COMPARISON OF A NOVEL REAL-TIME NEEDLE GUIDANCE ULTRASOUND TECHNIQUE WITH CONVENTIONAL ULTRASOUND FOR CENTRAL VENOUS LINE (INTERNAL JUGULAR VEIN) ACCESS AMONG PATIENTS IN INTENSIVE CARE UNIT OF UMMC

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ABSTRACT

Background Central venous line insertion is a common procedure performed in the intensive care unit and ultrasound guidance technique is widely practised currently. Despite the use of ultrasound, complications still persist, as exact needle location is often difficult to confirm with the conventional two dimension ultrasound. A novel real time needle guidance ultrasound approach allows the visualisation of the needle and tracks the needle during insertion.

Objective To compare between the conventional ultrasound and novel real time needle guidance ultrasound technique for insertion of central venous line into the internal jugular vein.

Methods This prospective, randomized controlled trial involved patients who underwent central venous line insertion in the intensive care unit of UMMC from Feb until Oct 2016. Participants were the doctors in anaesthesia who performed internal jugular vein cannulation via out of plane method using either the novel real time needle guidance ultrasound approach or conventional ultrasound. The primary outcome was to determine the performance time between the two techniques and the success rate. Participant's satisfaction and complication rate were also evaluated.

Results

Since the performance time was not distributed normally, it is described as median (inter- quartile range,IQR). The median performance time for the novel real-time needle guidance and conventional ultrasound approach were 25.50(22) seconds and 15.00(17) seconds respectively. The p-value was 0.01 and therefore clinically significant. 100% of the operators were satisfied with the conventional method compared to only 88% for the

novel real time needle guidance ultrasound method with a p- value of 0.012, which is clinically significant.

Conclusions: Internal jugular vein cannulation using the conventional ultrasound guidance approach needed a shorter performance time and had a higher satisfaction rate among the operators compared to the novel real-time needle guidance ultrasound approach.

ABSTRAK

Latar belakang Pemasangan central venous line adalah perkara sangat biasa dalam wad rawatan rapi, penggunaan ultrasound masa sebenar juga semakin biasa pada masa kini. Walau sedemikian pun, dengan pengguaan ultrasound untuk central venous line juga, komplikasi masih berlaku. Ini disebabkan penempatan jarum pada tempat yang tepat adalah agak susah dipastikan dengan teknik ultrasound konvensional (2 dimensi). Teknik ultrasound masa sebenar novel jarum bimbingan mengizinkan pengimejan jarum dan pengawalan hujung jarum semasa cucuk.

Objektif penyelidikan ini dijalankan untuk menilai kemudahan mendapat akses central venous line antara pesakit dengan mengguna teknik ultrasound konventional dan teknik ultrasound masa sebenar novel jarum bimbingan.

Cara kerja: penyelidikan ini adalah pusat tunggal, prospektif and "randomized controlled trial" melibatkan pesakit yang memerlukan central venous line dalam wad rawatan rapi di Pusat Perubatan Universiti Malaya dari Februari hingga Ogos 2016. Operator adalah doktor bius dengan pelbagai tahun pengalaman. Mereka akan menggunakan teknik "out of plane" untuk akses internal jugular vein sama ada teknik ultrasound konvensional ataupun ultrasound masa sebenar novel jarum bimbingan. Keputusan primum adalah aspirasis darah ke dalam syringe, jumlah masa digunakan untuk mendapat tusukan yang berjaya, kumulatif kali untuk tusukan yang berjaya, dan komplikasi yang disebabkan prosedure ini akan dinilai dan dicatat.

Keputusan: disebabkan distribusi prestasis masa tidak normal, median (interquartile range) akan digunakan untuk deskripsi data ini. Median prestasi masa untuk GPS adalah 25.50(22) saat dan median prestasis masa untuk ultrasound conventional adalah 15.00(17) saat. p-value adalah 0.01 dan ini adalah kurang daripada 0.05. Dengan

demikian, terdapat perbezaan prestasi masa di antara ultrasound konvensional dan GPS. Cara GPS memerlukan masa yang lebih panjang. 100% operator berpuas hati dengan ultrasound konvensional namun cuma 88% operator berpuas hati dengan ultrasound masa sebenar novel jarum bimbingan. p-value adalah 0.012, dan ini adalah kurang daripada 0.05.

