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Alexandra da Silva Ramalho Azevedo

Impacto das mudanças nos cuidados perinatais na displasia broncopulmonar: uma visão global das últimas duas décadas / Impact of changes in perinatal care on bronchopulmonary dysplasia: an overview of the last two decades

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DISSERTAÇÃO / MONOGRAFIA

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Projecto de Opção do 6º ano – DECLARAÇÃO DE REPRODUÇÃO

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Neonatologia

TÍTULO DISSERTAÇÃO

Impacto das mudanças nos cuidados perinatais na displasia broncopulmonar: uma visão global das últimas duas décadas / Impact of changes in perinatal care on bronchopulmonary dysplasia: an overview of the last two decades

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Professora Doutora Maria Hercília Ferreira Guimarães Pereira Areias

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Aos meus queridos avós,
Em especial ao meu avô Manuel

Impact of changes in perinatal care on bronchopulmonary dysplasia: an overview of the last two decades

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Impact of changes in perinatal care on bronchopulmonary dysplasia: an overview of the last two decades

Abstract

Objective: To compare the clinical approach and outcomes of bronchopulmonary dysplasia (BPD) patients in the last two decades (1996-2005 vs 2006-2015) in our neonatal intensive care unit.

Methods: Out of 1196 admissions, 96 had BPD and were dichotomized into two groups according to the year of birth (1996-2005 and 2006-2015). Their clinical data were studied and conclusions were drawn about their morbimortality.

Results: From 1996-2005, although infants were more severely ill (more small for dates, more lower Apgar Scores), there was a decrease in mortality (14.4vs.23.3%, $P<0.001$) and in BPD prevalence (6.1vs9.7%, $P=0.023$). In delivery room, early nasal continuous positive airways pressure was used in 42.1vs1.6%, $P<0.001$ and tracheal intubation, in 70.6vs96.8%, $P<0.001$. We observed an increase on the median duration of non-invasive ventilation (45.5 vs 22.5 days, $P<0.001$) and decrease of invasive ventilation (20 vs 39.5 days, $P=0.013$) from 1996-2005. On this, patients had more retinopathy (44.1 vs 22.6%, $P=0.028$) and intraventricular hemorrhage (38.2 vs 12.9%, $P= 0.004$), probably related to a more severe status at birth.

Conclusions: Improvement on perinatal and neonatal intensive care practices, namely the use of non-invasive methods of mechanical ventilation, implemented on the last years contributed to the better evolution of our preterm infants.

Keywords: Bronchopulmonary dysplasia, preterm, newborns, neonatal intensive care, respiratory outcome

Introduction

Bronchopulmonary dysplasia (BPD) is a frequent complication in preterm infants and its multifactorial etiology has not been fully established yet [1,2]. Multiple risk factors for BPD are known, namely, mechanical ventilation, inflammation and infection [3]. Prematurity is the most important risk factor and the incidence of BPD is inversely proportional to gestational age and birth weight [4].

The definition of BPD has undergone changes over time. Initially, BPD was described as a consequence of positive-pressure ventilation and oxygen therapy which cause severe lung injury proven by histologic evidences (inflammation, protein-rich edema, airway epithelial metaplasia, peribronchial fibrosis and hypertrophy of respiratory tract vascular smooth muscle), « the classic BPD» [5,6].

However, as time went by, perinatal care has improved and now very immature preterm infants have more chances to survive with BPD. These extremely low gestational age newborns frequently are born in the course of the late canalicular or early saccular stages of lung development and it seems to disturb the normal development of alveoli and vessels, resulting on the called « the new BPD»[7].

Initially, infants with BPD were mainly treated with invasive mechanical ventilation (IMV) and drugs such as diuretics and postnatal steroids. Nowadays, although there is no effective treatment for BPD, preventive strategies are of great importance [8,9].

The aim of this study was to describe and compare the clinical approach and the outcomes of patients with BPD in last two decades in our NICU.

