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Effectiveness of wearing masks during the COVID-19 outbreak in cohort and case-control studies: a systematic review and meta-analysis

Idevaldo Floriano[1], Antônio Silvinato[1,2], Hélio Arthur Bacha[3], Alexandre Naime Barbosa[4], Suzana Tanni[5], Wanderley Marques Bernardo[2,6]

1. Cooperativa Baixa Mogiana, Medicina Baseada em Evidências, Mogi-Guaçu (SP) Brasil.
2. Associação Médica Brasileira, Medicina Baseada em Evidências, São Paulo (SP) Brasil.
3. Hospital Israelita Albert Einstein, São Paulo (SP) Brasil.
4. Disciplina de Moléstias Infecciosas e Parasitárias, Departamento de Infectologia, Dermatologia, Diagnóstico por Imagem e Radioterapia, Faculdade de Medicina de Botucatu, Universidade Estadual Paulista – UNESP – Botucatu (SP) Brasil.
5. Disciplina de Pneumologia, Departamento de Clínica Médica, Faculdade de Medicina de Botucatu, Universidade Estadual Paulista – UNESP – Botucatu (SP) Brasil.
6. Faculdade de Medicina, Universidade de São Paulo, São Paulo (SP) Brasil.

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ABSTRACT

Objective: To evaluate the efficacy of wearing a mask to prevent COVID-19 infection. **Methods:** This was a systematic review and meta-analysis of cohort and case-control studies, considering the best level of evidence available. Electronic databases (MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and Clinical Trials.gov) were searched to identify studies that evaluated the effectiveness of wearing masks compared with that of not wearing them during the COVID-19 pandemic. Risk of bias and quality of evidence were assessed using the Cochrane risk of bias tool and the Grading of Recommendations Assessment, Development, and Evaluation. **Results:** Of the 1,028 studies identified, 9 met the inclusion criteria (2 cohort studies and 7 case-control studies) and were included in the analysis. The meta-analysis using cohort studies alone showed statistically significant differences, wearing a cloth mask decreased by 21% [RD = −0.21 (95% CI, −0.34 to −0.07); $I^2 = 0\%$; p = 0,002] the risk of COVID-19 infection, but the quality of evidence was low. Regarding case-control studies, wearing a surgical mask reduced the chance of COVID-19 infection [OR = 0.51 (95% CI, 0.37-0.70); $I^2 = 47\%$; p = 0.0001], as did wearing an N95 respirator mask [OR = 0.31 (95% CI, 0.20-0.49); $I^2 = 0\%$; p = 0.00001], both with low quality of evidence. **Conclusions:** In this systematic review with meta-analysis, we showed the effectiveness of wearing masks in the prevention of SARS-CoV-2 infection regardless of the type of mask (disposable surgical mask, common masks, including cloth masks, or N95 respirators), although the studies evaluated presented with low quality of evidence and important biases.

Keywords: Antiviral agents; COVID-19; SARS-CoV-2; Masks.

INTRODUCTION

After the first case of COVID-19 in November of 2019, the pandemic has widely spread worldwide, causing numerous deaths from SARS-CoV-2-related ARDS. The transmission of respiratory viruses such as SARS-CoV-2 can occur through saliva droplets, person-to-person contacts, or contaminated surfaces,[1,2] and it can be avoided by barriers and social distancing protection.

At the beginning of the pandemic, there was a sudden and marked increase in the consumption of personal protective equipment (PPE), which, in association with social distancing, were the only methods to prevent the spread of the virus before vaccine availability. With the advent of vaccines, there was a marked reduction in infection and mortality rates, but those were still high. Nowadays, the use of PPE is adaptive considering the recommendations of local health agencies and COVID-19 incidence rates. The WHO[3] and the U.S. Centers for Disease Control and Prevention[4] recognize that wearing well-fitted masks and maintaining social distancing, such as avoiding crowded or closed-contact settings, as well as cleaning hands regularly and covering sneezes and coughs, reduce COVID-19 transmission. Masks can be used to protect healthy people or to prevent onward transmission. On the other hand, there is a concern related to the real effectiveness of the different types of masks in reducing the transmission of COVID-19. Commercially, there are three types of masks commonly sold in order to protect against aerial contamination: cloth face masks, worn by the general population; medical face masks (surgical face masks), worn by health care agents; and N95 respirators or equivalents, worn by health care professionals in the presence of aerosol contaminants.

