REVIEW ARTICLE

DOES EVIDENCE BASED MEDICINE SUPPORT THE EFFECTIVENESS OF SURGICAL FACEMASKS IN PREVENTING POSTOPERATIVE WOUND INFECTIONS IN ELECTIVE SURGERY?

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Background: The incidence of postoperative wound infection is usually not the cause of death but it increases the length of hospital stay and cost of care and morbidity. Since their introduction a century ago there is still controversy about primary purpose of the facemasks as whether they provide protection for the patient from surgical team or weather they protect surgical team from the patient? The Objectives of this study were to critically analyze and systematically review the randomized trials regarding effectiveness of surgical facemasks in preventing post operative wound infection in elective surgery. **Method:** Systematic literature review and analysis of all available trials (randomized controlled trials) regarding use of surgical face masks in elective surgeries. Medline (1966–2007), Embase (1996–2007), Cochrane database, Pubmed, Google Scholar, were searched for the selection of literature for the review. **Results:** No significance difference in the incidence of postoperative wound infection was observed between masks group and groups operated with no masks (1.34, 95% CI, 0.58–3.07). There was no increase in infection rate in 1980 when masks were discarded. In fact there was significant decrease in infection rate ($p<0.05$). **Conclusion:** From the limited randomized trials it is still not clear that whether wearing surgical face masks harms or benefit the patients undergoing elective surgery.

Keywords: Surgical face mask, postoperative wound infection, surgical site infection, face masks, prevention of postoperative wound infection, effectiveness of surgical face mask

INTRODUCTION

The incidence of postoperative wound infection is usually not the cause of death but it increases the length of hospital stay and cost of care and morbidity. These infections are approximately 500,000 per year among 27 million surgical procedures in United States and account for 2 million nosocomial infections each year.[1]

Since their introduction a century ago there is still controversy about primary purpose of the facemasks as weather they provide protection for the patient from surgical team or weather they protect surgical team from the patient?[2] Practice of wearing facemasks is believed to minimize the transmission oropharyngeal and nasopharyngeal bacteria from operating theatre staff to the patient's wound.[3] Masks not only provide a barrier for airborne organisms but also protection for the wearer against blood and body fluid splashes.[4] In most modern hospital no one is allowed to enter into theatre without wearing a surgical facemask. Nowadays surgical facemask has become an integral part of the theatre uniform for theatre personnel.

Continuous use or withdrawal of surgical facemasks is still a debatable issue due to financial reasons as well. Increasing costs of medical services is now a real problem. In one major teaching hospital in 1990, £ 10,000 was spent on masks for theatre use.[5]

Although facemasks are being used widely in clinical practice especially in theatres, there is limited research on their effectiveness to prevent postoperative wound infection.

Objectives of the review were to critically analyze the literature regarding effectiveness of surgical face masks in preventing postoperative wound infection from evidence based medicine point of view.

MATERIAL AND METHOD

Medline (1966–2007), Embase (1996–2007), Cochrane database, Pubmed, Google Scholar, were searched for the title words surgical face mask, postoperative wound infection, surgical site infection, face masks, prevention of postoperative wound infection, effectiveness of surgical face mask, and uses of surgical face mask. All studies relating to use of facemasks in surgical procedures and operations were selected for the review. Back chaining was also used to identify the data, which has been missed in previous searches, and also to get extra pieces of information that were relevant to the current study.

Only those studies were selected which included the information regarding use of surgical facemasks in elective surgery and postoperative wound infection as endpoint (lot of studies in the literature were found to be measuring bacterial load or colony count around surgical field which actually is different from clinical wound infection). Patients who were operated in emergency situations were excluded because there are other factors which can contribute to the wound infection like existing contamination, poor preoperative preparation, sepsis and surgical technique (operations by

junior members of the team out of hours) (confounding factors). Importance was given to the metanalyses, systematic reviews and randomized controlled trials versus placebo-control (so as to reduce the chances of systematic bias, selection bias and performance bias) to obtain information regarding higher level of evidence and to draw sound results depending upon strength and level of evidence.

Studies were evaluated according to type and strength of efficacy evidence (Table-1) and evaluation criteria were used to determine the validity of trials.

Table-1: Designation of level of evidence[6]

LEVEL1	CONCLUSIVE: research based evidence with multiple relevant and high quality scientific studies or consistent reviews of metanalyses
LEVEL2	STRONG: Research based evidence from at least one properly designated, randomized, controlled trial; or research based evidence from multiple properly designated studies of smaller size, or multiple low quality trials.
LEVEL3	MODERATE: a) Evidence obtained from various pseudo-randomized controlled trials (alternate allocation or some other method. b) Evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies, case control studies, or interrupted time series with a control group. c) Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.
LEVEL 4	LIMITED: Evidence from well-designated non-experimental studies from more than one centers or research groups, or conflicting evidence with inconsistent finding in multiple trials.
LEVEL 5	INDETERMINATE: Opinions of respected authorities, based on clinical evidence, descriptive skills, or reports of expert committees.

