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**Original Research Article**

# A Randomised controlled equivalency trial on wiping with a cloth (no suction) versus routine suctioning of oronasopharynx at birth, in term neonates born elective Lscs with clear liquor

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## ABSTRACT

**Background:** Efficacy of wiping with a cloth compared to suction in routine care is not known. In term elective Lscs with clear liquor, we hypothesise that it has equivalent efficacy with suction.
**Methods:** Randomized controlled equivalency trial with parallel group design. Inclusion criteria was term neonates born elective Lscs, with clear liquor and cried at birth at Government Rajaji Hospital, Madurai. Major congenital anomalies, Depressed or asphyxiated at birth, Meconium staining, Preterm were excluded. The Primary outcome is the time to reach a saturation of 92%. After randomisation, one group received gentle electrical suction and the other wiping of face, mouth and nose using a sterile cloth. The Pulseoximeter readings in the first fifteen minutes of life were transferred to a computer. Other clinical data collected using a Proforma.
**Results:** Among 270 elective Lscs babies, 112 randomized, 58 received suction and 54 wiping. Excluding four babies, 56 Neonates in the suction group and 52 in the no suction group were analysed. The baseline data was similar except for maternal age. The primary outcome, median time to reach 92% saturation is significantly lesser (7 minutes (m)& 6 seconds(s)), [IQR 4m41s, 9m17s] in the no suction group, than the suction group (8 m18 s) [IQR 6m44s, 10m1s] (P value 0.009 ).
**Conclusions:** In term elective LSCS babies with clear liquor and cried at birth, wiping with a sterile cloth has equivalent efficacy compared to suction for routine care.

**Keywords:** Delivery room, Neonate, Resuscitation, Routine suction, Wipes

## INTRODUCTION

Routine Suction at delivery room is a major concern. Suction while reduces airway resistance, adverse effects like hypoxemia, bradycardia, decreased cerebral blood flow, and mucosal injury are reported by trials.[1-4] NRP 2011 Guideline say that "Secretions can be removed from the airway by wiping the nose and mouth with a towel or by suction catheter or suctioning with a bulb syringe". Whereas WHO does not recommend routine suction.[5]

When we looked into the trials based on which these recommendations are made, there are only few pilot studies and 2 RCTS done at the same centre are available.[5-7]

Using standard search criteria, (Oronasopharyngeal suction, Oral suction, Routine suction, Neonate, Birth, Resuscitation, Delivery room resuscitation) and searching in PUBMED, CINAHEL, CTRI and EMBASE databases we don't find any studies on Routine Suction from India.

(Although studies on suctioning in Meconium stained babies and endotracheal suctioning are available).

Hence, we believe that our study will highlight the evidence in Routine Suctioning versus wiping with a cloth in elective Lscs using a Pulseoximeter. We hypothise in Term neonates born Elective Lscs with clear liquor and cried at birth, the difference between the mean time taken to reach 92 % saturation in those neonates who underwent suctioning of oronasopharynx and those who underwent wiping of face, nose and mouth at birth, will not differ by more than 2 minutes.

## METHODS

Randomized controlled equivalency trial with parallel group design. Period: November 2013 to March 2014.Term neonates born elective Lscs with clear liquor and cried at birth at Government Rajaji Hospital, Madurai are eligible for the study.

### *Exclusion criteria*

- Major congenital anomalies
- Depressed (cried after tactile stimulation) or asphyxiated at birth
- Meconium stained neonates at birth
- Preterm deliveries <37 weeks.

The Primary outcome is the time taken for achieving a saturation value of 92%.

### *Secondary objectives*

- Time to reach 85 % saturation and 95% saturation.
- To compare the mean saturation values and the mean pulse rate values.
- Need for advanced resuscitation by positive-pressure ventilation, intubation, chest compression, emergency medications or a combination of these methods.
- Apgar score at 5 minutes.
- Need for nicu admission and length of stay in admitted babies.
- Tachypnea, defined as a respiratory rate higher than 60 breaths per min, at any time in the first 24 hrs after birth.
- Any Mortality in the first 28 days of life.

