in Rule 65 (11A) of the Drugs and Cosmetics Act, 1940, wherein liberty has been given to dispense generic drugs against branded ones. Central Drugs Standard Control Organization (CDSCO), the main drug licensing authority in India has issued guidelines for bioavailability (BA)/bioequivalence (BE) studies as well.[4] This is done to ensure purity, potency, efficacy and bioequivalence of the generic drugs. Medical Council of India (MCI) in its regulations (professional conduct, etiquette and ethics) in clause 1.5 stated that "Every physician should, as far as possible, prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs".[5] Guidelines by MCI have not been able to bring out a major change.

The success and implementation of use of generic drugs has to be interplay of regulators and healthcare providers/ clinicians. There seems to be lacunae existing among healthcare providers and this lack of trust percolates among patients as well. There has to be a metamorphosis in clinicians and it should start early from the phase of a medical student itself. They are taught about generic drugs in their 2nd/3rd year of MBBS course, but after they pass out (internship) the concepts and practical application of prescribing generic drugs evaporate. Neither any importance is given in the medical post graduation courses thereafter, regarding generics. This is so very relevant in a country like India.

Robust efforts should be made for in depth understanding of this concept of generic drugs. This should go on in sync with government regulations. An example can be taken from United States Food and Drug Administration and its Orange Book. It provides updated information on generic drugs and their therapeutic equivalence evaluations on a monthly basis.[6]

Continuous effort should be in place to improve the outlook of medical students not only in Pharmacology but thereafter in clinical practice as well. Keeping this in mind this study has been designed to gauge the knowledge and attitude concerning generic drugs among medical students in their 5th semester of MBBS course and those in the final six months of their compulsory rotatory residential internship (CRRI) program.

METHODS

It was a cross sectional, non-interventional, online-questionnaire based study conducted by the department of Pharmacology of Apollo institute of medical sciences and research, Hyderabad. It was initiated after approval from institutional research committee. The study period was from December 2019 to May 2020. The questionnaire included a set of twenty questions to assess the attitude and knowledge among four hundred participants. The participants comprised of two groups. One group was medical undergraduate students who had completed their 2nd professional MBBS exam. This implied they had recently cleared their pharmacology exam. The other group consisted of interns in their last six months of compulsory rotatory residential internship (CRRI) schedule. Each group had two hundred entrants. The participants were included from medical colleges all across Telangana state. The state has a population of 3.9 crores with total of 20 medical colleges and 2600 MBBS seats. It was divided into four quadrants and medical colleges were randomly selected from each quadrant. The questionnaire with twenty items was uploaded in Google forms. The same was circulated with the help of website link to students and interns' whatsapp groups. Participation was entirely voluntary and they responded to the questions after they had given their consent. The respondents remained anonymous.

Likert scale was used to assess the attitude regarding generic drugs. IBM SPSS (windows version 24, Inc., Chicago, Illinois, USA) was used for statistical analysis. Mean, SD and percentages were calculated for generic variables like knowledge and attitude with 95% Confidence Intervals. Comparison of mean knowledge and attitude scores across participants was done using t-test. Associations of these generic variables were assessed by chi square test. The level of significance was considered as 0.05.

RESULTS

The total number of participants in the study was four hundred. Two hundred MBBS students and two hundred interns took part from medical colleges selected randomly across Telangana. The state was divided into four quadrants and medical colleges were arbitrarily chosen from each quadrant.

In assessing the knowledge level (Table 1) between the two groups, 95.1% of interns and 92.7% of students knew about generic drugs. 70.9% of interns agreed that brand name drugs can be interchanged with generic ones. Majority (83.7 of interns and 84.1 of students) opined that side effect profile was not adverse with generic drugs. 63.8% of students were aware of the Medical council of India regulations regarding prescription of generic drugs compared to a 56.7% of interns. A significant ($p<0.05$) number of students (24.6%) felt that all brand name drugs

were for serious illnesses, compared to 16.3% of interns. Significant ($p<0.05$) lower percentage (79.8) of interns believed generic drugs could bring down the financial burden without affecting the treatment quality.

