ORIGINAL ARTICLE

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Use of face masks by non-scrubbed operating room staff: a randomized controlled trial

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Key words
mask, protective clothing, surgery, surgical wound infection.

Abbreviations
aOR, adjusted odds ratio; ASA, American Society of Anesthesiologists; BMI, Body mass index; CI, Confidence interval; Chi^2, Chi Square-statistic; I^2, Higgins I^2 statistic; OR, Odds ratio; SD, Standard deviation; SSI, Surgical site infection.

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Accepted for publication 30 January 2009.

doi: 10.1111/j.1445-2197.2009.05200.x

Abstract

Background: Ambiguity remains about the effectiveness of wearing surgical face masks. The purpose of this study was to assess the impact on surgical site infections (SSIs) when non-scrubbed operating room staff did not wear surgical face masks.
Methods: Eight hundred twenty-seven participants undergoing elective or emergency obstetric, gynecological, general, orthopaedic, breast or urological surgery in an Australian tertiary hospital were enrolled. Complete follow-up data were available for 811 patients (98.1%). Operating room lists were randomly allocated to a 'Mask group' (all non-scrubbed staff wore a mask) or 'No Mask group' (none of the non-scrubbed staff wore masks). The primary end point, SSI was identified using in-patient surveillance; post discharge follow-up and chart reviews. The patient was followed for up to six weeks.
Results: Overall, 83 (10.2%) surgical site infections were recorded; 46/401 (11.5%) in the Masked group and 37/410 (9.0%) in the No Mask group; odds ratio (OR) 0.77 (95% confidence interval (CI) 0.49 to 1.21), p = 0.151. Independent risk factors for surgical site infection included: any pre-operative stay (adjusted odds ratio [aOR], 0.43 (95% CI, 0.20; 0.95), high BMI aOR, 0.38 (95% CI, 0.17; 0.87), and any previous surgical site infection aOR, 0.40 (95% CI, 0.17; 0.89).
Conclusion: Surgical site infection rates did not increase when non-scrubbed operating room personnel did not wear a face mask.

Introduction

Using surgical facemasks to limit the spread of bacteria from the nose and mouth to reduce surgical site infection (SSI) rates has been standard practice for over a century.[1] There have been at least three investigations of their effectiveness in preventing surgical site infection.[2–4] Two of these were large studies, both of which reported fewer SSIs in the non-masked group;[2,4] the third trial was abandoned after 1 week because three out of five patients in the unmasked group developed a post-operative wound infection compared with no infections in the masked group.[3] Each of these studies had some design faults, which may explain why face masks continue to be worn by non-scrubbed staff and why professional bodies continue to support their use.[5,6] Moreover, a recent systematic review concluded that harms or benefits associated with wearing face masks in operating theatres remained unclear.[7] The authors recommended that future studies should discriminate between scrubbed and non-scrubbed staff, provide clear definitions of infection and randomize by theatre list.[7] Consequently, the objective of the current study was to assess if the SSI rate was affected when non-scrubbed members of the operating room team remained unmasked.

Methods

Reseach design

A randomized controlled trial was used.

Randomization process

Operating lists were randomized into two arms, Mask group and No Mask group, using a computer-generated randomization schedule. 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. The CONSORT guidelines were followed from the point of recruitment.

Participants and setting

We obtained Institutional Ethics approval to conduct the study. Consent to participate from the surgical teams was negotiated before the study commenced. All staff, including surgeons, anaesthetists, nurses and ancilliary staff were included in this process. At the time of the study, 17 operating theatres were functioning in our large tertiary centre; all of these were included. Only non-scrubbed staff, including anaesthetists, were asked to comply with the random assignment. The only exclusions were surgeries where it was considered necessary for all staff to wear masks; for example, if the patient was infected with an airborne bacteria. Apart from the intervention, no attempt was made to modify normal practice; masks were not standardized for the study.

