

Cost Variation Study of Various Brands of Oral Fluoroquinolones Available in India: An Economic Perspective

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Abstract

Fluoroquinolones are broad-spectrum antibacterial for treating respiratory tract, intra-abdominal, urinary tract, pelvic, joint, bone, soft tissue, and skin infections. The economic burden on patients affects compliance in developing countries like India. Therefore, the prices of drugs should be controlled effectively. Hence, this study was done to assess the cost variation of branded oral fluoroquinolones available in India compared with generic counterparts. The maximum and minimum cost of oral fluoroquinolones (INR per 10 tablets) of the same strength and dosage form manufactured by different companies was obtained from Drug Today April to July 2021 Volume 1, MIMS, and 1mg.com. The cost ratio and the percentage cost variation of individual drug brands were calculated. Prices of generic fluoroquinolones from the Jan Aushadhi scheme (JAS) were compared with branded drugs. Of 11 different oral fluoroquinolones, levofloxacin 500 mg had the highest percentage variation of 11.100%, and three formulations marketed by a few manufacturers have a percentage reduction of less than 100%. Of 23 different combinations available as 33 different dosages, the highest cost variations were observed in Norfloxacin 400 mg plus tinidazole 600 mg combination (1317%). When compared, some generic fluoroquinolones available under JAS were not cheaper than the minimum cost of their branded counterparts. Wide variation in the cost of the different brands of the same oral fluoroquinolones manufactured by other companies was observed. This adds to the economic burden for the patients. Hence, stakeholders should aim to decrease the cost variation among different brands while maintaining therapeutic efficacy.

Keywords: Pharmacoeconomics, fluoroquinolones, brands, generic, cost ratio, cost variation analysis

Introduction

Diseases due to infection are known health care concerns in India. Apart from endemic diseases, high vulnerability is seen for common infections. There has been a 66% rise in antibiotic usage during the past ten years, as stated by WHO. Thus, medicines are one of the expenses that patient pays directly to health care without a third-party involvement like insurers.¹ In India, the income per capita ranks low. Families face financial issues in the expenditure of medicines despite the availability of better affordable alternatives. Therefore, the economic burden on patients affects compliance, and in the case of anti-infective treatment, it leads to the more serious concern of antibiotic resistance. The prescriber should be aware of medications prices; thus, they can support the patient in lowering treatment costs by choosing cheaper alternatives.²

One of the alternatives is generic drugs available at low cost under the Government of India as the Jan Aushadhi Scheme (JAS).^{3,4} Generic drug stores are established to supply these low-cost generic drugs across the country. In India, fluoroquinolones are the most commonly prescribed antibiotic group. About 30% share of the Global Pharmaceuticals Market is contributed by them.⁵ The market is dominated mainly by levofloxacin and ciprofloxacin, together with charging 65% (\$3.3 billion) of global sales.⁶ Fluoroquinolones are available in a huge variety of brands in different formulations with wide cost variation; for example, more than 5000 oral ornidazole brands are available on the market in different dosages as single and combination drug therapy.

The availability of plenty of options of the same formulation in different brands has produced a need for comparative studies on their prices. The more comparison studies will guide and

help make selecting appropriate low-cost drugs easier. We found only a few studies on the cost comparison of various fluoroquinolones. Moreover, no studies compare the price of branded fluoroquinolones products with those of their generic counterparts available under JAS. Thus, we planned a study to assess the variations in prices of oral preparations of fluoroquinolones- branded or generic, available in single and combination therapy in India.

Methods

A cross-sectional descriptive study was done, and secondary data sources were utilized. Data was collected from Drug today (July – October 2021)⁷, an authentic commercial drug directory, from where the prices of various brands of fluoroquinolones manufactured in India were referred to. We chose a single source of drug prices to make certain of the constancy and to avoid any confusion in prices which may occur if multiple sources are used. The generic prices were noted from the recent price list of generic drugs provided by JAS.⁸ Cost of each fluoroquinolone available in the same strength in various brands, and an average of 10 tablets was estimated.

Drug formulations manufactured by a single company were excluded from the study as cost comparison cannot be done in that case. Minimum and maximum brand prices and the available generic price of a drug in the same formulations were observed. The formula calculated percentage cost variation and cost ratio.⁹

$$\text{Percentage cost variation} = \frac{\text{Maximum cost} - \text{Minimum cost}}{\text{Minimum cost}} \times 100$$

$$\text{Cost ratio} = \frac{\text{Price of costliest brand}}{\text{Price of least costly brand}}$$

Results and Discussion

The pharmaceutical industry in India has noted tremendous growth and has ranked 3rd worldwide by volume of production and

value.¹⁰ In that, anti-infective preparations are one significant contributing sector. Several brands are available for a single formulation with a wide price variation. This creates a complex situation of confusion for patients as there is general consideration that higher-priced drugs are more efficacious. If they go for lower-priced drug brands, they may compromise with quality. Thus, ultimately costlier brands are selected despite the availability of cheaper and better alternatives, leading to economic implications for patients. The cost of therapy is undoubtedly related to compliance to therapy among patients affecting their health. In the case of antibiotics, inadequate adherence to treatment becomes the more serious concern of antibiotic resistance.⁶

