ORIGINAL ARTICLE

The Clinical Value of Pharyngeal pH Monitoring Using a Double-Probe, Triple-Sensor Catheter in Patients With Laryngopharyngeal Reflux

Togay Muderris, MD; M. Kursat Gokcan, MD; Irfan Yorulmaz, MD

Objective: To determine the clinical value of pharyngeal pH monitoring for the diagnosis of laryngopharyngeal reflux (LPR) by using a double-probe, triple-sensor catheter in patients with symptoms of LPR.

Design: Prospective review of pH values recorded at the pharyngeal sensor, with the sensor placed in the proximal esophagus in patients with suspected LPR.

Setting: Tertiary care university hospital.

Patients: Thirty-three consecutive patients with symptoms of LPR.

Main Outcome Measures: A pH test result was considered abnormal if a single reflux episode was detected in the hypopharynx and if, in the proximal esophagus, the total percentage of time the pH value was below 4 was 1.0% or higher. Data obtained from sensors were compared to determine the validity of pharyngeal sensor. Correlation between patients' reflux finding scores, reflux finding indexes, and reflux episodes were analyzed.

Results: Of 33 patients, 17 had more than 1 reflux episode detected by the pharyngeal sensor and 19 had pathological reflux detected by the proximal esophageal sensor. Four patients who had pharyngeal reflux had a normal esophageal acid exposure time, and 6 patients who had pathological reflux detected by the proximal esophageal sensor did not experienced any pharyngeal reflux episode. Four patients would have had a false-negative test result and 6 subjects would have had a false-positive test result if a hypopharyngeal pH sensor was not implemented.

Conclusions: The adjustable, bifurcated, triple-sensor pH probe allows identifying true hypopharyngeal reflux episodes. If single-probe, double-sensor pH monitoring is to be performed, the proximal probe should be placed in the pharynx, not in the upper esophagus.

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Author Affiliations:
Department of Otolaryngology–Head and Neck Surgery, Ankara University Faculty of Medicine, Ankara, Turkey.

An accurate diagnostic tool for laryngopharyngeal reflux (LPR) does not exist. Symptoms including chronic or intermittent hoarseness, voice fatigue and breaks, frequent throat clearing, sore throat, excessive mucus or postnasal drip, cough, dyspnea, or dysphagia may alert a physician to the possibility of LPR.[1,2] Laryngeal findings such as erythema, edema, mucosal hypertrophy, nodularity, ulceration, granuloma, or leukoplakia may arouse a clinical suspicion of LPR, but they are not pathognomonic for reflux.[3] It should also be kept in mind that the presence and severity of laryngeal findings are not always associated with symptom severity.[4] Traditional diagnostic test results for gastroesophageal reflux disease are often falsely negative in individuals with LPR.[5,6] Dual-sensor, 24-hour pH monitoring is the most relied on method for the diagnosis of LPR. However, there are controversial issues in this diagnostic instrument, such as the precise position of the proximal sensor.

In esophageal pH monitoring, the distal sensor is placed 5 cm above the upper margin of the lower esophageal sphincter (LES) to avoid possible displacement into the stomach, especially during swallowing when the esophagus is shortened. Dual-sensor pH monitoring provides additional information concerning the occurrence of proximal esophageal reflux events, but no consensus exists for the placement of the proximal sensor. Various studies report probe placement at 15 or 20 cm above the LES or just below or up to 2 cm above the upper esophageal sphincter (UES).[7] However, proper positioning of the proximal hypopharyngeal sensor while maintaining the position of the distal esophageal sensor at the referenced location of 5 cm above the LES is difficult if a single-probe, double-sensor catheter with a fixed intersensor distance is used. Visual placement of the proximal

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Within the month, how did the following problems affect you?	0 = No problem 5 = Severe problem					
1. Hoarseness or a problem with your voice	0	1	2	3	4	5
2. Clearing your throat	0	1	2	3	4	5
3. Excess throat mucus or postnasal drip	0	1	2	3	4	5
4. Difficulty swallowing food, liquids, or pills	0	1	2	3	4	5
5. Coughing after you ate or after lying down	0	1	2	3	4	5
6. Breathing difficulties or choking episodes	0	1	2	3	4	5
7. Troublesome or annoying cough	0	1	2	3	4	5
8. Sensations of something sticking in your throat or a lump in your throat	0	1	2	3	4	5
9. Heartburn, chest pain, indigestion, or stomach acid coming up	0	1	2	3	4	5

Figure 1. Components of the reflux symptom index (total score, 0-45).

