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Original Research Article

Formulation and evaluation of herbal periodontal films of *M. paradisiaca* for periodontitis

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ABSTRACT

Background: The present work aims to formulate and evaluate the herbal films of *M. paradisiaca* for periodontitis.
Methods: Dental films were formulated using the ethanolic extract of *M. paradisiaca* by maceration with different polymers like HPMC K4M, Carbopol P71P. The ethanolic extract of *M. Paradisiaca* was subjected for the pre-formulations studies like preliminary phytochemical screening and the results showed the presence of flavonoids, carbohydrates, tannins, alkaloids, glycosides etc.
Results: The films were prepared by using the solvent casting technique and the films were subjected for various evaluation studies like thickness, hardness, folding endurance, surface PH. Based on the physiochemical parameters the formulation F1 were considered to be the best.
Conclusions: The present study reveals that both formulated films showed satisfactory film parameters. From the present investigation it can be concluded that film formulation incorporating banana peel extract can be a potential novel drug dosage form for treatment of Periodontitis.

Keywords: Locally applied antimicrobial agents, Hydroxy propyl methyl cellulose, Very low density lipoprotein, Low density lipoprotein, High density lipoprotein

INTRODUCTION

Periodontitis is a local infection in the gingival fissures caused by a primary bacterial aetiology that affects the periodontal ligament, connective tissue, and bone surrounding the teeth. It is a bacterial-caused inflammatory illness.[1] Periodontal pockets are bacterial colonisation due to reduced oxygen tension. As a result, periodontitis treatment focuses primarily on reducing the total bacterial load, which is the major cause of periodontal disease.[1] There are various formulations available like, mouthwashes, dentifrices, and gels have all been tried and found to be effective in controlling microbial plaque. Topical agents are only helpful in supra gingival areas since they do not penetrate deep into periodontal pockets. As a result, several controlled drug delivery methods have been developed to address all of these restrictions.[1]

To maintain an effective concentration in gingival reticular fluid, traditional treatment methods including oral administration of antimicrobial drugs must be given in high dosages. Antimicrobials at excessive doses, on the other hand, can cause gastrointestinal problems, the development of resistant bacteria, and supra infection. Thus, the intra periodontal drug delivery method for antimicrobial drugs was designed in order to solve the clinical issue that is experienced during systemic administration of antimicrobials.[1]

Various approaches to treat periodontitis

Gingivitis is usually easy to treat. Plaque and tartar are removed from teeth, and the inflammatory tissues around a tooth normally heal fast. Routine dental procedures are ineffective in treating more severe forms of periodontitis.[2]

Appropriate periodontal therapy varies greatly depending on the level and pattern of attachment loss, local anatomical variances, type of periodontal disease, and other factors. The therapeutic goals are stopping disease progression and resolving inflammation are the primary goals of treatment for people with chronic periodontitis.[2]

Conventional periodontal therapy

Periodontal treatment aims to heal inflamed tissue, lower the quantity of pathogenic bacteria, minimise the depth of diseased pockets, and prevent bone desorption. The traditional methods of pocket removal are more or less mechanical and are aimed at removing supraclavicular pockets. Scaling, root planning, and mechanical plaque and deteriorated and necrotic tissue along the gingival wall of periodontal pockets.[3]

Due to possible instrumentation or the capacity of microorganisms to enter deeper tissues, mechanical debridement alone frequently leaves a considerable number of pathogens behind. After scaling and root planning, pathogens may become inaccessible and recolonize the area. A pathogenic sub gingival microorganism may re-establish after a single periodontal debridement session if oral hygiene is not maintained.[3]

Antibiotic systemic therapy

Antibiotics are used in the treatment of periodontal illnesses to decrease or eliminate germs. Chemotherapeutic drugs can be given orally or intravenously. Antibiotics such as tetracycline's, imidazole derivatives, fluoroquinolones, and others are the most commonly used. Antimicrobials used to treat dental infections can be divided into two main categories, i.e., broad spectrum and narrow spectrum.[4]

Narrow-spectrum antimicrobials include penicillin, amoxicillin, cephalexin, macrolides as well as tetracyclines.