Previous systematic reviews in the literature on this topic[5-7] did not take into consideration the relationship between the type of respiratory viruses and their respiratory infection rate, and this directly impacted on the results. Moreover, those studies had different study designs, creating bias and reducing the quality and reliability of the data obtained. To improve the information regarding the effectiveness of masks used during the COVID-19 pandemic, this systematic review was carried out with a selection of studies published

Correspondence to:
Idevaldo Floriano. Rua Marcos Vedovello, 89. CEP 13840-221. Mogi-Guaçu, SP, Brasil.
Tel.: 55 19 3981-4992. Email: idfloriano@hotmail.com
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during the COVID-19 pandemic, which were stratified according to the types of masks (cloth masks, surgical masks, and N95 respirators) used around the world, as well as the types of study design.

METHODS

This systematic review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses recommendations.[8]

Eligibility criteria

The protocol of this study was based on the PICO methodology (**P**atients of interest, **I**ntervention to be studied, **C**omparison of intervention, and **O**utcome of interest). Therefore, the PICO framework in the present study was as follows: **P**atients: adults at risk of being infected with SARS-CoV-2; **I**ntervention: use of face masks; **C**omparison: individuals who did not wear face masks; and **O**utcome: COVID-19 infection. Observational (cohort or case-control) studies were included in this study, and no restrictions regarding the date of publication, language, or full-text availability were imposed.

Information sources and search strategy

Two authors developed a search strategy that was revised and approved by the team, selected information sources, and systematically searched the following databases: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov, as well as gray literature. The main search strategy used was the following: "(mask OR masks OR N95 OR (Respiratory Protective Devices OR Respiratory Protective Device) OR face shield) AND (COVID OR COV OR CORONAVIRUS OR SARS) AND (random*) OR therapy/broad[filter] OR comparative study OR comparative studies)." The search strategy included studies published by November 1, 2022.

Study selection

Two independent researchers selected and extracted the data from the studies included. First, the studies were selected based on their titles and abstracts. Second, full texts were evaluated to be included or excluded, and disagreements were resolved by consensus or following a discussion with a third researcher.

Data collection and investigated outcomes

Data regarding authorship, year of publication, patient description, interventions (wearing masks or control), absolute numbers of each outcome, and follow-up period were extracted from the studies.

Risk of bias and quality of evidence

The risk of bias for cohort and case-control studies was assessed using the current tool recommended by the Cochrane Collaboration to estimate the effectiveness and safety of nonrandomized interventional studies, designated Risk of Bias in Non-randomized Studies of Interventions.[9] This tool assesses seven domains of bias, classified by the time of occurrence, as were other fundamental elements, and are expressed as low risk, moderate risk, serious risk, critical risk, or no information.

The assessment of the risk of bias was conducted by two independent reviewers, and, in case of disagreement, a third reviewer deliberated on the assessment. The quality of evidence was extrapolated from the risk of bias and was described by using the Grading of Recommendations Assessment, Development and Evaluation terminology[10,11] as very low, low, moderate, or high; the quality of evidence was described by the GRADEpro Guideline Development Tool (McMaster University, Hamilton, ON, Canada) for meta-analyses.

Synthesis of results and statistical analysis

Categorical outcomes were expressed by group (wearing masks or control): number of events and calculated risk in percentage (by dividing the number of events by the total number of individuals in each group) for cohort and case-control studies. The effectiveness of wearing a face mask for preventing transmission of COVID-19 respiratory infections in community settings was assessed using ORs and their respective 95% CIs for case-control studies. For cohort studies, the effects of meta-analyses were reported as risk differences (RDs) or ORs and corresponding 95% CIs. The use of RDs shows the absolute effect size in the meta-analysis when compared with the relative risk or the OR, and this technique can be used when the binary outcome is zero in both study arms. We used the fixed-effect or the random-effect model in the meta-analysis to evaluate the effect of intervention vs. control on the outcome when these data were available in at least two studies. The heterogeneity of effects among studies was quantified using the I^2 statistic ($I^2 > 50\%$ indicating high heterogeneity). For the meta-analysis, we used the Review Manager software, version 5.4 (RevMan 5; Cochrane Collaboration, Oxford, United Kingdom).[12] Results were expressed using a methodological (observational cohort study) design.

