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A Cost Variation Analysis of Oral Contraceptive Pills Available in the Indian Market

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ABSTRACT

Background: Oral Contraceptive Pills (OCPs) are highly effective contraceptives if used regularly and adequately, and they also have added non-contraceptive benefits. This gives way to their increasing use in recent years, which has led to the introduction of numerous brands of drugs with different costs in the Indian market. Hence the current study was conducted to analyze the cost ratio and cost variation of different brands of OCPs available in the Indian market and to compare the cost of branded and generic drugs.

Materials and Methods: The cost of the drugs was obtained from the Current Index of Medical Specialties (CIMS) - 44th Year April – July 2022 and from the website https://www.mims.com/india/. The Cost Ratio (CR) and Percentage Cost Variation (CV) was calculated. The cost of generic drugs was obtained from the website http://janaushadhi.gov.in/SortingView.aspx.

Results: 124 brands of various OCPs were available in the Indian market. Among all the regular OCPs available, the CR and CV were highest for Ormeloxifene 30mg at 10.19 and 919.4%, respectively, and they were lowest for Dienogest +Ethinylestradiol which comes under combined OCPs with the results of 1.007 and 0.73% respectively. The cost of all generic OCPs was lesser when compared with brand OCPs, and the difference in cost was maximum for Ulipristal.

Conclusion: There is wide variation in the cost of Oral Contraceptive Pills available in the Indian market, and the cost of brand drugs is higher than their generic counterparts. Physicians have to be made aware of this price difference so that they can prescribe drugs that are more affordable to the patients to improve their adherence to the regimen.

Keywords: Covid-19 pandemic, pharmaceutical research and development, life sciences companies,

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Introduction

Contraception refers to various methods employed to inhibit reproduction following sexual intercourse. These methods can be classified as methods to permanently stop childbearing (Permanent methods) like Vasectomy and Tubectomy and as methods to delay childbearing by a few years (Temporary methods) like Oral Contraceptive Pills (OCPs), Intrauterine Devices (IUDs), Condoms, etc. Oral Contraceptives (OCPs) are an essential temporary method of contraception as they are very safe, effective, and convenient to use. [1] In India, according to the National Family Health Survey-5 (NFHS - 5), the use of OCPs has increased from 4.1% in 2015-16 to 5.1% in 2019-21 in married women between the age group of 15-49 years who are using various contraceptive methods thus signifying their popularity.[2]

Different oral contraceptive preparations exist: (1) Oestrogen and Progestin combinations, known as Combined OCPs, are the most common and efficacious method used. (2) Continuous Progestin-only therapy, known as Minipills, reduces the adverse effects of long-term estrogen use. (3) Emergency or Postcoital contraception is helpful in women who were not on any of the contraceptive methods and had unprotected sexual intercourse.[3] (4) Centchroman, also known as Ormeloxifene, is the only non-steroidal oral contraceptive now being used in clinical settings worldwide as a reversible postcoital/weekly oral contraceptive.[4]

OCPs are highly effective contraceptives if used correctly and regularly. The use of oral contraceptives has added non-contraceptive benefits. Reduction in the incidence of ovarian cysts, ovarian and endometrial cancer, benign breast diseases, and ectopic pregnancy is a few of their gynecological benefits. Advantages with OCPSs are also seen with fewer occurrences of iron deficiency and rheumatoid arthritis in the individuals who use them. They also manage premenstrual symptoms, dysmenorrhea, endometriosis, acne, and hirsutism.[5] Hence this gives way to their increasing use in recent years, which has led to the introduction of numerous brands of the same drugs in the market.

The Indian pharmaceutical market has developed into a veritable cornucopia of medications, with a wide range of pricing for the same medication sold under many brand names [6], and most physicians use brand names. At the same time, they prescribe drugs and are unaware of other brands and the wide variation in prices.[7] There will be an increased financial burden if brands with higher costs are prescribed, leading to non-adherence to the medications and therapeutic failure.[8] Analysing this variation in cost plays a huge part in planning and prioritizing health needs, indicating the need to review drug costs, assisting in the selection of less expensive options in the prescribing practice, and optimizing the cost of therapy, ultimately leading to rational drug use.[9-11]

Except for emergency contraceptives, regular OCPs must be taken for an extended period, daily, as long as the contraception is. This led to chronic usage of these pills, which will increase the financial burden, especially for low-income society leading to decrease adherence and compliance to the regimen. Hence, the current study was taken up with the aim to conduct a Cost Variation analysis of OCPs available in the Indian market to ensure better patient adherence and lower drug expenses, along with other healthcare costs, so that a more affordable brand can be recommended to a large variety of populationsm.

