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COMPARATIVE STUDY OF THE EFFICIENCY OF BRANDED AND GENERIC DRUGS ON ANAEMIA

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Abstract:
The present work was to evaluate the price, quality and efficiency of branded and generic drugs on Anaemia which are manufactured by the same pharmaceutical company in India. Clinical study was perfomed on three different groups of individuals like group 1,group 2,group 3 . These subjects were tested for their haemoglobin content by a qualified lab technician which showed that majority of the subjects were anaemic and hence Iron supplements like Glowfol-Z and Fefol were used in the study .Group 1 was selected as control, group 2 was selected for generic formulation and group 3 for branded formulation. They were prescribed with iron preparations by Registered Medical Practitioner and the results were noted before and after the medication. The obtained results were subjected to statistical analysis which showed that there is significant difference exists in the group 2 individuals who were subjected to generic medication showing generics are almost equal in efficiency to the branded ones except in cost because the generics are sold at a low price to the branded ones.

Keywords: *Branded medicines, generic, haemoglobin, Anaemia.*

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INTRODUCTION:

With a population of more than 100 crores, India accounts for 16 per cent of the global population. Sizeable population lives below the poverty line and 48 per cent of the people are illiterate. India accounts for huge morbidity &Healthcare costs are high and are increasing further. Expenditure on drugs constitutes about 50 % of the health care cost which increases up to 80 % in rural areas. World Health Organisation (WHO) says that 65% of the population still lacks regular access to essential medicines. With the rise in health care cost, over 23 % of the sick don't seek treatment because they are not having enough money to spend. At grocery store generic products can be of inferior to their brand counter parts. But in Pharmacy aisle, the rules are different. Generics are almost identical to that of branded drugs. But there is one major difference. Generics are 80% cheaper on average. Generic drugs play an important role in health care. The prescription and availability of generic drugs eliminates the monopoly of the drug companies. WHO calculates that generic prescribing of essential drugs could save 70 per cent of the drugs bill in rich countries alone. In poor countries benefit to the patients will be much more. Many people become concerned because generic drugs are often substantially cheaper than the brand-name versions. They wonder if the quality and effectiveness have been compromised to make less expensive products. The FDA (U.S.Food and Drug Administration) requires that generic drugs be as safe and effective as brand-name drugs. Another common misbelieve is that generic drugs take longer to work. The FDA requires that generic drugs work as fast and as effectively as the original brand-name products. So there's no truth in the myths that generic drugs are manufactured in poorer-quality facilities or are inferior in quality to brand-name drugs. The FDA applies the same standards for all drug manufacturing facilities, and many companies manufacture both brand-name and generic drugs. In fact, the FDA estimates that 50% of generic drug production is by brand-name companies. In United States generics account for less than 16 cents of every dollar spent on branded drugs [1]. The quality of prescription drugs, brand-name or generic, does not depend solely on the manufacturer but also on a strong and vigilant Regulatory. Both brand-name and generic drug companies are regulated by the Drug Administrative Department using the same standards for manufacturing facilities, quality and purity, and content of prescription drugs.

A 1990 study by FDA laboratories from all over the country found that for those classes of prescription drugs that theoretically could be most likely to pose safety or effectiveness problems if they were not manufactured properly, the generic drug met the applicable standards in virtually all cases. The classes of drugs tested included contraceptives, antibiotics, and medications prescribed for asthma, epilepsy, high blood pressure, and abnormal heart rhythms.

We knew that the actual cost of most of the drugs is very low. But, these were not available to patients at low rates because of three obstacles:

1. The doctors prescribe medicines by brand name of a particular drug company.

This prevents competition and creates monopoly in the drug market and enables the drug company to put a very high MRP.

2. As very high MRP is printed on the drugs, the chemists charge the same amount from the patient.
3. Consumers are not aware that the actual cost of production of most of the drugs is very low. Moreover, once doctor has prescribed a particular brand, the patient has got no option, but to buy it, even when other low cost brands are available in the market.

