Formulation and evaluation of Chocolate Lozenges for cessation of smoking

[*]Deepika Raina, Manish Kumar, Banti Rana, Prachi Mall
School of Pharmacy, Graphic Era Hill University, Uttrakhand, India.
[*]Email: deepika709@gmail.com
DOI 10.51129/ujpah-2022-34-1(9)

Received – 6 June, 2023
Revised – 9 June, 2023
Accepted – 12 June 2023
Published – 24 June, 2023

Abstract- The use of *Avena sativa*, also known as oat straw, in herbal lozenges for smoking cessation shows promise. This herbal ingredient has a long history of medicinal use and has demonstrated potential in reducing cravings and withdrawal symptoms related to quitting smoking. The lozenges were prepared by using *Avena sativa* sugar and other excipients. The physicochemical properties of the lozenges were evaluated, including weight, thickness, hardness, friability, and dissolution rate. The lozenges were also evaluated for their sensory properties, including taste, texture, and overall acceptability. 100 grams of dark chocolate was melted properly and the drug was added to it and mixed well and then added in the mold for the perfect shape and allowed to cool

Keywords: Cessation of smoking, *Avena sativa*, Lozenges, Soft lozenges.

Introduction

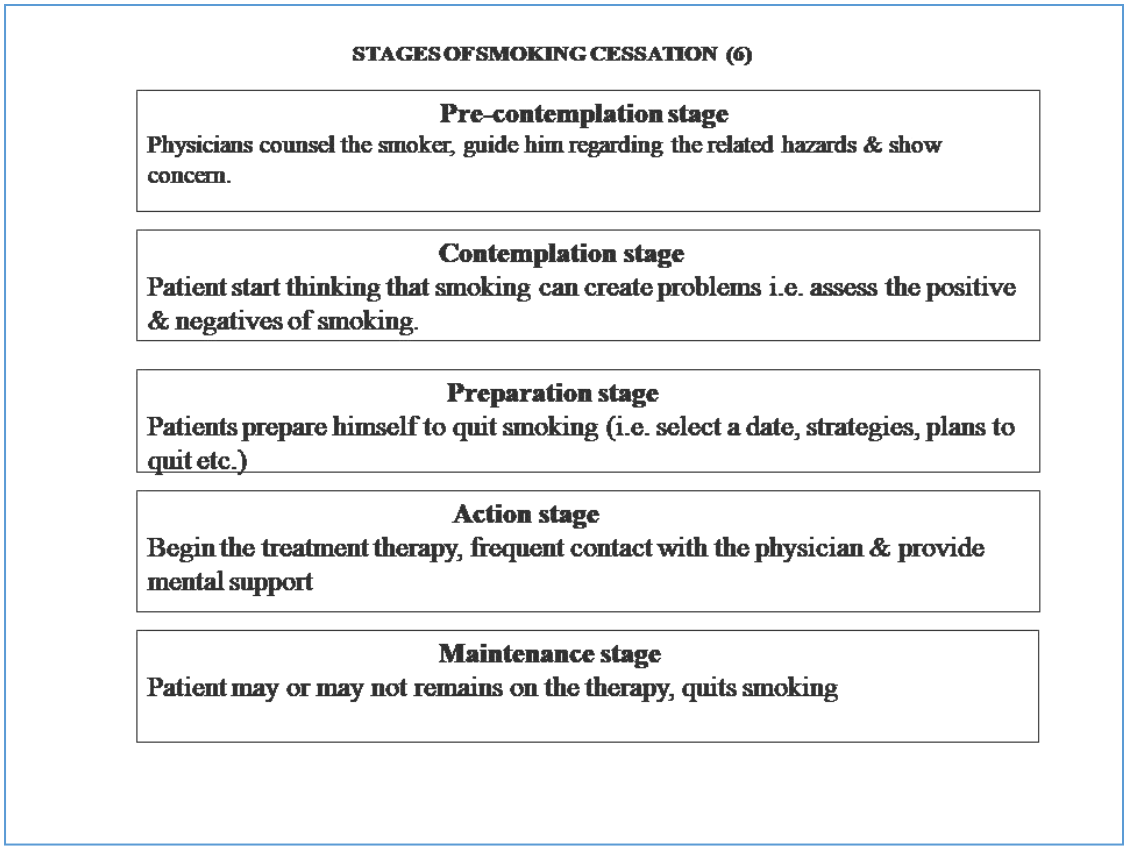
Smoking is the act of inhaling & exhaling the fumes of tobacco or any other burning plant material. Tobacco is the major cause of death and disability, leading to respiratory, cardiovascular, and cancer diseases. Smoking cessation is the most effective way to stop the advancement of COPD, as it is the most practical & effective way to do so[1,2,3] .

