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COST VARIATION ANALYSIS OF SINGLE NONSTEROIDAL ANTI-INFLAMMATORY AGENTS AVAILABLE IN INDIAN MARKET: AN ECONOMIC PERSPECTIVE

Brijalkumar S. Patel*, Falguni M Chavda and Shailesh G. Mundhava

Department of Pharmacology, P.D.U. Government Medical College, Jamnagar Road, Rajkot, 360001 Gujarat, India

Key words:

DPCO (Drug Price Control Order), Manufacturing companies, Percentage Price variation, NSAIDS

Correspondence to Author:
Brijalkumar S. Patel

Department of Pharmacology, P.D.U. Government Medical College, Jamnagar Road, Rajkot, 360001 Gujarat, India.

E-mail: dr.brijalpatel@gmail.com

ABSTRACT: Introduction: Nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used drugs to manage a variety of acute and chronic conditions associated with pain and/or inflammation. In the Indian market, various NSAIDs group of drugs are available in different formulations. This creates a lot of problem with physician to decide the drug of choice for individual patients. **Objective**: To evaluate price variation of different single NSAIDs formulations available in Indian market. Materials and Methods: Cost of a particular drug in the same strength and dosage forms being manufactured by different companies was obtained from "Current Index of Medical Specialties" (CIMS) Jan-Apr, 2015 and "Indian Drug Review" (IDR) Issue 1,2015. Difference between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies was calculated and percentage cost variation was calculated. Spearman correlation analysis and regression coefficient was done to observe the correlation between no. of manufacturing companies and their percentage price variation with the help of IBM Statistical Package for Social Sciences (SPSS v.21). **Results**: For Oral preparations, Diclofenc(50mg tab) showed maximum price variation of 1231.37% followed by Diclofenac 100mg sustained release preparations(782.00%). Diclofenac injection 75mg[3ml] & 25mg/ml[3ml] showed maximum variation of 483.94% & 416.67% respectively. Percentage variation in cost was found to be 325.11% with Diclofenac 1%gel while minimum price variation was found with Nimesulide 1% gel (22.92%). **Conclusion:** Our findings revealed that the prices of various NSAIDs formulations show great variation. Modifications in pharmaceutical policy are required, and prices of the drug should be controlled in effective way for all the drugs.

INTRODUCTION: Cost of drug therapy is the major hurdle in effective treatment of disease and compliance towards the drug regimen. There are evidences describing that the prices of prescription medicines affect users, suppliers, and in particular payers in the healthcare system. Several reports describe that users tend to reduce medications when the prices are higher, resulting in decreased health levels. Furthermore high cost of medicines could lead to non-compliance in patients with regard to medication.[1]

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It is found that uninsured individuals purchase medicines with lower unit costs than insured individuals.[2] Currently the selection of medicines for hospital formularies or for patient therapy is based not only their effectiveness, safety but also on their prices.

Rational use of medicines is that the patient receives medication appropriate to the clinical need, at the proper dose, for the proper duration and at the lowest cost.[3] So for rational prescribing, prescriber should also consider cost while writing prescription along with other criteria of rational use of the drug so that the patient can afford the drug.

In Indian market, there is tough competition between the domestic and foreign manufacturers. There is inundation of brands in Indian markets for

a single drug which is manufactured by various companies and consequently, leads to wide variation in prices for the same drug. There are more than 100,000 formulations available for all the category of drugs under the umbrella of various brand names, there is no system of registration of these formulations [4].

Nonsteroidal anti-inflammatory drugs (NSAIDs) inhibit cyclo-oxygenase enzymes and are used to manage a variety of acute and chronic conditions associated with pain and/or inflammation. They are widely used drugs for the relief of the symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), sprains and strains, sports injuries and menstrual disorders, and have a small role in the management of patent ductus arteriosus in the neonate.[5] All NSAIDs inhibit both COX 1 and 2 enzymes but most of the NSAIDs that have been developed in recent years show greater activity as inhibitors of COX 2.[6] Some NSAIDs require frequent dosing and others can be administered once a day, which may influence patient compliance, affect convenience, and/or influence cost.

Improper knowledge about the cost of various brands of different NSAIDS can lead to difficulties in prescribing most cost effective treatment regime for the patient. Also in the literature no such study was done that compares the cost of different brands of NSAIDS. So, we decided to carry out price variation study of different NSAIDS formulations.