Objectives

1. To analyze the cost ratio and variation of different brands of OCPs available in the Indian market.

2. To compare the cost of different brands of OCPs with the cost of their generic counterparts.

Material and Methods

Data collection

A Descriptive, Cross-sectional study was done after getting clearance from the Institutional Ethics Committee of Kempegowda Institute of Medical Sciences to analyze the cost variation of OCPs available in the Indian market. The data about prices of different drugs and of the same drugs marketed under different brands were obtained from the resource book- Current Index of Medical Specialties (CIMS) - 44th Year April – July 2022 and from the website https://www.mims.com/india/.

The calculation was done for ten pills for normal OCPs and a single packet, as only one such packet should be taken at a time, for the Emergency contraceptive pills. The cost was expressed in Indian Rupees (INR).

The Cost Ratio (CR) and Percentage Cost Variation (PCV) for various formulations and different brands of the same formulations were calculated using the following formulae:

$$cost\ ratio = \frac{\text{Cost of the most expensive brand}}{\text{Cost of the least expensive brand}}$$

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

The cost of the least-priced branded drug was compared with the cost of the generic drugs

available under the Janaushadhi scheme, and the list of drugs available was obtained from the website to know the difference in cost between the brand and generic drugs: http://janaushadhi.gov.in/SortingView.aspx. The costs were calculated as calculated for cost variation analysis.

Data Analysis

The data collected was entered in Microsoft Excel 2021. Cost ratio and percentage cost variation were calculated according to the formulae mentioned above, and the results were presented in the form of tablets

Results

A total of 124 brands of various OCPs were available in the Indian market, of which 79 (63.70%) were combined OCPs, 16 (12.90%) were Progestin-only pills (minipills), 21 (16.93%) were Emergency contraceptive pills, and 8 (6.45%) were Ormeloxifene. (Table-1).

Table-2 shows the cost ratio and percentage cost variation of Combined OCPs available in the Indian market. The estrogen component of all combinations is Ethinylestradiol, with a change in the progesterone component. A total of 6 different combinations were available in two formulations – plain tablets and coated tablets. Cyproterone, Dienogest, and Norgestrel were available in a single strength. Desogestrel and Drosperidone were available in two different strengths, and Levonorgestrel was available in three. Out of all the available brands of combined OCPs (n = 79), most brands were of Drosperidone + Ethinylestradiol available in 22 different brands, followed by Desogestrel+ Ethinylestradiol and Levonorgestrel+ Ethinylestradiol, each available in 20 different brands while the least number of brands were of both Dienogest+ Ethinylestradiol and Norgestrel+ Ethinylestradiol which were each available in only two brands. (Table-2)

The CR and PCV were highest for Levonorgestrel (0.1mg) + Ethinylestradiol (0.02mg) plain tablet at 4.32 and 332.09%, respectively. The cost ratio and percentage cost variation were lowest for Dienogest+ Ethinylestradiol at 1.007 and 0.73%, respectively. (Table-2)

Table-3 shows the Cost ratio and percentage cost variation of Progestin-only pills (Minipills) available in the Indian market. Only two drugs, Desogestrel (0.075mg) and Dienogest (2mg) were used as Minipills and were available as plain tablets, coated tablets, and capsules. Desogestrel was available as a single brand under the plain and coated tablet formulations. At the same time, Dienogest was available in 13 different brands for the plain tablet formulation and a single brand for the capsules. Hence the CR and PCV were calculated for Dienogest plain tablets only, which were 3.36 and 236.67%, respectively.

Table-4 shows the Cost ratio and percentage cost variation of Emergency contraceptive pills available in the Indian market. Levonorgestrel of two strengths and Ulipristal of single strength were the only available drugs. Levonorgestrel was available as plain and coated tablets, but Ulipristal was available as only plain. Out of the total 21 brands of emergency contraceptive pills, Levonorgestrel 1.5mg plain tablets had the maximum number of brands (10), and its coated tablet had the minimum number of brands at 2. Ulipristal was available in 4 different brands.

The CR and PCV were highest for Levonorgestrel 1.5 mg plain tablet at 1.66 and 66.69%, respectively; the lowest was for the Levonorgestrel 1.5mg coated tablet as it had no variation in cost. Ulipristal has a cost ratio of 1.15 and a percentage cost variation of 15.39%. (Tablet-4).

