Generic Versus Branded Medicines Available on the Local Market

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ABSTRACT

This paper presents a survey study of generic and branded medicines available on the local market. The study was carried out on solid dosage forms (Tablets and capsules) for 53 medications available at the time of study in 69 pharmacies located in Tripoli, Libya. Physical specifications (generic name, batch number, manufacture date, expiry date and the manufacturer) as appeared on the package for each product were recorded in a designed form. The retail price at the time of study for each innovator brand and the counterpart generic was also recorded and compared. Results showed that 234 (89%) generics and 29 (11%) branded medicines were available for the studied medicines. The generics medicines were antibiotics (28%), cardiovascular (24.36%), analgesics and antipyretics (12.5%), gastrointestinal (12.8%), for respiratory tract (0.85%), anti-histamine (7.26%), for adiabatic (3%), for vitamins and minerals (6%) and corticosteroid (1%) medicines. The original suppliers of the generics were European countries (42%), Arabian countries (41%) and other region of the world (17%). The retail prices for the generics were significantly ($p > 0.05$) lower compared to the price of innovator brand counterpart. The study suggests post-marketing surveillance studies for the available generics in comparison to the innovators especially in terms of therapeutic efficiency.

Key words: generic drugs, innovator, brand, narrow therapeutic index

INTRODUCTION

A brand-name drug product is originally discovered and developed by a pharmaceutical company. Generic medicinal products are 'copies' of patented drugs and can be marketed following patent expiration of the brand product (Minghetti, 1996). The generic drug may differ in colour, shape, taste, inactive ingredients, preservatives and packaging. However, because of these differences, the generic drug manufacturers are required to submit additional paper work to the FDA to prove that their product is manufactured in accordance with good manufacturing practices (GMPs), and is as pure and stable as the brand-name product. Additionally, the generic needs to meet pharmacokinetic parameters in the body. Once all the equivalency tests have been conducted, the generic drug is considered a therapeutic equivalent. This means that the drug will do the same effect via the same mechanism, and will follow the same distribution, metabolism and elimination pathways in the body (Shaw & and Hartman , 2010). The phenomenal growth of the generic pharmaceutical industry and the abundance of multisource products have prompted some questions regarding the therapeutic equivalency of generics, particularly those in certain critical therapeutic categories such as anticonvulsants and cardiovascular disease treatment drugs. Medline search published between 1973 and 2003 highlighted a number of different categories and patient subpopulations for which generic substitutions can still prove to be problematic Meredith, 2003). Other studies indicated the bioequivalence of generic to the innovator brand drugs (Antonio et al., 2004). Although generic drugs are widely believed to provide the same therapeutic effects as their brand-name alternatives, several issues and concerns relevant to the switching of brand to generic antiepileptic drug have recently been raised (Kesselheim et al., 2008). Some generics dissolved differently than their branded counterparts. This can clearly question the interchangeability between the branded and its generic counterpart or even among generics (Ameri

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et al., 2012);. A study to assess patients' attitudes towards and experiences of generic substitution 3 years after generic substitution of prescription medicines permitted in Norway showed that about 33% of the patients who had their medication substituted reported negative experiences (Kjoenniksen et al., 2006). Accordingly, the author concluded that generic drug substitution for a number of patients is not considered an equal alternative to branded drugs, and these patients may need additional information and support. Several studies indicated that increased generic drug use is an important means of controlling drug costs without compromising quality of care (Fischer and Avorn, 2004), (Fischer and Avorn, 2004) & (Kohl, 2007). This paper presents a survey study of the available generic drugs relative to the counterpart branded medicines for solid dosage forms of different pharmacological categories available in Libyan privet market. Tablets and capsules were selected for the study as they popular dosage forms available in pharmacies and their exchange is less restricted.

METHODOLOGY

This study involved a survey of generic and branded medicines available on the local privet market, Tripoli, Libya. The study was performed during the shift hours of 69 pharmacies located in different area of Tripoli. In order to avoid any adherence in data, no previous notes about the aim of the study was give to the pharmacies. Generic name, batch number, manufacture date, expiry date, strength and manufacturer name as appeared on the package for each medicament were recorded in predesigned forum. The local sale price for each drug at the time of study was also recorded and compared.

