Near-Infrared Imaging in Intravenous Cannulation in Children: A Cluster Randomized Clinical Trial

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**Key Words**
peripheral catheterization, child, infrared rays, veins

**Abbreviation**
NIR—near-infrared

This trial has been registered with the Dutch Trial Register (identifier NTR2277).


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**What’s Known on This Subject:** Gaining intravenous access in children can be difficult. Recently, several near-infrared devices have been introduced attempting to support intravenous cannulation by visualizing veins underneath skin. Only one of those devices has been evaluated systematically thus far and results are inconclusive.

**What This Study Adds:** Although it was possible to visualize veins with near-infrared in most patients, the VascuLuminator did not improve the success of cannulation. An explanation is that the main problem is probably not localization of the vein but insertion of the cannula.

**Abstract**

**Objective:** Intravenous cannulation is a widespread medical procedure that can be difficult in children. Visualization of veins with near-infrared (NIR) light might support intravenous cannulation. Therefore, we investigated the effectiveness of an NIR vascular imaging system (VascuLuminator) in facilitating intravenous cannulation in children in the operating room.

**Methods:** This was a pragmatic, cluster randomized clinical trial in all consecutive children (0–18 years) scheduled for elective surgery and in need of intravenous cannulation at a tertiary pediatric referral hospital. Daily operating rooms (770 patients) were randomized for allocation of the VascuLuminator or control group. The primary outcome was success at first attempt; the secondary outcome was time to successful cannulation.

**Results:** Success at first attempt was 70% (171/246) with and 71% (175/245) without the use of the VascuLuminator ($P = .69$). Time to successful cannulation was 162 ($\pm 14$) seconds and 143 ($\pm 15$) seconds respectively ($P = .26$). In $83.3\%$, the vein of first choice was visible with the VascuLuminator.

**Conclusions:** Although it was possible to visualize veins with NIR in most patients, the VascuLuminator did not improve success rate or time to obtain intravenous cannulation. There are 3 possible explanations for this result: first, it could be that localization of the vein is not the main problem, and therefore visualization is not a solution; second, the type of system used in this study could be less than optimal; and, third, the choice of the patient population in this study could be inappropriate. Pediatrics 2013;131:e191–e197
Intravenous cannulation is one of the most widespread medical procedures performed in children. Especially in children, gaining access to a vein can be problematic, and in about a third of the patients multiple punctures are required. Multiple puncture attempts cause pain and distress, and increase the risk of complications, such as hematoma or nerve injury. Visualization of veins that are invisible to the naked eye could be an aid to facilitate intravenous punctures. To this purpose, ultrasound has been used, but with inconclusive results, mainly because the use of ultrasound requires skill and experience. Transillumination with visible (mostly red) light might be another option; however, penetration depth of visible light is limited and therefore most suitable for neonates. Near-infrared (NIR) light is known for its deep tissue penetration, and is therefore more suited to visualize veins in older children.

A previous study with a prototype of an NIR vascular imaging system showed it to be useful for blood withdrawal. In the current study, we hypothesized that success at first attempt would be higher and time of cannulation would be shorter when an NIR vascular imaging system is used as guidance during intravenous cannulation in pediatric surgical patients.

METHODS

The study was a pragmatic cluster randomized clinical trial, conducted in the operating room complex of a tertiary pediatric referral hospital, randomizing the assistance of NIR during intravenous cannulation. The present trial is registered at the Dutch Trial Registry (NTR2277).

The NIR vascular imaging system (VascuLuminator, De Koningh Medical Systems, Arnhem, NL), has been described in detail previously. In short, a small NIR light source is used to transilluminate the puncture site. The NIR light is processed by an NIR-sensitive camera, and projected on a display, located above the puncture site, showing a 2-dimensional image of the veins (Fig 1). A patent was filed by the University Medical Center Utrecht.

When the NIR vascular imaging system was allocated, the performer was obliged to use the NIR vascular imaging system to visualize the veins before the start of the intravenous cannulation. The device is an assisting tool that does not hamper normal visualization of vessels. It was left to the discretion of the performer whether to use the device during the actual skin puncture.

