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Evaluating drug release potential of *Solanum nigrum* local drug delivery chip: An *in vitro* study

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Abstract:

Solanum nigrum extract was added to hydroxypropylcellulose, polyethylene glycol and polyvinyl pyrrolidone and centrifuged at 1000 rpm for 45 mins for infusion. A simulation of a continuous flow chamber was created to evaluate the *in vitro* drug release potential of the *Solanum nigrum* chip at three different concentrations of *Solanum nigrum*, i.e., 50, 100 and 150 microgram / ml. The drug release profile of *Solanum nigrum* chip over a 15-days period for three different initial concentrations (50 µg/ml, 100 µg/ml and 150 µg/ml) showed gradual decrease in the drug concentration over time, which is typical of controlled release formulations. Thus, data shows that *Solanum nigrum* chip can effectively be used as a controlled release local drug delivery agent in the management of periodontitis.

Keywords: Herbal medicine, *solanum nigrum*, anti-infective, periodontitis

Background:

Periodontitis is a chronic inflammatory and infectious disease of microbial origin which is characterized by the progressive destruction of tooth supporting structures [1]. The main contributing factors that are responsible for initiating inflammatory reactions in periodontitis are subgingival periodontal pathogens and the resultant inflammatory host response [2]. The key periodontal pathogens includes the "Red complex" bacteria such as *Porphomonas gingivalis*, *Tannerella forsythia* and *Treponema denticola*. Along with this *Aggregatibacter actinomycetemcomitans* that release endotoxins and inflammatory mediators that results in inflammation and progressive destruction of structural proteins like collagen [3, 4]. The periodontal disease manifests clinically as supragingival and subgingival plaque formation, typically accompanied by gingival inflammation and calculus production [5]. For ease of use, we refer to the initial lesion, early lesion, established lesion and advanced lesion as the well-known stages of gingivitis and periodontitis, as defined by Page & Schroeder in 1976. Because it signifies the change from gingivitis to periodontitis, the advanced lesion is also known as the destructive phase, which leads to bone loss and pocket formation that signifies the hallmark feature of periodontitis [6]. Periodontal diseases are treated through both surgical and non-surgical procedures for effective results. The primary approach to the treatment is phase I non-surgical therapy that aims in the removal of local factors through scaling and root planing (SRP) [7, 8]. Considered the "gold standard" initial therapy for periodontitis, this entails mechanically debriding plaque and calculus [8]. Apatzidou and Kinane evaluated reduction in probing pocket depth (PPD) and gain in clinical attachment levels as primary outcome measures following scaling and root planing. In the treatment of periodontitis, systemic antibiotics combined with scaling and root planing (SRP) can provide an extra advantage over SRP alone in terms of clinical attachment loss (CAL), pocket depth change and decreased risk of further CAL loss [9]. Inappropriate antibiotic administration, bacterial resistance to microorganisms, impaired host defences and patient noncompliance are the common drawbacks of systemic antibiotics [10]. Maintaining an effective medication concentration in the periodontal pockets for an adequate amount of time is crucial for treating periodontitis. A Local Drug delivery is therefore a valuable adjunctive for

periodontal treatment with lesser systemic adverse effects [11]. Fibers, strips and films, micro particles, nanosystems, gel, membranes and scaffolds are the various forms in which LDD are available [11, 12]. The proven and approved agents are chlorhexidine gluconate (1.5%), Metronidazole gel (5%), Tetracycline fibres (10%) and Minocycline microspheres (2%) but all these drugs have their own adverse effects like staining of teeth, metallic taste, etc. [13]. A variety of herbs and medicinal plants are available that are scientifically proven and validated as an effective alternative to the modern drugs. *Acacia catechu*, *Aloe vera*, *Azadirachta indica*, *Glycyrrhiza glabra*, *Cinnamomum zeylanicum*, *Allium sativum*, *Propolis*, *Mikania laevigata*, *Mikania glomerata*, *Drosera peltata*, *Helichrysum italicum*, *Coptidis rhizome*, *Piper cubeba*, *Azadirachta indica*, *Syzygium aromaticum* and tea tree oil are some of the herbs that are commonly tested for the treatment of periodontitis [13]. In addition to the herbal medicines listed above, several other products based on herbs are currently undergoing clinical studies. This study is about one such herb, "*Solanum nigrum*" (Nightshade); a plant member of solanaceae family, which is usually cultivated in tropical and subtropical regions [13]. *Solanum nigrum* is known for its anti-microbial, anti-inflammatory, anti-pyretic, anti-oxidant and other medicinal properties [14, 15]. *Solanum nigrum* has been evaluated in systemic administration (oral route) in various other systemic conditions. *Solanum nigrum* is known to be effective in the treatment of many malignant tumors, including liver, lung, cervical, esophageal, breast and nasopharyngeal cancer [15]. Therefore, it is of interest to evaluate the efficacy of *Solanum nigrum* extract as a LDD in periodontitis by determining the concentration of drug released every day till its resorption and by estimating its time for further clinical application.

