

Costs analysis of hip osteonecrosis treatment: cell therapy and total arthroplasty in people with sickle cell disease from the SUS perspective

Análise de custos do tratamento da osteonecrose de quadril: terapia celular e artroplastia total em pessoas com doença falciforme na perspectiva do SUS

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Abstract: Objective: This study set up to perform an analysis on the effective spending on cell therapy and arthroplasty in hip osteonecrosis in people with Sickle Cell Disease, in the context of the Brazilian Unic Health System (In portuguese, Sistema Único de Saúde – SUS). Methods: A descriptive, comparative and cross-sectional study with people, in the age group of 18 to 40 years old, assisted at the Professor Edgard Santos University Hospital Complex, with hip osteonecrosis secondary to Sickle Cell Disease and submitted to cell therapy, within the period of 2015 to 2019. To evaluate health expenditures, the micro-costing methodology was applied and the SUS perspective was used as the purchasing organization of public and private health services. In addition, data from the SUS database, DATASUS, were consulted. Results: 74 patients were tended, with 88 surgical procedures being performed. The expenses obtained with each procedure were R\$ 3,265.22 for cell therapy and R\$ 4,764.08 for total hip arthroplasty. Based on scientific evidence, the loosening of prostheses referring to primary total arthroplasty in Sickle Cell Disease, where the value of R\$4,764.08 has an average useful life of 5 to 10 years, requires a total revision arthroplasty, a procedure with estimated expenses of R\$ 6,365.18. It was verified that, while cellular therapy generated an expense of R\$ 287,339.36, sickle cell disease the traditional method was adopted, the amount spent would be R\$ 979,374.88. Conclusions: Cell therapy proved to be more economical, being a treatment that makes it possible to treat more people in less time.

Keywords: Health Expenditures, Sickle Cell Anemia, Femur Head Osteonecrosis, Hip Arthroplasty. Cell Therapy.

Resumo: Objetivo: Este estudo se propôs a realizar uma análise sobre os gastos efetivos com terapia celular e artroplastia na osteonecrose no quadril em pessoas com Doença Falciforme, no contexto do Sistema Único de Saúde (SUS). Métodos: Estudo descritivo, comparativo e transversal com pessoas, na faixa etária de 18 a 40 anos, atendidas no Complexo Hospitalar Universitário Professor Edgard Santos, com osteonecrose de quadril secundária à Doença Falciforme e submetidas à terapia celular no período de 2015 a 2019. Para avaliar os gastos em saúde, aplicou-se a metodologia de microcusteio e utilizou-se a perspectiva do SUS como organização compradora de serviços de saúde pública e privadas. Além disso, foram consultados dados dos bancos de dados do SUS, DATASUS. Resultados: Foram atendidos 74 pacientes, sendo realizados 88 procedimentos cirúrgicos. Os gastos obtidos com cada procedimento foram de R\$ 3.265,22 para terapia celular e R\$ 4.764,08 para artroplastia total do quadril. Com base em evidências científicas, a soltura de próteses referentes à artroplastia total primária na Doença Falciforme, cujo valor de R\$ 4.764,08 tem vida útil média de 5 a 10 anos, exige uma artroplastia de revisão total, procedimento com gastos estimados em R\$ 6.365,18. Verificou-se que, enquanto a terapia celular gerou um gasto de R\$ 287.339,36, na doença falciforme o método tradicional foi adotado, o valor gasto seria de R\$ 979.374,88. Conclusões: Terapia com células tronco mostrou-se mais econômico, sendo um tratamento que possibilita tratar mais pessoas em menos tempo.

Palavras-chave: Despesas De Saúde, Anemia Falciforme, Osteonecrose da cabeça do fêmur, Artroplastia do quadril, Terapia celular.

Introduction

Sickle Cell Disease (SCD) is defined as an autosomal recessive disorder characterized by the presence of abnormal Sickle hemoglobin (HbS). When deoxygenated, the HbS undergoes polymerization and results in the deformation of red blood cells, which assume the shape of a sickle or a half-moon and are therefore called sickle cell (LEBOUVIER et al., 2015). The SD can manifest as the homozygous form HbSS, characterizing Sickle Cell Anemia (SCA), with severe manifestation of the disease or in association with other hemoglobinopathies (HbSC, HbSD, HbSE), β -thalassemia (β^+ and β^0) and in the heterozygous form (HbAS), called sickle cell trait, in which there is no clinical manifestation (Brasil, 2015).

