International Journal of Homoeopathic Sciences

E-ISSN: 2616-4493
P-ISSN: 2616-4485
www.homoeopathicjournal.com
IJHS 2023; 7(2): 250-255
Received: 23-03-2023
Accepted: 25-04-2023

Dr. Siddesha G
Assistant Professors, Department of Psychiatry, MNR Homoeopathic Medical College, Sangareddy, Hyderabad, Telangana, India

Dr. Girish Navada UK
Professor and HOD, Department of Psychiatry, Father Muller Homoeopathic Medical College, Deralakatte, Mangalore, Karnataka, India

Dr. Justina M Steefan
Assistant Professors, Department of Psychiatry, MNR Homoeopathic Medical College, Sangareddy, Hyderabad, Telangana, India

Corresponding Author:
Dr. Siddesha G
Assistant Professors, Department of Psychiatry, MNR Homoeopathic Medical College, Sangareddy, Hyderabad, Telangana, India

The efficacy of homoeopathic medicine anacardium Orientale as an adjuvant medicine in the treatment of bipolar affective disorder: A randomized controlled trail

Dr. Siddesha G, Dr. Girish Navada UK and Dr. Justina M Steefan

DOI: https://doi.org/10.33545/26164485.2023.v7.i2d.838

Abstract
Background: Bipolar disorder, also known as manic-depressive illness, is a brain disorder that causes unusual shifts in mood, energy, activity levels, and the ability to carry out day-to-day tasks which cause the significant psychological distress, affects one's work, family, social life and may even result in suicide. During the homoeopathic drug proving of Anacardium Orientale, as per the provers Materia Medica the recorded mental symptoms were similar to BPAD symptoms. Hence, this study was done to assess the efficacy of Anacardium Orientale in the treatment of Bipolar Affective disorder as an Adjuvant Medicine.
Methodology: Total 30 cases were selected and randomized as Anacardium group and placebo group. For all the cases GB scale score was measured before and after the treatment and BPAD Symptom Severity (SS) Scale was used to check the effectiveness of Anacardium Orientale. A 6-month follow-up was done for every case. Two from each group discontinued the treatment, total 26 patients were taken for statistical analysis.
Results: In Anacardium group, 10 patients had shown significant improvement (76.92%) whereas the condition of three patients had not improved (23.07%). According to the treatment outcome Anacardium Oreintale was found more effective in the patient who has current episode mild or moderate depression (F 31.3) and current episode hypomanic (F 31.0) and in patients with current episode mania without psycotic symptoms (F 31.1).
Conclusions: After the statistical analysis of the score obtained from Goldberg Scale and BPAD symptom severity scale, Anacardium Orientale the homoeopathic medicine was found effective in the management of bipolar affective disease as an adjuvant medicine than the placebo.

Keywords: Subclinical hypothyroidism (SCH), thyroid-stimulating hormone, neck swelling, nat. MUR, individualisation, homoeopathy

Introduction

Bipolar disorder, also known as manic-depressive illness, is a brain disorder that causes unusual shifts in mood, energy, activity levels, and the ability to carry out day-to-day tasks which cause the significant psychological distress, and also affects one's work, family, and social life may even result in suicide. These moods range from periods of extremely "up," elated, and energized behaviour known as manic episodes to very sad, "down," or hopeless periods known as depressive episodes. Less severe manic periods are known as hypomanic episodes [1].

Bipolar affective disorder (BPAD) is becoming more and more frequently a burden on modern society. A community study using the Mood Disorder Questionnaire (MDQ) revealed a prevalence of 3.7 percent. A euphoric (joyful, energetic) mood, hyperactivity, a positive, irritable, expansive outlook characterize mania, manic people may demonstrate a decreased need for sleep, racing thoughts, rapid speech, heightened distractibility and sometimes grandiosity. They will be impulsive in actions and prone for engaging risky or dangerous behaviours and activates.

Feeling of lethargy or lack of energy, a negative outlook on life, low self-esteem, a sense that nothing is possible, hopelessness, characterize depression, depressed people tend to lose interest in things that give them pleasure and enjoyment. They may sleep too much or too little, feel tired always and fatigued, their moods tend to be dysphoric, these negative feeling states helps depressed people lose confidence in their abilities, become pessimistic and sometimes concludes that life is no longer worth living [2-3].

