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Disposable surgical face masks for preventing surgical wound infection in clean surgery

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Version published: 26 April 2016 Version history
https://doi.org/10.1002/14651858.CD002929.pub3

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Abstract

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Background

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx of healthcare workers during surgery, thereby providing protection for the patient. However, there are several ways in which surgical face masks could potentially contribute to contamination of the surgical wound, e.g. by incorrect wear or by leaking air from the side of the mask due to poor string tension.

Objectives

To determine whether the wearing of disposable surgical face masks by the surgical team during clean surgery reduces postoperative surgical wound infection.

Search methods

In December 2015, for this seventh update, we searched: The Cochrane Wounds Specialised Register; The Cochrane Central Register of Controlled Trials; Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE and EBSCO CINAHL. We also searched the bibliographies of all retrieved and relevant publications. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

Randomised controlled trials (RCTs) and quasi-randomised controlled trials comparing the use of disposable surgical masks with the use of no mask.

Data collection and analysis

Two review authors extracted data independently.

Main results

We included three trials, involving a total of 2106 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials. We identified no new trials for this latest update.

Authors' conclusions

From the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery.

Plain language summary

Available in English | Deutsch | Español | Français | Hrvatski | Bahasa Malaysia | Русский

Disposable surgical face masks for preventing surgical wound infection in clean surgery

Background

Surgeons and nurses performing clean surgery wear disposable face masks. The purpose of face masks is thought to be two-fold: to prevent the passage of germs from the surgeon's nose and mouth into the patient's wound and to protect the surgeon's face from sprays and splashes from the patient. Face masks are thought to make wound infections after surgery less likely. However, incorrectly worn masks may increase the likelihood of the wound getting contaminated with germs. We wanted to discover whether wearing a face mask during surgery makes infections of the wound more likely after the operation.

Review question

This review aimed to find out if wearing disposable face masks increases or decreases the number of cases of wound infection after clean surgery.

Study characteristics

We searched for all studies that had been done in the past relevant to this topic. Studies included in our analysis were those looking at the use of face masks in 'clean' surgery in adults and children. Clean surgery is when the operation does not go into organs that may contain bugs such as the lungs, gut, genitals and bladder. Infections of the wound are less likely to occur after 'clean' surgery, compared to 'unclean' surgery. We chose to look at this type of surgery because infections occurring after clean surgery would more likely be due to the use of the face mask, and not because of the nature of the operation. We also only looked at one particular type of study, the randomised controlled trial (RCT), where the people involved (participants) were randomly put into one of two groups: one group where the surgical team wore a face mask during the operation and one group where the surgical team did not wear a face mask. We compared the number of wound infection cases occurring after surgery between two groups.

Key results

Overall, we found very few studies and identified no new trials for this latest update. We analysed a total of 2106 participants from the three studies we found. All three studies showed that wearing a face mask during surgery neither increases nor decreases the number of wound infections occurring after surgery. We conclude that there is no clear evidence that wearing disposable face masks affects the likelihood of wound infections developing after surgery.

Quality of the evidence

The findings from this review cannot be generalised for several reasons: the studies included only looked at clean surgery, some of the studies did not specify what type of face mask was used and one of the studies did not involve many participants therefore making the findings less credible. The quality of the studies we found was low overall. The way in which participants were selected for the studies was not always completely random, which means the authors' judgements could have influenced the results. More research in this field is needed before making further conclusions about the use of face masks in surgery.

This plain language summary is up to date as of 22nd December 2015.

Authors' conclusions

Implications for practice

From the limited results, it is unclear whether the wearing of surgical face masks by the surgical team either increases or reduces the risk of surgical site infection in patients undergoing clean surgery.