Table 1: Association of knowledge about generic drugs by students and interns.

Q. no.	Variable	Category	Interns (N=203)	3rd year MBBS (N=232)	Chi square	P value
1	Do u know what are generic drugs	Yes	95.1	92.7	1.07	0.300
		No	4.9	7.3		
2	Do you think Generic drugs are a replica/ copy of the brand name drugs	Yes	59.6	62.9	0.505	0.477
		No	40.4	37.1		
3	Do you think Brand name drugs can be interchanged with generic drugs	Yes	70.9	69.8	0.064	0.801
		No	29.1	30.2		
4	Do you think Therapeutic efficacy of brand name drugs are same as generic drugs	Yes	54.7	58.1	2.734	0.098
		No	45.3	41.9		
5	Do you think Generic drugs have more side effects	Yes	16.3	15.9	0.008	0.931
		No	83.7	84.1		
6	Is there any MCI (Medical Council of India) regulation on generic drug prescription?	Yes	56.7	63.8	2.311	0.128
		No	43.3	36.2		
7	Are generic drugs available in your pharmacy?	Yes	52.2	56.9	0.957	0.328
		No	47.8	43.1		
8	Brand name drugs have to meet higher levels of safety and efficacy compared to generic drugs	Yes	61.6	60.3	0.069	0.793
		No	38.4	39.7		
9	Do you think Brand name drugs are for serious illnesses	Yes	16.3	24.6	4.559	0.033
		No	83.7	75.4		
10	Do you think Generic drugs can reduce treatment cost without affecting the quality of treatment	Yes	79.8	87.5	4.750	0.029
		No	20.2	12.5		

Table 2: Association of attitude about generic drugs by Interns and students.

Q. no.	Variable	Category	Interns	3rd years	Chi square	P value
11	Prescribing generic drugs should be mandatory	Strongly agree	14.3	11.6	1.897	0.755
		Agree	26.6	31		
		Neutral	51.7	49.1		
		Disagree	6.4	6.5		
		Strongly disagree	1	1.7		
12	Generic drugs take a longer time to produce therapeutic benefits	Strongly agree	2	1.6	2.46	0.652
		Agree	17.2	16.1		
		Neutral	28.1	30.3		
		Disagree	38.4	39.5		
		Strongly disagree	14.3	12.4		
13	Your prescribing decision will be/is influenced by medical representative	Strongly agree	0.5	3	8.449	0.076
		Agree	25.1	27.6		
		Neutral	28.1	33.2		
		Disagree	29.6	20.7		
		Strongly disagree	16.7	15.5		
14	There should be incentives for prescribing generic drugs	Strongly agree	4.9	7.8	20.456	0
		Agree	29.1	43.5		
		Neutral	34.5	33.6		
		Disagree	22.7	11.2		
		Strongly disagree	8.9	3.9		
15	Brand name drugs from multinational companies are superior to generic drugs from Indian manufacturers	Strongly agree	6.4	4.1	6.314	0.177
		Agree	25.6	24.6		
		Neutral	24.1	25.7		
		Disagree	30	29.7		
		Strongly disagree	13.8	17.7		
16	It is easier to remember a brand name than a generic	Strongly agree	2.5	1.3	16.92	0.002
		Agree	20.2	31.5		

Continued.

