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### Drug pricing of various formulations used for the management of acid peptic disorders

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#### ABSTRACT

##### Introduction

Affordability determines accessibility to drugs in developing countries. Variation in the cost of drugs is noted to be high in India, which can affect drug compliance. Acid Peptic disorders are prevalent in India and require long term therapy. Hence the present study was undertaken to analyse the cost variation of various brands of anti-ulcer drugs currently available in India.

##### Materials & methods

The drugs listed under the section “Antacids and Anti-ulcer agents” in Current Index of Medical Specialties (CIMS) October 2016-January 2017 edition was noted to analyze the variation in drug prices of various brands of drugs available in India. Further analysis was done by using Percentage Cost Variation.

##### Results

Wide variation in the prices of Antacids and anti-ulcer agents was noted. Among the H<sub>2</sub> (Histamine 2) receptor blockers, the maximum percentage of cost variation was noted with Ranitidine (50 mg injection) 871.54%, and among proton pump inhibitors (PPIs), it was noted with Pantoprazole (40 mg EC-Tab) 500.75%. Among the PPIs, lowest percentage of cost variation was noted with Omeprazole 40 mg injection; among the H<sub>2</sub> blockers, it was Ranitidine 300mg FC-TAB.

Among the Fixed Dose combinations (FDCs), maximum and minimum % of cost variation was noted with Ranitidine 150mg+Domperidone 10mg TAB (242%) and Pantoprazole 40mg+Domperidone 30mg SR-CAP (1%) respectively.

##### Conclusion

More than 100% cost variation was seen with different brands of all PPIs and H<sub>2</sub> receptor blockers.

**Keywords:** Anti-ulcer drugs, Cost analysis, Cost ratio, Cost variation

## INTRODUCTION

Acid peptic disorders (APD) which include Gastro-esophageal reflux disorder (GERD) and peptic ulcer disease (PUD) are common conditions reported in daily clinical practice. The prevalence of PUD is noted to be 7.8% in India [1]. Indian Society of Gastroenterology Task Force reported that 7.6% of Indian subjects have significant GERD symptoms. About 2%-14% of the ulcers are known to have high risk of perforation and the mortality may range between 10-40% [2]. Hence, these disorders can influence the quality of life and productivity of individuals.

APD, if treated promptly produces favourable outcomes. Antacids and anti-ulcer agents are commonly used in clinical practice. But, the chronicity of the condition adds significantly to the healthcare cost. The main source of health funding comes from out of the pocket expenditure in India. The healthcare cost spent on medicines ranges from 60-90% by the poor people in India [3] [4].

Pharmaceutical market in India has over 100000 medicine formulations and majority of them are sold under brand names. A variation of 25-3400 percent was reported in the price of the same drug, but sold under different brand names. The prices of not all drugs are under price control which could account for such cost variation. Hence, drug price may hinder the accessibility to drugs among the poor in India. The same was noted by Kaiser family foundation survey in 2015, that nearly 25% of those taking prescription medications have reported that they have not filled a prescription in past 12 months due to cost concerns [5].

The present study was therefore undertaken to evaluate the heterogeneity in the prices of the same drug sold under various brand names. The result of the study is expected to provide information to the clinicians about cost effective prescribing and also to develop policy interventions to control drug pricing.

## MATERIALS & METHODS

The costs of various drugs were obtained from Current Index of Medical Specialties (CIMS) October 2016 to January 2017. Price in Indian rupees (INR) of drugs listed under the category "Gastro-intestinal drugs", subtopic "Antacids and Anti-ulcerants" manufactured by different pharmaceutical companies in India were considered for analysis. Formulations containing same strength of the drug were included. Fixed dose combinations and paediatric formulations were also included. The cost of 10 tablets/capsules was calculated. The formulation manufactured by a single company was excluded.

### Cost variation was calculated as follows

Cost Ratio = Maximum cost/Minimum cost

% Cost variation = (Maximum cost-Minimum cost/minimum cost) X 100

Cost Difference = Maximum cost-Minimum cost

## RESULTS

The retail cost of 9 drugs inclusive of antacids, antiulcerants, antireflux agents (single drug) belonging to four different categories available in 36 different formulations and 43 combinations from Gastro Intestinal Tract of CIMS October 2016-January 2017 were analyzed.

