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Review Article

MEDICATED NAIL LACQUERS – FOR EFFECTIVE TREATMENT OF NAIL DISORDERS

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Abstract:

Transungual drug delivery system is related with the drug delivery over the nail, which is hard because of presence of keratin network into the nail. So in this review mainly concentrated on drug delivery over nail by using nail lacquer formulations, which containing drug on it. The drug delivery via nail plate is done due to association of several diseases into nail, for e.g. onychomycosis, psoriasis, paronychia, onycholysis. These nail diseases are occurred due to presence of several microorganisms like- several fungi, bacteria, parasites and to cure these diseases of nail, several medications should be used. Generally used medications are antifungals- fluconazole, Itraconazole, butenafine, Clotrimazole and also used several antibiotics such as- ciprofloxacin, ofloxacin, levofloxacin. There are several factors such as- Molecular size of the drug, hydrophilicity and lipophilicity of diffusing molecule, nature of vehicle, formulation effect, which affected the delivery of drug over the nail plate. The penetration of the drug molecules should be difficult so for the drug delivery use some penetration enhancers. In the present review main focus on that delivery of drug is done by using formulation in the form of the nail lacquer.

Keywords: *Medicated nail lacquers, Transungual, nail disorders, antifungals, antibacterials, Penetration enhancers.*

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1. INTRODUCTION [1-5]:

Topical drug delivery system is advantageous over oral drug delivery that, it should have a less number of systemic side effects. In topical drug delivery drug concentration in the tissue is in higher concentration, which is generally required for topical infection of the nails or skin. Currently there should have several advancement in the transungual drug delivery (delivery through the nails) have been developed. By this route antifungal drug therapy should be given for treating the nail diseases. Paronychia is defined as an infection of the paronychium (epidermis bordering the nails) and it occurs locally or, superficially. It is one of the usual infections of hand and grow after an interruption between the sealing of proximal nail fold and nail plate. The nail drug delivery is given in the form of nail lacquer which act by forming a film on upper surface of nail. The nail lacquer formulations act as a Film forming system (FFS) and these systems are

generally used in a place of conventional formulations which are given topically and transdermal formulations. This formulation contains drug and film former as a major constituent after application it leaves as film in the surface of application on evaporation of the volatile solvent. The film forming polymer thus act as a matrix system for sustained or controlled release of the drug into the nail. The nail is a hard structure, so for the drug delivery through the nail, several types of penetration enhancers is generally used for e.g. physical, chemical and mechanical methods to increase penetration of the drug via hard keratin network of the nail.

2. Nail anatomy and physiology ^(6,7)

The nail is a distinctive structure of human body. It mainly comprises of Nail plate, nail bed, nail matrix, nail folds, Hyponychium.

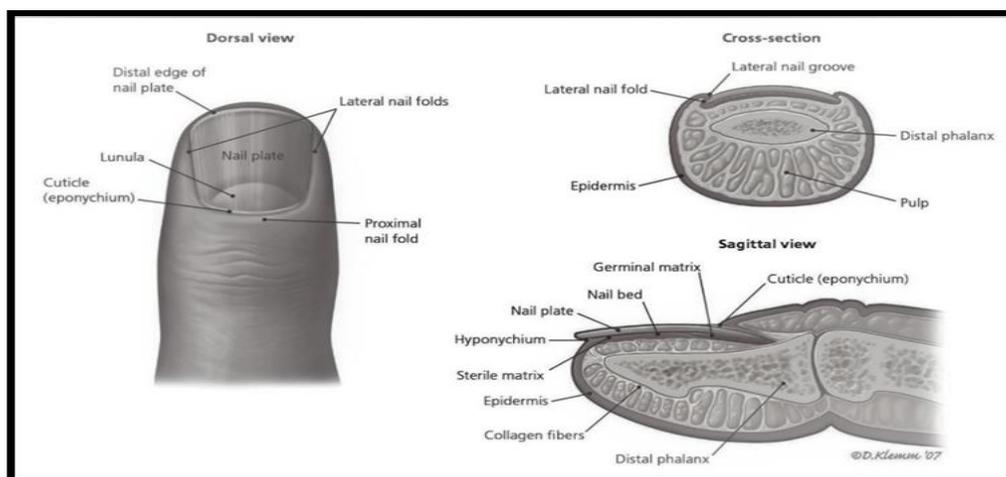


Fig 1-Anatomy of nail ⁽²⁾

2.1. Nail matrix ^(6,7)

It is a germinative epithelium responsible for origination of nail plate. Nail matrix are generally accountable for the nail plate substances. The proximal part is generally resides in nail fold, through nail plate distal edge is clearly seen as a white lunula. The superficial portion are generally constituted by proximal matrix and the undersurface of nail plate is formed by distal part of matrix. In the lowest cell layer of the nail matrix it contains melanocytes and gives pigments to the keratinocytes. Under normal circumstances in the nail plate of white individuals the pigments are not perceptible, but in people who are black pigment shows melanogenesis as a pigmented bands.

