Proceedings of the 2020 Design of Medical Devices Conference
DMD2020
April 6, 7-9, 2020, Minneapolis, MN, USA

DMD2020-9007

A REALISTIC PHANTOM FOR ULTRASOUND-GUIDED CENTRAL VENOUS CANNULATION

Si Yen Ng, Chi-Lun Lin[1]
National Cheng Kung University
Tainan City, Taiwan (R.O.C)

ABSTRACT

Ultrasound-guided central venous cannulation (CVC) has become standard to care. Ultrasound imaging allows the CVC procedure to be completed much safer than a standard blind landmark approach. To enhance medical personnel's skill in performing challenging ultrasound-guided CVC, an adult size CVC phantom that simulated the human head to the chest, with a detachable CVC operational part, was proposed in this study to provide medical personnel with realistic needle insertion haptic feedback and ultrasound imaging. The detachable CVC operational part could be customized to simulate different patient conditions, such as adult patient (with normal standard size of vascular), the elderly (with collapsed vascular), children (with smaller diameter of vascular), vascular fibrosis patient (with hardening of vascular) and obese patient (with thick fat tissue). In the current stage of prototype development, a CVC operational part with simulated blood vessels and clavicle embedded inside the fat- and muscle-mimicking tissue was produced. Both the fat- and muscle-mimicking tissue pose mechanical and acoustic properties similar to real tissues. The target vein for CVC procedure could be recognized from the ultrasound imaging of the CVC operational part.

Keywords: Ultrasound-guided, central venous cannulation, phantom

INTRODUCTION

The traditional method of procedural teaching has been widely applied in medical practices instead of simulation training. However, issues such as difficulty in evaluating the effectiveness of clinical skill training, patient respect, and medical ethics may arise. Central venous cannulation, a procedure associated with risks of complications such as air embolism, arrhythmia and catheter malposition [1], is recommended to operate with the aid of ultrasound to reduce its operational risk [2, 3], improve the insertion accuracy, and reduce the insertion number [4]. Besides, simulation training has been found to aid in infection controlling of CVC [5]. Hence, simulation training on phantom can effectively enhance the skill of residents in CVC procedure, safety, predictability and respect for patients [6].

Challenging situations such as age-related vascular pattern differences, obese patients, and vascular fibrosis patients may face by the physician during CVC operation. A simulation training on CVC phantom has been conducted for residents of PGY1, and significant improvement has been found in their overall performance [7, 8]. Operating needle insertion and ultrasound scanner at the same time requires skill and experience. According to the report by Pain Medicine, simulation training on phantom can effectively improve the spine ultrasound operation skill of trainees [7]. Therefore, simulation training on CVC phantom has a substantial effect on improving the technical skills of medical personnel and further reducing the pain and complications of patients.

Available training models in the market can help users in acquiring the basics of ultrasound-guided CVC procedure and enhance their concept of anatomy. However, the homogeneous material in the expensive commercial phantom cannot simulate the different mechanical properties of real tissues. Although a low cost and reusable CVC phantom was proposed in previous literature, it fails to simulate both the acoustic and mechanical properties of real tissues. In order to provide the physicians with realistic needle insertion haptic feedback and ultrasound imaging, this study aims to develop a realistic CVC phantom by

[1] Contact author: linc@mail.ncku.edu.tw. Other authors should not list their full contact information (email address, mailing address, phone number) in the author section.

embedding the simulated blood vessels and clavicle inside the fat- and muscle- mimicking tissues.

MATERIALS AND METHODS

2.1 Preparation of Tissue Mimicking Materials

The liquid and powder components of the International Electromechanical Commission (IEC) tissue mimicking material (TMM) in Table 1 [9] were mixed and heated to produce fat- and muscle-mimicking tissue samples. The cooled mixture was poured into a cylindrical perspex mold, and a layer of saran wrap was applied to prevent the TMM sample from desiccating before acoustic testing.