Implications for research

Important messages for future research:

1. The CONSORT statement should be used as a guideline for reporting of future trials (Schulz 2010).
2. Trials should be large enough to detect clinically important differences in infection rates.
3. Trials must discriminate between scrubbed and non-scrubbed personnel.
4. Trials must include clear definitions of surgery, surgical face masks and surgical wound infection.
5. Randomisation should be 'per operating list' (cluster randomisation) rather than 'per case' to avoid potential contamination of the surgical environment. To guard against selection bias, the randomisation allocation should be unpredictable, concealed and take place immediately prior to the commencement of the operating list.
6. Follow-up should be appropriate to the surgery performed. This may extend to the involvement of primary care.
7. Outcome assessors should be blinded to allocation.
8. Analysis should be by intention-to-treat of all patients following randomisation.
9. Economic evaluations should be incorporated into future trials.

Areas for further investigation include:

- disposable surgical face mask compared with wearing no mask;
- disposable surgical face mask compared with other mechanisms for protecting both patients and staff, such as visors/helmets.

Background

Description of the condition

Surgical face masks were originally developed to contain and filter droplets containing microorganisms expelled from the mouth and nasopharynx during surgery. They were introduced around a century ago as a method of protecting patients from the risk of surgical wound infections (Belkin 1997). The costs incurred when a patient contracts a surgical wound infection are considerable in financial as well as social terms. It has been estimated that each patient with a surgical wound infection requires an additional hospital stay of 6.5 days and that hospital costs are doubled (Plowman 2000). When extrapolated to all acute hospitals in England, it is estimated that the annual cost nationally is almost GBP 1 billion.

Description of the intervention

The primary purpose of a surgical mask is to provide protection for the patient from the surgical team. Masks have also been advocated as a barrier to protect the surgical team from the patient (Garner 1996; Weber 1993). This systematic review does not investigate the use of surgical masks for this purpose.

Surgical face masks are disposable and generally made up of three or four layers, often with two filters that prevent passage of material greater than 1 micron, therefore trapping bacteria of that size or larger. Face masks of this type are claimed to provide protection for a minimum of four hours (UHS 2000). Worn correctly, the mask should cover the nose with the metal band contouring the bridge of the nose. The mask should be drawn underneath the mouth and secured by tying the tapes firmly around the back of the head.

Although the surgical mask is designed to protect the patient, there are several ways in which it could actually contribute to the contamination of surgical wounds. Firstly, insufficient tension on the strings causes 'venting', or leakage of air from the side of the mask. The exhalation of moist air increases resistance, which is thought to exacerbate the problem of venting (Belkin 1996). Secondly, Belkin 1996 also cites 'wicking' as a method of conveying liquid via capillary action as possibly contributing to the passage of bacteria. Thirdly, a mask could cause contamination by 'wiggling'. This is a term used to describe friction of the mask against the face, which has been shown to cause the dispersal of skin scales from the face resulting in possible contamination of surgical wounds (Schweizer 1976). In addition, the mask may be worn incorrectly, for example, allowing exposure of the nose or mouth. Removal of the mask by grasping the filter section could result in contamination of the wearer's hands whereas disposal is recommended by handling the tapes only (Perry 1994).

How the intervention might work

These issues call into question the effectiveness of the design and highlight the incorrect use of surgical face masks. As with many interventions, surgical face masks were introduced without standard specifications or formal evaluation. Despite acknowledging the controversy surrounding the use of masks, they are currently recommended by numerous operating department organisations (AORN 1998; AfPP 2007).

There is evidence that face mask practice is inconsistent, possibly due to an inadequate rationale for their use. For example, the use of surgical face masks has been abandoned by some surgical teams (in part or whole) and during certain procedures. In choosing to not wear a mask, members of the surgical team could be leaving the patient vulnerable to the risk of wound infection via droplet contamination.

A clean surgical wound is classified as "an uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tract is not entered" (Mangram 1999). Non-clean wounds may be classified as clean-contaminated, contaminated or dirty-infected, depending upon the area of the body operated upon and the level of infection and inflammation present. A surgical wound is less likely to become infected postoperatively if it is classified as clean, therefore any infection arising could be more reasonably attributed to other factors such as the use of a surgical face mask (Mangram 1999).

