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Effects of individualized homoeopathic medicaments in Psoriasis: A single blind, simple randomized, placebo controlled study

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Abstract
Psoriasis is a non-contagious, chronic skin condition that produces plaques of thickened, scaling skin. It is considered as an incurable, long-term (chronic) inflammatory skin condition. Psoriasis is estimated to affect 2–4% of the population of the western world. Commonly appears for the first time between the ages of 15 and 25 years. In India the prevalence varies from 0.44 to 2.8%.Specific medical signs used for diagnosis are Auspitz's sign, Koebner phenomenon, Candle grease sign with itching, pain localized to papules and plaques. As it was understood to be a chronic, intractable & incurable disease, hence it was felt imperative to carry out a systematic constitutional treatment to validate the observations of earlier Homoeopaths and the subtle homoeopathic philosophy.
Research Objectives: Primary objectives were to observe the change in disease severity and change in quality of life of the people. Secondary objective was to ascertain the effect on frequency of relapse and recurrence interval.
Methodology: The study was simple randomized and single blind method. The sample size was fixed at 90.Test group 60 i.e. Group – I(Centesimal -30), Group – II(50 Millesimal -30) & Group – III(Control) 30. Duration of study was for two years. It was carried out at International Study & Research Centre on Homoeopathy, Bhubaneswar. There were inclusion & exclusion criteria, treatment plan, follow up with Psoriasis Area Severity Index (PASI), Psoriasis Disability Index (PDI), Relapse and Recurrence Interval (RRI).
Results: Were documented on following points. Psoriasis Area Severity Index (PASI)/Psoriasis Disability Index (PDI)/ Relapse & Recurrence Interval (RRI).
Statistical Analysis: By Kruskul Wallis Test, H_0 was rejected. In paired 't' test for PASI, Group – I and II results (P< 0.0001, CI= 95%). It means significantly effective in reducing the severity & area affected. Group – III, results were (P< 0.3811, CI= 95%) not significantly effective in reducing the severity & area affected. PDI results for paired 't' test, for both Group –I & II were (P<0.0001, CI= 95%), it means significantly effective in enhancing the quality of life. Group – III results (P< 0.9294, CI= 95%) were non significant in enhancing the quality of life. Chi-Square test for comparison of R.R.I. in medicine group and placebo group were significant. But comparison between Centesimal and Fifty Millesimal potency was non significant. Overall response result were put to Chi-Square test for comparison of medicine groups and placebo group. It was statistically significant.
Conclusions: 1. Constitutional Homoeopathic medicine is the first line of approach to treat Psoriasis. 2. Both potencies are equally important.

Keywords: Scaly plagues, auspitz's sign, koebner phenomenon, candle grease sign, constitutional homoeopathic medicine

Introduction
Psoriasis is a non contagious, chronic skin condition that produces plaques of thickened, scaling skin. The dry flakes of skin scales result from the excessively rapid proliferation of skin cells. The proliferation of skin cells is triggered by inflammatory chemicals produced by specialized white blood cells called lymphocytes. Psoriasis commonly affects the skin of the elbows, knees, and scalp. Psoriasis is considered an incurable, long-term (chronic) inflammatory skin condition. It has a variable course, periodically improving and worsening. It is not unusual for psoriasis to spontaneously clear for years and stay in remission. Many people note a worsening of their symptoms in the colder winter months [1-5].
Psoriasis is considered mild if it affects less than 5% of the surface of the body; moderate, if 5-30% of the skin is involved and severe, if the disease affects more than 30% of the body surface [6-8].

Psoriasis is generally thought to be a genetic disease which is triggered by environmental factors [9]. In twin studies, identical twins are three times more likely to both be affected compared to non-identical twins; this suggests that genetic factors predispose to psoriasis. Symptoms often worsen during winter and with certain medications such as beta blockers or NSAIDs [10]. Infections and psychological stress may also play a role [9, 11]. Psoriasis is not contagious. The underlying mechanism involves the immune system reacting to skin cells. Diagnosis is typically based on the signs and symptoms [10].

Psoriasis is estimated to affect 2–4% of the population of the western world [12]. The rate of psoriasis varies according to age, region and ethnicity; a combination of environmental and genetic factors is thought to be responsible for these differences [12]. It can occur at any age, although it most commonly appears for the first time between the ages of 15 and 25 years. Approximately one third of people with psoriasis report being diagnosed before age 20 [14]. Psoriasis affects both sexes equally [13].

People with inflammatory bowel disease such as Crohn's disease or ulcerative colitis are at an increased risk of developing psoriasis [15]. Psoriasis is more common in countries farther from the equator [15].

In India the prevalence of psoriasis varies from 0.44 to 2.8%, it is twice more common in males compared to females, and most of the patients are in their third or fourth decade at the time of presentation [16].