The state govt. has issued various circulars or orders, which directs all govt. Doctors to use generic names, instead of brand names.

There are a number of reasons why the prices of drugs in India, indeed all over the world, are so high. One of them is the business of branding. In many developing countries, consumers buy the same drug marketed by several different producers under different brand names, not realizing that they are all the same product. Paracetamol, for example, is the generic name, for a painkiller. It is available under more than 20 brand names - Crocin, Calpol, Metacin, Pyrin - all of which are paracetamols. The consumer, however, is not aware of this. Drug companies and doctors may swear that one particular drug is more effective than the other, although this cannot be so as they all contain the same ingredient and conform to the same quality control standards.

A generic drug must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties.

There is a strong misunderstanding and belief among the Medical Practitioners that Branded drugs are more therapeutically efficient than Generic by

extension drugs. Some surveys have revealed that though Generic drugs are safe and cheap but not effective as branded drugs [2,3,4].

ANAEMIA

Anaemia is not one disease, but a condition that results from a number of different pathologies. It can be defined as a reduction from normal of the quantity of hemoglobin in the blood. The World Health Organisation defines anaemia in adults as hemoglobin levels less than 13g/dL for males and less than 12g/dL for females. Anemia (in Greek, meaning lack of blood) is a decrease in number of red blood cells (RBCs) or less than the normal quantity of hemoglobin in the blood [5,6].

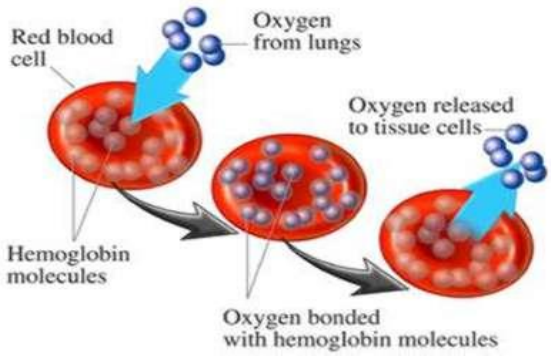

Fig 1: Exchange of oxygen in RBC

In India it is estimated suggest that over one third of the world's population suffers from anaemia, mostly iron deficiency anaemia. India continues to be one of the countries with very high prevalence. National Family Health Survey (NFHS-3) reveals the prevalence of anaemia to be 70-80% in children, 70% in pregnant women and 24% in adult men. Prevalence of anaemia in India is high because of low dietary intake, poor availability of iron and chronic blood loss due to hook worm infestation and malaria. While anaemia has well known adverse effects on physical and cognitive performance of individuals, the true toll of iron deficiency anaemia lies in the ill-effects on maternal and fetal health. Poor nutritional status and anaemia in pregnancy have consequences that extend over generations. Women have a markedly lower incidence of X-linked anaemias, such as G-6-PD deficiency and sex-linked sideroblastic anaemias, than men do. In addition, in the younger age groups, males have a higher incidence of acute anaemia from traumatic causes.[7,8]

A thorough dietary history is important in a patient who is anaemic. This history must include foods that the patient eats and those that he/she avoids, as well as an estimate of their quantity. A meal-by-meal description is necessary to obtain appropriate estimates. Even then, patients frequently attempt to deceive the physician because of embarrassment regarding dietary idiosyncrasies or financial restrictions. In these circumstances, a close and concerned family member participating in the dietary history can often be helpful, because this person is usually more objective than the patient. Changes in body weight are important with regard to dietary intake and can suggest the presence of malabsorption or an underlying wasting disease of infectious, metabolic, or neoplastic origin. Anaemia can be classified in associated with Iron Deficiency, Chronic Renal Disease, Folate Deficiency, Acute Blood Loss, Vitamin B12 Deficiency, Chemotherapy Induced, drug-induced immune hemolytic Anaemia etc.

