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RESEARCH ARTICLE

Clinical Safety Evaluation of Mercury based Siddha Medicine (*Rasaganthi Mezhugu*) in NIS IPD & OPD Patients

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ABSTRACT

RasaganthiMezhugu is one of the mercury based Siddha medicine. It is widely used by Siddha doctors for various diseases. Nowadays most people are wary of using Siddha Medicines because of heavy metal preparations. But this medication does not cause any side effects. In this study, we observed the safety parameters and mercury level in blood of patients who consumed with mercury based Siddha Medicine for 48 days in NIS OPD (Before and after treatment) New patients of NIS OPD satisfying the inclusion criteria will be included in the study. I planned to detect the Blood parameters (Before and after treatment) and I will select 5 patients out of 50 patients through Simple Random Sampling (lottery method of sampling) for detection of blood mercury level by ICP-MS method. Paired sample t-test was conducted to compare safety parameters and the mercury level in blood (Before and after treatment). There is no impairment in hepatic, renal, haemopoitic functions and mercury level in blood. Rasaganthi Mezhugu was does not produce any untoward reaction and is completely harmless.

Keywords: Mercury, Siddha medicine, RasagandhiMezhugu[RGM], ICP-OES

INTRODUCTION

Siddha medicine is nature's gift for our well-being from our Siddhars. Siddhars propounded the therapeutic properties of herbs, metals and minerals using their wisdom and these formulations are being used by mankind. Every metal and mineral used for medicine preparation has to undergo various cleansing process for toxicity and adulteration removal [1]. Nowadays most of the people are cautious about using Siddha medicines due to the extensive use of heavy metals like Lead, Mercury in the preparations. So, the Siddha physicians to prove that "Siddha medicines are totally safe, does not have any side effects and Siddha medicines are completely harmless and free of complications. It is only proved through scientific and modern methods. RasaganthiMezhugu is one of the herbo-metal medicines. Mercury is the major drug of this medicine [2].There is no evidence of clinical toxicity study on mercury based medicines. So, this study was conducted to prove the clinical safety of RGM through observes the safety parameters and to investigate the Mercury Levels in Blood who consumed RasagandhiMezhugu for 48 days in NIS OPD& IPD (Before and After Treatment).

MATERIALS AND METHODS

The study was approved by our Institutional Ethics committee and its number was 22-02-2019; NIS/IEC/2019/M-43. This trial was register in Clinical Trial Registry India and its number was CTRI/2019/05/019060.

Patients and setting

It is an observational study conducted in the Outpatient department of AyothidossPandithar hospital, National Institute of Siddha. The Sample size was 50 patients were selected by Simple Random sampling technique and included with strict inclusion and exclusion criteria, the enrolled patients provided their written informed consent to participate in the study. The inclusion criteria: 1) Adults aged between 25 and 60 years 2) Sex-Both sex 3) Patients who taking RasagandhiMezhugu for 48 days. Exclusion criteria: 1) Pregnant/Lactating Women 2) Patients with the History of any Major systemic illness at the start of the treatment

Study design

I detect the Blood parameters (RBC, WBC, Haemoglobin and platelet count, Bilirubin, SGOT, SGPT, Urea and Creatinine) of RGM treated patients before and after treatment with RasagandhiMezhugu for 48 days and I was select 10 patients out of 50 patients through Simple Random Sampling for detection of blood mercury level by ICP-OES method before and after treatment with RasagandhiMezhugu for 48 days.

Data collection through

- Data Collection Form
- OPD Books
- Laboratory form

Statistical analysis

All collected data were entered in MS Access software using a pre-designed form for data entry and STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distribution and cross-tabulations were performed for qualitative analysis, paired Sample't test' used for the statistical analysis.

RESULTS

Effect of blood parameters of RGM treated patients which was analysed by various methods. The results of Urea level (Table No.2, Fig. No.1), Creatinine level (Table No.3, Fig. No.2), Bilirubin level (Table No.4, Fig. No.3), Mercury level (Table No.5, Fig. No.4) of RGM treated patients blood parameter is tabulated.

