Review Article

Protection From COVID-19

The Efficacy of Face Masks

Christoph Josef Hemmer, Frank Hufert, Stefan Siewert, Emil Reisinger

Summary

Background: Since the beginning of 2020 the SARS-CoV-2 virus has spread to nearly every country in the world. The mainly airborne pathogen has led to large numbers of deaths, principally in elderly and vulnerable segments of the population. Protective vaccines have recently become available, but it is not yet clear whether and when population-wide immunity will be achieved. The existence of evidence for the protective effect of masks covering the mouth and nose is a topic of public debate.

Methods: A selective literature search was carried out in PubMed. Data from the German Robert Koch Institute and the Centers for Disease Control and Prevention were also taken into account.

Results: When talking, as many as 20 000 droplets ranging in size from 20 to 500 µM are released every second. According to PCR tests, the amount of virus exhaled is highest immediately before the onset of symptoms. No randomized trials have been conducted on the effect of masks covering the mouth and nose. A meta-analysis of 29 studies on infection with SARS-CoV-2, SARS, or MERS revealed that type N-95 masks (corresponding approximately to FFP-2), surgical masks, or similar multilayer cotton masks can greatly reduce the infection risk for the wearers (RR 0.34 [0.26; 0.45], with moderate heterogeneity [I2 = 48%]). Model experiments and case reports suggest that masks covering the mouth and nose afford considerable protection against transmission of SARS-CoV-2 and other airborne diseases by reducing release of and exposure to potentially infectious droplets; in addition, infections that do occur take a milder course. A limitation of the studies analyzed is that in most cases, this effect cannot be viewed in isolation from the protective impact of other measures (distancing, hygiene precautions).

Conclusion: It can plausibly be assumed that consistent use of masks covering the mouth and nose can play an important role in containing the spread of SARS-CoV-2.

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Since the outbreak in Wuhan (China) in early 2020, SARS-CoV-2 has spread into a pandemic. The pathogen is mostly transmitted via the respiratory route. It has caused many deaths, especially in older and vulnerable populations. Vaccines have become available recently, but it is not known how quickly vaccinations will help to establish immunity at the population level (1). The most important protective measures against infection with SARS-CoV-2 include:

- Adhering to safe minimum distances
- Complying with hygiene measures, and
- Wearing a face covering over nose and mouth (mask).

Data from the scientific literature and case examples corroborate the importance of masks (see *Box 1*).

Method

We conducted a selective literature search in PubMed using combinations of the search terms "COVID-19", "SARS-CoV-2", "virus", "viral", "masks", "droplets", "aerosol", "transmission", and "prevention", without restrictions to the search period. We searched for English-language and German-language articles on the protective effects of masks with regard to COVID-19. Information from the German Robert Koch Institute and the US Centers of Disease Control and Prevention (CDC, Atlanta, USA) was also taken into account.

Infection pathways, viral load, and infectiousness

SARS-CoV-2 is transmitted by droplets and aerosols (4). Experiments have shown that in aerosols, SARS-CoV-2 can remain infectious for 3 hours (5). Infection can also be passed by direct person to person contact. Transmission from surfaces is currently regarded as less probable, although SARS-CoV-2 can remain infectious on steel surfaces for up to 48 hours and on plastic surfaces for up to 72 hours (5, 6). SARS-CoV-2 can probably be transmitted even if the index person has left an enclosed space shortly before the person to be infected enters it. A case report has implied this for the changing area of a squash center, but it was not possible to rule out that squash center staff present at the same time as the person to be infected were asymptomatic carriers (7).

The threshold for differentiating between droplets and aerosols is usually assumed to be a fluid particle size of 5–10 µm. Video studies have shown that

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BOX 1

Case examples of the protective effects of face masks

As early as March 2020, Chinese scientists described an outbreak of SARS-CoV-2 infections during a bus trip (2). A passenger who was infected with SARS-CoV-2 without being aware of it did not wear a mask during the first leg of a bus journey, which took two hours and ten minutes. Of the 39 fellow passengers, five became infected with SARS-CoV-2. During a change, the man obtained a mask. The second leg of the journey, in a minibus, took 50 minutes. During this leg of the journey, none of the 14 fellow passengers was infected with SARS-CoV-2.

