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Simulated workplace protection factors for respirators with N95 or higher filters for health care providers in an emergency medical centre: A randomized crossover study

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Abstract

Introduction: Health care providers in emergency medical centres often encounter infected sources during medical procedures; these sources can generate droplets. Wearing respirators could help to protect against infection risk. However, to the best of our knowledge, no previous study has reported the efficacy of N95 or higher respirators for health care providers in emergency medical centres.

Methods: A randomized, crossover study of 26 health care providers was conducted to examine the protective performance of respirators. Quantitative fit tests with three types of respirators (cup type, fold type without valve and fold type with valve) were performed using seven exercises. Primary outcomes were the fit factors. Secondary outcomes included the percentage of fit factors above 100 and respirator preference.

Results: After excluding one participant, data for 25 participants were analysed. The fit factors and the percentage of fit factors above 100 were higher when participants wore a fold-type respirator (200 fit factors [38.6–200], 100% [0–100]) relative to those for the cup-type respirator (114.0 fit factors [16.0–185.2], 60% [0–100]) and valve-type respirator (84.9 fit factors [14.2–170.8], 23.8 % [0–100]) in normal respiration. There was no clear preference regarding the type of respirator.

Conclusion: The type of respirator could influence protective performance for health care providers. Health care providers in emergency medical centres should be aware of and wear the type of respirator that is well-fitted for them in advance.

Keywords

N95 filtering face-piece respirator, fit factor, emergency medical centre

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Introduction

Emergency medical centres may be the front-line base for confronting risk of exposure to emerging infectious hazards. In South Korea, emergency medical services–related Middle East respiratory syndrome (MERS) coronavirus infections were reported in 91 (49%) of 186 total cases.[1] Emergency medical centres pose an increased infection risk because of the prevalence of the following factors: (1) overcrowding,[2] (2) invasive procedures generating aerosolised droplets,[3–8] (3) inconsistent degrees of knowledge and proficiency about using personal protective equipment such as respirators and (4) functioning as the main route of entry for inpatients with potential infections.[9]

Over the past decade, emergency medical centre crowding has progressed. Consequently, health care providers confront unscreened patients at overcrowded emergency medical centres. Furthermore, health care providers perform invasive procedures generating aerosolized droplets; such procedures include endotracheal intubations or use of a nebulizer. Infected health care providers may then act as the source for infection transmission to many patients in emergency medical centres. Accordingly, health care providers should be knowledgeable regarding and use personal protective equipment such as respirators.

Respirators with N95 or higher filters have been recommended by many health care organizations for various emerging infectious diseases.[10] The National Institute for Occupational Safety and Health (NIOSH) certifies respirators according to filter efficiencies in order to standardize protective performance among various types of respirators.[11] Protection using respirators with N95 or higher filters is dependent on not only filter efficiencies but also on the seal quality. In a clinical study, inward leakage of contaminants due to face seal leakage occurred three to five times more frequently than that due to filter penetration.[12] Current guidelines recommend fit tests that involve either qualitative or quantitative methods for health care providers wearing N95 or higher respirators.

In addition, head movements during procedures could affect respirator fitness due to the relative position change between the respirator and the face surface. To reflect the effect of head movements on respirator fitness, the Occupational Safety and Health Administration (OSHA) respiratory protection regulation recommends a standard eight-exercise procedure in most respirator fit tests.[13] We performed this study to determine the protective performance of N95 or higher filters for health care providers engaged in emergency medical centres seven of the exercise procedures.

Methods

Study design

We conducted a randomized crossover study at Hanyang University Medical Centre in September 2016. The local ethics committee approved this study in January 2016 (HYUH 2015-11-020-004).We registered the study protocol with the Clinical Research Information Service before study initiation (cris.nih.go.kr: PRE20160810-003).

Participants

We recruited health care providers engaged in one tertiary medical centre in August 2016. We included healthy volunteers aged between 16 and 60 years. We excluded subjects who had lung disease (uncontrolled chronic asthma and pneumonia), high blood pressure (i.e. systolic > 160 mm Hg and diastolic > 95 mm Hg) and musculoskeletal disease. All participants signed a written consent form before being included. The sample size was calculated based on a pilot study of eight participants regarding the differences of fit factor between three types of respirators. The mean (standard deviation (SD)) of cup type was 81.01 (36.71), fold type was 102.07 (37.19) and valve type was 48.19(38.86). The estimated sample size was 24 participants (effect size of 0.57, error of 0.05 and power of 0.8) with G-power 3.1.2® programme (Heine Heinrich University, Düsseldorf, Germany). However, 26 participants were enrolled in order to take into consideration a 10% drop-out rate.