Classification of BPAD

Table 1: Classification of BPAD according to ICD-10 [4]

ICD Code	
F31	**Bipolar affective disorder**
F31.0	Bipolar affective disorder, current episode hypomanic
F31.1	Bipolar affective disorder, current episode manic without psychotic symptoms
F31.2	Bipolar affective disorder, current episode manic with psychotic symptoms
F31.3	Bipolar affective disorder, current episode mild or moderate depression.
F31.30	Without somatic syndrome.
F31.31	With somatic syndrome.
F31.4	Bipolar affective disorder, current episode severe depression without psychotic symptoms
F31.5	Bipolar affective disorder, current episode severe depression with psychotic symptoms
F31.6	Bipolar affective disorder, current episode mixed
F31.7	Bipolar affective disorder, currently in remission
F31.8	Other bipolar affective disorders
F31.9	Bipolar affective disorder, unspecified

Table 2: Classification of BPAD according to DSM-V [5]

Bipolar and Related Disorders
Bipolar I disorder
Bipolar II disorder
Cyclothymia
Substance-induced bipolar disorder

Presently there are wide range of treatment options for management of BPAD, which can be broadly classified as mood stabilizers, antidepressants, antipsychotics, electro-convulsive therapy (ECT), adjunctive medications like Anticholinergics, benzodiazepines, hypnotic-sedatives, anticonvulsants, lithium carbonate. The long-term use of these medications may cause side effects like tremors, drowsiness, and dryness of mouth, gastritis, skin complaints and renal system problems [6-9].

In homoeopathic system, there are medicines, which can be used to treat BPAD without side effects and can treat the side effects caused by allopathic system of medications, few medicines like Hyoscyamus, Stramonium, Veratrum album, Ignatia, Anacardium Orientale are found more effective in the treatment of BPAD [10-13].

As per the homoeopathic basic principle 'similia similibus cur enter', during the homoeopathic drug proving of Anacardium Orientale, as per the provers Materia Medica the recorded mental symptoms were similar to the symptoms of Bipolar Affective disorder,

Hence, this study was done to assess the efficacy and effectiveness of Anacardium Orientale in the treatment of Bipolar Affective disorder as an Adjuvant Medicine and treat the one who is in need.

Objectives

To assess the effectiveness of homoeopathic medicine Anacardium Orientale as an adjuvant medicine in the treatment of bipolar affective disorder.

Methodology

Sources of data

The study was conducted in patients who reported to the OPD, IPD and Peripheral units of Father Muller Homoeopathic Medical College Hospital, Deralakatte, Mangalore.

A total number of 45 cases of both sexes aged 18 to 55 years were enrolled for the study. The diagnosis was made based on strong clinical presentation and examination findings, as per ICD 10. The case selection for the study was done by purposive sampling, after fulfilling the inclusion as well as exclusion criteria.

Inclusion criteria

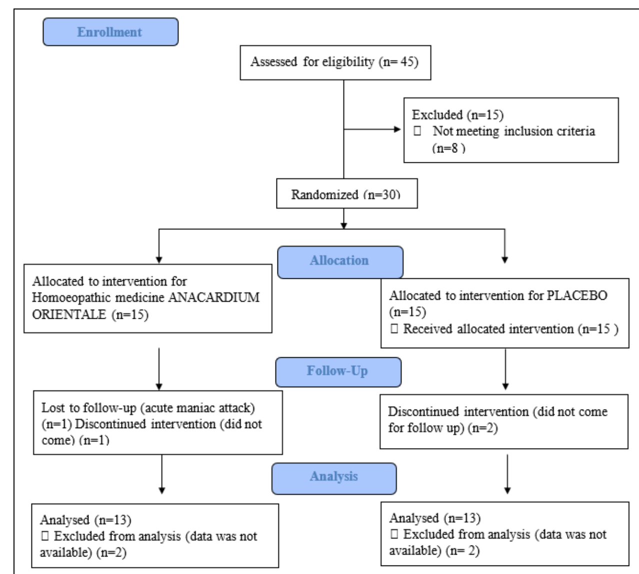
- Patients who were on regular modern psychiatric treatment, parents, guardian, or relatives who are willing to give a written and informed consent for the purpose of study.
- Age group of 18-55 years of either sex
- All the diagnosed of bipolar disorder affective disorder as (F31) as per ICD10, who are under the regular treatment under the modern psychiatric (allopathy) treatment.

