

A Study of Knowledge, Attitude And Practice of Generic Drugs Among General Practitioners of Pune Region

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Abstract

Objective: MCI regulatory code for doctors has made generic prescription mandatory. However, physician's perceptions about generic medications may represent an important barrier to greater generic use. Hence this study was conducted to know about knowledge, attitude and practice of generic medicines among physicians.

Methods: A prospective, cross-sectional, questionnaire based study was conducted in general practitioners (n = 100) of either gender from different pathies but also practicing allopathy in Pune region. They were interviewed using structured, validated questionnaire of 20 multiple choice questions to obtain information about knowledge, attitude and practice of generic drugs.

Results: 100 physicians responded. Internet (45%) was most common source of information about generic medication. 95% of the physicians - were aware about low cost of generic drugs. However, 65% were unacquainted about exact reason for their low cost and also about whether generic drugs are therapeutic or pharmaceutical alternative. Although 83% were aware about effectiveness yet only 55% agreed that they can be equally effective alternative. In practice only 40% physician prescribed generic drugs as per patient's requirements. 31% physicians avoid use for their concern about efficacy and failure. But 52% physician had desire to know more about bioequivalence.

Conclusion: The present study showed that participants had an idea but lacked detailed knowledge about generic drugs. This was therefore reflected in their prescribing behavior that impressed concerns of therapeutic failure. Therefore providing detailed information about generic is utmost important to promote prescription of these drugs

Keywords: Generic drug, Knowledge, Attitude and Practice.

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I. Introduction

World Health Organization (WHO) reports that nearly 80% of total health care expenses are shared by out-of-pocket payments.[1] The Indian government spends just 1.2 percent of the GDP on the health sector, which is among the lowest in the world India has the worst figures in the health sector spending. India spends \$43 per person on average, while the expenditure per person in Sri Lanka, China and Thailand is \$87, \$155 and \$261, respectively [2] More than 70 percent of India's population lives in rural areas and nearly 40 percent of the population is either below the poverty line or hovering close to it. Most of the people don't have medical insurance. And as they cannot afford private medical practitioners, they end up going to quacks or don't take treatment at all. The infant mortality are more and life expectancy are much less in Indian states. It is well known fact that branded medicines are at significantly higher prices in India and given wide spread poverty across country. Making available reasonably priced quality medicines in market would benefit everyone especially poor & disadvantaged people this has been a major concern for government of India department of pharmaceuticals ministry of chemical & fertilizers that has been taking several regulatory measures from time to time towards realizing objectives. As we strive to provide high-quality health care in a time of limited resources, increased use of generic medications, when clinically appropriate, can reduce costs without reducing quality.[3] According to Food and Drug Administration (FDA) a "brand name drug" is a medicine that's discovered, developed and marketed by a pharmaceutical company. Once a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drug. "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 brand-name drug. When a generic drug product is

approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency as generic drug .[4]Generics only become available after the patent expires on a brand name drug. Patent periods may last up to 20 years on some drugs .Despite of various studies evaluating the clinical equivalence of generic medications and have been reassuring[5 ,6] yet generics remain underused.