2.2. Nail bed ^(6,7)

It generally comprises of an epidermal and underlying part of dermis, which are opposing to the periosteum of the distal phalanx. In nail bed there are absence of subcutaneous fat layer, although microscopically a dermis cells are perceptible. The epidermis of the nail bed, are not much thicker, and living keratinocyte to dead ventral plate of nail the transitional zone are instantaneous, and occurring in the space of one horizontal cell layer.

2.3. Nail folds ⁽⁶⁾

The nail fold is mainly divided into two types, proximal and lateral nail folds and main function of

nail folds is to support & protect the nail from harmful agents. The proximal nail fold generally comprises cuticle, as it is a distal finish product of proximal nail fold and cuticle directly attaches in the nail plate and its main function is to protect the nail from irritants and environmental pathogens.

2.4. Hyponychium ⁽⁶⁾

Another part of nail which is present under the nail plate, in the joint of free edge and skin of fingertips. The main function of Hyponychium is formation of sealer for the protection of nail bed from external microorganism.

2.5. Nail plate ^(6,7)

The basic structure of nail plate is made up of three basic layers, first one is dorsal layer, second one is intermediate layer and last one is ventral layer. The nail plate consist of huge amount of calcium in the concentration of 0.1% by weight, that is substantial 10 times than hairs. The other elements which are existing in the nail plate are, copper, manganese, zinc and iron, in a small amount. Calcium doesn't remarkably any contribution into nail hardness. The hardness of the nail is occurs because of presence of Sulphur as a protein, which is different from soft keratin relatively of epidermis.

3. Diseases of nail ^(5, 6, 7)

There are several diseases which are related to nail and affecting different parts of the nail (nail matrix, nail bed, nail fold), Main diseases which are related to nail are as follows-

3.1. Paronychia

3.2. Onychomycosis

3.3. Psoriasis

3.1. Paronychia

Paronychia is defined as an infection of the paronychium (epidermis bordering the nails) and it occurs locally or, superficially. It is one of the usual infections of hand and grow after an interruption between the sealing of proximal nail fold and the nail plate. Which will allow the entry for infecting organisms?

Paronychia is mainly divided into two types:

- Acute Paronychia
- Chronic Paronychia.



Fig 2-Representation of Paronychia ⁽⁸⁾

3.1.1 Acute paronychia

The usual cause of acute Paronychia are nail biting, finger sucking, aggressive manicuring, a hang nail or penetrating trauma, with or without retained foreign body and the most common infecting organism is *Staphylococcus aureus*, followed by *Streptococci* and *Pseudomonas* organisms. Other causative organism are *herpes simplex* virus, dermatophytes, yeasts and *Gram-negative* organisms.

3.1.1.1. Symptoms of acute paronychia

In acute Paronychia mainly shows symptoms are localized pain and tenderness in the nail fold. The main appear symptoms are in perionychial area shows erythema and inflammation and nail become discolored and deformed. If the treatment is not done primarily formation of pus should develop throughout the perionychium. The collection of pus may result in increased size of the nail plate.

3.1.1.2. Treatment of acute Paronychia

In the early stage of paronychia, the nondrug treatment should be soaking effective parts into warm water for two or three times in a day. An occurrence of further infection addition of oral antistaphylococcal agents should be preferred. The antibiotic therapy should be used for those who crunch their nails. For the treatment of oral bacteria most preferred antibiotics are Penicillin and ampicillin but there are some organism like- *S. aureus* and *Bacteroides* are resistant to antibiotics therapy. There are also use of some other antibiotics like- Clindamycin (Cleocin) and the combination of amoxicillin– clavulanate potassium (Augmentin) are having potency against these microorganisms.

