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RESEARCH ARTICLE

A Pilot study to evaluate safety and efficacy of Papenglow (Herbal Face-Pack) in healthy human subjects.

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Abstract

Background: Homemade natural face packs and masks make way for smooth, radiant and silky skin. The Natural face packs do contain some vital vitamins that are required for the health and glow of your skin. The Natural face packs do contain some vital vitamins that are required for the health and glow of your skin.

Aims and objectives: This study was planned to evaluate the efficacy and safety of the PAPENGLOW (Herbal Face Pack) on " Oilyskin " application and to achieve instant glow on skin in healthy human subjects.

Material and methods: After confirming eligibility, 30 patients were enrolled in the study and each of the patients was provided with Papenglow (Herbal Face Pack). This was conducted in accordance to the ICH-GCP guidelines with approval from Independent Ethics Committee. Written Informed consent was obtained from these patients after a thorough explanation of the study.

Results and discussion: A total of 30 (15 females and 15 males) patients were enrolled in the study. There was significant improvement in the facial skin texture and glow, after a week's application, and the improvement trend continued, till the end of the study period.

Conclusion: This study observed a significant improvement in the facial skin texture and glow, after a week's application in almost all persons; and also, there were no clinically significant adverse reactions, with excellent overall compliance. This beneficial effect might have been due to the synergistic antioxidant, anti-inflammatory, and UVR protective properties of the ingredients, which also have excellent safety profile.

Limitations and recommendation: This was a pilot study conducted only on 30 subjects with only single study centre furthermore comprehensive and detailed multi centric study can be done to evaluate the effectiveness of "Papenglow".

Introduction:

Cosmetics are defined as the products used for the purposes of cleansing, beautifying, promoting attractiveness or alternating one's appearance[1,2] (BM Mithal 2000, Shoba rani R et al. 2000) Homemade natural face packs and masks make way for smooth, radiant and silky skin[3] (Millikan, Larry E. 2001). If pimples, acnes and other skin problems are troubling you too much there is always an effective natural remedy awaiting for you which not only helps in removing these problems but also gives you a healthy and glowing skin[4] (Swarnalatha Saraf 2005). There are multiple ways of maintaining healthy skin and your aim is to choose the right place to make a fresh start. The Natural face packs do contain some vital vitamins that are required for the health and glow of your skin. These substances also prove to be beneficial for your skin in many ways. They foster your skin by not only improving its

color but also by cleansing and reducing interstices. Natural Facial Packs are less complicated and pretty simple to use. They help you in looking after skin and also prove its worthiness by increasing the circulation of the blood within the veins of the face.

Effects of the facial packs are generally temporary and for the regular glow you should use it 2-3 times a week. A mix of face pack is prepared before it is used for applying. Face pack should be applied on clean skin and there should be no cosmetics on skin[5-8] (Deep Chanchal et al.2009, Mandeep Singh et al. 2011, Kotta Kranthi Kumar 2011).

In present study the poly-herbal face pack "PAPENGLOW" is a mixture of various potential herbal ingredients like Carica papaya, Aloe vera, Malus domestica, Cucumis sativus and therefore aimed at achieving instant fairness and smoothness of facial skin with minimal or no side effects.

Aims and objectives:

- To evaluate safety and efficacy of Herbal face pack in healthy human subjects.
- To achieve instant fairness on application of herbal face pack.
- To achieve smoothness, softness, glow and improvement in overall appearance on application of herbal face pack.

Key inclusion and exclusion criteria:

Healthy human subjects of both sex aged between 18-30 years giving their consent and willing to participate in the study were included.

Non cooperative individuals, those who were suffering for any systemic illness or skin disease, those with history of previous allergic skin reactions or with chronic use of medications were excluded.

Materials and methods:

A baseline history was obtained in order to determine the patient's eligibility for enrolment in the study. The baseline assessment included personal data, a description of symptoms and details of past medical history (family history, history of possible exacerbating factor/s, etc.). All the patients were advised to apply the "Herbal face pack", daily for a period of 3 weeks. The subjective improvement evaluation was done by a predefined global grading system, which included following gradations: "No improvement", "fair improvement", "remarkable improvement", "very good improvement" and "excellent improvement".

All the patients were followed up for a period of 3 weeks, and at each weekly follow-up visit, the dermal safety, and the improvement in skin wrinkling was evaluated. At the end of the 3week, the overall performance of the "Herbal face pack" was evaluated.

After confirming eligibility, 30 patients were enrolled in the study and each of the patients was provided with Herbal Face Pack. This was conducted in accordance to the ICH-GCP guidelines with approval from Independent Ethics Committee. Written Informed consent was obtained from these patients after a thorough explanation of the study.

Adverse events:

All the adverse events either reported or observed by the patients were recorded with information about the severity, date of onset, duration and action taken regarding the study drug. Relation of adverse events to the study medication were predefined as "Unrelated" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug), "Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other modes of therapy administered to the patient), and "Probable" (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient's clinical state).