### *Procedure*

Prospective mothers with term gestation, posted for elective Lscs are screened, enrolled after informed consent. The primary investigator, a paediatric postgraduate and a nursing sister attended the deliveries. The newly posted paediatric postgraduates and the assisting sisters, on their initial 2 days of posting, are given mock training at the neonatal ward by the primary investigator. Two Pulseoximeter machines (MASIMO RADICAL 7) were switched on and kept ready before delivery, at newborn care corner. On delivery of a neonate with inclusion criteria, the nursing sister opens the randomization cover and informs the intervention to the investigator. The baby's birth time is noted from the time displayed in the Pulseoximeter in 3 digits (hrs, mints, and seconds). After cutting the cord, baby was positioned in the warmer and given the intervention, suction or wipe by the investigator. Meanwhile one of the resuscitators wraps a reusable neonatal saturation sensor in the right palm of the baby.[6] A Electrical suction machine with a set pressure limit of 100 mm hg and a sterile Delee's catheter was used for giving suction. The catheter was gently inserted in to the mouth at a depth not more than 5cm and then at the nose. In the No-suction group (WIPES Group), a sterile soft surgical packing towel in the theatre is used to wipe away any visible secretions in the mouth, nose and face.

If subsequent wipes are needed sterile gauze pieces are used. In babies with profuse secretions, the head is tilted laterally to one side before wiping. The Saturation and heart rate data are recorded upto 15 minutes from the birth time. The Pulseoximeter was set with an averaging time of 2 seconds and the recordings stored in the memory of the Pulseoximeter. The baseline data, Apgar scores, are recorded in a prescribed Proforma and the follow up was done in newborn and postoperative wards. The baby is examined for tachypnea at 30 minutes after birth and at 6-8 hrs of life and the next day morning 24 hrs.

### *Exit criteria*

- If a baby develops bradycardia (HR <100/mn) or apnea or hypotonia during resuscitation or suspected to have airway obstruction after wiping, that baby will be given gentle electrical suction if needed and further resuscitation was done as per NRP 2011 protocol.[6]
- loosening of Pulseoximeter probe or technical fault in recording or disconnection during resuscitation.

### *Sample size estimation*

From a previous study, (time to reach 92% saturation was 6.8 ± 1.8 min in No suction group, and 10.2 ± 3.3 min suction), the effect size was 3.4 minutes difference between the two groups.[8] We aimed to detect a difference of 2 minutes between both the groups. For 80% power and a standard deviation of 3.3 the calculated sample size is 47/group total (94). Considering 20% loss, 112 patients are required. Calculations are based on an online tool at www.sealedenvelope.com for an equivalency trial.

A computerized block randomization sequence was generated with 1:1 allocation and a block size of six using an online tool at www.randomization.com.Group selection was determined by assignments from sequentially numbered sealed opaque envelopes opened in the delivery room. Masking the intervention allocation from the medical personnel within the Resuscitation area

was not practically possible. Data entry person and statistician were blinded from study details.

The data from the pulseoximeter is transferred to a computer using data transfer software (Masimo –Trend) by a data entry person. During analysis using the birth date, birth time and time period of recording, the individual patient's data was retrieved. If the Pulseoximeter alarm messages displayed in the excel sheet show low perfusion, low IQ signal, sensor off, ambient light, then the corresponding saturation and pulse rate values are excluded.[9,10] If at least three consecutives two second recordings are ≥92%, that time (6th second) is taken as the stable time to reach 92% and is used for analysis. A similar criterion was used to identify the time to reach 85% and 95% saturation.

### *Statistical analysis*

Statistical analysis was performed using the statistical software SPSS 16.0. Categorical variables were analysed with Chi-square or Fisher's exact test. Continuous variables were analysed with independent samples t test or Mann-Whitney U test. Results were defined as statistically significant when the *P* value (2-sided) was less than 0.05.

## RESULTS

Among the 270 elective Lscs babies, about 112 babies were randomized. 58 babies received suction and 54 wiping with a towel. About 8 Neonates (7.1%) drop out occurred after randomisation in our study. Finally, 52 Neonates in the no suction group and 56 Neonates in the suction group were included for analysis (Figure 1).