Variable, score

- Subglottic edema
  - Present, 2
  - Absent, 0
- Ventricular obliteration
  - Partial, 2
  - Complete, 4
- Erythema/hyperemia
  - Arytenoids only, 2
  - Diffuse, 4
- Vocal cord edema
  - Mild, 1
  - Moderate, 2
  - Severe, 3
  - Polypoid, 4
- Diffuse laryngeal edema
  - Mild, 1
  - Moderate, 2
  - Severe, 3
  - Obstructing, 4
- Posterior commissure hypertrophy
  - Mild, 1
  - Moderate, 2
  - Severe, 3
  - Obstructing, 4
- Granuloma/granulation
  - Present, 2
  - Absent, 0
- Thick endolaryngeal mucus/other
  - Present, 2
  - Absent, 0

Figure 2. Components of the reflux finding score (total score, 0-24).

sensor in the hypopharynx is an accurate method, but if it is done while monitoring with a single-probe catheter, the fixed distance between the proximal and distal sensors of the probe signifies that the distal sensor is placed in an unknown position in reference to the LES.[8] The distal esophageal acid exposure data cannot be standardized in this situation.

Recent methods, such as catheter designs that incorporated 3 antimony sensors into a bifurcated probe[9] or single-probe, multisensor catheters,[10] were developed to overcome this problem. This prospective study investigated the clinical value of pharyngeal pH monitoring for the diagnosis of LPR by comparing pH values recorded at the pharyngeal sensor site and the sensor placed 20 cm above the LES, by using a double-probe, triple-sensor catheter in patients with symptoms of LPR. We also analyzed reflux symptom indexes, reflux finding scores, and pH values detected at the pharyngeal and esophageal sensor sites for every patient to search for a possible correlation.

METHODS

The study group comprised 33 consecutive patients (14 men and 19 women; age range, 20-67 years [mean, 42.2 years]) with laryngopharyngeal complaints and physical examination findings suggesting LPR. The reflux symptom index (RSI) was used for determining symptom severity (**Figure 1**).[4] A complete head and neck examination together with videolaryngoscopy was performed, and physical examination findings were scored according to the reflux finding score (RFS) (**Figure 2**).[11] Patients underwent double-probe, triple-sensor pH monitoring



Figure 3. Bifurcated, triple-sensor pH probe with antimony electrodes. One of the arms has a single sensor that was placed 1 cm above the upper esophageal sphincter. The other arm has 2 sensors 15 cm apart for placement in the distal and proximal esophagus.

if their RSI was higher than 15 or their RFS was higher than 3. These cutoff values of RSI and RFS are based on the data obtained from 50 healthy subjects in our own laboratory (unpublished data, November 2005). We also used RSI and RFS values to analyze the correlation between patients' symptoms, findings, and reflux characteristics because these values are shown to be highly reliable and validated for documenting symptom and finding severity.[11,12]

Ambulatory 24-hour pH monitoring was performed using a MMS Orion II device (Medical Measurement Systems BV, Enschede, the Netherlands). The use of medications that would relax the UES and stimulate or inhibit the secretion of gastric contents were stopped 1 week before the procedure. Patients were instructed to continue their daily activities and to consume their usual diet except for acidic food and drinks during recordings. The patients maintained a diary that documented starting and ending times of meals, liquid swallows, sleep, periods while supine, heartburn, regurgitation, and any other notable symptoms.

