

Preoperative bathing or showering with skin antiseptics to prevent surgical site infection (Review)

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ABSTRACT

Background

Surgical site infections (SSIs) are wound infections that occur after invasive (surgical) procedures. Preoperative bathing or showering with an antiseptic skin wash product is a well-accepted procedure for reducing skin bacteria (microflora). It is less clear whether reducing skin microflora leads to a lower incidence of surgical site infection.

Objectives

To review the evidence for preoperative bathing or showering with antiseptics for the prevention of hospital-acquired (nosocomial) surgical site infection.

Search strategy

We searched the Cochrane Wounds Group Specialised Register (December 2005), the Cochrane Central Register of Controlled Trials (The Cochrane Library Issue 4, 2005), MEDLINE (January 1966 to December 2005) and reference lists of articles.

Selection criteria

Randomised controlled trials comparing any antiseptic preparation used for preoperative full-body bathing or showering with non-antiseptic preparations in patients undergoing surgery.

Data collection and analysis

Two authors independently assessed studies for selection, trial quality and extracted data. Study authors were contacted for additional information.

Main results

Six trials involving a total of 10,007 participants were included. Three of the included trials had three comparison groups. The antiseptic used in all trials was 4% chlorhexidine gluconate (Hibiscrub). Three trials involving 7691 participants compared chlorhexidine with a placebo. Bathing with chlorhexidine compared with a placebo did not result in a statistically significant reduction in SSIs; the relative risk of SSI (RR) was 0.91 (95% confidence interval (CI) 0.80 to 1.04). When only trials of high quality were included in this comparison, the RR of SSI was 0.95 (95%CI 0.82 to 1.10). Three trials of 1443 participants compared bar soap with chlorhexidine; when combined there was no difference in the risk of SSIs (RR 1.02, 95% CI 0.57 to 1.84). Two trials of 1092 patients compared bathing with chlorhexidine with no washing. No difference was found in the postoperative SSI rate between patients who washed with chlorhexidine and those who did not wash preoperatively (RR 0.70, 95% CI 0.19 to 2.58).

Authors' conclusions

This review provides evidence of no benefit for preoperative showering or bathing with chlorhexidine over other wash products, to reduce surgical site infection. Efforts to reduce the incidence of nosocomial surgical site infection should focus on interventions where effect has been demonstrated.

PLAIN LANGUAGE SUMMARY

Using chlorhexidine for preoperative bathing or showering is unlikely to prevent surgical site infection.

Surgical site infection is a serious complication of surgery and may be associated with increased length of hospital stay for the patient and higher hospital costs. The use of an antiseptic solution for pre-operative bathing or showering is widely practiced in the belief that it will help to prevent surgical site infection. However, the review found six trials that included over 10,000 patients that did not show any evidence of benefit for the use an antiseptic solution over other wash products.

BACKGROUND

Surgical site infections (SSIs) are wound infections that occur after invasive procedures. SSI is the third most frequently hospital-acquired (nosocomial) infection (Smyth 2000) amongst hospital patients. The Centers for Disease Control and Prevention (CDC) have used the National Nosocomial Infections Surveillance system (NNIS) to monitor nosocomial infections in acute care hospitals in the United States since 1970. Between 1986 and 1996 the CDC studied approximately 600,000 operations. Surgical site infections developed after three per cent (15,523) of these operations. During the period of data collection, 551 patients (out of the 15,523 who developed an surgical site infection) died, and 77% of deaths were attributed to the infection (Mangram 1999). Apart from the morbidity and mortality associated with surgical site infections, there are significant cost implications. A recent study, using the NNIS system found that it cost over \$3000 more to treat a patient with an SSI than a non-infected patient. These costs were attributable to a greater likelihood of admission to an intensive care unit, a longer than usual post-operative stay (five days) and an increased rate of hospital re-admission (Kirkland 1999). Potential litigation is also a concern (Rubinstein 1999). Consequently, prevention of surgical site infection has become a priority for health care facilities.

An SSI is defined as one occurring within 30 days after the operation and involves either a purulent discharge, with or without laboratory confirmation, an organism isolated from an aseptically obtained culture or signs and symptoms of infection, such as localised swelling, redness, tenderness (Mangram 1999). The CDC has developed a set of standardised criteria for defining SSI in an attempt to make surveillance and rate calculation more accurate and amenable to comparison (Mangram 1999). SSIs are classified as being: superficial incisional (involving only skin or subcutaneous tissues); deep incisional (involving deeper soft tissue and fascia); or organ/space (involving any other part of the anatomy that was opened or manipulated). To help predict the likelihood or SSI risk, surgical sites can be assessed preoperatively and classified into one of four categories with clear definitions: Class I (clean), Class II (clean-contaminated), Class III (contaminated) and Class IV (dirty/infected) (Mangram 1999). Clean wounds are defined as uninfected surgical wounds in which the respiratory, alimentary, genital or uninfected urinary tract are not present and

in which no inflammation is encountered. Non-clean wounds are defined according to the anatomical area of operation, aetiology of wound, presence of existing clinical infection, and intra-operative contamination. Since clean wounds are less likely to become infected, SSIs following clean surgery are usually associated with either (1) patient risk factors: such as age, nutritional status, diabetes and obesity; (2) risk factors related to the procedure: including incomplete preoperative hand and forearm antisepsis by one of the surgical team, length of surgical procedure and surgical technique; or (3) risk factors associated with preoperative preparation of the patient: for example, antimicrobial prophylaxis, preoperative hair removal and preoperative antiseptic showering (Mangram 1999).

Skin is not sterile. Indeed, thousands of bacteria live on skin permanently and contribute to health by maintaining a steady colony that inhibits establishment of harmful yeast and fungal infections. These bacterial populations are referred to as the 'resident flora'. A number of bacteria are present on the skin for a short period due to transfer from other people or the environment, and these constitute the 'transient flora'. At present, whole body bathing or showering with skin antiseptic in order to prevent SSIs is a widespread practice before surgery. The aim of washing is to make the skin as clean as possible by removing transient flora and some resident flora. Chlorhexidine 4% in detergent ('Hibiscrub' or 'Hibiclens') or a triclosan preparation is usually used for this purpose, and there is evidence that the numbers of bacteria on the skin are reduced when it is applied (Byrne 1991; Kaiser 1988). Moreover, use of a skin antiseptic on consecutive days not only reduces microbial counts from baseline measurements, but also reduces the counts progressively over time (Paulson 1993). Although this body of evidence demonstrates the effectiveness of antiseptics as skin cleansing agents, the more important question is whether preoperative bathing or showering with an antiseptic reduces the incidence of SSI. In a 10-year prospective surveillance study, the SSI rate was lower amongst patients showering with hexachlorophene before surgery than in those who either did not shower or showered using a non-medicated soap (Cruse 1980). In addition, at least two studies have used a before and after design to test the effect of introducing preoperative showering with triclosan to control methicillin-resistant *Staphylococcus aureus* (MRSA) SSIs. In the first of these, showering before and after surgery was introduced to reduce the MRSA SSI rate. However, this intervention was only one of a battery of measures introduced, so it was not possible to de-

termine the independent effect of preoperative showering (Brady 1990). In the second, the incidence of MRSA SSI was reduced amongst orthopaedic patients after presurgical showering with triclosan was introduced, however, the patients were also treated with nasal mupirocin for five days before surgery (Wilcox 2003). While these observational studies provide some support for the practice of preoperative showering with an antiseptic, the evidence is not definitive.

