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Cost of the treatment for venous ulcers in an outpatient clinic and in the household: a descriptive study

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ABSTRACT

Aim: To compare the direct costs of treatment of venous ulcers involving the use of carboxymethylcellulose gel in domiciliary and outpatient environments. **Method:** This is a descriptive study, in which 96 consultations were performed in the Wound Healing Clinic of a university hospital between April and December 2013. Cost categories were identified, monetary values were defined and calculations were based on the consumption of materials used in the clinic and later released to the patients' homes. The study was approved by the Research Ethics Committee of the hospital under the number 196/08. **Results:** After 84 days of follow-up, outpatient treatment costs were higher than the home care costs, and the main reason for this difference was nursing manpower. **Conclusion:** It is necessary to define strategies for conducting effective nursing consultations and these strategies should include guidelines for home care and the dispensing of the material for patients.

Descriptors: Costs and Cost Analysis; Leg Ulcer; Nursing.

INTRODUCTION

The vasculogenic ulcers represent a major world-wide disorder, and a serious public health problem in Brazil. This clinical condition is responsible for high rates of mortality, in addition to causing a major economic impact⁽¹⁾.

The treatment of such lesions may include the use of various types of products, for example, the use of Unna's Boot, papain (powder and gel) and elastic compression therapy. The treatment of uninfected venous ulcers with 2% carboxymethylcellulose (CMC) gel has shown an average decrease of 16.9 cm² in the lesion area⁽²⁾.

Although the effectiveness of these and other products have already been widely studied and verified^(3,4,5), it is necessary to conduct reviews of economic developments for better allocation and distribution of monetary resources in the different areas of health. The availability of different products with the same therapeutic purpose for the treatment of wounds and a great variability of prices on the market hinder both the professional decision-making in choosing the most appropriate coverage and patient compliance with the treatment. These issues justify the implementation of this type of study.

These analyses are just beginning in Latin America and Brazil stands out in the local scenario. A recent survey of studies published between 2005 and 2014 regarding pharmacoeconomic analysis of treatments for leg ulcers showed that, of a total of 17 articles included, only two have been developed in Latin America: one in Colombia and one in Brazil⁽⁶⁾.

Direct costs are those directly related to health services that imply immediate expenditures and are easy to identify⁽⁷⁾. Some international studies, when analyzing the components of the total direct costs of treatments for leg ulcers, found that clinical care is their main

contributor due primarily to the value of the professional workforce of nurses who are responsible for nursing consultation^(8,9,10,11).

It is noteworthy that the vasculogenic ulcers are chronic conditions that require long-term treatment that needs outpatient and home care, including daily activities such as injury hygiene, use of products for wound coverage and the application of dressings with bandages and appropriate bandaging, besides the monitoring and control of several comorbidities, such as hypertension and diabetes. Therefore, the complexity involved in the therapeutic process of these lesions can be understood.

In view of the overview above, this study aimed to compare the direct costs of treatment of venous ulcers with carboxymethylcellulose gel in the household and in the clinic.

METHOD

This is a descriptive study, carried out with wounded patients, that aims to evaluate the costs of treatment with CMC gel in the clinic and in the household. For conducting a pharmacoeconomic analysis, it is necessary for the researcher to define the perspective of the study, that is, which picture will be used to assess the costs and who is interested in the results of this evaluation. In this study we adopted the perspective of paying health service sources, which may include both the public system (Unified Health System - UHS), as well as covenants and private insurance companies in the private sector.

To estimate the values, it was necessary to identify the cost categories, set monetary values and perform calculations. Costs were divided into three categories: product for injury treatment (carboxymethylcellulose gel), inputs

(materials needed for curative treatment) and procedures (nursing consultation in the case of outpatient care).

