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MANAGEMENT OF PSORIASIS: A COMPARATIVE CLINICAL STUDY OF STANDARD AYURVEDA & ALLOPATHIC PROTOCOLS

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ABSTRACT

Psoriasis is a common, chronic and non- infectious skin disease characterized by well-defined slightly raised, dry erythamatous macules with silvery scales Modern medicine offers treatment with PUVA, Corticosteroids & Anti mitotic Drugs but therapy gives serious side effects like Bone Marrow depletion, Liver & kidney Failure. While treating Kustha, Ayurvedic Classics especially focused on *Panchakarma Treatment. So Vaman, Virechana & Laghu-Manjisthadi Ghan* was selected for trial. Total 30 well diagnosed patients were selected & divided in two groups. One group receiving Ayurvedic Treatment & other Allopathic Regimen (Tb. Methotraxate7.5 mg/week) for 2 months & comparative study was done. Assessment was done on improvement in clinical symptoms as well as on Laboratory parameters.

Keywords: PUVA, Methotrexate, Psoriasis

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1. INTRODUCTION

Psoriasis is a papulosquamatous disorder of skin characterized by sharply defined erythamatous lesions. It is notoriously chronic & is well known for its course of remission & exacerbation. In India approx 80 lakhs (0.8%) Population is affected by this dreadful disease. The exact cause is still unknown. The intensity of disease is such high that to increase awareness among people, patients & doctors **29 October** is officially declared as **"World Psoriasis Day".** Modern medicine offers treatment with PUVA, Corticosteroids & Antimitotic Drugs. But therapy gives serious side effects like Bone Marrow depletion, Liver & kidney Failure.

Classical Ayurveda treats this disease as a one of a type of Kustha. Besides all treatments while treating the *Kustha* all *Acharyas* specially focused on P*anchakarma (Shodhana Therapy)* to control & to prevent the remission. As Kustha is also described as one of a Raktapradoshaj *vyadhi* so *Laghumanjisthadi Ghan* having *Raktashodhak, Raktaprasadak, kushthaghna kandughna* properties was selected for trial & a clinical comparative study was done.

Need of Study

A lot of research work has been done on treatment of Psoriasis in both modern & Ayurveda Sciences & lot of is still going on. Each science has its own claims over the management & success rate. But still a promising cure for Psoriasis is not found. According to the survey of the US National Psoriasis Foundation on 40,350

patients shows that **78% of severe psoriatic Patients were still frustrated by the lack of efficacy of treatment**. Archives of Dermatology (2001) So now a day it became essential to find out a safe, economic, effective treatment for psoriasis.

2. AIMS & OBJECTIVES

Present study was undertaken with following aims & objectives

- Conceptual & clinical study on Psoriasis according to *Ayurveda* as well as Modern science on various scientific parameters.
- Clinical evaluation of role of *Vaman, Virechana & Laghu-Manjisthadi Ghana* in Management of Psoriasis.
- A comparative clinical study of trial drug along with standard allopathic regimen.

3. MATERIALS & METHODS

Selection of patients

The study was conducted on 30 clinically diagnosed & confirmed cases of Psoriasis from OPD & IPD section of **National institute of Ayurveda Jaipur & S.M.S. Medical College & hospital Jaipur**.

Criteria of diagnosis

The main criteria of diagnosis of patients were based on the cardinal and associated signs and symptoms of the disease based on the Ayurvedic and modern texts. These have been depicted in detail in the criteria of inclusion.

Inclusion criteria

1) Patients between the age group of 15 to 60 yrs in either sex presenting clinical symptoms of disease.
2) Patients willing to sign the consent form.

Exclusion criteria

1) Patients with age below 15 & above 60 yrs.
2) Pregnant women's & lactating mothers.
3) Patients suffering from serious systemic disorders like Diabetes Mellitus, Cardiac & Renal Disorders, Malignant disease etc.
4) Patients Contraindicated for Vaman & Virechana as per classical Ayurvedic Texts.

Method of study (protocol of Study)

Consent

Written informed consent was taken on prescribed Performa before the inclusion of patient in trial. They are briefed about merits and demerits of research plan before taking consent.

Therapeutic study

- **Selection of the trial drug:** Drug selected for current clinical trial was **Laghu Manjisthadi Ghana**. Tripathi (2008)
- **Dose:** 2 gm / day (2 Capsules BD).
- **Duration of Trial:** 2 months.

- **Randomization of patients:** All the patients fulfilling the criteria of diagnosis and inclusion were randomly divided into two groups named as Trial Group A & Trial Group B consisting 15 patients each.