**Table 1: Cost variation among proton pump inhibitors**

Drug	Dose	Dosage	Minimum cost	Maximum cost	Cost ratio	% cost variation	Cost difference
Esomeprazole	20 mg	EC Tab	33.00	35.93	1.09	8.89%	2.93
		Tablet	17.00	35.00	2.06	105.88%	18.00
	40 mg	EC Tab	55.00	56.93	1.04	3.52%	1.93
		Injection	77.00	81.60	1.06	5.97%	4.60
Lansoprazole	15 mg	Tablet	21.12	60.00	2.84	184.09%	38.88
		Capsule	21.80	26.25	1.20	20.41%	4.45
	30 mg	Capsule	41.00	103.00	2.51	151.22%	62.00
Omeprazole	10 mg	Capsule	20.00	28.98	1.45	44.90%	8.98
		Capsule	23.00	50.00	2.17	117.39%	27.00
		EC-Cap	39.00	54.40	1.39	39.49%	15.40

		FC-Tab	58.76	70.00	1.19	19.13%	11.24
		Tablet	24.50	39.60	1.62	61.63%	15.10
	40 mg	Capsule	43.00	73.00	1.70	69.77%	30.00
		Injection	23.25	23.75	1.02	2.15%	0.50
Pantoprazole	20 mg	EC-Tab	25.00	54.39	2.18	117.56%	29.39
		Tablet	18.55	58.00	3.13	212.67%	39.45
	40 mg	EC-Tab	13.33	80.08	6.01	500.75%	66.75
		Injection	43.38	65.00	1.50	49.84%	21.62
		Tablet	30.74	78.00	2.54	153.74%	47.26
Rabeprazole	10 mg	EC-Tab	10.30	44.30	4.30	330.10%	34.00
		Tablet	21.25	44.32	2.09	108.56%	23.07
	20 mg	EC-Tab	15.90	76.50	4.81	381.13%	60.60
		FC-Tab	29.00	59.10	2.04	103.79%	30.10
		Injection	50.00	89.00	1.78	78.00%	39.00
		Tablet	18.50	86.50	4.68	367.57%	68.00

EC Tab- Enteric Coated Tablet; FC Tab-Film Coated Tablet; EC Cap-Enteric Coated Capsule

**Table 2: cost variation among H2 receptor blockers**

Drug	Dose	Dosage	Minimum cost	Maximum cost	Cost ratio	% cost variation	Cost difference
Famotidine	20 mg	Tablet	2.29	11.46	5.00	399.81%	9.17
	40 mg	Tablet	3.59	24.90	6.93	593.04%	21.31
Ranitidine	150 mg	FC-Tab	5.00	6.00	1.20	20.00%	1.00
		Tablet	4.82	6.60	1.37	36.86%	1.78
	25 mg	Injection	2.38	3.54	1.49	48.74%	1.16
	300 mg	FC-Tab	10.18	10.19	1.00	0.13%	0.01
		Tablet	8.34	12.31	1.48	47.60%	3.97
	50 mg	Injection	2.67	25.94	9.72	871.54%	23.27
	75 mg	Syrup	0.70	1.27	1.82	82.25%	0.57

FC-Tab: Film Coated Tablet

**Table 3: cost variation among prostaglandin analogues**

Drug	Dose	Dosage	Minimum cost	Maximum cost	Cost ratio	% cost variation	Cost difference
Misoprostol	200 mcg	Tablet	152.50	174.35	1.14	14.33%	21.85

**Table 4: cost variation among ulcer protectives**

Drug	Dose	Dosage	Minimum cost	Maximum cost	Cost ratio	% Cost variation	Cost difference
Sucralfate	1 g/5ml	O:Susp for 200ml	105.11	145.00	1.38	37.95%	39.89
Sucralfate	1 g	O:Susp for 200ml	103.80	139.00	1.34	33.91%	35.20
Sucralfate	1 g	Tablet	18.00	39.90	2.22	121.67%	21.90