Clinical features are well delineated red, scaly plaques [17]. Nail changes include pitting of the nails (pinhead-sized depressions in the nail is seen in 70% with nail psoriasis), whitening of the nail, small areas of bleeding from capillaries under the nail, yellow-reddish discoloration of the nails known as the oil drop or salmon spot, thickening of the skin under the nail (subungual hyperkeratosis), loosening and separation of the nail (onycholysis), and crumbling of the nail [18].

Flexural psoriasis refers to plaque psoriasis at submammary, groin, axillary, genital and natal cleft sites, and is typically less scaly. Seborrhoeic psoriasis ('sebopsoriasis') is similar in appearance and distribution to seborrhoeic dermatitis and may occur in isolation or associated with plaque psoriasis elsewhere. Other types of psoriasis include guttate psoriasis (an acute eruption of small (< 1 cm) papules of psoriasis which appear over a period of a month or so and is preceded by a streptococcal infection in around 2/3rd of people). Distinctive nail changes occur in around 50% of all those affected and are more common in those with psoriatic arthritis [19].

In addition to the appearance and distribution of the rash, specific medical signs may be used by medical practitioners to assist with diagnosis. These may include Auspitz's sign (pinpoint bleeding when scale is removed), Koebner phenomenon (psoriatic skin lesions induced by trauma to the skin) [20], Candle grease sign and itching and pain localized to papules and plaques [20, 21].

Causes & risk factors are as follows: Around one-third of people with psoriasis report a family history of the disease, and researchers have identified genetic loci associated with the condition. Identical twin studies suggest a 70% chance of a twin developing psoriasis if the other twin has the disorder. The risk is around 20% for non-identical twins. These findings suggest both a genetic susceptibility and an environmental response in developing psoriasis [22].

Conditions reported as worsening the disease include chronic infections, stress, and changes in season and climate [23]. Others that might worsen the condition include hot water, scratching psoriasis skin lesions, skin dryness, excessive alcohol consumption, cigarette smoking, and obesity [23-25].

Psoriasis tends to be more severe in people infected with HIV [26]:-Drug-induced psoriasis may occur with beta blockers, [27] lithium [27], antimalarial medication [27], non-steroidal anti-inflammatory drugs [27], terbinafine, calcium channel blockers, captopril, glyburide, granulocyte colony-stimulating factor [27], interlukins, interferons [27], lipid-lowering drugs [28] and paradoxically TNF inhibitors such as infliximab or adalimumab [15]. With drawl of corticosterois (topical steroid cream) can aggravate psoriasis due to the rebound effect [29].

Research objectives

I. **Primary objective:** To study the response of Homoeopathic medicaments in Psoriasis with response to change in disease severity and change in quality of life of the people.
II. **Secondary objectives:** To ascertain the frequency of relapse and recurrence of Psoriasis in patients during the course of treatment.

Study hypothesis

I. **Null hypothesis (H_0):** There is no response to disease severity, quality of life and increase in relapse recurrence interval of patients of Psoriasis measured on identified parameters with Homoeopathic treatment.
II. **Alternative hypothesis (H_1):** Homoeopathic treatment causes statistically significant improvement in disease severity and quality of life of patients suffering from Psoriasis measured on identified parameters.

Assessment Parameter

Parameter	Measurement scale	Null hypothesis	Alternative hypothesis
Disease severity	Psoriasis Area and Severity Index (PASI)	Pre-treatment PASI score ≤ post treatment PASI score	Pre-treatment PASI score > post treatment PASI score
Quality of life	Psoriasis Disability Index (PDI)	Pre-treatment PDI score ≤ post treatment PDI score	Pre-treatment PDI score > post treatment PDI score
Relapse & recurrence interval (RRI)	(a) Positive response-No relapse, reduced lesion (b) Negative response-Increased, unchanged lesion	Positive response≤ Negative response	Positive response> Negative response
Overall response result	a) Positive response: PASI/PDI scores reduced & RRI reduced, no relapse after treatment (b) Negative response: PASI/PDI Score increased or standstill & RRI increased /unchanged after treatment	Pretreatment score ≤post treatment	Pretreatment>post treatment

Methodology

I. **Study settings:** At International Study and Research Center on Homoeopathy, 92, Dharma Vihar, Khandagiri, Bhubaneswar. Ethical approval was obtained from the Institutional Ethical Committee of ISRCH. Written informed consent was obtained from all patients before to this study.
II. **Study duration:** It was decided to follow up for a period of two years.
III. **Sample size:** It was determined to take 90 patients.
IV. **Sampling method:** It was decided to adopt simple randomized and single: blind method from 209 patients enrolled for the project.
V. Primarily the entire sample size was divided into three groups such as:-

a) Group I: Test group with Centesimal potency
b) Group II: Test group with 50 Millesimal potency
c) Group III: Control with Placebo

Following inclusion and exclusion criteria were fixed.