Exclusion criteria

- Patients, parents, guardian, or relatives who have not consented for the study.
- The diagnosed patients of bipolar affective disorder who are not on regular medication.
- Age group of below 18 and above 55 years of either sex.
- Organic mood (affective) disorder.
- Chronic neurological conditions like epilepsy, stroke and degenerative disorder like dementia, Alzheimer's disease.

Method of collection of data

Methodology Flow Diagram



Results and Observations

Total twenty-six cases were followed up for a period of minimum six months. These cases were subjected to statistical study. The statistical analysis is given below.

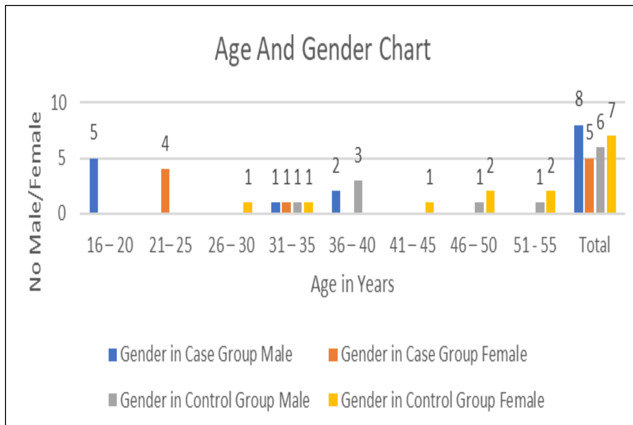


Fig 1: Representation of cases according to Age and Gender.

Case Group: Out of 13 patients, there are five patients in age group 16-20, 5 male and 0 female. Whereas zero male and four female from age group 21-25. One male and one female in age group 31-35 and one male on age group of 36-40.

Control Group: Out of 13 patients, one male and one female in age group of 31-35, three males in 36-40 yrs. of age, one female in 26-30, one female in 41-45, one male and 2 female in 46-50, one male and two female in 51-55 years age.

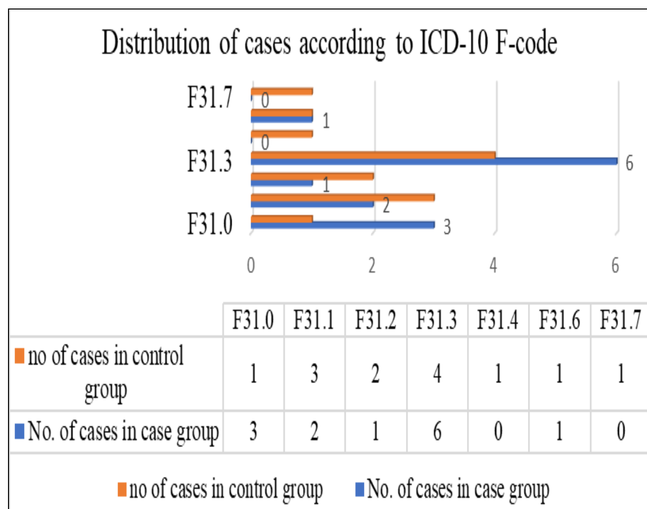


Fig 2: Representation of cases according to clinical presentation as per ICD 10.

According to clinical presentation as per ICD10, distribution of cases are as follows; BPAD, current episode Hypomanic (F31.0)- one in Placebo group and three in Anacardium group, BPAD, current episode manic without psychotic episode (F31.1)- three in control and 2 in case group, BPAD, current episode manic with psychotic symptoms (F31.2)- two in Placebo group and one in Anacardium group, BPAD, current episode mild or moderate depression (F31.3) - four in Placebo group and six in Anacardium group, BPAD, current episode severe depression without psychotic symptoms (F31.4) - one in Placebo group, BPAD, current episode mixed (F31.6) - one in each group, BPAD current episode remission (F31.7) - one in Placebo group.

