
DATE: 18 July 2012

CONTEXT AND POLICY ISSUES

Central venous catheters (CVCs) are often used to deliver drugs, supply nutrients, or draw blood samples in some severely ill patients. A peripherally inserted central venous catheter is a type of central venous line. During placement of the CVC, the correct position of the tip is of paramount importance and should be verified immediately after placement before infusion to avoid any catheter-related complications. Post-procedural chest x-ray is a commonly used method for verification of the CVC tip position. X-rays, however, have some limitations as they are not readily available until the end of the surgical procedure, the method is not 100% accurate and there is a risk of patients being exposed to radiation. Moreover, when a misplacement of the CVC tip is detected by chest x-ray, a further procedure is required to reposition the line, which implies more potential problems and costs.

Electrocardiogram (ECG)-based positioning of the CVC tip is of growing interest, because it allows control of the catheter position during insertion procedure. The ECG method uses the catheter as an intracavitary electrode occurring with two different techniques: metal guidewire and column of saline. In the metal guidewire technique, a metal guidewire inserted inside the catheter is used as an intracavitary electrode, whereas, in the column saline technique, the column of physiological saline solution contained in the catheter is used. As the catheter advances through the superior vena cava towards the right atrium, the intracavitary monitoring of the electrical conductivity represented in the variations in the height of the p-wave of an ECG rhythm would indicate the position of the catheter. The preferred access site for CVC placement is the right internal jugular vein (IJV), while alternative sites, which may lead to high incidence of malpositioning and procedural complications, include left IJV, subclavian veins and right external jugular veins. Although the ECG-based method has been considered to be safe, accurate, quick and easy to perform, radiation-free, and real-time verification, its clinical effectiveness and cost-effectiveness compared with post-procedural chest x-ray method remains to be determined.

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This purpose of this report is to review the evidence regarding the clinical effectiveness and cost-effectiveness of electrocardiograms versus x-rays for the guided placement of central venous catheter tips.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of electrocardiograms versus x-rays for the guided placement of central venous catheter tips?

2. What is the cost-effectiveness of electrocardiograms versus x-rays for the guided placement of central venous catheter tips?

KEY MESSAGE

ECG-guided CVC placement can improve the accuracy of CVC positioning compared with no-ECG guided positioning followed by post-procedural chest x-ray method. No relevant economic studies were identified.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including Ovid MEDLINE, PubMed, The Cochrane Library (2012, Issue 6), University of York Centre for Reviews and Dissemination (CRD), ECRI (Health Devices Gold) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and June 19, 2012.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications and evaluated the full-text publications for the final article selection, according to selection criteria presented in Table 1.

Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults requiring central venous catheter (CVC); also may be referred to as PICC line (peripherally inserted central catheter)</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>ECG (for example, Sapiens)</td>
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<tr>
<td>Comparator</td>
<td>X-ray</td>
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<tr>
<td>Outcomes</td>
<td>Clinical benefits: immediate CVC tip placement confirmation; appropriate (accurate) and consistent tip placement; reduced wait times for x-ray and radiology reports; improved process flow</td>
</tr>
<tr>
<td>Harms: improper placement resulting in DVT, entry into another vein, erosion of myocardia, arrhythmia</td>
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<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized controlled trials, economic evaluations</td>
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</table>
Exclusion Criteria

Studies were excluded if they did not satisfy the selection criteria in Table 1, if they were published prior to 2007, duplicate publications of the same study, or included in a selected health technology assessment or systematic review.

Critical Appraisal of Individual Studies

The quality of the included studies was assessed using Downs and Black checklist.¹⁴ For the critical appraisal of studies, a numeric score was not calculated. Instead, the strength and limitations of the study were described.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 234 citations. Upon screening titles and abstracts, 227 citations were excluded and seven potential relevant articles were retrieved for full-text review. One additional relevant report was retrieved from the grey literature. Of the eight potentially relevant articles, one randomized controlled trial (RCT) on the clinical effectiveness of ECG guidance for placement of CVC tip met the inclusion criteria. No cost-effectiveness studies were identified. The study selection process is outlined in a PRISMA flowchart (Appendix 1).

