Original Article

A randomized controlled trial comparing the AccuVein AV400 device to standard insertion technique for peripheral intravenous cannulation by experienced nurse anesthetists in obese patients undergoing elective surgery

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Abstract

Introduction: Obesity is a predictive factor for difficulty in peripheral intravenous insertion. The AccuVein AV400 device was developed to assist in peripheral vein identification and venipuncture. It can identify peripheral veins lying 10 mm subcutaneously using near infrared laser light. Objective was to evaluate the efficacy of the AccuVein AV400 device in improving the first-time success rate of peripheral intravenous cannulation in obese patients.

Method: Seventy-two patients with a body mass index (BMI) of 30 kg/m^2 or more were randomized into two groups; the AV400 group (using the AccuVein AV400 device for peripheral venous insertion) and a standard group (using the naked eye and/or palpation for peripheral venous insertion). The providers were three experienced nurse anesthetists. An observer recorded the number of attempts to successful cannulation and the time between tourniquet application and successful cannulation. Failure was defined as when more than four cannulation attempts were done in either technique.

Result: The BMIs of the two groups were comparable [33.7 $\pm$ 4.6 kg/m^2 in the AV400 group and 34.0 $\pm$ 4.6 kg/m^2 in the standard group; ($p = 0.77$)]. There was no significant difference in the first-attempt success rate between the AV400 group (52.8%) and the standard group (58.3%) ($p = 0.81$). The time to success was 41.5 (17.5 - 62.5) seconds (95% CI, 36.1 - 115.8) using the AV400 device and 77 (27 - 120) seconds (95% CI, 57.3 - 214.3) with the standard technique ($p = 0.12$).

Discussion and Conclusion: Although the AccuVein AV400 improved visualization of the peripheral veins, we found no statistically significant difference in first-attempt success rates between standard cannulation and the use of the AccuVein AV400 device in unselected obese patients.

Key words: Obesity, Peripheral venous access, Intravenous cannulation, Near-infrared light, AccuVein AV400

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Introduction

Peripheral intravenous cannulation is one of the most common procedures performed on patients who are scheduled for surgery under anesthesia. Obesity is one of the predictive factors of difficult intravenous (IV) cannulation.[1 - 4] Adipose tissue causes peripheral veins to be located deep in the subcutaneous tissue and therefore difficult to visualize or palpate. The results of difficult cannulation events are patient discomfort, increased cost, increased time required for the cannulation[4] and the need for central venous cannulation which is an invasive procedure, thus causing or worsening patients' needle phobia.

Many techniques have been used on types of patients known to be difficult for peripheral intravenous cannulation, including newborns, dark-skinned patients, burn victims, malnourished patients and obese patients.[5] These techniques include active warming, glyceryl trinitrate ointment, near infrared devices,[6 - 8] and ultrasonography,[9] among others.

The AccuVein AV400 (AccuVein Inc., Huntington, New York, United States) device detects the haemoglobin in the vessels by red and infrared light reflection and shows a vasculature map.[10] (Figure 1) To empirically determine whether the AccuVein AV400 device (AV400) improves the success rate of intravenous cannulation in obese patients, we conducted a randomized, controlled trial. Our primary outcome measure was the success of the first attempt at cannulation; our secondary outcome measure was time to successful IV cannulation.

