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Efficacy of a topical ayurvedic preparation (Zandu ultra power balm) – relief from cold and associated symptoms

G. Gandhimathi

drgandhigr27@gmail.com

GR Ayurvedic Research Centre, Chennai, Tamil Nadu

ABSTRACT

Zandu Ultra Power Balm is a topical ayurvedic preparation that contains various active ingredients such as Menthol, Gaultheria oil, clove oil, cajeput oil, ajwan satva etc. This present study attempts to support the product claims made by the above mentioned (OTC) product for cold and pain relief. Consenting adults (n=30) who were experiencing cold and related symptoms were enrolled in a prospective open-label, phase 4 study. Each of them was provided 1 bottle of the product for the study (7 days) and asked to answer questions regarding product efficacy on a visual analogue scale. The scores were traced on days 0, 2, 4 and 6. Subjects observed an effective reduction in cold and congestion over 2 days and a reduction of headache and backache due to cold over 6 days (p <0.001). Conclusion: Zandu Ultra Power Balm works effectively as a remedy for cold and its associated symptoms.

Keywords: Zandu, Common Cold, Pain, Nasal Congestion

1. INTRODUCTION

The common cold is the most recurrent cause of illness among adults as well as children. It is an upper respiratory tract infection caused by certain viruses and is transmitted by virus-infected droplets or by direct contact with infected secretions. The symptoms of the common cold are cough, sore throat, sneezing, and nasal congestion which presents as a runny or blocked nose. Pain is a disturbing sensation that is often caused by intense stimuli, pain during a cold usually manifests as a headache and/or backache. The management of the common cold and its symptoms are frequently addressed by OTC medication such as topical medication or tablets since it is a self-limiting disease. Hence studies of consumer navigation and selection behaviours for OTC products in retail selling reveals that consumers most frequently purchase OTC medications for pain relief, allergy and cough / cold symptom. Topical pain relief medications are available in the form of cream, ointment or gels and a majority of them contain ayurvedic components. Statistics show that ayurvedic products are gaining popularity and among the ayurvedic products about 25+% of the sale is from OTC products.

Zandu Ultra Power Balm is an ayurvedic preparation that is largely composed of Menthol (17%) and Oil of Gaultheria (25%), clove oil (5%), cajeput oil (5%), ajwain satva (0.5%), Eucalyptus globulus-oil (0.2%), Nutmeg oil (0.1%) and Capsicum annum satva (0.02%) along with Tony Red (colour) and Quinizarine green SS (colour) as excipients. The preparation is rubbed on to the areas for relief of pain or congestion such as the head, neck, chest and back.

Zandu Ultra Power Balm claims to be a remedy for headaches due to cold, cold (nasal congestion) and backache due to cold. This study is undertaken to substantiate these claims.

2. MATERIAL AND METHODS

Study design

This was a prospective open-label phase 4 study that was carried out with Zandu Ultra Power Balm market samples. 30 subjects all between the age of 18-60 years and those who were experiencing cold, congestion, headache due to cold and body ache due to cold were included after presenting them with informed consent in their mother tongue or English. Participants who had preexisting conditions such as allergy, hypersensitivity and migraine was not included in the study.

We conducted the study over two months (Dec 7th 2019 to Feb 7th 2020) while the subjects were observed for 6 days. During the study duration, each participant was given a bottle of Zandu Ultra Power Balm (net wt: 25ml) The participant's feedback was

recorded by the investigators through specifically curated questions. The responses were recorded on a visual analogue scale of 0-4 as 'poor' -0, 'fair' -1, 'good' -2, 'very good' -3, 'excellent' -4. The test parameters that were taken into consideration were: Existing issues related to cold, Cold and congestion, Headache due to cold, Head and backache due to cold. The scores were noted on the 0,2,4 and 6 days.

Statistical methods

A two-tailed student t-test was carried out to find the significance of the efficacy parameters of Zandu Ultra Power Balm.

