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# Pin site care for preventing infections associated with external bone fixators and pins

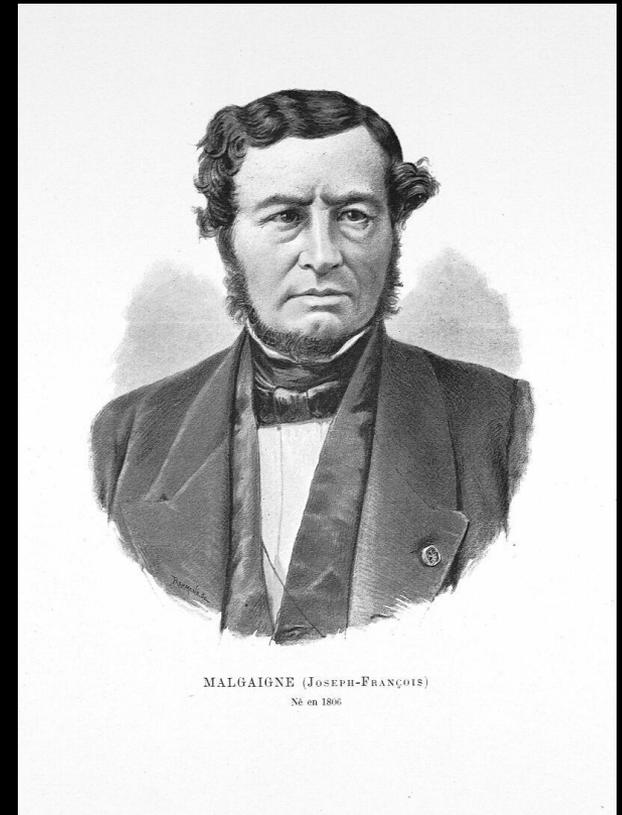
Anne Lethaby, Jenny Temple, Julie Santy

Presented by Fellow 李偉群



# Background

- External fixation proposed by *Malgaigne, 1853*
  - Early mobilisation
  - Axial loading of the fracture
  - Easy observation of the limb
  - Access to the skin for wound care
- **Pin sites infection** (1% for major infections to 80% for minor infections) (*Green 1983*)
  - Failure of fixation
  - Osteomyelitis and systemic infection



# Pin sites infection

- **Reaction**
    - Normal changes subside after 72 hours
  - **Colonisation**
    - Pain + microbes on culture
  - **Infection**
    - Pus, pin loosening and increased microbial growth
    - Minor: benign, easily treatable with antibiotics (*Ward 1998*)
    - Major: require removal of the pins before the infection controlled (*Lee-Smith 2001*)
- **Effective insertion techniques** + subsequent nursing care  
(*Green 1984; Kroll 1973; Sisk 1983*)

# Effective pin site care?

- Many different **regimens**
  - Hydrogen peroxide (*Jones-Walton 1991*)
  - 0.9% normal saline or cooled boiled water (*Sims 1996*)
  - Kurgan Ilizarov Institute: 70% alcohol and 0.2% chlorhexidine
- Optimal **frequency** of pin site care (no consensus)
  - Daily (*Tolo 1983*)
  - Weekly (*Ahlborg 1999*)
  - Fortnightly (*Grant 1992*)
- **Massage** to promote drainage of exudate?  
(*Gordon 2000; McKenzie 1999; Sims 1996*)
- Which care regimen is the most effective?  
→ **systematic review of the evidence**

# Objectives

- To assess the evidence for the effects of cleansing, massage and dressing techniques for pin sites on postoperative infection

# Methods : studies for review

- **Types of studies**
  - RCTs which compare different methods of managing pin sites
- **Types of participants**
  - Adults and children with pins inserted for either external fixators or skeletal traction (Any age and any care setting)
  - Exclude treatment regimens for established infections
- **Types of interventions**
  - A. Cleansing solutions
  - B. Methods of cleansing
  - C. Primary dressing
  - D. Massage

# Methods: outcome measure

- **Primary outcomes:** Incidence of **infection** (as classified by *Sims 1996*)
  - Grade 1: responds to local treatment, increased cleaning and massage
  - Grade 2: responds to oral antibiotics
  - Grade 3: responds to intravenous antibiotics
  - Grade 4: responds to removal of pin
  - Grade 5: removal of pin and surgery required to control infection
  - Grade 6: chronic osteomyelitis (unresponsive to treatment)

