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Original Article

Evaluation of Filtration Efficiency and Inhalation Airflow Resistance of Uncertified Masks in Asian Countries

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ABSTRACT

Background: During the coronavirus pandemic, masks played a critical role in preventing respiratory infections. While the performance of masks such as KF-certified masks and N95 masks was evaluated and managed by the authorities, the performance of common masks was not.

Objectives: This study aimed to evaluate the performance of uncertified masks in four Asian countries against certification standards (Korean KF80, KF94, and US N95).

Methods: Thirty uncertified mask products from Indonesia, 20 from South Korea, 26 from Taiwan, and 30 from Thailand were purchased to perform performance evaluations. The uncertified masks included disposable dental masks, cloth masks, and children's masks. Filtration efficiency and inhalation airflow resistance tests were conducted according to Korean KF80, KF94, and US N95 protocols.

Results: None of the 106 identified masks complied with the KF94 standard. A few complied with the KF80 standard: four from Indonesia, four from South Korea, 13 from Taiwan, and 16 from Thailand. Some of the masks met the N95 standard: one from Indonesia, three from South Korea, two from Taiwan, and one from Thailand.

Conclusions: Since many uncertified masks did not comply with performance standards, wearing them might not have provided sufficient protection. Performance of uncertified masks could provide critical information for next pandemic management.

Key words: Mask, filtration efficiency, inhalation airflow resistance, KF-certification, N95

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Highlights:
- Evaluated 106 uncertified masks from Indonesia, Korea, Taiwan, and Thailand against standards.
- None of the uncertified masks met the KF94 standard across all countries.
- Many uncertified masks used during the pandemic did not provide sufficient protection.

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I. Introduction

Face masks have been used as the primary tool to prevent the transmission of respiratory infections. Masks are widely recognized for their crucial role in preventing the transmission of viruses by impeding the spread of respiratory droplets. Health authorities, including the Centers for Disease Control and Prevention, advocate the use of respirators and masks to block droplet transmission and safeguard against airborne hazards, such as infectious respiratory diseases.[1)] During past respiratory pandemics, the use of masks was often recommended to help prevent the spread of infections.[2)] This shows the importance of masks in public health strategies to control the spread of viruses.

During past pandemics, authorities often recommended the use of certified masks. During the coronavirus disease pandemic, healthcare workers and vulnerable populations were provided with certified masks to ensure safety and effective protection. By contrast, the general public often relied on uncertified masks due to shortages of certified masks and distribution priorities.[3] In 2020, the Korean government issued guidelines on mask usage due to shortages. They recommended that individuals with respiratory symptoms wear KF80 or higher-grade masks and advised healthy people to use cloth masks or other materials that can block droplets.[4] Health authorities compared the effectiveness of these masks. They described certified masks as providing protection against particles, whereas they cautioned that uncertified masks might not filter small particles effectively.[5]

Certified masks are tested for essential performance factors, such as filtration efficiency and facial inhalation resistance. The primary certification method considered in Korea is the KF certification managed by the Ministry of Food and Drug Safety (MFDS). Korea's certification for medical masks, such as KF94 and KF80, indicates the masks' ability to filter out 94% and 80% of particulate matter, respectively. These masks are specifically tested for their ability to block fine dust and other particulates.[6] In the United States, masks are certified by the National Institute for Occupational Safety and Health (NIOSH). This certification, though primarily used for industrial purposes, is also widely considered appropriate for medical use. The N95 designation means that the mask filters at least 95% of airborne particles. N95 certifications test filtration efficiency for both oil and non-oil particles.[7] These certification standards not only evaluate particle filtration efficiency but also consider breathability, chemical safety, face fit, and structural integrity to comprehensively assess and certify the masks. Therefore, masks that meet these certifications are guaranteed to be suitable for use in medical, industrial, and public health applications.

During the coronavirus disease pandemic, consumers in many Asian countries often used uncertified masks. However, their performance and protection cannot be guaranteed owing to the lack of testing. In Korea, uncertified masks, such as anti-droplet, surgical,[6] cloth, and disposable masks,[8] are not required to undergo all performance tests, though they must meet basic safety standards. Uncertified masks are frequently used to prevent the transmission of respiratory diseases despite the lack of clear evidence of their filtration efficiencies.[4] This knowledge gap in mask performance highlights the need for comprehensive performance evaluations to ensure that uncertified masks can effectively block harmful particles and provide protection comparable to that of certified masks.