Patterns of resistance have developed with some antiseptics (Thomas 2000), leading to calls to restrict their use to situations where effectiveness can be demonstrated. In addition, hypersensitivity to chlorhexidine is not uncommon. Consequently, the potential benefit of bathing/showering with antiseptics needs to be assessed alongside the potential for harm (Beaudounin 2004; Krauthem 2004). As it is unclear whether the use of antiseptics for preoperative bathing or showering leads to lower rates of SSIs, a systematic review is justified to guide practice in this area.

OBJECTIVES

To review the evidence for preoperative bathing or showering with antiseptics for the prevention of surgical site infection.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All published and unpublished randomised controlled trials that allocate surgical patients individually or by cluster, comparing any antiseptic preparation used for preoperative full body or showering, with non-antiseptic preparations. Quasi-randomised trials were not included (e.g. trials that allocate treatment by day of the week, medical record number, sequential admitting order).

Types of participants

Men, women and children undergoing any type of surgery in any setting.

Types of intervention

Any type of antiseptic solution (any strength, any regimen at any time before surgery) used for preoperative tub or bed bathing or showering compared with:

- (1) non-antiseptic soap;
- (2) non-antiseptic soap solution;
- (3) no shower or bath.

Antiseptic solutions were defined as liquid soap products containing an antimicrobial ingredient such as chlorhexidine, triclosan, hexachlorophene, povidone-iodine or benzalkonium chloride. Trials comparing different types of antiseptic with each other would

also be compared if evidence for the benefit of showering was either equivocal, or if there was evidence of benefit with showering with antiseptic.

Types of outcome measures

Trials were considered if they reported the primary outcome:

Primary outcome

Surgical site infection. (Note: Despite development of standardised criteria for defining SSI, the diagnosis of SSIs continues to vary between studies. We therefore accepted the definition used by the original authors to determine the proportion of patients who develop any SSI before or after discharge).

Secondary outcomes

- (1) Mortality (any cause).
- (2) Allergic reactions (e.g. contact dermatitis, anaphylaxis).
- (3) Postoperative antibiotic use.
- (4) Length of hospital stay.
- (5) Re-admission to hospital.
- (6) Cost.
- (7) Other serious infection or infectious complication, such as septicæmia or septic shock.
- (8) Postoperative fever higher than 38°C on at least two occasions more than four hours apart, excluding the day of surgery.

Secondary outcomes were only extracted if the primary outcome was reported.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Wounds Group methods used in reviews.

We searched the Cochrane Wounds Group Specialised Register (December 2005).

The Cochrane Wounds Group Specialised Register is maintained by searching:

- (1) MEDLINE, CINAHL and EMBASE;
- (2) the Cochrane Central Register of Controlled Trials (CENTRAL);
- (3) hand searching of wound care journals and relevant conference proceedings.

There was no restriction by language or date of publication. Reference lists of all retrieved articles were searched for additional studies. Manufacturers of antiseptic products were contacted in order to obtain any unpublished data.

In addition, we searched MEDLINE (2002 to present) to allow for any lag-time in the Wounds Group Specialised Register.

The following strategy was used to search CENTRAL (Issue 4 2005):

1. DETERGENTS explode all trees (MeSH)
2. POVIDONE-IODINE explode all trees (MeSH)

3. CHLORHEXIDINE explode all trees (MeSH)
4. DISINFECTION explode all trees (MeSH)
5. ALCOHOL DETERGENTS explode all trees (MeSH)
6. detergent*
7. Betadine
8. chlorhexidine
9. (povidone and iodine)
10. (alcohol or alcohols or soap)
11. ANTI-INFECTIVE AGENTS LOCAL single term (MeSH)
12. antiseptic*
13. iodophor*
14. (#1 or #2 or #3 or #4 or #5 or #6 or #7)
15. (#8 or #9 or #10 or #11 or #12 or #13)
16. (#14 or #15)
17. SURGICAL WOUND INFECTION explode all trees (MeSH)
18. PREOPERATIVE CARE explode all trees (MeSH)
19. PERIOPERATIVE CARE explode all trees (MeSH)
20. (preoperative near care)
21. (perioperative near care)
22. (wound* near infect*)
23. (surg* near infect*)
24. (surg* near wound*)
25. (#17 or #18 or #19 or #20 or #21 or #22 or #23 or #24)
26. shower*
27. bath*
28. wash*
29. clean*
30. (#26 or #27 or #28 or #29)
31. (#16 and #25 and #30)

METHODS OF THE REVIEW

Selection of studies

Both authors independently assessed the titles and abstracts of references identified by the search strategy. Full reports of all potentially relevant trials were then retrieved for assessment of eligibility based on the inclusion criteria. Reference lists of retrieved studies were screened to identify further studies, which were also retrieved. Differences of opinion were settled by consensus or referral to the editorial base of the Wounds Group.

Methodological quality assessment

The two authors assessed the quality of eligible trials independently. A pre-defined quality assessment form, based on the assessment criteria listed below, was used. Once again, disagreements between authors were resolved by consensus or referral to the editorial base of the Wounds Group. When possible, contact was made with investigators of included trials to resolve any ambiguities.

Trials that met the eligibility criteria were coded as follows for:

Generation of random allocation sequence

A = Adequate (if the method used was described and the resulting sequences were unpredictable);
 B = Unclear (if the method was not described);
 C = Inadequate (for sequences such as alternative allocation).

Allocation concealment

A = Adequate (if participants and the investigators enrolling participants could not foresee assignment);
 B = Unclear (method not described);
 C = Inadequate (if investigators enrolling participants could foresee next assignment).

Blinding of intervention

A = Double blind (neither the participant nor the person providing the intervention knew which treatment was given);
 B = Single blind (the participant or person providing the intervention knew which treatment was given);
 C = No blinding (all parties were aware of treatment);
 D = Unclear (method not described).

Blinding of outcome assessment

A = Outcome assessment was blinded (person performing assessment did not know which treatment had been given);
 B = Cannot tell whether outcome assessment was blinded;
 C = Outcome assessment was not blinded (person performing assessment was aware of treatment given).

Intention to treat analysis (analysed according to allocated treatment group, irrespective of adherence to treatment)

A = Yes, intention to treat analysis performed;
 B = Cannot tell;
 C = No, intention to treat analysis not performed.

Completeness of primary outcome reporting

A = Adequate (more than 90% of all participants randomised were included in the analysis);
 B = Unclear (not clear how many participants were originally randomised);
 C = Inadequate (less than 90% of those randomised were included in the analysis).

High quality trials were defined as those receiving an A rating for the criterion of allocation concealment (central computerised randomisation service or sealed opaque envelopes) and for blinding of the intervention (from the person providing the intervention and from trial participants).

Data extraction

The following data were extracted from each study by both authors independently using a piloted data extraction sheet: type of study, study setting, number of participants, sex, mean age, predisposing risk factors, type of antiseptic solutions, use of prophylactic antibiotics, procedure and timing for full body wash, period of community follow-up, all primary and secondary outcome descriptions and outcome measures reported, including infection rates and authors' conclusions.

Data synthesis

Analyses were performed using the RevMan 4.2 software. Relative risks and 95% confidence intervals (CI) were calculated for dichotomous outcomes, and mean differences and 95% CI calculated for continuous outcomes. Results of comparable trials were pooled using the fixed-effect model and 95% CI. Heterogeneity was investigated by calculating the I^2 statistic (Higgins 2002). If evidence of significant heterogeneity was identified (a value greater than 50%), potential sources of heterogeneity were explored and a random-effects approach to the analysis undertaken. A narrative review of eligible studies was conducted where statistical synthesis of data from more than one study was not possible or considered inappropriate.