3. RESULTS

On observing the demographics of the subjects (Table 1 and Table 2) it was found that male subjects (53.66%) comprised the majority of the sample population than the female subjects (43.34%). Also, the mean age for the male and female subjects was 39.41 years and 32.77 years, respectively. In terms of occupation distribution (Table 3 and Graph 1) majority of the subjects belonged to the service industry (26.67%) followed by the labourers (23.33%). The least amount of participants belonged to the business industry (6.67%). Regarding the existing conditions (Table 4 and Graph 2) before the start of the study majority of the participants reported cold/nasal congestion (46.67%) followed by headache due to cold (30%) and headache and backache due to cold (23.33%). The two-tailed test for significance (Table 5) portrayed a significant difference between the results of day 2 and day 0 ($p < 0.001$). Regarding headache due to cold and headache with backache due to cold, there was significant variation seen on days 2, 4, and 6 when compared to day 0.

With respect to the scores given on the visual analogue scale, Table 6 shows the efficacy parameters in percentage distributions. Graph 3 conveys that the majority of the subjects scored 'excellent' (71.43%) for cold and congestion relief on day 6 when compared to day 2 where 21% of the subjects reported 'fair' and 29% reported 'good',

The same trend of excellent scores was seen on day 6 in respect to headache due to cold where 34% reported good and 66.67% reported "excellent" scores when compared to day 2 where 22% reported 'fair', 22% reported 'good', 56% reported 'very good' (Graph 4)

In terms of the symptoms of headache and backache due to cold 28% reported 'very good' and 71% reported 'excellent' on day 6 compared to day 2 where 14% reported 'fair', 57% reported 'good', 29% reported 'very good' (Graph 5)

Table 7 and Graph 6 presents the overall performance of the product, day zero was set at 100% to observe the reduction in cold and its symptoms. The symptoms of cold and congestion reduced from 100% to 55.81% on day 2, 23.26% on day 4 and 9.30% on day 6. While The symptoms of headache due to cold reduced from 100% to 60% on day 2, 26.67% on day 4 and 10% on day 6, and symptoms of head and backache due to cold reduced from 100% to 59.09% on day 2, 27.27% on day 4 and 9.09% on day 6.

4. DISCUSSION

The efficacy of the topical ayurvedic preparation was observed in 30 subjects over the course of 6 days. The efficacy and performance of the product were analyzed from the visual analogue scores provided by the subjects on days 0, 2, 4 and 6. A two-tailed test, carried out to test the significance exhibits that there was an evident decrease of cold and congestion symptoms among subjects from day 2 itself when compared to day 0 ($p < 0.001$), while other symptoms such as headache due to cold and headache with backache due to cold saw a significant reduction on day 2, 4 and 6 when compared to day 0. ($p < 0.001$) This implies that the Zandu Ultra Power Balm has shown an effective reduction of cold and its associated symptoms.

The visual analogue score collected from the participants were converted to percentage distributions to observe the efficacy parameters. The efficacy on cold and congestion symptoms on day 0 was scored either fair, good or very good but on day 6, 71% of the subjects reported excellent scores

With regards to symptoms of headache due to cold and headache with backache due to cold, the scores were scattered among fair, good and very good on day 2. While 66% and 71% "excellent" scores were reported on day 6 for headache due to cold and headache with backache due to cold respectively. All of the data collectively conveys the use of Zandu Ultra Power balm improves symptoms associated with cold.

By observing the positive effect of Zandu Ultra Power Balm on cold and its associated symptoms, the overall performance was also studied. The scores were kept at 100% to observe the reduction in the efficacy parameters viz cold and congestion, headache and backache. Cold and congestion was seen to reduce to 9.30% on day 6 while headache due to cold and headache with backache due to cold was seen to have an effective reduction from 100% to 10% and 9.09% on day 6 respectively. Hence the overall performance implies about 10 fold reduction in cold and its associated symptoms

5. CONCLUSION

For the study population, the above 60-day prospective open-label clinical trial findings on Zandu Ultra Power Balm evaluated for efficacy suggest that Zandu Ultra Power Balm works as a remedy for headaches due to cold, cold (nasal congestion), and backaches due to cold. All of the above complaints experienced by the study population irrespective of the severity were shown to be effectively relieved by the use of the product. There was excellent overall compliance to the treatment and no clinically significant adverse reactions Hence it may be concluded that the Zandu Ultra Power Balm work effectively as a remedy for Headache due to cold, Cold (nasal congestion) and Backache due to cold significantly.

