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Emergency button cannula vs. umbilical catheter as neonatal emergency umbilical vein access – a randomized cross-over pilot study

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Abstract

Objectives: Establishing immediate intravenous access to a newborn is challenging even for trained neonatologists in an emergency situation. Correct placement of umbilical catheter or an intraosseous needle needs consistent training. We evaluated the time required to correctly place an emergency umbilical button cannula (EUC) or an umbilical catheter (UC) using the standard intersection (S-EUC or S-UC, respectively) or lateral umbilical cord incision (L-EUC) by untrained medical personnel.

Methods: Single-center cross-over pilot-study using a model with fresh umbilical cords. Video-based teaching of medical students before probands performed all three techniques after assignment to one of three cycles with different sequence, using a single umbilical cord divided in three pieces for each proband.

Results: Mean time required to establish L-EUC was 89.3 s, for S-EUC 82.2 s and for S-UC 115.1 s. Both application routes using the EUC were significantly faster than the UC technique. There was no significant difference between both application routes using EUC (p=0.54).

Conclusions: Using an umbilical cannula is faster than an umbilical catheter, using a lateral incision of the umbilical vein is an appropriate alternative.

Keywords: button cannula; new-born resuscitation; umbilical catheter; umbilical cord; umbilical vein.

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Introduction

Establishing access to the neonatal vascular system is still one of the most challenging procedures in the delivery room. Even well-trained neonatologists are frequently faced with technical difficulties, which becomes the more important the higher the level of emergency is. Being confronted with a resuscitation in the delivery room is still a rare situation (0.1–1%) [1], but afflicts the medical staff from the obstetric department and anaesthesiologists rather than highly qualified neonatologists. Specific training measures are able to improve the quality of resuscitation in high level facilities up to 30% and up to 20% in low level units [2]. Besides respiratory stabilization the administration of medication, fluids and blood products is the most essential part of resuscitation. Well-trained neonatologists often need more than one attempt to establish a peripheral venous access, too. Therefore, different techniques of quasi- or true vascular access have been evaluated [3] such as the intraosseus needle (ION) insertion, the intratracheal drug administration and the umbilical venous catheter (UC) placement [4]. There is some evidence that ION is faster to place than UC [5, 6]. Based on only scarce scientific background but more than 60 years of experience since its initiation for exchange transfusion and use all over the world [7], current guidelines proclaim the UC as the gold standard emergency procedure and primary method to use [8, 9]. When handling the umbilical vein emergency access, three aspects must be considered: first, to decide which of the different devices should be used: a standard UC, or an emergency umbilical button cannula (EUC); second, the modality, how to cut the umbilical cord to expose the umbilical vein, i.e. the standard intersection or the rarely used lateral incision [10]; third, to consider how these

different techniques can be trained without being too time- and resource-consuming. Neonatologists improve their technical skills while placing UCs in their daily routine, but teaching this technique to new fellows, obstetricians and anaesthesiologists needs time and adequate equipment. Most often a manikin is used for teaching emergency techniques, but there are only few simulators usable for training of vascular access in a newborn. These devices are expensive and most often hardly represent real-life circumstances with regard to feel and consistency of human tissue [11, 12]. To evaluate the optimal access to the umbilical vein as well as the handiest application device, we used an easy to reproduce, real-life teaching model from fresh human umbilical cord specimens and used specified videos as teaching method. We hypothesized that EUC might be an easy to handle device and even faster to place than the UC. Also, the EUC, placed through a lateral incision, might be the preferable technique, compared to the standard intersection.

Materials and methods

Setting and subjects

Our single-center, prospective randomised controlled study in a 3 × 3 cross-over design was conducted at the level III neonatal intensive care unit of the University Medical Center of Freiburg, Germany. 45 medical students, studying in their third to tenth semester at University Medical School Freiburg, were enrolled between November 2019 and February 2020. Each participant had to consent to the potential bio-hazard of working with human tissue. None of the students had practical experience in obstetrics or neonatology before. The Ethics Committee of the University of Freiburg, Germany, approved the trial (No.10007/20), which is registered at the German Clinical Trials Register, registration number DRKS00019197.