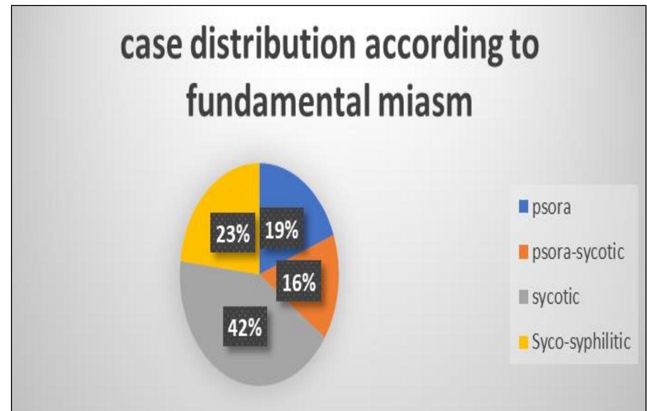


Fig 3: Representation of cases according to Fundamental Miasm

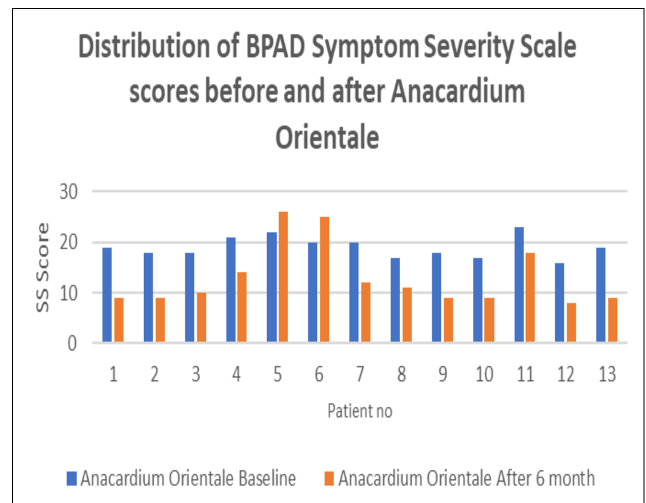


Fig 4: Representation of case Distribution of BPAD Symptom Severity Scale scores before and after Anacardium Orientale

It is noteworthy that except for two patient all other have good response in their symptoms after 6 months of treatment with Anacardium Orientale as an adjuvant with allopathic treatment.

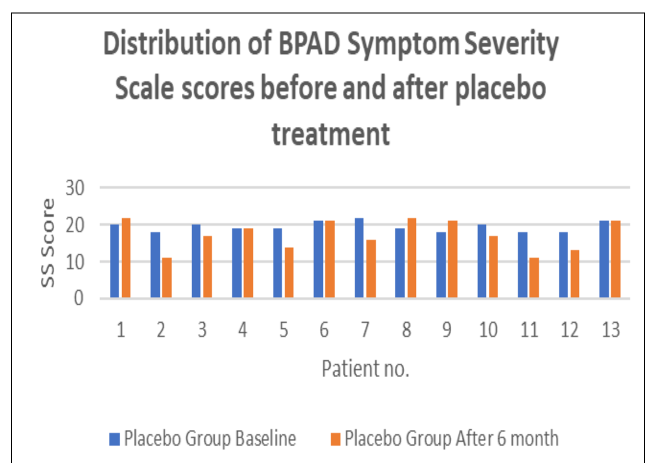


Fig 5: Representation of case Distribution of BPAD Symptom Severity Scale scores before and after placebo treatment

7 patients of Control group have shown that there is considerable effect when Allopathic medicines alone is administered without homoeopathic adjuvant.

Table 3: Distribution of cases according to the treatment outcome

Treatment outcome	Case group		Control group	
	No. of cases	Percentage (%)	No. of cases	Percentage (%)
Improved	10	76.92	7	53.86
Same	0	0	3	23.07
Worsen	3	23.07	3	23.07
Total	13	100	13	100

Out of the 13 cases, which had received Anacardium Orientale except for three cases (one in F-31.2 and two cases of F- 31.3), all other cases have shown marked improvement. Among the improved cases, four cases are of F-31.3, three cases are of F- 31.0, two cases are of F- 31.1 and one case F-31.6.

Statistical Analysis

Paired and unpaired 't' test was done using SPSS software.

Table 4: Distribution of GB scale scores before and after Anacardium Orientale and placebo group

Score	Anacardium Orientale		Placebo	
	Baseline	After 6 months	Baseline	After 6 Months
Mean	34.77	23.15	34.69	32.69
SD	1.79	9.25	2.06	4.53
SEM	0.50	2.56	0.57	1.26
N	13	13	13	13

Paired *t* test results.

