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The Effect of Different Masks Used by Pregnant Women on Vital Signs and Non-Stress Test During the COVID-19: Randomized Clinical Study

COVID-19 Sürecinde Gebelerin Kullandığı Farklı Maskelerin Yaşam Bulguları ve Nonstres Test Üzerine Etkisi: Randomize Klinik Çalışma

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ABSTRACT Objective: In the during coronavirus disease-2019 (COVID-19), the unprecedented increase in the use of face masks and their variants has been associated with the emergence of several concerns on human health regarding their safety and impact on physiology. This study was conducted to examine the effects of different masks used by pregnant women on vital signs and non-stress test (NST) during the COVID-19. **Material and Methods:** The study consisted of a single surgical mask group (n=30), double surgical mask group (n=30), and N95 mask group (n=31). Masks were given to the resting pregnant women 30 minutes (min) before the NST, and they were provided to wear masks. Vital signs of the pregnant women were measured 30 min after wearing the mask, just before and after the NST, and the images of the NST traces were taken. **Results:** After NST, the systolic blood pressure of the double surgical mask group was lower than the other groups. Diastolic blood pressure before and after NST was lower in the double surgical mask group than in the N95 mask group. The respiratory rate decreased significantly in the N95 mask group ($p<0.05$). Before and after NST, SpO2 and pulse were similar between and within the groups. The groups were similar in terms of fetal heart rate, acceleration, variability, contraction, deceleration, reactivity/non-reactivity ($p>0.05$). **Conclusion:** It is difficult to say that statistically significant results obtained with vital signs were clinically significant. Besides, the use of different masks had no effect on the NST parameters.

Keywords: COVID-19; pregnant women; fetus; masks; nursing

ÖZET Amaç: Koronavirüs hastalığı-2019 [coronavirus disease-2019 (COVID-19)] sürecinde, yüz maskelerinin ve çeşitlerinin kullanımındaki benzeri görülmemiş artış, güvenlikleri ve fizyoloji üzerindeki etkileri ile ilgili insan sağlığına ilişkin çeşitli endişelerin ortaya çıkmasıyla ilişkilendirilmiştir. Bu araştırma, COVID-19 sürecinde gebelerin kullandığı farklı maskelerin yaşam bulguları ve nonstres test (NST) üzerine etkisinin incelenmesi amacıyla yapılmıştır. **Gereç ve Yöntemler:** Araştırma tek cerrahi maske grubu (n=30), çift cerrahi maske grubu (n=30), N95 maske grubundan (n=31) oluşmuştur. NST yapılmadan 30 dk önce istirahat hâlindeki gebelere maskeler verilerek takılması sağlanmıştır. Maske takılmasından 30 dk sonra NST yapılmadan hemen önce ve sonra gebelerin yaşam bulguları ölçülmüş ve NST traselerinin görüntüsü çekilmiştir. **Bulgular:** NST sonrası çift cerrahi maske grubunun sistolik kan basıncı diğer gruplardan daha düşüktür. NST öncesi ve sonrası diastolik kan basıncı çift cerrahi maske grubunda N95 maske grubuna göre düşüktür. Solunum sayısı N95 maske grubunda anlamlı olarak azalma göstermiştir ($p<0,05$). NST öncesi ve sonrası SpO2 ve nabız değerleri gruplar arasında ve grup içinde benzerdir. Gruplar fetal kalp atım hızı, akselerasyon, deselerasyon, kontraksiyon, variabilite, reaktiflik, nonreaktiflik yönünden benzerdir ($p>0,05$). **Sonuç:** Yaşam bulguları ile elde edilen istatistiksel olarak anlamlı sonuçların klinik açıdan önemli olduğunu söylemek zordur. Farklı maske kullanımının NST parametreleri üzerinde herhangi bir etkisi olmamıştır.

