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Postoperative Wound Infections and Surgical Face Masks: A Controlled Study

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It has never been shown that wearing surgical face masks decreases postoperative wound infections. On the contrary, a 50% decrease has been reported after omitting face masks. The present study was designed to reveal any 30% or greater difference in general surgery wound infection rates by using face masks or not.

During 115 weeks, a total of 3,088 patients were included in the study. Weeks were denoted as "masked" or "unmasked" according to a random list. After 1,537 operations performed with face masks, 73 (4.7%) wound infections were recorded and, after 1,551 operations performed without face masks, 55 (3.5%) infections occurred. This difference was not statistically significant ($p > 0.05$) and the bacterial species cultured from the wound infections did not differ in any way, which would have supported the fact that the numerical difference was a statistically "missed" difference.

These results indicate that the use of face masks might be reconsidered. Masks may be used to protect the operating team from drops of infected blood and from airborne infections, but have not been proven to protect the patient operated by a healthy operating team.

In 1897, Mikulicz, professor of surgery in Breslau, was the first to mention the use of a face mask [1]. One year later, his assistant Hübener published a study showing that wearing a face mask diminished droplet spread from the mouth of a test person [2]. After this, many studies [3–7] have been published comparing different surgical face masks and how to wear them. The history of the use of face masks as told by Rockwood and O'Donoghue [8] is impressive and they speak in favor of the use of face masks in the operating room. It has never been shown, however, that wearing face masks causes fewer postoperative wound infections unless worn to protect from a sore throat [9].

Letts and Doermer [10] showed that wearing a complete hood overlapping the face mask, with no gaps at the sides or bottom of the mask, diminished the fall-out of microspheres applied under the mask and in the nostrils. Ritter and associates [11] found a 33-fold increase in counts of airborne bacteria when 5 persons entered an empty operating room, but there was no difference in regard to whether masks were worn or not. It seems that any difference in bacterial fall-out between a masked and an unmasked person drowns in the fall-out from the rest of the body.

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Later, Orr [12] reported a 50% decrease of wound infections after omitting face masks; however, this report was not based on a controlled study. Chamberlain and Houang [13] made a controlled study during gynecological operations to test the results reported by Orr. Their study was discontinued after 3 infections in the unmasked group, although they found no correlation between bacteria found in the infected wounds and those isolated from the staff.

In a study of infection rates after suture of laceration wounds in an emergency department, Ruthman and colleagues [14] found no difference in regard to whether cap and mask were used or not.

The reduction of postoperative wound infections reported by Orr could be explained by the findings of Letts and Doermer. The hypothesis might be that a face mask, by friction, releases skin scales carrying bacteria, most often staphylococci, from the faces of the surgical team. This friction would be avoided by omitting the mask. Instead of being contaminated by pathogenic skin staphylococci, the wound would be contaminated by an increased number of alpha-streptococci, not known to cause wound infections in general surgery [15, 16]. It must, however, be remembered that alpha-streptococci are found in wound infections after surgery with implantation of prosthetic devices as described by, e.g., Fitzgerald and Washington [17].

Orr's report of a 50% decrease in wound infection rates after omitting face masks is spectacular. The present study was designed to reveal any 30% or greater difference in wound infection rates using face masks or not. This lower percentage was set, since it seemed a more realistic figure and still of clinical importance. Any difference less than 30% would be impossible to verify from the number of operations performed (around 2,000/year) during a 2-year test period in our hospital.

In order to test the hypothesis that face masks significantly increase the bacterial fall-out into the surgical wound, the bacterial cultures from the wound infections were compared. If a face mask significantly increased the fall-out of bacteria into the wound, it should increase the number of infections caused by bacteria normally found on the skin.

Material and Methods

At the surgical department of Danderyd Hospital, Stockholm, Sweden, postoperative wound infections have been registered continuously since 1981. The hospital serves a region with about 260,000 inhabitants. Registration has included around 90% of all patients and around 90% of all infections, shown by an independent controller, during several test periods. All general surgery patients operated on through intact skin, anal procedures excluded, and sutured by primary intention were registered. Outpatient, orthopedic, or urologic operations were not included.

Preoperatively, all "elective" patients had 2 or 3 whole-body washes with a detergent containing 4% chlorhexidine (Hibiscrub, ICI). Most of the "acute" patients had at least one wash. Depilation, when needed, was performed with a depilatory cream. The area around the incision site was disinfected with chlorhexidine in alcohol just prior to the operation. Three different face masks were in use during the time of the study (Comfort Clinimask, Mölnlycke; Surgine II Antifogmask, Surgikos; and Aseptex, 3M, in order of numbers used).

