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Effectiveness of N95 Respirator versus Surgical Mask against Sars-Cov2 - Systemic Review and Meta Analysis

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Abstract

Introduction: The effect of N95 respirators for the protection against the infection is still undetermined. Hence in this study we evaluated the effectiveness of N95 respirators against surgical masks for inhibition of SARS- COV2 by gathering randomized controlled trials (RCTs).

Materials and Methods: Online data from PubMed, EMBASE, Cochrane Library was searched for period of one year from Jan-2020 to jan-2021. The studies between 2009 and 2020 were searched. The systematic reviews were considered. The RCTs incorporated in systematic reviews were recognized. We also searched for the RCTs done independently. Risk of the bias was evaluated by 2 reviewers independently after data extracted. Meta-analyses were done to calculate pooled estimates by RevMan 5.3 software.

Results: A total of six RCTs involving 9171 participants were included. There were no statistically significant differences in inhibiting laboratory-confirmed SARS- COV2 (RR = 1.09, 95% CI 0.92- 1.28, P > .05), laboratory-confirmed respiratory viral infections (RR = 0.89, 95% CI 0.70-1.11), laboratory-confirmed respiratory infection (RR = 0.74, 95% Cl 0.42-1.29) and influenza like illness (RR = 0.d1, 95% CI 0.33-1.14) using N 95 respirators

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and surgical masks. Meta-analysis indicated a protective effect of N95 respirators against laboratory-confirmed bacterial colonization (RR - 0.58, 95% CI 0.43-0.78).

Conclusion**:** The use of N95 respirators matched with surgical masks is not associated with a lower risk of laboratory-confirmed SARS- COV2. It suggests that N95 respirators should not be recommended for general public and non high-risk medical staff those are not in close contact with SARS- COV2 patients or suspected patients.

Keywords: Surgical masks, N95 respirator, Respiratory tract infections.

Introduction

Severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) have mortality rates about 10% and 37%, correspondingly.1 Ever since the outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), facemasks have been deliberated to be vitally important to reduce the risk of infection because vaccination or specific anti-infective treatments are unavailable.2,3 N95 respirators are used to protect users from inhaling small airborne particles and must fit tightly to the user's face. Surgical masks are intended to protect wearers from microorganism transmission and fit slackly to the user's face.5,6 Though surgical masks cannot stop inhalation of small airborne particles, both of them can defend users from large droplets and sprays.7,8 There are inconsistent recommendations for severe acute respiratory syndrome (SARS) and pandemic influenza: the World Health Organization (WHO) recommends using masks in low-risk situations and respirators in high-risk situations, but the Centers for Disease Control and Prevention (CDC) endorses using respirators in both low and high-risk situations.9 However, N95 respirators may play a incomplete role in low-resource settings, where there are a limited number of N95 respirators, or it may be too expensive.9 Also, previous meta-analyses determined there was insufficient evidence to determine the effect of N95 respirators due to a small number of studies that is prone to lack of statistical power.10,11 Furthermore, these meta-analyses were limited by the small number of included randomized control trials (RCTs). More, well planned RCTs of comparing N95 respirators with surgical masks against influenza published in recent years were not incorporated in previous meta-analyses.12-14 In light of the growing number of RCTs of masks use for protecting against, this systematic review and meta-analysis intended to evaluate the effectiveness of N95 respirators versus surgical masks for prevention of` SARS- COV2.

Materials and method

This meta-analysis was piloted based on the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.15 We included only the studies that were

(1) RCT (including cluster randomized trial) and nonrandomized controlled study;

(2) COVID patients

(3) N95 respirators and surgical masks

(4) RTPCR- confirmed cases only was taken as primary outcome variable

(5) Other lab confirmed respiratory viral, bacterial infections are taken as secondary outcome variables

(6) Hospital or community.

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All the other human studies with improper design were excluded.

Search approach

Online data from PubMed, EMBASE, Cochrane Library was searched for period of one year from Jan-2020 to jan-2021. The terms like N95 mask, surgical mask, SAR-COV2, systemic reviews, meta analysis. Later, primary RCTs included in the systematic reviews were identified. Furthermore, we piloted an additional search to identify RCTs published in the past five years from January 27, 2015, to January 27, 2020, using the databases and search strategies described above.

