

# Voice Differences When Wearing and Not Wearing a Surgical Mask

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**Summary: Objective.** The purpose of our study was to investigate the impact of surgical mask on some vocal parameters such as F0, vocal intensity, jitter, shimmer and harmonics-to-noise ratio in order to understand how surgical mask can affect voice and verbal communication in adults.

**Methods.** The study was carried out on a selected group of 60 healthy subjects. All subjects were trained to voice a vocal sample of a sustained /a/, at a conversational voice intensity for the Maximum Phonation Time (MPT), wearing the surgical mask and then without wearing the surgical mask. Voice samples were recorded directly in Praat.

**Results.** There were no statistically significant differences in any acoustic parameter between the masked and unmasked condition. There was a non-significant decrease in vocal intensity in 65% of the subjects while wearing a surgical mask.

**Conclusions.** The statistical comparison carried out between all the acoustic voice parameters observed, extracted wearing and not wearing a surgical mask did not reveal any significant statistical difference. Most of the subjects, after wearing the surgical mask, presented a decrease in vocal intensity measured. Our conclusion was that wearing a mask is likely to induce the unconscious need to increase the vocal effort, resulting over time in a greater risk of developing functional dysphonia. The reduction of intensity can affect also social interaction and speech audibility, especially for individuals with hearing loss.

**Key Words:** COVID-19—Praat—Intensity—Surgical mask—Acoustic voice analysis.

## INTRODUCTION

Novel 2019 coronavirus disease (COVID-19) was declared a pandemic by the World Health Organization (WHO) in March 2020.<sup>1</sup> The major modes of human transmission of the SARS-CoV-2 virus are through respiratory droplets and contact.

Surgical face masks have been in use since the early 1900s to help prevent infection of surgical wounds from staff-generated oral and nasal bacteria.<sup>2</sup> Today, applications of surgical face masks have evolved from prevention of patient infection to prevention of all citizens' respiratory viral infection exposure.<sup>3</sup>

Even if masks alone are not enough to control the disease and must be coupled with other non-pharmacological interventions such as quarantining, isolation, social distancing and hand hygiene, surgical mask use should be as nearly universal as possible and implemented without delay: this measure could contribute greatly to controlling the COVID-19 pandemic.<sup>4</sup> Face masks cover the lower portion of the face, the mouth and nose and it is not yet clear whether this obstruction could result in quieter or distorted voice reaching the listener's ears.

There is little research on how wearing face masks affects the acoustical properties of voice and speech. Previous

studies<sup>5-7</sup> demonstrated how the propagation of the sound wave is hindered when a mask covers a talker's mouth/nose: the acoustic energy of certain spectral components of the signal may be attenuated or filtered out. Consonant intelligibility, as well as the discrimination of unfamiliar talkers may be greatly compromised by the use of face mask,<sup>5</sup> as well as the intensity and spectral features of the voiceless fricatives /f, s, ʃ/, as it was studied in acoustic analysis of Persian language.<sup>6</sup> The transmission loss characteristics of different facewear materials will be dependent upon the sound absorbing properties of the particular material.<sup>7</sup>

Literature shows no previous detailed study on the statistical differences of the acoustic analysis between voice samples recorded when wearing and not wearing a surgical mask.

The purpose of our study was to investigate the impact of surgical mask on some vocal parameters such as F0, vocal intensity, jitter, shimmer, and harmonics-to-noise ratio in order to understand how surgical masks can affect voice and verbal communication in adults.

## MATERIALS AND METHODS

The study was carried out on a group of 60 healthy subjects (24 males and 36 females, mean age 47 years, range 26-69) recruited among hospital workers of the ENT Department of the Polyclinic Hospital, University of Bari "Aldo Moro", Italy.

Participants were approached and informed about the study significance and objectives. All participants who agreed to participate in the study signed an informed consent form, previously approved by the local hospital Ethics Committee.

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The exclusion criteria included: reporting recent voice problems or a voice disorder history, a condition that might affect the normal voice function, any respiratory infection for the 2 weeks before recording, any previous formal voice training or voice therapy, any laryngeal, mouth, or throat abnormality. Inclusion criterion was to be able to phonate and sustain a vowel for at least 10 seconds. The subjects who met eligibility criteria were recruited.

