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ORIGINAL ARTICLE

An Integrated System for Fetal Scalp Visualization, Blood Collection and Analysis

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Abstract

Key Message **The new NB scope aids in better visualization of the scalp and blood collection and analysis at bed side.**

Objective Caesarean section rates and inherent complications are on the rise all over the world. One way to avoid a caesarean is to measure fetal scalp blood lactate levels. The methods available to visualize fetal scalp, obtain the blood sample and perform the blood test are separate, cumbersome and expensive, needing a certain level of expertise. We propose a device that incorporates all the steps of obtaining a fetal scalp blood lactate into one sleek, easy to use device.

Methods The initial design, 3-D print and was tried on mannequin. After ethics committee approval, the prototype was experimented on patients in labour with singleton live fetus in cephalic presentation with no evidence of distress.

Results There were ($n=9$) patients recruited. There were ($n=5$) primigravida and ($n=4$) multigravida all of whom were in active labour. Parity did not seem to influence ease of instrumentation. Of the ($n=9$) mothers ($n=2$) had meconium-stained liquor and the rest ($n=7$) had clear liquor, meconium-stained liquor did not affect visualization. The mean time taken to collect the sample was 184.11(± 33.04) seconds.

Conclusion The Neeraj-Bhaskar (NB) scope is an easy to use, affordable device that can be used time and again to decide on cases where emergency caesarean section can be avoided due to fetal distress.

Keywords NB scope · Fetal scalp blood sampling · Fetal scalp lactate · Fetal scalp visualization

Introduction

Having the best chance for a natural, safe delivery is a basic right for every woman. Unfortunately, in today's world of quick litigation and small families, caesarean section has become the norm instead of the exception. Six and a half million women in India have caesarean sections per year according to the NFHS—4 (National Family Health Survey—4), with most of these being conducted in the private sector. Experts in Obstetrics, Gynecology and allied fields the world over are striving to decrease the caesarean delivery rate [1, 2].

About 10–25% of caesareans are performed when the fetal heart pattern is found to be non-reassuring [1, 3, 4]. It is the most common cause of intrapartum caesarean section [1]. Fetal heart rate is monitored by means of cardiotocography (CTG). The subjective nature of CTG, along with a high false positive rate, leads to many unnecessary caesarean section [5]. Measuring fetal scalp blood lactate values seems to be an objective and reliable method to diagnose fetal distress. Major obstetric societies are now advocating its use [6].

Current devices are cumbersome with the clinician needing to kneel down at the foot end of the bed to use them. We propose a device which combines all the elements into one simple scope and can be used time and again.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s13224-020-01313-9) contains supplementary material, which is available to authorized users.

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Materials and Methods

The study design was reviewed by the institutional review board, Christian Medical College (IRB Min. No. 11133 dated 24/01/2018). After ethical committee approval, it was decided to conduct this trial in two phases. Phase one includes testing the feasibility of the NB scope and validation of design, with phase two to be reserved for fetal blood collection and analysis. Device was gas sterilized.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

The patients above 36 weeks in labour with singleton, live fetus, in no distress and cephalic presentation, with no evidence of infection were recruited. After voiding completely, the patient was positioned in lithotomy. Per vaginal examination was done and cervical dilation, position, presentation of fetus, colour of liquor was confirmed. Cervical dilation was at least 3 cm. The fetal scalp was visualized on a handheld device, connected via USB. A mock run was conducted, where accessibility of the fetal scalp and feasibility of pricking of the fetal scalp were evaluated using a dummy scalpel. The following parameters were evaluated and graded—clarity of vision, ease of navigation, resolution, stability of device and pain experienced by the patient attributable to the procedure.

Design Concept

Current Devices to Measure Scalp Lactate

The devices currently available in the market usually consist of a kit with the following elements.

- Self-illuminating scope and obturator
- Heparinized capillary tubes
- Swab sticks
- Paraffin swabs
- Scalpel mounted on a probe

Drawbacks of Currently Available Devices

1. They are for limited use only. These are not cost effective, especially in low resource settings.
2. Even though there is a self-illuminated scope, there can be issues in visualizing the fetal scalp. There is technical difficulty when the cervix is less than 7 cm dilated, or the fetal head is too high up.
3. In these devices, after removing the obturator, the scalp has to be cleaned of blood amniotic fluid, etc., and a layer of paraffin has to be applied to enable the blood to form a droplet.
4. After the scalp is suitably prepared, the swab needs to be withdrawn, and a lancet mounted on a probe inserted to make an incision on the scalp. After waiting for a suitable droplet to form, a heparinized capillary tube needs to be inserted and adequate sample obtained.
5. Withdrawing and inserting all these elements contribute to wastage of time. As highlighted earlier, median time taken for this procedure is 18 min.
6. These kits will only help the Obstetrician to obtain a blood sample. To then find out the lactate value, one must use a separate lactate analyzer. This leads to loss of valuable time, and this cost may not be feasible in low resource settings.