Data collection

Preoperative information

Baseline data were collected to allow an assessment of how comparable patients were in terms of their risk for developing a wound infection. The surgical site surveillance – Composite Risk Index was used for this purpose. The Index, recommended by National Nosocomial Infection Surveillance System, consists of three factors: (i) the patients physical status; (ii) the length of sugery; and (iii) wound classification. All wounds were rated using classifications adapted from the Centre for Disease Control Guideline for the Prevention of Surgical Site Infection.[5] Wound classification usually occurs at the time of incision by the surgical team. If this did not occur, the Infection Control Practitioner attempted to obtain an opinion from the surgical team post-operatively. Additional information collected included age, gender, weight, body mass index (BMI), any history of previous wound infection, current co-morbidities, smoking status, American Society of Anesthesiologists (ASA) classification, use of preoperative antibiotic prophylaxis, the date and type of surgery and length of time in the operating room, number of staff in the operating room and whether the wound was drained. These details were obtained from the wound surveillance database or the patients' medical record.

Post-operative information

Additional information was added during the post-operative inpatient stay. This included administration of post-operative antibiotics and the length of preoperative and post-operative hospital stay. Details about any post-operative wound infection were obtained by routine surveillance methods, that is, by the medical officer, ward staff or infection control nurse who were blinded to the treatment protocol. SSIs occuring after hospital discharge were captured using a number of strategies: (i) through the hospital's routine follow-up system, which used a standard questionnaire seeking information from the patient about wound status; (ii) information from post-discharge follow-up clinics; (iii) chart reviews; and (iv) where no information could be retrieved by any of these methods, a phone call was made to the patient or to their general practitioner, both of whom were unaware of treatment allocation.

Definition of SSI

For surgical site surveillance, the infection control team adheres to criteria defined by the National Nosocomial Infection Surveillance System.[5] These include superficial incisional (an infection involving skin or subcutaneous tissue of the incision and excluding stitch abscess), deep incisional (an infection involving deep soft tissue of the incision) and organ space (an infection involving any part of the anatomy, other than the incision, which was opened or manipulated during an operation).[5]

Sample size justification

Based on preliminary data from obstetric theatres, approximately 12% of patients developed an SSI, either in hospital or after discharge. We calculated that a sample size of at least 450 in each arm of the study would be sufficient to achieve a power of 80% using a 95% confidence interval (CI) to detect a 40% difference in the SSI rate between the Mask and No Mask groups.

Data analysis

Baseline patient characteristics were compared using Student's *t*-test for continuous variables and the chi-square statistic with Yate's correction when appropriate for categorical variables. All patients randomized were analysed by intention to treat, regardless of the treatment received. We used standard methods to calculate the odds ratio (OR) of an outcome in the No Mask group compared with the Mask group, with a 95% CI. In both groups of patients, parameters are expressed as means $\pm$ standard deviation (SD) or as the number of patients. All tests of significance were two-sided. The proportion of patients with a surgical wound infection (Mask versus No Mask) was calculated using the formula adopted by the Infection Control Department, that is, numerator (total number of wound infections) divided by denominator (total number of surgeries where data were collected). The infection control staff were blinded to the study allocation.

Results

Based on two separate funding grants, data were collected in two phases (between 15 June 2007 and 30 September 2007 and between 2 June 2008 and 12 September 2008). A total of 827 patients were enrolled and 811 (98.1%) patients completed the trial; 401 Mask group and 410 No Mask group (Fig. 1). Two hundred and eighty-two patients were obstetric (34.1%), a further 96 (11.6%) were gynaecology, 118 (14.3%) were undergoing breast surgery, 311 (37.7%) were general surgical patients (180 open surgery and 131 laparoscopy surgery) and 18 (2.2%) were urology cases. The majority of patients (671; 81.1%) were admitted on the day of surgery. The mean age of the sample was 45.03 (SD 16.73). Participants were similar at base line for risk factors related to SSI (Table 1).

