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Valérie Gonçalves Vieira

The golden hour in infants <29
weeks of gestational age

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Doutora Hercília Guimarães

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Neonatologia

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

The golden hour in infants <29 weeks of gestational age

ORIENTADOR

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COORDINADOR (se aplicável)

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É AUTORIZADA A REPRODUÇÃO INTEGRAL DESTES TRABALHOS APENAS PARA EFEITOS DE INVESTIGAÇÃO, MEDIANTE DECLARAÇÃO ESCRITA DO INTERESSADO, QUE A TAL SE COMPROMETE.	☒
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Faculdade de Medicina da Universidade do Porto, 22/03/2019

Assinatura conforme cartão de identificação:

Valérie Gonçalves Vieira

Ao meu pai,

À minha mãe,

Às minhas irmãs, Nelita e Elisée

À minha sobrinha Inês

The golden hour in infants <29 weeks of gestational age

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The golden hour in infants <29 weeks of gestational age

Abstract

Objective. The main goal of this study was to evaluate the impact of the golden hour in the early neonatal outcomes and mortality, specifically in infants with less than 29 weeks of gestational age (GA).

Methods. Newborns with <29 weeks of GA admitted to our level III neonatal intensive care unit (NICU) between June 2011 and June 2018 were analyzed retrospectively. Data about demographics, prenatal period, delivery room (DR), NICU and outcomes were recorded. Logistic regressions were performed to evaluate the predictors of early neonatal outcomes.

Results. Our study included 101 newborns and showed an association between days of oxygen in NICU and bronchopulmonary dysplasia (BPD) (odds ratio (OR) 1.50; 95% confidence interval (95%CI) 1.01-2.24; $p=0.045$); systolic pressure at admission in NICU and intraventricular hemorrhage (IVH) $\geq$ grade 3 (OR 1.37; 95%CI 2.035-4.014; $p=0.019$); and continuous positive airway pressure (CPAP) in the NICU and death (OR 0.011; 95%CI 0.101-0.401; $p=0.014$). We did not find any statistically significant association between resuscitation in DR, temperature, peripheral capillary oxygen saturation (SpO₂%), heart rate, respiratory rate at admission in NICU and short term outcomes. The overall mortality in our center was 33.7%.

Conclusions. Overall lower GA and birth weight (BW) are risk factors for mortality and retinopathy of prematurity (ROP). The first minutes after birth have a big impact in neonatal outcomes, we have shown in our study that neonates who died required more mechanical ventilation (MV), epinephrine, and less CPAP in DR; and infants with IVH $\geq$ grade 3 compared to IVH < grade 3 had an upper mean ($\pm$ SD) systolic pressure. The administration of post-natal steroids (PNS) was beneficial for the majority of the newborns.

Keywords: preterm infants, newborn, golden hour, morbidity, mortality, determinants

Introduction

The term “Golden Hour” of neonatal life, adapted from adult trauma, is defined as the initial first hour after delivery, in both preterm and term neonates [1].

Recently introduced in the field of neonatology, this concept and his interventions have already showed good results on previous research. In the initial sixty minutes of postnatal life, experienced neonatologists and neonatal nurses provide the best treatments and interventions, using evidence-based protocols, reducing neonatal complications such as hypotension, hypothermia, hypoglycemia, hypoxemia and infection. With the stabilization of this golden hour parameters, it is possible to reach the principal goal: reduce or prevent immediate and long-term outcomes like IVH, BPD, ROP, and PDA [1, 2, 3].

Characterization of neonatal outcomes by GA is important, because this is one of the major determinants with negative impact in neonatal mortality and morbidity, and having this information it will help clinicians to realize which interventions should have priority in the first minutes of life of a preterm infant [4].

The objectives of this study were to describe the characteristics, morbidities and mortality of infants <29 weeks of GA; to identify medical interventions; and to evaluate the impact of the golden hour variables in early neonatal outcomes and mortality.

Materials and methods

We performed a retrospective observational study with 101 neonates with <29 weeks of GA born from June 2011 to June 2018 and admitted to our Level III NICU.

The inclusion criteria were: newborns with <29 weeks of GA, regardless of BW, born in our hospital and transferred after birth to the NICU. The transferred newborns to another hospital after birth, the outborn infants, and those with major congenital anomalies were excluded.

Data regarding mothers and newborns were collected from medical records.

We recorded perinatal and individual characteristics of the mother: maternal chronic diseases; maternal pregnancy diseases such as diabetes mellitus; hypertension,

defined as maternal blood pressure >140 mmHg systolic and >90 mmHg diastolic; pre-eclampsia, defined as hypertension accompanied with proteinuria; Hellp syndrome; infectious risk; fetal growth restriction (FGR), defined as BW of <10th percentile for gender and GA; abnormal umbilical flow; placental abruption; premature membrane rupture, defined as leakage of amniotic fluid for more than 18 h before delivery; peripartum antibiotics; and steroids.

We have studied peripartum period and early neonatal period and outcomes: type of delivery; infectious risk; apgar score at 1st and 5th minute; gender; GA (recorded as completed weeks); BW; multiple gestation; neonatal resuscitation (positive pressure ventilation, endotracheal tube, chest compression and medication with epinephrine); ventilation devices (CPAP and MV); oxygen therapy; vascular catheterization (umbilical artery, umbilical vein, both); and other post-natal drugs (surfactant, antibiotics, steroids).