Equipments and materials

Three types of N95 or higher respirators were used in this study; (1) cup type which is pre-formed to cup shape (3M 1860 or 3M 1860 S (size small); 3M™, Elyria, OH, USA); (2) fold type which is flexible and free-folded (3M 1870); and (3) valve type which is similar to the fold type with the valve reducing the exhalation resistance (3M 9332). We selected these respirators which were usually used in emergency medical centres when MERS was an epidemic in South Korea. Quantitative fit test of respirators was done using the PortaCount®Plus (TSI, Inc., St. Paul, MN, USA) (Figure 1). This device equipped two sampling tubes. One sampling tube is exposed to atmosphere to measure ambient particles, and the other sampling tube is connected to respirator measuring particles in respirators. The fit factor is calculated using the ratio of measured ambient articles to within respirators. The fit factors were reported out a maximum score of 200 and a fit factor of >100 was defined as passing a quantitative fit test. A tube was supported by a wire hanging around the neck to support the weight of the tube.

Interventions

All participants completed a brief questionnaire consisting of demographic information (age, sex, body weight and height) and prior experiences of donning respirators. A total of 26 participants were enrolled and 1 participant who had complained discomfort on perioral area during study was excluded. Therefore, 25 participants were randomly allocated to three groups according to the type of respirator first worn

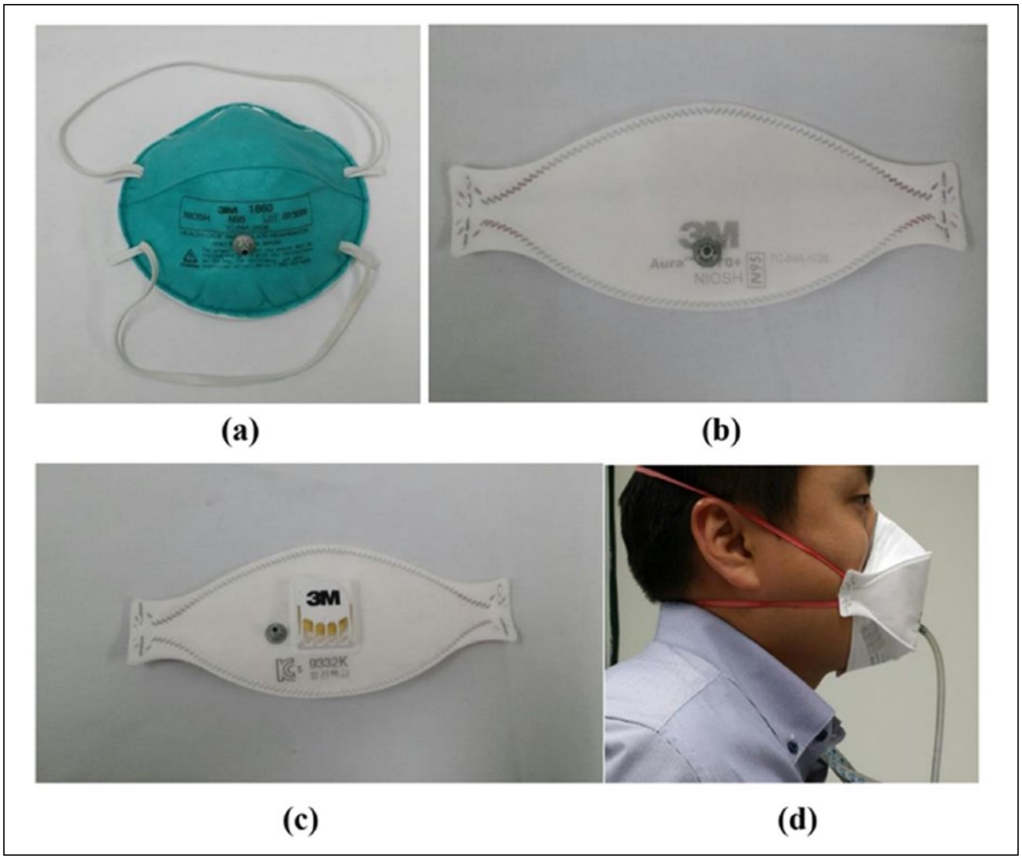

Figure 1. Quantitative fit test was performed using the Porta-Count® Plus device. (a) Cup-type respirator is pre-formed into a cup shape (3M 1860 or 3M 1860S (small)). (b) Fold-type respirator is flexible and free-folded (3M 1870). (c) Valve-type respirator is similar to the fold type and has a valve for reducing exhalation resistance (3M 9332). (d) One sampling tube was connected to the respirator, and the other sampling tube was exposed to the atmosphere.

