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ORIGINAL RESEARCH ARTICLE

A Comparative Clinical Study to Evaluate the Effect of Sigru Leaf Powder and Sigru Bark Powder in the Management of Sannipatika Pandu with Reference to Sickle Cell Anemia

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ABSTRACT

Background: Various ailments are related to *Panduroga*, either as a symptom or as an *Upadrava*, according to Ayurvedic literature. The present clinical study is a humble effort to assess the effect of the trial drug, *Sigru* leaves powder and *Sigru* bark powder on *Sannipatika Pandu* (sickle cell anemia).

Materials and Methods: A total of 30 patients of Sannipatika Pandu (sickle cell anemia) were taken for the present study, 15 patients each in Group A (Trial Group-1) and Group B (Trial Group-2). This is a clinicopathological study (single-blind study). Group A (Trial Group-1): 15 patients were treated with Sigru leaves powder 3 g twice daily with water for 30 days after food. Group B (Trial Group-2): 15 patients were treated with Sigru bark powder 3 g twice daily with water for 30 days after food.

Results and Discussion: As per the statistical tests, we can conclude that there is no significant change observed in Group A and Group B.

Conclusion: It is found that the trial medications can be safely supplied to everyone for an extended period of time and may offer the best chance of recovery for sickle cell anemia.

1. INTRODUCTION

Charak Samhita describes the general etiology or *Samanya Nidana* of *Sannipatika Pandu roga*.^[1] All of these elements are mostly related to *Aharaja*, ^[2] *Viharaja*, and *Nidanarthkar roga*.^[3] The term "*Nidana*" appears in Ayurvedic classics in the broadest sense. This word is derived from the Sanskrit Dhatu "*Ni*," which means "carrier," identifying the meaning (*Ni*—*Nishchaya Deeyate Jnanam*). This term either refers to the disease's etiopathogenesis in general or the etiology of the sickness in particular. *Panduroga*^[4] is a clinical condition characterized by whitishyellow discoloration of skin, eyes, nails, etc. The person with this disease suffers from decreased blood amount, strength, and complexion. He becomes *Nihsara* (loss of natural integrity, tone, and strength of Dhatus).

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Various ailments have been linked to *Panduroga*, [5] either as a symptom or as an *Upadrava*, according to Ayurvedic literature. All of these can be *Sannipatika Panduroga* causes or *Nidanarthakara rogas* of *Sannipatika Panduroga*. *Raktatipravartana*, *Raktarsha*, *Raktarbuda*, *Asrigdara* or *Raktapradara*, [6] *Arsha Raktarsha* or *Kaphajarsha*, *Rajayakshma*, and *Punaravartaka* are a few examples. Although *tridosha* is the most important factor in the appearance of *Sannipatika Panduroga*, [7] *Vata* and *Kapha* are also involved. The present clinical study is a humble effort to assess the effect of the trial drug, *Sigru* leaves powder and *Sigru* bark powder on *Sannipatika Pandu* (sickle cell anemia).

1.1. Aims and Objectives

- To find the effective treatment of sickle cell anemia in Ayurveda.
- To evaluate the effect of Sigru leaf powder and Sigru bark powder.

2. MATERIALS AND METHODS

2.1. Ethical Clearance

The study was approved by the Institutional Ethical Committee (IEC), Government Ayurvedic College and Hospital, Balangir, vide Letter No.1084/G.A.C and H of dated May 26, 2021, and also registered in Clinical Trial Registry of India (CTRI; www.ctri.nic.in) vide Registration No.-CTRI/2022/09/045910 on dated September 27, 2022. The study has been conducted among the patients registered for the purpose. Written consent was obtained from each patient who participated in the study with prior proper information.

2.1.1. Source of patients

Patients were selected from OPD and IPD of Government Ayurvedic College and Hospital, Balangir, and Sardeswari Government Ayurvedic Hospital, Balangir. The clinical study period of 30 patients was from dated July 06, 2022, to March 06, 2023.

2.1.2. Study design

This is a clinicopathological study (single-blind Study).

2.2. Grouping

2.2.1. Method of collection of patients

A total of 30 patients of Sannipatika Pandu (sickle cell anemia) were taken for the present study, 15 patients each in Group A (Trial Group-1) and Group B (Trial Group-2). They were screened by a special pro forma which included details of history taking, physical sign and symptoms, and pathological investigation mentioned in classics and modern science. The patient examination pro forma is placed in the appendix of this dissertation.