The first cost category refers to the product used in this study, namely the 2% CMC gel produced by the university pharmacy. The production process of this gel was mapped by international standards of quality control to ensure a perfect reproduction of the product. The gel was dispensed in tubes of 100 grams for the procedure in the clinic and in tubes of 50 or 100 grams for dispensing to the patient, depending on lesion characteristics such as size and degree of exudation. Its composition is carboxymethylcellulose (active ingredient), propylene glycol (humectant), methylparaben (preservative) and water (vehicle). These gels were given a shelf life of 90 days.

The cost calculation was based on prices provided by the university pharmacy so the tube of 100 grams of 2% CMC costs R\$ 8 (US\$ 3.35). This value was the basis for calculating the price per gram of the product through a simple rule of three. The conversion of costs from Brazilian reais to US dollars was made due to the need to consider the international standards in which Brazil is also included. The value exchange rate used as a basis was R\$ 2.39 per dollar, according to the currency value on February 10, 2014.

To compute the product cost, we checked the gel consumption using a non-commercial battery-based scale of the Hidromel® brand with a precision of one gram, always ready at the same previously marked location to avoid measurement bias and the tare of the scale is always set before starting day care. To control consumption, the tubes were weighed before and after each service (for outpatient use) and before being delivered to patients and the subsequent consultations (for household consumption). The total consumption was

multiplied by the price of a gram of the product.

In the second category, we calculated the cost of inputs needed for using the dressings at home: packages containing 10 units of sterile compresses of hydrophilic gauze; a crepe bandage; a roll of waterproof tape; a bottle containing 500 ml of 0.9% saline solution; a flask containing 100 ml of liquid petrolatum; a flask containing liquid soap with neutral pH and without glycerin; and a double-sheeted white aerated paper towel roll.

The inputs needed for using the dressings at the clinic are the same as described above, plus white disposable surgical masks; pairs of disposable gloves for procedures; pairs of sterile surgical gloves for single use; 40 X 12 (18G X 1 ½) a hypodermic disposable needle; and scalpel blades number 20.

The monetary values of these materials were collected by consulting the electronic auctions of the Ministry of Health for the purchases made by the university hospital in the years 2012 and 2013. The amount used by each participant was entered on a worksheet to calculate costs.

The consumption of materials used in the clinic was controlled through the completion of a worksheet, and this survey was carried out at the end of each service. The materials needed to complete the dressings in the household were given to patients in a Dressing Kit, which included elements needed for a week of using the dressings in the household. The quantity used was entered on another worksheet for monitoring consumption. The amounts of supplied raw materials vary according to the characteristics of the lesions. The survey was conducted on each visit.

Participants and/or their legal representatives were asked to take any materials that had not been used to the clinic for effective consumption monitoring.

The third cost category, related to the procedure, is related to the weekly nursing visits for applying the bandages in the clinic. For this, we timed this examination in minutes, so that the value of the professional labor was included in the evaluation. The calculation of this value was based on the Honorary Table determined by Resolution 301/2005 of the Federal Nursing Council (COFEN), which set the minimum amount of R\$ 66.07 (US\$ 27.64) per hour for the realization of nursing consultations. The value was divided by 60 to obtain the fees per minute. The cost of the procedure was represented by this value and was multiplied by the time spent at each consultation.

In order to minimize the variables of interpretation for the timing, we had previously determined the moment of the beginning and the end of the procedure as the time the patient enters the clinic and the time he leaves it.

The survey was conducted in a university hospital in the period from April to December 2013. The sample consisted of eight participants who met the inclusion criteria and strictly followed the care in the clinic. The follow-up time was 84 days, with weekly monitoring, totaling 96 consultations. We included patients of both sexes, older than 18 years with uninfected venous ulcers who had treatment with 2% CMC gel.

Following the determination of Resolution 466/12 of the National Health Council, this study was submitted to the Research Ethics Committee of the Faculty of Medicine, Fluminense Federal University for its assessment and any adjustments, and it was approved under number 196/08. The Terms of Free and Informed Consent was offered to all research participants.

Information was distributed in a spreadsheet in order to subject them to statistical procedures. First, a normality test was performed to verify that the data sets show normal or not normal distribution. We performed descriptive

statistics through measures of central tendency and dispersion.