Table 1: Age

	N	Mean
Female	13	32.77
Male	17	39.41
Total	30	36.54

Table 2: Gender

	N	%
Female	13	43.34
Male	17	56.66
Total	30	100

Table 3: Occupation

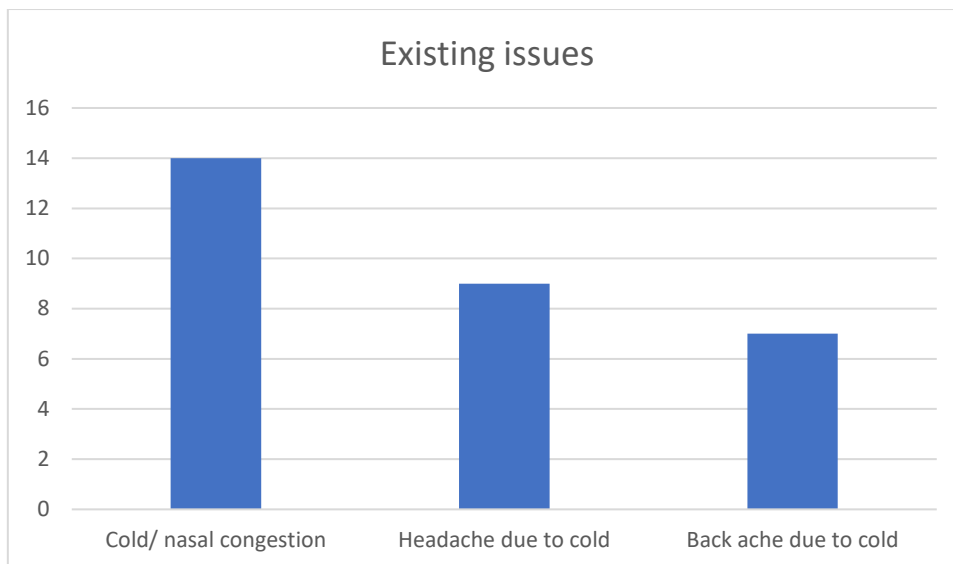
Occupation	Subjects	Percentage
Maid	4	13.33
Labour	7	23.33
Student	3	10.00
House wife	6	20.00
Business	2	6.67
Service	8	26.67



Graph 1: Occupation

Table 4: Efficacy In Pain Reduction

Existing problems	N	Percentage
Cold/ nasal congestion	14	46.67
Headache due to cold	9	30
Head and backache due to cold	7	23.33
Total	30	100