In the control group, intravenous cannulations were performed as usual without the guidance of any device. Intravenous cannulation (BD Venflon 18, 20, 22, 24 G, Franklin Lakes, NJ or Abbocott 20, 22 or 24 G, Abbott Laboratories, Chicago, IL) was most often performed after the child had been anesthetized using inhalation induction with sevoflurane by face mask. If the patient was awake during the procedure, a local anesthetic (EMLA, Eutectic Mixture of lidocaine and prilocaine, AstraZeneca, Södertälje, Sweden) was applied and covered with a plastic foil dressing for at least 60 minutes before intravenous cannulation. The cannulations were performed by experienced pediatric anesthesiologists and nurse anesthetists or by trainee anesthesiologists/trainee nurse anesthetists. The attending anesthesiologist decided which team member was to perform the cannulation before start of the cannulation, after allocation of the device, but before visualization of the veins with the NIR vascular imaging system.

Before the start of the study, there was a 3-week introduction period with the VascuLuminator in which it could be used in patients without any study recording and all members received training in operating the NIR vascular imaging system by the manufacturer. The VascuLuminator is designed to be intuitive in use, and the image on the screen is clear and easily interpretable. Therefore, it was not deemed necessary to implement long training sessions before the start of the study.

The study was designed as a pragmatic trial with randomization on the level of the anesthetic team (the performer). The presence and allocation of the NIR vascular imaging system at the operating complex was block randomized by computer in clusters of a week. Because only 2 NIR vascular imaging systems were available during the current study, each day 2 operating rooms (accommodating 2 surgical specialties) were randomized by computer to participate. The other operating rooms did not participate in the study on that day. Subsequently, all consecutive patients up to 18 years old, scheduled for elective noncardiac surgery in the selected operating rooms, were included. Because of this
subsequent randomization of the original cluster (the anesthetic team) by daily operating room (operated by 1 anesthetic team), the daily operating room is therefore the relevant cluster in the current study.

The study design and method of inclusion were approved by the Medical Ethics Committee. The Medical Ethics Committee waived the need for individual informed consent by the patients and parents because the intervention (use of the NIR vascular imaging system) would not harm the patient and the present pragmatic cluster randomized clinical trial is conducted on the level of the performer, not on the level of the individual patient. The performers were, at any time, allowed to use standard techniques during cannulation (such as palpation), besides visualization with the NIR vascular imaging system. Patient confidentiality was guaranteed in accordance with the Dutch law on personal data protection. Oral consent to participate in the study was obtained from all performers and recording of skills was anonymous (only profession of performer was recorded, not the name).

The primary outcome parameter in this study was success at first attempt (ie, the first attempt leads to a successful cannulation). An attempt was defined as every penetration of the skin with the needle. Redirection of the needle tip while underneath the skin was not counted as a separate attempt. Total time of cannulation was a secondary outcome. Timing, using a stopwatch, was started as soon as the search for a vein was initiated. Timing was stopped when the cannula was secured and could be flushed adequately with saline. Measurements were registered by self-report by a member of the anesthetic team not performing the cannulation. Visibility of the veins with the NIR vascular imaging system at the location of the first puncture was recorded and the performer registered the perceived helpfulness of the device (“helpful” indicates that the performer is of the opinion that, without the device, specific cannulation would probably not have succeeded). Patient characteristics (age, gender, weight and length, skin color, and awake or not), profession of the performer (anesthesiologist, nurse anesthetist, or trainee, which includes trainee anesthesiologists and trainee nurse anesthetists), location of the punctures, and surgical specialty were recorded. Weight and length were converted to BMI percentiles, or to weight-to-age percentiles when younger than 2 years old or if data on length were missing. Skin color was determined using the Fitzpatrick skin type scale, in which type V and type VI indicate a dark skin color.