Two general approaches like kinetic and morphological which can be used to identify the causes of anemia. Kinetic approach includes excessive destruction of erythrocytes, Blood loss due to frequent blood sampling for laboratory testing, Trauma or surgery, Gastrointestinal tract lesions, menstruation. Morphological approach like Microcytic anemia where the mean cell volume(MCV) is low (less than 80), haemoglobin concentration is reduced. Normocytic anemia where the mean cell volume(MCV) is in the normal range (80-100), and haemoglobin concentration remains constant. Macrocytic anemia where the mean cell volume (MCV) is high.[9,10]

Iron deficiency is defined as decreased total iron body content which occurs when iron deficiency is severe enough to diminish erythropoiesis and cause the development of anemia. It is more prevalent single deficiency state on a worldwide basis which is economically because of the capability of individuals to perform physical labor, and it diminishes both growth and learning in children. Iron is vital for all living organisms because it is essential for multiple metabolic processes, including oxygen transport, DNA synthesis, and electron transport. Iron equilibrium in the body is regulated carefully to ensure that sufficient iron is absorbed in order to compensate for body losses of iron whereas body loss of iron quantitatively is as important as absorption in terms of maintaining iron equilibrium, it is a more passive process than absorption.

The total body iron in a 70-kg man is about 4 g. This is maintained by a balance between absorption and body losses. Although the body only absorbs 1 mg daily to maintain equilibrium, the internal

requirement for iron is greater (20-25 mg). An erythrocyte has a lifespan of 120 days so that 0.8% of red blood cells are destroyed and replaced each day. A man with 5 L of blood volume has 2.5 g of iron incorporated into the hemoglobin, with a daily turnover of 20 mg for hemoglobin synthesis and degradation and another 5 mg for other requirements. Most of this iron passes through the plasma for reutilization. In healthy people, the body concentration of iron (approximately 60 parts per million [ppm]) is regulated carefully by absorptive cells in the proximal small intestine, which alter iron absorption to match body losses of iron.Oral iron supplements are the best way to restore iron levels for people who are iron deficient, but they should be used only when dietary measures have failed [11,12,13,14,15] .

MATERIALS & METHODS:

The prescription was given by Registered Medical Practitioner to all the subjects who were grouped into group 2 and group 3 on their name.The blood samples were collected by a qualified lab technician.
RBC diluting fluid (Indian Fine Chem), N/10 Hydrochloric acid (Span Diagnostics Ltd).
Disposable needles 24GX1/0.56 ×25 mm (Dora single use hypodermic needles).
Disposable Syringes 3m– 517506 l (Oyster hypodermic syringes with needles).
Haemo Meter (Superior, Germany),
Neubauer Chamber, R.B.C. Pipette (Mico Glass Industries).

Table 1: Generic and Branded Iron formulations used in the study

S NO	Name of the drug	composition	Manufacturer	Cost per strip (15 Tablets)
1	GLOWFOL-Z (GENERIC)	Dried ferrous sulphate IP 150 mg, Folic acid IP 1.0 mg Zinc sulphate monohydrate USP 61.8mg	BIOCHEMPHARMACEUTICAL INDUSTRIES LTD	Rs 12
2	FEFOL (BRANDED)	Dried ferrous sulphate IP 150 mg Folic acid IP 0.5mg	GLAXOSMITHKLINE PHARMACEUTICALS LTD	Rs 57

METHOD

Estimation of Haemoglobin (Sahli's method)

With the help of a dropper, N/10HCLwas taken in the graduated haemoglobin meter tube up to its lowest mark(usually 10% or 2%),the finger was pricked under aseptic precautions. When a drop of reasonable size has collected, hold the pipette horizontally, apply its tip to the drop and draw exactly 20 cumm of blood with no air bubbles. The pipette was taken and wiped off the blood adhering to the tip.Immediately the blood was transferred from the pipette into N/10 HCL in the graduated haemoglobin meter tube and rinsed several times by drawing the N/10 HCL which is used for mixing the blood, foaming should be avoided.The contents were mixed thoroughly and solution was allowed to stand for about 10 minutes for the maximum of haemoglobin in acid to convert into haematin. Now dilute the acid haematin by adding distilled water in drops. The dilution was continued till its colour matches with that of the standard. The reading of the meniscus from the scale provided on the haemoglobin meter tube were noted which express the haemoglobin content as gm per 100ml of blood.