While we are gradually shifting towards concepts like rational drug prescription, as stated by the WHO, rational use of drugs requires that patients should receive medications for their therapeutic needs in doses appropriate to their requirements for an adequate duration and at the lowest price in their community.¹¹ Therefore, medicine price is also a basic criterion for prescribing. Although there are numerous studies on the efficacy and safety of drugs, there is still a lack of studies comparing the prices of drugs.

Inadequate information on comparative prices of brands makes a choice difficult to prescribe the economical treatment.¹² Some meta-analyses also mentioned that there is ignorance about drug prices, and doctors also acknowledge that appropriate cost information will improve their prescription choices.¹⁰ Previous studies report that the availability of a comparative manual of drug prices will aid in decision making and prescribing the economically cheaper drug to the patient and reduce unnecessary expenses on drugs.¹³

The government of India's national pharmaceutical pricing authority has limited the highest price of medicines according to the drug price control order (DPCO 2020).¹⁴ Pharmaceutical companies can fix the prices of their products below the ceiling prices as per DPCO. Medicines listed in DPCO should be sold under the cost mentioned. Despite these efforts to control drug prices, a wide range of cost variations is observed. Henceforth, there should be regular monitoring of drug prices. The list of drugs under DPCO should be dynamic and revised periodically by the availability of newer, more efficacious, and safer drugs.¹⁵

Another effective and alternative way for economic benefit for patients is the promotion of generic drugs. Generic drugs are replicas of brand-name drugs with the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug.¹⁶ Often, issues have been raised regarding generic drugs' therapeutic efficacy and bioequivalence compared to their branded counterparts. However, it should be kept in mind that generic drugs are identical and bioequivalent to an innovator brand.¹⁷ Many meta-analyses studies have also reported clinically equivalence of generic and branded drugs.¹⁸⁻²⁰

Generic drugs are a good alternative for prescribing economic medications. The government of India began the Jan Aushadhi Scheme in 2008. It aims to provide generic drugs at lower prices to the population. The therapeutic efficacy of generic drugs under Jan Aushadhi sources is equivalent to or comparable to their branded counterparts in the market.²¹ However, findings in our study show that not all drugs available under JAS are cheaper than their branded counterparts, which seems to fail the main objective of this scheme. Hence, the prices of medicines in

Table 1. Cost Variation and Cost Ratio of Single Drug Therapy

| S.NO. | DRUGS | FORMULATIONS AVAILABLE | DOSAGE | MINIMUM PRICE | MAXIMUM PRICE | COST RATIO | PERCENTAGE COST VARIATION |
|-------|---------------|------------------------|---------|---------------|---------------|------------|---------------------------|
| 1 | CIPROFLOXACIN | 6 | 100 mg | 12.07 | 104.65 | 8.67 | 767.02% |
| | | | 200 mg | 29 | 200 | 6.89 | 589.65% |
| | | | 250 mg | 9.97 | 171.42 | 17.19 | 1619.35% |
| | | | 500 mg | 16.87 | 221.7 | 13.14 | 1214.16% |
| | | | 750 mg | 40.29 | 142.94 | 3.54 | 254.77% |
| | | | 1000 mg | 75 | 191.22 | 2.54 | 154.96% |
| 2 | LEVOFLOXACIN | 4 | 100 mg | 59.73 | 205 | 3.43 | 243.21% |
| | | | 250 mg | 24.42 | 143 | 5.85 | 485.58% |
| | | | 500 mg | 7.5 | 840 | 112 | 11100% |
| | | | 750 mg | 56 | 159.5 | 2.84 | 184.42% |
| 3 | SPARFLOXACIN | 3 | 100 mg | 24 | 110.7 | 4.61 | 361.25% |
| | | | 200 mg | 24.9 | 374 | 15.02 | 1061.44% |
| | | | 400 mg | 33.82 | 183.33 | 5.42 | 442.07% |
| 4 | GEMIFLOXACIN | 1 | 320 mg | 131.42 | 775 | 5.89 | 489.71% |
| 5 | OFLOXACIN | 6 | 50 mg | 35 | 103.43 | 2.95 | 195.51% |
| | | | 100 mg | 11.25 | 100 | 8.88 | 788.80% |
| | | | 200 mg | 10 | 299.5 | 29.95 | 2895% |
| | | | 300 mg | 40.38 | 133 | 3.29 | 229.37% |
| | | | 400 mg | 20.62 | 297.14 | 14.41 | 1341.02% |
| | | | 800 mg | 213.34 | 245 | 1.14 | 14.80% |
| 6 | MOXIFLOXACIN | 2 | 250 mg | 36.35 | 119.18 | 3.27 | 227.86% |
| | | | 400 mg | 25 | 780 | 31.2 | 3020% |
| 7 | PEFLOXACIN | 1 | 400 mg | 24.06 | 222.03 | 9.22 | 823.06% |
| 8 | PRULIFLOXACIN | 1 | 600 mg | 450 | 1053.7 | 2.341 | 134.15% |
| 9 | BALOFLOXACIN | 2 | 100 mg | 155 | 255.7 | 1.64 | 64.96% |
| | | | 200 mg | 70 | 191.6 | 2.73 | 173.71% |
| 10 | NORFLOXACIN | 4 | 100 mg | 3.52 | 20 | 5.61 | 468.18% |
| | | | 200 mg | 19.64 | 60 | 3.05 | 205.49% |
| | | | 400 mg | 6 | 133.55 | 22.25 | 2125.83% |
| | | | 500 mg | 41 | 80 | 1.95 | 95.12% |
| 11 | LOMEFLOXACIN | 1 | 400 mg | 19.25 | 187.5 | 9.74 | 874.02% |