There were five studies that investigated the reliability of the use of ECG to guide the placement of CVC tips that was confirmed by post-procedural chest x-ray. These studies had no comparator arm, and therefore did not meet the inclusion criteria. They are listed in Appendix 2.

Summary of Study Characteristics

The study characteristics of the RCT are summarized in Appendix 3.

The study by Gebhard et al¹⁵ was a single-center, prospective, open-label RCT. A total of 300 adult patients (mean age = 50 years) undergoing elective surgery during daytime hours were enrolled to receive CVC as part of their anesthetic management. Patients were either randomized to the ECG group (CVC placement using ECG-guidance) or the non-ECG group (CVC placement without ECG-guided positioning). All patients were underwent chest x-ray immediately after the conclusion of surgery in either the postanesthesia recovery unit or in the intensive care unit. The radiologists who read the x-ray results were blinded to group assignment. The CVC position was judged correct if the tip was located either in the proximal portion of the superior vena cava (SVC), the middle portion of the SVC, or the atrio caval-junction. Positions in the right atrium or right ventricle and other positions were considered incorrect.

Summary of Critical Appraisal

The strengths and limitations of the RCT are listed in Appendix 4.

The study objective and main outcomes were explicit. Data were analyzed using both Student’s t-test and X² test. The radiologists who read the chest x-ray results were aware of the study protocol but blinded to group assignment. Patients in both groups were recruited from the same
hospital and were randomized to the intervention groups using internet-based computer program. Power calculation was reported. Several limitations included unclear description of patient baseline characteristics, and inability to determine if the study sample represented the entire population.

**Summary of Findings**

The overall findings are summarized below, and findings from the individual studies are provided in Appendix 5.

Overall, CVCs were positioned correctly in 142 patients (96%) in the ECG group and in 108 patients (76%) in the non-ECG group (p ≤ 0.001, 95% confidence interval [CI] not reported). Placement time was similar in both groups (7 versus 6 minutes). CVCs were significantly more often positioned in the middle of the superior vena cava in the ECG group compared with the non-ECG group (p ≤ 0.001, 95% CI not reported). In the ECG group, no CVCs were placed into the right atrium or right ventricle, whereas 14 CVCs (10%) in the non-ECG group were malpositioned into the right atrial or right ventricle (p ≤ 0.001, 95% CI not reported). The rate of CVC malpositioned into other locations was lower in the ECG group compared with non-ECG group (3% v 15%, p ≤ 0.001, 95% CI not reported). Fewer numbers of CVCs in the ECG group (2%) had to be corrected post-operatively according to chest x-ray compared with non-ECG group (14%, p ≤ 0.001, 95% CI not reported). No CVC was placed into the arterial system, and no pneumothorax was observed during CVC placements.

**Limitations**

The evidence was limited to one RCT. The study was an open label RCT which was left to the discretion of the anesthesia care team in performing CVC placement with or without ECG-guided positioning. The results may have been impacted by the experience and performance of the anesthesiologists. As well, radiographic interpretations of the CVC tip location by chest x-ray may be imprecise and subject to observer variability. The majority of CVCs (89%) were placed through the right internal jugular vein; therefore, no conclusion can be drawn regarding ECG guidance results when using other accessed routes such as the left internal jugular vein, right subclavian vein or left subclavian vein. Although overall incidence of arterial puncture, hematomas and pneumothorax was reported for the entire study population, the study did not clearly report major adverse events associated with each intervention. The trial design may have been inappropriate to detect adverse events.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING**

The number of direct head-to-head studies that compared ECG and x-ray methods in the placement CVC tips was limited. Evidence from one RCT suggests that ECG-based positioning of CVC can be more accurate than the post-procedural chest x-ray method. The success rate of the ECG guided for the placement of CVC tip was based mainly on the preferred access site at the right internal jugular vein, while the conclusion regarding the use of other access routes remains uncertain. No economic studies regarding the cost-effectiveness of ECG-based compared with chest x-ray in the correct placement of CVC tips were identified.