3.1.2. Chronic paronychia

It having a similar appearance like acute paronychia and it is not characterised easily and hard to treat

.The paronychia is developed in those having their hands to water and it carry irritants or alkali, and exposed for longer time to moist environments. The chances of chronic paronychia in those Persons which are bartenders, housekeepers, dishwashers and swimmers, homemakers, as well as diabetic and immunosuppressed persons. The main cause of chronic paronychia include those who are repeatedly exposed to water containing irritants or alkali, and those who are repeatedly exposed to moist environments. The most common infecting organism is *Candida albicans* (95 percent), atypical *mycobacteria*, and *gram-negative* rods.

3.1.2.1 Symptoms of chronic paronychia

The symptoms of chronic Paronychia nail folds are swollen, red, tender and boggy. The symptoms of chronic paronychia vary for more than six weeks or more. Further symptoms due to exposure into moist environment Inflammation, pain and swelling are initial symptoms. The other secondary symptoms of chronic Paronychia are thickened of nail plate and discoloration of nail occurs and the separation of nail folds and cuticles may take place due to *Candida albicans*.

3.1.2.2. Treatment of chronic paronychia

The primary treatment of chronic paronychia is to avoid predisposing factors such as- finger sucking, high exposure to irritating substances, extended exposure to water, manicures, nail trauma. The secondary treatment should be done by using a combination of topical steroids with antifungal drugs and oral antifungal agents should not be used necessarily. For secondary bacterial infections most preferred therapy is use, primarily acetic acid soaks (1:1 ratio of vinegar to water) and then use oral antibiotics antibacterial solutions or ointments.

Table 1- Treatment of paronychia based on causative organism (9, 10, 11, 12, 13, 14)

s.no.	Causative organism	Drugs used for the treatment
1	<i>Candida albicans</i>	Echinocandins caspofungin, micofungin, anidulafungin along with fluconazole, amphotericin B, ketoconazole, fluconazole
2	Gram positive bacteria	Vancomycin, quinupristin/dalfopristin, streptogramin, linezolid, oxazolidinone, first generation cephalosporin's (cefazolin, cephalothin, cephalixin), penicillin resistant penicillin (f luclloxacillin, dicloxacilli), clindamycin, erythromycin, cotrimoxazole, newer antibiotics (linezolid, quinupristin/dalfopristin)
3	Gram negative bacteria	Combination of two antibiotics, extended spectrum penicillin with aminoglycosides or third generation cephalosporin's. Triple drug combination (i.e. penicillin with cephalosporin and aminoglycosides) Polymyxin, salbactam
4	Herpes simplex virus	Acyclovir, valacyclovir, famciclovir

3.2. Onychomycosis

Onychomycosis is defined as the infection of the nail which is caused due to certain category of organisms, yeasts (*Candida spp.*) or molds (*Fusarium spp.*, *Acremonium spp.*, *Scopulariopsis spp.*, *Onychocola Canadensis*, *Scytalidium spp.*).



Fig 3: Representation of onychomycosis in the nail
(15)

3.2.1. Types of onychomycosis

There are several types of onychomycosis which are as follows-

- ❖ Distal/lateral Subungual Onychomycosis
- ❖ Proximal subungual onychomycosis
- ❖ Superficial white onychomycosis
- ❖ Total dystrophic onychomycosis

The half of diseases of nail are not caused by fungi, there are having some other organisms which are responsible for diseases of the nail so for that a proper diagnosis should be required. The pervasiveness of this disease should be more in the people of old age. The most common fungi which is responsible for this is dermatophytes and the main target of these organisms are onto nail, hair and, skin.

3.2.2. Treatment of onychomycosis

The treatment of onychomycosis is mainly done by using oral antifungal agents such as- fluconazole, ketoconazole, itraconazole. The use of ketoconazole is now a days is limited due to its toxic effect on liver. Now a days terbinafine is comes into consideration, it is categorized under class allylamine and it is used for 84 days and dose of should be preferred is 100 mg two times a day. Itraconazole can also be given for the treatment of onychomycosis, it is used as a continuous dose of 100 mg twice daily for 12 weeks. The treatment of onychomycosis by using topical drugs should be more effective and Ciclopirox is

approved by FDA for the effective treatment of this disease.

3.3. Psoriasis

This is a cutaneous disorder and it attacks mainly skin and nails, in this disease mainly increased cell proliferation may occurs. People which are having cutaneous psoriasis (more than 50% of People) are more prone to Psoriasis of the nails. It having symptoms like- Pitting& designated participation of the nail matrix. Another symptoms of this disease is 'oil -drop' discoloration or salmon-colored portions into the nail.



