Disposable surgical face masks for preventing surgical wound infection in clean surgery (Review)

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[Intervention Review]

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

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Editorial group: Cochrane Wounds Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 1, 2012.
Review content assessed as up-to-date: 15 September 2011.

Citation: Lipp A, Edwards P. Disposable surgical face masks for preventing surgical wound infection in clean surgery. *Cochrane Database of Systematic Reviews* 2002, Issue 1. Art. No.: CD002929. DOI: 10.1002/14651858.CD002929.

ABSTRACT

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 disposable surgical face masks worn by the surgical team during clean surgery prevent postoperative surgical wound infection.

Search methods

We searched The Cochrane Wounds Group Specialised Register (searched 14 September 2011); The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2011, Issue 3); Ovid MEDLINE (2008 to August Week 5 2011); Ovid MEDLINE (In-Process & Other Non-Indexed Citations September 13, 2011); Ovid EMBASE (2008 to 2011 Week 35); and EBSCO CINAHL (2008 to 9 September 2011).

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

Three trials were included, involving a total of 2113 participants. There was no statistically significant difference in infection rates between the masked and unmasked group in any of the trials.

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

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

Surgeons and nurses performing clean surgery wear disposable face masks to prevent them passing germs from their noses and mouths into patients' wounds. Face masks are thought to reduce the number of postoperative wound infections. Incorrectly worn masks may increase the contamination of the wound. This review of trials found no clear evidence that wearing disposable face masks increases or reduces the number of surgical wound infections in clean surgery. More research is needed.

BACKGROUND

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 £1 billion.

The primary purpose of a surgical mask is to provide protection for the patient from the surgical team. Recently, masks have been advocated as a barrier to protect the surgical team from the patient (Garner 1996; Weber 1993). This systematic review will 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).

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).

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, the trial author's definition of disposable surgical mask was used.

Types of outcome measures

Primary outcomes

- The incidence of postoperative surgical wound infection (the definition of wound infection used by the trial authors will be 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

For the search strategies used in the fourth update of this review see Appendix 1

Electronic searches

For this fifth update, we searched the following databases:

- Cochrane Wounds Group Specialised Register (searched 14 September 2011);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library 2011*, Issue 3);
- Ovid MEDLINE (2008 to August Week 5 2011);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations September 13, 2011);
- Ovid EMBASE (2008 to 2011 Week 35);
- EBSCO CINAHL (2008 to 9 September 2011)

The following strategy was used to search The Cochrane Central Register of Controlled Trials (CENTRAL):
#1 MeSH descriptor Masks explode all trees
#2 "mask" or "masks" or facemask or facemasks:ti,ab,kw
#3 (#1 OR #2)
#4 MeSH descriptor Surgical Wound Infection explode all trees
#5 MeSH descriptor Surgical Wound Dehiscence explode all trees
#6 surg* NEAR/5 infection*:ti,ab,kw
#7 surg* NEAR/5 wound*:ti,ab,kw
#8 wound* NEAR/5 infection*:ti,ab,kw
#9 (postoperative or post-operative) NEAR/5 infection*:ti,ab,kw
#10 (#4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11 (#3 AND #10)
The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2, Appendix 3 and Appendix 4 respectively. The Ovid MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-

maximizing version; Ovid format (Lefebvre 2011). The EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (SIGN 2009). No date or language restrictions were applied.

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.

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 Collaboration 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 5 for details of 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 RevMan software (RevMan 2011). 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

See: Characteristics of included studies; Characteristics of excluded 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. Eleven were subsequently excluded from the review due to study design, or ineligible outcome measures (e.g. bacterial load) and two were included. No unpublished studies were identified which 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 three further studies; two did not meet the inclusion criteria after assessment (Alwitry 2002; Sjol 2002) and one met the criteria for inclusion and was added to the review at the last update (Webster 2010). No new studies were found at this 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, studies performed in the operating department were included and other areas such as the laboratory, maternity ward and accident and emergency were excluded.

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. Only data relating to clean surgery were extracted in all three studies.

Type of mask

Only one study specified the types of face mask used (Tunevall 1991), which were Comfort Clinimask (Molnycke) and 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 the study would have to include over 3,000 patients to demonstrate a decrease of 30% in wound infection rate. It is unclear whether the power calculation took account of the clustered nature of the data. Although the 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.

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

A total of 13 studies were added to the Characteristics of excluded studies table.