The collected laboratory data at admission of the newborn to NICU included: SpO₂%, systolic, diastolic and mean blood pressure (mmHg), temperature (°C), umbilical cord pH, hemoglobin (g/dL), platelets ($10^3/\mu\text{L}$) and blood glucose level (mg/dL).

We have selected and recorded some neonatal determinants and outcomes in NICU: need for surfactant; use and days of (oxygen therapy, MV and parenteral nutrition); early-onset and late-onset sepsis, diagnosed by a positive blood culture and clinically; pneumothorax; congenital pneumonia; hyaline membrane disease, diagnosed according to clinical and chest X-ray criteria; BPD; PDA and treatment (surgical, medical or both); necrotizing enterocolitis (NEC) if grade ≥ 2 according to modified Bell et al criteria [5]; IVH if grade ≥ 3 according to Papile et al [6]; cystic periventricular leukomalacia (CPVL), more than two small cysts in the periventricular area; ROP if

grade $\geq$ 2 according to the International Classification of Retinopathy of Prematurity [7]; and hydrocephalus with shunt or reservoir.

We have analysed the duration of stay in NICU and mortality.

This study was approved by our institutional ethics committee and the access to medical records was authorized by the office designated for this function.

Statistical analysis

Statistical analysis was performed using SPSS, version 25. Categorical variables were analysed by absolute and relative frequencies and continuous variables were analysed according to their distribution by mean ($\pm$ standard deviation) for symmetric distribution or median (minimum–maximum) for asymmetric distribution. Categorical variables were evaluated by Chi-square or Fisher's Exact Test and continuous variables by Independent T Test or Mann–Whitney U Test.

Predictors for BPD, IVH $\geq$ grade 3, ROP $\geq$ grade 2, PDA, NEC $\geq$ grade 2, CPVL and death, were evaluated by a multivariate analysis using logistic regression. A p value <0.05 was considered as statistically significant.

Results

A total of 101 infants with <29 weeks of GA were born at our center and included in this study. Data about mother, prenatal period, newborn demographics, golden hour and NICU evolution are summarized in Table 1.

Univariate analysis

Comparing neonates with BPD (n=35) to non-BPD (n=65), the univariate analysis showed statistically significant differences in the respiratory rate [50 ($\pm$ 15) vs 44 ($\pm$ 12); p=0.034] and diastolic blood pressure at NICU's admission [24.6 ($\pm$ 11.4) vs 29.8

(± 12.2); $p=0.047$]; in the use of CPAP in NICU [31 (88.6%) vs 43 (66.2%); $p=0.015$]; the need of transfusions [34 (97.1%) vs 45 (69.2%); $p=0.001$]; the use of PNS [19 (54.3%) vs 3 (4.6%); $p<0.001$]; the duration of MV [41 (1-90) days vs 9 (1-71) days; $p<0.001$] and in the duration of oxygen therapy [37 (1-109) days vs 2 (1-75) days ; $p<0.001$].

Comparing neonates with PDA ($n=70$) to non-PDA ($n=26$), the univariate analysis showed statistically significant differences in blood glucose level at NICU's admission [$61.8 (\pm 33.3)$ vs $90.4 (\pm 35.9)$; $p=0.002$], the need of transfusions [64 (91.4%) vs 16 (61.5%); $p<0.001$] and in nosocomial sepsis IN NICU [38 (55.9%) vs 8 (32%); $p=0.041$].

All newborns with NEC $\geq$ grade 2 needed amines in NEC $<$ grade 2 [3 (100%) vs 1 (16.7%); $p=0.048$] and their mothers had pre-eclampsia [3 (100%) vs 0; $p=0.012$].

Comparing neonates with ROP $\geq$ grade 2 ($n=23$) to ROP $<$ grade 2 ($n=27$), the univariate analysis showed statistically significant differences in GA [$26.0 (\pm 1.0)$ vs $27.2 (\pm 0.9)$; $p<0.001$], BW [814 (± 194) vs 984 (± 192); $p=0.003$] and in the used PNS [13 (56.5%) vs 7 (25.9%); $p=0.028$].

Comparing neonates with IVH $\geq$ grade 3 ($n=30$) to IVH $<$ grade 3 ($n=17$), the univariate analysis showed statistically significant differences in FGR [0 vs 4 (23.5%); $p=0.013$], abnormal umbilical flow, [1 (3.3%) vs 5 (29.4%); $p=0.018$], systolic pressure at NICU's admission [$48.2 (\pm 11)$ vs $40.46 (\pm 6.78)$; $p=0.017$], GA [$25.5 (\pm 1.4)$ vs $26.5 (\pm 1.1)$; $p=0.023$], platelets count [208 (± 51) vs 151 (± 68); $p=0.003$], nosocomial sepsis [11 (39.3%) vs 12 (70%); $p=0.042$] and death [17 (36.7%) vs 3 (17.6%); $p=0.014$].