The vocal signal was recorded and analyzed using Praat.<sup>8</sup>

Praat is a computer software package for speech, phonetic and voice analysis. It was first designed in 1992 by Paul Boersma and David Weenick from the Institute of Phonetic Sciences, University of Amsterdam. Praat can be used on various operating systems and relies on the finest algorithms including the most accurate algorithm of pitch analysis, articulatory synthesis and gradual learning algorithm for free variation. We used the inbuilt option of voice report in Praat pulses menu.

The participants were asked to stand in front of a microphone (Samson Meteor Mic - USB Studio Condenser Microphone, frequency response of 20Hz–20kHz) at a distance of 20 cm from the lips, in a quiet room (< 30 dB background noise).

The microphone was calibrated in the following way: using a dB meter (Decibel Meter PCE-MSL 1), located at the same position as the microphone of the recording, we measured the Sound Pressure Level of a noise produced by a noise generator. When we later opened the sound recorded through the microphone in Praat's sound window, the software showed that its average intensity in dB matched the intensity perceived by the dB meter.

We set the sampling rate at 44 kHz at 16 bits.

Each subject was given a short practice period before the first recording to adapt to procedure. All subjects were trained to voice a vocal sample of a sustained /a/, at a conversational voice intensity, keeping their usual pitch, as constant as possible, for the Maximum Phonation Time (MPT).

Voice recording was performed for each participant first with the surgical mask on and then without the surgical mask, after a waiting period of 10 minutes during the which no talking was allowed.

Three-ply surgical masks were used.

The three-ply material consists of a melt-blown polymer, most commonly polypropylene, placed between two layers of non-woven fabric.

The voice samples collected were analyzed by selecting the middle three seconds from the recordings.

The vocal parameters analyzed with Praat were median pitch, mean pitch, minimum pitch, maximum pitch, vocal intensity (dB), number of pulses, number of periods, jitter (local), jitter (rap), jitter (ppq5), jitter (ddp), shimmer (local), shimmer (apq3), shimmer (apq5), shimmer (apq11), shimmer (dda) and mean harmonics-to-noise ratio (HNR).

The fundamental frequency or mean pitch (F0) of a speech signal refers to the approximate frequency of the (quasi) periodic structure of voiced speech signals. Vocal

Intensity can be measured in decibels (dB) and indicates the strength of vocal fold vibration. To extract the intensity in Praat, the vertical scale view range was set from 50 to 100 dB.

The number of pulses corresponds to the number of glottal pulses measured in the voice sample. Jitter (%) is defined as cycle-to-cycle and short-term perturbation in the fundamental frequency of the voice.

The measurement of jitter can be done by the following parameters<sup>9</sup>:

- The Jitter (local) is the average absolute difference between consecutive periods, divided by the average period.
- Jitter (rap) is the Relative Average Perturbation, the average absolute difference between a period and the average of it and its two neighbors, divided by the average period.
- Jitter (ppq5) is the five-point Period Perturbation Quotient, the average absolute difference between a period and the average of it and its four closest neighbors, divided by the average period.
- Jitter (ddp) is the average absolute difference between consecutive differences between consecutive periods, divided by the average period.

The shimmer (%) is a cycle-to-cycle, short-term perturbation in the amplitude of voice.

The measurement of shimmer was performed by the following parameters<sup>9</sup>:

- Shimmer (local) is the average absolute difference between the amplitudes of consecutive periods, divided by the average amplitude.
- Shimmer (apq3) is the three-point Amplitude Perturbation Quotient, the average absolute difference between the amplitude of a period and the average of the amplitudes of its neighbors, divided by the average amplitude.
- Shimmer (apq5) is the five-point Amplitude Perturbation Quotient, the average absolute difference between the amplitude of a period and the average of the amplitudes of it and its four closest neighbors, divided by the average amplitude.
- Shimmer (apq11) is the 11-point Amplitude Perturbation Quotient, the average absolute difference between the amplitude of a period and the average of the amplitudes of it and its ten closest neighbors, divided by the average amplitude.
- Shimmer (ddp) is the average absolute difference between consecutive differences between the amplitudes of consecutive periods.

Another acoustic parameter (HNR) is influenced by both the shimmer and jitter and referred to as the mean ratio of harmonics to non-harmonics.<sup>10</sup>

The results are recorded as average and standard deviation (SD).