Anahtar Kelimeler: COVID-19; gebe kadın; fetüs; maskeler; hemşirelik

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The coronavirus disease-2019 (COVID-19), which has been declared a pandemic by the World Health Organization (WHO), has caused the death of millions of people worldwide.[1,2] In order to prevent transmission and provide maximum protection, many preventions have been taken within the strategies that reduce the infection rate. Among the preventions taken within these strategies was the community use of face masks.[3-6] The use of face masks was also suggested by WHO.[7]

The unprecedented increase in the use of face masks and their variants in this process has been associated with the emergence of various concerns on human health regarding their safety and effects on physiology, and a lot of research has been done on this subject.[8-13] Among these, studies evaluating the effect of mask use or the use of different mask types on parameters related to vital signs have also been published. In these studies, there are results showing whether each of the parameters evaluated regarding vital signs has a different effect or not.[14-16] Moreover, there are also studies on pregnant women that have similar results to the results of this studies.[17,18] However, among these studies, there is no research in the literature that compares the effects of using three different masks (single surgical mask, double surgical mask, N95 mask) and their differences from each other on pregnant women and the impact of masks during non-stress test (NST). However, the oxygen supply of the fetus throughout fetal life is completely linked to maternal circulation and respiration, gas exchange in the placenta, placental perfusion, and fetal and umbilical circulations. Problems in any of these structures lead to decrease in the oxygen concentration in the fetal blood and then in the fetal tissues and cause permanent damage.[19] In this respect, NST is one of the important diagnostic tests that evaluate fetal well-being through some parameters.[20] Therefore, this research was conducted to examine the effects of different masks used by pregnant women on vital signs and NST during COVID-19.

RESEARCH HYPOTHESES

H_1: Different masks (single surgical mask, double surgical mask, N95 mask) affect the vital signs of the pregnant woman.

H_2: Different masks (single surgical mask, double surgical mask, N95 mask) affect NST parameters.

MATERIAL AND METHODS

STUDY DESIGN AND SAMPLE SIZE

This research was carried out as a single-blind and randomized controlled. The study was conducted in the obstetrics and gynecology department of a university hospital, in Türkiye.

Participants, who applied to the obstetrics and gynecology policlinic between February 2022 and June 2022, were followed up and were in the 37-40th week of pregnancy, accepted in the research. According to the power analysis, with an effect size of 0,5, a 5% error level and with a 95% confidence interval, a total of 90 participants, 30 of whom were in the single and double surgical mask and N95 mask groups were included. However, since losses may occur while collecting data, it was decided to take 35 participants for each group. The research was concluded with 30 participants from single and double surgical masks and 31 participants from N95 masks. The flow diagram of the research is given in Figure 1. All participants in the research were grouped according to the randomization table prepared in the electronic environment.

Participants aged 19 or over, healthy at 37-40 weeks of gestation, and outpatient follow-ups were included in the research. Having multiple pregnancies, having chronic and psychiatric/psychological diseases/problems, having risky pregnancy, smoking, alcohol, and substance use, having never done NST before, having a risky condition related to the fetus, having barriers to communication, being foreign national, have had or are currently having COVID-19, being COVID-19 contact were excluded from the research. A total of 12 participants (four foreign nationals, three risky pregnancy, three multiple pregnancy, two smokers) who met the exclusion criteria of this study were not included in the study.

Participants whose NST result was not good, who were considered for emergency treatment, and whose general condition deteriorated before, during or after NST formed the termination criteria of the