Kesimpulan: ultrasound conventional memerlukan masa yand pendek untuk central venous line dan operator lebih berpuas hati dengannya. Dengan demikian, ultrasound convensional adalah cukup baik untuk tujuan ini.

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LIST OF ABBREVIATION

GPS -	Guided positioning system
BMI-	Body mass index
ICU-	Intensive care unit
UMMC-	University Malaya Medical Centre
CI-	Confidence interval
PLT-	Platelet

INTRODUCTION

Percutaneous arterial and venous punctures using ultrasound guidance are common procedures and have become the standard of care in many centers[1]. Multiple studies have demonstrated that the use of ultrasound guided puncture improves success rates and decreases procedure related complications.

The traditional landmark approach for vascular access is based on anatomic reference structures. There are increasing data showing superior patient safety in certain procedures when ultrasound guidance was used compared to landmark based approach[19]. Multiple randomized controlled trials have demonstrated that real time ultrasound guided internal jugular vein cannulations have a higher first attempt success rate, reduced access time, higher overall success rate and decreased arterial puncture compared with the landmark technique[20,21,22]. Although with substantial clinical training and experience, the landmark technique may result in unsuccessful attempts because of anatomic variations[16]. If landmarks are poor, multiple needle passes may be required, increasing the incidence of procedure-related complications, such as secondary tissue damage, bleeding and hematoma. Compared with the landmark technique, ultrasound visualization during vascular access has been shown to increase procedure success, at the same time also reducing the complication rates[1]. Using ultrasound beforehand to locate the vascular structure or using real-time imaging during cannulation, ultrasound has been shown to reduce central venous catheterization time compared with the landmark technique. It can be very challenging to acquire the technical and manual skills for ultrasound imaging during vascular access procedures, especially for inexperienced anesthesiologists[16]. Correct needle visualization and precise needle tip control during vascular access require clinical experience and training and very often proved to be difficult, especially for the beginner. For the novel guided positioning

system (GPS) technology tested in this study, real-time ultrasound imaging is combined with on screen navigation to assist in visualizing and guiding the needle and controlling the needle tip. Visualizing and projecting the needle path during vascular access, ultrasound procedures potentially can be simplified by real-time navigation, providing benefits for both the experienced and inexperienced anesthesiologists. In this prospective trial, null hypothesis is made that GPS ultrasound navigation offers no significant benefit over conventional ultrasound for vascular access.

OBJECTIVES

General objective

Comparing the difference in effectiveness between conventional ultrasound and novel real time needle guidance ultrasound for inserting central venous line into internal jugular vein

Specific objectives

Primary outcome

To determine the performance time between conventional ultrasound and novel real time needle guidance ultrasound

To compare cumulative cannulation success by method

To determine 1st pass cannulation success by method and operator

To determine arterial puncture by method and operator

Secondary outcome

To assess any complications that arise from the procedure such as secondary tissue injury, hematoma, bleeding, pneumothorax, hemothorax or arterial puncture will be documented

To assess satisfaction of operator towards the methods

METHODOLOGY

Study design

This research will be single center, prospective, randomized controlled trial involving patient undergoing central venous line insertion in intensive care unit in UMMC from Feb till Oct 2016. Participants will be classified as doctors in anaesthesia with <1 year, 1≤year<2, 2≤year<3 and year ≥ 3 year of experience. Participants are to perform cannulating internal jugular vein access via out of plane method using either navigated ultrasound (GPS) or conventional ultrasound (conventional) for the patients. Each participant will receive a standardized 5 minute verbal introduction to the GPS technology with navigated ultrasound (GPS), testing of device using phantom blue gel is allowed before participation. Consent is taken either from the patient or the next of kin. Emergency verbal consent is obtained if the next of kin is not immediately available. The participants are randomized to either using GPS or conventional. Procedure time from placing needle on the skin to achieving vascular access was measured in seconds using a stopwatch. The time measurement begins from placing the needle on the skin to successful vessel puncture as indicated by blood withdrawn into the syringe. Primary outcome measures are visualization of blood aspirate into syringe, total time to successful puncture of the vessel and the cumulative success. Any complication arise from this procedure will be assessed and documented.