Sample Size
In a previous study, we found that success at first attempt for intravenous cannulation in children is about 70%. An increase in success at first attempt to 85% with the use of the NIR vascular imaging system was considered to be clinically relevant. If clustering would not be taken into account at all, the relevant clinical effect could be detected by including a total of 270 patients (assuming 2-sided testing with a level of significance of .05 and a power of 80%). If clustering would be taken into account at the level of the performer (which would be too conservative in this situation), we would need 540 patients (assuming an intracluster correlation of 0.1, and 25 performers participating in the study). Because randomization is not strictly performed at the level of the performer but on the level of the daily operating room, the actual needed sample size lies between these 2 estimates. Therefore, our estimated sample size was selected at 400 patients. Assuming a dropout rate of 30% of the patients because of exclusion of patients or staff forgetting to complete a measurement form, we aimed to include 600 patients.

Statistical Analysis
SPSS statistical package (version 17, SPSS Inc, Chicago, IL) was used for all statistical procedures. Continuous data are presented with median and interquartile range and compared with a Mann-Whitney U test. Dichotomous data are presented as a ratio to the total and a percentage and compared with a Fisher’s exact test. Time to successful cannulation is described by a Kaplan-Meier log-rank test taking censored data (ie, unsuccessful cannulation) into account. A logistic regression and a Cox proportional hazards survival regression are used to generate odds ratios and hazard ratios with a 95% confidence. Pre-specified subgroup analyses were performed on patients younger than 3 years old and children with a BMI >85th percentile. Intracluster coefficients were calculated using variance estimations from a linear mixed model to evaluate the influence of clustering on outcomes. A P <.05 was considered statistically significant.

RESULTS
A total of 770 patients distributed among 179 daily operating rooms were included from May 2010 to November 2010. Seventy-seven patients were excluded because they already had a cannula in situ or their surgery was cancelled, whereas for another 199 patients both the primary and secondary outcomes were not registered (Fig 2). Demographics of patients with missing values were comparable in control and NIR groups: median age: 3.4 years (1.1–8.0) and 4.4 years (1.3–9.8; P = .21) respectively and percentage of males 64% (89/137) and 74% (98/132; P = .11) respectively.
Finally, 494 patients were analyzed (246 in the control group and 248 in the NIR group, Table 1 and Fig 2). Patient characteristics and other parameters were equally distributed between clusters and patients, with the exception of profession of the performer: anesthesiologists more often performed cannulations in the control group (34%) than in the NIR group (21%, \( P = .02 \)). There was no difference among the proportion of trainees in both groups.

The success at first attempt was 70% when the NIR vascular imaging system was used, compared with 71% in the control group (\( P = .69 \), Table 2). The intracluster coefficient for success at first attempt was very small (0.05), indicating that the variance within clusters was not very different from the variance between patients outside clusters. Fig 3 shows success at first attempt over a period of time for each subsequent group of 50 patients.

Time to successful cannulation in the NIR group was 162 (±14) seconds and 143 (±15) seconds in the control group (\( P = .26 \), Table 3 and Fig 4). Median total number of attempts was 1 (interquartile range: 1–2) in both groups, with a maximum of 10 in the control group and 12 in the NIR vascular imaging system group (\( P = .56 \)). Success at first attempt and time to successful cannulation in children younger than 3 years of age was not significantly different between both groups (\( P = .88 \), Table 2, and \( P = .36 \), Table 3). In children with a BMI or weight-to-age above the 85th percentile, success at first attempt and time to successful cannulation was also not significantly different (\( P = .79 \), Table 2, and \( P = .21 \), Table 3).

Adjustment of the outcomes for profession of the performer, to correct for potential bias, had little effect; for success at first attempt, the adjusted odds ratio (95% confidence interval) was 0.85 (0.57–1.27) and for time to successful cannulation the adjusted hazard ratio (95% confidence interval) was 0.84 (0.70–1.02).