Data analysis

Data were analysed with Excel Version 2010.The number of generics for each dosage form (tablets and capsules) was recorded. The ratios of generics to innovators available for each drug were estimated. The price for the available innovator was compared to the lower sale price for the corresponding generic. The generics then classified according to their pharmacological group and compared. Two-sample t-test was used to test the significance of the difference in change in the measurement between the two groups was applied in comparison of data. The results of this study were expressed as % (95% Confidence Intervals (CI)). Variations were evaluated using the one-way analysis of variance (ANOVA) and $P \leq 0.05$ was considered statistically significant.

RESULTS

Overall, 53 medicines were surveyed in 69 pharmacies. The study revealed that 234 (89%) generics versus 29 (11%) innovators were available at the time of study for these medicines. Table 1 illustrates the generics and counterpart innovator brand for each medicine. The available generics were antibiotics (28%), analgesics and antipyretics (13%), gastrointestinal drugs (12%), cardiovascular systems (24%), respiratory tract infection treatment drugs (0.85%), anti-histamine (7%), anti-diabetic (2.5%), lipid lowering (5%), dietary supplement (6%) and corticosteroids (0.9%) drugs. Figure 1 shows the innovator brands (%) relative to the number of medicine for each pharmacological category. The highest innovator was for lipid lowering (22%) with lowest was for respiratory tract system with (0%) among other studied items. In contrast generics (%) were between 100 % for respiratory tract and 80% for Lipid lowering medicines respectively (Fig 2). Contrasting the total available generics for each pharmacological category to total number of generics showed that Antibiotic generics were with the highest percentage (28%) and respiratory and corticosteroids with the lowest (1%) available among other generics (Fig 3). Table 2 shows the local price for generics and their counterpart innovator brands for 23 medicines. Comparison study showed that 95% of generics were priced lower than their counterpart branded innovator. Two generics (5%) had similar prices to the innovator indicating that none of generics were priced more than the counterpart innovator. The prices of generics on an average were significantly lower than the innovator brands prices. In order to avoid any biased error due to different packaging systems, the prices of generics were also compared based on the unit price. Table 3 shows the unit prices for 21 medicines (generics and counterpart innovator brand) for different pharmacological categories. Results showed that the price of generic was always lower than the innovator price

Table 1. Generic and innovator branded medicines available on the local market.

Pharmacological category	Medicine	Innovator Brand	Number of Generics
Anti-infective Antibiotics/	Amoxycllin/Clavunic acid	Augmantin	7
	Ampicillin	NA	4
	Amoxycllin	Amoxil	16
	Clarithromycin	NA	8
	Co-tromoxazole	Bactrim	5
	Ciprofloxacin	Cipro	7
	Cephalexin	NA	3
	Doxycycline	Vibramycin	2
	Fluconazole	Diflucan	4
	Methacycline HCl	Tetracycline	3
	Metronidazole	Flagyl	7
Cardiovascular system Medicines	Amilodipine	Amlor	5
	Atenolol	Tenormin	3
	Clopidogrel	NA	6
	Captopril	NA	10
	Digoxin	Lanoxin	3
	Diltazem	NA	4
	Enalpril	Renitec	8
	Frusemide	NA	4
	Lisinopril	NA	5
	MethylDopa	Aldomet	3
	Propanalol HCL	Inderal	2
	Spironolactone	Aldactone	4
Analgesics/ Anti-inflammatory and antipyretic	Acetylsalicylic acid	Aspirin	5
	Indomethacin	NA	4
	Ibuprofen	NA	6
	Melxicam	Mobic	1
	Orphenadrine citraye	NA	5
	Paracetamol	NA	4
	Voltaren	Voltaren	5
Gastro intestinal and ulcer Medicines	Albendazole	NA	1
	Cimetidine	NA	2
	Hyoscine butyl bromide	Buscopan	4
	Lansoprazole	NA	4
	Metalopramide	NA	4
	Omeprazole	Prilosec/losec	8
	Ranitidine	Zantac	6
Respiratory system Medicines	Salbutamol sulphate	NA	2
Antihistaminic Antidepersent/ Tranquilizer	Chlorphiramine maleate	NA	1
	Cyprohepatidine HCL	NA	2
	Diazepam	Valium	3
	Imipramine	Tofranil	1
	Loratadine	Claritin	10
Antidiabtic Medicines	Metformin	Glucophage	6
Lipid lowering	Atarvastatin	Tahor	5

	Fenofibrate	Lipanthyl	1
	Simvastatin	Zocor	5
Dietary supplement	Ferrous sulphate	NA	2
	Folic acid	NA	2
	Vitamin A	NA	2
	Vitamin C	Calcivita	3
	Vitamin B complex	Bcozyme	5
Corticosteroids	Prednisolone	NA	2