Literature review

There were only fours papers found in the literature, which has addressed this issue in clinical practice. One of them was systematic review and other three were randomized trials with different clinical settings. In the literature below author has critically appraised the evidence that supported or unsupported the evidence effectiveness of surgical facemasks in surgical practice. Special attention has been paid to the study methodology, sampling and randomization. Authors view and comments are discussed in discussion conclusion and recommendations section.

Lipp and Edward (2002) systematic review

Lipp and Edward[8] conducted the systematic review of all randomized controlled trials comparing use of disposable surgical facemasks with no facemasks in preventing surgical wound site infection in clean surgery (adults and children). All relevant publications about the use of surgical facemasks were sought through Cochrane wound group specialized register (2006) and Cochrane central register of controlled trials (2006). In addition to contacting manufacturers and distributors of disposable surgical facemasks, National Association of Operating Room Nurses and Association of American Operating Room Nurses were contacted to get any details regarding unpublished literature. Two experts analyzed the trials independently. Cochrane RevMan software was used for analysing the data and results were presented in 95% confidence intervals. Following outcome were measured Table-2:

Table-2: Outcome measures

Primary outcome measure	Secondary outcome measure
Incidence of postoperative wound site infection (definition of wound infection was same as used by the original author).	Costs Length of hospital stay Mortality rate

For the original review 13 studies were selected but only two randomized controlled trials met the inclusion criteria. Main reasons for the exclusion were study design, or ineligible outcome measures, for example bacterial load. Following results were extracted from these trials,

Table-3: Results (postoperative wound infection)

	Masks group	No masks group	Odds Ratio
Study 1	13/706 (1.4%)	10/723 (1.4%)	1.34, 95% CI 0.58–3.07*
Study 2	0	3/10 (30%)	0.07, 95% CI 0.00–1.63*

*Difference was not statistically significant

It was a comprehensive systematic review on the topic under discussion however it is surprising to note that this was the only systematic review available in the literature despite widespread use of surgical facemasks. Out of 250 citations yielded in early search only 84 had relevance and out of these 13 were considered to be potentially relevant. Out of 13 only 2 trials matched the inclusion criteria and were selected for analysis. Neither of the study considered secondary outcome measures listed in the review of costs, length of hospital stay and mortality rate. Strength of evidence achieved from these trials is weak (level III). Both these trial are not true randomized but are quasi randomised with doubtful allocation concealment. Study 2 only included 45 subjects (type II error and wide confidence interval). There is no clear description for the criteria for wound infection in study 1 which can affect the incidence rate for surgical site infection. Type of surgical facemask used in these trials is not specified. Also only included gynaecology case (females only) therefore selection bias creeps into the results. Study 2 was abandoned after 7 weeks due to several infection rates and hence results are unreliable and incomplete.

There are shortcomings in the review. Results are only applicable for the clean surgery and not for other types of surgeries. Both trials included scrubbed members in the inclusion, but it is important

to note that there are non-scrubbed member of the team as well who are potential source of infection and are important confounding factor. Nowadays significant number of interventional procedures is performed outside theatre environment and results of the review cannot be applied to them as well.

Orr (1981) prospective trial of face masks

Orr[9] in their prospective trial (6 months) decided not to wear facemasks by all the members of the surgical team in the theatre. Surgical wound infection rates in those 6 months were compared with those in previous 5 years (when all members were wearing facemasks). Infection control sister whose criteria for infection did not change monitored whole period. Most of theatre routines remained unchanged except theatre personnel were not wearing facemasks. Results extracted from the trial are shown in Table-4.

Table-4: Infection rates

	1976	1977	1978	1979	1980
Throughput	955	1054	1046	1078	1049
Wounds	333	447	419	435	432
Infection	18	19	19	16	8
Rate%	5.4%	4.2%	4.5%	3.7%	1.8%

According to the above results there was no increase in infection rate in 1980 when masks were discarded. In fact there was significant decrease in infection rate ($p<0.05$). Also there was no relation with the throat culture results of theatre personnel to the culture results from the infected wound (*Stahp. aureus, Staph. albus*).

It was a poorly constructed trial with no standardization or randomization among the groups. There was no explanation regarding definition for wound infection, nature of surgeries weather elective or emergency. No explanation regarding inclusion or exclusion criteria. Due to various biases in the results trial is not clinically valid and reliable.