Overcoming These Drawbacks

The components for fetal blood sampling are-

1. Visualizing the fetal scalp
2. Making an incision on the fetal scalp
3. Collecting the blood sample with a capillary tube
4. Transferring this sample to a lactate analyzer
5. Interpreting the result

Our novel idea is to combine all these components into one, easy to use device.

Detailed Design and Assembly

A CAD model (2D) of the scope was developed at the beginning of the research work. The virtual design of the scope was built using the SolidWorks (SW 2017) software program to help us explore design ideas, visualize concepts and simulate how design will perform in the real world. Digital prototyping solution let our team test and optimizes 3D designs, helping to drive innovation, achieve higher quality and spend time to market. The optimal 3D design of the scope has been manufactured (Fig. 1a).

The scope has four parts:

1. Head
2. Body
3. Base
4. Inner guides

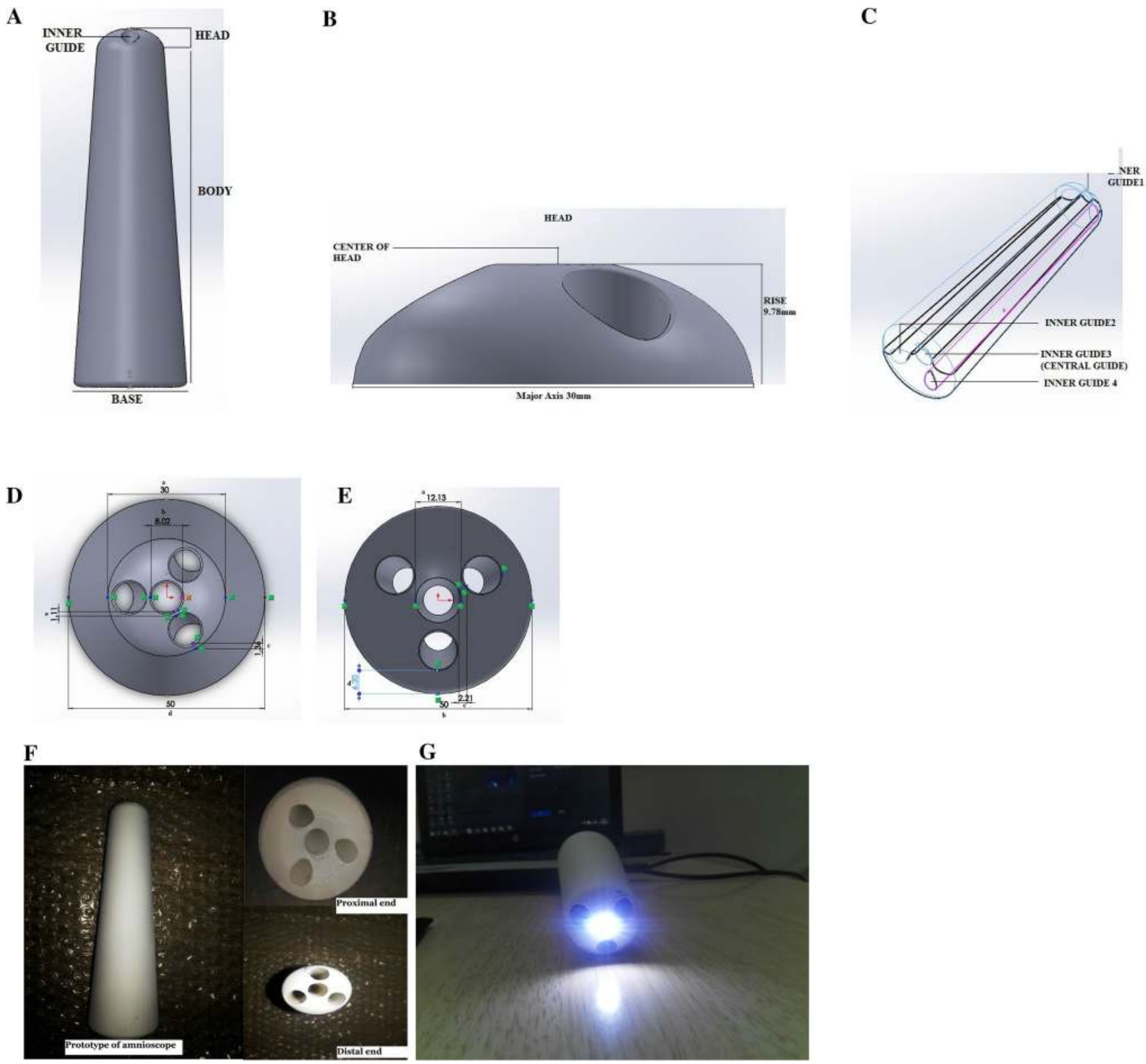

Fig. 1 **a** Scope. **b** Head. **c** Inner guides. **d** Front view of the scope. **e** Back view of the scope. **f** A prototype of NB scope was fabricated using fused deposition modelling (FDM) 3D printing technology. **g** Camera in the central guide of the NB scope

Head

Head of the scope (Fig. 1b) is in the shape of a half ellipse. The rise in the head is 9.78 mm. The major axis of the head is 30 mm.

Body

The body of the scope is in the shape of a conical frustum of height 146.38 mm, base radius 25 mm and top radius 15 mm. The smaller radius of the truncated cone is attached to a half elliptical-shaped head.

Base

The base is towards the clinician's end with a diameter 50 mm.

Inner Guides

The scope includes four inner semi-conical guide tubes extending to the top of the head from the base of the conical frustum (Fig. 1c). The four guides are designed inside the scope to permit the simultaneous introduction of a camera, a fetal blood collection system, a blood sampling pH or lactate sensor.

Front View (Fetal End)

Fig. 1d depicts the diameter of the major axis of head; 30 mm, b. represents diameter of the inner guides at the head region, 8.02 mm each, c. gives the minimum distance between a guide and the outer surface of the scope's body which is 1.36 mm, d. the diameter of scope's base is 50 mm and e. is the minimum distance between an inner guide and the central guide, which is 1.11 mm.

