La Medicina del Lavoro

Med Lav 2020; 111, 5: 365-371
DOI: 10.23749/mdl.v111i5.9692

Surgical masks vs filtering facepiece respirators for the protection against coronavirus infection: current state of the art

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Key words: Surgical masks; filtering facepiece respirators; aerosols; droplets; SARS-CoV-2; Covid-19

Parole chiave: Maschere chirurgiche; respiratori facciali filtranti; aerosol; droplet; SARS-CoV-2; Covid-19

Abstract

Background: *During the Covid-19 outbreak, a recurrent subject in scientific literature has been brought back into discussion: whether surgical masks provide a sufficient protection against airborne SARS-CoV-2 infections.* **Objectives:** *The objective of this review is to summarize the available studies which have compared the respective effectiveness of surgical masks and filtering facepiece respirators for the prevention of infections caused by viruses that are transmitted by the respiratory tract.* **Methods:** *The relevant scientific literature was identified by querying the PubMed database with a combination of search strings. The narrower search string "(surgical mask *) AND (respirator OR respirators)" included all the relevant articles retrieved using broader search strategies. Of all the relevant articles found, seven systematic reviews were selected and examined.* **Results:** *The currently available scientific evidence seems to suggest that surgical masks and N95 respirators/FFP2 confer an equivalent degree of protection against airborne viral infections.* **Discussion:** *Since surgical masks are less expensive than N95 respirators but seem to be as effective in protecting against airborne infection and they are also more comfortable for the user, requiring less respiratory work, they should be the standard protective device for health care workers and especially for workers who carry out non-medical jobs. Filtering facepiece respirators, whose extended use is less comfortable for the wearer, may be preferred for procedures which require greater protection for a shorter time.*

Riassunto

***«Confronto tra maschere chirurgiche e respiratori con filtro facciale per la protezione contro le infezioni da SARS-CoV-2. Lo stato dell'arte»*. Background:** *Durante l'epidemia di Covid-19, un argomento ricorrente di discussione nella letteratura scientifica è se le maschere chirurgiche forniscano una protezione sufficiente contro le infezioni da SARS-CoV-2.* **Obiettivi:** *Questa revisione della letteratura si propone di riassumere gli studi disponibili che hanno confrontato l'efficacia delle maschere chirurgiche e dei respiratori con filtro facciale per la prevenzione delle infezioni causate da virus che vengano trasmessi per via respiratoria.* **Metodi:** *La letteratura scientifica pertinente è stata identificata interrogando il database PubMed con una combinazione di stringhe di ricerca. La stringa di ricerca più stretta "(surgical mask*) AND (respirator OR respirators)" comprendeva tutti gli articoli pertinenti recuperati*

Received 3.5.2020 - Accepted 23.5.2020
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utilizzando strategie di ricerca più ampie. Tra tutti gli articoli pertinenti trovati, sono state selezionate ed esaminate sette revisioni sistematiche. **Risultati:** *Le prove scientifiche attualmente disponibili sembrano suggerire che le maschere chirurgiche e i respiratori N95 / FFP2 conferiscano un grado equivalente di protezione contro le infezioni virali nell'aria.* **Discussione:** *Poiché le maschere chirurgiche sono meno costose dei respiratori N95, ma sembrano essere altrettanto efficaci nella protezione dalle infezioni nell'aria e sono anche più comode per l'utente, richiedendo minor impegno respiratorio, dovrebbero essere il dispositivo di protezione standard per gli operatori sanitari e in particolare per i lavoratori che svolgono mansioni non mediche. I respiratori con filtro facciale, il cui uso prolungato è meno confortevole per chi lo indossa, possono essere preferiti per le procedure che richiedono maggior protezione per un tempo più breve.*

Introduction

The SARS-CoV-2 storm coming from China hit Italy, other European countries, and eventually the United States and the rest of the world, finding all those Countries largely unprepared, particularly with regards to the availability of personal protective equipment. Among these, devices for the protection of health personnel and other workers (such as employees involved in the production and distribution of essential goods and services, law enforcement, etc.) who remain active even during periods of isolation of the rest of the population, the so called "lock-down", were particularly scarce.

The shortage of devices for the protection of health care personnel has been underlined both by the general information media and by scientific literature (4, 5, 13-15).