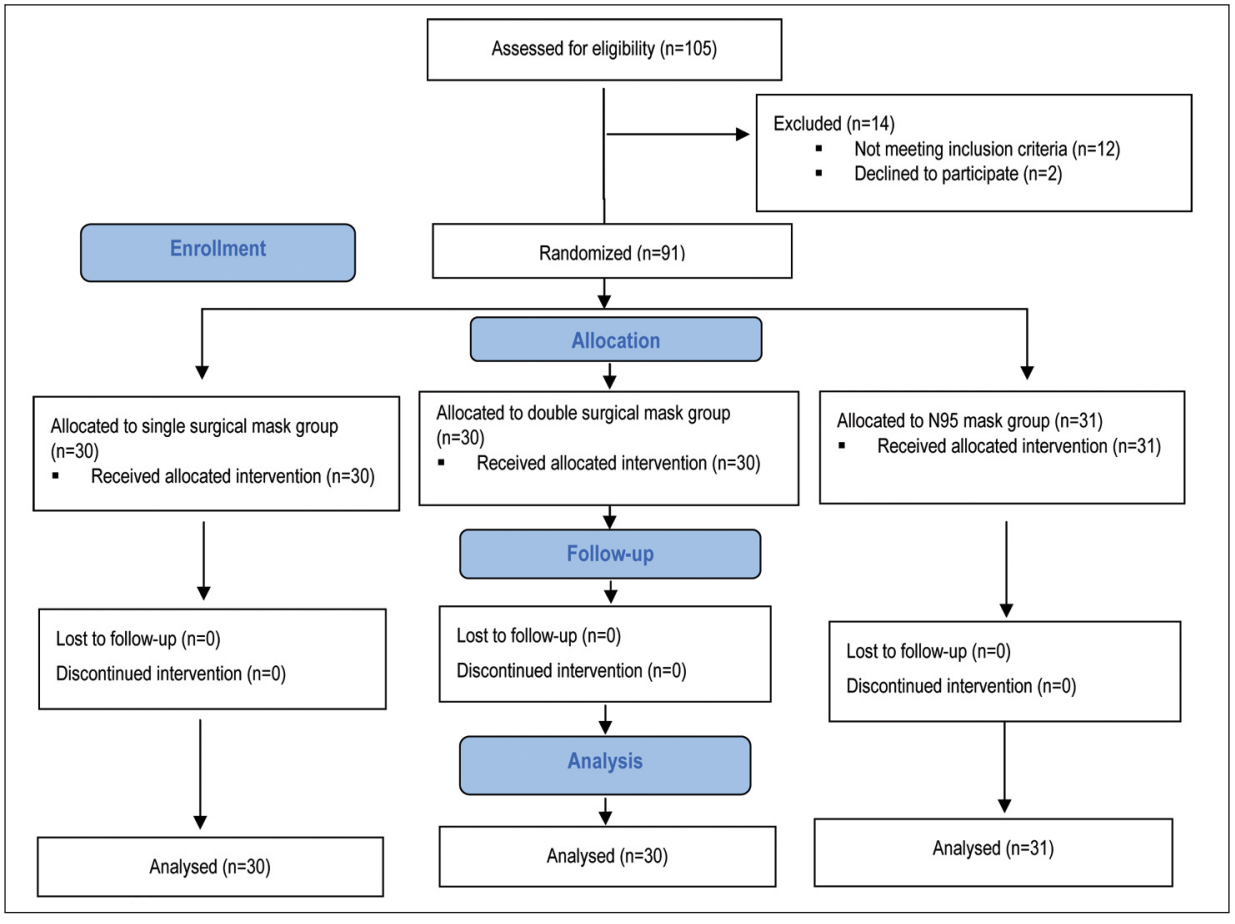

FIGURE 1: The flow diagram of the research.

study. Conditions in which participants were required to eat, not drink caffeine, not do sports, and empty their bladders just before the NST, at least two hours prior to the NST.

DATA COLLECTION TOOLS

Personal information form, vital signs information form and NST findings information form were used to collect the data of the research.

Personal Information Form

The form, which was created in line with the literature and expert opinions, consists of questions that determine the sociodemographic and obstetric characteristics of participants.[21,22]

Vital Signs Information Form

In this form, systolic/diastolic blood pressure, respiratory rate, oxygen (SpO_2) saturation, and pulse were recorded.