O:SUSP- Oral Suspension

**Table 5: Cost variation among FDC<sub>s</sub>**

<b>Drug</b>	<b>Dosage</b>	<b>Minimum cost</b>	<b>Maximum cost</b>	<b>Cost ratio</b>	<b>% Cost variation</b>	<b>Cost difference</b>
Al(OH) <sub>3</sub> gel 0.426g+ Belladonna dry extract 10mg + Phenobarbitone 8mg	Tablet	2.02	2.41	1.19	19%	0.39
Dried Al(OH) <sub>3</sub> 300 mg+Mg(OH) <sub>2</sub> 83mg	Tablet	1.70	2.16	1.27	27%	0.46
Esomeprazole(EC)40mg+Domperidone (SR)30mg	Capsule	73.00	89.70	1.23	23%	16.70
Esomeprazole40mg+Domperidone (SR)30mg	Capsule	73.80	75.00	1.02	2%	1.20
Esomeprazole40mg+Domperidone 30mg	Capsule	90.00	179.00	1.99	99%	89.00
Omeprazole20mg+Domperidone 10mg	Capsule	32.00	86.10	2.69	169%	54.10
Omeprazole20mg+Domperidone(SR)20mg	Capsule	57.20	70.00	1.22	22%	12.80
Pantoprazole(EC)40mg+Domperidone (SR) 30mg	Capsule	54.00	89.00	1.65	65%	35.00
Pantoprazole(EC)40mg+Domperidone(IR)10mg+Domperidone (SR) 20mg	Capsule	59.00	85.00	1.44	44%	26.00
Pantoprazole(ER)40mg+Domperidone (SR) 30mg	Capsule	66.00	68.75	1.04	4%	2.75
Pantoprazole20mg+Domperidone 10mg	Capsule	35.00	54.00	1.54	54%	19.00
Pantoprazole20mg+Domperidone 10mg	Tablet	30.70	49.50	1.61	61%	18.80
Pantoprazole40mg+Domperidone (SR) 30mg	Capsule	43.89	90.00	2.05	105%	46.11
Pantoprazole40mg+Domperidone 10mg	Capsule	63.00	79.00	1.25	25%	16.00
Pantoprazole40mg+Domperidone 10mg	Tablet	50.55	75.00	1.48	48%	24.45
Pantoprazole40mg+Domperidone 20mg	Tablet	60.90	69.80	1.15	15%	8.90
Pantoprazole40mg+Domperidone 30mg	Capsule	63.00	89.00	1.41	41%	26.00
Pantoprazole40mg+Domperidone 30mg	SR-Cap	69.00	69.50	1.01	1%	0.50
Pantoprazole40mg+ItoprideHCl 150mg	SR-Cap	96.68	199.50	2.06	106%	102.82
Pantoprazole40mg+Itopride(SR) 150mg	Capsule	88.00	130.00	1.48	48%	42.00
Pantoprazole40mg+Levosulpride 75mg	Capsule	110.00	189.00	1.72	72%	79.00
PantoprazoleNa20mg+Levosulpride (SR)75mg	Capsule	149.00	189.00	1.27	27%	40.00
Rabeprazole(EC)20mg+Domperidone	Capsule	37.00	65.00	1.76	76%	28.00

