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Effect of Palatal Botulinum Toxin Injection in Habitual Snoring

Mustafa Shamkhi Abbood[1*], Samah Abbas Hammadi[2], Hakim Fadhil Khudhair[3]

[1]Bachelor of Medicine, Bachelor of Surgery (M. B. CH. B.). Arab Board of ORL & Head and Neck Surgery (ABORL& HN). Specialist Otolaryngologist. Skull base fellowship, Baghdad, Iraq, Lecturer, College of Medicine, Ibn Sina University of Medical and Pharmaceutical Sciences, Iraq, Baghdad
[2]M.B.Ch.B. CAB(ORL-HNS), Specialist Otolaryngologist, Lecturer, College of Medicine, Al-Nahrain University, Iraq
[3]Bachelor of Medicine, Bachelor of Surgery (M. B. CH. B.). Arab Board of ORL & Head and Neck Surgery (ABORL& HN). Specialist Otolaryngologist. Skull base fellowship, Baghdad, Iraq, Lecturer, Al-Iraqia University, College of Medicine, Iraq, Baghdad

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***Corresponding author:** Mustafa Shamkhi Abbood
Bachelor of Medicine, Bachelor of Surgery (M. B. CH. B.). Arab Board of ORL & Head and Neck Surgery (ABORL& HN). Specialist Otolaryngologist. Skull base fellowship, Baghdad, Iraq, Lecturer, College of Medicine, Ibn Sina University of Medical and Pharmaceutical Sciences, Iraq, Baghdad

Abstract **Original Research Article**

Snoring is a loud buzzing noise caused by the soft palate and pillar vibration. Loud snoring at least three nights per week is described as habitual snoring (HS). ***Aim of the Study*:** To evaluate the effect of palatal botulinum toxin in snoring patients. ***Patients and Methods*:** An Experimental clinical trial study was conducted on thirty-seven patients with habitual snoring between July 2021 and January 2022. The participants and their partners completed a questionnaire submitted before and after injection. Recordings of snoring sounds before injection (as a baseline) and after injection were monitored by a mobile application designed to record and analyze snoring (Goodsomia Lab.). Unilateral injections of 10 botulinum toxin type A units were done into the soft palate muscles. ***Result*:** Snoring was improved in all patients, with no significant side effects reported. Epworth Sleepiness Scale was 9.9 ± 0.9 before botulinum toxin injection and 8.2 ± 1.7 one week after injection, while the snoring index was 131 ± 66 and 61.5 ± 28, respectively. The average Intensity of Snoring and maximal Intensity of Snoring before botulinum injection were 57 ± 7.5 and 90.5 ± 1.6, respectively, and changed to 44 ± 4.2 and 87.8 ± 1.9 seven days after injection. Regarding the lowest pulse oxygen saturation, there is a statistically better rate after toxin injection, 90.7 ± 0.9, than before injection, 89.1 ± 1.8. ***Discussion*:** Snoring treatment with botulinum toxin is safe, easy to perform, non-invasive, and reversible.

Keywords: Botulinum toxin, injection, habitual, snoring, sleep.

INTRODUCTION

Snoring is a loud buzzing noise caused by the soft palate and pillar vibration of the oropharyngeal inlet, which occurs mainly during sleep. The presence of loud snoring at least three nights per week or 10% to 20% of a monitored night is described as habitual snoring (HS), which is closely linked to obstructive sleep apnea (OSA) (Young *et al*., 2009, Young *et al*., 1993). Snoring is defined by the American Academy of Sleep Medicine (AASM) as a sound originating from vibrations of different tissues in the upper airway and not associated with apnea or hypoventilation (Thorpy, 2012). Depending on many points, such as the frequency of snoring episodes, body movements during sleep, and its impact on daily life, snoring can be classified into three degrees, which are mild, moderate, or severe, and the simple one does not affect patient sleep or cause excessive daytime sleepiness (Bearpark *et al*., 1995). HS is linked to various physiological and social implications, including sleep fragmentation, familial strife, excessive daytime drowsiness, and, more dangerously, the development of systemic hypertension in those over 50 (Lindberg *et al*., 1998). After considering age, sex, body mass index (BMI), diabetes, level of education, smoking, and alcohol use, loud snorers had a 40% higher risk of hypertension and increased rate of heart attack and stroke than non-snorers (Dunai *et al*., 2008). Heavy snoring has lately been linked to carotid atherosclerosis, and reducing it has been indicated as an essential objective in stroke prevention (Lee *et al*., 2008).

Snoring is a widespread sleeping issue that affects about 37 million people in the United States. However, information on the frequency and impact of HS in Middle Eastern nations is insufficient (Hur, 2008). Snoring is more common among adults, men, and overweight people, and it typically gets worse with age.

