

Comparing Surgical Site Infection With and Without the Use of Forced-Air Warming Devices During Surgical Procedures: A Systematic Review and Meta-Analysis.

ABSTRACT (max 150 words)

Forced-air warming (FAW) is effective in preventing hypothermia, yet its impact on surgical site infections (SSI) remains debated. This systematic review synthesizes available evidence on the impact of FAW devices on SSI incidence among surgical patients. We searched CINAHL, EMBASE, Medline, and CENTRAL databases. Fourteen included studies were randomized controlled trials (RCTs), non-randomized controlled trials, and observational studies comparing FAW devices to other warming methods or no warming in adult patients undergoing elective or emergency surgeries. The Effective Public Health Practice Project (EPHPP) tool was used for quality assessment, and a narrative synthesis and meta-analysis was performed. Fourteen studies met the inclusion criteria. The pooled analysis did not show a significant increase in SSI risk with FAW use. However, heterogeneity in study designs and small sample sizes limit the generalizability of findings. Future research should focus on larger, multicenter RCTs in diverse surgical settings and documenting patient characteristics and anaesthetic methods.

Key words: Forced-Air Warming, Surgical Site Infection, Wound complications, Systematic review, Meta-analysis

INTRODUCTION

Advances in surgical and anesthetic technologies have led to an increase in the number and complexity of surgical procedures¹. A critical issue in perioperative care is preventing hypothermia, defined as a core body temperature below 36°C, which is common in patients under anesthesia.^{2,3}. Anesthesia disrupts the body's temperature regulation, leading to reduced heat production and increased heat loss. Anesthetics, such as volatile agents, IV agents, and

1 spinal/epidural anesthesia causes significant temperature drops within the first hour due to
2 heat redistribution and vasodilation. Heat loss occurs mainly through radiation, convection,
3 conduction, and evaporation, further exacerbated by cold operating rooms, cold IV fluids, and
4 exposed body cavities.^{4,5}

5
6 Perioperative hypothermia occurs up to 70% of patients undergoing elective surgery⁶. The
7 consequences of hypothermia are substantial, leading to an increased risk of SSIs, prolonged
8 recovery times, cardiac complications, excessive bleeding, and extended hospital stays.
9 Previous investigations have shown that a 2°C decrease in core temperature can triple the
10 incidence of surgical site infections (SSI) and extend the length of hospital stays by up to
11 20%.^{7,9} This not only impacts patient outcomes and satisfaction but also significantly raises
12 healthcare costs. Preventing hypothermia is essential for improving surgical outcomes and
13 reducing the financial burden on healthcare systems.

14
15 To prevent perioperative hypothermia, the utilization of intraoperative warming systems has
16 become a standard practice. There are three common types of warming systems: Forced-Air
17 Warming (FAW), resistive polymer fabric warming, and circulatory warming systems with a
18 closed fluid circuit. Since the 1990s, FAW has been introduced and become a dominant
19 method in perioperative patient warming¹⁰. FAW system uses a blower and heat generator to
20 circulate warm air through compartmentalized blankets, which then heats the patient by
21 convection. The devices are equipped with several temperature control systems that monitor
22 the air's heat to prevent the patient from overheating or sustaining burns, but limited by the
23 surface area they can cover, the noise it generates, the cost of consumables and the potential
24 risk of contamination from the pump and air hose system.

Resistive heat warming utilizes resistive polymer technology, employing low-voltage currents that pass through a semi-conductive polymer fiber fabric. This fabric's temperature is regulated by a central computer, allowing for precise control over distinct sections of the body. This system allows for large non-operative body areas to be warmed, is reusable, noiseless, and lacks disposable components, offering a potential cost advantage. However, the blankets are less flexible, which may prevent them from being placed directly on the patient's skin and needing careful decontamination between users.

Circulatory devices like water mattresses and blankets are infrequently used in surgeries due to their limited effectiveness. These devices can cause 'pressure heat necrosis' where the patient's weight and excessive heat compress and damage tissues. Additionally, radiant heat sources are sometimes used. However, these radiant systems are less favoured by surgical staff because they heat the entire room, not just the patients. Beyond these, alternative methods to prevent hypothermia during surgery include warmed intravenous fluids, lavage, and endotracheal warming systems, which help regulate temperature in anesthetized patients¹⁰⁻¹².