NST Findings Information Form

Fetal heart rate, acceleration, deceleration, contraction, variability, reactivity/non-reactivity were registered in this form.

DATA COLLECTION

The participants included in the research were directed to the researcher by the health personnel working in the clinic and the data were collected by the researcher by face-to-face interview technique. A single and double surgical mask, and N95 mask (Medizer, İstanbul, Türkiye) used for the research were distributed to each participant 30 minutes before the NST by the same researcher and participants were provided to wear masks. Vital signs (systolic/diastolic blood pressure (measured in mmHg), respiratory rate (respiratory rate per minute was measured), SpO_2 saturation (SpO_2 measured in %), pulse (pulse was measured in beats per minute/bpm) of partici-

pants who were at rest were measured in the sitting position in the NST room 30 minutes later, just before the NST. During the NST, all participants were placed in the left lateral position, their NSTs were taken for 20 minutes, and after the NST, the vital signs of the participants were measured and recorded in a sitting position while resting. Pulse and SpO_2 were measured on the right index finger with a finger-type pulse oximeter (Berry®, Shanghai, China). The respiration rate was measured with a stopwatch. Finally, systolic/diastolic blood pressure was automatically measured from the upper right arm with a sphygmomanometer (Respirox, Jiangsu, China). All measurements were carried out by the same researcher. After the NST was finished, the images were taken by numbering the traces. Moreover, the personal information form was filled out within the 30 minutes waiting period of the participants.

DATA ANALYSIS

Analysis of the data was performed in IBM SPSS Statistics Standard Concurrent User V 26 (IBM Corp., Armonk, New York, USA). Descriptive statistics were given as the number of units, median, mean±standard deviation, percent, minimum and maximum values. The normal distribution of the data belonging to the numerical variables was done with the Shapiro-Wilk test of normality. Homogeneity of variances was done by Levene's test. Comparison of groups for numerical variables were made with the Kruskal-Wallis H test. The systolic/diastolic blood pressure, saturation, respiratory rate and pulse values of the groups before and after NST were compared with a two-way analysis of variance in repeated measurements. Bonferroni correction was performed to compare the main effects in the two-way analysis of variance in repeated measures. Chi-square tests were used for intergroup comparisons of categorical variables. In cases where there was a correlation in the chi-square test, the differences between the groups in the categories were made with the Bonferroni-corrected two ratio z test. Statistically, $p<0.05$ was accepted as significant.

Evaluation of NST Result

A folder containing the NST traces that were imaged and numbered for each participant in the study was created. After collecting all of the research data, NST tracings were evaluated by an gynecology and obstetrics specialist (associate professor) who did not know which group the participants were in and took part as a researcher in this study. All NST traces were evaluated simultaneously. The same numbers on the NST traces were marked on the NST findings information form and the results were recorded on the form after the NST traces were evaluated.

ETHICAL APPROVAL

Approval for the research from the Clinical Research Ethics Committee of Yozgat Bozok University (Decision No: 2017-KAEK-189_2021.09.22_01) and written permission were obtained from the hospital where the research was carried out for the pre-application and application. An informed voluntary consent form was received from the participants. The research was done in accordance with the principles of the Declaration of Helsinki.

RESULTS

The distribution of participants in the groups with regard to age, working status, and job/occupation was statistically similar ($p>0.05$). There was a difference between the groups according to the educational status. While 41.9% of the participants with a Bachelor's degree were in the N95 mask group, 13.3% were in the single surgical mask group. According to their bachelor graduation status, the number of participants in the N95 mask group was higher than the participants in the single surgical mask group ($p<0.05$) (Table 1).

The distribution of the participants in the groups in terms of the gestational week, the number of pregnancies and miscarriages, and the number of living children was not different ($p>0.05$) (Table 2).