The objective of this study was to confirm the protective effectiveness of uncertified masks by examining the particle filtration efficiency and inhalation airflow resistance to assess the performance of uncertified masks, comparing them against the certification standards of certified masks. To achieve this, uncertified masks from four countries were collected and their performance was tested and evaluated according to the certification standards of Korean KF and NIOSH N95 methods. This comparison aims to provide information on the use of uncertified masks for respiratory protection.

II. Materials and Methods

1. Sample selection

Researchers collected uncertified masks from Korea, Indonesia, Taiwan, and Thailand. The uncertified masks were conveniently sampled, and their types, number of layers, shapes, and manufacturers were recorded. In each country, masks were purchased from online sources or retail stores: 20 from Korea, 30 from Indonesia, 26 from Taiwan, and 30 from Thailand. Thirty samples were obtained from each product for repeated tests.

2. Performance evaluation

The masks were evaluated according to the Guide to Standards and Specifications for Medical Masks[9] and NIOSH (NIOSH 42 CFR 84) standards.[7] To compare uncertified masks with KF94 and KF80 masks, filtration efficiency tests

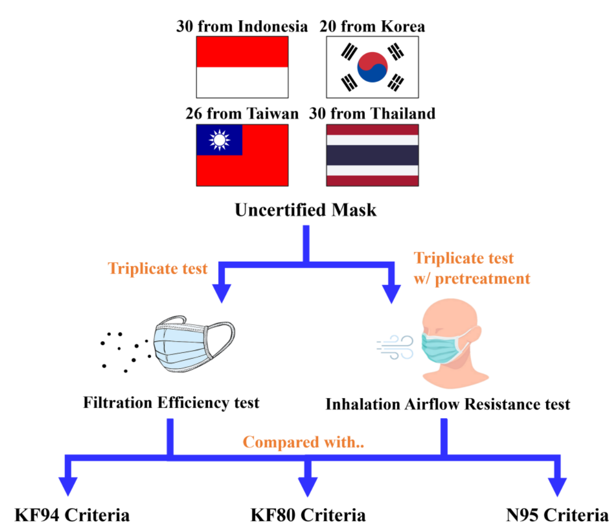

Fig. 1. The scheme of evaluations in this study

and inhalation airflow resistance tests using sodium chloride and paraffin aerosols based on MFDS protocols were conducted. For comparison with the N95 standards, the NIOSH certification requirements for sodium chloride aerosol filtration efficiency and inhalation airflow resistance tests were followed. Each mask was tested thrice for each test method. The schemes for these methods are illustrated in Fig. 1.

2.1. Filtration efficiency test

The filtration efficiency of the masks was tested against sodium chloride particulate aerosols and paraffin oil aerosols using an Automated Filter Tester 8130A (TSI). The tests followed the medical mask certification methods of the Korean MFDS for KF94 and KF80 and the NIOSH certification methods for N95 respirators. For KF94 certification, the tests involved sodium chloride aerosol and paraffin oil, which are influenced by electrostatic charge and not influenced by electrostatic charge, respectively. Meanwhile, NIOSH's N95 method specifies testing with an electrostatically neutralized sodium chloride aerosol.

Three samples per mask type were tested three times without pretreatment, and three samples with pretreatment were tested. Aerosols were generated from a 1 % NaCl solution using salt aerosol generators (8118A and 8118A-EN; TSI, USA). The average concentration of the aerosol was 8±4 mg/m^3, and the pump flow rate was set at 95 L/min. The filtration efficiency was determined by measuring the aerosol concentration before and after mask penetration using the following formula:

$$F\,(\%) = \frac{C_1 - C_2}{C_2} \times 100$$

where F is the filtration efficiency, C_1 is the concentration before the mask, and C_2 is the concentration after the mask.

The same process was applied to the three untreated and three pretreated masks using paraffin oil. Aerosols were generated from paraffin oil using oil generators (1081414R-EN; TSI, USA). The concentration of the aerosol was 20±5 mg/m^3, and the flow rate was set to 95 L/min.

For the NIOSH N95 respirator certification method, aerosols were generated using a 2% NaCl solution with a salt aerosol generator. The flow rate was adjusted to 85±4 L/min, and the concentration was set to not exceed 200 mg/m^3 before measuring the mask's filtration efficiency.