According to the UK's National Institute for Health and Care Excellence (NICE) guidelines, FAW devices are recommended for patients undergoing anesthesia for more than 30 minutes or at higher risk of inadvertent perioperative hypothermia¹³. Although the warm air from FAW devices is beneficial for maintaining body temperature^{11,14,15}, FAW systems can potentially disturb the flow of filtered air above the surgical field, leading to contamination within the device and around the sterile surgical area¹⁶⁻¹⁹. This raises concerns about their impact on increased susceptibility to SSIs.

SSI is the most common and costly type of healthcare-associated infection, is described as infections that develop in the surgical area after an operation. These infections may be limited to the skin or more extensive, affecting deeper tissues, organs, or any implanted materials²⁰. The annual expenses of SSIs are estimated approximately £700 million (\$1 billion) in the UK and around \$3.3 billion in the US ^{20,21}. It is reported that SSI accounts for 20% of all Hospital Acquired Infections (HAIs) and is associated with a 2-to-11-fold increase in the risk of mortality, with 75% of SSI-associated deaths directly attributable to the infection. Patients with SSIs experience longer hospital stays, delayed wound healing, and require antibiotics, which increases psychological and financial strain ²¹⁻²³. Severe SSIs can also be fatal. Given the significant detrimental impact of SSIs and the additional care costs, prevention of this type of healthcare-associated infection is critically important.

While FAW device is widely used to prevent hypothermia, its impact on the sterile field and its potential contribution to remains a topic of significant debate. Our systematic review aims to synthesize available evidence on the impact of FAW devices on SSI among patients who have undergone surgical procedures. We will compare the incidences of SSIs, surgical site contamination levels in patients using FAW devices against those using non-FAW technologies. In the era of evidence-based practice, the findings of this review will provide insight for perioperative practitioners and healthcare providers to be aware of the available evidence and balance thermal comfort with infection control, ultimately aiming to enhance patient outcomes in diverse surgical settings.

VARIABLES AND OPERATIONAL DEFINITIONS

Inadvertent hypothermia is defined as an unintentional reduction in core body temperature below 36°C³.

1 A **surgical site infection (SSI)** is described as infections that develop in the surgical area
2 after an operation. These infections may be limited to the skin or more extensive, affecting
3 deeper tissues, organs, or any implanted materials. SSIs can range from mild, superficial
4 infections to severe, deep infections leading to complications, prolonged hospitalization, and
5 potentially death.²⁰

6 **Surgical site contamination** refers to the presence of microorganisms in or around the
7 surgical area before or during a procedure, arising from various sources such as the patient's
8 skin, environment, surgical instruments, or surgical team.²⁴

10 **PURPOSE OF THE LITERATURE REVIEW AND OBJECTIVES**

11 The purpose of this review was to critically appraise and synthesize available evidence on
12 the impact of FAW on SSIs among patients undergone surgical procedures. This review
13 sought to address four specific objectives.

14 1) To gather and analyze data from various eligible studies, including randomized
15 controlled trials (RCTs), non-randomized controlled trials, and observational studies to assess
16 the impact of FAW devices on SIs.

17 2) To evaluate the methodological quality of the included studies to ascertain the
18 reliability of the findings.

19 3) To compare the incidences of SSIs and levels of site contamination in patients using
20 FAW devices against those using non-FAW technologies.

21 4) To identify the gaps and needs for future research and recommend clinical
22 implications.

24 **REVIEW METHODS/SEARCH STRATEGY**

We established a systematic review protocol for identifying, retrieving, and evaluating the evidence. Our review was registered in an international systematic review database PROSPERO with registration ([PROSPERO \(york.ac.uk\)](https://www.crd.york.ac.uk/PROSPERO/)). The registration number is CRD42021243250

Inclusion Criteria: The primary analysis included various types of eligible studies such as clinical controlled trials (e.g., RCTs, non-randomized controlled trials, quasi-experimental studies), prospective cohort studies, and case-control studies that compared FAW devices to any other active or passive warming technologies. Other criteria included studies with: 1) adult patients aged 18 years and above undergoing elective and emergency surgery (including trauma surgery) with general or regional anesthesia, or a combination of both; 2) interventions comparing FAW devices to any other active or passive warming technologies; and 3) outcome measures evaluating SSI, and surgical site contamination levels

Exclusion Criteria: We excluded those studies that did not compare FAW devices, did not report SSI outcomes, were laboratory or animal studies, or used mannequins. We also excluded studies with participants under 18 years old, those presented in conference proceedings, articles written in non-English languages or without full-text availability, as well as review papers, commentaries, and book chapters.

