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ORIGINAL ARTICLE

POTENTIAL BLOOD DONORS UMBILICAL AND PLACENTAL FOR STEM CELL COLLECTION: CROSS-SECTIONAL STUDY

POTENCIAIS DOADORAS DE SANGUE UMBILICAL E PLACENTÁRIO PARA COLETA DE CÉLULAS-TRONCO: ESTUDO TRANSVERSAL

SANGRE POSIBLES DONANTES UMBILICAL Y PLACENTARIO PARA RECOLÈCCION DE CÈLULAS MADRE: ESTUDIO DE LA CRUZ

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ABSTRACT

Objective*:** to identify mothers' ability to donate Umbilical cord blood for obtaining stem cells. ***Method*:** cross-sectional study with analysis of 550 medical records of women who gave birth in a public hospital in 2014. The obstetric and neonatal data were collected in January and March 2015, from a form and analyzed using descriptive statistics. ***Results*:** maternal age at 18 was the most recurrent qualification criteria, followed by gestational age greater than 35 weeks. The presence of infectious process or disease during labor that might interfere with placental vitality was the criterion that most determined the disqualification of women for donation. ***Conclusion: according to the provisions of the Collegiate Board Resolution (RDC) No 56 of 16 December 2010, ANVISA, part of the school maternity patients would be able to blood donation Umbilical cord. ***Descriptors:*** Fetal Blood; Stem Cells; Maternal-Child Nursing; Obstetric Nursing.

RESUMO

Objetivo: identificar aptidão de parturientes para doar sangue de cordão umbilical e placentário para a obtenção de células-tronco. ***Método:*** estudo transversal, com análise de 550 prontuários de mulheres que pariram em uma maternidade pública em 2014. Os dados obstétricos e neonatais foram coletados em janeiro e março de 2015, a partir de um formulário e analisados pela estatística descritiva. ***Resultados:*** a idade materna superior aos 18 anos foi o critério de qualificação mais recorrente, seguido da idade gestacional maior que 35 semanas. A presença de processo infeccioso ou doença durante o trabalho de parto que possam interferir na vitalidade placentária foi o critério que mais determinou a desqualificação de mulheres para doação. ***Conclusão:*** de acordo com o estabelecido na Resolução da Diretoria Colegiada (RDC) nº 56, de 16 de dezembro de 2010, da ANVISA, parte das pacientes da maternidade escola estaria apta para a doação do sangue do cordão umbilical e placentário. ***Descritores:*** Sangue Fetal; Células-Tronco; Enfermagem Materno-Infantil; Enfermagem Obstétrica.

RESUMEN

Objetivo*:** identificar la capacidad de las madres a donar la sangre del cordón umbilical para obtener células madre. ***Método*:** estudio transversal con análisis de las 550 historias clínicas de las mujeres que dieron a luz en un hospital público en 2014. Se recogieron los datos obstétricos y neonatales en enero y marzo de 2015, de una forma y analizados utilizando estadística descriptiva. ***Resultados*:** la edad materna a los 18 fue el criterio de calificación más recurrentes, seguido por la edad gestacional superior a 35 semanas. La presencia de un proceso infeccioso o enfermedad durante el parto que podrían interferir con la vitalidad de la placenta fue el criterio que más determina la descalificación de las mujeres para la donación. ***Conclusión*:** de acuerdo con lo dispuesto en la Resolución de la Dirección Colegiada (RDC) n ° 56, de 16 de diciembre de 2010, ANVISA, parte de los pacientes de maternidad escuela sería capaz de donación de sangre de cordón umbilical. ***Descriptores: Sangre Fetal; Células Madre; Enfermería Maternoinfantil; Enfermería Obstétrica.

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INTRODUCTION

Brazil has been undergoing significant changes in its demographic profile, as a result of factors such as urbanization, industrialization, and advances in science and technology. These new features of the population are reflections of new lifestyles, even more intense, and risk factors own the modern world. This demographic change process, known as "aging" of the population, associated with the transformation in the relationship between people and their environment, brought an important change in the morbidity and mortality profile, reducing the occurrence of infectious diseases, and putting chronic degenerative diseases as new center of attention of health problems and death of the population.[1]

Scientific and technological advances have brought important contributions to society, especially in health. The implementation of new features and new processing techniques have provided better quality of life for patients and also the extension of life. In this context, it is the transplantation of hematopoietic stem cells, which has been developing as an important method in the treatment of hematologic, oncologic, hereditary and autoimmune diseases in recent years.[2]