Comparing neonates with CPVL ($n=10$) to non-CPVL ($n=88$), the univariate analysis showed statistically significant differences in heart rate at NICU's admission

[167 (± 10) vs 155 (± 18); $p=0.005$ of heart rate], in the use of steroids in NICU [6 (60%) vs 16 (18.2%); $p=0.008$] and duration of MV [44 (0-76) vs 18 (0-90); $p=0.011$].

Other results from univariate analysis, namely about death are shown in Table 2. We did not find statistically significant differences in other variables including golden hour.

Multivariate analysis by logistic regression

In this analysis, duration of oxygen therapy was associated to BPD (OR 1.50; 95%CI 1.01-2.24; $p=0.045$) adjusted to GA, BW, nosocomial sepsis, abnormal umbilical flow, CPAP in NICU, transfusion, PNS, death, days of MV, days in NICU, respiratory rate, days of parenteral nutrition, days of oxygen therapy, PDA and surfactant; systolic pressure at NICU's admission to IVH $\geq$ grade 3 (OR 1.37; 95%CI 2.035-4.014; $p=0.019$) adjusted to GA, nosocomial sepsis and FGR; and the use of CPAP in the NICU to death (OR 0.011; 95%CI 0.101-0.401; $p=0.014$) adjusted to epinephrine, pneumothorax, BPD and SpO₂. We did not find predictors for the other neonatal outcomes.

Discussion

Infants who survived were more likely to be delivered by C-section delivery, and had less morbidities. Like several other studies [4, 8], our study showed that lower GA and BW are risk factors for mortality. The majority of newborns were resuscitated in the DR and needed MV. Neonates who died required more MV, epinephrine, less CPAP in DR, and from this last ones, 3 (8.8%) failed and had to start MV in NICU vs 4 (6.9%) Dargaville P.A. et al, concluded that CPAP failure in newborns (principally <29 weeks of GA) was associated with increased risk of mortality and morbidities, like BPD [9].

Post-natal steroids have an important role in preterm infants. In our study neonates with BPD, CPVL, ROP $\geq$ grade 2, used more PNS, compared to non-BPD, non-CPVL, and ROP < grade 2 respectively. Between death neonates only one used PNS, which means that the administration was beneficial for the majority. But we did not establish an independent association after multivariate logistic regression analysis. Fortin-Pellerin et al. study suggests that PNS were not associated with an improved survival rate but with an upper time of death [10]. A meta-analysis of randomized controlled trials of PNS in some groups suggests a reduction in mortality [11].

Infants with PDA did more transfusions and had more nosocomial sepsis compared to non-PDA. According to Alvaro Gonzalez MDa et al. infection increases prostaglandins and inflammatory mediators that influence the PDA closure or the risk of reopening. In their results, late PDA occurred more in infants with infection than in those without infection [12].

Beyond PDA, we also found higher prevalence of nosocomial sepsis in the outcomes BPD and IVH < grade 3.

Such as Khaterine C. et al [13], we show in extreme low gestational age newborns (ELGAN) that, number of days of oxygen therapy in NICU is independently associated with BPD. In our study, BPD neonates had higher median days of MV and oxygen therapy, and this can be explained because these two interventions can cause destruction or injury in airways, and eventually permanent sequelae. The neonates with BPD had upper respiratory rates and lesser diastolic blood pressure.

Infants with IVH $\geq$ grade 3 had less FGR, abnormal umbilical flow, nosocomial sepsis, and GA, but in contrast they had higher mortality rates. Several studies have placed emphasis on the association of fluctuation of blood pressure [14] or hypotension [15, 16, 17] during the early postnatal period, with development of IVH in any grade.

With our analyses we have shown an upper mean ($\pm$ SD) systolic pressure in infants with IVH $\geq$ grade 3 compared to IVH $<$ grade 3 and a MABP of 34.1 ($\pm$ 10.2) vs 28.1 ($\pm$ 6.9). We found an independent association of systolic blood pressure with IVH $\geq$ grade 3. In our perspective abnormal hemodynamics can cause dysregulation of cerebral blood flow and lead to development of IVH. Moreover, newborns with IVH $\geq$ grade 3 had a superior mean ($\pm$ SD) platelets number compared to IVH $<$ grade 3 ($p=0.003$). These results can be explained by the influence of platelets on the damage of vascular integrity of the germinal matrix, a major factor for IVH [18].

We did not find any statistically significant association of golden hour variables and NEC $\geq$ grade 2, ROP $\geq$ grade 2 and CPVL.

One of the most important risk factor for development of ROP is low GA [19, 20], consistent with our results. The use of supplemental oxygen has also been associated with increased risk of ROP [21, 22], findings not found in our study. Recent studies point out an association between restrictive use of oxygen and higher mortality [23, 24], showing that lower SpO₂ targets (85-89% vs 91-95%), is not a good preventive approach to decrease ROP rates, but definitive recommendations are still needed [24, 25].

Although previous studies shown that temperature is a strong predictor for neonatal mortality at all GA, increasing the risk of IVH, late-onset sepsis, and respiratory distress, these findings were not found in our study [26].

The retrospective nature of our study is one of it's limitation, but prospective studies of ELGAN are difficult to perform given the relatively low prevalence in our NICU. In addition, data from a single institution (outborn infants and those transferred to another hospital after birth were excluded) is a limitation for sample size.