Patients were allowed to voluntarily withdraw from the study if they experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study, efforts were made to ascertain the reason for dropout. Non-compliance was not regarded as treatment failure and reasons for non- compliance were noted.

Statistical analysis:

Statistical analysis was done according to intent-to-treat principles. The changes in various parameters from baseline values and the values after 6 weeks were evaluated by "Paired 't' Test". The minimum level of significance was fixed at 99% confidence limit and a 2-sided p value of <0.01 was considered significant.

Results:

A total of 30 (15 females and 15 males) patients were enrolled in the study. There was significant improvement in the facial skin texture and glow, after a week's application, and the improvement trend continued, till the end of the study period. Out of 30 subjects, 14 (47%) had "remarkable" improvement, 14(47%) had "very good" improvement, and 2 (6%) had "excellent" improvement in the facial skin wrinkles (Figure 1).

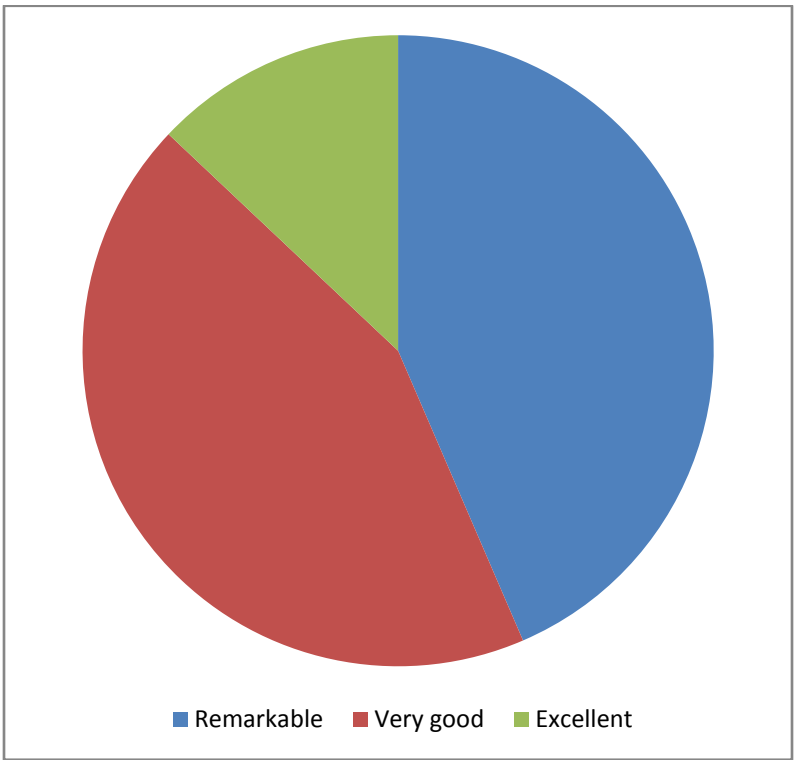

Figure 1: Response to Herbal face pack.

No. of Subjects	Response to herbal face pack	Percentage (%)
14	Remarkable	47%
14	Very good	47%
02	Excellent	06%
Total = 30		

There were no clinically significant adverse reactions, either reported or observed, during the entire study period and the overall compliance to "Herbal face pack" was excellent.

Discussion:

Atmospheric pollutants are an important source of oxidative stress, and skin, which has a highly differentiated complex organizational structure, is particularly vulnerable to free radical damage because of its contact with oxygen and with other environmental stimuli.

The principle constituents of Aloe vera are anthraquinones (aloe-emodin and aloin A/barbalin),Cinnamoyl, p-coumaroyl, feruloyl, caffeoylaloesin, aloemannanacemannan, verectinelgonica dimer A and bisbenzopyran.Aloe vera has been long recognized as an effective remedy for wound-healing and other inflammatory skin disorders.Esteban et al. identified a peroxidase, which may scavenge H_2O_2 in skin surface and thereby prevent free radical damage of the skin.

Caricapapaya is a source of nutrients such as provitamin A carotenoids, vitamin C, folate and dietary fiber. In preliminary research, danielone, a phytoalexin found in papaya fruit, showed antifungal activity against Colletotrichumgloesporioides, a pathogenic fungus of papaya. Papain is also applied topically for the treatment of cuts, rashes, stings and burns.

Conclusion:

This study observed a significant improvement in the facial skin texture and glow, after a week's application in almost all persons; and also, there were no clinically significant adverse reactions, with excellent overall compliance. The facepack was effective in controlling oil in all the patient and also was beneficial in controlling Acne. This beneficial effect might have been due to the synergistic antioxidant, anti-inflammatory, and UVR protective properties of the ingredients, which also have excellent safety profile. There over all increase in skin tone and was recommended by 90% of the patient .Therefore, it may be concluded that PAPENGLOW is effective and safe for usage.

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