RESULTS

A flow diagram of the literature search and related screening process is shown in Figure 1. The search strategy identified 1,367 studies, and, after screening titles and abstracts, we identified 57 potentially eligible citations. After applying inclusion and exclusion criteria, we retrieved 18 citations for full-text analysis, and 9 studies[13-21] were included in this systematic review, 2 of those being cohort studies[13,14] and 7 being case-control studies.[15-21] The list of excluded studies and the reasons for their exclusion are available in the supplementary material. The characteristics of the studies included are described in Table 1. The

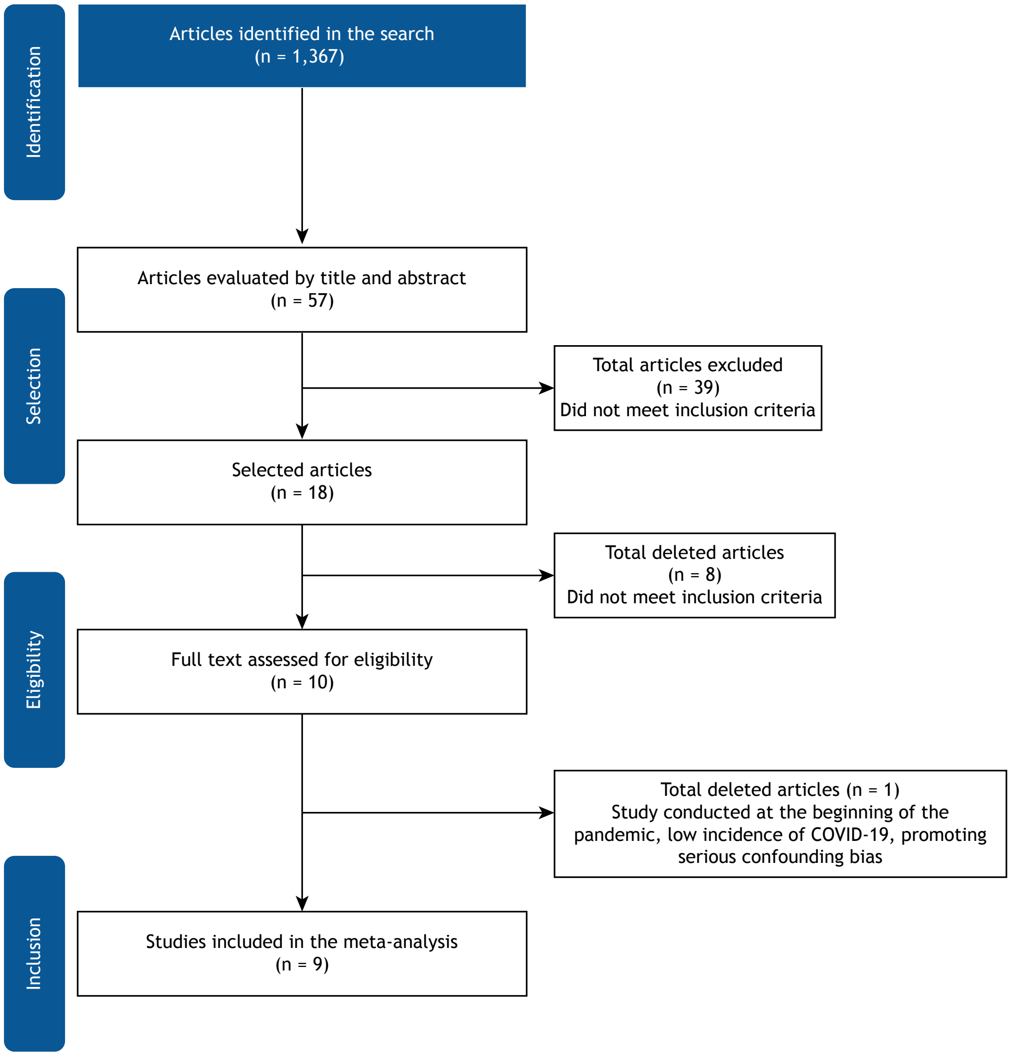

Figure 1. Flow chart of study selection process.