Reducing the high rates of morbidity and mortality among ELGAN remains a challenge for clinicians and investigators [27]. From our study, lower GA and BW are risk factors for mortality and ROP. The first minutes after birth have a big impact in neonatal outcomes, we have shown that neonates who died required more MV, epinephrine, and less CPAP in DR; and infants with IVH $\geq$ grade 3 compared to IVH $<$ grade 3 had an upper mean ($\pm$ SD) systolic pressure. The administration of PNS was beneficial for the majority of the newborns.

Larger clinical studies are required in order to find strategies to prevent the short-term morbidities and consequently improving rates of survival and reducing long-term outcomes.

Declaration of interest:

The authors report no conflicts of interest.

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Table 1. Data about mother, prenatal period, newborn demographics, golden hour and NICU evolution (n=101).

Mother and prenatal period data	
Multiple gestation, n (%)	35 (34.7)
Twins	33 (94.3)
Medically Assisted Reproduction, n (%)	21 (20.8)
Maternal habits, n (%)	
Tobacco	14 (13.9)
Alcohol	3 (3.0)
Drugs	2 (2.0)
Maternal chronic diseases, n (%)	40 (39.6)
Maternal pregnancy diseases, n (%)	
Diabetes	17 (16.8)
Hypertension	2 (2.0)
Pre-eclampsia	21 (20.8)
Hellp syndrome	9 (8.9)
Infection	60 (59.4)
FGR, n (%)	17 (16.8)
Abnormal umbilical flow	15 (88.2)
Placental abruption, n (%)	19 (18.8)
Premature membrane rupture, n (%)	13 (13.1)
Steroids, n (%)	99 (98.0)
Complete cycle	67 (67.7)
C-section, n (%)	67 (66.3)
Newborn demographics and golden hour	
Male gender, n (%)	51 (50.5)
GA (wk), mean ($\pm$ SD)	26.4 ($\pm$ 1.48)
BW (g), mean ($\pm$ SD)	872.2 ($\pm$ 221.9)
Apgar score, n (%)	
1 st min <7	69 (68.3)
5 th min <7	30 (29.7)
Resuscitation, n (%)	
O2	101 (100)
Positive pressure ventilation	89 (88.1)
Endotracheal tube	64 (63.4)
Chest compressions	4 (4.0)
Epinephrine	4 (4.0)
CPAP in the DR, n (%)	42 (41.6)
MV in the DR, n (%)	64 (63.4)
Vascular catheterization, n (%)	
Umbilical artery	58 (58.0)
Umbilical vein	71 (71)
Umbilical cord pH, median (min-max)	
Arterial	7.31 (6.90-9.43)
Venous	7.33 (6.96-7.5)
pH, median (min-max)	7.2 (3.4-7.4)

Hemoglobin (g/dL), mean ($\pm$SD)	15.5 ($\pm$ 2.6)
Platelets (10^3/uL), mean ($\pm$SD)	182.8 ($\pm$ 5.7)
Blood glucose level (mg/dL), mean ($\pm$SD)	70 ($\pm$ 36.1)
SpO2, median (min-max)	95 (19-100)
Blood pressure (mmHg), mean ($\pm$SD)	
Systolic	48.7 ($\pm$ 12.4)
Diastolic	27.9 ($\pm$ 12.1)
Mean	34.6 ($\pm$ 10.8)
Heart Rate (bpm), mean ($\pm$SD)	155.3 ($\pm$ 18.1)
Respiratory Rate (cpm), mean ($\pm$SD)	46.2 ($\pm$ 13.2)
Temperature ($^{\circ}$C), mean ($\pm$SD)	36.2 ($\pm$ 0.9)
NICU evolution	
Hyaline membrane disease, n (%)	87 (86.1)
DBP, n (%)	35 (35.0)
Pneumothorax, n (%)	17 (16.8)
Sepsis, n (%)	
Early	20 (20.6)
Late	46 (48.9)
PDA, n (%)	70 (72.9)
Medical treatment	56 (80.0)
Surgical ligation	13 (18.6)
NEC $\geq$ grade 2, n (%)	3 (3.0)
ROP $\geq$ grade 2, n (%)	23 (46.0)
IVH $\geq$ grade 3, n (%)	30 (63.8)
CPVL, n (%)	10 (10.2)
Hydrocephalus with shunt or reservoir, n (%)	9 (9.2)
MV, n (%)	99 (98)
MV (days), median (min-max)	34 (1-90)
Oxygen, n (%)	92 (91.1)
Days, median (min-max)	9 (1-109)
Surfactant, n (%)	82 (81.2)
Steroids, n (%)	22 (21.8)
Amines, n (%)	40 (40.0)
Parenteral nutrition, n (%)	96 (95.0)
Days of parenteral nutrition, median (min-max)	22 (1-90)
Days in NICU, median (min-max)	60 (1-191)
Deaths, n (%)	34 (33.7)

Table 2. Univariate analysis for neonatal mortality.