These drugs are having a limited antimicrobial efficacy, as they are not effective against aerobic and anaerobic beta lactamase producers.[4]

Systemic periodontal antimicrobial therapy is based on the premise that specific microorganism causes destructive periodontal disease and that the antimicrobial agent in the periodontal pocket can exceed the concentration necessary to kill the pathogens.[4]

Long-term usage of systemic antibiotics is associated with the development of resistant strains and super illnesses. If an antibacterial agent is applied locally, these drawbacks can be significantly decreased.

Topical chemotherapy is safer than systemic chemotherapy in terms of preventing antibacterial agent adverse effects due to the lower amount employed.[4]

Local drug delivery

Antimicrobials can be targeted using locally applied antimicrobial agents (LAAs), which require a lower dose than if administered systemically and release the antimicrobial in a controlled manner at/ above minimum inhibitory concentration (MIC) over several days.[5]

In addition to being effective at a lower dose, LAAs have not been linked to antibiotic resistance. The usage of LAAs has been shown to enhance clinical metrics in studies.[5]

Antimicrobial sub gingival irrigation provides local medication administration but not controlled release. There are two types of local medication delivery devices. The first type of medication delivery system is designed to distribute the agent locally in the periodontal pocket, but there is no mechanism to maintain therapeutic levels for a long time. Second type is the controlled release local drug delivery devices which may secure antimicrobial effect for a prolonged period of time at the diseased site, than that can be achieved by systemic or local topical applications and also bypasses the systemic complications. The controlled release delivery of antimicrobials directly into periodontal pocket has received greatest interest and appears to hold some promise in periodontal therapy.[5]

Controlled release local delivery devices

These devices use controlled release technology to maintain therapeutic antimicrobial concentrations in the sub gingival area for a long time after a single treatment. To keep the drug concentration in the gingival cervicular fluid stable, a number of specific local delivery systems (i.e. intra-pocket devices) have been developed (GCF).

Films are most widely used intra pocket drug delivery device prepared either by solvent casting or direct milling. Bigger film either could be applied directly applied on cheek mucosa or gingival surface or can be cut into appropriate size so as to insert into site of infection. Films are matrix type of drug delivery device in which drug is distributed throughout matrix and drug release occurs by erosion, matrix dissolution/drug diffusion. Non-degradable water insoluble polymers are used to make films that release drugs by diffusion alone, while water soluble or biodegradable polymers are used to make films that release drugs through diffusion plus matrix erosion or dissolution.[6]

It is interesting fact to note that two of the most populated countries in the world China and India have used herbal medicine for the managing of oral infections, comprising periodontal disease as well for more than duration of 2000 years. It has been found that in adults with chronic periodontitis, scaling and root planning along with use of an adjunctive antimicrobial mediator increases patient outcomes over a period of time compared to scaling alone.[7]

The peel of a banana is said to be a great source of natural

compounds for human health. Banana peel (*Musa paradisiacal*) is an herbaceous plant with a sturdy tree-like pseudo- stem and a canopy of huge elongated oval deep-green leaves with noticeable midrib that grows up to 9 metres in length. In the wild, the fruits are rectangular, fleshy, and 5-7 cm long; in the cultivated forms, they are long. *Musa paradisiacal* fruit is used to treat diarrhoea, dysentery, ulcerative colitis, diabetes, uraemia, nephritis, gout, hypertension, and cardiovascular disease. Leaves are used to treat eczema, as well as blisters and burns. Dysentery and menorrhagia are treated with flowers.[8] Phenolic and flavonoid compounds that are commonly found in plants have been reported to have potential biological effects, including antibacterial, antifungal, and antioxidant activities. Banana peel extract has been reported to contain naringinin, a flavanone glycoside, and rutin, a flavonol glycoside. Other compounds, such as lutein, α- and β-carotene, auroxanthin, violaxanthin, neoxanthin, β-cryptoxanthin, isolutein, and α-cryptoxanthin have been identified in peel extracts.[9]

Phytochemicals of banana peel

The peel of *M. paradisiaca* was used to isolate cellulose, hemicelluloses, arginine, aspartic acid, glutamic acid, valine, phenyl amine, and threoine. From the flower of *M. paradisiaca*, hemiterpenoid glycoside (1, 1 dimethylallyl alcohol), syringin, and benxyl alcohol glycoside have been identified.[10]

Bioactive chemicals found in banana peel include flavonoids, tannins, alkoids, glycosides, and terpenoids. These bio actives have pharmacological properties, including antioxidant, anti-diabetic, anti-inflammatory, and antibacterial properties. Vitamins A, C, E, B6, gallocatechin gallate, dopamine, succanic acid, palmitic acid, magnesium, phosphorus, potassium, fibres, iron, and fatty acids are also found in banana peel.[10]

