N95 filtering facepiece respirators do not reliably afford respiratory protection during chest compression: A simulation study

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ABSTRACT

Background: N95 filtering facepiece respirators (N95 respirators) may not provide adequate protection against respiratory infections during chest compression due to inappropriate fitting.
Methods: This was a single-center simulation study performed from December 1, 2016, to December 31, 2016. Each participant underwent quantitative fit test (QNFT) of N95 respirators according to the Occupational Safety and Health Administration protocol. Adequacy of respirator fit was represented by the fit factor (FF), which is calculated as the number of ambient particles divided by the number inside the respirator. We divided all participants into the group that passed the overall fit test but failed at least one individual exercise (partially passed group [PPG]) and the group that passed all exercises (all passed group [APG]). Then, the participants performed three sessions of continuous chest compressions, each with a duration of 2 min, while undergoing real-time fit testing. The primary outcome was any failure (FF < 100) of the fit test during the three bouts of chest compression.
Results: Forty-four participants passed the QNFT. Overall, 73% (n = 32) of the participants failed at least one of the three sessions of chest compression; the number of participants who failed was significantly higher in the PPG than in the APG (94% vs. 61%; p = 0.02). Approximately 18% (n = 8) of the participants experienced mask fit failures, such as strap slipping.
Conclusions: Even if the participants passed the QNFT, the N95 respirator did not provide adequate protection against respiratory infections during chest compression.

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1. Introduction

Emergency departments (EDs), the principal portals of entry into healthcare systems, are increasingly required to screen and treat patients with communicable infections [1,2]. In 2015, a large outbreak of Middle East respiratory syndrome (MERS) coronavirus infection occurred after exposure to a single patient in an over-crowded ED of a hospital in South Korea; several individuals, including healthcare workers (HCWs), were infected [3,4]. The World Health Organization and the U.S. Centers for Disease Control and Prevention recommend that HCWs must use a particulate fil-tering facepiece respirator that is at least as protective as the

National Institute for Occupational Safety and Health (NIOSH)-certified N95 filtering facepiece respirator (N95 respirator) or its equivalent when treating patients with airborne infectious dis-eases [5,6]. However, such facepiece respirators can provide pro-tection only when the face seal fits tightly. Therefore, fit testing is essential; a qualitative or quantitative approach must be used to identify respirators that best suit each individual [7,8].

The quantitative fit test (QNFT) objectively determines the ade-quacy of respirator fit by measuring leakage around the face seal using the respirator fit tester [9,10]. This device measures the fit factor (FF) (the number of ambient particles divided by the number inside the respirator when simulating eight workplace activities). An overall FF ≥100 is considered the passing level [9]. However, although the overall FF may be ≥100, the FFs for individual exer-cises may be <100 (for example, during bending).

Cardiopulmonary resuscitation (CPR), a common ED procedure, generates infectious aerosols, and this is associated with an

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increased risk of pathogen transmission to HCWs [11,12]. Some exercises for the conventional QNFT mimic chest compression, which include bending at the waist and head up-and-down movement [9]. However, chest compression during CPR is significantly more dynamic and rapid than QNFT exercises. Therefore, it is unclear whether the protective effects of the N95 respirators will be maintained during chest compression particularly in those who failed at least one individual conventional QNFT exercise. Previously, Shin et al. have evaluated the effects of movements during chest compression on the protective performances of various N95 respirators in the simulated setting [13]. They demonstrated that the FFs of certain respirators decreased during chest compression, thereby seriously compromising respiratory performance.

No study has yet explored the stability of N95 respirators in a group that only partially 'passed' the QNFT. Thus, we compared the respirator failure (FF < 100) rates during chest compression between a partially passed group (the overall fit factor was adequate, but at least one specific exercise was failed; the PPG) and an all passed group (group that passed all exercises: the APG).