	Death (n=34)	Alive (n=67)	P value
C-section, n (%)	17 (50.0)	50 (74.6)	0.013 [*]
GA (weeks), mean (±SD)	25.3 (±1.5)	26.9 (±1.1)	<0.001 [∞]
BW (g), mean (±SD)	727 (± 160)	946 (±213)	<0.001 [∞]
Endotracheal tube in DR, n (%)	28 (82.4)	36 (53.7)	0.005 [*]
Epinephrine in DR, n (%)	4 (11.8)	0	0.011 ^{**}
CPAP in DR, n (%)	6 (17.6)	36 (53.7)	0.001 [*]
MV in DR, n (%)	28 (82.4)	36 (53.7)	0.005 [*]
Arterial Ph in NICU, mean (±SD)	6.66 (±1.12)	7.25 (±0.14)	0.040 [∞]
SpO2, mean (±SD)	85 (±20)	95 (±5)	0.008 [∞]
CPAP in NICU	11 (32.4)	63 (94.0)	<0.001 [*]
MV in NICU, n (%)	31 (91.2)	40 (60.6)	0.001 [*]
Amines, n (%)	27 (81.8)	13 (19.4)	<0.001 [*]
Pneumothorax, n (%)	12 (35.3)	5 (7.5)	<0.001 [*]
Steroids in NICU, n (%)	1 (2.9)	21 (31.3)	0.001 ^{**}
IVH ≥ grade 3, n (%)	17 (85.0)	13 (48.1)	0.014 [*]
Days of O2 therapy, median (min-max)	7 (0-96)	2 (0-109)	0.001 [¥]
Days of Parenteral nutrition, median (min-max)	6.50 (0-79)	25 (0-90)	0.001 [¥]
Days MV, median (min-max)	7 (0-90)	38 (0-88)	<0.001 [¥]

*Chi square test; **Fisher's exact test; ¥Mann whitney U test; ∞Independent t test

Agradecimentos:

Ao orientador, Dr. Henrique Soares,

À co-orientadora, Doutora Hercília Guimarães,

À Dra. Filipa Flor-de-Lima

Ao Dr. Mário Mateus

Instructions for authors

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

Word Limits

Original Articles: The maximum length is 3000 words (excluding references), including headings and 600-word abstract, maximum of 2 figures and/or tables, a brief rationale and an addendum. The addendum allows to include materials, methods, statistics, references etc. Original articles should have a maximum of 50 references.

Style Guidelines

Font: Times New Roman, 12-point, double-line spaced. Use margins of at least 2.5 cm (or 1 inch).

Title: Use bold for your article title, with an initial capital letter for any proper nouns.

Abstract: Indicate the abstract paragraph with a heading or by reducing the font size.

Keywords: Please provide keywords to help readers find your article. If the Instructions for Authors do not give a number of keywords to provide, please give five or six.

Headings: Please indicate the level of the section headings in your article:

1. First-level headings (e.g. Introduction, Conclusion) should be in bold, with an initial capital letter for any proper nouns.
2. Second-level headings should be in bold italics, with an initial capital letter for any proper nouns.
3. Third-level headings should be in italics, with an initial capital letter for any proper nouns.
4. Fourth-level headings should be in bold italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.
5. Fifth-level headings should be in italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.

Tables and figures: Indicate in the text where the tables and figures should appear, for example by inserting [Table 1 near here]. You should supply the actual tables either at the end of the text or in a separate file and the actual figures as separate files. Please use American spelling style consistently throughout your manuscript.

Formatting and Templates

Word templates are available for this journal. Please save the template to your hard drive, ready for use.

References

Endnote output style: TF- Standard NLM

Checklist: What to Include

1. **Author details.** All authors of a manuscript should include their full name and affiliation on the cover page of the manuscript. Where available, please also include ORCiDs and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted.
2. Should contain a structured abstract of 600 words. focused on key findings (short summary of the article), including one of the main figures/tables: no mention to material, methods etc.
3. Between 5 and 6 **keywords**..
4. **Disclosure statement.** This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research.
5. **Data availability statement.** If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). [Templates](#) are also available to support authors.
6. **Supplemental online material.** Supplemental material can be a video, dataset, fileset, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare.
7. **Figures.** Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour, at the correct size). Figures should be supplied in one of our preferred file formats:

EPS, PS, JPEG, GIF, or Microsoft Word (DOC or DOCX). For information relating to other file types, please consult our [Submission of electronic artwork](#) document.

8. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
9. **Equations.** If you are submitting your manuscript as a Word document, please ensure that equations are editable.
10. **Units.** Please use [SI units](#) (non-italicized).

Unidade de Investigação

Tomei conhecimento. Nada a opor.

19 de Novembro de 2018

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)



SÃO JOÃO

n.º 300 / 18

Aprovado. Ao CA.

(Prof.ª Doutora Ana Azevedo)

DIRECÇÃO CLÍNICA

20/11/2018

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

Exmo. Senhor Presidente do Conselho de Administração
do Centro Hospitalar de São João

Nome do Investigador Principal:

Valérie Gonçalves Vieira

Título da Investigação:

The golden hour in infants < 29 weeks of gestational age

Pretendo realizar no(s) Serviço(s) de:

Neonatologia

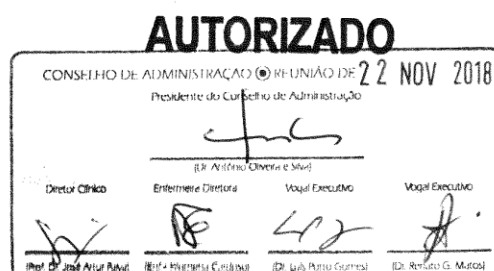
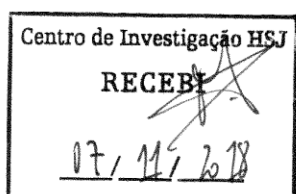
a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de São João/Faculdade de Medicina da Universidade do Porto respeitante à investigação, à qual enderecei pedido de apreciação e parecer.