Snoring is frequently overlooked as a separate entity, with attention instead focused on its connection to obstructive sleep apnea (OSA). On the other hand, snoring can have significant, if not profound, repercussions for the individual and anyone sharing a sleeping area. Snoring interrupts sleep, leading to increased daytime drowsiness, poor performance and productivity, irritability, and reduced libido (Luboshitzky *et al*., 2002, Klingman *et al.*, 2019, Hanak *et al*., 2008, Macarthur *et al*., 2019). Snoring at night very likely impairs the sleep of others in close vicinity, resulting in identical sleep deprivation symptoms, social strife, and even alienation (Armstrong *et al*., 1999, Gall *et al*., 1993, Cartwright and Knight, 1987, Fitzpatrick *et al*., 1993).

Snoring may be classified as noise by its occurrence time, length, and intensity, as can all sounds. In practice, recording techniques are most commonly used to determine the snoring index, which means the number of snoring times in one hour, average snoring intensity and cumulative snoring length (Dalmasso and Prota, 1996). Before the last few years, most of the published data on snoring and OSAS severity was based on subjective accounts of snoring, either from the snorer himself or family members (Lim and Curry, 1999, Morris *et al*., 2008, Bliwise *et al.*, 1991).

Botulinum toxin is a potent neuroparalytic chemical produced naturally by the anaerobic bacteria Clostridium botulinum. It is divided into seven kinds (A to G) (Kuhnel *et al*., 2008). A and B are mainly utilized because of the toxin's immunological specificity (Jabbari and Machado, 2011).

Following an initial history, sleep hygiene examination, and Epworth Sleepiness Scale screening, primary care doctors increasingly refer patients to sleep specialists. The patient estimates their likelihood of falling asleep in eight distinct settings that they face regularly. The Epworth Sleepiness Scale ranges from 0 to 24, with a 16 or more being deemed extremely drowsy and requiring further inquiry (Johns, 1991).

MATERIAL AND METHOD

Population Study of the Patient:

The Department of General Surgery, College of Medicine, Ibn Sina University of Medical and Pharmaceutical Sciences approved this research. Subjects who have been snoring for at least three months and are seeking treatment for snoring are included in the research. To rule out the nasal blockage and pharyngeal infection and inject the botulinum toxin, standard otolaryngology tools such as a nasal speculum, headlight, Karl Storz® 0 Degree ENT Endoscope, and Storz® light source were used.

Inclusion Criteria:

- Patients age from 18 to 70.
- A bed partner for at least three months before the beginning of the study.
- Subjects know the study's purpose and submit written informed consent at the screening appointment.
- Subjects who have a good understanding of the research procedures and the capacity and willingness to follow them throughout the study.

Exclusion Criteria:

- Patients were suffering from a severe degree of obstructive sleep apnea.
- Persons suffering from craniofacial disorders.
- Patients with nasal blockage or other abnormalities, such as polyps.
- Subjects that have previously had Botulinum toxin therapy complications like allergy.
- Subjects with generalized muscular activity abnormalities like myasthenia gravis.
- Acute infections at the site of injection.

METHODS

This study was conducted in the Iraq Governorate of Baghdad from July 12, 2021, to January 22, 2022. Thirty-seven patients with habitual snoring were included.

A written consent was taken from each patient participating in the study, containing all information such as the follow-up period, the number of scheduled visits and their dates, the type of substance used in the injection, possible complications, and how to treat them if they occurred and this method of treatment will be included in research with another group of participants to obtain results, documented contact information between the patient and the researcher and possible communication at any time during the treatment period.

Thirty-seven people with habitual snoring were evaluated in a prospective randomized control clinical trial.

The patients and their bed partners filled out a questionnaire before and after therapy. The soft palate muscles were injected unilaterally with 10 U of Dysport, which is more diluted and spreads to a larger area than Botox. In all cases, snoring was decreased. The patients reported no severe side effects apart from a change in voice or simple swallowing difficulty that returned to normal for nearly two to three days.

Patients were followed up for one month after the injection at a rate of one visit per week. Some patients stopped communicating before the injection and were not counted in the study. Only one patient stopped communicating after three weeks, with 97% completing the study with continuous periodic visits according to a pre-agreed schedule.

The first night effect was considered when the participant felt difficulty sleeping when there was a sense of the presence of devices monitoring his sleep (Tamaki *et al*., 2005). The opposite of the effect of the first night 'reverse first-night effect' when the patient's sleep is better when he feels that he is under surveillance due to psychological insomnia (Lorenzo and Barbanoj, 2002). Therefore, it is crucial to note that a negative sleep study may not exclude the presence of various sleep disorders (Meyer *et al*., 1993).