In the midst of the debate surrounding the lack of masks (mainly surgical), a theme already known in scientific literature has re-emerged: namely, whether surgical masks are a sufficient tool for the prevention of infections caused by viruses that are transmitted by the respiratory tract or if other respiratory protective devices would be more effective. Here, we will reference the individual protective devices of the respiratory tract typically used on an industrial level (filtering facepiece respirators: that is, half-masks covering the nose and mouth, made of materials capable of filtering particulate and aerosols). Before diving into the topic, however, it is useful to make a short reference to surgical masks and filtering facepiece respirators.

In Europe, surgical masks must have the characteristics indicated by the EN 14683:2019 standard which encompasses three types of masks. Type I masks, intended for patients or other people of the public, must have a breathability index (pressure drop caused by the mask) lower than 40 Pa/4.9 cm^2, a minimum bacterial filtration efficiency of 95% (measured by spraying on the mask an aerosol of liquid particles of the size of 3 μm containing Staphylococcus aureus ATCC 6538 in the range between 1.7×10^3 - 3.0×10^3 CFU) and a maximum microbial load of 30 CFU/g. Type II masks, intended for healthcare professionals, must have a breathability index (pressure drop caused by the mask) of less than 40 Pa/4.9 cm^2, a minimum bacterial filtration efficiency of 98% and a maximum microbial load of 30 CFU/g. Type IIR surgical masks, also intended for healthcare professionals, must have a breathability index (pressure drop caused by the mask) lower than 60 Pa/4.9 cm^2, a minimum bacterial filtration efficiency of 98%, a maximum microbial load of 30 CFU/g and must pass a test that evaluates the penetration of a splash of synthetic blood. The EN 14683:2019 standard, which specifies the filtration characteristics that must be possessed by surgical masks, does not contemplate the evaluation of the ability to filter particulate (while the ability to filter aerosol is indicated, indirectly, by the measurement of the bacterial filtration efficiency).

In Europe, filtering facepiece respirators must have the characteristics indicated by the EN 149:2001 (+ A1: 2009) standard, which mandates that these masks, among other things, must have specific characteristics of breathability, inward leakage, flammability, accumulation of CO_2, etc. The EN 149:2001 (+ A1: 2009) standard requires that the filtering capacity of the masks be tested both with an aerosol of NaCl particles having a diameter distribution median between 0.06 and 0.10 μm

and with an aerosol of particles of paraffin oil (CAS number 8012-95-1) having a median diameter distribution between 0.29 and 0.45 μm; no bacterial filtration efficiency test is requested. Based on their filtering capacity, the filtering facepiece respirators are classified into type FFP1 (filtration capacity of NaCl aerosol and paraffin oil equal to 80%), FFP2 (filtration capacity of NaCl aerosol and paraffin oil equal to 94%) and FFP3 (filtration capacity of NaCl aerosol and paraffin oil equal to 99%).

In the USA, respirators must comply with the NIOSH N95 or N100 standard by law (1). Respirators of the N95 type are tested for NaCl aerosol resistance with a median particle distribution of 0.075 ± 0.020 μm, and must have a filtration efficiency of at least 94% and, like European respirators facepieces, they are not tested for bacterial filtration efficiency.

Although the filtration efficiency seems similar between FFP2 and N95 filtering facepiece respirators, the tests required by the European and US standards are different in a number of ways (flow rate, inward leakage, inhalation and exhalation resistance, and so on) so that the two devices may not be considered exactly interchangeable.

Since the filtering facepiece respirators are tested for the filtration of sub-micrometric particles, it is common belief that they confer greater protection than surgical masks against airborne infections by bacteria or viruses (see below for a short discussion of the droplet/aerosol debate): this belief is shared by documents of national or international institutions that tend to recommend respirators (N95 in the USA, FFP2 in Europe) on those occasions in which it is possible to assume a greater risk of transmission of bacteria or viruses by air. Given the importance of the prevention of airborne infections (especially for healthcare professionals, who are the most exposed category), a systematic review of scientific literature was conducted to answer the following question: based on the scientific evidence available to date, which airway protection devices have a greater degree of protective efficacy against airborne viral infections, surgical masks or filtering facepiece respirators?

Viral infections, in this study's question, is a proxy for SARS-CoV-2 infection: as SARS-CoV-2 is a novel virus, of course, scientific studies on this specific virus are scarce.

Methods

We searched for original studies, or reviews, aimed at comparing the effectiveness of surgical masks vs filtering facepiece respirators in preventing droplets/airborne infections in humans: we did not take in consideration laboratory-only studies as they could not be informative for the research question.