About generic medicines, when it comes to price; there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 20 to 80 percent lower than the brand name product.[7,8]Multiple generic companies are often approved to market a single product; this creates competition in the market place, often resulting in lower prices. When a company develops a new drug, they spend a substantial amount on research and development of the drug, and must perform expensive studies to prove the safety and efficacy of the new drug. This takes many years and an average of \$1.1 billion [9]The brand name manufacturers are rewarded for this investment with a patent – a time during which no other manufacturer can produce the drug. The price set by the brand name manufacturer factors in the money spent in research and development. Once patent expires, the generic drug companies are free to manufacture and sell the drug. US Food and Drug Administration (FDA) and European regulations consider the products to be bioequivalent if the mean maximum concentration achieved, the time at which that concentration is achieved, and the area under the concentration– time curve for the generic product falls within 80%–125% of the innovator or branded product, when administered under a fed or fasting state[10,11] Since they do not have to invest in research and development they can bring their version of a drug to market for a much lower cost—it has nothing to do with a lower quality product or substandard manufacturing. Despite this, there can be differences in formulation between the innovator brand-name drug and a generic counterpart. It is not a regulatory requirement that the “inactive” ingredients in a generic version be identical to those in the innovator formulation.[12,13] However, small changes or impurities in the excipients used in a formulation can alter the properties of a medication and lead to unexpected adverse effects on drug absorption, bioavailability, efficacy, and safety.[14,15] Branded to generic switching for classes of drugs with narrow therapeutic indices, such as antiepileptic, antiarrhythmic, thyroid medications, and anticoagulants, is particularly problematic and may result in adverse clinical outcomes[16,17]Indeed, generic prescribing already accounts for 83% of prescriptions in the United Kingdom.[18,19] In the United States, generic medicines account for over 70% of prescriptions dispensed.^[20] However, in developing countries like India the generic drugs are not as widely used as they are and also the awareness about generic drugs both in prescribers and in patients are not well documented. Attitudes toward generic substitution are related to prescribing behaviors, and to experiences with and beliefs about generic substitution [21]

Physician perceptions about generic medications may represent an important barrier to greater generic use. Understanding their attitude and perceptions about the quality and efficacy of generics may help identify potential barriers to greater generic medication use. Additionally, identifying physician characteristics associated with negative perceptions about generics may help insurers and policymakers to target educational interventions or more restrictive policies. In this regard the present KAP (Knowledge, Attitude and Practice) study will be taken-up to generate a useful data on awareness about generic drugs among Physician and to propose methods of promoting the use of generic drugs.

II. Materials & Methods

This descriptive study was conducted in Pune region. Approval from institutional ethics committee was taken. This was a descriptive questionnaire-based cross-sectional study (survey) that was carried out in general practitioners possessing different levels of qualification in their field and belonging to different pathies(e.g. M.D./M.S.,MBBS,B.H.M.S, B.A.M.S)but practicing allopathy. A sample size 100 (100 Doctors) was enrolled by purposive sampling method. After explaining about the nature and purpose of the study, a written informed consent was taken from the participants and a validated questionnaire containing 20 question was filled by these general practitioners. Thus data for knowledge attitude and practice of generic drugs was collected from these general practitioners.

Questionnaire consisted of mix of structured, Likert-type, open-ended questions, or closed ended Yes/No type of questions. The Likert-type questions are defined as “strongly agree, agree, disagree, strongly disagree and undecided[21] Some multiple response type questions to be answered as either Yes, No, or Don’t know, some question was a direct response question. Questionnaire was prepared in only in English. With regard to generic medications, we will assess attitudes toward cost, quality, and effectiveness; personal and family use; and prescribing practices (physician- related) and preferences among doctors. In the analysis, we will combine some answers (for example, strongly agree and somewhat agree, strongly disagree and somewhat disagree). The data in study was recorded and analyzed using standard statistical software.

2.1 Inclusion Criteria-

2.1.1. Primary care physicians (general practitioners possessing different levels of qualification in their field and belonging to different pathies (eg .M.D./M.S.,MBBS,B.H.M.S, B.A.M.S) ;but practicing allopathy in Pune region.

2.1.2. Super-Specialists (including dialectologists endocrinologists, pulmonologists) in this survey was also chosen from Pune region.

2.1.3. Participants who was willing to participate study or answer the questionnaire

2.2 Exclusion Criteria-

2.2.1 Physician who was not willing to participate, or answer the questionnaire.

2.2.2 Physicians who was belonging to other pathies than allopathy and practicing their own pathy (e.g. Ayurveda ,Acharya , Homeopathy doctors ,Unani doctors ,Etc) .

