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Research

The Effects of Lavender and Rosemary Extracts on Sore Throat and Hoarseness After Endotracheal Intubation in Patients Undergoing Percutaneous Nephrolithotomy: A Randomized Clinical Trial

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Keywords:
tracheal intubation
sore throat
hoarseness
surgery
rosemary
lavender

A B S T R A C T

Purpose: This study aimed to compare the effects of lavender and rosemary extracts on sore throat and hoarseness after endotracheal intubation in patients undergoing percutaneous nephrolithotomy.
Design: Randomized clinical trial.
Methods: This study was conducted on 90 patients undergoing percutaneous nephrolithotomy at Bahonar Hospital in Kerman in 2021. The patients were selected by convenience sampling method and randomly assigned to three groups: lavender, rosemary, and control. After general anesthesia with endotracheal intubation, an anesthesiologist put sterile gauzes impregnated with 3 cc of rosemary and lavender extracts into patients' throats in the intervention groups, while the control group received 3 cc of distilled water. After the surgery, the gauzes and tracheal tubes were removed and the patients were transferred to the postanesthesia care unit (PACU), their sore throat and hoarseness were measured and recorded during and 2 to 6 to 24 hours after recovery. A significance level of < .05 was considered.
Findings: The study results showed a significant difference in the severity of sore throat between the 3 groups 2, 6, and 24 hours after surgery; sore throat in the rosemary group and then in the lavender group was lower than that in the control group ($P < .05$). The results also indicated a significant difference in hoarseness intensity between the three groups 2 and 6 hours after surgery; hoarseness intensity in the rosemary and lavender groups was lower than that in the control group, but it was not different between 3 groups 24 hours after surgery ($P < .05$).
Conclusions: Rosemary and lavender extracts had a positive effect on sore throat and hoarseness. As these herbs cause no complications in patients and are available and inexpensive, further studies are necessary to confirm the use of these herbs during intubation.
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Endotracheal intubation is essential to control respiration and protect the airways under general anesthesia.[1] But it may result in several complications, including sore throat and hoarseness.[2] Studies report that the incidence of sore throat after intubation varies from 6% to 100%.[3] Sore throat is the eighth unpleasant complication of general anesthesia, which often occurs 12 to 24 hours after extubation and 5 to 7 days after recovery,[4,5] affects patients' satisfaction and quality of care, and increases the length of hospital stay and cost.[6,7] Age, sex, cuff pressure, perioperative tube movement, tracheal tube size, intubation method,

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.
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and smoking are among the other factors influencing the sore throat after surgery.[5] Hoarseness is another complication that is prevalent in 14.4% to 50% of the cases and causes direct damage and inflammation to the vocal cords ,[3,6] and even some patients experience vocal cord paralysis after intubation.[7]

Various pharmacological and nonpharmacological methods are available to reduce the complications of endotracheal intubation, such as the use of betamethasone gel on the endotracheal tube (ET),[8] but pharmacological methods are always expensive and have complications. Therefore, many individuals seek to use complementary and alternative medicine due to low cost and complications, and easy access.[9] Herbal medicine is one type of complementary and alternative medicine in which a plant or its essential oil (aromatherapy) is used.[10–12] Medicinal plants are very important due to the presence of natural substances and compounds, including flavonoids, volatile oils, phenolic compounds, alkaloid compounds, organic acids, essential oils, and alcoholic compounds, which affect pain.[13]

Lavender is a well-known medicinal and aromatic herb that is used in complementary and alternative medicine[14] due to its analgesic, anti-inflammatory, and antioxidant effects. Several studies have reported the effect of lavender on reducing pain and inflammation in burn patients and acute inflammations and pain after removing kidney stones.[15,16]

Rosemary is a suitable anti-inflammatory herb due to the presence of carnosol and ursolic acid with no complications with researchers suggesting it instead of chemical drugs.[17] Rochal et al[18] studied the anti-inflammatory effects of rosemary extract on mice and found the positive effects of this extract on the reduction of inflammation. The authors also reported positive effects of this extract on reducing inflammation in neuropathic pain of a mouse model.[18] Braidy et al[19] pointed out the positive effects of rosemary extract on reducing the excitability of cells in the central nervous system due to its antioxidant and anti-inflammatory effects.