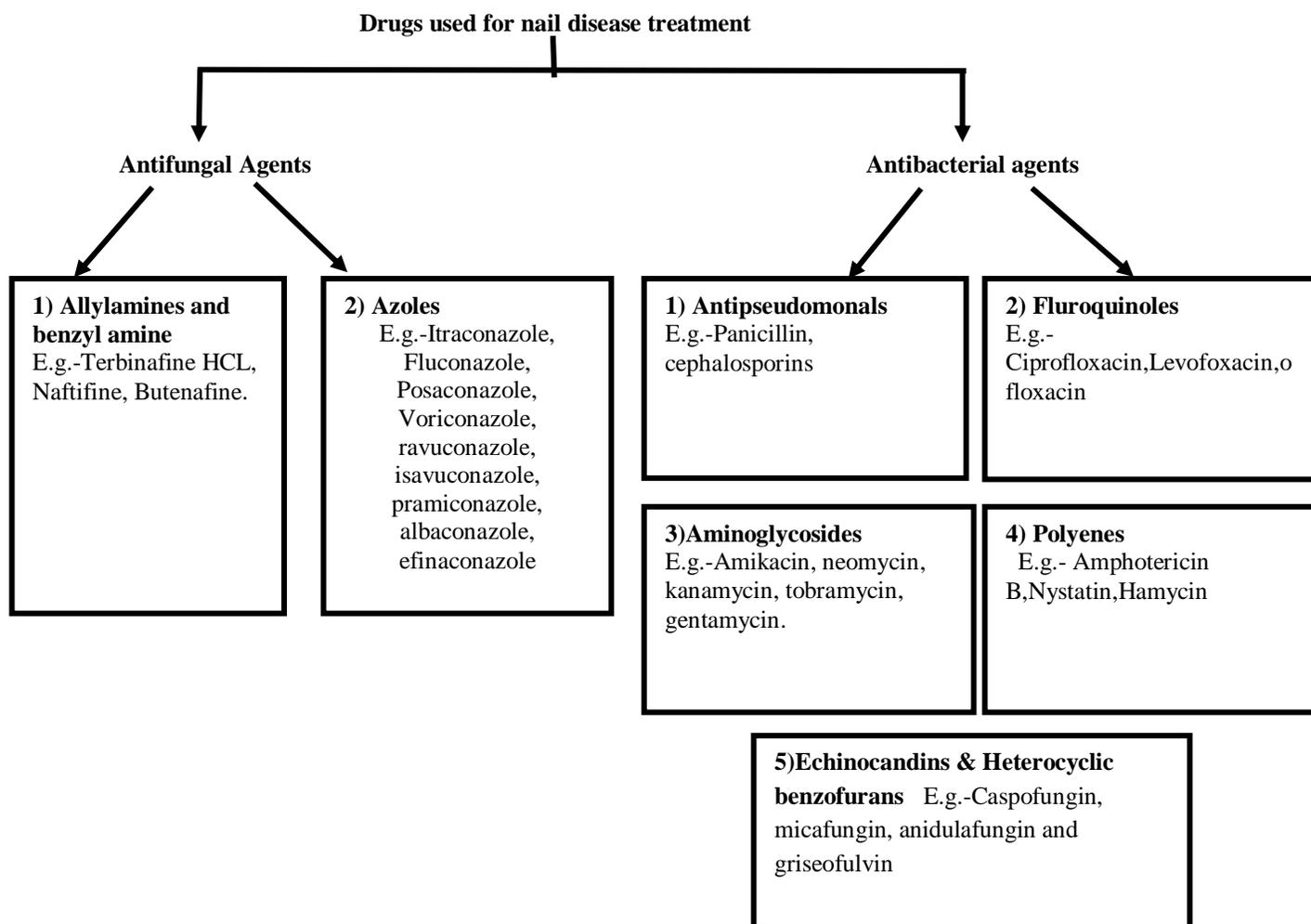
Fig 4:Representation of Psoriasis⁽¹⁶⁾

3.3.1. Treatment of nail psoriasis

The primary treatment of disease requires patients and some incentive on behalf of the patient. The treatment of psoriasis is mainly done by using topical corticosteroids which is highly potent. Other topical agents which used are calcipotriol and tazarotene. The most effectual treatment preferred is triamcinolone acetonide, is injected into the proximal portion of nail fold. The dose are about 2.5 to 3 mg per ml, is injecting by diluted the drug using lidocaine.

