Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: A randomized controlled trial

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Background: Health care workers outside surgical suites in Asia use surgical-type face masks commonly. Prevention of upper respiratory infection is one reason given, although evidence of effectiveness is lacking.
Methods: Health care workers in a tertiary care hospital in Japan were randomized into 2 groups: 1 that wore face masks and 1 that did not. They provided information about demographics, health habits, and quality of life. Participants recorded symptoms daily for 77 consecutive days, starting in January 2008. Presence of a cold was determined based on a previously validated measure of self-reported symptoms. The number of colds between groups was compared, as were risk factors for experiencing cold symptoms.
Results: Thirty-two health care workers completed the study, resulting in 2464 subject days. There were 2 colds during this time period, 1 in each group. Of the 8 symptoms recorded daily, subjects in the mask group were significantly more likely to experience headache during the study period ($P < .05$). Subjects living with children were more likely to have high cold severity scores over the course of the study.
Conclusion: Face mask use in health care workers has not been demonstrated to provide benefit in terms of cold symptoms or getting colds. A larger study is needed to definitively establish noninferiority of no mask use

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In 1973, a letter to the editor appeared in a prominent medical journal from Jack Resnick, MD, suggested "… perhaps the ancient oriental custom of wearing gauze or cloth, surgical-type masks during a cold has some merit? Perhaps Western society has another lesson to learn by observing the oriental customs besides acupuncture." He suggested this matter be studied in a rigorous manner.[1]

Since then, there has been limited study directed at addressing Dr. Resnick's implied question: does wearing a surgical mask protect from the common cold? A meta-aanalysis of the published literature reveals that conclusive evidence is not available.[2] Despite this, the practice of wearing a face mask seems to be commonplace in Japan and elsewhere. It is time to heed Dr. Resnick's call.

Reasons given for face mask use are many and include decreasing risk of upper respiratory infection (URI; or cold).[3] In Japanese cities and other densely populated areas in Asia, crowding on public transport can be extreme.[4] In these situations, taking measures to limit respiratory droplet spread to minimize the risk of URI has strong face validity, although definitive evidence for its effectiveness is lacking.

Health care workers are at particular risk of exposure to and acquisition of URI.[5] In light of the common use of face masks to limit spread of URI, the present study was undertaken to investigate the superiority of face mask over no mask use in preventing this clinical outcome.

METHODS

The study was a 77-day prospective randomized controlled trial beginning in January 2008. Subjects were recruited from a population of health care providers at a 520-bed tertiary care hospital in Tokyo, Japan. Exclusion criteria were self-identification of conditions predisposing to URI or taking antibiotics. Participants were given ¥9000 (approximately 90 US dollars equivalent) each. All underwent informed consent. The hospital ethics board approved the study.

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Mask and no mask groups were formed using block randomization of subjects within their respective job categories: nurses, doctors, and comedical personnel. Those in the mask group wore a face mask while on hospital property serving in their role as a health care worker. The hospital-standard disposable surgical mask MA-3 (Ozu Sangyo, Tokyo, Japan) was used. Subjects in the no mask group refrained from wearing a face mask while on hospital property unless required to do so as part of their job duties (eg, surgical nurse in the operating room).

An intake survey was administered to measure demographic data, health information, and quality of life. Each subject kept a daily health diary to record any of 8 symptoms of URI on a 4-point scale (0, none; 1, mild; 2, moderate; 3, severe; for fever: 0, absent; 1, present). Criterion for URI was a 2-day total symptom score greater than 14 (modified Jackson criteria[6]).

Fisher exact test was used to measure the difference between groups for URI. Student *t* tests were used for frequency of symptoms. Univariate analyses were performed to differentiate subjects with total Jackson scores below the median and those at or above the median. Factors analyzed were subject group assignment and those differentiating items on the intake survey. All analyses were conducted using SPSS version 15 J (SPSS Japan Co, Tokyo, Japan). A *P* value of less than .05 was considered significant.

RESULTS

Thirty-three volunteers met inclusion criteria. One subject in the no mask group dropped out after 1 week of data collection. Intake survey questions' results and subject demographics are summarized in Table 1.

One participant in each group had a Jackson-verified URI (not significant). Analyses were performed following the principles of intention-to-treat. The mean (standard deviation [SD]) Jackson score over the length of the study was 43.3 (SD, 47.7), the range was 0 to 210, and the median was 28.5. As shown in Table 2, the likelihood of having a higher total Jackson score was significant only for the factor of having children in the household.

Compliance with mask use and nonuse was good, with most (84.3% of subjects) self-reporting full compliance (remainder complying 79.2%-98.7% of the time). Table 3 shows the number of days of the different symptoms among all participants with cold symptoms (98% of subjects). Subjects in the mask group were significantly more likely to experience more days of the symptom ''headache'' and had a trend to experience more days of the symptom ''feel bad.'' There were no significant differences between the 2 groups for symptom severity scores.

