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■ ARTHROPLASTY

Forced-air warming and ultra-clean ventilation do not mix

AN INVESTIGATION OF THEATRE VENTILATION, PATIENT WARMING AND JOINT REPLACEMENT INFECTION IN ORTHOPAEDICS

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We investigated the capacity of patient warming devices to disrupt the ultra-clean airflow system. We compared the effects of two patient warming technologies, forced-air and conductive fabric, on operating theatre ventilation during simulated hip replacement and lumbar spinal procedures using a mannequin as a patient. Infection data were reviewed to determine whether joint infection rates were associated with the type of patient warming device that was used.

Neutral-buoyancy detergent bubbles were released adjacent to the mannequin's head and at floor level to assess the movement of non-sterile air into the clean airflow over the surgical site. During simulated hip replacement, bubble counts over the surgical site were greater for forced-air than for conductive fabric warming when the anaesthesia/surgery drape was laid down ($p = 0.010$) and at half-height ($p < 0.001$). For lumbar surgery, forced-air warming generated convection currents that mobilised floor air into the surgical site area. Conductive fabric warming had no such effect.

A significant increase in deep joint infection, as demonstrated by an elevated infection odds ratio (3.8, $p = 0.024$), was identified during a period when forced-air warming was used compared to a period when conductive fabric warming was used. Air-free warming is, therefore, recommended over forced-air warming for orthopaedic procedures.

It has been acknowledged that the operating theatre's ventilation system has a critical role in preventing joint infection.[1] Charnley postulated that the 'surgical implant might provide a nidus for the growth of airborne bacteria which ordinarily are accepted as non-pathogenic'.[1] This has been confirmed through animal studies[2] and a national clinical trial involving over 8000 operations demonstrating the contribution of clean air to the reduction of the rate of infection after arthroplasty.[3] Following that report, ultra-clean ventilation became the standard for joint replacement procedures. The system protects the surgical site from airborne contamination through the constant delivery of a downward uniform-velocity (0.3 m/s to 0.5 m/s), highly filtered (> 99.997%) airflow.[4] However, the performance of ultra-clean ventilation depends critically on airflow volumes and proper temperature gradients. The latter may be disrupted by excess heat released by patient warming devices.

Forced-air warming is now commonly used in operating theatres to ensure normothermia of the patient. The vented airflow from forced-air warming is released at up to 43°C, which is often 20°C above ambient operating theatre conditions.[5,6] The release of excess thermal energy can establish temperature gradients that impede the downward flow of ultra-clean air. Reductions in the velocity of downward flow have also been shown to increase the entry of contaminants into the surgical site.[7] In addition, the release of heat may generate convection currents that rise against the downward airflows, drawing non-sterile floor-level air into the surgical site.

Air-free alternatives, such as conductive fabric warming, have been developed that are comparably effective for the prevention of hypothermia.[8-14] These offer higher thermal efficiencies than forced-air warming and therefore release only a fraction of the excess heat.[6] Accordingly, we chose to compare the effects of forced-air and conductive fabric warming on clean airflow patterns over the surgical site in a partial-walled ultra-clean operating theatre during two simulated procedures: a hip replacement with upper-body warming, and a lumbar spinal procedure with lower-body warming. Ventilation airflow patterns were

