EFFICACY OF AYURVEDIC MEDICINE

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Abstract

Herbal drugs have been used since ancient times as medicines for the treatment of various diseases. Ayurveda is an ancient health care tradition that has been practiced in India for atleast 5,000 years. It is estimated that about 25 percent of all modern medicines are directly or indirectly derived from plant sources. Clinical trials explore that whether a medical strategy, treatment, or a device is safe and effective for humans. These studies also show which medical approach work best for certain illness in humans. Further these trials produce the best data to facilitate the scientific decisions. Acute respiratory infections (ARI) and acute gastroenteritis are the most common cause of illness in children and it is a major cause of childhood mortality throughout the World. Antibiotics have little effect on viruses, and there are sparse evidences that antibiotics will prevent secondary or superimposed bacterial infections in a patient with a viral infection.

This is an open label randomized clinical trial to evaluate the efficacy of a Ayurveda syrup for acute respiratory infections and acute enteritis conducted during year 2018. The objective of the trial was to evaluate the efficacy of the syrup as a therapy for diarrhea and ARI in children and to observe untoward effects; if any.

Inclusion criterion was either gender with the age 5 months to 6 years. We excluded cases with severe malnutrition, hospitalization and diarrhea of more than 14 days duration. As it is not a comparative study, a single group was considered for the trial medicine. Dosage was given for 7 days, 4 times a day, in different quantity for different age groups. On enrolment, 4th and 7th day assessment was done according to assessment criteria mentioned in protocol. We also collected clinical data on sneezing, running nose, congestion/stuffiness, total nasal symptoms, eye symptoms, chronic cough, headache, throat symptoms. We ranked all these parameters as least to most pain. Based on the required sample size calculation by considering 30 percent dropout rate, we enrolled 130 participants in this clinical trial. We used Wilcoxon rank test, Chi–square test and Fisher's test study association with drug. Assessment of efficacy of medicine was checked in this study. After comparing initial and 7th day clinical parameters, analysis showed that the study syrup was effective at the study endpoint. As there were no placebo/control group so further studies are required for generalization of study results.

Keywords: Open labelled, drug efficacy, clinical trial

INTRODUCTION

Acute respiratory infection and diarrhea are the leading causes of morbidity and mortality in children under the age of 5, throughout the world. Each year ARI causes 15% of all deaths in children under the age of 5 years, while diarrhea is the second leading cause of the deaths in children. At 1-59 months, the mortality rate from pneumonia declined by 63% from 11·2 (in 2000) to 4.2 (in 2015) per 1000 live-births and the rate for diarrhea fell by 66% from 9·4 (in 2000) to 3·2 (in 2015) per 1000 live-births. Despite this decline, mortality due to diarrhea and ARI(pneumonia) is still high. ARI and diarrhea are two life threatening but preventable diseases. Antibiotics are the most common solutions to such diseases. But antibiotics have no effect on viruses, and there is no clinical evidence that antibiotics will prevent secondary or superimposed bacterial infections.

Modern medicine has grown extensively to an unimaginable extent with the grasp of technological innovations, yet a medicine that is effective for both diarrhea and ARI is not in use till date. Unfortunately, modern medicines do not provide a complete cure, which is provided by Ayurveda. Ayurvedic medicine, the traditional

medication with a longer history in India has been practiced for more than 5000 years. Even during the Vedic period, the traces of Ayurveda has been mentioned. According to the World Health Organization, about 70–80% of the world populations rely on nonconventional medicines mainly of herbal sources in their healthcare. Undoubtedly, in comparison to allopathic treatment, Ayurvedic treatment is more effective in most of the chronic diseases. However, the popularity of Ayurveda is rather lesser as the majority of the global population prefers modern medicine because of its ability to give fast relief from diseases as compared to Ayurvedic treatment. Recently, the awareness and thus fear of toxicity to allopathic drugs and the high cost of healthcare are causing an increasingly large number of people to seek alternatives. Rather than competing and veering towards the Western medicine, the Ayurvedic scientists should work to enhance the core competency of Ayurveda without compromising its fundamental principles. Ayurveda is not merely treatment. It is a science teaching one to live a long healthy life. One who follows it, can live without needing treatment.