2.2.2. Methodology

Group A (Trial Group-1): 15 patients were treated with Sigru leaves powder 3 g twice daily with water for 30 days after food. Group B (Trial Group-2): 15 patients were treated with Sigru bark powder 3 g twice daily with water for 30 days after food.

2.2.3. Duration

30 days.

2.2.4. Single group design

Gr-A (BT) Vs Gr-A (AT) Effectiveness of treatment-1 (Trial group A) was assessed.

Gr-B (BT) Vs Gr-B (AT) Effectiveness of treatment-2 (Trial group B) was assessed.

(Gr= Group, BT=Before Treatment, AT=After Treatment).

2.2.5. Double group design

Group A (AT) versus Group B (AT) comparison of effectiveness of treatment of both (Trial group) was assessed.

2.3. Diagnostic Criteria

The patients were diagnosed on the basis of multiple parameters (*Trividha*, *Ashtavidha*, *Dashavidha Pariksha*). Clinical signs and symptoms as described in classical text were considered for the diagnosis of *Sannipatika Pandu*.

- Panduta, Durvalata, Angamarda, Jwara, Swasa, Aruchi, Gourava, Mala-Mutra, and Netraswetata
- Complete blood count (CBC)
- Sickling test (24 h method).

2.4. Inclusion Criteria

- Patients with sickle cell trait and disease
- Hemoglobin >6 g/dL
- Patients not having any bleeding disorder
- Age group 10–50 years.

2.5. Exclusion Criteria

- Age <10 and >50 years
- Hemoglobin <6 g/dL
- Anemia induced by drugs
- Malignancy and any life-threatening condition
- Pregnant and lactating women
- Patients taking immunosuppressive medicines such as steroids
- Viral hepatitis, aplastic anemia, osteoporosis, and osteopenia will be excluded from the study
- Organ failure and other complications.

2.6. Assessment Criteria

For the purpose of the assessment of result, severity of the signs and symptoms will be graded as 3, 2, 1, and 0 grade for severe (+++), moderate (++), mild (+), and normal (0) accordingly. The detail pathogenesis of clinical study will be carried out based on *Trividha*, *Sadvidha*, and *Dashavidha parikshya* as per Ayurvedic classics.

2.6.1. Subjective

The subjective signs and symptoms such as weakness, loss of appetite, fatigue, giddiness, breathlessness on exertion, and glossitis will be graded as per their severity as grade 3, 2, 1, 0.

2.6.2. Objective

Objective signs and symptoms such as pallor, edema, splenomegaly, and hepatomegaly will be graded on the basis of their severity. Laboratory investigation parameters such as CBC, ESR (per hour), sickling test (24 h method), hemoglobin (Hb) electrophoresis, blood peripheral smear, serum urea, and serum creatinine test are also being done. As the improvement will be observed during the trial the grading of features, the assessment will be shifted back accordingly.

2.7. Grading

2.7.1. Dose and administration procedure

- Sigru twak churna
 - For adult, 3 g twice a day after food for 30 days
 - For children 1.5 g twice a day after food.
- Sigru patra churna
 - For adult, 3 g twice daily after food for 30 days
 - For children, 1.5 g twice a day after food.
- Anupana
 - Water
- Dietary regimen
 - The patients will be advised to take the usual diet.

2.8. Follow-up

Follow-up was done every 15-day gap, i.e., 15th and 30th days of the clinical trial. During follow-up, an assessment of both subjective and objective parameters was done to assess the result.

2.9. Assessment for Result

The degree of severity as per the above gradation criteria and data collected from pathological investigations as mentioned in table 1 after 15 days (AT1) and 30 days (AT2) of treatment was assessed. The assessment has been done in two stages as follows:

2.9.1. Clinical assessment

The average percentage improvement in the severity of different clinical sign and symptoms was calculated. The overall clinical assessment has been done considering the sign and symptoms as follows:

- Marked Improvement: 73.33% relief in signs and symptoms
- Moderate Improvement: 26.67% relief in signs and symptoms
- Mild Improvement: 0.00% relief in signs and symptoms
- Unsatisfactory: 0.00% relief in signs and symptoms.

2.9.2. Statistical analysis

The subjective and objective data, such as the sign and symptoms, CBC, gathered from the patients were subjected to statistical analysis. Data were analyzed statistically in terms of mean, median, standard deviation, Wilcoxon-W test, and P-value. The statistical analysis after 15 days (AT1) and 30 days (AT2) of treatment had been done. For the effectiveness of Trial drug-1 and Trial drug-2, Mann–Whitney-U test was used. The effectiveness of Trial drug-1 and Trial drug-2 had been assessed through the *P*-value.