Diagnosis of a surgical wound infection is not without its challenges. For example, some patients such as the elderly and the immunocompromised do not always display the cardinal signs of infection. However, correct diagnosis of surgical wound infections is imperative to ensure accurate surveillance. A surgical wound infection is defined by purulent drainage and at least one of the following signs or symptoms: pain, localised swelling, redness or heat (Mangram 1999).

Why it is important to do this review

The above discussion indicates that the role of the surgical mask as an effective measure in preventing surgical wound infections is questionable and warrants a systematic review.

Objectives

To determine whether the wearing of disposable surgical face masks by the surgical team during clean surgery reduces postoperative surgical wound infection.

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised controlled trials comparing the use, by members of the surgical team, of disposable surgical masks with the use of no mask.

Types of participants

Adults and children undergoing clean surgery.

Types of interventions

The specific comparison to be made is the wearing, by the surgical team (scrubbed and not scrubbed), of disposable surgical face masks compared with no masks. Due to the difference in specifications, we used the trial author's definition of disposable surgical mask.

Types of outcome measures

Primary outcomes

- The incidence of postoperative surgical wound infection (the definition of wound infection used by the trial authors is used throughout).

Secondary outcomes

- Costs.
- Length of hospital stay.
- Mortality rate.

Publication date, language and publication status did not influence eligibility decisions.

Search methods for identification of studies

Electronic searches

For this seventh update, we searched the following databases to identify reports of relevant clinical trials:

- The Cochrane Wounds Specialised Register (searched 22 December 2015);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2015, Issue 11);
- Ovid MEDLINE (1946 to 22 December 2015);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (searched 22 December 2015);
- Ovid EMBASE (1974 to 22 December 2015);
- EBSCO CINAHL Plus (1937 to 23 December 2015).

The search strategies used for these databases can be found Appendix 1. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version; Ovid format (Lefebvre 2011). We combined the EMBASE search with the Ovid EMBASE trial filter terms developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filter terms developed by the Scottish Intercollegiate Guidelines Network (SIGN 2015).There were no restrictions with respect to language, date of publication or study setting.

Searching other resources

We searched the bibliographies of all retrieved and relevant publications identified by these strategies for further studies.

Data collection and analysis

Selection of studies

Two review authors independently assessed titles and abstracts of references identified by the search strategy according to the selection criteria. We obtained copies of those articles and studies that appeared to satisfy these criteria in full. When it was unclear from the title or abstract if the paper fulfilled the criteria, or when there was disparity between the review authors, we obtained a full-text copy. The two review authors jointly decided whether the study met the inclusion criteria. For this update, one review author assessed titles and abstracts of references identified by the search strategy. Again, when it was unclear from the title or abstract if the study fulfilled the criteria, the full-text was obtained and reviewed by one review author, all decisions were discussed with a member of the editorial team of Cochrane Wounds.

Data extraction and management

We used a piloted data extraction sheet to extract and summarise details of the studies. When data were missing from the study, we attempted to contact the trial authors to obtain missing information. Data extraction was undertaken independently by the two review authors and compared. We excluded studies if they were not randomised or quasi-randomised trials of disposable surgical face masks. Excluded studies are listed in the Characteristics of excluded studies table with reasons for their exclusion.

We extracted the following data from each study.

- Trial setting.
- Number of air filtration changes in the surgical field per hour.
- Filtering capacity/specification of masks.
- Types of surgery.
- Number of wound infections.
- Definition of wound infection.
- Depth of wound infection.
- Documentation of co-interventions.
- Use of prophylactic antibiotics.
- Use of antiseptic irrigation.
- Identified bacteria associated with staff and patients.
- Measurement of compliance in the wearing of surgical face masks (i.e. mask covered nose and mouth, presence of wicking and venting).
- The size of the surgical team.

Assessment of risk of bias in included studies

Two review authors independently assessed each included study using the Cochrane tool for assessing risk of bias (Higgins 2011). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance) (see Appendix 2 for details of the criteria on which each judgement was based). We assessed the studies to detect potential sources of bias in the study design. We extracted data regarding the following aspects of risk of bias.