RESULTS AND DISCUSSION:

We have done the haemoglobin content under the supervision of registered medical practitioner and a qualified lab technician. The haemoglobin content values were given in the table 2.Using these values the subjects were categorized into three groups namely Group 1 which are selected for control.Group 2 for generic formulation and Group 3 for branded formulation.

Table 2: Total subjects tested for Haemoglobin Content

S NO	ID NO	Hb %	S.NO	ID.NO	Hb%
1	HB1	12.2	57	HB57	11.0
2	HB2	9.8	58	HB58	10.0
3	HB3	12.8	59	HB59	8.2
4	HB4	8.8	60	HB60	9.0
5	HB5	6.2	61	HB61	11.2
6	HB6	9.8	62	HB62	5.0
7	HB7	14	63	HB63	11.0
8	HB8	13	64	HB64	8.0
9	HB9	10.8	65	HB65	10.0
10	HB10	10	66	HB66	10.0
11	HB11	10.2	67	HB67	11.0
12	HB12	9.8	68	HB68	9.8
13	HB13	10.4	69	HB69	10.8
14	HB14	15.0	70	HB70	9.8
15	HB15	11	71	HB71	10.0
16	HB16	11.8	72	HB72	13.0
17	HB17	12.0	73	HB73	11.8
18	HB18	8.6	74	HB74	11.8
19	HB19	11.8	75	HB75	12.6
20	HB20	11.0	76	HB76	10.8
21	HB21	10.0	77	HB77	11.0
22	HB22	12.0	78	HB78	8.4
23	HB23	10.2	79	HB79	11.8
24	HB24	5.0	80	HB80	13.2
25	HB25	13.6	81	HB81	13.6
26	HB26	10.0	82	HB82	13.0
27	HB27	10.2	83	HB83	8.0
28	HB28	11.6	84	HB84	8.0
29	HB29	10.0	85	HB85	9.2
30	HB30	12.4	86	HB86	12.8
31	HB31	13.0	87	HB87	10.8
32	HB32	14.0	88	HB88	11.0
33	HB33	8.4	89	HB89	14.6
34	HB34	13.0	90	HB90	8.0
35	HB35	11.8	91	HB91	10.4
36	HB36	11.6	92	HB92	13.4
37	HB37	12.2	93	HB93	11.8
38	HB38	11.6	94	HB94	12.0
39	HB39	9.8	95	HB95	9.8
40	HB40	10.0	96	HB96	11.6
41	HB41	13.0	97	HB97	9.0
42	HB42	9.4	98	HB98	13.0
43	HB43	11.2	99	HB99	9.0
44	HB44	12.6	100	HB100	10.0
45	HB45	10.0	101	HB101	11.0
46	HB46	9.6	102	HB102	9.6
47	HB47	5.8	103	HB103	11.0
48	HB48	10.8	104	HB104	9.4
49	HB49	10.8	105	HB105	11.6
50	HB50	13.0	106	HB106	8.8
51	HB51	10.0	107	HB107	9.6
52	HB52	9.4	108	HB108	14.4
53	HB53	7.8			
54	HB54	8.0			
55	HB55	8.4			
56	HB56	9.4			

Table 3: Haemoglobin estimated in Control subjects before and after 15 days

S.No	ID . No	Hb % before (gm/ml)	Hb% after (gm/ml)	Variation
1	CGOO1	11.6	12.2	0.6
2	CG002	10.0	8.0	-2
3	CG003	11.2	12.2	1.0
4	CG004	11.8	10.4	-1.4
5	CG005	11.8	11.0	-0.8
6	CG006	11.0	11.4	0.4
7	CG007	11.8	12.0	0.2
8	CG008	11.8	11.0	-0.8
9	CG009	11.0	12.0	1.0
10	CG0010	13	13	0
11	CG0011	11.0	10.0	-1.0
12	CG0012	11.0	11.2	0.2
13	CG0013	11.2	11.4	0.2
14	CG0014	11.0	13	2.0
15	CG0015	11.6	11.8	0.2
16	CG0016	11.6	10.2	-1.4
17	CG0017	11.6	11.2	-0.4
18	CG0018	11.0	13	2.0