A second example concerns the outbreak of COVID-19 in the maternity hospital of the University of Regensburg (3). On 9 February 2020, one day after returning from a skiing holiday in Ischgl, Austria, a midwife developed a fever and respiratory symptoms after a team meeting and a night shift and called in sick. When she tested positive for SARS-CoV-2 on 15 February, the obstetric ward started to require that masks be worn at the workplace. A day later, the mask requirement was extended to the entire maternity hospital. Furthermore, all contacts of infected staff were tested for SARS-CoV-2 and isolated if the result was positive. In addition, distancing rules were introduced. Prior to that day, 18 more SARS-CoV-2 infections had been detected among healthcare staff. Sixteen further cases of SARS-CoV-2 infection were identified up to 23 February 2020, two more infections thereafter. Thus, the SARS-CoV-2 outbreak in the maternity hospital was contained eight days after the introduction of the mask requirement along with other measures.

human speakers will—depending on how loudly they speak—exhale between 277 and 347 droplets measuring 20–500 µm each over a period of 16.7 ms (i.e., the exposure time of a single frame when filming at 60 frames per second) (8). This corresponds roughly to 20 000 droplets/second.

Most large droplets fall to the floor within a distance of 1.5–2 meters from the speaker, whereas smaller droplets evaporate, and the non-soluble components remain in the air as droplet nuclei. This means that the exposure to droplets in exhaled air is far more intense at a distance of less than 1.5–2 meters from the speaker than at greater distances (9). A face covering reduces the number of droplets also at closer distances (15 cm from the mask), namely by 60–95% (cotton mask) and 99% or more (surgical mask and N95 mask without valve) (*Figure*) (10).

Data on the viral load that will cause infection or disease in 50% of exposed persons (ID-50) are largely lacking for SARS-CoV-2. Experimental infection trials in humans are not possible for ethical reasons, as no effective treatment is available. Macaques that are intratracheally inoculated with 0.5×10^6 plaque-forming units (PFU) of SARS-CoV-2 excrete the virus, but usually do not develop manifest disease (11). When inoculated with a dose of 4.75×10^6 PFU they will develop mild to moderate disease (12). Disease severity therefore seems to depend on the infectious dose, as seen, for example, in influenza (13).

Boxes 2 and *3* explain the role of polymerase chain reaction (PCR) in diagnosing SARS-CoV-2 infection and the association between the shedding of viral RNA and infectiousness, diagnosing SARS-CoV-2 infection.