# Methods: search & assessment

- **Electronic searches**
  - Cochrane Wounds Group Specialised Register
  - Cochrane Central Register of Controlled Trials
  - Ovid MEDLINE
  - Ovid EMBASE
  - EBSCO CINAHL
- **Assessment of risk of bias:** tool developed by the Cochrane Collaboration (*Higgins 2011*)
  - 1. Sequence generation
  - 2. Allocation concealment
  - 3. Blinding of participants, personnel and outcome assessors
  - 4. Incomplete outcome data
  - 5. Selective outcome reporting
  - 6. Other sources of bias

# Methods: assessment of heterogeneity

- Heterogeneity:  $I^2$  quantity (*Higgins 2003*)
  - 25% or less: low heterogeneity
  - 50% : moderate heterogeneity
  - 75% or more: high heterogeneity
- No clinical or statistical heterogeneity → fixed-effect model
- Heterogeneity & meta-analysis is appropriate → random-effects model

# Methods: data synthesis

- Meta-analysis appropriate:
  - Dichotomous outcomes : relative risk (RR) with 95% CIs
  - Continuous data: converted to the weighted mean difference (WMD) or standardised mean difference (SMD) and overall effect sizes with 95% CIs
- Meta-analysis was not appropriate
  - reported in narrative format

# Results

- Included: **8 RCTs, 448 participants**
- Meta-analysis only for the comparison of cleansing regimens with no cleansing regimens
- Significant heterogeneity
  - **Types of participants** (type and location of surgery and protocol for pin placement)
  - **Types of regimens** used for pin site care
  - **Outcomes** (different methods for classifying infection)

# Results: table of included study

Study ID	N	Participants	Interventions	Infection rate	Definition of infection	Duration	Antibiotic prophylaxis
Camilo 2005 Brazil	30	Ilizarov external fixators; no infection.	(1) Daily: shower, cleanse with saline, gauze dressing soaked with polyvinylpyrrolidone-iodine; (2) Daily: shower, cleanse with saline; dry dressing	(1) 66.7%; (2) 46.7%; NS	Defined as purulent secretion.	Follow-up for time external fixator in place, mean = 273 days (95-726 days)	Not reported.
Egol 2006 USA	118	Adults; displaced, unstable, distal radial fracture	(1) Daily: cleansing with 1/2 saline/ 1/2 hydrogen peroxide; (2) Biopatch dressing changed weekly; (3) No pin site care; dry dressing changed weekly.	(1) 22.5%; (2) 5%; (3) 2.5%.	Defined as requiring antibiotics.	Follow-up for mean of 5.9 weeks (4-8 weeks). External fixator removed at 6 weeks and patients followed-up for 6 months.	Standard prophylaxis given to all patients: before and immediately after surgery.

# Results: table of included study

<p>Grant 2005</p> <p>Australia</p>	<p>20</p>	<p>18+ years</p>	<p>(1) Daily: saline cleansing, soft white paraffin ointment; (2) Twice daily: saline cleansing, 10% povidone-iodine.</p>	<p>(1) 34.1%; (2) 18.1% (pin sites, not participants).</p>	<p>Defined as redness, induration, haemorrhous ooze and pain.</p>	<p>Follow-up until clinical infection or removal of pin.</p>	<p>Intraoperative or postoperative period: 83%.</p>
<p>Henry 1996</p> <p>UK</p>	<p>30</p>	<p>Aged 11-18 years</p>	<p>(1) Daily: cleansing with 0.9% sodium chloride; (2) Daily: cleansing with 70% alcohol; (3) Daily: no cleansing. All groups had pin site care consisting of sterile gauze covering, ease of crusting; massage, dry povidone-iodine spray.</p>	<p>(1) 25%; (2) 17.5%; (3) 7.5%. NS</p>	<p>Defined as pain, redness and swelling and when a significant number of pathogenic bacteria cultured.</p>	<p>Pin in place for mean of 150 days (56-244 days)</p>	<p>Not reported.</p>