Primary outcome

Wound infection

The mean follow-up period for the Mask group was 33.4 days (SD 22.1) and for the No Mask group it was 33.4 days (SD 22.8). During

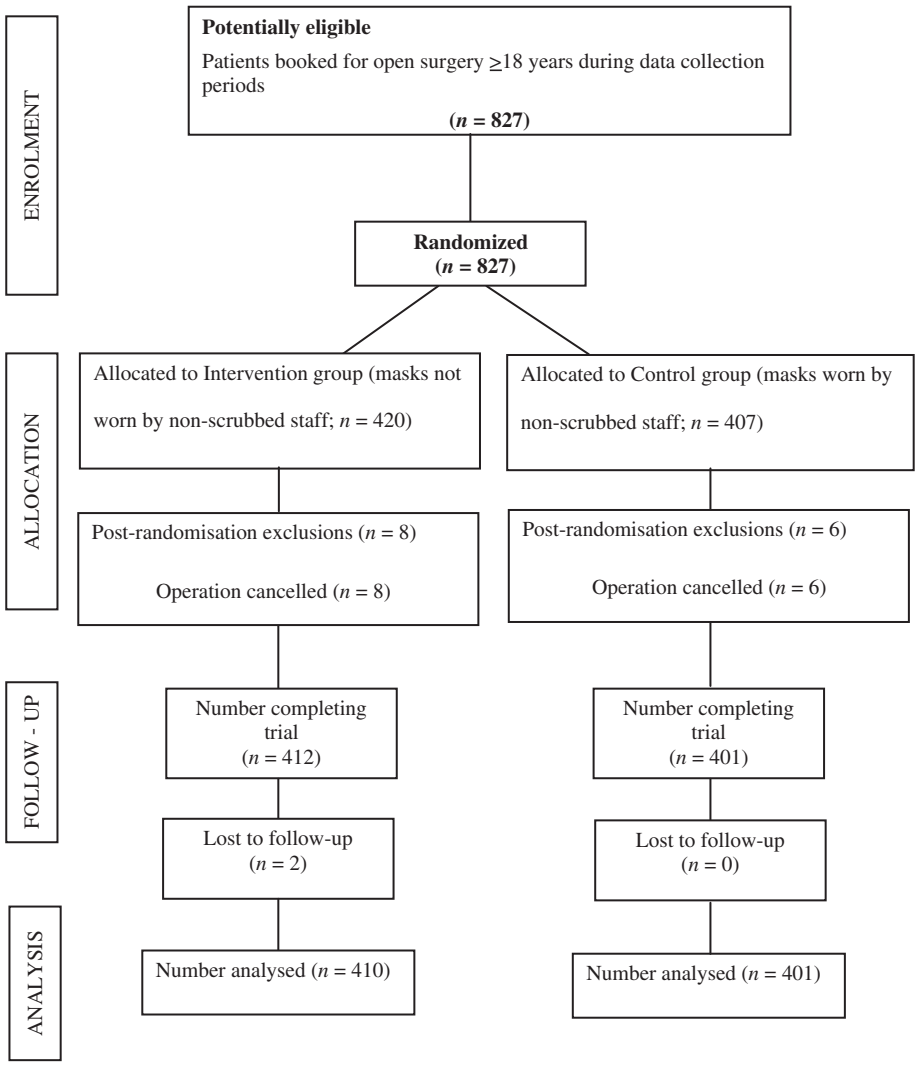

Fig. 1. Flow of participants through the study.