risk of bias and the quality of evidence are described in Tables 2 and 3, respectively. No publication bias was identified.

A total of 2,803 participants (192 in the cohort studies and 2,611 in the case-control studies) were included in the analysis (wearing a mask or not) in terms of effectiveness to decrease the indices of COVID-19 infection.

Regarding the risk of bias, all of the studies included showed high or critical biases due to confusion, selection of participants, or missed dates. Overall, the studies were considered to have a high risk of bias (Table 2): a serious risk in 5 studies and a moderate risk in 3 studies.

The cohort studies evaluated 192 participants on the effectiveness of wearing a mask (disposable surgical masks or common masks, including cloth masks) in preventing COVID-19 infection. The wearing of masks was associated with an important reduction (by 21%) in the risk of COVID-19 infection [RD = −0.21 (95% CI, −0.34 to −0.07); I^2 = 0%; p = 0.002], which indicated that it was necessary that 5 participants should wear a mask to avoid 1 COVID-19 case, with a low quality of evidence (Figure 2).

Six case-control studies included 729 subjects in the intervention group and 1,074 in the control group. The meta-analysis showed that the chance of contracting COVID-19 infection was 0.49 times lower in those who wore masks [OR = 0.51 (95% CI, 0.37-0.70); I^2 = 47%, p = 0.0001] when compared with the control group, with a low quality of evidence (Figure 3). The specific use of the N95 respirator masks was assessed in 4 case-control studies, which included 414 participants in the N95 mask group and 395 in the control group. The N95 mask group showed to have a 0.69 lower chance of acquiring COVID-19 infection in comparison with those who did not wear a mask [OR = 0.31 (95% CI, 0.20-0.49); I^2 = 0%, p = 0.00001], with a low quality of evidence (Figure 3).

Summary of evidence

- The use of masks (disposable surgical masks or common masks, including cloth masks) caused a

Table 1. Description of the studies included in the systematic review.

Study	Design	Population	Intervention	Comparator	Outcome	Follow-up
Andrejko et al.[15]	Case-control	2,749 participants from the state of California, USA, were evaluated between February 18 and December 1, 2021. All participants reported having been in indoor public settings 14 days before SARS-CoV-2 testing	Wearing masks (cotton, surgical, or N95/KN95.	Not wearing masks	COVID-19 infection	14 days
Chen et al.[13]	Cohort	Risk factors were evaluated in 105 healthcare workers having had contact with 4 individuals positive for COVID-19 in nursing homes in China	Wearing masks (disposable nonsurgical face masks, surgical masks, or N95)	Not wearing masks	Demographic characteristics, clinical symptoms, and COVID-19 infection	14 days
Doung-Ngern et al.[16]	Case-control	1,050 people who attended public companies, nightclubs, and boxing stadiums in Thailand between March 1st and May 30, 2020 were interviewed via telephone	Wearing surgical masks	Not wearing masks	COVID-19 infection	21 days
Guo et al.[17]	Case-control	72 orthopedic surgeons working at hospitals in Wuhan, China, between December 31, 2019 and February 24, 2020	Wearing N95 masks	Not wearing masks	COVID-19 infection	N/A
Heinzerling et al.[18]	Case-control	37 hospital workers, contacting the first case of SARS-CoV-2 in California, USA.	Wearing surgical masks	Not wearing mask	COVID-19 infection	N/A
Khalil et al.[19]	Case-control	190 physicians who worked in hospitals in Bangladesh between May and June of 2020	Wearing community masks and N95 masks	Not wearing masks	COVID-19 infection	N/A
Rebmann et al.[20]	Case-control	9,335 students from the University of St. Louis, USA. were tested by PCR, resulting in 265 positive cases for COVID-19, and 378 students who had close contacts with positive cases between January and May of 2021 (26 cases and 352 controls)	Wearing surgical masks	Not wearing masks	COVID-19 infection	N/A
Wang et al.[14]	Retrospective Cohort	124 families with cases of COVID-19 infection in family members; hygiene behaviors, individual protection, and social distancing were evaluated	Wearing community masks	Not wearing masks	COVID-19 infection	14 days
Wang et al.[21]	Case-control	493 physicians and nurses working at the Zhongnan University Hospital, Wuhan, China, between January 2 and 22, 2020	Wearing N95 masks	Not wearing N95 masks	COVID-19 infection	N/A