# Results: table of included study

<p>Patterson 2005</p> <p>USA</p>	<p>101</p>	<p>All ages (3-80 years); 65% male; no inclusion criteria reported.</p>	<p>(1) Twice daily: 1/2 strength peroxide, rinse with saline, apply stable gauze/sponge;          (2) Same cleansing; apply Xeroform/Xeroflo dressing;          (3) Twice daily; saline cleansing, apply stable gauze/sponge;          (4) Same cleansing; apply Xeroform/Xeroflo dressing;          (5) Twice daily: antibacterial soap and water cleansing, apply stable gauze/sponge;          (6) Same cleansing; apply Xeroform/Xeroflo;          (7) No cleansing, apply gauze/sponge (change only if wet/soiled).</p>	<p>(1) 46%;          (2) 9%;          (3) 33%;          (4) 27%;          (5) 39%;          (6) 50%;          (7) 36%. NS</p>	<p>Rating scale that measured redness, swelling, discomfort, tenting, loosening of pins, crusting and drainage. Stage II infection defined as score &gt;3 and requiring treatment with antibiotics; stage III infection defined as score &gt; 7, treatment with IV antibiotics and/or removal of pin.</p>	<p>6-week follow-up.</p>	<p>Not reported.</p>
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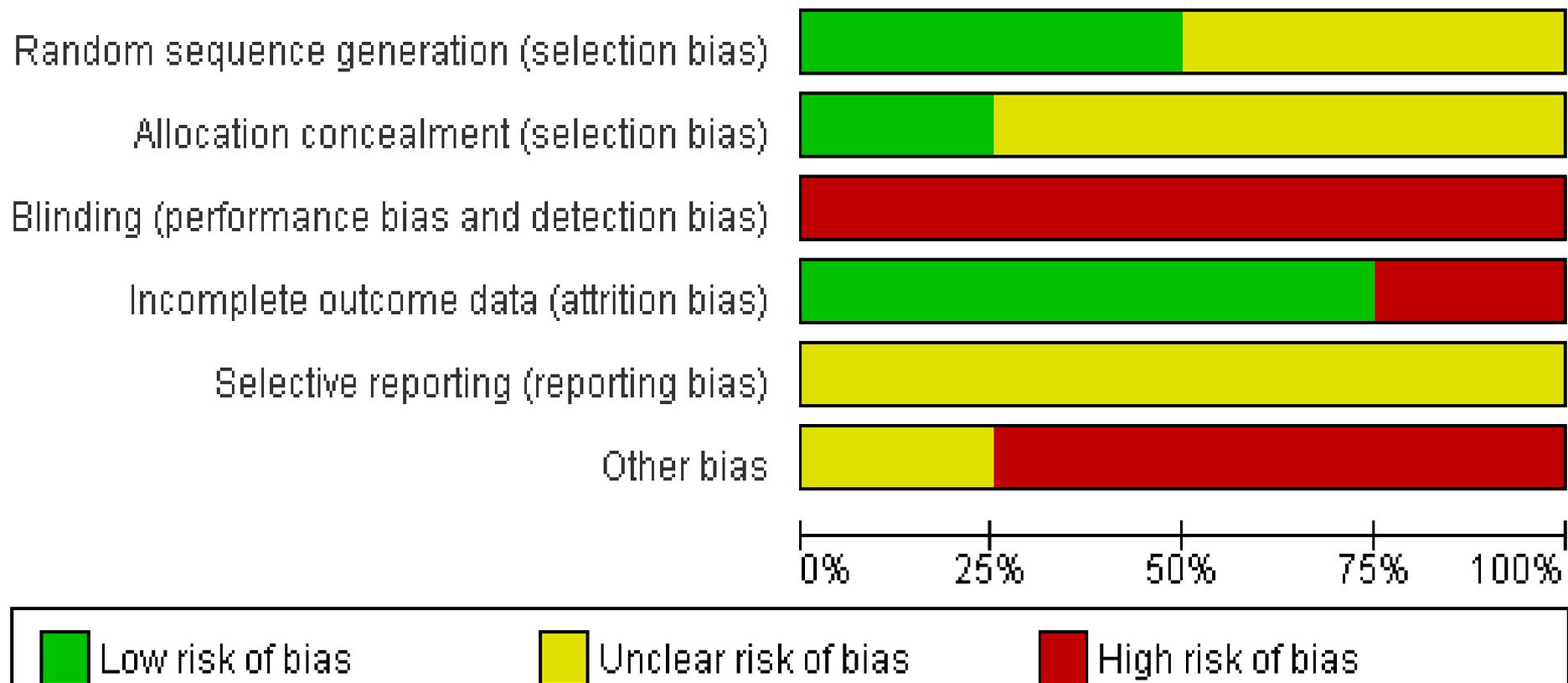
# Results: table of included study