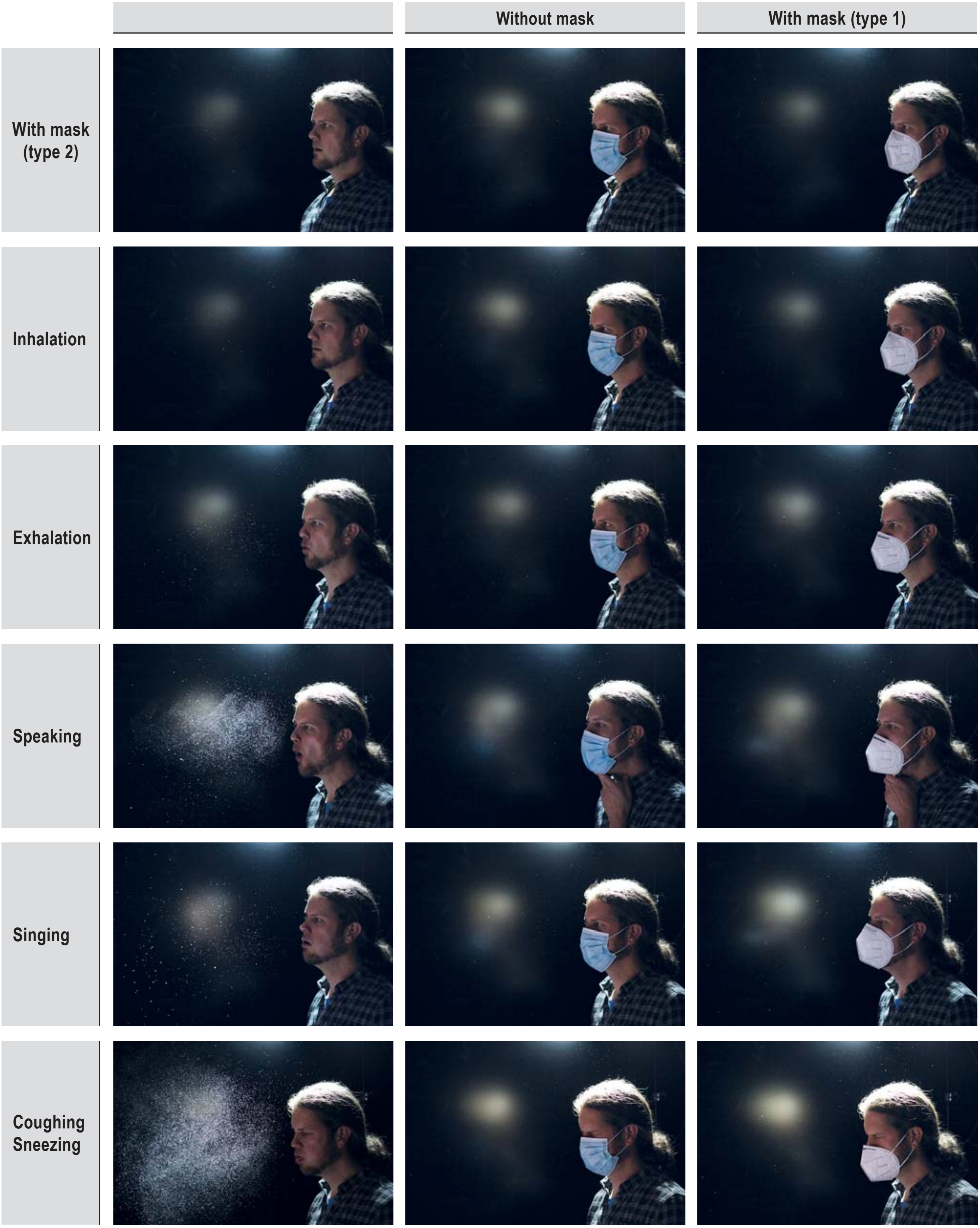
In enclosed spaces, the exposure to air exhaled by another person decreases significantly above a distance of 1.2 meters (20). A study in healthcare workers showed an increased risk of being infected if they failed to keep a minimum distance of 1.8 m away from patients with influenza (21). The US health authorities (CDC) therefore recommend a minimum distance of 1.8 m (6 ft) from patients with respiratory infections. Since virus-containing aerosols in exhaled air can spread up to 8 m—e.g., when sneezing—the minimum distance of 1.8 m may not always be sufficient (22). In experimentally created aerosols, infectious SARS-CoV-2 showed a half life of 1.1 hours (4), but even 90 minutes after aerosol release, replication-competent SARS-CoV-2 was still detectable (23).

Data from experiments

In an experimental model using 99-technetium-marked aerosols emitted and received by plastic replicas of human heads (so-called dummies), surgical masks worn by the aerosol-emitting index dummies reduced the amount of "exhaled" radioactivity by a factor of 250, but for optimal protective effect the room had to be well ventilated (24). Masks worn by the recipient dummy had no significant protective effect in this experiment. The aerosol composition was modeled on the situation in vivo regarding the particle size (about 95% of particles smaller than 2 µm). Nevertheless, the generalizability of findings from model experiments to the situation in humans is likely to be limited, since the biophysical characteristics of aerosols can differ in different environments.

Another study found that surgical masks have an average aerosol filtration efficacy of 96% for test bacteria and 90% for test viruses (25). The filtration efficacy of homemade masks varied—depending on the material they were made from—between 60% and 94% for bacteria and between 49% and 86% for viruses (25).

A study from Taiwan also showed the filtration efficacy of masks (26). Wearing masks in bedrooms (3.30 m × 3.60 m) and in cars reduced the amount of particles between 0.02 µm and 1 µm detected at 1 m distance from the test subject to almost background levels (i.e., absence of the mask-wearing persons). This was seen for surgical masks as well as homemade cotton masks. In persons with respiratory infections caused by seasonal coronaviruses, surgical masks reduce the viral load in exhaled air, as measured by PCR, to undetectable levels, both for droplets with a particle size >5 µm and for aerosols with a particle size <5 µm. Since case numbers were low (10 patients without and 11 with a mask), however, only the results for aerosolized particles attained significance (27).



Visualization of the effect of masks in different forms of respiration

A digital single-lens reflex camera (Canon EOS 70D, Canon, Japan) equipped with a macro lens (SP 90 mm F/2.8, Tamron, Japan) was used, with a high-performance LED light source (Constellation 120E15 6200K, Veritas, USA).

