

Needless intravenous systems compared to conventional intravenous systems

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SUMMARY STATEMENT

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REQUEST

Needleless intravenous systems compared to conventional intravenous systems

REQUESTED BY

Noleen Bennett, Infection Control Consultant, Infection Control, Monash Medical Centre, Clayton.

METHODOLOGY

Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined National Health and Medical Research Council (NHMRC, 2000) criteria (see Appendix 1).

First, we search for systematic reviews, evidence based clinical practice guidelines, health technology assessments and randomised controlled trials. If we identify sound, relevant material of this type, the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

Details of Evidence Request

Patients (Subjects): All patients requiring an intravenous system

Intervention: Needleless intravenous systems

Comparison: Conventional intravenous systems

Outcomes: Patient comfort, nursing time, other benefits (not needlestick injury)

Search terms

(see Appendix 2 for exact search strategy)

Patient (Subject): intravenous

Intervention: needleless, needlefree, needle-free

Resources Searched

We searched the following databases and internet websites:

The Cochrane Library (CD-ROM) Issue 1 2001

Medline (OVID)- 1966 to February 2001

Best Evidence (OVID)- 1991 to January/ February 2001

CINAHL (OVID)- 1982 to March 2001

Current Contents (OVID)- 1993 Week 26 to 2001 Week 16

Journals @Ovid Fulltext- April 5, 2001

PREMEDLINE (OVID)- April 2, 2001

Australasian Medical Index- April 11, 2001

National Guideline Clearinghouse- April 11, 2001

Refinements, Searching & Reporting Constraints

We included items of evidence that were available to us on 12 April, 2001. We excluded articles that focussed on risk of needlestick injuries as the outcome. We only included articles that directly compared needleless systems to conventional intravenous systems. Critical appraisal was performed on the subset of studies published in English.

RESULTS

From our sources we identified 10 potentially relevant articles. We obtained the full text of these articles to determine their relevance.

After examination of the 10 articles, the following five were excluded as follows:

| Reason for exclusion | Number |
|------------------------|----------|
| Level IV evidence | 1 |
| Opinion | 2 |
| Not needless IV system | 1 |
| Qualitative study | 1 |
| Total | 5 |

Five articles then remained for appraisal. These studies are classified as follows:

| Study Design of Included Studies | Number |
|---|----------|
| Systematic reviews or meta-analyses | 0 |
| Evidence-based clinical practice guidelines | 0 |
| Randomised controlled trials | 1 |
| Pseudorandomised controlled trials | 0 |
| Controlled trials, cohort or case-control analytic studies | 4 |
| Total | 5 |

Based on our refinements, searching and reporting constraints, we are reasonably confident these articles represent the most relevant findings published to date.

EVIDENCE SUMMARIES

Format

Evidence summaries are presented as spreadsheets attached to this report. Each spreadsheet contains the article citation, details of the study design, patient description, scientific validity of the article, results, and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

REFERENCES

ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

Level II evidence- randomised controlled trial

Cooper JA, Bromley LM, Baranowski AP *et al.* (2000). Evaluation of a needle-free injection system for local anaesthesia prior to venous cannulation. *Anaesthesia* 55: 247-250.

Level III-2 evidence- comparative study with concurrent controls

Luebke MA, Arduino MJ, Duda DL *et al.* (1998). Comparison of the microbial barrier properties of a needleless and a conventional needle-based intravenous access system. *American Journal of Infection Control* 26: 437-441.

Level III-3 evidence- comparative study with historical controls

Danzig LE, Short LJ, Collins K *et al.* (1995). Bloodstream infections associated with a needleless intravenous infusion system in patients receiving home infusion therapy. *Jama: Journal of the American Medical Association* 273: 1862-1864.

Kellerman SMD, Shay DKMD, Howard JRNMSCIC *et al.* (1996). Bloodstream infections in home infusion patients: The influence of race and needleless intravascular access devices. *Journal of Pediatrics* November 129: 711-717.