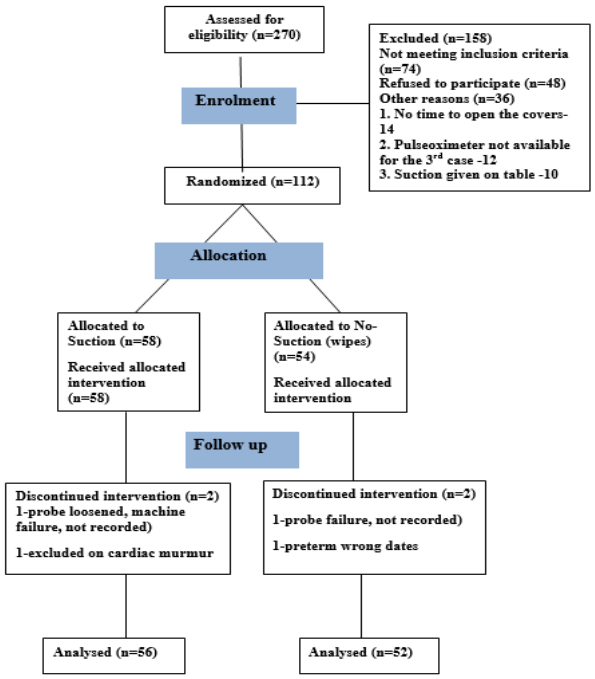


**Figure 1: Suction flow.**

**Table 1: Baseline data.**

| Baseline Maternal Characteristics | No suction | Suction |
|---|---|---|
| [Median (IQR)] age (years) | 25 (24-28) | 24 (23-26) |
| **Indications for LSCS** | | |
| Previous LSCS | 43 (82.7) | 44 (78.6) |
| Bad obstetric history | 2 (3.8) | 1 (1.8) |
| Oligohydramnios | 0 | 1 (1.8) |
| Medical Illness | 7 (13.5) | 5 (8.9) |
| Breech | 0 | 2 (3.6) |
| Short stature | 0 | 3 (5.4) |
| **Mode of anaesthesia** | | |
| Spinal | 48 | 53 |
| General anaesthesia | 4 | 3 |
| **Maternal Illness** | | |
| Anaemia | 2 (15.4) | |
| PIH | 4 (30.8) | 1 (9.1) |
| Heart disease | 4 (30.8) | 5 (45.5) |
| Polyhydramnios | 0 | 1(9.1) |
| Others (hypothyroidism, diabetes) | 3 (23.1) | 4 (36.4) |
| **Baseline neonatal characteristics** | | |
| Male | 24 (46.2) | 35 (62.5) |
| Female | 28 (53.8) | 21 (37.5) |
| Median (IQR) Birth weight (kg) | 3.00 (2.52, 3.20) | 2.9 (2.75, 3.10) |
| Median (IQR) gestational age weeks) | 38 (38, 38) | 38 (38, 38) |

Data are n (%) unless stated otherwise.

**Table 2: Time taken to reach 92%, 85% and 95% saturation values.**

| Primary outcome | No suction (n=52) | Suction (n=56) | P value |
|---|---|---|---|
| Median (IQR) time taken to Reach 92% saturation. (Minutes: seconds) | 07:06 (04:41, 09:17) | 08:18 (06:44, 10:01) | 0.009 |
| **Secondary outcomes (Pulse oximeter)** | | | |
| Median (IQR) time taken to 85% saturation (Minutes: seconds) | 5:06 (3:21, 5:09) | 6:17 (6:25, 8:24) | 0.001 |
| Median (IQR) time taken to 95% saturation (Minutes: seconds) | 08:42 (5:59, 10:56) | 10:26 (08:14, 12:41) | 0.003 |

In the 1, 2, 3, 4$^{th}$ minute of life, the number of babies for whom data available, was n=12, 46, 51, 52 in the wipes group and n= 5,46,54,55 in the suction group respectively.

The baseline maternal characteristics were similar in both the groups, except for maternal age, which has no clinical relevance (Table 1). The primary outcome median duration (Time) taken by No-suction (wipes group) to

reach 92% saturation was significantly lesser (7 minutes 6 seconds) in the no suction group than suction group (8 minutes 18 seconds) (Table 2).