MATERIALS AND METHODS:

Data Analysis:

Cost of a particular drug in the same strength and dosage forms being manufactured by different companies was obtained from "Current Index of Medical Specialties" (CIMS) Jan-Apr, 2015 and "Indian Drug Review" (IDR) Issue 1, 2015**.** The drug prices available in CIMS & IDR were compared, as they are readily available source of drug information and are updated regularly. The drugs being manufactured by only one company or the drugs, price of which were not given in the CIMS and the IDR were excluded. Difference between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies was calculated and Percentage cost variation was calculated as follows: Cost Variation (%) = Max cost-Min cost/Min cost*100 [7]

Statistical Analysis:

Spearman correlation analysis and regression coefficient was done to observe the correlation between no. of manufacturing companies and their percentage price variation with the help of IBM Statistical Package for Social Sciences (SPSS v.21).

RESULTS:

We have evaluated cost of total 18 NSAIDS which are available in 90 different formulations and manufactured by different pharmaceutical companies.

Oral Single Formulations of NSAIDS:

Table 1(a). shows price variation of oral single formulations of NSAIDS in which Diclofenc(50mg tab) shows maximum price variation of 1231.37% followed by Diclofenac 100mg sustained release preparations(782.00%). Aceclofenac 100mg tab shows price variation of 216.80% while Aceclofenac 100mg mouth dissolving tablets shows no variation in price but it is manufactured by small number of companies.

TABLE 1(a). NSAIDS: ORAL SINGLE FORMULATIONS

Drug(No. of formulations)	Dose & Dosage formulations(Quantity)	Number of manufacturing companies	Minimum Cost(INR)	Maximum Cost(INR)	% Variation in Cost
Aceclofenac[7]	100mg tab [10]	59[9*]	12.5	39.6	216.80
	200mg tab [10]	29[3*]	25	53	112.00
	100mg FC tab [10]	12	16	31.5	96.88
	200mg SR tab [10]	30[3*]	20.5	48	134.15
	100mg MD tab [10]	2	30	30	0.00
	200mg CR tab [10]	2	24	45	87.50
Aspirin[3]	75mg tab[10]	2	1.94	3.91	101.55
	75mg tab[14]	4	3.86	7.81	102.33

	150mg [10]	2	2.85	4.21	47.72
Celecoxib[1]	100mg cap [10]	12	20	55.3	176.50
	200mg cap [10]	12	39	96.8	148.21
Diclofenac[10]	50mg tab[10]	37[1*]	5.1	67.9	1231.37
	50mg DIS tab[10]	4	15	41.6	177.33
	50mg EC tab[10]	5	5.1	24	370.59
	75mg SR tab[10]	2	23	54	134.78
	100mg SR tab[10]	24	10	88.2	782.00
	100mg FC SR tab[10]	3	17	26.5	55.88
Etoricoxib[2]	60mg tab [10]	16[2*]	33.6	76.9	128.87
	60mg FC tab [10]	9	37.5	67.5	80.00
	90mg tab [10]	33[5*]	49.5	99	100.00
	90mg FC tab [10]	9	55.42	94.3	70.16
	120mg tab [10]	15[2*]	72.5	129	77.93
	120mg FC tab [10]	9	69.8	130	86.25
Etodolac[4]	300mg tab [10]	2	48	125	160.42
	400mg tab[10]	6	49	135	175.51
	400mg FC tab [10]	3	49	99	102.04
Ibuprofen[6]	200mg tab [10]	5	2.8	3.73	33.21
	200mg FC tab [10]	2	3.27	5.98	82.87
	400mg tab [10]	8	5.19	9.13	75.92
	400mg FC tab [10]	2	6.34	10.2	60.88
	600mg FC tab [10]	2	7.41	14.4	94.33
Indomethacin[3]	25 mg Cap [10]	2	10.81	17.5	61.89
Ketorolac[3]	10mg tab [10]	8[6*]	14.9	35.4	137.58
Lornoxicam[4]	4 mg tab [10]	15 [1*]	20.9	46	120.10
	4 mg FC tab [10]	4	19	39.9	110.00
	8 mg tab [10]	21 [1*]	41.25	89	115.76
	8 mg FC tab [10]	4	40	69.5	73.75