JAS could fail the scheme to meet their aim rather than the quality of drugs.¹ The code of ethics for doctors by the Medical Council of India promotes prescribing of generic drugs only.²² Thus, greater emphasis should be given to generic or cost-effective drugs. Hence, the government of India should revise the JAS plan and review the current prices of generics so that the lowest-cost generic drugs can be supplied to the patients.

Pharmacoeconomics is an evolving branch and is still at a slow pace in India. It helps in decision-making for evaluating the affordability and access to the proper medication to the right patient at the right time. It compares two drugs of the same therapeutic class of drugs with a similar mechanism of action.²³ Hence, principles of Pharmacoeconomics should be implemented in daily practice to sensitize doctors towards increasing the expenses of medications.

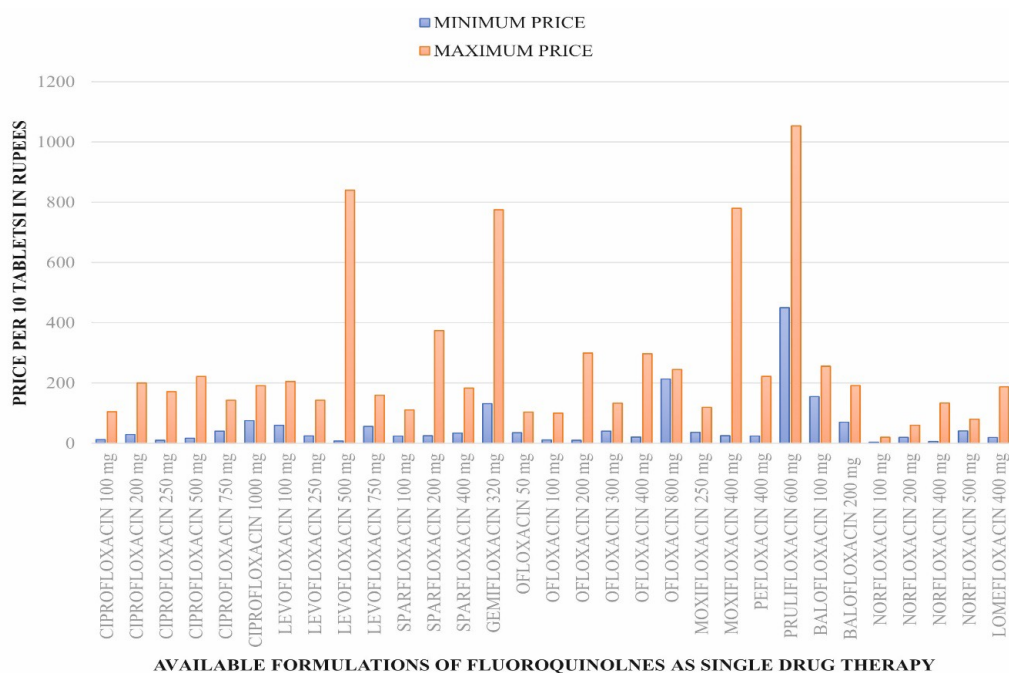


Figure 1. Maximum and Minimum Prices of Fluoroquinolones per-10 Tablets (Single Drug Therapy)

