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Original Article

Improvement of a prototype device using near-infrared light to visualize invisible veins for peripheral intravenous cannulation in healthy subjects

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Abstract

Background: Puncturing invisible peripheral veins with the naked eye is not always successful and may cause nerve damage. Some techniques have been used for visualizing veins; however, none of them are widely used in clinical practice. We developed the prototype of a vein visualization device using near-infrared light that qualitatively improved the vascular imaging process. The purpose of this study was to compare the visualization capability of invisible veins between the AccuVein® and the prototype.
Design: This is an observational cross-sectional study.
Materials and Methods: We identified invisible veins of the upper extremity in healthy women aged 20–39 years, without avascularization. The diameter and depth of the veins were measured using an ultrasonic diagnostic device, without the need for skin contact, and the transducer ultrasonic diagnostic device. A nurse subjectively evaluated vein visibility of images that have been taken with each device.
Results: We analyzed 71 veins from 18 participants. The mean age was 31 years (95% CI: 29–33 years), and the mean BMI was 21.7 kg/m2 (95% CI: 21.2–22.3 kg/m2). The vein visualization rate was 33.8% with the AccuVein® (24/71, 95% confidence interval: 23.9–45.4%) and 74.6% with the prototype (53/71, 95% confidence interval: 63.4–83.3%). The visualization rate was significantly higher with the prototype than with the AccuVein® ($p = 0.001$). The mean depth of visualized veins was 3.5 mm using the AccuVein® (95% confidence interval: 3.0–4.1 mm) and 4.4 mm using the prototype (95% confidence interval: 4.0–4.9 mm). The veins visualized with the prototype were significantly deeper than those visualized by the AccuVein ($p = 0.023$).
Conclusion: The visualization capability of the prototype was superior to that of the AccuVein®, with regard to visualization rate and depth. By increasing the prototype's range of visualization depth, our prototype showed an improved visibility of deep veins.

Key Words

Near-infrared light, peripheral vein, visibility, cannulation, image processing

Introduction

Visible veins are recommended to enable peripheral intravenous access with a high degree of safety and certainty [1,2]. However, some veins are difficult to locate because they lack characteristic color and venous distention toward the skin surface when a tourniquet is applied. Puncturing invisible peripheral veins with the naked eye is not always successful, and it may cause nerve damage [2-4]. Several devices have been used and developed for venous visualization using ultrasonography and near-infrared (NIR) rays [5-10]. Medical care providers require visual guidance when puncturing invisible veins,

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so these devices allow them to access invisible peripheral veins safely and accurately. Peripheral intravenous access conducts many clinical situations, for example emergency, children, older adult, and home care. However, these devices are not widely used in clinical situations. The reason for this is that these devices can not be used for easy and acquired image of these devices is illegible. Ultrasonography has been used for peripheral intravenous access, but it requires skill and extra assistance, is expensive [11] , and has the risk of arterial puncture [7, 12] . Other techniques include NIR light-reflecting devices, and their operability has improved in recent years [9, 10, 13] . However, penetration depth and the quality of the vascular images are limited [14] .

The basic concepts of a venous visualization device in clinical practice are the device's operability and vein visibility. The use of NIR light may be a better solution if its use improves vein visibility. Thus, our department developed a prototype device based on the reflection of NIR light [14] . We improved the prototype device by adding image processing [15] . An important role of a vein visualization device is to enable successful invisible intravenous access by making invisible veins visible. Careful attention should be paid to prevent potential patient suffering by puncturing without evaluating vein visibility. However, few studies have evaluated the capability of devices in facilitating the visualization of invisible veins.

We predicted that our prototype would have superior capability to visualize invisible peripheral veins. Therefore, in this study, we compared the visualization capabilities of invisible peripheral veins between our prototype and that with the AccuVein® , and thus determined whether our prototype more was superior the AccuVein® .