When a new treatment for a particular disease is proposed, the key question is whether the treatment is sufficiently safe and efficacious to be adopted by physicians as part of their routine clinical practice. In recent decades the medical and scientific communities have developed an elaborate infrastructure for conducting clinical trials, which are experiments to evaluate the effects of medical treatments on human subjects. Since there is a high degree of variability between patients in the effects of a given treatment, statistical methods are required for clinical trial design, conduct and analysis. Clinical trials form the main source of evidence-based medicine (EBM) and thereby forming the backbone of clinical practice. Phase II clinical trials evaluate the efficacy of new drugs, the safety of said treatments and dosage specifications. Phase II research is targeted to patients afflicted with the condition the drugs intend to treat.

This is an open label randomized phase 2 clinical trial to evaluate the efficacy of a Ayurveda syrup for acute respiratory infections and acute enteritis conducted during year 2018. The objective of the trial was to evaluate the efficacy of the syrup as a therapy for diarrhea and ARI in children and to observe untoward effects; if any.

METHODOLOGY

Population and Sample

The sample size for this study was calculated using:

*Sample Size = (Z-score)^2 *StdDev *(1-StdDev) / (margin of error)^2*

where,

- Z-score = Confidence Level —We have taken our confidence interval as 95% and for 95% – Z Score = 1.96.
- Margin of Error or Confidence level (e) for this study is chosen as 5%, i.e. 0.05.
- Standard of Deviation(σ): Since we haven't actually administered our survey yet, the safe decision is to use it 0.5.

  Hence,

$$\text{Sample Size} = \frac{(Z_\alpha)^2 * \sigma(1-\sigma)}{(e)^2}$$

= $(1.96)^2$ x .5(.5)) / $(.05)^2$

= .9604 / .0025

= 384.16 ≃ 385

The sample size for the study so obtained is 385.

As it is a Phase-II clinical trial, a sample of 66 subjects was taken.

Data and Data Source

For this open labelled clinical trial, primary data has been collected .The total study duration of this two phase clinical trial was 7 days. From the study centre, 66 subjects between age group of 6 months to 5 years of either gender was selected and was evaluated for 8 symptoms on first, fourth and seventh day. And for the analysis purpose data of initial and final data was considered. The name of the company and the product is blinded as per the conditions of ethical committee.

Theoretical framework

Dosage of the drug:

The medicine is given for seven days of active treatment, four times in a day in a quantity as follows:

- 6 to 12 Months - 8 to 10 drops
- Above 1 year - 2.5 ml
- 2 years – 5 ml
- 3yers - 5 year – 10 ml

Special handling requirements:

The investigational product containers should be stored at room temperature away from direct sunlight.

Follow up:

The follow up is done at the interval of 3 days for 7 days. All subjects were required to continue their regular diet and follow the instruction of the investigator regarding any special diet or activity if suggested.

Inclusion/Exclusion criteria:

The children between the age group of 6 months to 5 years who were having fever less than 101 F were included for the study. Participants of both genders with mild or moderate ARI for not more than two days were included. Enteritis with no or some dehydration were part of this study. Children with no significant medical or surgical diseases at the time of screening were considered. Inclusion criteria included the children whose parents were ready to provide informed consent and were willing to take their child for follow ups.

Children with severe malnutrition, dehydration and diarrhea for more than 14 days were excluded. Cases with blood and mucus in stool and needed hospitalization were eliminated. Candidates who took antibiotics or any anti-diarrheal medication for current episode of diarrhea were not taken into consideration. Subjects who participated in another clinical study within three months before recruitment were prohibited.

Subject shall be withdrawn from the study at their parents'/ legally accepted guardian's request, if in the investigators opinion for subject's well-being.

