



## **Video Apgar Trial**

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### **Hypothesis**

In preterm infants <32;0 weeks of gestational age a correlation exists between specific delivery room interventions and short term outcome.

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### Main study center

University Children's Hospital in Greifswald and Dresden

### Introduction

The Test-Apgar trial was set to find the best way how to evaluate preterm infants in the delivery room. Its results will be known soon and allow better than previously to evaluate infants. With a more reproducible tool to evaluate infants after birth we have a solid base to compare groups of infants taken care for at different hospitals. This would allow prospective trials comparing different interventions in the delivery room in a multi center approach - the intention to perform the Test-Apgar trial.

At this stage however it seems rather impossible to design such an intervention study because a common language is missing that would allow to agree on details of such a study. Terms used would be understood differently at different centers leading to a different kind of intervention. For example, the term "gentle care" is used by almost every neonatal center worldwide to characterize its general approach to preterm infants. But at the same time it will be hard to find two units that agree on all details of this gentleness in their delivery room management. In addition, many NICUs do not have written concepts of the delivery room management intended to be practiced. As NICU teams tend to be large it therefore can be anticipated that substantial differences exist in most units regarding their delivery room management. In the past little has been done to minimize or only observe these differences and to ensure that every infant is taken care for according to specified guidelines.

In order to overcome these problems and to come to a more common language of what we intend to do in the delivery room the following prospective observational trial was designed. It follows the same study population of preterm infants <32 weeks of gestational age included in the Test-Apgar trial but observes them throughout their whole stay in the delivery room. The Apgar score as evaluated by the Test-Apgar trial is taken at 1, 5 and 10 minutes and will be the basis to stratify the infants into three groups of vitality.

A video of the delivery room management will be taken using standardized conditions. The video will be evaluated either locally by those directly involved in the delivery room care of this specific infant or anonymously at the main study center. Using a standardized evaluation form a set of predefined interventions is rated regarding at what time they took place and at what time they should have taken place. The difference in time for all interventions is summed up to a score. This score should allow to assess the delivery room management in comparison to the desired standard as well as between hospitals. The evaluation forms of all centers will be analyzed at the main study center to define correlations between certain delivery room interventions and short term outcome.

### Aim of the study is to

- gather data on how delivery room care is currently done,
- come closer to an agreement between different NICUs towards what should be done in the delivery room under what circumstances in which way,
- find those interventions with potential influence on short term outcome.

Those aspects of management that are different between centers and show correlation with short term outcome will be the focus of future prospective intervention trials in order to find the best way how to take care of preterm infants in the delivery room.

## Hypothesis

In preterm infants <32;0 weeks of gestational age a correlation exists between specific delivery room interventions and short term outcome.

## Methods:

### 1. Study population

Included are preterm infants <32;0 weeks of gestational age taken care for in the delivery room by the local study centers team from birth on, independent of birth weight. As this is an observational study with no interventions or drugs and no influence on any management infants participating in other studies can be included.

Infants in whom no life support is being planned – e.g. those with lethal malformations – are excluded from this study.

The study is conducted according to the declaration of Helsinki and to "Good Clinical Practice" guidelines in their current version.

### 2. Video taping

Videos are made using a standard Web-Camera (e.g. Logitech QuickCam<sup>®</sup> S 7500<sup>™</sup>, €80) connected to a PC via USB and the software included with the camera. Other cameras can be used if done so in the past. Videos send to the main study center for evaluation should have avi format. It is recommended to use a separate laptop computer not connected to the hospital information system that can be taken to the delivery room for video recording and from there to view the video for the evaluation. This ensures that the videos can not be accessed by others not involved in the study.

The camera should be attached to the resuscitation unit in a way that equipment and people do not obstruct the view and that the infant is fully seen but no faces of others. This is usually done best by mounting the camera to the back top corner of the unit / heater (see photo). Thereby, the infant is seen from the top and only the hands and no faces of those taking care of the infant. In addition, at least the monitor with saturation and heart rate as well as that measuring FiO<sub>2</sub> should be visible on the video. If possible, results of other measurements (e.g. temperature) should be shown towards the video camera as soon as obtained.

Before delivery the time of the computer should be checked and corrected if necessary. The date should be set to a false date to enhance anonymity.