Q. no.	Variable	Category	Interns	3rd years	Chi square	P value
	name of a drug	Neutral	18.7	26.7		
		Disagree	35	26.3		
		Strongly disagree	23.6	14.2		
17	Government should take strong steps to implement generic prescribing of drugs?	Strongly agree	28.1	25.4	1.317	0.858
		Agree	47.8	53		
		Neutral	20.7	19		
		Disagree	3	2.2		
		Strongly disagree	0.5	0.4		
18	There should be no incentives for prescribing brand name drugs	Strongly agree	15.3	9.5	13.266	0.01
		Agree	41.9	31		
		Neutral	31.5	42.2		
		Disagree	7.9	13.8		
		Strongly disagree	3.4	3.4		
19	Indian manufacturers are following the good manufacturing practices (GMP) guidelines as multinational companies	Strongly agree	4.4	4.3	9.4909	0.052
		Agree	26.1	38.8		
		Neutral	56.7	46.1		
		Disagree	8.4	8.6		
		Strongly disagree	4.4	2.2		
20	Generic drugs are for poor patients	Strongly agree	7.4	9.1	2.084	0.72
		Agree	19.7	18.1		
		Neutral	25.1	23.3		
		Disagree	30	34.9		
		Strongly disagree	17.7	14.7		

While we looked into the attitude of two groups (Table 2), only 14.3% of interns and 11.3% of students strongly opined that prescribing generic drugs should be mandatory. 1.0% of interns and 1.7% of students strongly disagreed for the same. Majority in both the groups maintained a neutral opinion. 38.4% of interns and 39.5% of students disagreed that generic drugs take a longer time to produce therapeutic benefits ($p>0.05$). Higher percentage (29.6) of interns compared to students (20.7) of students disagreed that their prescribing decision will be influenced by medical representatives. Significant ($p<0.001$) number of students (43.5%) opined that there should be incentives for prescribing generic drugs compared to interns (29.1%). 30% of interns and 29.7% of students disagreed on the point that, brand name drugs from multinational companies were superior to generic drugs from Indian manufacturers ($p>0.05$). Significant ($p<0.01$) interns (35.5%) did not agree that was easier to remember a brand name than a generic name, compared to students (26.3%). 47.8% of interns and 53.3% of students felt that Government should take strong steps to implement generic prescribing of drugs ($p>0.05$). Higher percentage (41.9) of interns agreed ($p<0.01$) that there should be no incentives for prescribing brand name drugs compared to students (31%). Regarding the incentivisation aspect, more of students (43.5%) felt generic drugs should have benefits related to their prescribing and only 29.1% of interns thought the same ($p<0.01$).

Only 4.4% of interns and 2.2% of students strongly felt that Indian manufacturers were not following the good manufacturing practices (GMP) guidelines as multinational companies ($p>0.05$). 30% of interns and 34.9% of students disagreed that generic drugs are for poor patients ($p>0.05$).

Table 3: Mean and 95% confidence interval of knowledge and attitude of participants.

Participants	Sample size (N)	Knowledge	Attitude
Interns	203	67.5 (65.0-70.0)	48.6 (45.5-51.8)
3rd year MBBS students	232	69.5 (67.3-71.7)	44.6 (41.7-47.4)
Total	435	68.6 (66.9-70.2)	46.5 (44.3-48.6)
P value		0.227	0.060

In assessing the attitude and knowledge about prescription of generic drugs among 232 students and 203 interns of means with 95% confidence interval, mean was similar for both the students and interns in both the parameters of knowledge and attitude,67.5% of interns and 69.5% of students had similar knowledge about generic drugs. There was a slight trend or increase in the attitude towards generic drugs in the intern group of 48.6% when compared to students of 44.6%, it is not statistically significant. 20.2% of intern and 19.8% of students had knowledge score of less than 60.

38.9% of interns and 38.8% of students had knowledge score of 60-80. 40.9% of interns and 41.4% of students had knowledge score of more than or equal to 80.

Table 4: Association of knowledge of participants.

Knowledge score (%)	Interns	3rd year MBBS students	Chi square value	P value
<60	20.2	19.8		
60-80	38.9	38.8	0.014	0.993
≥80	40.9	41.4		

The proportion of knowledge scores (Table 4) was similar in both the groups of students and interns. The knowledge scores are based on the tertile values, such that <60 corresponds to 33.3%, 60-80 to 66.7% and ≥80 is more than 66.7%.