Hematopoietic stem cells give rise to all kinds cells that comprise the blood, such as the immune system, transporting oxygen and are responsible for blood clotting in this way, these cells are classified as multi-potent stem cells capable of differentiating into several cell types in the same embryonic origin.[3]

Hematopoietic progenitor cells can be obtainer's own bone marrow, from peripheral blood, umbilical cord and embryonic cells. The transplant results from the intravenous infusion of hematopoietic cells, designed to restore spinal cord and immune function. Thus, there is the replacement of diseased or destroyed cells by other normal bone marrow capable of producing healthy cells in patients with a number of malignant and non-malignant, inherited or acquired.[4]

In 2004, from its creation, through Ordinance No. 2381, the National Network of Cord Banks was in charge of the service to the new demand of blood banks umbilical and placental cord that are responsible for obtaining processes, conducting laboratory tests, processing, storage and supply of hematopoietic stem cells from blood umbilical cord for therapeutic use. These banks should conduct their processes obeying technical criteria determined by the National Health Surveillance Agency (ANVISA). The correct procedure for collecting Umbilical cord blood represents the quality and safety of stem cells available, resulting in the lowest possible risk to the health of the patient that uses.[5]

The Collegiate Board Resolution (RDC) No 56 of 16 December 2010, ANVISA, determines that the collection of Umbilical cord blood is performed by a top-level health professional, revoking the DRC 153 2004.[6] The Federal Nursing Council published Resolution 304/2005, which regulates the collection of blood Umbilical cord for storage as an assignment of nurses. Thus, a new playing field is opened for the category, which began operating in the blood bank services umbilical cord and placental.[7]

Pregnant women are candidates for blood donation of umbilical cord and placenta for allogeneic use unrelated, provided they meet the following conditions: maternal age over 18 years, have undergone at least two prenatal visits documented; gestational age less than 35 weeks; stock route for less than 18 hours; no labor abnormality; and no infectious process and / or disease during pregnancy that may interfere with placental vitality.[6]

The nurse's performance aims to obtain blood samples from the umbilical cord and placental volume and satisfactory cell numbers, in order to provide the umbilical cord blood and placental banks with high quality cell samples. For this, it is necessary for nurses to be instrumentalized for the selection and collection of umbilical cord blood. Knowing the obstetric and neonatal factors is important to select donor.[8] Thus, the nursing indisputably plays a crucial role in the process of collecting blood Umbilical cord. Nurses should have information related to this collection in order to obtain stem cells for the use of unrelated transplant, as this is the professional responsible for best practices for the correct collection of stem cells. According to information from analysis of the review of medical records, this study aims to identify mothers' ability to donate Umbilical cord blood for obtaining stem cells

METHOD

A retrospective descriptive study, with a quantitative approach, performed at the Maternity School of the Federal University of Rio de Janeiro in February and March 2015, with medical records.

Women of the records were eligible to have their children via vaginal delivery or caesarean section, from January to December 2014; and having passed the revision sector health unit. This sector consists of the

multidisciplinary team, which reviews all records of the institution before being forwarded to the billing sector in order to identify the absence of records or discrepancies.

Records with incomplete information are excluded, they prevented the proper filling of the collection instrument, and mothers who had a dead fetus at delivery time.

To determine the sample proceeded prorated for each type of procedure to determine the minimum records to be examined. Therefore, it adopted confidence level of 95%, and margin of error of 0.05% standard percentage. The formula employed is expressed:

$$n = \frac{N * \hat{p} * \hat{q} * (z\alpha_{/2})^2}{\hat{p} * \hat{q} * \left(z\alpha_{/2}\right)^2 + (N-1) * (E)^2}$$

$\hat{p}$ is the proportion of births (C-sections or trans pelvic); $\hat{q}$ is $(1-p)$; Z is the level of significance; E is the maximum percentage error; and N, population.

It was found that there were a total of 1,903 records of births for analysis, of which 1,023 were transpelvic delivery and 880 caesarean section. The sample size calculation determined the analysis of 285 records relating to transpelvic births and 265 Cesareans. The selection of records was random: after numbered, the charts were drawn. The data collection instrument was based on the form used by the National Cancer Institute José Alencar Gomes da Silva (INCA) for screening and interviews for selection of potential donor, after completion of the delivery. We collected data to identify the demographic profile of pregnant women, prenatal and obstetric evaluation, laboratory tests, labor and the newborn.

