EVALUATION OF THE CLEAR GUIDE ONE SYSTEM VS CONVENTIONAL ULTRASOUND-GUIDED VASCULAR CANNULATION IN SWINE

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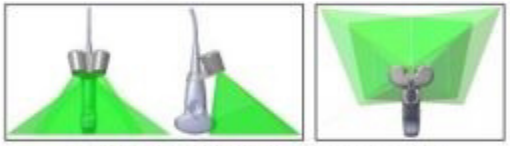
Introduction

- Ultrasound (US) guidance is the golden standard for percutaneous vascular access.
- According to ELSO Ultrasound Guidance for ECMO 2015, real-time ultrasound use during percutaneous ECMO cannulation helps to identify and cannulate vessel without any local complications.
- US is also useful during cardiopulmonary resuscitation when it's impossible to differentiate the artery from vein by palpation.

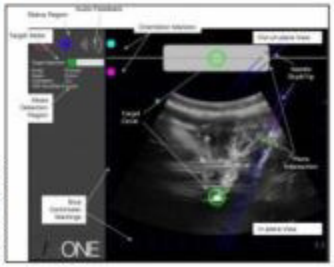
Purpose of the study: This study explores the potential of a new device, the Clear Guide ONE system (CLEAR GUIDE MEDICAL, Baltimore, MD), for improved percutaneous ultrasound-guided vascular access.

Specifications: The Clear Guide ONE system consists of the Clear Guide Core, which is a touchscreen computer connected to a portable ultrasound machine FUJIFILM SonoSite M-turbo (Bothell , WA USA), and Clear Guide SuperPROBE, an optical head with stereo cameras mounted onto the ultrasound probe.



CLEAR GUIDE SuperPROBE (in-plane field of view).

The system allows performance of stereo imaging with needle detection and real-time needle tracking. It also provides in-situ guidance projection and calculates the alignment deviation in real time while giving visual and audio feedback as beep signals, which helps maintain correct targeting.



CG User Interface
(instrument tracked & target defined)

Hypothesis:
Use of the Clear Guide (CG) system permits faster intravascular access as well as reduced number of attempts needed per successful cannulation.

Methods

- This is a preliminary report from an ongoing study. Eleven Yorkshire pigs were used in accordance with an IACUC approved protocol. All animals were anesthetized before, during, and after procedures using inhaled Isoflurane at 2-5 Vol/% titrated to effect. Average weight of animals was 36.5 kg (±1.8SD).

CLEAR GUIDE system in use.

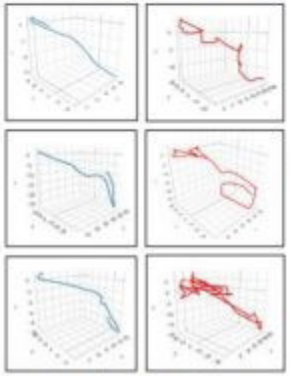
Procedure: Vessels were cannulated under ultrasound guidance with and without Clear Guide (CG) system: right and left external jugular veins, right and left femoral veins, right and left femoral arteries, and right and left carotid arteries. Standard vascular access kits with 18G needles were utilized.

CLEAR GUIDE SuperPROBE.

Results

- The use of CG needle trajectory prediction helped decrease the amount of attempts per cannulation and reduce the time of cannulation.
- Successful first-attempt cannulations rate with CG was 89% (35/39) and with ultrasound only was 43% (13/30). See Tables 1-2.
- Median time for vascular access in CG group was 50 seconds (IQR 34-69) and median time in US only group was 133 seconds (IQR 73-207). See Table 2.
- Success rate with CG was 95% (41/43), and 78% (30/38) with US only.

This study continues and will include cases of cannulation in non-heart beating conditions.



3D needle tracking patterns during ex-vivo cannulation test with and without CG.

Table 1.

Vessel	Ultrasound		Clear Guide One System	
	Successful cannulation	*Complications*	*Successful cannulation*	*Complications*
Jugular vein	90% (9/10)*	-	100% (13/13)	-
Carotid artery	54% (6/11)	Hematoma. Loss of visibility x 2, arterial spasms x 2	85% (6/7)	Loss of visibility, arterial spasms.
Femoral vein	100% (7/7)	-	100% (12/ 12)	-
Femoral artery	80% (8/10)	Vein instead of artery	90% (10/11)	-

* Data presented as percentages and ratios (i.e. 'x/n' - 'x successful cannulations out of 'n').

Table 2.

Vessel	Ultrasound		Clear Guide One System		Diameter in mm (short axis)
	Time (sec) per cannulation	*Attempts per cannulation*	*Time (sec) per cannulation*	*Attempts per cannulation*	
Jugular vein	207 (157-207)*	3(3)	51 (28-51)	1(1)	0.54 (0.42-0.63)
Carotid artery	93 (92-93)	1(1)	70 (40-70)	1(1)	0.39 (0.35-0.49)
Femoral vein	102 (45-102)	1(1-2)	49 (35-49)	1(1)	0.5 (0.43-0.5)
Femoral artery	103 (62-103)	2(1-3)	53 (35-53)	1(1)	0.34 (0.31-0.39)

* Data presented as median and interquartile rate in brackets.

Discussion

- In several cases, after the first failed attempt the vessel was in severe vasospasm and further cannulation was difficult to perform. After the second failed attempt, the vessel lumen was unidentifiable and cannulation was unsuccessful. In 2 such cases the utilization of CG (after failed cannulation with US only) helped to establish vascular access despite this complication. This experience suggests that in difficult cases after multiple attempts when precision was required, the CG was helpful to establish vascular access.
- The CG system currently has few limitations. The CG visual field does not allow the user to perform cannulation in the short axis if camera was positioned longitudinally. In this case, another technique "out-of-field" can be used. Also, CG can falsely track adjacent lines or guidewires if they stay in the visual field. This problem can be fixed by utilization of specially marked visitip needles.

Conclusion

- The Clear Guide system is a navigation accessory for ultrasound machines that may potentially decrease complication rates of vascular access. Preliminary results to date show certain favorable outcomes in that CG reduced the number of attempts and overall time to cannulation and thus may be a useful adjunct during vascular access.
- The added benefits of CG might be especially important in complicated cases where additional visualization improvements might be beneficial. Such cases include extracorporeal membrane oxygenation or emergency catheterization of patients in non-heart beating state during ECPR.

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