The P-value was interpreted as

- >0.05 statistically insignificant at 5% level
- <0.05 significant at 5% level
- <0.01 significant at 1% level
- <0.005 significant at 0.5% level
- <0.001 highly significant at 0.1% level.

3. RESULTS

In the present study, 30 patients of *Sannipatika Panduroga* were registered, out of which 15 patients were treated under Group A and 15 patients were treated under Group B. General data of 30 patients of *Sannipatika Panduroga* registered for the present study are being presented here in tabular form (Graph 1).

3.1. Registration of Patient

A total of 30 patients (Group A and Group B) were registered randomly in two groups, and all the patients had completed the study.

3.2. Individual Assessment of Subjective Parameters (Table 2)

3.2.1. Panduta (pallor)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank Test to test efficacy in Group A and Group B. We can observe that *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.2.2. Dourbalya (weakness)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, P-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.2.3. Angamarda (body ache)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.2.4. Jwara (fever)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that effect observed in Group A and Group B is not significant.

3.2.5. Swasha (dyspnea)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that *P*-value for Group A and Group B is >0.05. Hence, we can conclude that effect observed in Group A and Group B is not significant.

3.2.6. Gaurava (heaviness)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

3.2.7. Aruchi (loss of appetite)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.2.7.1. Liver: (hepatomegaly)

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.2.7.2. Spleen

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that effect observed in Group A and Group B is not significant.

3.3. Individual Assessment of Objective Parameters (Table 3)

3.3.1. Total leukocyte count

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, P-value for Group A and Group B is >0.05. Hence, we can conclude that effect observed in Group A and Group B is not significant.

3.3.2. Hb%

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that effect observed in Group A and Group B is significant.

3.3.3. Mean corpuscular Hb

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that effect observed in Group A and Group B is not significant.

3.3.4. Mean corpuscular Hb concentration

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that, effect observed in Group A and Group B is not significant.

3.3.5. Mean corpuscular volume

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

3.3.6. Packed cell volume

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

3.3.7. Total red blood cells

Since observations are on ordinal scale (gradations), we have used Wilcoxon signed-rank test to test efficacy in Group A and Group B. We can observe that, *P*-value for Group A and Group B is <0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

Mann—Whitney U test is carried out for comparison between Group A and Group B. We can observe that, *P*-value for almost parameters is >0.05. Hence, we can conclude that, there is no significant difference observed between Group A and Group B.

3.4. Differential Count (Table 4)

3.4.1. Neutrophil

Since observations are quantitative, we have used paired t-test to test significance in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that there is no significant change observed in Group A and Group B.

3.4.2. Eosinophil

Since observations are quantitative, we have used paired t-test to test significance in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that there is no significant change observed in Group A and Group B.

3.4.3. Basophil

Since observations are quantitative, we have used paired t-test to test significance in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that there is no significant change observed in Group A and Group B.

3.4.4. Lymphocyte

Since observations are quantitative, we have used paired t-test to test significance in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that there is no significant change observed in Group A and Group B.

3.4.5. Monocyte

Since observations are quantitative, we have used paired t-test to test significance in Group A and Group B. We can observe that, *P*-value for Group A and Group B is >0.05. Hence, we can conclude that there is no significant change observed in Group A and Group B.

Unpaired t-test is carried out for comparison between Group A and Group B. We can observe that, *P*-value for all parameters is >0.05. Hence, we can conclude that there is no significant difference observed between Group A and Group B (Table 5).

4. DISCUSSION ON MODE OF ACTION OF TRIAL DRUGS

4.1. Trial Drug-1: Sigru Leaf Powder

Predominant rasa of Sigru leaf is katu, tikta, rasa having katu vipaka. Mainly, katu, tikta, rasa act on Kapha dosha. The drugs also pose ushna Veerya act on kapha and vata dosha. Laghu, rukshya, tiksha guna act as kapha shamaka and snigdha guna act as vata Shamaka. This drug is predominantly having Deepana Pachana properties.

4.2. Trial Drug-2: Sigru Bark Powder

Predominant rasa of Sigru bark is katu, tikta, rasa having katu vipaka. Mainly, katu, tikta, rasa act on Kapha dosha. The drugs also poses ushna Veerya act on kapha and vata dosha. Laghu, rukshya, tiksha guna act as kapha shamaka and snigdha guna act as vata Shamaka. This drug is predominantly having Deepana Pachana properties.