I. Inclusion criteria

a. Ages- 18 – 60 years
b. Gender – Both
c. Case presenting with plaque type Psoriasis i.e. well-defined, erythematous, scaly lesion which becomes silvery on attempt to scrape.
d. Auspitz's sign/Candle grease sign/ Koebner phenomenon

II. Exclusion criteria

a. Not taken other treatment for psoriasis within last 6 months
b. Patient using allopathic treatment for other complaints.
c. Presence of other disease conditions (i.e eczema, lichen planus, tinea, pityriasis rosea, seborrhic dermatitis, syphilitic psoriasis).

I. **Treatment plan:** Symptoms were collected in a prescribed case taking/ recording format. Totality was built up as per regular procedures. Each case was repertorised. Medicine prescribed after repertorisation with due consultation with Materia medica. Repetition schedule was infrequent both for 50 millesimal and centesimal. Medicine was procured from a GMP compliant pharmaceutical firm i.e Dr. Willmar Schwabe India Pvt. Ltd.
II. **Follow up:** Response of medicine was identified and recorded by change with signs & symptoms periodically at 1 month interval along with change in PASI, PDI and RRI for a period of two years.

Outcomes Parameters

I. Primary outcome

- Change in Psoriasis severity, which is assessed by grading system using PASI score. Psoriasis Area Severity Index (PASI) is an established Psoriasis assessment tool that will be used as a measure of the effects of Homoeopathic treatment in patients of Psoriasis at baseline and at monthly intervals for 2 years.
- Change in participant quality of life score as measured by validated Psoriasis specific quality of life scale i.e. Psoriasis Disability Index (PDI).

Secondary outcomes

- Time to next relapse and recurrence interval (RRI) during the period of follow up.

Results

Table 1: Results of Psoriasis Area & Severity Index results (PASI)

Group – I(centesimal)			Group – II(fiftymillesimal)			Group – III(placebo)		
Sl. No.	Before treatment	After treatment	Sl. No.	Before treatment	After treatment	Sl. No.	Before treatment	After treatment
1	19.4	2.8	31	5.2	0	61	18.6	19.4
2	16.8	4.2	32	8.2	0	62	18.2	17.4
3	14.6	0	33	10.6	1.2	63	13.4	10.4
4	10.6	2.6	34	6.2	0	64	17.4	14.4
5	10.4	1.4	35	4.4	0.8	65	18.6	8.6
6	20.8	9.4	36	16.8	3.4	66	9.4	9.4
7	10.6	2.2	37	18.6	4.2	67	10.6	10.6
8	10.4	4.6	38	19.4	0	68	19.4	19.4
9	11.6	2.4	39	12.4	0	69	16.8	16.8
10	9.4	0.0	40	16.2	2.4	70	19.8	20.6
11	9.8	20.6	41	18.2	2.0	71	14.4	14.8
12	14.2	3.2	42	13.6	1.0	72	11.4	10.8
13	18.4	0	43	14.2	4.2	73	17.6	20.6
14	10.8	2.2	44	15.8	2.8	74	10.2	10.4
15	4.2	0.0	45	13.4	0	75	4.2	4.4
16	2.2	0	46	17.4	1.0	76	4.8	5.0
17	10.4	16.4	47	14.8	7.2	77	18.6	12.8
18	8.2	0	48	10.2	4.8	78	7.2	10.2
19	14.2	0	49	4.2	0.8	79	4.2	4.2
20	15.8	2.8	50	4.8	0.6	80	8.6	8.8
21	12.9	0	51	18.6	12.4	81	2.8	2.8
22	4.2	0	52	18.2	20.4	82	4.6	4.6
23	8.6	2	53	6.2	19.4	83	4.2	4.2
24	9.4	2.4	54	7.2	15.2	84	5.6	5.8
25	10.6	0	55	4.6	10.6	85	10.6	12.0
26	5.8	3.2	56	4.2	12.6	86	6.2	6.2

27	8.4	6.4	57	18.6	3.2	87	3.4	3.4
28	6.8	0	58	15.8	3.2	88	4.8	4.8
29	4.2	0	59	18.4	9.4	89	5.8	6.2
30	9.6	0	60	17.4	11.2	90	7.2	7.8

Table 2: Results of Psoriasis disability index results(PDI)