Registration Method

A blue registration form followed the patient from the day of admission to the ward during his stay in the hospital. Diagnosis, operations, whether acute or elective, and the degree of contamination were registered as well as postoperative wound infections. In case of a wound infection, a second form (yellow) was immediately sent to the secretariat to make it possible to intervene or at least search for a common source of infections when there were several infections in a short period of time. The yellow form was also used to report infections evident after discharge from the ward. From every wound infection a swab was taken for bacterial culture. Copies of the results of these bacterial cultures were collected separately at the laboratory of clinical bacteriology and, together with the blue and yellow forms, they gave a "triple" control of the number of infections.

During the study, the ordinary registration forms were supplemented with the following facts about the study:

1. Patient informed in writing and verbally about the study and patient's consent given—to be included in the study.
2. Patient not informed or consent not given, or not included because of increased risk of infection (synthetic graft to be inserted or hematologic disease)—not to be included in the study.
3. Number of persons, if any, wearing a face mask during an "unmasked" operation, and the reason for this (common cold or allergic rhinitis).
4. "Masked" operation performed.
5. "Unmasked" operation performed.

In order to confirm that the use of face masks gives a decrease of 30% in postoperative wound infection rate, i.e., to today's 5% (masked) from 7.2% (unmasked), 1,500 patients were needed in each group. Therefore, it was decided to include at least 3,000 patients in the study.

A random list was set up for 1 year, denoting weeks as "masked" or "unmasked." To avoid seasonal differences between the groups, the list was inversed for the second and for part of the third year. To randomize weeks instead of days or single operations was a way to assure a similar number of major and minor surgery in the 2 groups since elective major surgery is most often performed at the beginning of the week.

After 115 weeks, a total of 3,088 patients had been included according to the criteria and the study was closed (March, 1984 to May, 1986). During 1,537 operations, face masks were worn by everyone in the operating room according to the "normal" routine. During 1,551 operations, masks were not worn, except on 277 occasions when they were worn by 1 or 2 persons because of a common cold or an allergic rhinitis. There were no conscious changes in behavior during operations (talk, laughter, etc).

During the 115 weeks, more than 250 different persons took part in the operations. Two surgeons, 1 nurse, 1 staff nurse, 1–3 students, and 2 anesthetists often take part in the team work, meaning that about 8 persons are present during standard operations. This great number of persons was thought to assure a challenge by most common bacteria found in the respiratory tract in a healthy Swedish surgical staff. Therefore, no cultures were taken to establish the bacterial carrier rates among the personnel during the study. Antibiotics were used for prophylaxis during all colorectal operations and many other non-clean operations according to the guidelines of the clinic.

Definition

A postoperative wound infection was defined as pus, visible to the naked eye, or cellulitis without pus, both requiring debridement or percutaneous drainage and/or antibiotic therapy. This definition was chosen to make it easy to determine what to report as an infection—if measures have to be taken it is a clinical infection.

Ethics

The study was approved by the ethical committee of the Karolinska Institute.

Clinical Results

In all, during the 115 weeks, a total of 184 (4.6%) postoperative wound infections were recorded after 3,967 operations. Of these infections, 56 belonged to the group of 879 operations (56/879 = 6.4%) not included in the study because of increased risk of infection (n = 199), lack of patient consent (n = 243), or lack of information to the patient because of senility or acute states (n = 437).

Of the remaining 3,088 operations, a total of 699 were acute and 2,389 were elective. A further subdivision into 18 types of operations was performed (Table 1) without revealing any significant differences between the "masked" and "unmasked" groups. The average age in the groups was similar: for acute operations, 38 years in both groups, and for elective operations, 58 years in the "masked" and 57 years in the "unmasked" group. In Table 2, the numbers of infections per number of operations are given for acute, elective clean, and elective nonclean operations. As can be seen, no statistically significant differences in wound infection rates were reached ($p > 0.05$) comparing "masked" and "unmasked" operations. In the "masked" group, the infection rate was 4.7% (3.7–5.8%, 95% confidence limits) as compared to 3.5% (2.6–4.5%) in the "unmasked" group. During 277 "unmasked" operations (18% of all "unmasked"), when 1–2 persons wore face masks be-

Table 1. No. of operations[a] with and without face masks. Operations divided into 18 groups with acute and elective operations separated.

