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Pharmacological and Clinical Evaluation of Herbal Formulation for the Treatment of Various Hair/Scalp Problems

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Abstract. The study was conducted on a product based on herbal formulation of nine herbs in sesamum oil base supplemented with four essential oils and vitamin E. Clinical study was conducted on 175 human volunteers suffering from different kinds of hair and scalp problems. After clinical trials of 2-10 weeks, this formulation was found very effective in problems like head pustules, dryness and brittleness of hair, dandruff, itching, split hair, excessive hair fall and poor hair growth. In addition, it was also effective in cases of headache and sleeplessness. It was evaluated pharmacologically by acute oral toxicity test, dermal irritant test, eye irritation test and found safe and non toxic. Moreover, it did not cause any side effect.

Keywords: herbal formulation, hair/scalp problems, pharmacological evaluation, clinical trials

Introduction

Beautiful hair has been praised nearly in every culture throughout the world. Each culture has its own unique recipe to prevent hair problems and promote healthy hair growth depending on natural resources available to them. Nowadays hair and hair management has turned into a serious issue due to social, economical and financial problems beside disease, stress and strain. Common manifestations are dryness, roughness, premature greying, brittleness, baldness, excessive hair fall/loss of hair, dandruff etc. Poor dietary habits, personal hygiene, excessive use of hair dyes/chemicals, dryers, sprays, chlorinated water etc. aggravate the condition more. The aim of present research was to formulate a natural, safe non-hormonal remedy containing all necessary natural supplements (vitamins, amino acids, minerals, trace elements) and other physiological active compounds essential for healthy hair and scalp. (Soliman and Ghaim, 2005; Ezerietis *et al.*, 2003; Kim *et al.*, 1995).

The ingredients i.e. *Emblica officinalis, Acacia concinna, Nardostachys jatamansi, Terminalia chebula, Terminalia bellirica, Nigella sativa, Trigonella foenum-graeceum, Lageneria vulgaris*, and *Lawsonia alba* used in the formulation contain essential fatty acid, vitamins, amino acid and minerals (Gunduz *et al.*, 2002; Ahmed and Baig, 2001; Haq-Afrozul *et al.*, 1999; Mohammad, 1996; Chopra *et al.*, 1958). Presence of these constituents promotes healthy skin, strong healthy and shiny hair, prevents infection, improves damaged skin, darkens the hair, prevents baldness, stimulates hair growth, moisturizes skin and hair, removes dandruff and improves scalp/hair condition (Bagachi *et al.*, 2005; Brody, 1999; Khan, 1999; Kim *et al.*, 1995).

The herbs used in the formulation traditionally being used individually for different hair problems, brief account of which is in Table 1.

Acacia concinna. It belongs to family Mimosaceae. Pods have been used in oil preparation. These contain alkaloid, saponin, malic acid, resin, glucose, gum and coloring matter (Nadkarni, 1954). Traditionally used as a hair wash in lieu of soap, it promotes growth of hair and removes dandruff .The pods are ground up and used in skin diseases (Narayan and Kumar, 2003).

Emblica officinalis. It belongs to family Euphorbiacae. Its fruit is a rich source of vitamin C and contains twenty times vitamin C as compared to orange juice (Jain and Khurdiya, 2004; Cai *et al.*, 2004; Narayan and Kumar, 2003). It is used in hair conditioning and hair dying (Kripp *et al.*, 2005).

Nardostachys jatamansi. It belongs to family Valerianaceae. Rhizomes are used in nervous headache. It is also employed and mixed with sesamum oil for rubbing on head as a nerve sedative. These promote growth and blackness of hair. Rhizomes are used in hair loss and greying of hair, in conditions of insomnia and restlessness (Narayan and Kumar, 2003; Nadkarni, 1954). It is a rich source of antifungal and antibacterial agents which are helpful in treating skin infections related to hair (Sridhar *et al.*, 2003).