Data mining:

Two reviewers independently selected the articles based on the titles, abstracts and full texts. Then, two reviewers independently extracted the following data from included studies: first author, publication year, country, disease, details of study population and intervention, study design, sample size, settings, and results.

Risk of bias assessment

Two reviewers independently assessed the risk of bias of the selected RCTs using the Cochrane Risk of Bias tool,16 which includes domains on random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, and selective reporting. For each RCT, every domain was judged among 3 levels: high risk, unclear risk, and low risk. Disagreements were resolved by discussion.

Data analysis

All statistical analyses were performed using Review Manager (RevMan) version 5.3. Comparable data from studies with similar interventions and outcomes were pooled using forest plots. Relative risk (RR) with 95% confidence intervals (CIs) for dichotomous data was used as the effect measure. Between-study heterogeneity was assessed using the I^2 for each pooled estimate.17 We adopted a random-effects model for heterogeneity $P < 0.10$. We performed a subgroup analysis based on the settings (hospital, community) due to the possibility of clinical heterogeneity. A sensitivity analysis was conducted to evaluate the robustness of the results by excluding individual studies for each forest plot. Funnel plots were planned to assess publication bias. Because of the small number of studies available for each pooled estimate, we failed to assess publication bias.

Results

Search results and study characteristics

In total, we included six RCTs (12,18-22) and found no unpublished data of RCTs from ClinicalTrials.gov. The characteristics of these RCTs were presented in Table 1. The included studies published between 2009 and 2019. A total of 9171 participants in Canada, Australia, China, or America were included, and the number of participants in each RCT ranged from 435 to 5180 patients. The follow-up duration varied from 2 to 15 weeks. Five studies included participants in hospitals,12,18,20-22 and one in households.19 Because of different definitions of outcome in included studies, we redefined the laboratory confirmed respiratory infection as respiratory SARS- COV2, other viruses or bacteria infection. 3.2

Risk of bias

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The results of the risk of bias assessment can be found in Figure 2. Five studies reported the computer-generated random sequences, while only one mentioned randomization. All studies did not mention allocation concealment. Participants and trial staff were not blinded in two studies, and the other two studies failed to mention the blinding of participants and personnel. Four studies did not report whether the outcome assessors were blinded. All studies had complete outcome data or described comparable numbers and reasons for withdrawal across groups and prespecified outcomes.

Effectiveness

Five RCTs involving 8444 participants reported laboratory-confirmed influenza &/ SARS-COV2.12,18-21 Meta-analysis with fixed-effects model revealed that there was no statistically significant differences in inhibiting influenza using N95 respirators and surgical masks (RR = 1.09, 95% CI 0.92-1.28, P > .05) (Figure 3). The results of subgroup analyses were consistent with this regardless of the hospital or the community. The results of the sensitivity analysis were not altered after excluding each trial. Four RCTs18-21 involving 3264 participants reported laboratory confirmed respiratory viral infections. Meta-analysis with fixed-effects model revealed that there were no statistically significant differences in inhibiting respiratory viral infections using N95 respirators and surgical masks (RR = 0.89, 95% CI 0.70-1.11, P > .05) (Figure 4). The results of subgroup analyses were consistent regardless of the hospital or the community. However, the sensitivity analysis after excluding the trial by Loeb et al18 showed a significant effect of N95 respirators on stopping respiratory viral infections (RR=0.61, 95% CI 0.39-0.98, P < .05). Two RCTs21,22 involving 2538 participants reported laboratory confirmed bacterial colonization. Meta-analysis with fixed-effects model revealed that compared with surgical masks, N95 respirators significantly decreased bacterial colonization in hospitals (RR = 0.58, 95% CI 0.43-0.78, P < .05) (Figure 5). The sensitivity analysis showed that the results did not change after excluding each trial. Two RCTs12,22 involving 6621 participants reported laboratory confirmed respiratory infection. Meta-analysis with random-effects model revealed that there were no statistically significant differences in inhibiting respiratory infection using N95 respirators and surgical masks in hospitals (RR = 0.74, 95% CI 0.42-1.29, P > .05) (Figure 6). However, the sensitivity analysis after excluding the trial by Radonovich et al12 showed a significant effect of N95 respirators on inhibiting respiratory infection (RR = 0.53, 95% CI 0.35-0.82, P < .05). Five RCTs involving 8444 participants reported influenza like illness.12,18-21 Meta-analysis with random-effects model revealed that there were no statistically significant differences in inhibiting influenza like illness using N95 respirators and surgical masks (RR = 0.61, 95% CI 0.33-1.14, P > .05) (Figure 7). The results of subgroup analyses indicated that statistically significant superiority of N95 respirators over surgical masks against influenza like illness (RR = 0.37, 95% CI 0.20-0.71, P < .05) in the community (only one RCT). The sensitivity analysis showed results remained unchanged after excluding each trial.