Systolic blood pressures of participants before NST were similar between groups ($p>0.05$). In the measurements after NST, the systolic blood pressure of the double surgical mask group was lower ($p<0.05$). In the within groups, the systolic blood pressures of the groups before and after the NST did not change ($p>0.05$). Diastolic blood pressure before and after NST was lower in the double surgical mask

TABLE 1: Comparison of socio-demographic characteristics by groups.

Characteristics	Groups: Single surgical mask (n=30)	Double surgical mask (n=30)	N95 mask (n=31)	Test statistics: Test value	p value
Age Median (minimum-maximum)	26 (21-37)	27 (19-37)	28 (19-40)	H=0.462	0.794
	n (%)	n (%)	n (%)		
Educational status					
Illiterate	1 (3.3)	0 (0.0)	0 (0.0)	χ^2=19.066	**0.027**
Primary school	3 (10.0)	5 (16.7)	8 (25.8)		
Secondary school	10 (33.3)	4 (13.3)	4 (12.9)		
High school	7 (23.4)	10 (33.3)	6 (19.4)		
Associate degree	5 (16.7)	3 (10.0)	0 (0.0)		
Bachelor's degree	4 (13.3)[a]	8 (26.7)[ab]	13 (41.9)[b]		
Working status					
Yes	4 (13.3)	4 (13.3)	5 (16.1)	χ^2=0.130	0.999
No	26 (86.7)	26 (86.7)	26 (83.9)		
Job/occupation					
Employee	3 (10.0)	1 (3.3)	2 (6.4)	χ^2=2.139	0.753
Officer	1 (3.3)	3 (10.0)	3 (9.7)		
Unpaid family worker	26 (86.7)	26 (86.7)	26 (83.9)		

H: Kruskal-Wallis test; χ^2: Chi-square test, superscripts a and b indicate the difference between groups in the same row. There is no statistical difference between groups with the same superscripts.

TABLE 2: Comparison of obstetric characteristics by groups.

Characteristics	Groups: Single surgical mask (n=30) Median (minimum-maximum)	Double surgical mask (n=30) Median (minimum-maximum)	N95 mask (n=31) Median (minimum-maximum)	Test statistics: Test value	p value
Gestational week	37.5 (37-40)	37 (36-39)	37 (37-40)	H=3.095	0.213
Number of pregnancies	2 (1-6)	2 (1-6)	2 (1-6)	H=0.153	0.926
Number of living children	1 (0-3)	1 (0-3)	1 (0-3)	H=0.214	0.898
Number of miscarriage	0 (0-4)	0 (0-3)	0 (0-3)	H=0.316	0.854

H: Kruskal-Wallis test.

group than in the N95 mask group ($p<0.05$). In the within group, the diastolic blood pressures of the groups were similar before and after the NST. The respiratory rate before and after NST was similar between groups ($p>0.05$). In the within groups, the respiratory rate decreased in the N95 mask group ($p<0.05$). Moreover, SpO_2, pulse before and after NST were similar between groups and within group ($p>0.05$) (Table 3).

The median values of fetal heart rate, acceleration, deceleration and contractions showed a similar distribution between the groups ($p>0.05$). The presence of variability was 100.0% in all groups. Groups did not change according to their reactivity and non-reactivity status ($p>0.05$) (Table 4).

DISCUSSION

The results obtained from this research were discussed below in line with the literature. Different face masks can have some effects on human physiology and affect normal physiological parameters in their body.[23-25] In this study, in which different masks were used, it was determined that systolic blood pressure did not differ between groups before NST. However, after NST, the double surgical mask group was statistically lower. Diastolic blood pressure before and after NST in the double surgical mask group was found to be statistically lower than those in the N95 mask group. It was determined that the systolic and diastolic blood pressures before and after NST did