III. Statistical Analysis

The data in study was recorded and analyzed using standard statistical software. Some answers (for example, strongly agree and agree, strongly disagree and disagree) was combined for ease of analysis

IV. Results

The standard validated questionnaire was answered by 100 general practitioners. Amongst the total 100 practitioners, 30 were female practitioners (30%) and 70 were male practitioners (70%) (**Figure-1**). Most of the physicians in the study group were senior practitioners with a practice experience of more than 30 years (68%) whereas only 32% of physicians were having practice experience of less than 30 years (**Figure-2**). Among the practitioners there were total 25% responses from specialists group and 19% from MBBS private practitioners and 56% general practitioners from different pathies, but practicing in allopathy in Pune region (**Figure-3**).When the knowledge was evaluated about generics, 37 % of the practitioners correctly opted of generic as therapeutic equivalent (**Figure- 4**). A major chunk of them also aware of that recently a law regarding prescription of generics was implemented by Government of India (83%) and generics are cost-effective options as compared to their branded counterparts (95%) (**Figure- 5**). On the contrary the practitioners lacked the knowledge as to why the generics are cheaper (61%); whereas 15-10 % believed that it is so due to the substandard quality of generics and lack of stringent regulations for their manufacturing (**Figure-7**).When the attitude of the practitioners towards use of generics was evaluated contradictory results were observed. The practitioners apparently agreed to efficacy of generics (83%) ,were willing to use them even as self medication (69%) ,expressed that more generics should be available (75%) and also wanted to know more about pharmacies selling generic drugs (**Figure- 5**).Although an equal percentage of practitioners agreed to statement that generic medicine are equally efficacious as branded ones (55%) and also supported to substitute the brand drugs with suitable generic options ; yet 67% practitioners agreed that there is a risk of therapeutic failure with the generic options (67%)(**Figure- 6**). The participating practitioners also agreed that as regards to the practice of emphasis on prescribing brand drugs, it was mostly driven by patient pressure (90% practitioners opted yes) although patients were given cafeteria of choice (51 % practitioners opted yes). 70 % practitioners also asked the feedback as regards efficacy and adverse effect when patients were prescribed generic drug. Only 3 % of practitioners received free drug samples of generic drugs whereas 84% received free drug samples of branded drugs as drug promotion and marketing strategy (**Figure- 5**).The most interesting finding was that when practitioners were questioned about their view about the factors that govern the selection of brand as against generic; 37 % practitioners agreed to the statement that patients themselves wanted brand drugs, 33% said that concern of therapeutic failure with generics that prevented practitioners whereas only 11 % expressed concerns over poor patient outcomes (especially for chronic patient stabilized one a certain drug and brand) if they switch from brand to generic (**Figure- 7**). The main source of information about generics was internet (45%) followed by pharmacy (36%) and medical journals (30%)/ (**Figure- 8**).

A subgroup analysis was also done for the responses, between the two groups i.e. practitioners of other pathies practicing allopathy and the MBBS practitioners group (which also included the specialists).The relevant outcomes are presented in Table no.-1.

Figure -1 Demographic Characteristics of practitioners

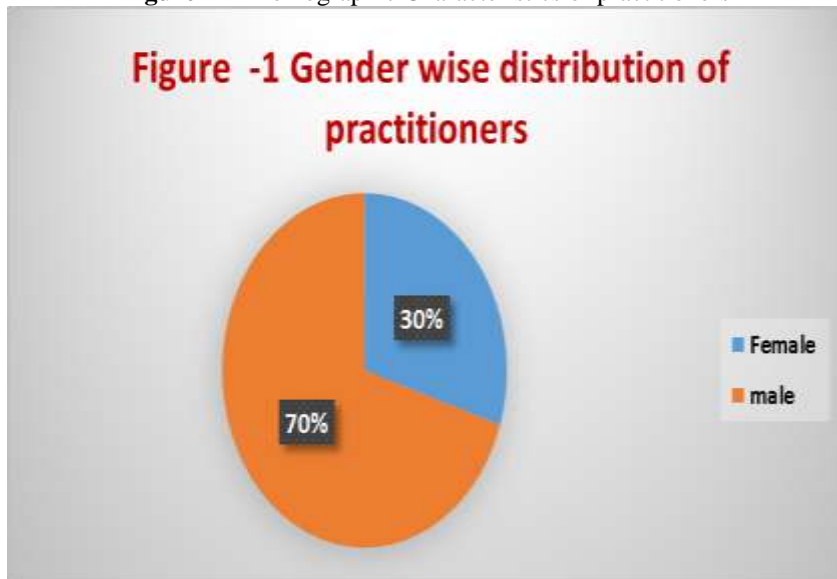


Figure-2 Practice experience of physicians (in years)