Inclusion criterias:

All the patients who require central venous line insertion will be included

Exclusion criterias:

Refusal to participate in this study by patient or the legal representative

Patient with history of difficult of getting central venous line at internal jugular vein

Sample size:

The sample size was determined by using power study. This power study was performed using web base sample size calculator **(http://www.stat.ubc.ca/~rollin/stats/ssize/n2.html)** which is a very useful tool in medical and biological research to determine the sample size. Considering 90% power and 1% marginal error (type one error for α value = 0.01), this study gives a minimum sample size of 47 per group (based on the median and IQR values obtained references[14]). Therefore we would like to use 50 per group in our study.

Randomization:

A computer generated randomized assignment will be used for this study

DATA ANALYSIS

Data was analyzed using IBM SPSS statistical program v.22.0. For presentation of data, the patient's age, gender, BMI, method of the central venous line insertion, cumulative cannulations, complications such as secondary tissue injury, hematoma, bleeding , pneumothorax or hemothorax, arterial puncture that have arised after the procedure, year of experience of the operators, and operator satisfaction with method are presented in frequency tables.

Difference in median (interquartile range) performance time for both method was compared. Operator satisfaction towards the method was analysed using Pearson Chi-Square test; these were presented as p-value.

In all circumstances, p-value of < 0.05 was taken to mean statistical significant.

RESULTS

A total of 100 patients were included in this study from February to August 2016 in ICU of UMMC. Each arm consists of 50 patients, using either novel real time ultrasound needle guidance or conventional ultrasound.

GENDER

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1=MALE	55	55.0	55.0	55.0
	2=FEMALE	45	45.0	45.0	100.0
	Total	100	100.0	100.0	

Above table shows the gender of the patients in this study. 45% of the patients are female and 55% of them are male.

BMI_CLASS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<18.5	3	3.0	3.0	3.0
	18.5-24.9	41	41.0	41.0	44.0
	25-29.9	35	35.0	35.0	79.0
	30-39.9	19	19.0	19.0	98.0
	40 and more	2	2.0	2.0	100.0
	Total	100	100.0	100.0	

Majority of the patient's BMI falls in the class of 18.5-24.9.

METHOD

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1=CONVENTIONAL	50	50.0	50.0	50.0
	2=GPS	50	50.0	50.0	100.0
	Total	100	100.0	100.0	

Each method of performing central venous catheter insertion consists of 50 patients

CUMULATIVE_CANNULATIONS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	99	99.0	99.0	99.0
	2	1	1.0	1.0	100.0
	Total	100	100.0	100.0	

All of the operators are successful in the first attempt except only 1 case where the operator required 2 times for cannulation. This happened in the conventional arm.

SECONDARY_TISSUE_INJURY

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2=NO	100	100.0	100.0	100.0

No secondary tissue injury was reported after procedure

HEMATOMA

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1=YES	1	1.0	1.0	1.0
	2=NO	99	99.0	99.0	100.0
	Total	100	100.0	100.0	

Almost all did not have hematoma. Only one developed hematoma due to severe thrombocytopenia (PLT =3) and the procedure was done after platelet transfusion.

BLEEDING

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2=NO	100	100.0	100.0	100.0

No bleeding was reported after procedure.

PNEUMOTHORAX

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2=NO	100	100.0	100.0	100.0

No pneumothorax occurred after procedure.

HEMOTHORAX

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 2=NO	100	100.0	100.0	100.0

No hemothorax occurred after procedure.

ARTERIAL_PUNCTURE

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 2=NO	100	100.0	100.0	100.0

No incidence of arterial puncture.

Operator_year_of_experience

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 2=1 to <2 year	6	6.0	6.0	6.0
3=2 to <3 year	8	8.0	8.0	14.0
4=3 year and above	86	86.0	86.0	100.0
Total	100	100.0	100.0	

In this study, majority of operator has 3 year and above experience which consists of 86%.