	With face masks		Without face masks	
	Acute	Elective	Acute	Elective
Inguinal hernias	9 (2)	337 (6)	9 (1)	336 (5)
Appendectomies	270 (12)	–	276 (10)	–
Cholecystectomies	7 (0)	183 (10)	9 (1)	210 (7)
Mammary/axillary operations	–	166 (2)	–	181 (0)
Intestinal resections	12 (1)	149 (14)	4 (1)	132 (8)
Exploratory laparotomies (no resection)	31 (2)	49 (1)	30 (4)	51 (2)
Thyroid/parathyroid operations	–	58 (0)	–	61 (0)
Other hernias	6 (0)	45 (1)	3 (0)	43 (3)
Esophageal/gastric operations	5 (3)	53 (5)	7 (1)	45 (4)
Enterostomies	4 (1)	35 (3)	4 (0)	37 (3)
Other clean operations	–	36 (0)	–	28 (1)
Varicose veins	–	26 (0)	–	28 (0)
Pancreatic/bile ducts	–	23 (8)	–	19 (3)
Splenectomies	–	9 (0)	1 (0)	11 (0)
Other non-clean operations	3 (0)	7 (0)	3 (1)	6 (0)
Vascular (nongraft operations)	3 (0)	5 (2)	3 (0)	6 (0)
Laparoscopies	–	3 (0)	–	6 (0)
Testicular hydrocele	–	3 (0)	–	2 (0)
Total	350 (21)	1,187 (52)	349 (19)	1,202 (36)
All operations	1,537 (73)		1,551 (55)	

[a]Nos. in parentheses are nos. of infections.

Table 2. No. of infections (Inf) and no. of operations (Op) in relation to acute and elective clean and non-clean operations.

	With face mask			Without face mask			
	Inf	Op	%	Inf	Op	%	*p*
Acute operations	21	350	6.0	19	349	5.4	NS
Elective clean operations	11	688	1.6	9	707	1.3	NS
Elective non-clean operation	41	499	8.2	27	500	5.4	NS
Total	73	1,537	4.7	55	1,551	3.5	NS

Statistics according to 2-tailed chi-square test ($p < 0.05$).
NS: not significant.
Inf: infections; Op: operations

cause of a common cold or an allergic rhinitis, only 4 infections occurred. During the remaining 1,274 "unmasked" operations, no one in the operating team, including the anesthetic team, wore a face mask (5–8 persons). In addition, 1–3 students followed the routine.

The 879 operations not included in the study according to the criteria had an infection rate of 6.4% compared to 4.1% for those included in the study ($p < 0.01$). This reflects the higher age and more acute states among those not included. In the "not informed" group, senility and the administration of analgesics in acute conditions were the most common reasons for not being included.

Table 3. Bacterial findings in cultures from wound infections after "masked" and "unmasked" operations. Cultures which revealed a single bacterial species are presented separate from the mixed infections.

	With face mask		Without face mask	
	73/1,537		55/1,551	
Infections/operations	Single	Mixed	Single	Mixed
Staphylococcus aureus	12	7	9	6
Staphylococcus epidermidis	3	7	3	3
Pyogenic Group A streptococcus	1	1	–	–
Pyogenic non–Group A streptococcus	–	4	–	6
Streptococcus viridans	–	8	–	3
Escherichia coli	1	22	4	12
Other aerobic gram negatives	–	22	1	16
Bacteroides fragilis	2	17	4	11
Bacteroides species	–	5	–	3
Anaerobic gram positive cocci	–	4	1	1
Clostridium perfringens Group A	–	5	–	3
Pseudomonas aeruginosa	–	1	–	1
Candida albicans	–	1	–	–
Anaerobic gram positive rods	–	1	–	–
Facultative anaerobic gram positive str.	2	1	–	–
Haemophilus parainfluenza	–	2	–	–
Propionibacterium	–	–	2	–
Bacillus subtilis	–	–	–	1
Pneumococci	–	–	–	1
No growth	3		3	
No culture	7		3	

Bacteriological Results

The results of cultures from the 128 wound infections are presented in Table 3. Infections after "masked" and "unmasked" operations are presented separately and mixed infections have been separated from those where a single bacterial strain was found. In order to make Table 3 easier to read, some bacterial species have presented as groups, e.g., Proteus and Klebsiella and other gram negatives are presented as "other aerobic gram negative." There were 6 cultures without growth and 10 infections where no cultures were taken. That leaves 112 cultures for evaluation. Staphylococci were found in 21 cultures after operations without face masks and in 29 cultures after operations with face masks. After correction for the difference in missed cultures, this gives staphylococcal infection rates of 1.5% and 2.2%, respectively. This means that 43% of the cultures from infections after operations without face masks revealed staphylococci, as compared to 46% after operations with face masks. This difference is clearly not significant ($p > 0.05$).