P Value and statistical significance.

The two-tailed P value equals 0.0009.

By conventional criteria; this difference is considered extremely statistically significant.

Table 5: Distribution of BPAD Symptom Severity Scale scores before and after Anacardium Orientale and placebo treatment

Score	Anacardium Orientale		Placebo	
	Baseline	After 6 months	Baseline	After 6 months
Mean	19.08	13.00	19.46	17.31
SD	2.06	6.18	1.33	4.07
SEM	0.57	1.71	0.37	1.13
N	13	13	13	13

Paired *t* test results.

P value and statistical significance:

The two-tailed P value equals 0.0008

Table 6: Distribution of BPAD SS scale scores After Anacardium Orientale and placebo treatment

score	Anacardium Orientale	Placebo
	After	After
Mean	13.00	17.31
SD	6.18	4.07
SEM	1.71	1.13
N	13	13

Unpaired *t* test results.

P value and statistical significance.

The two-tailed P value equals 0.0465.

By conventional criteria; this difference is considered statistically significant.

Inference

Finally unpaired t test done between the Anacardium oriental group and placebo group after the 6th month of treatment by using BPAD Symptom Severity scale shows p value is 0.0465, which is less than 0.05, and this is considered statistically significant thus we reject null hypothesis and accept the alternate hypothesis. Thus, Anacardium Orientale is effective as an adjuvant medicine in the treatment of bipolar affective disorder.

Discussion

The modern study of BPAD can be considered to have begun with Emil Kraepelin who advanced this French concept with his landmark descriptions and separation in 1899 of "dementia praecox," which roughly corresponds to what we now call schizophrenia, and "manic-depressive insanity." Kraepelin included what we would now call bipolar disorder plus recurrent major depression in the concept of manic-depressive insanity. Later in 1957 Leonhard coined the term "bipolar" to describe individuals who experienced mania and depression (i.e., two poles) as distinct from those with only recurrent major depression (i.e., one pole or "unipolar" depression) [14].

National Institute of Mental Health and Neurosciences (NIMHANS) Bengaluru, concludes that the Prevalence of Bipolar Affective Disorder in India is 0.3% for current and 0.5% for lifetime experience. Males (0.3%) had slightly higher prevalence rate than females (0.2%). Among various age groups and residence categories, those in the 40-49 (0.4%) and urban metro residents (0.7%) had a higher prevalence for current experience of bipolar affective disorder. Bipolar disorder is common, with types I and II affecting 1–3% of the population worldwide; less well-defined spectrum conditions may increase that rate to 6%. [15].

The present study was an attempt to find the efficacy of Anacardium Orientale in the treatment of BPAD as an adjuvant medicine by using Goldberg's and BPAD symptom severity scale.

Bipolar affective disorder (BPAD) is a severe mental disorder seen across all age groups, including elderly. The age group chosen for this study ranges from 18 to 55 years. In this study, it has been observed that out of 26 patients, majority i.e., 5 (19.26%) are in age group between 16-20 yrs. and 36-40 yrs.

According to the research 57.3% to 74.3% having at least 1 active psychiatric comorbidity, and 14.9% to 29.8% having two or more [16, 17, 18].

Table 7: Psychiatric Conditions Co-occurring with Bipolar Disorder

Condition	Lifetime Prevalence Bipolar Disorder	Lifetime Prevalence General Population
Alcohol use disorders	38-48%[1]	14-18%
Nicotine use disorders	46-80%	21%
Drug use disorders	21-41%[1]	6-8%
Anxiety disorders	42-77%	15-25%
Personality disorders	38-48%	9-13%
ADHD	28-90%[2]	5-10%

1 Higher in bipolar I than bipolar II disorder

2 Higher in younger individuals with bipolar disorder

A variety of studies has documented high rates of medical comorbidity among individuals with BPAD than the general population. Some 58.8–80% have at least one active medical problem while 19–23% have two such conditions and 35–50% have three or more.