Material and Methods

Infants with birth weight less than or equal to 1500g or less than or equal to 32 weeks gestational age admitted to our center (a level III neonatal intensive care unit) between 1st january 1996 and 31th december 2015 were included in this retrospective study.

Outborn neonates, children with major malformations, chromossomopathies and/or TORCH infections (Toxoplasmosis, Other (syphilis, varicella-zoster, parvovirus B19), Rubella, Cytomegalovirus and Herpes infections) were excluded.

Characteristics as gender, gestational age, birth weight, antenatal steroid pulses, mode of delivery, respiratory support in the delivery room and in the NICU, Apgar score, presence of respiratory distress syndrome (RDS), the need for exogenous surfactant, the need for oxygen therapy, the prevalence of BPD and major morbidity conditions (pneumonia, pneumothorax, sepsis, meningitis, patent ductus arteriosus, necrotizing enterocolitis, severe intraventricular hemorrhage, retinopathy of prematurity, cystic periventricular leukomalacia), length of mechanical ventilation and oxygen therapy, length of parenteral nutrition, length of NICU stay and survival were collected from clinical charts.

The diagnosis and classification of BPD was made according to the National Institute of Health Consensus Definition of Bronchopulmonary Dysplasia [10].

Gestational age (completed weeks) was assessed by menstrual age (women with regular menstrual cycles), ultrasound examination (when a discrepancy of two or more weeks existed between the gestational age calculated by menstrual dating and the age derived sonographically or in the absence of a menstrual date) [11] or the New Ballard Score (in the absence of obstetrical indexes) [12].

Small for gestational age was defined as a birth weight below 10th centile of Fenton's fetal growth charts [13].

Early nCPAP was considered if started in the first 15 minutes after birth and its failure was considered if patients needed invasive ventilation in the first 72 hours of life.

The 5th minute Apgar scores were registered and dichotomized in two groups (<7 and ≥7).

RDS diagnosis was made on a combination of clinical and radiographic features according to the criteria of RDS of the Vermont Oxford Network: PaO_2<50mmHg in room air, a requirement for supplemental oxygen to maintain PaO_2>50mmHg or to maintain a pulse oximeter saturation over 85% within the first 24 hours of life and a chest radiograph with reticulogranular appearance to lung fields with or without low lung volumes and air bronchograms within the first 24 hours of life.

Histological chorioamnionitis was defined according to Blanc's classification [14] and all the stages of chorioamnionitis were analyzed together.

Proven neonatal sepsis was defined as any systemic bacterial or fungal infection documented by a positive blood culture.

In all cases of preterm delivery whenever an infection cause cannot be excluded, a combination of ampicillin and gentamicin is used as first line therapy, while waiting for the results of blood culture.

For the diagnosis and staging of necrotizing enterocolitis (NEC) we used the criteria of Bell [15].

Retinopathy of prematurity (ROP) was staged according to the international classification [16,17].

Intraventricular hemorrhage (IVH) was classified according to Papile at al [18].

Periventricular leukomalacia (PVL) was classified according to L. de Vries and Rennie [19].

Hemodynamically significant patent ductus arteriosus (PDA) was diagnosed considering echocardiographic findings. The first evaluation was usually done between 24 and 72 hours of life with daily evaluations until closure of the ductus. The standard treatment was indomethacin until 2010, and ibuprofen after this date.

At our center, until 2003, the antenatal steroid regimen included dexamethasone (24 mg divided into two intramuscular doses every 12 h). Since then, treatment has consisted of betamethasone (24 mg divided into two intramuscular doses 24 h apart) in pregnancies at risk of preterm labor between 24 and 35 weeks gestation.

Caffeine was routinely used in all preterm infants since the first day of life until 34 weeks of corrected age [20].

Oxygen was used to maintain saturations given by pulse oximetry in the range of 88%-94% for RDS and ≥95% for established BPD until 2007. After this year, in preterm babies with RDS receiving oxygen, the saturation target is 90%-95% [20].

