Use of Magnifying Lens to Aid Neonatal Umbilical Arterial Catheter Insertion

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We conducted this trial to test the hypothesis that use of a magnifying lens would facilitate umbilical arterial catheter (UAC) insertion in neonates. Neonates <33 weeks' gestation requiring a UAC were randomized to conventional method of catheter insertion or an experimental method using a 2.0 X magnifying lens mounted on a headband. A total of 44 neonates (Conventional = 23, Experimental = 21) with comparable demographic characteristics completed the study. The time taken for (primary outcome) and rate of successful UAC insertion (secondary outcome) were not significantly different between the two groups (median times: conventional: 88 seconds, experimental: 70 seconds, P = 0.734) (Success rate: conventional: 19/23 (83%) vs experimental: 13/21 (63%), P = 0.179] Thus, our hypothesis was rejected.

Key words: *Arterial, Catheter, Lens, Neonates, Umbilical.*

Umbilical arterial catheters (UACs) are frequently used in neonatal intensive care units (NICU) for continuous monitoring of blood gases and arterial blood pressure(1-3). The conventional method of UAC insertion can be technically challenging and time-consuming at a time when rapid stabilization of the neonate is desired(4-5). Most of the difficulties in the insertion of a UAC in preterm neonates are due to the narrow vessel diameter. We therefore conducted a clinical trial to test the hypothesis that the use of a magnifying lens will facilitate insertion of UACs by making the vessel easier to identify and manipulate. Our aim was to evaluate the efficacy of a magnifying lens in reducing the time to insertion of UAC (primary outcome) and the frequency of successful insertion (secondary outcome).

Patients and Methods

This study was designed as a randomized controlled trial in a tertiary neonatal intensive care unit. Ethics committee approval was obtained prior to commencement of the study.

All neonates <33 weeks' gestation requiring UAC for hemodynamic monitoring were eligible for enrolment in the study after informed parental consent was obtained. Neonates were excluded if there was presence of congenital malformations (*e.g.*, diaphragmatic hernia, exomphalos), known chromosomal aberrations, single umbilical artery, umbilical infection, or necrotising enterocolitis.

In the conventional method of UAC insertion (without the use of magnifying lens)

all UACs were inserted under aseptic conditions with the neonate under a radiant warmer as per our unit protocol. Oxygen saturation and heart rate was monitored continuously throughout the procedure. Length of catheter insertion was determined by measuring the shoulder to umbilicus distance and referral to the graph(6). A size 3.7 or 5.0 French Guage UAC was used depending on the size of the neonate. All catheters were primed with normal saline prior to insertion. After cleaning the skin with chlorhexidine, the cord was transected parallel to the abdomen leaving a 1 cm umbilical stump. The cord stump was stabilized with artery forceps and the artery gently probed with the tip of curved iris forceps. The forceps were allowed to spring open, dilating the artery. The catheter tip was then introduced into the artery and advanced with steady pressure to the predetermined position. Confirmation of catheter placement was made by aspiration of free flow of blood followed by a radiograph. The assisting midwife timed catheter insertion using a LCD stopwatch. The watch was started when the cord was incised and stopped when either a pulsatile column of blood was aspirated into the UAC or the procedure abandoned due to failure of arterial cannulation.

The experimental method of UAC insertion was identical to the conventional method of UAC insertion except for the additional use of a commercially available power $2.0 \times$ magnifying lens (Megaview-Easifit) mounted on a head mount loupe. The mount loupe was a headband, which allows the operator to manipulate the lens position. The use of this device ensured sterility of the operating field.

Sample size calculations were based on the previously published data(7) and our own pilot data generated by monitoring UAC insertion (n = 5 each) by two registrars with comparable experience on 10 neonates <33 weeks gestation indicating a 10% rate of failed insertions and a mean $\pm$ SD time of insertion as 310 ± 132.7 sec. Group sample sizes of 22 each were estimated to achieve 82% power to detect a 40% reduction in the insertion time (considered clinically significant) from the 330 sec (without the use of magnifying lens) to 200 seconds while using a magnifying lens (common SD =144).

A two-sided Mann-Whitney test or t-test was planned to be as appropriate depending on the data normality, at a 0.05 significance level.

Neonates eligible for enrolment were randomized into the study (stratifying for birth weight $\leq$1000 g and >1000 g) using a computer generated sequence of treatment allocations (conventional or experimental method of UAC insertion) stored in sealed opaque envelopes that were opened after the parental consent was obtained. Two separate random sequences were generated to allow for the stratification by birth weight. Four registrars with comparable experience in level III neonatal care participated in the study.

The primary endpoint of insertion time was analyzed using Mann-Whitney test or t-test, and the secondary endpoint of success of UAC insertion was compared using Fisher exact test.

Results

A total of 44 neonates (conventional method = 23, experimental method = 21) completed the study (*Table 1*). Overall 16 (36%) neonates were born with birth weight <1000 g conventional: Nine (39%), experimental: 7 (33%). Groups were comparable with respect to gestational age at delivery, birth weight, intrauterine growth retardation, and CRIB scores.