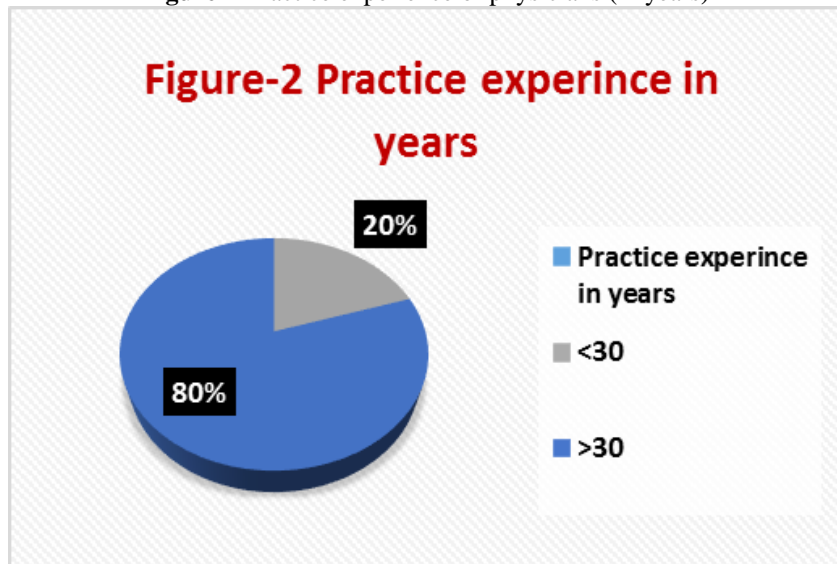


Figure – 3 Proportion of Physicians who were in the study (classified according to qualification)

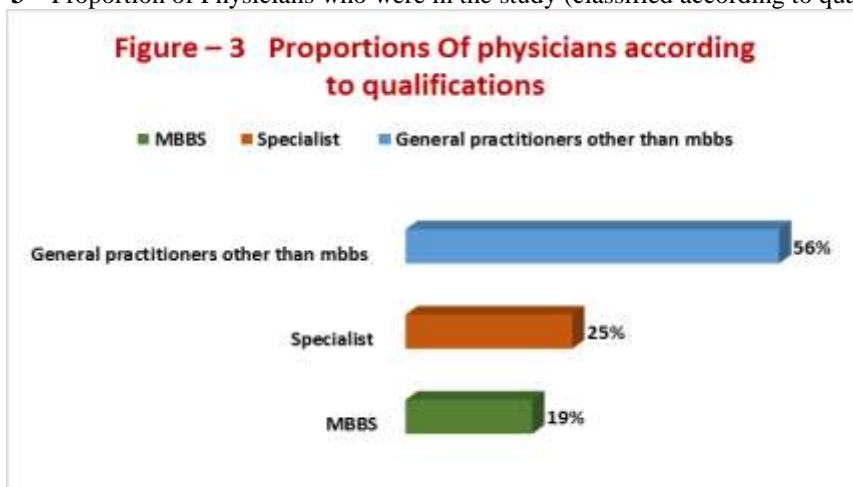


Figure – 4: Physicians’ Self-rated Knowledge about Generic drugs (as per question no 1 of questionnaire)