Masks examined: type 1: disposable medical mask, Zibo Qichuang Medical Products Co., Ltd., China; type 2: Kaisidun KN95 (corresponds to FFP2)

Photographs: Dr. S. Siewert, Institute for Implant Technology and Biomaterials e.V., Warnemünde

BOX 2

The role of polymerase chain reaction in diagnosing SARS-CoV-2 infection

The polymerase chain reaction (PCR) detects copies of the virus genome (RNA) and does not directly prove the presence of infectious viral particles. However, the number of viral genome copies correlates with the likelihood of successful cultivation of the virus. In specimens with a PCR cycle threshold (ct) value of 23 and below (i.e., high viral load), cultivation of SARS-CoV-2 was successful in 41 of 48 cases (85%), whereas in specimens with a ct of 37 and above (i.e., low viral load), cultivation was successful in only 5 of 60 cases (8%) (14). According to the Robert Koch Institute, SARS-CoV-2 can also be cultivated in specimens from presymptomatic or asymptomatic patients (15–17). This implies implies that these patients are infectious, because viral particles that can be cultured in vitro are likely to be infectious also in vivo. A defined universal ct value as a cut-off for infectiousness currently does not exist, due to differences between PCR testing systems, sampling/swabbing techniques, and other factors that affect infectiousness (e.g., the presence of coughing) (17, 18).

In an animal model, surgical masks fitted between the cages of infected and non-infected hamsters reduced transmission of the infection to non-infected animals (66.7% transmission without masks versus 25% transmission with surgical masks) (28).

Model calculations and infection models

Several epidemiological and practical indications now exist for the protective effect of facial coverings during the COVID-19 pandemic. In Jena, a city-wide mask mandate was enacted on 6 April 2020 and by a few days later the number of new infections with COVID-19 had fallen to almost zero. Twenty days after enactment of the mask mandate, the number of new cases was 75% lower than the weighted average case numbers in structurally similar regions without mask mandate (so-called synthetic controls). In other German regions, too, the enactment of a mask mandate led to a drop in new infections by 15% to 75%, depending on the region (29).

Mathematical modeling confirms that wearing masks—especially when combined with other non-medical measures (e.g., adhering to a safe social distance) slows down the spread of SARS-CoV-2 substantially and reduces the risk of infection. For the state of New York in the USA, model calculations indicated that 80% adherence to mask mandates would prevent 17–45% of deaths from COVID-19—even if the filtering efficacy of the masks worn were only 50% (30). When infection rates are lower—as initially observed in the state of Washington—even masks with a filtering efficacy of only 20% would reduce COVID-19 mortality by 24–65% if 80% of citizens were to wear such masks in public (30). Reducing the number of infections by mask wearing in these model studies was associated with a decrease in the number of deaths. The effect of mask wearing was strongest if it was started early in an outbreak, when infection rates are still low (30).

The experience so far suggests that in countries where a high proportion of the population wore masks from early on, the COVID-19 pandemic has cost notably fewer lives than in countries where this was not the case (31). However, other interventions probably contributed to lower numbers of deaths. An important epidemiological reason for the fact that masks, as well as contact restrictions, can prevent the spread of epidemics even if their effectiveness is well below 100% is that the spread of COVID-19 is best described with a model based on "percolation."

The classic S-I-R ("susceptible, infected, recovered") models of epidemics are based on the work of Kermack and McKendrick. They modeled data from a plague epidemic in Bombay in 1905/06 and assumed that an infection hits a homogenous group whose members are infected one after the other. By contrast, percolation models (32, 33) consider that susceptible individuals do not have contact with all other group members, but rather are organized in subgroups linked by certain persons who are members of several subgroups (so-called nodes). Even if an infection does not soon jump from one subgroup (e.g., family, school year/class, wedding party, travel party, old people's home) to the next, it can still "linger" or "smolder," i.e., remain undetected within an isolated subgroup for a long time. As soon as the isolation of the subgroup is broken, the infection spreads into other subgroups. This has been dramatically shown in animal populations (34, 35). In respiratory infections, masks can slow down this "percolation effect" (1, 31).

Wearing masks also protects mask-wearers

Masks are primarily intended to prevent the wearer from spreading the virus to others. However, masks also protect the wearer from becoming infected. A comprehensive meta-analysis included 172 observational studies of COVID-19 (64 studies), SARS (55 studies), and MERS (25 studies), as well as respiratory viruses and occupational protection (28 studies) (36). Among these studies, 44 non-randomized comparison trials with a total of 25,697 patients aged between 30 and 60 were evaluated (36). Of these 44 trials, 30 investigated the effect of masks in viral transmission (seven of them in COVID-19). Neither the authors of the cited meta-analysis nor we ourselves found any randomized or cluster-randomized trials that investigate the effect of masks on the transmission of coronaviruses.