Descriptives

	METHOD			Statistic	Std. Error
PERFORMANCE_TIME	1=CONVENTIONAL	Mean		18.26	2.662
		95% Confidence Interval for Mean	Lower Bound	12.91	
			Upper Bound	23.61	
		5% Trimmed Mean		15.37	
		Median		15.00	
		Variance		354.360	
		Std. Deviation		18.824	
		Minimum		2	
		Maximum		98	
		Range		96	
		Interquartile Range		17	
		Skewness		2.903	.337
		Kurtosis		10.016	.662
	2=GPS	Mean		25.38	2.514
		95% Confidence Interval for Mean	Lower Bound	20.33	
			Upper Bound	30.43	
		5% Trimmed Mean		23.67	
		Median		25.50	
		Variance		316.077	
		Std. Deviation		17.779	
		Minimum		5	
		Maximum		118	
		Range		113	
		Interquartile Range		22	
		Skewness		2.943	.337
		Kurtosis		14.214	.662

Since the performance time was not distributed normal, it is described as median (inter-quartile range, IQR). The median performance times for GPS method was 25.50 (22) seconds and median performance time for the conventional method was 15.00(17) seconds. The p-value for this test was 0.01, which is less than 0.05. Hence, there is a

difference between the conventional and GPS methods, the GPS method takes longer time for cannulating central venous line.

Operator_satisfaction_score_with_procedure

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2	2	2.0	2.0	2.0
	5	2	2.0	2.0	4.0
	6	2	2.0	2.0	6.0
	7	19	19.0	19.0	25.0
	8	26	26.0	26.0	51.0
	9	21	21.0	21.0	72.0
	10	28	28.0	28.0	100.0
	Total	100	100.0	100.0	

Chi-Square Tests

	Value	Df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	6.383[a]	1	.012		
Continuity Correction[b]	4.433	1	.035		
Likelihood Ratio	8.701	1	.003		
Fisher's Exact Test				.027	.013
N of Valid Cases	100				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.00.

b. Computed only for a 2x2 table

METHOD * operator satisfaction Crosstabulation

			satisfaction		
			not satisfied ≤6	Satisfied ≥7	Total
METHOD	1=CONVENTIONAL	Count	0	50	50
		% within METHOD	0.0%	100.0%	100.0%
	2=GPS	Count	6	44	50
		% within METHOD	12.0%	88.0%	100.0%
Total		Count	6	94	100
		% within METHOD	6.0%	94.0%	100.0%

This is the evaluation of operator satisfaction towards the methods, 100% of the operators using conventional method are satisfied are satisfied. While on the other hand, only 88% of the operator using GPS method are satisfied. The p-value 0.012, which is less than 0.05, thus it is statistically significant.

BASIC VARIABLES

Gender	**No (percentage)**
Male	55 (55%)
Female	45 (45%)
BMI	**No (percentage)**
<18.5	3 (3%)
18.5-24.9	41 (41%)
25-29.9	35 (35%)
30-39.9	19 (19%)
40 and above	2 (2%)
Method	**No (percentage)**
GPS	50 (50%)
Conventional	50 (50%)
Cumulative cannulations	**No (percentage)**
1	99 (99%)
2	1 (1%)
Secondary tissue injury	**No (percentage)**
Yes	0 (0%)
No	100 (100%)
Hematoma	**No (percentage)**
Yes	1 (1%)
No	99 (99%)
Bleeding	**No (percentage)**
Yes	0 (0%)
No	100 (100%)
Pneumothorax	**No (percentage)**
Yes	0 (0%)
No	100 (100%)
Hemothorax	**No (percentage)**

Yes	0 (0%)
No	100 (100%)
Arterial puncture	**No (percentage)**
Yes	0 (0%)
No	100 (100%)
Year of experience	**No (percentage)**
1 to < 2 years	6 (6%)
2 to < 3 years	8 (8%)
3 and above	86 (86%)
Performance time	**Median (interquartile range)/seconds**
Conventional	15(17)
GPS	25.5 (22)
Operator satisfaction	**No (percentage)**
Conventional ≤6 ≥7	0 (0%) 50 (100%)
GPS ≤6 ≥7	6 (12%) 44 (88%)