Graph 2: Existing Issues

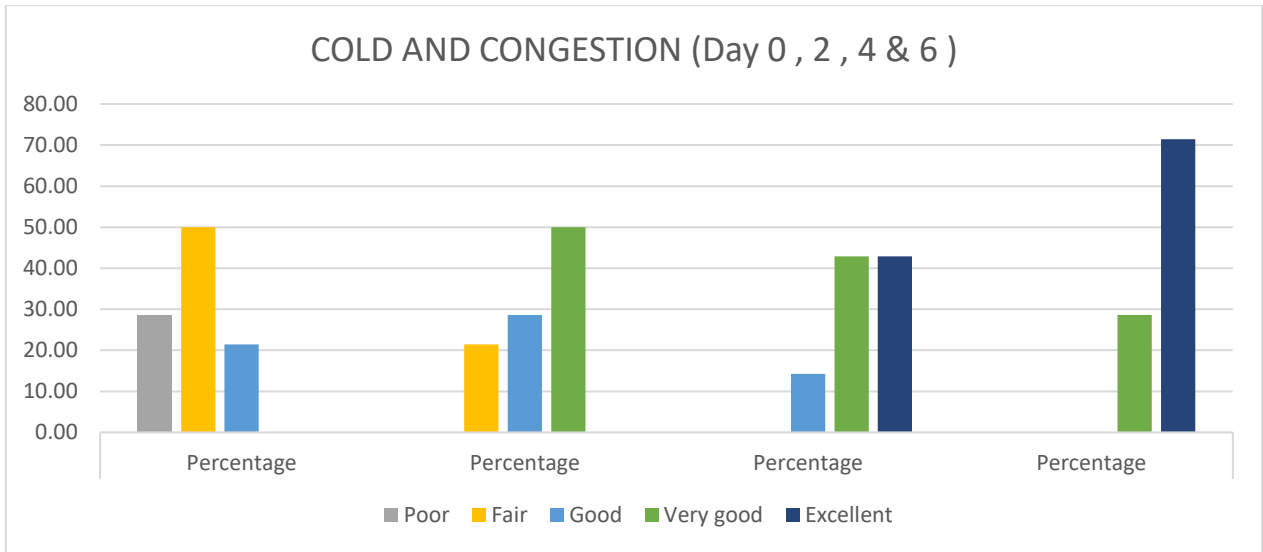
Table 5: Zandu Balm Ultra Power Efficacy Parameters - Test For Significance

Efficacy	Cold and congestion		Headache due to cold		Headache and Backache due to cold	
	T value	Sig	T value	Sig	T value	Sig
Day 0 vs Day 2	1.409	p<0.001	4.366	p<0.001	4.3	p<0.001
Day 0 vs Day 4	2.456	p<0.001	6.89	p<0.001	2	p<0.001
Day 0 vs Day 6	7.955	p<0.001	1.367	p<0.001	1.5	p<0.001
Day 2 vs Day 4	1.372	p<0.001	5.428	p<0.001	3.76	p<0.01
Day 2 vs Day 6	8.403	p<0.001	4.176	p<0.001	5.32	p<0.01
Day 4 vs Day 6	2.753	p<0.1	1.334	p<0.01	1.035	NA

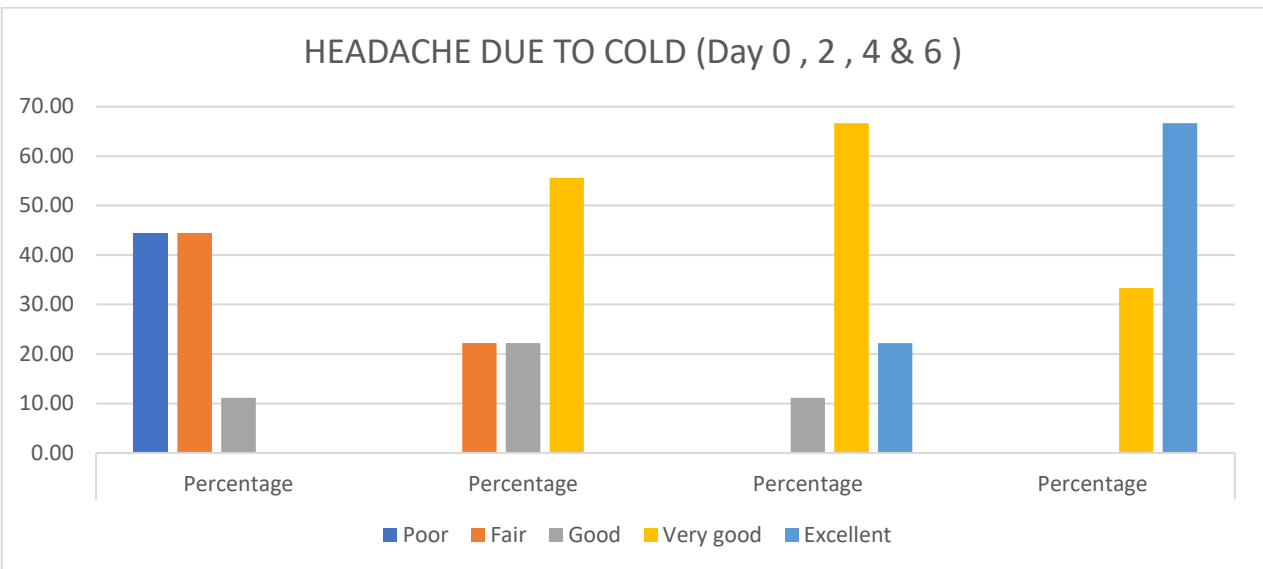
Table 6: Zandu Balm Ultra Power Efficacy Parameters- Percentage Distribution