Materials and methods

The study protocol was approved by the Medical Ethics Committee of Kanazawa University, and written informed consent was obtained from all subjects.

1. Study design

We conducted an observational cross-sectional study using prospective data collection.

2. Samples

The subjects enrolled in this study were healthy women aged 20–39 years; these healthy women had a substantial amount of intracellular water and subcutaneous fat content, and thus, the peripheral veins of these participants were prone to run deep. So, we predicted these peripheral veins become invisible. Further, we selected healthy subjects because NIR rays have been reported to raise body temperature at the investigated site [16] . We included women who fit our inclusion criteria; we explained to the subjects the study using an explanatory document and obtained their informed consent for inclusion.

Participants who had undergone venipuncture of their arms in the previous 2 days and those who had a skin disorder of their arms were excluded from the study. Peripheral veins, which were running through the investigational site, were observed for venous characteristic color or venous distention at the skin's surface.

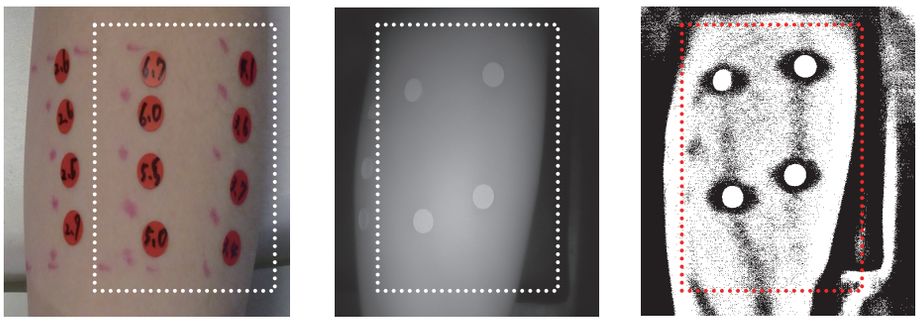
3. Investigated veins

The investigational site was located on the anterior forearm 2–7 cm from the elbow joint where peripheral intravenous cannulation is commonly used. We investigated the invisible cephalic vein, median veins/ median cubital vein, and the basilic vein running through the investigational site. Invisible veins were defined as follows: no color characteristic of vein and the absence of venous distention at the skin surface when a sphygmomanometer was applied to the upper arm for 20 s at a pressure of 80 mmHg. This duration and pressure was reported to be effective for vein dilation [17] . After vein visibility was assessed, the sphygmomanometer was removed to expand the peripheral veins.

4. Devices

1) Improvement of a prototype device

The prototype device was improved at our department based on the reflection of NIR light [14] . It comprises a ring of NIR light-emitting diodes (LEDs) with a wavelength of 850 nm to illuminate the object and a NIR-sensitive camera with 8-bit pixel format supporting 1,296 × 964 at 18 frames per second (fps) . The camera was connected to and controlled by an IBM compatible personal computer (PC) via a USB 2.0 connection. The video resolution was set to 640 × 480 at 15 fps with image processing of the applied local thresholding technique [15] . This image processing was effective for improving the image quality (Figure 1a – 1c) . However, we could not find previous studies that applied this image processing to peripheral veins. The vascular image was displayed on an 8.4-inch liquid crystal display. The prototype device was



(a) (b) (c)

Figure 1. (a) Still images of the two or three veins running longitudinally along the red dot markings taken with a digital camera. The numbers written on the red stickers between the markings indicate the depth of the vein observed using the ultrasonic diagnostic apparatus. (b) A still image taken with the prototype device before image processing. The two target veins are captured using the prototype device with the seal up and down, respectively. (c) A still image after image processing.

used 15–20 cm above the skin's surface at a right angle (perpendicular) to the vein (Figure 2a).