Nurses must control postoperative complications, provide comfort for patients, and manage the use of appropriate drugs and palliative methods.[7] Complementary and alternative medicine is an intervention for many nursing diagnoses, so nurses can use it to improve disease symptoms.[20] Most health care systems around the world are using medicinal plants as a nonpharmacological alternative treatment.[21] Plant extracts can relieve many problems and complications of the patients and the complementary and traditional medicine has attracted many people. We found no study on the effects of lavender and rosemary on sore throat and hoarseness after endotracheal intubation in patients undergoing percutaneous nephrolithotomy. These herbs have analgesic and anti-inflammatory properties and it may be possible to use them as a supplement with synthetic and chemical drugs. Therefore, this study aimed to compare the effects of lavender and rosemary extracts on sore throat and hoarseness after endotracheal intubation in patients undergoing percutaneous nephrolithotomy.

Method

Study Design and Setting

This randomized clinical trial study included patients who underwent general anesthesia with an endotracheal intubation for the percutaneous nephrolithotomy at the Bahonar Urology Department affiliated with Kerman University of Medical Science.

Sample Size and Sampling

Eligible patients were selected by convenience sampling method and randomly divided into three groups: lavender, rosemary, and control. The participants were placed in three groups according to sex and age (± 2). Inclusion criteria were patients over 18 years of age, who were under general anesthesia in a prone position for percutaneous nephrolithotomy and able to communicate and answer questions. The same tracheal tube brand for intubation (tracheal tube size: 7 to 8.5 for men and 7 to 7.5 for women) was used, with Mallampati airway and class I and class II based on the American Society of Anesthesiologists' classification system. Exclusion criteria were patients with a history of sore throat in the past week, intubation more than once, abnormal airway, upper airway infection, and respiratory diseases such as sinusitis, asthma and chronic obstructive pulmonary disease, history of sensitivity to lavender and rosemary, the use of anti-inflammatory drugs 2 weeks before the surgery, and the prolongation of the operation for more than 4 hours.

The results of similar studies and the sample size formula were used to determine the number of samples in this study. In previous studies, the mean and standard deviation of the pain score after the intervention were 26.3 ± 72.5 and 12.3 ± 72.2, respectively. Therefore, with a confidence coefficient of 95% (Z1 − α/2 = 1.96) and a test power of 80% (Z1 −B = 0.84), 26 participants were calculated for each group, but 30 participants were considered in each of the groups due to the dropout rate.

$$n = \frac{\left(Z_{\left(1-\frac{\alpha}{2}\right)} + Z_{1-\beta}\right)^2 \left(S_1^2 + S_2^2\right)}{(\mu_1 - \mu_2)^2}$$

$$n' = n^* \sqrt{g-1}$$

Measurement

The demographic and background information questionnaire, the visual analog scale (VAS), and the hoarseness questionnaire were used to collect data.

Demographic questionnaire. The demographic and background information questionnaire included age, sex, marital status, level of education, history of smoking, history of other surgeries in the last month, date of admission to the urology department, and operation date. Clinical information included underlying diseases such as gastrointestinal diseases, diabetes, hypertension, medications taken by the patient, the amount of fluids consumed before, during, and after the operation (24 hours), duration of laryngoscopy, frequency of suctioning, classification of anesthesia and Mallampati class, duration of surgery, the dosage of painkillers such as pethidine, tracheal tube brand, tracheal tube size (7 to 8.5 in men and 7 to 7.5 in women), tracheal cuff pressure, as well as the patient's hemodynamic status chart.

2. VAS is a self-report scale that includes a 10-cm horizontal line that is graded from 0 to 10. Zero indicates the absence of pain symptoms, while 10 means the maximum intensity of the symptoms. This is the simplest tool to check the pain level of the patients, which can be easily understood by patients. Rezvani et al[22] studied 150 patients with chronic back pain using the VAS and the McGill pain questionnaire and concluded that the VAS was a more suitable tool for measuring patients' pain.[23]

3. The hoarseness questionnaire is a self-report scale that consists of 4 items, in which zero means no hoarseness, 1 indicates mild hoarseness (patients felt no hoarseness during the interview but they felt it before the interview), 2 indicates moderate hoarseness (only felt by the patient), and 3 is severe hoarseness (perceived by the therapist while completing the questionnaire).[24] Researchers have frequently used it in similar research. Its validity and reliability have been confirmed by test-retest (r = 0.6) and Mann-Whitney U test ($P \leq .0004$).[25]