DISCUSSIONS

RasagandhiMezhugu (RGM) is an important herbo-mineral drug, which is widely used by Siddha practitioners for several diseases with good success [4]. Though Mercury and other inorganic drugs are used in RasaganthiMezhugu, its extensive usage in practice and earlier peer reviewed researches proves its safety. Moreover the drugs of plant origin used in RasaganthiMezhugu are found to be scientifically proven for their efficacy[5]. Insufficient data exist for most Siddha preparations to guarantee their quality, efficacy and safety [4]. The present study was done to explore the safety of RGM. A total of 50 patients adhered to study protocol and completed 48 days of treatment. There were 22 per cent (11/50) male and 78 per cent (39/50) female subjects. At baseline, majority of patients (50%) had Azhal keel vayu, 16% of them had vazhiazhalkeelvayu, 12% had keel vayu and Thandagavatham, 4% had vathasthambamandceganavatham and 2% had Karappan. All patients were monitored 5 once for a period of 48 days. They do not have any adverse drug reaction (oral ulcer, itching, vomiting, abdominal pain, loose stools etc.) during treatment period. All parameters obtained from the blood and serum (RBC, WBC, Hemoglobin and platelet count, Bilirubin, SGOT, SGPT, Urea and Creatinine) was in normal range indicating RGM did not show any noticeable significant changes. But, SGOT, SGPT levels were significantly decreased and Hemoglobin level was significantly increased (within the normal range). The US Environmental Protection Agency (EPA) has adopted a reference dose (RfD) for methyl mercury of 0.1 µg/kg body weight/day[6]. Thus, in its therapeutic dose, per day ingested mercury was many folds higher than the reference dose. It was observed that with this concentration of mercury in *RGM* given for 48 days did not cause significant change in liver and kidney functions of the patients. Blood mercury levels were significantly increased after treatment (within normal limit). Further study will be conducted to detect the elimination of mercury. In the present study reveals that RGM does not produce any untoward reaction.

CONCLUSION

This study is an attempt with scientific and analytical eyes on RasagandhiMezhugu, revealed that there is no impairment in hepatic, renal, hematopoietic functions and mercury level were observed throughout the study. My results showed that RasagandhiMezhugu does not have any untoward reaction and completely harmless.

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Table 1:Effect of blood parameters of RGM treated patients

Sl.No	Blood Parameters of RGM Treated Patients	Before Mean ±SD	After Mean ±SD	t value df=49	p value	Null hypothesis Accepted or Rejected (Before = After)	Significant changes present or Not	Difference
1	Urea	18.54±5.65	18.09±5.28	-0.33	0.74	Rejected	Significant changes seen	Before ≥ After
2	Creatinine	0.86± 0.17	0.84±0.15	-1.6	0.1	Rejected	Significant changes seen	Before ≥ After
3	Bilurubin	0.5± 0.22	0.3± 0.21	-8.9	0.0001	Accepted	No significant changes seen	Before = After
4	SGOT	18± 6.74	17.6±6.64	-1.45	0.1	Rejected	Significant changes seen	Before ≥ After
5	SGPT	18.6± 8.6	18.3±7.4	-0.6	0.5	Rejected	Significant changes seen	Before ≥ After
6	Alkaline phosphatase	80± 40.11	78.2±38.3	2.25	0.02	Accepted	No significant changes seen	Before = After
7	Cholesterol	154.9±35.3	151.3±32.1	-2.7	0.007	Accepted	No significant changes seen	Before = After
8	Protein	7.08± 0.45	7.06±0.44	-2.3	0.02	Accepted	No significant changes seen	Before = After
9	Calcium	8.35±0.75	8.35±0.74	-2.1	0.03	Accepted	No significant changes seen	Before = After
10	Uric acid	4.49± 1.4	4.45±1.4	-2.7	0.008	Accepted	No significant changes seen	Before = After
11	Hemoglobin	12.08±1.6	12.21±1.4	1.36	0.1	Rejected	Significant changes seen	Before ≤ After
12	Platelets	2.96± 0.71	3.02±0.71	2.03	0.04	Accepted	No significant changes seen	Before = After
13	RBC	4.42± 0.42	4.45±0.43	2.52	0.01	Accepted	No significant changes seen	Before = After
14	Mercury level using ICP-OES method	0.013±0.005	0.04±0.02	4.93	0.0008	Accepted	No significant changes seen	Before = After