Table-5 shows the Cost ratio and percentage cost variation of Ormeloxifene available in the Indian market. Ormeloxifene was available only in plain tablets. It was available in 8 brands, with five brands of 30mg and three brands of 60mg. The cost ratio and percentage cost variation were highest for Ormeloxifene 30mg at 10.19 and 919.4%, respectively, and lowest for Ormeloxifene 60mg at 1.5 and 50.97, respectively.

Table-6 shows the Comparison between the cost of least-priced branded drugs and their generic counterparts. Of all the brand OCPs in the Indian market, only five drugs have their generic counterparts, of which 3 were Combined OCPs, and 2 were emergency contraceptive pills. The cost of all generic OCPs was lesser when compared with brand OCPs. The difference in cost was maximum for Ulipristal, with a difference of 824 INR, and minimum for both Desogestrel (0.15mg) + Ethinylestradiol (0.03mg) and Levonorgestrel (0.15mg) + Ethinylestradiol (0.03mg) with a difference of 11.91 INR.

Discussion

Pharmacoeconomics is "the description and analysis of the cost of drug therapy to the health care system and society." It identifies and compares the costs and outcomes of

pharmaceutical products and services. A cost analysis is one of the types of pharmacoeconomic evaluation in which the costs of different medications are compared without considering the outcome. [12] The information derived from cost analysis studies will benefit doctors in selecting the best medicine for their patients and policymakers in effectively utilizing the limited resources available.

To the best of our knowledge, this study was the first to analyze the cost variation of OCPs available in the Indian market. In our study, we found a wide variation in the cost of OCPs available in the Indian market, which simulated the findings seen with the cost variation of other groups of drugs like anticancer drugs,11 antihypertensives,[13] antiepileptics,[14] and antidiabetic drugs[15]. Overall, among all the OCPs available, the cost ratio and cost variation were highest for Ormeloxifene 30mg at 10.19 and 919.4%, respectively, and they were lowest for Levonorgestrel 1.5mg coated tablet as it was available in only two brands with the same price and hence no variation in cost. Dienogest+ Ethinylestradiol had the second lowest cost ratio and cost variation at 1.007% and 0.73%, respectively.

There are several reasons for this price variation, including the majority of them being protected by patents and the market for new chemical entities being monopolistic. In this market structure, sellers significantly influence a product's price. [16] In India, the Drug Price Control Order (DPCO) 2013 was introduced to limit this cost variation. [17] The National Pharmaceutical Pricing Authority (NPPA) of India sets the drug price ceiling by DPCO 2013. A medicine covered by DPCO cannot be dispensed at a price higher than the government's. Despite these efforts to prevent unjustifiable drug pricing, there is a wide variation in drug costs within one parent drug due to the availability of different brands. Introducing cost control is not the end goal of the effort to reduce the cost burden of treatment, but regular monitoring is required. The DPCO drug list should be dynamic and updated regularly to reflect the availability of newer, more efficacious, and safer drugs. [18]

When comparing the cost between the brand and generic drugs, we found that even the least-costly branded drugs cost more than their generic counterparts, with the highest difference seen for Ulipristal at 824 INR. This difference is generally seen in the cost of generic and branded drugs. [19-20] Generic medicines are less expensive than branded medicines because there is no need to invest in research and development as there is with new drugs. Because of the intense competition, manufacturers must maintain low prices. [21]

Generic medicines are essential in providing cost-effective health care, and their use is growing globally. Prescription audits have revealed that generic medicines account for more than 80% of medicines prescribed in countries such as the United States, the United Kingdom, China, and Australia. Even though India is one of the world's largest exporters of generic medicines, less than 50% of medicines are prescribed by their generic names in India.[22] This is probably because of a need for more trust in doctors about generic drugs. The lack of strict regulatory criteria for the quantity of the drug in its generic version and the permitted contaminants in it has been one of the critical causes of this lack of confidence in generic drugs among doctors (and even patients). However, since 2016, definite recommendations have been made, stating that the 90% confidence range of the generic-to-brand medication ratio should lie between 80% and 125% of 1.00 for key pharmacokinetic parameters, such as maximum concentration and area under the curve [23] and scientific research has shown that the expensive brand of the identical generic drug is not in any way better to its economically more affordable alternative.8

So, the government has to implement strict rules to regulate the prices of branded medications and also promote the utilization of generic drugs by educating doctors and the public about their usefulness and, at the same time, ensuring the quality and supply of these generic drugs.

This study had its limitations as the sources of drug information (CIMS and mims.com website) selected were limited, and a few more private online platforms were not accessed, so some brands may have yet to be noticed. However, this was done as the credibility of those online platforms needs to be better established. This was the first study to analyse the CR and PCV of OCPs available in the Indian market, which can be a basis for future research where the effect of these OCPs can also be assessed, which adds to this study's strength.

