Cloth Masks

RECOMMENDATIONS

We recommend that healthcare workers not directly taking care of COVID-19 patients, and other persons with high risk of exposure to COVID-19 should use properly fitted surgical masks instead of cloth masks. *(Moderate quality of evidence; Strong recommendation)*

We suggest using a cloth mask that fits snugly on the face and made of at least two layers of cotton (e.g., t-shirt fabric) or non-woven nylon with aluminum nose bridge by the general public with low risk of exposure to COVID-19 in outdoor or indoor areas to prevent COVID-19 infections. *(Low quality of evidence; Conditional recommendation)*

Consensus Issues

The consensus panel agreed to base these recommendations on the exposure level to SARS-CoV-2 instead of population subgroups (i.e., general public versus healthcare workers). The ethical implications of recommending cloth masks instead of medical masks for the general public in cases where there are no shortages of medical masks was also considered.

A separate review question is needed to determine the appropriateness of cloth masks for vulnerable populations (e.g., immunocompromised patients, elderly, those with comorbidities), as the current evidence did not provide sufficient data to allow subgroup analysis for these vulnerable populations.

Although cloth masks are more practical to use than medical grade masks, the type of cloth and number of layers required should be specified. Guidelines on its proper disposal and reuse are also needed to reduce the risk of transmission. The need to educate the public on the proper wearing of mask was deemed to be equally important as well to achieve its intended protection against COVID-19.

EVIDENCE SUMMARY

Are cloth masks effective in preventing COVID-19 infections?

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Key Findings

There is low-certainty evidence on the effectiveness of cloth masks compared with medical masks in preventing COVID-19 infections among the general population. There are no completed clinical trials or observational studies directly evaluating cloth masks compared with surgical masks in preventing SAR-CoV-2 transmission among healthcare workers or community dwellers. However, there is indirect evidence from a randomized controlled trial (RCT) investigating the use of surgical masks in the general public to prevent SARS-CoV-2 infection.

Introduction

SARS-CoV-2 is primarily transmitted between people through respiratory droplets (> 5-10 μm in diameter) or close contact with an infected person [1]. Airborne transmission via aerosol (particles < 100 μm) formation has also been observed to be the culprit in community transmission and infection among healthcare workers [2]. Surgical masks, medical masks, respirators, and other personal protective equipment have been recommended in the healthcare setting, while physical distancing, regular handwashing, quick contact in indoor and outdoor areas have been promoted in the community to decrease the probability of infection. In countries with limited resources, together with other mitigating strategies, the use of cloth masks may be an option for both the general public and some healthcare workers.

Wearing non-medical masks or cloth face coverings appears to be one pragmatic method to protect the public against respiratory infections. A previous rapid review on cloth mask [3] concluded that its effectiveness in preventing COVID-19 compared with medical masks remains unclear. We sought to provide an update to this review.

Review Methods

Two reviewers independently conducted another search and screening using free text and MeSH terms of these keywords: "cloth mask," "nonwoven mask," "nonmedical mask," "face mask," “medical mask” “disposable mask” "COVID-19," "SARS-CoV-2," "coronavirus," "COVID" in MEDLINE via PubMed, CENTRAL, bioRxiv, medRxiv, ClinicalTrials.gov and the World Health Organization (WHO) database. We searched for systematic reviews, randomized controlled trials and cohort studies for appraisal until December 26, 2020.

Results

Two RCTs were included in this review: (1) evaluating effect of surgical mask among general population in preventing COVID-19 infection and (2) examining effect of cloth mask in preventing influenza-like illness among healthcare workers. In-vitro studies on cloth masks and a comprehensive systematic review and meta-analysis of 172 observational studies examining

effect of masks in general among both HCW and non-HCW were also looked into and considered in the recommendation.

Protection against infection

Direct evidence

In a cluster-randomized trial done in 2015, the risk of developing ILI was almost seven (7) times higher influenza-like illness (ILI) among health care workers (HCW) who wore two-layered cotton masks (aRR 6.64, 95% CI 1.45-28.65) compared with those who wore a medical mask in high-risk hospitals in Vietnam [10].