Mendelson MH, Short LJ, Schechter CB *et al.* (1998). Study of a needleless intermittent intravenous-access system for peripheral infusions: analysis of staff, patient, and institutional outcomes. *Infection Control & Hospital Epidemiology* 19: 401-406

ARTICLES NOT CRITICALLY APPRAISED

Level IV evidence- case series studies

Beason R, Bourguignon J, Fowler D *et al.* (1992). Evaluation of a needle-free intravenous access system. *Journal of Intravenous Nursing* 15: 11-16.

Opinion

Coppage D (1996). Technology assessment. A latex-free, needleless IV system. *Surgical Services Management* 2: 40-41.

Horner KA (1998). Technology assessment of two needleless systems. *Journal of Intravenous Nursing* 21: 203-208.

Qualitative study

Murray G (1998). Needle-free IV systems: safety, practicality and cost-effectiveness. *World of Irish Nursing* 6: 17-18.

Not a needleless IV system

Yu YK, Ishisaka DY, Nishizaki TT *et al.* (1996). Cost analysis of three intravenous drug delivery systems in a neonatal intensive care unit. *American Journal of Health-System Pharmacy* October 1 53: 2314-2318.

APPENDIX 1

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Levels Of Evidence

Based on "How to use the evidence: assessment and application of scientific evidence" (National Health & Medical Research Council, Canberra, 2000):

| | | |
|-----------|----|---|
| Level I | | Evidence obtained from a systematic review (or meta-analysis) of all relevant randomised controlled trials. |
| Level II | | Evidence obtained from at least one randomised controlled trial. |
| Level III | -1 | Evidence obtained from pseudorandomised controlled trials (alternate allocation or some other method). |
| | -2 | Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group. |
| | -3 | Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group. |
| Level IV | | Evidence obtained from case series, either post-test or pretest/post-test. |

APPENDIX 2

Search strategy

| | Search terms for MEDLINE, CINAHL, EBM- Best Evidence, PREMEDLINE, Current Contents, Journals @Ovid Fulltext |
|---|---|
| 1 | intravenous.mp |
| 2 | IV.tw |
| 3 | 1 or 2 |
| 4 | needleless.tw |
| 5 | needlefree.tw |
| 6 | needle-free.tw |
| 7 | or/ 4-6 |
| 8 | 3 and 7 |

