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Effect of cream containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing *Melia azedarach* flowers on skin diseases in children to the containing to the

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Abstract

A herbal cream containing a methanolic HPLC-standardized extract of *Melia azedarach* flowers has been prepared and found potent against bacterial skin diseases like cellulitis, pustules, pyogenic infections, etc. in children. The results obtained are comparable to those with neomycin.

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Introduction

The occurrence of skin diseases in developing countries is highly correlated with poor hygiene, over crowding, malnourishment, non-availability of potable water, high temperature and humidity. Further, drugs used to treat them are antibiotics, steroids and sulfonamides, which are not only out of reach of local population in remote areas but also associated with adverse effects like atrophy, telangiectasia, hirsutism and sensitizing dermatitis which are far more trouble-some.

Indigenous medicinal plants have been a readily available source of drugs since ancient times and even today almost 50% new drugs have been patterned after phytochemicals. Majority of the population in developing countries and approximately 25% people in

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[★] Ethical declaration: It is stated that studies on human subjects have been conducted strictly according to the internationally accepted principles and taking into consideration the ethical values mentioned in Helsinki Declaration of 1964 (revised in 2004). Since all the volunteers were up to the age of 10, their parents were informed about the efficacy and safety of drugs under trial. However, herbal practitioner involved in this project was fully aware of her responsibilities as a doctor for the welfare and benefit of human subjects and accepted to work mainly due to two reasons. First, plant used in the formulation of cream is already used to treat skin diseases in herbal system of medicine, and chemicals used in preparation of cream and placebo are commonly used items in such preparations and are generally harmless. Second, WHO in its 1997-guidelines, permitted the use of appropriate medicinal plant as a substitute drug.

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developed regions use herbal medicine for prevention and treatment of diseases. Recognizing the medicinal significance of indigenous plants, World Health Organization (WHO) in its 1997-guideline states that "effective locally available plants be used as substitutes for drugs. Research work on medicinal plants and exchange of informations obtained will go a long way in scientific exploration of medicinal plants for the benefit of man and is likely to decrease dependence on imported drugs" (Veerappan et al., 2007).

Hence, keeping the miseries of skin patients in view and WHO's recommendations for the use of indigenous medicinal plants as an efficient and readily available substitute of conventional drugs, the present work deals with the clinical trials of newly formulated herbal cream of *Melia azedarach* L., a plant which has a long history of its utilization to cure skin diseases at folk level.

Melia azedarach Linn., known in vernacular as Bakayn, is native of West Asia and has been naturalized in Pakistan and almost all warm regions of the world (Sastari, 1998). It has been reported to treat dermatological disorders like leprosy, scrofula and eruptive skin diseases in folkloric system of medicine (Nadkarni, 1976). Phytochemical investigations of plant have resulted in the isolation of hydroxycoumarins possessing synergistic antifungal activity (Carpinella et al., 2003a, b, 2005), β -carboline alkaloids with anti-inflammatory activity (Lee et al., 2000), monoterpens having bacteriostatic properties (Geris dos Santos and Rodrigues-Fo, 2002) and limonoids bearing antifeedant (Carpinella et al., 2002) and insecticidal (Carpinella et al., 2003a, b) activities. Meliacarpin (Alche et al., 2003) and meliacin (Alche et al., 2002) have been reported as antiviral components of the plant. Antifungal (Paula et al., 2002), (Carpinella et al., 2003a, b) and larvicidal (Wandscheer et al., 2004) activities of M. azedarach extract, along with its utilization in pharmaceutical preparations like disinfecting solution (Pan and Lian, 2005), antimicrobial cream (Prabhudesai et al., 1999) and an ointment for the treatment of tinea pedis (Li and Li, 2004) have recently been published. Present work is the first report of clinical trials with a cream containing extract of M. azedarach flowers against bacterial infections in children. Earlier, there is a report of antibacterial effect of extract of M. azedarach flowers on rabbits (Saleem et al., 2002).

Material and methods

Plant material

M. azedarach flowers were collected from Karachi and identified by plant taxonomist Dr. Surriya and a

voucher specimen (63495 KUH) was deposited in the Department of Botany, University of Karachi, Pakistan.

Extraction of plant

Flowers (2.5 kg) were extracted three times with MeOH (61). Extracts obtained were combined and evaporated under reduced pressure to give residue (311 g, 12.44%).

HPLC-fingerprint analysis of the MeOH-extract (Fig. 1)

Sample preparation: $0.1\,\mathrm{g}$ of the MeOH-extract residue was dissolved under heating in $10\,\mathrm{ml}$ MeOH, the insoluble part filtered off and $10\,\mathrm{\mu l}$ of the soluble extract injected into the HPLC-apparatus.

HPLC-data:

Apparatus: Merck HITACHI D-6000A Interface

Merck HITACHI L-4500A Diode Array

Detector

Merck HITACHI AS-2000 Autosampler Merck HITACHI L-6200A Intelligent

Pump

Separation LiChroCart[®] 125-4 with LiChrospher[®]

column: 60 RP-select B (5 µm), Merck

Precolumn: LiChroCart[®] 4-4 with LiChrospher[®] 60

RP-select B, Merck

Solvent A: 10 ml 0.1% H₃PO₄ (Merck)/11 water system: (Millipore Ultra Clear UV plus[®] filtered)

B: acetonitrile (Merck)

Gradient: 0–5% B in 30 min, 5–25% B in 10 min,

total runtime: 40 min

Flow: 0.8 ml/min Detection: 205 nm

Preparation of cream

Herbal cream was prepared by using 0.2% preservative (citric acid, methyl and propyl parabens), 10% humectant (propylene glycol), 10% emulsifying agent (cetamacragol and cetosteryl alcohol) and 10% methanolic extract of *M. azedarach* flowers in 234 g of distilled water with stirring and heating up to 70 °C. Cetosteryl alcohol was dissolved separately in 130 g liquid paraffin under similar conditions. Both aqueous and oily phases were mixed at 70 °C with continuous stirring and then methanolic extract of *M. azedarach* flowers was added. Reaction mixture was homogenized by Silverson Mixer (at 2000 rpm) into a creamy form.

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