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

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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)*
  - Majot: 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 \textit{(Higgins 2003)}
  – 25\% or less: low heterogeneity
  – 50\% : moderate heterogeneity
  – 75\% or more: high heterogeneity

• No clinical or statistical heterogeneity $\rightarrow$ fixed-effect model

• Heterogeneity & meta-analysis is appropriate $\rightarrow$ 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

<table>
<thead>
<tr>
<th>Study ID</th>
<th>N</th>
<th>Participants</th>
<th>Interventions</th>
<th>Infection rate</th>
<th>Definition of infection</th>
<th>Duration</th>
<th>Antibiotic prophylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camilo 2005</td>
<td>30</td>
<td>Ilizarov external fixators; no infection.</td>
<td>(1) Daily: shower, cleanse with saline, gauze dressing soaked with polyvinylpyrrolidone-iodine; (2) Daily: shower, cleanse with saline; dry dressing</td>
<td>(1) 66.7%; (2) 46.7%; NS</td>
<td>Defined as purulent secretion.</td>
<td>Follow-up for time external fixator in place, mean = 273 days (95-726 days)</td>
<td>Not reported.</td>
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<td>Brazil</td>
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<tr>
<td>Egol 2006</td>
<td>118</td>
<td>Adults; displaced, unstable, distal radial fracture</td>
<td>(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.</td>
<td>(1) 22.5%; (2) 5%; (3) 2.5%.</td>
<td>Defined as requiring antibiotics.</td>
<td>Follow-up for mean of 5.9 weeks (4-8 weeks). External fixator removed at 6 weeks and patients followed-up for 6 months.</td>
<td>Standard prophylaxis given to all patients: before and immediately after surgery.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Age Range</td>
<td>Intervention</td>
<td>Outcome Definition</td>
<td>Follow-up Duration</td>
<td>Intraoperative or Postoperative Period</td>
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<tr>
<td>Grant 2005</td>
<td>20</td>
<td>18+ years</td>
<td>(1) Daily: saline cleansing, soft white paraffin ointment; (2) Twice daily: saline cleansing, 10% povidone-iodine.</td>
<td>(1) 34.1%; (2) 18.1% (pin sites, not participants).</td>
<td>Follow-up until clinical infection or removal of pin.</td>
<td>Intraoperative or postoperative period: 83%.</td>
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<tr>
<td>Australia</td>
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<tr>
<td>Henry 1996</td>
<td>30</td>
<td>Aged 11-18</td>
<td>(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.</td>
<td>(1) 25%; (2) 17.5%; (3) 7.5%. NS</td>
<td>Pin in place for mean of 150 days (56-244 days)</td>
<td>Not reported.</td>
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<td>UK</td>
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<tr>
<td>Patterson 2005</td>
<td>101</td>
<td>All ages (3-80 years); 65% male; no inclusion criteria reported.</td>
<td>(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).</td>
<td>(1) 46%; (2) 9%; (3) 33%; (4) 27%; (5) 39%; (6) 50%; (7) 36%. NS</td>
<td>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.</td>
<td>6-week follow-up.</td>
<td>Not reported.</td>
</tr>
</tbody>
</table>
## Results: table of included study

<table>
<thead>
<tr>
<th>Study</th>
<th>No.</th>
<th>Treatment</th>
<th>Inclusion Criteria</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>W-Dahl 2003</td>
<td>50</td>
<td>Surgery for gonarthrosis by hemicallostosis technique; mean age 54 years; inclusion criteria not reported.</td>
<td>Daily: pin site care: cleansing with 0.9% sodium chloride, sterile compress fixed with soft dressing; Weekly; same pin site care protocol.</td>
<td>Grade 1: (1) 7.4%; (2) 12%. Grade II: (1) 2.8%; (2) 0%. NS</td>
</tr>
<tr>
<td>Chan 2009</td>
<td>62</td>
<td>Distraction osteogenesis using Ilizarov fixators; age ranged from 1-76 years; 37% &lt; 14 years; no inclusion criteria reported.</td>
<td>(1) Daily povidone-iodine cleansing solution; (2) Saline cleansing solution.</td>
<td>Any grade of Infection: (1) 19%; (2) 17%.</td>
</tr>
<tr>
<td>Study</td>
<td>Mean age and sex</td>
<td>Inclusion criteria</td>
<td>Minor infection:</td>
<td>Major infection:</td>
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<tr>
<td>-------</td>
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<tr>
<td>Cavusoglu 2009</td>
<td>50 and 47 years in two groups; 65% and 53% male</td>
<td>Yes</td>
<td>(1) 44%; (2) 51%</td>
<td>(1) 4%; (2) 4%</td>
</tr>
</tbody>
</table>
Risk of bias: Methodological quality

- Random sequence generation (selection bias)
  - Low risk of bias: 50%
  - Unclear risk of bias: 25%
  - High risk of bias: 25%

- Allocation concealment (selection bias)
  - Low risk of bias: 50%
  - Unclear risk of bias: 25%
  - High risk of bias: 25%

- Blinding (performance bias and detection bias)
  - High risk of bias: 100%

- Incomplete outcome data (attrition bias)
  - Low risk of bias: 50%
  - Unclear risk of bias: 25%
  - High risk of bias: 25%

- Selective reporting (reporting bias)
  - High risk of bias: 100%

- Other bias
  - High risk of bias: 100%
Risk of bias: Methodological quality

- **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
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

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Cleansing</th>
<th>No cleansing</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>East 2006</td>
<td>940</td>
<td>140</td>
<td></td>
<td>22.6 %</td>
<td>9.00 [1.20, 67.77]</td>
</tr>
<tr>
<td>Henry 1996</td>
<td>1780</td>
<td>340</td>
<td></td>
<td>35.8 %</td>
<td>2.83 [0.88, 9.10]</td>
</tr>
<tr>
<td>Patterson 2005</td>
<td>2884</td>
<td>411</td>
<td></td>
<td>41.7 %</td>
<td>0.92 [0.40, 2.12]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>204</td>
<td>91</td>
<td></td>
<td>100.0 %</td>
<td>2.30 [0.63, 8.33]</td>
</tr>
</tbody>
</table>

Total events: 54 (Cleansing), 8 (No cleansing)
Heterogeneity: $I^2 = 85\%$, $\chi^2 = 6.29$, df = 2 ($p = 0.04$); $I^2 = 68\%$
Test for overall effect: $Z = 1.27$ ($p = 0.21$)

→ 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

- 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
  – Poviodine-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
Massage

• 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
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 informa 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!