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References


APPENDIX 1: Selection of Included Studies

234 citations identified from electronic literature search and screened

227 citations excluded

7 potentially relevant articles retrieved for scrutiny (full text, if available)

1 potentially relevant report retrieved from other sources (grey literature)

8 potentially relevant reports

7 reports excluded:
- irrelevant population (1)
- no comparator (6)

1 report included in review
APPENDIX 2: Non-comparative Studies of Potential Interest


### APPENDIX 3: Characteristics of Included Clinical Study

<table>
<thead>
<tr>
<th>First Author, Publication Year, Country</th>
<th>Study Design</th>
<th>Patient characteristics, Sample Size (n)</th>
<th>Intervention</th>
<th>Comparators</th>
<th>Study Outcomes Measured</th>
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<tbody>
<tr>
<td>Gebhard et al. 2007&lt;sup&gt;13&lt;/sup&gt; US</td>
<td>Open-labeled prospective RCT, chest x-ray radiologists were blinded</td>
<td>Adult patients (N=300); mean age = 50 years; undergoing elective surgery; male to female ratio = 1:1 Excluded: known atrial fibrillation, pacemakers in place Ten patients were excluded from the statistical analysis:  - Radiologist report could not be obtained (n=3)  - CVC was accidently removed before x-ray (n=4)  - Abandoned placement of CVC (n=3)</td>
<td>Guidewire-ECG control (n=147) Chest x-ray after surgery</td>
<td>No-ECG (n=143) Chest x-ray after surgery</td>
<td>• Correct CVC positions • Final insertion depth • Number of venous puncture attempts • Incidence of premature ventricular contractions during CVC placement • Placement time • Complications (e.g., arterial puncture, hematoma, pneumothorax)</td>
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</tbody>
</table>

CVC=central venous catheter; ECG=electrocardiogram; RCT=randomized controlled trial
# APPENDIX 4: Summary of Study Strengths and Limitations

<table>
<thead>
<tr>
<th>First Author, Publication Year</th>
<th>Strengths</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>Gebhard et al. 2007”</td>
<td>- Hypothesis/objective was explicit&lt;br&gt;- Main outcomes to be measured were explicit&lt;br&gt;- Probability (p value) was reported for main outcome&lt;br&gt;- Radiologists who read chest x-ray to determine the main outcome were blinded&lt;br&gt;- Patients in both groups were recruited from the same hospital&lt;br&gt;- Patients were randomized to intervention groups using internet-based computer program&lt;br&gt;- Power calculation for primary outcome was calculated</td>
<td>- Patients characteristics were not clearly described&lt;br&gt;- Unable to determine if the included patients represent the entire population&lt;br&gt;- Unable to determine if patients were recruited from the same period of time</td>
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</tbody>
</table>
APPENDIX 5: Main Study Findings and Authors’ Conclusions

<table>
<thead>
<tr>
<th>First Author, Publication Year, Country</th>
<th>Main Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gebhard et al. 2007(^{13}) US</td>
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<tr>
<td></td>
<td>Outcomes</td>
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<tr>
<td></td>
<td>Overall correct CVC positions; % (n/N)</td>
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<tr>
<td></td>
<td>CVCs malpositioned into the right atrial or right ventricle; % (n/N)</td>
</tr>
<tr>
<td></td>
<td>CVCs malpositioned into other locations; % (n/N)</td>
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<tr>
<td></td>
<td>CVC had to be repositioned post-operatively according to chest x-ray; % (n/N)</td>
</tr>
<tr>
<td></td>
<td>Incidence of premature ventricular contractions; % (n/N)</td>
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<tr>
<td></td>
<td>Average final insertion depth for CVCs; mean ± SD</td>
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<tr>
<td></td>
<td>Insertion time; mean (range)</td>
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</table>

Authors’ Conclusions: “ECG guidance allows for more accurate CVC placement, and should be considered to increase patient safety and reduce costs associated with repositioning procedures” p.65

CVC=central venous catheter; ECG=electrocardiogram; NS=not significant; SD standard deviation