Group - I (centesimal)			Group - II (fiftymillesimal)			Group - III (placebo)		
Sl. No.	**Before treatment**	**After treatment**	**Sl. No.**	**Before treatment**	**After treatment**	**Sl. No.**	**Before treatment**	**After treatment**
1	28	3	31	13	0	61	26	25
2	24	8	32	16	0	62	26	24
3	22	0	33	18	2	63	21	18
4	18	4	34	14	0	64	25	22
5	18	2	35	12	2	65	26	20
6	29	10	36	24	4	66	17	18
7	18	3	37	26	5	67	16	16
8	17	5	38	27	0	68	28	28
9	19	3	39	20	0	69	24	24
10	16	0	40	24	3	70	28	29
11	16	28	41	26	3	71	22	23
12	22	4	42	21	1	72	19	19
13	26	0	43	22	5	73	25	27
14	18	3	44	23	3	74	18	18
15	12	0	45	21	0	75	12	12
16	10	0	46	25	1	76	13	15
17	18	24	47	19	8	77	25	20
18	16	0	48	20	5	78	15	18
19	22	0	49	12	2	79	13	13
20	23	3	50	13	0.6	80	16	17
21	20	0	51	26	12	81	10	11
22	12	0	52	27	30	82	12	14
23	16	3	53	13	27	83	13	13
24	17	3	54	14	23	84	13	14
25	18	0	55	12	18	85	18	20
26	13	4	56	14	20	86	14	14
27	16	7	57	26	4	87	12	12
28	14	0	58	23	4	88	13	14
29	12	0	59	26	12	89	13	15
30	17	0	60	25	15	90	15	16

Table 3A: Results of Rri Medicine Group

Types of responses	Number of Patients	Total no. of Patients	Positive Result (%)
Positive response	19	49	81.67%
No relapse			
Reduced	30		
Negative response	11	11	Negative Result (%)
Increased			18.33%
Unchanged	0		

Table 3B: Results of RRI Control Group

Types of responses	Number of Patients	Total no. of Patients	Positive Result (%)
Positive response	6	6	20%
Reduced			
No relapse	0		
Negative response	14	24	Negative Result (%)
Increased			80%
Unchanged	10		

Table 4: Overall Response Results

Category	Positive response no with %	Negative response no with %	Total
Medicine	53(88.3%)	7(11.7%)	60
Control	4(13.3%)	26(86.7%)	30
Total	57	33	90

Statistical Analysis/Discussion

Data were processed first for Kruskul Wallis Test. It was ascertained that computed value was 22.91 > than critical value 5.991 for PASI and computed value was 34.04> than critical value is 5.991 for PDI. Hence H_0 was rejected it implied there was significant difference between three values.

Thereafter data were processed for paired 't' test for PASI Group – I and II. It was ascertained that medicine was significantly effective (because calculated value 't= 1.7507> p value=0.0852 at df,=59,95% confidence interval) in the treatment of psoriasis, in reducing the severity & area affected. In Group – III, it was ascertained that it was not statistically significant (because calculated value 't'=0.8895< p value=0.3811 at df=29,95% confidence interval) in the treatment of psoriasis in reducing the severity & area affected.

Similarly the PDI results were processed for paired 't' test for both Group –I & II. It was ascertained that the medicines were significantly effective (because calculated value=11.6296 > p value is less than 0.0001 at df=59,95% confidence interval) in the treatment of psoriasis in enhancing the quality of life.

Group – III results were not statistically significant (because calculated value=0.0894<than p value =0.9294 at df=29,95% confidence interval) in the treatment of psoriasis in enhancing the quality of life.

Chi-Square test for comparison of R.R.I. in medicine group and placebo group was done, where Chi-Square without Yates correction Chi-Squared equals 32.003 with 1 degrees of freedom. The two-tailed P value was less than 0.0001 was considered to be extremely statistically significant, hence medicines have able to increase the relapse and recurrence interval.

Chi-Square test for comparison of Centesimal and Fifty Millesimal potency was done, where Chi-Square without Yates correction Chi-Squared equals 0.0647 with 1 degree of freedom. The two-tailed P value was less than 0.4212 is considered to be not statistically significant. There is no much difference between two potencies.

Thereafter Chi-Square test for comparison of overall response result of medicine group and placebo group was done, where Chi-Square without Yates correction Chi-Squared equals 48.445 with 1 degrees of freedom. The two-tailed P value was less than 0.0001 is considered to be extremely statistically significant that means medicines are effective in the treatment of psoriasis patients.

Conclusions

1. Constitutional Homoeopathic medicine is the first line of approach to treat a chronic intractable disease like Psoriasis.
2. Homoeopathic medicines do act curatively to the disease which is established by statistics.
3. 50 Millesimal scale and Centesimal scale are equally important in treating psoriasis and there is no superiority of one over another.
4. Homoeopathic medicines are effective in reducing the severity and area affected and enhancing the quality of life.
5. It confirms to the subtle Homoeopathic Philosophy of the Organon of Medicine of Hahnemann, C.S.F. i.e. "The highest ideal of cure is rapid, gentle and permanent restoration of the health and annihilation of the disease in its whole extent, in the shortest, most reliable and most harmless way, on easily comprehensible principle" [30].

