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Research Article

PREPARATION AND EVALUATION OF TOPICAL GEL OF NIGELLA SATIVA (KALONJI)

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ABSTRACT

The objective of this study was to check the effectiveness of Nigella Sativa against the microbial species Propronibacterium Acnes, to observe the zone of inhibition and to develop a topical formulation of Nigella Sativa for the treatment of Acne Vulgaris. The topical drug delivery system is simple, effective and very useful in treating acne. The gel was formulated using carbopol 940. Thus the gel developed was evaluated for various physico-chemical parameters like its physical appearance, pH, viscosity and homogeneity.

Keywords: Topical Gel, Kalonji, Nigella Sativa, acne vulgaris.

INTRODUCTION

Acne vulgaris is the most common chronic inflammatory disease of the skin to affect humans . [1] Many patients fail to improve with the current anti-acne therapy due to the cost of therapy, adverse effects leading to noncompliance or lack of therapeutic benefits of current antibiotics (resistance). The reported prevalence of acne varies from 35% to 90% turnover of adolescents at some stage.[2] Acne is a multi-factorial disease involving hormonal influences, altered keratinization, inflammation and immune changes.[3]

Skin has been considered as a promising route of drug administration of drugs due to its accessibility and larger surface area. Topical drug delivery system designed to deliver a variety of drugs to the body through diffusion across the skin layers.

Gels are transparent to opaque semisolids, containing gelling agent that merges or entangles to form a three-dimensional colloidal network structure. It is responsible for gel resistance to deformation and its visco elastic properties.[4][5] Gels have better potential as a vehicle to administer drug topically in comparison to ointment, because they are non-sticky, requires low energy during formulation, are stable and have aesthetic value.[5]

Current treatments of acne include topical and oral antibiotics, topical antimicrobial, topical and oral retinoids. All acne treatment has potential side effects. Some of which may be severe.[6] Many patients fail to improve with these agents due to the cost, adverse effects leading to noncompliance (irritation) or lack of therapeutic benefit (antibiotic resistance). The use of oral antibiotics and systemic retinoids increase both the cost and risk of adverse effects.[7]Gels have better potential as a vehicle to administer drug topically in comparison to ointment, because they are non-sticky, requires low energy during formulation, are stable and have aesthetic value.[5] Moreover synthetic drugs are very expensive to develop. Since, for the successful introduction of a new product approximately 3000 – 4000 compounds are to be synthesized, screened and tested, who's cost of development ranges from 0.5 to 5 million dollars. On the other hand many medicines of plant

origin had been used since long time without any adverse effects. It is therefore essential that efforts should be made to introduce new medicinal plants to develop cheaper drugs. [8][9][10][11]

One of the well-known medicinal plants used is Nigella Sativa, (English-Black Cumin, Hindi-Kalonji) a spice, which have been used traditionally in Middle Eastern folk medicine as natural remedy for various diseases for over 2000 years.[12] More than 150 studies conducted since 1959 confirmed the pharmacological effectiveness of Nigella Sativa seed constituents.[13] It has been shown that Nigella Sativa seed and oil are effective antimicrobial,[14] immunomodulatory,[15] antioxidant,[16] anti-inflammatory[17] and antitumor activity.[18]

Therefore, the present study was conducted to evaluate the anti-acne activity of Nigella Sativa seeds using appropriate methods and to formulate a suitable topical gel formulation for its anti-acne activity. The prepared gel was evaluated for appearance, pH and viscosity.

MATERIALS AND METHODS

Materials

The seeds of Nigella Sativa were obtained from the local market of Rajkot from the Kadar Vora store. The authentification of the seeds was primarily confirmed by Dr. Devang Pandya (M.Pharm, Pharmacognosy) and the certificate of the same was given by the Botanical Department of School of Science, RK University.

Preparation of Extract from Nigella Sativa seeds

The seeds obtained were dried to remove any moisture content if present in it. The seeds were powdered and extraction was done with petroleum ether to remove the lipid contents and then was extracted with methanol by cold maceration process. The extract was concentrated by evaporating the extraction solvent.

Anti-Bacterial activity testing

The newly synthesized compounds were screened for their antibacterial activity against Propronibacterium Acnes, as described by the guidelines in National Committee for Clinical Laboratory Standards (NCCLS)-approved standard document M7-A4, using the micro dilution broth procedure. [19] Ampicillin was used as the reference antibacterial agent. Antibacterial activity of the seed extract was performed in Mueller– Hinton broth medium at a pH of 7.2 with an inoculum of (1–2) × 103 cells/mL. The chemical compounds, broth medium serial tube dilutions inoculated with each bacterium were incubated on a rotary shaker at 37°C for 18 hours at 150 rpm.