Data were tabulated in a Microsoft Excel® spreadsheet program and analyzed in SAS version 9.1.3 program. Descriptive statistical analysis of qualification and disqualification variables was performed for fitness to donate umbilical cord blood for allogenic use, unrelated, following the parameters of RDC 56/2010 ANVISA.[4]

The study met national and international standards of ethics in research involving human subjects and was approved by the Ethics Committee of the Maternity School of UFRJ, look under number 722172.

RESULTS

♦ Profile of Parturients

The average age of pregnant women studied was 25 years (SD = 6,868); the youngest pregnant woman was 13 and the oldest 47 years. Most (38.9%) had, as education level, elementary school, followed by those with high school education (36.1%). The occupation "housewife" was reported by 41.0% of the sample, and "house maid" by 10.1%.

The mean gestational age was 38 weeks and 6 days (SD = 2.3), with minimum and maximum occurrence of 26 weeks and 42 weeks and 1 day, in that order. In terms of the number of prenatal visits, the average was 7 (SD = 2.86), with a maximum frequency of 18 queries.

Qualification criteria

Table 1 shows the women's qualifying criteria for fetal blood donation and distribution of case studies for the ability to donate. Observing the criteria alone, for all of them, more than 90.0% of mothers would be able to donate. In all cases and for cases of vaginal delivery, maternal age of 18 years was the criterion responsible for most of the non-qualifying women for donation, followed by gestational age less than 35 weeks; while for cases of Caesarean section the presence of diagnostic disease that interferes with the blood flow was the criterion.

The lower incidence of qualification criteria for both types of delivery, was the occurrence of abnormality in labor, found in only two cases.

Table 1. Distribution of women by type of delivery, according to eligibility criteria for blood donation of umbilical cord and placental allogeneic unrelated. Rio de Janeiro, 2015 (n = 550)

Eligibility Criteria	Not suitable for donation						Suitable for donation	
	Transpelvic		Cesarian		Total			
	n	%	N	%	N	%	n	%
Maternal age <18 years	33	11.6	12	4.5	45	8.2	505	91.8
Number of pre-natal appointments <2	7	2.5	1	0.4	8	1.5	542	98.5
Gestacional Age <35 weeks	19	6.7	17	6.4	36	6.5	514	93.5
Amniotic sac >18 horas	14	4.9	12	4.5	26	4.7	524	95.3
Diagnosis of disease that interferes with blood flow	5	1.8	24	9.1	29	5.3	521	94.7
Abnormality in labor	1	0.4	1	0.4	2	0.4	548	99.6

♦ Disqualification criteria

The qualification criteria are shown in Table 2, through which identifies that staff autoimmune disease or cancer history and historical personal and / or family of hematopoietic diseases did not represent the disqualification of any case.

The presence of infectious process or disease during labor that might interfere with placental vitality was the criterion that most determined the disqualification of women for fetal blood donation.

Table 2. Distribution of women by type of delivery, according to disqualification criteria for cord blood donation and placental allogeneic unrelated. Rio de Janeiro, 2015 (n = 550)

Disqualification criteria	Not suitable for donation						Suitable for donation	
	Transpelvic		Cesarian		Total			
	n	%	N	%	n	%	n	%
severe fetal distress Fetus with congenital abnormality	4	1.4	8	3.0	12	2,2	538	97,8
	0	0.0	3	1.1	3	0.5	547	99.5
maternal temperature equal to or higher than 38 ° C during labor	1	0.4	1	0.4	2	0.4	548	99.6
Pregnant women with increased risk for blood borne infections	7	2.5	1	0.4	8	1.5	542	98.5
Presence of infectious process and or illness during labor, which can (m) interfere with placental vitality	5	1.8	24	9.1	29	5.3	521	94.7
Pregnant women using hormones or drugs that are deposited in tissues	0	0.0	8	3.0	8	1.5	542	98.5
Pregnant women with personal history of systemic autoimmune disease or cancer	0	0.0	0	0.0	0	0.0	550	100.0
Pregnant women and their families, birth parents and their families or biological siblings of the newborn with a history of hereditary disorders of the hematopoietic system	0	0.0	0	0.0	0	0.0	550	100.0
Pregnant women included in the other exclusion criteria to the receiver protection, described in the current technical standards for blood donation	1	0.4	3	1.1	4	0.7	546	99.3

DISCUSSION

This retrospective study sought to identify the mothers of suitability to be donors of umbilical cord and placental blood to obtain stem cells, of a public hospital, according to qualification and disqualification criteria established in Brazilian law.