Data Collection

After obtaining the code of ethics from the ethics committee of the Kerman University of Medical Sciences and the study code from the

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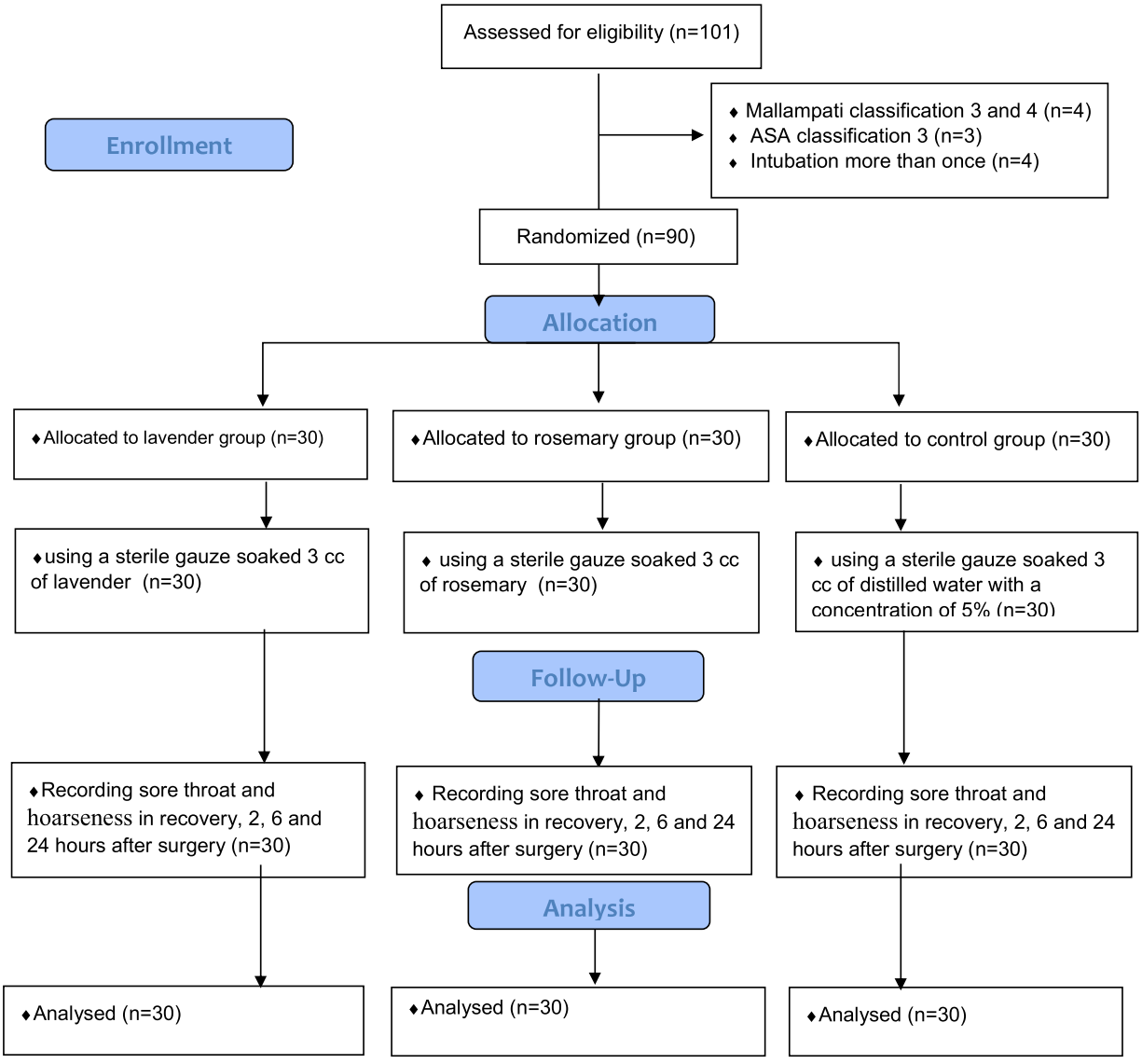