All parameters were analyzed in the same subjects during phonation with surgical mask (SM) and without surgical mask (NSM). The results, shown separately according to sex, were then submitted to statistical analysis by comparing mean values of each parameter. We used Student’s test with  $P = 0.05$  significance level after evaluating the  $t$  value in each parameter.

**RESULTS**

Table 5 shows a difference in the percentage of subjects who presented variations in vocal intensity after wearing surgical mask: the percentage of subjects who presented a decrease in vocal intensity is greater than the percentage of subjects who presented an increase in vocal intensity measured (65% vs 35%). Furthermore, most of the subjects showed a decrease in vocal intensity ranging from  $-2 \leq \text{dB} < -1$  (18.33%). As described in Table 6, the average value of increase in vocal intensity was 2.25 dB while the average value of decrease in vocal intensity was  $-3.03$  dB.

**DISCUSSION**

Voice acoustic analysis can be considered a very valuable technique in diagnosis of voice disorders or laryngological pathologies.<sup>11,12</sup> One of the most frequently investigated voice acoustic parameters has been voice perturbation.<sup>13,14</sup>

Previous studies<sup>15,16</sup> have found that fundamental frequency (F0) can be affected by different factors, such as age, vocal fold length and language or ethnological background but acoustic analysis that compares voice production with and without a surgical mask. A recent study<sup>17</sup> shows how wearing any type of face mask causes a low-pass filter effect, attenuating the highest frequencies (2000-7000 Hz) of the speaker’s voice, and a decibel reduction ranging from 3 to 4 dB (medical mask) to nearly 12 dB for the N95 mask (respirator/FFP).

We can therefore assert that during COVID 19 era, wearing a face mask (for example the surgical mask) profoundly changed social interaction.<sup>17</sup>

The impact that the face mask has on verbal communication must not be underestimated.

In our study we analyzed the voice samples recorded by each participant wearing and not wearing the surgical mask in order to find voice parameters measurements including the F0, vocal intensity, jitter, shimmer, and HNR.

The parameters obtained by means of the acoustic analysis have the advantage of describing the voice objectively rather than based on subjective perceptual analysis.

Although there were no statistically significant differences in all vocal parameters including vocal intensity when wearing the surgical mask and not wearing the surgical mask, the number of subjects who experienced a reduction in vocal

**TABLE 1.**  
**Acoustic analysis of Maximum Phonation Time (MPT), Median Pitch, Mean Pitch, Minimum Pitch and Maximum Pitch Values Wearing Surgical Mask (SM) and not Wearing Surgical Mask (NSM), Sex**

	Mean	Standard deviation	T-test
MPT (s) SM Males	25,291	5,520	$P = 0.8591$
MPT (s) NSM Males	25,583	5,792	
MPT(s) SM Females	19,861	4,168	$P = 0.4205$
MPT (s) NSM Females	20,638	3,972	
Median Pitch (Hz) SM Males	137,180	33,031	$P = 0.9232$
Median Pitch (Hz) NSM Males	138,184	38,470	
Median Pitch (Hz) SM Females	214,801	33,728	$P = 0.9879$
Median Pitch (Hz) NSM Females	214,669	39,694	
Mean Pitch (Hz) SM Males	132,273	24,337	$P = 0.9467$
Mean Pitch (Hz) NSM Males	131,800	24,402	
Mean Pitch (Hz) SM Females	211,199	33,382	$P = 0.8095$
Mean Pitch (Hz) NSM Females	213,344	41,404	
Minimum Pitch (Hz) SM Males	132,316	34,485	$P = 0.8218$
Minimum Pitch (Hz) NSM Males	134,700	38,311	
Minimum Pitch (Hz) SM Females	191,887	50,556	$P = 0.4374$
Minimum Pitch (Hz) NSM Females	201,574	54,602	
Maximum Pitch (Hz) SM Males	146,539	44,193	$P = 0.9586$
Maximum Pitch (Hz) NSM Males	147,224	46,685	
Maximum Pitch (Hz) SM Females	220,980	34,613	$P = 0.8632$
Maximum Pitch (Hz) NSM Females	219,469	39,367	