Electronic Searches

To ensure a comprehensive exploration of the current literature, the first author (LQL) conducted an extensive search across multiple databases, including MEDLINE, CINAHL, Embase, and the Cochrane Central Register of Controlled Trials. This search was planned and agreed upon by the second author (SM) to ensure a systematic approach. We searched all relevant literatures without language restrictions by utilizing a mix of Free-text, keywords,

1 and Medical Subject Headings (MeSH) terms to maximize the breadth and depth of the
2 search. Key search terms included 'hypothermia,' 'operating room,' 'surgical wound infection,'
3 and 'forced air warming,' with detailed documentation of these terms provided in Table 1 for
4 reference. Additionally, we also searched guidelines from the National Institute for Health
5 and Clinical Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), and
6 the Association of Perioperative Registered Nurses (AORN). This was complemented by a
7 thorough examination of study references and other relevant literature to ensure that all
8 eligible studies were identified and considered in the analysis.

9 **Data Extraction**

10 We exported all relevant articles to Endnote (Version X9.2) for duplicate removal and initial
11 abstract screening by the first reviewer (LQL). Accuracy was cross-checked by a second
12 reviewer throughout the process (SM). Any disagreement was discussed by two reviewers
13 (LQL&SM) for retrieving full texts.

14 Both reviewers read eligible articles and agreed for final inclusion. The first reviewer (LQL)
15 extracted data from eligible articles using Excel, including publication year, authorship,
16 study design, sample size, participant demographics, type of warming device, follow-up
17 duration, adverse events, study quality, outcome measures, and intervention effect. The
18 second reviewer cross checked accuracy.

19 **Quality Assessment**

20 We used the Effective Public Health Practice Project (EPHPP) Tool²⁵ for quality assessment
21 by the first reviewer, and cross-validated by a senior perioperative nurse. The EPHPP tool
22 evaluates selection bias, study design, confounding factors, blinding, data collection approach,
23 and withdrawals/dropouts. Each domain was rated as '1' for good, '2' for moderate, or '3' for
24 poor quality. The overall quality of each paper was categorized based on these ratings.

Data Synthesis and Analysis:

We used Microsoft Excel 2019 for descriptive statistical analyses, and Review Manager (RevMan version 5.3) for inferential and pooled analysis. We performed quantitative pooled analyses when studies reported consistent outcome measures and utilized similar populations, calculating the combined impact of warming devices on SSIs. Odds ratios with 95% Confidence Intervals (CIs) for categorical variables and weighted mean differences with 95% CIs for continuous variables were computed. We used a standard random-effects model based on heterogeneity levels among studies. We assessed heterogeneity using a Chi-square test with a I^2 value. When significant heterogeneity ($I^2 > 50\%$) was observed, we used a random-effects model. In cases of no heterogeneity ($I^2 < 50\%$), we used a fixed-effects model. We did not conduct a formal pooled analysis on the effect of FAW devices on surgical site contamination due to inconsistent outcome measures across studies; Data were descriptively synthesized, tabulated and analysed by the first reviewer (LQL) with advice and agreement with the second reviewer (SM).

FINDINGS

The literature search yielded a total of 1,426 references across four databases: 542 from MEDLINE, 446 from CINAHL, 295 from EMBASE, and 143 from the Cochrane Central. Additionally, three more articles were identified through the reference lists of reviewed papers. All 1,429 hits were imported into EndNote for eligibility evaluation. Fourteen studies met the inclusion criteria and underwent data extraction. Figure 1 illustrates a diagram of the study selection process.