TABLE 3: Comparison of before NST and after NST vital signs by groups.*

	Groups				
	Single surgical mask (n=30)	Double surgical mask (n=30)	N95 mask (n=31)	Test statistics†	
Characteristics	X̄±SD	X̄±SD	X̄±SD	F	p value
Systolic blood pressure					
Before	108.66±13.82	102.66±8.27	108.38±10.03	2.882	0.061
After	108.33±12.05[a]	101.33±9.37[b]	108.06±11.08[a]	3.994	**0.022**
Difference	0.33±13.76	1.33±9.73	0.32±7.52	0.090	0.914
Test statistics‡	F=0.030; p=0.864	F=0.472; p=0.494	F=0.029; p=0.866		
Diastolic blood pressure					
Before	69.33±10.48[ab]	65.00±7.76[a]	71.61±9.69[b]	3.890	**0.024**
After	68.00±12.14[ab]	64.00±7.70[a]	72.58±11.53[b]	4.459	**0.009**
Difference	1.33±13.32	1.00±9.94	-0.96±9.07	0.398	0.673
Test statistics‡	F=0.448; p=0.505	F=0.252; p=0.617	F=0.244; p=0.623		
Respiratory rate					
Before	20.26±2.18	19.63±1.03	19.83±1.36	1.226	0.298
After	19.86±1.67	19.63±1.35	19.19±1.35	1.661	0.196
Difference	0.40±2.38	0.00±1.17	0.64±1.31	1.107	0.335
Test statistics‡	F=1.648; p=0.203	F=0.001; p>0.999	F=4.430; **p=0.038**		
SpO_2 saturation					
Before	97.26±1.01	97.16±1.20	96.93±0.81	0.846	0.433
After	97.20±0.84	97.46±1.16	96.96±0.91	1.961	0.147
Difference	0.06±1.20	-0.30±1.57	-0.03±0.87	0.694	0.502
Test statistics‡	F=0.086; p=0.771	F=1.733; p=0.191	F=0.021; p=0.886		
Pulse					
Before	97.20±12.19	96.46±13.46	96.74±12.12	0.026	0.974
After	97.53±13.25	97.90±11.80	94.61±10.30	0.710	0.494
Difference	-0.33±9.86	-1.43±13.5	2.12±9.95	0.807	0.450
Test statistics‡	F=0.026; p=0.871	F=0.488; p=0.486	F=1.113; p=0.294		

*Two-way analysis of variance in repeated measurements; †Intergroup comparisons at each measurement time; ‡Comparisons between within-group measures in each group, superscripts a and b indicate the difference between groups in the same row. There is no statistical difference between groups with the same superscripts; NST: Non-stress test; X̄: mean; SD: Standard deviation.

TABLE 4: Comparison of NST parameters by groups.

	Groups				
	Single surgical mask (n=30)	Double surgical mask (n=30)	N95 mask (n=31)	Test statistics	
Characteristics	Median (minimum-maximum)	Median (minimum-maximum)	Median (minimum-maximum)	Test value	p value
Fetal heart rate	130 (110-150)	130 (120-145)	130 (115-150)	H=0.918	0.632
Number of accelerations	3 (0-10)	3 (0-14)	5 (0-13)	H=2.937	0.230
Number of decelerations	0 (0-3)	0 (0-1)	0 (0-3)	H=1.904	0.386
Number of contractions	0 (0-3)	0 (0-3)	0 (0-3)	H=0.863	0.649
	n (%)	n (%)	n (%)		
Variability					
Yes	30 (100.0)	30 (100.0)	31 (100.0)	-	-
No	0 (0.0)	0 (0.0)	0 (0.0)		
NST result					
Reactive	28 (93.3)	26 (86.7)	25 (80.6)	χ^2=2.145	0.378
Non-reactive	2 (6.7)	4 (13.3)	6 (19.4)		

H: Kruskal-Wallis test; χ^2: Chi-square test; NST: Non-stress test.