Table 2. Generic to Innovator Brand Price Differences

Pharmacological category	Medicine	Innovator Brand	Innovator branded Price (LYD)	Generic Higher Price (LYD)	Generic lower Price (LYD)	Generic Lower Price / innovator Branded price (%)
Antibiotics/ Anti-infective	Amoxycllin/Clavunic acid 625 mg	Augmantin	18	13.0	10	56
	Amoxycllin 500 mg	Amoxil	6	4.5	3	50
	Co-tromoxazole 480 mg	Bactrim	2.4	3	2.5	104
	Ciprofloxacin 500 mg	Cipro	50	14	4.5	9
	Doxycycline 100 mg	Vibramycin	6	2.5	2	33
	Methacycline HCl 250 mg	Tetracycline	5.5	3.5	1.5	27
	Metronidazole 250 mg	Flagyl	11	7.0	2	18
Caridovascular	Amilodipine 5 mg	Amlor	70	40	10	14
	Enalpril 10 mg	Renitec	12.5	5.5	3.5	28
	MethylDopa 250 mg	Aldomet	6.5	12.5	3	46
	Propanalol HCL 40 mg	Inderal	3.5	5.5	3.5	100
	Lisinopril 5 mg	Zesteril	5	6	4.5	90
	Acetylsalicylic acid 75 mg	Aspirin	3.5	3.5	3	86
Gastro intestinal and ulcer Medicines	Melxicam 15 mg	Mobic	9.5	3.5	3.5	37
	Voltaren 75 mg	Voltaren	14	3.5	3.5	25
Heartburn	Ranitidine 150 mg	Zantac	8	16	2.5	31
Antihistaminic Antidepersent/ Tranquilizer	Diazepam 2 mg	Valium	4.5	6	2	44
	Imipramine 25 mg	Tofranil	5	3	3	60
	Loratadine 10 mg	Claritin	9.5	12	2.5	26
Antidiabtic Medicines	Metformin 500 mg	Glucophage	12.5	6	4.5	36
	Atarvastatin 10 mg	Tahor	70	25	7	10
Dietary supplement	B- complex	Becozyme	8	4	3.5	44

LYD = Libyan Dinar

Table 3. Unit prices for branded name and contra part generic medicines.

Pharmacological Group	Brand-name (strength)	Brand name price per unit dose (LYD)	Generic (strength)	Generic price per unit dose (LYD)
Antibiotic	Cipro (750 mg)	0.70	Ciprofloxacin (750 mg)	0.65
Antibacterial	Flagyl (500 mg)	0.85	Amidazole (500 mg)	0.10
Heartburn/Ulcer	Zantac (150 mg)	0.45	Ranitidine	0.10
Hypertension	Renitic (20 mg)	0.25	Enalpril	0.25
	Zestril (10 mg)	0.55	Linopril (10 mg)	0.18

