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Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections

Abstract: Microbiological burden of room-air in operating theatres is a known risk factor for surgical site infections. However, it is unclear how to best evaluate efficacy and efficiency under routine clinical conditions. Moreover, there still is a lack of data to assess the impact on infection rates. The aim of this study was to evaluate a temperature-controlled ventilation system (TcAF) under routine clinical conditions and assess its impact on infection rates. 10 clinical installations of the TcAF system Opragon (Avidicare AB, Sweden) were assessed during live surgeries according to the Swedish SIS TS 39: 2015 standard. Furthermore, a retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1000 after installation of the TcAF system was performed. Endpoints for clinical outcome were length of stay and infection rates. Our results show that requirements of the Swedish standard were met or significantly exceeded by the TcAF system reliably and robustly ensuring "ultra-clean" air in the entire operating theatre and demonstrating the capability to reduce the risk of airborne microbial transmission under routine clinical conditions. The study shows positive impact on key clinical outcome parameters in line with previous research by Charnley and Lidwell.

Keywords: Temperature controlled Airflow, Surgical Site Infection (SSI), Ultraclean Air, Operating Room.

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1 Introduction

Surgical site infections (SSI) are among the most frequent hospital associated infections (HAI) and thus have long been the focus of scientific research. The use of ventilation systems is a known measure to reduce intraoperative bacterial and viral contamination of room air. Moreover, these systems create a physiological room climate and remove harmful gases from the operating room. The relevance of an adequate ventilation system to reduce SSI was demonstrated as early as 1959 by Sir John Charnley, who showed a correlation between colony forming units (CFU) and SSI. Using a ventilation system, the CFU level was reduced from 600 CFU / m³ to <1KBE / m³ reducing the infection rate during hip prosthesis surgery from 8.5% to 0.7%. [1] The Lidwell study from 1980 shows a connection between the air and subsequent wound infections and is most frequently used for all ventilation-related questions [2]. Nevertheless, other studies [3, 4] have questioned the clinical benefit of low-turbulence displacement flow (TAV). Still there is few data available regarding efficacy and efficiency of different ventilation systems under routine clinical conditions with respect to minimizing airborne microbial contamination and subsequent SSI rates. Therefore, the aim of this study was to evaluate a temperature-controlled ventilation system (TcAF) under routine clinical conditions and assess its impact on infection rates.

2 Material and Methods

10 clinical installations of the temperature-controlled ventilation system (TcAF) Opragon (Avidicare AB, Sweden) were assessed during live surgery according to the Swedish SIS TS 39: 2015 standard [5] using active air sampling (Fig. 1). Measurements were taken at the OR table/surgical site, instrumentation tray and in the periphery. The spectrum of

procedures included general surgical interventions and trauma / orthopaedic procedures. For the active air sampling the impaction method on blood agar plates was used (Klotz Impactor FH6, Fig. 2). Blood agar plates were incubated 72 hours at 35 ° C. Colonies were counted as colony forming units per cubic meter of air (cfu/m³). Moreover, a retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1,000 consecutive cases after the installation of an ultraclean airflow ventilation system (temperature controlled Airflow TcAF System Opragon AB, Avidicare Sweden), in the same operating room was performed. Clinical outcome was evaluated using length of stay and infection rates as endpoints. The proper function of the TcAF system was checked by intraoperative measurement using active air sampling (blood agar plates, Klotz Impactor FH6).

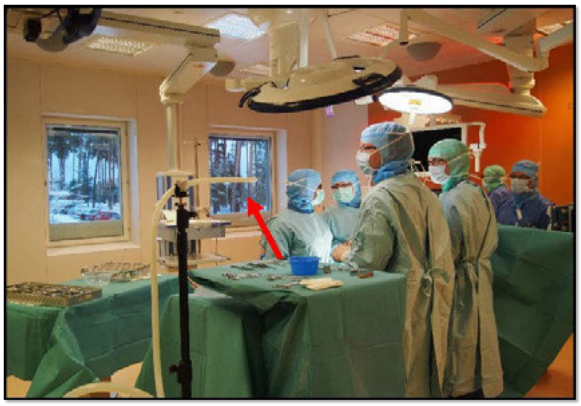

Figure 1: Set-up for the measurement of bacterial air burden with the active air sampling procedure (red arrows indicate the tube-tip for air sampling)

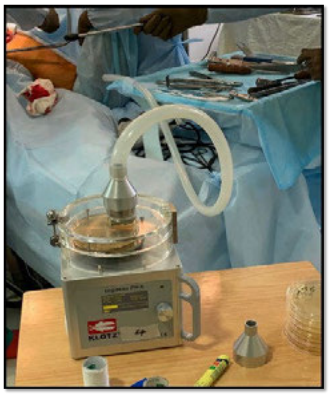

Figure 2: Klotz Impactor FH6 for active air sampling

3 Results

During the intraoperative measurements there were on average 6 persons in the room with a median (M) 6, mean (MW) 6.2 and standard deviation (SD) 1.3. The measurements showed values of median (M) 0 cfu/m³ over all measuring points in the room, mean value (MW) 1.8 cfu/m³, standard deviation (SD) 4.5 cfu/m³. In detail, the following germ counts were obtained: In the area of the surgical field median (M) 0 cfu/m³, mean value (MW) 0.4 cfu/m³, standard deviation (SD) 0.8 cfu/m³, in the range of the instrument table median (M) 0 cfu/m³, mean (MW) 1 cfu/m³, standard deviation (SD) 1.9 cfu/m³ and in the periphery median (M) 2 cfu/m³, mean (MW) 4 cfu/m³, standard deviation (SD) 6.7 cfu/m³. (Fig. 3)