Nicotine is a nicotinic cholinergic agonist which at low doses binds to the nicotinic cholinergic receptors and emulates the effects of acetylcholine. At high doses, it produces a biphasic reaction characterized by stimulation followed by a depressant effect. It stimulates the release of dopamine, norepinephrine, acetylcholine, serotonin, pituitary hormones, and epinephrine. It also stimulates the cholinergic mechanisms which appear to impact upon the memory, alertness, and learning[4].

Smoking Cessation

Despite of the several warnings & graphical representation on the packaging itself that "Smoking is injurious to health", smokers found it difficult to quit smoking but it can be dealt with the following steps:

1. Drug Therapies
2. Behavioral Interventions
3. Other Interventions[5]



Accounting for the several health hazards of smoking, drug therapy has been increasingly relied upon to assist in smoking cessation[7].

Available Drug Therapy	Mechanism of Action
Nicotine replacement therapy	NRT works by reducing symptoms of nicotine withdrawal, thereby increasing the likelihood of smoking cessation
Anti-depressant therapy especially Bupropion	Bupropion is a weak dopamine and nor-epinephrine reuptake inhibitor, thereby maintaining central levels of dopamine through the process of cessation
Varenicline	Varenicline is a nicotinic acetylcholine receptor partial agonist, these could stimulate the release of sufficient dopamine to reduce craving and withdrawal while simultaneously acting as a partial antagonist by blocking the binding and consequent reinforcing effects of smoked nicotine.

Cytisine	Cytisine is a partial agonist selective for α4β2 nicotinic acetylcholine receptors, responsible for nicotine effects, and it prevents nicotine binding[5].

Recent advances have been made towards herbal therapies, complementary & alternative medicine, and traditional Chinese medicine for smoking cessation. Less-studied interventions such as acupuncture, aversive therapy, exercise, lobeline, mecamylamine, opioid agonists, anxiolytics, hypnosis, silver acetate are also being explored[8,9,10,11].

This study aims to review existing evidence related to efficacy and safety of herbal medicines on smoking cessation to make smoking cessation more accessible to all individuals. The herbal medicines with evidence to help in the smoking cessation situations are mixed herbal tea, aromatic black pepper extract, *Rauwolfia serpentina*, kava-kava, St. Johnswort, *Rhodiola rosea*, licorice, and *Rhodiola rosea*. Additionally, *lobelia inflata* can be used as an effective substitute during the initial withdrawal, and it can be used as a smoking blend or as a supplement. Smoking blends can also serve multiple functions, such as a reflective break from the day, control of oral urges, and continued social interaction. Gradually, the amount of lobelia in the blend can be decreased[12].