1) **Group A:** 15 registered patient of Psoriasis was administered ***Laghu-Manjisthadi Ghan*** capsule 2 BD after Vaman & Virechana.
2) **Group B:** 15 registered patient of Psoriasis was administered Standard allopathic drug named Neotrexate **(Methotrexate) 7.5 mg / week** (2.5mg for 3 times at 12 hourly 8pm- 8 am-8pm/week) under observation of concern expert supervisor.

For local application patients in Group A were advised to apply Panchatikta ghrita & in Group B routine allopathic topical application Protar lotion (Coal Tar 5%) was advised as per instruction of supervisor

Method of preparation

- The ingredients of the trial drug i.e. ***Manjistha, Guduchi, Haritaki, Amalaki, Vibhitaki Vacaha, Daruharidra, Nimb & Kutaki*** were taken into equal amount and decoction was made per instructions in *Sharangdhar Samhita*. Then the decoction was again heated on water bath & active extract was collected then Capsules of 500 mg each was made in pharmacy of NIA Jaipur.

Vaman Karma

- Procedure of Vaman was carried out as follows, *Pachana* with ***Panchkol Churna*** 3 gm BD for 3 days, Snehpan was done with ***Panchtikta grhit*** till samyak sneh lakshana was observed, then Sarvang Snehan Swedan was done. *Vaman* was induced by ***Madanphaladi yoga*** (*Madanphal Pippali + Vacha+ Saindhav+ Honey*) then Dhoompan & Sansarjankram was carried out.

Virechana Karma

- *Pachana* with *Panchkol churna* 3 gm BD for 3 days after that Snehpan with ***Panchtikta Grhit*** till *samyak Sneha lakshana* were observed then *Sarvang snehan Sweden* for 2 days & Virechana with ***Abhayadi Modak*** Tripathi (2008) was done. Proper *Sansarjankram* was advised.

Criteria for Assessment

Assessment of clinical improvement was done according to severity of sign & symptoms. To assess the efficacy of treatment following criteria was adopted.

Subjective Criteria

PASI SCORE (Psoriasis area & Severity Index)

PASI Score was considered as both subjective & objective criteria as it covers both subjective as Erythema, scaling & indurations and objective parameters as coverage area.

Kandu (Itching index)

Symptom rating scale was as follows

0: No Itching

1: Mild Itching comes occasionally, duration 2/3 min,

2: Moderate itching occurs frequently, lasts for longer time, scratching is essential.

3: Severe Itching, occurs frequently, lasts More than 20-30 min, bleeding on Scratching.

Daha (Burning index)

Symptom rating scale was as follows

0: No burning.

1: Mild burning comes occasionally, duration 2-3 min.

2: Frequent burning sensation more than 3 times last for 10 min.

3: Severe burning sensation more than 5 times, lasting more than 15 min, disturbs daily routine.

Laboratory Parameters

Routine blood Investigation (Hb%, TLC, ESR).

Liver function test (SGOT, SGPT)

Overall Effect of Therapy

Each patient was assessed on the basis of signs & Symptoms of the disease on the basis of grading pattern as well as percentage relief, patients were classified as follows.

Complete improvement	100% relief
Marked improvement	More than 75% relief
Moderate improvement	50 to 75 % relief
Mild Improvement	25 to 50 % relief
No Improvement	Below 25 % or no relief

4. OBSERVATION & RESULTS

All selected patients successfully completed the trial. Obtained observations were analyzed statistically with the help of INSTAT GRAPHPAD 3 & the obtained results are as follows:

(Wilcox son matched pair single ranked test was applied.)

Table 1 showing effect of Therapy in Subjective Parameters

Variable	Group	Mean		MeanDiff.	% Relief	SD±	SE±	p	S
		BT	AT						
PASI Score	Gr. A	21.8	6.99	14.28	67.13	8.30	2.14	0.0001	HS
	Gr. B	19.32	5.97	13.35	69.09	7.29	188	0.0001	HS
Kandu *(*Itching Index*)*	Gr. A	2.66	1	1.66	62.5	0.72	0.98	0.0001	HS
	Gr. B	2.46	1.13	1.13	54.06	0.72	0.16	0.0002	HS

Daha (Burning Index)	Gr. A	1.4	0.6	0.8	57.14	0.41	0.10	0.0005	HS
	Gr. B	1.13	0.53	0.6	52.9	0.63	0.16	0.0078	S

(HS: highly Significant S: Statistically Significant NS: Non-Significant)

Effect on Total PASI Score

In **Group A** the mean PASI Score of before treatment was 21.82. It lowered down to 6.99 with SD±8.30 giving a relief of 67.13 % which was statistically **highly significant**.