Fall in infection rate during 6 months when masks were abandoned could well be due to the fact that all clean surgeries were performed in that particular period, or all surgeries were performed by only one team rather than different surgical teams from different specialties, or all patients might have been receiving prophylactic antibiotics.

Results of this trial are unreliable and have no external or internal validity (level IV). It is difficult to modify practice in the basis of these results.

Chamberlain and Elizabeth randomised controlled trial

Chamberlain and Elizabeth[10] on the basis of Orr's study[9] performed randomized controlled trial on 41 women undergoing elective gynaecology surgery. Over a period of seven weeks masks and no masks members of the team carried gynaecology operations alternatively.

Table-5: Randomisation

Number of patients operated by masks group*	Number of patients operated by no masks group*
25 (from 4 lists)	16 (from 3 lists)

*An independent microbiolist could monitor the trial that cold recommend discontinuation of the trial if adverse effects were found.

Outcome was measured by number of wound infections and bacterial counts obtained on settle-plates and from air sampling during the operation. Person evaluating the laboratory results was unaware about the group allocation. Results obtained are shown in Table-6.

It is evident from the above results that the colony count of alpha haemolytic streptococci in no masks group was higher than in masked group. In the similar way concentration of streptococci per litre of air was higher in unmasked group than in masked group.

Trial was discontinued after third case of wound infection was discovered in unmasked group.

From the results it appears that infection rate in unmasked group was higher but there are numerous deficiencies in this trial especially study methodology.

There was no description regarding method of randomization, no definition for wound infection was given, it was poorly blinded trial, having only females in the trial creates selection bias, no description for the proper inclusion or exclusion criteria was given, no mention regarding demographic characteristics of the patients, specification of face masks used was not described, and no record of the follow-up duration was given in the study. No power calculation was performed for the study. Power of the study is very low as only 45 subjects studied, which also creates wide confidence interval and type II error.

Overall it was weak evidence, which favoured use of facemasks in gynaecology surgery only (level IV), because of its unreliability and poor internal and external validity results are not acceptable for alteration of practice.

Table-6: Results[10]

Operations	Mask	Upper abdomen		Lower abdomen		Trolley		Mean duration of operation (min)	Number of cases
		T	S	T	S	T	S		
Major abdominal	Masked	129	0.43	56.9	0	49.5	1.4	69	4
	Unmasked	100	1.83	110.7	3.2	26.9	0.43	59	5
Minor abdominal	Masked	179.5	3.2	151.5	1.6	8.6	0	8	10
	Unmasked	170.9	10.5	176.3	5.3	21.5	0	10	5
Vaginal	Masked	250.5	0.75	259	-	45.15	0	16	11
	Unmasked	275.2	0	394.5	-	87.01	0	18	6

Tunvalle (1991) randomised controlled trial[11]

Tunvalle[11] performed a randomised controlled trial on total of 3,088 patients comprising over 115 weeks period (March, 1983–May, 1986). *T= total S= streptococci

Table-7: Randomisation masked/unmasked

Masks group*	No masks group*
1537 operations	1551 operations**

*A random list was set up for 1 year to denoting week as masked and unmasked (which was inversed for second and part of third year. **On 277 occasions masked were worn by 1 or 2 persons because of common cold or allergic rhinitis.

Inclusion and exclusion criteria used in the study are shown in Table-8.

Table-8: Inclusion/Exclusion criteria

Inclusion criteria* (3,967)	Exclusion criteria (879)
All general surgical procedures through intact skin and sutures by primary intension	Anal procedures, urological procedures, orthopaedic procedures, patients not willing for trial, increased risk of infection, senility, acute illness

*All elective patients had 2-3 whole body wash with chlorhexidin, most of acute patients had at least one wash, depilation when required was carried out using depilation cream, three different varieties of masks were used which were specified and documented. Antibiotics were used prophylactically according to the local guidelines.

Table-9: Results of Tunvalle study

	With face mask			No face mask		
	Inf	Op	%	Inf	Op	%
Acute operations	21	350	6.0	17	349	5.4*
Elective clean Operations	11	688	1.6	9	707	1.3*
Elective non-clean operations	41	499	8.2	27	500	5.4*
Total	73	1537	4.7	55	1551	3.5*

*p<0.05 (statistics according to 2-tailed chi square test
Inf=infection, Op=operations, %=percentage of wound infection.

Table-10: Comparison between mask and no mask groups in Tunvalle study

Masks group	No masks group
4.7% (3.7–5.8 CI)	3.5% (2.6–4.5 CI)

p>0.05 (no statistical significance)

Positive Staphylococcus growth was seen in 21 out of 112 cases in Mask group and 29 out of 112 cases of No mask group, the difference was not significant (p>0.05).

This is the only trial in the literature that shows respectable results according to which there is no difference in the incidence of postoperative wound infection in masked and unmasked groups.