Among the eligibility criteria is a minimum age of 18, without establishment of maximum age. In this research, this criterion determined the disability 8% of the cases. The impact of mother's age on the quality of cord

blood units (USCU) remains unclear. But a recent report found increased incidence of total nucleated cells (CNT) in women aged 30-34 years compared to those aged 20-24 years. [9] The number of CNT is relevant because the blood would only be collected undergo processing when the number was less than $5x10^8$.[4]

Regarding the number of prenatal visits, 98.5% (n = 542) of patients had more than two consultations, minimum number required for fitness to donate. This is because, prenatal plays a key role in the prevention and early detection of various fetal and maternal diseases such as hypertension, diabetes, anemia and HIV.[10]

Qualified attention and humanized prenatal care is through the incorporation of warm pipelines and without unnecessary interventions, easy access to quality health services, with actions that integrates all levels of care: promotion, prevention, and health care for the pregnant woman and the newborn, from basic outpatient care to hospital care for high-risk.[11]

After the analysis regarding the time of membrane ruptures, 93.5% (n = 524) of all women surveyed would be able to donate umbilical cord blood. The route exchange (premature rupture of membranes) is one of the biggest dilemmas of obstetric care, and major complications are maternal and fetal infection and prematurity. Thus, at birth, when the amniotic sac has been broken for more than 18 hours, the umbilical cord blood cannot be stored, because the possibility of the presence of infectious agents and low fetal oxygenation compromise the functioning of umbilical and placental cells.[12] This study found that 95.2% (n = 514) of patients had gestational age 35 weeks, and were suitable for donation according to this criterion. A comparative study with term and preterm newborns showed that gestational age can interfere with cell viability and the volume of placental and umbilical cord blood collected. The proliferative capacity of umbilical cord blood and placental stem cells from preterm infants, whose premature birth is associated with an abnormality of the fetus, preclude the use of the blood sample from the umbilical cord and placenta.[13]

A study developed at The Blood Center of Santa Catarina identified a statistically significant difference between the volume of cord blood and gestational age greater than 38 weeks, confirming a lower volume at the age of 37 weeks and six days, compared with gestational age between 38 and 39 weeks and 6 days.[14]

On the other hand, some studies indicate that gestational age (34-37 weeks) is predictive for increased power of USCU despite that premature babies have lower concentration of them. This power is related to the higher enrichment of USCU with colony-forming units, which give rise to blood cells, and CD34 antibodies, expressing the amount of hematopoietic stem cells.[15,16]

The presence of diseases that interfere with placental blood flow was observed in a few cases of this study, which can be explained in part by the unit profile, which is low and medium-risk pregnant women with hypertension and diabetes. In the case of hypertension, disqualification for donation is because the fetus of hypertensive pregnant women have high risk of having a compromised vitality during the course of pregnancy, as their placenta presents arterial obstructive lesions, which are associated with less blood flow.[17]

The main consequence to the health of the fetus is the progressive loss of placental vascular function, thereby resulting in low perfusion of the organ. The most frequent lesion in placental gestation hypertension is obliteration of the villi tertiary vessel and, in some cases, functional vasoconstriction. Thus, the collection of blood Umbilical cord should be assessed by Doppler placental, a test that identifies whether there is a change of placental flow to the fetus.[18]

Laboratory results or other abnormal findings in screening tests should be reported to the respective donor, with proper referral to a specialized assistance service, so that appropriate measures are taken. [4,6] Contact with the donor such as specified in caput (paragraph)of RDC nº 56. [4] and its proper referral, should be documented, keeping their records.

The use of hematopoietic stem cells in related or autologous allogeneic, does not fully meet the qualification criteria, requires an assessment considering the risk / benefit of the procedure, in joint decision between the medical team where collection and transportation are made, and the recipient or their legal guardians.[19] The quality and safety requirements set forth in this Regulation shall be followed, as well as other specific regulations in force, including at least a serologic test for high sensitivity detection of markers for blood borne infections.

CONCLUSION

It was found that in accordance with the provisions of the current resolution, considering the qualification criteria, 73.8% (n

= 404) were eligible for umbilical cord blood donation while under the disqualification criteria, 89 % (n = 490) would be suitable. Knowing the obstetric and neonatal factors is essential to the placental and umbilical cord blood collection process. And it is the duty of nurses to obtain information related to this collection in order to obtain stem cells for the use of unrelated transplantation, since this is the professional responsible for ensuring the quality and safety of stem cells available, resulting in lowest possible risk to the health of patients who use them. The limits of the results of this study were related to the cross-sectional design that did not allow the establishment of cause and effect relationships. So, new studies with different methodological designs applied to this study are recommended.

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