Brand versus generic dispensing trend for ciprofloxacin 500 mg, levofloxacin 500 mg, and moxifloxacin 400 mg (oral dosage forms) among pharmacies of Karachi, Pakistan

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Abstract

Introduction: Pakistan spends 0.7% of its gross domestic product on health. The public sector health-care system provides services to 22% of population thus paving the way for a dominant private sector. Patients in Pakistan mostly pay their medical expenses directly, and 64% of the health expenditures are borne by the household. Expenditure on medicine constitutes 43% of the total household expenditure.

Methods: A quantitative cross-sectional study was conducted in Karachi, Pakistan, for a month. It was aimed at gathering response from different pharmacies to understand the brand versus generic dispensing trend of ciprofloxacin 500 mg, levofloxacin 500 mg, and moxifloxacin 400 mg oral dosage forms. The study employed convenience sampling and used a survey checklist. The data gathered was entered in SPSS version 22.

Results: The mean price per tablet for ciprofloxacin brand and generic was reported at Pakistani Rupees (PKR) 48.44 and PKR 26.85, respectively. The trend for dispensing ciprofloxacin highlighted a split in the market between brand (51%) and generic (49%). For levofloxacin brand and generic, the price per tablet was reported at PKR 36.50 and PKR 36.15 respectively, and despite same price, the market was dominated by generic levofloxacin (92%). Due to a price difference between brand and generic moxifloxacin, i.e., PKR 129.44 and PKR 71.91, respectively, the market was mostly occupied by the generic form (75%).

Conclusion: Pricing mechanism must be revisited, and the authorities should take stern actions against any illegitimate price hike. The surging burden of drug expenditure on poorer sections of the society must be addressed by the government on an urgent basis.

Keywords: Antibiotics, brand-generic substitution, ciprofloxacin, fluoroquinolone, generic drug, levofloxacin, moxifloxacin, Pakistan

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INTRODUCTION

Inadequate access to affordable health care and medicines is one of the vital concerns in the developing countries.[1] United Nation's set of sustainable development goals place huge emphasis on the issue of health and well-being of people, particularly from developing countries. Goal 3 is of particular importance since it highlights the issue of providing access to effective and affordable treatment and medicines for everyone.[2]

Pakistan is one of the developing countries in South Asia. It spends 0.7% of its gross domestic product on health care. The public health-care system is not adequate to meet the demands of the masses. It provides services to merely 22% of the population thus paving way for a dominant private sector.[3] Moreover, in the absence of a national medical insurance; patients in Pakistan mostly pay their medical expenses directly out of their own pockets. 64% of the health expenditures are borne by the household themselves. Expenditure on medicine constitutes 43% of the total household expenditure in the country.[4] In this context, generic prescribing is advantageous in Pakistan as it lowers the price of medications thereby becoming less burdening on patient's pocket.[5]

A brand drug is a drug molecule which is developed by the parent pharmaceutical firm after years of research and investing huge finances. It is patented legally which stays in effect for a number of years. The generic drugs become available after the expiry of the patent of brand drug. Generic drugs are same as brand drugs and contain same active ingredient. Since they are the copies of brand drugs and do not require hefty amounts of finances to be invested in researching the molecule, they are less expensive and thus affordable for the poorer patients.[5-7]

However, generic prescribing has certain drawbacks in Pakistan where generic medicines can be registered in the country without bioequivalence studies.[8,9] This can lead to large number of generic drugs acquiring registration in the country. In addition, it can lead to competition among pharmaceutical companies and in the absence of vigilance on marketing and sales promotion activities, it can lead to unethical practices.[10]

According to the research literature and latest reports pertaining to pharmaceutical sector of Pakistan, the therapeutic category of systemic anti-infectives has a 24.7% market share which currently accounts for largest market share by any therapeutic category in the country and has a second highest growth rate, i.e., 13%. Further to this, a category of systemic anti-infectives, i.e., fluoroquinolone (FQL) antibiotic, namely, ciprofloxacin is the 3rd leading drug molecule in Pakistan with a sales volume over 6 billion Pakistani Rupees i.e., (PKR 6,004,295,567).