### 3. Evaluation

An evaluation form allows to record the delivery room management in a time based fashion. It consists of four parts:

Infant's characteristics: Video Apgar Trial number, time of birth, gestational age, birth weight, diagnoses known at birth;

Interventions: suction, stimulation, ventilator device and intubation, ventilator settings, cardiac massage, access as well as volumes and drugs given;

Measurements: Apgar, saturation, blood pressure, temperature, all Astrup (including from cord blood) as well as hematocrit, glucose and lactate as available.

In addition, the bottom part of the evaluation form allows recording transfer, names of persons involved and the infant's personnel data. Thereby, the evaluation form can be used as the standard form to record delivery room management for the patient's record.

Interventions done and measurements taken should be recorded using the evaluation form either during delivery room care by a person not involved in the infants care or as a second choice immediately after the infant has been stabilized. Corrections can be done when viewing the video.

If the evaluation is planned to be by the main study center at least the following items should be filled: infant's characteristics, Apgar score, interventions not visible on the video.

Interventions should be marked by an X at the minute they are done. Changes only should be recorded. Therefore, intervals between numbers are assumed to have had the identical intervention or measured value as the minutes before up to the last change noted. Only for stimulation, cardiac massage and attempts to gain venous / arterial access an end of the intervention should be apparent.

Values of measurements are written when the measurement has been made. It should be noted if a measurement did not lead to a result (e.g. blood pressure: no result). Blood sampling should be noted when the blood was taken and the results noted at the time they became known.

Lines for interventions not done and values not obtained are left empty.

The evaluation form should be used to record data until transfer to the NICU but for at least 15 minutes.

Once the infant is transferred to the NICU and stabilized the video is either evaluated locally by those directly involved in the delivery room care of this specific infant or send to the main study center for evaluation. In both cases this should be done as follows:

The evaluation team should consist of at least two persons. Additional people can be involved. The video should be evaluated from the time of birth until the infant has been stabilized as a minimum, preferably until the infant was transferred to the NICU.

The evaluation team should use the video to come to an agreement as good as possible at what time ideally each intervention should have taken place or parameters should have been changed. These time points or values should be marked by a circle. The view should be prospective using all information known at that moment and not retrospective using knowledge that was known at a later time point only.

Once a final judgment has been achieved the differences between real versus agreed optimal care are calculated: One point is given for each minute an intervention was considered to be either too early or too late or a parameter should have been set differently. For each row in the evaluation form the appropriate points are entered in the last column and all points summed up to a total delivery room management score (DRMS). This score is not an objective measurement of delivery room management. It represents a subjective judgment of those evaluating the video and does not differentiate the reasons. E.g. a high score might result from low quality delivery room management as well as a very critical team evaluating the video.

If the video is evaluated by a local team an anonymous copy (without the last 4 lines) of the completed evaluation form should be send to the main study center together with the short term outcome data sheet. This will usually be shortly after the infants discharge. In case the video is for evaluation sent to the main study center Greifswald it should be accompanied by an evaluation form containing the infant's characteristics, Apgar and interventions not on the video as well as the completed short term outcome data sheet. Make sure that videos and forms send do not contain any information that would allow de-anonymization of an infant or caretaker.

At the main study center the following calculations are done:

- correlation between interventions / DRMS and short term outcome data;
- DRMS over time in months for each and for all NICUs and median for all NICUs, stratified in 3 groups by Apgar score (0-3, 4-7, 8-10), by gestational age (<25, 26-28, 29-31) or by total score points (3 groups of comparable group size);
- interventions with highest and lowest DRMS and with most and least change of DRMS over time;
- agreement / disagreement between NICUs at the beginning and at the end of the study in all interventions recorded.

For all NICUs who have not done any video recordings in the past, the first 3 videos are regarded as pilot phase. These data are not part of this study and neither videos nor evaluation forms should be send to the main study center.

During the study the main study center will also write recommendations regarding some aspects of delivery room management which are common to most NICUs and make them available on an internet discussion forum. This internet forum will allow participants to discuss practices and ask questions. The recommendations will be finalized during a general meeting of all participating centers. Towards the end of the study all study centers will also be evaluated regarding their adherence to these recommendations as well as others established locally.