One trial (Rotter 1988) used a multi-centre design but patients were allocated individually to the treatment or control arm. Two trials (Hayek 1987; Wihlborg 1987) allocated clusters of patients to each intervention. In this review results were not analysed using the number of clusters as the unit of analysis but analysed as if the allocation was by individual. This was necessary because the authors of the trial did not use the cluster as the unit of analysis. Analysing cluster trials in this way has the potential to over-estimate the effect of treatment (Mollison 2000).

We included all eligible trials in the initial analysis and carried out sensitivity analyses to evaluate the effect of trial quality. This was done by excluding those trials most susceptible to bias based on the following quality assessment criteria: those with inadequate allocation concealment; high levels of post randomisation losses or exclusions; or unblinded outcome assessment; or where blinding of outcome assessment was uncertain.

Sub-group analyses were:

- (1) One preoperative bath or shower compared with more than one preoperative bath or shower.
- (2) Cluster-randomised trials compared with individually randomised controlled trials; this post hoc analysis was included because cluster randomised trials were found.

One of the planned sub-group analysis (clean surgery compared with clean contaminated surgery) was not conducted because data were not reported in a format that allowed this to be assessed.

DESCRIPTION OF STUDIES

For a detailed description of studies see table of 'Characteristics of included studies'.

Our search strategy identified 43 articles. Full-text assessment was conducted of 16 potentially eligible papers. Ten of these papers were excluded from further review because the studies were not randomised, or were randomised trials evaluating other interventions (e.g. preoperative scrub solutions), or other outcomes (e.g. intraoperative wound colonisation). The six remaining trials reported outcomes for 10,007 participants and were included in the

review (Byrne 1992; Earnshaw 1989; Hayek 1987; Randall 1983; Rotter 1988; Wihlborg 1987). The results of these six trials were reported in nine publications (Byrne 1992; Byrne 1994; Earnshaw 1989; Hayek 1987; Hayek 1988; Lynch 1992; Randall 1983; Rotter 1988; Wihlborg 1987). Four authors of included trials (Byrne 1992; Earnshaw 1989; Randall 1983; Wihlborg 1987) and one non-included trial author (Garibaldi 1988) responded to queries about study methods and/or requests for additional unpublished information.

Participants

The age range of the participants in the six included studies was nine to 90 years old. The trials enrolled men, women and children booked for elective surgery.

Byrne 1992 included clean and potentially infected cases but all other studies were of clean surgery. Two studies included general surgical patients (Byrne 1992; Hayek 1987); one involved participants undergoing general, orthopaedic and vascular surgery (Rotter 1988); and one included biliary tract, inguinal hernia or breast surgery (Wihlborg 1987). The remaining studies involved only one type of surgery (Earnshaw 1989 (vascular reconstruction); Randall 1983 (vasectomy)). Participants in the vasectomy study (Randall 1983) were day patients.

Four of the centres in which the studies were conducted were in the United Kingdom (Byrne 1992; Earnshaw 1989; Hayek 1987; Randall 1983); one was in Sweden (Wihlborg 1987) and one (Rotter 1988) included a number of European centres (eight from Denmark, five from the United Kingdom, four from Sweden, two from Austria, and one from both Germany and Italy).

All of the studies included the presence of pus in their definition of infection. Earnshaw 1989 and Hayek 1987 also included patients with severe cellulitis (although there was only such patient) and Randall 1983 included patients with a discharge of serous fluid in his definition of infection.

Interventions

There were inconsistencies in both the interventions and the control procedures between studies. One trial compared a regimen that included three preoperative washes (Byrne 1992), three trials included a two-wash regimen (Earnshaw 1989; Hayek 1987; Rotter 1988), and participants in two trials had only one wash preoperatively (Randall 1983; Wihlborg 1987).

The breakdown of the studies according to timing of bathing were as follows:

- One wash on admission, a second on the night before surgery and a third on the morning of surgery (Byrne 1992).
- One wash immediately after admission, and a second on the day of surgery (Hayek 1987).
- One wash on the day before surgery, and a second on the day of surgery (Rotter 1988).

- Two washes preoperatively, timing not specified (Earnshaw 1989).
- One wash on the day before surgery only (Wihlborg 1987).
- One wash not more than one hour before surgery (Randall 1983).

Three of the studies had two arms (Byrne 1992; Earnshaw 1989; Rotter 1988), whilst three had three arms (Hayek 1987; Randall 1983; Wihlborg 1987). The breakdown of studies according to bathing products is as follows:

- 4% Chlorhexidine gluconate (Hibiscrub) detergent solution compared with a matching placebo (i.e. the same detergent without chlorhexidine) (Byrne 1992; Hayek 1987; Rotter 1988).
- Hibiscrub compared with bar soap (Earnshaw 1989; Hayek 1987; Randall 1983).
- Chlorhexidine with no shower or bath (Randall 1983; Wihlborg 1987).
- Chlorhexidine full body bathing compared with localised washing, i.e. restricted to the part of the body to be subjected to surgery (chlorhexidine used in both arms of trial) (Wihlborg 1987).

Antibiotic prophylaxis was used routinely in only one study (Earnshaw 1989). In three other studies (Byrne 1992; Rotter 1988; Wihlborg 1987) there was no attempt to alter the treating surgeons' usual routine for administering antibiotic prophylaxis but, in these studies, the reported rate of prophylactic antibiotic use was low (1% - 15%). Two studies (Hayek 1987; Randall 1983) did not mention whether antibiotics were used before surgery.

Outcome measures

Primary outcome

The primary outcome measure for this review, the effectiveness of preoperative washing or showering with an antiseptic in preventing SSI, was reported in all of the studies (Byrne 1992; Earnshaw 1989; Hayek 1987; Randall 1983; Rotter 1988; Wihlborg 1987).

Secondary outcomes

The secondary outcomes of the review were reported as follow:

- (1) Mortality (any cause) was reported in two studies (Byrne 1992; Earnshaw 1989).
- (2) Allergic reactions (e.g. contact dermatitis, anaphylaxis) were reported in one study (Byrne 1992).
- (3) Post operative antibiotic use was not reported in any of the studies.
- (4) Length of hospital stay was not reported in any of the studies.
- (5) Re-admission to hospital was not reported in any of the studies.
- (6) Cost was reported in one study (Byrne 1992).
- (7) Other serious infection or infectious complication, such as septicaemia or septic shock was not reported in any of the studies.

(8) Postoperative fever exceeding 38°C on at least two occasions more than four hours apart, excluding the day of surgery, was not reported in any of the studies

METHODOLOGICAL QUALITY

Two of the six included studies (Byrne 1994; Rotter 1988) were assessed as being of high methodological quality using the assessment criteria described above.

Generation of random allocation sequence

All studies mentioned a process of randomisation. The method of generating the random allocation sequence was adequate in some studies (Byrne 1992; Randall 1983; Rotter 1988; Wihlborg 1987) and unclear in others (Earnshaw 1989; Hayek 1987). In three of the studies, the random sequence was computer generated (Byrne 1992; Randall 1983; Rotter 1988). One study used block randomisation in groups of six using computer generated random numbers (Byrne 1992). A large multi-centre study used cluster randomisation whereby randomisation was carried out for each surgical unit in the study by means of computer generated numbers (Rotter 1988). Personal correspondence with authors of two of the studies confirmed that they used either computer generated random numbers (Randall 1983) or a randomisation list (Wihlborg 1987).