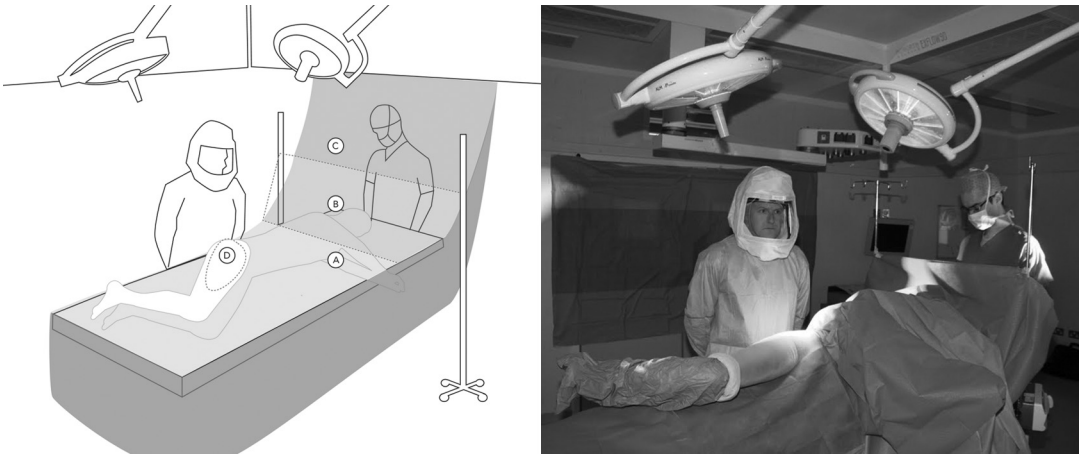

Fig. 1

Diagram (left) and photograph (right) showing the operating theatre set-up for hip replacement with upper-body warming showing surgical drape positions of laid-down (A), half-drape (B) and full-drape (C) and surgical site location (D).

visualised using neutrally buoyant detergent bubbles. In addition, observational data on arthroplasty infection rates were compared for the period each warming device was in clinical use in our hospital.

Materials and Methods

Ultra-clean operating theatre characteristics. Experiments were carried out in a partial-walled ultra-clean operating theatre (ExFlow 90; Howorth, Bolton, United Kingdom) used for orthopaedic and spinal surgery in the United Kingdom. Validation and verification checks according to Hospital Technical Memorandum 2025[15] showed the operating theatre airflows to be within specification and having a mean velocity of 0.44 m/s at a height of 2 m, which exceeds the threshold required by the standard (0.38 m/s). Owing to the location of the theatre preparation room an insignificant airflow imbalance was detected that affected the results of a single-particle entrainment test: entrainment values were 12% at that location, which marginally exceeded the recommended threshold of 10%.

Airflow visualisation procedures. High-intensity lighting was used to illuminate neutrally buoyant detergent bubbles having a diameter of approximately 4 mm (referred to here as 'bubbles'). A SAI bubble generator (SAI Model 5; Sage Action Inc., Ithaca, New York) was used to produce bubbles using a helium-mixed air supply and detergent. The equipment uses a centrifugal classifier to allow only bubbles of neutral buoyancy through the system, with heavier or lighter bubbles discarded. The bubble generator is specifically designed and validated for the visualization of air currents.[16] For photography, a digital camera (EOS 500D; Canon, Reigate, United Kingdom) was used and exposure time set to 0.25 s for time-lapse photography.

Experimental setup. *Hip replacement*. A mannequin was laid in the lateral position on an operating table and draped with a three-piece disposable draping set (Molnlycke Health Care, Manchester, United Kingdom) in accordance with standard protocols (Fig. 1). The drapes had adhesive edges and all were sealed during draping. A surgeon, dressed in occlusive clothing with head gear (T4; Stryker, Kalamazoo, Michigan), stood motionless in front of the surgical site and an anaesthetist stood at the head of the operating table. At the head end the drape was used to create an anaesthesia screen in one of three positions, either clipped to the ceiling to create a barrier between the surgical site and the anaesthesia area (full-drape); clipped to the intravenous stands and raised 0.75 m above the operating table (half-drape); or laid down over the mannequin's head (laid-down). The upper-body warming treatment was introduced under the drape and was either a torso forced-air blanket (Bair Hugger Model 540; Arizant Healthcare, Eden Prairie, Minnesota) or a torso conductive fabric blanket (Hot Dog Model B110; Augustine Temperature Management, Eden Prairie, Minnesota). The warming devices were powered by standard controllers set to 43°C. Bubbles were introduced at the head/neck of the mannequin to track under-drape resident air movements in the region where the excess heat from patient warming was being released.

***Lumbar spinal procedure*.** The same mannequin was laid in the prone position on the operating table and four drapes were arranged in a square configuration (Molnlycke Health Care) with the screen at full height (Fig. 2). A single surgeon stood motionless next to the surgical site for all experiments. A standard theatre gown and face mask were worn by the surgeon. The lower-body warming treatment was introduced under the drape and was either a lower-body forced-air blanket (Bair Hugger Model 525; Arizant

Fig. 2

Diagram (left) and photograph (right) showing the operating theatre set-up for lumbar spinal surgery with lower-body warming and full-drape, showing surgical site location (A).