| Evidence Summary Therapy <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> Needleless intravenous systems compared to conventional intravenous systems </div> | Study 1 Cooper JA, Bromley AP, Baranowski AP et al. (2000) Evaluation of a needle-free injection system for local anaesthesia prior to venous cannulation. <i>Anaesthesia</i> 55: 247-250 | Study 2 Leubke MA, Arduino MJ, Duda DL et al (1998) Comparison of the microbial barrier properties of a needleless and a conventional needle-based intravenous access system. <i>American Journal of Infection Control</i> 26(4): 437-441 |
|--|---|--|
| STUDY DESIGN & NHMRC LEVELS OF EVIDENCE | Randomised Controlled Trial Level II evidence | Comparative study with concurrent controls Level III-2 evidence |
| DESCRIPTION: Subjects, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria | Patients: Patients scheduled to undergo surgery. Intervention: Skin injected using the J-Tip needleless injector 3 minutes prior to cannulation Comparison: Skin injected with a conventional 25G needle and syringe 3 minutes prior to cannulation Outcomes: Pain of injection, efficacy of skin anaesthesia Incl & Excl Criteria: Included if over 18 years, and not prescribed an analgesic drugs as a premedicant | Patients: None, a laboratory study Intervention: Needleless intravenous access systems Comparison: Conventional intravenous access systems Outcomes: Levels of bacteria, transfer or organisms into the fluid path, Incl & Excl Criteria: None stated |
| VALIDITY: Methodology, rigour, selection, opportunity for bias | Randomisation: Yes, method not specified All patients accounted for: Yes Patients treated equally: Yes Similar groups: Yes for sex, and cannula site. The 14G cannula was used more in the injection group than the needleless group. The patients in the needleless group were older. There were more cases of failure to cannulate on first attempt in the conventional injection group. Potential for bias: It was not possible to totally blind patients and clinicians due to the different sounds the techniques make and the different marks left. Patients and clinicians were not however told of group allocation. | Randomisation: No All patients accounted for: Yes Patients treated equally: Yes Similar groups: Yes Potential for bias: The applicability of the study to the clinical setting is unclear. The contaminants used in this laboratory study may not be the same as those found in the clinical setting and the septa is not likely to be as highly contaminated in a real clinical setting. |
| RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate | Infiltration was judged to have made cannulation more difficult in 20/36 patients receiving conventional injection and 2/36 patients receiving needleless injection. Pain on infiltration scores were zero (range 0-0) for the needleless group and two (range 1.0-2.75) for the conventional needle group. The difference was significant ($p < 0.001$). Pain on cannulation scores were 0 (range 0-2.0) for the conventional injection group and 2.75 (range 1.0-5.0) for the needleless group, which was statistically significantly different ($p < 0.001$). | "With disinfection, the combined effects of the disinfection technique and the barrier properties of the septa prevented the transfer of organisms into the fluid path in 94% to 96% of needleless test articles and 96% to 100% of conventional test articles. Without disinfection, the barrier properties of the septa alone prevented the transfer of organisms into the fluid path in 20% to 69% of needleless test articles and 10% to 28% of conventional test articles." |
| AUTHORS COMMENTS: Risk/benefit, limitations | "We conclude that the device certainly delivers a less painful subcutaneous injection than a 25G needle, but perhaps provides less effective skin anaesthesia for venous cannulation at sites where the subcutaneous space is small: its use might be better suited to spaces where the subcutaneous space is deeper." | "The data demonstrate the needleless system performs as well as the conventional intravenous access system with respect to risk of microbial contamination and reinforce the need for appropriate spectrum disinfectant before accessing either system." |

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| <p>Evidence Summary Therapy</p> <p>Needleless intravenous systems compared to conventional intravenous systems</p> | <p>Study 1 (cont...)</p> <p>Cooper JA, Bromley AP, Baranowski AP et al. (2000) Evaluation of a needle-free injection system for local anaesthesia prior to venous cannulation. <i>Anaesthesia</i> 55: 247-250</p> | <p>Study 2 (cont...)</p> <p>Leubke MA, Arduino MJ, Duda DL et al (1998) Comparison of the microbial barrier properties of a needleless and a conventional needle-based intravenous access system. <i>American Journal of Infection Control</i> 26(4): 437-441</p> |
| <p>REVIEWER'S COMMENTS: Risk/benefit, methodology, conclusions</p> | <p><u>Strengths:</u></p> <ul style="list-style-type: none"> • Randomised study • No loss to follow up • Intervention and comparison were administered at the same time, and exactly the same anaesthetics were administered. <p><u>Weaknesses:</u></p> <ul style="list-style-type: none"> • The groups differed at baseline • The size of the cannula was greater in the needleless group which may affect pain on cannulation scores • The conventional group had more failure to cannulate on first attempt | <p><u>Strengths</u></p> <ul style="list-style-type: none"> • Both types of needle systems were treated equally • No loss to follow up • No baseline differences between the two needle systems <p><u>Weaknesses</u></p> <ul style="list-style-type: none"> • The results may not be generalisable to a clinical setting • The exact septa used in the laboratory may not be the same as in the clinical setting |