Allocation concealment

As with generation of the allocation sequence, concealment of allocation was adequate in some studies (Byrne 1992; Randall 1983; Rotter 1988; Wihlborg 1987) and unclear in others (Earnshaw 1989; Hayek 1987).

Blinding of intervention

Blinding of intervention in two studies was by a double blind method (Byrne 1992; Rotter 1988). In one study there was single blinding of the intervention in two arms of the study but no blinding in the third arm of the study (Hayek 1987). In the remaining studies, there was no blinding of intervention (Earnshaw 1989; Randall 1983; Wihlborg 1987).

Blinding of outcome assessment

In four of the studies, there was blinding of outcome assessment (Byrne 1992; Earnshaw 1989; Hayek 1987; Rotter 1988). In one of the studies there was no blinding of the outcome assessment (Wihlborg 1987). In one study it is unclear whether blinding of outcome assessment occurred (Randall 1983).

Sample size calculations

None of the trials reported how the sample size was calculated.

Intention to treat analysis

In one study analysis by intention to treat was not done (Byrne 1992). For all of the other studies it could not be determined whether analysis by intention to treat occurred (Earnshaw 1989; Hayek 1987; Randall 1983; Rotter 1988; Wihlborg 1987).

Completeness of reporting

All of the studies reported the status of all people entered into the trials. One study reported only one of 94 patients lost to follow up (Randall 1983). Byrne 1992 reported a 99.4% completeness of follow up. All other studies reported that all patients were followed up (Earnshaw 1989; Hayek 1987; Rotter 1988; Wihlborg 1987). In one study, 140 patients out of the 2953 enrolled were withdrawn from the study for several reasons: failure to have two preoperative showers, not meeting inclusion criteria, transferring out of unit, or no identification number on patient protocol (Rotter 1988). Despite this, the study reports on all remaining patients (n = 2813), resulting in 95.2% completeness of reporting.

Two authors (Byrne 1992; Hayek 1987) recorded SSIs during hospitalisation and then followed patients for 6 weeks after hospital discharge, Rotter 1988 followed patients for 3 weeks, Randall 1983 for 7 days, Wihlborg monitored SSIs that occurred in hospital and among those returning for an outpatient visit and Earnshaw reviewed patients twice weekly until hospital discharge.

Of the six included studies, two (Byrne 1992; Rotter 1988) were assessed as having high methodological quality using the assessment criteria described above.

RESULTS

This review includes outcomes data from six trials with a total of 10,007 participants. Six comparisons were undertaken: chlorhexidine 4% versus placebo (Analysis: 01), (Byrne 1992; Hayek 1987; Rotter 1988) chlorhexidine 4% versus bar soap (Analysis: 02), (Earnshaw 1989; Hayek 1987; Randall 1983) chlorhexidine versus no bath or shower (Analysis: 03) (Randall 1983; Wihlborg 1987) whole body wash with chlorhexidine versus washing only that part of the body to be submitted to surgery (Analysis: 04) (Wihlborg 1987) more than one wash versus one wash (Analysis: 05) (Byrne 1992; Hayek 1987; Randall 1983; Rotter 1988), and one post hoc comparison, individual allocation versus cluster allocation (Analysis: 06) (Byrne 1992; Earnshaw 1989; Hayek 1987; Randall 1983; Rotter 1988; Wihlborg 1987). A random-effect meta-analysis was used when significant heterogeneity was present (i.e. where the I^2 value was greater than 50%) .

Chlorhexidine versus placebo (Analysis 01)

This comparison includes three trials (Byrne 1992; Hayek 1987; Rotter 1988) of 7691 participants and includes four outcomes (SSI, allergic reactions, mortality and cost).

Surgical site infection (Analysis 01:01)

Participants in each trial had more than one wash. Hayek 1987 and Rotter 1988 included patients having elective surgery whereas Byrne 1992 included patients undergoing "clean or potentially infected surgery". None of the individual trials found that washing with chlorhexidine had a statistically significant effect on SSI. All of the trials were included in the meta-analysis. When compared with

placebo, bathing with chlorhexidine did not result in a statistically significant reduction in the SSI rate (chlorhexidine 9.2%, placebo 10.1%); the relative risk (RR) was 0.91 (95% confidence interval (CI) 0.80 to 1.04).

Surgical site infection - high quality trials (Analysis 01:02)

For this outcome we conducted a separate analysis of trials rated as high quality by the criteria described in the 'Methods of the Review' section (Byrne 1992; Rotter 1988) and obtained a similar result, the RR was 0.95 (95% CI 0.82 to 1.10). The event rate was 9.3% for the chlorhexidine group and for 9.7% for the placebo group.

Allergic reaction (Analysis 01:03)

One study (Byrne 1992) included allergic reaction as an outcome. There were 19 events reported, nine (0.5%) in the chlorhexidine group and 10 (0.6%) in the placebo group; no evidence of a statistically significant difference in allergy rate, the RR was 0.89 (95% CI 0.36 to 2.19).

Mortality (any cause)

One trial in this comparison reported mortality data (Byrne 1992). A total of 23 patients died in the study period but these were not reported in groups.

Cost

There was an estimate of cost in one study (Byrne 1992). The average total cost (based on drug costs, hotel costs, dressing costs and outpatients' costs) of patients washing with chlorhexidine was UK £936 compared with UK £897 when patients washed with a placebo. Standard deviations were not reported but, according to the authors, the difference was not statistically significant.

Chlorhexidine versus bar soap (Analysis 02)

Three trials compared washing with chlorhexidine with washing with bar soap (Earnshaw 1989; Hayek 1987; Randall 1983). These included 1443 participants and reported on two outcomes (SSI and mortality). Due to small numbers in two of the trials (Earnshaw 1989; Randall 1983) and methodological inconsistencies in the Hayek 1987 trial (all patients did not receive the same washing instruction and the bar soap was found to contain antimicrobial properties and was changed during the study) estimates of effect are imprecise and need to be interpreted with caution. Significant heterogeneity was present in this comparison, so we used a random-effects model for the meta-analysis. There are two possible explanations for heterogeneity. First, different types of surgery were conducted in each trial; Earnshaw 1989 included patients undergoing vascular reconstruction, Hayek 1987 included patients booked for routine elective surgery and Randall 1983 included only vasectomy patients. Alternatively, a different definition of SSI was used by Randall 1983, who included patients with a wound which discharged pus or serous fluid, whereas Earnshaw 1989 and Hayek 1987 defined SSI as the discharge of pus.

Surgical site infection (Analysis 02: 01)

Two of the trials that compared washing with chlorhexidine with washing with soap (Earnshaw 1989; Randall 1983) found no difference between the treatments in postoperative SSI rate. However, one trial (Hayek 1987), reported statistically fewer SSIs when patients washed preoperatively with chlorhexidine compared with patients who washed with soap; the RR was 0.70 (95% CI 0.51 to 0.96). When results of the three trials were combined no differences were detected, the RR was 1.02 (95% CI 0.57 to 1.84), an event rate of 10.9% for chlorhexidine and 13.6% for bar soap.

Mortality (any cause)

Two patients died in the Earnshaw 1989 trial but these were not reported by group.

Chlorhexidine versus no wash (Analysis 03)

Two trials compared washing with chlorhexidine with not washing (Randall 1983; Wihlborg 1987). These included 1042 patients and reported on SSI only. There was significant statistical heterogeneity between the two trials (P value < 0.01), and clinical heterogeneity (outpatient surgery versus inpatient surgery; different types of included patients). Randall 1983 enrolled patients undergoing vasectomy, whereas Wihlborg 1987 included patients undergoing elective surgery of the biliary tract, inguinal hernia or breast cancer. In addition, Randall 1983 defined SSI as a wound which discharged pus or serous fluid, whereas Wihlborg 1987 defined SSI as the discharge of pus, so a random-effects model was used for the meta-analysis.