2) Comparison with the AccuVein®

The AccuVein® (AV300; Avant Medical, Cold Spring Harbor, NY, USA) was used for comparison to our prototype. The reason we selected this devices was because this device is most prevalent in clinical. This device is based on the principle of reflection, and the vascular image via the NIR laser light projects the resulting image on the puncture site itself, using light with a wavelength of 642 to 745 nm.[17] The AccuVein® was positioned 18–30 cm above the investigated site at a right angle (perpendicular) to the vein (Figure 2b).

5. Evaluation of vein visibility

Before using the devices, the evaluation of vein visibility was described by four ranks: visible, slightly visible, poorly visible, and not visible. Visible or slightly visible veins were referred to as visible veins, while not very visible or not visible veins were referred to as invisible veins.

Visibility evaluation of the vein image obtained by the devices was also described by four ranks: visible, slightly visible, poorly visible, and not visible. Visible or slightly visible veins were referred to as visualized vein, while not very visible or not visible veins were referred to as not visualized vein.

In a previous study, the inter-rater agreement (κ-value) was moderate on vein visibility[18]. In our preliminary study, to validate the subjective evaluation for inter-rater reliability, two nurses analyzed 50 consecutive invisible peripheral veins. The κ-value was good for the AccuVein® (0.75, 95% confidence interval [CI]: 0.57–0.94). Therefore, only one nurse with extensive experience with venipuncture (10 years) assessed the vein visibility. We did not explain to the nurse which device was our prototype.

6. Measured variables and measurement methods

When evaluating the vein visibility, the local illuminance and temperature of the investigation room of participants belonging to the institution were measured. The

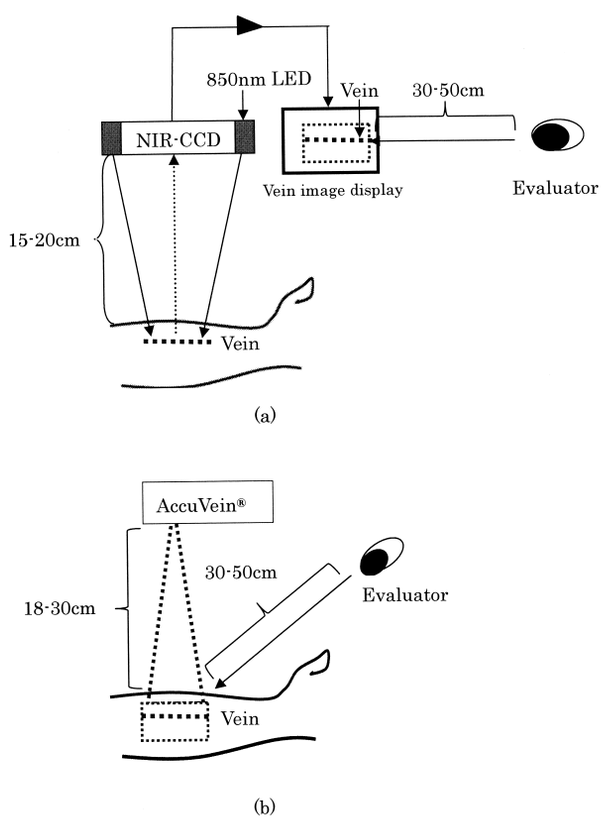


Figure 2. Appearance of two devices (a) the prototype (b) the AccuVein®

temperature of the water in which the subjects' anterior forearm and the ultrasonic diagnostic device's transducer were soaked was measured to establish environmental parameters.

Variables of the investigated vein

First, subjects' age, height, and weight were measured to calculate their body mass index (BMI, kg/m^2) . The skin color near the investigated vein was measured using a colorimeter (Handy Spectrophotometer NF 333; Nippon Denshoku Industries Co., Ltd., Tokyo, Japan) . The Commission International de l'Eclairage (CIE) L*a*b* values are most commonly used for the quantification of skin color. The diameter and depth of the investigated veins were measured using an ultrasonic diagnostic device with a 15-MHz linear transducer (MyLab Five, Hitachi Medical Corporation, Tokyo, Japan) to obtain short axis views. To prevent the pressure from the transducer on the vein from affecting the measurement of vein depth, the forearm of the subjects and the transducer were placed in water heated to 37° C, and the transducer was used 1 cm above the investigated site (Figure 3) . After the diameter and depth of the investigated vein were measured, the subject removed their forearm from the water. Then, the nurse evaluated the vein visibilities of the vascular image of the investigated vein acquired with the AccuVein® and the prototype device.