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

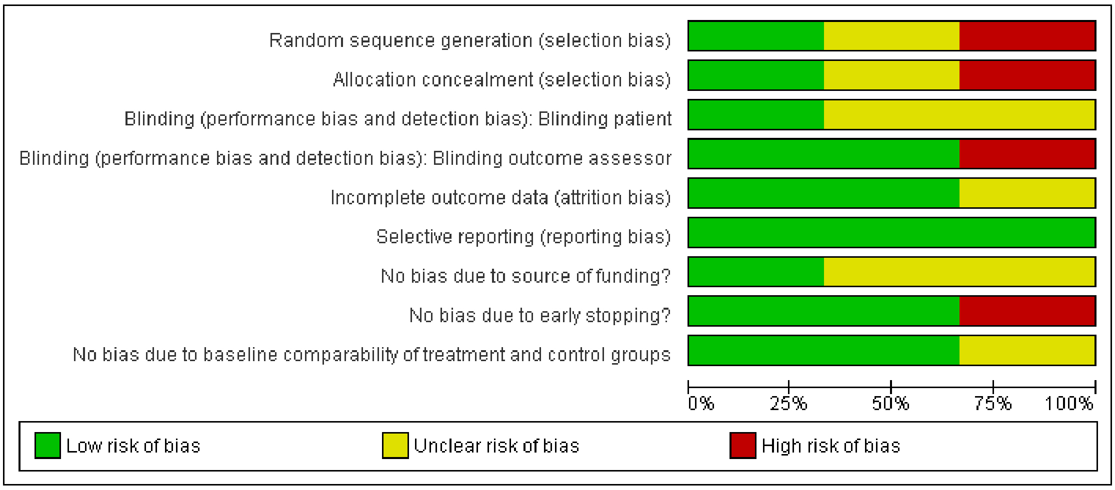
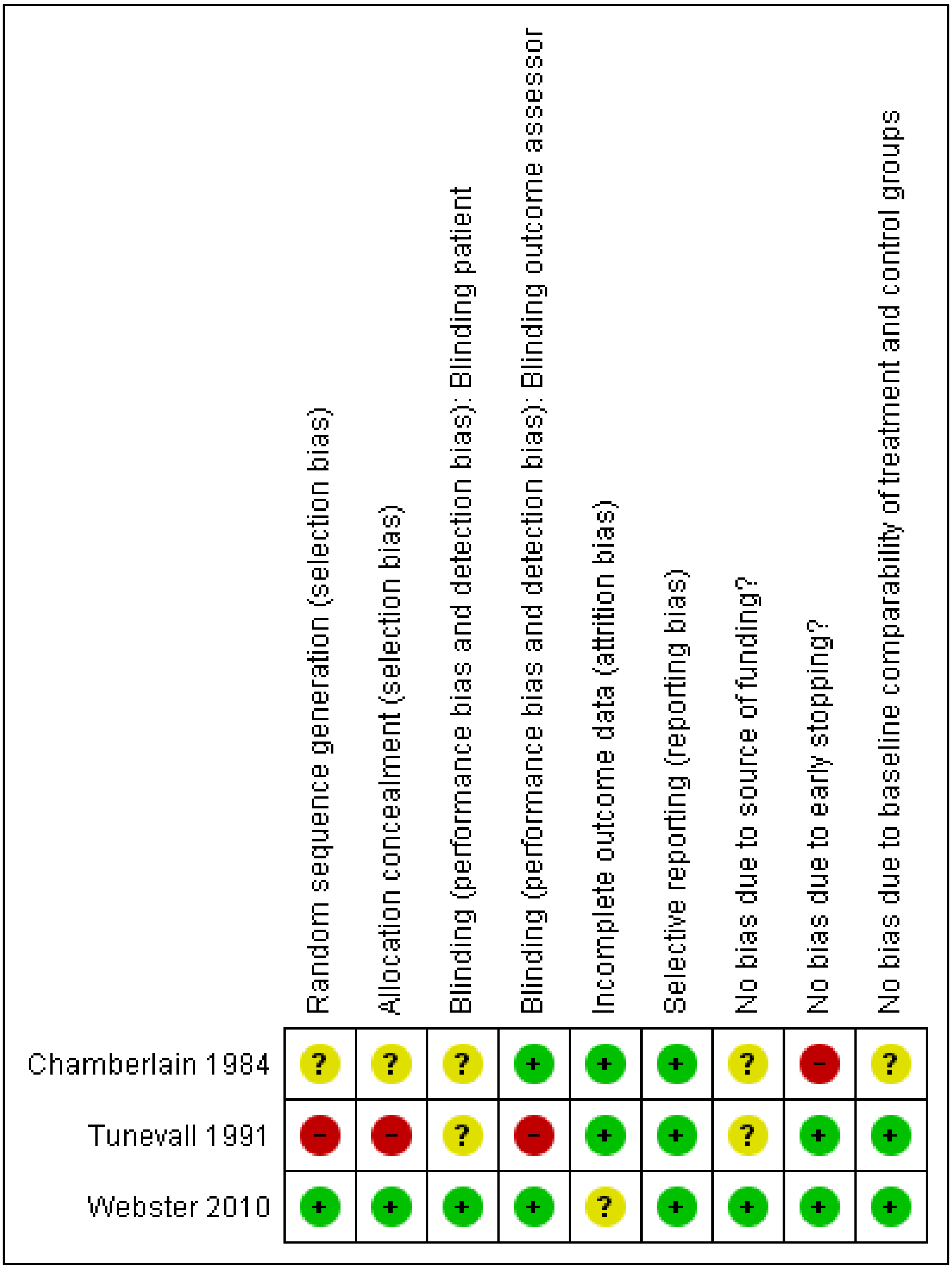


Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



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 which 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 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. Clinical and methodological homogeneity was assessed. 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: 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, OR 1.34, 95% 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 which 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 of 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 overestimation of the effects of wearing a surgical face mask.
The review authors were surprised at the small number of published studies. This could be due 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 funnel plot due to the small number of included studies.

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

The review authors 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 the review authors 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. The review authors 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 the results 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, no trials of this nature were found therefore limiting application of the review's results to this type of surgery. One study differentiated between scrubbed and non-scrubbed members of the team (Webster 2010) 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 studies included were based in the operating department and so application of the results to other invasive procedures in other clinical areas is limited.

The potential of surgical face masks to benefit the patient by reducing surgical wound infections or harm the patient by increasing surgical wound infections was examined in this review. Analysis was not undertaken 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 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. No other reviews in this area were found 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.

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 (Begg 1996).

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.

ACKNOWLEDGEMENTS

Alun Davies, Lorraine Foster, Michael Walker, Anne Humphreys and Pearl Shahib refereed the protocol for relevance, readability and rigour.

Vicky Arrowsmith, Sue Clark, Alun Davies, Michael Walker and Pearl Shahib who refereed the review. Jenny Bellorini who copy edited the recent updated review. We would like to thank Nicky Cullum and Andrea Nelson for methodological advice, Sally Bell-Syer for her support and the Cochrane Wounds Group for their help and assistance.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Chamberlain 1984

Methods	Quasi-randomised controlled trial.
Participants	41 female patients undergoing surgery. 24 clean and 17 non-clean. Inclusion criteria: gynaecology Exclusion criteria: none stated Baseline comparability; none reported.
Interventions	Group 1. Mask (n = 14) Group 2. No mask (n = 10)
Outcomes	Wound infection defined as serious enough to warrant antibiotics in 2 of the cases and via a high vaginal swab in the third case Follow up until discharge only.
Notes	Study discontinued due to 3 surgical wound infections in unmasked group, although not proven as causal. Data extracted for clean surgery only. Unit of analysis error present

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomly allocated per list, but method unclear.
Allocation concealment (selection bias)	Unclear risk	Time between allocation of masked and unmasked list and the list start was unclear
Blinding (performance bias and detection bias) Blinding patient	Unclear risk	Not described.
Blinding (performance bias and detection bias) Blinding outcome assessor	Low risk	Quote "The laboratory work was carried out by a member of staff who was not aware of the group allocation of the specimens obtained" Comment: Blinding of outcomes assessors reduces risk of performance and detection bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis not stated. No drop outs reported
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed

Chamberlain 1984 (*Continued*)

No bias due to source of funding?	Unclear risk	No funding sources stated.
No bias due to early stopping?	High risk	The study was discontinued after the third case of postoperative infection in the unmasked group. The study authors state that the bacterial strain of the infections did not correspond to those isolated from the staff
No bias due to baseline comparability of treatment and control groups	Unclear risk	Baseline comparability not stated. All participants were female undergoing gynaecological surgery