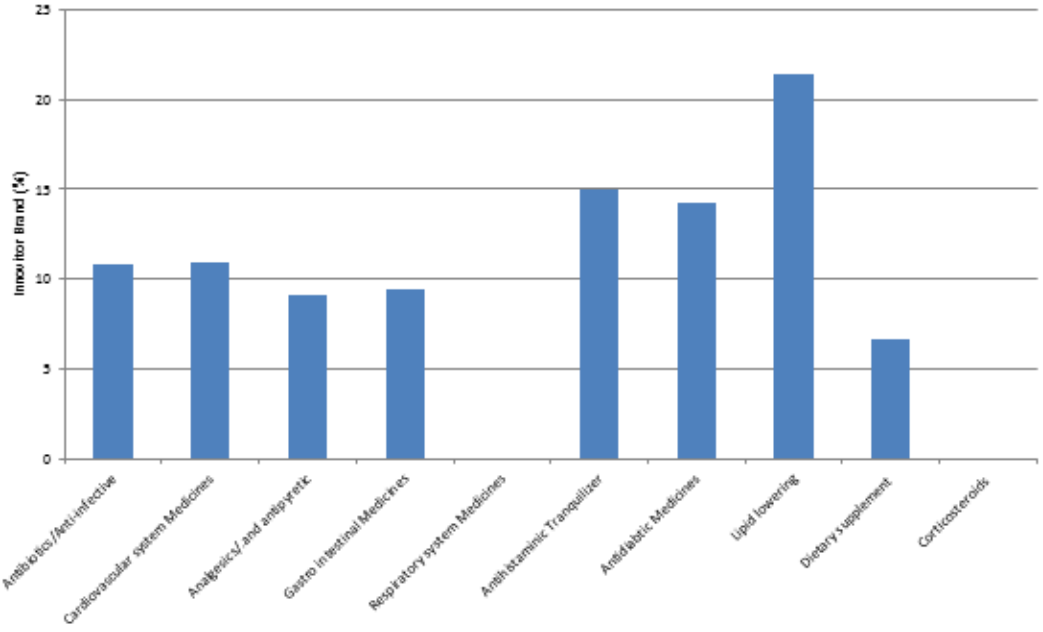

Figure 1. I innovator Brand (%) for the studied medicine of different Pharmacological category.

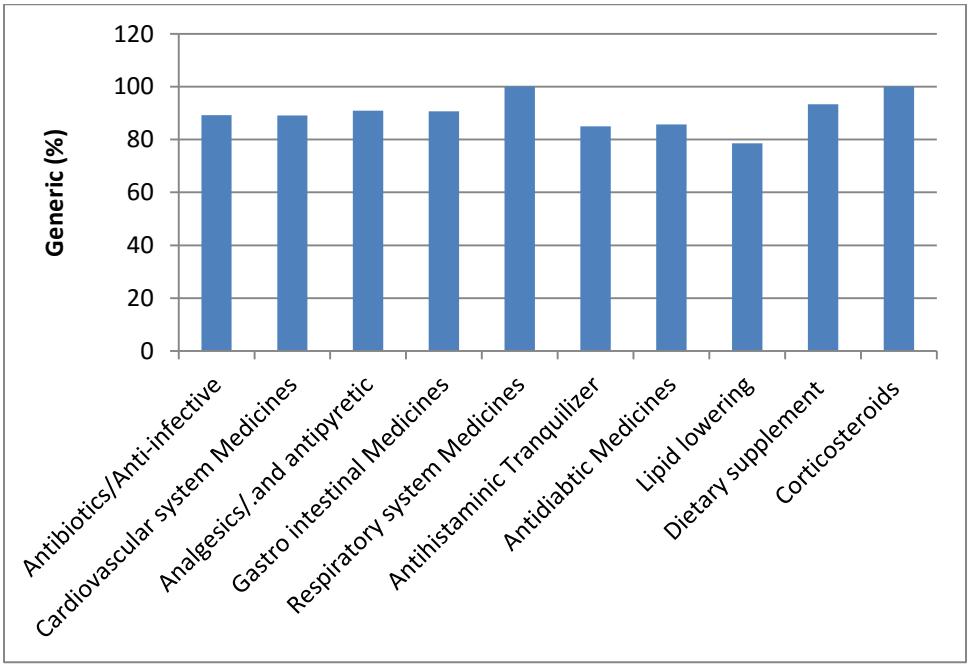

Figure 2. Generics (%) for the studied medicines of different pharmacological categories.