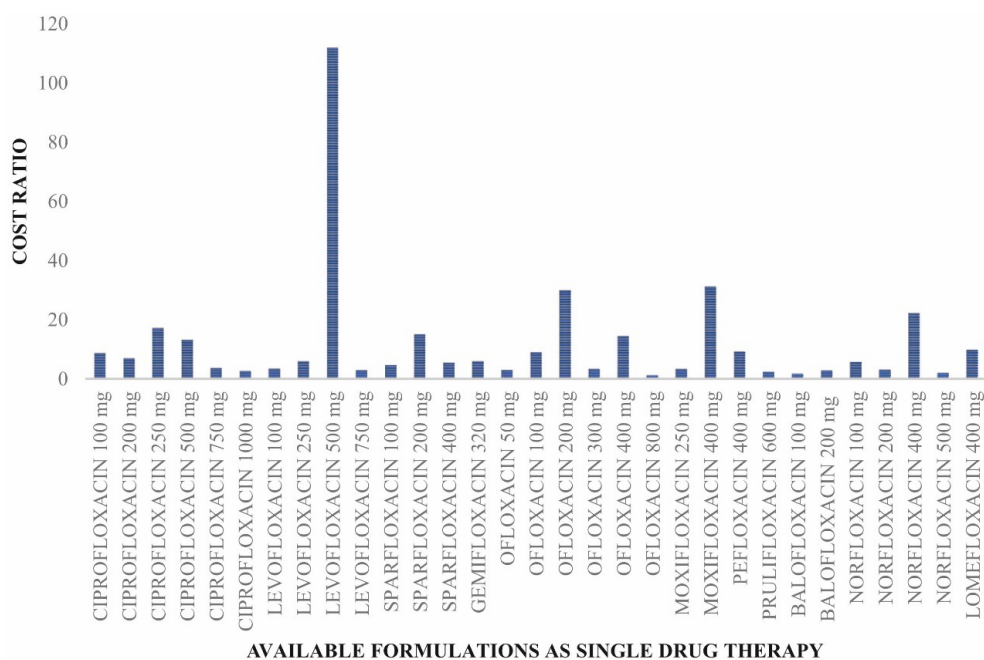


Figure 2. Cost Ratio of Fluoroquinolones (Single Drug Therapy)

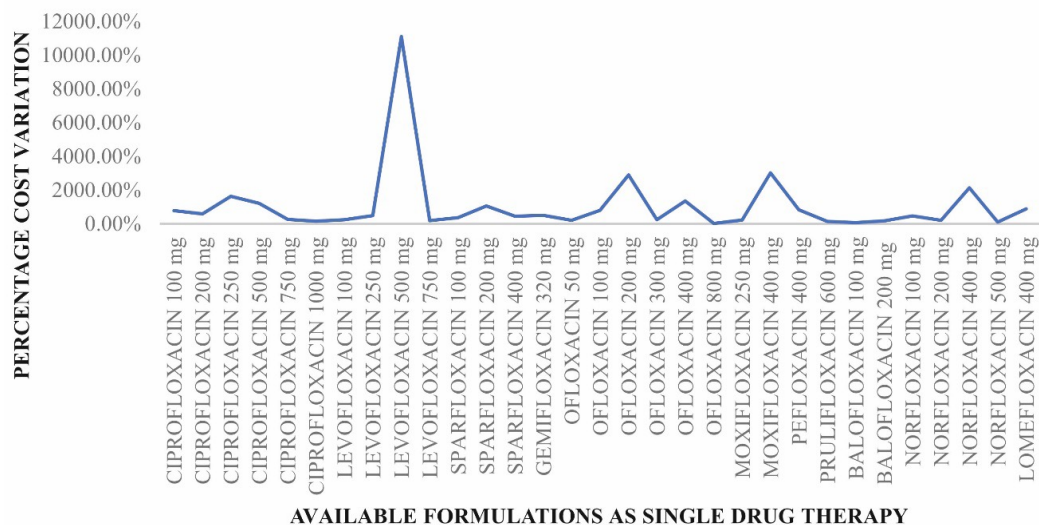


Figure 3. Percentage Cost Ratio of Fluoroquinolones (Single Drug Therapy)