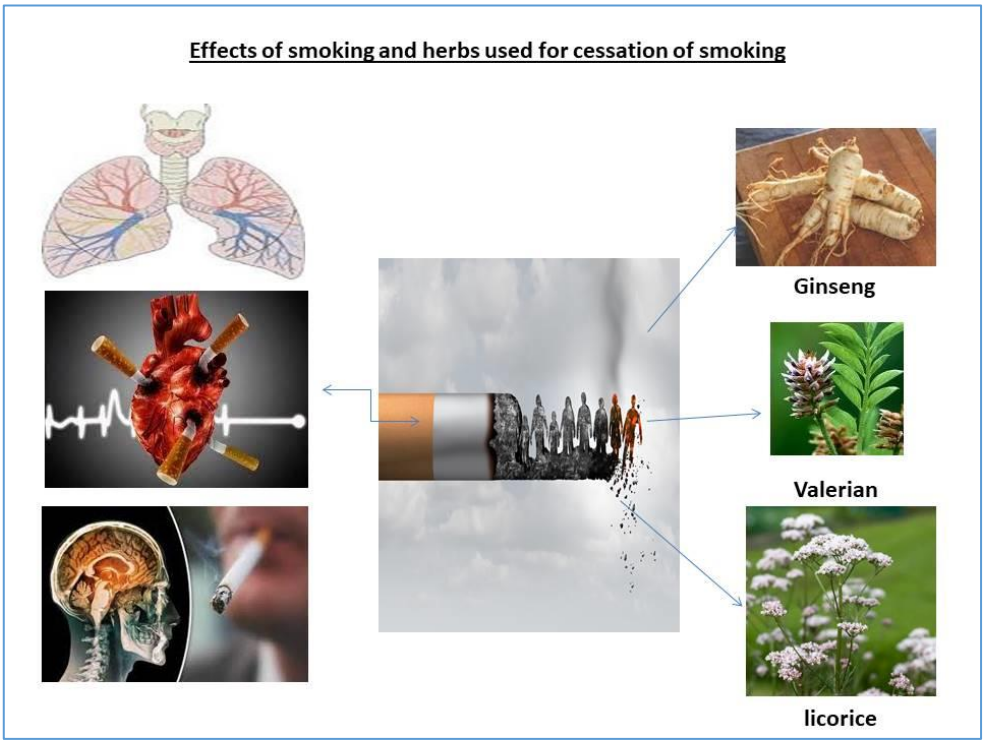


Figure-1 Smoking effects and role of herbs.

Material and methods

Table-1 Formulation of Lozenges[13]

S. No	Ingredient	Quantity Used
1.	Drug	10 G
2.	Chocolate	100 G

Preparation of soft lozenges

Chocolate weighing around 100 gm was melted using a water bath and then approximately 10 gm of crude extract was added to it. The mixture was stirred and thoroughly blended before being poured into molds. Subsequently, it was left to cool down and solidify at room temperature[14,15,16].

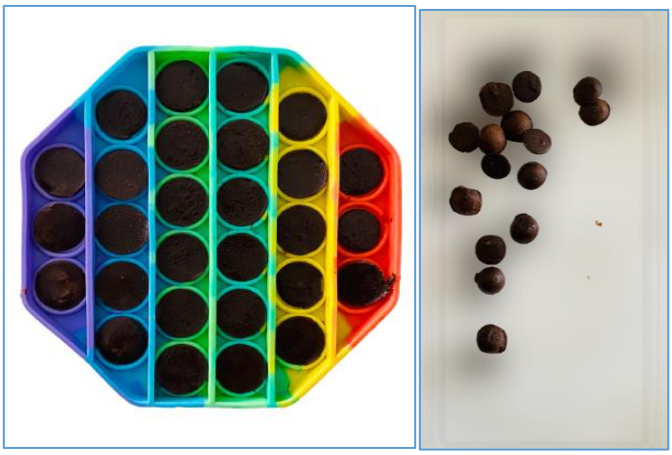


Figure-2 Lozenges in a mold and chocolate lozenges.

Quality control of lozenges[17]

1. Hardness test- The firmness of lozenges is measured using either a Pfizer or Monsanto hardness tester. The ability of lozenges to withstand shipping or breakage during storage, transportation, and handling prior to use is dependent on their hardness.

2. Diameter and thickness: The tool utilized to measure the diameter and thickness of lozenges is a Vernier caliper.

3. Weight variation: In this study, 20 lozenges were chosen randomly, and each one was weighed individually with an electronic balance. The mean weight and standard deviation were calculated for the 26 tablets, or the initial weight was compared to the computed average weight.

4. Disintegration test: The USP Disintegration apparatus is utilized to determine the disintegration time of lozenges, which is recorded in either pH 6.8 phosphate buffer or artificial saliva at a temperature of 37ºC. In an in-vitro drug dissolution study, the rate of drug absorption is determined by the rate of

drug dissolution of the lozenges. The efficacy of the lozenges is directly related to their rate of dissolution and bioavailability. This study is carried out using the USP II Dissolution type apparatus, which is a paddle-type instrument. The dissolution study is conducted in 900 ml of buffer pH 6.4 or artificial saliva by the USP II paddle method at 100 rpm. Samples are taken at 5-minute intervals and immediately replaced with an equal volume of fresh buffer or artificial saliva. The samples are then analyzed spectrophotometrically, and the temperature is maintained at 37^0C ± 2^0C during the dissolution studies.

Results and Discussion

Table-2 Evaluation

S.No	Tests Performed	Result
1.	Shape	Semi-circle
2.	Color	Brown
3.	Taste	Sweet
4.	Flavor	Chocolate
5.	Hardness	5 kg/cm^2
6.	Diameter	Avg. 14 mm
7.	Thickness	Avg. 0.66 mm
8.	Average weight	1.16 g (0.5 g weight variation)
9.	Disintegration time at 30 °C	7 minutes 15 seconds

Conclusion

The preparation of herbal lozenges using *Avena sativa* as a potential aid for smoking cessation shows promise. *Avena sativa*, commonly known as oat straw, has been used for its medicinal properties for centuries and has been found to have potential benefits in reducing cravings and withdrawal symptoms associated with smoking cessation.