W-Dahl 2003 Sweden	50	Surgery for gonarthrosis by hemicallotaxis technique; mean age 54 years; inclusion criteria not reported.	(1) Daily: pin site care: cleansing with 0.9% sodium chloride, sterile compress fixed with soft dressing; (2) Weekly; same pin site care protocol. District nurse	Grade I: (1) 7.4%; (2) 12%. Grade II: (1) 2.8%; (2) 0%. NS	Checketts-Otterburns classification of pin site infections.	10-week follow-up	Prophylaxis with IV antibiotics during surgery and 2 doses within 24 hours post operatively followed by 14 days of oral prophylaxis.
Chan 2009 Malaysia	62	Distraction osteogenesis using Ilizarov fixators; age ranged from 1-76 years; 37% < 14 years; no inclusion criteria reported.	(1) Daily povidone-iodine cleansing solution; (2) Saline cleansing solution.	Any grade of Infection: (1) 19%; (2) 17%.	Three point grading of infections by system developed in Department of Orthopaedic Surgery in University of Malaya Medical	Every 2 weeks for 6 months.	Antibiotics only prescribed for patients with grade 2 or 3 infections.

# Results: table of included study

<p>Cavusoglu 2009</p> <p>Turkey</p>	<p>39</p>	<p>Mean age 50 and 47 years in two groups; 65% and 53% male; no inclusion criteria reported.</p>	<p>(1) Daily showering; cleaning crusts with sterile gauze with iodine solution; (2) Daily showering; brushing pin sites with soap and water.</p>	<p>Minor infection: (1) 44%; (2) 51%. Major infection: (1) 4%; (2) 4%.</p>	<p>Minor infection: Grade 1 and 2 on a modification of the Dahl system by Gordon - not requiring any extra pin site care. Major infection: Grade 3 and above - requiring treatment with oral antibiotics.</p>	<p>Pin site inspection on 5th, 10th, 15th, 30th, 45th, 60th, 75th, 90th, 120th and 150th days of follow-up until fixator removal.</p>	<p>Prophylaxis for closed fractures: preoperative and postoperative single dose intravenous cephalosporin sodium (1 g); open fractures: preoperative 1 day and postoperative 4 day intravenous cephalosporin sodium (1 g 3 X day), intravenous gentamicin (160 mg/day) and oral ornidazole (500 mg 2 X day).</p>
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# Risk of bias: Methodological quality



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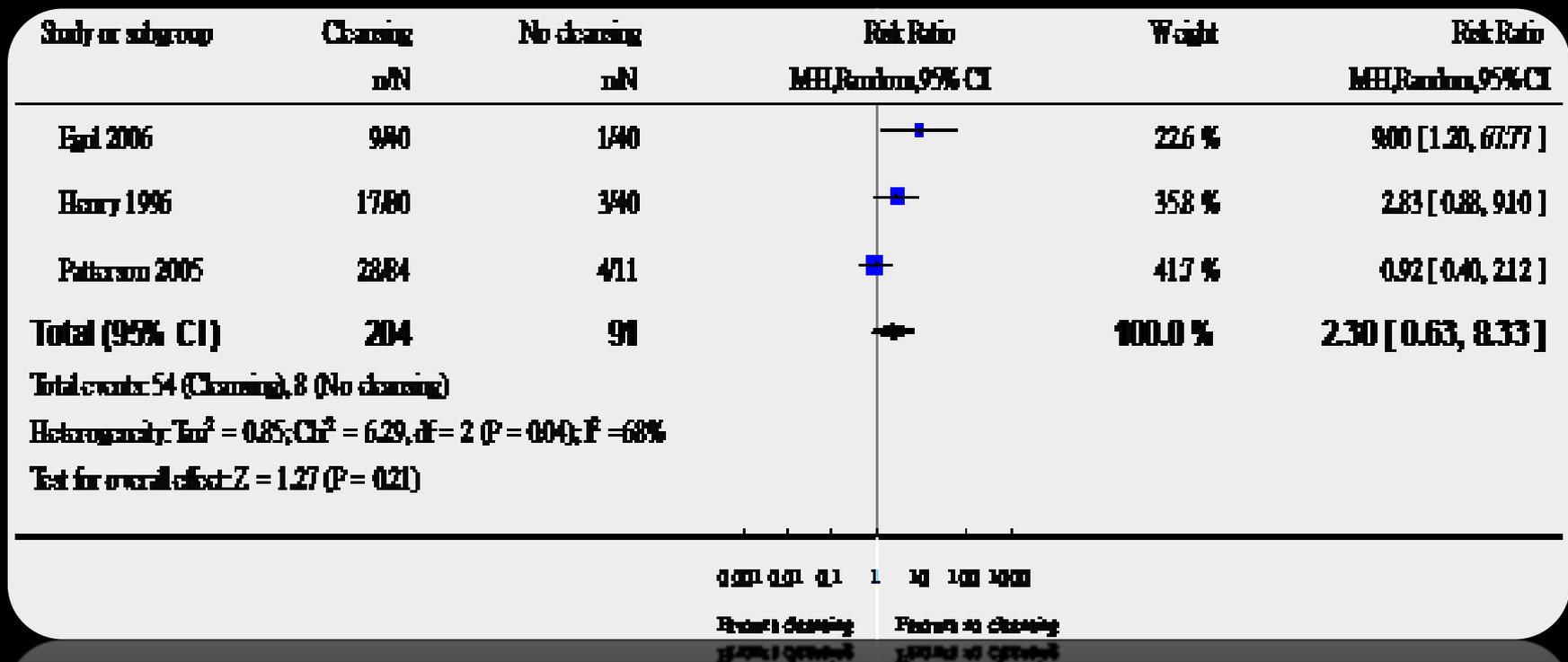
- **Incomplete outcome assessment**
  - Withdrawals of 10% (Grant 2005), 9% (Patterson 2005)
  - Grant study : all withdrawals were from the soft white paraffin group
- **Other bias**
  - Baseline imbalance
  - Randomised participants had multiple pin sites
    - unit of analysis errors → the potential to overestimate effects
  - Prophylactic antibiotics
  - Insufficient information about types of fixators, application of pins, insertion techniques and location of sites