Sample Characteristics

The participant population in all 14 articles ²⁶⁻³⁹ comprised adult patients undergoing surgical procedures. Five studies were conducted in USA, four in the United Kingdom, , and one each in Austria, Australia, Canada, China, and Italy. The number of patients per study ranged from 30 to 5,018, covering various surgical specialties including neurology, breast, hernia, orthopaedic, vascular, cardiac interventional procedures, **obstetrics**, open thoracic, and colorectal surgery. Six of the 14 studies described the type of anaesthesia used: four reported general anaesthesia, and the remaining reported neuraxial anaesthesia, and spinal or general anaesthesia, respectively. Of the 14 studies, eight were RCTs ^{27,29,31,33,37,39}, three were case-control studies ^{26,30,32} one was a non-RCT³⁶, one was a two-group cohort analytic study²⁸, and one was a single-group cohort study³⁴.

Intervention

All 14 studies compared SSI rates between a FAW device and other warming technologies or non-use of warming technology. The FAW temperature settings were 43°C in two studies^{28,38}, 45°C in one study²⁷, with the remaining eleven studies not reporting temperature settings. FAW was mainly used during surgery, but two studies applied it before surgery as a pre-surgery warming method.^{31,33}

Outcome Measure

All 14 studies reported post-operative SSI rates. Two studies measured surgical site contamination near or on patients' skin^{34,35}. Seven studies reported SSI as a primary outcome, and the other seven as a secondary outcome or side effect. Two studies reported surgical site contaminations^{35,36}. Oguz et al. quantified bacterial counts using sedimentation agar plates and nitrocellulose membranes near patients during surgery within the operating room³⁶.

Moretti examined bacteria on patients' skin at the incision site before skin antiseptic application³⁵.

Quality Assessment

Among the eight RCTs^{27,29,30,33,35,37-39}, seven used appropriate randomization methods, while one did not describe its method³³. Six RCTs indicated blinding of the outcome assessor, and one was a double-blinded RCT³⁸. All eight RCTs reported participant withdrawals and reasons. Seven RCTs were classified as high quality^{27,29,30,33,37-39}, one RCT³⁵ was scored with '2' as moderate quality. Among other type of studies, one cohort analytic study was classified as moderate quality²⁸, while remaining five studies were classified as low quality.^{26,31,32,34,36}. Sample characteristics and quality scores for each study are in Table 2.

Data Pooling and Meta-Analysis

Effect of FAW on SSI in comparison to other warming technologies

Five out of the 14 studies reported a trend towards a higher number of SSIs in patient groups who used FAW compared to those who used non-FAW technologies^{29,30,31,32,37}. Only one of these five studies reported a statistically significant difference³². Two other studies reported divisive results. For example, the study by Melling et al³³ showed that patients given FAW had a significantly lower number of SSIs than those without any pre-operative warming ($p = 0.026$). However, patients receiving FAW experienced more wound infections compared to those in the local warming group, though this difference was not statistically significant ($p = 0.4$). Similarly, the study by Brown et al²⁶ reported that using FAW was associated with a lower number of 30-day SSIs among a neurosurgery cohort, while it increased the odds of SSI among a general surgery cohort. One of the 14 studies showed FAW associated with

lower SSI incidence compared to non-FAW technologies³⁹. The remaining six studies reported no SSI cases developed in patients who used either FAW or non-FAW devices during the study period.

Taken as a whole, analysis of all eight RCTs showed an insignificant difference in SSI events between patients who used FAW versus other types of warming devices or no warming device. The heterogeneity for studies in this pooled analysis was moderate ($I^2 = 45\%$), indicating some variations between each RCT, including types of surgical procedures, lengths of surgeries, and patients' conditions.

Additional subgroup analyses were performed: 1) Three RCTs ^{27,29,31} reported 30-day SSIs; and 2) three studies ^{27,31,32} reported 90-day SSIs. Neither analysis showed significant differences in SSIs between FAW and non-FAW devices. The heterogeneity of the pooled analyses of studies^{27,29,31} reporting SSI within 30 days is substantial ($I^2 = 82\%$), indicating a large variation among those studies, including types of surgery and variations of warming device interventions. However, the heterogeneity for the pooled analysis of those three studies ^{31,32,39} reporting 90-day SSIs is minimal ($I^2 = 6\%$), suggesting that the three studies shared similar methods, interventions, and outcome measures.