Table 4: Haemoglobin estimated in Group 2 before and after 15 days treatment with Generic drug (Glowfol)

S.No	Patient ID No	Hb% before (gm/ml)	Rbc count (mil/cu mm)	Hb% after (gm/ml	Variation
1	GD0001	8.8	3.3	8.8	0.0
2	GD0002	6.2	2.9	7.0	0.8
3	GD0003	10.8	4.1	12	1.2
4	GD0004	9.0	4.0	10	1.0
5	GD0005	10.0	3.7	11	1.0
6	GD0006	8.4	2.9	10.8	2.4
7	GD0007	8.0	2.8	10	2.0
8	GD0008	8.4	3.8	9.2	0.8
9	GD0009	8.0	3.1	9.8	0.8
10	GD0010	8.6	3.0	10	1.4
11	GD0011	9.0	4.4	11.0	2.0
12	GD0012	10.0	4.0	10.2	0.2
13	GD0013	5.0	2.8	6.6	1.6
14	GD0014	10.2	3.5	10.2	0.0
15	GD0015	10.0	3.4	12.8	2.8
16	GD0016	10.6	4.0	12.8	2.2

Table 5:Haemoglobin estimated in Group 3 before and after 15 days of treatment with Branded drug (Fefol)

S no	ID no	Hb% Before (gm/ml)	Rbc count mil/cu mm	Hb% after(gm /ml)	variation
1	BD0001	9.8	3.1	11.0	1.2
2	BD0002	10.8	4.6	10.0	-0.8
3	BD0003	9.8	3.2	10.8	1.0
4	BD0004	8.0	3.2	9.2	1.2
5	BD0005	10.0	3.8	11.4	1.4
6	BD0006	5.8	3.0	7.0	1.2
7	BD0007	9.6	3.3	10.2	0.6
8	BD0008	10.8	4.2	12.4	1.6
9	BD0009	10	4.3	10.4	0.4
10	BD0010	9.6	3.8	11.0	1.4
11	BD0011	7.8	2.6	8.0	0.2
12	BD0012	9.4	3.0	10.2	0.8
13	BD0013	9.8	3.6	8.0	-1.8
14	BD0014	8.4	3.2	11.0	2.6
15	BD0015	9.4	3.9	9.0	-0.4
16	BD0016	8.0	3.6	10.0	2.0
17	BD0017	9.0	3.6	9.0	0.0
18	BD0018	10.2	4.2	11.0	0.8

STATISTICAL ANALYSIS

The statistical package for the clinical values version 5 Prism graph pad was used for analysis. The continuous variables were expressed as mean± Standard Deviation (S.D.)

Data were collected twice on the same subjects, i.e., subjects biochemical parameters were measured before and after ferrous salts treatment. In this study measurement of interest was to study the effect of Generic and Branded formulation by estimating Haemoglobin levels of blood. Group means standard deviation of subjects before and after treatment was determined.These were being dependent samples. Paired t-test was conducted. Differences with $P<0.05$ were considered as statistically significant.

Group 1 was Control were treatment was not suggested. Special diet was not mentioned. The results obtained were presented in Table 3 and their statistical analysis was shown in Table 6.Table 3 indicated only in 8 subjects the haemoglobin levels were slightly increased in 15 days without drug treatment and without diet monitoring. The mean Haemoglobin values of this group and SD's before and after 15 days were respectively 11.43±0.61 and 11.31±1.29. There is reduction in group mean value.

The paired t test revealed that mean difference was not statistically significant. The reduction in hemoglobin in control group was not statistically significant.

Table 6: Statistical Analysis of Control Group 1 before and after 15 days without any treatment.