done(SR)20mg+Domperidone (IR) 10mg							
Rabeprazole(EC)20mg+Domperidone (SR) 30mg	Capsule	34.30	95.00	2.77	177%	60.70	
Rabeprazole(EC)20mg+Itopride (SR) 150mg	Capsule	89.00	150.00	1.69	69%	61.00	
Rabeprazole(EC)20mg+Levosulpiride (SR) 75mg	Capsule	99.00	198.00	2.00	100%	99.00	
Rabeprazole(ER)20mg+Domperidone (SR) 30mg	Capsule	40.00	65.00	1.63	63%	25.00	
Rabeprazole20mg+Domperidone (SR) 30mg	Capsule	72.00	91.50	1.27	27%	19.50	
Rabeprazole20mg+Domperidone 10mg	Tablet	65.00	87.00	1.34	34%	22.00	
Rabeprazole20mg+Domperidone(SR)20mg+Domperidone (IR) 10mg	Capsule	58.00	98.00	1.69	69%	40.00	
Rabeprazole20mg+Domperidone (SR) 30mg	Capsule	34.30	96.00	2.80	180%	61.70	
Rabeprazole20mg+Domperidone (SR) 30mg	Tablet	75.00	79.00	1.05	5%	4.00	
Rabeprazole20mg+Domperidone 10mg	Tablet	40.00	65.00	1.63	63%	25.00	
Rabeprazole20mg+Domperidone 30mg	Capsule	60.00	117.50	1.96	96%	57.50	
Rabeprazole20mg+Itopride (SR) 150mg	Capsule	86.00	140.00	1.63	63%	54.00	
Rabeprazole20mg+Itopride 150mg	Capsule	96.68	175.50	1.82	82%	78.82	
Rabeprazole20mg+Levosulpiride (SR) 75mg	Capsule	89.00	194.00	2.18	118%	105.00	
Rabeprazole20mg+Levosulpiride 75mg	Capsule	79.90	175.00	2.19	119%	95.10	
Rabeprazole20mg+Sodium Bicarbonate 100mg	Tablet	35.00	45.00	1.29	29%	10.00	
Ranitidine150mg+Domperidone 10mg	Tablet	5.26	18.00	3.42	242%	12.74	
Sucralfate 1gm+Oxetacaine 10mg/5ml for 100ml	O:Susp	115.00	122.00	1.06	6%	7.00	
Sucralfate 1gm+Oxetacaine 20mg/10ml for 100ml	O:Susp	77.00	110.00	1.43	43%	33.00	
Sucralfate 1gm+Oxethazaine 20mg/10ml for 200ml	O:Susp	95.00	98.00	1.03	3%	3.00	

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SR-SUSTAINED RELEASE; SR CAP-SUSTAINED RELEASE CAPSULES; O:SUSP- ORAL SUSPENSION.

Among the H2 Antihistamines, the maximum % of cost variation was noted with Ranitidine (50 mg injection) 871.54%, and among PPIs, the maximum % of cost variation was noted with Pantoprazole (40 mg EC-Tab) 500.75%.

Among the proton pump inhibitors, lowest % of cost variation was noted with Omeprazole 40 mg Injection and among H2 blockers, Ranitidine 300mg FC-TAB had lowest % of cost variation.

Overall, maximum and minimum % of cost variation (single drug) was noted with Ranitidine (50 mg injection) 871.54%, Ranitidine 300mg FC-TAB respectively.

Among the combinations, maximum and minimum % of cost variation was noted with Ranitidine 150mg+Domperidone 10mg TAB (242%) and Pantoprazole 40mg+Domperidone 30mgs SR-CAP (1%) respectively.

More than 100% cost variation was noted for all PPIs viz. Esomeprazole (20mg tablet, 40mg tablet), Lansoprazole (30mg tablet), Omeprazole (20mg capsule), Pantoprazole (20mg, 40mg, Tablet & EC-tablet), Rabeprazole (10mg-Tablet, EC-Tablet), Famotidine (40mg tablet), Ranitidine (50mg injection) and Sucralfate (1g tablet).

Among FDCs, more than 100% variation was seen for Omeprazole 20mg + Domperidone 10mg, Pantoprazole 40mg+Domperidone 30mg, Pantoprazole 40mg+Itopride HCl 150mg, Rabeprazole 20mg+Domperidone 30mg, Rabeprazole 20mg+Levosulpride 75mg and Ranitidine 150mg+Domperidone 10mg.

## DISCUSSION

Peptic ulcer is the most important organic gastrointestinal disease. It is widely prevalent in India, with South Indians being affected more than the North Indians. It is known to reduce work productivity as nocturnal heartburn interferes with sleep. Hence, it can adversely affect quality of life and increase health care utilization. In United States, \$12.2 billion as direct medical costs and \$81.7 billion as indirect costs are attributed to GERD [6].