Acknowledgement

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Annexture of histogram for table

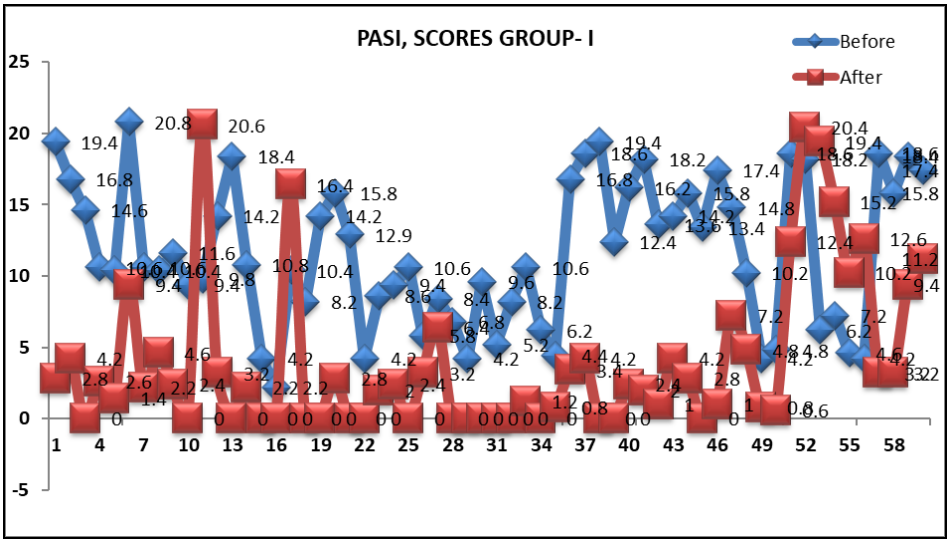

Table 1a: Pasi Result (Centesimal)

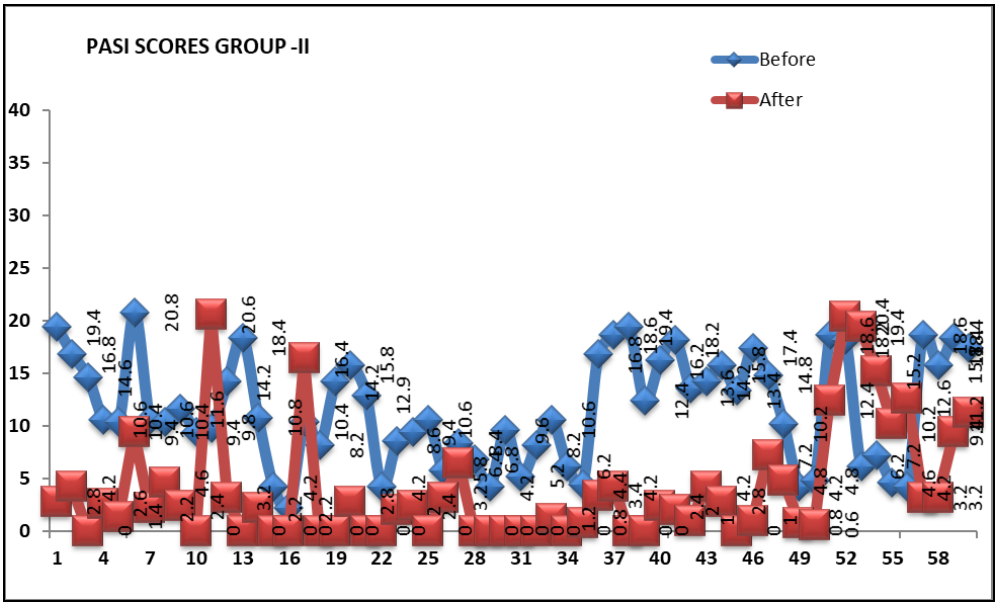

Table 1b: Pasi, Result (Fifty Millesimal)