#### 4. Short term outcome data sheet

Data at discharge / transfer / death, IVH, PVL, pneumothorax, BPD, nutrition, NEC, ROP.

#### 5. Definitions

Time of birth = please write the time when infants' head is developed

Suction: mark each time any kind of oral or nasal suction is done

Stimulation: mark as long as stimulation of any kind is given

CPAP: specify device used (e.g. bubble CPAP, Infantflow)

Intubation: mark when done, specify route (nasal / oral), size of tube (e.g. 2.5 Vigon), and cm at nose / mouth

Ventilation: specify device used (e.g. Draeger Babylog 2, Stefanie) and type of ventilation (e.g. SIMV+VG)

FiO<sub>2</sub>: specify inspired oxygen given at that moment

PIP / PEEP in cm H<sub>2</sub>O: specify maximal and minimal pressure used at that moment. For CPAP record PEEP only

Ventilator frequency / Ti: specify setting of ventilator frequency and of inspiratory time

Cardiac massage: mark each time and as long as given

Venous / arterial access: mark each time and as long as any access is tried as well as where and what type of access

Glucose: specify concentration of glucose and rate of infusion

Fluid: specify type of fluid and rate of infusion

Drugs: specify generic name and dosage

Thoracic movements: 2 = regular, 1 = irregular, 0 = none

Color: 2 = all pink, 1 = centrally pink with blue extremities, 0 = centrally blue or white

Muscle tone: 2 = appropriate for gestational age, 1 = reduced for GA, 0 = none

Reflexes: 2 = appropriate for gestational age, 1 = reduced for GA, 0 = none

Heart frequency: 2 = >100/min, 1 = 1-100/min, 0 = 0

Apgar: give total score at 1, 5 and 10 minutes

SO<sub>2</sub>: measured at the right wrist / hand during good pulse tracing

Mean arterial pressure: give value in mmHg at the time of measurement. Specify if measurement is arterial or oscillatory

Temperature: specify value in °C at the time of measurement

art./ven./cap.: specify values of Astrup at the time blood for measurement was taken, specify blood sampling method (arterial/venous/capillary), the first box is for values measured in cord artery blood

pH

pCO<sub>2</sub>: specify values in mmHg

HCO<sub>3</sub>: specify values in mmol/L

Base excess: specify values in mmol/L

Hematocrit: specify values as percent

Glucose: specify values in mmol/L

Lactate: specify values in mmol/L

IVH: specify maximal grade according to Deeg et al. (Ultraschall in Med. 20 (1999) 165–170, DEGUM-classification): Grade I = subependymale, Grade II = intraventricular <50% of ventricle volume, Grade III = intraventricular >50% of ventricle volume, Parenchymal = hemorrhagic infarct of brain tissue

PVL: answer yes if at least one cyst of  $\geq 3$ mm diameter is seen by any technique (e.g. ultrasound, MRI) not resulting from an IVH at this area. Specify No only if the infant was at least 3 weeks old at the last examination

Pneumothorax: Specify yes if any kind of air leak is seen by X-ray. Give DOL when seen first.

Oxygen at 28 days: specify % oxygen on day of life 28 to achieve saturation of 90% for 15 minutes independent of ventilator support

BPD: specify disease severity according to NIH definition (Jobe A, Bancalari E. Bronchopulmonary dysplasia. Am J Respir Crit Care Med. 2001;163:1723-1729): 0 = no additional oxygen and no ventilatory support, moderate = less than 30% oxygen and no ventilatory support, severe = equal or more than 30% of oxygen and/or any positive pressure to achieve saturation of 90% at rest when the infant is 36;0 weeks of corrected gestational age

Nutrition: specify first day of life (DOL) when the infant received 120mL/kg oral feeds

NEC: specify maximal stage 1 to 3 according to Bell (J Pediatr 1990; 117:836): stage 1 = suspicion (non-specific signs, hemocult positive); stage 2a = limited (distended abdomen, no bowel sounds, pneumatosis); stage 2b = severe (acidosis, thrombocytopenia, edema of abdominal wall, pain to abdominal pressure, ascites); stage 3 = advanced (ventilation, hypotension, anuria, neutropenia, DIC, shock, abdomen red and hard, perforation)