Spontaneous breathing infants were stabilized with continuous positive airways pressure (CPAP) of at least 5-6 cmH_2O via mask or nasal prongs. Intubation was used in infants who did not respond to CPAP and in these babies surfactant was administrated [20]. For non-invasive mechanical ventilation we used Infant Flow® SiPAP System (Care Fusion, Yorba Linda, California, U.S.A.).

Exogenous surfactant was administered for RDS by endotracheal tube in neonates on invasive mechanical ventilation or by INSURE (intubate-surfactant-extubate) in preterm infants requiring FiO_2>0.40 and/or arterial PCO_2>65mmHg and pH<7.20.

The DART protocol was used if mechanical ventilation and oxygen therapy are increasingly needed after 10 days of life and the baby could not be weaned off invasive ventilation [21].

In 2003 we started to use volume guarantee with synchronized ventilator modes (pressure support ventilation, synchronized intermittent mandatory ventilation or synchronized intermittent positive pressure ventilation), using Babylog 8000 Plus®, Dräger, Lubeck, Germany and Fabian HFO® , Acutronic Medical Systems, Hirzel, Switzerland.

Parenteral nutrition was started in the first day of life and enteral nutrition, as soon as possible, according the clinical stability of the patient. According to our protocol parenteral nutrition starts with 70-80 ml/kg/d on the first day of life with daily increments of 10-15 ml/kg/day to a maximum of 150 ml/kg/day in the 1st week of life [22].

Statistical analysis

The statistical analysis was performed using SPSS® for Windows, version 23. Continuous variables were characterized by mean (± standard deviation) or median (minimum-maximum) if there was symmetric or asymmetric distribution, respectively, and categorical variables by absolute and relative frequencies. To compare continuous variables, parametric tests (independent t test) or non-parametric tests (Mann Whitney-U test) were used, and Chi-Square or Fisher's exact test to compare categorical variables, the latter for expected values below 5. A multivariate analysis by logistic regression was performed to evaluate the evolution of morbidity in newborn with BPD between both epochs. A *P* value below 0.05 was considered statistically significant.

The study protocol was approved by the Ethics Committee of our hospital.

Results

Out of 1196 neonates ≤ 1500g of birth weight or ≤ 32 weeks gestational age, 229 (19.1%) died, being 149 (23.3%) in the first decade and 80 (14.4%) in the second one, (P<0.001) and 96 (8.0%) had BPD as discharge diagnosis (table1).

Maternal, prenatal and perinatal data are shown in table 2.

With regard to neonatal period, there was a significant decrease on invasive mechanical ventilation median duration (39.50 days from 1996 to 2005 and 20.00 from 2006 to 2015) and a significant increase on nCPAP median duration (22.50 days from 1996 to 2005 and 45.50 days from 2006 to 2015). ROP and IVH had a significantly increase in the second decade (22.6% vs. 44.1% and 12.9% vs. 38.2%, respectively).

There was a significant lower incidence of nosocomial sepsis among preterm infants admitted in our NICU (83.9% from 1995 to 2005 and 64.7% from 2006-2015) in the second decade, as shown in table3.

A multivariate analysis by logistic regression revealed in the second epoch an OR= 8.112 (95%CI: 1.396-47.134; P= 0.020) for ROP and OR = 12.313 (95%CI: 1.921-78.920; P= 0.008) for IVH.

Discussion

In the last decades, there have been several changes in perinatal care around the world with a consequent implementation of the clinical better practices during pregnancy as well as in management of the preterm infants. Our hospital accompanied these changes having as main objective the improvement of patient's outcome, favoring them the better quality of life. Our data showed an improvement in morbimortality of preterm infants admitted in our NICU in last two decades, as shown in table 1.

There has been a statistically significant increase in pregnancy associated pathologies as preeclampsia and flows changes, which may be related to the birth of more small for gestational age infants and consequently with more severe neonatal consequences. However, some studies showed that hypertensive disease during pregnancy is a protective factor for major IVH [23,24]. Our results did not show a decrease in IVH despite the increase of hypertensive disease on pregnancy and it can be related with a small sample or with better diagnostic acuity for IVH.