Figure 1. Flow diagram of the study progress. ASA, American Society of Anesthesiologists. This figure is available in color online at www.jopan.org

registry of clinical trials, the researcher received the necessary permission from the management of hospital (Shahid Bahonar Hospital) and urology department. The attending physician provided permission and written informed consent was obtained from patients. A demographic and background information questionnaire was completed using patients' medical records, when necessary. Eligible patients were divided into three groups of lavender, rosemary, and control using convenience sampling and randomized block method. The same analgesics and sedatives were used for all patients undergoing percutaneous nephrolithotomy in Bahonar Hospital in Kerman. An anesthesiologist who was unaware of the intervention performed general anesthesia with endotracheal intubation in the operating room. The same brand of tracheal tube was used for all patients (tracheal tube size: 7.5 to 8 for men and 7 to 7.5 for women). The relevant anesthesiologist put sterile gauzes impregnated with rosemary or lavender into patients' throats using McGill forceps. Therefore, the gas of the intervention group was impregnated with three teaspoons of rosemary and lavender syrup. The decision to use 3 cc was based on previous studies findings that showed this dosage was effective in delivering the desired therapeutic outcomes without causing significant adverse effects.[26,27] We used standardized extracts of lavender and rosemary produced by Barij Essence company in Kashan, Iran. The gases of the control group were impregnated with three teaspoons of distilled water with a concentration of 0.5%. The vital signs of all patients were kept within the normal range, and more than 10% of changes in vital signs excluded the samples from the study process. After the operation, an anesthesiologist removed the endotracheal tube (ETT). Muscle relaxants were reversed with neostigmine (0.05 mg/kg and atropine 0.04 mg/kg). The gauzes inside patients' mouths were removed and the secretions inside the mouth were suctioned with a suction catheter No. 12 to prevent damage to the soft tissue. All patients were transferred to the postanesthesia care unit (PACU) after regaining consciousness. Then, using the VAS and the hoarseness questionnaire, an anesthesia student measured patients' sore throat and hoarseness during and 2 to 6 to 24 hours after recovery. The same analgesic (50 mg of pethidine injected intravenously) was used for all patients (Figure 1).

Ethical Consideration

We conducted this study after receiving the code of ethics No. IRKMU.REC.1400.494 from the ethics committee of Kerman

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Table 1
Participants' Characteristics in Interventions and Control Groups (N = 90)

Group Variable	Lavender (n = 30)		Rosemary (n = 30)		Control (n = 30)		Statistical Test (*P* Value)
	Mean	SD	Mean	SD	Mean	SD	
Age (y)	41.50	11.56	42.10	11.90	44.60	12.56	F = 0.56 (.57)
	N	%	*N*	%	*N*	%	
Sex							
Female	15	50.0	15	50.0	16	53.3	χ^2 = 0.09 (.96)
Male	15	50.0	15	50.0	14	46.7	
Marital status							
Married	27	90.0	26	86.7	27	90.0	χ^2 = 0.22 (.89)
Single	3	10.0	4	13.3	3	10.0	
Education							
Illiterate	1	3.3	3	10.0	3	10.0	χ^2 = 5.19 (.74)
Elementary	7	23.3	5	16.7	6	20.0	
Upper secondary	6	20.0	9	30.0	8	26.7	
Diploma	11	36.7	11	36.7	7	23.3	
Academic	5	16.7	2	6.7	6	20.0	
Occupation							
Unemployed	14	46.7	11	36.7	10	33.3	χ^2 = 4.31 (.64)
Employed	4	13.3	6	20.0	8	26.7	
Self-employed	11	36.7	10	33.3	8	26.7	
Retired	1	3.3	3	10.0	4	13.3	
History of addiction							
Yes	5	16.7	5	16.7	3	10.0	χ^2 = 0.72
No	25	83.3	25	83.3	27	90.0	
History of smoking							
Yes	6	20.0	3	10.0	4	13.3	χ^2 = 1.26 (.53)
No	24	80.0	27	90.0	26	86.7	

F, analysis of variance; SD, standard deviation.