29.1% of intern and 34.9% of students had attitude score of less than 60. 33% of interns and 32.8% of students had attitude score of 60-80. 37.9% of interns and 32.3% of students had attitude score of more than or equal to 80.

Table 5: Association of attitude of participants.

Attitude score	Interns	3rd year MBBS students	Chi square value	P value
<60	29.1	34.9		
60-80	33.0	32.8	2.126	0.345
≥80	37.9	32.3		

The proportion of attitude scores (Table 5) was similar in both the groups of students and interns. The knowledge scores are based on the tertile values, such that <60 corresponds to 33.3%, 60-80 to 66.7% and ≥80 is more than 66.7%.

DISCUSSION

According to National Health Accounts Estimates of India (NHAEI) prepared by the Minister of Health and Family Welfare (MOHFW), New Delhi, Telangana spent Rs 1,019 per person every year. In comparison USA spends approximately Rs 70,000/- per person per year. India's total healthcare spending (out-of-pocket and public), at 3.6% of GDP, is way lower than that of other countries.

One of the major expense area in the healthcare segment was towards medicines. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJK) campaign was initiated by the government of India and one of the significant observations was 'non-prescription of generic drugs'. The knowledge level regarding generic drugs was adequate among both the participant groups in our study. This is different from the study done by Deb et al done at Kohlapur, Maharashtra wherein they found a deficiency in the overall knowledge.[7] Both the groups in our study, were aware of the medical council of India (MCI) regulations regarding generic prescription and were agreeable on terms that branded drugs can be interchanged with generic versions. In our state, majority of both the students (84.1%) and interns group (83.7%) knew that generic drugs do not produce more side effects, which is similar to the Kohlapur, Maharashtra study.[7] This was different from the study done at Nepal by Gyawali et al, where 17% of the participants thought generic medicines are less effective and produce more side effects compared to brand-name medicines while almost 25% neither agreed or disagreed to the point.[8] In our study, more of MBBS students (24.6%) believed that serious ailments required brand drugs. On the other hand, the same group (87.5%) felt that generic drugs could decrease the financial burden on patients without affecting the quality of treatment. The intern group had some reservations regarding the same. This means that the understanding and theoretical knowledge of generic drugs among students was adequate, but once they moved on in their course and saw the practical scenario skepticism set in. This could be attributed to the fact that the interns had a change of mindset, observing their seniors' practices. A systematic review conducted by Colgan et al brought out negative attitude about generics not only in pharmacists and doctors, but also among lay people.[9] Quality checks and trust in medicine quality must be implemented from the top which will then percolate down.

The new competency based medical education (CBME) curriculum by MCI also provides a scope in the form of 'electives'. Medical colleges can innovate in this aspect and can design electives in a generic drug manufacturing units or in certified laboratories doing pharmacokinetic/ pharmacodynamic (PK/PD) studies. This can give a practical 'hands on' experience to medical graduates and therefore better ingrained memory.

Majority in both the MBBS students and the interns maintained neutrality whether prescribing generics drugs should be mandatory. There was a favourable trend in the interns group regarding medical representatives' influence on their prescribing habits. And most of them (35.5%) disagreed that remembering brand names were any easier. This was a positive aspect of our study which implied that if concept/names of generics were more and repetitively stressed upon, it could bring about a palpable change in attitude. Later on, it would translate into a change in practices. The concepts of generic drugs could be reintroduced in later stages of medical career by promoting more research in generic drugs. Hospital formularies of the medical colleges could store more of generic drugs, thereby exposing the interns and the senior faculty to their use. A brief exposure to pharmacoeconomics could be introduced in the CRRI period, wherein they could understand the financial privileges of generic drugs. All these measures would also ensure that the individual had repetitive encounters about generics, instead of a onetime affair of pharmacology classes in MBBS curriculum. More of students felt incentives should be given for prescribing generic drugs, and more of interns (41.9%) felt there shouldn't be any incentives for brand drugs. The entire trend is towards generic drugs and the Government along with regulatory