In the twentieth century, the National Institutes of Health and the American College of Obstetricians and Gynecologists published a consensus statement defending the use of antenatal steroids in preterm deliveries of 24 to 34 of weeks gestational age in order to induce fetal maturation and reduce the risks for RDS, IVH and neonatal death [25]. According to our results the number of completed antenatal steroids cycles increased since 2006, showing better obstetric practices.

In addition to the admission of more small for gestational age infants, the worse 5th Apgar scores on the second decade also indicate that, from 2006 onwards, there has been an admission of more severe patients, and consequently, a greater number of neonatal consequences such as ROP and IVH. The significant increase on ROP incidence in the second decade may be due to the admission of more severe patients, but it can be also due to the improvement in diagnostic acuity, as previous mentioned for IVH.

Despite the clear admission of more severe patients in the second decade, it was found a statically significant decrease in invasive mechanical ventilation (and in its duration) and increase in the use and duration of non-invasive mechanical ventilation (nCPAP). Also, on the delivery room, there was a higher prevalence of the use of early nCPAP. This highlights a good neonatal care practice, once, since nCPAP was introduced by Keszler in the 70's, it has shown promising results in BPD's incidence and severity

[26]. Invasive mechanical ventilation is a well-known risk factor for the development of BPD and all efforts must be done to implement non-invasive mechanical ventilation in this high risk preterm infants [3,27].

Another fact that reinforces the good practices in peri and neonatal care of our hospital is the statistically significant decrease of nosocomial sepsis, which had already been reported by another study [28]. The importance of this data relates not only to the association between nosocomial sepsis and unfavorable neonatal outcomes, as was observed in a recent multicenter study showing that sepsis is one of the most common cause of deaths in NICUs [29] and BPD development [3,27].

With regard to BPD severity, our data show that there was a lower number of severe BPD diagnosed in the second decade of the study (table 1). Comparing the two decades, in spite of no significant difference was observed, the prevalence of severe BPD decreased and the cases of mild/moderate BPD increased. Probably in the first ten years of this study, severe BPD was related to the greater use of IMV, since there was an association between these two entities [3]. Although there were no significant difference in gestational age and birth weight between the two epochs of our study, in the second epoch there were admitted more severe patients, proven by worse Apgar scores as mentioned previously. Clinical practices in neonatal intensive care units differ from one to another and benchmarking among them it´s crucial to improve outcomes [30].

With respect to clinical status at the discharge there were no significant differences between the two epochs. Taking into account that in the second decade more severe infants were admitted, this seems to be an encouraging information.

In conclusion, the improvement on perinatal and neonatal intensive care practices implemented on the last years, contributed to the better evolution of our preterm infants. Moreover, even in the absence of an effective therapy for BPD, professionals should be

sensitized to prevent known BPD risk factors and to improve the management of these preterm infants.

Disclosure of interest

The authors report no conflicts of interest.

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Table 1. Number of preterm infants with ≤1500g of birth weight or ≤32 weeks gestational age admitted in our Neonatal Intensive Care Unit in the study period.

	Total	*1996-2005*	*2006-2015*	*P value*
NICU admissions, *n* (%)	1196 (100)	640 (53.5)	556 (46.5)	**0.047**[*]
Deceased preterm infants, *n* (%)	229 (19.1)	149 (23.3)	80 (14.4)	**<0.001**[*]
Deceased and preterm infants with bronchopulmonary dysplasia , *n* (%)	325 (27.2)	211 (33.0)	114 (20.5)	**<0.001**[*]
Survivors with bronchopulmonary dysplasia, *n* (%)	96 (8.0)	62 (9.7)	34 (6.1)	**0.023**[*]

Abbreviation: NICU – neonatal intensive care unit

[*]Chi-square test

Table 2. Maternal, prenatal, and perinatal data of infants with bronchopulmonary dysplasia.