Conclusions

There is wide variation in the cost of Oral Contraceptive Pills available in the Indian market, and the cost of brand drugs is higher than their generic counterparts. Physicians have to be made aware of this price difference so that they can prescribe drugs that are more affordable to the patients. This can improve compliance and adherence to the OCP regimen to prevent unwanted pregnancies and medication failure.

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Conflict of Interest
No conflict of interest was reported.

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No funding was obtained

Ethical Considerations
All ethical considerations were taken into account.

Tables

Table 1. Number of OCP brands available in the Indian market

Type of OCP	Number of brands available (n = 124)
Combined OCP	79 (63.70%)
Progestin-only pills (Minipills)	16 (12.90%)
Emergency contraceptive pills	21 (16.93%)
Ormeloxifene	8 (6.45%)

Table 2. Cost ratio and percentage cost variation of Combined OCP

Drug	Strength	Formulation	Number of brands (n)	Minimum price (INR)	Maximum price (INR)	Cost ratio	% cost Variation
Cyproterone + Ethinylestradiol	2mg + 0.035mg	Tablet	11	75	179.52	2.39	139.36
		Coated tablet	2	179.93	187.14	1.04	4.00
Desogestrel + Ethinylestradiol	0.15mg + 0.03mg	Tablet	10	54.76	138	2.52	152.01
	0.15mg + 0.02mg	Tablet	10	52.85	119.04	2.25	125.24
Dienogest + Ethinylestradiol	2mg + 0.03mg	Tablet	2	491.4	495	1.007	0.73
Drospirenone + Ethinylestradiol	3mg + 0.03mg	Tablet	12	105.3	312.14	2.96	196.42
		Coated tablet	3	220.3	252.85	1.14	14.77
	3mg + 0.02mg	Tablet	5	117.91	166.66	1.41	41.34
		Coated tablet	2	143.98	145.41	1.01	0.99
Levonorgestrel + Ethinylestradiol	0.15mg + 0.03mg	Tablet	9	28.57	33.92	1.18	18.71
		Coated tablet	1				
	0.1mg + 0.02mg	Tablet	3	28.57	123.45	4.32	332.09
		Coated tablet	1				
	0.25mg + 0.05mg	Tablet	6	27.85	96.80	3.47	247.5
Norgestrel + Ethinylestradiol	0.5mg + 0.05mg	Tablet	2	91.56	213.92	2.33	133.63

Table 3. Cost ratio and percentage cost variation of Progestin-only pills (Minipills)

Drug	Strength	Formulation	Number of brands (n)	Minimum price (INR)	Maximum price (INR)	Cost ratio	% Variation
Desogestrel	0.075mg	Tablet	1				
		Coated tablet	1				
Dienogest	2mg	Tablet	13	399.2	1344.64	3.36	236.67
		Capsule	1				

Table 4: Cost ratio and percentage cost variation of Emergency contraceptive pills

Drug	Strength	Formulation	Number of brands (n)	Minimum price (INR)	Maximum price (INR)	Cost ratio	% Variation
Levonorgestrel	1.5mg	Tablet	10	60	100	1.66	66.69
		Coated tablet	2	110	110	1	0
	0.75mg	Tablet	5	34	48	1.41	41.17
Ulipristal	5mg	Tablet	4	1299	1499	1.15	15.39

Table 5: Cost ratio and percentage cost variation of Ormeloxifene

Drug	Strength	Formulation	Number of brands (n)	Minimum price (INR)	Maximum price (INR)	Cost ratio	% Variation
Ormeloxifene	30mg	Tablet	5	15	152.91	10.19	919.4
	60mg	Tablet	3	140	211.36	1.5	50.97

Table 6: Comparison between the cost of branded drugs v/s generic drugs

Drug	Strength	Formulation	Brand drug cost* (INR)	Generic drug cost (INR)	Difference between the brand drug and generic costs (INR)
Cyproterone + Ethinylestradiol	2mg + 0.035mg	Tablet	75	42.85	32.15
Desogestrel + Ethinylestradiol	0.15mg + 0.03mg	Tablet	54.76	42.85	11.91
Levonorgestrel + Ethinylestradiol	0.15mg + 0.03mg	Tablet	28.57	16.66	11.91
	0.25mg + 0.05mg	Tablet	27.85	14.28	13.57
Levonorgestrel	1.5mg	Tablet	60	20	40
Ulipristal	5mg	Tablet	1299	475	824

*Brand drug cost: Cost of the least-costly brand of the drug

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