A Quantitative Assessment of the Efficacy of Surgical and N95 Masks to Filter Influenza Virus in Patients with Acute Influenza Infection

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We assessed the in vivo efficacy of surgical and N95 (respirator) masks to filter reverse transcription-polymerase chain reaction (RT-PCR)–detectable virus when worn correctly by patients with laboratory-confirmed acute influenza. Of 26 patients with a clinical diagnosis of influenza, 19 had the diagnosis confirmed by RT-PCR, and 9 went on to complete the study. Surgical and N95 masks were equally effective in preventing the spread of PCR-detectable influenza.

Influenza virus is a well-recognized nosocomial pathogen spread from person to person through transmission via large droplets (droplet transmission), small particle aerosols (airborne transmission), or direct and indirect contact (contact transmission). The primary mode of influenza transmission is uncertain, although droplet transmission appears to be the dominant form [1, 2].

Recommendations for mask use vary according to whether use is to prevent disease transmission or acquisition. To prevent disease transmission from patients with acute influenza to other patients and staff, the Centers for Disease Control and Prevention, the American Occupational Safety and Health Administration, and the World Health Organization each recommend that either a routine surgical or procedure mask be worn by the infected patient [3–5]. In contrast, to prevent influenza acquisition by health care workers (HCWs) from infected patients, these bodies vary in their recommendations with respect to the type of mask used (surgical or N95) and whether the influenza outbreak is seasonal or pandemic [3–5].

Surgical masks are designed to trap respiratory secretions (including bacteria and viruses) expelled by the wearer and prevent disease transmission to others [4]. Surgical masks are not designed to prevent inhalation of airborne particles, and their ability to protect HCWs from disease acquisition varies. In contrast, N95 masks (termed *respirators* in the United States) are designed to reduce an individual's exposure to airborne contaminants, including infectious viral or bacterial particles. Although N95 masks are designed to primarily protect the wearer from infection, they presumably also prevent transmission if fitted correctly on a patient at high risk of transmitting a virus [4]. However, some HCWs find the more expensive N95 masks difficult to tolerate [2, 6].

Data assessing the ability of masks to filter influenza virus are limited [7]. Most research has been in vitro in design [8], using nonbiological particles [9] rather than assessing their efficacy in preventing influenza transmission. Thus, we assessed the efficacy of both standard surgical masks and N95 masks to adequately filter influenza virus among patients with laboratory-proven acute influenza A and B to determine which was more appropriate to prevent spread.

Methods. Study participants (age, >18 years) with a clinical diagnosis of influenza were recruited from our hospital emergency department during the 2007 winter influenza season. Clinical influenza was defined as previously by the presence of cough and fever during an influenza outbreak [10]. Informed written consent was obtained for all participants, and the study was approved by the Research Ethics Committee at Austin Health.

All referred patients who fulfilled the clinical entry criteria had 2 nasal swabs performed for assessment by a rapid point-of-care test (Binax-Now Influenza A and B; Binax) and for a respiratory reverse transcription-polymerase chain reaction (RT-PCR) that detected influenza A and B, parainfluenza virus, picornavirus, respiratory syncytial virus, and adenovirus [11]. The point-of-care test is reported to have a sensitivity of 62%–82% for influenza A, a sensitivity of 58%–71% for influenza B, and a specificity of 92%–100% for influenza A and B [12]. Only patients who had cases that met the clinical criteria of influenza and who had a positive point-of-care test result were

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Table 1. Efficacy of surgical and N95 masks to filter influenza in point-of-care assay–positive patients.

Patient or variable	Influenza type	Cycle number					Duration of illness, days per week
		Nasal swab	No mask, before control (step 1)	N95 mask (step 2)	Surgical mask (step 3)	No mask, after control (step 4)	
Patient							
1	A	31	38	Negative	Negative	39	3
2	A	26	40	Negative	Negative	Negative	1
3	A	22	Negative	Negative	Negative	40	3
4	A	26	34	Negative	Negative	35	1
5	A	23	32	Negative	Negative	33	2
6	A	25	27	Negative	Negative	25	1
7	B	22	38	Negative	Negative	27	2
8	A	29	34	Negative	Negative	Negative	3
9	B	27	Negative	Negative	Negative	39	3
Mean cycle time for patients with detected influenza A	…	26[a]	34.17[a]	0	0	34.4[a]	2[b]
Estimated viral load for detected influenza A, copies/mL	…	5 million[a]	50,000[a]	0	0	50,000[a]	…

NOTE. Cycle number indicates real-time reverse transcription-polymerase chain reaction cycle number. The cycle number value is inversely proportional to the titer of virus present.

[a] Mean value calculated from patients with detectable influenza A.
[b] Mean duration.

included in the assessment of the mask efficacy, because their influenza status was confirmed in real time.