Materials and Methods:

Study design and study setting:

This study was an experimental, *in vitro* study designed to evaluate the efficacy of *Solanum nigrum* chip as a controlled release agent in three different concentrations, by obtaining the quantity of drug released per day and to evaluate the time period taken for its complete disintegration. This study was carried out at Tagore Dental College and Hospital, Chennai from June 2024 to December 2024.

Procedure:

Preparation of extract:

The fruits of the *Solanum nigrum* were procured. They were initially sundried for 7 days for 5 hours. Later they were dried in laboratory for the evacuation of moisture content. They were macerated and dried powder was obtained. 100mg of the powder was dissolved and soaked in 70% ethanol at room temperature. The extract is filtered and re-extracted again until absolute extraction depletion is done. They were then concentrated for 50 microgram/ml, 100microgram /ml and 150 microgram /ml concentrations.

Preparation of chip:

The obtained extracts were diluted in distilled water and centrifuged at 2000rpm for 20 mins. Later the sedimented extracts in the purified form were inculcated into the solution of polyethyleneglycol (plasticizer), polyvinylpyrrolidone (base) and carbopol (gel base). Later they are centrifuged at 2500 rpm for 20 mins and the drug is collected and placed in the sterile moulds for structurizing it in the chip format (Figure 1).

Evaluation of in vitro drug release:

A simulation of continuous flow chamber was created and the prepared *Solanum nigrum* chip was placed between two moist single-way absorption membranes simulating the periodontal pocket environment. The base membrane will be placed on surface of PBS. The chamber is incubated overnight every day. The supernatant was procured and the PBS was changed every 24 hours. In the similar way three experimental chambers were created to test three different concentration of *Solanum nigrum*, i.e., 50, 100 and 150 microgram/ml. The supernatant is collected and evaluated for drug release profile and period of partial disintegration and complete dissolution.

Results:

Current study in the case of the parameter of drug released each day in the apparatus shows the time taken for partial and complete disintegration of three different concentrations (50µg/ml, 100 µg/ml and 150 µg/ml) of *Solanum nigrum* chip over a period of 15 days. Table 1 indicates that on average within the first 3 days, all three different concentrations (50µg/ml, 100 µg/ml and 150 µg/ml) were able to achieve the minimum inhibitory concentration which is kept at 50 µg/ml. The higher initial concentrations (100 µg/ml and 150 µg/ml) were able to sustain the minimum inhibitory concentration (MIC) until 9th day when compared to the 50 µg/ml concentration which was able to maintain the MIC only on the 3rd day. This suggests that, in contrast to the lower 50 µg/ml concentration of the chip, larger drug concentrations (100 µg/ml and 150 µg/ml) were able to maintain the MIC for a longer amount of time over those 15 days By Day 15, the release for both the 50 µg/ml and 100 µg/ml concentrations is zero, while the 150 µg/ml concentration still shows a residual amount (4 µg/ml). This indicates that the drug is fully released from the chip by Day 15 for lower concentrations, while the higher concentration formulation may release drug over a slightly

longer period, though still showing a decreasing trend. Figure 1 indicates the drug release profile of *Solanum nigrum* chip over a 15-days period for three different initial concentrations (50 µg/ml, 100 µg/ml and 150 µg/ml).

Table 1: Drug release profile

Day	50 microgram/ml	100 microgram/ml	150 microgram/ml
1	25 microgram/ml	86 microgram/ml	121 microgram/ml
2	32 microgram/ml	89 microgram/ml	139 microgram/ml
3	49 microgram/ml	91 microgram/ml	141 microgram/ml
4	43 microgram/ml	99 microgram/ml	145 microgram/ml
5	41 microgram/ml	86 microgram/ml	122 microgram/ml
6	40 microgram/ml	74 microgram/ml	111 microgram/ml
7	39 microgram/ml	65microgram/ml	98 microgram/ml
8	35 microgram/ml	61 microgram/ml	89 microgram/ml
9	32 microgram/ml	48 microgram/ml	67 microgram/ml
10	29 microgram/ml	35 microgram/ml	45 microgram/ml
11	22 microgram/ml	21 microgram/ml	36 microgram/ml
12	18 microgram/ml	9 microgram/ml	18 microgram/ml
13	8 microgram/ml	0	11 microgram/ml
14	0	0	4 microgram/ml
15	0	0	0