4. Drugs associated with diseases of nail^(17, 18)

There are number of organism or factors which are related to cause diseases of nail, some diseases are harmful and some are not so much harmful and easy to cure by some prevention. Those diseases which are harmful, there are some medication which is used to cure that disease and many medication therapies are there to treat these infectious diseases, there are discussed few of them which are as follows-



5. Medicated Nail Lacquer as transungual drug delivery system ^(4, 19)

Medicated nail lacquer is defined as the nail lacquer which containing the drug and it is defined as the formulation which on top of the nail after evaporation of solvent forms the film. These formulations are generally used to drug delivery for treating the diseases of nail. These preparations are generally used to penetrating the antifungal and antimicrobial agents by using some penetration enhancers, penetration enhancers are used physically, chemically and mechanically. The nail lacquer having advantage over other topical formulation that other topical formulations for e.g.-cream and gel are not stable for longer period and these are easily remove by wiping and not adhere for a longer period of time. The medicated nail lacquer act by sustained the formulation by which absorption of the drug is increased which leads to targeting of the drug and improve patient compliance by decreasing

application frequency. Now a days these formulations are used to treat fungal diseases of the nail (onychomycosis and psoriasis, paronychia).

5.1. Advantages of nail lacquer ^(19, 20)

- These formulations are not removed by wiping and rubbing whereas other conventional topical formulations are easily removed by rubbing and wiping.
- These formulations having prolonged contact with the applied surface so controlled release of the drug for a longer period has been done.
- In these formulations systemic adverse effects are absent.
- The effect of these formulations for a longer period because these formulations act by forming a film on the applied surface.
- There are lesser drug- drug interactions has been occurred.

5.2. Disadvantages of nail lacquer ⁽¹⁹⁾

- These formulations are having local side effects such as periungual erythema and proximal nail fold erythema.
- Other adverse effects are generally including the nail disorders such as shape change, irritation at application site and discoloration of the nails and ingrown toenail.
- The therapy is longer, it takes longer time to cure diseases of the nail. It usually takes 9-12 months for toe nails treatment.

6. Mechanism of film formation and Permeation ⁽⁴⁾

The nail lacquer as a film forming system is directly applied to the nail or skin and forms a thin, transparent film after solvent evaporation. As nail lacquer is applied directly to the nail, the film forming composition changes because of loss of volatile composition from the formulation. Which is then formed a residual film on surface of the nail. These formulations generally penetrates through the nail by breaking disulfide bond of the nail, then new pores will be formed and better the penetration of drug via nail plate which is beneficial in treating the diseases of nail.

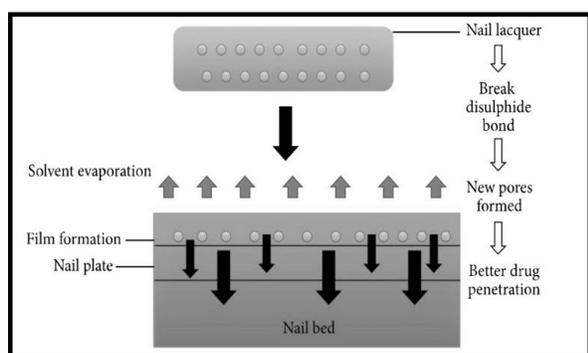


Fig 5: Mechanism of film formation of nail lacquer into the surface of nail ⁽¹⁷⁾

7. Factors responsible for transportation of the drug into and via nail plate ^(21, 22, and 23)

7.1. Molecular size of drug

Molecular size of drug is inversely proportional to the penetration of drug into nail plate. So if the drug molecular size is enlarge, it is tougher to the molecules to diffuse via keratin network of the nail, and then it results in diminish the permeability coefficient via nail plate.

7.2. Hydrophilicity / lipophilicity of diffusing molecule

The permeation of lipophilic molecule over the nail by the means of lipid pathway. If the lipophilicity of the molecule is higher, then it leads to increase permeation across the nail. The permeation of aqueous molecule over the nails by swelling of the nail. The nail swells because water is act by hydrating the nail and enlarging keratins network, which finally leads to formation of larger pores, which in turn easier the permeation of diffusing molecule.

7.3. Nature of vehicle

For the transport of drug via nail plate nature of vehicle plays an major role. The use of aqueous vehicle mainly act by moisturizing the nail which causes to swelling the nail plate. The swelling of nail then causes increase in distance between keratin network, it is than increase permeation of large molecule across it. If in place of water use nonpolar solvents, leads to decrease hydration of the nail when formulation is given via nail.