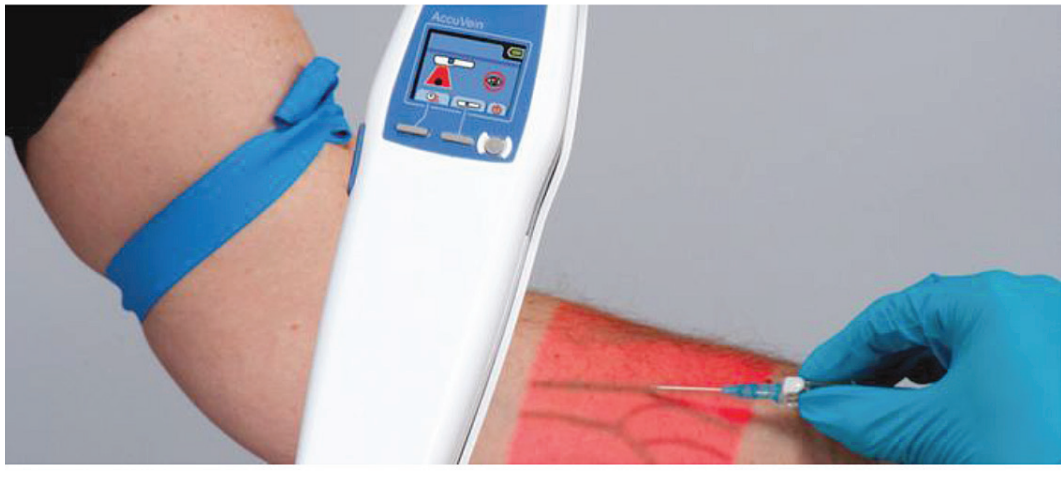

Figure 1 The AccuVein AV400 device uses red and infrared reflection to detect the haemoglobin in the vessels[10]

Method

This research was a prospective, single-blinded randomized clinical trial. It was conducted in accordance with the Ethical Review Committee of the Faculty of Medicine, Thammasat University. Patients were pre-screened on the basis of inclusion/exclusion criteria. Inclusion criteria were age 18 - 65 years; body mass index (BMI) of 30 kg/m^2 or more; American Society of Anesthesiologists (ASA) physical status I, II or III; scheduled elective surgery, examination, or diagnostic imaging under anesthesia; no existing intravenous access; and no requirement for an interpreter. Exclusion criteria were malformation or infection at the potential site (dorsum site of non-dependent hand); anticipated need for an IV cannula size other than 20G; patients who were scheduled for hand and/or wrist surgery on the non-dependent side; edema; pregnancy; and state of shock. A clinical researcher contacted the recruited patients at the preoperative area on the day of their surgery to provide information and give written material and the informed consent document to the patients who had agreed to

participate in our study.

Participants were randomly assigned, by using a block of four randomization provided by www.randomization.com, into two groups; an AV400 group (using the AccuVein AV400 for peripheral venous insertion) and a standard group (using the naked eye and/or palpation for peripheral venous insertion). The performers of cannulation were three nurse anesthetists, each having a minimum of five years of experience in standard technique IV cannula insertion but no or minimal experience (less than 5 times) with the AccuVein AV400 device. A company provided one AccuVein AV400 on loan for clinical evaluation prior to possible purchase and the company did not participate in the conception, design, implementation, analysis, interpretation or report of this study.

At the preoperative area, the experienced nurse anesthetists were not allowed to inspect for peripheral veins before the study started. When the nurse anesthetists were ready to do the IV cannulation, the study group allocation was revealed. A 20G IV cannula was used for both groups at the dorsum of the patient's non-dominant hand.

On each occasion, the observer recorded the time of tourniquet application, the time of successful cannulation or four skin punctures, and the number of cannulation attempts. A cannulation attempt was defined as any backward and forward movements of the needle, regardless of whether the needle was out of the skin. Successful cannulation was defined by the absence of tissue swelling around the puncture point after injection of 5 ml of crystalloid solution. Failure of each study group was defined as failure on the fourth cannulation attempt.

Statistical analysis, a block-randomization scheme was implemented with assigned patients to be the AV400 and standard method groups. A sample of 72 patients (36 per group) was calculated as needed to detect an absolute change of 20% between the standard and AV400 methods in the first-attempt success rate by using Fisher's exact test, with 80% power and a 5% probability of type I error. BMIs between the two groups were compared using the independent t-test. Number of attempts to successful or failed cannulation, success rate and success rate on first attempt were compared by Fisher's exact test. Median time to success and median patient's satisfaction were shown in the interquartile range (IQR) and compared between the two groups by the Wilcoxon rank-sum test. The time for successful cannulation in each group was also plotted in a Kaplan-Meier failure curve and compared by risk ratio. A p-value of less than 0.05 was considered to indicate a significant statistical difference.