SCD is considered a public health problem in northeastern Brazil, where it affects 6 to 15.7% of various population groups (DALTRO et al., 2008). About 50% of patients with SCD suffer from avascular necrosis, which consists of a massive necrosis of bone and bone marrow, resulting in chronic pain. Avascular necrosis primarily affects the femoral epiphysis, and is commonly associated with osteonecrosis of the humeral epiphysis, found in 80% of cases (Daltro et al., 2008). The treatment of femoral epiphysis osteonecrosis is considered challenging, being a severe and debilitating complication of SCD.

Hip osteonecrosis is associated with high rates of hospitalizations and surgeries in about 90% of affected hips as a result of the natural course of the disease. This condition mainly affects patients in the age group of 18 to 40 years-old, considered the most productive phase of the Brazilian population, leading to major repercussions on the economy (Hernigo et al., 2018). In addition, the lack of specific treatment of hip osteonecrosis associated with sickle cell disease leads to reduced blood flow in the femoral head, degeneration in trabecular architecture, collapse of the subchondral bone and secondary arthrosis in up to 70% of the cases (Hernigou et al., 2006).

In Brazil, in 2019, 8,940 hospitalizations were performed for non-conventional hip arthroplasty, partial hip arthroplasty and total hip conversion arthroplasty (THA) (DATASUS, 2020), the expenses with these procedures were R\$ 38,878,305.48. There were also 1,992 procedures for revision or reconstruction of hip arthroplasty with an additional expense of R\$ 9,513,206.92, representing a total expense of R\$ 48,391,512.84 (DATASUS, 2020).

Total hip arthroplasty is an invasive procedure with high morbidity and mortality rates and unsatisfactory results in up to 50% of patients after 5 to 10 years of the surgery (Martí-Carvajal et al., 2019). Moreover, around 75% of the patients develop pain and limitations after the procedure (Patel et al., 2014). The high risk of morbidity and mortality can be explained by the fact that the procedure is invasive, exposing the patient to possible thrombotic complications, secondary contaminations and the need for blood transfusions (Salles, 2012).

On the other hand, in HF, the use of Cell Therapy (CT) is based on the ability of bone marrow-derived mesenchymal stromal cells, as well as bone marrow-derived endothelial progenitor cells to enhance angiogenesis and tissue repair. In addition, other cell types may be present such as macrophages, T lymphocytes, B lymphocytes, dendritic cells, natural killer cells, and neutrophils, which in turn may allow for improved pain and function (Hernigou et al., 2018). Patients with SCD are found to have better prognoses with CT, showing a 5% failure rate (Hernigou et al., 2006).

Many studies reveal that the use of CT in the treatment of hip osteonecrosis in people with SC contributes to the improvement of the patient's quality of life, reduction in the risk of infections and surgical complications. (Hernigou et al., 2018; Hernigou et al., 2006; Sarat et al., 2019) However, studies showing the cost-effectiveness of CT in the treatment of hip osteonecrosis and its repercussions on the health system and the patient's quality of life are still incipient. With the publication of Law No. 12,401, which provides for therapeutic assistance and the incorporation of technologies in health within the SUS (Brasil, 2018), it becomes extremely important to search for new therapies aimed at patients with HF, whose treatment is still a challenge (Hernigou et al., 2006).

In Brazil, the SUS (Single Health System) presents a unique role in ensuring care, quality of life and increased longevity of the population with SCD. Through the Hemorrhagic Network and reference hospitals, the public health system allows patients with DF to have access to treatment and new technologies in health (Segre & Ferraz, 1997). In this regard, considering the efficiency of CT, the aim of this study is to perform an analysis of the effective expenditure with cell therapy and arthroplasty in hip osteonecrosis in people with sickle cell disease, within the SUS.

Methods

Study design

A descriptive, comparative, cross-sectional study was conducted with people treated at COMHUPES, with hip osteonecrosis secondary to SCD and submitted to CT, in the age range of 18 to 40 years old, in the period between 2015 and 2019. From the patients' medical records, the expenses of CT and THA were estimated for analysis and comparison purposes.

Considering the topic of this study, it is of fundamental importance to differentiate between expense and cost. Thus, cost is defined as the value of all resources spent on the production of a good or a given service. When the cost becomes essential for an institution, it is given great relevance due to the scope and transformations in the various stages of the process of creating a product or service (Koliver, 2009). The expense is defined as the expenditure on goods or services purchased. It is established when there is a need to produce some good; in other words, when a debt is assumed and thereby causing a reduction of the asset given in payment, thus being divided into investments (Dubois et al, 2006).

This work is part of the project entitled: "Analysis of the clinical-epidemiological profile of patients in outpatient follow-up in the orthopedics and traumatology service of the Professor Edgard Santos University Hospital Complex". It was approved by the Research Ethics Committee of the Professor Edgard Santos University Hospital, under the number of the CEP's substantiated opinion: 3.460.241 and Certificate of Submission for Ethics Appreciation - CAAE: 13790619.6.0000.0049. The work was carried out in compliance with resolutions 196/96, 340/04, 347/2005 and 466/2012 of the National Research Ethics Committee (CONEP) and their complementary.