ROP: specify maximal stage 1 to 5 according to the International Classification of Retinopathy of Prematurity (Arch Ophthalmol 102:1130-5. 1984): stage 1 = demarcation line, stage 2 = ridge, stage 3 = ridge with extraretinal fibrovascular proliferation, stage 4 = partial retinal detachment, stage 5 = total retinal detachment

Age of death, even if after discharge: if known give age of death when infant died after being discharged home

For all outcome data specify if they occurred after transfer to another hospital

## 6. Data safety

Only anonymous videos, evaluation forms and short term outcome data are transferred outside the local study center. Transfer is done via safe internet site (https), mail or FAX. No material should be sent by regular email.

At the beginning of the study each local study center receives together with the other study material

1. an electronic version of the study protocol including patient information and declaration of consent as well as the evaluation and the short term outcome forms. The data should be typed into an electronic format by the local study center before transfer;
2. a set of numbers unique to each study center. Each infant included in the study is given one of these numbers. They have to be used when naming video, evaluation form and short term outcome data before sending;
3. username and password for access of a safe internet site for upload and download of data.

Before transferring data the local study administrator has to double check that neither video nor forms contain or show names or caretakers faces. It is in each study centers responsibility to guarantee compliance with this rule.

In order to minimize the chance of de-anonymization of the video and its misuse for legal issues the following procedure is recommended:

- before starting the video confirm that no faces will be seen and that the computer has the wrong date/time
- if you *do* evaluate the video yourself: fill in the evaluation form including the Video Apgar Trial Number as soon as possible
- if you *do not* evaluate the video yourself: upload the video to the safe internet site using the infants Video Apgar Trial Number as soon as possible
- immediately thereafter make sure that the video has no name do identify its origin and store it on a safe device and together with all other videos to hamper any assignment. You may also delete the video if it will not be used for other purposes

Each study center should once per month transfer to the main study center one set of data consisting of either a video or an evaluation form each together with short term outcome data sheet.

The main study center will control compliance with all aspects of data safety. Study centers who after admonition do not comply may be excluded from further participation in the study at the discretion of the principle investigators.

#### 7. Parental informed consent

The parents or legal guardians are informed about the study by the physician in charge using the informed consent attached as appendix. This should be done before birth. The parent's free decision to agree or to refuse participation in the study without any disadvantage for the infant or the parents is particularly stressed.

At least one of the parents has to sign and date the agreement. The original of the parental consent is kept in the infants study file. A copy can be kept in the infants chart.

If the parents withdraw their consent later the video is to be destroyed if it still can be identified. The evaluation form has to be destroyed also except if it is used as part of the infants' record.

#### 8. Agreement from personnel

Depending on the local law a central committee (workers' council; in Germany Betriebsrat / Personalrat) may have to be either informed on the study or asked for their consent to perform such a study with staff partially been seen on videos. Each staff member involved might have to give their individual personnel consent before being part of a video. Each study center has the responsibility to make sure the study complies with local laws.

If people other than those involved in the individual infants' delivery room care are to be involved in the evaluation this should be agreed to in advance by all involved.

#### 9. Insurance

No insurance is needed because the study is purely observational and without any influence on patient care. No diagnostic, therapeutic or other management is influenced, no drug given.

#### 10. Ethics committee

All study centers are requested to obtain a positive vote of their local ethics committee.

#### 11. Costs

The study is free of costs both for the participating study centers and for the patients participating in the study.

#### 12. Publications

The first major publication in a peer reviewed journal using data from this study the following order of authors is intended: Helmut Küster, one author per local study center sorted according to

the number of infants included, Mario Rüdiger. All secondary papers publishing data from this study should have one person of each study center as a co-author. All manuscripts are to be sent to all participating study centers before submission. Every author has 4 weeks to give his/her comments. Otherwise the manuscript is considered to be accepted as is.

## **Patient information**

### **Apgar Video Trial**

Dear parents,

the first minutes of life are very important for a premature infant. It comes from a protected environment where its mother takes care of delivery of oxygen and nutrients. Immediately after birth the infant has to take over these functions. This transition period is very critical and therefore several of the most experienced persons of the neonatal team will accompany your infant during these first minutes.