2. Methods

2.1. Study design and setting

This was a single-center simulation study that explored potential issues that may be encountered when wearing an N95 respirator during chest compression. The study was conducted in a laboratory in Samsung Medical Center (a tertiary, university-affiliated, referral hospital located in a large city in Korea) from December 1, 2016, to December 31, 2016. The temperature and humidity of the room were controlled at approximately 23 °C and 30%, respectively, to minimize the impact of environmental factors on outcomes. The institutional review board of our institution approved the study, and a written informed consent was obtained from each participant.

2.2. Selection of participants

The inclusion criteria were as follows: HCWs aged ≥20 years, those certified for the delivery of basic life support or advanced cardiovascular life support by the American Heart Association (AHA) or those who had completed our institutional training program, and those who delivered CPR in the clinical field [14]. The exclusion criteria were as follows: HCWs who were pregnant, those with any musculoskeletal diseases that compromised the capacity to deliver chest compression, and those with medical conditions, including asthma, congestive heart failure, or coronary heart disease. Moreover, the participants who failed the fit tests for all three respirators were not included.

2.3. Methods of measurements

2.3.1. Preparation for simulation

At the beginning of the simulation, the investigators conducted a brief training session for the participants, which included providing instructions for the overall flow of the study using slides and via demonstration and practice in using the standardized N95 respirator donning technique. They were instructed to complete questionnaires about the demographic characteristics of the participants after the training session. Then, every participant took the QNFT for the N95 respirator. We divided the participants into two groups (PPG and APG) (Fig. 1).

2.3.2. N95 respirator

Since the MERS epidemic in 2015, all employees in our institution must be fit tested using three N95 respirators: the 1860 and 1870+ (3 M, St. Paul, MN) and the 46,727 (Kimberly Clark, Irving, TX). The best-fitting respirator is identified based on the QNFT FF and comfort of the person who wears such device. We selected respirators based on earlier data available for all participants. However, if the shape of the face had changed because of weight change, plastic surgery, or dental correction, the fit test was repeated.

2.3.3. QNFT

We used the PortaCount Pro+ 8038 Respirator Fit Tester (TSI Inc., Shoreview, MN) for QNFT. The QNFT for the N95 respirator was conducted according to the Occupational Safety and Health Administration (OSHA) protocol [9,15]. While wearing the respirator, eight test exercises were performed in the following order: normal breathing, deep breathing, head side-to-side moving, head up-and-down motion, talking, grimacing, bending over, and normal breathing. For the talking exercise, the participants read identical text prepared in advance. Each exercise was performed for 1 min except for grimacing (15 s). The FF of grimacing was excluded from the final calculation according to the OSHA protocol [9]. An FF > 200 was scored as 200 by the tester. All FFs were continuously monitored and considered passing if the final score was ≥100.

2.3.4. Real-time QNFT during chest compression

After the fit test, the participants were instructed to perform continuous chest compression on a Resusci Anne mannikin (Laerdal Medical, Stavanger, Norway) three times for 2 min each (with 4-min rest between each session) while undergoing further fit testing (Fig. 1); they were not allowed to touch or adjust the mask. If the mask strap loosened, it was re-adjusted during the break. To ensure that the CPR was of high quality, which is in accordance with the 2015 AHA guidelines, all data were collected using a Laerdal PC Skill Reporting System (Laerdal Medical) [16]. One investigator provided feedback to all participants in real time while watching the computer monitor. The participants rested for 20 min after the three sessions of chest compression, followed by an additional compression for 2 min while wearing the same respirator after performing a user-seal-check.

2.4. Outcomes

The primary outcome was any failure (FF < 100) of the fit test during the three bouts of chest compression. The secondary outcome was the slipping down of respirator during chest compression.

2.5. Data analyses

A priori sample size calculations were made in terms of primary outcome achievement; we assumed an α value of 0.05 for two-sided hypothesis testing and a β error of 0.20 (power = 80%). A preliminary study of 10 participants has revealed a failure rate of 50%. We considered that a 40 percentage point increase in the failure rate was clinically significant; we assumed that the PPG might evidence failure. A total of 42 patients were required to detect this hypothesized failure rate.