University of Medical Sciences as well as registering the study No. IRCT20211124053172N2 in the Iranian registry of clinical trials (Registration date: 2022-01-09, https://www.irct.ir/trial/60581). The researcher explained the study objectives and results to the participants, received their written consent, and assured them that their information would remain confidential and they could discontinue the study at any time. If necessary, the results of the study were provided to the authorities. All methods were carried out in accordance with relevant guidelines and regulations.

Data Analysis

SPSS18 (SPSS, Inc, Chicago, IL) was used to analyze the data. Descriptive statistics (frequency, percentage, mean, and standard deviation) were used to describe the demographic and background characteristics of the research units in three groups. Chi-square and Fisher's exact tests were used to compare demographic and background information, while the Dunnett T3 test was used to compare the mean scores of sore throat and hoarseness. A significance level less than .05 was considered.

Results

The study results showed no significant difference in age, sex, marital status, education level, occupation, history of addiction, and history of smoking among the three groups ($P > .05$) (Table 1).

Table 2 shows no significant difference in diastolic blood pressure, systolic blood pressure, and heart rate between the 3 groups ($P > .05$), but the amount of SpO_2 was different between the 3 groups at some time ($P < .05$).

The study results indicated no significant difference in the duration of surgery, cuff pressure, frequency of suction, American Society of Anesthesiologists' classification, Mallampati class, and ETT size between the 3 groups ($P > .05$). The duration of laryngoscopy was 30 seconds in most of the samples (Table 3).

Table 4 illustrates the median and interquartile range of the sore throat in the 3 groups at different times. We found a significant difference in the severity of sore throat between the 3 groups 2, 6, and 24 hours after surgery (the rosemary-, the lavender-, and the control group, respectively) (Table 4). Dunnett T3 test showed that sore throat in the rosemary group was significantly less than that in the lavender and control groups 2 hours after surgery. In addition, sore throat in the lavender group was significantly less than that in the control group 2 hours after surgery. Sore throat in the rosemary and lavender groups was significantly less than that in the control group 6 and 24 hours after surgery, while there was no difference between the rosemary and lavender groups.

Table 5 indicates the median and interquartile range of hoarseness in three groups at different times. We observed a significant

Table 2
Participants' Hemodynamic Parameters in Interventions and Control Groups (N = 90)

Group Variable		Lavender (n = 30)		Rosemary (n = 30)		Control (n = 30)		Analysis of Variance (*P* Value)
		Mean	SD	Mean	SD	Mean	SD	
Immediately after surgery	SBP, mm Hg	128.90	15.14	130.03	18.82	133.87	21.04	0.59 (.55)
	DBP, mm Hg	80.23	9.71	79.70	14.93	77.37	25.26	0.22 (.80)
	PR, bpm	72.83	9.54	68.60	9.38	70.80	8.16	1.64 (.2)
	SpO_2, %	97.10	1.67	97.23	1.19	96.0	1.51	6.36 (.003)
2 h after surgery	SBP, mm Hg	123.43	23.83	129.47	16.10	125.10	33.70	0.44 (.64)
	DBP, mm Hg	78.53	8.87	79.50	17.34	78.93	16.81	0.03 (.97)
	PR, bpm	73.0	6.66	68.47	8.07	70.23	7.71	2.78 (.07)
	SpO_2, %	98.30	4.24	97.40	1.04	96.67	1.21	2.93 (.06)
6 h after surgery	SBP, mm Hg	125.0	12.04	127.23	12.93	119.47	31.13	1.12 (.33)
	DBP, mm Hg	80.87	7.74	81.20	10.38	82.33	7.86	0.23 (.79)
	PR, bpm	72.0	5.60	68.60	6.26	69.60	6.08	2.56 (.08)
	SpO_2, %	97.60	1.0	97.67	0.80	96.47	1.20	13.29 (< .001)
24 h after surgery	SBP, mm Hg	124.13	8.34	125.03	8.72	125.83	9.54	0.28 (.76)
	DBP, mm Hg	81.07	5.16	79.80	7.68	80.37	6.32	0.29 (.75)
	PR, bpm	71.27	5.45	69.0	6.04	71.0	7.18	1.17 (.31)
	SpO_2, %	97.77	0.90	97.53	0.78	96.63	1.07	12.67 (< .001)
24-h intake (cc)		1,720.0	235.48	1,606.67	294.7	1,736.67	257.95	2.16 (0.12)

DBP, diastolic blood pressure; PR, pulse rate; SBP, systolic blood pressure; SD, standard deviation; SpO_2, oxygen saturation.