Indirect evidence

A community- based RCT in Denmark (DANMASK-19) showed that the reduction of risk of COVID-19 infections with mask-wearing is uncertain [11]. This one-month experiment of wearing surgical masks with ear loops looked at SARS-CoV-2 infection (confirmed through oropharyngeal/nasal swab test (RT-PCR), antibody test (IgM or IgG) within the study duration, or a medical diagnosis of COVID-19 infection from hospital) and positive PCR results for other respiratory viruses, as the primary and secondary outcomes, respectively. The results showed inconclusive evidence that the odds of acquiring COVID-19 infection from wearing surgical mask can be lowered by 20% (odds ratio, 0.82 [CI, 0.54 to 1.23]; p= 0.33). However, the study cited various limitations in the methodology and data collection such as lack of blinding among participants and inadequate follow-up. They imputed missing values to complete the 20% loss to follow-up for the intention-to-treat analysis.

A similar comparison of intervention (face mask vs. no face mask) from a well-conducted systematic review and meta-analysis [12], including 172 observational studies including COVID-19 cases, supported that face masks, in general, compared with no face mask, can provide adequate protection from viral transmission (adjusted OR 0.15, 95% CI 0.07 to 0.34). Medical or N95 respirators compared with no mask at all still show a superior effect in decreasing chances of viral infection (aOR 0.04, 95% CI 0.004-0.30). Surgical masks or other similar masks such as 12-16-layer cotton surgical mask had much lower effect but seemed adequate to protect oneself from SARS infection (aOR 0.33, 95% CI 0.17-0.61) [12].

Filtration Efficiency

Four systematic reviews of laboratory studies [3-6] have already examined the filtration efficiency of fabric or cloth masks, an essential property of masks reducing contamination by droplets. It is defined as the number of particles of a certain size that the medium used can filter [7]. A systematic review [5] of 11 in-vitro studies found that masks made with cotton blends with at least two layers can offer some level of protection against transmission of aerosol particles because of 80-90% filtration efficiency; the same study found that commercially-grade fabric masks can do the same because of their less than 10% penetration level of particle size <0.03μm.

It is supported by a more recent laboratory evaluation of fitted filtration efficiency (FFE) of consumer-grade masks for a bit larger particles (0.05μm NaCl) [8]. Some fabric masks such as

two-layer nonwoven nylon mask with improved fit (with aluminum nose bridge, with or without one nonwoven insert and washed) showed a high FFE (74.4%, 4.8 SD and 79%, 4.3 SD) and considered to be similar to surgical masks in terms of pragmatic effectiveness [8].

Another recent laboratory experiment in January 2021 was conducted by the Center for Disease Control and Prevention [9]. Results showed that: (1) a cloth mask alone blocked 51.4% (SD 7.1), (2) a medical procedure mask (surgical mask) blocked 56.1% (SD 5.8), (3) surgical mask with knotted loops and tucked edges blocked 77% (SD 3.1) and (4) cloth mask over surgical mask blocked 85.4% (SD = 2.4) of cough particles (0.1-7 μm potassium chloride) in three 15-minute trials. This experiment highlighted the importance of good fit to optimize protection.

It is important to be reminded that these are laboratory experiments and that the required filtration efficiency value to prevent respiratory illness from viruses under real circumstances is still not exactly known.

Recommendations from Other Groups

The World Health Organization released new interim guidance in December 2020 on non-medical masks for the general public despite the lack of direct evidence [13]. Healthcare workers not performing aerosol-generating procedures and people suspected or confirmed of having COVID-19 are advised to wear a medical mask [13]. Non-medical masks should be used by the general public in indoor or outdoor areas where physical distancing of at least one meter is difficult to maintain [13-14].