Terminalia chebula. It belongs to family Cobbretaceae. Dried fruits contain tannic acid and gallic acid, used in skin diseases, headache, paralysis, tonic to brain and vision (Nadkarni, 1954). It also has anti-inflammatory, antiseptic, bactericidal and anti allergy properties (Wang, 2005; Narayan and Kumar, 2003).

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Table 1. Herbs used in formulation

Botanical name	Local name	Parts used in formulation
Acacia concinna	Sika kai	Pods
Emblica officinalis	Amla	Dried fruit
Nardostachys jatamansi	Balchar	Rhizomes
Terminalia chebula	Herr	Dried fruit
Terminalia bellirica	Bahera	Dried fruit
Nigella sativa	Kalongi	Seed
Trigonella foenum-graeceum	Methi	Seed
Lagneria vulgaris	Kaddu	Seed
Lawsonia alba	Mehndi	Dried leave

Terminalia bellirica. It belongs to family Combretaceae. Fruit of plant consists of gallotanic acid, colouring matter, resins and greenish yellow oil .Oil obtained from the seeds is useful in leucoderma and greying of hair, it is tonic for brain and used in headache (Narayan and Kumar, 2003; Nadkarni, 1954).

Nigella sativa. It belongs to family Ranunculaceae. Seeds of *N. sativa* contain yellowish volatile oil, essential oil, albumen, sugar and organic acids. They have antibacterial antifungal and anti inflammatory properties used in skin diseases (Muhammad, 2005; Morsi, 2000; El-Kamal *et al.*, 1998; Al- Okbi *et al.*, 1997).

Trigonella foenum-graeceum. It belongs to family Fambaceae. Its seeds are used traditionally in inflammatory conditions, in skin diseases. They prevent falling of hair and promote its growth (Narayan and Kumar, 2003; Nadkarni, 1954), also used in pharmaceutical and cosmetic compositions for hair growth (Keller and Frey, 2006).

Lagneria vulgaris. It belongs to family Cucurbitaceae. Seeds of *L. vulgaris* yield clear lipid oil which forms an emollient application for head and for relief of headache (Nadkarni, 1954), used in skin diseases, inflammation and as brain tonic (Narayan and Kumar, 2003).

Lawsonia alba. It belongs to family Lythraceae, traditionally used in headache, as cosmetic in hair dye, promotes healthy growth of hair, prevents premature greying and falling of hair, used in scabies and insomnia (Amano, 2006; Inagaki, 2005; Narayan and Kumar, 2003; Mohammad, 1996; Nadkarni, 1954).

Materials and Methods

Nine herbs including *A. concinna, E. officinalis, N. jatamansi, T. chebula, T. bellirica, N. sativa, T. foenum-graeceum, L. vulgaris,* and *L. alba* were purchased from local market of Karachi and confirmed by taxonomist.

Each herb weighed accurately in equal quantity and was grind separately up to mesh size 60, mixed thoroughly and soaked into lukewarm sesamum oil with continuous gentle stirring in closed system maintained at 60 °C for 5 h for 3 days. The extracted oil was then filtered to remove the particulate matter and supplemented with essential oils of different seeds (olive, mustard, great pumpkin, pumpkin, watermelon, melon and almond) including vitamin E (Sigma). The product was left for aging for 24 h.

Product was then studied pharmacologically and clinical trials were conducted on 175 human volunteers.

Pharmacological studies. ***1. Acute oral toxicity test.*** Four groups of albino rats each comprising of four male and five female animals were made. **Group 1, 2** and **3** were given 0.1 ml, 0.2 ml and 0.4 ml of herbal formulation orally, respectively, while **group 4** was treated as control, and fed with 0.4 ml seasamum oil according to standard method of acute oral toxicity test (Loomis, 1978). Experiment continued for 3 days and animals were observed for 3 days. Any animal did not show any toxic or untoward effect because the herbs used in this formulation are also used orally for different complaints in eastern system of medicines. The added essential oils of different seeds (almond, pumpkin, great pumpkin, watermelon, melon, olive and mustard oil) are all edible oils (Table 2).

