MEDICATED PAPER SOAP STRIPS FOR DERMAL INFECTIONS
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ABSTRACT
Fungal infections are extremely common and some of them are serious and even fatal. With the control of most bacterial infections in the developed countries, fungal infections have assumed greater importance. Fungal infections are contagious, spread from person to person, thus it needs to be controlled in their initial stage by proper medications. For this purpose there are many topical drug delivery systems available including medicated gel and creams, medicated soap bars and shampoos. Amongst them medicated soap is considered to be the convenient and 1st line treatment for skin diseases. But this medicated soap has several disadvantages like economy, wastage, no accurate dosage, no proper foam formation & contamination of soap. Therefore it was found essential to find an alternative, equally effective in topical drug delivery and economical in therapeutic work. Presence of thick foam on the infected part causes hydration of stratum corneum for better penetration of drug. Hence the current article focuses on medicated paper soap strips to counter all the above disadvantages of soap, gel and creams.
INTRODUCTION:
The skin often has been referred to as the largest of the body organs. An average adult’s skin has surface area of about 2m². Its accessibility and the opportunity it affords to maintain applied preparation intact for a prolonged time has resulted in its increasing use as a route of administration whether for local, regional or systemic effects [1].

Fungal infections are contagious and spread easily just by close contact or sharing of comb with an infected person. Fungal infections are termed as mycoses and in general can be divided into superficial infections (affecting skin, nails, hairs or mucous membranes) and systemic infections (affecting deeper tissues and organs). Systemic fungal infections need extensive treatment by oral or I.V administration of antifungal drugs [2][3]. Whereas superficial fungal infection of skin and mucous membrane respond easily to topical application of antifungal agents. They are available in various forms like gels, powders, shampoos, soap bars. Amongst them medicated soap is considered to be the convenient and 1st line treatment for skin diseases. But this medicated soap has several disadvantages like economy, wastage, no accurate dosage, no proper foam formation & contamination of soap [4]. Therefore it was found essential to find an alternative, equally effective in topical drug delivery and economical in therapeutic work. Literatures have shown that presence of thick foam on the infected part causes hydration of stratum corneum for better penetration of drug. Thus to overcome the disadvantages of soap bars, medicated paper soap strips are formulated [5][6].

Advantages of the medicated soap strip:
- Economic
- Ease of transport
- Convenience to patient
- Ease of applying and removing
- Avoid inconvenience associated with intravenous therapy
- Eliminate the problem of gastric irritation
- Termination of therapy is possible if irritation is observed
- It increases the solubility of poorly soluble drug.
- It has dual action, cleaning the affected area and medicating it.
- Maximum rate of skin permeation of drug

Fungal infections:
Common type of superficial infections is tinea infections and candidiasis.

Tinea is a Latin word meaning ‘gnawing worm or moth’. Additional Latin descriptors are added to indicate the area of the skin involved:
- Tinea capitis – scalp infection
- Tinea faciei – facial infection

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• Tinea manum – hand infection
• Tinea pedis – foot infection

Most common type of Tinea Infections are Tinea versicolor and Tinea corporis:

a) **Tinea versicolor**: It is also known as pityriasis versicolor, is a superficial fungal infection of the skin that is often confused with other common rashes.

**Cause of tinea versicolor**: The yeasts, *Pityrosporum orbiculare* and *Pityrosporum ovale*, are a part of the normal skin flora. They reside in the stratum corneum and hair follicles and have an affinity for oil glands. Certain factors can cause these yeasts can convert to a pathogenic form known as *Malassezia furfur*, which causes the rash of tinea versicolor. Some of these predisposing factors include:

- Removal of the adrenal gland
- Cushing’s disease
- Pregnancy
- Malnutrition
- Burns

Tinea versicolor can occur at any age, but is most common in adolescence and early adulthood, a time when the sebaceous gland are more active. It is also more common in tropical and semi-tropical climates. Tinea versicolor has a recurrence rate of 80% after 2 years.

**Appearance of tinea versicolor**: The rash of tinea versicolor is a hypopigmented, hyperpigmented or red flat eruption that may coalesce into large patches with an adherent fine scale. This rash occurs mainly on the trunk, but can also occur on the extremities. Hypo pigmentation occurs because the yeast produces a chemical that turns off the melanocytes, resulting in decreased melanin production. The hyper pigmentation or redness occurs as a result of the inflammatory response in the skin.