Subjects were assessed for the following eight parameters:

- Sneezing
- Running Nose
- Congestion/Stuffiness
- Itchy Nose
- Eye symptoms
- Total nasal symptoms
- Chronic cough
- Throat symptoms

where sneezing and running were considered main parameters for this statistical study, and others were secondary parameters.

This study is approved by internal ethics committee confidentially. Any changes in this study plan or protocol will be implemented only after reviewed and approved by the ethical committee.

Statistical Analysis

The sample size for this trial is 385 and for Phase-II open trial 66 subjects were assessed.

Subjects were evaluated on the basis of two main parameters, sneezing and running nose and the remaining secondary parameters.

Assessment of ARI was done according to three point scoring criteria given by WHO;

0 = Mild/No ARI (Presence of cough or cold)

1 = Moderate ARI (Fast breathing without chest indrawing.)

2 = Severe ARI (Presence of chest indrawing (severe pneumonia) and signs of

very severe disease like convulsions, abnormally sleepy, severe malnutrition,

wheezing, grunting, nasal flaring etc.)

Subjects were examined on the basis of these parameters on initial, fourth and seventh day of study and evaluation was being done using a three-point scale of 0-2,0 being mild and 2 being severe. Paired t –test, Fisher's exact test and Wilcox Sign Rank test were used for the statistical analysis. Statistical analysis was done using open source R software.

RESULTS

Table 1: p-value for considered symptoms

	0(mild)	1(moderate)	2(severe)	P value	
Days				T test	wilcox
Sneezing					
1^{st} DAY	14	46	7		
4^{th}DAY	42	24	0	1.45E-12	3.10E-09
7^{th}DAY	61	6	0	6.81E-15	2.40E-10
Running nose					
1^{st} DAY	5	50	12		
4^{th}DAY	28	37	1	2.20E-16	3.13E-11
7^{th}DAY	54	31	1	2.20E-16	7.08E-12
Congestion					
1^{st} DAY	26	40	1		
4^{th}DAY	52	14	0	2.07E-09	9.98E-08
7^{th}DAY	63	4	0	2.39E-10	4.48E-08
Itchy nose					
1^{st} DAY	41	26	0		
4^{th}DAY	53	13	0	3.85E-05	0.000129
7^{th}DAY	63	4	0	4.75E-06	4.66E-05
Throat symptoms					
1^{st} DAY	50	17	0		
4^{th}DAY	61	5	0	0.000273	0.000537
7^{th}DAY	67	0	0	3.56E-05	0.000116
Eye symptoms					
1^{st} DAY	53	14	0		
4^{th}DAY	63	3	0	0.000404	0.000898
7^{th}DAY	67	0	0	0.000633	0.000544
Chronic cough					
1^{st} DAY	26	42	5		
4^{th}DAY	50	16	0	2.97E-10	1.11E-08
7^{th}DAY	64	3	0	9.64E-12	2.01E-09
Total nasal symptoms					
1^{st} DAY	41	26	6		
4^{th}DAY	37	29	0	1.47E-12	6.99E-09
7^{th}DAY	63	4	0	3.98E-14	1.79E-09