Table 2. Risk of bias of the studies included in the analysis.

Risk of bias domains

Study	D1	D2	D3	D4	D5	D6	D7	Overall
Chen, 2020[13]	+	+	+	−	−	+	+	−
Doung, 2020[16]	+	−	+	−	×	+	+	×
Guo, 2020[17]	+	−	+	−	+	+	+	−
Heinzerling, 2020[18]	−	−	+	+	+	+	+	−
Khalil, 2020[19]	×	×	+	+	+	+	+	×
Rebmann, 2020[20]	×	×	+	+	+	+	+	×
Wang X, 2020[21]	×	−	+	+	+	+	+	×
Wang Y, 2020[14]	×	!	+	+	+	+	+	×
Andrejko, 2020[15]	+	−	+	+	+	+	+	−

Judgment
! Critical
× Serious
− Moderate
\+ Low

Domains:
D1: Bias due to confounding
D2: Bias due to selection of participants
D3: Bias in classification of interventions
D4: Bias due to deviations from intended interventions
D5: Bias due to missing data
D6: Bias in measurement of outcomes
D7: Bias in selection of the reported result

In accordance with Sterne et al.[9]

Table 3. Summary of results and analysis of certainty of evidence (GRADE) of the use masks during the COVID-19 outbreak.

Outcome	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of evidence
	Risk of not wearing masks	Risk of wearing masks			
Wearing surgical masks during SARS-CoV-2 pandemic Case-control	Lower		RR 0.63 (0.51 to 0.79)	729 cases 1,074 controls (6 observational studies)	⊕⊕OO Low[a]
	0 per 1,000	0 per 1,000 (0 to 0)			
Wearing N95 masks during SARS-CoV-2 pandemic Case-control	Lower		RR 0.54 (0.42 to 0.69)	414 cases 391 controls (4 observational studies)	⊕⊕OO Low[a]
	0 per 1,000	0 per 1,000 (0 to 0)			
Wearing disposable surgical masks or common masks, including cloth masks during SARS-CoV-2 pandemic Cohort	368 per 1,000	154 per 1,000 (92 to 268)	RR 0.42 (0.25 to 0.73)	192 (2 observational studies)	⊕⊕OO Low[b]

GRADE: Grading of Recommendations Assessment, Development, and Evaluation; and RR: risk ratio. *The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
Explanations
a. Case-control studies with severe biases in confounding and patient selection domains.
b. Cohort studies with bias due to confounding, deviation from intended intervention, missing data, and participant selection domains.

reduction of 21% in the risk of COVID-19 infection [RD = −0.21 (95% CI, −0.34 to −0.07); I^2 = 0%, p = 0.002] in the cohort studies included, with a low certainty of evidence

- The use of surgical masks decreased the chance of COVID-19 infection by 49% [OR = 0.51 (95% CI, 0.37-0.70); I^2 = 47%, p = 0.00001] in the case-control studies included, with a low certainty of evidence
- The use of N95 respirator masks demonstrated a significant protective effect in decreasing (by 69%) the chance of COVID-19 infection [OR =