Routine disposable surgical masks (TECNOL classical surgical mask; Kimberly Clark) were compared with standard N95 respirator masks (Proshield N95 Medium; BSN Medical). Neither mask was formally fit tested, but all were carefully placed on the patients by the study clinician who was trained and accredited in fit testing N95 masks. The presence of influenza was assessed using a technique whereby participants coughed 5 times onto a 90-mm diameter (14-mm deep) Petri dish (Sarsted) containing 1 mL of viral transport media (influenza sample plate [ISP]; Victorian Infectious Diseases Reference Laboratory). The ISP was held 20 cm directly in front of the participant's mouth. After coughing, viral transport media from each of the ISPs were assessed by quantitative real-time RT-PCR for influenza A and B, with the quantity of virus detected expressed as a cycle number and an estimate of viral copy number calculated as previously described [13]. The lower limit of sensitivity of the RT-PCR was ~250 copies/mL.

A 4-stage schedule was used to assess the presence of detectable influenza virus during coughing and the efficacy of each mask. This required the participant to cough 5 times onto a unique ISP during each of the 4 steps of the study; performed in the following sequence: (1) coughing without a mask (before control), (2) coughing while wearing a fitted N95 mask, (3) coughing while wearing a routine surgical mask, and (4) coughing without a mask (after control). Thus, each participant coughed a total of 20 times (5×4) for the study. The order of coughing with a surgical and N95 mask (steps 2 and 3) was randomized between patients.

Results. Twenty-six patients with a clinical diagnosis of influenza were enrolled during the 8 weeks from 9 August 2007 through 8 October 2007; 19 were confirmed to have influenza by RT-PCR of a nasal swab. Ten (52%) of these 19 participants had influenza also confirmed by the point-of-care assay and participated in the mask efficacy protocol. Of these 10 participants, 1 participant (influenza A) was unable to complete the protocol because of respiratory distress; thus, 9 (7 with influenza A and 2 with influenza B) completed the mask efficacy. Results are given in table 1. All 9 patients had influenza detected by RT-PCR during stage 1 (before control) and/or stage 4 (after control). The estimated mean viral titer from coughing 5 times was ~2 $\log_{10}$ less than that detected by direct nasal swab (table 1). Surgical and N95 masks appeared to be equally effective in filtering influenza, given that no influenza could be detected by RT-PCR of the ISP viral transport medium in any of the 9 participants for either mask (table 1).

Discussion. To our knowledge, this is the first human study to assess the comparative efficacy of surgical versus N95 masks in patients with laboratory-confirmed acute influenza and suggests that, within our study design, both masks are equally effective when used for short periods to prevent the spread of infection. Our findings support current guidelines recommending surgical or procedural masks be worn by patients with suspected influenza to limit viral dissemination to others. The findings also support the guidelines that N95 respirators (de-

signed to prevent disease acquisition) may not be necessary, because they appear to offer no additional benefit over surgical masks [3–5]. Thus, the choice of masks may be reasonably influenced by other factors, such as cost, fit testing, availability, and tolerability [2, 6]—all factors that favor routine surgical masks. Of course, our data may be less relevant to HCWs (or patients) who are wearing a mask to prevent disease acquisition. In such circumstances, the greater filtration capacity of N95 masks may have some benefits as long as they can be worn appropriately and tolerated. However, our study did not assess this latter form of mask use.

Although our study is small, we believe it is unique because most previous research has been conducted in vitro using predominantly nonbiological particles [8, 9]. Previous epidemiological studies have focused on prevention of disease acquisition rather than on spread. They include a study that suggested that both N95 and surgical masks were protective during the severe acute respiratory syndrome outbreak in 2003 [14]. Similarly, 2 recent presentations suggested that the use of masks reduced the incidence of seasonal influenza-like illness (not laboratory confirmed) in both the community and health care situations [15, 16].

Our study has some limitations. First, only participants with a positive point-of-care assay result participated in the mask assessment protocol. Thus, we cannot be sure that other patients who have negative point-of-care assay results but positive PCR results would necessarily generate the same results; however, this would seem likely. Second, because of our strict study entry criteria, we were able to only recruit a relatively small number of participants. Third, we did not formally demonstrate that the virus detected in the study participants was infectious and could be transmitted to other individuals. However, given the clinical presentation of the patients, it is likely that the virus quantitated by real-time PCR was infectious. Fourth, our method for detecting influenza during coughing may have been too insensitive to detect small differences in mask filtration efficacy or influenza expelled from around the edge of the mask. Finally, because our protocol required the mask to be worn for only 3–5 minutes, we cannot be sure that longer periods of mask use, such as may occur in some clinical situations, would be associated with the same efficacy. Thus, our data provide important preliminary information to allow appropriate planning for larger future study cohorts that focus on prevention of influenza dissemination and protection from acquisition of influenza.

On the basis of these preliminary findings, both surgical and N95 masks appear equally effective in preventing influenza dissemination from patients with confirmed influenza. These findings support current guidelines regarding mask use by patients with acute influenza.

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