In this context, we designed a study targeting the above-mentioned therapeutic group which included antibiotics, namely, ciprofloxacin 500 mg, levofloxacin 500 mg, and moxifloxacin 400 mg, and documented the brand versus generic dispensing trend among the three drug molecules in the city of Karachi, Pakistan.[11-13]

METHODS

A quantitative cross-sectional study of 1-month duration was conducted among pharmacies located in different areas of the city of Karachi, Pakistan. The data collection began in April 2015 and was completed in May 2015. It was aimed at gathering response from different pharmacies regarding the brand versus generic dispensing trend for oral dosage forms of 3rd generation FQL antibiotics, namely, ciprofloxacin 500 mg, levofloxacin 500 mg, and moxifloxacin 400 mg. The scope of the study was to report the brand versus generic dispensing trend regardless of the prescribing patterns and patient demands for the said drugs. The study adhered to STROBE guidelines.

Operational definition

The study identified the following definitions for the terminologies used in the methodology:

Brand drug

A brand drug is a drug molecule developed a pharmaceutical firm after research and is patented for a number of years depending on the country's drug regulations.[5,7]

Generic/me-too drugs

Generic or me-too drugs are copies of the brand drug molecule and contain same active ingredient. They are available after the expiry of the patent period and are less expensive thus affordable for the poorer patients.[5]

Fast-moving and slow-moving drugs

Fast-moving drugs were those which according to the pharmacy's sale data had a relatively higher inventory turnover rate (ITOR) as compared to the other drugs and vice versa. ITOR is the number of times a particular drug stock is completely sold in the pharmacy.[14]

Participants and eligibility criteria

Community and hospital pharmacies were included in the study. Each pharmacy was represented by a pharmacy manager or owner. All medical and drug stores, marts,

general stores, and pharmacies without a pharmacist were excluded from the study. In addition, pharmacies which did not consent to participate in the study were also excluded from the study. One response was gathered from each pharmacy.

Sampling technique

The study employed convenience sampling and gathered data from tertiary care hospital pharmacies and large community-based pharmacies in four districts of Karachi, namely, Central, East, Malir, and West. The reason to conduct a field survey in these districts was the presence of tertiary care hospitals and a large number of community pharmacies. Pharmacies were approached in their off-peak hours.

Research instrument and piloting

The study employed a checklist termed as FQL checklist for gathering the data which was exclusively developed by a team of experts comprising of a health economist and pharmacists with clinical, pharmaceutical, and regulatory knowledge. It was subjected to physical piloting and reliability analysis. The research instrument was piloted among 12 pharmacies and was validated. The reliability analysis reported Cronbach alpha value of 0.7.

The FQL checklist contained 6 items out of which 3 items, namely, location in districts, name of drug, price of drug were open-ended, and other 3 items i.e., type of pharmacy, type of drug, category of drug were close ended. The variables identified were demographics of the pharmacy such as the location in the city which was identified by city districts. Second, the type of the store, i.e., community-based or hospital-based was also identified as a variable. The other set of variables was the information about the drugs. Type of drug, i.e., fast- and slow-moving, category of the drug such as brand or generic and price of the drug were recognized as variables.

Data analysis and presentation

The data gathered was entered in Statistical Package for Social Sciences IBM SPSS version 22 (Statistical Package for Social Sciences) SPSS Inc., Chicago USA. software and was analyzed using frequency descriptive statistics, Chi-square (χ^2) test, and cross tabulation. A significance level alpha (α) was noted at 0.05. The results were expressed as sample counts (N), percentages (%), and mean values (X). Statistical significance was reported in terms of significant $P < 0.05$.

Informed consent and ethical approval

Before data collection, informed consent was obtained from pharmacy representative. The participation in the study was voluntary. The representatives of the pharmacies were neither pressurized nor incentivized to participate. The study was subjected for ethical approval and was deemed exempted by the Department of Pharmacy Practice, Faculty of Pharmacy, Hamdard University Karachi, Pakistan, in April 2015. In addition, the study was also subjected to the ethical review and was granted exemption by the Institutional Review Board, Clifton Central Hospital, Karachi 75600, Pakistan (Letter #CHC234-1e-415).