	Total n=96	*1996-2005 n=62*	*2006-2015 n=34*	*P value*
Gender, *n* (%)				
Male	66 (68.8)	43 (69.4)	23 (67.6)	0.863*
Female	30 (31.3)	19 (30.6)	11 (32.4)	
Gestational age, mean (±SD) (weeks)	27.63 (0.220)	27.74 (0.250)	27.41 (0.425)	0.475§
Birth weight, mean (±SD) (grams)	962.53 (33.891)	995.42 (40.065)	902.56 (61.292)	0.192§
Small for gestational age, *n* (%)	22 (22.9)	10 (16.1)	12 (35.3)	**0.033***
Less than 1000g, *n* (%)	63 (65.6)	38 (61.3)	25 (73.5)	0.227*
Maternal age, median (min-max) (years)	31.00 (16-42)	30.50 (16-42)	31.00 (20-39)	0.979¥
Preeclampsia, n (%)	21 (21.9)	9 (14.5)	12 (35.3)	**0.019***
Change in umbilical flows, n (%)	17 (17.7)	6 (9.7)	11 (32.4)	**0.005***
Change in cerebral flows, n (%)	16 (16.7)	6 (9.7)	10 (29.4)	**0.013***
Antenatal steroids, *n* (%)	87 (90.6)	55 (88.7)	32 (94.1)	0.485**
Full cycle	56 (65.9)	29 (54.7)	27 (84.4)	**0.005***
Histological chorioamnionitis, *n* (%)	24 (25.8)	14 (23.7)	10 (29.4)	0.546*
Delivery mode, *n* (%)				
Vaginal	32 (33.3)	25 (40.3)	7 (20.6)	0.050*
C-section	64 (66.7)	37 (59.7)	27 (79.4)	
Apgar score, *n* (%)				
1st minute <7	73 (76.0)	48 (77.4)	25 (73.5)	0.669*
5th minute <7	26 (22.7)	12 (20.0)	14 (41.2)	**0.027***
Respiratory management in the delivery room, *n* (%)				
Spontaneous ventilation	3 (3.1)	2 (3.2)	1 (2.9)	0.999**
Endotracheal intubation	84 (87.5)	60 (96.8)	24 (70.6)	**<0.001****
Early nCPAP	15 (15.6)	1 (1.6)	14 (41.2)	**<0.001****

Abbreviation: nCPAP – nasal continuous positive airway pressure

*Chi-square test; **Fisher's exact test; ¥ Mann-Whitney U test, §Independent t test

Table 3. Neonatal Period: morbimortality and management of infants with bronchopulmonary dysplasia.