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Figure 1: Flowchart of retrieved studies.

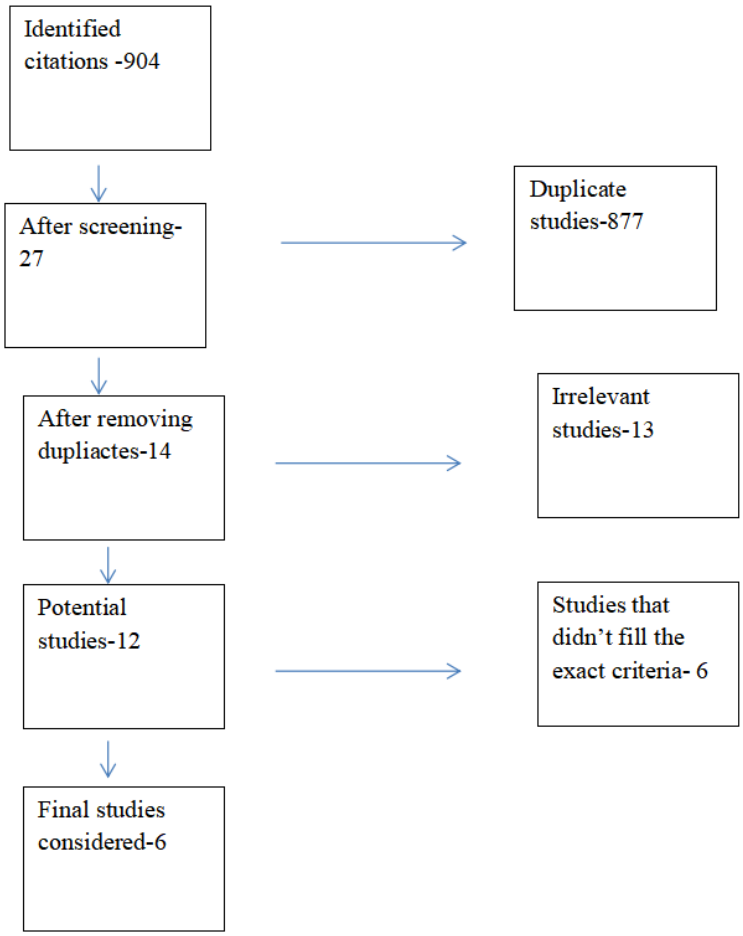

TABLE 1: Characteristics of studies included in the meta-analysis

Study	Setting	Participants	Intervention	Outcomes	Notes
Loeb et al 2009[18]	8 hospitals in Ontario, Canada: emergency departments, acute medical units and pediatric units	446 nurses; individual-level randomization	•Intervention: targeted use, fit-tested N95 respirator • Control: targeted use, surgical mask	•Laboratory-confirmed respiratory infection, influenza-like illness, workplace absenteeism • 5-week follow-up	•Noninferiority trial • Detection of influenza A and B, respiratory syncytial virus metapneumovirus, parainfluenza virus, rhinovirus-enterovirus, coronavirus and adenovirus
MacIntyre	145	145 index	Intervention	•Laboratory-	Detection of

