Assessment of Efficacy of Multi Herbal Extracts Product (FluAct® Syrup) against Flu Indications in Pakistani Population

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Authors’ contributions

This work was carried out in collaboration among all authors. Author YM designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors HY and HU managed the analyses of the study. Author HR managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

One of the most common diseases to human is flu which direly needs appropriate therapies. Fever, throat pain and runny nose are the eminent indication of flu which is irritating to the patients. The consumption of herbal medicines is the most reliable alternative treatment all over the globe because of its compatibility within body and rare side effects when compared to synthetic chemicals. The main objective of the study was in-vitro screening and evaluation of anti-flu potential of multi extract herbal product FluAct syrup. This cross sectional study work encapsulates observation on 250 patients for treatment of flu by using a novel multi extra for above seven days of duration. After the approval from ethical committee of Rashid Latif College of Pharmacy (RLCP), a questionnaire was designed and collects information within flu patients who used FluAct syrup. An independent statistician for analysis (Microsoft excel) was used to analyze collected data. Result showed that most of the patients’ cured by using FluAct syrup. Some of them did not completely
cure in terms of headache (92.92%), sore throat (91.5%), lethargy (92%) and temperature (97.7%). The findings showed abrupt improvement in patient health within three days by using FluAct syrup. It was reported that patients have excellent tolerance and showed willingness to adopt this therapy to treat flu. The study was used to confirm the data. It can be concluded that novel preparation of multi extracts (FluAct syrup) has effective herbal constituents to treat symptoms of flu in patients along with better tolerance and quick relief efficacy.

Keywords: Flu; health; extract; herbal; medicinal.

1. INTRODUCTION

Flu is most common health problem throughout the world. People with flu are most contagious in the first 3-4 days after their illness begins. Most of the people suffer from severe health problems even after a week of illness. The main reason of improper symptomatic relief is due to self-medication by using over-the-counter drugs or just a nuisance perception by the patient [1-3]. It is evinced by Meltzer, et al. in past that improper treatment of flu or untreated flu sacrifices patient quality of life. The occurrence of flu is mostly concomitant to various comorbid complications such as pain, headache, runny nose, asthma and hyperthermia along with disordered sleep or obstructive sleep apnea. In addition, the symptoms of flu can become worse if left untreated resulting in spiral of worsening complications. The viral reaction is the most prevalent cause of flu [4]. Above symptoms appear in both cases and require treatment [5-7].

There are numerous medicines present in market for symptomatic relief of flu [8,9]. Recently, there has been a shift in universal trend from synthetic to herbal medicine, which we can say Return to Nature [10]. It is not mandatory that herbal medicines contain antimicrobial agent but they can also stimulate immune response against any allergen [11-13]. The conventional herbs have merits than synthetic agents such as easy availability, cheaper, and rich in culture. On contrary, fewer synthetic agents cause severe adverse reactions [13-15]. This study was designed to enlighten the better anti-flu potential of traditional herbs multi extract over other synthetic agents available in market. Echinacea purpurea, sambucus, lavender, piper longum or pinus pinaster multi extract in FluAct syrup was formulated in a single dosage form by ROUTE2 Health and administered to patients with flu symptoms and findings were recorded. This study is beneficial to provoke use of traditional medicinal plants to treat symptoms of flu. In Pakistan, FluAct syrup has been marketed commercially for more than 3 years by ROUTE2 Health. For effective and quick relief of flu and flu like symptoms, FluAct syrup is a best multi-herbal natural remedy.

2. METHODS

This cross sectional study included 250 patients over age 40 years (median age: 30 years, range 20-40) that were treated with FluAct syrup for flu and related symptoms. These patients were initially weakened due to flu (100%) and nobody was taking medicine (100%). The effects of FluAct syrup, was evaluated at 3rd day and 7th day after medicine intake with visual analog scales for generalized pain, fever, runny nose, sneezing, headache, throat infection or throat pain and lethargy. ROUTE2-001 questionnaire was developed to collect information. Adverse effects of FluAct syrup were also evaluated. The data were analyzed with SPSS 18.0 and Microsoft excel.