Fig.3a

Fig.3b

Photographs showing a) the definition of the region where bubble counts were performed over the surgical site for hip replacement with upper-body warming, with bubbles (white steaks) appearing in the photograph for the experimental setup of forced-air warming and half-drape, and b) bubbles exiting the diffuser in still air.

Healthcare) or a lower-body conductive fabric blanket (Hot Dog Model B103; Augustine Temperature Management). The deviceswere powered by the same controllers as listed above and set to 43°C. Bubbles were introduced at floor level between the surgeon's body and the operating table in the area where the excess heat from patient warming was being released.

Sampling procedures. ***Hip replacement.*** Bubble counts over the surgical site were measured using a sequence of five photographs taken at ten-second intervals. The number of bubbles reaching the surgical site was determined by counting the number of bubbles in a 0.5 × 0.5 m region over the surgical site in each photograph (Fig. 3).

Lumbar spinal procedure. A different airflow pattern was observed with the spinal simulation, therefore time-lapse photography was chosen rather than bubble counts for data presentation. Time-lapse photography also provides directional information on airflow patterns that cannot be easily captured in quantitative data.

Experimental design. ***Hip replacement.*** . A replicated (n = 2) $3^1 2^1$ full factorial design was used to assess changes in bubble counts over the surgical site. The experimental factors considered were the anaesthesia/surgery screen: laid-down, half-screen or full-screen; and the patient warming device: conductive fabric or forced-air.

Lumbar spinal procedure. . No design was either used or necessary to demonstrate the difference in ventilation performance between forced-air and conductive fabric warming systems.

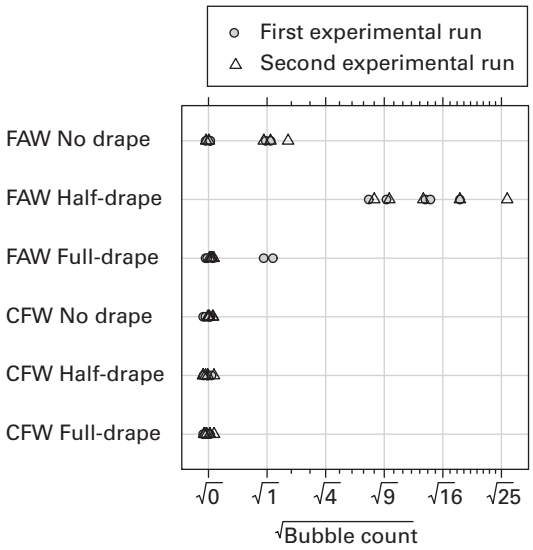

Fig. 4

Chart showing bubble counts over the surgical site for each photograph (data are staggered for clarity). Five photographs were taken for each experimental run (FAW, forced-air warming; CFW, conductive fabric warming).

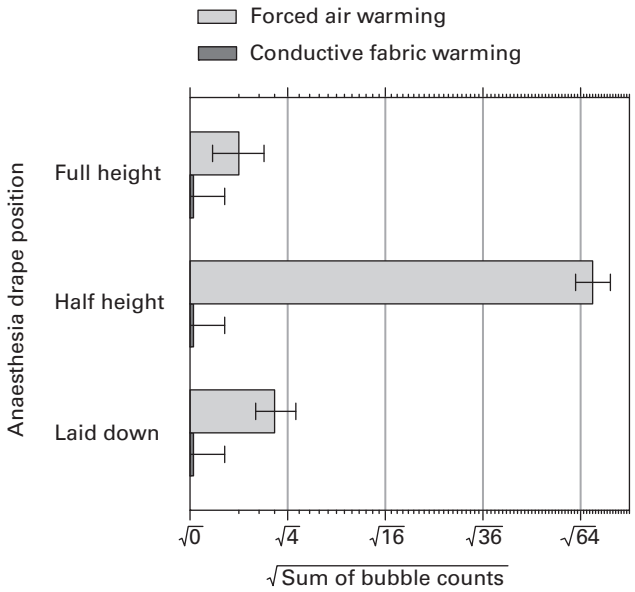

Fig. 5

Bar chart showing the mean bubble count for experimental runs when the bubble counts were summated over the five photographs. Error bars represent the standard error of the mean. Wald tests were used for statistical inference.