Beta-hemolytic streptococci Group A were found in 2 cultures, both after masked operations, while 1 infection with pneumococci in a mixed culture was noted in the unmasked group. No upper respiratory tract infections were noted during these operations. Alpha-streptococci were found in 3 mixed cultures after unmasked operations and in 8 cultures after masked operations.

Discussion

In most hospitals, no one is allowed to even enter an operating room without wearing a face mask, although the scientific background to this routine is lacking. In studies of surgical face masks, different designs and materials and ways of wearing the face masks have been compared in regards to fall-out, but not in regards to the effect on wound infection rates. In the uncontrolled report by Orr, he found a decrease of 50% in infection rates after omitting the face masks. This figure, if true, would mean that, today, we pay for a negative effect. Since those findings could be theoretically supported by the studies of Letts and Doermer, it must be of theoretical as well as economical interest to have this hypothesis controlled.

Since Letts and Doermer found a difference in fall-out of particles from the face depending on whether a face mask was carried under or over the cap, it seems possible that abandoning the face mask would avoid colony-forming units being set free by friction from the face mask against the skin. In that case, there would be less infections caused by bacteria normally found on the skin such as staphylococci. This decrease should be greater than a possible increase in infections caused by bacteria normally found in the respiratory tract, according to the report by Orr.

A problem in studies of infection rates is that a reduction of 5% means a decrease from, e.g., 4.5% to 4.3% in infection rates. This means that there will be one infection less in 445 operations. In order to prove this in a 2-year study, it would be necessary to involve most Swedish hospitals in a multicenter study, which is, of course, impossible to realize. The decrease of 50% reported by Orr could, however, be controlled in an ordinary study. It was calculated that during 2 years, about 3,000 operations could be included in a study at Danderyd Hospital and this would reveal any 30% or greater difference by using face masks or not.

In the present study, there was no statistically significant difference in wound infections after operations with or without face masks even if there was a numerical difference in favor of unmasked operations. Therefore, it is possible that a difference would be significant with a larger number of patients. In that case, the numerical difference in this study ought to be reflected in fewer infections with staphylococci after unmasked operations, but this was not shown.

It has not been possible to demonstrate any advantages for the patient when the surgical team wears face masks. Therefore, the routine use of face masks ought to be reconsidered. Masks may be used, however, to protect the operating team from drops of blood, which might be infected with hepatitis B viruses or HIV. Masks might also be used to protect the staff from airborne infections in patients, but has not been proven to protect the patient. This aspect is also valid for the increasing use of face masks in the wards and during diagnostic and therapeutic procedures.

In another study [18], we tested the effect of face masks on acutely ill and febrile patients with beta-hemolytic streptococci Group A in the throat. In those cases, there seemed to be a good protective effect by the mask, as measured by the numbers of bacteria spread by the patient while reading a book aloud. This probably means that if a febrile surgeon with a sore throat has to take part in an operation, he should wear a face mask. In the present study, however, both infections with beta-hemolytic streptococci Group A were found after masked operations!

All over the world the increasing cost for medical service is a serious problem. Therefore, it is a responsibility for the professional team to reevaluate old routines in a critical way, also in order to save money. The cost for face masks in Sweden is more than $180,000 U.S. per million inhabitants per year. This also includes the face masks used elsewhere, e.g., in the wards where masks are often unnecessarily worn during the performance of wound dressings. If 8 masks on average are used during 1 operation, the cost is more than $2 U.S. and a great deal of this, maybe half, could be saved by reconsidering the use of face masks.

Résumé

Il n'a jamais été démontré que le port d'une bavette chirurgicale diminue le nombre des infections pariétales. Au contraire, on a même rapporté une diminution de 50% lorsqu'on ne les utilisait pas. Cette étude a été élaborée pour déceler l'influence du port de la bavette dans la réduction des taux d'infections pariétales chez l'opéré en chirurgie générale de 30% au moins.