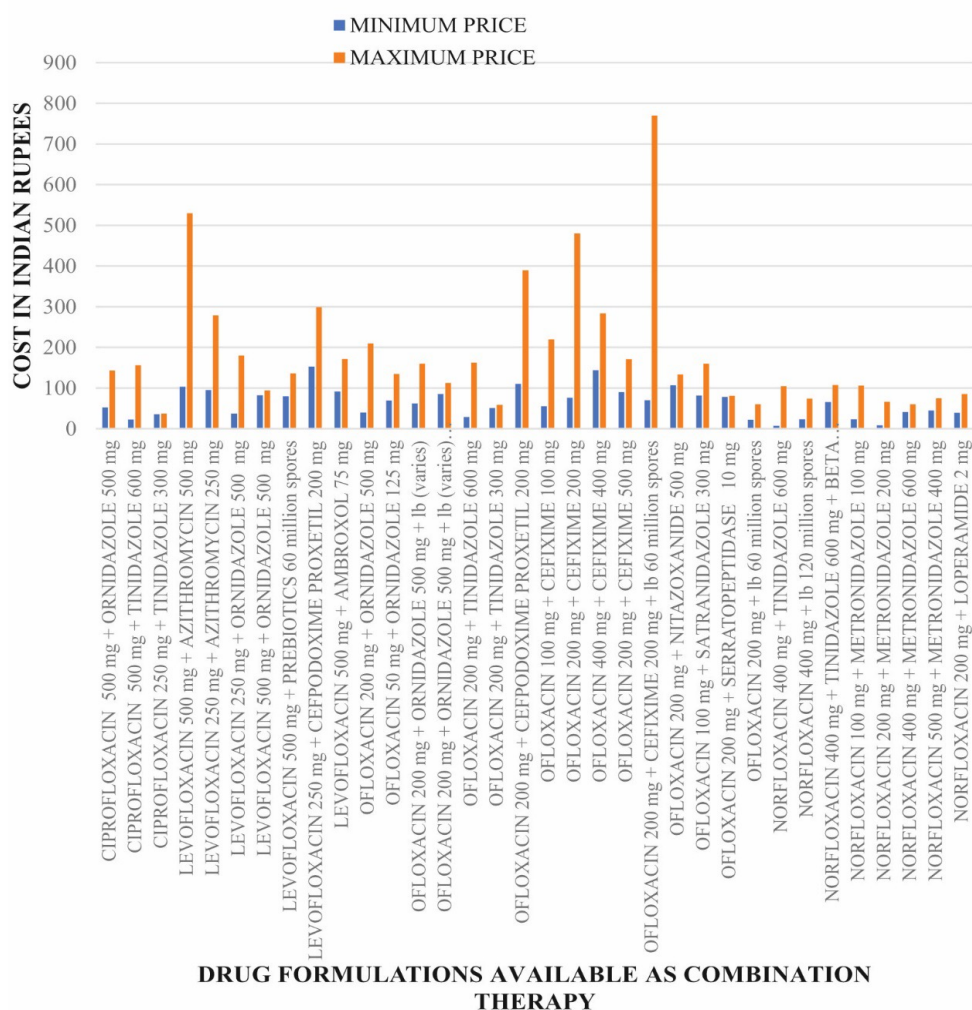


Figure 4. Maximum and Minimum Prices of Fluoroquinolones per-10 Tablets (Combination Drug Therapy)

The present study addressed the issue of price variations focusing on fluoroquinolones. We found enormous variation in prices of multiple brands of the same preparation ranging from 14.8% to as high as 11.100%.

It is observed that Levofloxacin (500 mg) shows the highest price variation of 11.100%, which is available in a variety of brands and is the most commonly prescribed dose. Out of 31 formulations, only three formulations have a percentage cost variation less than 100%, which are ofloxacin (800 mg) 14.8%, Balofloxacin (100 mg) 64.96%, and Norfloxacin (500 mg) 95.12% as these formulations are marketed by a few manufacturers, least commonly used drugs and very less commonly prescribed dose. Similar results were observed in studies conducted previously by Chawan et al¹³ and Dhanvijay et al⁶ which revealed high price variations among different brands of a single formulation. Levofloxacin (500 mg) had the highest price variation of 14526.87% (Dhanvijay et al) which is almost similar to our study (11.000%).

Among combinations with fluoroquinolones, the costs of 23 different fluoroquinolone combinations available in 35 formulations were evaluated. It is found that the combination of Norfloxacin (400 mg) + Tinidazole (600 mg) shows the highest price variation of 1317%. This combination is usually a preferred choice for managing respiratory, urinary, and gastrointestinal tract infections in men and animals. Due to their complementary modes of action and single daily dosing regimens, these are highly prescribed regimens by treating physicians.²⁴ Due to their high demand, these are manufactured by many pharmaceutical companies, leading to a high price variation among those brands.

Out of 35 formulations, 11 formulations have a percentage cost variation of less than

100%, among which the lowest is 2.86 % of Ciprofloxacin (250 mg) + Tinidazole (300 mg).

Our study showed more significant price variations among available combinations compared to previous studies' findings. A cost variation study among available combinations of fluoroquinolones conducted by Chawan et al¹³ revealed that the ofloxacin ornidazole combination had the highest price variation of 390.63%, in contrast, our study showed the highest price variation of 1317% was observed in norfloxacin and tinidazole combination.

More than 500% variance was observed in 5 formulations. This situation has worsened in the present scenario due to the tremendous increase in several pharmaceutical companies. Many studies have found that price variation is directly related to the number of companies manufacturing a particular drug.^{15,25,26} Therefore, it can be concluded that this worsening price variation is due to an increase in various competitive and marketing strategies among manufacturing companies.

Table 3 shows the prices of 11 available generic drugs listed under the JAS and the minimum costs of their branded counterparts. Surprisingly, only three generic equivalents were cheaper than the branded drugs on the market. For the rest of the 11 generic drugs, even cheaper branded counterparts are available on the market. Our results also indicate a huge cost variation among different available brands of fluoroquinolones, both as single-drug formulations and in combinations.

