Meta-analysis

Systematic review and meta-analysis of preoperative antisepsis with chlorhexidine *versus* povidone–iodine in clean-contaminated surgery

A. Noorani[1], N. Rabey[3], S. R. Walsh[1] and R. J. Davies[2]

[1]Department of Surgery and [2]Cambridge Colorectal Unit, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, and [3]Department of Plastic and Reconstructive Surgery, St Andrew's Centre, Broomfields Hospital, Chelmsford, UK
Correspondence to: Mr R. J. Davies, Cambridge Colorectal Unit, Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ, UK
(e-mail: justin.davies@addenbrookes.nhs.uk)

Background: **Surgical-site infection increases morbidity, mortality and financial burden. The preferred topical antiseptic agent (chlorhexidine or povidone–iodine) for preoperative skin cleansing is unclear.**
Methods: **A meta-analysis of clinical trials was conducted to determine whether preoperative antisepsis with chlorhexidine or povidone–iodine reduced surgical-site infection in clean-contaminated surgery.**
Results: **The systematic review identified six eligible studies, containing 5031 patients. Chlorhexidine reduced postoperative surgical-site infection compared with povidone–iodine (pooled odds ratio 0·68, 95 per cent confidence interval 0·50 to 0·94; $P = 0{\cdot}019$) .**
Conclusion: **Chlorhexidine should be used preferentially for preoperative antisepsis in clean-contaminated surgery.**

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Introduction

Surgical-site infection (SSI) increases morbidity, mortality, length of hospital stay and cost after surgical procedures[1–3]. A recent Cochrane review of preoperative antiseptic agents failed to reach a definitive conclusion, and recommended further primary research[4]. The Cochrane review was restricted to clean surgery only, and considered all methods and agents of antisepsis. A number of randomized controlled trials have been published since the review.

Preoperative skin antisepsis is based on the knowledge that a patient's skin is a significant source of pathogens[5]. Povidone–iodine and chlorhexidine both destroy bacterial structural integrity and have been studied extensively[6]. Recent evidence favours chlorhexidine as a skin antiseptic before central venous line insertion[7]. The preferred preoperative skin preparation agent is still unknown. A systematic review and meta-analysis were conducted to determine whether povidone–iodine or chlorhexidine should be the preferred agent for cleansing the skin before clean-contaminated surgery.

Methods

The systematic review and meta-analysis were conducted in accordance with the PRISMA guidelines[8]. The MEDLINE and Embase databases were searched in January 2010 using the search terms 'povidone–iodine', 'chlorhexidine' and 'iodine'. A supplementary search was undertaken in February 2010 using the terms 'surgical wound infection' and 'disinfection'. Conference proceedings from major general surgery and gynaecology meetings (Association of Surgeons of Great Britain and Ireland, American College of Surgeons Annual Congress, American Congress of Obstetrics and Gynecology, British International Congress of Obstetrics and Gynaecology) were searched from 2000 to 2010 for eligible abstracts. Reference lists from eligible reports were scrutinized to identify further potentially eligible studies. Antiseptic manufacturer websites were searched for relevant publications or presentations.

Studies were eligible for inclusion in the meta-analysis provided they met the following criteria: clinical trial, conducted in patients aged 18 years or older, and at least one clinical endpoint reported by trial authors. Two reviewers individually assessed trial reports to determine eligibility. Trial quality was evaluated using the Jadad score[9]. This score assigns points for randomization, double-blinding and reporting of losses owing to withdrawals and dropouts. Potential scores range from 0 to a maximum of 5.

The primary outcome for the meta-analysis was postoperative SSI. The secondary outcome was intra-abdominal infection. Data were entered into a Microsoft® Excel (Microsoft, Redmond, Washington, USA) spreadsheet for analysis. Pooled odds ratios (ORs) with 95 per cent confidence intervals were calculated using the random-effects model of DerSimonian and Laird, which was deemed most appropriate as the nature of surgical populations is inherently heterogeneous[10]. Heterogeneity was assessed using Cochran's Q test. In this test, $P < 0{\cdot}050$ indicated significant heterogeneity between the pooled studies. Bias was assessed by visual inspection of funnel plots and by the Egger test. Significance in the Egger test was set at 10 per cent. For all the other tests, the 5 per cent level was considered significant[11]. The statistical analyses were performed using Statsdirect 2.5.7 (Statsdirect, Altrincham, UK).

Results

The search results are presented in *Fig. 1*. Of 21 potentially relevant studies identified by the systematic review[12–32], six were ultimately eligible for the meta-analysis[12–16,31]. A review of manufacturers' websites yielded one potential abstract. Upon contacting the manufacturer, it became apparent that the study included healthy volunteers and was ineligible[33]. One of the included studies used a sequential implemental design rather than random allocation[14]. Further study details are reported in *Table 1*.