Pendant 115 semaines, 3,088 patients ont été inclus dans cette étude. Pendant une semaine donnée, tirée au sort, les chirurgiens mettaient ou ne mettaient pas de bavette. Aprés 1,537 opérations effectuées avec bavette, on a trouvé 73 (4.7%) abcès de paroi alors qu'après 1,551 interventions sans bavette, il y a eu 55 (3.5%) infections. Cette différence n'est pas statistiquement significative ($p > 0.05$) et les cultures bactériennes à partir de la plaie opératoire ne différaient en aucune manière ce qui renforçait la conclusion que cette absence de différence statistiquement significative était réele.

Ces résultats indiquent que l'utilisation de la bavette chirurgicale pourrait être remise en question. La bavette joue un rôle de protection de l'équipe chirurgicale contre les infections portées par le sang éclaboussé en salle ou contre les infections aériennes, mais son effet sur la protection du patient n'a pas été prouvé lorsque l'équipe chirurgicale elle-même est en bonne santé.

Resumen

No ha sido demostrado que el uso de la máscara facial quirúrgica disminuya la tasa de infefión postoperatoria; por el contrario, algunos autores han informado una reducción de 50% al omitir su uso. El presente estudio fue diseñado con el propósito de revelar una diferencia de 30% o más en las tasas de infección de la herida en procedimientos de cirugía general con el uso y sin el uso de la máscara quirúrigica.

En el curso de 115 semanas, 3,088 pacientes fueron incluídos en el estudio. Las semanas fueron designadas como "con máscara" o "sin mascara," según la lista de randomización. En 1,537 operaciones realizadas con máscara se registraron, 73 (4.7%) infecciones de herida y en 1,551 operaciones realizadas

sin máscara se informaron 55 (3.5%) infecciones. Esta diferencia no es estadísticamente significativa ($p > 0.05$); las especies de bacterias aisladas de las heridas no exhibieron diferencias que puedieran hacer pensar que la diferencia númerica en favor de las operaciones sin máscara tenga importancia.

Tales resultados indican que el uso de máscaras faciales puede ser reconsiderado. Las máscaras pueden ser utilizadas para proteger al personal quirúrgico de gotas de sangre infectada y de infecciones en el ambiente, pero no han demostrado que protejan al paciente que es operado por un equipo quirúrgico sano.

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Invited Commentary

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The ability of surgeons to perform operations with the full expectation that the surgical wound will heal primarily without infection is a remarkable achievement of Twentieth Century surgery. In the last century, surgical operations were commonly followed by wound suppuration. Purulent infection was a major cause of hospital death, and if the patient survived at all, the wound healed by secondary intention. With the appreciation of the microbiologic and transmissible nature of infections, principles of antisepsis and asepsis were developed by Lister in Scotland and Bergmann in Germany. In accord with these principles, elaborate surgical rituals were developed to minimize the risk of exposure of wounds to bacteria from the operating surgeon, the assistants, the instruments, the environment, or the patient himself. These techniques were dramatically effective. Bloodgood [1], at the Johns Hopkins Hospital, reported a reduction in his own wound infection rate following elective hernia repair from 20% to 1% with the consistent use of gloves and other aseptic techniques. Our current practices of operating room management and sterile technique, including the use of face masks, are direct descendants of these early surgical rituals.

In the past 100 years, there have been tremendous advances in all aspects of the care of sick and critically ill patients. Purulent infection in cleanly-made surgical wounds is infrequent in most centers. If a wound infection should develop, it is usually not a cause of death; however, it usually does increase morbidity, length of stay, and cost of care. Therefore, prevention of surgical wound infection continues to be a major goal for surgeons and their hospital staffs. One of the most effective strategies to this end is the development of an active wound surveillance program in which all surgical wounds are inspected by a trained observer, the presence or absence of wound infection documented, and the information given to individual surgeons and to chiefs of service [2, 3]. This approach leads to changes in behavior by surgeons and their associates that reduce the incidence of wound infection, thereby indicating that attention to the details of perioperative management still makes a difference in patient outcome.

It is less clear which of the myriad details of perioperative care, both old and new, have an important determining role in the incidence of postoperative surgical wound infection. These often ritualistic practices add to the complexity and cost of surgical care, and might be well abandoned if shown to be ineffective. Thus, Dr. Tunevall and his colleagues at the Karolinska Institute, Danderyd Hospital, in Stockholm evaluated the efficacy of surgical face masks. Not only does the widespread use of face masks add to the cost of medical care, but some studies suggest that surgical face masks might actually increase the incidence of wound infection.

This prospective study began in 1984 and was designed to answer a straightforward question: how does the use of surgical face masks influence the incidence of postoperative wound infection? The randomization process addressed known components of variability and the study design was universally