**Treatment of tinea versicolor**: There are a number of different medications used to treat tinea versicolor. Because the yeast inhabits the top layer of the skin, topical antifungal medications are very effective. If the rash is extensive, oral antifungal medications may be needed. Because this rash has a high recurrence rate, medication may be needed periodically to prevent recurrence [3].

b) **Ringworm**: It is known in medical terms as tinea corporis, is actually not caused by a worm, but by a fungus. Tinea corporis refers to a fungal infection of the body or face, not including the beard area on men. Ringworm occurs more commonly in warm, tropical environments, affects men and women equally, and affects all ages equally. Ringworm is a dermatophyte infection. Dermatophytes are a group of related fungi that infect and survive on deadkeratin, the top layer of the epidermis.
The following are the most common fungi responsible for ringworm:

- Trichophyton rubrum
- Microsporum canis
- Trichophyton mentagrophytes

**Appearance of ringworm:** The most common appearance of ringworm is a lesion that starts as a flat, scaly spot which then develops as a raised border that advances outward in a circle. The advancing border is red, raised, and scaly while the central area is more normal appearing, usually still with fine scaling.

**Treatment of ringworm:** In general ringworm responds well to topical treatment. Topical antifungals are applied to the lesion twice a day for at least 3 weeks. The lesion usually resolves within 2 weeks, but therapy should be continued for another week to insure the fungus is completely eradicated [3].

c) **Candidiasis:** Candida is a normal resident of the mouth, digestive tract, and vagina that usually causes no harm. Under certain conditions, however, Candida can infect mucous membranes and moist areas of the skin. Typical areas of infection are the lining of the mouth and vagina, the genital area and anus, the armpits and the skin folds of the stomach. Conditions that enable Candida to infect the skin include hot, humid weather; tight, synthetic underclothing; poor hygiene; and inflammatory diseases, such as psoriasis, occurring in the skin folds.

**Treatment of candidiasis:** Topical (applied to the skin) over-the-counter antifungal creams, such as those that contain miconazole, ketoconazole or similar ingredients are often effective in controlling simple fungal infection. Severe or chronic infection may require further treatment by the health care provider. Oral antifungal medications may be given in some cases [3].

**Components of medicated soap strips:**

- Papers
- Soap
- Antifungal drug
- Distilled water

**Papers:** Various papers are used to prepare soap strip such as Whatman filter paper no.1,41,42, bond paper, butter paper, filter paper.

**Whatman filter paper:** What man filter paper no.1 and 41 shows better result. It acts as a supporting medium. These filter papers are made from super-refined cellulose and have been specifically designed to have particular properties for each technical application. These are the supreme quantitative filter papers featuring high wet strength and chemical resistance.
These papers are acid hardened, which reduces ash to an extremely low level. Their tough surfaces make them suitable for a wide range of critical analytical filtration operations. Each grade offers a convenient combination of filtration speed and particle retention [7].

**Bond paper:** It is a high quality durable writing paper similar to bank paper but having a weight greater than 50 g/m². The name comes from it having originally been made for documents such as government bonds it is now used for letterheads, other stationary and as paper for electronic printers. Bond paper can sometimes contain rag fiber pulp, which produces a stronger, though rougher, sheet of paper [8].

**Butter paper or tracing paper:** It is a type of translucent paper. It is made by immersing uncut and unloaded paper of good quality in sulfuric acid for a few seconds. The acid converts some of the cellulose into amyloid form having a gelatinous and impermeable character. When the treated paper is thoroughly washed and dried, the resultant product is much stronger than the original paper. Butter paper is resistant to oil, grease and to a large extent impervious to water and gas. This type of paper is roughly 25% lighter than regular paper [9].

**Soap:** It is an anionic surfactant used in conjunction with water for washing and cleaning. It consisting of sodium or potassium salts of fatty acids is obtained by reacting fat with lye in a process known as saponification. The fats are hydrolysed by the base, yielding alkali salts of fatty acids and glycerol. In the field of cleansers, bath soap is by far the most generally used detergent. The great proportions of bath soaps consist of milled, tallow soap base suitably perfumed and coloured [10][11][12].

**Antifungal drugs:** This medicated paper soap strip can be prepared by using following antifungal drugs.

Antifungal drugs- classification:

1. **Antibiotics**
   - Polyenes: Amphotericin B, Nystatin, Hamycin.
2. **Antimetabolite:** Flucytosine
3. **Azoles:**
   - a) Imidazoles: Clotrimazole, Econazole, Miconazole, Ketoconazole.
   - b) Triazoles: Fluconazole, Itraconazole.
4. **Allylamine:** Terbinafine
5. **Other topical agents:** Tolnaftate, Benzoic acid, Sodium thiosulfate.

Among these imidazoloes, triazoles, terbinafine and other topical agents can be used for superficial fungal infections[13].
Distilled water: It is generally used as a solvent. The chemical composition of the portable water is variable, this potable water is been purified by distillation process in pharmaceutical practices. Eg. Water for injection. Miscible with most solvents. Water is stable in physical states. Water can react with drugs and other excipients that are susceptible to hydrolysis. Water can react violently with alkali metals and rapidly with alkaline metals and their oxides, such as calcium oxide and magnesium oxides [14].