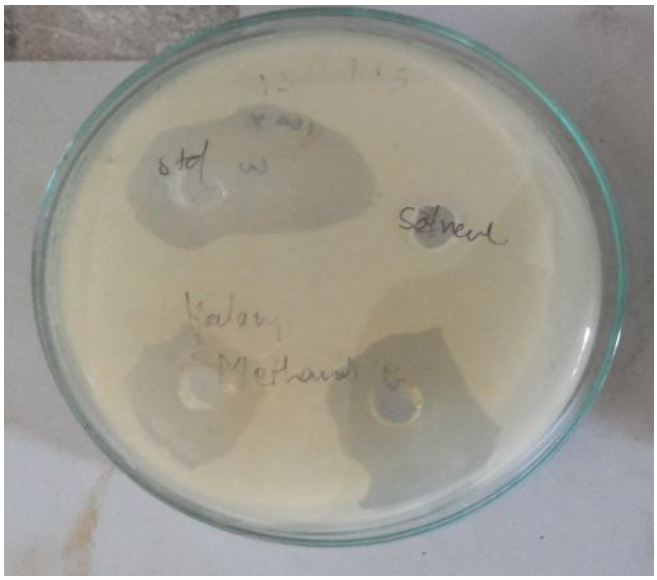

Figure-1: Anti-Acne activity of Nigella Sativa seeds extract

RESULTS

From the observation of the agar plate containing Kalonji seed extract against Propronibacterium Acnes gave a sufficient zone of inhibition similar to that of the standard drug Ampicillin. So it can be concluded that Nigella Sativa seeds showed a sufficient anti-acne activity in the anti-bacterial test performed. As it proved the anti-acne activity, this was formulated in a gel to treat acne by topical action.

Chemicals

Carbopol 940 and sodium alginate (Astron chemicals), propylene glycol (Merck chemicals), glycerine (Oxford chemicals Ltd.), sodium hydroxide (Seva Chemicals), methyl paraben (Oxford chemicals Ltd.), etc., were used for preparation of gel.

Preparation of Gel [20]

The gels were prepared with varying amount of the Carbopol 940 polymer on trial and error bases. The required amount of Carbopol 940 was added in to distilled water with vigorous stirring and left for overnight for proper dissolving of the polymer. The required amount of Kalonji extract obtained after cold maceration was dissolved in methanol and added. Required quantity of methyl paraben as a preservative was also added into this mixture. This mixture was slowly dispersed in the Carbopol 940 dispersion

with vigorous mixing at 300 rpm. The beaker was covered with aluminium foil and left mixing for approximately 15 minutes. The mixture was also homogenised with a homogenizer for 5 minutes at low speed. After complete addition of the polymer and proper mixing, the pH was adjusted at 7 with the addition of sodium hydroxide 1% solution and gels were spontaneously formed. To this gel required amount of glycerine was added. The gel was left at room temperature to set and to allow the air bubbles produced by the mixing to escape from the gel by putting on ultrasonicator for 15 min.

Evaluation of formulated gels

Prepared Kalonji gel was evaluated for appearance, pH and viscosity. The gel was visually inspected for clarity, colour homogeneity, presence of particles and fibres.

Table 1: formulation data for *Nigella sativa* gel

Ingredients	Quantity
Carbopol 940	1 g
Kalonji seeds Extract (extract obtained from cold maceration process)	10%
Methanol	5 ml
Glycerine	15 ml
Sodium Hydroxide Solution (1%)	q.s.
Methyl paraben	0.5 g
Distilled water	up to 100 g

Appearance

The gel was yellowish transparent in appearance.

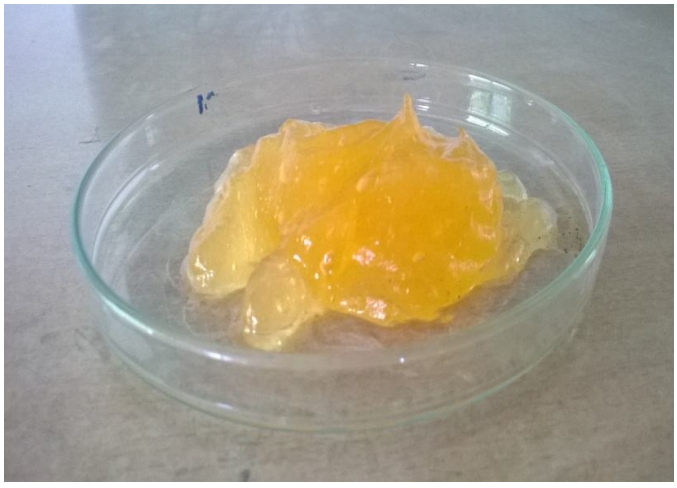

Figure-2: Topical gel of Kalonji seeds (*Nigella Sativa*)

Measurement of pH

The pH of gel formulation was determined by using digital pH meter. One gram of gel was dissolved in 100 ml distilled water and stored for two hours. The measurement of pH was done in triplicate and average values are calculated.

Viscosity study

The measurement of viscosity of the prepared gel was done with a Brookfield Viscometer. The gels were rotated at 50 rotations per minute. At each speed, the corresponding dial reading was noted. The viscosity of the gel was obtained by multiplication of the dial reading with factor given in the Brookefield Viscometer catalogues.

RESULTS

The various parameters evaluated for gels are represented in Table 2.