Simulation models

After positive consent of the parents' fresh umbilical cord specimens were anonymously collected by midwives directly after birth in the delivery room. The umbilical cords were cleaned externally, the umbilical vein was rinsed with saline fluid and stored at 7 °C in a refrigerator (ultimate storage time: 120 h). Thickness and coiling index over a length of 10 cm was measured in each umbilical cord with a minimum length of 30 cm. Cord specimens were divided in three equal parts and mounted into three true-to-life models to simulate the situation in the delivery room. For this purpose, the umbilical cord was drawn through the extended opening of a baby bottle suction teat (Fa. NUK, Zeven, Germany, Size one) and clamped on the placenta-sided part. Umbilical veins were filled with coloured Aqua ad iniectabilia (Fa. BRAUN, Melsungen; Colour solution: RAL Diff-Quik Solution II, Fa. RAL Diagnostics, Martillac) to imitate the blood filling of the umbilical vein, afterwards the cord was clamped. The cord specimen model was then covered with an incised sterile drapery to create a scenery comparable to the situation in the delivery room (Figure 3). Each test was continuously observed by the instructor who did not intervene except for holding and "milking" the umbilical cord to improve filling.

Randomisation

As recommended by our statistical department the three different techniques had to be tested in the same order. To avoid potential carry-over effect, participants were electronically randomized to one of three groups, varying only the initial technique, but keeping the subsequent order. Group 1 started with "lateral incision emergency button cannula" (L-EUC), followed by "standard intersection umbilical catheter" (S-UC) and finally "standard intersection emergency button cannula" (S-EUC); Group 2: S-EUC/L-EUC/S-UC; Group 3: S-UC/S-EUC/L-EUC. Study participants had no contact to each other during the evaluation process and did not know, which group they were assigned to (Figure 1).

Teaching

Each technique was illustrated via a teaching video of 2 min length (Supplementary Material), explaining the procedures under consideration and the equipment at hand which comprised: 1 anatomical forceps, 1 surgical forceps, 1 scalpel size 11, 1 umbilical cord string, 1 umbilical catheter (Fa. Vygon, Ecouen, France, Size 4 Fr; 20 cm), 1 umbilical emergency button cannula ("MeiCan"; Fa. Meiser Medical GmbH, Neuenstein, Germany, Size 70 mm) and a saline filled 2 mL syringe (Fa. BRAUN, Melsungen, Germany). The button cannula is a medical device (flexible polypropylene luer lock cannula) approved for surgical irrigation, application and aspiration (Figure 3). Participants were tested in all three techniques consecutively. Each video was available for 10 min directly before the respective testing. There was an interval of 10 min between each test (Figures 2 and 3).

Outcomes

The primary outcome was the duration in seconds to establish access to the umbilical vein defined as the aspiration of the coloured solution after successful insertion of the device to an insertion depth of 5 cm. Failure was defined as inability to gain intravenous access or prolonged attempt of >300 s.

Sample size

Due to our pilot study approach and according to published data we assumed a mean time to venous access of 117 s (67–194 s) [11, 13] which yielded a sample size of 45 participants in total for a significance level of $p<0.05$.

Statistical analysis

Statistical analysis was performed using SPSS (V.24.0; IBM) and GraphPad Prism 7.04. Data are described using means and 95% confidence intervals (CI). We applied the non-parametric Mann-Whitney rank sum test for evaluation of non-parametric data as well as the Chi-