All six studies reported postoperative SSI rates. SSI occurred in 145 (5·7 per cent) of 2529 patients who had chlorhexidine and 198 (7·9 per cent) of 2502 who had povidone–iodine antisepsis. This yielded a pooled OR of 0·68 (0·50 to 0·94; $P = 0{\cdot}019$) (*Fig. 2*). There was no evidence of heterogeneity (Cochran's Q 8·21, 5 d.f, $P = 0{\cdot}144$) or bias (Egger test $-0{\cdot}35$, $P = 0{\cdot}789$). The analysis was repeated after excluding the sequential study by Swenson and colleagues[14]. SSI occurred in 93 (6·1 per cent)

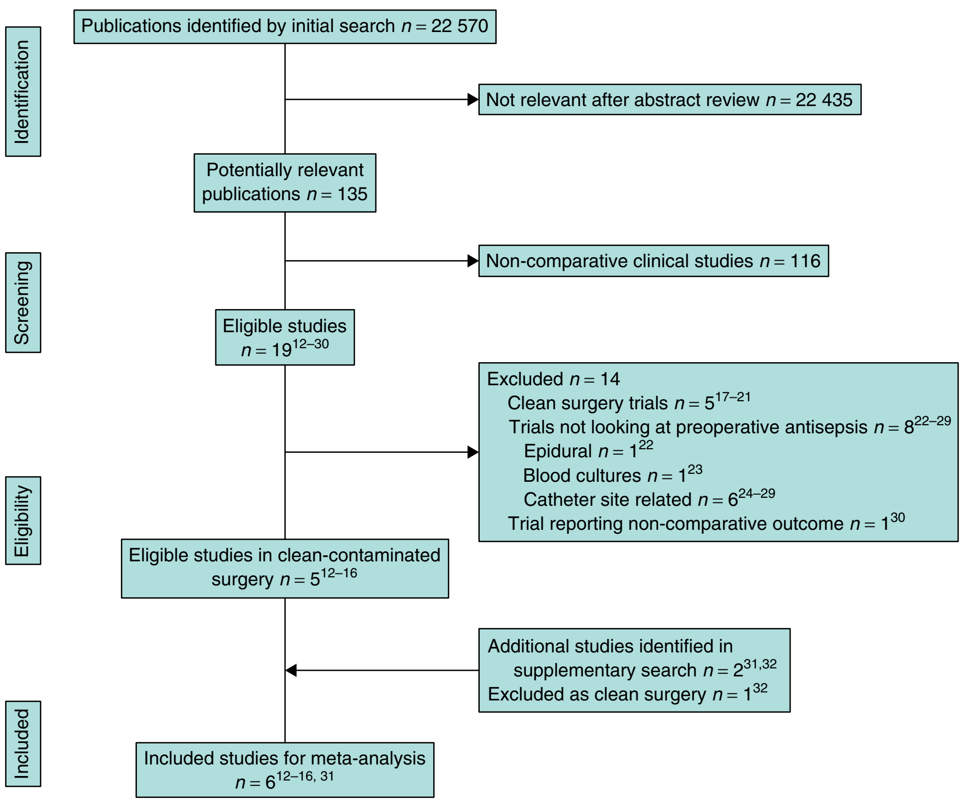

Fig. 1 Flow diagram of screening and selection of articles for the meta-analysis

Table 1 Characteristics of eligible trials

Reference	Year and country	Treatments	Method	Inclusions	Exclusions	Outcomes reported	Outcome	Study type	Jadad score
12	2010 USA	10% PVI *versus* 2% CHG in 70% IA	Scrub then paint	Age > 18 years, clean-contaminated surgery	Allergy, infection at adjacent site, inability to follow up for 30 days	SSI (superficial, deep, incisional, organ space) Sepsis from SSI	WI: 51 of 466 (10·9) PVI *versus* 21 of 431 (4·9) CH IAS: 20 of 466 (4·3) PVI *versus* 18 of 431 (4·2) CH	RCT	3
13	2009 Thailand	PVI *versus* 4% CH in 70% IA	5 min scrubbing, 5 min painting	Age 18–60 years, clean, clean-contaminated and contaminated surgery, ASA 1 and 2	Patient refusal, uncontrolled diabetes, dirty wound, immunosup pressants, allergy, serum albumin < 30 mg/dl	Reduction in bacterial coloniza tion, visible SSI	WI: 8 of 250 PVI (3·2) *versus* 5 of 250 (2·0) CH	RCT	1
14	2009 USA	PVI *versus* 2% CH and 70% IA *versus* iodine povacrylex in IA*	Period 1*: PVI (PVI soap, then IA, then 3 applications of 10% PVI) Period 2: 2% CH and 70% IA Period 3: iodine povacrylex in IA (not included in meta-analysis)	All adult patients undergoing general surgery	Not stated	SSI (superficial, deep, organ space)	WI: 49 of 987 (5·0) PVI *versus* 52 of 994 (5·2) CH IAS: 14 of 987 (1·4) PVI *versus* 19 of 994 (1·9) CH	Prospective study; sequential implemental design	0