Tunevall 1991

Methods	Quasi-randomised controlled trial.
Participants	3088 patients undergoing general, vascular, breast, acute and elective surgery. Clean surgery was performed on 1429. Non-clean surgery was performed on 1659. Trial setting; operating department Inclusion criteria: operation through intact skin and primary closure. Exclusion criteria: patients not informed or consent not given; outpatients; orthopaedics; urology; anal surgery; insertion of synthetic grafts; or haematologic disease. Baseline comparability; similar for age, acute and cold surgery
Interventions	Group 1. Mask (n = 706) Group 2. No mask (n = 723)
Outcomes	Wound infection defined as visible pus and/or cellulitis without pus requiring debridement, drainage and/or antibiotics Duration of follow up not stated but until after discharge from the ward
Notes	Data extracted for clean surgery only. Patients had 2 to 3 body washes pre-operatively with 4% chlorhexidine prior to elective surgery. In most acute cases, at least one body wash was given. Unit of analysis error present

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote "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 the third part of the year" Comment: This makes selection at high risk of bias.

Tunevall 1991 (*Continued)*

Allocation concealment (selection bias)	High risk	Inadequate as investigators enrolling participants could possibly foresee allocation and thus introduce selection bias
Blinding (performance bias and detection bias) Blinding patient	Unclear risk	Not described.
Blinding (performance bias and detection bias) Blinding outcome assessor	High risk	Notification of the trial was issued with each wound swab.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Not analysed on an intention-to-treat basis. No drop outs reported
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed
No bias due to source of funding?	Unclear risk	No funding sources stated.
No bias due to early stopping?	Low risk	The rial was based on a power calculation and was not stopped early
No bias due to baseline comparability of treatment and control groups	Low risk	Baseline comparability stated for age and type of surgery.

Webster 2010

Methods	Randomised controlled trial.
Participants	811 patients undergoing gynaecological, obstetric, general (open), general (laparoscopic), urology and breast surgery. Clean surgery was performed on 660 patients and non-clean on 151 patients Inclusion criteria: none stated. Exclusion criteria: surgery where a mask was specifically required, e.g. air borne infection. Participants were similar at baseline for age, gender, weight, prophylactic antibiotics and ASA classification
Interventions	Group 1. Mask (n = 313) Group 2. No mask (n = 340)
Outcomes	Wound infection defined by criteria used by National Nosocomial Infection Surveillance System: superficial incisional, deep incisional and organ space Group 1. Mean follow up 33.4 days (SD 22.1) Group 2. Mean follow up 33.4 days (SD 22.8)

Notes	Missing data for 7 clean cases. Unit of analysis error present Quote: "Only non-scrubbed staff, including anaesthetists, were asked to comply with the random assignment" Comment: Scrubbed staff were not included in the trial.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote " Operating lists were randomised into two arms, mask group and no mask group using a computer-generated randomisation schedule" Comment: This precaution reduces the risk of selection bias.
Allocation concealment (selection bias)	Low risk	Quote " Allocation occurred immediately before the commencement of the session, following a phone call to a person who was unaware of the type of list in each theatre" Comment: This precaution reduces the risk of selection bias.
Blinding (performance bias and detection bias) Blinding patient	Low risk	Patients were unaware of treatment allocation.
Blinding (performance bias and detection bias) Blinding outcome assessor	Low risk	Quote " Details about any post operative Swound infection was obtained by routine surveillance methods, that is by the medical officer, ward staff or infection control nurse who were blinded to the treatment protocol"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Clean data not analysed on an intention-to-treat basis, 7 drop outs reported
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but trial protocol not accessed
No bias due to source of funding?	Low risk	Quote "JW received grant support through two Queensland Health Nursing Research Grants" Comment: This grant is unlikely to have biased the results of the trial
No bias due to early stopping?	Low risk	The trial was based on a power calculation and was not stopped early
No bias due to baseline comparability of treatment and control groups	Low risk	Groups were comparable for baseline characteristics of type of surgery, wound and ASA classification as well as age, gender, preoperative hospitalisation, weight and prophylactic antibiotics