RESULTS

A survey was conducted in the city of Karachi, Pakistan, which incorporated various districts of the city. The result of the study is divided in the following subsections.

Demographic information

A total of 100 pharmacies were surveyed in the city of Karachi. The highest number of responses gathered ($N = 40$, 40%) were from the district West of Karachi; significant $P < 0.01$ were obtained. Furthermore, the survey also included responses from both community ($N = 79$, 79%) and hospital pharmacies ($N = 21$, 21%); significant $P < 0.01$ were reported. The summary is presented in Table 1.

Description of drugs

Furthermore, the trend reported that for fast-moving ciprofloxacin 500 mg, the market was split between brands (51%) and generics (49%) drugs. Contrastingly, generic levofloxacin dominated the market (92%). Similar figures were obtained for fast-moving moxifloxacin. The summary of FQL drugs with respect to brand and generic is reported in Table 2.

Price per tablet

Regarding the prices of drug in fast-moving category, the mean price per tablet for ciprofloxacin 500 mg brand and generic was reported at PKR 48.44 and PKR 26.85, respectively. The slow-moving ciprofloxacin 500 mg brand and generic price were PKR 32.84 and PKR 26.72, respectively. The mean price of levofloxacin 500 mg brand and generic was reported at PKR 36.50 and PKR 36.15, respectively. The pricing information is tabulated in Table 3.

Table 1: Demographics of pharmacies

Demographics	Sample (*n*)	Percentage	*P*
District			
West	40	40	0.007 (<0.01)
Malir	20	20	
East	20	20	
Central	20	20	
Pharmacy type			
Community	79	79	0.0001 (<0.01)
Hospital	21	21	

Table 2: Fast-moving and slow-moving fluoroquinolone

Fluoroquinolone	Brand drugs		Generic drugs	
	Sample (*n*)	Percentage	Sample (*n*)	Percentage
Fast moving				
Ciprofloxacin 500 mg	51	51	49	49
Levofloxacin 500 mg	08	08	92	92
Moxifloxacin 400 mg	25	25	75	75
Slow moving				
Ciprofloxacin 500 mg	20	20	80	80
Levofloxacin 500 mg	36	36	64	64
Moxifloxacin 400 mg	30	30	70	70

Table 3: Pricing information

Price of drugs	Minimum	Maximum	Mean	SD
Ciprofloxacin 500 mg				
Brand drugs (fast moving)	26	53	48.44	5.917
Generic drug (fast moving)	15	38	26.85	4.746
Brand drugs (slow moving)	12	51	32.84	11.591
Generic drug (slow moving)	13	160	26.72	16.279
Levofloxacin 500 mg				
Brand drugs (fast moving)	13	83	36.50	28.304
Generic drug (fast moving)	13	120	36.15	28.154
Brand drugs (slow moving)	10	84	40.56	27.069
Generic drug (slow moving)	10	110	57.45	41.974
Moxifloxacin 400 mg				
Brand drugs (fast moving)	90	162	129.44	28.209
Generic drug (fast moving)	32	95	71.91	11.623
Brand drugs (slow moving)	50	160	139.03	32.702
Generic drug (slow moving)	18	95	57.48	22.146

SD: Standard deviation

Cross tabulation of districts with drug category

The association of districts of Karachi with the use of ciprofloxacin 500 mg fast-moving drug was statistically significant with Chi-square value reported at 9.264 and $P = 0.026$, i.e., <0.05. The strength of phi was strong, i.e., 0.304 effect size. However, in the case of slow moving, no statistical significance was observed, i.e., $P = 0.172$. The association of districts with levofloxacin 500 mg fast-moving drug was statistically significant as Chi-square value reported was 17.120 and $P = 0.001$, i.e., <0.05. The strength of phi for this association was strong, i.e., 0.414 effect size. Similarly, the association of districts with slow-moving levofloxacin 500 mg drug was also statistically significant with high value reported for Chi-square, i.e., 20.464, $P = 0.0001$, i.e., <0.01 and strong effect size with phi = 0.452. There was no statistical significance for the use of fast- and slow-moving moxifloxacin 400 mg with districts of Karachi with P value reported at 0.158 and 0.343, respectively. The summary of cross tabulation is presented in Table 4.