We used a catheter that incorporated 3 sensors into an adjustable, bifurcated probe with a single connector and recording box for pH monitoring. One arm of the probe has a single sensor at the tip, and the second arm contains 2 sensors placed at a 15-cm interval with a 5-cm blind tip (**Figure 3**). The pH probes were calibrated using buffer solutions of pH 7.0 and pH 4.0 just before and at the end of each examination. There was no notable drift in the pH signal during examination. Following calibration, the double-sensor arm was introduced transnasally and advanced until gastric pH was reached by the distal sensor. The probe was then withdrawn slowly until the distal sensor showed an abrupt increase in pH value (suggesting the gastroesophageal inversion point), and then the probe was withdrawn another 5 cm and fixed to the nose so that the distal sensor was positioned approximately 5 cm above the LES and the proximal sensor was positioned 20 cm above the LES, just below the UES. Next, the single sensor was positioned 1 cm above the UES with the help of transnasal flexible endoscopy and secured to the nose (**Figure 4**). Examinations were continued for 24 hours.

Data were downloaded to a computer and analyzed for number of reflux episodes (pH <4) and percentage of time the pH value was less than 4 (acid exposure time) at all 3 recording sites for the upright and recumbent positions. A pH test result was considered abnormal if a single reflux episode was detected in the hypopharynx[5] and if, in the proximal esophagus, the total

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percentage of time the pH value was below 4 was 1.0% or higher.[8]

A drop in pH value at the pharyngeal sensor site was considered a pharyngeal reflux episode only if the following occurred: (1) a drop in pH value below 4; (2) a decrease in the pharyngeal pH value immediately following distal esophageal acid exposure; (3) no decrease in the pH value during eating or swallowing; or (4) a rapid and sharp decrease in pH value rather than a gradual one.[8] With pH recording in pharyngeal or proximal esophageal locations, 2 types of artifacts can produce pH values below 4 and misclassify the identification of true reflux.[9] These artifacts are pseudoreflux, which is thought to be due to loss of mucosal contact or drying of the electrode, and ingestion of acidic food or drink. Pharyngeal episodes of acidification that did not occur with esophageal acidification were not categorized as LPR. All tracings were individually reviewed rather than relying on computer interpretation, to determine those that had the 4 aforementioned characteristics and were thus considered true LPR.

The Wilcoxon signed rank test was used to determine the association between the pH sensors. Spearman rank correlation was used to compare nonparametric data. All statistical calculations were performed using commercially available software (SPSS for Windows; SPSS Inc, Chicago, Illinois).

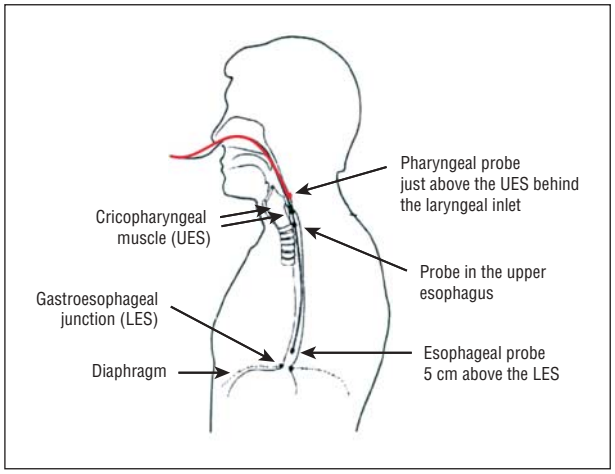


Figure 4. Implementation of double-probe, triple-sensor catheter. The long arm of the catheter with the 2 sensors is secured to the nose, and its distal sensor is placed 5 cm above the lower esophageal sphincter (LES); thus, the proximal sensor is placed just below the upper esophageal sphincter (UES). The short arm that has a single sensor at the tip (shown in red) is placed 1 cm above the UES by the help of transnasal flexible endoscope.

RESULTS

Patients' age, sex, pharyngeal and esophageal pH monitoring results, and RSI and RFS values are given in **Table 1**. The percentage of time the pH value was below 4 and the number of reflux episodes is shown for the total time and the time in the upright and supine positions, both for the pharyngeal and proximal esophageal probes. The total number of reflux episodes and the total percentage of time the pH value was less than 4 were significantly less in the hypopharynx than in the proximal and distal esophagus, as expected (**Table 2**). The number of hypopharyngeal acid reflux episodes was significantly correlated with those detected at the proximal esophagus (**Figure 5**).