Joint infection data. Demographic information on relevant risk factors for surgical site infection (SSI) were collected for primary hip and knee replacement procedures performed at our hospital during a 2.5-year period starting 1 July 2008. Infection was diagnosed by SSI nurses according to English Health Protection Agency criteria for deep infection.[17] In order to standardise the duration of follow-up, only infections presenting within 60 days of surgery were included. Microorganism identification was performed on isolates from septic joints. A transition in patient warming systems from forced-air to conductive fabric was made in all three elective orthopaedic theatres, starting on 1 March 2010 and ending on 1 June 2010. Unfortunately, the prophylactic antibiotic regimen was not constant during the study period. From July 2008 to February 2009, a single dose of gentamicin 4.5 mg/kg was given at induction. In March 2009 this was changed to teicoplanin 400 mg and gentamicin 3 mg/kg. Gentamicin-loaded cement (0.5 g per 40 g mix) was used for both groups. Similarly, the thromboprophylaxis regimen from July 2008 to the end of July 2009 was tinzaparin (Leo Pharma, Princes Risborough, United Kingdom) from day one to day 14 or 28 post-operatively for knee or hip replacement, respectively. From August 2009 to February 2010 rivaroxaban (Bayer PLC, Newbury, United Kingdom) was provided from day one post-operatively, but in February 2010 to the end of the study this reverted to tinzaparin from day one post-operatively.

Statistical analysis. A Poisson regression model was fitted to the hip replacement data having the sum of bubble counts for each experimental run (five photographs) as the response and the factors identified in the experimental design as predictors. Differences in demographics and comorbidities between the patient warming groups were assessed by analysis of variance (ANOVA) or log-linear contingency table methods. Univariate odds ratios (OR) for the development of joint sepsis were computed using separate logistic regression models for each risk factor. Logistic regression was used to determine mean infection rates and dispersion indices for the periods of forced-air warming, transition and conductive fabric warming. Further details on statistical methods are provided in each table or figure. A p-value < 0.05 was considered statistically significant.

Results

Hip replacement. Bubble counts per photograph show that forced-air warming mobilised under-drape air so that it passed over the anaesthesia/surgery drape and into the surgical site (Fig. 4), but conductive fabric warming did not have a mobilising effect. Further, the position of the drape had a large effect on under-drape air mobilisation for forced-air warming.

Based upon Wald tests, differences in the sum of bubble counts for each experimental run (Fig. 5) were significant between conductive fabric and forced-air warming for the drape configurations of half-drape (0 *versus* 68, $p < 0.001$) and laid-down (0 *versus* 3, $p = 0.010$); differences for full-drape (0 *versus* 1, $p = 0.283$) did not reach statistical significance.

Lumbar spinal procedure. Excess heat from forced-air warming resulted in the development of hot-air convection currents between the surgeon's body and the operating table that transported floor-level air upwards and into the surgical

Table I. Demographics of surgical site infection risk factors by patient warming device (SEM, standard error of the mean)

	Forced-air warming	Conductive fabric warming	p-value*
Mean age (years) (SEM)	68.7 (0.30)	68.8 (0.50)	0.867†
Number of procedures (n)			
Hip	423	135	-
Knee	643	236	-
Hip : knee (%)	*40:60*	*37:63*	0.261
Diabetes (n, %)			
Type I	17 (*1.6*)	6 (*1.6*)	0.976
Type II	127 (*11.9*)	36 (*9.7*)	0.240
Duration of pre-operative hospital stay (n)			
0 days	990	357	
≥ 1 days	76	17	
0 : ≥ 1 (%)	*93:7*	*95:5*	0.075

* likelihood ratio chi-squared test (contingency table), unless otherwise stated
† analysis of variance