Com os melhores cumprimentos.

O Investigador/Promotor

Porto, 8 de Outubro de 2018. Valérie Gonçalves Vieira
assinatura



Parecer da Comissão de Ética para a Saúde do
Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto

Título do Projecto: The golden hour in infants < 29 weeks of gestation age

Nome da Investigadora Principal: Valérie Gonçalves Vieira, aluna do Mestrado Integrado em Medicina da FMUP

Onde decorre o Estudo: No Serviço de Neonatologia do CHUSJ. Dispõe de autorização da Prof.^a Doutora Hercília Guimarães.

Objectivos do Estudo:

Este trabalho de investigação, observac tem como principal objectivo estudar o impacto da *golden hour* na mortalidade e morbilidade dos recém-nascidos com idade gestacional inferior a 29 semanas.

Estudo realizado no âmbito do Mestrado Integrado em Medicina da FMUP, sob orientação do Prof. Doutor Henrique Soares.

Concepção e Pertinência do estudo:

Benefício/risco: Não aplicável

Confidencialidade dos dados: Dupla codificação dos processos assegurará a confidencialidade do estudo.

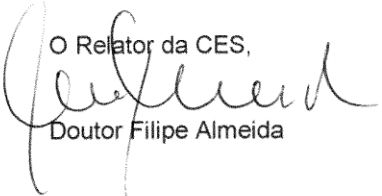
Respeito pela liberdade e autonomia do sujeito de ensaio: Não aplicável

Curriculum da investigadora: Adequado à investigação.

Data previsível da conclusão do estudo: Março de 2019

Conclusão: Proponho um parecer favorável à realização deste projecto de investigação.

Porto, 19 de Outubro de 2018


O Relator da CES,
Doutor Filipe Almeida



Questionário para submissão de Investigação

Exmo. Sr. Presidente da Comissão de Ética do Centro Hospitalar de São João/
Faculdade de Medicina da Universidade do Porto,

Pretendendo realizar a investigação infracitada, solicito a V. Exa., na qualidade de Investigador, a sua apreciação e a elaboração do respetivo parecer. Para o efeito, anexo toda a documentação requerida.

IDENTIFICAÇÃO DO ESTUDO

Título da investigação: THE GOLDEN HOUR IN INFANTS < 29 WEEKS OF GESTATIONAL AGE

Nome do investigador: VALÉRIE GONÇALVES VIEIRA

Endereço eletrónico: valerie.goncalves@hotmail.com Contacto telefónico: 931408958

Caracterização da investigação:

☒ Estudo retrospectivo

☒ Estudo observacional

☐ Estudo prospetivo

☐ Inquérito

☐ Outro. Qual? _____

Tipo de investigação:

☐ Com intervenção

☒ Sem intervenção

Formação do investigador em boas práticas clínicas (GCP): ☐ Sim ☐ Não

Promotor (se aplicável): _____

Nome do orientador de dissertação/tese (se aplicável): HENRIQUE SCARES

Endereço eletrónico: hcscares@europa.com

Local/locais onde se realiza a investigação: NEONATOLOGIA

Data prevista para início: ____ / ____ / ____

Data prevista para o término: ____ / 03 / 2019

PROTOCOLO DO ESTUDO

Síntese dos objetivos: Estudar o impacto da golden hour na mortalidade e morbilidade dos recém-nascidos com idade gestacional inferior a 29 semanas.

Fundamentação ética (ganhos em conhecimento/ inovação; ponderação benefícios/ riscos):

Melhorar as práticas clínicas futuras, pontuando os resultados das práticas actuais.

CONFIDENCIALIDADE

De que forma é garantida a anonimização dos dados recolhidos de toda a informação?

O investigador necessita ter acesso a dados do processo clínico? ☒ Sim ☐ Não

Está previsto o registo de imagem ou som dos participantes? ☐ Sim ☒ Não

Se sim, está prevista a destruição deste registo após o sua utilização? ☐ Sim ☐ Não

CONSENTIMENTO

O estudo implica recrutamento de:

Doentes: ☐ Sim ☒ Não Voluntários saudáveis: ☐ Sim ☒ Não

Menores de 18 anos: ☐ Sim ☒ Não

Outras pessoas sem capacidade do exercício de autonomia: ☐ Sim ☒ Não

A investigação prevê a obtenção de Consentimento Informado: ☐ Sim ☒ Não

Se não, referir qual o fundamento para a isenção:

Porque trata-se de um estudo observacional retrospectivo sem envolvimento direto de doentes e sendo mantida a confidencialidade dos dados em dupla codificação dos processos.