Of 33 patients, 17 (52%) had more than 1 reflux episode detected by the pharyngeal sensor. Of these patients with pharyngeal reflux, 10 experienced reflux episodes just in the upright position. Only 7 patients had pharyngeal reflux in the supine position; the number of reflux events in the supine position was less than the number of reflux events seen in the upright position in all 7 of these patients. Overall, 90% of all hypopharyngeal reflux episodes occurred while in the upright position. The mean number of reflux episodes was 8.5 per patient (range, 2-26). Total percentage of time the pH value less than 4 at the pharyngeal sensor site was between 0.1% and 3.1% (mean, 0.7%) among patients with pharyngeal reflux.

All 33 patients had at least 1 reflux episode determined by the proximal esophageal sensor, but only 19 patients had pathological reflux (total percentage of time the pH value was <4 was $\geq 1.0\%$). Mean acid exposure time was 3.2% (range, 0%-24%).

Four patients who had pharyngeal reflux had normal esophageal acid exposure times at the proximal esophageal sensor site, and 6 patients who had pathological reflux at the proximal esophagus sensor site did not experienced any pharyngeal reflux episodes. Thus, 4 patients would have had a false-negative test result and 6 subjects would have had a false-positive test result if a hypopharyngeal pH sensor was not implemented.

There was no correlation between RSI values and the percentage of time the pH value was below 4 at the pharyngeal ($P=.90$) and proximal ($P=.15$) esophageal sensors and the total number of acid reflux episodes at the pharyngeal ($P=.51$) and proximal ($P=.23$) esophageal sensors. We also could not find any correlation between RFS values and the total number of reflux episodes ($P=.41$) and percentage of time the pH value was below 4 ($P=.34$) in the pharyngeal segment, and there was no correlation between RFS values and total number of reflux episodes detected in the proximal esophageal segment ($P=.07$). There was a slight but statistically significant correlation between RFS values and proximal esophageal acid exposure time ($P=.03$; $r=0.38$).

COMMENT

Previous pH monitorization studies either did not focus on the exact position of the pharyngeal sensor or suggested that the hypopharyngeal sensor location did not have to be precise if the sensor was placed up to 3 cm above the UES.[3,10,13] We placed a sensor just below the UES and another sensor 1 cm above the UES to compare acid exposure results of pharyngeal and proximal esophageal pH monitoring. We reviewed each tracing and compared it with the diary kept by the subjects to exclude artifacts. We did not encounter any pseudorefluxes that were due to drying of the hypopharyngeal sensor.

We detected LPR in 17 patients, 4 of whom had normal esophageal acid exposure times in the proximal esophagus. Thus, the esophageal acid exposure times were in the normal range, but some esophageal reflux reached the pharynx. Therefore, if only an esophageal study had been performed in our patients with LPR, 24% would have been falsely assumed not to have LPR.

In our study, there were 19 patients with abnormal acid exposure times in the proximal esophagus, 6 of whom did

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Table 1. Patient Data, pH Monitoring Results, and RSI and RFS Values