We have considered brands mentioned in drugs today, CIMS, MIMS, etc. Brands that are available in the market but not mentioned in these sources were excluded. This study design considered only the costs of different preparations available. Still, there may be a

Table 2. Cost Variation and Cost Ratio of Available Combinations

| S.NO. | COMBINATION FORMULATIONS | MINIMUM PRICE | MAXIMUM PRICE | COST RATIO | PERCENTAGE COST VARIATION |
|-------|---|---------------|---------------|------------|---------------------------|
| 1 | CIPROFLOXACIN 500 mg+ ORNIDAZOLE 600 mg | 52.56 | 143 | 2.72 | 172.07 |
| 2 | CIPROFLOXACIN 500 mg+ TINIDAZOLE 600 mg | 22.5 | 155.96 | 6.93 | 593.16 |
| 3 | CIPROFLOXACIN 250 mg + TINIDAZOLE 300 mg | 35.97 | 37 | 1.03 | 2.86 |
| 4 | LEVOFLOXACIN 500 mg + AZITHROMYCIN 500 mg | 103.5 | 530 | 5.12 | 412.08 |
| 5 | LEVOFLOXACIN 250 mg + AZITHROMYCIN 250 mg | 95.15 | 279 | 2.93 | 193.22 |
| 6 | LEVOFLOXACIN 250 mg + ORNIDAZOLE 500 mg | 37 | 180 | 4.86 | 386.49 |
| 7 | LEVOFLOXACIN 500 mg + ORNIDAZOLE 500 mg | 82.7 | 94 | 1.14 | 13.66 |
| 8 | LEVOFLOXACIN 500 mg + PREBIOTICS 60 million spores | 80 | 136 | 1.70 | 70.00 |
| 9 | LEVOFLOXACIN 250 mg + CEFPODOXIME PROXETIL 200 mg | 153 | 299 | 1.95 | 95.42 |
| 10 | LEVOFLOXACIN 500 mg + AMBROXOL 75 mg | 91.8 | 171.5 | 1.87 | 86.82 |
| 11 | OFLOXACIN 200 mg + ORNIDAZOLE 500 mg | 40 | 210 | 5.25 | 425.00 |
| 12 | OFLOXACIN 50 mg + ORNIDAZOLE 125 mg | 68.95 | 135 | 1.96 | 95.79 |
| 13 | OFLOXACIN 200 mg + ORNIDAZOLE 500 mg + lb (varies) OFLOXACIN 200 mg + ORNIDAZOLE 500 mg + lb (varies) + Saccharomyces 2 million spores | 62.21 | 159.9 | 2.57 | 157.03 |
| 14 | | 85 | 112.45 | 1.32 | 32.29 |
| 15 | OFLOXACIN 200 mg + TINIDAZOLE 600 mg | 28.56 | 162.62 | 5.69 | 469.40 |
| 16 | OFLOXACIN 200 mg + TINIDAZOLE 300 mg | 50.95 | 58.7 | 1.15 | 15.21 |
| 17 | OFLOXACIN 200 mg + CEFPODOXIME PROXETIL 200 mg | 110 | 390 | 3.55 | 254.55 |
| 18 | OFLOXACIN 100 mg + CEFIXIME 100 mg | 55.5 | 220 | 3.96 | 296.40 |
| 19 | OFLOXACIN 200 mg + CEFIXIME 200 mg | 76 | 480 | 6.32 | 531.58 |
| 20 | OFLOXACIN 400 mg + CEFIXIME 400 mg | 144 | 284 | 1.97 | 97.22 |
| 21 | OFLOXACIN 200 mg + CEFIXIME 500 mg | 90 | 171 | 1.90 | 90.00 |
| 22 | OFLOXACIN 200 mg + CEFIXIME 200 mg + lb 60 million spores | 69.85 | 770 | 11.02 | 1002.36 |
| 23 | OFLOXACIN 200 mg + NITAZOXANIDE 500 mg | 106.5 | 133.43 | 1.25 | 25.29 |
| 24 | OFLOXACIN 100 mg + SATRANIDAZOLE 300 mg | 81.77 | 160 | 1.96 | 95.67 |
| 25 | OFLOXACIN 200 mg + SERRATOPEPTIDASE 10 mg | 78 | 81 | 1.04 | 3.85 |
| 26 | OFLOXACIN 200 mg + lb 60 million spores | 22 | 60 | 2.73 | 172.73 |
| 27 | NORFLOXACIN 400 mg + TINIDAZOLE 600 mg | 7.41 | 105 | 14.17 | 1317.00 |
| 28 | NORFLOXACIN 400 mg + lb 120 million spores NORFLOXACIN 400 mg + TINIDAZOLE 600 mg + BETA CYCLODEXTRIN 10 mg | 22.96 | 74.03 | 3.22 | 222.43 |
| 29 | | 66 | 107.5 | 1.63 | 62.88 |
| 30 | NORFLOXACIN 100 mg + METRONIDAZOLE 100 mg | 23 | 106 | 4.61 | 360.87 |
| 31 | NORFLOXACIN 200 mg + METRONIDAZOLE 200 mg | 8.45 | 66.6 | 7.88 | 688.17 |
| 32 | NORFLOXACIN 400 mg + METRONIDAZOLE 600 mg | 41.38 | 60 | 1.45 | 45.00 |
| 33 | NORFLOXACIN 500 mg + METRONIDAZOLE 400 mg | 45 | 75 | 1.67 | 66.67 |
| 34 | NORFLOXACIN 200 mg + LOPERAMIDE 2 mg | 39.2 | 85 | 2.17 | 116.84 |