7. Primary data analysis

The primary endpoint was compared to the visualization rate of the investigated veins between the two devices. The sub-endpoint was compared to the visualized veins between the two devices according to the following: 1) Variables with significant differences between the visualized and not visualized veins using the AccuVein® or the prototype; and 2) Variables with significant differences when comparing visualized veins between the AccuVein® and the prototype. We performed univariate analysis in order to extract candidate variables for allowing the comparison of visualized veins between the two study devices using a permissive significance level of $p < 0.1$. Because some variables might have no significant difference between visualized veins and non-visualized veins. Those variables were considered to have a high clinical plausibility for difference visualizations of each device.

For quantitative data, the mean (interquartile range [IR]) or 95% CI was calculated. McNemar's test was used to compare the visualization rate of each device, and Student's t-test was used to compare visualized veins between each device. Statistical analysis was performed using JMP® software, version 9.0 (SAS Institute Inc., Cary, NC, USA) .

8. Sample size calculation

In our preliminary study, the visualization rate was 43.4% for the AccuVein® and 83.3% for the prototype [19] . Therefore, we estimated that a sample size of 35 veins would identify a 40% difference in vein visualization rate with a two-tailed alpha-value of 0.05 and a power of 0.80.

Results

Eighteen subjects were enrolled. The mean age was 31

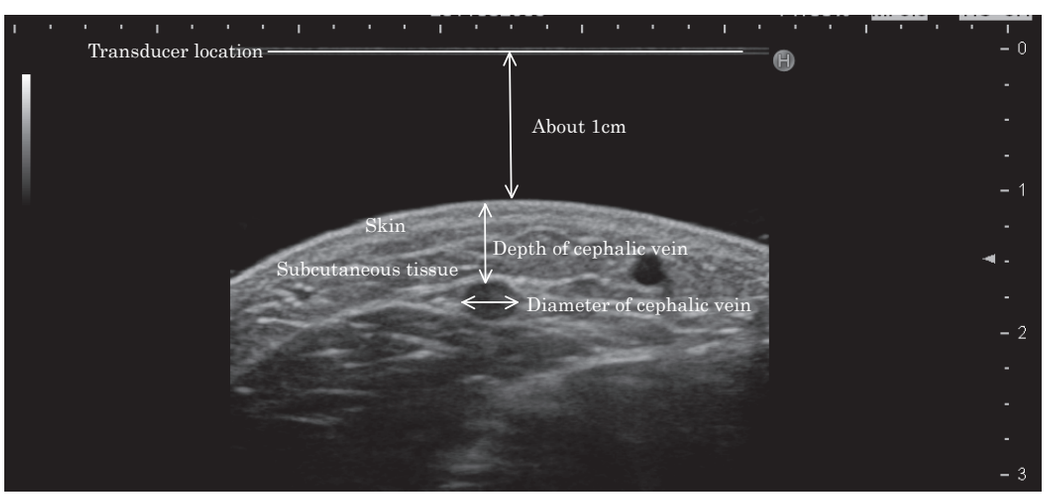


Figure 3. Ultrasound image of a vein in the short-axis view taken using the ultrasonic diagnostic device with a 15-MHz linear transducer. The vein is the black circle in the center of the image. As the subject's arm is immersed in water, the skin's surface and the position of the ultrasound probe transmission are separated by approximately 1 cm.

years (95% CI: 29–33 years), and the mean BMI was 21.7 kg/m2 (95% CI: 21.2–22.3 kg/m^2). All subjects completed the study. No participants showed an increase in the temperature of their skin at the investigated site, which was illuminated by our prototype device.