this time, a total of 83 (10.2%) SSIs were recorded; 46 (11.5%) were in the Mask group and 37 (9.0%) in the No Mask group. The difference was not statistically significant; OR 0.77 (95% CI 0.49–1.21), $P = 0.151$. Of the 83 infections recorded, 70 (84.3%) were superficial, 11 (13.3%) were deep incisional and two (2.4%) occurred in an organ space. Obstetric surgery had the highest SSI rate (14.9%) and general laparoscopic surgery had the lowest (6.3%). Table 2 shows further details. Only 26 (31%) patients had microbiological information recorded. Six were positive for *Staphylococcus aureus*, two for *Escherichia coli*, and one each of *Pseudomonas aeruginosa, Enterobacter* species, *Enterococcus faecalis, Proteus mirabilus, Candida albicans, Streptococcus agalactiae, Streptococcus* species Group G and *Corynebacterium* species. The remainder recorded either no growth, or mixed skin flora or mixed *enterococcus* species.

Factors associated with SSI

In the univariate analysis, 12 factors were associated with an SSI in this sample. Statistically significant factors were entered simultaneously into a binary logistic regression model predicting SSI. After adjustment, any preoperative hospital stay, having high BMI and having a history of SSI remained significant predictors of SSI.

Discussion

Wearing face masks had no statistically significant effect on the development of SSI in this cohort. Results concur with outcomes from a previous large trial, which also found a non-significant but lower rate of infection in the Non-masked group.[4] The result seems counter-intuitive, given the long and embedded history of wearing masks to prevent infection. However, several small experimental studies investigating the role of wearing masks in containing the spread of microorganisms provide some explanation. In one experiment, staff were randomly allocated to wear or not wear masks during 30-min operating sessions. Air was sampled and comparable bacterial counts were recovered whether masks were worn or not.[8] Similarly, when unmasked volunteers were asked to talk loudly within the vicinity of the operating table, they failed to contaminate settle plates, which had been placed on the table.[8,9] Moreover, organisms recovered from settle plates placed on the operating room table

during obstetric surgery were different to organisms recovered from infected wounds.[3] This suggests that masks are less important than other well-known factors, such as weight, length of hospital stay and duration of surgery, in preventing SSI.

Risk factors for surgical site infection in the current study were similar to those found elsewhere.[10,11] The one exception was the operation classification of caesarean section, where the range of SSI rates generally falls between 1.6 and 7.4%.[12,13] However, in an earlier study at this hospital, the SSI rate among clinic patients was 15.8%, comparable with our current rate.[14] It is also possible that some of the common univariate factors associated with SSI, such as weight and length of post-operative stay would have remained predictive in the regression analysis if the sample had been larger.

Staff response to the study was generally positive. After initial hesitation borne of long tradition, staff expressed relief when they were assigned to a theatre randomized to the No Mask group. The discomfort of wearing a mask, often through long surgical procedures, is one difficult aspect of operating room work. For some, who cannot wear masks for long periods, it may be a reason for excluding surgery as a career choice or curtailing a chosen option. Guidelines for use of face masks by anaesthetists already suggest that masks need only be worn by the scrub team,[15] and our results provide further support for the recommendation.

One of the strengths of the study was our extensive follow-up. The hospital surveillance rate is based on laboratory data and on postal returns from patients. According to infection control staff, the postal response rate is between 30 and 40%. In our study, we used the hospital data where available and, where it was not, we retrieved data from medical records (including information from follow-up clinics). If follow-up data were unavailable from any of these sources, the patient was contacted by phone and asked a series of questions about the condition of their wound. If doubt still existed, we spoke to the patient's general practitioner (GP). We found that patients who were contacted by phone were very pleased to be able to discuss their hospital care. On a number of occasions, where post-operative care with a GP had been unsatisfactory and the wound had not healed, we were able to arrange a follow-up visit to the hospital.

Post hoc analysis indicated that our study was underpowered; slightly less than 70% with an alpha of 0.05. However, when we combined our results with those of Tunevall (Figure 2), results statistically favoured not wearing a mask ($P = 0.04$).[4] Even so, to be confident of these results, it would be useful to repeat this study as an equivilence trial; or ensure that any superiority trial was suitably powered.