Table 1. Weight composition of the TMM (by %)

Component	Weight Composition (%)
Distilled, degassed, deionized water	82.97
Glycerol	11.21
Benzalkonium chloride	0.46
Agar	3.00
Silicon carbide (17 µm)	0.53
Aluminum oxide (3-5 µm)	0.95
Aluminum oxide (0.3 µm)	0.88

2.2 Characterization of Mechanical Properties

The cooled TMM in cylindrical mold (76mm diameter and 25mm height) was prepared for the indentation test at room temperature (25ºC) using the MTS INSIGHT-1 machine. Young's modulus, *E,* of the TMM sample, was characterized through an indentation test. An indenter with a diameter of 12 mm compressed the TMM sample with a velocity of 0.5 mm/s until a depth of 6 mm was reached.

2.3 Characterization of Acoustic Properties

The acoustic testing system included an ultrasound research platform (Vantage 256, Verasonics, Redmond, WA, USA), a three-axis motor stage, and the programming software MATLAB 2018b (MathWorks, Natick, MA, USA). A linear ultrasound probe (L7-4, Broadsound Corporation, Taiwan) with a frequency centered at 7MHz was used in this system.

The acoustic measurement used an ultrasound probe to scan the reflector and computed the time interval between the peaks of the radiofrequency pulses. The measurement was performed first with the sample placed between the probe and the reflector to obtain a result (sample data). The sample was then removed to measure another result as reference data. All acoustic measurements were carried out in degassed water. Equation 1 was used to calculate the speed of sound of the sample, c_m

$$c_m = \left(\frac{T_w - T_m}{t_2 - t_1} + 1\right) c_w \qquad (1)$$

where T_m and T_w are time periods for the pulse signal to travel between the probe and the reflector calculated from the sample data and the reference data, and t_1 and t_2 are time periods for the pulse signal to reach the front and rear faces of the sample after being fired. The measurement was repeated three times for each sample. The attenuation coefficient, $\alpha\ (\boldsymbol{dB.cm^{-1}})$, was calculated by Eqn. 2, where d is the thickness of the sample, $A(f)$ is the sample magnitude spectrum at frequency f, and $A_o(f)$ is the reference magnitude spectrum at frequency f.

$$\alpha(f) = -\frac{20}{2d} log_{10} \frac{A(f)}{A_o(f)} \qquad (2)$$

2.4 Fabrication of CVC Phantom

The realistic CVC phantom is made up of two parts – the human body appearance model and the CVC operational part (neck module block). The human appearance model, which was made of silicone will simulate the human head to the chest, and present in an adult size. Near the neck of the human appearance model, there will be a groove for the placement of the CVC operational part. However, the development of this prototype will mainly focus on the fabrication of the CVC operational part, which consisted of simulated blood vessels and bone that were embedded inside the fat- and muscle-mimicking materials.

Two water-filled strip shape balloons were used to simulate the jugular vein and carotid artery. The simulated blood vessels were attached to a clavicle and placed into a rectangular container (Fig. 1). Firstly, resin and hardener were mixed in a mix ratio of 100:2 as followed the instruction in the product manual. The mixture of silicone liquid was then poured into the container. This layer of silicone will simulate the base for which CVC operational part will be placed on. After the silicone layer was cured, the muscle-mimicking material was prepared and poured on the top of the silicone layer until the simulated blood vessels and clavicle were fully covered. Lastly, a final thin layer of fat-mimicking material was prepared and poured into the container. The final prototype of the CVC operational part was shown in Fig. 2.