Preparation of medicated soap strips [2][5]:
Medicated paper soap strip is prepared by accurately weighing antifungal drug and mixing it with soap powder, distilled water was added under constant and continuous stirring until a uniform soap-drug solution was formed.
Then paper soap strips were prepared by Dipping Technique using modified disintegration apparatus, air dried overnight.

Evaluation of medicated soap strips:

a) Size and shape: The size selected was 3 x 5 cm, rectangular shaped paper soap strip. The size and shape was randomly selected as it was convenient for dipping in a beaker and it was also similar to that of commercially available paper soap[2].

b) Weight gain test:
Weight gain was calculated by using digital electronic balance. Subtracting the dry weight of the paper from the formulated paper soap strip represented the value for soap absorption capacity of the paper. An average of 20 non-medicated and medicated paper soap strips was considered [2][5].

c) Thickness test:
The thickness of paper soap strip was calculated by using standard precalibrated Screw Gauge, by randomly measuring the thickness of the paper soap strip at five different parts and then calculating the mean average. An average of 20 non-medicated and medicated paper soap strips was considered [2].

d) Foam test:
Foam test helps in determining the cleansing action of the soap. A 100ml measuring cylinder was taken containing about 20ml of distilled water, the soap strip was placed into it and shaken vigorously for a min and immediately measure its foam height (F1) after 5-10 min measure the foam height (F2). An average of 20 non-medicated and medicated paper soap strips was considered [2][5].

Foam height = F1 - F2

e) pH determination:
The medicated soap strips were placed in beaker containing 20ml distilled water and shaken. The pH of dispersion was measured by using digital pH meter [2][5].
f) Drug content:
The soap strip is dissolved in 100ml of 0.1N HCl by stirring it with magnetic bead. The content is filtered by using whatman filter paper and estimated spectrophotometrically [2][6].

g) In-vitro evaluation of medicated soap strips:
The diffusion medium used was 0.1 N HCl. It was carried out by using franz diffusion cell. The diffusion cell was placed on the magnetic stirrer ; the outlet of the resorvior was maintained at 37°C. The receptor compartment was filled with fluid (0.1 N HCl). Prehydrated cellophane paper was used as the membrane in this study and the medicated soap strip was moistened and placed over the membrane .The speed of the stirrer was kept constant. With the help of micropipette, sample was taken for specified period of time[2][5].

h) Primary skin irritation test:
2 healthy rabbits (1 male and 1 female) were selected for the study. They were kept in different cages and supplied with fresh food and water during the test period. 24 hours prior to test, the hair from the upper portion of wiest was shaved to expose sufficiently large test area. The test site was cleaned with surgical spirit. By moistening the Medicated Soap Strips in distilled water it was applied to test area. The test site was observed for erythema and edema for 24 hrs. 48 hrs. and 72 hrs after application. This test was conducted to evaluate the irritancy of the prepared medicated soap strips on the intact skin of rabbits[2].

i) Microbial study:
Microbial study has been done using microorganisms such as C.albicans, S.typhi, S.aureus, E.coli, klibsiella, B.subtilis, P.aeroginosa, A.niger and A.fumigatus species. For measuring the effectiveness of an antimicrobial agent sswabbed uniformly across a culture plate. Then a soap strip of 5×5 mm was placed on the surface of the agar. Then the plates were placed in incubator for 24 hrs at 30˚C. The drug diffuses out from the paper soap strip into the agar. The concentration of the compound will be higher next to the strip, and will decrease gradually as distance from the strip increases [2][6].

j) Stability study:
Short term accelerated stability study was carried out for the period of 45 days for the formulations. The samples were stored at different storage conditions of room temperature, elevated temperature such as 40°C at 75% RH and refrigerator (2 to 80°C). Samples was withdrawn on weakly interval and analysed for visual appearance, clarity, pH and drug content [5][6].

CONCLUSION:
Fungal infections are extremely common and some of them are serious and even fatal. These infections are contagious, spread from person to person. Thus it needs to be controlled in their initial
stage by proper medications. Various medications are available such as gel, cream, soap, but these medications have several disadvantages like economy, wastage, no accurate dosage, no proper foam formation & contamination of soap. Literatures have shown that presence of thick foam on the infected part causes hydration of stratum corneum and results in better penetration of drug. Thus to overcome the disadvantages of soap bars, medicated paper soap strips are formulated. These medicated soap strips are simple, convinient to use, economical and can be used by patients of all ages and sex.

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