In **Group B** the mean PASI Score of before treatment was 19.32. It lowered down to 5.97 with SD± 7.29 giving a relief of 69.09 % which was statistically **highly significant**.

Effect of Drug on Kandu (Itching Index)

In **Group A** Mean Itching index before treatment was 2.66 which was reduced to 1 showing 62.5 % relief which is statistically **highly significant**.

In **Group B** mean Itching index before treatment was 2.46 which was reduced to 1.33 showing 54.05 % relief which is statistically **highly significant**.

Effect of Drug on Daha (Burning Index)

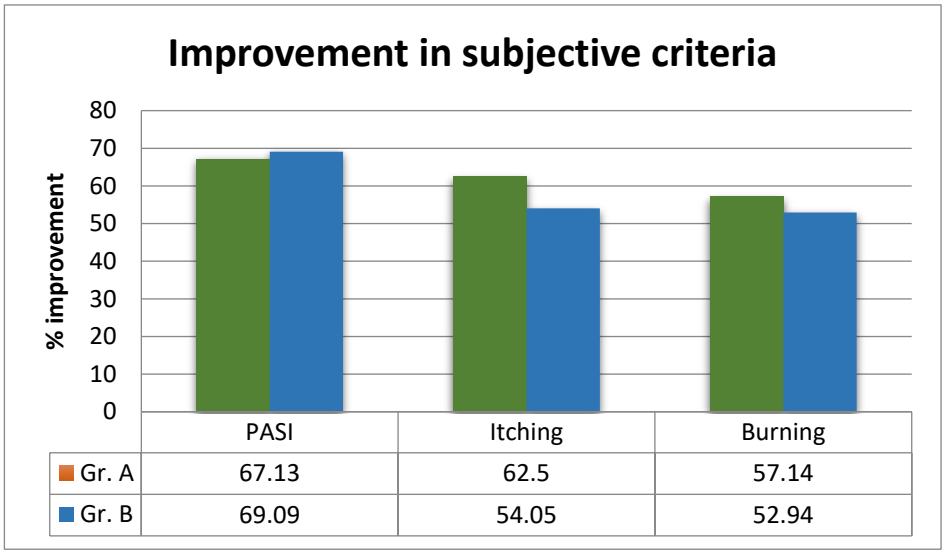
In **Group A** mean burning index before treatment was 1.4 which was reduced to 0.6 showing 57.14 % relief which is statistically **highly Significant**.

In **Group B** mean burning index before treatment was 1.13 which was reduced to 0.53 showing 52.9 % relief which is statistically.

Table 2: Calculation Details of Wilcox son matched pair test are as follows

Variable	Group	W	T+	T-	No. of Pairs
PASI Score	A	118.00	119.00	-1.000	15
	B	118.00	119.00	-1.000	15
Itching Index	A	105.00	105.00	0.000	14
	B	91.000	91.000	0.000	13
Burning Index	A	78.000	78.000	0.000	12
	B	36.000	36.000	0.000	8

(W= Sum of all Signed ranks, T+ = sum of Positive ranks, T-= Sum of negative ranks)



Graph no 1: Showing Improvement in subjective criteria.

Intergroup Comparison

To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric, we used **Mann-Whitney Test** for stastically analysis. The results are as follows

Table 3: showing Intergroup Comparison of Group A & Group B

Variable	Groups	Mean diff.	SD±	SE±	P	S
PASI Score	A	14.28	8.30	2.14	0.7400	NS
	B	13.35	7.29	1.88		
Itching Index	A	1.66	0.732	0.1869	0.2224	NS
	B	1.33	0.732	0.1869		
Burning Index	A	0.8	0.141	0.1059	0.2473	NS
	B	0.6	0.632	0.1633		

Intergroup comparison shows that for all variables p value is statistically non-significant which clearly indicates that there is **no statistically significant difference** in the efficacy of the both drugs.

Table 4: Showing Calculations Details of intergroup comparison:

Variable	U	U'	Sum of ranks in Gr. A	Sum of ranks in Gr. B
PASI Score.	104.00	121.00	241.00	224.00

Itching.	85.500	139.50	259.50	205.50
Burning.	88.500	136.50	256.50	208.50

(U= Manwhitney's U statistics)

Effect of Drug on Laboratory Parameters

- **Hematological Investigations**

Patients were advised to go for lab investigation before & after Treatment. Data collected was analyzed & students **Paired 't' Test** was applied. The results found are as follows...