	Total n=96	*1996-2005 n=62*	*2006-2015 n=34*	*P value*
Respiratory distress syndrome, *n* (%)	88 (91.7)	55 (88.7)	33 (97.1)	0.253**
Surfactant administration, *n* (%)	81 (84.4)	51 (82.3)	30 (88.2)	0.563**
Surfactant, median (min-max) (doses)	2.00 (1-5)	2.00 (1-3)	2.00 (1-5)	0.361¥
Invasive mechanical ventilation, *n* (%)	90 (93.8)	60 (96.8)	30 (88.2)	0.181**
Invasive mechanical ventilation, median (min-max) (days)	30.50 (1-211)	39.50 (1-211)	20.00 (2-138)	**0.013¥**
nCPAP, *n* (%)	82 (85.4)	50 (80.6)	32 (94.1)	0.128**
nCPAP, median (min-max) (days)	32.00 (1-161)	22.50 (1-161)	45.50 (7-76)	**<0.001¥**
Oxygen, *n* (%)	96 (100)	62 (100)	34 (100)	-
Oxygen, median (min-max) (days)	70.00 (22-260)	69.00 (28-260)	71.50 (22-191)	0.412¥
Bronchopulmonary dysplasia, *n* (%)				
Mild/Moderate	70 (72.9)	43 (69.4)	27 (79.4)	0.458*
Severe	26 (27.1)	19 (30.6)	7 (20.6)	
Patent ductus arteriosus, *n* (%)	65 (67.7)	43 (69.4)	22 (64.7)	0.641*
With medical treatment	59 (95.2)	37 (94.9)	22 (95.7)	0.999**
With surgical treatment	10 (16.1)	4 (10.3)	6 (26.1)	0.153**
Nosocomial sepsis, *n* (%)	74 (77.1)	52 (83.9)	22 (64.7)	**0.033***
Necrotizing enterocolitis ≥2A, *n* (%)	3 (3.1)	3 (4.8)	0 (0)	0.550**
Retinopathy of prematurity ≥2, *n* (%)	29 (30.2)	14 (22.6)	15 (44.1)	**0.028***
Intraventricular hemorrhage ≥III, *n* (%)	21 (21.9)	8 (12.9)	13 (38.2)	**0.004***
Cystic periventricular leukomalacia, *n* (%)	7 (7.3)	4 (6.5)	3 (8.8)	0.695**
Parenteral nutrition, n (%)	95 (99.0)	61 (98.4)	34 (100)	0.999**
Parenteral nutrition, median (min-max) (days)	36.00 (8-145)	40.00 (8-145)	33.0 (12-101)	0.070¥
NICU stay, median (min-max) (days)	78.50 (21-259)	74.00 (29-259)	86.00 (21-191)	0.191¥
Sequels, n (%)				
O_2 requirement	25 (30.1)	14 (26.4)	11 (36.7)	0.328*
Tracheostomy	2 (2.4)	1 (1.9)	1 (3.3)	0.999**
No feed autonomy	1 (1.2)	1 (1.9)	0 (0)	0.999**
Jejune/iliostomy	1 (1.2)	1 (1.9)	0 (0)	0.999**
Ventriculoperitoneal shunt	2 (2.4)	0 (0)	2 (6.7)	0.128**
Deceased, *n* (%)	13 (13.5)	9 (14.5)	4 (11.8)	0.999**

Abbreviations: nCPAP – nasal continuous positive airway pressure; NICU – neonatal intensive care unit

*Chi-square test; **Fisher's exact test; ¥ Mann-Whitney U test

Agradecimentos

Dirijo-me, em primeiro lugar, à Professora Doutora Hercília Guimarães, agradecendo-lhe pela orientação na realização desta dissertação, por toda a disponibilidade demonstrada ao longo dos últimos meses e pela inspiração que se tornou. Agradeço, ainda, à Dr.ª Filipa Flor-de-Lima e ao Dr. Gustavo Rocha pelo auxílio na redação deste trabalho.

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Um obrigada à Faculdade de Medicina da Universidade do Porto pela oportunidade de realizar este trabalho, em particular, mas também pelos últimos seis anos cheios de memórias que levo para a vida.

E porque não poderia falar dos últimos seis anos sem referir a segunda família que cá encontrei, quero agradecer, por amizades e momentos inesquecíveis à minha querida "turma 16", à Lúcia e ao Andrade.

Porque também me ajudaram a superar as vicissitudes deste curso, um obrigada muito especial a todos os meus "amigos de Vila do Conde", em especial à Joana Costa, pela amizade que temos e que, por certo, não consigo descrever em palavras… Por cada momento de distração, por suportar as minhas frustrações, por celebrar as minhas vitórias como se dela fossem…o meu muito obrigada. Que assim seja para sempre.

Agradeço ao João, por ser um apoio incondicional no atingimento desta etapa. Agradeço por cada dia dos últimos anos. Foi, também, graças a ele que me tornei a mulher que sou hoje e tudo o que pudesse aqui escrever ficaria aquém do que realmente sinto que tenho para lhe agradecer. Que o futuro nos reserve incontáveis dias de felicidade.