Table 8: Common Medical Conditions in Bipolar Disorder

Condition	Bipolar I Disorder (%)	Bipolar II disorder (%)
Obesity	21-35	20-36
Diabetes (type II)	8-17	6-8
Cardiovascular disease	11-50	7-20
Migraine	25-40	7-16

This study shows that in Anacardium group, the patients who had shown significant improvement (76.92%) in which 4 had F 31.3 and comorbid illness like GAD, OCD, Allergic Rhinitis, 3 were F 31.0 and comorbid illness like Fibromyalgia, and eczema, 2 were F 31.1 with comorbid illness like TBS and one was F 31.6, whereas the condition of three patients had deteriorated (23.07%) in which 2 were F 31.3 with comorbid illness like Migraine and GAD, 1 case was F 31.2 with GI complaints.

In placebo group out of 4 patients who have shown marked improvement in their symptoms one patient belongs to F31.1 with no comorbid disease, two patients are having F31.3 in that one patient is having social phobia and other patient is having OA as comorbid disease and one patient is having F31.6 with allergic rhinitis. 3 patients have no change in their symptomatology they are having F31.1 with dermatitis, F31.2 with PCOD and F31.3 with GAD. 3 patients have deteriorated in which one Patient had F31.1 with diabetes and Hypertension, one patient with F31.31.3 with OA and one had Diabetes and OA.

Several psychiatric conditions occur in bipolar disorder at rates much higher than in the general population and are particularly relevant as they can confound illness management and, typically, worsen illness course.

Homoeopathy and bipolar affective disorder

In the field of mental health, Dr. Hahnemann was a pioneer, according to the history noted by Richard Haehl, Hahnemann started spreading the humanistic treatment of the mentally ill in 1793, in the asylum of Georgenthal near Gotha, Germany. Regarding mental disorders, in § 215 of his Organon, he writes: "Almost all so-called mental and emotional diseases are nothing but physical diseases in which the symptom of mental and emotional disorder characteristic of each one increases more or less rapidly as the physical symptoms diminish, almost like a local disease transferred into the invisible subtle mental or emotional organs" [19, 20]. In § 220 he mentions the occurrence of cases with a periodicity of violent insanity with melancholic depression, and the return of certain conditions during specific months of the year. Hahnemann made a distinction between organic and psychological diseases. In fact, he prescribed psychotherapeutic techniques. In § 224 and following aphorisms he explains the different ways of treatment including the use of "mesmerism", which is regarded today as the antecedent of hypnosis. (Organon, § 17, 288.) [21].

Anacardium which is commonly known as marking nut or Malacca nut is a very good homoeopathic remedy in the treatment of mood disorders. Some of the original proving symptoms of Anacardium by Hahnemann which is noted in The Chronic Disease book are Hypochondriac, troubled mood; depression; unsuitableness; anxiety; fear of approach of death; lack of moral sense (flagitiousness, impiety, inhumanity, hardheartedness); a condition as if he had two wills, of which the one annuls what the other impels him to do; sensation as if his spirit were unconnected with the body, sadness, An excitement which is unnaturally cheerful, the laughs, when ought to be serious [22]- which are the symptoms of BPAD.

Conclusion

The present RCT study was aimed at finding the effectiveness of Anacardium Orientale as an adjuvant medicine in the management of BPAD, after 6 month follow up of both case and control group and from the statistical analysis, we can infer that BPAD is more common in adult males. Sycosis was found as the fundamental and dominant miasm. Through the Statistical analysis, Anacardium Orientale the homoeopathic Medicine was proved to be effective in the management of bipolar affective disease as an adjuvant medicine than the placebo.

Limitations

This study was done on specific remedy and RCT, because of this we could not administer Homoeopathic similimum, which were well indicated for the case.

Recommendations

There is very few research done on Homoeopathic management of bipolar affective disorder, I recommend further studies can take on management of BPAD by using Homoeopathic constitutional medicines than specific medicines.

In the available literature, Anacardium was described more as a maniac drug but in my study, it showed more effective on patients who had depression with anxiety and GIT symptoms so I recommend it may be further verified with different study population.

Source of funding: None

Conflict of interest: None

Acknowledgment

I am very thankful to all the patients who trusted me and without whom I could not have completed this study.

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How to Cite This Article
Siddesha G, Girish Navada UK, Steefan JM. The efficacy of homoeopathic medicine anacardium Orientale as an adjuvant medicine in the treatment of bipolar affective disorder: A randomized controlled trail. International Journal of Homoeopathic Sciences. 2023;7(2):250-255.

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