15	2005 USA	10% PVI *versus* 4% CH	Not stated	Vaginal hysterectomy	Not stated	Proportion of contami nated specimens, clinical infections weeks 2 + 6	WI: 0 of 27 (0) PVI *versus* 0 of 23 (0) CH	RCT	2
16	1982 UK	10% PVI *versus* 0·5% CH	Painting	Clean, clean-contaminated, dirty, elective procedures	Sensitivity to solutions	Bacterial counts, clinical infection	WI: 61 of 413 (14·8) PVI *versus* 44 of 453 (9·7) CH	RCT	0
31	1984 USA	10% PVI scrub *versus* 0·5% CHG in 70% IA spray	6-min scrubbing with PVI soap, then absorbed with sterile towel, then painting with PVI solution or CHG spray	Laparotomy of all types, mastectomy, caesarean section	Not stated	Wound infection (minor or major), separation, haematoma, seroma	WI: 29 of 359 PVI (8·1) *versus* 23 of 378 (6·1) CH IAS: 5 of 359 (1·4) PVI *versus* 1 of 378 (0·3) CH	RCT	2

Values in parentheses are percentages. *Each period lasted 6 months; the total study interval was 18 months. PVI, povidone–iodine; CHG, chlorhexidine gluconate; IA, isopropyl alcohol; SSI, surgical-site infection; WI, wound infection; CH, chlorhexidine; IAS, intra-abdominal sepsis; RCT, randomized controlled trial; ASA, American Society of Anesthesiologists.

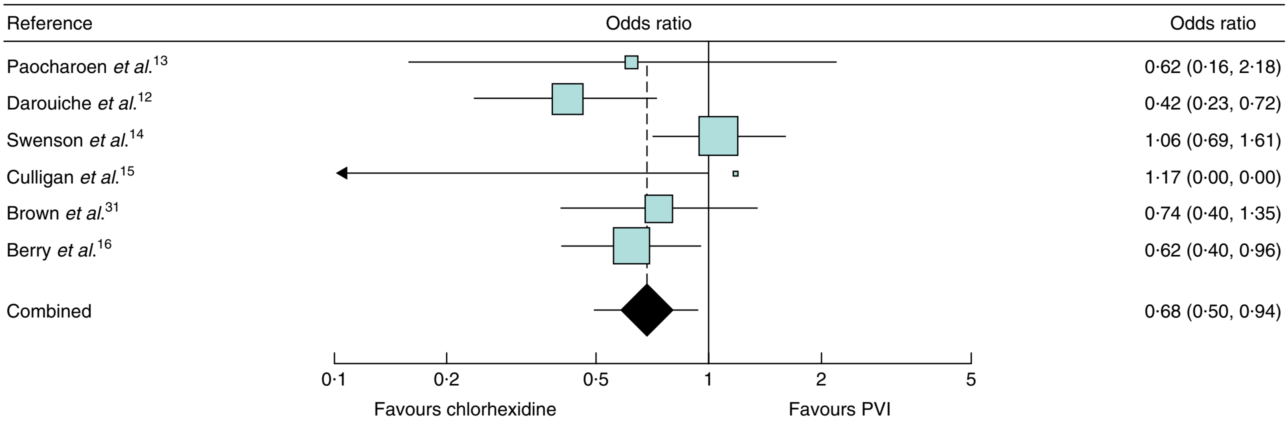

Fig. 2 Forest plot comparing the incidence of surgical-site infection following skin preparation with chlorhexidine *versus* povidone–iodine (PVI). The meta-analysis was done using a random-effects model. Odds ratios are shown with 95 per cent confidence intervals. The vertical dashed line represents the summary estimate

of 1535 patients treated with chlorhexidine compared with 149 (9·8 per cent) of 1515 who had povidone–iodine. This sensitivity analysis yielded a pooled OR of 0·58 (0·44 to 0·75; $P < 0{\cdot}001$). There was no evidence of heterogeneity (Cochran's Q 2·34, 4 d.f., $P = 0{\cdot}672$) or bias (Egger test 0·14; $P = 0{\cdot}868$).