4.3. Acceptability of the Trial Drugs

The trial drugs *Sigru* leaf powder and *Sigru* bark have such composition which strongly possesses *tridoshahara* properties according to the text and also act as anti-sickling effect. As per this study, both drugs are effective in controlling the sign and symptoms of the sickle cell anemia.

The drugs were well tolerated, accepted, and accomplished by the patients. In my entire study period, I noticed no unpleasant incident due to drug therapy which would compel discontinuation. Along with anti-sickling properties, both the drugs possess antibacterial, antipyretic, antimicrobial, antioxidant, immunomodulatory, antifungal, anti-inflammatory, hepatoprotective, cardioprotective, and spasmolytic effects which in turn provide a productive, peaceful, and blissful life to the patients.

5. CONCLUSION

Constituents of both the trial drugs are abundantly cultivated and easily available in market of our country, hence affordable, congenial and can reduce the cost of treatment of the disease, making it accessible to poor people. As per the statistical tests, we can conclude that there is no significant change observed in Group A and Group B. Hence, it is to be concluded that the trial drugs can be safely prescribed for the long term to one and all without any hesitation and may prove the bacon hope for sickle cell anemia.

6. ACKNOWLEDGMENTS

None.

7. AUTHORS' CONTRIBUTIONS

All the authors contributed equally in design and execution of the article.

8. FUNDING

Nil.

9. ETHICAL APPROVALS

The study was approved by IEC, Government Ayurvedic College and Hospital, Balangir, vide Letter No.1084/G.A.C and H of dated May 26, 2021, and also registered in Clinical Trial Registry of India (CTRI; www.ctri.nic.in) vide Registration No.-CTRI/2022/09/045910 on dated September 27, 2022.

10. CONFLICTS OF INTEREST

Nil.

11. DATA AVAILABILITY

This is an original manuscript and all data are available for only research purposes from principal investigators.

12. PUBLISHERS NOTE

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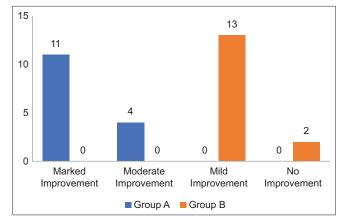
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Table 1: Subjective parameters: Objective parameters

ILLNESS	SEVERITY SEVERITY	GRADE
	SEVERITI	GRADE
Subjective parameters		
PANDUTA (pallor) Twak, Nakha,	Found in all these areas	3
Netravartma, Jihva,		
Hastapadatala		
	Found in nakha, jihva, netravartma	2
	Found in netravartma	1
	Not found in any of these areas	0
Daurbalyata (weakness)	Present in resting condition	3
	Present after little work	2
	Present after moderate to heavy work	1
	Absent	0
Angamarda (Body ache)	Patient cannot do its normal work	3
	Patient is able to do routine work but have to take some rest	2
	Patient can do his/her normal work	1
	Not present	0
Jwara (Fever)	High fever (more than 103f)	3
	Moderate fever (100.5 f to 103 f)	2
	Mild fever (98.6 f to 100.4 f)	1
	Absent	0
Swasha (Breathlessness)	Present in resting condition	3
	Present after little work	2
	Present after moderate to heavy work	1
	Absent	0
Gaurava (Heaviness)	Severe	3
	Moderate	2
	Mild	1
	Not present	0
Aruchi (Loss of appetite)	Patient taking meal only once in a day	3
	Feeling of hunger in 8–10 h after taking first meal	2
	Feeling of hunger in 5–6 h after taking first meal	1
	Patient having usual hunger	0
Objective parameters		
LIVER	3 Finger	3
	2 Finger	2
	1 Finger	1
	Not palpable	0
SPLEEN	3 Finger	3
	2 Finger	2
	1 Finger	1

Table 1: (Continued)

ILLNESS	SEVERITY	GRADE
Objective parameters		
	Not palpable	0
Hb%	6–7.4 g%	3
	7.4–8.5 g%	2
	8.5–10 g%	1
	>10 g%	0
TRBC	<3.4 Mill/cu mm	3
	3.5–4 Mill/cu mm	2
	4-4.5 Mill/cumm	1
	4.6-6.2 Mill/cumm	0
TLC	>13500/cumm	3
	12000-13500/cumm	2
	10500-12000/cumm	1
	4500-10500/cumm	0
MCH	12–17 pg	3
	17–22 pg	2
	22–27 pg	1
	27–32 pg	0
MCHC	15–20%	3
	20–25%	2
	25–30%	1
	30–38%	0
MCV	57–64 FI	3
	64–71 FI	2
	71–78 FI	1
	78–90 FI	0
PCV	25–30%	3
	30–35%	2
	35–40%	1
	40–45%	0



Graph 1: Overall effect of the intervention on both the groups

(Contd...)