Effect of FAW on Surgical Site Contamination Compared to other warming technologies

Two studies aimed to determine the degree of bacterial contamination on the surgical site or in the air near the patients in the OR. One study by Moretti and colleagues³⁴ examined a total of 30 female patients undergoing hip replacement surgery. Twenty patients received warming by FAW device, while ten did not receive any warming. As a group, the mean bacterial load increased significantly under operation conditions after the patients were properly positioned

on the operating table. The regions near the 20 patients who underwent surgery with the FAW warming system activated showed a significant increase in average bacterial load values compared to those where FAW was not in use.

An RCT by Oguz and colleagues³⁵ measured the number of bacteria near patients randomized to intraoperative warming with either a FAW device or a upper-body non-FAW electric blanket during minor orthopaedic surgeries. No difference was found in bacterial proliferation on the sampling sites near patients between the FAW and non-FAW groups. The absence of uniform outcome parameters in these two studies means that a pooled analysis of the effect of FAW on surgical site contamination cannot be performed.

DISCUSSION

Inadvertent perioperative hypothermia remains a clinical challenge for nurses caring for patients undergoing surgical procedures. While warming devices can effectively warm patients in the OR and prevent perioperative hypothermia, the role of the FAW device as a potential source of SSI has been debated in the literature. This systematic review and meta-analysis, which included fourteen studies directly comparing SSI and other wound complications between patients who underwent surgery with FAW and those who used non-FAW methods for patient warming, did not reveal a significant increase in the risk of SSI for individuals receiving FAW warming during surgical procedures.

Our findings of narrative synthesis and pooled analysis align with previous studies^{40,41} suggesting that existing evidence is insufficient to definitively establish a relationship between FAW and the development of SSI or other wound complications. Interestingly, Zheng and colleagues⁴² conducted a systematic review and meta-analysis of seven RCTs to

1 assess whether preoperative warming with mixed active warming methods can reduce SSI
2 after surgery. Their results suggested that preoperative warming using mixed warming
3 devices, including FAW, can reduce SSI rates after surgery. The lower rate of hypothermia in
4 the mixed warming group may play a key role in decreasing postoperative SSIs.

5
6 In terms of surgical site contamination within the perioperative timeframe, we excluded
7 studies examining contamination using only mannequins or healthy volunteers, as these do
8 not provide direct clinical evidence on the link between FAW and SSI in patients. Our review
9 included only two studies with comparison groups that directly measured bacteria near or on
10 the patients during surgery. Neither of these studies supports the claim that FAW usage
11 increases SSIs. However, one study³⁵ by Oguz suggested that surgery of longer duration is
12 associated with a higher bacterial load. Another study by Moretti³⁴ suggested that bacterial
13 load increased during patient transfer to the operation table. These findings differ from
14 previous studies measuring surgical site contamination indirectly under controlled conditions
15 either in the air of ORs using mannequins or healthy volunteers^{11,13,31} which suggest that
16 FAW increased bacteria counts.

17
18 In appraising current available evidence, our review found more studies including RCTs²⁷⁻
19 ^{29,31,35,37-39} conducted, directly compare the use of FAW to other non-FAW devices over the
20 past 14 years since 2010. Seven out of 14 studies were classified as high-quality
21 methodological studies using the EPHPP evaluation tool in this review. However, a few
22 studies had limited statistical power, and five studies employed observational study such as
23 cohort or retrospective case-control design^{26,28,30,32,34} rather than prospective controlled trial
24 methods^{27,29,33,35,39}. There is recognition of moderate to high heterogeneity in the pooled
25 analyses due to large variations in comparisons of warming methods, patient populations,

1 anesthesia, and surgical procedures across the 14 studies included in this review. The
2 anesthesia method, warming device parameters (such as temperature levels, length of use),
3 and surgical types need further investigation. Current evidence on SSI rates linked to the use
4 of FAW primarily relies on studies focusing on clean surgical cases involving populations
5 with relatively low SSI risk.

6
7 Based on the existing literature and the range of controlled studies comparing the use of
8 FAW devices against without FAW, there is no conclusive evidence to directly link the use of
9 FAW with an increased risk of SSIs in patients undergoing surgery. We advocate for future
10 studies to robustly evaluate FAW devices on a broad range of patient populations undergoing
11 different anesthetic methods and surgical procedures. The type of surgical specialties
12 alongside characteristics of patients, i.e., age, Body Mass Index, duration of surgery, and
13 anesthetic method, need to be better identified and documented. It is worth mentioning that
14 very few studies were carried out in low- and middle-income countries. Future research is
15 needed to offer a better understanding of how different factors or variables may impact the
16 effect sizes observed in a study.

