Original Article

Clinical and epidemiological profile of patients with leprosy-related reactions

Perfil clínico e epidemiológico de pacientes em reação hansênica

Perfil clínico y epidemiológico de pacientes con reacción de lepra

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ABSTRACT

Objective: To identify the clinical and epidemiological profile of patients under treatment for leprosy-related reactions.

Method: This is a descriptive, cross-sectional and quantitative study, conducted from October 2013 to April 2014 with 61 individuals in a reference center in the Brazilian northeast region. The statistical test used considered a significance level of 0,05.

Results: Most individuals were males (57.38%), with low family income (50.82%) and incomplete elementary education (75.41%). In the moment of leprosy diagnosis, 52.45% of patients presented some degree of physical disability established. There was significant association between the observed clinic form and the moment of manifestation of leprosy reactions (p= 0.034). The residual analysis indicated that pure neural leprosy is associated to a manifestation of reactions before treatment and dimorphous leprosy was associated to manifestations during treatment.

Conclusion: The disclosure of the clinical picture of pure neural leprosy and early detection of cases strongly contribute to the promotion of population health enabling the fulfillment of the goal of eradicating leprosy.

Keywords: Nursing. Leprosy. Millennium Development Goals. Neglected diseases.

RESUMO

Objetivo: Identificar o perfil clínico e epidemiológico de pacientes em tratamento para reações hansênicas.

Método: Estudo quantitativo, descritivo, transversal, realizado entre outubro de 2013 e abril de 2014, com 61 usuários, em um centro de referência de um estado nordestino. Os testes estatísticos utilizados consideraram um nível de significância de 0,05.

Resultados: Predominou o sexo masculino (57,38%), com baixa renda familiar (50,82%) e ensino fundamental incompleto (75,41%). No diagnóstico, 52,45% já apresentava algum grau de incapacidade física. Houve associações entre a forma clínica e o momento de manifestação das reações (p= 0,034). A análise de resíduos apontou que a forma neural pura associa-se às reações antes do tratamento e a dimorfa associa-se às reações durante o tratamento.

Conclusão: A divulgação do quadro clínico da forma neural pura e a detecção precoce dos casos contribuiriam fortemente para a promoção da saúde da população, possibilitando o cumprimento do objetivo de erradicar a Hanseníase.

Palavras-chave: Enfermagem. Hanseníase. Objetivos de Desenvolvimento do Milênio. Doenças negligenciadas.

RESUMEN

Objetivo: Identificar el perfil clínico y epidemiológico de pacientes en tratamiento para las reacciones leprosas.

Método: Estudio descriptivo, transversal y cuantitativo, efectuado entre octubre de 2013 y abril de 2014, con 61 usuarios en un centro de referencia para la lepra ubicado en la región Nordeste de Brasil. La prueba estadística utilizada considerando un nivel de significación de 0,05.

Resultados: Predominaron las personas del sexo masculino (57,38%), con ingreso familiar de hasta un salario mínimo (50,82%) y enseñanza primaria incompleta (75,41%). En el momento del diagnóstico, 52,45% de los pacientes ya presentaban algún grado de discapacidad física instalada. Había asociaciones entre forma y tiempo de la manifestación de las reacciones (p = 0,034) clínica. El análisis de residuos señaló que la forma neural pura está asociada a una manifestación de reacciones antes del tratamiento y que la forma dimorfa de la lepra estuvo asociada a manifestaciones durante el tratamiento.

Conclusión: La divulgación del cuadro clínico de la forma neuronal pura y la detección temprana de los casos contribuyen fuertemente a la promoción de la salud de la población que permite el cumplimiento de la meta de erradicar la lepra.

Palabras clave: Enfermería. Lepra. Objetivos de Desarrollo del Milenio. Enfermedades desatendidas.

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INTRODUCTION

Leprosy is a chronic disease caused by *Mycobacterium leprae* and has a clinical course depending on the interaction between the host immune response and this pathogen, which predominantly infects the skin and peripheral nerve cells, leading to lesions at these sites[1-2]. The degree of immunity of individuals determines the clinical form of the disease, which can be classified as indeterminate, tuberculoid, borderline, lepromatous or pure neural, with variations between dermatological and neurological damage in each of these classifications[2].