Back View (Clinician's End)

In Fig. 1e, the diameter of the central guide is 12.13 mm, b. diameter of base of the scope, c. minimum distance between the central guide and the inner guides is 2.21 mm each, d. the minimum distance between the inner guides and the outer surface of the scope's base is 6.20 mm.

Visualizing Mode

The camera for illuminating the fetal scalp is integrated inside the scope through the central guide. A built-in six LED; two-meter-long wired, waterproof camera is incorporated inside the scope. This 7-mm-diameter camera head makes use of optoelectronic technology to investigate hard to reach area. The resolution of this camera is 640 × 480 and 300 K pixels. The camera has an USB 2.0 interface and can be supported in Windows 2000/XP/Vista/7/8 /10/Android 4.0 and above having OTG (On-The-Go) and UVC (Universal Virtual Computer) support.

Table 1 Patient characteristics

Sl. no	Age	Parity	Cervical dilatation (cm)	Station of fetal head	Liquor colour
Group I					
1	30	Primi	6	0	Clear
2	23	Primi	8	+1	MSAF
3	27	Primi	5	0	Clear
4	31	Primi	7	1	Clear
Group II					
5	24	Multi	4	−2	MSAF
6	25	Multi	3	−2	Clear
7	26	Multi	5	−1	MSAF
8	32	Multi	7	0	Clear
9	23	Multi	6	−1	Clear

Blood Collection System

A specialized fetal scalp needle approximately 51 mm in length is used to make a clean incision of the scalp, blood is collected from the formed droplet into a 45-microlitre-heparinized capillary tube; blood flows naturally into the tube by capillary action.

Cutting Needle

Conventional cutting needles have the cutting edge on the concave surface. The needle is of 51 mm in length which creates an incision of 3 mm deep in the fetal scalp.

Heparinized Capillary

Plastic capillary of polyethylene terephthalate (PETG) material, with an inner diameter of 0.90 mm ± 0.05 mm and outer diameter of 1.60 mm ± 0.05 mm, length: 75 mm ± 0.05 mm capable of collecting 45uL blood is used in the scope.

pH or Lactate Sensing Technology

Fetal blood lactate samples are more likely to be successfully performed, have less scalp incisions and require a smaller amount of blood for analysis. Lactate measurements can be analyzed with a small amount of blood (5 µl), whereas pH analysis can require 30–50 µl of blood.