Result

Between May to November 2014, seventy-two patients were enrolled and randomly assigned to be the standard intravenous cannulation group or the AccuVein AV400 group. No patient was excluded from the study. The patient characteristics and their distribution in the two randomization groups were presented in Table 1.

Table 1 Patients demographics

Variables	AccuVein AV400 group (n = 36)	Standard group (n = 36)	p-value
Sex			
Male 21	(58.3%)	27 (75%)	
Female15	(41.7%)	9 (25%)	
Age (years)	41.5 ± 13.1	40.3 ± 15.8	0.72
BMI*	33.7 ± 4.6	34.0 ± 4.6	0.77
Obesity (30 - 34.99)	24 (67%)	27 (75%)	
Morbid obesity (≥ 35)	12 (33%)	9 (25%)	

* BMI = Body mass index (kg/m^2)

The first-attempt cannulation success rate was 58.3% with standard method and 52.8% using the AV400 (p = 0.81). The number of skin punctures to cannulation success or failure were not significantly different between the AV400 and standard groups (p-value = 0.77). (Table 2)

Table 2 Comparison of attempts and time between the AccuVein AV400* and standard technique

Outcomes	AccuVein AV400 group (n = 36)	Standard group (n = 36)	p-value
Number of attempts			0.77[2]
119 (52.7%)	21 (58.3%)		
26 (16.6%)	6 (16.6%)		
35 (13.8%)	2 (5.5%)		
43 (8.3%)	2 (5.5%)		
> 43 (8.3%)	5 (13.8%)		
Success rate	33 (91.7%)	31 (86.1%)	0.71[2]
Success rate in first attempt	19 (52.8%)	21 (58.3%)	0.81[2]
Median time (IQR)[1]	41.5 (17.5 - 62.5)	77 (27 - 120)	0.12[3]
Median satisfaction (IQR)[1]	2 (1.5 - 3)	2 (1 - 3)	0.03[3]

[1] Time shown in IQR (Interquartile range), [2] p-value from Fisher's exact test, [3] Wilcoxon rank-sum test

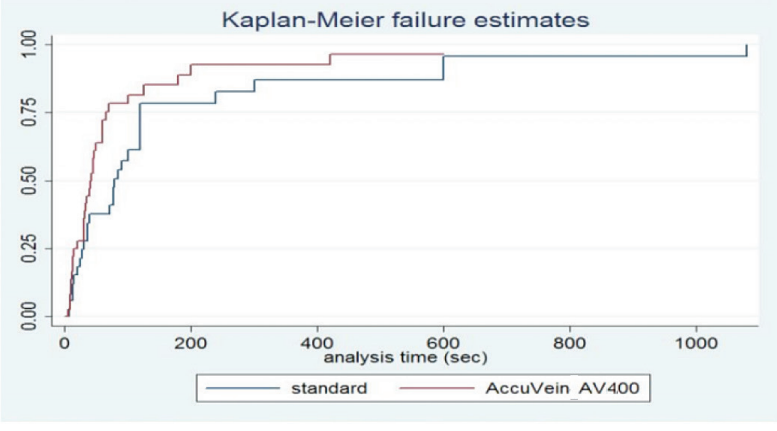

Figure 2 Comparison of success rate between AccuVein AV400* and standard technique by Kaplan-Meier failure curve (* p-value = 0.071)

In this study, there was no significant statistical difference in the cannulation time between the two groups (median time (IQR), 41.5 (17.5 - 62.5); 95%CI, 36.1 - 115.8 in the AV400 group and median time (IQR), 77 (27 - 120); 95%CI, 57.3 - 214.3; p-value = 0.12 in the standard method group (Table 2)). Nevertheless, when we plotted the time for successful cannulation of both groups on the Kaplan-Meier failure curve, we found that the 50% survival time of the standard group was 79 (31, 120) seconds (25% - 75% survival time), and the 50% survival time of the AV400 group was 41 (15, 65) seconds (25% - 75% survival time). The risk ratio was 1.93 (95% CI, 1.17 - 3.19 and p-value = 0.009). We could conclude that 50% of the success population in the AV400 group used less time than 50 of the success population in the standard group significantly. (Figure 2)

Discussion and Conclusion

In this study, we found no significant difference between using the AccuVein AV400 device and the standard technique in first-attempt success rate intravenous cannulation in obese patients. We also found no difference between the two groups in the number of skin punctures to successful cannulation or failed cannulations. When we used survival analysis, we found the time for successful cannulation of the AV400 group was shorter than the standard group significantly.