2. Dermal irritant/patch test. Three groups of guinea pigs, one control, and two tests were made, each comprising of four male and five female. Both sides of experimental animals were carefully shaved covering an area of two square inches. Herbal formulation (5 ml) was applied on right side of test **group-1**, and 5 ml sesamum oil on right side of test **group 2**. In control **group 4,** 5 ml olive oil was applied on right side of animals. All the experiments were conducted according to standard method of dermal irritant test. (Robert, 1965). Experiment continued for 15 days and animals were observed for 30 days. No animal showed any untoward/toxic effects. Moreover, it was observed that in the shaved area of test groups of experimental animals

Table 2. Oral acute toxicity test of herbal formulation

No. of groups	No. of test animal	Sex of test animal	Dose of products per 100 g	Duration of observation period	Toxic effect
1. (Test)	9	5:4	0.1 ml	72 h	nil
2. (Test)	9	5:4	0.2 ml	72 h	nil
3. (Test)	9	5:4	0.4 ml	72 h	nil
4. (Control) (Sesamum oil)	9	5:4	0.4 ml	72 h	nil

(Each group comprises of 9 albino rats; test groups received herbal formulation while control received only sesamum oil)

where, herbal formulation was applied hair growth was very fast, and skin was soft, and shiny, whereas, dandruff was totally removed (Table 3).

3. Eye irritant test. Two groups of guinea pigs (one test and one control) and two groups of rabbits (one test and one control), each comprising of four male and five female animals were made, 0.1 ml herbal formulation was inserted into the left eye of each **test group**, and 0.1 ml olive oil was poured into the left eye of **control group**, according to standard method of eye irritation test (Loomis, 1978). No irritation was observed during 72 h observation period (Table 4).

4. Clinical trials of herbal formulation on human volunteers facing hair problems. The study protocol was approved by ethical committee of PCSIR Laboratories Complex, Karachi. Patient consent form was filled by each volunteer, and they were briefed about the procedure of study. 41 patients were recruited with complaints of headache and sleeplessness. 40 patients with complaints of excessive hair fall and poor hair growth, 25 patients with split hair, 7 patients with baldness due to pustules, 30 patients with dryness/brittleness and 17 patients with dandruff. All patients were employees of PCSIR laboratories and selected according to study protocol under the supervision of medical doctor. The study had been conducted in Pharmacology section of PCSIR Laboratories Complex, Karachi.

According to study protocol patients were advised to massage gently with this herbal formulation in quantity of 10-15 ml in the hair roots, and left at least for 2-4 h. The results obtained within 2-10 weeks were tabulated in Table 5, and showed in Fig. 1.

Results and Discussion

Oral acute toxicity test (Table 2) indicates that, if in any case herbal oil formulation comes in oral contact it will not produce any toxic effect and it is also safe for human consumption as it did not show any sign of injurious effects on skin during 30 days of study period (Table 3). It is observed commonly that during head massage some times oil comes in contact with eyes. Therefore, herbal oil was also tested for eye irritation test (Table 4), and test animals showed that there was no severe type of irritation during study; slight redness appeared in the eyes of test animals. Clinical trials data (Table 5) clearly indicates that herbal formulation is very effective against different diseases of hair. It stops hair fall excellently, and split

Table 3. Dermal irritant test

No. of groups	Dose of drug	No.of test animals	Sex of test animals	Toxic effect
1. (Test) Guinae pigs	Herbal formulation (5ml)	9	5:4	nil
2. (Test) Guinae pigs	Sesamum oil (5ml)	9	5:4	nil
3. (Control) Guinae pigs	Olive oil (5ml)	9	5:4	nil
		9	5:4	nil

(Each group comprises of 9 animals; test 1 received herbal formulation application test 2 received sesamum oil, while, control received olive oil application)

Table 4. Eye irritant test

No. of groups	No. of test animals	Sex of test animals	Qty/ml poured in the eye	Response	
				irritation	redening
1. (Test) Guinae pigs	9	5:4	0.1	-ve	-ve
2. (Test) Rabbit	9	5:4	0.1	-ve	-ve
3. (Control) Guinae pigs	9	5:4	0.1	-ve	-ve
Rabbits	9	5:4	0.1	-ve	-ve