Patient No./ Sex/Age, y	Proximal Esophagus						Pharynx						RSI	RFS
	AET, %			Reflux Events, No.			AET, %			Reflux Events, No.				
	U	S	T	U	S	T	U	S	T	U	S	T		
1/M/55	1.4	3.4	2.3	17	5	22	0.1	1.0	0.5	3	2	5	5	8
2/F/20	1.7	0.4	0.8	9	6	15	1.4	0.2	0.6	7	3	10	18	2
3/F/58	3.0	0.3	1.9	18	1	19	2.1	0.4	1.2	12	2	14	26	4
4/F/35	0.5	0.2	0.4	6	2	8	0	0	0	0	0	0	22	4
5/F/35	0.2	0	0.1	2	0	2	0	0	0	0	0	0	21	4
6/M/54	1.9	1.3	1.8	15	6	21	0	0	0	0	0	0	16	5
7/F/51	1.2	0	0.6	12	0	12	0	0	0	0	0	0	19	5
8/M/63	1.9	1.3	1.8	15	6	21	0	0	0	0	0	0	12	4
9/M/66	2.4	0.5	1.7	23	4	27	0	0	0	0	0	0	25	5
10/F/67	19.6	24.0	21.0	41	17	58	2.4	1.6	2.0	12	3	15	27	7
11/M/27	2.8	1.4	2.2	12	8	20	2.0	0	1.2	16	0	16	17	2
12/F/37	1.6	0.4	1.2	12	3	15	0.4	0.0	0.2	3	0	3	8	4
13/F/52	0.2	4.4	1.1	3	2	5	0.1	3.6	0.9	3	2	5	18	7
14/F/23	3.0	1.7	2.4	22	6	28	0.1	0	0.1	3	0	3	28	4
15/M/42	0.4	0	0.3	2	0	2	0.2	0	0	2	0	2	2	4
16/M/20	0.8	0	0.5	7	0	7	0.5	0	0.3	5	0	5	9	4
17/F/57	1.3	0.4	0.8	5	1	6	0.2	0.1	0.1	2	1	3	17	2
18/F/42	9.1	0.6	7.1	54	1	55	0.1	0	0	0	0	0	27	6
19/F/50	5.9	0	4.2	37	0	37	4.4	0	3.1	26	0	26	37	10
20/M/36	1.9	0	1.3	14	0	14	1.6	0	1.1	15	0	15	17	9
21/M/37	3.0	1.2	2.4	22	6	28	0	0	0	2	0	2	7	5
22/F/50	2.1	3.3	2.8	5	11	16	0.6	0	0.3	9	0	9	33	6
23/M/41	16.3	13.0	14.0	59	48	107	0	0	0	0	0	0	26	4
24/F/53	2.6	0.4	2.7	9	1	10	1.0	0	0.4	5	1	6	25	3
25/M/42	0.3	0	0.3	3	0	3	0	0	0	0	0	0	18	3
26/F/52	3.4	3.6	3.3	10	4	14	0.5	0	0.3	6	0	6	14	9
27/F/52	22.3	27.0	24.0	23	7	30	0	0	0	0	0	0	41	6
28/M/35	0.7	0.7	0.7	9	4	13	0	0	0	0	0	0	20	4
29/F/21	0.1	0	0	1	0	1	0	0	0	0	0	0	16	3
30/F/38	1.4	0.4	0.8	10	2	12	0	0	0	0	0	0	28	9
31/M/42	0	0.9	0.5	0	7	7	0	0	0	0	0	0	30	1
32/F/53	0.1	0	0	1	0	1	0	0	0	0	0	0	31	6
33/M/30	0.1	0	0	1	0	1	0	0	0	0	0	0	23	5

Abbreviations: AET, acid exposure time; RFS, reflux finding score; RSI, reflux symptom index; S, supine; T, total; U, upright.

Table 2. Results of Double-Probe, Triple-Sensor pH Monitoring for Laryngopharyngeal Reflux in 33 Patients

Result	Hypopharynx	Proximal Esophagus	Distal Esophagus
Total No. (range) of reflux episodes	4.4 (0-26)	19.6[a] (1-107)	80.0[a] (5-329)
Total % (range) of time the pH value was <4	0.7 (0-3)	3.2[a] (0-24)	12.1[a] (0.3-36)

[a] $P < .001$ (compared with the hypopharynx).

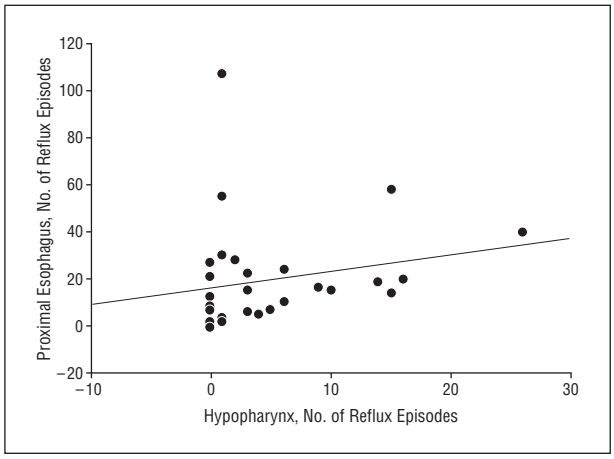


Figure 5. Correlation of the total reflux episodes in the proximal esophagus compared with the hypopharynx. The diagonal line represents the mean number of reflux episodes

not experience any pharyngeal reflux. The use of esophageal pH data (even at a proximal esophageal location) to prove the presence or absence of LPR is invalid because the UES functions as the final barrier against LPR. Abnormal esophageal reflux as determined by pH monitoring does not imply LPR; conversely, normal esophageal reflux as determined by pH monitoring does not rule it out.