Surgical site infection (Analysis 03: 01)

Randall 1983 found no difference in the postoperative SSI rate between patients who washed with chlorhexidine compared with patients who did not wash preoperatively. In the other trial, Wihlborg 1987 found that chlorhexidine wash when compared with no wash resulted in a reduction in the number of patients with a SSI; the RR was 0.36 (95% CI 0.17 to 0.79). When the results from both trials were combined, they showed no overall benefit of washing with chlorhexidine over not washing, the event rate for chlorhexidine was 3.7% and when patients did not follow a protocol for washing it was 6.2%, the RR was 0.70 (95% CI 0.19 to 2.58). Although patients in the no-wash groups were given no instructions to shower or bathe pre-operatively, it is unclear whether any did so.

Chlorhexidine total body wash versus localised wash (Analysis 04)

One trial compared washing the whole body with chlorhexidine with a localised wash (Wihlborg 1987). This trial included 1093 participants and assessed one outcome; SSI.

Surgical site infection (Analysis 04: 01)

Data from one trial making this comparison (Wihlborg 1987) showed a reduction in SSIs when whole body washing (1.7%) was compared with localised washing (4.1%); the RR was 0.40 (95% CI 0.19 to 0.85).

More than one wash versus one wash (Analysis 05)

The treatment effect for the primary outcome was compared based on number of washes before surgery. A total of 7,683 participants in four of the trials had more than one wash (Byrne 1992; Earnshaw 1989; Hayek 1987; Rotter 1988). In one trial (Randall 1983), 62 patients had one wash.

Surgical site infection (Analysis 05: 01)

For SSI, the effect of chlorhexidine was similar regardless of whether participants had more than one wash (Byrne 1992; Hayek 1987; Rotter 1988), where the RR of SSI was 0.91 (95% CI 0.80 to 1.04) or one wash (Randall 1983), where the RR of SSI was 1.13 (95% CI 0.57 to 2.21). The infection rate in both the chlorhexidine group (37.5%) and the control group (33.0%) was much higher in patients having one wash compared with patients having more than one wash (chlorhexidine 9.3% and control 10.1%). The most likely explanation for the difference was the broader definition of infection that was used in the one wash cohort, the authors included patients with either a pus or serous discharge. The confidence intervals for the no wash group were also wide, and crossed the no-effect line. This means that the true effect could be anything from almost a halving in the risk of SSI associated with having one wash to a more than doubling.

Individual versus cluster randomisation (Analysis 06)

Four trials addressed this comparison involving 6,430 participants where allocation was by individual (Byrne 1992; Earnshaw 1989; Randall 1983; Rotter 1988) and two trials of 2,367 participants where allocation was by cluster (Hayek 1987; Wihlborg 1987). In both of the cluster trials, treatment was randomly allocated by the ward to which patients were admitted.

Surgical site infection (Analysis 06: 01)

Among the trials that allocated patients individually (Byrne 1992; Earnshaw 1989; Randall 1983; Rotter 1988), there was no difference in the SSI rate between participants washing with chlorhexidine compared with participants washing with other products, the RR was 0.97 (95% CI 0.84 to 1.12). In trials that allocated participants by cluster, both authors reported fewer SSIs in wards where chlorhexidine was used pre-operatively, in one of these trials (Wihlborg 1987) the difference was statistically significant, the RR was 0.36 (95% CI 0.17 to 0.79) When results of both of these trials were combined, there was a trend towards fewer infections with chlorhexidine; RR of SSI was 0.90 (95% CI 0.79 to 1.02) though not significant. This difference is probably due to the effect of the cluster design and the way data has been analysed; as if randomisation had been by individual rather than by cluster, which tends to over estimate the treatment effect. Methods for correctly analysing data when reported in this way are described in the Cochrane Handbook (version 4.2.5 p 154-157) but information about the number in each cluster and number of events in each cluster or the intra cluster correlation must be known. This information was not able to be extracted from either study.

DISCUSSION

Widespread use of preoperative antiseptic washing agents to prevent SSI continues. This review summarises trial data from over 10,000 patients, that compared washing with chlorhexidine with either a placebo solution, or a bar soap, or no preoperative washing at all. There was no evidence that washing with chlorhexidine reduced the incidence of SSI. The results of the review are strengthened by the heterogeneous nature of the participants; the trials included men, women and children undergoing a range of surgeries that were either clean or potentially infected, and undertaken in both inpatient and outpatient settings. These studies were published over a nine-year period between 1983 and 1992. Despite the fact that there have been no recent studies published in this area, it is unlikely that further trials would achieve different results. The product used in the trials (chlorhexidine 0.4%) remains unchanged and the quality of the two largest trials (that included over 6,000 participants) was high, concealing the randomisation process and blinding the interventions. Both of these trials also included community follow up.

One of the limitations of the review was the quality of some of the studies. Community follow-up was attempted in only three studies, none of the authors provided justification for their sample sizes and in both studies where a cluster design was used, analysis was conducted as if participants had been allocated individually. However, results from the high quality trials and from trials where participants were allocated individually, no statistical benefit for the use of chlorhexidine for preoperative washing could be demonstrated.

Only one of the trials provided data for other outcomes in which we were interested. Byrne (1992) assessed complications or undesirable effects attributable to the use of an antiseptic. In this trial patients assigned to chlorhexidine use were no more likely to suffer an adverse reaction than those assigned to the placebo group. There were no comparisons with bar soap for this outcome. Byrne (1992) also assessed the cost of washing with chlorhexidine compared with placebo and found a non-significant cost reduction in the placebo group. Costs included length of hospital stay, so, even though the SSI rate was 1.1% higher in the placebo group, using a placebo still resulted in an overall cost benefit.

AUTHORS' CONCLUSIONS

Implications for practice

This review provides evidence that pre-operative showering or bathing with chlorhexidine over other wash products does not reduce SSI rates. Efforts to reduce the incidence of nosocomial SSI should focus on interventions where effect has been demonstrated.

Implications for research

Issues of effectiveness have been adequately addressed. It is unlikely that further trials would result in any clear benefit for chlorhexidine over other non-antiseptic wash products. Comparisons between placebo and other antiseptics could be addressed in future trials. However, based on results from this review, the feasibility of conducting such a large trial may be difficult. All of the included studies involved either clean or potentially infected cases.