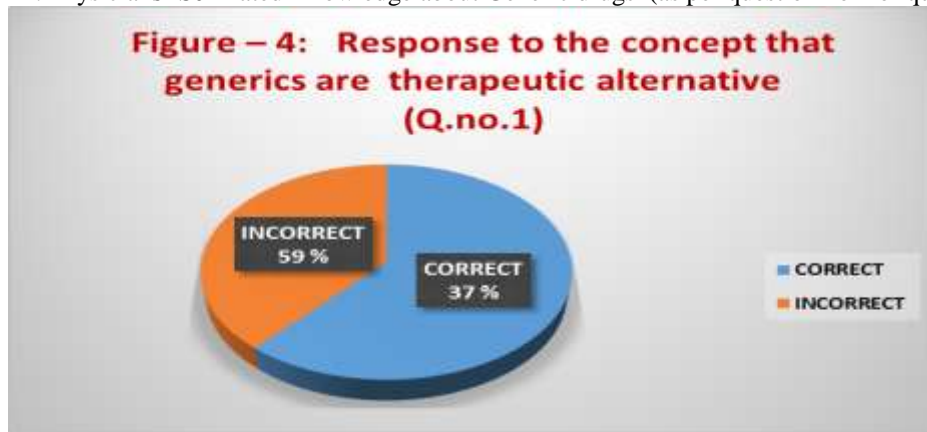


Figure – 5: Response to Yes/No type Questions :

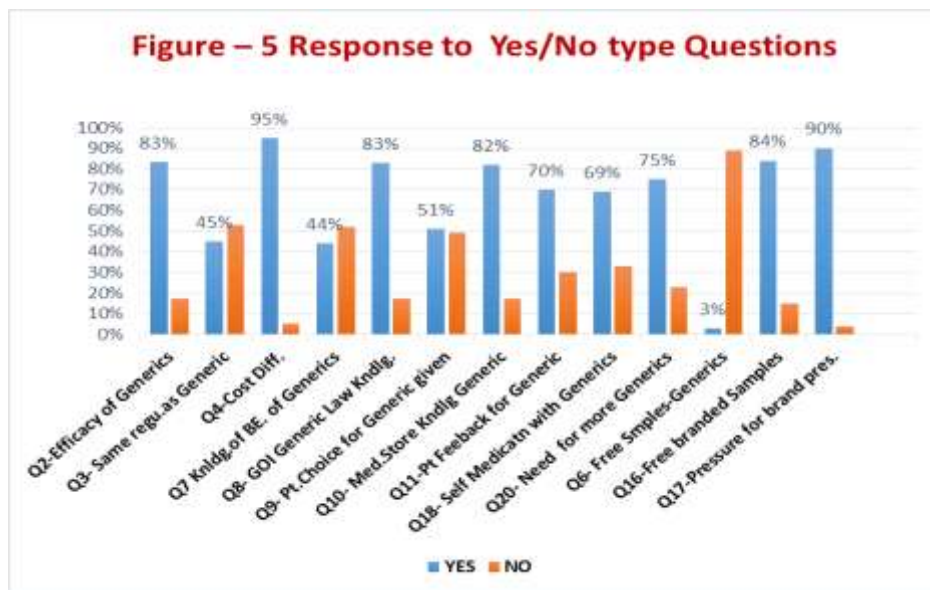
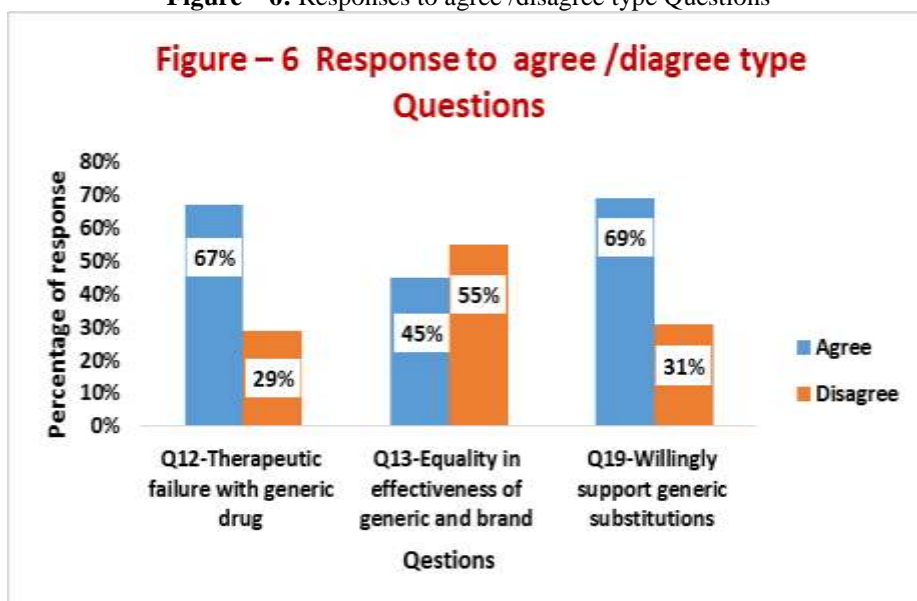