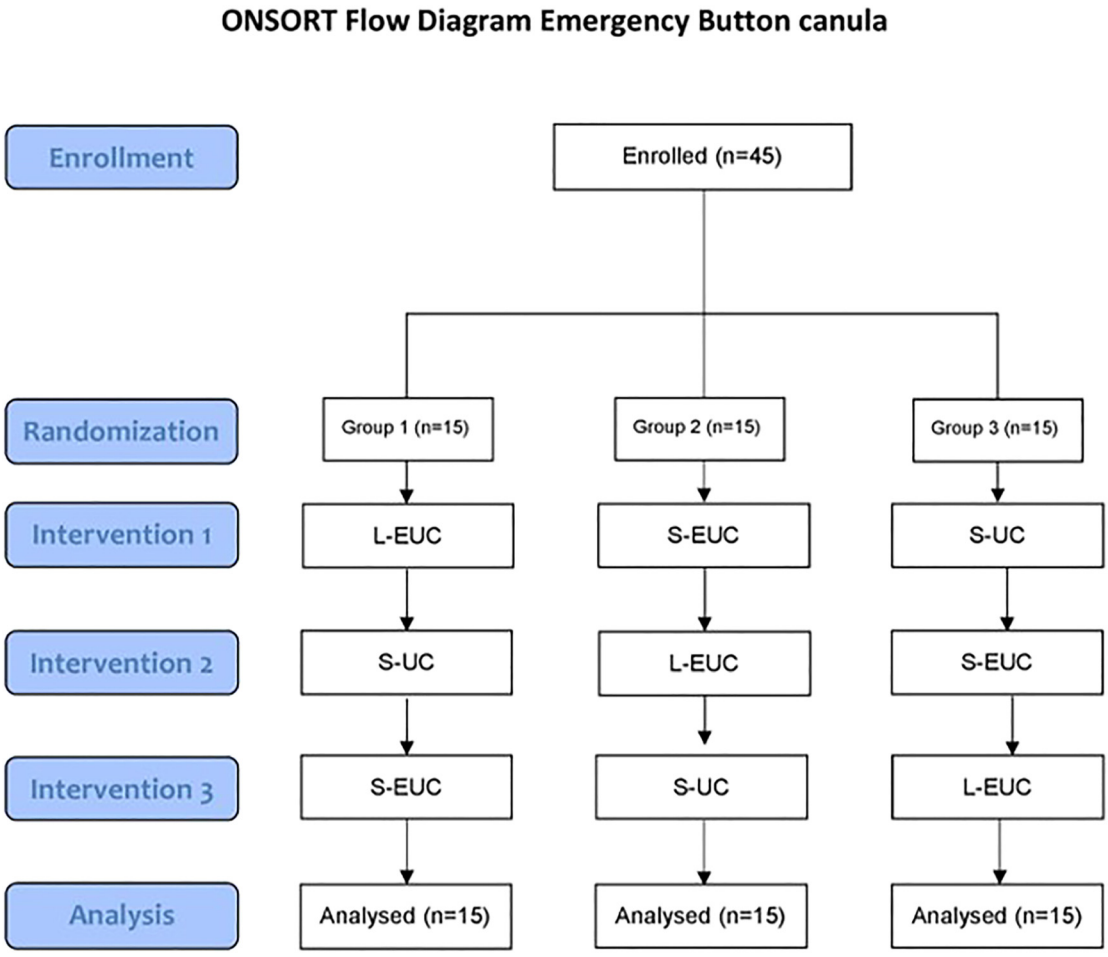

Figure 1: Flow diagram. L-EUC, lateral incision – emergency umbilical cannula; S-UC, standard intersection – umbilical catheter; S-EUC, standard intersection – emergency umbilical cannula.