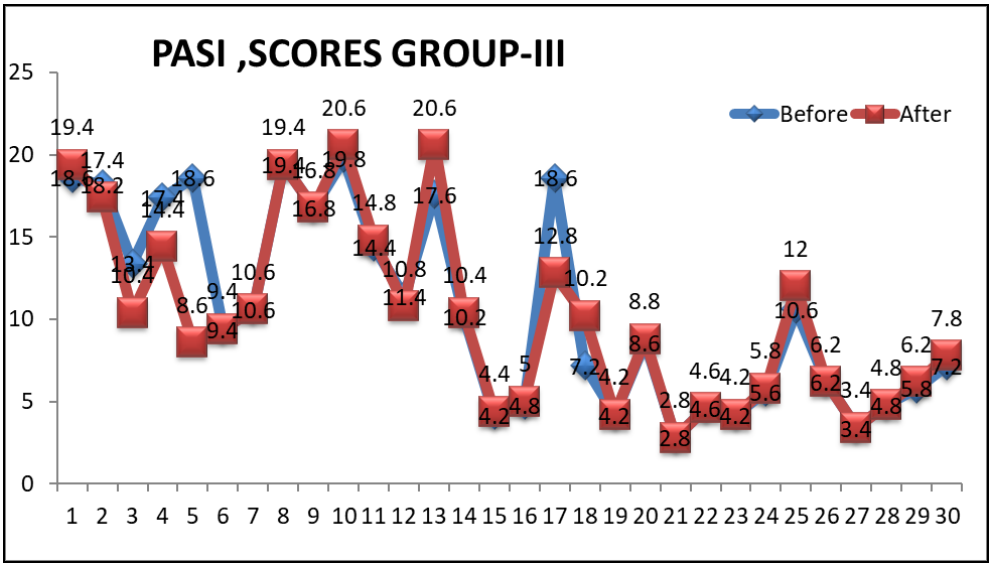

Table 1c: Pasi, Result (Placebo)

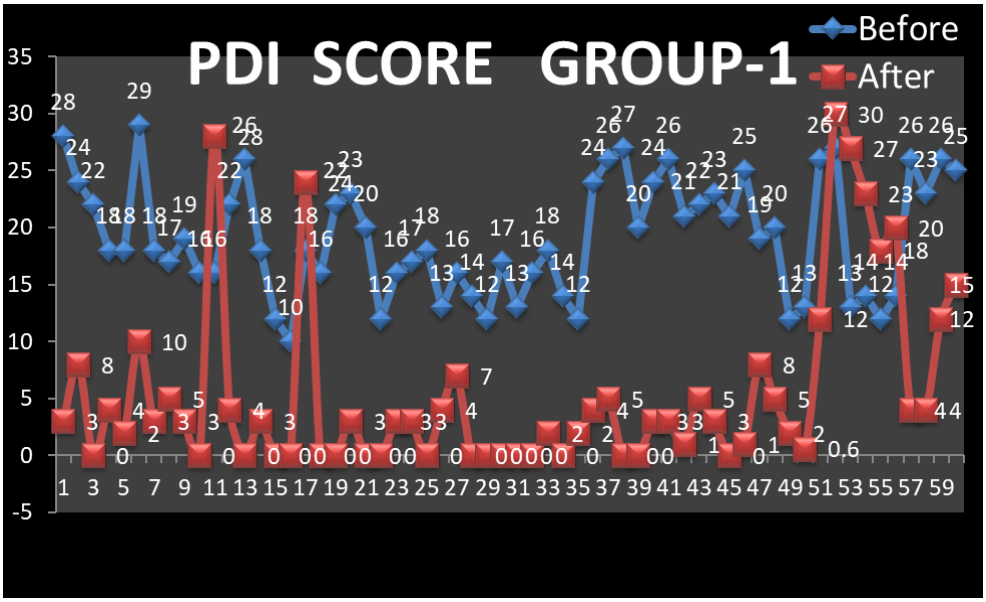

Table 2a: PDI, Result (Centesimal)