In 145 (83.3%) of 174 patients, the vein of the first puncture was visible with the NIR vascular imaging system. The NIR vascular imaging system was recorded as “helpful” by the anesthetic team in 38 (21.6%) of 176 patients during the intravenous cannulation; these patients were 2.6 (1.1–5.4) years old, BMI/weight-to-age percentile was 0.53 (0.24–0.87) and 3 (7.9%) of 38 had a dark skin color. Success at first attempt in the group of patients in which the NIR vascular imaging system was

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**TABLE 1** Demographic Data With and Without the NIR Vascular Imaging System

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Control Group</th>
<th>NIR Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients (clusters(^a))</td>
<td>246 (74)</td>
<td>248 (75)</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Otolaryngologic surgery, patients/clusters</td>
<td>21/8</td>
<td>14/6</td>
</tr>
<tr>
<td>Ophthalmologic surgery, patients/clusters</td>
<td>32/8</td>
<td>28/10</td>
</tr>
<tr>
<td>Urologic surgery, patients/clusters</td>
<td>85/23</td>
<td>79/20</td>
</tr>
<tr>
<td>General surgery, patients/clusters</td>
<td>44/14</td>
<td>49/15</td>
</tr>
<tr>
<td>Reconstructive surgery, patients/clusters</td>
<td>34/10</td>
<td>38/10</td>
</tr>
<tr>
<td>Pediatric interventions, patients/clusters</td>
<td>13/3</td>
<td>15/5</td>
</tr>
<tr>
<td>Neurosurgery, patients/clusters</td>
<td>5/5</td>
<td>6/4</td>
</tr>
<tr>
<td>Maxillofacial surgery, patients/clusters</td>
<td>4/2</td>
<td>12/3</td>
</tr>
<tr>
<td>Orthopedic surgery, patients/clusters</td>
<td>8/3</td>
<td>5/2</td>
</tr>
<tr>
<td>Age in years, median (interquartile range)</td>
<td>4.9 (1.2 to 9.4)</td>
<td>5.0 (1.8 to 9.8)</td>
</tr>
<tr>
<td>Age range in years</td>
<td>0.0 to 18.5</td>
<td>0.0 to 18.7</td>
</tr>
<tr>
<td>Male/total (%)</td>
<td>144/246 (58.5)</td>
<td>160/248 (64.5)</td>
</tr>
<tr>
<td>BMI/weight-to-age percentile</td>
<td>0.46 (0.15 to 0.71)</td>
<td>0.49 (0.20 to 0.78)</td>
</tr>
<tr>
<td>Dark skin color/total (%)</td>
<td>5/248 (2.0)</td>
<td>13/248 (5.2)</td>
</tr>
<tr>
<td>Awake/total (%)</td>
<td>41/235 (17.4)</td>
<td>38/223 (17.0)</td>
</tr>
<tr>
<td>Location of primary puncture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand/total (%)</td>
<td>185/240 (77.1)</td>
<td>195/235 (83.0)</td>
</tr>
<tr>
<td>Foot/total (%)</td>
<td>36/240 (15.0)</td>
<td>37/235 (15.7)</td>
</tr>
<tr>
<td>Other/total (%)</td>
<td>22/240 (9.2)</td>
<td>14/235 (6.0)</td>
</tr>
<tr>
<td>Profession of performer(^b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesiologist/total (%)</td>
<td>78/229 (34.1)</td>
<td>47/223 (21.1)</td>
</tr>
<tr>
<td>Nurse anesthetist/total (%)</td>
<td>52/229 (22.7)</td>
<td>76/223 (34.1)</td>
</tr>
<tr>
<td>Trainee/total (%)</td>
<td>99/229 (43.2)</td>
<td>100/223 (44.8)</td>
</tr>
</tbody>
</table>

\(^a\) Clusters consist of daily operating rooms.

\(^b\) Significant at the .05 level.
found to be “helpful” was 74% (28/38) and not significantly different from patients in whom the NIR vascular imaging system was not considered helpful (67.6%, 92/138, \( P = .56 \)). Time to successful cannulation in this group was 213 (±47) seconds.