***** Prices were not written

TABLE 1(b). NSAIDS: ORAL SINGLE FORMULATIONS

Drug(No. of formulations)	Dose & Dosage formulations(Quantity)	Number of manufacturing companies	Minimum Cost(INR)	Maximum Cost(INR)	% Variation in Cost
Mafenamic Acid[3]	100mg DIS tab [10]	2	16	19	18.75
	100mg/5ml Susp [60 ml]	3	25.25	35.1	39.01
	250mg tab [10]	5	14	21	50.00
	500mg tab [10]	6	18.3	30.08	64.37
Meloxicam[1]	7.5mg tab [10]	10	9.5	36	278.95
	15mg tab [10]	10	15.5	55	254.84
Neproxen[2]	250 mg tab [10]	2	34	39	14.71
Nimesulide[7]	100mg tab [10]	67[6*]	8.6	57	562.79
	100mg tab [15]	2	36	57	58.33
	200mg tab [10]	4	24	42.5	77.08
	100mg DIS tab [10]	10[1*]	12.5	41.14	229.12
	200mg DIS tab [10]	2	37.5	43	14.67
	100mg MD tab [10]	5[1*]	14.5	24	65.52
Paracetamol[11]	100mg/ml O:dps [15ml]	10	18	34	88.89
	100mg O:dps [15ml]	5	16	24.5	53.13
	120mg/5ml Susp [60ml]	5	15	34.32	128.80
	125mg/5ml Susp [60ml]	15	19.9	35	75.88
	125mg Syr [60ml]	4	19	28	47.37
	125mg/5ml Syr [60ml]	7[1*]	14	28	100.00
	125mg/ml Syr [60ml]	3	14	24	71.43
	125mg DIS P tab[10]	6	4	30	650.00
	150mg O:dps [15ml]	3	15.8	23.1	46.20
	240mg/5ml Susp [60ml]	2	29	37.26	28.48
	250mg DIS tab[10]	2	8.92	36	303.59
	250mg Syr [60ml]	4[2*]	30.5	35	14.75

	250mg/5ml Syr [60ml]	5	28	34	21.43
	250mg/5ml Susp [60ml]	28[2*]	20	45	125.00
	300 mg tab [10]	2	10	10	0.00
	500 mg tab [10]	30[1*]	4.88	20	309.84
	500 mg tab [15]	4	14.66	22.53	53.68
	500 mg DIS tab [10]	2	9.72	16.15	66.15
	650 mg tab [10]	39[2*]	8.62	39	352.44
	650 mg DIS tab [10]	4	17	19	11.76
	1000mg tab[10]	3[1*]	12	20	66.67
Piroxicam[6]	10mg cap [10]	2	9.6	14	45.83
	20mg MD tab [10]	3	32	50	56.25
	20mg cap [10]	4	14.9	47.2	216.78
	20mg DIS tab [10]	10[1*]	27	66	144.44
	20mg tab [10]	11[1*]	20	86.9	334.50
Tenoxicam[1]	20mg tab [10]	2	51.8	54.08	4.40

***** Prices were not written

Table 1(b). shows Maximum percentage of price variation was seen with Paracetamol 125mg dispersible pediatric tab(650%) and Nimesulide 100mg tab(562.79%). Formulations of Paracetamol shows a huge fluctuation in minimum and maximum price.

Parenteral Single Formulations of NSAIDS:
Table 2. shows variation in the cost of parenteral single formulations of NSAIDS. It comprises of seven drugs, out of which Diclofenac injection 75mg [3ml], 25mg/ml[3ml] and 25mg/ml[30ml] shows maximum variation of 483.94%, 416.67%, & 316.67% respectively. Parecoxib 40mg injection. shows a minimum variation of 1.88% only.

TABLE 2: PARENTERAL SINGLE FORMULATIONS OF NSAIDS

Drug [No. of formulations]	Dose & Strength[Quantity]	Number of manufacturing companies	Minimum Cost(INR)	Maximum Cost(INR)	% Variation in Cost
Aceclofenac[1]	150mg/ml [1ml]	5	14.9	29.9	100.67
Ketorolac[1]	30mg/ml [1ml]	6	8.52	18.7	119.48
Lornoxicam[1]	8 mg [2ml]	4	37	60.1	62.43
Parecoxib[1]	40mg inj [1]	3	63.9	65.1	1.88
	40mg inj [2ml]	2	59.61	65	9.04
Piroxicam[1]	20mg inj [2ml]	3[1*]	11.8	16	35.59
	20mg/ml inj [2ml]	4	18	25.5	41.67
	40mg inj [2ml]	8	14.5	22.1	52.41
Diclofenac[1]	25mg inj[1ml]	2	7.1	12	69.01
	25mg inj[3ml]	10[2*]	3.08	9.5	208.44
	25mg/ml [1ml]	3[1*]	3.11	9	189.39
	25mg/ml [3ml]	20	3	15.5	416.67
	25mg/ml [30ml]	4	12	50	316.67
	75mg inj[1ml]	2	20	21	5.00
	75mg inj[3ml]	10[2*]	2.74	16	483.94
	75mg/ml [1ml]	19[2*]	12.8	21.67	69.30
	75mg/3ml [3ml]	10	4.59	16.9	268.19
Paracetamol[2]	10mg/ml inf [100ml]	3	190	280	47.37
	1000mg/ml inf [100ml]	2	185	275	48.65
	150mg/ml inj [2ml]	7	5	18	260.00
	150mg/ml inj [15ml]	2	22	27	22.73
	1g/100ml inj[100ml]	2	250	280	12.00