Table 5. Response of herbal formulation to patients with different hair problems (clinical trial data)

Condition	Total no.	Excellent	Good	Fair	No result *	No response **
Headache, sleeplessness	41	27 (67.5 %)	8 (19.5%)	4 (9.76%)	1(2.4 %)	1(2.4%)
Excessive hair fall and poor hair growth	40	25 (57.5 %)	9 (22.5 %)	3 (7.5%)	-	3(7.5%
Splitted hair	25	17 (68 %)	3 (12 %)	2 (8%)	1(4%)	2(8%)
Itching of head	10	6 (60 %)	2 (20 %)	-	-	2(20 %)
Head pustules	7	3 (42.8 %)	1 (14.3%)	2 (28.6 %)	-	1 (14.3%)
Baldness	5	2 (40 %)	1 (20 %)	-	-	2(40%)
Dryness/brittleness	30	21 (70 %)	3 (10%)	4 (13.3%)	-	2 (6.7%)
Dandruff	17	10 (58.8 %)	2 (11.8 %)	2(11.8 %)	-	3(17.6 %)

* = neither negative nor positive response; ** = no feed back was received

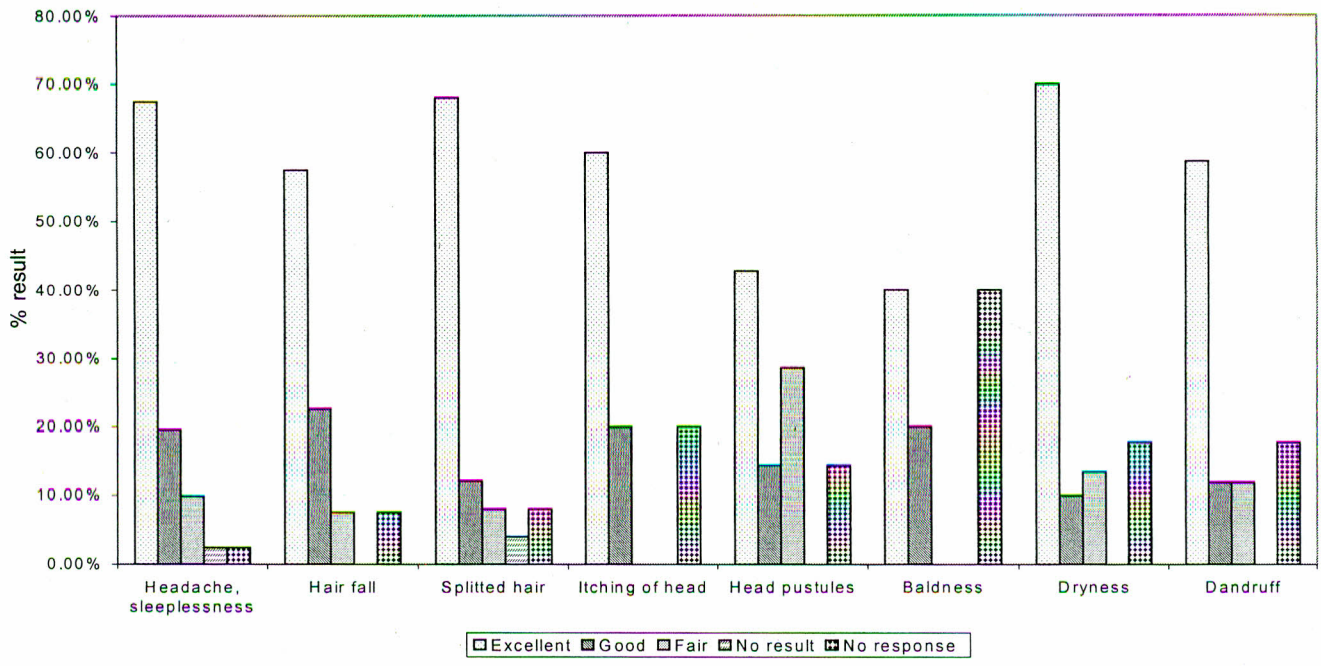

Fig. 1. Efficacy of herbal formulation in different hair and scalp problems.