Standard descriptive statistics were used to present all data. Continuous variables were provided as medians with interquartile ranges (IQRs), and the Wilcoxon rank-sum test was used for comparisons. Categorical data were presented as numbers with percentages and compared using the chi-square test. STATA version 13.0 software (STATA Corporation, College Station, TX) was used to perform all statistical analyses.
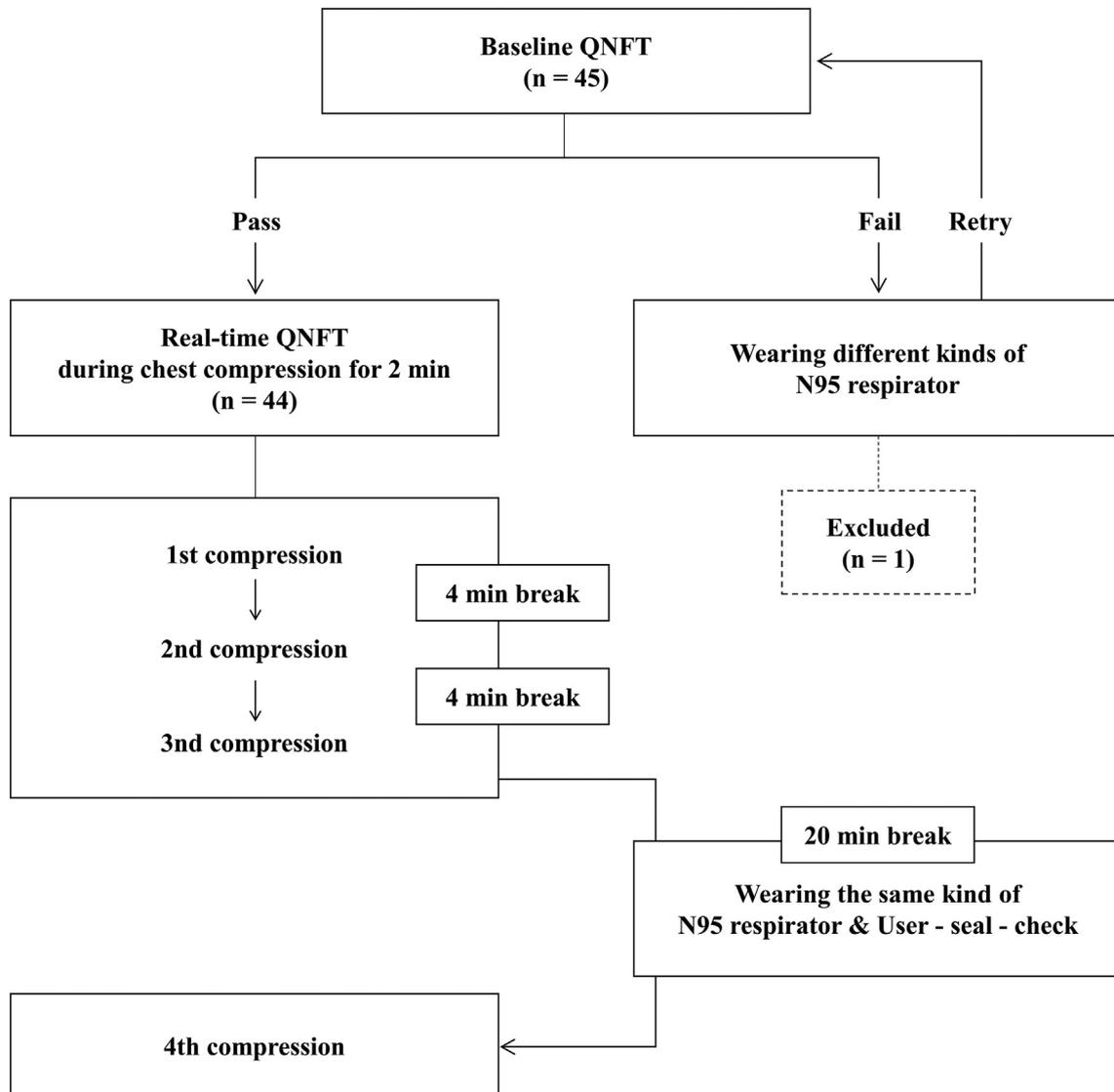
Fig. 1. Flow chart of the study. QNFT, quantitative fit test.