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alwitry 2002	The measurement of bacterial load was used rather than infection rates
Berger 1993	The study was concerned with both contamination and wound infection. It was poorly designed as all procedures had varying mask positions at different times of the procedure. It was impossible to distinguish from the results the masked and unmasked periods. Settle plates were used to measure contamination and no infections were recorded. This study was discontinued after recruitment of 30 patients due to the unacceptable level of contamination of the settle plates
Ha'eri 1980	This study was primarily concerned with surgical site contamination by human albumen microspheres and not surgical wound infection
Hubble 1996	Excluded as a theatre-based simulation that did not involve any surgery. Contamination was measured using settle plates at various distances from the subject. This study included hats as well as masks in traditional and laminar flow theatres
McLure 1998	A laboratory simulation involving the analysis of bacterial colonies on agar plates. No surgery was involved
Mitchell 1991	An operating department simulation, therefore not involving surgery. The study measured the contamination of settle plates as a method of recording bacterial dispersal
Moore 2001	This study investigated the use of visors against masks. There were no surgical episodes where the surgical team's faces were uncovered. The surgical site infection rate was calculated on the outcome of a patient questionnaire. The subjective nature of these results meant that the study could not be used in the review
Norman 1995	The use of visors and masks by staff was compared for acceptability and contamination. A group not wearing either mask or visor was not included
Orr 1981	Excluded as it was not possible to distinguish how many clean operations were included in the study. Contact attempted with author
Ritter 1975	This study was concerned with contamination of the environment rather than surgical site infection. Settle plates were used during non-operating period
Ruthman 1984	The study examined the use of cap and a mask in A & E department. These 2 variables could not be differentiated
Sjol 2002	Stated as an RCT, but this study was observational and followed up patients for surgical wound infections post-discharge via a questionnaire
Tunevall 1992	This study took place during actual operations but the specific outcome measure of the study was contamination of settle plates. Although it was reported that no surgical site infections occurred during the study period, the cross-over design of the study meant that all patients were exposed to a masked and non-masked period. The authors therefore could not utilise the results of this study

A & E: Accident and Emergency
ASA classification: the American Society of Anaesthesiologists physical status classification system is a system for assessing the fitness of patients before surgery
RCT: randomised controlled trial
SSI: surgical site infection

DATA AND ANALYSES

Comparison 1. Masks versus no masks

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound infection	3		Odds Ratio (M-H, Fixed, 95% CI)	Totals not selected

WHAT'S NEW

Last assessed as up-to-date: 15 September 2011.

Date	Event	Description
24 November 2011	New search has been performed	Fifth update, new search, no new studies identified, no change to conclusions

HISTORY

Protocol first published: Issue 4, 2000

Review first published: Issue 1, 2002

Date	Event	Description
19 January 2010	New search has been performed	New search, one additional trial included (Webster 2010), no change to conclusions. Clarification of participants being the patients undergoing surgery not the members of the surgical team wearing the face mask
18 June 2008	Amended	Converted to new review format.
4 February 2008	New search has been performed	For this third update new searches were carried out in February 2008. No new relevant studies were identified. The authors' conclusions remain unchanged. Published in *The Cochrane Library*, Issue 2, 2008.
10 February 2006	New search has been performed	For the second update new searches were carried out in February 2006. One new study (Alwitry 2002) was identified but was excluded from the review. Published in *The Cochrane Library*, Issue 3, 2006.

(*Continued)*

16 April 2004	New search has been performed	For the first update, new searches were carried out in April 2004. One new study (Sjol 2002) was identified but was excluded from the review. Published in *The Cochrane Library*, Issue 3, 2004.
20 November 2001	New citation required and conclusions have changed	Substantive amendment.

CONTRIBUTIONS OF AUTHORS

Allyson Lipp coordinated the review update, extracted data, checked the quality of data extraction, undertook quality assessment, analysed or interpreted data, checked quality assessment, performed and checked quality of statistical analysis, completed the first draft of the review update including part of writing or editing the review update, made an intellectual contribution, approved the final version prior to submission, advised on the review update, secured funding for updating the review, performed previous work that was the foundation of the current review, wrote to study authors, experts or companies, provided data and is guarantor of the review update.

Peggy Edwards identified studies from the initial search and selected studies independently for data extraction, devised the data extraction sheet, independently extracted the data from studies, drafted the protocol and the review jointly with AL, provided content expertise and agreed with the update of the review.

Contributions of editorial base:

Nicky Cullum: edited the review, advised on methodology, interpretation and review content. Approved the final review and review update prior to submission.
Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited the review and the updated review.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section for the update.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

- Faculty of Health, Sport and Science University of Glamorgan, UK.

External sources

- Theatre Nursing Trust Fund, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Masks; Disposable Equipment; Randomized Controlled Trials as Topic; Surgical Wound Infection [*prevention & control]

MeSH check words

Humans