The temperature of the investigation room ranged from 20–23℃. The local illuminance was 780–850 lux and met the Z9110 (750–1,500 lux), which is the illuminance standard for visual inspection and injection in hospitals, as specified by the Japanese Industrial Standards Committee. When the ultrasonic diagnostic device was used, the water temperature ranged from 34–37℃.

We investigated 72 veins. One vein was excluded from statistical analysis because it was located 9.5 mm under the skin's surface and was determined as "not visualized" by the AccuVein® and the prototype device. We had thought that visualizing vascular with around 10 mm depths was not needed because the minimum value of artery depth was 10 mm [19]. Therefore, we directly analyzed 71 veins.

The mean diameter of the investigated veins was 2.7 mm (95% CI: 2.5–3.0 mm), and the mean depth was 4.6 mm (95% CI: 4.2–5.0 mm). Regarding the color of the skin, the mean values for L*, a*, and b* were 62.34 (95% CI: 61.95–62.74), 2.0 (95% CI: 1.7–2.3), and 9.6 (95% CI: 9.3–10.0), respectively.

1. Comparison of visualization rates between the devices

The visualization rate was 33.8% (24/71, 95% CI: 23.9–45.4%) with the AccuVein® and 74.6% (53/71, 95% CI: 63.4–83.3%) with the prototype. The visualization rate was significantly higher with the prototype than with the AccuVein® (p = 0.001).

2. Comparison of vein visibility using the devices

1) Extraction of suitable candidate variables from the differences in vein visibility

Tables 1 and 2 show the results of the univariate analysis for assessing candidate variables for vein visibility using the AccuVein® and the prototype device, respectively. Based on this analysis, the suitable candidate variables for assessing vein visibility were diameter (using the AccuVein®) and depth (using the AccuVein® and the prototype).

2) Comparison of the diameter and depth of visualized veins

According to Table 3, the prototype device was able to visualize veins at a significantly deeper depth than the AccuVein®. The mean diameter of the visualized veins was 2.5 mm using the AccuVein® (95% Cl: 2.1–2.8 mm) and 2.7 mm (95% Cl: 2.4–2.9 mm) using the prototype. There was no significant difference in the AccuVein® and our prototype (p = 0.343). The mean depth of visualized veins was 3.5 mm (95% Cl: 3.0–4.1 mm) using the AccuVein® and 4.4 mm (95% Cl: 4.0–4.9 mm) using the prototype. The depth of the visualized veins using the prototype was significantly deeper than the AccuVein® (p = 0.023).

Table 1. Comparison of vein visibility on AccuVein®

Variables	Visualized vein (n=24)	Not visualized vein (n=47)	p
Mean (95% confidence interval)			
Vein diameter (mm)	2.5 (2.1-2.8)	2.9 (2.6-3.2)	0.074
Vein depth (mm)	3.5 (3.0-4.1)	5.2 (4.7-5.6)	<0.001
Skin color L*	62.72 (61.80-63.62)	62.18 (61.75-62.60)	0.211
Skin color a*	1.91 (1.40-2.43)	2.00 (1.66-2.35)	0.781
Skin color b*	9.30 (8.49-10.10)	9.79 (9.40-10.19)	0.212

Student-t test

Table 2. Comparison of vein visibility on the prototype

Variables	Visualized vein (n=53)	Not visualized vein (n=18)	p
Mean (95% confidence interval)			
Vein diameter (mm)	2.7 (2.4-2.9)	2.9 (2.5-3.4)	0.318
Vein depth (mm)	4.4 (4.0-4.9)	5.2 (4.5-5.9)	0.079
Skin color L*	62.50 (62.03-62.98)	61.91 (61.17-62.64)	0.179
Skin color a*	1.92 (1.59-2.26)	2.11 (1.56-2.67)	0.552
Skin color b*	9.46 (9.03-9.90)	10.11 (9.47-10.75)	0.109