difference in therapeutic efficacy among other available brands of a single drug formulation which is not considered while assessing cost variance.

Conclusion

Our study observed vast differences in the prices of the different preparations of oral fluoroquinolones- branded or generic. These wide variations pose severe economic implications for the patients. Hence, stakeholders should aim to decrease this

wide range of cost variations among different brands while maintaining therapeutic efficacy. Pharmaceutical companies should provide information regarding bioequivalence, quality, and cost of all their preparations to the doctors as a basic supporting document.

The government launched policies in place that should be strictly followed and should be revised periodically. Ideally, generic drugs should be prescribed to decrease health care costs and enhance compliance. Hence, it is

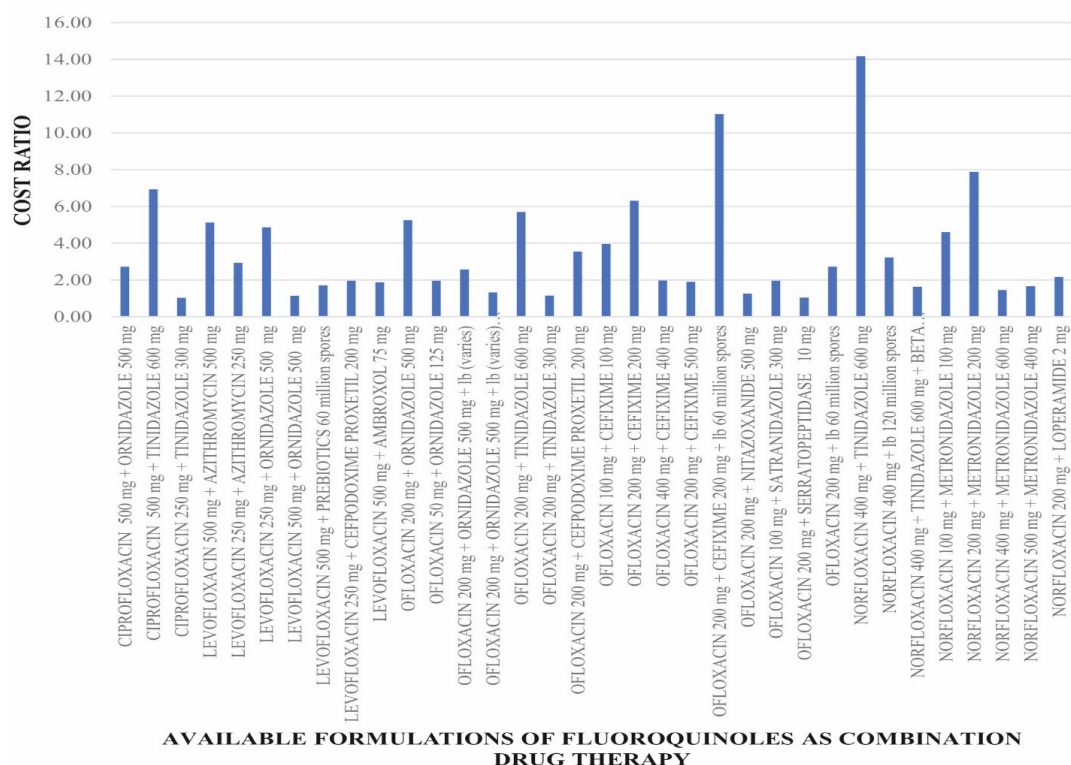


Figure 5. Cost Ratio of Fluoroquinolones (Combination Drug Therapy)