DISCUSSION

Recently, various NIR devices have been launched to support intravenous cannulation. Although it is generally believed that visualization of veins with NIR might aid intravenous cannulation, thus far only 1 NIR device (the VeinViewer; Christie Medical Innovations, Memphis, TN) has been evaluated systematically.\(^{16-18}\) In the current study, we evaluated the clinical use of another such device at the operating rooms of a tertiary pediatric referral university hospital. The Vascu-Luminator was able to visualize the veins in more than 80% of the patients and was rated helpful by the performer in 21.6% of the cases. Nevertheless, the use of the device did not result in a significant improvement in success at first attempt or time to successful cannulation. Even when the NIR vascular imaging system was considered helpful, the rate of success at first attempt was not significantly higher.

In interpreting our findings, several aspects have to be taken into account. First, we chose a pragmatic, cluster randomized clinical trial instead of a classic explanatory randomized clinical trial. An explanatory randomized clinical trial is generally considered the gold standard to evaluate efficacy of an intervention, but may lack external validity.\(^{19}\) For our purpose of evaluating the clinical effectiveness of a device developed as an assisting tool, which cannot be isolated from daily clinical practice, a pragmatic trial is the most fitting choice. The minimal alteration of the standard clinical practice with this design (including use of a heterogeneous group of users, minimal intervention in the usual care, and a minimum of exclusion criteria) maximizes external validity.\(^{20}\) The wide range of performers of the cannulations may add confounding data but is in agreement with routine clinical practice in which multiple anesthesiologists are involved with intravenous cannulation. Another advantage of randomization on cluster level was avoiding the risk of “contamination” (ie, the VascuLuminator is used in a patient who is not randomized to the VascuLuminator group, but where it is deemed to be useful), because the VascuLuminator was not available at the operating complex on control days.

Second, about 25% of the forms were not completed. We have strong reasons to believe that these missing data would not be a source of bias. Missing data were most likely because of the anesthetic team forgetting to complete the measurements, as self-report was used to collect the data. Furthermore, the number of incomplete forms was distributed evenly over both groups and demographics of the complete forms were equally distributed. Furthermore, the success rate in the current study is comparable to the success rate in a previous study from our group in the same situation (varying between 70% and 73% in both studies).\(^{3}\)

Third, the nurse anesthetists were more likely to perform a cannulation in the group with the VascuLuminator compared with anesthesiologists than

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**TABLE 2** Success at First Attempt (%) and Risk Difference With a 95% Confidence Interval in Both Groups

<table>
<thead>
<tr>
<th></th>
<th>Control Group Ratio/Total (%)</th>
<th>NIR Group Ratio/Total (%)</th>
<th>Risk Difference (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>175/245 (71.4)</td>
<td>171/246 (69.5)</td>
<td>1.9% (–6.1 to 9.9)</td>
</tr>
<tr>
<td>Patients &lt;3 y</td>
<td>52/99 (52.5)</td>
<td>47/86 (54.7)</td>
<td>2.1% (–12.1 to 16.2)</td>
</tr>
<tr>
<td>Patients ≥55th percentile(a)</td>
<td>21/28 (75.0)</td>
<td>28/40 (70.0)</td>
<td>5.0% (–16.9 to 24.8)</td>
</tr>
</tbody>
</table>

\(a\) BMI or weight-to-age \(z\)-score.

---

**FIGURE 3**

Success at first attempt with a 95% confidence interval for each subsequent group of 50 patients in both control and NIR groups.
in the control group and this could be a source of bias. This might be because the attending anesthesiologist, deciding on who was to perform the cannulation, was aware of allocation of the device, but before visualization of the veins with the NIR vascular imaging system; however, adjustment by performer did not significantly alter the results. Also, in our previous study, we showed that the influence of profession of the performer is relatively small, and that nurse anesthetists have a higher success at first attempt than anesthesiologists.\(^3\) Furthermore, almost half of the cannulations were performed by trainees, who were equally distributed over both groups.

Fourth, most children in the current study were sedated. It is debatable whether awake children are more difficult to puncture than sedated children.\(^3\) If so, it is possible that results with the NIR vascular imaging system in the present population might not be applicable to awake patients, as intravenous cannulation in awake children might require skills other than those needed in sedated children.