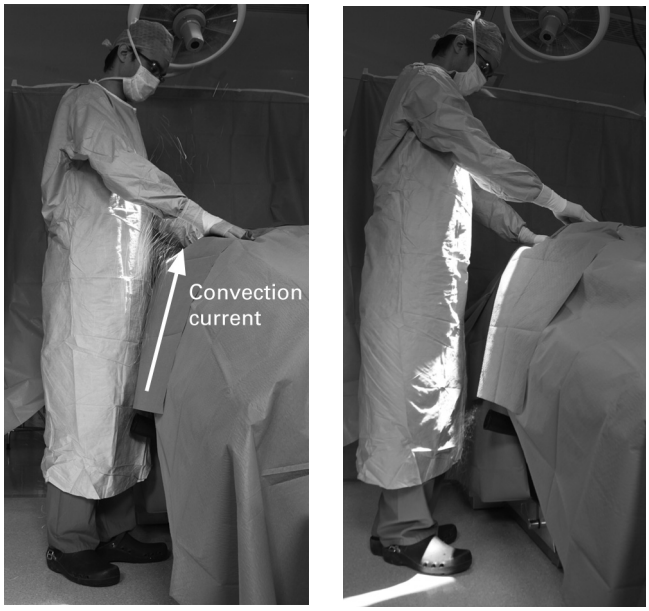

Fig. 6a

Fig. 6b

Time-lapse photographs of bubbles depicting airflow patterns for a lower lumbar spinal implant procedure with a) forced-air warming with the resulting convection current annotated, and b) with conductive fabric warming.

site (Fig. 6). In contrast, conductive fabric did not release sufficient excess heat to establish these convection currents.

Joint infection risks. The demographics of 1437 patients undergoing hip or knee replacement revealed no significant difference between the two types of warming for SSI risk factors of age, type of surgery, diabetes and length of pre-operative stay (Table I). Unfortunately, record keeping was incomplete for the additional risk factors of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection.[4,18]

The risks of developing deep infection (Table II) were significantly greater for patients undergoing hip *versus* knee replacement (OR 4.1, $p < 0.001$), and patients treated with forced-air *versus* conductive fabric warming (OR 3.8, $p = 0.024$). The factors of age, diabetes and pre-operative length of stay had no significant impact on the risk of infection. Further, the ORs for hip *versus* knee infection were similar for the subgroups of forced-air and conductive fabric warming, having values of 4.1 and 3.5, respectively.

Micro-organisms isolated from septic joints were predominately skin commensals for both forced-air (81%) and conductive fabric (100%) warming (Table III); the remainder were from intestinal bacteria. Of the skin-based organisms, staphylococcus species were the most common sources of infection (93%).

Logistic regression identified a significant reduction in infection rates (Fig. 7) for the conductive fabric (0.8%) *versus* forced-air warming (3.1%) periods ($p = 0.024$, Wald test). Differences in infection rates were significantly different between the conductive fabric and transition periods (0.8% *versus* 3.7%, $p = 0.028$, Wald test); differences were not significant between the forced-air and transition periods (3.1% *versus* 3.7%, $p = 0.662$, Wald test).

Discussion

Forced-air warming was found to have a significant and disruptive impact on the clean airflow patterns over the surgical site compared to conductive fabric warming, which had no noticeable effect. Further, forced-air warming established convection currents that mobilised resident air from non-sterile areas such as the floor and under the anaesthesia/surgery drape into the surgical site. This disruption in the ventilation of the surgical site was associated with significantly higher risks of joint sepsis for the forced-air *versus* the conductive fabric warming groups.

Perhaps the most striking finding was the detection of hot-air convection currents originating where the 'mass flow' of hot air exited from the forced-air warming blanket:

Table II. Univariate comparison of risk factors on the development of deep joint infection (CI, confidence interval)