- Method of randomisation: how the randomisation schedule was generated, the method of randomisation, e.g. envelopes, computer etc.
- Allocation concealment.
- Blinding of patients (recipients).
- Blinding of outcome assessors to wearing of masks.
- Extent of loss to follow-up and use of intention-to-treat analysis.
- Source of funding.
- Early stopping.
- Baseline comparability of treatment and control groups.

Data synthesis

We entered data into the Cochrane Review Manager (RevMan) software (RevMan 2014). Results are presented with 95% confidence intervals (CI). Methods of synthesising studies were dependent upon the quality, design and heterogeneity of the studies identified. We reported estimates for dichotomous outcomes as odds ratio (OR) as the event rate was less than 30% (Altman 1991). Where synthesis was inappropriate, we undertook a narrative overview.

Results

Description of studies

Results of the search

The initial search, for the original review, yielded 250 citations; we examined the abstracts of these papers to assess potential relevance. We subsequently retrieved 97 papers for fuller examination. Of these, 84 were clearly not relevant to the review and 13 appeared potentially relevant. We subsequently excluded 11 from the review due to study design, or ineligible outcome measures (e.g. bacterial load). We included two studies. We identified no unpublished studies that met the criteria for inclusion. There was no response to requests for further information from the authors of two included studies (Chamberlain 1984; Tunevall 1991). No studies were published in duplicate. During subsequent updates of the review, we identified five further studies; four did not meet the inclusion criteria after assessment (Alwitry 2002; McGovern 2013; Salassa 2014; Sjol 2002), and one met the criteria for inclusion and we added it to the review (Webster 2010). We identified no new trials for this latest update.

This review took at face value any description in the original studies of the type and cleanliness category of surgery performed. In one study, we contacted the author who provided data for clean surgery only (Webster 2010). As a result, we included studies performed in the operating department and excluded other areas such as the laboratory, maternity ward and accident and emergency.

Included studies

See the Characteristics of included studies table.

Type of surgery

Tunevall 1991 included all types of surgery: clean, clean-contaminated and contaminated. Chamberlain 1984 involved gynaecological operation lists carried out by masked and unmasked staff. Webster 2010 randomised non-scrubbed staff per list into masked and unmasked groups. Surgery included obstetrics, gynaecology, general, orthopaedics, breast and urological. We only extracted data relating to clean surgery from all three studies.

Type of mask

Only one study specified the types of face mask used (Tunevall 1991), which were Comfort Clinimask (Molnycke), Surgine II antifog mask (Surgikos) and Aseptex (3M). In one study the type of mask was not mentioned (Chamberlain 1984), and in the other study standard masks were used (Webster 2010).

Number of patients

A power calculation informed Tunevall 1991 that their study would have to include over 3000 patients to demonstrate a decrease of 30% in the wound infection rate. It is unclear whether the power calculation took account of the clustered nature of the data. Although the Tunevall's study involved a total of 3088 patients, only 1429 patients undergoing clean surgery met the criteria for this review. In the study by Chamberlain 1984 only 41 patients were recruited because the study was discontinued. Out of this number, only 24 cases were clean surgery. With such a small number of female patients in this study, it is unlikely that they were representative of the population. Webster 2010 calculated that a sample size of at least 450 in each arm of the study would be needed to detect a 40% difference in surgical site infection rate between the two groups. Although 827 enrolled on the study, only 653 patients undergoing clean surgery met the criteria for this review (communication with trial author).

Outcome measures

The outcome measure used in Tunevall 1991 was wound infection defined as pus visible to the naked eye, or cellulitis without pus, both requiring debridement or percutaneous drainage and/or antibiotic therapy. With this study, follow-up was until after discharge but it was not explicit how these patients were followed up once discharged. Chamberlain 1984 did not define wound infection, but two out of the three wound infections reported were noted as serious enough to warrant antibiotics, the other infection being identified by a high vaginal swab. All patients in this study were examined daily until discharge. Webster 2010 used the National Nosocomial Infection Surveillance system, which categorises surgical site infections as superficial incisional, deep incisional and organ space. Follow-up was up to six weeks with the mean being 33.4 days for both groups.