It was carefully constructed and planned trial; most of the flaws in the earlier similar trials were omitted in this study to make it more acceptable. Although it was not a classical randomised controlled trial due to poor allocation concealments yet it has significant validity in terms of results (level-III). There was clear description for inclusion and exclusion criteria, sample size and power of study was calculated beforehand, clear description for the criteria for wound infection was given for the first time, type of facemasks used were specified and ethical approval was sorted out for the trial. Another good thing about the trial is that it also differentiates elective clean surgery, and non-clean surgery. In the previous trial all non-clean surgeries were excluded.

Results of the study could be applied to the elective clean as well as non-clean general surgical procedures. However all Urological and Orthopaedic surgeries were excluded so results are not applicable in these specialities.

Also surgeries involving implants prosthesis, grafts and interventional element like Cardiology and Radiology are not included in this trial therefore results cannot be generalised in these branches.

DISCUSSION

Postoperative surgical site infection (<3%) is a major source of illness and a less frequent cause of death in surgical patients.[1] The incidence of wound infection is usually not the cause of death but it increases the length of hospital stay and cost of care and morbidity. In addition to the proper surgical technique and health status of the patient there are many other factors, which contribute to the postoperative wound infection in clean surgical procedures Infection in these patients may be due to airborne exogenous microrganisms.[7] It has been standard practice since the beginning of 20th century to wear facemasks in operating theatres.[9] In most of the hospitals no one is allowed to enter into the theatre without facemask, although scientific background to this routine is lacking.[11]

Everyday new and sophisticated facemasks are introduced into our theatres with an aim of prevention of wound infection. Increasing costs of medical services is now a real problem. In one major teaching hospital in 1990, £ 10,000 was spent on masks for theatre use.[5]

It is surprising that despite of the widespread use of facemasks in the theatres, research into this topic is relatively neglected. There are only few trials, which looked into the area of effectiveness of facemasks in preventing wound infection.

According to Lipp and Edward[8] there is still no clear evidence that facemasks benefit or harm the patient by preventing postoperative wound infection in clean surgery. In clinical practice there is very limited applicability of this review as it only applies to clean surgeries. There are a huge number of emergency procedures as well as interventional procedures, which involve cut to the skin, and has potential for wound infection. On the basis of these limited results it is still debateable to abandon wearing facemasks, as they are still a source of personnel protection for the operating individual. According one of the studies the rate of blood contact during surgical cases was 10.2%[13] Surgeons are twice

likely to be affected than other healthcare individuals. According to McClure *et al*[14] standard, soft, pleated facemasks effectively prevent dispersal of upper respiratory tract bacteria downwards during talking and head turning.

According to Orr[9] there was actually fall in infection rate in those 6 months when masks were discarded. Although facemasks are meant to protect patient, there are several ways in which they could contribute to contamination of surgical wound. Venting, wicking, wiggling and exhalation of moist air are few ways described by Belkin[2] as few of the possible means by which masks can contribute to the increase in wound infection.

Although Chamberlain and Elizabeth[10] managed to prove three major wound infections in no masks group their study was predominately related to the gynaecology surgery and trial was abandoned as well. These results have very limited applicability to the other specialities; therefore their evidence is also deficient in strength to alter practice regarding use of facemasks.

Only reasonably bigger trial in the literature was that from Tunvalle[11] that for the first time included contaminated surgeries in the trial as well and performed the power calculation for the study as well for their study.

It is evident from the above studies that there is very limited research in this field and applicability of the results in only limited to the general surgery and gynaecology surgery also studies are performed in theatre environment and on theatre personnel only. There is no study regarding use of masks in orthopaedics, vascular, cardiac, plastic &reconstructive surgery. Majority of these branches of surgery use implants and grafts where wound infection could have dangerous consequences and on the basis of current literature no recommendations could be made regarding change of practice of wearing facemasks.

CONCLUSION

Evidence regarding effectiveness of surgical facemasks in preventing postoperative wound infection in elective surgery is inconclusive. It is difficult to alter current clinical practice of wearing facemasks in theatres on the basis of current evidence.

RECOMMENDATIONS

1. Surgical facemasks are still a means of protection for the surgeons and help to avoid contact with face and mucus membranes therefore they should be worn by the theatre staff.
2. In the absence of available evidence masks should be worn according to local theatre policies.
3. Since there is no trial or evidence regarding use of facemasks in Orthopaedics and Trauma, Cardio thoracic, transplant, Interventional procedures and Radiological procedures involving cut to the skin therefore masks should be worn in these procedures.
4. There is need to conduct more research regarding effectiveness of facemasks in preventing postoperative wound infection in above-mentioned specialities.

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