2.2. Inhalation airflow resistance test

The inhalation airflow resistance of the uncertified masks was assessed with the Mask Inhalation Resistance Tester ARE-1651 (ARTPlus). This evaluation followed the medical mask certification protocols established by the Korean MFDS and the NIOSH respirator certification methods. Three untreated and three pretreated samples were tested.

The MFDS method requires the measurement of the pressure drop by passing air through a mask fitted on a test mannequin. The NIOSH test also requires measurement of the pressure drop by ensuring a complete seal of the mask on a testing apparatus that provides a continuous airflow. The facepiece of the specimens was fitted on a headform, with the airflow set to 30 L/min according to the MFDS method and 85±2 L/min according to the NIOSH method. The differential pressure was measured for 1 min, and the average value of the measurements taken during that minute was used as the result for each sample.

2.3. Pretreatment of mask samples

For the performance evaluation after pretreatment, as required by the medical mask certification protocol of the KFDS, the samples were maintained in a constant temperature and humidity chamber (TH3-ME-100, Jeio Tech). The conditions were 38±2.5°C and 85±5% RH for 24±1 hours. Pretreated samples were tested in triplicate for each test method.

3. Data analysis

The filtration efficiency and inhalation airflow resistance of each mask type were measured six times, and the results are presented as arithmetic mean values. For comparison with certification standards, the smallest value of the filtration efficiency measurements was chosen as the representative value, and the largest value of the breathing resistance measurements was selected as the representative value. The Kruskal-Wallis test and Dunn's post hoc test were performed to compare the results based on the characteristics of the masks. Statistically significance was set at $p < 0.01$. All analyses and graphs creations were performed using Excel for Windows 2019 (Microsoft, Washington, USA) and Rex software (version 3.3.1.1; Rexsoft, Co. Ltd., Seoul, KR), an R-based statistical analysis program.

III. Results

1. Characteristics of collected uncertified masks

The Korean samples consisted of three anti-droplet type masks, three children's masks, three cotton type masks, three disposable dental type masks, and eight fashion-type masks. The Indonesian samples consisted of three imported certified masks, 11 cotton-type masks, and 16 disposable dental-type masks. The Taiwanese samples consisted of seven children's masks, four cotton-type masks, and 15 disposable dental-type masks. The Thailand samples consisted of 25 disposable dental-type masks, two children's masks, and three cotton-type masks. These differences among countries were due to convenience sampling, which reflects the market share.

Overall, the different types of masks collected, without being distinguished by country, included three anti-droplet-type masks, 12 children's masks, three imported certified masks, 17 cotton-type masks, 59 disposable dental-type masks, and 12 fashion-type masks. Among the 106 products collected, the majority (70) had three layers. There were nine single-layer masks, 15 double-layer masks, 11 four-layer masks, and one five-layer mask. The masks also varied in shape, including conical, pleated, flat, and trifolded. The most common shape was pleated (57 masks), followed by cone-shaped (31 masks), trifold-shaped (10 masks), and flat masks (eight masks).

2. Filtration efficiency and inhalation airflow resistance of uncertified masks

The filtration efficiencies and inhalation airflow resistances are listed in Table 1. According to the MFDS certification method using NaCl aerosol, the average particle filtration efficiency was 67.54%. When paraffin aerosols were used for testing, the average filtration efficiency was 66.40%; when the NIOSH method was used, the average filtration efficiency was 67.46%. The differences in the results obtained using each test method were not statistically significant. Upon examining the results by mask type, cotton-type and fashion-type masks exhibited relatively lower filtration efficiency than that of other

Table 1. Filtration efficiency and inhalation airflow resistance of uncertified masks by their characteristics