	Developing infection	Not developing infection	Odds ratio (95% CI)	p-value*
Age group (n, %)				0.818
Youngest third (≤ 64 years)	13 (*2.7*)	472 (*97.3*)	1.0	
Middle third (> 64 and < 73 years)	12 (*2.5*)	459 (*97.5*)	0.9 (0.4 to 2.1)	
Oldest third (≥ 73 years)	10 (*2.1*)	471 (*97.9*)	0.8 (0.3 to 1.8)	
Type of surgery (n, %)				< 0.001
Knee	10 (*1.1*)	869 (*98.9*)	1.0	
Hip	25 (*4.5*)	533 (*95.5*)	4.1 (1.9 to 8.6)	
Diabetes (n, %)				0.110
None	34 (*2.7*)	1219 (*97.3*)	1.0	
Type I or II	1 (*0.5*)	183 (*99.5*)	0.2 (0.0 to 1.4)	
Pre-operative stay (n, %)				0.327
0 days	34 (*2.5*)	1310 (*97.5*)	1.0	
1 or more days	1 (*1.1*)	92 (*98.9*)	0.4 (0.1 to 3.1)	
Patient warming device (n, %)				0.024
Conductive fabric	3 (*0.8*)	368 (*99.2*)	1.0	
Knee	1	235		
Hip	2	133		
Forced-air	32 (*3.0*)	1034 (*97.0*)	3.8 (1.2 to 12.5)	
Knee	9	634		
Hip	23	400		

* likelihood ratio chi-squared test (logistic regression)

Table III. Bacterial species isolated from septic hip and knees by patient warming device

	Forced-air warming	Conductive fabric warming
Number of operations	1066	371
Number of species identified		
Skin-carried		
Staphylococcus aureus	11	0
Staphylococcus aureus and CNS*	2	0
CNS	12	2
Other	1	1
Total	26	3
Intestinal		
Gram-negative bacteria	6	0
Total	6	0
Total	32	3

* CNS, coagulase-negative staphylococcus

for the hip replacement with upper-body warming convection currents formed near the mannequin's head, whereas for the spinal procedure with lower-body warming, convection currents formed along the lower drape edge by the surgeon's legs. The formation of such convection currents may at first appear to be theoretically unsupported, as forced-air warming exhausts a heated airflow of only 40 cubic feet per minute into a ventilation environment having an airflow of 6000 cubic feet per minute.[19] However, one must consider the effects of surgical lighting, drapes and personnel on ventilation, all of which create localized disturbances of airflow that aid the formation of convection currents.

Prior research in ultra-clean ventilation theatres has shown surgical lighting to be a significant source of disruption of ventilation through the downstream wake and associated recirculation zone.[20] In our study, the use of bubbles allowed us to visualise this recirculation zone, which was found to extend about 1 m below the body of each surgical light. The presence of a raised anaesthesia/surgery drape was shown to further magnify the size and effect of this vortex, as the drape blocked the natural passage of air out of the ventilation field and created a still zone. Lastly, the presence of a surgeon or anaesthetist near this zone created an added obstacle,[20] resulting in a situation where even the slightest movement adversely affected the natural airflow patterns over the surgical site. Under such fragile conditions the mass flow of hot forced-air being exhausted from the device was sufficiently buoyant to push upwards and into this locally compromised ventilation region.

The clinical concern regarding the formation of such convection currents is twofold. First, these currents oppose the natural clean airflow patterns that are intended to sweep contaminants down and away from the surgical site.[21] Thus, contaminants released in the vicinity of the surgical site are less likely to be cleared. Secondly, the upward mobilisation of floor-level and under-drape air could potentially compromise the sterility of the surgical site, as resident air from these locations is typically laden with pathogens shed from the surgical staff.[22] Either mechanism offers a plausible explanation for the significant association between the patient warming device and the risks of SSI in this study. Further, the types of organism isolated from septic joints were predominately skin flora and hence likely to have been transmitted by and deposited from the air.[23] It was, however, somewhat unusual that the odds of infection associated with hip replacement were