As illustrated in Table 1, the acoustic analysis showed no significant difference (at the 0.05 level) in MPT values (Males: Mean SM= 25.291; SD SM= 5.520; Mean NSM=25.583; SD NSM=5.792;  $P = 0.8591$ ; Females: Mean SM= 19.861; SD SM=4.168; Mean NSM=20.638; SD NSM= 3.972;  $P = 0.4205$ ), median pitch values (Males: Mean SM= 137.180; SD SM=33.031; Mean NSM=138.184; SD NSM= 38.470;  $P = 0.4205$ ; Females: Mean SM= 214.801; SD SM=33.728; Mean NSM=214.669; SD NSM= 39.694;  $P = 0.9879$ ) and in the mean pitch values (Males: Mean SM =132.273; SD SM=24.337; Mean NSM=131.800; SD NSM=24.402;  $P = 0.9467$ ; Females: Mean SM =211.199; SD SM=33.382; Mean NSM=213.344; SD NSM=41.404;  $P = 0.8095$ ); in the two different situations (wearing surgical mask – not wearing surgical mask).

With significance level at 0,05, values obtained by means of Student  $t$  test (calculated) in the same subjects with surgical mask and without surgical mask are not statistically significant. =213.344; SD NSM=41.404;  $P = 0.8095$ ); in the two different situations (wearing surgical mask – not wearing surgical mask).

**TABLE 2.**  
**Acoustic Analysis of Intensity, of the Number of Pulses, Number of Periods and of the HN (Harmonics-to-Noise Ratio) Values Wearing Surgical Mask (SM) and not Wearing Surgical Mask (NSM), Sex**

	Mean	Standard Deviation	T-test
Mean vocal intensity (dB) SM Males	68,678	6,482	$P = 0.9463$
Mean vocal intensity (dB) NSM Males	68,549	6,724	
Mean vocal intensity (dB) SM Females	68,075	6,141	$P = 0.1622$
Mean vocal intensity (dB) NSM Females	70,078	5,884	
Number of pulses <b>SM Males</b>	427,833	98,710	$P = 0.9674$
Number of pulses NSM Males	429,083	111,915	
Number of pulses SM Females	653,861	109,649	$P = 0.7487$
Number of pulses NSM Females	644,472	136,546	
Number of periods SM Males	426,792	98,742	$P = 0.9664$
Number of periods NSM Males	428,083	111,915	
Number of periods SM Females	652,750	109,667	$P = 0.7515$
Number of periods NSM Females	643,472	136,546	
Mean HNR (dB) SM Males	19,461	4,082	$P = 0.6342$
Mean HNR (dB) <b>NSM Males</b>	18,915	3,809	
Mean HNR (dB) SM Females	20,870	3,464	$P = 0.8000$
Mean HNR (dB) NSM Females	21,087	3,769	

As can be seen in Table 2, differences in vocal intensity values were not significant (Males: Mean SM= 68.678; SD SM=6.482; Mean NSM= 68.549; SD NSM= 6.724;  $P = 0.9463$ ; Females: Mean SM= 68.075; SD SM=6.141; Mean NSM= 70.078; SD NSM= 5.884;  $P = 0.1622$ ). No significant differences were found in HNR values (Males Mean SM= 19.461; SD SM =4.082; Mean NSM=18.915; SD NSM=3.809;  $P = 0.6342$ ; Females: Mean SM= 20.870; SD SM = 3.464; Mean NSM=21.087; SD NSM=3.769;  $P = 0.8000$ ). With significance level at 0,05, values obtained by means of Student t test (calculated) in the same subjects with surgical mask and without surgical mask are not statistically significant.

intensity while wearing the surgical mask compared to while not wearing the surgical mask was a little higher than the number of subjects who presented an increase in vocal intensity (65% vs 35%).

On the basis of our results, we believe that the material the masks are made does not seem to represent a real and

defined barrier<sup>18</sup> capable of causing significant alterations of the vocal signal of the participants in our study.

Our hypothesis in this respect is therefore a subjective and unconscious extra vocal effort that modulates the vocal intensity produced which accounts for the increased intensity that was measured in the 35% of the subjects.