**Table 3: Secondary outcomes morbidity and mortality.**

| Clinical outcome | No suction (N=52) | Suction (N=56) | P value |
|---|---|---|---|
| APGAR Score at 5 Minutes (Mean, S. D) | 8.82, 0.39 | 8.87, 0.34 | 0.535 |
| Number of babies admitted (n, %) | 5 (9.6) | 6 (10.7) | |
| **Indication for admission (n)** | | | |
| Bad obstetric history | 1 | 1 | |
| Rh incompatibility | 2 | 1 | |
| Infant of diabetic mother | 1 | 2 | |
| Iugr, LBW<2 kg | 1 | 1 | |
| Hypothyroid mother | 0 | 1 | |
| Days of stay in admitted babies. Mean, (Range), (S. D) | 4.4 (3,7) (1.67) | 3.83 (3,5) (0.75) | 0.588 |
| Neonates under Observation Care | 7 | 3 | |
| Tachypnea >60 respiratory rate on follow up in the first 24 hour. | 0 | 0 | |
| Mortality within 28 days | 0 | 0 | |

**Table 4: Minute to minute comparison of mean saturation.**

| Min. (M) after birth. | No Suction | | | Suction | | | P |
|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | |
| 1M | 12 | 68.17 | 7.51 | 5 | 55.6 | 17.5 | 0.05 |
| 2M | 46 | 73.39 | 7.91 | 46 | 65.2 | 12.51 | 0 |
| 3M | 51 | 78.25 | 7.33 | 54 | 71.98 | 9.42 | 0 |
| 4M | 52 | 82.63 | 7.11 | 55 | 75.49 | 11.05 | 0 |
| 5M | 52 | 86.12 | 6.65 | 56 | 80.32 | 9.33 | 0 |
| 6M | 52 | 88.54 | 6.07 | 56 | 84.18 | 7.95 | 0.002 |
| 7M | 52 | 90.5 | 5.23 | 56 | 87.39 | 6.75 | 0.009 |
| 8M | 50 | 91.86 | 4.79 | 56 | 89.91 | 5.46 | 0.055 |
| 9M | 52 | 93.81 | 3.78 | 56 | 91.82 | 4.7 | 0.018 |
| 10M | 52 | 95.06 | 3.11 | 56 | 93.48 | 3.84 | 0.022 |
| 11M | 52 | 95.88 | 2.56 | 56 | 94.55 | 3.29 | 0.022 |
| 12M | 52 | 96.48 | 2.16 | 56 | 95.38 | 2.78 | 0.024 |
| 13M | 52 | 96.83 | 1.69 | 56 | 96.2 | 2.5 | 0.13 |
| 14M | 52 | 97.06 | 1.42 | 56 | 96.41 | 1.65 | 0.031 |
| 15M | 52 | 97.27 | 1.42 | 56 | 96.96 | 1.32 | 0.143 |

P value (1-14 minutes) - T test for independent samples, 15th min- mann whitney test. Mean Saturation values are significantly higher in the No- suction (wipes group) from 2-12 minute and then at 14 minute.

The time taken to reach 85% saturation and 95% saturation, was also significantly lesser in the no- suction group. There was a significantly higher mean heart rate at 4th and 5th minute in the No suction group compared to the suction group (Table 5). The mean saturation levels were significantly more in the No-suction group from 2 to 12 minutes and then at 14th minute compared to suction group (Table 4). Other secondary outcomes like mortality and morbidity was not significantly different between both the groups (Table 3).

**Table 5: Comparison of mean pulse rate minute by minute.**

| Time after birth | No suction | | | Suction | | | P |
|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | |
| 1 M | 10 | 115.1 | 8.8 | 5 | 122.8 | 11.56 | 0.172 |
| 2 M | 30 | 134.5 | 13.22 | 25 | 136.8 | 15.11 | 0.544 |
| 3 M | 38 | 145.4 | 10.8 | 36 | 149.9 | 13.76 | 0.121 |
| 4 M | 48 | 155.1 | 10.95 | 44 | 149.4 | 15.54 | 0.045 |
| 5 M | 52 | 162.2 | 9.36 | 53 | 155.2 | 14.88 | 0.005 |
| 6 M | 52 | 156.6 | 17.37 | 55 | 154.7 | 13.96 | 0.532 |
| 7 M | 51 | 155.7 | 16.8 | 55 | 155.3 | 12.88 | 0.892 |
| 8 M | 50 | 157.6 | 16.28 | 54 | 155.7 | 13.18 | 0.518 |
| 9 M | 52 | 156.8 | 15.39 | 55 | 154.1 | 13.49 | 0.327 |
| 10 M | 51 | 154.8 | 14.59 | 56 | 152.8 | 14.5 | 0.467 |
| 11 M | 52 | 154.8 | 15.18 | 56 | 151.3 | 15.8 | 0.236 |
| 12 M | 52 | 151.4 | 16.26 | 56 | 151.8 | 14.68 | 0.874 |
| 13 M | 52 | 151.9 | 15.39 | 56 | 153.1 | 14.29 | 0.669 |
| 14 M | 52 | 154.3 | 14.29 | 56 | 153.1 | 13.56 | 0.646 |
| 15 M | 51 | 154.5 | 13.21 | 51 | 150.9 | 12.61 | 0.164 |