Several studies have evaluated devices or techniques to improve the success rate in intravenous access in anticipated difficult venous access groups such as newborns, dark-skinned or obese patients.[6 - 8] In a recent study, researchers used the AccuVein AV300 device (a near-infrared vein visualizer) for intravenous cannulation of anesthetized children compared to the standard insertion technique by experienced pediatric anesthesiologists[7], and found no evidence that it was superior to the standard method (75% first-time success with the device vs 73% without the device). Another study evaluated the effectiveness of three near-infrared devices (the veinviewer, AccuVein AV300 and VascuLuminator Vision) and a control group in facilitating peripheral intravenous cannulation in 1,913 children.[6] They concluded that although vein visibility was enhanced, the near-infrared devices did not improve cannulation (the first attempt ranged from 73.1% to 75.3% and p = 0.93) which is not different from our study.

Although the AccuVein AV400 improved the visualization of veins, there are several possible reasons for our finding no significant difference between groups. The first reason may be from the device. The AccuVein AV400 provides a 2-dimensional image of the veins, therefore we could not estimate the depth of the veins. Holding the device 10 to 45 cm from the skin as the AccuVein AV400 user manual suggests is a wide range, and the device sometimes overestimated the size of superficial veins. This wide range of distance for holding the device from the skin was a limitation of the study. Another reason for our findings may be that the number of obese patients in our institute was small, which may be the cause of inability to reliably detect a significant difference. Although the AccuVein AV400 is guaranteed to not cause any eye injury, there were complaints from the providers of eye strain after staring under the infrared light while they were providing intravenous cannulation with the AccuVein AV400. For these reasons, we recommend users to use this device as an assist for locating the superficial veins and turn it off before doing intravenous access.

We have concluded that the AccuVein AV400 device did not improve the first-attempt success rate or reduce cannulation attempts.

Acknowledgements

PCL Holding Co., Ltd. Thailand, provided one AccuVein AV400 device on loan for clinical evaluation prior to possible purchase. Our hospital prohibits the acceptance of gifts of equipment. The company did not participate in the conception, design, implementation, analysis, interpretation, or reporting of the study. We are also grateful to Assoc. Prof. Paskorn Sritipsukho, pediatrician and staff member of the Epidemiology Unit, Faculty of Medicine, Thammasat University for his assistance in data analysis.

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บทคัดย่อ

การศึกษาเปรียบเทียบความสำเร็จของการใช้เครื่อง AccuVein AV400 กับการใช้วิธีมาตรฐานในการเปิดหลอดเลือดดำส่วนปลายเพื่อให้สารน้ำในกลุ่มผู้ป่วยที่มีภาวะอ้วนซึ่งมารับการระงับความรู้สึกระหว่างผ่าตัดแบบไม่ฉุกเฉินโดยวิสัญญีพยาบาลที่มีประสบการณ์

ชลทิชา ศรีภักดี, ศิรินทิพย์ สว่างวงศ์, ปริฉัตร เคอร์รี่, ศิริวัน ตติยานุพันธ์วงศ์