Student-t test

Table 3. Comparison of the diameter and depth of visualized veins

Variables	AccuVein® (n=24)	Prototype (n=53)	p
Mean (95% confidence interval)			
Diameter (mm)	2.5 (2.1-2.8)	2.7 (2.4-2.9)	0.343
Depth (mm)	3.5 (3.0-4.1)	4.4 (4.0-4.9)	0.023

Student-t test

Discussion

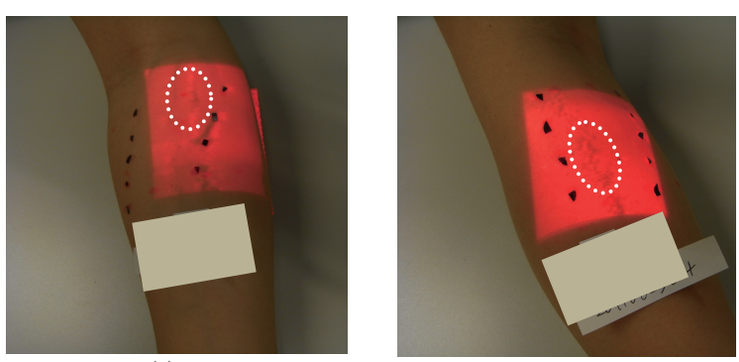
Our study has two important observations: First, the visualization rate was approximately 75% with the prototype device, which was significantly higher than that of the AccuVein®. Second, the prototype device could enable visualization of significantly deeper veins than the AccuVein®. These observations suggest that the prototype device is superior to the AccuVein® in terms

of venous visualization capability.

Although we enrolled healthy subjects, our results for the visualization rate are of practical value because the investigated site was a site of catheterization, the investigated vein had an extrapolated condition of being invisible, and a single person rated the visibility of the vein, and since we made a decision based on the definition of vein visibility, all investigated veins were considered invisible. The literature on the visualization rate of invisible veins when using vein visualization devices is limited. Our visualization rate with the prototype device and the AccuVein® was about 20–60% lower than the data obtained using other devices, including the AccuVein® alone, the VeinViewer, and the VascuLuminator, in previous studies [21, 22] . These previous studies do not accurately represent the visibility of the investigated veins in detail, the vein before using the device and whether it was visible or not, the evaluation methods of vein visibility, the visualization rate, and the investigated site. Therefore, there is a possibility that the veins in previous studies were easily visible by venous distention at the skin's surface and the characteristic color of the vein. It is inferred that our investigated veins ran deeper. In a previous study that did not use a vein visualization device, the invisible veins were deeper than the depth of the visible veins [20] . The challenges of using near-infrared light are penetration depth and the quality of visibility, which are limited [16] . Therefore, we surmise that our investigated veins traveled deep and were difficult to visualize. The visualization rate with the AccuVein® was significantly lower than the prototype. The artifact and noise associated with the AccuVein® may have affected the subjective evaluation of vein visibility (Figure 4a –4b) , and the depth of the visualized vein with the AccuVein® was shallower than with the prototype. We describe the difference in the depth of the visualized veins between the devices in the preceding text.

Our newly acquired rate of venous depth and diameter are free from the influence of venous buckle caused by pressure from the transducer of the ultrasonic diagnostic device, because we used heated water and placed the transducer 1 cm above the skin's surface. Long-wavelength and image processing function with our prototype affected the change in depth of the visualized veins. It operated at a high ratio of visualized veins and width of visualization range. However, the depth of visualized veins with our prototype does not offer significant improvements over those of visualized veins with the AccuVein® . We need to visualize the vein, but need not visualize the artery using the devices. That is distinguished by depth. The veins are less than 10 mm depth, and the arteries are more than 10mm depth [20] . Our prototype has not been able to visualize the vein of a little less than 10mm depth. The visualization range of not visualized veins needs to be examined in future studies.