POTENTIAL CONFLICT OF INTEREST

None

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- * Indicates the major publication for the study

TABLES

Characteristics of included studies

Study	Byrne 1992
Methods	<p>RCT</p> <p>Generation of random number sequence: adequate</p> <p>Blinding of intervention: double</p> <p>Blinding of outcome: yes</p> <p>Completeness of reporting: yes</p> <p>Power calculation: yes</p> <p>Follow up period: 6 weeks after discharge</p>
Participants	<p>3733 patients undergoing elective or potentially contaminated surgery</p> <p>Exclusion: patients undergoing day surgery, emergency surgery, re-operation or contaminated surgery and those unable to comply with the washing procedure, or with a known allergy to chlorhexidine or having more than the standard prophylactic antibiotic regimen</p> <p>Baseline comparability: age, sex, type of surgery, ASEPSIS score</p>
Interventions	<p>All patients showered 3 times (on admission, the night before surgery and the morning of surgery) using 50mls of either</p> <p>(1) 4% chlorhexidine or</p> <p>(2) a placebo.</p> <p>Written instructions were provided to all participants.</p>
Outcomes	<p>Primary outcome:</p> <p>Wound infection was defined as discharge of pus from a wound for inpatients or outpatients; or an ASEPSIS score greater than 10.</p> <p>(1) 256/1754 (14.6%)</p> <p>(2) 272/1735 (15.7%)</p> <p>Secondary outcomes:</p>

Characteristics of included studies (Continued)

	Death Allergic reactions Cost
Notes	Data were extracted from 3 papers reporting results from the one study (see Lynch 1992 & Byrne 1994). There were minor discrepancies in numbers reported between the 3 studies. The version reported is the definitive study (personal correspondence with author)
Allocation concealment	A – Adequate

Study	Earnshaw 1989
Methods	RCT Generation of random allocation sequence: unclear Blinding of intervention: none Blinding of outcome: yes Completeness of reporting: yes Power calculation: no Follow up period: Until hospital discharge
Participants	66 patients undergoing vascular reconstruction surgery Exclusion: none reported Baseline comparability: Stated that groups were similar, no data
Interventions	All patients had 2 baths. (1) painted entire body with undiluted 4% chlorhexidine followed by rinsing in the bath. Precise instructions given (2) Non-medicated soap used. No specific instructions provided.
Outcomes	Primary outcome: Wound infection was defined as discharge of pus from a wound; one patient with severe cellulitis was also included. (1) 8/31 26% (2) 4/35 11.4% Secondary outcome: Death
Notes	Different washing information provided to participants in each group.
Allocation concealment	B – Unclear

Study	Hayek 1987
Methods	Cluster RCT Generation of random allocation sequence: unclear Blinding of intervention: none Blinding of outcome: yes Completeness of reporting: yes Power calculation: no Follow up period: until hospital discharge
Participants	2015 patients undergoing routine surgery Exclusion: those receiving antibiotics or with an existing infection Baseline comparability: age, sex, preoperative skin preparation, wound classification, proportion who washed their hair
Interventions	All patients had either a shower or bath on the day before and morning of their operation. (1) Chlorhexidine 4%. Instruction card for washing provided (2) Placebo. Instruction card for washing provided

Characteristics of included studies (Continued)

(3) Bar soap. No washing instructions provided. (Five months into the study, the bar soap was found to have antimicrobial properties and was changed)

Outcomes	Primary outcome: Wound infection was defined as discharge of pus from a wound or erythema or swelling considered greater than expected. (1) 62/689 (9.0%) (2) 83/700 (11.7%) (3) 80/626 (12.8%)
Notes	Data were extracted from 2 papers reporting results from the one study (Hayek 1988)
Allocation concealment	B – Unclear

Study **Randall 1983**

Methods	RCT Generation of random allocation sequence: adequate Blinding of intervention: none Blinding of outcome: cannot tell Completeness of reporting: yes Power calculation: no Follow up period: 1 week after discharge
Participants	94 patients undergoing vasectomy Exclusion: none stated Baseline comparability: none stated
Interventions	1) One preoperative shower with Chlorhexidine 4% 2) One shower with normal soap 3) No shower
Outcomes	Primary outcome: Wound infection was defined as discharging either purulent or serous fluid. (1) 12/32 (37.5%) (2) 10/30 (33.3%) (3) 9/32 (28.1%)
Notes	
Allocation concealment	A – Adequate

Study **Rotter 1988**

Methods	Cluster RCT Generation of random number sequence: adequate Blinding of intervention: double Blinding of outcome: yes Completeness of reporting: yes Power calculation: no Follow up period: 3 weeks after discharge
Participants	2953 patients undergoing elective clean surgery Exclusion: patients with fever > or = to 37.5 on the day of or day before surgery, infection remote from operation site, antibiotics given within 7 days prior to surgery for infection, incarcerated inguinal hernia, radical mastectomy Baseline comparability: age, sex, type of surgery, antibiotic prophylaxis, hair washed, hair removal method, wound drainage
Interventions	All patients had two showers. One on the day before and one on the day of surgery 1) Using 50 ml of Chlorhexidine 4% for each shower

	2) Placebo Special application instructions were provided to all participants.
Outcomes	Primary outcome: Wound infection was defined as inflammation of the surgical wound with discharge of pus, spontaneous and/or after surgical intervention that occurs during hospitalisation or during routine follow-up 1) 37/1413 (2.6%) 2) 33/1400 (2.4%)
Notes	
Allocation concealment	B – Unclear

Study	Wihlborg 1987
Methods	RCT Generation of random number sequence: adequate Blinding of intervention: none Blinding of outcome: no Completeness of reporting: yes Power calculation: no Follow up period: until hospital discharge
Participants	1530 patients undergoing elective surgery of the biliary tract, inguinal hernia and breast cancer Exclusion: none stated Baseline comparability: age, duration of surgery > 2 hours, steroids, diabetes, malignancy (other than breast cancer), type of surgery
Interventions	1) Patients washed their entire body with chlorhexidine on the day before surgery using two consecutive application followed by rinsing under the shower 2) Washed only that part of the body to be submitted to surgery 3) No chlorhexidine wash
Outcomes	Primary outcome: Wound infection was defined as a definite collection of pus emptying itself spontaneously or after incision 1) 9/541 (1.7%) 2) 23/552 (4.2%) 3) 20/437 (4.6)
Notes	This study was conducted over a 7 year period between 1978 through 1984. It was unclear from the text whether patients allocated to the 'no chlorhexidine wash' group had any preoperative shower. Three patients died and were not included in the analysis. Strength of wash solution not stated.
Allocation concealment	A – Adequate

Characteristics of excluded studies

Study	Reason for exclusion
Ayliffe 1983	Not a randomised controlled trial
Bergman 1979	No data on wound infection. Not a randomised controlled trial
Brandberg 1980	Not a randomised controlled trial Local wash versus full body wash with chlorhexidine
Garibaldi 1988	No none antiseptic group Did not report infection rates by group

Characteristics of excluded studies (Continued)

Leigh 1983	Not a randomised controlled trial
Newsom 1988	Not a randomised controlled trial. Patients were allocated by month.
Wells 1983	Not a randomised controlled trial Did not report infection rates by group

ANALYSES

Comparison 01. Chlorhexidine 4% versus placebo

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	3	7691	Relative Risk (Fixed) 95% CI	0.91 [0.80, 1.04]
02 Surgical site infection (high quality studies)	2	6302	Relative Risk (Fixed) 95% CI	0.95 [0.82, 1.10]
03 Allergic reaction	1	3489	Relative Risk (Fixed) 95% CI	0.89 [0.36, 2.19]

Comparison 02. Chlorhexidine 4% versus bar soap

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	3	1443	Relative Risk (Random) 95% CI	1.02 [0.57, 1.84]

Comparison 03. Chlorhexidine 4% versus no shower or bath

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	2	1042	Relative Risk (Random) 95% CI	0.70 [0.19, 2.58]

Comparison 04. Chlorhexidine full wash versus partial wash

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	1	1093	Relative Risk (Fixed) 95% CI	0.40 [0.19, 0.85]

Comparison 05. More than one wash versus one wash

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	5	7745	Relative Risk (Fixed) 95% CI	0.92 [0.80, 1.04]

Comparison 06. Individual versus cluster randomisation

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Surgical site infection	6	8797	Relative Risk (Fixed) 95% CI	0.90 [0.79, 1.02]