Management of peptic ulcer has undergone essential changes from prescription of antacids, H2 blockers to PPIs and H.Pylori eradication regimens. PPIs or H2 receptor blockers are primarily indicated for treatment of GERD, risk reduction of NSAID-associated gastric ulcer, H. pylori eradication to reduce the risk of duodenal ulcer recurrence,

pathological hyper-secretory conditions including Zollinger-Ellison syndrome. NICE (National Institute for Health and Care Excellence) guidelines recommend that full-dose PPI or H2 receptor blocker therapy should be offered for 4 to 8 weeks to people who have tested negative for H. pylori and who are not taking NSAIDs [7]. Though many PPIs are available in the market, to best of my knowledge no studies have shown a significant difference between them used in standard doses for the treatment of reflux oesophagitis or duodenal ulcer. But Lansoprazole and Rabeprazole may display a more rapid onset of maximal acid suppression than the other proton pump inhibitors [8]. These gastro-protective agents contribute to the majority of the drugs used in the hospital. Drug utilization study conducted in emergency department at Chandigarh revealed that 20.8% of the drugs used were gastro-protective agents and the same was shown to be 10-30% in critical care units at Gujarat [9] [10]. Owing to the higher clinical utility of these drugs and longer duration of therapy, cost of the drug becomes a major factor in determining the compliance. Though no significant differences in the clinical outcome have been identified among these drugs, more than 100% cost variation has been identified among formulations of the same drug in the present study. Hence, the differences in drug pricing may increase the cost of therapy which could become unaffordable to many patients.

Affordability of medicines is a major issue which determines access to medicines especially in developing countries like India as the patients pay for their medicines. WHO defines affordability as the number of days the lowest paid unskilled government worker would have to work in order to afford the cost of treatment. Vandana Roy et al in Delhi, showed that the cost of treatment of community acquired Pneumonia required 1-3 days of work by a daily wage earner, depending on the brand of medicine prescribed [11].

Variation in drug pricing is a common phenomenon noted across many countries in the world. A study by Iyengar S et al to evaluate the cost of treating Hepatitis C population in 30 different countries revealed that the total pharmaceutical expenditure varied from 10.5% in the Netherlands to 190.5% in Poland [12]. In 1996, a study by Balasubramaniam reported that retail medicine prices in developing countries of Asia Pacific Region varied



from minimal difference of 233% to maximum of 32,757% [13]. In India, cost variation among antihypertensives was noted by Kamath L et al, anti-epileptic drugs by Wagle L et al, non-steroidal anti-inflammatory agents by Patel BS et al. Monaghan MJ et al in a literature review on drug price discrimination in United States, identified many factors that influence pricing of drugs within US: unique market structure of the pharmaceutical industry, asymmetry of information, research and development costs, numerous channels of distribution and government laws and regulations of prescription drugs. [14], [15], [16], [17].

WHO framed the Millennium Development Goals to provide access to affordable, essential drugs in developing countries in cooperation with pharmaceutical companies. WHO Guideline on Country Pharmaceutical Pricing Policies recommended these policy interventions: Regulation of mark-ups in the pharmaceutical supply and distribution chain, Tax exemptions/reductions for pharmaceutical products, Application of cost-plus pricing formulae for pharmaceutical price setting, Use of external reference pricing, Promotion of use of generic medicines and Use of health technology assessment.

In India, The Ministry of Health and Family welfare directly regulates the issues of drugs, cosmetics and medical devices in India. The prices and availability of drugs in National List of Essential Medicines (NLEM) is regulated by National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals. The Drugs Prices Control Order (DPCO) is an order issued by the government under Section 3 of the Essential Commodities Act, 1955 empowering it to fix and regulate the prices of essential bulk drugs and their formulations. In view of reducing the burden of treatment, Medical council of India mandates doctors to prescribe generic medicines and the number of medicines in NLEM 2015 is increased to 376 from 348 in NLEM 2011. DPCO 2013 included 628 formulations including the drugs listed in NLEM 2011. DPCO 2016 has 820 formulations including the drugs in NLEM 2015.

The present study findings show a wide variation in the prices of different brands of anti-ulcer drugs listed in CIMS. The result of the present study is expected to guide the prescribers in choosing cost-effective therapy for their patients.

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