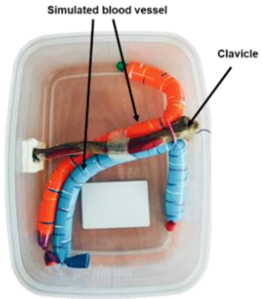


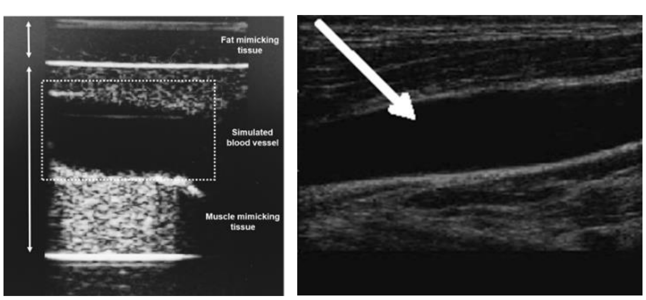
FIGURE 1: SIMULATED BLOOD VESSELS AND CLAVICLE WERE PLACED IN THE CONTAINER

FIGURE 2: FINAL PROTOTYPE OF CVC OPERATIONAL PART

RESULTS

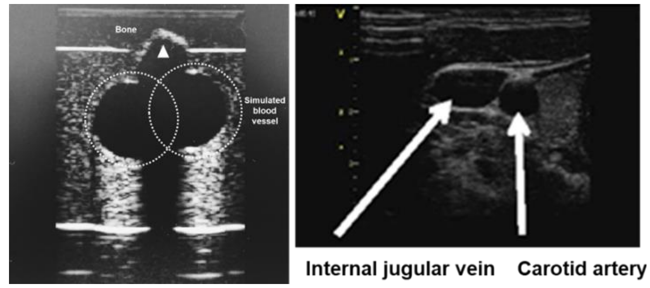
The mechanical (Young's modulus) and acoustic (speed of sound and attenuation coefficient) properties for real tissues and TMMs were listed in Table 2. The Young's moduli of both fat- and muscle-mimicking materials were higher than the real tissues. However, this result is acceptable because Young's modulus ratio of muscle- to fat-mimicking tissues (4.5 times) was nearly the same as that between real tissues (5.1 times). Meanwhile, the speeds of sound and attenuation coefficients of the fat- and muscle-mimicking materials were nearly fit into the ranges for real tissues.

Two different views (sagittal and transverse) of ultrasound images acquired from the developed CVC operational part phantom were compared with those in a real case, as shown in Fig. 3 and 4. The internal jugular vein in a real case ultrasound image was able to be duplicated in our CVC phantom's ultrasound image and could be recognized.



(A) (B)

FIGURE 3: SAGITTAL VIEW OF INTERNAL JUGULAR VEIN, (A) ULTRASOUND IMAGE OF CVC OPERATIONAL PART, (B) ULTRASOUND IMAGE ACQUIRED FROM THE REAL CASE [10]



(A) (B)

FIGURE 4: TRANSVERSE VIEW OF INTERNAL JUGULAR VEIN, (A) ULTRASOUND IMAGE OF CVC OPERATIONAL PART, (B) ULTRASOUND IMAGE ACQUIRED FROM THE REAL CASE [10]

Table 2. Mechanical and acoustic properties for real tissues (targeted outcome) and TMMs (experimental result).

		Fat tissue	Muscle tissue
Targeted outcome	Young's modulus (kPa)	2.5	12.8
	Speed of sound (m/s)	1476-1480	1555-1616
	Attenuation coefficient (dB/cm)	0.6-5.2	1.03
Experimental results	Young's modulus (kPa)	104.1	472.5
	Speed of sound (m/s)	1666.07	1624.16
	Attenuation coefficient (dB/cm)	1.30	0.99

DISCUSSION

In this stage of prototype development, a simple configuration of the CVC operational part was produced. The CVC operational part consisted of simulated blood vessels (normal patient) and clavicle, which were embedded inside the fat- and muscle mimicking tissues. The mechanical and acoustic properties of fat- and muscle-mimicking tissues were emphasized to provide medical personnel with realistic haptic feedback and ultrasound imaging during needle insertion.

The speed of sound and attenuation coefficient of the TMMs used in our CVC phantom were nearly fit into the range of real tissues. Although Young's moduli of TMMs were larger than the real tissues, Young's modulus ratio of muscle- to fat-mimicking tissues (4.5 times) was nearly the same as Young's modulus ratio of real tissues (5.1 times). Ultrasound images at sagittal and transverse views of the internal jugular vein in the real case were also able to be duplicated by our CVC phantom.