As we were interested in human studies, PubMed was chosen as a reference database as we assumed that the probability of finding a relevant study in another database but not in PubMed was negligible. No language limitation was used.

Initially we applied a very broad search string "(viral or virus) and (mask or masks)" which retrieved more than 2.800 citation which were independently reviewed by both authors: less than five per cent of the citations where retained after just screening the title.

After this broad screening, a narrower search strategy was attempted, with a combination of the following terms: (surgical mask*), respirator, respirators, N95, N100, FFP2, FFP3: the pertinent citations selected with the broader search string were also all retrieved using the narrower search strategy.

A final search strategy used was the simple string "(surgical mask*) AND (respirator OR respirators)", which retrieved 225 citations, including all the pertinent articles retrieved with the broader search strings: this latter research was originally conducted in April 2020 and repeated on the date in which the final version of this manuscript has been written (12.7.2020, 241 citations retrieved). The articles retrieved were examined one by one in abstract format: this allowed for the identification of 7 systematic reviews that were recovered in full-text and examined in detail. The most recent of these systematic reviews examined the literature published up to 21.3.2020: no other relevant study providing sound original data on the matter appears to have been published since the most recent systematic review, and so the present review is actually a "review of systematic reviews". Five articles citing only FFP3 or N100 filtering facepiece respirators have been ex-

cluded from this review as none of them was a comparative study with surgical masks. The most recent systematic review on this topic (3) was excluded as it pooled together surgical and home-made masks; a scoping review (6) was not included as it did not focus on the comparative effectiveness of surgical masks and filtering facepiece respirators.

Results

The results of the 7 identified systematic reviews are listed below, in order of publication date. Between 2007 and 2011 Jefferson et al published four systematic reviews on interventions capable of stopping or reducing the spread of respiratory viruses (8-11). In the most recent review (that of 2011), which included 67 studies, 19 considered the use of surgical masks or N95 respirators. As for the comparison between the use of surgical masks and that of N95 respirators, the authors conclude: "*We found no evidence that the more expensive, irritating and uncomfortable N95 respirators were superior to simple surgical masks*".

In 2016 Smith et al. (16) published a systematic review and meta-analysis of studies on the effectiveness of N95 respirators compared with surgical masks in protecting healthcare workers from acute respiratory infections. The review considers 6 clinical studies (3 randomized clinical trials, one cohort study and 2 case control studies and 23 laboratory studies in which exposure is simulated). The authors conclude: "*In the meta-analysis of the clinical studies, we found no significant difference between N95 respirators and surgical masks in associated risk of (a) laboratory-confirmed respiratory infection (RCTs: odds ratio [OR] 0.89, 95% confidence interval [CI] 0.64–1.24; cohort study: OR 0.43, 95% CI 0.03–6.41; case–control studies: OR 0.91, 95% CI 0.25–3.36); (b) influenza-like illness (RCTs: OR 0.51, 95% CI 0.19–1.41); or (c) reported workplace absenteeism (RCT: OR 0.92, 95% CI 0.57–1.50). Although N95 respirators appeared to have a protective advantage over surgical masks in laboratory settings, our meta-analysis showed that there were insufficient data to determine definitively whether N95 respirators are superior to surgical masks in protecting health care workers against transmissible acute respiratory infections in clinical settings)*".

In March 2020 Long et al. (12) published a systematic review and meta-analysis of studies on the effectiveness of N95 respirators compared with surgical masks in protecting healthcare workers from the flu. The review considers 6 randomized clinical trials involving a total of 9,171 participants. The authors conclude: "*There were no statistically significant differences in preventing laboratory-confirmed influenza (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% CI 0.42-1.29) and influenza-like illness (RR = 0.61, 95% CI 0.33-1.14) using N95 respirators and surgical masks. … The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and non high-risk medical staff who are not in close contact with influenza patients or suspected patients. … The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza. It suggests that N95 respirators should not be recommended for general public and non high-risk medical staff who are not in close contact with influenza patients or suspected patients)*."