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Camilo 2005	?	+	-	+	?	-
Cavusoglu 2009	+	?	-	+	?	?
Chan 2009	?	?	-	+	?	?
Egol 2006	+	+	-	+	?	-
Grant 2005	?	?	-	-	?	-
Henry 1996	+	?	-	+	?	-
Patterson 2005	?	?	-	-	?	-
W-Dahl 2003	+	?	-	+	?	-

# Effects of interventions

- Cleansing V.S. no cleansing (3 studies)
- Sterile antiseptic cleansing V.S. sterile non-antiseptic cleansing (3 studies)
- Sterile cleansing V.S. non-sterile cleansing (2 studies)
- Comparisons between dressings

# Cleansing V.S. no cleansing



→ Insufficient evidence of an effect of pin site cleansing on pin site infection from 3 small studies at high risk of bias

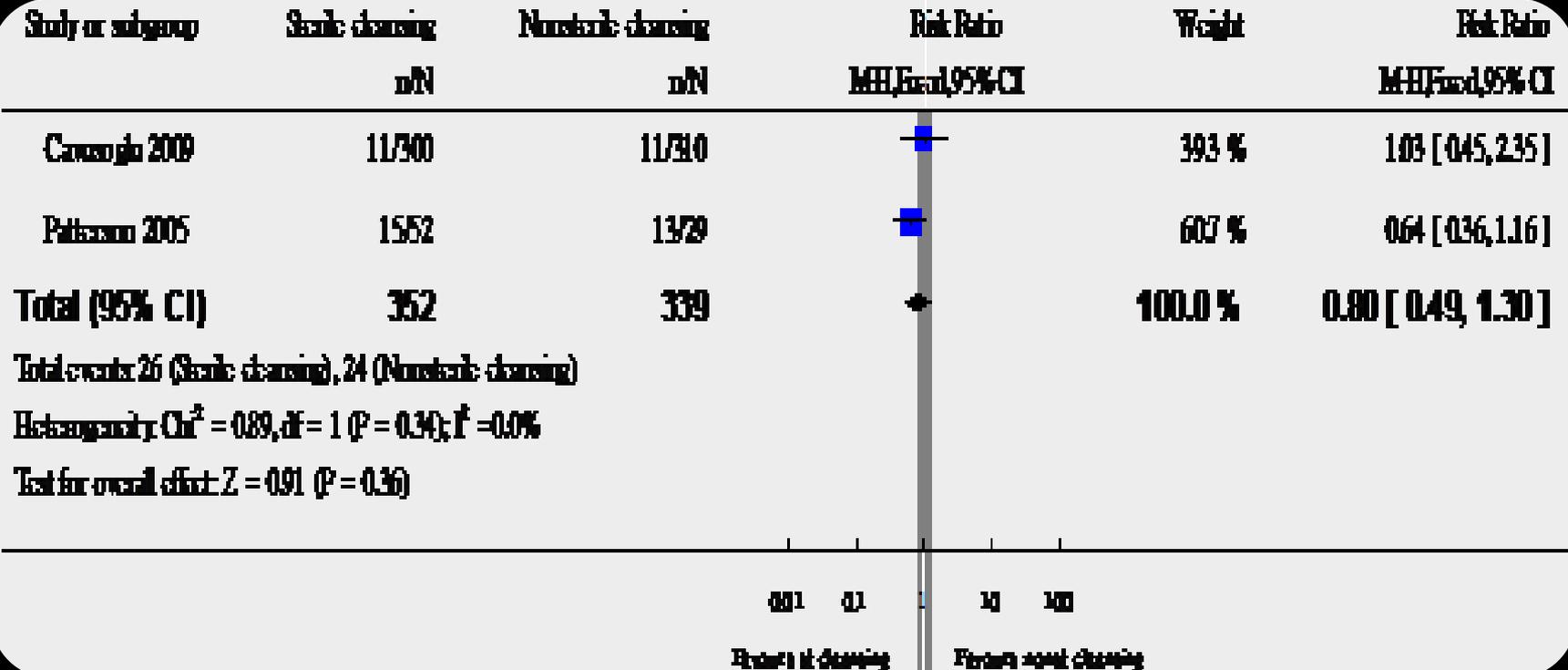
# Different cleansing solutions

Study or subgroup	st antiseptic n/N	st non antiseptic n/N	Risk Ratio M-H,Fixed,95%CI	Weight	Risk Ratio M-H,Fixed,95%CI