Figure – 6: Responses to agree /disagree type Questions



Response to multiple response type questions

Figure – 7 Response to reason for low cost of generic drugs (as per the Q.no 5)

Figure – 8 Response to factors contribution in selecting brand name drug (as per Q.no 14)

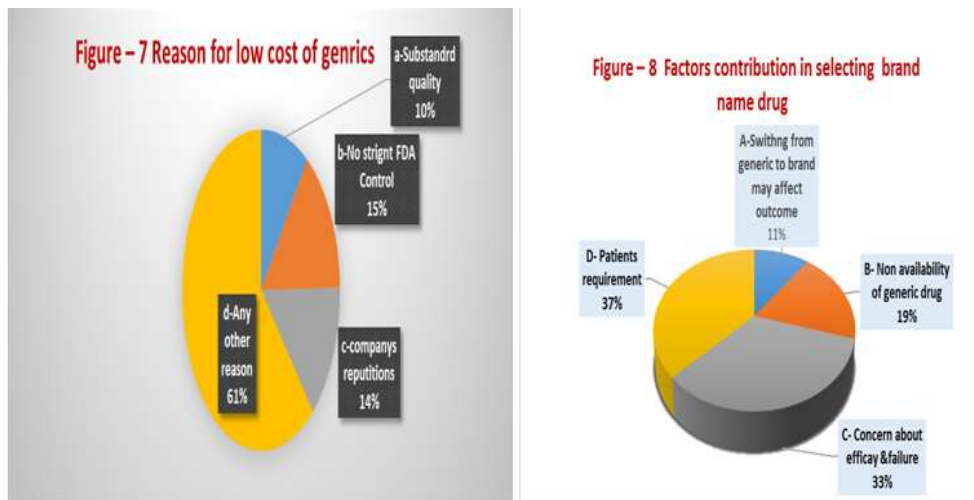


Figure – 9 : Response to source of information about availability of generic drugs (as per the Q.no 15)

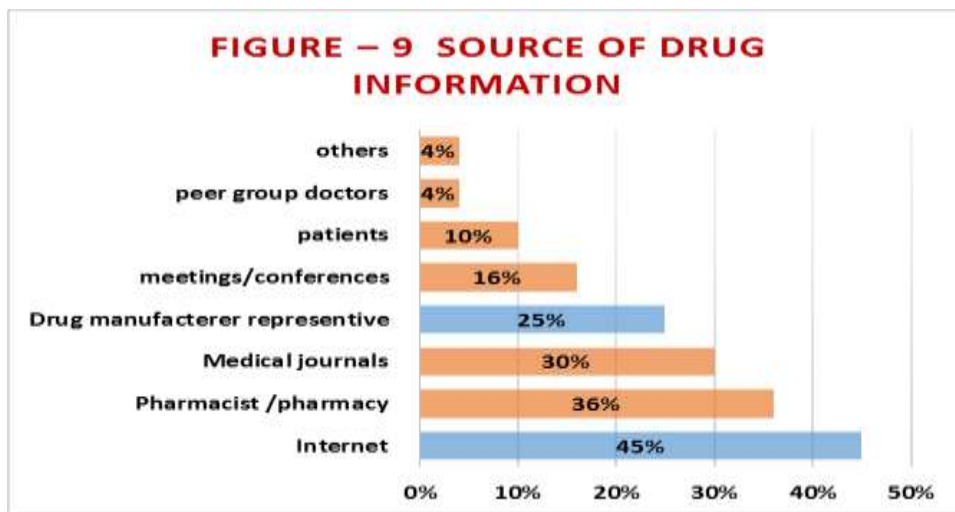


Table no – 1 Sub group analysis Among non MBBS group and MBBS and specialist group