None of the studies took any steps to measure compliance in relation to the correct wearing of surgical face masks, or recorded any events such as venting, wicking or wiggling. No study considered the other secondary outcome measures listed in this review.

Consent

One study author specified that consent was obtained from the staff involved in the study (Webster 2010). Tunevall 1991 stated that consent was obtained from patients, but Chamberlain 1984 and Webster 2010 did not specify that consent from patients had been obtained.

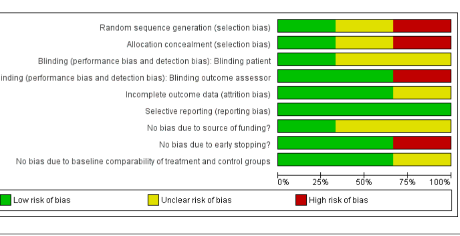
Excluded studies

We added a total of 15 studies to the Characteristics of excluded studies table. In summary, we excluded six studies because the focus of the study was not on assessing the rate of surgical site infection (Alwitry 2002; Ha'eri 1980; McGovern 2013; Norman 1995; Ritter 1975; Tunevall 1991). We excluded two studies because variables in addition to the rate of surgical site infection and the use of face masks were investigated (Berger 1993; Ruthman 1984). We excluded three studies because they did not involve any surgery and, rather, were simulation-based (Hubble 1996; McLure 1998; Mitchell 1991). Two studies were not RCTs or quasi-RCTs (Salassa 2014; Sjol 2002), one study assessed surgical site infection through the means of a patient questionnaire (Moore 2001), and one study did not state how many clean operations were included in their study (Orr 1981).

Risk of bias in included studies

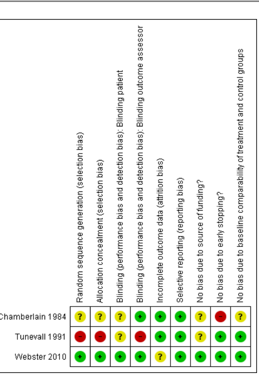
See Figure 1 for the graph showing the review author's judgements about each 'Risk of bias' item presented as percentages across all included studies. See also Figure 2 for the summary showing the review author's judgements about each 'Risk of bias' item

Figure 1 Open in figure viewer



Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

Figure 2 Open in figure viewer



Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

Allocation

Neither Chamberlain 1984 nor Tunevall 1991 used true randomisation with allocation concealment. Tunevall 1991 set up a random list for one year at a time denoting weeks as masked or unmasked but did not describe the method by which weeks were randomised to be masked/unmasked. A week, rather than an operating list or single operation, was the unit of allocation chosen for a period of one year, to ensure a similar number of major and minor cases (most major cases were performed at the beginning of the week). The randomisation list was inversed for the second and part of the third year due to anticipated seasonal differences. Allocation was not concealed as members of the theatre team were able to calculate whether any week was likely to be masked or unmasked. It is not clear whether the members of the admitting personnel had access to the randomisation list.

Chamberlain 1984 stated that patients on the operating lists of one surgical team were randomly allocated to a masked or unmasked group over two months. Later he indicated that masked and unmasked staff carried out the gynaecological operation lists alternately. The time between allocation of each list as masked or unmasked and the start of the list is not stated, making the extent of allocation concealment unclear.

Webster 2010 randomised participants per operating list. Allocation was concealed as randomisation occurred immediately before the start of the operating list via a phone call to a person blinded to the type of list.

In all studies the surgical team was the unit of randomisation and the patient was the unit of assessment, thus creating a unit of analysis error. There is no information in any study as to how patients were allocated to particular operating lists and so selection bias cannot be excluded.

Blinding

It was impossible to blind the care providers of the trials to wearing or omitting a surgical face mask. The blinding of patients was described by Webster 2010 but not by either Chamberlain 1984 or Tunevall 1991. No study distinguished between the use of local anaesthetic and general anaesthetic. Blinding of outcome assessors was achieved for Chamberlain 1984, where members of laboratory staff were unaware of the group allocation of the specimens obtained. Outcome assessors were also blinded in Webster 2010, where details of surgical site infections were obtained via routine surveillance or staff blinded to the intervention. In Tunevall 1991, specific notification of the trial was given with each wound swab submitted for culture, allowing the potential for detection bias.