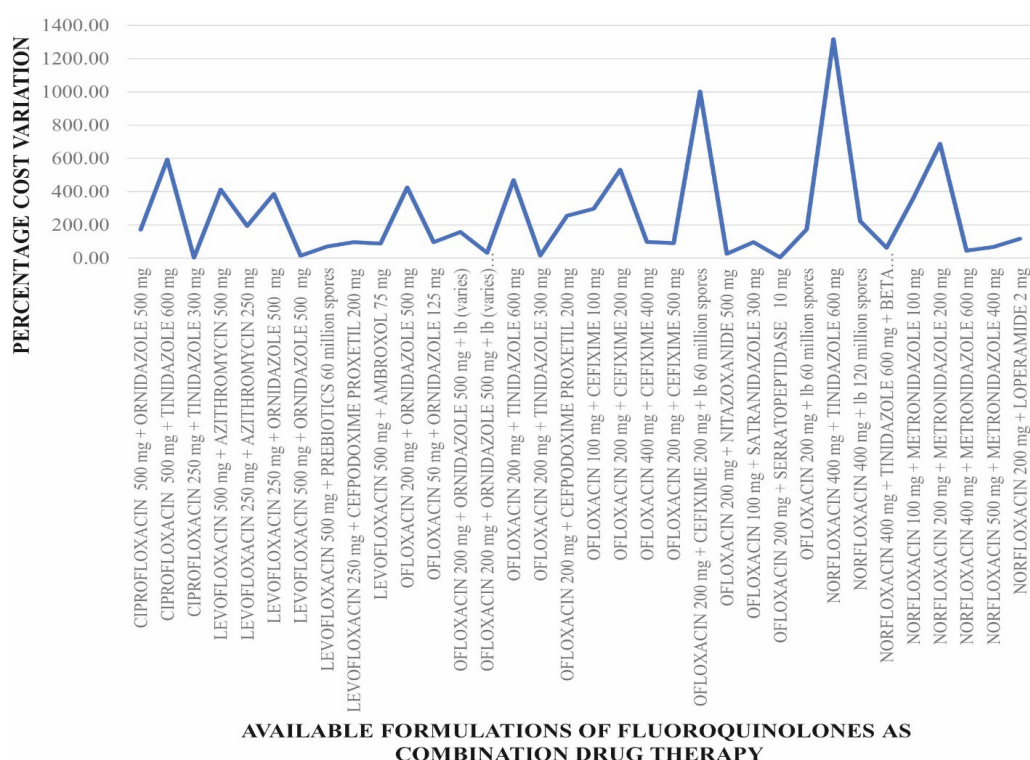


Figure 6. Percentage Cost Ratio of Fluoroquinolones (Combination Drug Therapy)

Table 3. Prices Comparison of Generic vs Branded Drugs

| DRUG DOSAGE | MINIMUM PRICE OF BRANDED DRUG | PRICE OF GENERIC EQUIVALENT |
|--|--|-----------------------------------|
| CIPROFLOXACIN 250 mg | 9.97 | 11 |
| CIPROFLOXACIN 500 mg | 16.87 | 18 |
| LEVOFLOXACIN 250 mg | 24.42 | 17 |
| LEVOFLOXACIN 500 mg | 7.5 | 30 |
| OFLOXACIN 200 mg | 10 | 13 |
| OFLOXACIN 400 mg | 20.62 | 35 |
| NORFLOXACIN 400 mg | 6 | 18 |
| CIPROFLOXACIN 500 mg + TINIDAZOLE 600 mg | 22.5 | 35 |
| CIPROFLOXACIN 250 mg + TINIDAZOLE 300 mg | 35.97 | 24 |
| OFLOXACIN 200 mg + ORNIDAZOLE 500 mg | 40 | 25 |
| OFLOXACIN 200 mg + CEFIXIME 200 mg | 76 | 40 |
| NORFLOXACIN 400 mg + TINIDAZOLE 600 mg | 7.41 | 37 |

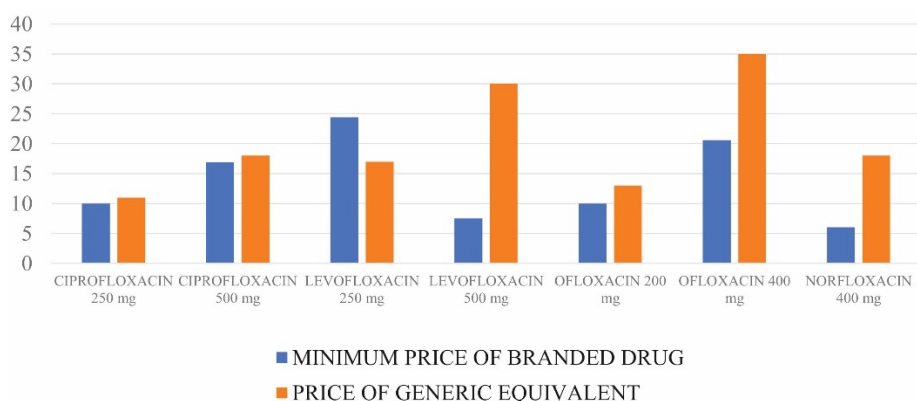


Figure 7. Generic vs Branded Drugs

suggested that the government of India should stringently review the policy for pricing medicine under JAS, and prescription audits could also be incorporated.

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Conflict of Interest

Nil

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