In June 2020 Iannone et al. (7) published a GRADE rapid review on the effectiveness of N95 respirators compared with surgical masks in protecting healthcare workers from respiratory infections. The review considers 4 randomized clinical trials involving a total of 8,736 participants. The authors conclude: "*However, wearing N95 respirators can prevent 73 more (95% CI 46-91) clinical respiratory infections per 1000 HCWs compared to surgical masks (2 RCTs; 2594 patients; low quality of evidence). …We found no direct high-quality evidence on whether N95 respirators are better than surgical masks for HCWs protection from SARS-CoV-2. However, low quality evidence suggests that N95 respirators protect HCWs from clinical respiratory infections.*"

Discussion

The majority of the systematic reviews previously reported (considering only the last of those published by Jefferson and others) do not provide clear evidence that N95 respirators (roughly equivalent to

European FFP2) are in fact more effective than surgical masks in preventing respiratory infections, and in particular viral respiratory infections, in health workers (who are obviously the most studied population group, as they are those most at risk). This conclusion appears to be based on the best scientific evidence available to date, despite going against current "conventional wisdom".

In particular, the systematic review by Long et al. considered 6 randomized clinical trials (i.e. the type of experimental study believed to provide the most reliable evidence); the review by Iannone et al. also considered only randomized clinical trials, including 4 instead of 6 original studies. However, it is true that all studies, including randomized trials, that compare the relative degree of protection against infections provided by two different personal protective equipment still suffer from possible uncertainties that randomization process can mitigate but not completely control. One of these uncertainties lies in the definition of the exposure, which should ideally consist of the number of contacts at risk the operator wearing the protective device had during the study observation period. Another source of uncertainty concerns the actual time in which each participant in the study wore the device assigned to him (which in the studies carried out to date is assumed but not verified): from this point of view a respirator of N95 type (or FFP2) is more inconvenient to use due to the obstacle it creates to breathing, which is much greater than that created by a simple surgical mask (which is therefore more likely to be worn continuously throughout the period in which risky contacts may occur). The assumed superiority of N95 type respirators (or European FFP2 equivalents) compared to surgical masks in protecting against airborne infections appears to be based on the fact that the former are tested for their ability to filter smaller aerosols than the aerosols with which surgical masks are tested (0.1 versus 3 μm): this has led to believe that this capacity translates into a greater protective power especially against viruses (that of influenza has a size of about 100 nanometers, that is 0.1 μm). However, this assumption does not consider the fact that the microorganisms emitted by respiration or by the voice of infected people are actually housed in liquid particles which have a typical diameter much greater than that of a virus, up to 500 μm (2): this would explain why in the clinical studies that compared N95 respirators and surgical masks, the former did not show a greater ability to prevent airborne viral infections than the latter.

An additional consideration which is used in favor of the use of FFP2/N95 respirators is that they must have a specific, maximum level of inward leakage, whereas no such requirement exists for surgical masks (hence, the possibility that some inward flow of air will not pass through the filtering fabric).

As expected, the above-mentioned reviews cross-posted several original studies and also employed different outcome definitions: this should be born in mind while considering the summary of evidence that is reported in this paper.

An additional issue to consider with reference to the concept of "airborne induced infections" is the actual debate between "droplet" or "aerosol" induced infections, which is also relevant for SARS-CoV-2 induced Covid-19. Although a strict definition is lacking, "aerosols" it is often used to indicate liquid exhaled particles (mostly with a diameter equal or less than 5 μm) emitted with respiration or voice which exhibit Brownian motion and may remain suspended in air for longer periods of time than "droplets", a term which is often used to designate particles with a diameter larger than 5 μm (usually associated with coughing or sneezing), which fall rapidly to surrounding surfaces following a ballistic trajectory. Experts in the field have debated if the categorization aerosol/droplet is accurate enough, considering that evidence has shown that some pathogens, including viruses, although mainly transmitted through droplet, can be transmitted through aerosol in the absence of aersol generating procedures. This, of course, affects the definition of "exposure" in studies attempting to compare the relative protection offered by surgical masks or filtering facepiece respirators.

An additional issue for the generalizability of the results of the studies on this issue, is that, to date, (somewhat expectedly) no study has yet addressed the protection offered by surgical masks or filtering facepiece respirators against SARS-CoV-2 infection: thus, information gained from studies addressing,

for example, influenza virus, may not be completely extensible to the context of Covid-19 epidemics. A retrospective observational study (17) was published about the risk of specific infection by SARS-CoV-2 in 44 Chinese anesthetists comparing the number of subjects who tested positive to SARS-CoV-2 infection having had contact with Covid-19 patients using unspecified "Category 3 PPE" "including positive pressure (pressure demand), self-contained breathing apparatus" or Category 1 PPE "limited to surgical mask". The percentage of anesthetists who tested positive to SARS-CoV-2 in the (small) group using Category 1 PPE was larger than those in the group using Category 3 PPE, but, as the authors of the paper state, "We also cannot exclude that anesthetists became infected through other sources (e.g. colleagues in the hospital)."