Two studies included all members of the surgical team and neither of those studies examined whether particular members of the team were more or less likely to cause a surgical wound infection (Chamberlain 1984; Tunevall 1991). One study included only non-scrubbed staff (Webster 2010).

Incomplete outcome data

Chamberlain 1984 and Tunevall 1991 did not undertake an intention-to-treat analysis. Webster 2010 performed an intention-to-treat analysis. Chamberlain 1984 was discontinued after seven weeks after a third case of postoperative infection in the unmasked group was diagnosed. However the trial authors acknowledged that, although two of three wounds grew *Staphylococcus aureus*, in neither case was it a strain that corresponded to those isolated from the staff. No drop-outs were reported in Tunevall 1991. Webster 2010 reported seven drop-outs for clean surgery.

Other potential sources of bias

Source of funding

Two studies did not state a source of funding (Chamberlain 1984; Tunevall 1991), and one study declared a grant from Queensland Health Nursing Research (Webster 2010).

Early stopping of trial

Chamberlain 1984 was discontinued after seven weeks after a third case of postoperative infection in the unmasked group was diagnosed; this may well have been a chance difference, so potentially biasing the results in favour of masking.

Baseline imbalance

A description of the baseline characteristics of the patients is important to decide whether the results are generalisable and to compare characteristics of the two groups to ensure that the randomisation was successful. Tunevall 1991 confirmed baseline comparability for age and types of surgery. All patients in Chamberlain 1984 were female undergoing gynaecological surgery; no baseline comparability was reported. Groups were similar at baseline in Webster 2010 in terms of surgery, wound and American Society of Anaesthesiologists (ASA) classification as well as age, gender, preoperative hospitalisation, weight and prophylactic antibiotics.

Effects of interventions

The included studies compared the use of disposable surgical face masks with using no surgical face masks. A total of 2106 patients, undergoing clean surgery, were included in this review. We assessed clinical and methodological homogeneity. The observed clinical heterogeneity between the trials was reflected in parameters such as study population, time lapse between the first and latest study influencing technique and equipment, diagnosis and length of follow-up. Potential sources of clinical heterogeneity could be attributed to type of disposable surgical face mask, restricting non-scrubbed staff to the intervention group, operating theatre design (e.g. air flow rates) and country of study. Given this clinical heterogeneity, it was inappropriate to pool any of the studies.

Primary outcome: incidence of postoperative surgical wound infection

There were 2106 participants in three trials. Tunevall 1991 reported 13/706 (1.8%) postoperative wound infections in the masked group and 10/723 (1.4%) in the non-masked group (no statistically significant difference: odds ratio (OR) 1.34, 95% confidence interval (CI) 0.58 to 3.07). Chamberlain 1984 reported no postoperative wound infections in the masked group and 3/10 (30%) in the non-masked group (no statistically significant difference: OR 0.07, 95% CI 0.00 to 1.63). Webster 2010 reported 33/313 (10.5%) in the masked group and 31/340 (9.1%) in the non-masked group (no statistically significant difference: OR 1.17, 95% CI 0.70 to 1.97) (Analysis 1.1).

Secondary outcomes

None of the studies considered the secondary outcome measures specified in the review, i.e. costs, length of hospital stay and mortality rate.

Discussion

Given the widespread use of surgical face masks, research into this topic remains surprisingly neglected. It was disappointing that only two trials met the inclusion criteria for the original review and these were undertaken prior to 1991. The inclusion of a more recent trial has helped to address the lack of evidence (Webster 2010).

Much of current national and international policy is based upon equivocal evidence from laboratory studies of the filtration efficiency of surgical face masks and of potential contamination of the surgical field using settle plates. Such indirect evidence is of questionable clinical relevance.