Chan 2009	72/871	71/417		79.1 %	1.14 [0.85, 1.53]
Henry 1996	7/40	10/40		11.8 %	0.70 [0.30, 1.66]
Patterson 2005	6/22	9/30		9.0 %	0.91 [0.38, 2.18]
<b>Total (95% CI)</b>	<b>433</b>	<b>487</b>		<b>100.0 %</b>	<b>1.07 [0.82, 1.39]</b>

Total events: 85 (st antiseptic), 90 (st non antiseptic)  
 Heterogeneity:  $\text{Chi}^2 = 1.24$ ,  $\text{df} = 2$  ( $P = 0.54$ );  $I^2 = 00\%$   
 Test for overall effect:  $Z = 0.48$  ( $P = 0.63$ )

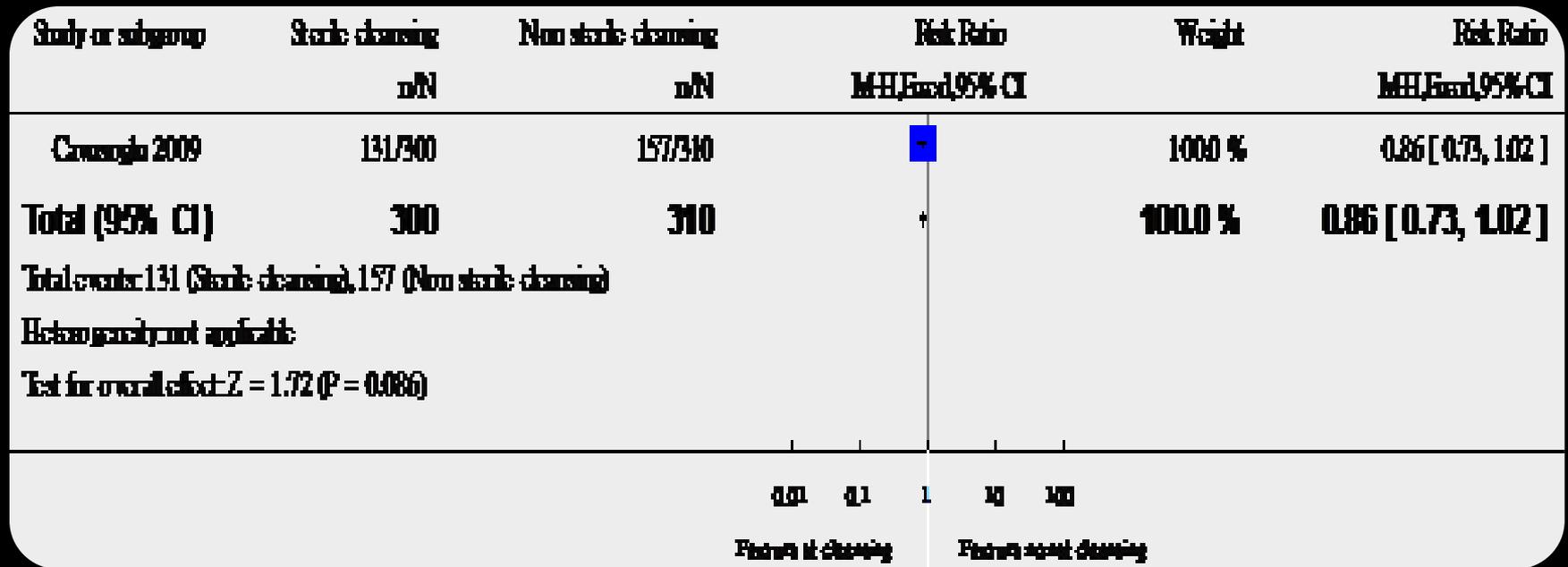
- Henry 1996, 70% alcohol: N/S
  - Patterson 2005, Half-strength peroxide V.S. N/S
  - Chan 2009, Iodine : N/S
- Insufficient evidence to determine whether one particular cleansing solution is more effective