Pharmalogical activities in banana peel antimicrobial activity

Anti-oxidant activity

Because of the presence of dopamine, ascorbic acid, and other antioxidants in bananas, plasma oxidative stress in healthy humans is dramatically reduced after just one banana meal.[11]

The levels of LPO in plasma, very low density lipoprotein (VLDL), LDL, and high density lipoprotein (HDL) all dropped significantly in the 2 hour post-dose phase, according to the findings. The findings show that eating bananas lowers plasma oxidative stress and improves LDL22 resistance to oxidative alteration.[11]

Hypoglycaemic activity

M. paradisiaca's green fruit has been shown to have hypoglycaemic effects via stimulating insulin production and glucose utilisation. The glycemic effect has been linked to its high potassium (K) and sodium (Na) content.[12] The hydromethanolic extract of *M. paradisiaca* root has been demonstrated to have a substantial antihyperglycemic effect.[12]

The findings revealed a considerable decrease in blood glucose and glycosylated haemoglobin, as well as an increase in total haemoglobin. Thiobarbituric acid reactive glutathione, glutathione peroxides, superoxide dismutase, and catalase all decreased. As a result, the study concludes that banana flower extract is beneficial.[12]

Objectives

Objectives were to carry out extraction process for banana peel, preparing periodontal films from raw banana peel and banana peel extract and to evaluate the efficacy of prepared films as an adjuvant therapy for the periodontitis.

METHODS

Type of study

It was an experimental research study.

Study period

Study conducted from September 2022 to February 2023.

Study place

Study carried out at Yenepoya university, Kuthar, Mangalore.

Sample collection and preparation

Healthy ripe banana peels were obtained from the Banana shop, Kuthar, Mangalore. The peels were washed and were removed by hand and were cut into small pieces for easy drying.

The peels were air dried for two weeks and the dried peels were grounded using a mechanical blender into powder. The powdered samples were stored in screwed bottles until needed for use.[13]

Preparation of ethanolic extract of banana peel

The ethanolic extract of the peels were prepared by soaking 50 grams of dried powdery samples in 500 ml of the solvent for 48 hours, during which the mixture is intermittently shaken on a shaking orbit machine.

It was later filtered through Whatman no. 42 filter paper. The filtrate was evaporated under reduced pressure at 40°C by a rotatory evaporator and the final solvent elimination was done with water bath.[14]

Table 1: Screening of phytochemicals in ethanolic extract of banana peel.

Phytochemicals	Ethanolic extract
Flavanoids	(+)
Carbohydrates	(+)
Reducing sugar	(+)
Tannins	(+)
Saponins	(+)
Antraquinones	(-)
Steroids	(-)
Alkaloids	(+)
Glycosides	(-)
Phytosterols	(-)
Phenols	(+)
Terpenoids	(-)

Fabrication of films

Periodontal films were prepared by solvent casting technique. Ethyl cellulose, Carbopol 971P, and HPMC K4M combinations were dissolved in 10mL of ethanol using magnetic stirrer to get different concentrations of polymer solution. Banana peel extract of required quantity and plasticizer were added to the polymer solution with continuous stirring using magnetic stirrer.

After complete mixing, the solution was poured into a clean petridish placed on a horizontal plane. The solvent was allowed to evaporate slowly by inverting a glass funnel plugged with cotton. The stem kept at room temperature for 24 h. After complete evaporation of solvent, cast films were obtained, which were then wrapped in an aluminum foil and stored in a desiccator.[15]

Table 2: Composition of dental film.

Ingredients	F1	F2
Banana peel extract (mg)	150	150
Ethyl cellulose (mg)	-	-
HPMC K4M (mg)	350	350
Carbopol 97IP (mg)	500	550
PEG (mg)	100	100
Ethanol (ml)	10	10

Evaluation of dental films

Thickness

Film thickness was evaluated using a screw gauge with a range of 0-10 mm and revolution 0.001 mm. The anvil of the thickness gauge was turned and the film was inserted after making, sure that the pointer was set to zero (0). The film was held on the anvil and the reading on the dial was noted down. The estimations were carried out in the triplicate.[16]

Variation in mass

The mass of 0.5 cm^2 film from different batches of the formulations was noted on an electronic balance. The estimations were carried out in triplicate.[16]

Folding endurance

Folding endurance was determined by repeated folding of the film at the same place until the film broke. This gives an indication of the brittleness of the film. The number of times the film was folded without breaking was computed as the folding endurance value. The estimations were carried out in triplicate.[17]

Surface pH

The surface pH of the film is determined in order to investigate the possibility of any irritation in vivo. As an acidic or alkaline pH may cause irritation to the oral mucosa, it is necessary to keep the surface pH as close to neutral as possible. A combined pH electrode was used for this purpose.