(M- Minute). The No-suction group had significantly high mean pulse rate at 4 and 5 minutes of life compared to suction group.

## DISCUSSION

The Primary outcome measured in the present study is, the time taken for 92% saturation. This is based on previous trials reporting it as the lowest acceptable saturation value in term neonates at birth.[8,11,12] In another trial, the mean respiratory rate in the first 24 hrs was used as the primary outcome.[13] The Pulseoximeter used in 2005 by Gungor and associates was system III, infant monitor, Air shields, USA) for monitoring and measurements were documented minutes by minutes.[11,12] But in our study, we used Masimo radical – 7, newer generation Pulseoximeter for recording pulse rate and Saturation and the data was transferred to a computer for analysis. The accuracy of the machine established elsewhere.[14] In present protocol, we choose 15 minutes recording based on previous studies reporting an average 12 -13 minutes stabilization time.

Oxygenation is early and the mean saturation values were higher in the no suction- wipes group in the present study. Previous studies also reported similar findings, but the time to reach 92 % saturation was much lesser in the no suction group (6.8±1.8 minutes) than the suction group (10.2 minutes±3.3).[8,11,12] But, in the present study the median difference was only 1 minute 6 seconds ahead

in the wipes group. One small trial reported bradycardia in the routine Suction group while in a RCT by Gungor et al, reported lower mean heart rates in the No-Suction group.[12,15] But in the present study the heart rates were within the normal limits and were higher in the 4th and 5th minute in the wipes group. Also, we don't find any significant adverse effects with a gentle electrical suction except for one baby requiring supplemental oxygen. This may be due to strict control of pressure, gentle suctioning, lesser secretions in babies cried at birth in a trial setting. But in practical settings, vigorous or prolonged suctioning can cause adverse effects.

***Other outcomes***

There is no mortality in either arm and none of the baby required additional resuscitation in our study. In Contrast, in Kelleher study, 10% of the wipe group and 7% in the suction group required advanced resuscitation.[13] This is probably because of the broad inclusion criteria in their study. Also, our study includes only neonates cried at birth and hence those neonates depressed or asphyxiated at birth requiring resuscitation was excluded. Kelleher reported 18% of the wipe group (no suction) and 12% of the bulb suction group required admission in their study, with no statistically significant difference.[13]

In present study, seven babies in the wipes group had mild retraction at birth and the distress resolved within 1hour, after observation in the neonatal ward. One neonate in the suction group had <95% saturation at 15 minutes, improved after supplemental oxygen, was observed and monitored for 1 hour. At the start of the study, more number of neonates were taken for observation since wiping was not a routine practice in our hospital.

## CONCLUSION

Present study is an adequately powered randomised controlled trial for the primary outcome. Presence of multiple resuscitators in the present study mimics real life situations and this gives strength to the finding. The outcome, saturation and heart rate are recorded by the machine, and direct data transfer to the computer avoided observer bias in recording during resuscitation. Hence, in term elective LSCS babies, with clear liquor, who cried at birth, wiping with a sterile cloth can be used for routine care. Suction can be reserved for more obvious obstruction.

The study limitations are, we had less number of recordings in the initial 3 minutes of life due to the time taken for shifting the baby and time to place the probe and to get the signal. The study is not done in the other higher risk situations like emergency Lscs, vaginal delivery, preterm infants and neonates born with meconium stained liquor, babies not cried at birth. We recommend further trials in these populations to address the above issues.

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