7.4. Formulation effects

The formulation should also having s effect on permeation of the drug via nail. The pH of the formulation having inflicting effect on degree of ionization of weak acid and weak base which is then reduces the permeation via the nail plate. Than It will leads to minimizing the solubility in the formulation and splitting of the formulation when it apply into the nail plate which is then leads to minimizing the interaction of formulation with keratin network of the nail.

8. Major Challenges ⁽²⁴⁾

There are some major challenges in the permeation or transportation of the drug through the nail which are as follows-

- In the nail sulphide bonds are there, which generally makes the nail harder and restricted the penetration of medicated agents via nail to cure the diseases of the nail. So for delivery of the drugs there are using some penetration enhancers (i.e. Physical, chemical and mechanical) which can easily penetrate through the nail barriers by breaking sulphate bonds of the nails and delivers the drug into required site.
- Designing the drug delivery, for the absorption of the drug via topical route it should be extremely important to consider the physiochemical properties like- formulations characteristics (solvents, film formers, plasticizers, pH and concentration), drug molecule (size, log P, shape and charge),

possible penetration, possibility of drug and keratin content of nail.

9. Approaches of unguinal drug delivery system ^(17, 20, 23, 25)

There are several approaches which are related with unguinal drug delivery system, which are physical (iontophoresis, etching), chemical (Mercaptans and Thiols, Keratolytic agent, organic solvents) and mechanical methods (Nail abrasion, Nail avulsion) are there-

9.1. Physical method

Physical method having advantage in this aspect that it delivers the hydrophilic and macromolecular substances through the nail plate.

There are several types of physical method of enhancement of drug delivery through nail which are as follows-

9.1.1. Iontophoresis

In iontophoresis transportation of the substance over a membrane is done by using an electric field in terms of electromotive force. Iontophoresis is mainly considered for drug delivery over a keratin network of a nail. It is generally used to enhance the penetration of the drugs (which is generally used to cure infection at that site) through the nail. Iontophoresis is now a days used in anesthesia of the skin, antibiotic penetration, hyperhidrosis management and the treatment of herpes simplex. Recently Lidosite^R (iontophoretic patch of lidocaine HCL/ epinephrine topical) and glucoWatch^R (glucose measurement in diabetics) are approved by FDA.

9.1.2. Etching

'Etching' the name indicates that occurs as a result of chemical exposure such as-Phosphoric acid, which

can result emergence of profuse microporosites. These microporosites are then enlarge wettability and surface area and it decreases contact angle and it delivers a surface for bonding material. After etching the nail plate, a sustained-release, hydrophilic, drug delivery containing film former system may be delivered easily.