Data collection and evaluation

A questionnaire was used to collect the following data from the patient's medical records: patient's name, age, birthplace, city, sex, etiology, type and location of the hip injury according to the Ficat- Arlet classification, comorbidities, race/color, level of education, occupation, and marital status, as well as access to an informed consent form. The costs of arthroplasty were quantified based on the SUS reference.

The microcosting methodology, also known as bottom-up methodology, was used to determine the expenses. Through its application, it was possible to identify in a detailed way all the items presented in the SUS table, related to the expenditures, and the medical chart review was used, as it presents more precise data. From the SUS perspective, data from the SUS Computer Department (DATASUS) were used, which presents the main information to obtain costing data. Furthermore, information systems on mortality (SIM), hospital (SIH-SUS) and outpatient (SAI-SUS) data, as well as scientific literature were consulted.

Expenditure estimation with CT and HAT

Table 1. Expenses with surgery using stem cells.

	Cost per unit	Unit	Total cost
Surgical Expenses	R\$ 57.61	1	R\$ 57.61
Material Expenses	R\$ 300.00	1	R\$ 300.00
Cell separation kit (SEPAX®)	R\$ 2,300.00	1	R\$ 2,300.00
Ficoll-Paque Plus	R\$ 250.00	1	R\$ 250.00
Inpatient daily fees	R\$248.06	1	R\$ 248.06
ICU reservation	Does not apply	-	R\$ 0
Total			R\$ 3,265.22

Source: HUPES (2019).

Table 2. Expenses with primary total hip arthroplasty (PTHA).

	Cost per unit	Unit	Total cost
Surgical Expenses	R\$ 1,214.72	1	R\$ 1,214.72
Material Expenses (OPME)	R\$ 3,549.36	1	R\$ 3,549.36
*Inpatient daily fees	R\$ 0	-	R\$ 0
*ICU reservation	R\$ 0	-	R\$ 0
Total			R\$ 4,764.08

Source: DATASUS. procedure 04.08.04.004-4 - Available at: <<http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/spauf.def>>.

Expenditure estimation with HAT review

Table 3. Expenses with primary total hip arthroplasty (THAR).

	Cost per unit	Unit	Total cost
Surgical Expenses	R\$ 1,678.87	1	R\$ 1,678.87
Material Expenses (OPME)	R\$ 3,549.36	1	R\$ 3,549.36
*Componente de Proc.			
07.02.03.010-4	R\$ 1,027.28	1	R\$ 1,027.28
Acetabular Screw			
Proc. 07.02.03.076-7	R\$ 109.67	1	R\$ 109.67
*Inpatient daily fees	R\$ 0	-	R\$ 0
*ICU reservation (daily fee)	R\$ 0	-	R\$ 0
Total			R\$ 6,365.18

Source: DATASUS. Procedure 04.08.04.007-6- Available at: <<http://tabnet.datasus.gov.br/cgi/tabcgi.exe?sih/cnv/spauf.def>>.

Results

Table 4. Profile of the 74 patients treated at HUPES according to gender, hemoglobinopathy, hip osteonecrosis site, and number of surgeries performed.

	Right femur	Left femur	Both sides	Total of surgeries	Total of patients
Female					
SC	9	8	2	21	19
SS	4	8	5	22	17
Male					
SC	11	8	3	25	22
SS	5	7	4	20	16
Total	29	31	14	88	74

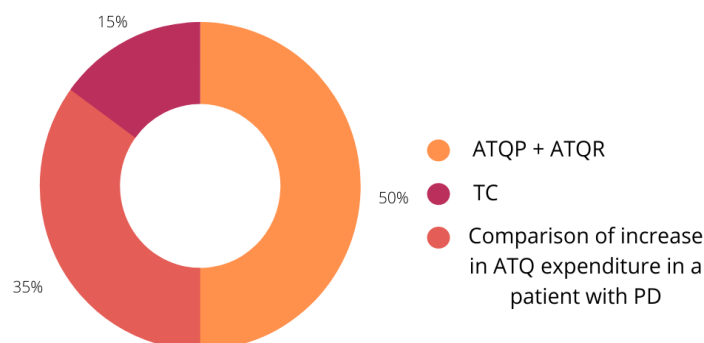
Source: Botelho et al.2020.

The data in Table 4 reveal that of 74 patients treated at HUPES, 48.64% were females, 53.66% of whom had hemoglobinopathy SC, and 51.36% were males, 55.51% of whom had anemia SS. The results showed that 44.60% of the individuals with Hb SC had necroses on the right side of the hip, while 55.40% of the individuals with Hb SS had necroses on the left side of the hip. On the other hand, 27.27% of the patients presented necrosis on both sides of the hip.