INDEX TERMS

Medical Subject Headings (MeSH)

Anti-Infective Agents, Local [*administration & dosage]; Baths [*methods]; Chlorhexidine [administration & dosage; *analogs & derivatives]; Disinfection [methods]; Preoperative Care [*methods]; Randomized Controlled Trials; Soaps [administration & dosage]; Surgical Wound Infection [*prevention & control]

MeSH check words

Humans

COVER SHEET

Title	Preoperative bathing or showering with skin antiseptics to prevent surgical site infection
Authors	Webster J, Osborne S
Contribution of author(s)	JW conceived, designed, coordinated the review and conducted the initial literature search. The protocol was jointly written by JW and SO. JW and SO separately reviewed the abstracts and selected papers for review. JW and SO separately reviewed and scored the trials. Both authors contributed to the final version of the review.
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Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	09 December 2005
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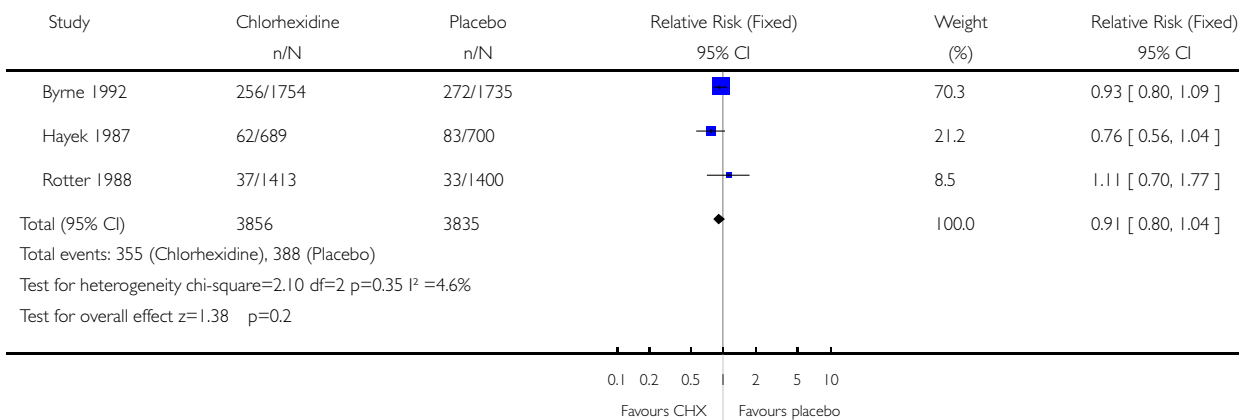
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Chlorhexidine 4% versus placebo, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 01 Chlorhexidine 4% versus placebo

Outcome: 01 Surgical site infection

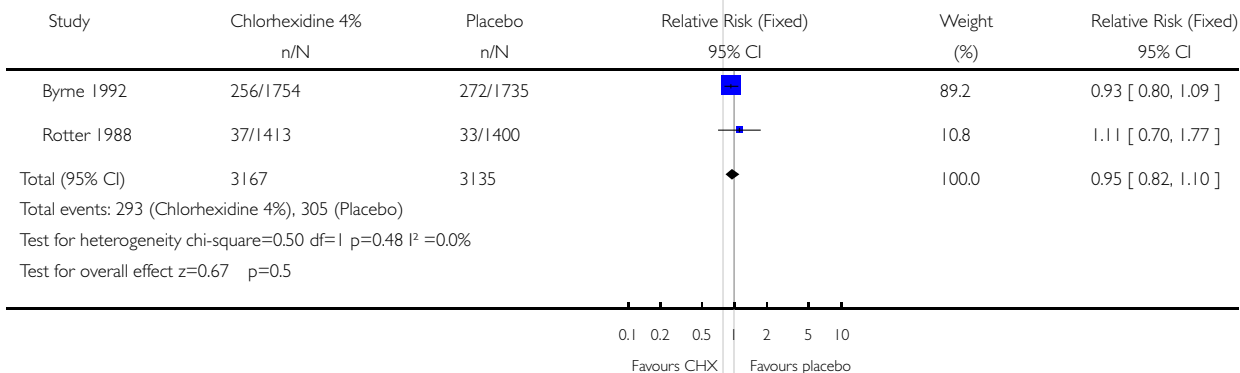


Analysis 01.02. Comparison 01 Chlorhexidine 4% versus placebo, Outcome 02 Surgical site infection (high quality studies)

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 01 Chlorhexidine 4% versus placebo

Outcome: 02 Surgical site infection (high quality studies)

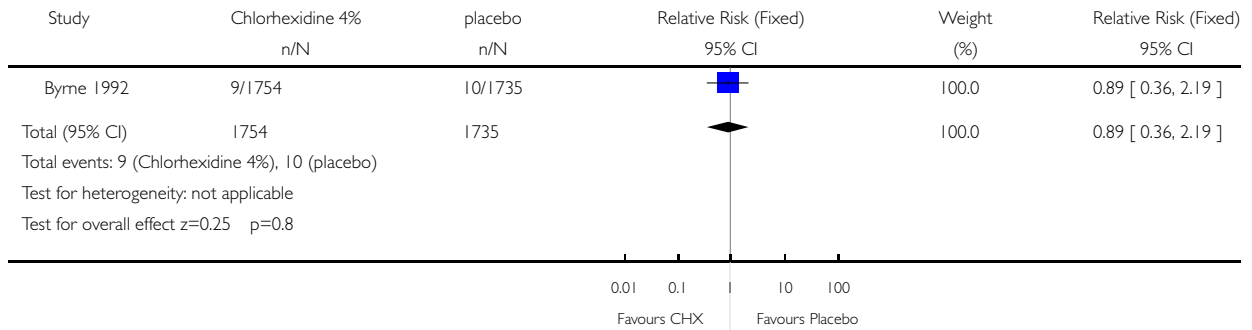


Analysis 01.03. Comparison 01 Chlorhexidine 4% versus placebo, Outcome 03 Allergic reaction

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 01 Chlorhexidine 4% versus placebo

Outcome: 03 Allergic reaction

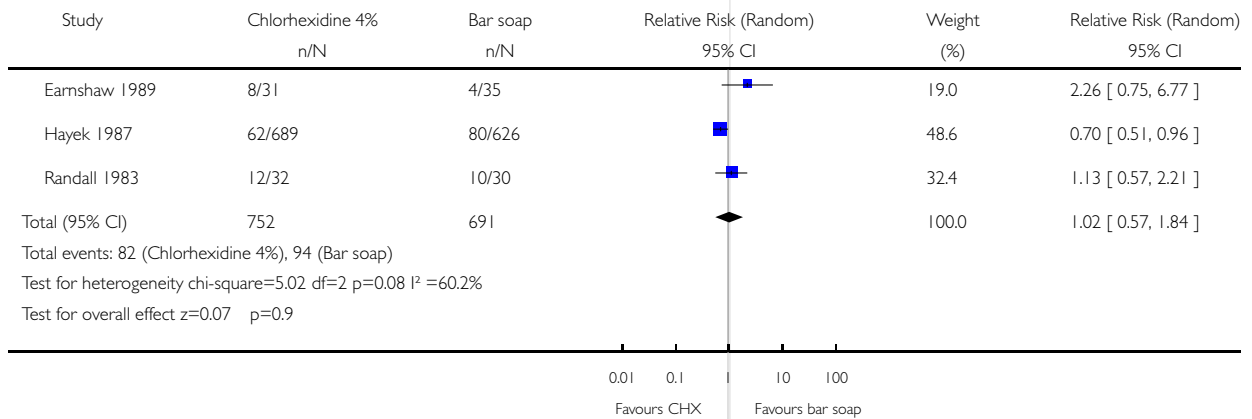


Analysis 02.01. Comparison 02 Chlorhexidine 4% versus bar soap, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 02 Chlorhexidine 4% versus bar soap