9.1.3. Laser

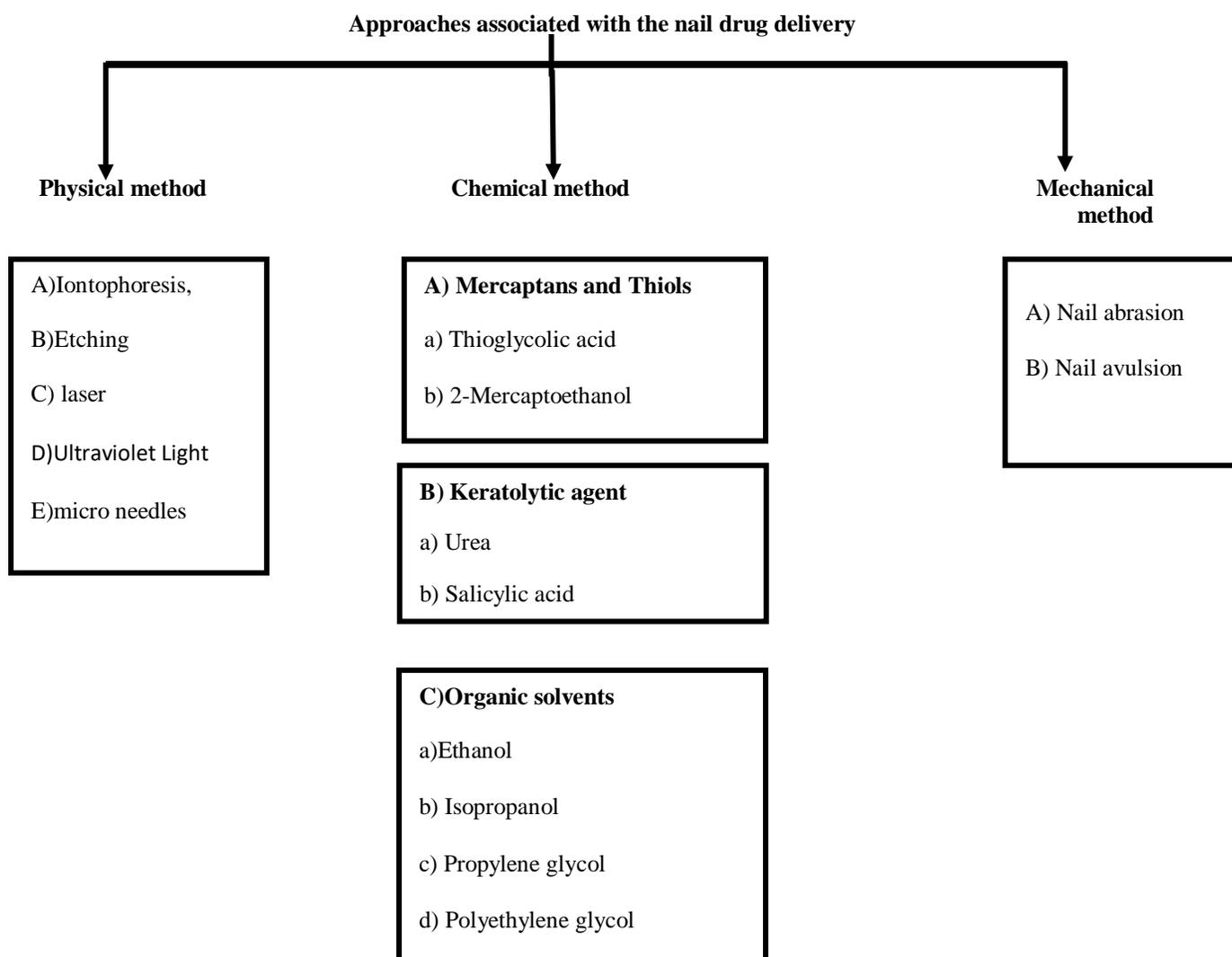
In this technique, a microsurgical laser apparatus should be used by using laser, generally makes a holes in the nails and then topical drugs (i.e. antifungals and antibacterial) should be directly by making holes on the nails for the topical disease treatment.

9.1.4. UV light

Currently by using ultraviolet light treating the onychomycosis has been developed. In this method, firstly heated up the nail and then exposing it into UV light, it usually done to treating the diseases of the nail.

9.1.5. Phonophoresis

Phonophoresis is defined as the process via ultrasound waves are transferred into a tissue surface by using a coupling medium. In this techniques, a chemical, thermal and mechanical alterations in the tissue describes the increase delivery of the drug. It may result as improvement in penetration of the drug via transcellularly as subcutaneously or via cellularly, finally increases pore size of cell membrane results in increasing drug diffusibility via membrane. The method is now a days mainly used to increase percutaneous penetration to joints, muscle, nerves and by this technique increased penetration of several anesthetics, fluocinolonone acetone and amphotericin B is generally done.



9.2. Chemical method

In chemical method, the used substances generally increase the permeability of the drugs by shattering physical and chemical bonds of the keratin which are responsible for the stability of keratin of the nail. This results in the stability of keratin and leads to the passage of the drug via nail.

There are several chemical agents which are used to increase the penetration of the drug, which are as follows-

9.2.1. N acetyl-L-cysteine and 2- Mercaptoethanol

The combination of two such compounds e.g. - N acetyl-L-cysteine and 2- Mercaptoethanol is generally taken into consideration to increase the penetration of the Tolnaftate (antifungal) into the nail samples. Recently

the N- acetyl -L- cysteine alone shows a penetration enhancer property in vivo with the oxiconazole and it also advances the detection of the drug in the upper layer of the nail.

9.2.2. Keratolytic agent (Urea, Salicylic acid, Papain)

These agents are used to increase the antifungal penetration of little numbers of agents which are ketoconazole, itraconazole, miconazole. In the absence of these agents, there is not any unequal permeability in a specific duration of about 60 days. If the pretreatment with these agents for e.g. - use 15% papain (for 1 day) with 20% salicylic acid (for 10 days) generally increases the penetration rate of the drugs which is used to treat nail diseases.

9.2.3. Organic solvents

The organic solvents which is mainly used as penetration enhancer's are- ethanol, isopropanol, propylene glycol and polyethylene glycol, these solvents increases the penetration of the agents via the nail. These solvents generally act by increasing the nail barrier resistivity and they are manipulate the nail hydration state.