2.1 Study Design

A questionnaire based study was conducted based on a self-administered questionnaire; study was conducted at local hospitals for a period of seven days 23-10-2019 to 30-10-2019. Questionnaire was in local and English language and was design by Assistant professor (RLCP).

2.2 Sampling and Sample Size

The sample size was estimated by using Krejcie and Morgan’s sample size calculator (Krejcie RV and Morgan DW, 1970). A suitability sampling technique was used to recruit a sample of 250 participants from residents of Pakistan.

2.3 Survey Instrument

The survey questionnaire used to assess the treatment outcomes or cure after the use of FluAct syrup. The questionnaire contains three sections. The first section contained of items related to sign and symptoms before cure. The second section contains treatment outcomes after the exposure of FluAct syrup. The last portion of questionnaire contains the information
about the adverse effect after the exposure of FluAct syrup.

2.4 Materials Used in the Study

- FluAct Syrup

2.5 Inclusion and Exclusion Criteria

The following inclusion criteria were used for the selection of patients.

(a) Patients having age above 19 years.
(b) Flu symptoms.
(c) Patients don’t suffer any other viral disease.

The following exclusion criteria were used for the selection of patients:

(a) Patients having age less than 19 years.
(b) Patients having severed viral problems.
(c) Patients already taking medicines.

2.6 Statistical Analysis

The data expressed as mean ± SD was analyzed by one-way analysis of variance (ANOVA) and data was analyzed with Microsoft excel (graph). Sample values with $p \leq 0.05$ and $p \leq 0.01$ were considered statistically significant and highly significant, respectively.

3. RESULTS

Clinical Benefits of FluAct syrup as shown in Table 2, temperature decreased (Norma) in 90.2%, runny nose cured by 100% patients, lethargy cured by 88%, headache cured by 79.2% and sneezing cured by 100% in the 1st three days of treatment. During the first three days of treatment 83.05% of patients also cured from sore throat. Several patients experienced issues in performing quality of tasks listed in the ROUTE2-001 questionnaire (not mentioned in paper), which required moderate efforts such as driving, office work, playing ball due to their general health condition. Those patients felt better after FluAct syrup treatment.

3.1 Characteristics According to Status of Patients

In this study we have 279 patients, 29 remain non respondent or did not provided proper data. Total 250 patients were included in this study and most the patients’ cured by using FluAct syrup. Some of them did not completely cure in terms of headache (92.92%), sore throat (91.5), lethargy (92%) and temperature (97.7%). It was reported that patients feel better after taking multiple dose of FluAct syrup (syrup 3 times a day). There was significant cure found in all patients. About order, taste and color patients response was overall good.

![Patient profile and characteristics](image)

**Fig. 1. Patient sign and symptoms before treatment**
Table 1. Patient profile and characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (Average)</td>
<td>30±3.1</td>
</tr>
<tr>
<td>Mean ±SD</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>20-40</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>117 (46.8)</td>
</tr>
<tr>
<td>Female</td>
<td>133 (53.2)</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
</tr>
<tr>
<td>Heart rate</td>
<td>Normal (60 to 100 beats per minute)</td>
</tr>
<tr>
<td>Blood pressure (120/80)</td>
<td>Normal (196) (78.4)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12 (4.8)</td>
</tr>
<tr>
<td>Temperature</td>
<td>225 (90)</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>Normal (12 to 20 breaths per minute)</td>
</tr>
<tr>
<td>Headache</td>
<td>142 (84.8)</td>
</tr>
<tr>
<td>Runny nose</td>
<td>250 (100)</td>
</tr>
<tr>
<td>Lethargy</td>
<td>250 (100)</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>118 (47.2)</td>
</tr>
<tr>
<td>Sneezing</td>
<td>223 (89.2)</td>
</tr>
</tbody>
</table>