*Prices were not written

Topical Single Formulations of NSAIDS:
Table 3. shows price variation between various topical formulations of NSAIDS. Diclofenac 1%gel & 1.16% gel shows maximum price variation of 325.11% & 173.68 respectively while Nimesulide 1% gel shows minimum variation of 22.92%.

TABLE 3: NSAIDS: TOPICAL FORMULATIONS

Drug (No. of formulations)	Strength(Quantity)	Number of manufacturing companies	Minimum Cost(INR)	Maximun Cost(INR)	% Variation in Cost
Nimesulide[1]	Nimesulide 1%w/w T gel [20g]	3	24	29.5	22.92
	Nimesulide 1%w/w T gel [30g]	3[1]	16.41	31	88.91
Ketoprofen[1]	2.5 % gel [30g]	2	40.6	78	92.12
Diclofenac[5]	1.16% gel [30g]	8[1]	23.75	65	**173.68**
	1% gel [30g]	13[2]	21.9	93.1	**325.11**

Comparison of drug price which are under control of DPCO: Table 4. shows comparison of ceiling price of drugs which are given by NPPA in accordance with DPCO. Diclofenac tablet(50mg) & injection(25mg/ml), Paracetamol 500mg tab and Acetyl salicylic acid 100mg tab shows maximum price difference in ceiling price(almost thrice) in comparison with DPCO.

TABLE 4: COMPARISON OF DRUG PRICE WHICH ARE UNDER CONTROL OF DPCO

No.	Name of formulations/Medicines[Quantity]	Ceiling price in Rs.[Pack size],2014 [8]	Ceiling price in Rs.[Pack size],NPPA Price revision 2015 [9]	Ceiling price of same formulations available in market
1	Diclofenac Tablets[50 mg]	20.7[10 tab]	21.5[10 tab]]	67.9
2	Diclofenac Injection[25 mg / ml]	1.58[1ml]	1.64[1ml]	9
3	Paracetamol Injection[150mg/ml]	7.3[2ml]	7.58[2ml]	18
4	Paracetamol Syrup[125mg/5ml]	20.4[60ml]	21[60ml]	28
5	Paracetamol Tablets[500mg]	10[10 tab]	10.4[10 tab]	20
6	Paracetamol Suppository[80mg]	37[5 supp]	38.4[5 supp]	80
7	Paracetamol Suppository[170mg]	42.9[5 supp]	44.55[5 supp]	36
8	Acetyl Salicylic Acid[75mg]	3.64[14 tab]	4.06[14 tab]	7.81
9	Acetyl Salicylic Acid[100mg]	1.4[10 tab]	1.5[10 tab]	6.16
10	Acetyl Salicylic Acid[325mg]	6.16[14 tab]	6.44[14 tab]	9.4

DISCUSSION: This study was carried out with the objectives of computing the costs and percentage price variation among Nonsteroidal anti-inflammatory drugs across the different brands available in the Indian market.

Our findings reveal that the prices of most of the NSAIDS have percentage price variation above 100%, which is not acceptable situation for patients. Out of 17 drugs studied, most of which are commonly prescribed, percentage price variation is very wide leading to unfair burden on the consumer. Among different dosage formulation of NSAIDS, 46 dosage formulations have price variation of 100% or more than 100%, only 2 dosage formulations of drugs have price variation <1%. Highest price variation was seen with Diclofenac, Nimesulide, Paracetamol and Aceclofenac which are also very commonly prescribed NSAIDS.