Haemoglobin g%	N	Mean	S.D	P-value	Decision
BEFORE	20	11.43	0.61	0.03166	N.S
AFTER	18	11.31	1.29		
DIFFERENCE			0.2	29.74766	

Note: Anaemic subjects less than 11g% were selected and were grouped in to three.

Table 7: Statistical Analysis of Generic drug treated Group 2 before and after 15 days treatment.

Haemoglobin g%	N	Mean	S.D	P-value	Decision
BEFORE	20	8.55	1.51	0.0001	**Significant**
AFTER	16	10.13	1.7		
DIFFERENCE		0.2	-1.26		

Note: To study the effect of ferrous salt formulation Glowfol, a Generic drug costs Rs. 12/- per strip was administered one tablet a day after lunch daily for 15 days to Group 2 subjects. Their hemoglobin levels of blood were estimated before and after treatment. The results obtained were presented in Table 4 and its statistical analysis was in Table 7.

The mean Haemoglobin value and SDs of individuals before treatment was 8.55±1.51% and after treatment was 10.13±1.7. Table 7 indicated that the mean difference was statistically significant at P value 0.0001. The treatment with Generic formulation Glowfol, in Group 2 subjects had increased hemoglobin level. The improvement is statistically significant**.**

Table 8: Statistical Analysis of Branded drug treated Group 3 before and after 15 days treatment

Haemoglobin g%	N	Mean	S.D	P-value	Decision
BEFORE	20	9.0	1.45	0.008	**Significant**
AFTER	18	9.97	1.37		
DIFFERENCE		0.97	-1.26		

To study the effect of ferrous salt formulation on iron deficiency anemia, Fefol, a Branded formulation was selected. The cost of tablet per strip is Rs.57 /- These tablets were administered to Group 3 subject daily one after lunch. The treatment was given for `15 days.

The haemoglobin of blood was estimated before and after treatment. The results obtained were presented in Table 5 and statistical analysis in Table 8. Table 8 provided statistical analysis of Haemoglobin values of Group 3. The mean Haemoglobin values before camp were 9.0 % and S.D. was 1.45. The mean Haemoglobin values and its S.D. after treatment with Branded drug formulation was 9.97±1.37. There was increase in mean value of Haemoglobin. Statistical analysis by paired 't' test indicated that the difference was statistically significant at p value 0.008.

Note: There was an increase in hemoglobin concentration in Group 3 subjects after treatment with Fefol formulation which is a branded drug. The increase is statistically significant.

CONCLUSION:

In the western societies the commonest cause of iron deficiency is due to blood loss. In women of childbearing age, this is most commonly due to menstrual loss. Among adult males, the most likely cause is gastro-intestinal bleeding. Other causes of blood loss associated with iron deficiency anaemia include hemorrhoids, nosebleeds or postpartum hemorrhage. A loss of 100 ml of blood represents the amount of iron normally absorbed from western diet over 40 days.

In India the scenario is different. The root cause of Iron deficiency anemia is poor diet and nutrition. India accounts for 22 per cent of the global illness with only 2 per cent of the global drug production of which only 0.7 per cent are essential drugs. Yet 1.3 per cent is non essential, profit-oriented formulations which are highly priced, irrational or useless. Crores of our people, living in abject poverty, can barely afford a square meal a day, and are not able to afford to spend on costly medicines.

Vedavathi et. al [15] carried out a comparison of quality of life and improvement in blood pressure and blood glucose values of patients using branded and generic medicines for hypertensive and diabetes treatment. They concluded that there is no difference between the therapeutic efficacy of the selected products of branded generic medicines and generic medicines. They found that there was good correlation between improvements in biochemical values.

Govt. Cooperative Medical Stores and Life-line drug stores (run by Jeevanadhara in Andhra Pradesh) provide low cost medicines of well reputed companies. Pharmacists also play a vital role in educating the doctors about the availability of generic drugs. Thus the right medication could be given to the patients at the best possible price. Generics are as good as branded drugs. Thus if generic drugs are bought by the patient, the patient may not lose money by going in for branded drugs, which are too costly.

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