17 **Implications for Perioperative Nursing:**

18 Given the lack of conclusive evidence regarding increased SSI risks in patients receiving
19 FAW, perioperative nurses can continue to consider FAW as a viable option for maintaining
20 patient normothermia during the surgical procedure period. However, it remains important
21 for perioperative nurses to adhere to established infection control practices to minimize any
22 potential contamination. Clinicians can use FAW judiciously, as all patients need optimal
23 warming - not just those undergoing clean surgical procedures. Incorporating the insights
24 from this study into perioperative nursing education is essential. Highlighting the lack of
25

conclusive evidence supporting an increased risk of SSI can alleviate unnecessary concerns and foster informed decision-making in the use of FAW technology. It is imperative to emphasize that further research, ideally in the form of RCTs is necessary.

Limitations:

Systematic reviews have their advantages in enhancing the statistical strength of modest sample sizes in individual studies. They also, however, often exhibit certain drawbacks, including the possibility of publication bias, especially favouring positive findings. Additionally, language restrictions, heterogeneity across studies, and the coding of key terms can pose challenges. Furthermore, incomplete reporting of critical factors, such as patients' physical condition, the type of anesthesia used, and the duration of surgery, along with a limited number of cases for specific surgical types (e.g., only one case of caesarean and one colorectal case included in this review), precludes us from conducting a comprehensive pooled analysis for each surgical category. Therefore, it is difficult to draw firm conclusions in terms of generalizability to a wide range of surgeries.

Another limitation in this review is the inclusion of one trial published in one in 2002³³. It may be argued that surgical practices have changed during the last two decades. This RCT of higher methodological quality or lower risk of bias and assessed SSI related to FAW versus non-FAW technology, which met our inclusion criteria. We appreciate that including only the most updated articles may contribute more directly to stakeholders' guideline development. However, as empirical research, our review aimed to synthesize all available evidence within a historical context since FAW's introduction to the market, providing a systematic contribution to existing knowledge of FAW on SSI with a direct comparison of clinical studies. Although FAW has been widely investigated for hypothermia prevention, clinical

research directly comparing SSI outcomes between FAW and non-FAW is scarce. In light of the lack of studies directly comparing SSI between FAW and non-FAW in the literature, our study strengthens the rigor of methodology compared to any single primary study or other types of secondary analysis. Thus, providing all available evidence since FAW's introduction to the market can advance the knowledge of perioperative care teams in infection control. An additional limitation was the exclusion of literature in languages other than English due to the absence of adequate translation resources. However, in collaboration with our librarian, we devised a well-structured search strategy to mitigate potential bias as much as possible.

At last, our review did not consider the aspect of operating room environment, specifically the distinction between mixed or turbulent airflow and laminar airflow, and its relevance to the effectiveness and safety of FAW systems. We recognize that different type of airflow can influence the dispersion of particles and pathogens, potentially impacting the sterile field. For instance, laminar airflow is designed to minimize contamination in the surgical area by maintaining unidirectional airflow, which could theoretically reduce the risk of contamination from FAW devices compared to environments with mixed or turbulent airflow. This differentiation in airflow types could significantly affect the outcomes related to the use of FAW in maintaining sterility. We suggest the need for further research to systematically evaluate the interaction between different airflow types in operating rooms and the operation of FAW devices.

CONCLUSION

Our findings indicate that the use of FAW significantly lowers the risk of hypothermia in patients after surgery, in comparison to those who do not use FAW. However the evidence does not definitively establish a connection between the use of FAW and increased risks of

SSI among patients who undergo surgical procedures. The conclusions drawn in this review are based on studies of mixed quality, with a variety of surgical procedures, most of which were considered clean. Further studies are needed to support current practices in heterogeneous populations. These studies should be multicentre, well-designed RCTs using larger sample sizes, focus on a broader range of surgical specialties, and incorporate well-documented patient characteristic data and anesthetic methods.

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