In conclusion, the currently available scientific evidence suggests that surgical masks and N95 respirators (FFP2) seem to confer an equivalent degree of protection against airborne viral infections (i.e., that the use of N95 filtering facepiece respirator does not seem to confer a significantly greater protection than surgical masks).

Based on the available scientific evidence, however, the use of "any mask", especially when the device is donned both by the patient and the health care worker, seems indeed very effective in reducing the risk of SARS-CoV-2 infection (P. Boffetta, personal communication).

Therefore, if (based on theoretical considerations about the protective characteristics of the device) the use of filtering facepiece respirators to protect healthcare workers from the risk of airborne infections is considered preferable, it seems advisable that the use of such devices should be preferred for operations at greater risk (which typically have reduced duration) due to the greater respiratory work that the use of N95/FFP2 respirators involves, compared to the use of surgical masks.

With regards to workers who carry out non-medical jobs, surgical masks are even more so an adequate protective device against viral infections.

However, high-quality randomized trials are desirable, to further investigate the relative protection offered against viral infections (and specifically SARS-CoV-2) by surgical masks and filtering facepiece respirators, also considering their usability, which may actually affect the willingness of the health care worker to don the device for extended periods of time.

References

1. 42 CFR Part 84 - Approval of Respiratory Protective Devices, United States Government Publishing Office, https://www.ecfr.gov/
2. Anfinrud P, Stadnytskyi V, Bax CE, Bax A: Visualizing Speech-Generated Oral Fluid Droplets with Laser Light Scattering. N Engl J Med 2020 Apr 15. doi:10.1056/NEJMc2007800
3. Chu DK, Akl EA, Duda S, et al: Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis [published online ahead of print, 2020 Jun 1]. Lancet. 2020; S0140-6736(20)31142-9
4. Dargaville T, Spann K, Celina M: Opinion to address a potential personal protective equipment shortage in the global community during the COVID-19 outbreak. Polym Degrad Stab 2020 Apr 5:109162
5. Dyer C: Covid-19: doctors are warned not to go public about PPE shortages. BMJ 2020 Apr 21;369:m1592
6. Garcia Godoy LR, Jones AE, Anderson TN, et al: Facial protection for healthcare workers during pandemics: a scoping review. BMJ Glob Health. 2020;5(5):e002553
7. Iannone P, Castellini G, Coclite D, et al: The need of health policy perspective to protect Healthcare Workers during COVID-19 pandemic. A GRADE rapid review on the N95 respirators effectiveness. PLoS One 2020;15(6):e0234025
8. Jefferson T, Foxlee R, Del Mar C et al: Interventions for the interruption or reduction of the spread of respiratory viruses. Cochrane Database Syst Rev 2007 Oct 17;(4):CD006207
9. Jefferson T, Del Mar C, Dooley L, et al: Physical interventions to interrupt or reduce the spread of respiratory viruses: systematic review. BMJ 2009;339:b3675
10. Jefferson T, Del Mar C, Dooley L, et al: Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database Syst Rev 2010 Jan 20;(1):CD006207
11. Jefferson T, Del Mar CB, Dooley L, et al: Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database Syst Rev 2011 Jul 6;(7):CD006207
12. Long Y, Hu T, Liu L, et al: Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis. J Evid Based Med 2020 Mar 13

13. Mandrola JM: COVID-19 and PPE: Some of Us Will Die Because of the Shortage. Medscape Mar 20, 2020
14. O'Sullivan ED: PPE guidance for covid-19: be honest about resource shortages. BMJ 2020 Apr 17;369:m1507
15. Rowan NJ, Laffey JG: Challenges and solutions for addressing critical shortage of supply chain for personal and protective equipment (PPE) arising from Coronavirus disease (COVID19) pandemic - Case study from the Republic of Ireland. Sci Total Environ 2020 Apr 6;725:138532
16. Smith JD, MacDougall CC, Johnstone J et al. Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis. CMAJ. 2016 May 17;188(8):567-574
17. Zhong Q, Liu YY, Luo Q, et al: Spinal anaesthesia for patients with coronavirus disease 2019 and possible transmission rates in anaesthetists: retrospective, single-centre, observational cohort study [published correction appears in Br J Anaesth. 2020 Jul 3]. Br J Anaesth. 2020; 124:670-675

No potential conflict of interest relevant to this article was reported by the authors