Table 5: showing improvement in Hematological Investigations

Variables	Group	AT	BT	Diff	% Imp	SD±	SE±	t	p	S
Hb%	A	14.4	15.03	0.56	3.86	0.52	0.13	4.11	<0.01	S
	B	14.02	14.14	0.12	0.9	0.46	0.12	1.05	<0.1	NS
TLC	A	6786.6	6766.6	20	0.29	174.2	44.93	0.44	<0.1	NS
	B	6153	6180	26.66	0.43	174.9	44.95	0.59	<0.1	NS
ESR	A	34.73	20.4	14.33	41.26	13.35	3.44	4.15	<0.001	HS
	B	29.33	18.93	10.4	35.4	9.50	2.45	4.23	<0.001	HS

- **In Group A**

HB%: Mean Hb% before treatment was increased from 14.4 gm% to 15.03 having 3.86 % improvement which is statistically **significant**.

TLC: Results obtained in TLC were **not significant**.

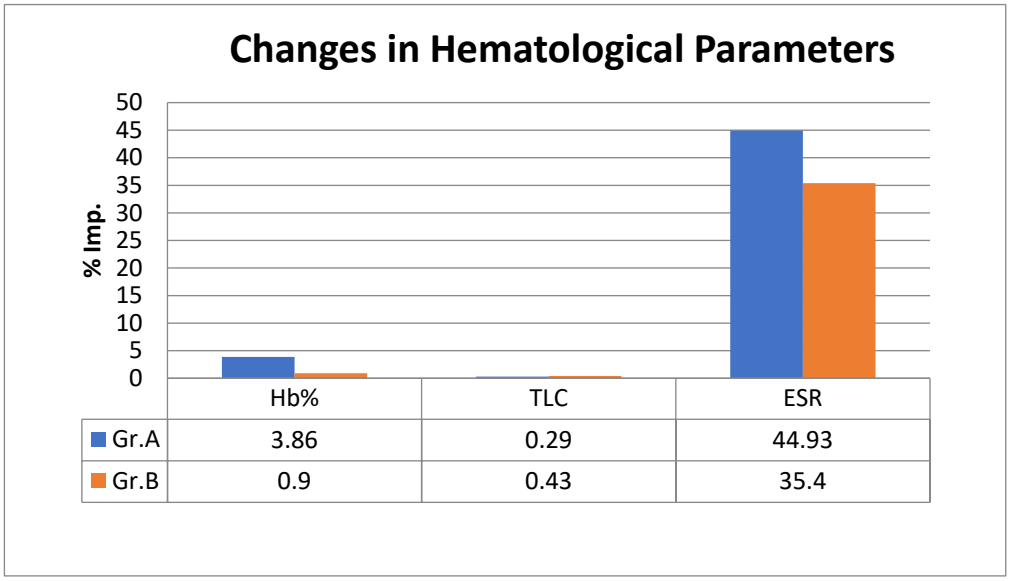
ESR: Mean ESR before treatment was reduced from 34.73 to 20.4 mm/ hr showing 41.26 % improvement which is stastically **highly significant**.

- **In Group B**

HB%: Mean Hb% before treatment was increased from 14.02gm% to 14.14 having 0.9% % improvement which is statistically **non-significant**.

TLC: Results obtained in TLC were **not significant**.

ESR: Mean ESR before treatment was reduced from 29.33 to 18.93 mm/ hr showing 35.4 % improvement which is stastically **highly significant**.



Graph 2: Showing changes in Hematological parameters.

Effect on Liver Function Test:

Changes in Liver function tests before & after treatment are as follows...