# Different methods of cleansing: major infection



→ Insufficient evidence to determine whether sterile cleansing is more effective

# Different methods of cleansing: minor infection



- Cavusoglu 2009, daily showering, per pin minor infection , sterile gauze containing iodine solution : brushing with soap  
 → Insufficient evidence to determine whether sterile cleansing is more effective

# Different methods of cleansing

- W-Dahl 2003, **daily V.S. weekly** cleansing with N/S using a **sterile technique by district nurse**
  - Per pin infection rate: 7.4% v.S. 12%
  - Pain (mean VAS score): 1.5 V.S. 1.6
  - Use of antibiotics (days): 41 V.S. 53
  - Use of analgesics

→ all no significant difference

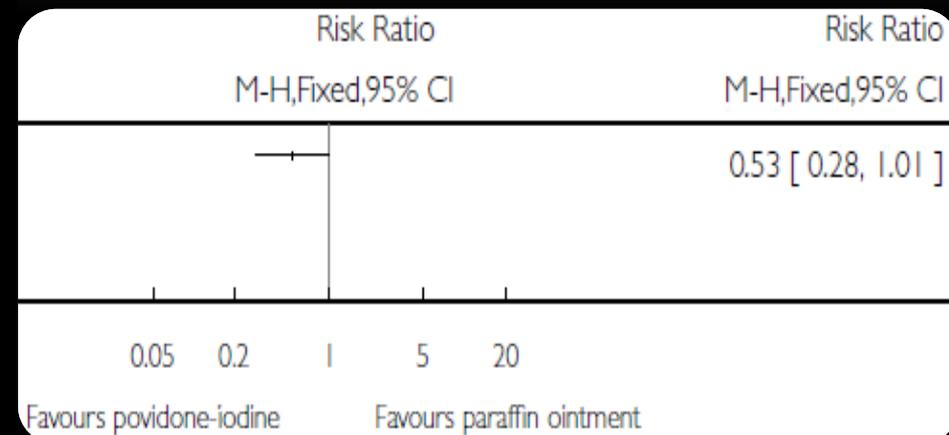
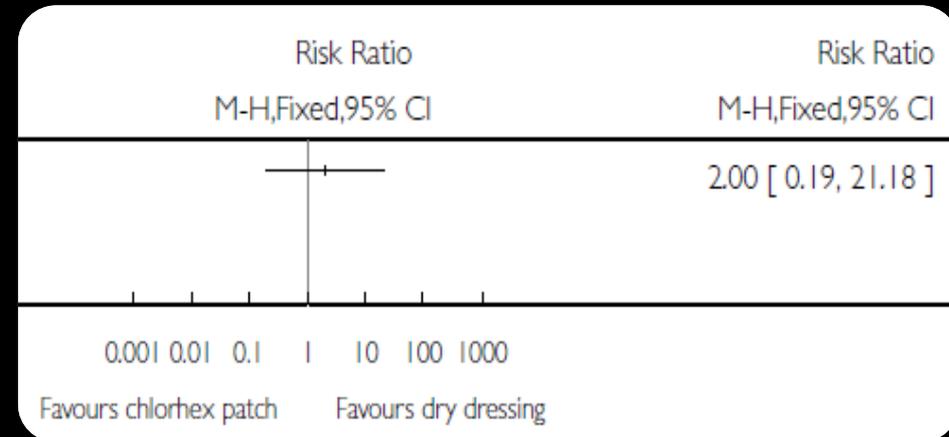