Question no	Incorrect Response by non MBBS group	Incorrect Response by MBBS +Specialist group
Q.no -1 Pharmaceutical or therapeutical alternative ?	80% - (Pharmaceutical Equivalent)	50 % - (Pharmaceutical Equivalent)
Q no -3 same manufacturer procedures& regulations	50% (No)	20% (NO)
Q no- 5 Reason for low cost of generic drugs	40% (substandard quality)	0% (substandard quality)

V. Discussion

Cost of prescriptions is an important concern and it accounts for major health care expenditure that attributes to most of the health care systems in the world [22]. Around one third of the global population encounters difficulties in accessing medicines due to high price, whereas 50% Indians are facing this problem [23]. Since practitioners have a key role in prescribing medicine, they can contribute to minimize such hardships, by prescribing generic medicines whenever appropriate. This research was conducted among different groups of practitioners to study the knowledge, attitude and practices as regards to prescribing generic medication so as to assess hurdles from the practitioners’ point of view in doing so. Three-fourths (70%) of the practitioners in this study were males. The average age of the sample was 39 SD(±6.13) years. The study sample was heterogeneous as regards to the educational qualification. Most of (56%) practitioners had done their

bachelors' degree in pathies other than allopathy i.e. Homeopathy, Ayurveda, etc but practiced allopathic medicine and hence were included as general practitioners (other pathies) . A smaller portion (25%) of the study group included various specialist (allopathic doctors) like diabetologist, endocrinologist, etc .Only 19% of practitioners who recorded their response belonged to 'MBBS only group'. Similar study including only practitioners in tertiary care hospital carried by Gupta SK et al [24], and private practitioners in the study of Rohit Kumar et al [25]. Among 100 practitioners who recorded response about 70% of them answered all the questions. The most unanswered question (80%) was the one that evaluated the practitioners' knowledge regarding reason of low cost of generics. Many practitioners also did not attempt the question about 'the factor that influenced decision to switch to brand'. 83% physicians knew about various government policies about generic drugs and aware about the new law of Government of India , which made it mandatory to prescribe generic medicines compulsory, whenever clinically appropriate. Same was observed in other study [24] Most of the practitioners in the study group were seniors with a practice experience of more than 30 years (68%) yet only 37 % of the practitioners correctly opted for generic as 'therapeutic equivalent', this clears the idea that years of experience did not affect the knowledge about generics .Interestingly, in the subgroup analysis ,this concept that 'generics are therapeutic equivalent' was much lacking(80%) Table no -1 among the general practitioners of other pathies (but practiced allopathy) comparing to (50%) amongst MBBS and specialist group. Most of the practitioners in the whole study sample also totally lacked knowledge (61 %) as to why the generics are cheaper as compared to innovator brand .Similar finding was earlier reported in study of general population but not in practitioners wherein the participants ,either lacked knowledge or opted for a vague option of 'any other reason' [26] A small fraction of them (14%) stated that reason for low cost is non stringent FDA control and a remaining few blamed substandard /low quality of the generic products. Astonishingly in the subgroup analysis none of practitioners among MBBS and specialist group (i.e allopathic doctors), attributed low cost to substandard quality.(Table no 1) Therefore the whole study group had an awareness related to generics but lacked precise knowledge.