	Wearing mask		Control			Risk Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Chen 2020[13]	10	78	8	27	48.1%	-0.17 [-0.36, 0.02]
Wang Y 2020[14]	8	46	17	41	51.9%	-0.24 [-0.43, -0.05]
Total (95% CI)		**124**		**68**	**100.0%**	**-0.21 [-0.34, -0.07]**
Total events	18		25			

Heterogeneity: Chi² = 0.29, df = 1 (P = 0.59); I² = 0%
Test for overall effect: Z = 3.05 (P = 0.002)

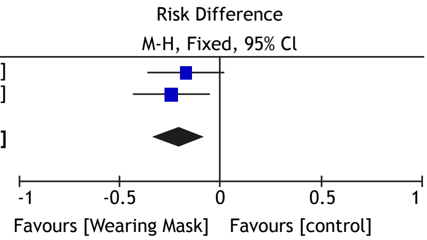

Figure 2. Forest plot of comparison: wearing disposable surgical masks or common masks, including cloth masks vs. control group regarding COVID-19 infection (cohort studies).

	Wearing mask		Control			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
1.1.1 Wearing surgical mask						
Andrejko 2020[15]	113	252	24	35	13.0%	0.37 [0.18, 0.79]
Doung-ngern 2020[16]	29	227	102	602	27.2%	0.72 [0.46, 1.12]
Guo 2020[17]	7	40	17	32	8.7%	0.19 [0.06, 0.55]
Heinzerling 2020[18]	0	3	3	37	0.3%	1.41 [0.06, 33.21]
Khalil 2020[19]	89	181	9	16	4.7%	0.75 [0.27, 2.11]
Rebmann 2021[20]	2	26	114	352	8.1%	0.17 [0.04, 0.75]
Subtotal (95% CI)		**729**		**1074**	**61.9%**	**0.51 [0.37, 0.70]**
Total events	240		269			
Heterogeneity: Chi² = 9.35, df = 5 (P = 0.10); I² = 47%						
Test for overall effect: Z = 4.08 (P < 0.0001)						
1.1.2 Wearing N95 mask						
Andrejko 2020[15]	10	21	24	35	5.3%	0.42 [0.14, 1.27]
Guo 2020[17]	4	23	20	49	5.9%	0.31 [0.09, 1.03]
Khalil 2020[19]	36	92	62	98	20.4%	0.37 [0.21, 0.67]
Wang 2020[21]	0	278	10	213	6.6%	0.03 [0.00, 0.60]
Subtotal (95% CI)		**414**		**395**	**38.1%**	**0.31 [0.20, 0.49]**
Total events	50		116			
Heterogeneity: Chi² = 2.93, df = 3 (P = 0.40); I² = 0%						
Test for overall effect: Z = 5.00 (P < 0.00001)						
Total (95% CI)		**1143**		**1469**	**100.0%**	**0.43 [0.33, 0.56]**
Total events	290		385			

Heterogeneity: Chi² = 14.24, df = 9 (P = 0.11); I² = 37%
Test for overall effect: Z = 6.17 (P < 0.00001)
Test for subgroup differences: Chi² = 2.91, df = 9 (P = 0.09); I² = 65.7%

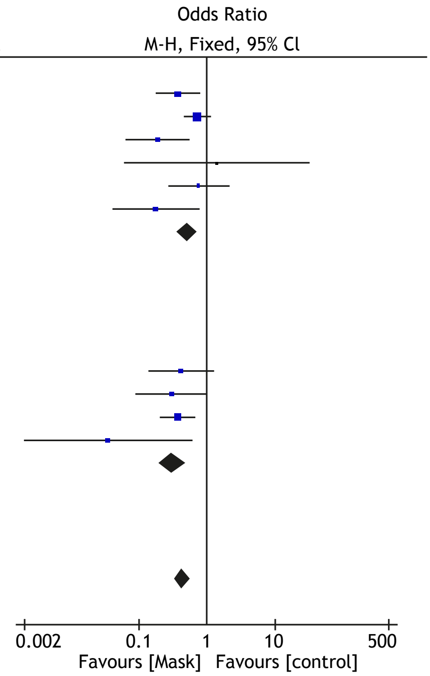

Figure 3. Forest plot of comparison: wearing surgical masks or N95 respirator masks vs. control group regarding COVID-19 infection (case-control studies).