Table 2: The assessment of subjective parameters before and after treatment in Group A and Group B (n=30)

Variable	Group	n	Mean Rank	Sum of Ranks	Mann-Whitney U	<i>P</i> -value
Panduta	Group A	15	23.00	345.00	0.000	0.000
	Group B	15	8.00	120.00		
	Total	30				
Dourbalya	Group A	15	22.40	336.00	9.000	0.000
	Group B	15	8.60	129.00		
	Total	30				
Angamarda	Group A	15	21.43	321.50	23.500	0.000
	Group B	15	9.57	143.50		
	Total	30				
Jwara	Group A	15	16.53	248.00	97.000	0.276
	Group B	15	14.47	217.00		
	Total	30				
Swasha	Group A	15	20.00	165.00	45.000	0.000
	Group B	15	11.00	300.00		
	Total	30				
Gourava	Group A	15	20.10	301.50	43.500	0.002
	Group B	15	10.90	163.50		
	Total	30				
Aruchi	Group A	15	20.20	303.00	42.000	0.002
	Group B	15	10.80	162.00		
	Total	30				
Liver	Group A	15	21.83	327.50	17.500	0.000
	Group B	15	9.17	137.50		
	Total	30				
Spleen	Group A	15	15.50	232.50	112.500	1.000
	Group B	15	15.50	232.50		
	Total	30				

Table 3: The assessment of objective parameters before and after treatment in Group A and Group B (n=30)

Variable	Group	n	Mean rank	Sum of ranks	Mann-Whitney U	<i>P</i> -value
TLC	Group A	15	14.90	223.50	103.500	0.614
	Group B	15	16.10	241.50		
	Total	30				
Hb%	Group A	15	18.87	283.00	62.000	0.026
	Group B	15	12.13	182.00		
	Total	30				
MCH	Group A	15	14.43	216.50	96.500	0.464
	Group B	15	16.57	248.50		
	Total	30				
MCHC	Group A	15	16.10	241.50	103.500	0.614
	Group B	15	14.90	223.50		
	Total	30				
MCV	Group A	15	14.37	215.50	95.500	0.452
	Group B	15	16.63	249.50		
	Total	30				
PCV	Group A	15	18.27	274.00	71.000	0.072
	Group B	15	12.73	191.00		
	Total	30				
TRBC	Group A	15	15.50	232.50	112.500	1.000
	Group B	15	15.50	232.50		
	Total	30				

Table 4: The assessment of Differential Count before and after treatment in Group A and Group B (n=30)

Creap Traine Creap B (iv 20)							
Variable	Group	n	Mean	SD	SE	<i>t</i> -value	<i>P</i> -value
Neutrophil	Group A	15	12.07	8.78	2.27	1.406	0.171
	Group B	15	7.60	8.63	2.23		
Eosinophil	Group A	15	1.33	0.90	0.23	0.333	0.742
	Group B	15	1.20	1.26	0.33		
Basophil	Group A	15	0.67	0.82	0.21	-1.485	0.149
	Group B	15	1.27	1.33	0.34		
Lymphocyte	Group A	15	11.13	9.13	2.36	1.274	0.213
	Group B	15	7.33	7.07	1.82		
Monocyte	Group A	15	0.73	0.70	0.18	-1.860	0.073
	Group B	15	2.20	1.52	0.39		

Table 5: Clinical assessment of Result in Group A and Group B

Overall effect	Group A		Group B		
	n	%	n	%	
Marked improvement	11	73.33	0	0.00	
Moderate improvement	4	26.67	0	0.00	
Mild improvement	0	0.00	13	86.67	
No improvement	0	0.00	2	13.33	
Total	15	100.00	15	100.00	
Gr-A (BT) versus Gr-A (AT)		Effectiveness of treatment-1 (Trial group A) was assessed.			
Gr-B (BT) versus Gr-B (AT)		Effectiveness of treatment-2 (Trial group B) was assessed.			

Gr: Group, BT: Before treatment, AT: After treatment