Outcome: 01 Surgical site infection

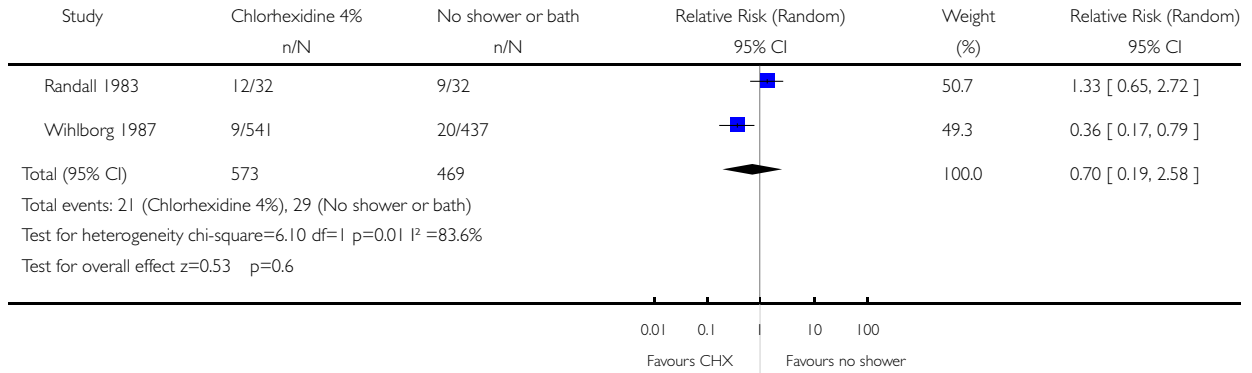


Analysis 03.01. Comparison 03 Chlorhexidine 4% versus no shower or bath, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 03 Chlorhexidine 4% versus no shower or bath

Outcome: 01 Surgical site infection

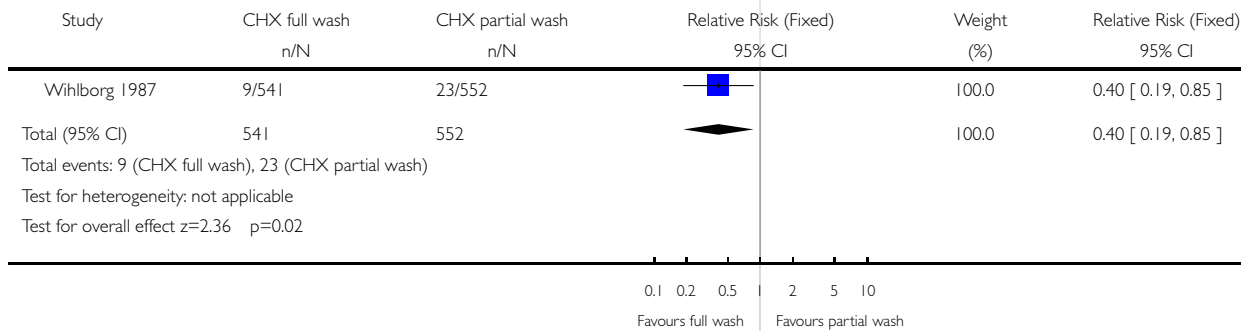


Analysis 04.01. Comparison 04 Chlorhexidine full wash versus partial wash, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 04 Chlorhexidine full wash versus partial wash

Outcome: 01 Surgical site infection

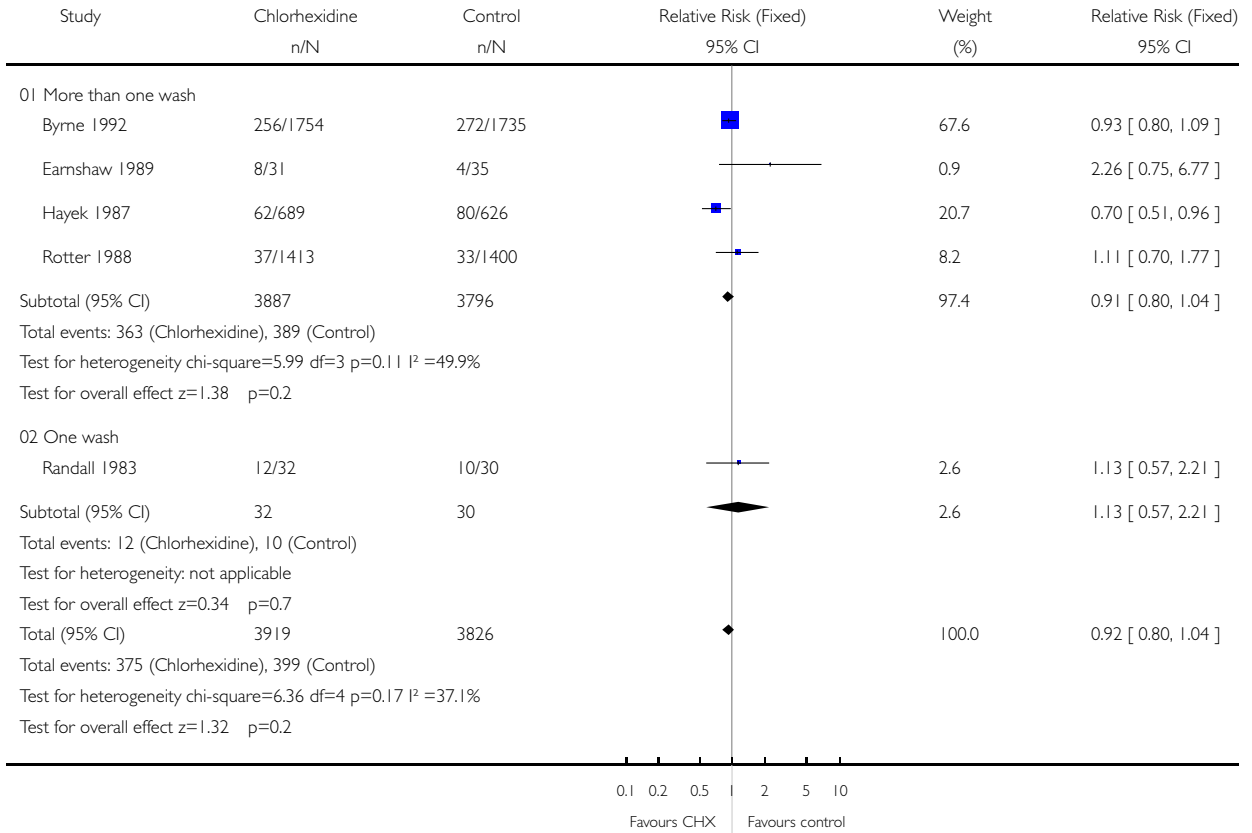


Analysis 05.01. Comparison 05 More than one wash versus one wash, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 05 More than one wash versus one wash

Outcome: 01 Surgical site infection



Analysis 06.01. Comparison 06 Individual versus cluster randomisation, Outcome 01 Surgical site infection

Review: Preoperative bathing or showering with skin antiseptics to prevent surgical site infection

Comparison: 06 Individual versus cluster randomisation

Outcome: 01 Surgical site infection