The cited meta-analysis (36) analyzed statistical associations by pooling relative risks (RR) and adjusted odds ratios (aOR). The pooling of 29 non-adjusted and 10 adjusted studies revealed that wearing a mask of the type N95 was associated with a reduction in the absolute risk (AR) for the mask wearer to contract COVID-19, SARS, or MERS from 17.4% without mask to 3.1% with mask (RR 0.34; 95% confidence interval [0.26; 0.45] for non-adjusted studies, aOR 0.15 [0.07; 0.34] for adjusted studies), although the evidence level is classified as low. A sensitivity analysis for COVID-19 yielded an aOR of 0.40 [0.16; 0.97]. The protective effect is likely to be strongest for N95 type masks (aOR 0.04; [0.004; 0.3]), but other types of masks (aOR 0.33; [0.17; 0.61]) also reduce the risk of infection and disease for their wearer (moderate degree of certainty) (36). According to this meta-analysis, this also applies to studies of aerosol-producing medical procedures. Type N95 masks confer better protection than surgical masks, and N95 masks and surgical masks both confer better protection than single-layer masks.

Further observations also imply that the risk of developing symptomatic disease after infection with SARS-CoV-2 is strongly dependent on the infectious dose (37). This corroborates the assessment that masks protect not only those in proximity to the wearer but also the wearer themselves from COVID-19.

An example is provided by soldiers from a Swiss army unit (38). In two companies housed together in one building, mask wearing and physical distancing were mandated only nine days after the first case of SARS-CoV-2 infection. Of the 345 soldiers, 102 (30%) became ill with COVID-19. Of 181 tested soldiers without symptoms, 113 (62%) were found to have SARS-CoV-2 RNA or SARS-CoV-2 antibodies.

In another company housed in a separate building, masks and minimum distances were mandated even before the first case of infection. Of the 154 soldiers, none became ill, and SARS-CoV-2 RNA or antibodies were detected in only 13 of 88 tested soldiers (15%).

In outbreaks in food-processing plants in the US states of Oregon and Arkansas, where the staff wore masks, 95% of infections took an asymptomatic course (39, 40).

Statistics indicate that even in the case of a large rise in the infection rate, complication rates and mortality remained low in countries where mouth–nose facial coverings are widely used (37, e1). This is the case, for example, in Japan, Hong Kong, and South Korea, where mask wearing has long been common during the cold season, even before the COVID-19 pandemic. High testing rates, stringent tracking/tracing, and quarantine measures also contribute to limiting the spread of the pandemic (see www.worldometers.info/coronavirus for comparison between countries). In other countries, however, contradictory messages have confused the population and reduced compliance. In addition to clear communication, those carrying political responsibility are clearly tasked with serving as role models (e2).

A recently published study has refuted the notion that mask wearing would impair the respiratory gas exchange (e3). Masks of different types increase the rise in the partial CO_2 pressure associated with strenuous exercise (100 W; 40.5 ± 4.9 mm Hg with FFP2 mask versus 38.4 ± 4.3 mm Hg without mask; $p < 0.001$). Also, FFP2 masks can minimally lower the peripheral O_2 saturation (97.4 ± 1.4 % with mask versus 98.0 ± 0.8 % without mask; $p = 0.005$). However, these changes are so small that they are unlikely to have any clinical relevance in healthy persons.

To reduce the transmission of SARS-CoV-2 in everyday settings, fabric masks are usually sufficient, but they should consist of at least three layers of dense fabric (e4, e5) and be combined with other measures (minimum distances). In medical settings, surgical masks are standard. For high-risk activities, especially when caring for patients with SARS-CoV-2 infection who themselves are not wearing a mask, the German Federal Institute for Occupational Safety and Health recommends FFP2 masks for healthcare staff (e5). We wish to stress here that masks with exhalation valves do not offer the intended protection (i.e., for persons in close proximity to the wearer), as infected wearers spout copious quantities of unfiltered infectious virus particles through the valve when they exhale. The use of masks with an exhalation valve should therefore be prohibited in the setting of COVID-19.

The evidence we have presented in this article stems from observational studies, which usually offer a lower level of certainty than randomized controlled trials. However, these observational studies constitute the best evidence that is currently available, and they support the assertion that masks are highly effective in preventing SARS-CoV-2 infection and COVID-19. We therefore strongly advise mask wearing to prevent infection with SARS-CoV-2.