In 1989, Wiener et al[14] first placed a pH electrode in both the hypopharynx and distal esophagus in an attempt to document acid reflux into the pharynx. Although most of their patients had severe gastroesophageal reflux disease, only a few showed an actual decrease in pH value at the pharyngeal electrode. In 1990, Katz[15] showed in a small number of patients with LPR that reliance on only an esophageal probe can result in false-

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negative results. Postma et al[16] showed that, of 334 positive pharyngeal pH test results, 126 (38%) had normal esophageal acid exposure times. Similarly, in a pediatric population, Little et al[17] showed that 78 of 168 children (46%) with pH-documented LPR had normal esophageal acid exposure times.

In 2005, Harrell et al[10] designed a new catheter that has an additional hypopharyngeal sensor on a single probe, and they stated that adding a hypopharyngeal pH sensor increased the detection of abnormal pH values and supported the diagnosis of LPR more often than traditional dual-sensor esophageal monitoring. In a study conducted among 518 patients with suspected reflux-induced airway disease, Oelschlager et al[18] found that 24% of patients with pharyngeal reflux had normal amounts of esophageal acid exposure. They used a single probe that contained a double sensor, so their distal pH sensor was not consistently placed in a definite localization in the esophagus. Because we used a double-probe, triple-sensor catheter, we could determine whether a pH catheter would have given a normal or abnormal value more precisely.

We could not find any correlation between RSI and the number of reflux attacks and acid exposure times at both localizations. There are similar observations that could not demonstrate an apparent relationship between the intensity of symptoms and the magnitude and patterns of acid reflux.[19,20] Current reflux parameters obtained from pharyngeal or esophageal segments are probably not sufficient to explain why some patients have severe laryngeal symptoms or findings although they do not have obvious LPR or some have nonsevere laryngeal symptoms or findings although they have relatively more reflux attacks or higher acid exposure times in the pharyngeal segment.

There was a slight correlation between RFS values and proximal esophageal acid exposure times, but we could not find any correlation between RFS and the number of pharyngeal reflux attacks. This may suggest that duration of gastric acid exposure is more important than the number of pharyngeal reflux episodes in the analysis of laryngeal findings.

In this study, we could not detect LPR in 16 patients with presumed LPR owing to clinical findings. Using only RSI or RFS values for the diagnosis of LPR might lead us to false-positive diagnoses, because of 33 patients who were clinically positive for LPR, only 17 ended up being positive.

In conclusion, the importance of the pharyngeal sensor in 24-hour pH monitoring cannot be overemphasized in the determination of suspected LPR. It is clear that measuring esophageal acid exposure does not allow us to make any assumptions concerning the presence or absence of pharyngeal reflux. The adjustable, bifurcated, triple-sensor pH probe allows identifying true hypopharyngeal reflux episodes, and it is the best way of monitoring both the esophagus and the hypopharynx at the same time. The advantage of 3 sensors is basically the accuracy of placement (1 above the UES, 1 below the UES, and 1 in the distal esophagus). If single-probe, double-sensor pH monitoring is going to be performed, the proximal probe should be placed in the pharynx, not in the upper esophagus. The actual number of reflux events and percentage of acid exposure in the pharynx diagnostic for LPR was not examined in this study and requires further investigation.

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Correspondence: Togay Muderris, MD, Ankara Universitesi Tip Fakultesi Ibni Sina Hastanesi, KBB ABD, Altindag, 06100 Ankara, Turkey (togaymuderris@yahoo.com).
Author Contributions: Dr Muderris had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Muderris and Yorulmaz. *Acquisition of data:* Muderris, and Gokcan. *Analysis and interpretation of data:* Muderris, Gokcan, and Yorulmaz. *Drafting of the manuscript:* Muderris, Gokcan, and Yorulmaz. *Critical revision of the manuscript for important intellectual content:* Muderris and Yorulmaz. *Statistical analysis:* Muderris. *Administrative, technical, and material support:* Muderris and Yorulmaz. *Study supervision:* Gokcan and Yorulmaz.
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