CDC on December 18, 2020 specifically recommended using breathable but tightly woven cotton fabrics such as quilting fabric, cotton sheets, or T shirt fabrics for the general public [14]. On February 13, 2021, CDC released a report highlighting the importance of fitted masks and additional layers of fabric [9]. Using a mask with a nose wire, mask fitter or brace, regardless whether it is cloth or surgical mask, is encouraged to maximize mask performance. Double masking (i.e., wearing disposable mask underneath a cloth mask), supported by Johns Hopkins University, is also used because the top mask will supposedly push the edges of the inner mask against the face to enhance fitting. However, it is not encouraged in the medical setting as reported.

The Canadian government recognized lack of evidence on effectiveness of cloth masks in protecting people from acquiring COVID-19 infection [15]. However, they still recommend using non-medical masks or homemade masks as an additional intervention in the community because they can be useful for short periods and for areas where physical distancing is not possible [15-16]. Non-medical masks may include cloth mask made of cotton and mask with pockets or filters [15-16]. The general public may consider use of medical masks if they are placed in higher risk of exposure to COVID-19 due to work and living situations [16].

Research Gaps

There is still a paucity of direct evidence evaluating the effectiveness of cloth masks compared with the single-use medical mask in preventing COVID-19 infections. More randomized controlled trials are needed.

Ongoing Studies

A cluster-randomized trial from Denmark is already underway (NCT04471766) to examine the effectiveness of cloth masks in preventing the novel coronavirus transmission among residents, both adults and children (10 years and older). It is expected to end in August 2021 with 40,000 participants [17].

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Appendix 1: Characteristics of Included Studies

Study ID	Type of study	Population	Intervention	Comparison	Outcomes
McIntyre 2015	Cluster RCT	Health care workers (n=	Cloth mask - Two-layer cotton - Washed and reused	Surgical mask or without	Influenza-like illness
Bundgaard 2020	Community-based RCT	Community-dwelling adults without COVID-19 Or without symptoms of COVID-19	Surgical mask	No mask	COVID-19 infection
Chu 2020	Systematic review and meta-analysis of observational studies	Health care workers and non-health care workers	Surgical mask	No mask	SARS infection
Santos 2020	Systematic reviews of in-vitro studies	None	Cloth mask - combination of cotton and other fabric	-	Filtration efficiency
Clapp 2020	Laboratory study	None	Cloth mask - consumer grade masks	-	Filtted fitration efficiency
Brooks 2021	Laboratory study	None	Cloth mask	-	Fitted filtration efficiency

Appendix 2: GRADE Evidence Profile

Face mask compared to none in preventing COVID-19 infection

Patient or population: general public
Setting: community
Intervention: face mask (including cloth mask 12-16-layer cotton)
Comparison: none

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with none	Risk difference with face mask
COVID-19 infection	4862 (1 RCT)	⊕⊕◯◯ LOW [a,b]	**RR 0.10** (0.01 to 1.70)	21 per 1,000	**19 fewer per 1,000** (21 fewer to 15 more)
Viral infection (SARS)	315 cases 744 controls (6 observational studies)	⊕◯◯◯ VERY LOW [c,d,e]	**OR 0.33** (0.17 to 0.61)	241 per 1,000	**146 fewer per 1,000** (190 fewer to 79 fewer)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. surgical mask was used instead of cloth mask
b. Wide confidence interval. Inconclusive result,
c. Risk of bias was reported to be high by the systematic review
d. High heterogeneity = 76%
e. although cloth mask was included surgical masks were used in most of the studies

Cloth mask compared to medical/single-use mask in preventing COVID-19 infection among healthcare workers

Patient or population: healthcare workers
Setting: healthcare setting
Intervention: cloth mask
Comparison: medical/single-use mask

Outcomes	№ of participants (studies) Follow up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with medical/single-use mask	Risk difference with cloth mask

Influenza-like illness	1319 (1 RCT)	⊕⊕⊕◯ MODERATE [a,b]	**RR 6.64** (1.45 to 28.65)	3 per 1,000	**15 more per 1,000** (1 more to 74 more)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. issues in allocation concealment and blinding of participants
b. indirect in terms of outcome: influenza-like illness