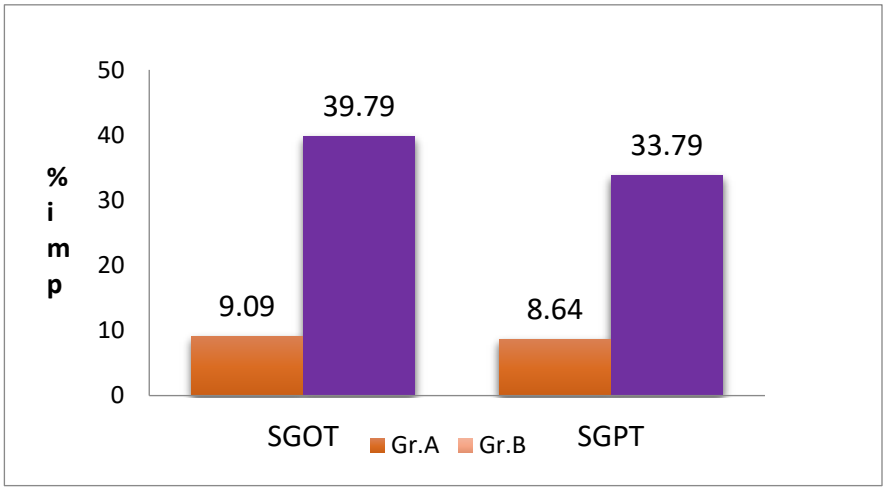
Table 6: Showing Effect of Drug on LFT.

Variable	Group	AT	BT	Diff	% Imp	SD±	SE±	t	p	S
	A	26	28.06	2.06	9.09	5.57	1.44	1.80	<0.05	NS
SGOT	B	26.13	36.53	10.4	39.79	9.68	2.50	4.14	<0.01	S
	A	26.06	28.53	2.46	8.64	4.35	1.12	2.19	<0.05	NS
SGPT	B	29	38.8	9.8	33.79	10.5	2.59	3.77	<0.01	S

Changes occurred in SGOT & SGPT were not significant in Group A

In Group B

- **SGOT:** Level of SGOT was increase from 26.13 to 36.53, showing 39.79 % increase which is **statistically significant**.
- **SGPT:** Level of SGPT was increase from 29 to 38.8, showing 33.79 % increase which is **statistically significant**.



Graph 3: showing changes in LFT.

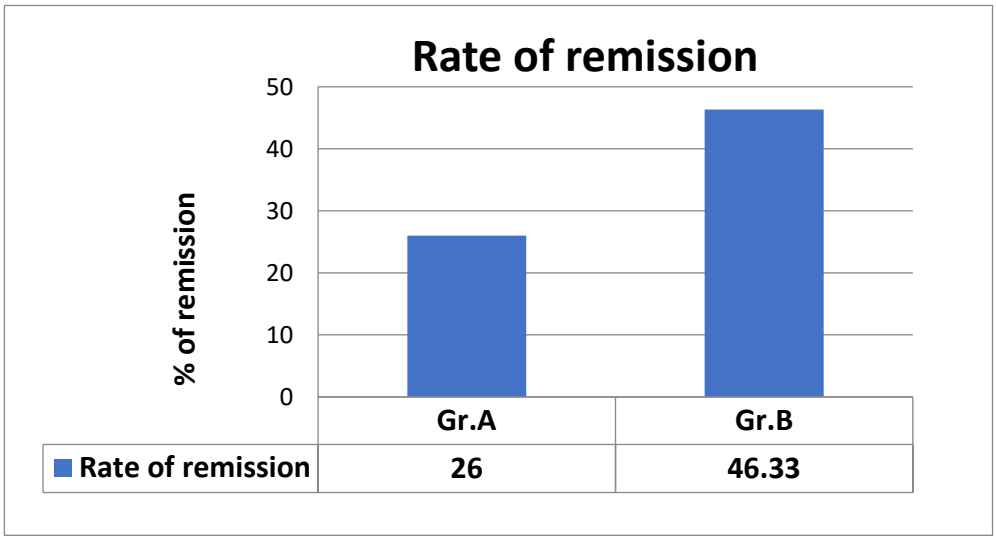
Overall effect of Therapy

In Group A: Complete improvement was observed in 20% patients; marked improvement was observed in 66.66% patients, moderate improvement was observed in 13.33% patients.

In Group B: Complete improvement was observed in 20% patients; marked improvement was observed in 40% patients, moderate improvement was observed in 33.33% patients & 6.66% Shows Mild improvement.

Follow up Study

Follow up study was done at **30 days & 60days** after successful completion of trial it shows that in group A out of 15 patients at the end of 2 months only 4 patients **(26%)** show signs of remission on other hand in group B, 7 out of 15 patients **(46.66%)** shows signs of remission.



Graph 4: Showing Rate of remission in both groups.