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Table 3
Surgery-related Factors in Interventions and Control Groups (N = 90)

Group Variable	Lavender (n = 30)		Rosemary (n = 30)		Control (n = 30)		Statistical Test (*P* Value)
	Mean	SD	Mean	SD	Mean	SD	
Surgery time (min)	96.67	25.40	98.50	21.98	92.33	31.89	0.42 (.66)
Cuff pressure (cmH_2O)	20.0	0.0	20.0	0.0	20.0	0.0	-
	N	%	*N*	%	*N*	%	
Suction times (No.)							
2	6	20.0	7	23.3	12	40.0	χ^2 = 3.43 (.18)
3	24	80.0	23	76.7	18	60.0	
ASA classification							
1	27	90.0	25	83.3	24	80.0	χ^2 = 1.18 (.55)
2	3	10.0	5	16.7	6	20.0	
Mallampati class							
1	16	53.3	18	60.0	18	60.0	Fisher's Exact
2	8	26.7	6	20.0	7	23.3	test = 2.57
3	6	20.0	5	16.7	5	16.7	(.97)
4	0	0	1	3.3	0	0	
ETT size (mm)							
5.0	0	0	1	3.3	0	0	Fisher's Exact
7.0	4	13.3	4	13.4	5	16.7	test = 3.47
7.5	12	40.0	10	33.3	14	46.6	(.84)
8.0	14	46.7	15	50.0	11	36.7	

ASA, American Society of Anesthesiologists; ETT, endotracheal tube; F, analysis of variance; SD, standard deviation.

difference in hoarseness intensity between the 3 groups 2 and 6 hours after surgery; it was lower in the rosemary and lavender groups than in the control group (Table 5). Dunnett T3 test showed that hoarseness severity in the rosemary and lavender groups was significantly lower than that in the control group 2 and 6 hours after surgery, while there was no difference between the rosemary and lavender groups. We found no significant difference between the 3 groups 24 hours after surgery.

Discussion

The present study aimed to compare the effects of lavender and rosemary extracts on sore throat and hoarseness after endotracheal intubation in patients undergoing percutaneous nephrolithotomy. Nearly all patients who undergo surgery, whether for a short or extended duration, experience some degree of airway damage.[28] Sore throat and hoarseness result from inflammation after intubation, so anesthesiologists take medicinal and preventive measures to deal with these problems due to complaints of patients after anesthesia. Medicinal measures have no considerable effect on the reduction of sore throat and hoarseness and the intensity of inflammation is sometimes so high in those who have problems with intubation that they need several drugs.[29,30] Therefore, both anesthesiologists and patients are interested in preventive measures so that patients do not experience sore throat and hoarseness.[31] Our results suggested that lavender and rosemary significantly reduced sore throat and hoarseness in patients after surgery. Since no study addressed the effects of lavender and rosemary on sore throat and hoarseness after endotracheal intubation in patients undergoing percutaneous nephrolithotomy, the researchers compared the results of this study with the results of similar studies.

Our results differed from Dehghani and Mohammadipour Anvari[26] who indicated no significant difference in the sore throat after anesthesia with endotracheal intubation between the rosemary and control groups. One of the reasons for this contradiction may be the difference in the research population, the type of surgery, and the methodology (type, amount, and dose of the extract).

Many studies have supported the anti-inflammatory effects of rosemary.[18,32,33] Gonçalves et al[34] reported that rosemary showed anti-inflammatory activity before and after induction therapy by reducing the level of inflammatory biomarkers and increasing oxidative stress biomarkers. Ghasemzadeh Rahbardar et al[35] observed the effect of rosemary on pain relief and inflammatory disorders and showed that the ethanol extract of rosemary and rosmarinic acid might be potential candidates in the treatment of neuropathic pain and various neurological disorders related to inflammation by modulating neuroinflammation. Ghasemzadeh Rahbardar and Hosseinzadeh[36] found that rosemary was a valuable source for treating inflammation, pain, and anxiety and enhancing memory.