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| <p>Evidence Summary Therapy</p> <p>Needleless intravenous systems compared to conventional intravenous systems</p> | <p>Study 3</p> <p>Mendleson MH, Short LJ, Schechter CB, et al. (1998) Study of a needleless intermittent intravenous access system for peripheral infusions: analysis of staff, patient, and institutional outcomes. <i>Infect Control Hosp Epidemiol</i> 19: 401-6</p> | <p>Study 4</p> <p>Kellerman S, Shay DK, Howard J et al. (1996) Bloodstream infections in home infusion patients: The influence of race and needleless intravascular access devices. <i>The Journal of Pediatrics</i> 129(5): 711-17</p> |
| <p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p> | <p>Comparative study with historical controls Level III-3 evidence</p> | <p>Comparative study with historical controls Level III-3 evidence</p> |
| <p>DESCRIPTION: Subjects, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p> | <p>Patients: Patients requiring peripheral infusions Intervention: Needleless intermittent intravenous (IV) access system (NL) Comparison: Conventional heparin-lock system (CHL) Outcomes: Erythema, purulence, bacteraemia, complications, and staff rated product evaluation Incl & Excl Criteria: Paediatrics, obstetrics-gynaecology and intensive care units were excluded.</p> | <p>Patients: Children on the haematology/oncology service with central venous catheters (CVCs) Intervention: Needleless CVC-access device Comparison: Injection port system Outcome: Bloodstream infection (BSI) Incl & Excl Criteria: Excluded patients with only exit-site infections or positive blood culture results on specimens obtained from a CVC in the absence of clinical symptoms.</p> |
| <p>VALIDITY: Methodology, rigour, selection, opportunity for bias</p> | <p>Randomisation: No All patients accounted for: 594 out of 602 patients were included. No reason is given for not including the eight patients. Unclear whether all patients were measured for every outcome. Patients treated equally: Yes, for staff to patient ratio. Strict infection control procedures were in place for both groups. Similar groups: Yes, for degree of illness of patients. No indication of the other baseline characteristics of the two groups. Potential for bias: It was not possible to blind clinicians or patients as the site of access was exposed.</p> | <p>Randomisation: No All patients accounted for: Yes Patients treated equally: Yes Similar groups: Groups are different due to the case control study design. Potential for bias: The needle system changed part way through the study. There would have been other differences that could have contributed to BSI rates besides the type of needle system.</p> |
| <p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p> | <p>CHL devices were more likely to have a score >0 (indicating complication) on the first observation day compared to NL devices (OR 2.04; 95% CI 1.02-4.16; p<0.05). There was no significant difference in scores for the devices after the first day. The rate of death for the two groups was not significantly different. There were four device related cases of bacteraemia, three were associated with CHL and one with NL (p=0.3). According to patients self-reports backflow of blood through the device occurred more frequently for NL than CHL (p=0.01). Difficulty with infusion (p<0.001) and disconnection of IV tubing (p<0.001) were reported significantly more frequently with CHL than NL. Of the staff surveyed 94% felt completely comfortable with NL after using it at least 5 times, 99% felt it was easy to use, 88% said it require a slight or no change in technique, 95% felt worker safety increased, 84% felt patient safety increased, and 95% preferred NL.</p> | <p>The overall BSI rate increased significantly after the introduction of the needleless devices from 0.8 to 1.4 BSIs per 1000 CVC days (RR 1.8; 95% CI 1.12 to 2.89; p<0.02).</p> |

| <p>Evidence Summary Therapy</p> <p>Needleless intravenous systems compared to conventional intravenous systems</p> | <p>Study 3 (cont...)</p> <p>Mendleson MH, Short LJ, Schechter CB, et al. (1998) Study of a needleless intermittent intravenous access system for peripheral infusions: analysis of staff, patient, and institutional outcomes. Infect Control Hosp Epidemiol 19: 401-6</p> | <p>Study 4 (cont...)</p> <p>Kellerman S, Shay DK, Howard J et al. (1996) Bloodstream infections in home infusion patients: The influence of race and needleless intravascular access devices. The Journal of Pediatrics 129(5): 711-17</p> |
|---|---|--|
| <p>AUTHORS COMMENTS: Risk/benefit, limitations</p> | <p>"A needleless intermittent intravenous access system with a reflux valve for peripheral infusions is... not associated with an increase in either insertion-site complications or nosocomial bacteremia. Institutions should consider these data, (and) available institutional resources... when selecting the above or other safety devices."</p> | <p>"Our data suggest that pediatric haematology/ oncology patients receiving home health care via needleless devices may have increased risks of BSIs, and this risk may vary by race."</p> |
| <p>REVIEWER'S COMMENTS: Risk/benefit, methodology, conclusions</p> | <p><u>Strengths</u></p> <ul style="list-style-type: none"> • There was an equal staff to patient ratio for both groups <p><u>Weaknesses</u></p> <ul style="list-style-type: none"> • The study was not randomised • The sample did not include all consecutive patients • All patients were not measured for every outcome • The groups may have differed at baseline • The groups may have been treated differently due to the needle systems being used in different time periods | <p><u>Strengths</u></p> <ul style="list-style-type: none"> • Clearly defined patient population <p><u>Weaknesses</u></p> <ul style="list-style-type: none"> • Non randomised study • Historical control group, other factors apart from the type of needle device may also have varied • The results may not be generalisable to patients receiving a needleless device outside of the home setting • Sample size may not have been large enough to show true difference between groups |