Table 1 Baseline characteristics and risk factors for surgical site infection for Mask and No Mask groups (results are number and % unless otherwise indicated)

Factor	No Mask *n* (%)		Mask *n* (%)	
Mean age [SD]	45.4	[16.9]	44.7	[16.6]
Male gender	76	(18.1)	87	(21.4)
Any pre-operative hospitalization	81	(19.3)	75	(18.4)
Mean weight [SD]	77.9	[19.4]	80.7	[19.7]
Prophylactic antibiotics	324	(82.7)	305	(85.0)
Surgery classification				
Elective	326	(77.6)	322	(79.3)
Sub-acute	44	(10.5)	34	(8.4)
Emergency	50	(23.4)	50	(23.8)
Wound classification				
Clean	344	(82.5)	316	(78.0)
Clean contaminated	70	(16.8)	86	(21.8)
Contaminated/dirty/infected	3	(0.7)	3	(0.7)
ASA classification				
One	148	(35.5)	122	(30.1)
Two	105	(25.2)	113	(27.9)
Three	50	(12.0)	49	(12.1)
Four	3	(0.7)	0	(0.0)
Not specified	111	(26.6)	121	(29.9)
Mean length of surgery in minutes [SD]	85.8	(63.9)	88.4	[69.2]

ASA, American Society of Anesthesiologists; SD, standard deviation.

Table 2 Infection characteristics for each surgical specialty

Type of surgery	No infection	Superficial	Deep incisional	Organ space
Gynaecology	87 (91.9)	4 (4.2)	4 (4.2)	0 (0.0)
Obstetric	239 (85.1)	39 (13.9)	3 (1.1)	0 (0.0)
General (open)	157 (90.2)	13 (7.5)	2 (1.1)	2 (0.0)
General (laparoscopic)	112 (94.9)	5 (4.2)	1 (0.8)	0 (0.0)
Urology	15 (88.2)	2 (11.8)	0 (0.0)	0 (0.0)
Breast	119 (93.7)	7 (5.5)	1 (0.8)	0 (0.0)
Total	729 (89.8)	70 (8.6)	11 (1.4)	2 (0.2)

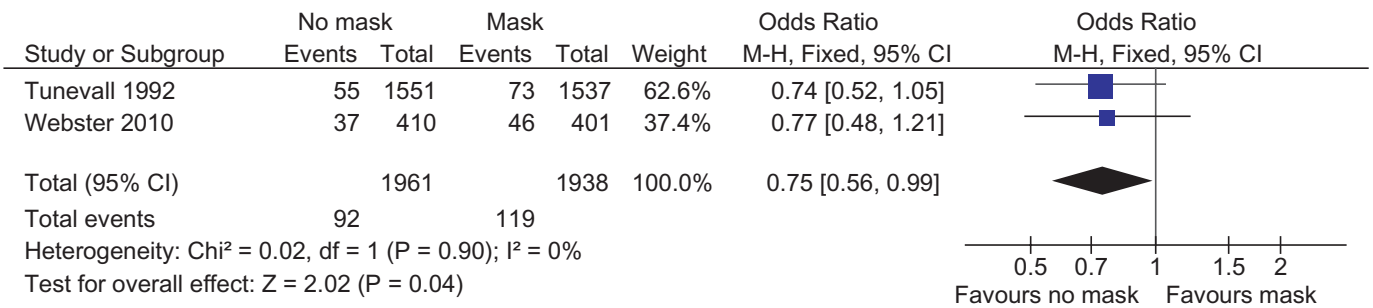

Fig. 2. Forest plot of two clinical trials investigating use of face masks to prevent surgical site infection.

Conclusion

In our generic surgical cohort, surgical site infection rates did not increase when non-scrubbed operating room personnel did not wear a face mask.

Acknowledgement

JW received financial grant support through two Queensland Health Nursing Research Grants. There was no conflict of interest.

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