RESULTS

The consumption survey of each cost category identified was carried out. We had a total household consumption of 868 gauze packages, 44,000 mL of 0.9% saline solution, 605 inelastic bandages, 4,946 grams of gel, 14 tape rolls, 3,040 mL of liquid soap, 1,430 ml of liquid petroleum jelly and 18 paper towel rolls.

With regard to the consumption of the ambulatory patient treatment with 2% CMC gel we have a total of 201 gauze packs, 102 pairs of sterile gloves, 162 pairs of procedure gloves, 9,710 ml of 0.9% physiological saline, 106 inelastic bandages, 622 grams of gel, 66 masks, 50 needles, 44 scalpel blades and a total time of 4,316 minutes of nursing consultation.

The total cost of the treatment with CMC gel 2% in the residential and outpatient environments were calculated based on these intakes and are summarized in Table 1.

Table 1 - Total direct costs in Brazilian Reais of the home and outpatient care with 2% CMC gel per research volunteer during 84 follow-up days. Niterói, 2014.

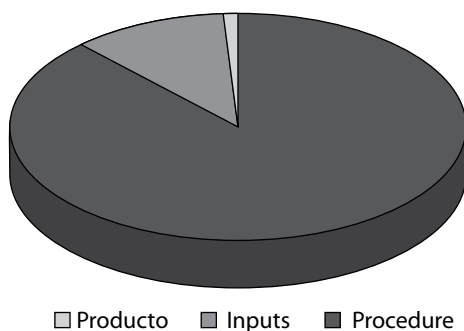
Voluntary	Total household cost	Total outpatient cost	Total Cost
DO	139,07	557,19	696,26
CBC	307,41	946,11	1253,52
CLMS	212,45	564,49	776,94
CADR	498,94	934,34	1433,28
CAM	291,03	660,8	951,83
CPS	251,76	592,92	844,68
JPP	186,65	744,49	931,14
MLFS	146,89	412,97	559,86
Total	2034,2	5413,31	7447,51
Total (U\$)	851.13	2264.98	3116.11

The analysis of Table 1 allows us to observe that total direct home cost is lower than the total direct costs of the outpatient clinic, representing 27.31% of the total cost. It is noteworthy that the outpatient clinic costs refer to the 12 nursing consultations carried out per patient during follow-up, and the domiciliary costs regard the other 72 days of treatment. Thus, when calculating the cost per treatment day, we have the values of R\$ 28.25 (US\$ 11.82) for home treatment and R\$ 451.11 (US\$ 188.75) for outpatient treatment.

It can be seen by examining the table that the CBC and CADR volunteers had much higher costs than the other study participants. The CADR volunteer, who presented the highest costs, had a larger wound in terms of cm² and with a high degree of exudation; the CBC volunteer had two venous ulcers which also featured high exudation. Both required greater gel and input consumption and longer nursing visits for curatives.

Considering the discrepancy between treatment costs in the clinic and in the household, we performed a decomposition of outpatient costs to check which category most overloads the cost of treatment in the outpatient environment. The results can be analyzed in Picture 1.

Picture 1 - Components of the total direct cost of outpatient treatment with 2%CMC gel. Niterói, 2014.



Source: Research Data, 2013.

Abbreviation: CMC – Carboxymethylcellulose

It is noted that the category that most overloads the cost for outpatient treatment with 2% CMC gel is the consultation, namely the value of the workforce of nurses who are responsible for carrying out the procedure, including dressing exchange, diagnosis, care prescriptions, medical records and instructions to patients. The product used accounted for less than 1% of the cost.

DISCUSSION

Due to the fact that venous ulcers account for approximately 75% of leg ulcers and represent a common problem in Western countries, their treatment causes significant economic impact and is largely responsible for the total costs of public health systems. Nevertheless, in Brazil, there are no records of actual costs with these therapeutic resources⁽¹²⁾. However, in the United States, it is estimated that the annual cost for treating these injuries is between 1.5 and 3.5 billion dollars⁽¹³⁾. In the UK, the cost for the treatment of venous ulcers is estimated at £1,500 to £1,800 per patient⁽¹⁴⁾.