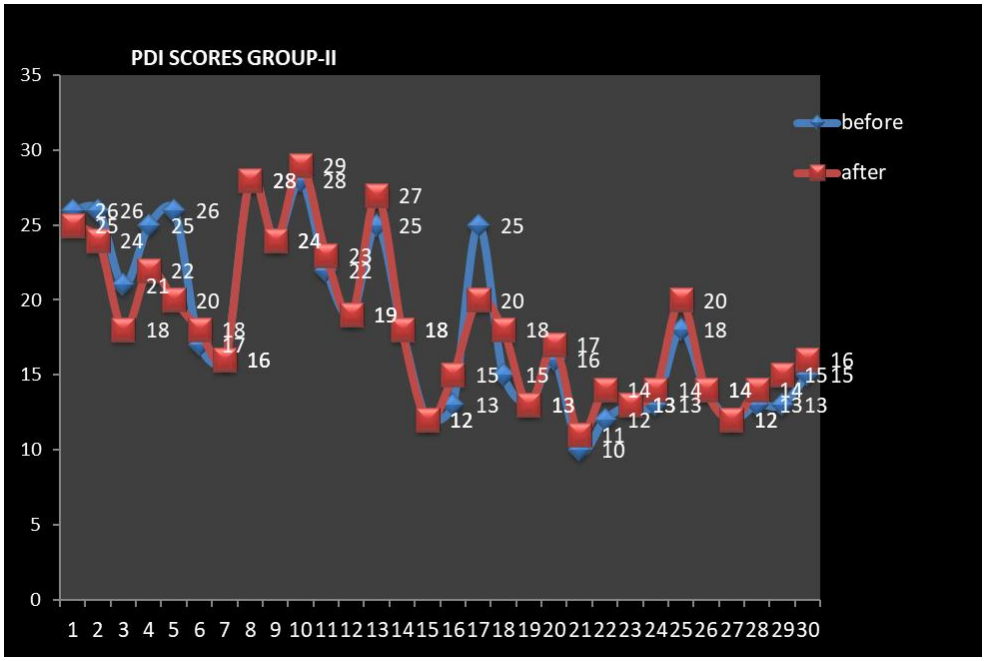

Table 2b: PDI, Result (Fifty Millesimal)

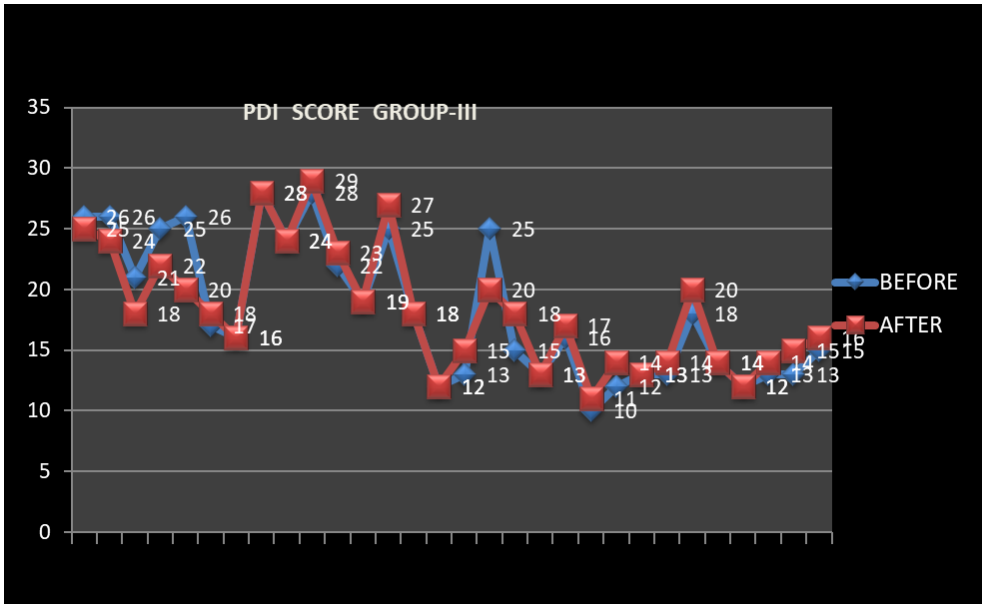

Table 2: PDI, Result (Placebo)