Intra-abdominal sepsis was reported in three trials[12,14,31]. Overall, intra-abdominal infections occurred in 38 (2·1 per cent) of 1803 chlorhexidine-treated patients *versus* 39 (2·2 per cent) of 1812 who had povidone–iodine. The pooled OR for intra-abdominal infection was 0·98 (0·53 to 1·86; $P = 0{\cdot}971$). There was no evidence of heterogeneity (Cochran's Q 3·05, 2 d.f., $P = 0{\cdot}217$). There were insufficient studies to undertake an Egger test.

Discussion

Extensive efforts have been made to reduce SSI by comparing different prophylactic antibiotic regimens[34–36]. Other factors such as normothermia and supplemental oxygen therapy may also reduce SSI, although the evidence for the latter is conflicting[37–39]. However, the choice of preoperative surgical-site antisepsis remains controversial and surgeons have long debated the choice of skin preparation.

Studies of skin antiseptics have tended to use variable endpoints, rendering results difficult to interpret[17,20]. For example, the clean nature of orthopaedic surgery is such that clinical infection is very rare. Consequently, orthopaedic trials have relied on quantitative and qualitative skin cultures to determine the efficacy of antiseptic solutions[17,20]. These outcomes are difficult to compare and ideally a large trial is required to validate them as reliable surrogate markers of clinical infection. Moreover, findings from trials conducted in clean surgery may not be generalized to patients undergoing clean-contaminated general surgical and gynaecological procedures.

The superiority of chlorhexidine over povidone–iodine has been demonstrated before insertion of central venous catheters[7,24–29]. This is a cleaner, briefer procedure than the operations included in this meta-analysis. Despite this, chlorhexidine conferred a significant reduction in SSI. There are some limitations that need to be considered. One study included in the meta-analysis was not randomized, employing a sequential implemental design[14]. The study authors defended this decision, stating that this design was more likely to produce consistent application in each group, compared with different methods being employed in the same time frame if the patients had been randomized. The apparent benefit of chlorhexidine persisted in the sensitivity analysis performed after exclusion of this study, so it did not bias the meta-analysis. Variation in application methods constituted another source of clinical heterogeneity in the meta-analysis. Darouiche and colleagues[12] and Paocharoen and co-workers[13] employed a scrub followed by a paint technique, whereas Berry *et al.*[16] simply painted the agent on to the skin before operation. However, this is unlikely to have made a difference to the results as recent evidence suggests that painting alone is equivalent to scrubbing followed by painting in reducing postoperative infection[40]. Other trials used more elaborate methods of preoperative skin preparation, employing the use of povidone–iodine soap and chlorhexidine spray[14,31], whereas some did not clearly state the method of application.

The chlorhexidine concentration also varied. Two trials used 0·5 per cent[16,31], two used 2 per cent[12,14] and two used 4 per cent[13,15]. Chlorhexidine was also mixed with isopropyl alcohol in some trials[12–14,31]. *In vitro* studies have suggested that chlorhexidine concentrations as low as 0·01 per cent can eradicate common hospital organisms[41]. Further studies have been conducted *in vivo*, but these have focused more on assessing the safety of varying concentrations of chlorhexidine, as opposed to its efficacy[42]. Hence there is not sufficient evidence to suggest that varying the concentration of chlorhexidine could improve antiseptic efficacy.

Different operative procedures were pooled in the meta-analysis. Orthopaedic and plastic surgery trials were deliberately excluded as they are types of clean surgery and hence different groups of pathogens are involved. In addition, postoperative SSI was often not recorded in these trials. A variety of potential pathogens was encountered in the studies included here, especially when comparing a vaginal hysterectomy with a laparotomy; there might be a theoretical argument for different antiseptic regimens between these groups. Only further trials in each category of surgery will provide further clarification.

Postoperative SSI is a clinical diagnosis and is dependent on the recorder. Darouiche and colleagues[12] and Swenson *et al.*[14] clearly defined SSI according to the criteria developed by the Centers for Disease Control and Prevention (CDC)[43]. The remaining studies used varying definitions[13,15,16,31], making the outcomes more difficult to compare. This introduced further clinical heterogeneity, and systematic bias cannot be ruled out. Only two studies[12,14] used independent assessors to record SSI according to the CDC guidelines[43] and in only one trial[12] were these assessors clearly blinded to the intervention. Further potential bias was introduced in studies where the assessors were not blinded[14], or where surgeons themselves assessed SSI without adhering to independent guidelines[13,15,16,31].

Based on the currently available data, preoperative skin cleansing with chlorhexidine is superior to povidone–iodine in reducing postoperative SSI after clean-contaminated surgery. There was no clear benefit in favour of either agent in preventing intra-abdominal sepsis.

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