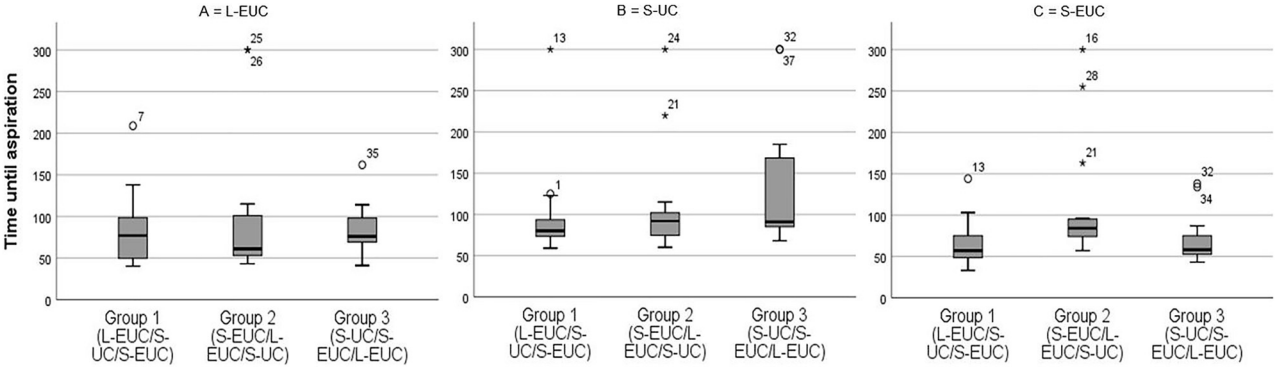

Figure 2: Top: Mean times of the rotation groups to establish access to the umbilical vein for all three testing-techniques. * and ° indicate single extreme values. L-EUC, lateral incision – emergency umbilical cannula; S-UC, standard intersection – umbilical catheter; S-EUC, standard intersection – emergency umbilical cannula.

Square-Test for contingency data. We applied a linear mixed-effects model to analyse data in this cross-over design with three groups, which can separate the effect of the period from the effect of the treatment using regression coefficients (rc) and R^2 as determination coefficient. The methods for the placement of the catheters differ sufficiently to assume that no carry-over effects

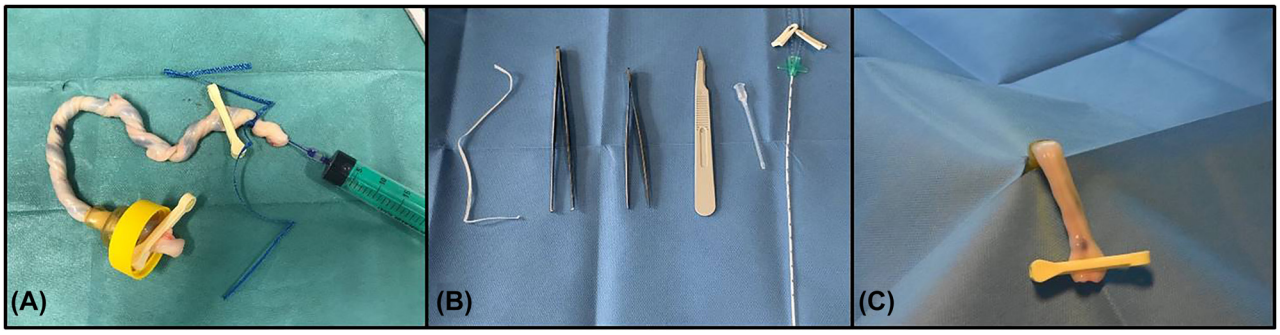

Figure 3: Experimental setup. (A) Umbilical cord after retrograde filling of the umbilical vein with dye. (B) Study equipment used in each of the three parts of the experiment: umbilical cord string, forceps (2×), scalpel, emergency button cannula and umbilical catheter (from left to right). (C) Final umbilical cord set-up at the beginning of a test.

are present [14]. A two-tailed p-value of <0.05 was considered significant.