We can also see great heterogeneity in the products used for the treatment of ulcers analyzed in economic studies, ranging from infrared spectroscopy and magnetic resonance imaging to treatment with an Unna boot, foam with silver release, vacuum therapy, larva therapy, compression therapy, ultrasound therapy, amniotic membrane transplantation and dressing with honey⁽⁶⁾. This data hinders the implementation of reliable comparisons between studies.

When calculating the direct costs of treatment with the CMC gel, we have obtained the total amount of R\$ 7,447.51 (US\$ 3,116.11), and the outpatient care accounted

for 72.69% of the total. These results are in agreement with the data found in a British study that compared the cost-effectiveness of antimicrobial dressings with silver release with non-adherent bandages, in which the clinical care for monitoring venous ulcers was the largest contributor to the total cost, representing 61% to 66% of this⁽¹⁰⁾.

By decomposing the outpatient direct cost, it is observed that the primary cause of its increase was the value of the nurse workforce, which can also be observed on data found in international studies. In one of them, when comparing two compressive therapies for the treatment of venous ulcers, it was noticed that the major cost components were the bandages and the workforce of nurses who were responsible for care. Thus, the average cost was 563 U.S. dollars for the four-layer bandage and 653 U.S. dollars for the short extension bandage⁽⁹⁾.

Another study, which compared treatments with free larvae, "bagged" larvae and CMC gel, noted that the main component of total costs was the clinical consultation by nurses, representing 85%, 77% and 82%, respectively⁽⁸⁾.

The completion of the dressing in the clinic is part of the nursing consultation to patients with tissue damage. During the consultation we collect, initially, the data relating to the identification of patients (gender, age, marital status and place of residence), health history (comorbidities, previous surgeries and risk factors) and socioeconomic conditions. An evaluation of the wound is performed; its characteristics and measurements are recorded through the decal technique and photography in the medical record.

As nursing consultations are the component that most overloads the treatment costs, it must be effective, meeting the real needs of

each individual. Improving the quality of nursing consultation equips patients for a more active role in their treatment, collaborating with the correct performance of the dressing in the household.

It is necessary to promote the view that patients need to receive all the guidance on the care of the wound in the household, in addition to food, lifestyle changes and the information necessary for controlling comorbidities in a clear and appropriate manner, aiming at understanding individuals in terms of their health condition.

Furthermore, it is essential to ensure an individual's access to the materials needed for curatives in the household, since the purchase of these products leads to the commitment of a large portion of the income of patients treated at a public clinic. For this, a plausible strategy is the dispensation of material by the clinic, which can contribute to the minimization of direct patient costs.

CONCLUSION

There is an important difference in treatment costs in outpatient and home environments; therefore, the home treatment is 62.42% less expensive. Thus, strategies to stimulate this type of monitoring, such as enabling the supply of material so that the patient is able to perform the dressing properly at home, should be developed. This would allow the continuation of the treatment, thus reducing costs and promoting the individual's self-care and encouraging better life quality.

It is noteworthy that, although nursing care costs make outpatient treatment more expensive, the benefits of good consultations are essential for patients to understand their health status and collaborate with their

treatment, leading to a faster recovery and a reduced number of visits to the clinic. Therefore it is essential to keep appointments at the clinic, as they allow constant evaluation by nurses who should determine the frequency individually through effective clinical examination.

Dispensing the material to the patient for home use, along with the performance of nursing consultations with the appropriate guidelines, are important elements in the recovery of the health status of these individuals.

Although this study has helped in terms of understanding the pattern of consumption and costs of the materials used in outpatient and home treatments with CMC gel, it was unclear whether the costs are high or not, since a joint analysis of these data is essential for clinical outcomes by means of cost-effectiveness studies.

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