Drugs are available with different brand names and prices of all the brands are different. Drug prices are controlled according to drug price control order 2013 (DPCO).[10] Ceiling price of drugs are fixed by national pharmaceutical pricing authority (NPPA), government of India in accordance with DPCO 2013. The price of drugs is revised every year according to the wholesale price index. The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.[10]

According to DPCO, 2013 all drugs in the national list of essential medicine 2011 should be under price control. Among NSAIDS formulations, only Diclofenac (50mg tab, 25mg/ml inj.), Ibuprofen(200mg,400mgtab, 100mg/5ml syp), Paracetamol(150mg/ml inj,125mg/5ml syp, 500mg tab, 80mg,170mg supp.) and Acetyl salicylic acid (325mg, 350mg tab) are included in National list of essential medicine, 2011 as well as in WHO Essential medicine list for adults, 2015(except Diclofenac formulations) and they are included in DPCO 2013 as well. All NSAIDS formulations are

not in drug price control. Drugs in the national list of essential medicine and included in DPCO 2013 like Diclofenac, Paracetamol, Ibuprofen and Acetyl salicylic acid also showed high price variation in our study. Some measures must be taken by the government to bring about the uniformity in the price.

Currently, very few medicines are under drug prices control order. Hence, it is desired that the Government should bring all lifesaving and essential medicines under price control. Combinations of NSAIDS are not included in essential drug list (EDL) which should be taken into consideration while revising the list. Due consideration must be placed on the pricing of drugs in the EDL to increase their accessibility to common people. DPCO appears to be an effective tool to keep in rein the drug prices which should be implemented for all drugs included in EDL.

Spearman rank correlation (r_s=0.53) revealed interesting result. We observed that a significant positive correlation exists between the number of manufacturing companies and the percentage price variation. Regression coefficient was also done to evaluate the fact that as the number of manufacturing company's increases the percentage price variation also increases. Our results showed that there is an urgent need of controlling price variation among different brands of available NSAIDs agents.

Indian market is predominantly a branded generic market i.e., more than one company sells a particular drug under different brand names apart from the innovator company. Hence, the number of pharmaceutical products available in the market also is very high in the range of 60,000-70,000 products. This situation has led to greater price variation among drugs marketed. Skewness of information, raw material costs, government regulation and pricing policies also could be the possible reason for above results as evident from the literature. [4, 11]

The phrase OTC has no legal recognition in India but all the drugs not included in the list of 'prescription only drugs' are considered to be OTC drugs.[12] Indian pharmaceutical market faces the problem of 'Deemed OTC market' where in ethical drugs are also sold without a prescription due to poor monitoring and control.[13] Prices of non-scheduled drugs are fixed by the manufacturer subject to a maximum increase of 10% on the prevailing price over a 12-month period.[10] we have found that non scheduled drugs such as paracetamol showed a huge price variation in context to recent revision of NPPA, 2015 which is also available as OTC drug so it creates a confusion and financial burden on payers due to availability of wide number of brands.

There is a need for concerted action from regulatory authorities, doctors, pharmacists and general public at large to address this issue of NSAIDS price variation. Many doctors are not very conscious about price variation. So the treating physician must keep this factor in mind while prescribing appropriate brand drugs considering the financial background of the patient. It is felt that physicians could provide better services and reduce costs of drugs if information about drug prices was readily available.[14] Studies have shown that providing a manual of comparative drug prices annotated with prescribing advice to physicians reduced their patients' drug expense.[15] Hence, wherever possible a cheaper brand should be prescribed because the superiority of any particular brand over the others has never been proved scientifically. [14] Patient compliance is poor for the expensive brands; they buy only a few tablets because of the high cost of medicine.

The pharmacist also has role in this system. Some pharmacist also don't give the same brand of drug that is prescribed, they change it and give some costly drug. Pharmacist has some gain in selling that brand of drug.[16] Pharmacoeconomics could also be introduced as a practical lesson to undergraduate medical curriculum, wherein students could be taught to use CIMS or MIMS for selecting the cheapest available formulation of a particular drug. In this context, students would also come to realize the enormous difference in cost of the newer agents compared to the older drugs.[17]

CONCLUSION: Our study results make the prescriber informed about various brands of NSAIDS and their price variations. So the

prescriber can chose the cost effective agents for a patient to achieve rational prescribing. This will help in reducing the economic and health burden on both patient as well as the healthcare system. Generic drug prescribing can decrease the expenditure of patient on the drug. Modifications in pharmaceutical policy are required, and prices of the drug should be controlled in effective way for all the drugs.

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