The absence of clinical improvement with the NIR vascular imaging system in the current study might be related to either the visualization of veins in general, the type of NIR vascular imaging system used (in particular the way the vein images are displayed: on-screen versus projected on the skin), the characteristics of the patient population, or the effect of a learning curve. An explanation might be that difficult insertion of the cannula, instead of localization of the vein, is the primary cause of failure of intravenous cannulation in children. Unfortunately, palpability and visibility of the vein without the NIR device was not taken into account in this study. However, patients in whom the NIR vascular imaging system was deemed to be helpful can be considered a proxy for lack of visibility and palpability of the vein. Nonetheless, there was also no significant improvement in success at first attempt in this “difficult” subgroup.

It might also be possible that the type of NIR vascular imaging system used in the current study is an explanation for the absence of improvement on clinical outcome. The VascuLuminator presents an image of the veins on a display, which requires extra skills in eye-hand coordination while puncturing a vein. On the other hand, most anesthesiologists are familiar with this skill by the increasing use of ultrasound for central venous cannulation and peripheral nerve blocks.\(^{21,22}\) Presently, there are 2 other devices on the market, the VeinViewer and the AccuVein (AccuVein LLC, Cold Spring Harbor, NY), that attempt to bypass this problem by projecting the image of the veins directly onto the puncture site. A disadvantage of that solution is the resulting absence of normal vision on the puncture site. Also, detail might be lost and artifacts might be more likely to occur by projecting a simplified image of the veins on the puncture site. Three recent clinical trials on the use of one of those NIR vascular imaging systems (the VeinViewer) in pediatric patients were also unable to demonstrate an improvement in success.

![Figure 4](image-url)

**TABLE 3** Time to Cannulation in Seconds (±SD) and Hazard Ratio with a 95% Confidence Interval in Both Groups

<table>
<thead>
<tr>
<th></th>
<th>Control Group Mean (±SD)</th>
<th>NIR Group Mean (±SD)</th>
<th>Hazard Ratio (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>143 (±15)</td>
<td>162 (±14)</td>
<td>0.90 (0.75 to 1.08)</td>
</tr>
<tr>
<td>Patients &lt;3 y</td>
<td>228 (±35)</td>
<td>257 (±33)</td>
<td>0.78 (0.65 to 1.17)</td>
</tr>
<tr>
<td>Patients ≥85th percentile*</td>
<td>118 (±23)</td>
<td>178 (±36)</td>
<td>0.74 (0.45 to 1.21)</td>
</tr>
</tbody>
</table>

A hazard ratio >1 indicates a higher chance of successful cannulation within a certain period of time when the NIR vascular imaging system is used.

* BMI or weight-to-age z-score.

**FIGURE 4** Kaplan-Meier plot showing cumulative cannulation rate versus time (P < .26). Control group (solid line) and NIR group (dotted line). The marks indicate procedures that did not succeed. Only part of the plot is shown.
at first attempt in a general population of pediatric patients. In 2 of those trials, however, an effect was seen in respectively a subgroup of patients younger than 2 years old and a subgroup of patients with difficult veins. The results from these studies seem to indicate another reason for the lack of effect found in the current study: the characteristics of the patient population. It might still be possible that NIR vascular imaging is useful in certain subgroups of patients who are difficult to cannulate. The Vasculuminator was originally developed to overcome difficulties of vein localization by a low visual contrast between skin and vein in children with a very dark skin color. It is possible that in these patients, visualization of veins with NIR techniques is more useful. Unfortunately, only 18 patients with a dark skin color (4%) were included in the current study, a number too small to draw any meaningful conclusions regarding the benefits of vein visualization in children with a dark skin color.

As for the effect of a learning curve on the results, the device is developed to be very intuitive in use, with a clear and easily interpretable image of the veins on the screen and the study was preceded by an introduction period with the device. Furthermore, Fig 4 gives no indication to a change in success at first attempt over time.

CONCLUSIONS
Visualization of veins with NIR light by the Vasculuminator did not improve the clinical success rate of intravenous cannulation in a general pediatric population. There is still a persisting clinical problem (ie, the relatively high rate of failures at first attempt) in intravenous cannulation in children.

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