3.2 Treatment Response at 3rd Day and 7th Day

In this study, we administered FluAct syrup to patients with flu symptoms and collected information. Out of 250 patients, 117 were male and 133 were females. All patients had submitted questionnaire to project administrator. Vital signs (heart rate, and blood pressure was measured) before starting treatment. Sign and symptoms of flu was observed and tabulated in Table 1. Treatment time line was decided 7th days and most of patients were cured after 3rd day. Runny nose and sneezing was 100% cured after 3rd day of treatment. Temperature (36.5–37.5°C) 90.2%, sore throat 83.05%, lethargy 88% and headache 79.245 were cured. Rest of patients was cured after 7th day of treatment.

3.3 Adverse Effect

There were no specified symptoms of adverse effect. Subjects did not report specific symptoms including diarrhea, fatigue, nausea, dizziness and sleepiness. One subject reported adverse effect headache but it was not included because at the same he had high blood pressure. One more subject had reported dizziness and itchy skin and after one day he became normal. As strict principles were undertaken, only few cases of adverse events were reported as shown in Table 3.
Table 2. Therapy efficacy and safety characteristics

<table>
<thead>
<tr>
<th>Patients characteristics</th>
<th>Flu and flu symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of disease</td>
<td>Flu and flu symptoms</td>
</tr>
<tr>
<td>Duration of treatment</td>
<td>7 days</td>
</tr>
</tbody>
</table>

**Status n (%) after 3rd days**
- Temperature: 203 (90.2)
- Headache: 168 (79.24)
- Runny nose: 250 (100)
- Lethargy: 220 (88)
- Sore Throat: 98 (83.05)
- Sneezing: 223 (100)

**Status n (%) after 7th days**
- Temperature: 220 (97.7)
- Headache: 197 (92.92)
- Runny nose: 250 (100)
- Lethargy: 230 (92)
- Sore Throat: 108 (91.5)
- Sneezing: 223 (100)

Table 3. Adverse events reported during the study period 3rd day and 7th day

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinuation of treatment due to adverse effect</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

**Adverse Events**
- Fatigue: 10 (10)
- Nausea: 2 (2)
- Insomnia: 4 (4)
- Pruritus: 2 (2)
- Diarrhea: 0 (0)

4. DISCUSSION

This preliminary observational prospective study reported results from a real life experience of FluAct syrup treatment in flu patients (median age 30 years). Although limited in terms of number of patients, our results suggested that this treatment would be more beneficial for every age patients specially 20 to 40 years. FluAct syrup treatment was well supported: no severe adverse effect was observed over the treatment duration (7th days). These findings suggested that FluAct syrup holds promise as an alternative to other medicines like antibiotics and antihistamine which are known for their side effects and contraindications particularly in older patients. The study limitations were its observational design, the small number of patients (n = 250) and the short follow up duration (7 days). Our study showed that FluAct syrup contained multiple herbal extract and was tested its efficacy and safety during 7 days of twice daily. FluAct syrup showed significant improvement in flu patients. The results showed that these authentic herbal extract was effective against flu and flu like symptoms.

5. CONCLUSION

In conclusion, the results of this preliminary study suggested that FluAct multiple extract product is useful in managing the symptoms of flu in every age patients with very minimal undesired effects. Majority of patients were cured within 3 days after treatment and our study findings concluded that Pakistani patients respond to FluAct syrup.

CONSENT AND ETHICAL APPROVAL

This study was endorsed by Ethics Committee of Rashid Latif College of Pharmacy, Lahore Pakistan and was carried in acquiescence with the Helsinki Declaration. The need for informed consent was renounced because of the study design.

DISCLAIMER

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing
company rather it was funded by personal efforts of the authors.

**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

**REFERENCES**


