Bulletin of Environment, Pharmacology and Life Sciences
Bull. Env. Pharmacol. Life Sci., Vol 11 [11] October 2022 : 13-16

Online ISSN 2277-1808
Journal's URL:http://www.bepls.com
CODEN: BEPLAD

ORIGINAL ARTICLE **OPEN ACCESS**

Efficacy of *Nigella sativum* extracts as herbal mouthwash in the treatment of chronic gingivitis: a randomized controlled clinical trial.

Sneha Puri[1], Priyanka Ghogare[2], Akhilesh Shewale[3], Mahvash Fatema[4], Rashmi Bele[5]
[1]Reader, Department of Periodontology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India.
[2]Post graduate student, Department of Periodontology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India.
[3]Senior lecturer, Department of Periodontology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India.
[4]Post graduate student, Department of Periodontology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India.
[5]Post graduate student, Department of Periodontology, Swargiya Dadasaheb Kalmegh Smruti Dental College and Hospital, Nagpur, India.
Corresponding authors Email- priyankaghogare12@gmail.com

ABSTRACT
To assess the efficacy of a newly formulated mouthwash containing Nigella sativa (NS) extract in gingivitis.40 patients having gingivitis were randomly distributed into two groups, 20 patients in experimental and 20 patients in control group. NS oil based mouthwash was used as adjunctive to periodontal therapy. NS oil based mouthwash was formulated and given to the patient, instructed to rinse the mouth and spit out, twice a day; morning and evening. The test group received mouthwash containing Nigella sativa extract and the control group received Chlorhexidine mouthwash. Clinical parameters assessed were gingival index (GI), plaque index (PI) and papillary bleeding index (PBI) at baseline and at 4weeks interval. The mean reduction in GI (0.53±0.03) and (0.42±0.02), PI (0.32±0.02) and (0.23±0.01) and PBI (2.21–0.76) and (2.17–1.29) noted in the experimental and control groups. Formulated mouthwash exhibits an anti-inflammatory property, which may be useful as an adjunct to mechanical therapy in the prevention and treatment of gingivitis and showed significant decrease in gingivitis.
Keywords: *Nigella sativum, Chronic gingivitis, anti-inflammatories, antimicrobial, adjunctive periodontal therapy; herbal product*

Received 12.08.2022 Revised 21.09.2022 Accepted 05.10.2022

INTRODUCTION

Recently, worldwide attention is towards therapeutic herbal products in the treatment of different diseases has been growing extensively as they are showing promising outcomes and rare side effects**.**

Nigella sativa is known as called as miracle herb [1, 2],it is a yearly blossoming plant from the family Ranunculaceae also known as black cumin, black seed, habbatul barakah, black caraway, kalojeera, kalonji or kalanji and is native to the southern regions of Asia and numerous countries in the Middle East and the Mediterranean region [2-4]. The medicinal use of NS have been established in the Islamic medicine, Chinese traditional treatments, Unani, Ayurveda and other medicinal systems. Among the pharmacologically active components that have been isolated from NS up to now the most described active and therapeutic constituent is thymoquinone (TQ) [5].

Biomedical properties such as antioxidant, antimicrobial, anticancer, anti-inflammatory, antihypertensive, hypoglycemic, antiparasitic and anti-asthmatic effects are of great medical use [6]. Thymoquinone makes up almost 50% of all NS oil constituents [7].

Active compounds and elements isolated from *Nigella sativa* seeds and their percentages. Compound and Elements Percentages are Thymoquinone 30–48% Thymohydroquinone, dithymoquinone, p-cymene 7–15% Carvacrol 6–12% 4-Terpineol 2–7% t-Anethol 1–4% Longifolene (a sesquiterpene) 1–8%

Nigellicimine, nigellicimine-N-oxide, nigellidine, nigellicine, α-hederin, saponin, carvone, limonene, citronellol [6].

To the best of our knowledge no such studies have been carried out before using nigella sativa in combination with mint in treatment of chronic gingivitis. This study was conducted to assess the efficacy of a newly formulated mouthwash containing *Nigella sativa* extract in gingivitis.

MATERIAL AND METHODS

40 systemically healthy adult patients were included in this study and were diagnosed with gingivitis. Patients were selected from the outpatient department of periodontology, following prior approval from Institutional Ethical Board and taking prior informed consent from the patients. The patients with active orthodontic therapy or those who are on antibiotic coverage; having smoking, drinking etc habits and received any periodontal intervention in last 6 months were excluded from the study.

The study was designed as a single blinded randomized clinical trial. Wherein forty patients were randomly assigned to two groups (20 Test & 20 Control) using computer generated random allocation. The test group received mouthwash containing Nigella sativa extract and the control group received Chlorhexidine mouthwash.

Clinical parameters assessed were gingival index (GI) [8], plaque index (PI) [9] and papillary bleeding index (PBI)[10] at baseline and at 4weeks interval. All the patients received complete oral prophylaxis, including scaling and rootplaning (SRP), using ultrasonic scaler (Woodpecker, UDS-N1, Guilin, China) and hand instruments (Hu-Friedy, Chicago, IL, USA) [11].

In vitro Preparation of Mouthwash

The seeds of Nigella sativum (kalonji), were obtained from local vendors. The collected plant materials were washed with distilled water and dried. The aqueous oil extract of plant material was obtained by wooden cold compress machine.