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| <p>Evidence Summary Therapy</p> <p>Needleless intravenous systems compared to conventional intravenous systems</p> | <p>Study 5</p> <p>Danzig LE, Short LJ, Collins K et al. (1995) Bloodstream infections associated with a needleless intravenous infusions system in patients receiving home infusion therapy. JAMA 273(23): 1862-64</p> |
| <p>STUDY DESIGN & NHMRC LEVELS OF EVIDENCE</p> | <p>Comparative study with historical controls Level III-3 evidence</p> |
| <p>DESCRIPTION: Subjects, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria</p> | <p>Patients: Patients receiving home intravenous infusion therapy (RIHT) Intervention: Needleless infusion device Comparison: Protected needle access system Outcome: laboratory confirmed primary bloodstream infection (BSI) Incl & Excl Criteria: Patients were included if they received intravenous therapy via a central venous catheter (CVC) or peripheral catheter.</p> |
| <p>VALIDITY: Methodology, rigour, selection, opportunity for bias</p> | <p>Randomisation: No All patients accounted for: Yes, although 11/113 were excluded because of incomplete data Patients treated equally: Unclear, the same nursing protocol was used for both types of needle systems but the two needle systems were used in different time periods when other factors may have varied Similar groups: Unclear, no data provided Potential for bias: The use of historical controls means there are many factors that could be different besides the type of needle system used. It is hard to attribute any difference between groups solely to the needle system.</p> |
| <p>RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate</p> | <p>Case patients (those with laboratory confirmed bloodstream infection-BSI) were significantly more likely than controls (those without a BSI) to have had a needleless device (10/41 vs 1/61; RR 14.9; 95% CI 2.0 to 111.8) or to have received total parenteral nutrition (TNP) through a needleless device (8/15 vs 3/87; RR 9.45; 95% CI 4.3 to 21.0). These results were still significant when adjusting for duration of therapy. When the analysis was stratified by receipt of TNP and the use of a needleless device to assess for confounding, only the receipt of TNP together with use of a needleless device remained significant ($p < 0.001$) as a risk factor for BSI.</p> <p>Positive cultures were significantly more common from needleless device injection caps than from protected needle device injection caps (5/23 vs 0/18; RR undefined; $p = 0.04$). No clinical infections were detected in these patients.</p> |
| <p>AUTHORS COMMENTS: Risk/benefit, limitations</p> | <p>"Our data suggest that a needleless device used for TPN/IL was associated with increased risk of BSI when injection caps were changed every 7 days."</p> |
| <p>REVIEWER'S COMMENTS: Risk/benefit, methodology, conclusions</p> | <p><u>Strengths</u></p> <ul style="list-style-type: none"> • Clear objective outcome measure of laboratory confirmed BSI <p><u>Weaknesses</u></p> <ul style="list-style-type: none"> • The study was not randomised • Patients may have been treated differently in ways aside from the type of needle system. • The results have very wide confidence intervals, indicating much variation in the data |