Today, this transition period from intrauterine to extrauterine life is not completely understood. Therefore, it is not clear for all details what should be done to help the infant to go through this transition most easily and with best results.

In order to understand what happens in the delivery room and to find the best way to intervene we would like to use a video taken during these first minutes of transition in the delivery room. This video will only show your infant and the hands of those taking care of him or her. No other faces will be seen, the recording will be without voices. In addition, we will collect some data from your child in order to later analyze them in relation to the interventions done in the delivery room. This trial has no influence on the management of the delivery room care. It implies no interventions, no drugs are given or blood taken, only data are collected.

The video and all data are collected anonymously, i.e. without mentioning your name or any dates so that nobody will later be able to reconstruct who is seen on the video. The name of your child will not be given to any person outside your hospital and will not be mentioned in any publication. No individual data will be given to persons outside this trial.

With the results of this trial we hope to be able to improve quality of care in the delivery room in the future.

We would like to ask you to agree in the participation of your child in this trial. According to your agreement the video will be evaluated either

- only by those who were involved in the delivery room care of your infant, or
- also by other members of the NICU team, or
- also by members of other NICUs participating in this trial, or
- also used for teaching, training and meetings.

In all cases, the video will be anonymous so that your infants name does not appear anywhere.

No disadvantages will arise for you or your child if you do not participate in this trial. This agreement can be withdrawn at any time without any reason and without negative consequences for you or your child. If you withdraw your consent later it might not be possible to identify and destroy the video of your infant because it has been made anonymous.

If you have any questions please do not hesitate to ask your child's physician or the principal investigators of this trial at any time.



# Delivery room care evaluation sheet

VIDEO APGAR TRAIL NUMBER		Time of birth			GA		BW		Diagnoses known at birth				DRMS POINTS
Time (minutes)	1	2	3	4	5	6	7	8	9	10			
Suction													
Stimulation													
CPAP: device													
Intubation nasal / oral size of tube													
Ventilation: device type													
FiO <sub>2</sub>													
PIP / PEEP													
Ventilator frequency Ti													
Cardiac massage													
Ven / art access where / what													
Glucose: __ % __ ml/h													
Fluids: ____ ml/h type _____													
Drugs: name _____ dose _____													
													TOTAL DRMS
Thoracic movements													
Color													
Muscle tone													
Reflexes													
Heart frequency													
Apgar Score total													
SO <sub>2</sub>													
Mean blood pressure													
Temperature													
art./ven./cap cord blood													
pH													
pCO <sub>2</sub>													
HCO <sub>3</sub>													
Base excess													
Hematokrit													
Glucose													
Lactate													
Transfer		from		to									Time
Names of people involved							More Diagnoses						
Name of infant			First name				Number of multiple				Date of birth		

**Short term outcome data sheet**

Video Apgar Trial number \_\_\_\_\_

Mode of discharge

- Home
- Transfer to another hospital
- Died

Age at discharge [days]

\_\_ \_\_ \_\_

Gestational age at discharge [weeks / days]

\_\_ \_\_ / \_\_

Weight at discharge

\_\_ \_\_ \_\_ \_\_ g

Head circumference at discharge

\_\_ \_\_ cm

Intraventricular hemorrhage

- No
- Grade I
- Grade II
- Grade III
- Parenchymal

Cystic periventricular leukomalacia  $\geq 3\text{mm}$

- No
- Yes

Pneumothorax

- No
- Yes, DOL \_\_ \_\_

Oxygen at 28 days of life

- No
- Yes

Bronchopulmonary dysplasia at 36 weeks

- No additional oxygen / no ventilatory support
- Moderate ( $\text{FiO}_2$  0.21 - 0.29) / no vent. support
- Severe ( $\text{FiO}_2 > 0.3$  or ventilatory support)

Nutrition

\_\_ \_\_ DOL when first time 120mL/kg oral feeds

Necrotizing enterocolitis

- Stage 1
- Stage 2a
- Stage 2b
- Stage 3

Retinopathy of prematurity

- No
- Stage 1
- Stage 2
- Stage 3
- Stage 4
- Stage 5

Age of death after discharge

\_\_ \_\_ \_\_

Photo of resuscitation unit with camera and laptop attached