3. Results

3.1. Characteristics of the study participants

We recruited 45 participants, of whom 1 was excluded due to failure in the baseline QNFT using all three N95 respirators; 44 participants were ultimately included, of whom 66% (n = 29) were female. The median age of the participants was 31 (IQR: 26.5–36) years. Most participants were nurses (52%, n = 23) with an average clinical experience of 6 (IQR: 3–10) years. Baseline data, such as age, sex, career duration, body mass index, occupation, CPR training, and respirator type, did not significantly differ between the two groups (Table 1). The 3M 1870 + N95 respirator (n = 25, 57%) was most frequently used, followed by the Kimberly Clark 46727 (n = 15, 34%) and the 3M 1860 (n = 4, 9%).

3.2. Quality of chest compression

No significant differences were observed in the quality of chest compression between the two groups except in terms of compression rate during the second cycle (PPG vs. APG: 113.5, IQR: 109–116.5 vs. 108.5, IQR: 105–114, p = 0.04) (Table 2).

3.3. Outcome measures

The outcomes are shown in Table 3 and Fig. 2. Overall, 73% (n = 32) of the participants failed at least one of the three chest compression sessions; the failure rate was significantly higher in the PPG than in the APG (94 vs. 61%; p = 0.02). In total, 18% (n = 8) of the participants experienced respirator failure, such as strap loosening. The overall failure rate of the fit test after user-seal-check was 59% (n = 26), and it was not different between the PPG and APG (63% vs 57%, p = 0.73).

4. Discussion

Even when the participants passed the QNFT, N95 respirators did not afford adequate protection during chest compression. Notably, in 94% of the participants in the PPG, the FF decreased to <100 during at least one session of chest compression. Facepiece respirators only work properly when the face seal is tight [17,18]. Body movements during chest compression are both dynamic and intense, and sweat further compromises respirator fit, creating a gap permitting disease transmission. Therefore, our findings are clinically significant in terms of the safety of HCWs who are at high

Table 1
Baseline characteristics of the participants.

	Total (n = 44)	Partially passed (n = 16)	All passed (n = 28)	p-Value
Age (years)	31 (26.5–36)	34 (26.5–37.5)	30.5 (26.5–35)	0.34
Sex, female (%)	29 (66)	10 (63)	19 (68)	0.72
Career (years)	6 (3–10)	6.5 (3–12)	6 (2.5–8.5)	0.31
BMI (kg/m^2)	20.8 (19.8–23.9)	21.0 (19.0–23.2)	20.7 (20.2–24.0)	0.45
Occupation				0.93
Medical doctor	14 (32)	5 (31)	9 (32)	
Nurse	23 (52)	8 (50)	15 (54)	
Emergency medical technician	7 (16)	3 (19)	4 (14)	
CPR training				0.94
ACLS or BLS provider	36 (82)	13 (81)	23 (82)	
Institutional program only	8 (18)	3 (19)	5 (18)	
Respirator model				0.41
3M 1870+	25 (57)	7 (44)	18 (64)	
3M 1860	4 (9)	2 (13)	2 (7)	
KIMBERLY CLARK 46727	15 (34)	7 (44)	8 (29)	

Data were presented as median with interquartile range or n (%). BMI, body mass index; CPR, cardiopulmonary resuscitation; ACLS, advanced cardiovascular life support; BLS, basic life support.

risk for airborne disease transmission during chest compression even when wearing adequately fit-tested N95 respirators.