Table 2:Effect of blood parameters of RGM treated patients - Urea

Treatment	Number of patients	Mean	Std.Dev	Std.Err	95%CONFIDENCE INTERVAL
Before	50	18.54	5.65	0.79	±1.56 (±8.63%)
After	50	18.09	5.28	0.74	±1.46 (±8.10%)
Diff		0.45	0.37	0.05	

Table 3: Effect of blood parameters ofRGM treated patients – Creatinine

Treatment	Number of patients	Mean	Std.Dev	Std.Err	95%CONFIDENCE INTERVAL
Before	50	0.86	0.17	0.02	±0.04 (±5.25)
After	50	0.84	0.15	0.02	±0.04 (±5.60)
Diff		2	2	0	

Table 4: Effect of blood parameters of RGM treated patients – total Bilirubin

Treatment	Number of patients	Mean	Std.Dev	Std.Err	95%CONFIDENCE INTERVAL
Before	50	0.5	0.2	0.03	±0.06 (±11.9%)
After	50	0.3	0.2	0.03	±0.06 (±15.3%)
Diff	50	1	0	0	

Table 5: Effect of blood parameters of RGM treated patients Mercury level using icp-oes method

Treatment	Number of patients	Mean	Std.Dev	Std.Err	95%CONFIDENCE INTERVAL
Before	10	0.013	0.006	0.001	±0.003 (±29.35%)
After	10	0.04	0.02	0.007	±0.014 (±32.85%)
Diff		0.027	0.014	-0.006	

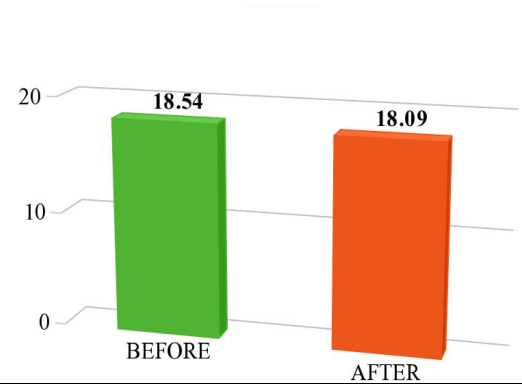

Fig. 1: Effect of blood parameters of RGM treated patients – Urea

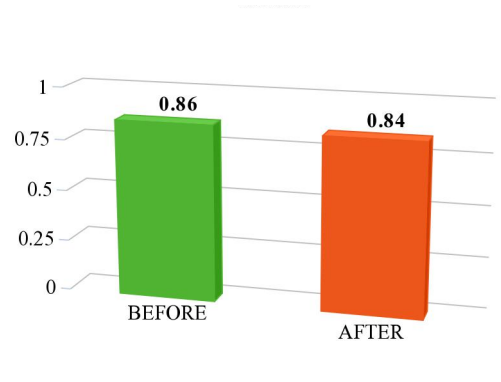

Fig. 2: Effect of blood parameters of RGM treated patients – Creatinine

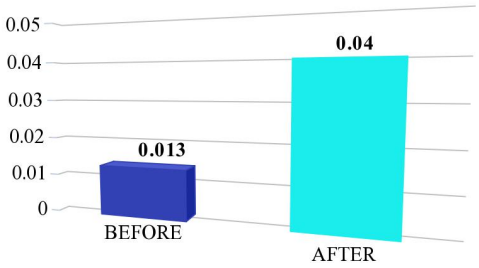

Fig. 3: Effect of blood parameters of RGM treated patients total Bilirubin

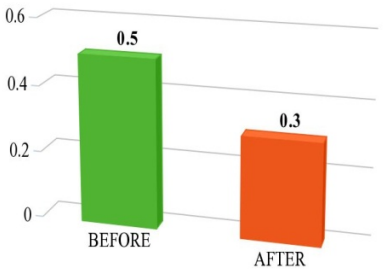

Fig. 4: Effect of blood parameters of RGM treated patient Mercury level using ICP-OES method