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et al 2009[19]	households in Sydney, Australia	patients and 290 household contacts in 145 households; cluster randomization by household	1: continual use, surgical mask • Intervention 2: continual use, nonfit-tested N95 • respirator • Control: lifestyle measures	confirmed respiratory virus infection, influenza-like illness • 2-week follow-up	influenza A and B, respiratory syncytial virus, parainfluenza virus, rhinovirus-enterovirus, coronavirus, coronavirus, adenovirus
MacIntyre et al 2011[20]/2014[22]	15 hospitals in Beijing, China: emergency departments and respiratory wards	1441 nurses, doctors and ward clerks; cluster randomization by hospital	• Intervention 1: continual use, fit-tested N95 respirator • Intervention 2: continual use, nonfit-tested N95 respirator• Control: continual use, surgical mask	Laboratory-confirmed respiratory infection, influenza-like illness • 5-week follow-up	Detection of influenza A and B, respiratory syncytial virus, metapneumovirus, parainfluenza virus, rhinovirus-enterovirus, coronavirus, adenovirus, streptococcus pneumoniae, bordetella pertussis, chlamydophila pneumoniae, mycoplasma pneumoniae and haemophilus influenzae type B
MacIntyre et al 2013[21]	19 hospitals in Beijing, China: emergency departments and respiratory wards	1669 nurses, doctors and ward clerks; cluster randomization by ward	• Intervention 1: continual use, fit-tested N95 respirator • Intervention 2: targeted use, fit-tested N95 respirator • Control:	• Laboratory-confirmed respiratory infection, influenza-like illness • 5-week follow-up	Detection of influenza A and B, respiratory syncytial virus metapneumovirus, parainfluenza virus, rhinovirus-

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			continual use, surgical mask		enterovirus, coronavirus, adenovirus, S. pneumoniae, B. pertussis, C. pneumoniae, M. pneumoniae and H. influenzae type B
Radonovich et al 2019[12]	7 hospitals in US: primary care facilities, dental clinics, adult and pediatric clinics, dialysis units, urgent care facilities and emergency departments, and emergency transport services	5180 nurses/nursing trainees, clinical care support staff, administrative/clerical staff, physicians/advanced practitioners/ physician trainees, registrations/ clerical receptions, social workers/pastoral cares and environmental service workers/housekeepers; cluster randomization by outpatient clinic or outpatient setting	•Intervention: targeted use, fit-tested N95 respirator • Control: targeted use, medical mask	•Laboratory-confirmed respiratory infection, laboratory-confirmed influenza, laboratory-detected respiratory illness, influenza-like illness, acute respiratory illness • 12-week follow-up •	Effectiveness study • Detection of influenza A and B, respiratory syncytial virus, metapneumovirus, parainfluenza virus, rhinovirus-enterovirus, coronavirus, coxsackie/echovirus

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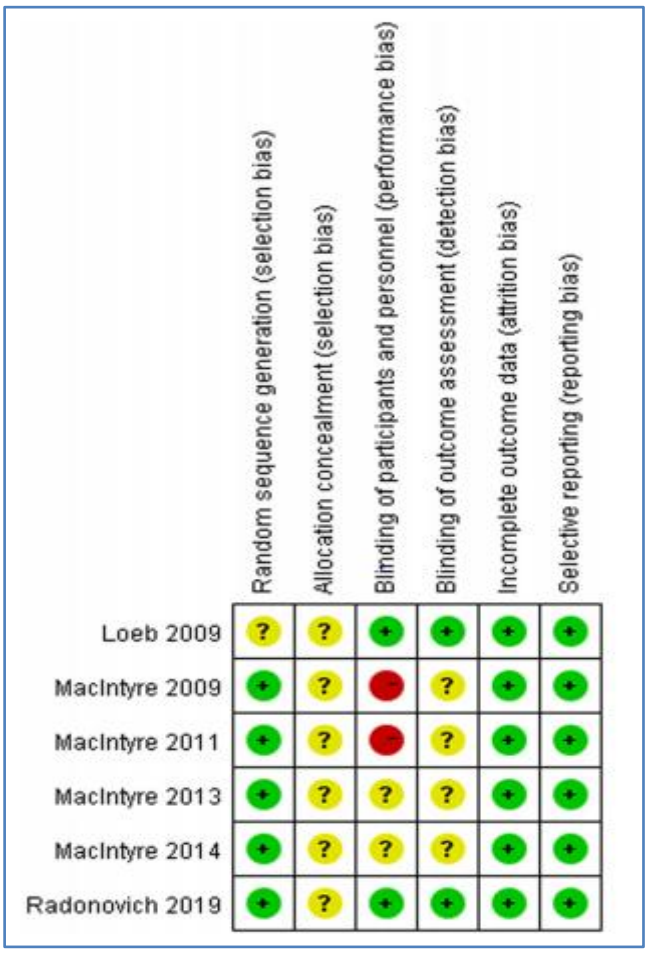

FIGURE 2: Risk of bias summary

FIGURE 3: N95 respirators vs surgical masks against laboratory-confirmed "SARS-COV2"