Table 2: Quality control data for *Nigella sativa* gel

Parameters	Values
Clarity	Good
pH	6.9
Viscosity	18515 cps
Homogeneity	good

DISCUSSION

Kalonji has been traditionally used, since ancient times, to treat various diseases and disorders. Topical application of Kalonji seeds oil has been recommended for treatment of various skin diseases. We have tested the antibacterial activity of Kalonji extract. The zone of inhibition for Kalonji seeds extract and the standard drug Ampicillin gave similar results. Thus in the present study we formulated a gel formulation of Kalonji seeds for treatment of acne vulgaris, using carbopol 940. The gel was evaluated for various physicochemical parameters like clarity, pH, viscosity and homogeneity.

CONCLUSION

Kalonji seed extract showed a good anti-bacterial activity for Propronibacterium Acnes. Thus we can conclude that the methanolic extract of Kalonji were able to give anti-bacterial activity. So Kalonji topical gels was developed using carbopol 940. The gel showed good physico-chemical properties.

REFERENCES

1. Thiboutot, D., M., Straus, J., S.: Diseases of the sebaceous glands. In: Freedberg IM et al. editors. Dermatology in general medicine. Sixth edition. New York: the McGraw-hill com. 2003;1: 675-85.
2. Stathakis, V., Kilkenny, M., Marks, R. :Descriptive epidemiology of acne vulgaris in the community. Australas J Dermatol, 1997; 38:115-23.
3. Webster, G., F.: Inflammation in acne vulgaris. J Am Acad Dermatol, 1995; 33:247-53.
4. Lorraine Pena G, Gel Dosage Forms, Theory Formulation and Processing, The Upjohn Company Kalamazoo, Michigan, 381- 87.
5. Jyotsana Madan, Ramnik Singh, Formulation and Evaluation of Aloe Vera Topical Gels, Int. J. Ph. Sci., May-Aug, 2010; 2(2):551-555.
6. Charakida, A., Charakida, M., Chu, A., C.: Double-blind, randomized, placebo-controlled study of a lotion containing triethyl citrate and ethyl linoleate in the treatment of acne vulgaris. Br J Dermatol, 2007;157:569-74.
7. Heffernan, M., P., Nelson, M., M., Anadkat, M., J.: A pilot study of the safety and efficacy of picolinic acid gel in the treatment of acne vulgaris. Br J Dermatol, 2007; 156:548-52.
8. Ikram M, Hamdard Medicus, 1983; 26:16-17.
9. Fayyaz Ahmad, Rafeeq A. Khan, Shahid Rasheed, Study of Analgesic and Anti Inflammatory Activity FromPlant Extracts of Lactuca Scariola and Artemisia Absinthium. J. Islam. Acad. Sci, 5: 111- 114, (1992).
10. N. Duganath, S. Rubesh Kumar, R. Kumanan and K. N. Jayaveera, Evaluation of Anti-Denaturation Property and Anti-Oxidant Activity of Traditionally Used Medicinal Plants, International Journal Of Pharma And Bio Sciences V1(2) 2010, P.No.1-7.
11. Sharma Jagriti, Samagandi Kashinath, P Suresh, Evaluation of Analgesics Activity of Angamard Prashman Ghan Vati and Kakatinduk Vati WSR to its Anti Nociceptive Action, International Journal of Ayurvedic and Herbal Medicine 2:3 (2012) 510:514.
12. Zaoi, A., Cherrah, Y., Alaoui, K., Mahassini, N., Amarouch, H., Hassar, M.: Effects of Nigella Sativa fixed oil on blood homeostasis in rats. J Ethnopharmacol, 2002; 79:23-6.
13. Salem, M., L.: Immunomodulatory and therapeutic properties of the Nigella Sativa L. seeds. Int Immunopharmacol, 2005;5: 1749-70.
14. Toama, M., A., El-Alfy, T., S., El-Fatatry, H., M.: Antimicrobial activity of the volatile oil of Nigella Sativa Linneaus seeds. Antimicrobial Agents and Chemotherapy, 1974; 6: 225-26.
15. Haq, A., Abdullatif, M., Lobo, P., I., Khabar, K., S., Sheth, K., V., Al-Sedairy, S., T.: Nigella Sativa: effect on human lymphocytes and polymorphonuclear leukocyte phagocytic activity. Immunopharmacol, 1995; 30:147-50.
16. Kruk, I., Michalska, T., Lichszteld, K., Klanda, A., Aboul-Enin, H., Y.: The effect of thymol and its derivatives on reactions generating reactive oxygen species. Chemosphere, 2000;41:1059-64.
17. Al-Ghamdi, M., S.: The anti-inflammatory, analgesic and antipyretic activity of Nigella Sativa. J of Ethnopharmacology, 2001;76:45-48.
18. Ait Mbarek, L., A., Mouse, H., A., Elabadi, N. et al.: Anti-tumor properties of blackseed (Nigella Sativa L.) extracts. Braz J Med Biol Res, 2007:1-8.
19. Clause, G.W. Understanding Microbes: A Laboratory Textbook for Microbiology; W.H. Freeman and Company: New York, USA, 1989.
20. http://www.pharmasm.com/pdf_files/2013012110591 3_ketan_306.pdf.