(www.random.org; Figure 2). All participants were prohibited from smoking, eating, chewing gum and drinking (except for plain water) for at least 30 min before starting the quantitative fit test.[14] This simulation trial was performed in a resuscitation room (24.3 m^3) without operating air-conditioning systems. We used a TSI model 8026 Particle Generator to generate a sodium chloride aerosol to ensure that the ambient air contained at least 100 particles/cc in the proper size range. All participants were given respirators based on their face and lip length measurements as recommended by the NIOSH panel.[15] Fit factors were measured after a user seal check in accordance with the manufacturers' instructions. Fit factors of three types of respirators were measured performing the following seven exercises for 1 min each: (1) normal breathing, (2) deep breathing, (3) moving the head side to side, (4) moving the head up and down, (5) reading the rainbow passage aloud, (6) grimacing and (7) bending at the waist. All participants had about a 2-min break between each test.

Outcomes

Primary outcomes were the fit factors of the three respirators. Secondary outcomes were adequate protection, which was defined as the percentage of fit factor greater than or equal to 100, as this suggests that the respirator provided proper protection,[16–18] the overall fit factor and the preference of respirator. The overall fit factor was calculated from the individual fit factors determined for each test exercise performed by each participant

$$\text{Overall fit factor} = \frac{7}{\frac{1}{FF1}+\frac{1}{FF2}+\frac{1}{FF3}+\frac{1}{FF4}+\frac{1}{FF5}+\frac{1}{FF6}+\frac{1}{FF7}}$$

where FFn is the fit factor of n movement of one participant.

Respirator preference was determined by asking the participants to choose the respirators that would be most favourable when performing intubations with risk of infection.

Statistical analysis

The data were compiled using a standard spreadsheet application (Excel; Microsoft, Redmond, WA, USA) and were analysed using the Statistical Package for the Social Sciences (SPSS) 18.0 KO for Windows (SPSS Inc., Chicago, IL, USA). We generated the descriptive statistics and presented