Statistical Analysis:

All data has been typed into the computer. All samples were gathered, and a database for each patient was established based on the information provided by the patient and their companion. Statistical analyses were performed to compare the efficacy of soft palate injection with botulinum using the statistical software SPSS version 20 in addition to Microsoft Excel version 2021. All significant statistical relationships for all patients, such as mean and standard deviation (SD), have been considered. The P value was considered statistically significant when less than 0.05.

Result and Discussion

The participating patients were followed up for an entire month at one weekly visit. The first week's readings were adopted as the results of this study because the results of the following weeks were similar. Snoring was reduced in all cases. Patients did not report any significant adverse effects. Epworth Sleepiness Scale was 9.9 ± 0.9 before botulinum toxin injection and 8.2 ± 1.7 one week after injection, while the snoring index was 131 ± 66 and 61.5 ± 28, respectively. The average Intensity of Snoring and maximal Intensity of Snoring before botulinum injection were 57 ± 7.5 and 90.5 ± 1.6, respectively, and changed to 44 ± 4.2 and 87.8 ± 1.9 seven days after injection with less response of the average intensity of snoring than the maximal intensity of snoring to injection.

Regarding the lowest pulse oxygen saturation, there is a statistically better rate after toxin injection, 90.7 ± 0.9, than before injection, 89.1 ± 1.8.

Parameters such as the snoring index and Epworth Sleepiness Scale changed more with Botox injections because the injection of the soft palate muscles caused paralysis of these muscles and opened the area that causes the blockage and the vibration that produces the sound during snoring.

The severity of OSAS correlates better with the rate and maximal intensity of snoring than with the average intensity (Souha *et al*., 2020).

Errors may occur due to monitoring patients' conditions through a mobile application. In order to avoid such errors, the correct use of the application was confirmed with continuous reviews before Botox injections.

It was noticed that patients were interested in this treatment method and asked for re-injections when the effect of Botox disappeared, indicating its effectiveness in improving their lives.

Table I: Snoring parameters result during the study

Group Statistics					
Criteria	**Status**	**N**	**Mean**	**Std. Deviation**	**P-value**
ESS	Before injection	37	9.9	0.994428926	0.0000345
	After injection	37	8.2	1.751190072	
SI	Before injection	37	158.4	65.98013169	0.006008
	After injection	37	65.4	28.74098893	
AIS	Before injection	37	55.96	7.564942535	0.37684
	After injection	37	43.774	4.153194754	
MIS	Before injection	37	90.594	1.63480342	0.562788
	After injection	37	87.457	1.833115442	
LSpO2	Before injection	37	89.1	1.852925615	0.039219366
	After injection	37	90.7	0.948683298	

Where ESS Epworth Sleepiness Scale, SI Snoring Index (event/hour), AIS Average Intensity of Snoring (dB), MIS Maximal Intensity of Snoring (dB), and LSpO2 Lowest pulse oxygen saturation.

Conclusion

The critical conclusion reached in this research is that Botox injections are effective in snoring because snoring decreased in all patients to varying degrees, and no severe side effects appeared in the patients participating. These results are consistent with other research in the same regard, like [Treatment of habitual snoring with botulinum toxin: a pilot study, Kuhnel TS *et al*.,].

The most essential points obtained from this study are:

- Snoring treatment with Dysport botulinum toxin is safe.
- Easy to perform, non-invasive, and completely reversible.

- This method is suitable for treating a vital condition in society, snoring, without serious complications arising during treatment.
- The treatment method applies to patients of different ages and health conditions that may prevent or hinder surgical intervention.
- The treatment method applies even with an experienced medical staff and simple medical procedures without specializations or advanced centres.
- Monitoring patients before and after treatment through a mobile application in their usual bedrooms without needing sleep laboratories that are usually expensive and may disturb the patient's daily activity.
- Patients asked for re-injections when the effect of Botox disappeared, indicating the effectiveness of the treatment.

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STRENGTHS AND LIMITATIONS

The short patient collection time and the small number of subjects may impact specific outcomes. As a result, in future studies, we recommend lengthening the duration and expanding the sample size with multicentric research under double-blind, placebo-controlled settings is required.

Follow-up of patients via a mobile application without an ideal sleep laboratory may affect the accuracy of the results. For this reason, we recommend that in the future, following up with the participants in a typical sleep laboratory while monitoring more activities during sleep give better results for the effectiveness of the study.

Ethical Clearance: Researchers have an obligation to conduct their research with integrity and transparency.

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Conflict of Interest: The author declares that there is no conflict of interest.

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