Existe informação escrita aos participantes: ☐ Sim ☒ Não

PROPRIEDADE DOS DADOS

A investigação e os seus resultados são propriedade intelectual de:

☐ Investigador ☐ Promotor ☐ Ambos ☒ Serviço onde é realizado

☐ Não aplicável

Outro: _____

BENEFÍCIOS, RISCOS E CONTRAPARTIDAS PARA OS PARTICIPANTES

Benefícios previsíveis:

Melhorar as práticas clínicas

Riscos/incómodos previsíveis:

São dadas contrapartidas aos participantes:

· pela participação ☐ Sim ☐ Não ☒ Não aplicável

· pelas deslocações ☐ Sim ☐ Não ☒ Não aplicável

· pelas faltas ao emprego ☐ Sim ☐ Não ☒ Não aplicável

· por outras perdas e danos ☐ Sim ☐ Não ☒ Não aplicável

CUSTOS / PLANO FINANCEIRO

Os custos da investigação são suportados por:

☐ Investigador ☐ Promotor ☐ Serviço onde é realizado

☒ Não aplicável

Outro: _____

Existe protocolo financeiro? ☐ Sim ☒ Não

LISTA DE DOCUMENTOS ANEXOS

- ☐ Pedido de autorização ao Presidente do Conselho de Administração do Centro Hospitalar de São João (se aplicável)
- ☐ Pedido de autorização à Diretora da Faculdade de Medicina da Universidade do Porto (se aplicável)
- ☐ Protocolo do estudo
- ☐ Declaração do Diretor de Serviço onde decorre o estudo
(sendo um estudo na área de enfermagem deve anexar também a concordância da chefia de enfermagem)
- ☐ Profissional de ligação
- ☐ Informação dos orientadores
- ☐ Informação ao participante
- ☐ Modelo de consentimento
- ☐ Instrumentos a utilizar (inquéritos, questionários, escalas, p.ex.): _____
- ☐ Curriculum Vitae abreviado (máx. 3 páginas)
- ☐ Protocolo financeiro
- ☐ Outros:

COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

Declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (1960 e respetivas emendas), e da Organização Mundial da Saúde, Convenção de Oviedo e das "Boas Práticas Clínicas" (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CES o relatório final da investigação, assim que concluído.

Porto, 08 de Outubro de 2018

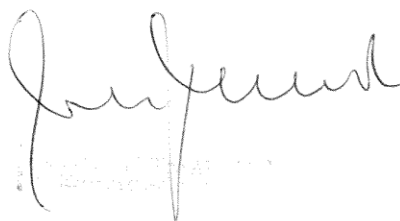
Nome legível: VALÉRIE GONÇALVES VIEIRA

Valérie Gonçalves Vieira
assinatura

Parecer da Comissão de Ética do Centro Hospitalar de São João/FMUP

Emitido na reunião plenária da CE de 2018/10/19

A Comissão de Ética para a Saúde
APROVA por unanimidade o parecer do
Relator, pelo que nada tem a opor à
realização deste projecto de investigação.



RESPONSÁVEL PELO ACESSO À INFORMAÇÃO



Pedido de Reutilização de Registos Clínicos para Investigação e Desenvolvimento (I&D)

Exmo. Senhor
Responsável pelo Acesso à Informação
(Artigo 9.º da Lei n.º 26/2016 de 22 de agosto)
Dr. Rui de Vasconcellos Guimarães



AUTORIZADO

RAI - Responsável pelo Acesso à Informação no Centro Hospitalar de São João
(Art. 9.º, Lei 26/2016, de 22/8)

Número do Pedido

1181013128

(A preencher pelo Gabinete de Apoio ao RAI)

VASCONCELLOS GUIMARÃES
Administrador Hospitalar
6 de 11/2018

1. Identificação do(s) Investigador(es) Preenchimento Obrigatório

1.1. Investigador Principal

Nome VALÉRIE GONÇALVES VIEIRAContacto telefónico 91311410181915181Endereço eletrónico valerie.goncalves @ hotmail.com

1.2. Investigador(es) Associado(s)

Número Total: ☐Nome HENRIQUE EDUARDO CORREIA SAMESContacto telefónico 9116110187611Endereço eletrónico hecsoares @ europa.com

Nome _____

Contacto telefónico _____

Endereço eletrónico _____ @ _____

Nome _____

Contacto telefónico _____

Endereço eletrónico _____ @ _____

1.3. Afiliação Institucional do Investigador Principal

1.3.1. Grupo Profissional

☐ Médico(a) ☐ Enfermeiro(a) ☐ Docente ☒ Estudante☐ Outro. Qual? _____

1.3.2. Documento de identificação pessoal ou profissional

☒ Cartão de Cidadão ☐ Bilhete de Identidade ☐ Célula Profissional☐ Cartão de Docente ☐ Cartão de Estudante ☐ Outro. Qual? _____Número de Documento 114410101510112. Enquadramento e Identificação do Trabalho de Investigação e Desenvolvimento Preenchimento Obrigatório

2.1. Enquadramento da investigação

☒ Trabalho académico de investigação e desenvolvimento:☐ Não conferidor de grau☒ Conferidor de grau: ☐ Licenciatura ☒ Mestrado ☐ Doutoramento☐ Projeto de investigação e desenvolvimento

Dados indicados no formulário, em 30/10/2018, o DRAI

VASCONCELLOS GUIMARÃES
Administrador Hospitalar

30
10
0018

2.2. Entidade(s) que tutela(m) a investigação

☒ Centro Hospitalar de São João

Serviço: Nenotale fis

☒ Universidade do Porto

Faculdade/Instituto: FMVP

☐ Outra Instituição. Qual? _____

Há alguma parceria entre instituições?