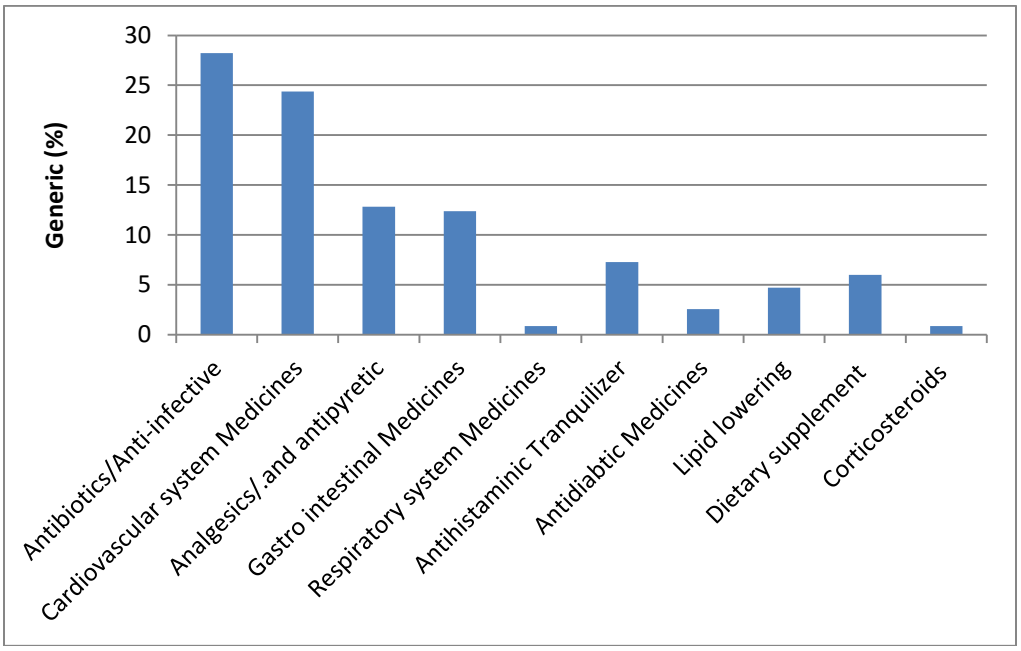

Figure 3. Pharmacological category generics (%) versus the total number of generics studied.

DISCUSSION

The use of generics in health service is controversial. Many patients and health care practitioners believe that brand name drugs are clinically superior to generic drugs. However, this opinion is maintained unfounded (Kesselheim, et al., 2008). Published summary of nearly 25 years of randomized clinical trials comparing brand name and generic cardiovascular medications addressed editorials concerning generic substitution for brand name drugs. Among all the drugs examined by the authors, no evidence indicated that brand name drugs were clinically superior to generic equivalents. Interestingly, though, of the 43 editorials written on generic substitution, more than half (53%) of the authors had a negative view of generic drug use. Our study showed similar trends as none of the pharmacological category drugs tested was free from generics. Several studies have been conducted to correlate the bioavailability of generic and branded antibiotics (Skipper and Vejlin, 2015), (Liu et al., 2009) & (Bagheri et al., 2014) . Post-market in-vitro bioequivalence study of six brands of ciprofloxacin tablets/caplets indicated that 3 of the 6 (50%) brands may not be used interchangeably with the chosen 'innovator' brand (Ngwuluka et al., 2009). The highest percentage (28%) of generics was for antibiotics that could be explained by the expired patient license for this group. Cardiovascular medicines were among the drugs studied in this work. The substitution of innovator cardiovascular medicines with generics still point of debate. Number of studies indicated the bioequivalence of generic cardiovascular drugs to the innovator but with no support for the substitution of branded drugs (Kesselheim et al., 2008). This study showed that the percentage of generic cardiovascular medicines available in the market was 24%. Some drugs are categorized as narrow therapeutic index where the margin of safety and toxicity is short. The small differences between therapeutic and toxic doses raised the concern over careful dosage adjustment and patient monitoring. Comparative bioavailability of three oral sustained release theophylline (narrow therapeutic index) with another brand in healthy human subjects showed no bioequivalent to reference product (Parvez et al., 2009). Our study did not cover this type of drug categories (antiepileptic) as these drugs are controlled and mostly dispensed through public sector in hospitals. Generics were supplied by many companies other than the innovator company. Pharmaceutical companies from industrialized countries, exporting generic drugs to emerging markets, can benefit from the favorably perceived country of origin (COO) of their drugs and thus help the acceptance of generic drugs in these markets (Smaoui et al., 2016). The countries of origin for the studied generics were Arabian countries (42%), European countries (41%) and the rest were

countries from different regions. The cost of generics versus the innovator drug was shown to be a major factor in the acceptance of generics by physicians (Gossell-Williams, 2007). Generic drugs are typically less expensive than brand name drugs, and prices for generics have historically increased less than those for brand-name drugs (Kaiser, 2001). Patients purchasing innovator brands from private outlets usually pay substantially more than they would for generic equivalents (Dunne et al., 2013). Our study revealed similar findings. The prices of the available innovator drugs were found high compared to their generics counterpart for antibiotics, cardiovascular and lipid lowering drugs (Table 2). The unit price for innovator brand was also higher than the generic indication insignificant effect of the packaging and number of unites from different suppliers and manufactures (Table 3). Clearly these prices would have an impact on the affordability of the patient especially for long treatment drugs.

CONCLUSION

The outcome from this study suggests growing of generics versus branded medicines in respect of pharmacological category. Prices based on package and the unit was always lower for generic compared to their innovator counterpart. Post-marketing surveillance for the available generic in comparison to the innovator drugs especially for drugs with narrow therapeutic index is essential.

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