The conventional QNFT is widely used to measure N95 respirator performance in HCWs. However, the exercises performed during the fit test are not similar to those executed in real-world setting. Suen et al. have used a portable aerosol spectrometer to evaluate the performance of N95 respirators during various nursing procedures, including suction and nasogastric tube insertion for 10 min [19]. The average FF decreased significantly from 184.85 to 134.71 after completing the procedures, and the FF fell to <100 in 33% of the participants. This study indicated that N95 respirators may not provide consistent protection against respiratory infection for HCWs.

The QNFT failure rates during chest compression after the user-seal-check did not differ between the two groups. Several previous studies have suggested that this user-seal-check alone inadequately evaluates respirator fitting [20,21]. Nevertheless, in clinical practice, all treatments are performed after a user-seal-check alone. Therefore, our results suggest that pre-passing the

N95 QNFT did not ensure respiratory safety during chest compressions.

It is known that the risk of disease transmission from patients to rescuers during CPR is extremely low [22,23]. One review article has shown that the number of infections acquired during CPR is approximately <1/200,000 [24]. However, previous studies have

Table 3
Outcomes

	Total (n = 44)	Partially passed (n = 16)	All passed (n = 28)	p-Value
Any failure	32 (73)	15 (94)	17 (61)	0.02
1st chest compression failure	24 (55)	12 (75)	12 (43)	0.04
2nd chest compression failure	25 (57)	13 (81)	12 (43)	0.01
3rd chest compression failure	27 (61)	14 (88)	13 (46)	<0.01
User-seal-check	26 (59)	10 (63)	16 (57)	0.73
Slipping down of strap	8 (18)	5 (31)	3 (11)	0.09

Data were presented as n (%).

Table 2
Quality of chest compression

	Total (n = 44)	Partially passed (n = 16)	All passed (n = 28)	P-value
First chest compression				
Mean rate, counts/min	108 (104.5–113)	111.5 (107.5–114.5)	107 (104–112)	0.12
Mean depth, mm	54 (50–57)	53.5 (48–56.5)	54.5 (51–57)	0.70
Complete relaxation rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.89
Correct hand position rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.78
Second chest compression				
Mean rate, counts/min	111 (106–114.5)	113.5 (109–116.5)	108.5 (105–114)	0.04
Mean depth, mm	55 (51.5–58)	55 (49–58)	55 (52–58)	0.93
Complete relaxation rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.59
Correct hand position rate, %	100 (100–100)	100 (94–100)	100 (100–100)	0.59
Third chest compression				
Mean rate, counts/min	111 (105.5–114)	111.5 (108.5–116)	110 (103.5–114)	0.11
Mean depth, mm	55 (50–57.5)	55 (50–57)	55 (48.5–57.5)	0.86
Complete relaxation rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.18
Correct hand position rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.93
Chest compression after user-seal-check				
Mean rate, counts/min	111.5 (106–115)	110.5 (107–115)	113 (106–115)	0.73
Mean depth, mm	54 (51–58)	54 (53–56)	54 (50.5–59)	0.89
Complete relaxation rate, %	100 (100–100)	100 (100–100)	100 (100–100)	0.89
Correct hand position rate, %	100 (100–100)	99.5 (100–100)	100 (100–100)	0.23