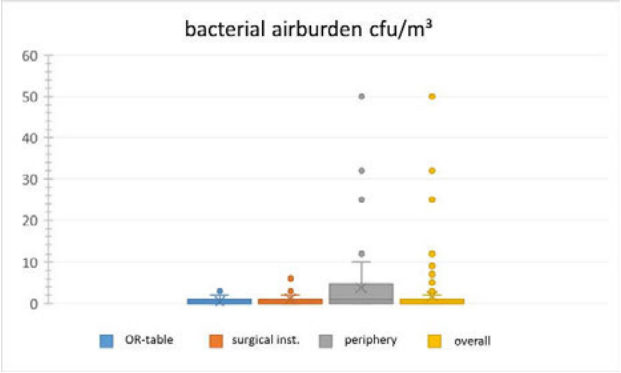

Figure 3: Measurement results active airsampling

For the retrospective study the measurements of the TcAF system were always within the limit demanded by the Swedish SIS TS39: 2015 requirements for infection sensitive surgery, which proved proper function of the TcAF system. Ultraclean air provided by the TcAF system was associated with a decrease in mean postoperative hospital stay from 11,0 to 8,64 days, a decrease in percentage of patients who stayed inpatient over 14 days after surgery from 7,3% to 2,2% and a decrease of infectious complications from 3,3% to 1,1%.(Fig. 4) The data analysis of the disease histories shows that only two repeat hospitalizations (0,2%) were registered in the test group (ultraclean air) due to infectious complications after primary arthroplasty. Another nine patients (0,9%) with superficial postoperative wound infection were treated on an outpatient basis. Analogous values in the control group were eight rehospitalizations (0,8%) and 25 patients (2,5%) treated on an outpatient basis for superficial postoperative wound infection (Fig 5 and 6).

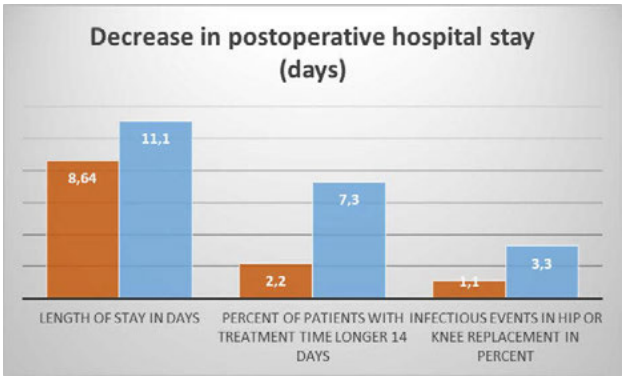

Figure 4: Decrease in length of stay for hip and knee replacement by TcAF-system

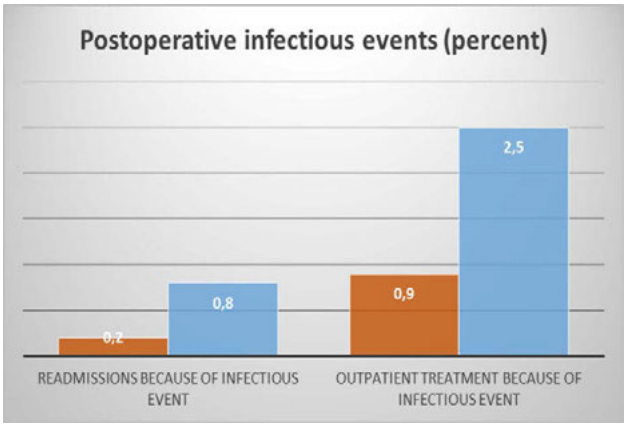

Figure 5: Decrease in length postoperative infectious events by TcAF-system

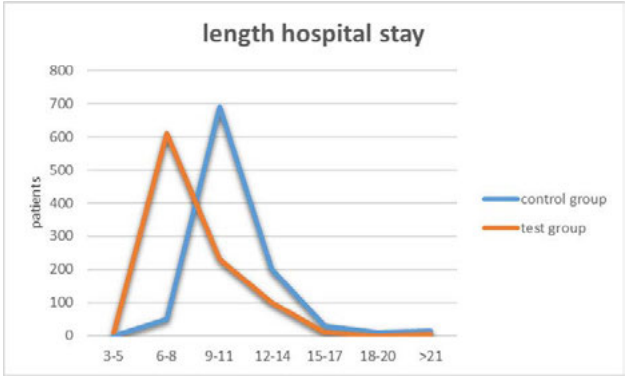

Figure 6: Hospital length of stay test group (TcAF) vs. control group

4 Conclusion

All of our results showed that the requirements of the Swedish standard were met or significantly exceeded by the TcAF system. The median cfu counts for the whole room, the area around the surgical field and the instrument table were 0 cfu /m³. The temperature controlled airflow reliably and robustly ensures "ultra clean" air <10 cfu /m³ in the operating theater and therefore is capable to reduce the risk of airborne microbial transmission under routine clinical conditions. Despite the limitations of a retrospective study the results show relevant impact on key clinical outcome parameters by using a TcAF ventilation system that ensures ultra clean air in the critical areas of the OR. This is in line with previous research by Charnley and Lidwell. These promising findings encourage further and more comprehensive research to ultimately prove the clinical impact and efficacy by prospective clinical studies.

Author Statement

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Conflict of interest: C. Bulitta has received consulting and speaker fees from Avidicare AB

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