9.3. Mechanical method

Mechanical method of nail penetration generally included two main methods which are as follows-

9.3.1. Nail avulsion

These methods are mainly divided into two main types which are-

- ✓ Total nail avulsion
- ✓ Partial nail avulsion

The avulsion of nail is defined as the process as removal of entire or partial nail plate, which is

generally effected by microorganism. In this process, firstly use keratolytic agents such as-urea and salicylic acid, which is generally used to soften the nail. In some studies keratolytic agents like-urea and salicylic acid has been taken into consideration for the treatment of disease like-onychomycosis.

9.3.2. Nail abrasion

It is second method of mechanical penetration enhancement in which sanding of nail plate should be done for decreasing the nail plate thickness or we can say that to destroy it completely. In this method, generally sandpaper of number 150 or 180 is used. The sanding of the nail plate should be done on edges so this is not causes any kind of discomfort. In this method, additionally the dentist's drill should be used, generally it makes a hole in the nail plate and which results in increasing topical penetration of the required drugs to the nail.

Table 2: Marketed formulations of the nail lacquer ⁽²⁶⁾

S.no.	Marketed product	Composition	Uses and its indications	Company name
1	Loceryl nail lacquer	Amorolfine	Amorolfine film is formed on the surface of nail plate and it usually stands for one week. It act by sustaining the formulation via film and increases absorption of drug.	Galderma Australia pvt ltd
2	Eco nail lacquer	5% Econazole +15% SEPA nail lacquer	These nail lacquers act by increasing the Econazole release generally from the nail lacquer formulation. These agents act mainly by forming a dried film from which drug is release at a controlled rate for a longer period.	Macro chem corporation
3	Umecta nail film	40%Urea	Urea is act as a keratolytic agent and it act mainly by breaking disulphide bond and it mainly used in nail psoriasis, brittle and thick nail.	JSJ Pharmaceuticals
4	Tazorac 0.1% gel	Tazarotene	It should be used for fingernail psoriasis	Allergan Inn
5	Penlac nail lacquer	Ciclopirox topical solution	It is categorized under broad spectrum antifungal activity and also it should having an antibacterial and anti-inflammatory property	Dermik laboratories Inn
6	Zalain nail patch	Sertoconazole nitrate	It should be comes in a form of medicated nail patch and this drug is given once in a week for treating diseases like- onychodystrophy. and onychomycosis	Labtec

10. Recent advancement in nail (ungual) drug delivery ^(2, 19, 20)

There are several other formulations like- nail lacquers ,nail vanish & nail patches, other than those formulations there are recent techniques ,which are used to delivered drug molecule into the nail. There are following few techniques for nail drug delivery are as follows-

- Electro chemotherapy
- Nano patch nail fungus
- Mesosclissioning technology

10.1. Electro chemotherapy

Recently by using electric current, drugs are delivered directly over the nail plate is developed. The main aim of electro chemotherapy is to develop a proper method to deliver the drug over the nail plate. This method increases the success of therapy and also decreases the nail treatment duration which generally helps to improve patient compliance. The electro chemotherapy resembles with the iontophoresis, which is used to enhance transfer of drug across the nail.

10.2. Nano patch nail fungus

In this technique targeting the drug directly into the nail by using Nano patch nail fungus, which pushes the antifungal drugs directly into the targeted site where need of the drug should be maximum .This treatment having main advantage that it is preferred treatment or we can say that is the first treatment for targeting into fungus of nail and source of nail fungus directly.

10.3. Mesosclissioning technology

In this technique an open pathway of about 300-400 microns diameters, is generates throughout the nail without any sensation and it is used for drug delivery over the membrane to treat nail fungus and bacteria.



Fig 5: Processing of Mesosclissioning technology ⁽¹⁹⁾

11. CONCLUSION:

The topical drug delivery system having advantages over oral drug delivery system that in topical drug delivery system targeting of drugs directly into required site .In this review we concluded that for the diseases of the nail ,we generally used nail lacquer as topical drug delivery because the nail lacquer having greater penetration rate than other topical formulations .Medicated nail lacquers generally act on a principle that it will form a film on the application surface from which drug is released at a controlled rate for an extended period of time .So we can say that nail lacquers are the best, cheap and it should having better patience compliance then other formulations or newer techniques which are employed for enhancement of drug delivery over the nail plate.

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