Table 2 Time taken for procedure

S. no	Parity	Time taken (s)	SD
Group I			
1	Primi	175	184.11 (±33.04)
2	Primi	198	
3	Primi	214	
4	Primi	180	
Group II			
5	Multi	247	178 (±38)
6	Multi	148	
7	Multi	182	
8	Multi	176	
9	Multi	137	

Table 4 Overall evaluation of parameters

Parameter	Result	Scale
1. Visualisation	1.88 (±0.78)	1–5 (1—very good, 5 very bad)
2. Navigation	1.9 (±0.81)	
3. Resolution	2.55 (±1.01)	
4. Stability	1.77 (±0.83)	
5. Pain due to entire procedure	4.33 (±1.00)	1–10 (1—no pain, 10—severe pain)

Table 5 Patient tolerance

S. no	Parity	Pain score	SD
Group I			
1	Primi	4	5(±0.8)
2	Primi	5	
3	Primi	6	
4	Primi	5	
Group II			
5	Multi	4	3.8(±0.8)
6	Multi	3	
7	Multi	5	
8	Multi	4	
9	Multi	3	

Prototype

Testing of Camera Integration

Preliminary Testing in Clinical Setting We recruited nine patients after informed consent. The patients were recruited in labour room of Christian Medical College, South India.

There were ($n=9$) patients recruited. All the patients were less than 35 years of age. There were ($n=5$) primigravida and ($n=4$) multigravida all of whom were in active labour. Parity did not seem to influence ease of instrumentation. The station of foetal head ranged from −1 to +1 station. Of the ($n=9$) mothers, ($n=2$) had meconium-stained liqour and the rest ($n=7$) had clear liquor (Table 1), meconium-stained liquor did not affect visualization. The mean time taken to collect the sample was 184.11(±33.04) seconds (Table 2). It was noted that lesser degree of cervical dilatation and higher foetal station increased the time taken to collect the sample. Visualization, ease of navigation and stability were graded favourably, with resolution of image receiving a slightly lower grade (Tables 3, 4). Pain due to the procedure was generally well tolerated, with only one patient scoring > 5 on the pain scale (Tables 4, 5).

Table 3 Evaluation of the parameters

S. no	Age	Parity	Visualisation	SD	Navigation	SD	Resolution	SD	Stability	SD
Group I										
1	30	Primi	2	2 (±0.8)	2	2 (±0.8)	2	2.5 (± 1.2)	2	2 (±0.8)
2	23	Primi	1		3		1		1	
3	27	Primi	2		2		4		3	
4	31	Primi	3		1		3		2	
Group II										
5	24	Multi	2	1.8 (±0.8)	1	1.8 (±0.8)	2		1	1.6 (±0.8)
6	25	Multi	1		2		3	2.6 (± 0.8)	1	
7	26	Multi	3		3		4		2	
8	32	Multi	2		2		2		3	
9	23	Multi	1		1		2		1	

Discussion

Caesarean section, a major surgery, can be avoided in many cases by measuring fetal scalp lactate. Unfortunately, devices currently available to obtain fetal blood and measure scalp lactate are cumbersome and need expertise.

We integrated visualization of fetal scalp, pick up of blood sample and testing of blood sample into one device. This device can be sterilized and reused. This device was tested in the Christian Medical College labour room. We found insertion of scope to be easy, with minimal discomfort to the patient. Each of the consultants found the device easy to assemble, visualization of scalp satisfactory to clear, and by majority, feasible for clinical practice. The lactate analyser was not used in the current study by the authors. With these encouraging findings, we plan to conduct phase II of this trial, where actual pricking of the fetal scalp, pick up of fetal blood and measurement of scalp lactate will be integrated. To prove the efficacy of the instrument, larger sample size is required. If successful, this device could revolutionize the use of fetal scalp lactate in hospitals in India and around the world. With the alarming rise in caesareans today, there is an urgent need to stem this epidemic, and we believe the NB scope is a definite contender to help do so.

Conclusion

The NB scope is potentially easy to use, less time consuming, affordable and could be used time and again to decide on cases where caesarean section can be avoided. We await the results of phase II of this trial to introduce this device into clinical practice.

Compliance with Ethical Standards

Conflict of Interest All the authors do not have any conflict of interest. The manufactures also do not have any conflict of interest. Intellectual Property India No. 201741011937.

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