Results

All 45 students, randomized into three groups of 15 participants each, finished the study. The groups showed no significant statistical difference concerning distribution of gender, stage of education and previous experience in insertion of peripheral and central lines. Subject demographics and umbilical cord measurements are shown in Table 1. Using L-EUC technique, overall mean duration to establish intravascular access was 89.3 s (95% CI: 72.3–106.5 s): 85.4 s (60.6–110.2 s) in group 1, 99.5 s (52.7–156.2 s) in group 2 and 83.3 s (66.5–100.0 s) in group 3. Failure rate to place the device correctly in the L-EUC technique was 4.4% (n=2). With the S-EUC technique an overall mean duration of 82.2 s (95% CI: 66.9–97.6 s) was observed: 65.5 s (49.6–81.3 s) in group 1, 110 s (69.9–150.5 s) in group 2 and 71.1 s (55.0–87.2 s) in group 3. Failure rate with the S-EUC technique was the lowest overall with 2.2% (n=1). S-UC technique required the longest overall mean duration with 115.1 s (95% CI: 94.7–135.5 s): 98.7 s (66.1–131.3 s) in group 1, 108.7 s (72.6–144.9 s) in group 2 and 137.4 s (95.3–180.2 s) in group 3. Here, the overall failure rate was highest with 8.9% (n=4) (Figure 2). The mixed linear regression model analyses revealed a significant difference of overall time for L-EUC vs. S-UC (–25.7 s; 95% CI: –48.6–2.7 s: p=0.029), so the mixed model estimated L-EUC to require on average 25 s less time than S-UC from start of the procedure until aspiration of fluid. Comparing S-UC vs. S-EUC (32 s; 95% CI: 9.9–55.7 s; p=0.006) the model estimated for S-EUC to be on average 32 s faster than S-UC. Even though vascular access was fastest with S-EUC, the difference of mean duration was not significant from L-EUC (7.1 s; 95% CI: –15.8–30.0 s; p=0.54). The linear mixed effects model for periodic influences also showed a significant decrease in the time needed to complete the third technique compared to the first technique (25,29 s [CI 2,35–48,23}; p=0.031). There was no difference between technique 2 and 3. Results are shown in Table 2.

Discussion

There is an increasing demand but lacking time for repeated and stringent education of healthcare professionals for emergency techniques. Emergencies require a high grade of familiarity with procedures and processes, since success in a timely manner is mandatory. Therefore, emergency procedures require frequent teaching with instructive media but also repeated self-studying. The intention of our study was to create a real-life simulation model and to study suitability of different techniques and devices with regard to success rate and time requirement in probands without a high grade of special experience. Our cohort of students was deemed to best represent the personnel present during unexpected emergency deliveries in lower-level obstetric departments. Prerequisite for this study was to compile teaching videos of different techniques for immediate vascular access in the delivery room for probands. To implement this knowledge most practically we used a model with umbilical cord specimens easily obtainable in obstetric units from a standing start. The umbilical vein is accessible without much preparation in an emergency, as is the intraosseous (i.o.) access. But in contrast to the umbilical access techniques, real anatomic objects are not available for bone puncture training.

Table 1: Demographic data and pre-existing knowledge of handling peripheral and central lines.

		Group 1 L-EUC/S-UC/S-EUC		Group 2 S-EUC/L-EUC/S-UC		Group 3 S-UC/S-EUC/L-EUC		
		n/15 (%)	Mean (CI 95%)	n/15 (%)	Mean (CI 95%)	n/15 (%)	Mean (CI 95%)	p-Value
Gender	Female	8 (53.3)	–	9 (60)	–	8 (53.3)	–	–
	Male	7 (46.7)	–	6 (40)	–	7 (46.7)	–	–
Age		–	23.9 (22.7–25)	–	24.4 (22.8–26)	–	23.5 (22.2–24.9)	0.75
Semester		–	8.1 (7.2–9)	–	7.7 (6.8–8.7)	–	7.7 (6.6–8.9)	0.77
Experience with peripheral lines		–	2.93	–	2.67	–	3.13	0.63
Experience with central lines		–	1.60	–	1.53	–	1.47	0.59

Experience was rated on a 4-point Likert scale: 1=none (<1× line-placement) to 4=often (>10× line-placement). p-Value for comparison of the 3 groups. L-EUC, lateral incision – emergency umbilical cannula; S-UC, standard intersection – umbilical catheter; S-EUC, standard intersection – emergency umbilical cannula.

Table 2: Results of the comparison of the three techniques via linear regression model.