hair are treated very effectively by herbal oil formulation. Approximately 60% patients recovered from head pustules and baldness. In cases of dryness/brittleness and dandruff more than 80% patients gave the positive response. Moreover, patients with headache and sleeplessness also got relief by massage with herbal formulation. Results were 80-90% positive in these type of cases. This indicates that herbal formulation is very effective against hair/scalp problems and can be used safely as it is free from all kinds of side effects. Moreover, it is proven good for maintenance of hair as the formulation is supplemented with essential oils and vitamin E. It can be concluded easily from clinical study that the herbal formulation is a valuable source which can provide nutrition to hair, but also has excellent antibacterial, antifungal (Martinez *et al.*, 2005; Randhir *et al.*, 2004; Mouhajir *et al.*, 1999; Rao, 1986), anti allergic and anti-inflammatory properties (Mutabagani and El-Mahdy, 1997).

References

Al-Okbi, S.Y., Ammar, N.M., El-Kader, Madiha, M.A. 1997. Studies of some biochemical, nutritional and anti-inflammatory effects of *Nigella sativa* seeds. *Egypt. J. Pharm. Sci.* **38:** 451-469.

Ahmed, I., Baig, A.Z. 2001. Antimicrobial and phytochemical studies on 45 Indian medicinal plants against multi-drug resistant human pathogens. *J. Ethnopharmacol.* **4:** 113-123.

Amano, T. 2006. Hair Dye Compositions Containing Natural Dye and Method and Kit for Hair Dying, JP Patent No. 2006 45, 180, 16^{the} February, 2006.

Bagchi, D., Bagchi, M., Agarwal, A., Saxena, V.N. 2005. Oxidative stress, inflammation and health. In: *Oxidative Stress and Disease*, vol. **8**, pp. 549-585, CRC Press LLC, USA.

Brody, T. 1999. *Nutritional Biochemistry,* pp. 311-491, 2nd edition, Academic Press, USA.

Cai, Y., Lai, Z., Jaing, Q., Wu, Z., Chen, Y., Pan, D. 2004. Analyses of V_c (vitamin C) content in *Phyllanthus emblica* L. *Jaingxi Nongye Daxue Xuebag* **26:** 601-607.

Chopra, R.N., Chopra, I.C., Honda, K.L., Kapur, L.D. 1958. *Chopra's Indigenous Drugs of India,* pp. 22-506, 2nd edition. UN Dhur & Sons (Pvt) Ltd., 15 Bonkin Chatterjee Street, Calcutta-12, India.

El-Kamal, H.H., Ahmed, A., Mohammad, A.S., Yahia, A.A.M., El-Tayeb, I.H., Ali, A.A. 1998. Antibacterial properties of essential oils from *Nigella sativa* seeds,*Cymbopogan citrates* leaves and *Pulicaria undulata* aerial parts. *Fitoterapia* **69:** 77-78.

Ezerietis, E., Eglite, A., Krumina, B. 2003. Anti-inflammatory Ointment, Russ, Patent No. 13, 015, 20th October, 2003.

Gunduz, H., Dede, S., Agaogh, Z.T., Atasoy, N., Mart, N. 2002. Serum trace elements status of rabbits supplemented with *Nigella sativa*, vitamin C and E and selenium against damage by N-methyl-N'-nitro-N-nitrosoguanidine. *Biol. Trace Elements Res.* **89:** 65-74.

Haq-Afrozul, Lobo, P.I., Al-Tufail, M., Roma, N.R., Al-Sedairy, S.T. 1999. Immuno modulatory effects of *Nigella sativa* proteins fractionated by ion exchange chromatography. *Int. J. Immuno. Pharmacol.* **21:** 283-295.

Inagaki, T. 2005. Hair Dye Composition Containing Henna and Hydrogen Water, JP Patent No.187, 447, 14th July, 2005.