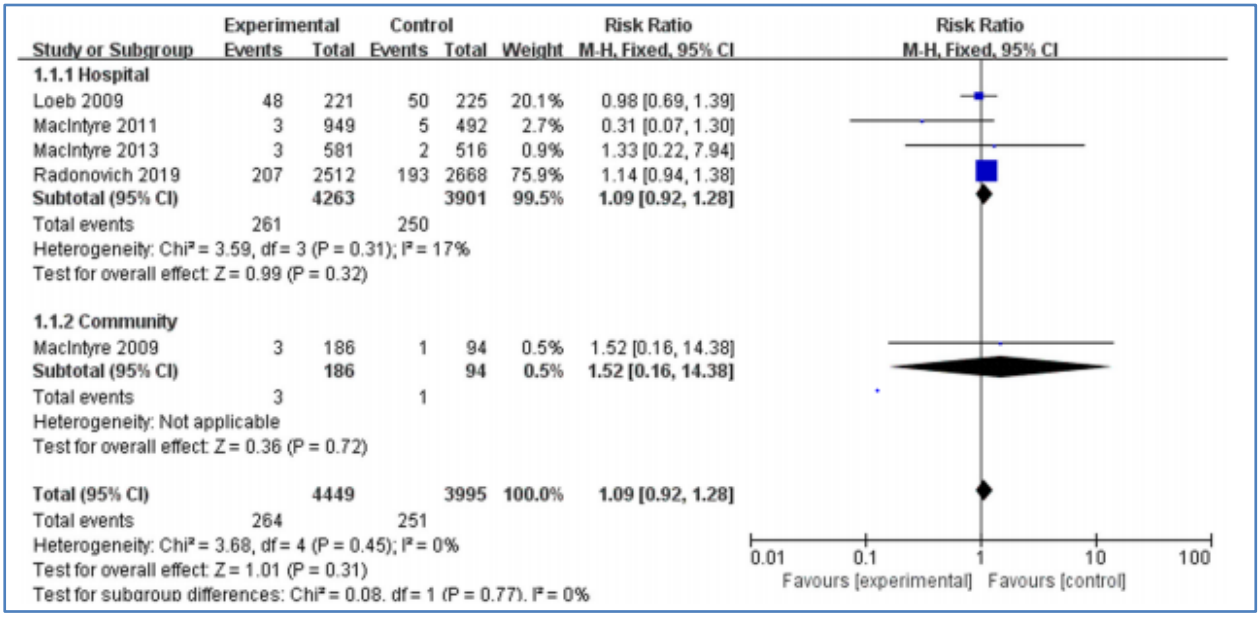

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FIGURE 4: N95 respirators vs surgical masks against laboratory-confirmed respiratory "viral infections"