5. DISCUSSION

Probable Mode of Action

Laghu Manjisthadi Ghana

1) Main content of *Laghu-Manjisthadi Ghana* is Manjistha which has *Raktashodhana & Raktaprasadan Kusthaghna, Vishaghna, Varnya, property*. Chunekar (2009) According to *Ayurveda Yakrut* & *Pleeha* (Liver & Spleen) are site of formation of *Rakta dhatu*. Shatri (2003) *Kutaki, Daruharidra, Amruta* are having potent Hepatoprotective action. These drugs act on the formation site of the *Rakta dhatu* & break the basic pathogenesis of *Kustha*.
2) Recent research studies shows that Manjistha has potent inhibitory action on **HaCa T cell** Proliferation Wai-Pui et al. (2006) which plays key role in establishment of Psoriasis. It also has potent role in **inhibiting Keratinocyte's proliferation** Lin et al. (2010). This helps in reducing the rapid shading of epithelium in psoriasis.
3) Mollugin one of active principle of Manjistha showed inhibition of passive cutaneous anaphylaxis (PCA) and **protection of mast cell degranulation in rats**. Gupta et al. (1999) This reveals it has potent Anti-Itching & Anti-Allergic Property.
4) *Guduchi, Amalaki, Haritaki, Vibhitaki, Manjistha* has potent Anti-inflammatory, Analgesic, Antibacterial, Immunomodulatory, Antioxidant property Database on medicinal plants used in Ayurveda (2000). It plays key role in reducing inflammation & early prematuration of cells.
5) Stress is one of the major trigger factors for disease; *Vacaha* having potent *Medhya* property helps in reducing stress Database of medicinal plants used in ayurvead (2000).
6) Drugs like *Amruta, Amalaki, Haritaki; Vibhitaki* has potent *Rasayan* property which helps in preventing the multiple relapses of the disease by strengthening body's own immune system. Shatry (2006)
7) According to *Ayurveda* treatment procedure *kosthashodhan* is the basic step in the management of *Kustha*. *Triphala* is the main ingredient of *Laghu-Manjisthadi Ghana* which is the one of the best medicines having property of *Kosthashodhana*.
8) *Panch Tikta Ghrita* contains *Vasa, Nimb, Patol, Guduchi & Kantakari*. All these drugs have *Tikta rasa, Kandughna* & *kusthagna property* Chunekar (2009).
9) According to dermal drug delivery system of modern science skin shows the better absorption of lipid & lipid soluble substances than water soluble molecules Katare et al. (2010). So according to this theory Panchatikta ghrita shows better penetration in skin than other *snehas* with carrying properties of drugs added to it.
10) The patches of Psoriasis are dry & Scaly. The *Panchatikta ghrita* provides proper moisture to it resulting in slowing of rapid turnover of epithelium.
11) When scales of psoriasis are removed tiny bleeding points (Auzpits sign) are observed. As *Tikta & Kashaya* rasa has potent *vranshodahan & vranropan* property Shatry (2003) & Ghrita is well known for its healing action results in proper early healing of lesions of Psoriasis.
12) *Vamana & Virechana* acts on microcellular level, eliminates the toxins (Vitiated *doshas*) from body & helps in maintaining normal functioning of body. It strengthens the immune mechanism and helps in preventing relapse.

6. CONCLUSION

- Both the groups show considerable efficacy which is highly significant clinically as well as statistically (P<0.001) however intergroup comparison shows that there is no major difference in efficacy of *Ayurvedic* trial drug & control Allopathic drug. It suggests that *Ayurvedic* formulation is as much potent as Methotrexate in controlling the disease.
- The above data reveals that both drugs show highly significant results in reducing the PASI Score. Better resonse was seen in *Kandu & Daha* in patients treated with *Ayurvedic* formulation.
- In liver function test significant increase in SGOT & SGPT levels were observed in patients treated by Allopathic drug. Though the increased SGOT &SGPT were in normal ranges it suggests that prolonged administration of drug may detoriate Liver functions. While in patients with *Ayurvedic* formulation no significant changes were observed. Thus, *Ayurvedic* formulation has distinct advantage in safety profile over Allopathic counterpart.
- Significant reduction in ESR which is supposed to be an inflammatory marker proves potent Anti-inflammatory action of *Ayurvedic* Trial drug.
- Relapse is major problem in treatment of Psoriasis. Ayurvedic trial drug shows **26%** relapse rate as compare to Methotrexate showing **46.33%** relapse. It shows that *Ayurvedic* drug is more potent in preventing the relapse of disease than Allopathic counterpart.

Thus, it can be concluded that Ayurvedic trial Formulation has potent action in controlling disease as well as it is much better in preventing the recurrent relapse than standard allopathic regime. In safety profile Ayurvedic formulation has distinct advantage over allopathic counterpart.

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