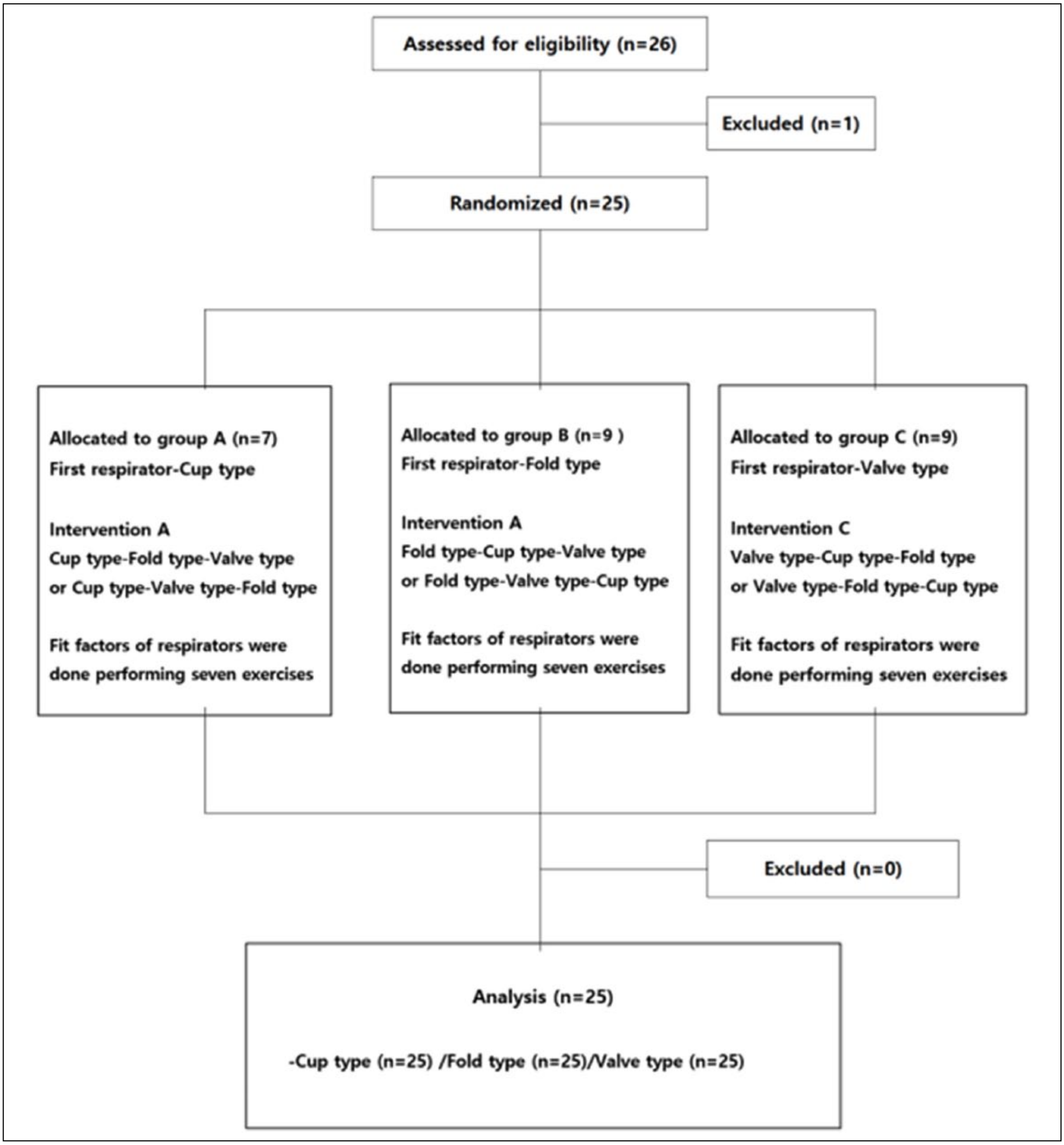

Figure 2. Study flow chart. The cup-type respirator is pre-formed into a cup shape (3M 1860 or 3M 1860 S (small)). The fold-type respirator is flexible and free-folded (3M 1870). The valve-type respirator is similar to the fold type and has a valve for reducing exhalation resistance (3M 9332).

them as frequencies and percentages for categorical data and medians with interquartile ranges for continuous data because the data were not normally distributed. To compare fit factors among the three N95 respirators, the Kruskal–Wallis test was used for continuous variables. A post hoc analysis was conducted using the Mann–Whitney test with a Bonferroni correction. A value of $p<0.05$ was considered significant.

Results

General characteristics

A total of 26 participants were enrolled; 1 participant was excluded because of experiencing discomfort during the fit test. The general characteristics of the participants are shown in Table 1.

NIOSH panel

The mask sizes required for the NIOSH 2 variable panel classification were small (9 participants, 36%), medium (10 participants, 40%) and large (6 participants, 24%). All participants belonged to the NIOSH panel that represents 95% of all workers. Overall, 16 subjects were fitted with the Model 1860 and 9 subjects were fitted with the Model 1860 S.

Fit factors based on the seven exercises

The median fit factor of fold-type respirators was higher than the median fit factor of cup-type and valve-type respirators for all seven exercises (all, $p < 0.05$). There were no significant differences between cup-type and valve-type respirators for all seven exercises (all, $p > 0.05$). The median fit factor during grimacing was lower than that for the other six exercises for all respirators (all, $p < 0.05$). The overall fit factor of fold-type respirators was higher than cup-type and valve-type respirators (both, $p < 0.05$) (Table 2).

Adequate protection during performance of the seven exercises

Adequate protection of fold-type respirators was higher than that for cup-type and valve-type respirators for six exercises with the exception of normal breathing (all, $p < 0.05$). There were no significant differences in adequate protection between cup-type and valve-type respirators for all seven exercises (all, $p > 0.05$). Adequate protection during grimacing was lower than that for the other six exercises for all respirators (all, $p < 0.05$) (Table 3).