The film was slightly wet with the help of water and the pH was measured by bringing the electrode in contact with the surface of the oral film. This study was performed in triplicate and mean±standard deviation calculated.[18]

RESULTS

The results are found to be the thickness was measured with a screw gauge at different places of the film in order to evaluate the reproducibility of the preparation method. The thickness was in the range of 470±0.09 to 490±0.03 µm and the films of 0.5 cm^2 were cut from different batches and weighed.

The weights of different formulations were in the range of 0.0098 to 0.0100 gm and the folding endurance test was in the range of 122 to 146 folds and no films developed any visible cracks or breaks, thus showing good folding endurance among the two formulations, F1 has the highest folding endurance due to the presence of a higher concentration of ethyl cellulose (2.00% w/v) when compared with the other films and surface pH of all films was in the range of 6.37±0.08 to 6.79±0.01. This assured that there will not be any kind of irritation to the mucosal lining of the oral cavity.

Table 3: Results of the evaluation studies.

Formulation code	Variation in mass (g)	Thickness (µm)	Surface pH	Folding endurance
F1	0.100±0.0007	490±0.03	6.79±0.024	130
F2	0.100±0.0003	476±1.66	6.62±0.015	140

DISCUSSION

Overall, the study demonstrates that the films exhibit high consistency in terms of thickness, weight, and folding endurance. The good mechanical properties, particularly the high folding endurance of F1, suggest that the films can withstand handling and mechanical stress without breaking. Additionally, the neutral surface pH ensures that the films are biocompatible, reducing the risk of irritation or damage to sensitive tissues.[19]

These findings point to the reliability and reproducibility of the film preparation method, which is essential for pharmaceutical or biomedical applications. The films durability, uniformity, and safety profile make them promising candidates for use in oral drug delivery systems or other applications where controlled release and patient comfort are paramount. However, further studies, such as drug release profiles and stability testing, would be necessary to fully evaluate the films' performance in their intended application.[19]

Suryono et al found that banana peel extract gel effectively promotes angiogenesis**,** alveolar bone regeneration, and collagen production in rats with periodontitis. They concluded that it could be a promising adjuvant therapy for enhancing periodontal healing.[20]

Urmi et al developed ornidazole periodontal films using the solvent casting method for targeted drug delivery into periodontal pockets. The study concluded that a combination of hydrophilic and hydrophobic polymers is suitable for film formulation and that the prepared films are effective as antibacterial agents in periodontal diseases.[21]

Our research showed that the prepared films showed good uniformity in thickness and weight, confirming the reproducibility of the formulation method. They also exhibited satisfactory folding endurance and a near-neutral surface pH, indicating good mechanical strength and suitability for safe oral application.

Limitations

The study was limited to *in vitro* evaluation of physicochemical parameters, and no *in vivo* or clinical studies were conducted to confirm therapeutic efficacy in the treatment of periodontitis. The stability of the formulated dental films over long-term storage under different environmental conditions was not evaluated. The antimicrobial and anti-inflammatory activities of the banana peel extract within the formulated films were not extensively investigated

CONCLUSION

The main objective of the study was to formulate and evaluate an oral dental film containing banana peel. The films can be easily formulated by solvent casting using polymers such as ethyl cellulose, HPMC K4M, Carbapol in different ratios with a suitable plasticizer like poly ethylene glycol. It was observed that the physicochemical characteristics such as uniformity of weight, thickness, folding endurance, surface pH, and uniformity of drug content of all the film samples showed satisfactory results with respect to variation in these parameters between films of the same formulation. Based on the physiochemical parameters the formulation F1 were considered to be the best. The present study reveals that both formulated films showed satisfactory film parameters. From the present investigation it can be concluded that film formulation incorporating banana peel extract can be a potential novel drug dosage form for treatment of Periodontitis.

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