TABLE I– *Characteristics of Infants Requiring UAC**

Variable	Conventional (n = 23)	Experimental (n = 21)
Gestational age (weeks)	28 (26-30)	30 (27-31)
Birth weight (grams)	1115 (925-1460)	1455 (798-1550)
SGA	-	2 (10%)
CRIB score	2 (1-4)	1 (0-6)

* value expressed as medians and interquartile ranges (IQR = Q_{25} - Q_{75}).

* SGA = small for gestational age ($\leq$10th centile).

No significant differences were found between the median times for successful UAC insertion between the two study groups. (conventional: 88 sec (IQR 50 - 192, range 24-780), Experimental: 70 sec (IQR 55-222, range 27-642), P = 0.734.

Similarly, there were no significant differences between the two groups (conventional versus experimental method of UAC insertion) with respect to the frequency of successful UAC insertion. (Conventional: 19/23 (83%) vs Experimental: 13/21 (63%), P = 0.179). The median insertion times in the unsuccessful cases were 345 sec (IQR 205-529, range 163-900), and 900 sec (IQR 370-900, range 148-900) with no statistically significant differences (P = 0.683). The comparisons in this case however were based on small sample sizes (n = 4 and 8).

Group comparison performed at the completion of the study indicated that the median (and mean) times to UAC insertion were considerably shorter than anticipated before the study commenced (189.6 vs 167 seconds). This resulted in only 6% power to detect statistically significant differences between the study arms. Approximate sample sizes of 100 neonates per group would be required to detect a 40% reduction in the insertion times between median times of 187 sec and 112 sec with 80% power at 5% significance level using a sequential design with a single interim analysis. Given that the insertion times achieved in the two groups during the trial were very close and significantly shorter than those before the study, continuation of the study was considered unfeasible due to the very low

TABLE II–*Time and Success of UAC* Insertion*

	Conventional (n = 23)	Experimental (n = 21)	P value
Successful insertion			
All cases	19 (83%)	13 (63%)	0.179
< 1000 g	7 (78%)	5 (71%)	1.000
³ 1000g	12 (86%)	8 (57%)	0.209
Time (secs)*			
All cases	88 (50-192)	70 (55-222)	0.734
<1000g	96 (32-780)	239 (70-642)	0.268
³ 1000g	85 (24-770)	62 (27-205)	0.181

*Value expressed as medians and interquartile ranges (IQR = Q_{25} - Q_{75}).

Key Message

- Use of magnifying lens does not help in reducing the insertion time or success rate for placement of umbilical artery catheter in neonates <33 weeks.

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probability of finding statistically significant differences between the study groups.

Discussion

Insertion of the UAC plays a vital role in the stabilization and management of ill preterm neonates. Reducing the time to insert these catheters is desirable to minimize handling and allow rapid and appropriate interventions for the altered cardiorespiratory status at a critical time(4,5). Most of technical difficulties in the insertion of UACs are related to the small calibre of the vessel. Vasospasm, vascular perforation, subintimal cannulation and tunica intima invagination have also been proposed as factors responsible for failure of UAC cannulation (3,8).

Mehods to overcome the technical difficulties in insertion of UACs have received little attention in the past. Results of a randomized controlled trial by Squire *et al.*(7) have shown that compared with the conventional method the side-entry method led to successful UAC insertions more frequently and the time to successful insertions was significantly shorter. (Correct placement (n/N): side entry (15/16) vs conventional (11/16), P = 0.09), (time) to insertion in seconds: side entry (143 ± 24) vs conventional (330 ± 36), P = 0.01).

Our results (comparable but overall significantly reduced insertion times compared with our pilot data) may be explained by a great variability between the operators which was probably far more important than the benefits of using a magnifying glass to aid the UAC insertion. This was also important, as one of the two registrars whose UAC insertion timings were used for the pilot data could not participate in the clinical trial due to unexpected circumstances. Though considered comparable (with other three operators) before the trial, the UAC insertion skills of the replacement registrar may also have differed significantly during the trial. The other possibility could be an improved awareness (benefits of inclusion in a clinical trial) with possibly an improved performance in UAC insertion during the study. The side entry method described by Squire *et al.*(7) involves visual identification of the umbilical arteries through the cord stump, transection of the Wharton's jelly to the artery, followed by incision only through the upper arterial wall to expose the lumen. We have found complete transection of the umbilical artery to be a significant problem with this method of UAC insertion especially in extremely low birth weight neonates (ELBW). Our median times and frequency of successful UAC insertions are significantly better than those reported by Squire *et al.*(7). The differences again could be explained by variability in operator skills. In summary given the importance of speedy and successful vascular access in stabilization of ELBW neonates it is important to study methods to optimize the success of conventional method of UAC insertion. Our results emphasize the importance of considering the variability of (inter and intra) operator skills during the study before undertaking any such trials.

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