Data were presented as median with interquartile range or n (%).
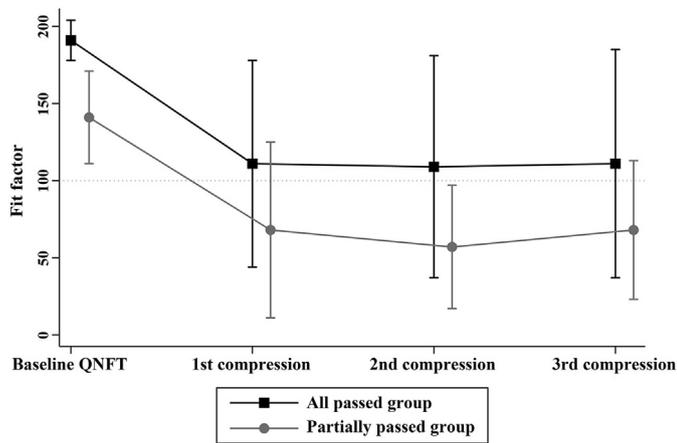
Fig. 2. Outcomes. The plots represent the median fit factor with interquartile ranges of the baseline QNFT and three sets of chest compression. QNFT, quantitative fit test.

mainly focused on diseases, such as acquired immune deficiency syndrome, hepatitis B, hepatitis C, and tuberculosis, which are transmitted via mouth-to-mouth ventilation or needlestick injury. HCWs can be infected in various ways when performing CPR. The actual incidences of infection among HCWs due to contact with patients with airborne disease during CPR are not fully elucidated. One retrospective cohort study has reported that one of nine HCWs who participated in cardiac compression developed severe acute respiratory syndrome (SARS) [25]. Of the six HCWs who performed CPR on a patient with MERS, one acquired the infection [11]. Experiences from the outbreaks of highly contagious diseases, such as SARS and MERS, taught us that HCWs should be protected from air-borne disease transmission when performing CPR [11,12,26,27].

The current international CPR guidelines do not address the extent of airway protection required by HCWs when performing CPR on patients with suspected or confirmed airborne diseases [22]. Infection-prevention strategies for HCWs tend to take second place in life-threatening situations requiring minimization of no-flow time [11,12]. However, the safety of HCWs is in fact para-mount. Mechanical compression devices can be used to minimize HCW participation in CPR. In addition, HCWs engaging in chest compression of patients with airborne diseases could wear pow-ered air-purifying respirators with hoods (PAPRs) rather than N95 respirators. However, this may result in resuscitation difficul-ties, and both movement and communication are compromised [28,29]. In addition, the protective effects of PAPRs during chest compression have not been explored, and further studies are warranted.

4.1. Limitations

Our study had certain limitations. First, we aimed to maximally reflect actual clinical settings. However, we worked in a simulation laboratory, and the outcomes of the present study might differ from those of real-world settings. The participants performed continuous chest compression based on the assumption that the patient had an advanced airway. However, in patients without an advanced airway, chest compressions are briefly paused to provide ventilation [16]. CPR is complex, featuring chest compression, endotracheal intuba-tion, defibrillation, bag-valve ventilation, intravenous line insertion, and drug administration. However, we focused on chest compres-sion only. If the participants carried out other tasks, then the out-comes might have differed. In addition, in the present study, the participants were instructed not to talk as much as possible. We believed that such action was reasonable when providing CPR to patients with air-borne disease. However, HCWs need to talk for

communication in real settings, which can loosen the fitting of the N95 respirator. Second, we had only three respirator types available; thus, our results cannot be generalized to other models. Third, although chest compression lasted for 2 min, the FF was obtained after excluding data from the first 20 s because the time was used for ambient purge, ambient sample, and mask purge.

5. Conclusion

Even in individuals who passed the initial fit test, N95 respira-tors did not provide adequate protection during chest compres-sion. The participants in the PPG were at particular risk of airborne disease transmission during chest compression. Further study must be conducted to establish specific guidelines about the level of respiratory protection for HCWs during CPR of patients with airborne diseases.

Prior presentations

None.

Author contribution

Conceptualization: Yoon H, Hwang SY. Simulation: Yoon H, Hwang S, Yoon A. Writing - original draft: Yoon H, Hwang SY. Writing - review & editing: Yoon H, Hwang SY, Yoon A, Kim T, Lee G, Jung KY, Park JH, Shin TG, Sim MS, Kim S. Study supervision and approval of final manuscript: Yoon H, Hwang SY.

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