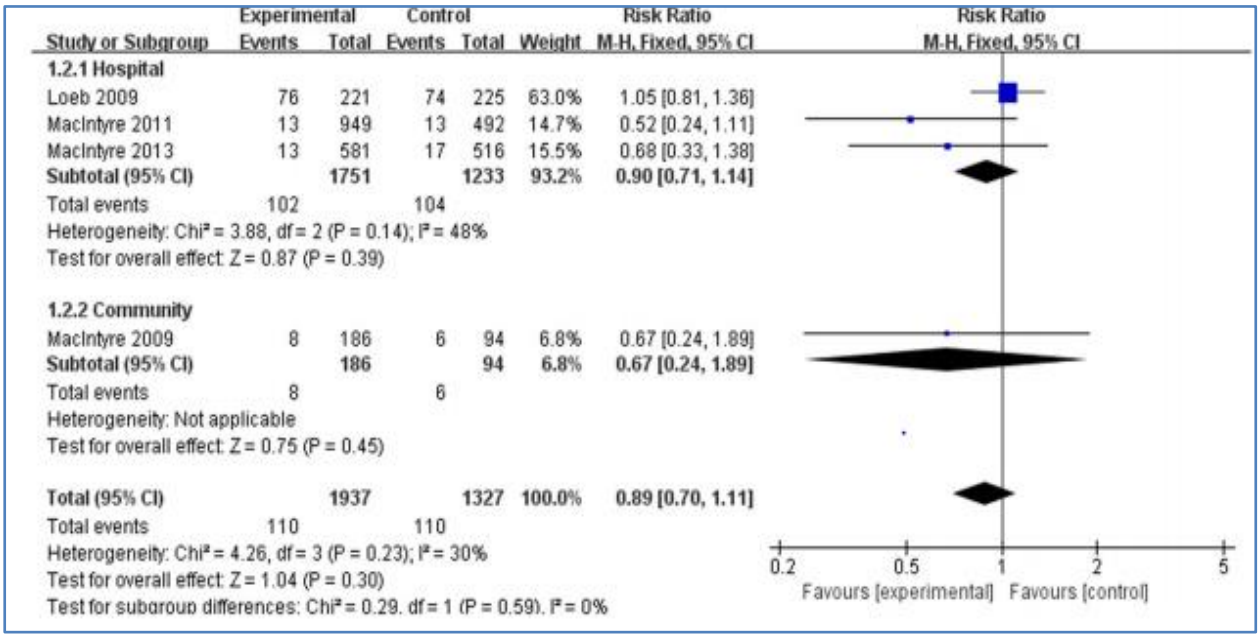

FIGURE 5: N95 respirators VS surgical masks against laboratory-confirmed bacterial colonization

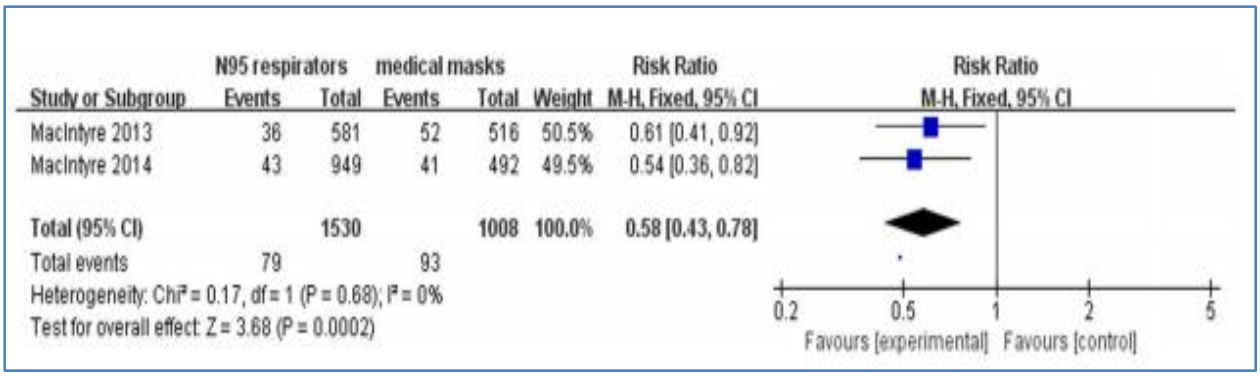

FIGURE 6: N95 respirators VS surgical masks against laboratory-confirmed respiratory infection