Efficacy	Day 0		Day 2		Day 4		Day 6	
	N	Percentage	N	Percentage	N	Percentage	N	Percentage
Cold, congestion								
Poor	4	28.57	0	0.00	0	0.00	0	0.00
Fair	7	50.00	3	21.43	0	0.00	0	0.00
Good	3	21.43	4	28.57	2	14.29	0	0.00
Very good	0	0.00	7	50.00	6	42.86	4	28.57
Excellent	0	0.00	0	0.00	6	42.86	10	71.43
Headache due to cold								
Poor	4	44.44	0	0.00	0	0.00	0	0.00
Fair	4	44.44	2	22.22	0	0.00	0	0.00
Good	1	11.11	2	22.22	1	11.11	0	0.00
Very good	0	0.00	5	55.56	6	66.67	3	33.33
Excellent	0	0.00	0	0.00	2	22.22	6	66.67
Headache & Backache due to cold								
Poor	2	28.57	0	0.00	0	0.00	0	0.00
Fair	4	57.14	1	14.29	0	0.00	0	0.00
Good	1	14.29	4	57.14	2	28.57	0	0.00
Very good	0	0.00	2	28.57	4	57.14	2	28.57

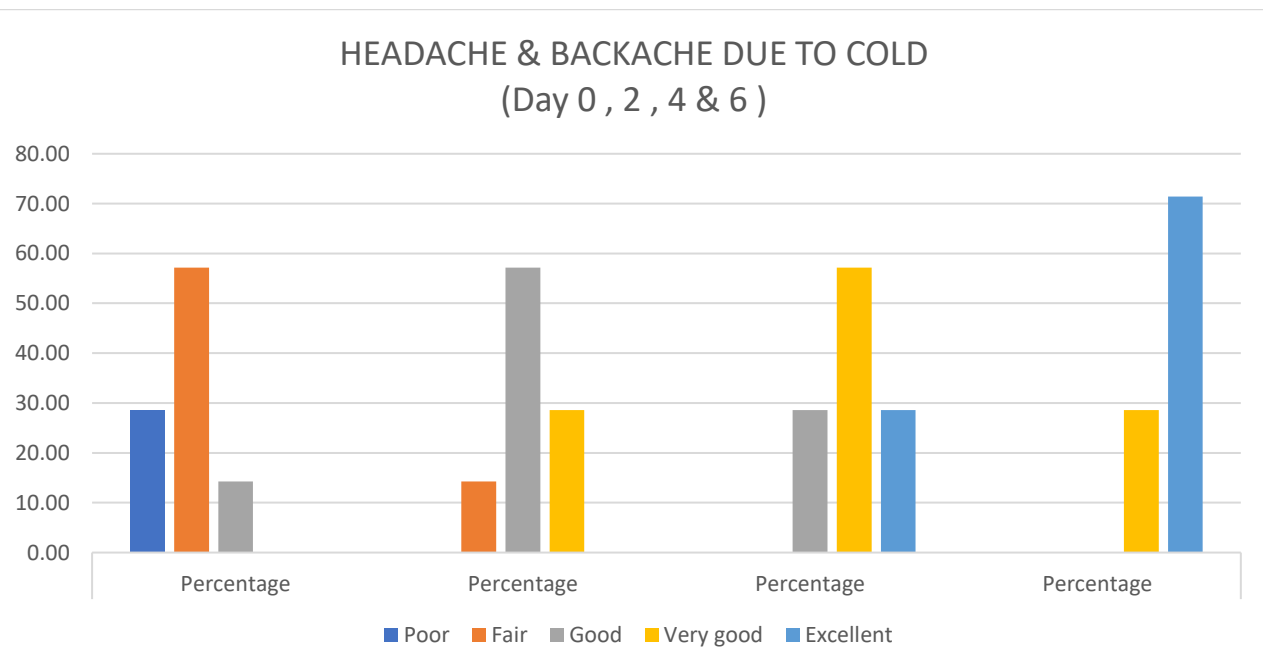
Excellent	0	0.00	0	0.00	2	28.57	5	71.43



Graph 3: Efficacy Parameters – Cold And Congestion



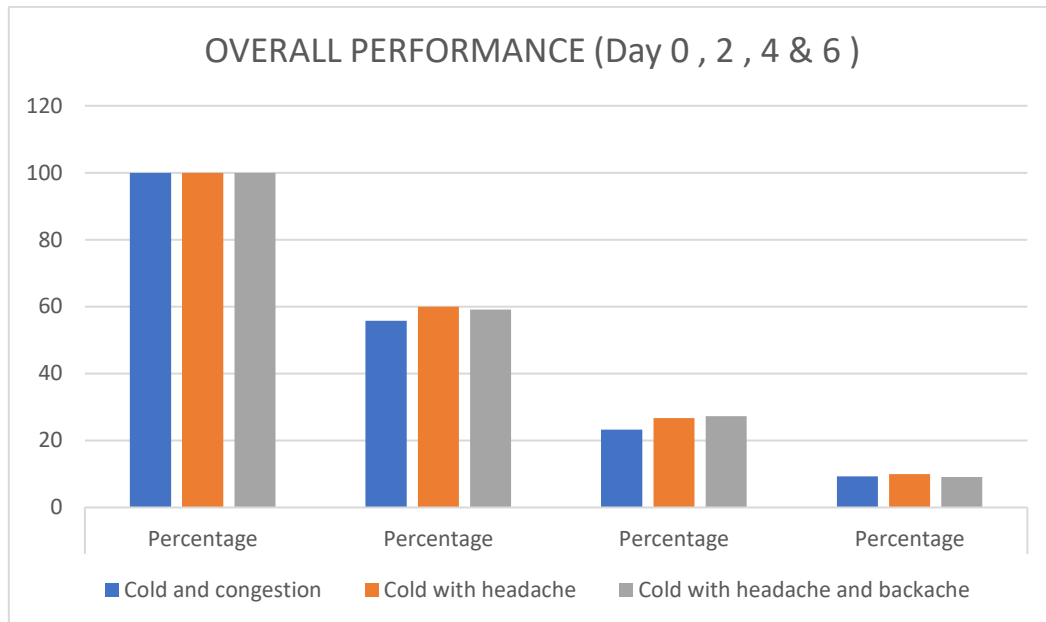
Graph 4: Efficacy Parameters – Headache Due To Cold



Graph 5: Efficacy Parameters – Headache And Backache Due To Cold

Table 7: overall performance

Efficacy parameters	Day 0		Day 2		Day 4		Day 6	
	N	Percentage	N	Percentage	N	Percentage	N	Percentage
Cold and congestion	3.07	100	1.71	55.81	0.71	23.26	0.29	9.30
Cold with headache	3.33	100	2.00	60.00	0.89	26.67	0.33	10.00
Cold with headache and backache	3.14	100	1.86	59.09	0.86	27.27	0.29	9.09



Graph 6: Overall Performance