ภาควิชาวิสัญญีวิทยา คณะแพทยศาสตร์ มหาวิทยาลัยธรรมศาสตร์

บทนำ: ภาวะอ้วนเป็นปัจจัยอย่างหนึ่งที่มีผลต่อความสำเร็จในการเปิดหลอดเลือดดำส่วนปลาย ซึ่งเครื่อง AccuVein AV400 เป็นอุปกรณ์ที่ใช้แสงอินฟราเรดในการช่วยส่องหาหลอดเลือดดำส่วนปลายได้ลึกถึง ๑๐ มิลลิเมตรจากผิวหนัง การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อศึกษาว่าการใช้เครื่อง AccuVein AV400 สามารถช่วยเพิ่มความสำเร็จในการเปิดหลอดเลือดดำส่วนปลายในครั้งแรก ซึ่งกระทำในผู้ป่วยที่มีภาวะอ้วนได้หรือไม่

วิธีการศึกษา: ได้มีการแบ่งผู้ป่วย ๗๒ คนที่มีดัชนีมวลกายอย่างน้อย ๓๐ กิโลกรัม/เมตร^2 เป็นสองกลุ่มคือ กลุ่มที่เปิดหลอดเลือดดำโดยนำอุปกรณ์ AccuVein AV400 เข้าช่วย กับกลุ่มที่ใช้วิธีมาตรฐานในการเปิดหลอดเลือดดำส่วนปลาย ซึ่งผู้ที่ทำการเปิดหลอดเลือดดำคือพยาบาลเฉพาะทางวิสัญญีที่มีประสบการณ์ในการเปิดหลอดเลือดดำทั้งหมด ๓ คน ผู้สังเกตการณ์จะทำหน้าที่จดบันทึกจำนวนครั้งที่แทงเข็มหรือเปลี่ยนทิศทางเข็ม และระยะเวลาตั้งแต่เริ่มรัดทูนิเกต์จนกระทั่งเปิดหลอดเลือดดำส่วนปลายสำเร็จหรือล้มเหลว โดยถือการล้มเหลวคือ การแทงเข็มหรือเปลี่ยนทิศทางของเข็มมากกว่า ๔ ครั้ง

ผลการศึกษา: ดัชนีมวลกายของผู้ป่วยทั้งสองกลุ่มไม่แตกต่างกัน [๓๓.๗ ± ๔.๖ กิโลกรัม/เมตร^2 ในกลุ่มที่ใช้เครื่อง AccuVein AV400 และ ๓๔.๐ ± ๔.๖ กิโลกรัม/เมตร^2 ในกลุ่มที่ใช้วิธีมาตรฐาน; (p = ๐.๗๗)] และพบว่าไม่มีความแตกต่างกันอย่างมีนัยสำคัญในจำนวนครั้งแรกที่เปิดหลอดเลือดดำสำเร็จระหว่างกลุ่มที่ใช้เครื่อง AccuVein AV400 (ร้อยละ ๕๒.๘) กับกลุ่มที่ใช้วิธีมาตรฐาน (ร้อยละ ๕๘.๓) (p = ๐.๘๑) นอกจากนี้ยังพบว่ากลุ่มที่ใช้เครื่อง AccuVein AV400 ใช้ระยะเวลาตั้งแต่รัดทูนิเกต์จนเปิดหลอดเลือดดำสำเร็จ ๔๑.๕ (๑๗.๕ - ๖๒.๕) วินาที (95% CI, ๓๖.๑ - ๑๑๕.๘) ในขณะที่กลุ่มที่ใช้วิธีมาตรฐานใช้เวลา ๗๗ (๒๗ - ๑๒๐) วินาที (95% CI, ๕๗.๓ - ๒๑๔.๓) (p = ๐.๑๒)

วิจารณ์ และสรุปผลการศึกษา: ถึงแม้ว่าการใช้เครื่อง AccuVein AV400 จะช่วยทำให้เห็นหลอดเลือดดำส่วนปลายชัดเจนขึ้น แต่พบว่าความสำเร็จในการเปิดหลอดเลือดดำในครั้งแรกในผู้ป่วยที่มีภาวะอ้วนระหว่างกลุ่มที่ใช้เครื่อง AccuVein AV400 กับกลุ่มที่ใช้วิธีมาตรฐานไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ

คำสำคัญ: ภาวะอ้วน, การเปิดหลอดเลือดดำ, อุปกรณ์, อินฟราเรด, เครื่องมือ AccuVein AV400