**TABLE 3.**  
**Acoustic Analysis of Jitter Values Wearing Surgical Mask (SM) and not Wearing Surgical Mask (NSM), Sex.**

	Mean	Standard Deviation	T-test
Jitter local SM (%) Males	0,360	0,168	$P = 0.7215$
Jitter local NSM (%) Males	0,383	0,265	
Jitter local SM (%) Females	0,343	0,128	$P = 0.2465$
Jitter local NSM (%) Females	0,308	0,125	
Jitter rap SM (%) Males	0,186	0,151	$P = 0.8494$
Jitter rap NSM (%) Males	0,193	0,151	
Jitter rap SM (%) Females	0,205	0,085	$P = 0.1514$
Jitter rap NSM (%) Females	0,177	0,077	
Jitter ppq5 SM (%) Males	0,197	0,094	$P = 0.7230$
Jitter ppq5 NSM (%) Males	0,211	0,167	
Jitter ppq5 SM (%) Females	0,195	0,069	$p = 0.3525$
Jitter ppq5 NSM (%) Females	0,179	0,075	
Jitter ddp SM (%) Males	0,560	0,287	$P = 0.3682$
Jitter ddp NSM (%) Males	0,695	0,668	
Jitter ddp SM (%) Females	0,592	0,247	$P = 0.2856$
Jitter ddp NSM (%) Females	0,531	0,233	

With significance level at 0,05, values obtained by means of Student t test (calculated) in the same subjects with surgical mask and without surgical mask are not statistically significant.

**TABLE 4.**  
**Acoustic Analysis of Shimmer Values Wearing Surgical Mask (SM) and not Wearing Surgical Mask (NSM), Sex**

	Mean	Standard Deviation	t-test
Shimmer local SM (%) Males	3,920	2,219	$P = 0.4565$
Shimmer local NSM (%) Males	4,450	1,228	
Shimmer local SM (%) Females	3,519	1,649	$P = 0.1238$
Shimmer local NSM (%) Females	2,985	1,228	
Shimmer apq3 SM (%) Males	2,006	1,301	$P = 0.5526$
Shimmer apq3 NSM (%) Males	2,266	1,684	
Shimmer apq3 SM (%) Females	1,847	0,899	$P = 0.1258$
Shimmer apq3 NSM (%) Females	1,549	0,723	
Shimmer apq5 SM (%) Males	2,290	1,466	$P = 0.5468$
Shimmer apq5 NSM (%) Males	2,561	1,623	
Shimmer apq5 SM (%) Females	2,233	1,284	$P = 0.1090$
Shimmer apq5 NSM (%) Females	1,822	0,811	
Shimmer apq11 SM (%) Males	3,245	33,031	$P = 0.9523$
Shimmer apq11 NSM (%) Males	3,651	1,768	
Shimmer apq11 SM (%) Females	2,772	1,160	$p = 0.2390$
Shimmer apq11 NSM (%) Females	2,475	0,950	
Shimmer dda SM (%) Males	5,793	3,968	$p = 0.4479$
Shimmer dda NSM (%) Males	6,797	5,054	
Shimmer dda SM (%) Females	5,542	2,697	$p = 0.1250$
Shimmer dda NSM (%) Females	4,646	2,169	

At the same time (Table 3, Table 4), no significant differences were noticed in jitter or shimmer values (Males: jitter local Mean SM=0.360; SD SM= 0.168; Mean NSM=0.383; SD NSM = 0.265;  $P = 0.7215$ ; Females: jitter local Mean SM=0.343; SD SM= 0.128; Mean NSM=0.308; SD NSM = 0.125;  $P = 0.2465$ ; Males: shimmer local Mean SM=3.519; SD SM=1.649; Mean NSM = 2.985; SD NSM=1.228;  $P = 0.4565$ ; Females: shimmer local Mean SM=3.519; SD SM=1.649; Mean NSM = 2.985; SD NSM=1.228;  $P = 0.1238$ ;) With significance level at 0,05, values obtained by means of Student t test (calculated) in the same subjects with surgical mask and without surgical mask are not statistically significant

Theoretically, indeed, the decrease in vocal intensity found in 65% of the subjects could be simply explained by the fact that surgical mask material obstructs the stream of air coming from the speaker's mouth during speech, diminishing so the acoustic energy – which includes the loudness of a sound – that is transmitted through the air to the microphone. Nonetheless, the non-statistical significance in the acoustic analysis in all vocal parameters and the finding of the increase in intensity in the 35% of subjects when wearing the surgical mask does not make the concept of physical barrier absolute.