Contract	Estimate	Std.error	t	Sig.	95% Confidence interval	
					Lower bound	Upper bound
L-EUC–S-UC	−25.69	11.54	−2.23	0.029	−48.62	−2.75
S-UC–S-EUC	32.82	11.54	2.84	0.006	9.88	55.76
L-EUC–S-EUC	7.13	11.54	0.62	0.538	−15.81	30.07

L-EUC, lateral incision – emergency umbilical cannula; S-UC, standard intersection – umbilical catheter; S-EUC, standard intersection – emergency umbilical cannula.

Since many years the recommended way to gain the fastest access to the venous system in newborn resuscitation is still the umbilical vein. Even the most recent ERC-Guidelines mentioning the standard umbilical catheter as method of choice [8, 9]. However, they do not mention the button cannula as an alternative. Button testing probes are standard equipment for widening of the umbilical vessels but button cannulas were just recently recommended as vascular access device [3, 15]. Research on time requirement and success rate of different techniques of emergency venous access in newborns is sparse. For resuscitation of older children the i.o.-access is recommended as rapid vascular access since peripheral venipuncture is often difficult to perform and time-consuming [4]. For newborns neither peripheral venipuncture nor i.o.-access is recommended for resuscitation after birth [8]. I.o.-access was evaluated in bench studies vs. umbilical cord manikins with quite some success, but the use of real umbilical cords turned out to be more difficult [11, 13, 16]. In our study, venous access via an EUC was achieved significantly faster than with the standard UC even in the less practiced technique using a lateral incision. Even if the significant time difference may not be clinically relevant in an emergency situation, the less complex handling of a button cannula gives advantage over the more challenging soft catheter, which has to be handled with forceps. Measured time to success and the low-price of a single-use tool qualify the button cannula as an adequate alternative to the umbilical catheter. For adequate access to the umbilical vein *in vivo* an insertion depth of 2 cm below navel normally is sufficient to apply infusions, blood products or medication and to aspire blood samples; but is still an emergency-technique. Clinical experience shows that if the cannula is secured firmly by a cord clamp it is possible to replace this device on the neonatal ward by an umbilical catheter afterwards. The lateral incision cannot replace the standard intersection but seems to be an appropriate alternative. At least in the hand of unexperienced personnel it takes more time to place the cannula via lateral incision, a technique which needs assistance from another person who is most often as unexperienced as the caregiver.

Mean time until successful vascular access was within the expected and hitherto known ranges for other kinds of emergency access in manikin studies [13]. Our model is particularly suitable to imitate the real-life situation with only few resources. In Germany nearly 50% of all obstetric units have no inhouse neonatology department [17]. In

order to represent the untrained personnel in facilities with no neonatological attendance, i.e. obstetricians, midwives and anaesthesiologists, we used probands with limited experience in this field for our model assessment. We could observe a significant learning effect with increasing cannulation attempts supporting the benefit for this special collective of medical professions. However, there are different limitations of our model. Since each model study is never perfectly suited to real-life, we cannot exclude that in a real emergency success rate and time to success may vary from our model study. For instance, because the dye filled into the umbilical vein stained the vessel, this gave an advantage to the probands in comparison with the real-life situation.

Conclusions

In a delivery room emergency, the fastest way for untrained personnel to establish access to the venous system of a newborn is to use an emergency button cannula through the standard intersection of the umbilical cord. An easy-to-make, close-to-life model can be made from human umbilical cord specimen. How this model can be of value to the more experienced staff, i.e. anaesthesiologists, paediatricians and neonatologists has to be evaluated in further studies. Prospective randomised studies evaluating the different application routes and alternative devices with neonatological staff and unexperienced personnel would be desirable.

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Competing interests: Authors state no conflict of interest.
Informed consent: Each participant had to consent to the potential bio-hazard of working with human tissue.
Ethical approval: The Ethics Committee of the University of Freiburg, Germany, approved the trial (No. 10007/20), which is registered at the German Clinical Trials Register, registration number DRKS00019197.

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