Conclusions

Taken together, the data presented in this review indicate that wearing face masks in public spaces is an important part of the efforts to reduce the spread of SARS-CoV-2. Even where infection is not avoided, by reducing the infectious dose through mask-wearing,

BOX 3

Viral shedding and infectiousness

In SARS-CoV-2, viral shedding and infectiousness are likely to be greatest just before symptom onset (15). A Chinese study found between 1.03×10^5 and 2.25×10^7 RNA copies per hour in the exhaled air of 14 patients with COVID-19 (19). After symptom onset, the shed RNA volume fell continuously until the 38th day (19).

In residents of a nursing home in the US state of Washington, replication-competent virus was detected in throat swabs from infected residents between six and nine days after symptom onset. The cycle threshold (ct) values were between 13.7 and 37.9, and there were no relevant differences between symptomatic and asymptomatic infected residents. The doubling time of the number of infected persons was 3.4 days, shorter than in the county where the nursing home was situated. The authors (16) therefore assumed that nursing staff and residents with undetected/asymptomatic infections had probably contributed to the spread of infection in the nursing home.

symptomatic disease can be prevented or at least the severity of the disease decreased—according to the experience in Swiss soldiers and inoculation attempts in macaques, as described in this article. It remains to be seen to what extent the presented data apply to the newly emerging mutations of SARS-CoV-2.

All doctors should explain to their patients the crucial importance of mask wearing and address any doubts regarding its benefits. A certificate of exemption from mandatory mask wearing should be issued only if objective findings show that mask wearing is associated with a concrete health risk for the wearer.

Conflict of interest statement
The authors declare that no conflict of interest exists.

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► Supplementary material

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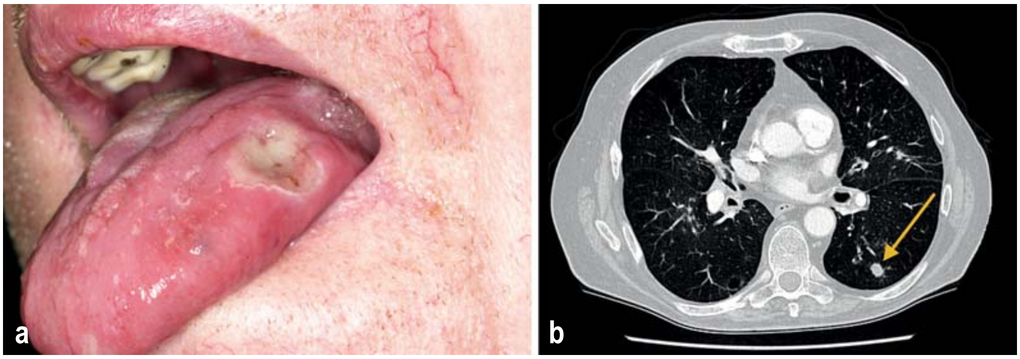
CLINICAL SNAPSHOT

Tongue Ulcer and Hemorrhagic Paronychia as Presenting Manifestations of Granulomatosis with Polyangiitis



A 77-year-old male patient presented to the ENT outpatient department due to a 1-week history of symptoms of odynophagia and hoarseness. Several small ulcerations could be seen in the region of the larynx as well as a painful ulcer on the left edge of the tongue *(Figure a)*. Hemorrhagic paronychia was visible on the fingers and toes. A biopsy of the tongue ulcer revealed nonspecific granulocytic infiltration. To rule out a paraneoplastic etiology, computed tomography imaging was performed, identifying isolated pulmonary nodules *(Figure b)*. Due to concomitant elevated C-reactive protein (206 mg/L), antibiotic therapy was initiated but produced no significant improvement in the findings. In the further course, an elevated titer for c-ANCA/anti-PR3 antibodies was determined, and acute renal failure (Acute Kidney Injury Network stage 3) with a nephritic sediment developed. Histology revealed a segmental necrotizing and proliferative extracapillary pauci-immune glomerulonephritis. Overall, the findings were consistent with granulomatosis (GPA) with polyangiitis. The skin and mucosal lesions, as well as renal function, improved with immunosuppressive therapy comprising glucocorticoids and rituximab. The pulmonary nodules remained unchanged in the long term.

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Supplementary material to:

Protection From COVID-19

The Efficacy of Face Masks

by Christoph Josef Hemmer, Frank Hufert, Stefan Siewert, and Emil Reisinger

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