Similarly, as talkers adjust their vocal effort to communicate at different distances,<sup>19</sup> the decrease or the increase of the vocal intensity caused by the use of the face mask, may be an unconscious attempt to adapt vocal intensity to the new and recent communication scenario in the COVID 19 era for which people in general are not prepared yet.

Furthermore, in the long run, wearing the mask in some subjects could induce the need to increase the vocal effort in order to make up both for the reduction of intensity of the voice and for the lack of the normal and important nonverbal language (kinetic facial expression) that contributes to communication.<sup>20,21</sup>

Vocal effort manifests as a series of changes to the voice signal, including those that can be quantified by amplitude-, time-, and spectral-based measures.<sup>22</sup>

Effortful voice production is a critical component of voice disorders and is considered to be a component of vocal hyperfunction.<sup>23,24</sup>

Therefore, the increased vocal effort that occurs in hyperfunctional voice disorders can be associated with altered patterns of intrinsic and extrinsic laryngeal muscle activation, attempts to compensate for a lack of vocal fold closure, changes in the vibratory patterns of the vocal fold and altered respiratory behavior.<sup>25</sup> It is reasonable to think that the widespread mask-wearing, by nearly all the world's entire population, could result over time in a higher number of subjects being at a greater risk of developing functional dysphonia.

A further consideration is needed on the role of the mask use on how listeners perceive speech: a noisy environment and social distancing have definitely an impact on speech audibility. Social distancing further compounds the negative effect of universal masking on audibility, especially for individuals with hearing loss.

The study has some limitations that are worth mentioning.

Firstly, the order effect of the recordings: it would be interesting to perform an acoustic analysis of the voice by reversing the order of the recordings (first when not wearing the surgical mask and then wearing the surgical mask).

Furthermore, this study should have been carried out wearing different types of masks (ffp2, ffp3, etc.).

**TABLE 5.**  
**Acoustic Analysis of Vocal Intensity Wearing Surgical Mask**

Increase in voice intensity wearing surgical mask (dB)	No. of Subjects	(%)	Decrease in voice intensity wearing surgical mask (dB)	No. of Subjects	(%)
dB ≤ 1	6	10	dB ≥ -1	6	10
1 < dB ≤ 2	5	8,33	-2 ≤ dB < -1	11	18,33
2 < dB ≤ 3	3	5	-3 ≤ dB < -2	3	5
dB > 3	7	11,67	dB < -3	19	31,67
TOTAL	21	35	TOTAL	39	65

**TABLE 6.**  
**Minimum, Maximum, Mean and Standard Deviation Values of Increase and Decrease of the Intensity of the Voice When Wearing a Surgical Mask**

	Increase in voice intensity	Decrease in voice intensity
Minimum value (dB)	0.090	-0.47
Maximum value (dB)	6.230	-7.490
Mean (dB)	2.35	-3.03
Standard Deviation	1.84	2.03

Future research may include autophonic loudness perception masked vs. unmasked and using accelerometer to measure a production measures (ie, subglottal pressure masked and unmasked).

Further studies could also measure any spectral differences and the intelligibility of speech with and without wearing a mask.

## CONCLUSIONS

Our study demonstrates that the statistical comparison carried out between all the acoustic voice parameters extracted with and without a surgical mask did not reveal any significant statistical difference. On the basis of these results, the material the surgical masks are made of do not seem to represent a real and defined barrier, capable of causing significant alterations of the vocal signal. Most of the subjects (65%), showed a decrease in the vocal intensity measured after wearing the surgical mask. This could be explained with a reduction of the acoustic energy induced by the surgical mask but also an unconscious variation in vocal intensity while wearing a face mask can be hypothesized. In some subjects (35%) wearing a mask could induce the need to increase the vocal effort, resulting over time in a greater risk of developing functional dysphonia. The reduction of intensity could affect also social interaction and speech audibility and cause discrimination, especially for individuals with hearing loss. Further studies could measure autophonic loudness perception, subglottal pressure, any spectral differences and the intelligibility of speech, comparing vocal parameters with vs. without the mask.

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## ETHICAL STATEMENT

The authors certify that they have no affiliations with or involvement in any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this manuscript.

All authors have been personally and actively involved in substantial work leading to the paper, and will take public responsibility for its content.

The paper is not currently being considered for publication elsewhere.

All the participants who agreed to participate the study signed an informed consent form, previously approved by the local hospital Ethics Committee.

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