Our prototype posed challenges for vein visualization. The visualization rate of approximately 75% is not sufficient for clinical practice. Health care workers expect to make invisible veins visible always using visualization device. The maximal depth at which veins could be visualized with the AccuVein® was 5.9 mm, and that with the prototype was 8.9 mm. However, the depth of not visualized veins with the AccuVein® and the prototype was shallower than the maximal depth of the visualized



(a) (b)

Figure 4. (a) A still image with an artifact. The vein appears dark due to the light absorption characteristics of the hemoglobin, but a shiny line similar to a running vein can be observed at the site where the vein is absent. (b) A still image with noise. Noise at the position of the vein could not be determined and is observed in the middle of the forearm middle.

veins of the two devices. The causes of vein visualization instability are uncertain from our results. Future work is needed to develop technology that more accurately visualizes the range of depth of invisible veins.

Limitation

We did not explained to the nurse which is the prototype. However, the nurse would have been able to predict which one prototype, so there is a possibility of observer bias.

A number of data sets were obtained from each subject, which potentially influenced the study findings. Regarding factors affecting venous visualization, we only assessed the attributes of the investigated veins and did not assess the effect of material used and the appropriate use of materials in more detail for venous visualization.

We did not perform intravenous access for catheter placement or blood drawing in the clinical setting on the investigated veins in ours study. To further verify the results, future clinical studies should be performed.

Conclusion

We found that approximately 75% of invisible veins could be visualized using our prototype device, which was significantly higher than that with AccuVein® . Additionally, deeper veins could be visualized using our prototype device than that with the AccuVein® . In the future, by increasing the prototype's range of depth, we could improve the visibility of deep veins and make our prototype intravenous access easier and more successful.

Contributions

Study design and data collection: KK and SJ; data analysis: KK and SJ; and manuscript preparation: KK, SJ, NK, MT, and NT.

Disclosure

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近赤外光を用いた静脈可視化装置の改良 －目視困難なカテーテル留置用末梢静脈における可視性評価－

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要　旨

【背景】

点滴療法などに使用している末梢静脈内カテーテル留置法は対象静脈が目視困難な場合、穿刺の成否、神経損傷等、合併症発生の頻度に影響を及ぼす。これまでいくつか静脈可視化技術が開発されてきたが、臨床に普及しているものはない。我々は臨床で重要視される静脈可視性と操作性をコンセプトに、本研究に先立ち近赤外光を用いた試作機を作成した。だが静脈可視性に課題が残ったため、画像処理機能を加え改良した。本研究の目的は改良した試作機の静脈可視化性能を AccuVein® と比較評価することである。

【方法】

対象者は年齢 20-39 歳の健常女性とした。対象静脈は対象者の前腕部を走行する非駆血下の目視困難静脈とした。対象静脈の血管径、深さ等を計測後、対象静脈に試作機と AccuVein® で透視した静脈画像を主観的に評価した。

【結果】

対象者は 18 名で、平均年齢は 31 歳（95% 信頼区間 : 29–33 歳）、BMI の平均は 21.7 kg/m2（95% CI: 21.2–22.3 kg/m2）であった。静脈可視化率は、試作機が 74.6%（53/71、95% 信頼区間 :）、AccuVein® では 33.8%（24/71、95% 信頼区間 : 23.9-45.4%）で有意に試作機が高かった（p< .001）。可視化静脈の深さの平均は、試作機が 4.4 mm（95% 信頼区間 : 4.0-4.9 mm）、AccuVein® では 3.5 mm（95% 信頼区間 : 3.0-4.1 mm）で有意に試作機の可視化静脈が深かった（p= .023）。

【結論】

これらの結果は有意に AccuVein® より試作機の静脈可視化性能が高いことを示す。試作機は可視化する静脈の深さ範囲が拡大し、静脈可視化率が向上したといえる。