DISCUSSION

In this study, we have included 100 patients for central venous catheter insertion using either conventional ultrasound or novel real time needle guidance ultrasound. For demographic description of the patient, we have 55 patients with the male gender and 45 patients are female. The large proportion of the patients has the BMI of 18.5-24.9, which is 44 of them (44%), 35 persons in the class of 25-29.9, 21 persons has BMI >30, and only 3 with BMI<18.5. All the operators were successful in the first attempt. Only in one case, the operator required 2 times for successful cannulation. All of the cases did not result in arterial puncture, secondary tissue injury, bleeding, pneumothorax, hemothorax or arterial puncture. Only one case were reported to have hematoma. Retrospectively, we found out patient was having severe thrombocytopenia (PLT =3) despite platelets were being transfused before procedure. The attempt was smooth and successful. Most operator experiences 3 years and above, which is 86% of them, 8% of them 2 years and less than 3 years, only 6% who are 1 year and less than 2 years.

Since performance time was not distributed normal, it is described as median (inter-quartile range, IQR). The median performance times for GPS method was 20.50 (25) seconds and median performance time for the conventional method was 15.50(18) seconds. The p-value for this test was 0.01, which is less than 0.05. Hence, there is a difference between the conventional and GPS methods, the GPS method takes longer time for cannulating central venous line, compared to the study on gel phantom model[12], which reveals shorter performance time using GPS (as well use out of plane technique)

By classifying operator satisfaction level satisfied (≥7) and not satisfied (≤6), 100% of operator in the arm of conventional ultrasound were satisfied, on the other hand, only 88% of operator in the arm of novel real time needle guidance were satisfied. The p-value is 0.012, which is less than 0.05, hence it is statistically significant. More operators were satisfied with conventional ultrasound method.

The present study investigated the efficacy of novel real time needle guidance ultrasound versus conventional ultrasound for internal jugular vein cannulation for patients in ICU UMMC. There is significant higher in performance time using GPS, p value <0.05, this data does not support the GPS navigation is beneficial in addition to conventional ultrasound for vascular access in real patients.

The operators who perform in this study are already ultrasound trained, and introducing the new modalities of navigation system does not seem to help much.

Both of these methods have comparable successful rate in cannulations and both methods are safe and rarely cause complications.

Satisfaction over novel real time needle guidance ultrasound is lesser than conventional ultrasound, 88% versus 100%, and it is statistically significant (p-value 0.012).

The navigation technology of ultrasound device is based on an electromagnetic field that communicates with a transducer and an electromagnetic sensor sheathed by a vascular access needle. Needle movements and related magnetic field variation allow navigation system to compute the locations of the transducer and needle in the three dimensional space.

To apply it on the patient, other electromagnetic devices such as watch, handphone, metal that can cause interference to this navigation technology have to be removed.

In some occasions, when the needle that sheathed with the electromagnetic sensor was placed near to the transducer, the image including the target box (square), trajectory pathway were not stable. Hence the operators required more time to adjust until a quality, stable image reappeared before able to perform the procedure.

For novel real time needle guidance ultrasound, the operators are required to angulate the needle against the transducer until the target box to fall onto the cross sectional image of internal jugular vein then only to advance the needle to reach the target. As the system is too sensitive, minute movement of the needle will cause the target box moves out of the cross sectional image of internal jugular vein, again reposition of the needle is required and hence more time is needed for this method.

The results as though could be because the operators have been familiar with the use of real time conventional ultrasound. And the results, could be different if the operators are novice users to ultrasound technology.

CONCLUSION

This prospective study tested a novel real time ultrasound navigation technique using GPS ultrasound navigation for internal jugular vein cannulation for patients in ICU UMMC. Novel real time needle guidance method showed a higher mean rank, which means requires longer time to perform. The satisfaction level is also much lower 88% versus 100%. Anyhow, more clinical studies are warranted to test the beneficial effects of GPS navigation technology in patient undergoing vascular access procedure or regional anaesthesia.

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