Por fim, mas de forma incondicional e eterna, quero agradecer aos meus pais pela nossa família e pelo exemplo que sempre foram e continuam a ser. Obrigada pelas conversas que, desde pequenina, me transmitiram os valores que hoje tenho. Espero que, ao olharem para mim, vejam a mulher que um dia sonharam. Por me priorizarem sempre e pelo amor que me dão todos os dias, o meu incondicional obrigada. Espero que saibam que os amo muito e que esta etapa tão feliz da minha vida nunca seria possível sem eles do meu lado.

Anexos

Normas da Revista

Parecer da Comissão de Ética

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Updated March 2016

9.2.16

Unidade de Investigação

Tomei conhecimento. Nada a opor.

13 de Abril de 2016

A Coordenadora da Unidade de Investigação

(Prof.ª Doutora Ana Azevedo)

AUTORIZADO

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DIRECÇÃO CLÍNICA

Aprovado. Ao CA. 26/4/2016

(Prof.ª Doutora Ana Azevedo)

Exmo. Senhor
Presidente do Conselho de Administração do
Centro Hospitalar de S. João – EPE

Assunto: Pedido de autorização para realização de estudo/projecto de investigação

Nome do Investigador Principal: Alexandra da Silva Ramalho Azevedo

Título do projecto de investigação: "Impact of changes in Perinatal Care on bronchopulmonary dysplasia: an overview of the last two decades"

Pretendendo realizar no(s) Serviço(s) de _____
do Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efectivação.

Para o efeito, anexa toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de S. João respeitante a estudos/projectos de investigação, à qual endereçou pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 22 / Fevereiro / 2016

O INVESTIGADOR/PROMOTOR

Alexandra da Silva Ramalho Azevedo

Comissão de Ética para a Saúde do CHSJ e da FMUP

Parecer

Título do Projecto: Impact of changes in perinatal care on bronchopulmonary dysplasia: an overview of the last two decades

Nome do Investigador Principal: Alexandra da Silva Ramalho Azevedo

Serviço onde decorrerá o Estudo: Serviço de Neonatalogia do Centro Hospitalar de S. João

Objectivo e Pertinência do Estudo:

O objectivo deste estudo é comparar os dados clínicos e o prognóstico dos doentes RN com displasia broncopulmonar internados na Unidade de Cuidados Intensivos Neonatais, entre 1996 e 2015.

A recolha dos dados, aparentemente de natureza retrospectiva, será feita em CRF anonimizado. Não é indicado como procederá a investigadora para concluir sobre o impacto das alterações aos cuidados perinatais nesta patologia, ao longo das últimas duas décadas.

O acesso aos processos clínicos será efectuado pela investigadora, sendo indicado como Elo de ligação a Directora do Serviço, que dispensou o seu aval à realização do referido estudo.

Benefício/risco: Sem benefício directo para as participantes.

Respeito pela liberdade e autonomia do sujeito de ensaio: NA.

Confidencialidade dos dados: Os dados recolhidos serão anonimizados, asseverando assim a confidencialidade que há-de ser dedicada ao tratamento dos mesmos

Elo de ligação: Prof.ª Doutora Hercília Guimarães

Indemnização por danos: NA

Continuação do tratamento: NA

Propriedade dos dados: Os dados inserem-se na realização de uma Tese de mestrado Integrado da FMUP.

Curriculum do investigador: Adequado ao perfil da investigação.

Data previsível da conclusão do estudo: 31 Julho 2016

Conclusão: Considerados os objectivos e a metodologia alocada à realização do Estudo, não se levantam objecções éticas à realização deste projecto de investigação.

Porto e H.S.João, 2016-03-18

O Presidente da CES

Doutor Filipe Almeida

7. SEGURO

a. *Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?*

SIM ☐ (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)
NÃO ☐
NÃO APLICÁVEL ☑

8. TERMO DE RESPONSABILIDADE

Eu, Alexandra da Silva Ramalho Azevedo,
abaixo-assinado, na qualidade de Investigador Principal, 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 (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, 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 no decurso do actual internamento ou da mesma consulta.

Porto, 22 / Fevereiro / 2016

Alexandra da Silva Ramalho Azevedo
O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES de ___/___/___

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.