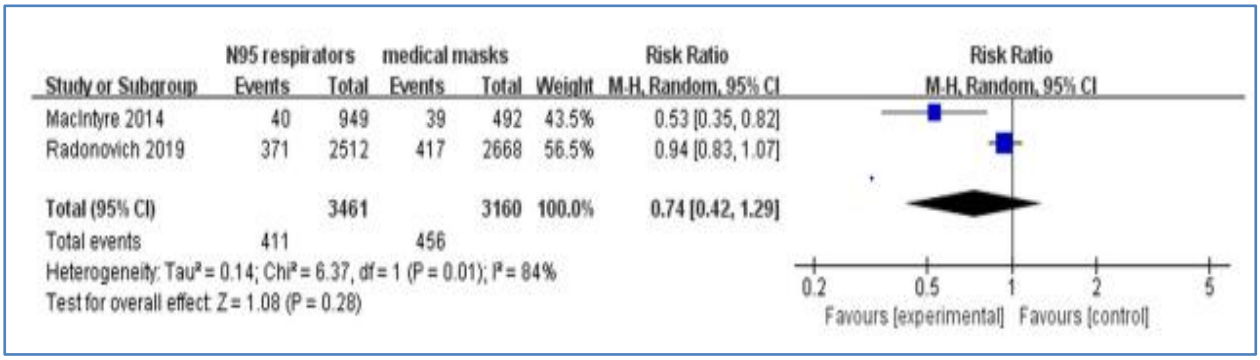

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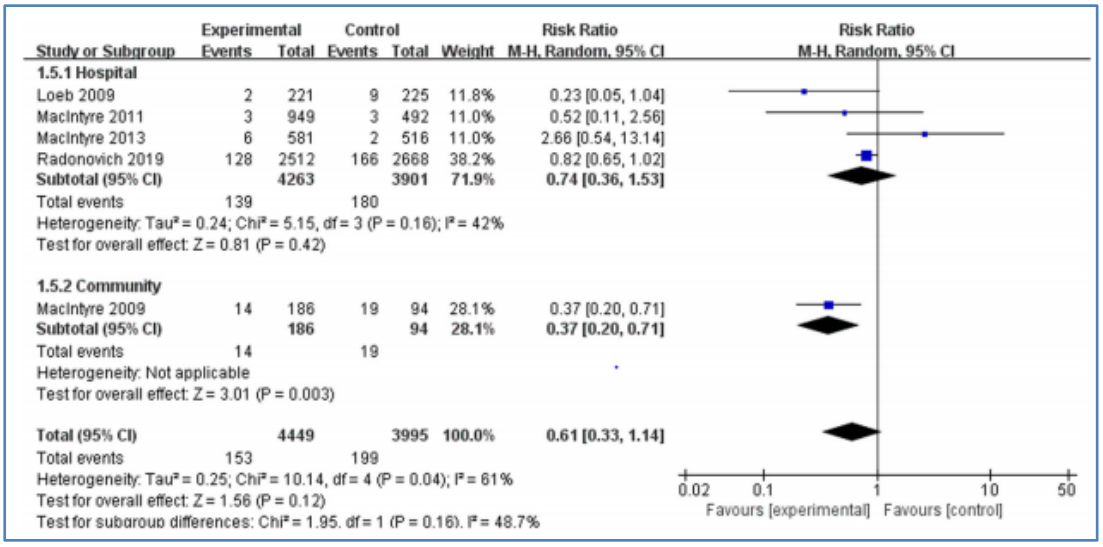
FIGURE 7: N95 respirators VS surgical masks against influenza like illness



Discussion

This meta-analysis showed that there were no statistically significant differences in inhibiting laboratory-confirmed SARS-COV2, laboratory confirmed respiratory viral infections, laboratory-confirmed respiratory infection and influenza-like illness using N95 respirators and surgical masks. N95 respirators delivered a protective effect against laboratory-confirmed bacterial colonization. In subgroup analysis, similar results could be found in the hospital and community for laboratory-confirmed influenza/ SARS- COV2 and laboratory-confirmed respiratory viral infections. Nonetheless, sensitivity analysis showed unstable results for the prevention of laboratory-confirmed respiratory viral infections and laboratory-confirmed respiratory infection. Over the course of influenza/ SARS- COV2 pandemics, large numbers of facemasks may be required to use in long periods to guard people from infections.23 Using N95 respirators is probable to result in discomfort, for instance, headaches.23 A earlier study3 reported that there was an converse relationship between the level of defiance with wearing an N95 respirator and the risk of clinical respiratory illness. It is problematic to ensure high compliance due to this discomfort of N95 respirators in all studies. The reason for the similar effects on inhibiting influenza/ SARS- COV2 for the use of N95 respirators versus surgical masks may be connected to low compliance to N95 respirators wear,23 which may lead to more common doffing compared with surgical masks.13 Though N95 respirators may confer more protection in laboratory studies designing to achieve 100% intervention adherence,24 the routine use of N95 respirators seems to be less acceptable due to more substantial discomfort in real-world practice.11 Consequently, the benefit of N95 respirators of fitting tightly to faces is offset or subjugated.13 Nevertheless, it should be noted that the surgical masks are primarily designed to protect the environment from the wearer, whereas the respirators are supposed to protect the wearer from the environment.25 There are some limitations to this study. First, some RCTs had a great risk of bias due to lack of allocation concealment and blinding; though it is impractical to blind participants who would know the type of masks they are wearing. Second, the number of comprised studies focusing on the community was small. Thus, the results of the subgroup analysis might be unreliable. Third, we identified RCTs from published systematic reviews, which may end in the omission of relative RCTs. Finally, there might be publication bias, and we cannot measure it due to an insufficient number of included RCTs.

Conclusion

In conclusion, the present meta-analysis shows the use of N95 respirators equated with surgical masks is not related with a lower risk of laboratory-confirmed influenza/ SARS-COV2. It proposes that N95 respirators should not be endorsed for the general public and non-high risk medical staffs those are not in close interaction with influenza/ SARS- COV2 patients or suspected patients.

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