# Dressing V.S. No Dressing

- No studies identified

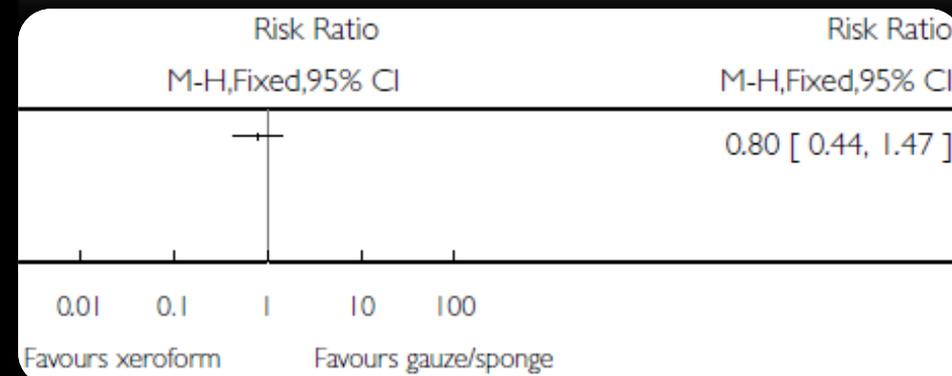
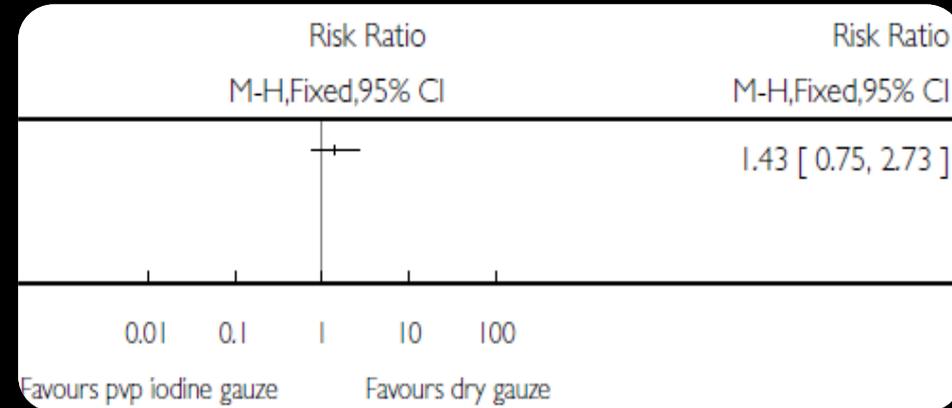
# Different types of dressings

- Egol 2006, antibiotics needed
  - Chlorhex patch: 2/40
  - Dry dressing: 1/40
    - Erythema, cellulitis, drainage, pin loosening → no difference
- Grant 2005, clinical sign of infection
  - Povidone-iodine: 13/72
  - **Paraffin ointment: 15/44**



# Different types of dressings

- Camilo 2005, superficial infection
  - Pvp iodine gauze: 10/15
  - Dry gauze: 7/15
- Patterson 2005, infection rate
  - Xeroform: 13/42
  - Gauze/sponge: 15/39



# Message

- No trials identified

# Discussion

- Included studies were not able to determine an optimal strategy for pin site care
  - **Small and underpowered** with methodological flaws
  - **None were blinded**
  - Minimal efforts were made to control
    - Patient compliance
    - Antibiotic use
    - Length of time pins were in place
    - Location of pins, pin insertion procedures, types of hardware
  - Heterogeneity in the age, condition
  - Reported using pin sites as unit (**unit of analysis errors**)
  - **Pin site infection was not consistently defined**

# Discussion

- Only one of these studies ensured that the sample size was adequately powered to find differences
  - Patterson 2005: cleansing with hydrogen peroxide followed by the application of **Xeroform** dressing had a lower rate of infection (9%) than the other combinations of cleansing and dressing and the control group with no cleansing



# Discussion

- National Association of Orthopaedic Nurses Guidelines in pin-site care (*Holmes 2005*)
  - Pins located in areas with considerable soft tissue → greater infection risk
    - *Henry 1996*: femoral > tibial , proximal femur > lower femur
  - After the first 48 to 72 hours, pin site care should be done daily, or weekly for sites with mechanically stable bone-pin interfaces
    - *W-Dahl 2003*: no differences between daily or weekly pin site care
  - Chlorhexidine solution may be the most effective cleansing solution for pin site care (*W-Dahl 2004*, non-randomized)
    - No particular cleansing agent is more effective
  - Patients and their families should be taught pin site care before discharge from the hospital
    - No attempts to measure patient compliance

# Conclusions

- **Implications for practice**
  - Insufficient evidence of adequate quality to inform a strategy for the best management of pin sites
  - Implementation of **general strategies** for minimising the risk of cross infection
- **Implications for research**
  - **Adequately-powered, well designed RCTs** are required
    - Consistent method for identification of infection rates
    - Subgroup analyses: control age , location of pin sites
    - Randomisation should be per participant

**Thanks for your attentions!**