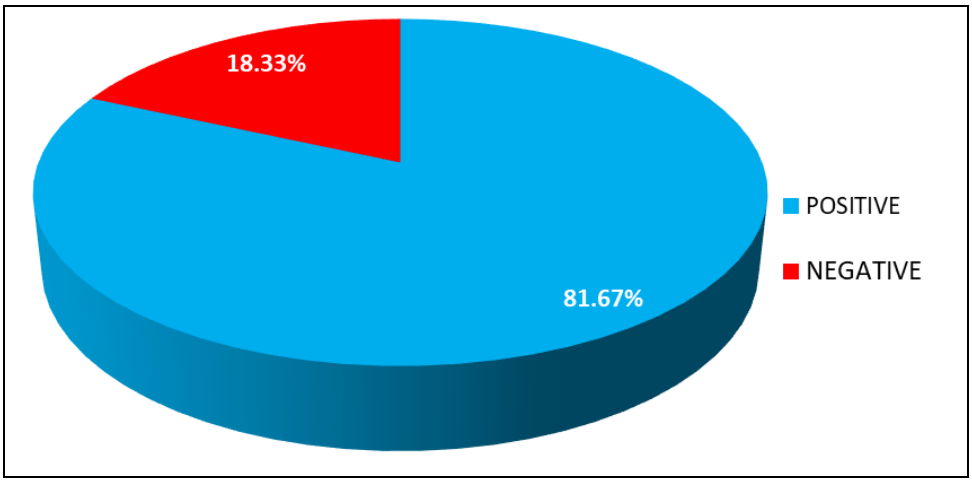

Table 3A: Result of RRI Medicine Group

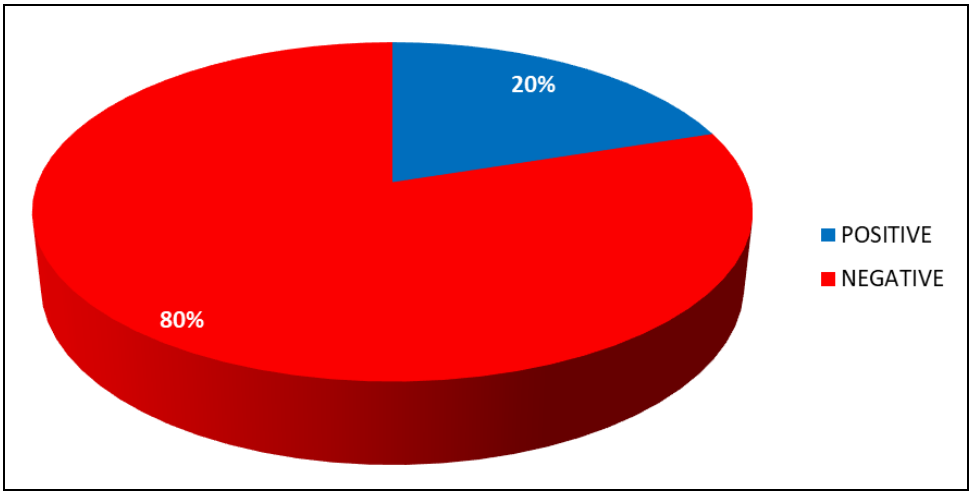

Table 3B: Result of RRI Cotrol Group

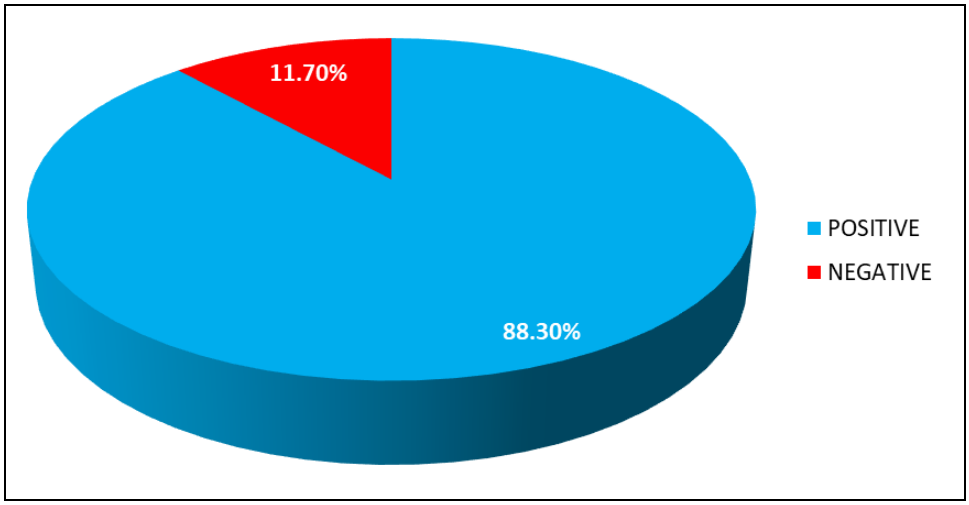

Table 4A: Overall Response Result of Medicin

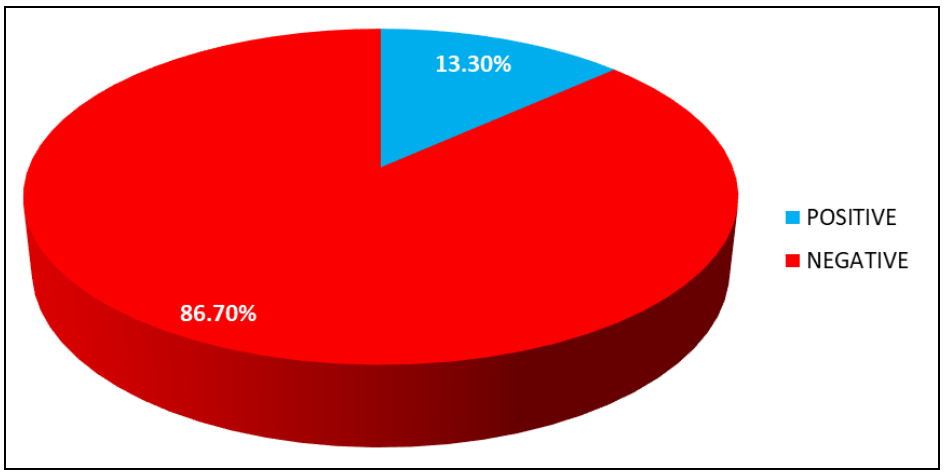

Table 4B: Overall Repon Seresult of Control

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