Respirator preference

In total, 12 participants (50.0%) preferred the valve-type respirator, 10 participants (43.5 %) preferred the fold-type respirator and the remaining 3 participants (8.7%) preferred the cup-type respirator.

Discussion

Respirators with N95 or higher filters have been recommended to protect health care providers against infection by droplet or aerosol for various infectious diseases.[10,11] However, no studies have provided evidence for the protective performance of respirators for Asian health care providers engaged in emergency centres. This is important, as the degree of face-seal leakages could be influenced by different anatomy of Asian faces.[19] Our simulation study demonstrated that different characteristics of respirators could influence the protective performance for health care providers.

Properties of the different types of respirators may influence the fitness and protective performance of respirators. The shape of the sealing surface in fold- and valve-type respirators is flexible and free-folding, but not in cup-type respirators. This allows users to more easily manipulate the shape of these respirators according to individual face shape. However, a previous study showed no significant difference in the face-seal area between fold- and cup-type respirators.[20] Respirators also have a nosepiece that functions to prevent face-seal leakage in the nasal area, which is the most frequently observed area.[21] In this study, the

Table 1. Demographic characteristics.

Characteristics	
Male sex, n (%)	23 (92)
Female sex, n (%)	2 (8)
Height in cm, median (IQR)	174 (170–180)
Weight in kg, median (IQR)	75 (65–80)
Postgraduate years, median (IQR)	4 (3–7)
Face width in mm, mean (SD)	133.48 (10.63)
Face length in mm, mean (SD)	112.15 (7.86)

IQR: interquartile range; SD: standard deviation.

Table 2. Fit factors during performance of seven exercises.

	Respirator type				Cup type vs fold type	Cup type vs valve type	Fold type vs valve type
	Cup type (n=25)	Fold type (n=25)	Valve type (n=25)	p-value			
Normal breathing	114.1 (16.0–185.2)	200.0 (38.6–200.0)	84.9 (14.2–170.8)	0.001	0.004	0.493	0.031
Deep breathing	77.1 (20.9–177.6)	200.0 (52.0–200.0)	106.8 (13.8–178.8)	0.001	0.001	0.946	0.013
Moving head side to side	108.9 (15.4–148.9)	200.0 (74.7–200.0)	94.4 (13.6–167.7)	<0.001	<0.001	1.000	0.002
Moving head up and down	75.3 (13.1–155.0)	189.4 (51.6–200.0)	66.4 (10.5–132.8)	<0.001	<0.001	0.882	0.004
Reading the rainbow passage aloud	108.2 (37.6–147.9)	192.8 (57.9–200.0)	75.0 (26.2–163.7)	<0.001	<0.001	0.696	0.003
Grimacing	10.4 (5.9–32.4)	26.5 (13.3–119.6)	12.8 (6.0–50.3)	<0.001	<0.001	0.459	0.006
Bending at the waist	58.8 (19.3–115.1)	121.8 (44.2–199.6)	44.2 (11.2–114.5)	0.006	0.001	0.778	0.009
Overall fit factor	35.1 (13.3–78.8)	94.5 (27.3–162.9)	27.1 (13.9–84.8)	<0.001	<0.001	0.904	0.003

Normally distributed variables are reported as mean (standard deviation) and nonparametric variables are reported as median (interquartile range).
Cup type: 3M 1860; fold type: 3M 1870; valve type: 3M 9332.

Table 3. Adequate protection during performing the seven exercises.

	Respirator type				Cup type vs fold type	Cup type vs valve type	Fold type vs valve type
	Cup type (n = 25)	Fold type (n = 25)	Valve type (n = 25)	p-value			
Normal breathing	60.0 (0–100)	100 (0–100)	23.8 (0–100)	0.108	0.017	0.306	0.010
Deep breathing	25.0 (0–100)	100.0 (12.8–100)	36.4 (0–100)	0.001	0.001	0.705	0.009
Moving head side to side	32.0 (0–88.9)	100 (17.9–100)	38.7 (0–98.0)	0.001	0.001	0.877	<0.001
Moving head up and down	16.7 (0–88.0)	100 (0 – 100)	17.9 (0–80.0)	0.009	0.003	0.906	0.029
Reading the rainbow passage aloud	50.0 (0–80.4)	100.0 (3.1–100)	17.1 (0–100)	0.016	0.002	0.709	0.018
Grimacing	0 (0–4.2)	6.9 (0–54.6)	0 (0–5.8)	<0.001	0.001	0.373	0.034
Bending at the waist	10.0 (0–50.8)	57.1 (0 – 100)	0 (0–54.3)	0.019	0.011	0.744	0.022
Overall fit factor	35.1 (13.3–78.8)	94.5 (27.3–162.9)	27.1 (13.9–84.8)	<0.001	<0.001	0.904	0.003