Equal quantity of oil extract of nigella sativa and mint water was mixed well. The oil obtained was left to collapse for 1 week and was recovered from the impurities by applying filtration. The oil obtained was preserved in brown glass bottles. The final concentrate was then diluted with sterile distilled water to make mouthwash and stored .

The bottle were distributed to individuals by the clinical examiner (AS) who was masked to the bottle contents. Individuals were instructed to use mouthwash thrice daily, 30 minutes after brushing, and further instructed not to rinse/eat anything for 30 minutes after mouthwash use. Individuals were also instructed to refrain from any forms of oral hygiene aids, including dental floss and chewing gum, during the study period. Analysis of data were carried out using Graph Prism statistical software (USA). Values of different parameters collected are expressed as mean – standard deviation (SD). Paired't' test was performed for comparison of differences among the two groups.

RESULT

In this randomized controlled clinical trial, an analysis of 40 patients (20 experimental group and 20 control group) was done. The experimental group showed uneventful healing with no signs of allergy, swelling, or inflammation. This ensures that the material is biocompatible and well tolerated by the patients.

The mean reduction in GI (0.53±0.03) and (0.42±0.02), PI (0.32±0.02) and (0.23±0.01) and PBI (2.21–0.76) and (2.17–1.29) noted in the experimental and control groups at baseline and at 4 weeks (TABLE 1). The results obtained were statistically nonsignificant at baseline and at 4weeks interval, in all the groups.

Remarkable improvement was noted from baseline to 4weeks interval as seen in FIGURE 1 and 2.

TABLE 1: The mean reduction in GI, PI and PBI noted in the experimental and control groups at baseline and at 4 weeks

MEAN REDUCTION	Control group	Test group
Gingival index	0.53±0.03	0.42±0.02
Plaque index	0.32±0.02	0.23±0.01
Papillary bleeding index	2.17–1.29	2.21–0.76

FIGURE 1- PRE-OPERATIVE

FIGURE 2 - POST OPERATIVE (AFTER 1 MONTH)

DISCUSSION

Among many herbal remedies that have been described in different regions of the world, NS is a well-established cultural and religion-based medication for various health conditions. Being a plant native to the southern European continent, North Africa, the Middle East, as well as being widely cultivated in areas around the Indian Peninsula, NS became a vastly used herbal remedy in many cultures and households [12].

Nigella sativa have anti-inflammatory activity and this is the one which helps in reducing oral inflammatory condition, this was proven in a study done by Gazal hassan *et al* [13] and Samra ashfaq *et al* 2021 [14].

In the present study, the test group had shown significantly decrease in PI, GI and PBI scores, which can be attributed to the properties of mouthwash content. The chlorhexidine group also showed reductions in both the tested scores, which can be attributed to the Hawthorne effect. No adverse effects were reported from subjects of both groups. The newly formulated mouthwash consists of Nigella sativum extract. Nigella sativum oil is known to have anti-inflammatory, antibacterial and antimicrobial properties. The addition of mint as a flavoring agent aids in patient's compliance. Similar action of nigella sativa was proved in the studies done by Gazala hasaan *et al* [13] and Gazala hassan et al [15].

In the study by Gazala hasaan *et al* [13], author used Nigella sativa oil-based mouth wash which was compared to placebo (normal saline) after non-surgical periodontal therapy in patients with chronic periodontitis. Salivary level of Matrix metalloproteinase-8 (MMP-8) which is a collagen degradation enzyme, is known to increase during chronic periodontitis is monitored pre and post treatment. As nigella sativa is having anti-inflammatory property, it helped in reducing salivary MMP-8 levels. The results were significant when compared to placebo that was normal saline.

In the study by Gazal hassan *et al* [13], author used nigella sativa oil-based mouthwash in comparison with normal saline based mouthwash in chronic periodontitis patients, in which clinical parameters like Periodontal Pocket Depth (PPD), CAL (Clinical Attachment Loss), PI (Plaque Index) and BoP (Bleeding on Probing) had shown significant reduction proving anti-inflammatory properties of nigella sativa.

In the present study the use of our newly formulated mouthwash showed non-significant reduction in the plaque score, gingival index score at baseline and at 4th week when compared to chlorhexidine mouthwash. Overall the ingredients used in our formulation led to a superior reduction in the microbial load and also reduces the plaque and gingival index scores.

CONCLUSION

The encouraging results of our study suggest that the newly formulated mouthwash containing Nigella sativum demonstrates anti-inflammatory properties, which may be useful as an adjunctive to mechanical therapy in the prevention and treatment of gingivitis. But additional long-term longitudinal trials are warranted to further assess the efficacy of the mouthwash to be utilized as an adjuvant to periodontal therapy.

ACKNOWLEDGEMENT

There is no financial support and personal assistance for this work.

CONFLICT OF INTEREST

No conflict of interest

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CITATION OF THIS ARTICLE

S Puri, P Ghogare, A Shewale, M Fatema, R Bele. Efficacy of Nigella sativum extracts as herbal mouthwash in the treatment of chronic gingivitis: a randomized controlled clinical trial.. Bull. Env.Pharmacol. Life Sci., Vol 11 [11] October 2022 : 13-16