DISCUSSION

This cross-sectional observational study was designed in the form of a survey using a checklist coined by the term FQL. The survey was conducted in the city of Karachi and gathered response from the pharmacies. The majority of the pharmacies surveyed were community-based (79%)

and were located in the district West of Karachi (40%). The survey observed that the drugs under investigation were fast moving and slow moving. This was established by a predefined criterion based on ITOR which has been explained previously in methodology. There could be no figure which defines this phenomenon as stocking of drugs depends on the size and work load of a pharmacy.

The survey reports that for ciprofloxacin 500 mg, the pharmaceutical market is split between brand (51%) and generic drugs (49%); however, the market is dominated by generic drugs (92%) for levofloxacin 500 mg and moxifloxacin 400 mg (75%). The category of slow-moving drugs largely comprises generic form, i.e., ciprofloxacin 500 mg (80%), levofloxacin 500 mg (64%), and moxifloxacin 400 mg (70%). In Pakistan, there is no restriction on the number of generic medicines registration, and no bioequivalence tests are required as a prerequisite to new drug registration. As a result, it is very easy to register a generic drug against a patented drug molecule or a brand drug. This results in the market being flooded with too many average quality generic drugs.[8,15]

The issue of price of drugs is of paramount importance keeping in view the health-care system of Pakistan where in most cases, patients have to pay out of their own pocket for treatments and drugs.[7,16] Regarding the price per tablet for ciprofloxacin 500 mg, the mean price of a fast-moving brand is PKR 48.44 with least expensive brand available for PKR 26 and most expensive for PKR 53. Similarly, the mean price per tablet for fast-moving generic ciprofloxacin is PKR 26.85 giving a price difference of PKR 21.59 between brand and generic form. Despite this price difference, the market is almost split between the two categories. Generic prescribing and dispensing are desired in developing countries where share of expenditure on drugs in the total out of pocket medical expenses account for almost 80% in most of the cases.[17] This is because generic medicines are generally less costly than brand; however, perceptions regarding generic medicines may not be positive, and this may lead to an increased preference for brand drug.[18]

Table 4: Cross-tabulation of districts with medications

Fluoroquinolone	Dosage (mg)	Type	Drug category	Sample count	Districts of Karachi			
					Central	East	Malir	West
Ciprofloxacin	500	Fast moving	Brand	Observed	16	9	7	19
				Expected	10.2	10.2	10.2	20.4
			Generic	Observed	4	11	13	21
				Expected	9.8	9.8	9.8	19.6
		Slow moving	Brand	Observed	6	1	3	10
				Expected	4	4	4	8
			Generic	Observed	14	19	17	30
				Expected	16	16	16	32
Levofloxacin	500	Fast moving	Brand	Observed	1	1	6	0
				Expected	1.6	1.6	1.6	3.2
			Generic	Observed	19	19	14	40
				Expected	18.4	18.4	18.4	36.8
		Slow moving	Brand	Observed	4	12	13	7
				Expected	7.2	7.2	7.2	14.4
			Generic	Observed	16	8	7	33
				Expected	12.8	12.8	12.8	25.6
Moxifloxacin	400	Fast moving	Brand	Observed	2	8	6	9
				Expected	5	5	5	10
			Generic	Observed	18	12	14	31
				Expected	15	15	15	30
		Slow moving	Brand	Observed	8	3	7	12
				Expected	6	6	6	12
			Generic	Observed	12	17	13	28
				Expected	14	14	14	28

In a study conducted in Pakistan, it was reported that the perceptions of health-care professionals toward generic medicines were negative.[5] Hence, they preferred prescribing the brand which was expensive. Moreover, there is a lack of technical expertise for the detection of substandard and counterfeit products at various levels of pharmaceutical supply chain.[19] It contributes to the apprehensions about generic prescribing in the country, and thus, it is observed that brand drugs are preferred despite being high-priced.