For future works, the anatomical sizes and hardness of simulated vascular will be adjusted to simulate patients of different ages (normal adults, elderly, and children) and special pathophysiological conditions (eg. vascular fibrosis patients). By adjusting the proportion of the mimicking tissues in the CVC operational part, patients with a specific body condition (eg. obesity) could be simulated.

Unskilled operators may cause pneumothorax during the CVC procedure. Therefore, a replaceable balloon could be used as the lung and be placed below the CVC operational part. Furthermore, grooves for placement of CVC operational part could be created at both left and right sides near the neck of adult size CVC phantom to simulate different sides of the CVC procedure.

ACKNOWLEDGMENTS

This research is supported by the Ministry of Science and Technology, Taiwan, under funding no. 107-2221-E-006-067.

We want to show our gratitude to Professor Peng-Ting Chen and teammates in Biodesign class I & II, who have made valuable comments and suggestions on this research project, which inspired us to improve our CVC phantom.

REFERENCES

[1] Bodenham, A., Babu, S., Bennett, J., Binks, R., Fee, P., Fox, B., Johnston, A., Klein, A., Langton, J., Mclure, H., and Tighe, S., 2016, "Association of Anaesthetists of Great Britain and Ireland: safe vascular access 2016," Anaesthesia, 71(5), pp. 573-585.

[2] Matsushima, K., and Frankel, H. L., 2010, "Bedside ultrasound can safely eliminate the need for chest radiographs after central venous catheter placement: CVC sono in the surgical ICU (SICU)," Journal of Surgical Research, 163(1), pp. 155-161.

[3] Smit, J. M., Raadsen, R., Blans, M. J., Petjak, M., Van de Ven, P. M., and Tuinman, P. R., 2018, "Bedside ultrasound to detect central venous catheter misplacement and associated iatrogenic complications: a systematic review and meta-analysis," Critical Care, 22(1), p. 65.

[4] Evans, L. V., Dodge, K. L., Shah, T. D., Kaplan, L. J., Siegel, M. D., Moore, C. L., Hamann, C. J., Lin, Z., and D'onofrio, G., 2010, "Simulation training in central venous catheter insertion: improved performance in clinical practice," Academic Medicine, 85(9), pp. 1462-1469.

[5] Burden, A. R., Torjman, M. C., Dy, G. E., Jaffe, J. D., Littman, J. J., Nawar, F., Rajaram, S. S., Schorr, C., Staman, G. W., and Reboli, A. C., 2012, "Prevention of central venous catheter-related bloodstream infections: is it time to add simulation training to the prevention bundle?," Journal of clinical anesthesia, 24(7), pp. 555-560.

[6] Sutcliffe, J., Hardman, R. L., Dornbluth, N. C., and Kist, K. A., 2013, "A Novel Technique for Teaching Challenging Ultrasound-Guided Breast Procedures to Radiology Residents," Journal of Ultrasound in Medicine, 32(10), pp. 1845-1854.

[7] Kwon, S. Y., Hong, S. H., Kim, E. S., Park, H. J., You, Y., and Kim, Y. H., 2015, "The efficacy of lumbosacral spine phantom to improve resident proficiency in performing ultrasound-guided spinal procedure," Pain Medicine, 16(12), pp. 2284-2291.

[8] Corvetto, M., Pedemonte, J., Varas, D., Fuentes, C., and Altermatt, F., 2017, "Simulation-based training program with deliberate practice for ultrasound-guided jugular central venous catheter placement," Acta Anaesthesiologica Scandinavica, 61(9), pp. 1184-1191.

[9] Brewin, M., Pike, L., Rowland, D., and Birch, M., 2008, "The acoustic properties, centered on 20 MHz, of an IEC agar-based tissue-mimicking material and its temperature, frequency and age dependence," Ultrasound in medicine & biology, 34(8), pp. 1292-1306.

[10] Schmidt, G. A., Maizel, J., and Slama, M., 2015, "Ultrasound-guided central venous access: what’s new?," Intensive care medicine, 41(4), pp. 705-707.