Evaluation method		Filtration efficiency (%)			Inhalation airflow resistance (Pa)	
		Mean±SD			Mean±SD	
Statistics	n	KFDS: NaCl	KFDS: paraffin	NIOSH: NaCl	KFDS	NIOSH
Total	106	67.54±25.42	66.40±22.80	67.46±25.11	37.27±25.77	126.18±82.37
Mask types						
Anti-droplet*	3	82.64±5.51	66.74±6.36	83.16±2.81	15.73±3.04	54.58±18.26
Children's	12	86.46±6.54	84.43±5.99	86.56±6.21	39.57±21.77	116.43±80.79
Certified†	3	77.83±16.64	69.71±5.90	81.87±14.73	32.34±5.98	115.97±43.26
Cotton	17	44.33±22.20	45.41±21.36	43.65±21.84	49.43±44.70	166.84±123.13
Disposable dental	59	76.65±18.21	75.24±16.53	76.15±18.41	35.20±19.07	121.93±67.87
Fashion	12	30.33±18.25	33.72±13.72	31.80±16.44	34.52±25.21	119.67±85.26
# of layers						
1	9	18.19±10.98	22.86±8.69	20.12±11.56	29.06±23.73	113.03±93.94
2	15	51.47±20.92	49.45±17.28	50.76±21.14	37.14±27.80	134.69±106.89
3	70	75.49±19.52	74.10±17.57	75.50±19.30	36.35±24.82	121.79±75.66
4	11	79.83±15.84	76.09±14.04	77.79±17.71	49.93±30.77	149.68±86.74
5	1	60.76	66.70	66.87	38.01	165.91
Shape of mask						
Cone	31	47.50±25.27	48.16±22.21	47.20±24.93	51.00±38.59	162.29±104.78
Flat	8	57.25±30.76	54.40±27.89	54.31±30.07	41.81±28.37	150.56±112.93
Pleated	57	77.83±18.99	76.71±16.21	78.40±17.73	30.27±10.43	107.95±51.19
Trifold	10	79.24±11.35	73.75±13.27	78.40±12.92	30.97±21.46	98.64±91.50

*Anti-droplet masks are distributed only in Korea.
†Certified masks refer to those imported into Indonesia after performance certification from foreign countries.

types of masks. Regarding the number of layers of the masks, those with three or four layers demonstrated relatively higher filtration efficiency compared to masks with only single or double layers. When evaluating the shape of the masks, cone-shaped masks showed lower filtration efficiency than that of pleated and trifold-shaped masks.

The average inhalation airflow resistance was 37.27 Pa and 126.18 Pa using the KFDS method and the NIOSH method, respectively. The differences in inhalation airflow resistance based on the type of mask or number of layers within the mask were not significant. However, regarding the shape of the masks, tests conducted using the KFDS method revealed that pleated masks showed relatively lower resistance compared with that of cone-shaped masks.

3. Comparison between certified standards and the performances of uncertified masks

In terms of the MFDS's KF94 criteria, none of the masks met the certification standards. Most uncertified masks did not achieve the filtration efficiency required by the KF94 standard (Fig. 2a). A total of 37 masks met the KF80 standard (Fig. 2b). Among them, there were four masks from Indonesia, four from Korea, 13 from Taiwan, and 16 from Thailand. In terms of the NIOSH N95 criteria, seven masks satisfied the certification standards (Fig. 2c). Among them, one mask was from Indonesia, three from Korea, two from Taiwan, and one from Thailand. For uncertified masks from Thailand and Taiwan, there were many instances where the masks, despite having lower filtration efficiency than that of the certification standards, met the inhalation airflow resistance criteria. By contrast, uncertified masks from Indonesia and Korea often exceeded the inhalation airflow resistance standards.

Regarding the compliance of the different mask types with certification standards, no masks met the KF94 criteria. For the KF80 standard, two out of three anti-droplet masks met the criteria, as did seven out of 12 children's masks, one out of three imported certified masks, and 27 out of 59 disposable dental masks. However, none of the 17 cotton-type masks and 12 fashion-type masks. In terms of the N95 standard, none of the three anti-droplet masks met the criteria, whereas two out of 12 children's masks, one out of three imported certified masks, one out of 17 cotton type masks, three out of 59 disposable dental masks, and none of the 12 fashion-type masks met the standard.