For levofloxacin 500 mg, the mean price per tablet for fast-moving brand is PKR 36.50 while the price for generic is PKR 36.15. The least expensive generic available costs PKR 13 and most expensive is available for PKR 120 which is far greater than the most expensive levofloxacin brand available, i.e., PKR 83. Despite same mean price per tablet for brand and generic levofloxacin drugs, the market is dominated by generic levofloxacin which presents an opposite picture when compared to the scenario of ciprofloxacin. This is contrary to the purpose generic drugs were introduced, i.e., to safely reduce the overall expenditure on drugs a patient had to make. In theory, the average cost of a generic drug is far lower than the brand; however, this case highlights an escalating price of generic instead of brand.[7]

The preference of a generic medicine normally results due to its economical price which is not observed in this case. However, it is still prescribed and dispensed largely; hence, highlighting the marketing and sales promotion activities of local pharmaceutical manufacturers. A number of studies have been conducted in Pakistan, especially in Karachi, that draw attention to the mal prescribing and unethical sales promotion activities of local pharmaceuticals in Pakistan.[5,10] Apart from this, the surging prices for generic drugs, in this case, highlight the issue of supply shortages. For many drugs, there are only few generic manufacturers that are responsible for the supply of the particular drug. These companies thrive on their market position and enjoy the little competition friction, thereby posing risks for creating drug shortage as well as exploitation of pricing power.[20]

For moxifloxacin 400 mg, the mean price per tablet for fast-moving brand is PKR 129.44 while generic is available for PKR 71.91. Our data reported that the generic form was dispensed mostly. This is logical in the context of Pakistani environment as poor economic conditions compel the patients to opt to cheaper alternatives. The important role of generic drugs in helping reduce the overall expenditure on health care can be observed in this particular case of moxifloxacin.

The results of cross-tabulation revealed that the location of pharmacies in the city were statistically associated with the dispensing trends. For fast-moving ciprofloxacin 500 mg, there is a high-dispensing trend of brand drug in the district central while generic form is routinely dispensed in more numbers in districts East, Malir, and West. For levofloxacin 500 mg and moxifloxacin 400 mg, fast-moving generic form dominates the market.

Generic drugs, in essence, can play a significant role in the development of a sustainable health-care system through their lower costs. However, in case of Pakistan, certain policy measures must be taken to fully realize the benefits of it. First, the Drug Regulatory Authority of Pakistan (DRAP) needs to take measures and devise plans for inclusion of bioequivalence tests as a prerequisite to new registrations for generic medicines. This may help in limiting the number of generics being registered and at the same time improving the quality of registered generics in the country. It must keep a vigilant eye on the unethical sales and promotion practices of pharmaceutical firms in the country. Steps must be taken for the detection of counterfeit and substandard drugs.

The surging burden of drug expenditure on poorer sections of the society must be addressed by the authorities on an urgent basis, and pricing mechanism must also be revisited. It should be structured after discussion with the various drug suppliers. The authorities should take stern actions against any illegitimate price hike or drug shortages which adversely affect the well-being of patients.

Efforts must be taken to improve the perceptions about generic drugs among all important stakeholders including physicians, pharmacists, and patients. Discussions must be held to address the misconceptions of all stakeholders. Literature highlights that apprehensions exist among physicians and patients regarding generic drugs which results in refusal of brand-generic substitution for various medicines.

CONCLUSION

Generic drugs are usually preferred in those countries where patients have to pay for the health-care expenditures out of their own pocket. The surging cost of the pharmaceuticals is a vital factor that impedes the access to medicines in the developing countries. The drug registration procedure of Pakistan lacks important steps such as bioequivalence testing. This makes the process easier for a new generic drug to obtain registration and enter the market without upholding quality standards. As a result, the market is filled with average-quality me-too drugs. In some cases, despite price of generic drug being much lower than the brand, a high dispensing trend for the brand is observed which highlights the negative perceptions of health-care professionals regarding generic prescribing. In another case where there is no gap between brand and generic in terms of price, dispensing of generic versus brand indicates the intensive marketing and sales activities of pharmaceutical firms.

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