Table 4
Median and Interquartile Range of Sore Throat in Three Groups of Lavender, Rosemary, and Control at Different Times (N = 90)

Group Sore Throat	Lavender (n = 30)		Rosemary (n = 30)		Control (n = 30)		Kruskal-Wallis Test	*P* Value
	Median	IQR	Median	IQR	Median	IQR		
2 h after surgery	1.0	1.0	0.0	1.0	2.0	3.0	18.41	< .001
6 h after surgery	1.0	2.0	0.0	1.0	2.0	5.0	9.79	.007
24 h after surgery	0.0	1.0	0.0	0.0	1.50	5.0	14.35	.001
Friedman test	8.35		5.31		6.12			
P value	.02		.07		.047			

IQR, interquartile range.

Table 5
Median and Interquartile Range of Hoarseness in Three Groups of Lavender, Rosemary, and Control at Different Times (N = 90)

Group Hoarseness	Lavender (n = 30)		Rosemary (n = 30)		Control (n = 30)		Kruskal-Wallis Test	*P* Value
	Median	IQR	Median	IQR	Median	IQR		
2 h after surgery	1.0	1.0	0.0	1.0	1.0	3.0	7.93	.02
6 h after surgery	0.0	0.0	0.0	1.0	0.0	2.0	11.30	.004
24 h after surgery	0.0	0.0	0.0	0.0	0.0	1.0	4.84	.09
Friedman test	18.20		14.25		16.91			
P value	< .001		.001		< .001			

IQR, interquartile range.

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Some studies mentioned the anti-inflammatory activity of lavender. For example, Horváth et al[37] and Silva et al[16] focused on the anti-inflammatory effect of lavender. Cardia et al[38] indicated that lavender essential oil had anti-edematogenic and anti-inflammatory activities in both topical and oral treatments. Pandur et al[39] found that lavender essential oil extracted at the flowering stage was a strong inhibitor of the synthesis of four proinflammatory cytokines (Interleukin 6, Interleukin 8, Interleukin-β, and tumor necrosis factor α Tohoku Hospital Pediatrics-1). They believed that there was an association between collecting lavender at the flowering stage and using it as an anti-inflammatory treatment.

Although there are very effective medications such as steroidal and nonsteroidal drugs to treat inflammation, they are not a good option and can cause severe side effects, including gastrointestinal, cardiovascular, and renal problems.[26] Therefore, there is a great need to further investigate new anti-inflammatory options with selective activity and less toxicity. Considering the known anti-inflammatory and antioxidant activities of plants and their isolated compounds, they may be a promising source of new treatments[34,40] and can also be effective in relieving sore throat and hoarseness after intubation.

Although other studies and our study mentioned the strong anti-inflammatory properties of rosemary and lavender extracts, more reliable trials are required to evaluate the safety and efficacy of their main active compounds in the management of various pathological conditions. In general, the use of medicinal plants on sore throat and hoarseness after intubation is at just beginning, and it is necessary to conduct more studies on postoperative patients to improve the existing knowledge in this field. Considering the anti-inflammatory properties of lavender and rosemary, more studies with changes in the dosage or length of treatment should be conducted. We also suggest that research on the effects of these herbs on patients who undergo other surgeries than percutaneous nephrolithotomy should be done.

Limitations

This study had limitations. The examination of the pain level was self-reported. Considering that the tolerance threshold of people varies, it may have affected the results. The researchers tried to control this limitation to some extent by giving the necessary explanations before collecting the data. One limitation of this study was the presence of individual differences in the threshold of stimulation intensity for sore throat, as well as the impact of stress and psychological factors. These factors can influence the perception of sore throat severity and voice harshness, and controlling them was the responsibility of the researcher. Herbal extracts can vary significantly depending on the soil in which the plants are grown, the season of collection, and the stage of plant growth. These variations can affect the concentration of active compounds and, consequently, the therapeutic effects of the extracts. While we used standardized extracts to minimize these variations, some inherent variability may still exist, potentially affecting the study's outcomes.

Conclusion

The study results showed that the extracts of rosemary and lavender could have a positive effect on sore throat and hoarseness. As these plants do not cause complications in patients and are available and inexpensive, further studies are suggested to confirm the effects of these plants during intubation.

Declaration of Competing Interest

None to report.

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