☐ Não ☐ Sim. Qual(is)? _____

2.3. Orientador Se Aplicável

Contacto telefónico 911611087611

Endereço eletrónico hcs@ares @ europa.eu

2.4. Título provisório

The golden hour in infants < 29 weeks of gestational age

Deverá posteriormente indicar o título definitivo para emissão do Certificado de Reutilização pelo RAI -
Data REuse Certificate for Research - DARE através dos contactos disponíveis no fim deste formulário.

2.5. Acesso requerido

☐ Ficheiro

Descrição do património informacional a que pretende ter acesso, identificando a informação a obter, i.e. nome, morada, diagnóstico, idade, códigos dos distritos, entre outros.

☐ Consulta de processos clínicos em ambiente papel:

☐ Bloco

☐ Consulta Externa

☐ Hospital de Dia

☐ Internamento

☐ MCDT

☐ Urgência

Deverá anexar ficheiro(s) contendo a identificação do pretendido, i.e. números de processos, episódios, números de utente, entre outros.

Anexar ficheiro(s) contendo a identificação do pretendido

☒ Consulta de registos clínicos eletrónicos

Especificar os Sistemas de Informação:

S. Único

Data previsível de fim de utilização das credenciais de acesso - -

☐ Outro Acesso. Qual? _____

2.3. Pareceres e Autorizações

☒ Autorização da Hierarquia

☐ Protocolo Científico Aprovado ¹

☐ Parecer da Comissão de Ética para a Saúde (CES) ¹

☐ Parecer do Centro de Epidemiologia Hospitalar ¹

Deverá anexar ficheiro(s) contendo cópia dos documentos referentes às opções selecionadas.

Anexar ficheiro(s) contendo cópia dos documentos

¹ Obrigatório quando aplicável

3. Observações Preenchimento Facultativo

4. Aceitação dos Termos e Condições da Reutilização

Cumulativamente com as obrigações decorrentes da lei já citada (n.º 2 e 3 do artigo 21 e o n.º 1 e 2 do artigo 12, ambos da Lei n.º 26/2016, de 22 de agosto) ao submeter o presente pedido concordo e fico ainda vinculado aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Não vou elaborar registos, susceptíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Não vou elaborar, nem ficar na posse, de cópias de bases de dados utilizadas na recolha de informação;
- Comprometo-me a obter junto da Comissão Nacional de Proteção de Dados (CNPd) as necessárias autorizações, para eventuais bases de dados que venha a conceber e utilizar no âmbito da presente investigação;
- Comprometo-me a devolver ao Centro Hospitalar de São João, na pessoa do seu Diretor Clínico, as bases de dados e o resultado da investigação;
- Comprometo-me a ocultar os elementos de identificação da(s) pessoa(s) a quem os registos digam respeito, em futuras e eventuais publicações de resultados;
- Comprometo-me a consultar os processos clínicos nas instalações que me forem indicadas para o efeito;
- Comprometo-me a obter os necessários pareceres, quer da Comissão de Ética do Hospital, quer do Centro de Epidemiologia Hospitalar, sempre que necessário;
- Comprometo-me a citar as fontes sempre que publicitar o trabalho de investigação independentemente de requerer a Certidão de Reutilização (Data REuse Certificate for Research – DARE);
- Tomei conhecimento, que a violação de qualquer dos compromissos aqui assumidos, resultará no apuramento de responsabilidades disciplinares, civis e penais e ainda, à impossibilidade futura de aceder a informação de saúde para fins de investigação.

5. Decisão do investigador sobre requerer a Data REuse Certificate for Research – DARE Preenchimento Obrigatório

- ☐ Pretendo desde já requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consulte em <http://portal-chsj.min-saude.pt/pages/710>.
- ☒ Não pretendo requerer a Certidão de Reutilização (DARE) cujo sentido, valor e significado consulte em <http://portal-chsj.min-saude.pt/pages/710>.

6. Assinatura

Nota 1: Se o presente pedido for submetido eletronicamente ou faz assinatura digital qualificada, ou posteriormente vem ao Centro Hospitalar de São João exibir o seu documento de identificação pessoal, ou no âmbito do seu espaço de liberdade e como manifestação expressa do seu consentimento envia cópia do referido documento, neste caso, concluído o processo ser-lhe-á devolvida ou eliminada a cópia do documento de identificação pessoal, conforme as indicações que dê.

Nota 2: Se o presente pedido for entregue presencialmente, assina e exibe o documento de identificação a quem recebe o pedido.

Data - -

Valérie Gonçalves Vieira
Investigador Principal

Em caso de dúvida no preenchimento contacte através dos endereços eletrónicos
rai.reutilizacao.id@chsj.min-saude.pt ou ruiguimaraes@chsj.min-saude.pt
ou pelos números de telemóvel 962 204 194 ou 918 880 299

SUBMETTER