Jain, S.K., Khurdiya, D.S. 2004. Vitamin C enrichment of fruit juice based ready beverages through blending of Indian gooseberry (*Emblica officianalis* Gaertin.) juices. *Plant Foods Hum. Nutr.* **59:** 63-66.

Keller, B., Frey, B. 2006. Pharmaceutical Compositions for Hair Growth Stimulation Containing Extracts of *Trigonella foenum-graecum* Seed and Linseed,UK, Patent No. 102, 004, 039, 983, 2nd March, 2006.

Khan, M.A. 1999. Chemical composition and medicinal properties of *Nigella sativa* Linn. *Inflammopharmacol.* **7:** 15-36.

Kim, Y., Ha, B., Kang, U. 1995. Hair Cosmetic Material Containing poly Polyethoxylated Vitamin E, KR Patent No. 9, 507, 044, 30th June, 1995.

Kripp, T., Grasser, B., Sallwey, A. 2005. Hair Conditioning Preparations Containing 1-methylpyridinium-3-carboxylate or Its Derivatives, Ger Patent No. 102, 004.013, 798, 20th March, 2005.

Loomis, T.A. 1978. *Essential of Toxicology,* pp. 198-231, 3rd edition, Lea and Febiger, Philadelphia, USA.

Martinez, C., Delrieu, M., Delpech, I. 2005. Plant Defense Stimulant Against Bacteria, Fungi and Viruses, FR, Patent No. 871, 997, 30th December, 2005.

Mohammad, A. 1996. Chemical and medicinal evaluation of *Lawsonia inermis* (Henna). *Hamdard Medicus* **39:** 43-48.

Morsi, N.M. 2000. Antimicrobial effect of crude extracts of *Nigella sativa* on multiple antibiotic resistant bacteria. *Acta Microbiol. Pol.* **49:** 63-74.

Mouhajir, F., Pedersen, J.A., Rejddi, M., Towers, G.H.N. 1999. Antimicrobial thymehydroquinones of Morrocan *N. sativa* seeds detected by election spin resonance. *Pharm. Biol.* **37:** 391-396.

Muhammad, T.S. 2005. A study of *Nigella sativa* seeds for antimicrobial activity with special reference to resistant bacteria. *M.Sc. Thesis*. J.N. Medical College, Aligarh Muslim University, India.

Mutabagani, A., El-Mahdy, S.A.M. 1997. A study of the anti-inflammatory activity of *Nigella sativa* L. and thymoquinone in rats. *Saudi Pharm. J.* **5:** 110-113.

Nadkarni, A.K. 1954. *Indian Materia Medica,* vol. **1**, pp. 14, 722-732 , 856-857, 1202-1241, 3rd edition, Popular Book Depot, Bombay, India.

Narayan, D.P., Kumar, U. 2003. *Agro's Dictionary of Medicinal Plants,* pp. 3, 122, 223, 343, 187, Agrobios, Jodhpur, India.

Rao, J.T. 1986. Antimicrobial properties of the essential oil of *Nardostachys jatamansi*. *Perfume and Flavour Association of India Journal (PAFAI J)* **8:** 27-28.

Randhir, R., Lin, Y.T., Shetty, K. 2004. Phenolics, their antioxidant and antimicrobial activity in dark germinated fenugreek sprouts in response to peptide and phytochemical elici-tors. *Asia Pac. J. Clin. Nutr.* **13:** 295-307.

Robert, A.T. 1965. *Screening Methods in Pharmacology*, vol. **1**, pp. 279-281, Academic Press, New York, USA.

Soliman, N., Ghaim, J. 2005. Anhydrous Skin Cleansing and Scrubbing Composition, US Patent No. 63, 198, 14th July, 2005.

Sridhar, S.R., Rajgopal, R.V., Rajavel, R., Masilamani, S., Narasimahan, S. 2003. Antifungal activity of some essential oils. *J. Agric. Food Chem.* **51:** 7596-7599.

Wang, H. 2005. Common Sage Herb Detergent with Cleaning Efficiency and Bactericidal Action. CN Patent No. 1, 670, 157, 21st September, 2005.