0.31 (95% CI, 0.20-0.49); I² = 0%; p = 0.00001] in the case-control studies included, with a low certainty of evidence

DISCUSSION

Our systematic review demonstrates a reduction in the risk of COVID-19 infection. By evaluating different subgroups of study designs (cohort studies whose intervention was the use of disposable surgical masks, common masks, including cloth masks, or N95 respirators; and case-control studies whose intervention was wearing surgical masks or N95 respirator masks), we obtained a relevant reduction in the risk of COVID-19 infection, regardless of the type of mask, but the certainty of evidence was low.

Comparing our results with those of other systematic reviews, we can claim that wearing masks can contribute to reducing COVID-19 infection. The previous literature studied the effect of wearing masks in different scenarios, different types of infectious aerosols, and different rates of infection. It is important to promote reliable knowledge and education to society regarding the use of facial masks as an instrument of individual protection. Japan is one of the countries that culturally educated its population to wear masks to protect others when they present respiratory symptoms. Nevertheless, this is not the only instruction that we can provide to protect against COVID-19 infection. We need to remember to maintain social distancing, hand hygiene, and other essential measures.

Xu et al.[22] have shown that indoor environments can contain high rates of aerosol dispersants, which may promote high rates of viral transmission; however, when wearing an N95 respirator or a surgical mask, the level of aerosols can be reduced significantly. Likewise, Araújo et al.[5] demonstrated that wearing face masks in a community scenario can significantly decrease viral infections. Moreover, surgical masks offer higher protection when compared with cloth masks. On the other hand, to achieve a significant reduction in COVID-19 transmission, more than half of the population needs to be wearing masks. Therefore, the rate of infection transmission is important to be considered by public health recommendations regarding the use of masks. Nowadays, when we observe a new and more transmissible SARS-CoV-2 strain, a low rate of vaccination, and/or no use of facial masks, we may await more critical outcomes, such as increases in the number of hospitalizations and deaths again.

When we evaluated the use of masks without stratifying the specific type of mask or study design, there was a 57% reduction in the chance of COVID-19 infection (Figure 3). Regarding the comparison between surgical masks and N95 respirators, regardless of the study design, we found a 49% and 69% reduction in the chance of COVID-19 infection, respectively The difference in protection between surgical masks and N95 respirators is due to the difference in the permeability of the material used in their manufacture, because the material used in N95 respirator masks is less impermeable than that used in surgical masks, offering greater protection. However, there are biases, such as time of use, training for use, and number of times of exposure to contaminants and to places with a higher chance of contamination, that are determining factors in greater or lesser protection when using PPE.

This systematic review had some limitations: the first and major limitation is the huge variability in viral incidence (i.e., lack of preliminary estimates of the basic reproduction number [R_0] of SARS-CoV-2); the assessment of the effectiveness of wearing a mask can directly correlate to adherence, time of use, type of location of exposure, incidence of COVID-19 infection at the study site, type of mask, social distancing, and other factors. In addition, the studies included in this review were performed during the COVID-19 pandemic; however, the R_0 of each study was probably different, a fact that can cause largely different results. Moreover, most of the studies included were considered to have a serious risk of bias and a low certainty of evidence.

Because of the difficulty in conducting good-quality randomized controlled trials during a pandemic that has spread around the world rapidly, we needed to work with the best evidence available.

FINAL CONSIDERATIONS

The use of masks showed effectiveness in the prevention of SARS-CoV-2, regardless of the mask type (disposable surgical masks, common masks, including cloth masks, or N95 respirators). However, the certainty of evidence was low.

AUTHOR CONTRIBUTIONS

IF, AS, HAB, AN, ST, and WMB: study concept and design. IF and AS: data collection. IF, AS, and WB: statistical analyses and interpretation of data. WMB and SET: drafting of the manuscript. IF, AS, SET, HAB, AN, ST, and WMB: critical review and approval of the final version of the manuscript.

CONFLICTS OF INTEREST

None declared.

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