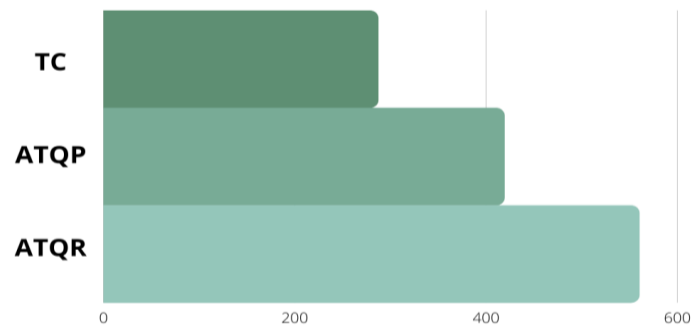
The costs of each procedure were R\$ 3,265.22 regarding CT and R\$ 4,764.08 regarding primary total hip arthroplasty (PTHA); showing a difference of 16% over the value of CT. DATASUS already shows that the expenses included hospitalization, ICU, food, and medicine.

Based on scientific evidence, prosthesis loosening for primary total arthroplasty in sickle cell disease, where the cost of R\$ 4,764.08 is estimated to last 5 to 10 years on average, requires a revision total arthroplasty, a procedure with estimated expenses of R\$ 6,365.18. Therefore, the expenses are even higher compared to CT, with an increase of R\$ 7,864.04 per procedure, which will generate an increase of 35% over the treatment with THA.

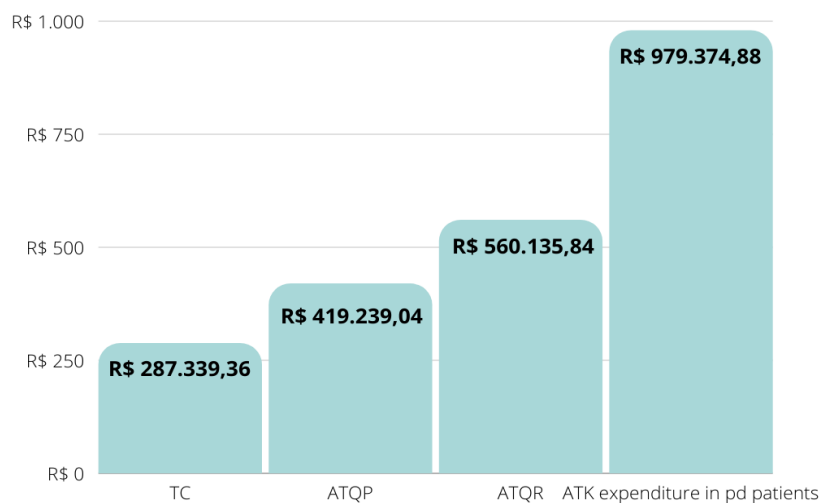
Furthermore, from the evaluation of expenses considering the 74 patients analyzed, which generated the demand for 88 surgical procedures, it was verified that, while cell therapy generated an expenditure of R\$ 287,339.36, if the traditional method were adopted, the amount spent would be R\$ 979,374.88.



Graph 1. Comparison of the costs of treating hip osteonecrosis with cell therapy versus total hip arthroplasty considering people with Sickle Cell Disease. Source: Botelho et al (2020).



Graph 2. Comparison of the expenses of procedures performed in patients with Sickle Cell Disease. **Source:** Botelho et al (2020).



Graph 3. Comparison of the expenses of the procedures performed in patients with Sickle Cell Disease. **Source:** Botelho et al (2020).

Conclusion

The present study was developed to evaluate the costs of procedures performed for the treatment of hip osteonecrosis in people with DF in a public health unit. After determining the costs, it was found that CT resulted in an expenditure of R\$287,339.36; if these same patients were treated by THA, the cost would be R\$979,374.88. Thus, it was demonstrated that CT is more economical, being a therapeutic method that allows treating more people in less time, because it is a procedure that requires a shorter period of hospitalization and patient recovery.

The study was developed focusing on the SUS perspective and provided to present a new procedure that takes into account the broader concept of health, defined by the World Health Organization (WHO) as a state of complete physical, mental and social well-being and not only the absence of disease. Thus, considering that the patient submitted to THA can evolve with limitation of movements affecting his quality of life, mental health, labor productivity and socioeconomic condition, CT shows itself as a treatment more aligned with the expanded concept of health, since it presents fewer risks of causing negative repercussions on the patient's health, allowing his insertion in social and productive life.

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