Table 1. Demographic and subject characteristics of mask (n = 17) and no mask (n = 15) groups

	Mask group	No mask group
Male (%)	5 (29)	4 (25)
Age in years (SD)	35 (14)	36 (9.6)
No. of MDs (%)	4 (24)	3 (19)
No. of RNs (%)	7 (41)	5 (31)
No. of comedical personnel (%)	5 (29)	6 (38)
No. of Administative staff (%)	1 (6)	2 (13)
Influenza vaccine (%)	17 (100)	13 (81)
Pneumonia vaccine (%)	1 (6)	0 (0)
Sleeping hours (SD)	6.2 (1)	6.2 (1.2)
Commute by train or bus (%)	10 (59)	11 (69)
No. with children in household (SD)	0.35 (0.7)	0.67 (0.9)
PCS8 (SD)	53 (3.8)	52 (4.9)
MCS8 (SD)	48 (4.7)	49 (4.6)

PCS, physical component score of Short-Form 8; *MCS*, mental component score of Short-Form 8.

Table 2. Univariate analysis of factors associated with subjects having Jackson score totals over the course of the study below the median of 28.5 versus at or above the median

	Below median group	At or above median group	*P* value
Sex, male, n (%)	5 (31.3)	4 (25.0)	.69
Mean age, yr (SD)	34.6 (9.1)	37.2 (14.6)	.55
Mask group, n (%)	6 (37.5)	9 (56.3)	.29
Clinicians, n (%)	8 (50.0)	10 (62.5)	.72
Living with children under 16 years old, n (%)	2 (12.0)	8 (53.3)	.02 *
Use public transportation everyday, n (%)	9 (56.3)	11 (73.3)	.32
Flu vaccine, n (%)	15 (93.8)	14 (87.5)	.54
Sleeping hours (SD)	6.2 (1.0)	6.3 (1.1)	.87
Daily gargling, n (%)	10 (62.5)	10 (62.5)	1.00
PCS8, mean (SD)	53.5 (4.1)	52.1 (3.8)	.33
MCS8, mean (SD)	48.3 (4.7)	48.7 (4.9)	.81

NOTE. Course of the study was 77 days.
PCS, physical component score of Short-Form 8; *MCS*, mental component score of Short-Form 8.
*$P < .05$.

DISCUSSION

The low number of participants in the study limits the interpretations of the results. However, the findings do not support the utility of surgical face masks in protecting health care workers in Japan from URI. There were significantly fewer people experiencing days with ''headache'' in the group that did not wear masks and a trend for this group to report fewer days with the symptom labeled ''feel bad.'' This clearly does not suggest a protective effect of masks for common cold symptoms. Our findings confirm previous reports that experience of cold symptoms is likely associated with living with children.[7]

Table 3. Mean number of days of cold symptoms in the mask (n = 17) and no mask (n = 15) groups

Symptoms (average days)	Total		Mask group		Non-mask group		*P* value
	Mean	SD	Mean	SD	Mean	SD	
Any symptoms	15.1	13.7	16.1	13.6	14.2	14.1	.81
Sore throat	4.2	6.7	3.8	7.9	4.5	5.8	.25
Runny nose	8.0	10.8	8.9	11.9	7.2	10.0	.67
Stuffy nose	5.8	8.8	3.7	4.5	7.6	11.2	.46
Sneeze	4.6	6.6	4.5	6.6	4.7	6.8	.80
Cough	4.8	8.6	4.3	9.6	5.2	7.9	.45
Headache	3.0	4.5	4.9	5.5	1.3	2.5	.01*
Earache	0.4	0.8	0.5	0.7	0.3	0.8	.22
Feel bad	4.0	5.7	5.6	5.9	2.6	5.2	.06

*$P < .05$.

Used properly, the surgical face mask obscures the face from just below the eyes to the chin. Patients or coworkers cannot see most facial expressions of a person wearing a mask. This may have a deleterious effect on the social bond needed in health care settings because it obscures an important nonverbal mode of communication. Wearing a face mask may also communicate to the other party that the individual with the mask is either (1) infectious or (2) thinks the person they are talking with is infectious. Both assumptions serve to distance the individuals involved, possibly harming the therapeutic relationship.

There are several limitations of the study. Sample size was only large enough to detect an absolute risk reduction for URI of 60% for those in the mask group. Recruitment was difficult. E-mail blasts, oral presentations to groups, cafeteria sign-ups, newsletter announcements, monetary inducement, and personal appeals were not effective in getting widespread participation. Additional constraints follow. Subjects were from 1 hospital in Tokyo and used only 1 type of face mask. Subjects' face mask wearing was controlled only in the hospital. Behavior outside of the hospital was not measured nor was frequency of replacing face masks. These factors make generalizability difficult.

Although a larger randomized controlled trial is indicated, the widespread use of face masks in Japan renders recruitment highly problematic. Sociocultural values may prevent the highest levels of evidence from being accrued. The Japanese Ministry of Health, Labour, and Welfare cites the level of evidence for using face masks to prevent colds as IIIA, no evidence, strongly recommended.[8] If the mask offers no benefit, forgoing a mask will save money and lessen environmental impact, as well as allow health care workers to interact with each other and with their patients with the full facial expression and other nonverbal communication at their disposal. If there is benefit, then health care workers throughout the world should be encouraged to use face masks.

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