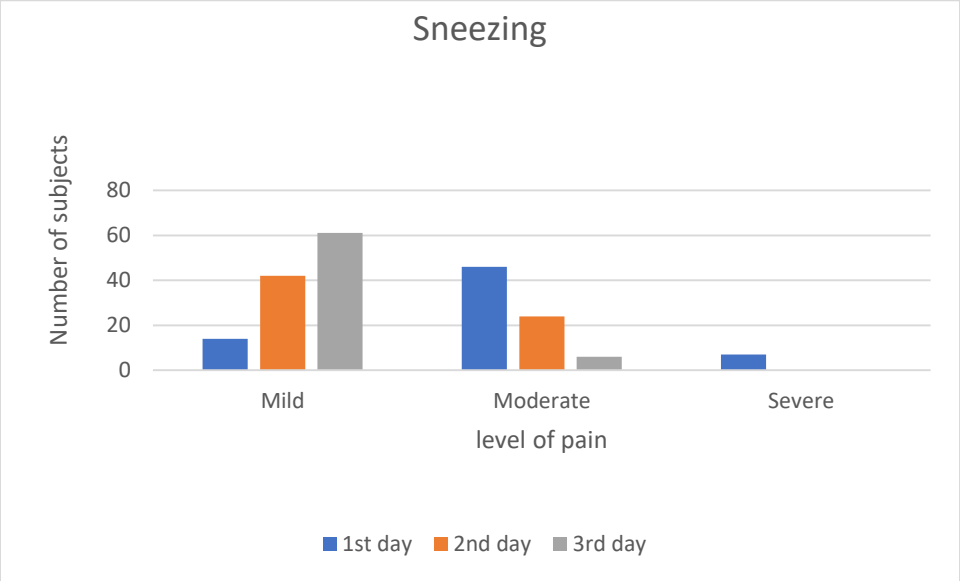

Fig. 1

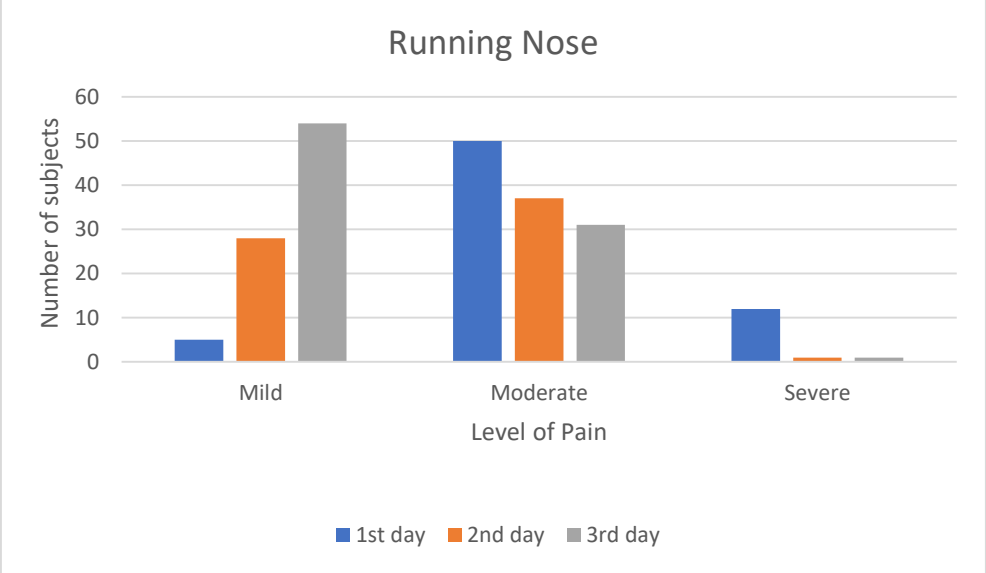

Fig. 2

From Fig.1, it can be seen that no cases of severe sneezing were observed and cases of moderate sneezing were reduced to fifty percent on fourth day. On seventh day, not a single case of severe sneezing can be seen while of moderate were only nine percent. Also, from Fig.2, cases of severe running nose were almost reduced to zero and cases of moderate running nose were reduced by twenty percent on fourth day. It shows a gradual reduction on seventh day.

From Table 1, the p-value for all the eight parameters is found to be less than .05 for all the tests on fourth day as well as on seventh day of trial, which implies that Ayurvedic syrup is effective for treatment of ARI.

DISCUSSION

When compared with quick recovery from any disease with modern medicine, Ayurveda works slowly but have no side effects. The results show us that the Ayurvedic syrup outruns this limitation of Ayurveda, since the effect is clearly visible on fourth day of intake. Since the medicine is showing effects even on fourth day, so it need not be taken for seven days in cases of moderate ARI. No other medicine in market still found to be a treatment for both ARI and diarrhea simultaneously.

In this phase II clinical trial, the main aim was to test the efficacy of the Ayurvedic syrup. Since, this was an open labelled randomized trial thus, further studies are recommended with large numbers.

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