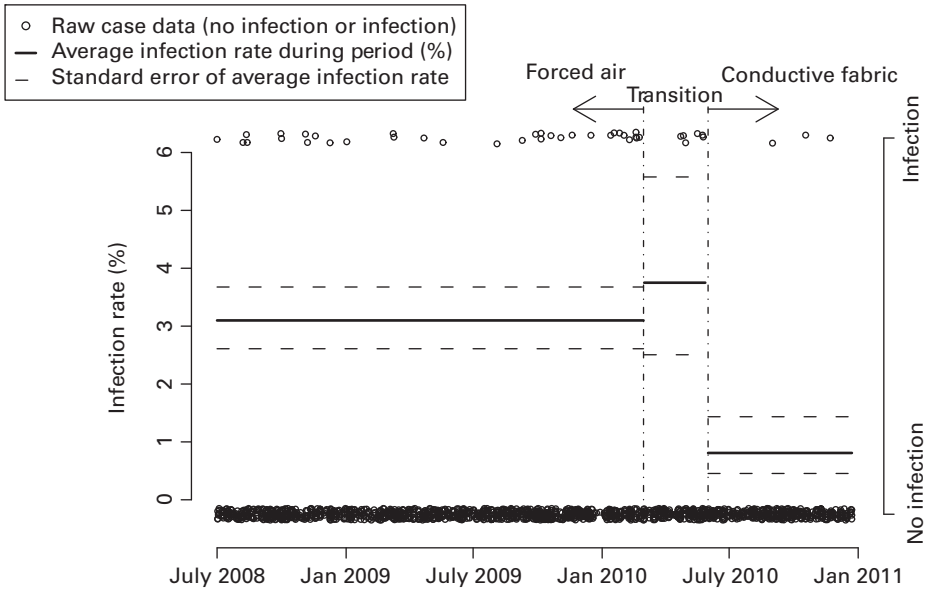

Fig. 7

Graph showing time-based trends of joint sepsis rates for hip and knee replacement cases. The outcome of each individual case is plotted on the right-hand axis (data are jittered to avoid overprinting). The infection rates for each period (forced-air, transition or conductive fabric) are plotted on the left-hand axis. Standard error of the mean was estimated using logistic regression.

4.1 times greater than the odds for knee replacement: typically, infection risks are greater for knee replacement.[24] A check of surgical practices revealed no differences in theatre dress or draping techniques between the procedures. Further, the OR for infection was consistent for both the forced-air and the conductive fabric subgroups (3.5 and 4.1, respectively), which suggests that there were no apparent changes in risk factors apart from warming device.

This study does not establish a causal basis for this association. Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010.[25] In addition, we were unable to consider all factors that have been associated with SSI, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection,[4,18] were not sufficiently detailed in the medical record. Moreover, prior research is limited to a handful of studies that have either looked at the disruption in ventilation due to forced-air warming in conventional operating theatres[26,27] or evaluated accumulation microbial contamination and emission issues.[28-32] Research in ultra-clean operating theatres is limited to a single orthopaedic study in which forced-air warming resulted in elevated microbial counts over the surgical site.[33] However, the increase in contamination was deemed to be less than that resulting from the movement of personnel, and did not exceed recommended bacterial levels. It is not known how these results translate to the range of arthroplasty procedures performed in ultra-clean operating theatres. Even minor differences in factors such as draping, procedural practices and theatre dress are likely to have large effects on both floor-level and under-drape contaminant levels and the formation of convection currents.

National studies on the benefits of ultra-clean laminar-flow ventilation may provide a better indication as to the impact of forced-air warming on the mobilisation of contaminants, as they take into account the full range of surgical draping, procedural practices and theatre dress. Over the past ten years these studies have shown either an upwards trend towards[34] or significantly higher[24,35] infection rates in laminar flow. Yet the results of these studies are not fully conclusive, as they are limited by their clinical design, which omits basic air pollution endpoint measurements such as wound washout or slit sampling. Moreover, the mobilisation of non-sterile air due to forced-air warming may be the explanatory factor, as historical studies[1,3] on laminar-flow ventilation conducted before the introduction of forced-air warming clearly showed a reduction in the rates of infection. Additionally, the widespread acceptance that forced-air warming reduces the rate of infection has only been demonstrated in colorectal surgery.[36]

Until the disruptive effects of forced-air warming on ventilation can be fully evaluated with regard to affecting the sterility of the surgical site, the use of air-free patient warming alternatives might be recommended for procedures involving implants carried out in ultra-clean theatres.

Supplementary material

A video demonstrating forced-air warming is available with the electronic version of this article on our website at www.jbjs.org.uk

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