Another interesting observation was that practitioners were quite aware (95%) about low cost of generic drug and significantly high number of doctors agreed that generic drugs are an important tool for reducing overall health expenditure, also nearly 83% of individuals knew that the generics are supposed to be as effective as branded medicines; yet they did not agree with this (55% disagreed) hence only 69 % practitioners were willing to support generics drugs. This is in agreement with the study to certain extent conducted by Rohit Kumar et al. where only physicians 23 % always prescribed generics [25] Overall, only 44% of the practitioners had the knowledge of bioequivalence of generic drugs whereas majority of the practitioners (52%) emphasized the need to know about their bioequivalence as compared to innovator product. Interestingly in subgroup analysis of these 52% of practitioners, a major 60 % of them belonged to the group of practitioners from other pathies (viz. B.A.M.S, B.H.M.S,etc) . On the other hand in another study most of practitioners (68%) said they knew enough about bioequivalence as this study population included interns , residents and academicians of a allopathic medical college whereas the current study included only private practitioners of various pathies as well.[27] Therefore if, the government body is keen in the implementation of the generic prescribing law in an appropriate manner ;there is a dire need to sensitize and update such practitioners about certain pharmacological aspects such as bioequivalence and its importance in prescribing generics. Assumptions about the decreased quality of generics could be eliminated by continuing medical education of practitioners about drug discovery, development, and regulations.[29,30] Particularly, the endeavor should be, to educate the practitioners early in their career about the relevance and advantages of prescribing generic drug.[29,31]

As regards the attitude, most of the practitioners (82%) were aware about the nearby generic medical stores and those who didn't know, showed keen interest in knowing about them. Most of the practitioners (75%) even opted to use generics for self-medication, thus showing a positive attitude. As against this only 51% of practitioners offered cafeteria of choice to patients, to select between generic and brand name drugs of the same medicine while, the rest i.e 49% of practitioners didn't offer any choice to the patients, yet a majority of the practitioners prescribed brand drug and the reason they mentioned was that 'they were pressurized by patients' most of time (90%) to do so.[28] Similarly in a different question in this study ,a similar finding was noted again- that patients requirement for brand drug contributes to maximum(37 %) in decision making ,while the practitioners were equally concerned towards efficacy and failure(33 %) related to generic medicines and 11% were of the opinion that therapeutic outcome may change with a switch from innovator to generic medicine. On the contrary other study [27] , availability of generic drugs contributes to the main factor for choosing between brand and generic drug. When the practitioners were assessed on the point of therapeutic failure with generics, a majority of them (67%) agreed to the statement the therapeutic failure is a serious concern with generic drugs. Similar finding were observed by Barret et al [28]. Also 70% of practitioners asked their patients for feedback after prescribing generic drugs, which expresses their concern for therapeutic efficacy with generics.[28] This skepticism to prescribe generic medicines was observed in this study was due to **practitioners'** apprehension about its therapeutic efficacy and safety. Such similar finding was also observed in study by Badwaik et al[27] and Jamshed et al[1].

Internet was most common source of information (45%) for availability of generic drugs, followed by pharmacist / pharmacy (40%). All practitioners, practicing modern medicine (84%), whether allopathic or non-allopathic doctors, claimed that they were more frequently visited by representatives of innovator drug for updating and reinforcing on prescribing their brand and even provided free samples for the same, but the scenario for generic drug promotion was dismal. This gives some food for thought about the role of industry as appendages to strengthen the implementation of government law of generic prescribing, indirectly, by providing appropriate information to practitioners about generic options and their efficacy as compared to their innovator brand. It is expected that bestowing knowledge about generic medicine to the practitioners will expedite the transfer of awareness to the patient. The practitioners also expressed the need for generics of higher antibiotics and dermal preparations, with the view of cutting down healthcare related costs.

The major limitation of this study is the small and heterogeneous sample size. Hence, findings of this study can be generalized with certain limitations. Another limitation is that the study focuses on doctor's perception and understanding about generic medicines. It would be appropriate to also know the opinion and level of understanding of pharmacist, and general populations including patients.

VI. Conclusion

Physicians had an idea but lacked detailed knowledge and there was a grave concern of therapeutic failure which reflected in their prescribing behavior which was particularly noticed as regards to practitioners of other pathies. The existing gorge in awareness and prescribing can be bridged with the help of inculcating confidence about generics that only comes with evidence based medicine. Updating practitioners about bioequivalence studies and innovator Vs generic outcomes may prove effective in strengthening the prescribing patterns for generics. As internet was most common source to get information about availability or updating the knowledge about generic drug therefore it is important to educate practitioners about authentic and reliable internet sites for such purposes.

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