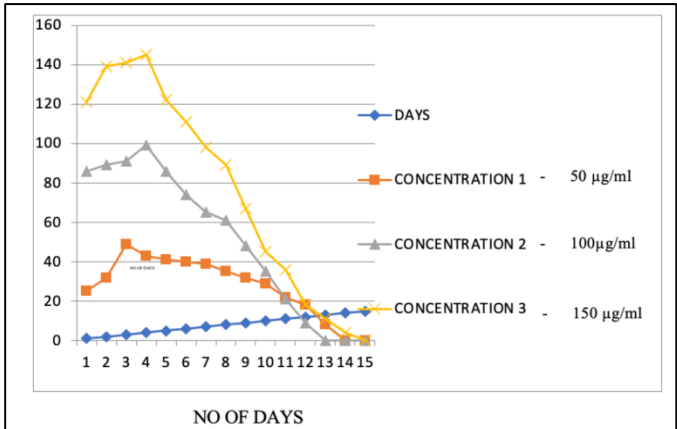


Figure 1: Drug release profile

Discussion:

Periodontitis is an inflammatory disease that causes degeneration of periodontal ligaments, formation of periodontal pockets and alveolar bone loss, leading to destruction of the teeth’s supporting structure. Periodontitis has been successfully treated through a variety of local and systemic strategies. Reducing bacterial biofilm, bleeding on probing (BOP) and pockets elimination are the main goals of periodontal treatment. As an adjuvant therapy to scaling and root planing (SRP) for periodontitis, local drug delivery systems (LDDSs) are currently a promising approach that increases efficacy and reduces side effects by managing drug release [16]. Recent years have seen an increase in the use of herbal plants, which may provide a new kind of effective treatment. Herbal drugs used in proper concentration do not modify natural flora [17]. In this study, *Solanum nigrum* which is known for its antitumor, antioxidant, anti-inflammatory, immunomodulatory, antihypertensive, antimicrobial and antiviral activities is formulated as a chip and has been evaluated for its drug release potential till its resorption and its disintegration time for the further clinical application of the chip in periodontal pockets as controlled release local drug delivery agent [18]. Anand et al. and Yaghini et al. conducted a

clinical trial using a new herbal medication in the gel form for subgingival treatment after scaling and root planing. It contained a combination of extracts from *Q. brantii* and *C. sativum*. The study aimed at analysing the effects of the herbal gel on periodontal indices in adult periodontitis patients [19, 20]. In the study conducted by Bajpai and Ramamurthy cytotoxicity of *Ocimum sanctum* (OS)-based hydrogel was evaluated for its use in local drug delivery in periodontitis and revealed that *O. Sanctum* is cytocompatible to be used as local drug delivery agent [21]. Studies have also showed the effectiveness of herbal adjuncts in patients receiving supportive periodontal therapy. In contrast to standard supportive periodontal therapy (SPT), the combination herbal formulation of *Centella asiatica* and *Punica granatum* was tested for potential further boosting efficacy in maintenance patients, with further monitoring of specific inflammatory indicators [22]. The study conducted by Behal *et al.* suggested that using 2% whole turmeric gel as an adjunct to scaling and root planing is more effective than scaling and root planing alone in the treatment of periodontal pockets as it showed Significant reduction in the trypsin-like enzyme activity of "red complex" [23]. Aloe vera gel is known for its antibacterial and anti-inflammatory properties, which may make them useful in the treatment of periodontitis. The objective of this research was to assess the impact of applying aloe vera gel locally as a supplement to scaling and root planing when treating patients with chronic periodontitis. Aloe vera gel used as an adjunct to scaling and root planning showed significant improvement in gingival index and probing depth in a research [17]. Tyagi *et al.* conducted a study evaluating the effect of pomegranate chip and gels used as LDD in periodontitis patients following scaling and root planning [24]. This study is the first to assess the use of *Solanum nigrum* as a local drug delivery agent in the treatment of periodontitis following scaling and root planing, despite the fact that numerous research studies have showed the plant's varied pharmacological qualities [25, 26 and 27]. The findings of our study revealed effective rate of drug release from the chip over the period of 15 days suggesting it to be used a controlled release LDD in the management of periodontitis. The study also evaluated the time taken for its complete disintegration for further clinical application of the chip.

Conclusion:

The drug release profile of *Solanum nigrum* chip suggests that it could be used as a locally delivered sustained-release agent. This can be used efficiently to manage chronic diseases like periodontitis and maintain drug levels in periodontal pockets over an extended period. Sustained release nature, cost-effectiveness and reduced reported side effects make them an attractive alternative option in the management of periodontitis.

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