The formulation of *Avena sativa* based lozenges requires careful consideration of the quantity and quality of ingredients as well as the manufacturing process. Factors such as the optimal temperature and duration of heating, mixing techniques, and the selection of excipients can influence the efficacy and safety of the final product.

Although more research is needed to confirm the effectiveness of *Avena sativa* lozenges in smoking cessation, initial studies have shown promising results. Overall, the development of herbal lozenges using *Avena sativa* represents a potential alternative or complementary approach to traditional smoking cessation methods and warrants further investigation.

Disclaimer Statement

Authors declare that no competing interest exists. The products used for this research are commonly used products in research. There is no conflict of interest between authors and producers of the product.

References

1. https://www.who.int/news-room/fact-sheets/detail/tobacco accessed on 12/06/2023.

2. Hammond, D.; Fong, G.T.; McNeill, A.; Borland, R. and Cummings, K.M. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tobacco control*, 2006; June 1;15(suppl 3):iii19-25.

3. Marlow, S.P. and Stoller, J.K. Smoking cessation. *Respiratory care*, 2003; Dec. 1; 48(12):1238-56.

4. Carmody, T.P. Affect regulation, tobacco addiction, and smoking cessation. *Journal of psychoactive drugs*, 1989; Jul. 1; 21(3):331-42.

5. Giulietti, F.; Filipponi, A.; Rosettani, G.; Giordano, P.; Iacoacci, C.; Spannella, F. and Sarzani, R. Pharmacological approach to smoking cessation: an updated review for daily clinical practice. *High Blood Pressure and Cardiovascular Prevention*, 2020; Oct.; 27(5):349-62.

6. Mallin, R. Smoking cessation: integration of behavioral and drug therapies. *American family physician*, 2002; Mar. 15; 65(6):1107-15.

7. Wu, P.; Wilson, K.; Dimoulas, P. and Mills, E.J. Effectiveness of smoking cessation therapies: a systematic review and meta-analysis. *BMC public health*, 2006; Dec.; 6(1):1-6.

8. Kitikannakorn, N.; Chaiyakunapruk, N.; Nimpitakpong, P.; Dilokthornsakul, P.; Meepoo, E. and Kerdpeng, W. An overview of the evidences of herbals for smoking cessation. *Complementary Therapies in Medicine*, 2013; Oct. 1; 21 (5):557-64.

9. Sood, A.; Ebbert, J.O.; Sood, R. and Stevens, S.R. Complementary treatments for tobacco cessation: a survey. *Nicotine & Tobacco Research*, 2006; Dec. 1; 8(6):7 67-71.

10. Wang, J.H.; Wang, M.; Liu, S.C.; Du, X.F.; Han, M.; Liu, J.F.; Qin, W.; Chen, B.; Van Haselen, R. and Liu, J.P. A bibliometric analysis of clinical study literature of traditional Chinese medicine therapies for smoking cessation. *Tobacco Induced Diseases*, 2018;16.

11. Lindson, N.; Pritchard, G.; Hong, B.; Fanshawe, T.R.; Pipe, A. and Papadakis, S. Strategies to improve smoking cessation rates in primary care. *Cochrane Database of Systematic Reviews*, 2021;(9).

12. Mitra, R.; Rai, A.; Kumar, A. and Mitra, J.K. Role of Herbal Medication in Tobacco Cessation Treatment: A Systematic Review and Meta-analysis. *Addiction and Health*, 2023; Jan. 1; 15(1):63-70.

13. Verma, Abhay. Review on Lozenges.RAPSR *Journal Der Pharmazie Forschung*, 2014; 2:1-10.

14. Renuka, P. and Madhusudan, Y. Lozenges Formulation and Evaluation: A Review. *International Journal of Advances in Pharmaceutical Research*, 2014; 5(5): 290-98.

15. Yadav, S.; Galib and Prajapati, P.K Pharmaceutical standardization of herbal lozenges vasa candy. *Ayurpharm. International Journal of Ayurvedic Allied Science*, 2014; 3(2): 22-27.

16. Ashwini, P.B. A REVIEW ON LOZENGES

17. Pothu, R. and Yamsani, M.R. Lozenges formulation and evaluation: *A review*. *IJAPR*, 2014; 1:290-4.