Normally distributed variables are reported as mean (standard deviation) and nonparametric variables are reported as median (interquartile range). Cup type: 3M 1860; fold type: 3M 1870; valve type: 3M 9332. Adequate protection was defined as a fit factor percentage of ≥100.

nosepiece was more freely flexible in fold- and valve-type respirators than in cup-type respirators. The nosepiece flexibility could influence the difference in leakage. Face-piece respirators were equipped with nonadjustable head straps for face sealing. The head strap of cup-type respirators had a greater length, thickness and cross-sectional area than that of fold- and valve-type respirators. Pressure generated by head straps may influence fitness. For instance, Niezoda G. et al showed that fold-type respirators could achieve a similar fit factor compared to cup-type respirators at lower seal pressure generated by head strap.[22] In addition, respirator valves reduce exhalation resistance;[22,23] however, exhalation valves on the N95 respirator did not affect respiratory protection in one study;[24] nonetheless, the presence of an exhalation valve might be a potential site for leakage.[25] These various characteristics of respirators (i.e. shape of respirator's sealing surface, type of nosepiece, head straps and valve reducing the exhalation resistance) could influence the fitness of respirator for the user's face in this study.

If respirator fitness decreases, leakage could occur through three pathways: (1) filter penetration, (2) face-seal leakage or (3) the exhalation valve. A previous study reported that face-seal leakage was the major component of respirator leakage.[21] Furthermore, locomotion of wearers could influence the degree of face-seal leakage. Simulated workplace testing for respirator fitness consists of eight standard exercises[26,27] that consider the usual motions of wearers and could influence face-seal leakage: (1) normal breathing, (2) deep breathing, (3) turning the head side to side, (4) moving the head up and down, (5) talking, (6) grimacing, (7) bending over and (8) normal breathing. In the seven exercises used in this study, fold-type respirators showed higher fit factors and adequate protection than the other two respirators for health care providers who engaged in the Emergency Medical Centre of Hanyang University. However, it could differ for health care providers who engaged in other medical centres. Selecting a better-fitted respirator could decrease the influence of motions on respirator fitness. However, motions performed during clinical procedures may differ from these exercises, and a simulation workplace test reflecting high-risk procedures is needed.

Long-term respirator use is required during outbreaks of emerging infectious diseases and bioterrorism attacks. Rebmann T. et al.[28] reported that long-term respirator use did not result in a clinically relevant physiologic burden for wearers, but wearers reported many subjective symptoms. To increase compliance for wearing respirators, selecting comfortable and preferred respirators is needed.[29,30] Facial seal areas with low pressure leak more easily, whereas facial seal areas with high pressure cause facial discomfort, which could negatively impact compliance.[22,23] In this study, cup-type respirators were more rigid and had higher pressure generated by the head strap than the fold- and valve-type respirators. These characteristics of cup-type respirators could cause facial discomfort and may have resulted in the lower preference for them.

There were several limitations of this study. First, we used three types of medical respirators, which were chosen based on their use during outbreaks of MERS in South Korea. Cup- and fold-type respirators have been certified as N95 filtering face-piece respirators by NIOSH, whereas valve type has been certified as FFP3 by EN 149. Clinical trials using more types of medical respirators are needed to confirm the protective performance of N95 respirators for health care providers engaged in emergency medical centres. Second, health care providers from a single emergency medical centre participated in this study. Health care providers have different experiences and knowledge according to their specific occupation, and only two nurses participated. Thus, clinical trials that also consider specific occupations are needed. Third, we performed quantitative fit tests using seven of the standard eight exercises. However, motions during procedures in medical centres may differ;

accordingly, simulated workplace testing that is more reflective of actual procedures is needed.

In conclusion, types of respirators could influence the protective performance for health care providers engaged in emergency medical centres. Health care providers in emergency medical centres should be knowledgeable regarding and wear the type of respirator that is well fitted for himself or herself in advance.

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Declaration of conflicting interests

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