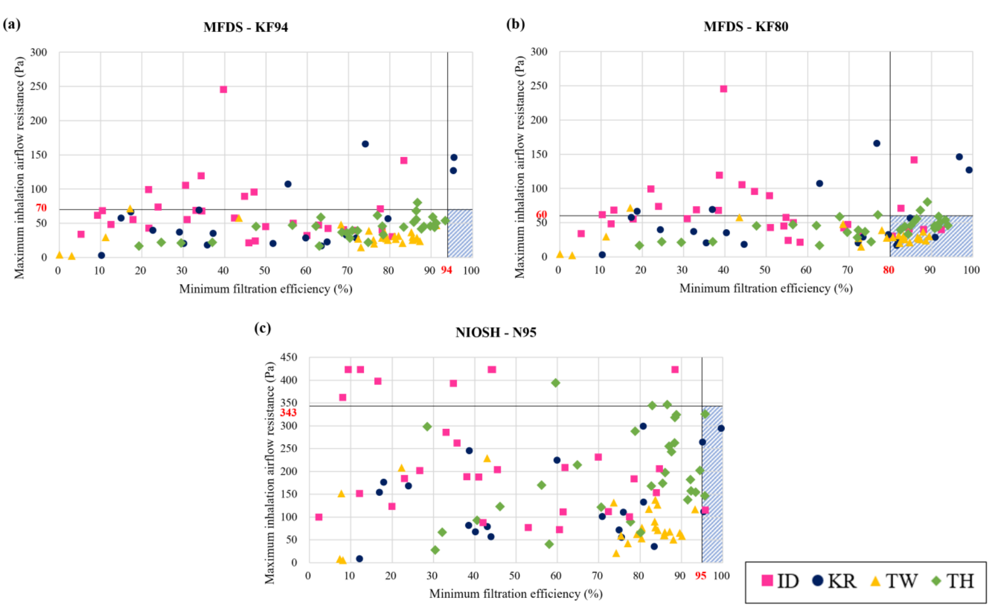

Fig. 2. Comparisons of filtration efficiency and inhalation airflow resistance limits for each protocol by country. (a) Results using the MFDS protocol and comparison with KF94 standards. (b) Results using the MFDS protocol and comparison with KF80 standards. (c) Results using the NIOSH protocol and comparison with N95 standards. ID means masks from Indonesia, KR means masks from Korea, TW means masks from Taiwan, and TH means masks from Thailand. MFDS: Ministry of Food and Drug Safety.
*The horizontal line represents the inhalation resistance limit and the vertical line represents the filtration efficiency limit for each certification. The blue area (the 4th quadrant) contains masks that complied with the standards.

IV. Discussion

This study examined the performance of uncertified masks from four Asian countries, revealing variations in particle filtration efficiency and inhalation airflow resistance across different types, layers, and shapes of masks. A significant number of mask samples did not meet the certification standards. More masks failed to meet the filtration efficiency standards than the inhalation airflow resistance standards. This indicates that many uncertified masks may offer good breathability, but their ability to block particles or viruses is inadequate.

Our study found that cotton-type and fashion-type masks exhibited relatively lower filtration efficiencies than those of other types of masks. Studies have reported similar findings for uncertified masks. Segovia et al. evaluated the filtration efficiency and pressure drop of surgical masks, cloth masks, and various fabrics. They found that uncertified masks, excluding surgical masks, had filtration efficiencies below 25%. Additionally, these uncertified masks had relatively lower inhalation airflow resistances than those of certified masks, indicating better breathability but lower protective performance.[10) Another study compared homemade double-layered cloth masks with certified masks and found filtration efficiencies ranging from 40% to 66%.[11)] These results highlight the variability and often inadequate performance of uncertified masks, emphasizing the need for thorough evaluations to inform public health recommendations and personal protective equipment choices.

A comparison of the masks based on the number of layers showed that masks with three or four layers had relatively higher filtration efficiency than that of masks with only single or double layers. In a previous study, it was observed that masks with double layers had significantly higher filtration efficiency than that of masks with a single layer, and masks with three layers showed even greater efficiency.[12)] Similarly, Konda et al. demonstrated that the filtration efficiency of masks increases with the number of layers.[13)] The increased filtration efficiency with additional layers is likely due to the enhanced barrier provided against particulate matter. In general, electrostatic forces are used to compensate for the insufficient barrier effect of masks with fewer layers.[14)] This study used both electrostatically charged and non-electrostatically charged aerosols, and the results showed that filtration efficiency varied with the number of mask layers in both cases.

The limitation of this study is that the selection of masks across different countries was not entirely fair. This could introduce bias, but also reflects the local market conditions and consumer preferences, as the masks were chosen by researchers familiar with each country's market. These findings provide valuable insights into the real-world performance of the masks available to consumers in these regions.

V. Conclusion

This study evaluated the performance of uncertified masks in Korea, Indonesia, Taiwan, and Thailand against certification standards. None of the 106 identified masks met the KF94 standard, and only a few complied with the KF80 or N95 standards. The study found that the mask efficiency varied depending on the type of fabric and number of layers. In general, masks with more layers performed better than those with fewer layers in terms of filtration efficiency. The performance test results revealed that many uncertified masks were significantly less effective than certified masks in preventing respiratory infections. Therefore, it is recommended to use certified masks to ensure sufficient protection against respiratory infections.

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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