authorities can consider incentivisation along with quality checks to boost the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJK) campaign. Majority in both the participant groups (30% of interns and 34.9% of students) disagreed that generics were for poor population. On extrapolation of this attitude, it can be deciphered they are ready to prescribe generics irrespective of patients' financial status. Neither do they have a doubt about Indian pharmaceutical manufacturers complying with good manufacturing practices (GMP) guidelines. In a study done at Turkey, 70% of the respondents opined that generics were as good as brand drugs and the country was experiencing an increase in the use of generics.10 Generics can make medical costs cheaper and also ensure sound treatment options for the patients.[11]

CONCLUSION

Our study revealed a similar knowledge level about generic in both students and interns groups. 40.9% of interns and 41.4% of students had a knowledge score of more than or equal to 80.

Both were of the opinion that generics and brand drugs could be prescribed interchangeably and that the former did not have an unfavourable safety profile in comparison with the later. Interns did not agree with incentivisation of brand drugs and disagreed that recollecting brand names were any easier. However both groups maintained neutrality regarding mandatory prescribing of generics. 37.9% of interns and 32.3% of students had an attitude score of more than or equal to 80. Therefore implementation of certain practices like stocking of more generics at medical college pharmacies, more research and incentivisation of generic drug use could translate into a rise of generic usage. Last but not the least there should be an effective interplay between healthcare providers and higher regulatory officials. All these could bring down medical costs and complement the low governmental healthcare spending.

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REFERENCES

1. World Health Organization (WHO). Generic drugs. Geneva: WHO; 2015. http://www.who.int/trade/glossary/story034/en/index.html. Accessed 21 June 2015.
2. Kefalas CH, Ciociola AA. The FDA's generic-drug approval process: similarities to and differences from brand name drugs. Am J Gastroenterol. 2011;106:1018-21.
3. Dunne S, Shannon B, Dunne C, Cullen W. A review of the differences and similarities between generic drugs and their originator counterparts, including economic benefits associated with usage of generic medicines, using Ireland as a case study. BMC Pharmacol Toxicol. 2013;14:1.
4. Revised checklist for BA/BE NOC effective from 01st February 2014. Cdsco.nic.in. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadAlertsFiles/BABwebsite%202014reviseddocumentrequired.pdf. Accessed on 12 April 2018.
5. Medical Council of India: Circular on Generic Medicine. 2017. Available from: https://old.mciindia.org/circulars/Public-Notice-Generic-Drugs-21.04.2017.pdf. Accessed on 5 June 2017.
6. Approved drug products with therapeutic equivalence evaluations (Orange Book) Available from: https://www.fda.gov/drugs/informationondrugs/ucm129662.htm. Accessed on 15 October 2018.
7. Deb A, Dhavalshankh AG, Burande MA, Patil SS, Tahashildar JC. Evaluation of knowledge, attitude and perception about generic medicines among medical students and interns in a tertiary care hospital. J Adv Med Dent Sci Res. 2017;5(11):8-12.
8. Gyawali S, Hassali MA, Saha A. A survey exploring the knowledge and perceptions of senior medical students in Nepal toward generic medicines. SAGE Open Med. 2016;4:2050312116662570.
9. Colgan S, Faasse K, Martin LR, Stephens MH, Grey A, Petrie KJ. Perceptions of generic medication in the general population, doctors and pharmacists: a systematic review. BMJ Open. 2015;5(12).
10. Toklu HZ, Dülger GA, Hıdıroğlu S, Akici A, Yetim A, Gannemoğlu HM, Güneş H. Knowledge and attitudes of the pharmacists, prescribers and patients towards generic drug use in Istanbul-Turkey. Pharm Pract. 2012;10(4):199-206.
11. Joshi SS, Shetty YC, Karande S. Generic drugs- the Indian scenario. J Postgrad Med. 2019;65(2):67-9.

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