not differ in the within groups. While the respiratory rate was similar between the groups before and after NST, it was determined that the change within the group showed a statistical decrease in the N95 mask group. Besides, there were similar the between and within groups in SpO_2 and pulse before and after NST. In line with these results, the hypothesis of *"Different masks (single surgical mask, double surgical mask, N95 mask) affect the vital signs of the pregnant woman*" has not been fully confirmed. Because there was no change in some vital signs. In the study conducted by Toprak and Bulut in which they examined the effects of masks used by term pregnant women during the COVID-19 process, it was found that the oxygen saturation values of the participants in the N95 mask group were statistically lower and the pulse was higher than the participants in the single surgical mask group. In addition, in the same study, no difference was found between participants in the single surgical mask and N95 mask group with regard to respiratory rate and systolic/diastolic blood pressure. Within the group, the pulse and oxygen saturation of the participants in the single surgical mask group decreased statistically. On the other hand, it was determined that the respiratory rate and pulse increased and the oxygen saturation decreased statistically in the participants in the N95 mask group.[17] The study carried out has similar features with the results of some findings of this study. In similar research conducted by Isikalan et al. on the use of masks by term pregnant women during the COVID-19 process, it was determined that systolic/diastolic blood pressure, pulse, oxygen saturation, and respiratory rate did not differ statistically between participants in the single and double surgical mask groups. Within the group, it was found that there was no difference in these findings in the participants in the single surgical mask group, and only statistically decreased oxygen saturation among these findings in the participants in the double surgical mask group.[18] The study carried out has similar features with the consequence of some findings of this research.

It is reported in the literature that NST parameters can be affected by many different situations or methods.[26-30] In this study, the effect of different masks on NST parameters was evaluated. It was found that participants in the single and double surgical mask and N95 mask groups were similar with regard to fetal heart rate, acceleration, variability, deceleration, contraction, reactivity/non-reactivity. This result shows that the use of different masks has no effect on NST during the mask-wearing period in this study. In line with these results, the hypothesis of *"Different masks (single surgical mask, double surgical mask, N95 mask) affect NST parameters"* was rejected. The result of this research is thought to be valuable in terms of being a source for the literature because no research has been found that examines the effect of different masks on NST parameters. However, in support of this research, in a different study from this research topic, in a research conducted by Roberge et al. on the evaluation of fetal well-being, it was found that wearing N95 masks by pregnant women did not affect fetal heart rate, similar to this study.[31]

LIMITATIONS OF THE STUDY

The limitation of this study is that face masks were given to the participants 30 minutes in advance and that no control group could be obtained due to COVID-19.

CONCLUSION

Systolic blood pressure was low among participants in the double surgical mask group. Diastolic blood pressure in the participants in the double surgical mask group was lower than the participants in the N95 mask group. Furthermore, the respiratory rate reduced in the participants in the N95 mask group, within the group. However, it is difficult to say that these statistically significant results were clinically significant. In addition, the use of different masks did not have any effect on the NST parameters during the mask usage time in the study.

RECOMMENDATIONS

It may be recommended to conduct similar studies using a control group. In addition, studies evaluating the effects of different masks on pregnant women with risky pregnancies or during physical activity can be planned. In addition, different measurement tools that evaluate fetal well-being can be used in similar studies.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Yeter Şener;* ***Design:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy, Demet Aydogan Kırmızı;* ***Control/Supervision:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy, Demet Aydogan Kırmızı;* ***Data Collection and/or Processing:*** *Yeter Şener, Rukiye Höbek Akarsu, Demet Aydogan Kırmızı;* ***Analysis and/or Interpretation:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy;* ***Literature Review:*** *Yeter Şener, Rukiye Höbek Akarsu;* ***Writing the Article:*** *Yeter Şener, Rukiye Höbek Akarsu;* ***Critical Review:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy, Demet Aydogan Kırmızı;* ***References and Fundings:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy, Demet Aydogan Kırmızı;* ***Materials:*** *Yeter Şener, Rukiye Höbek Akarsu, Hüseyin Aksoy, Demet Aydogan Kırmızı.*

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