Potential biases in the primary studies and the limitations they place on inferences

The strength of the evidence provided by the three studies that met the inclusion criteria for this review was weak. Two studies were quasi-randomised with unclear allocation concealment.

Methodologically, the results of Chamberlain 1984 and Tunevall 1991 may have been biased in several ways. Chamberlain 1984 did not specify the criteria used to detect the presence of a wound infection. Mangram 1999 reports that failure to use objective criteria to define surgical site infection has been shown to substantially affect reported surgical site infection rates. Chamberlain 1984 was limited by the discontinuation of the trial after seven weeks as result of several infections, thus creating a potential bias in the findings towards the use of surgical face masks.

Follow-up in Chamberlain 1984 continued until after discharge and up to discharge in Tunevall 1991. However the actual duration of follow-up could have varied considerably depending upon the type of surgery performed, with the potential for underestimating the number of surgical wound infections. Follow-up in Webster 2010 was more in keeping with international guidance of 30 days, but in some cases was less. It is likely that the inadequate allocation concealment and lack of blinding in the Chamberlain 1984 and Tunevall 1991 studies could have resulted in under or over-estimation of the effects of wearing a surgical face mask.

We were surprised at the small number of published studies. This could be due to a reluctance on the part of researchers to submit an equivocal trial for publication, and in turn for it to be accepted for publication. However, publication bias could not be tested by a funnel plot due to the small number of included studies.

Potential biases in the review and the limitations it places on inferences

Potential biases in the review and the limitations it places on inferences

We relied on the goodwill of experts in the field to provide information on completed or ongoing, published or unpublished studies. When critically appraising the validity of the studies we had to rely on adequate reporting of the trials. When there is minimal information in the trial report one cannot automatically assume that rigorous methods have not been followed. We attempted to obtain additional clarifying data from the investigators of two studies, however no responses were received. Webster 2010 provided data on patients undergoing clean surgery.

The examination of the effectiveness of disposable surgical face masks must be seen in the context of the number of variables associated with wound infections. It is difficult to interpret from small studies, such as Chamberlain 1984, whether the wearing of surgical face masks has an impact on rates of surgical wound infections in patients undergoing clean surgery.

Applicability of results

The results extracted for this review were limited to clean surgery and therefore cannot be extrapolated to other categories of surgery. The contribution that disposable surgical face masks make towards preventing infection is likely to be less consequential in contaminated wounds than in clean surgery.

The types of disposable surgical face mask used in the study were specified by Tunevall 1991 but not by Chamberlain 1984 or Webster 2010. It is possible that the specific mask composition changed in the years spanning the studies and this has the potential to influence results.

Although the review did not exclude trials involving the implantation of prostheses, we found no trials of this nature therefore limiting application of the review's results to this type of surgery. One study, Webster 2010, differentiated between scrubbed and non-scrubbed members of the team but, because only non-scrubbed staff were randomised into the study, it was not possible to discriminate between the contribution of the scrubbed and non-scrubbed members of the surgical team to any resulting surgical wound infection. It could be argued that non-scrubbed members of the team are less likely to be in a position to contaminate the surgical site.

All included studies were based in the operating department and so application of the results to other invasive procedures in other clinical areas is limited.

We examined the potential for surgical face masks to benefit the patient by reducing surgical wound infections or to harm the patient by increasing surgical wound infections in this review. We did not undertake analysis of the potential to harm or benefit the surgical team by way of protection. Although Chamberlain 1984 favoured the use of surgical face masks, the trial was relatively small and was discontinued due to the identification of wound infections in three out of the five major clean cases performed. This may have been a chance finding and thus these results are potentially biased in favour of wearing masks. Tunevall 1991 and Webster 2010 were larger trials, more rigorously designed and did not detect differences in the infection rate.

Both national and international guidelines acknowledge the controversy surrounding the use of disposable surgical face masks and yet continue to recommend their use. We found no other reviews in this area and the limited number of trials in this review make it unsafe to draw definitive conclusions about the effect of surgical face masks on reducing surgical wound infection in clean surgery.

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