Brazil is the second country in the world in the number of cases of leprosy and has maintained an average of 47000 new cases every year, of which over 20% have some degree of disability established. Thus, leprosy continues to show outstanding numbers compared to neglected diseases, which means this is an important public health problem. However, in recent years, the communicable disease elimination goals are closer to being achieved[3-4].

In the 2000s, the United Nations (UN) established eight Millennium Development Goals (MDGs). From this, 191 heads of State agreed to develop plans and actions that would enable the fulfillment of these goals by the year 2015. Due to high rates of leprosy in many countries and its impact on public health, leprosy is ranked as the sixth MDG: Figuring among HIV/AIDS, malaria and other diseases[5].

With regard to leprosy, seeking to achieve this goal, the Brazilian government launched in 2004 the National Program for the Elimination of Leprosy (PNEH), which established the redirection of the elimination policy and leprosy attention in Brazil. To make the actions of this program viable, in 2006, the Strategic Plan for Leprosy Elimination was created at municipal level 2006-2010, which had as its mission, the assistance of States and Municipalities to achieve the goal of disease prevalence of less than one case per 10,000 inhabitants in 2010[6].

However, in 2010, Brazil still had 1.56 cases per 10,000 inhabitants. Thus, the Ministry of Health remained committed to achieve less than one case per 10,000 inhabitants by 2015, and pointed as a key strategy to achieve this goal the increase of early detection and cure of diagnosed cases, which depends on efforts made by managers and health professionals[7].

Importantly, during the course of leprosy, a significant proportion of patients develop acute inflammatory complications, known as leprosy-related reactions or reaction conditions, which are classified as type 1 and 2 reactions and defined by the host immune response to *Mycobacterium leprae*[8].

The Type 1 reactions are characterized by the appearance of new lesions in the skin, under the form of patches or plates, by the presence of infiltrations, color change and edema in the existing lesions, pain and nerve thickening. The type 2 reactions are the most frequent manifestation, characterized by erythema nodosum leprosum, its main clinical features are the presence of red and painful subcutaneous nodules, fever, joint pains and malaise[9].

Leprosy reactions can be a major complication in these patients and are the leading cause of physical disability and permanent disabilities. They correspond to acute inflammatory episodes that are characterized by deregulation and exacerbation of immune response *to M. leprae*, but so far, there are no predictors laboratory markers of these events[10].

The identification and management of patients with reaction leprosy episodes constitute a challenge[11], and, although it can also prevent the occurrence of reactional condition, the search for the profile of patients affected by this complication may contribute in the early detection of cases, which is important for the prevention of the sequelae and disabilities. This study aimed to identify the clinical and epidemiological profile of patients with leprosy-related reactions in treatment at a referral center, located in the semi-arid northeastern region of Brazil.

It is also important to note that prejudice and decreased quality of life of people with leprosy are accentuated even more with the presence of physical disabilities resulting from reactive conditions, since these factors directly affect the physical, psychological, social and economic conditions of individuals[12].

In this sense, this study use Health Promotion as the theoretical framework due to its basic principle for the transformation of social reality and to meet the needs of individuals using leprosy services and the general population.

METHOD

This is a descriptive and cross-sectional study, with quantitative no experimental approach, developed on the premises of Professor Vingt-Un Clinical Center, a reference center for leprosy in the city of Mossoró, Northeastern Brazil.

To obtain the population, we initially conducted a survey of all existing records in the referred center, reaching the number of 279 records. This number includes active and inactive records, that is, individuals who are undergoing treatment at the time of the study and who are not in treatment, but have their records archived. A screening was also performed to define the number of active records, and we obtained 108 records. A final screening was con-

ducted to know the number of patients affected by leprosy reactions, then, we defined the study population, corresponding to 72 patients. Given the population, the sample, defined by convenience, was calculated by a statistician using a formula for finite samples considering a sampling error of 5% and 95% confidence interval, resulting in a total of 61 individuals.

The inclusion criteria were: patients of any age and gender who were part of the spontaneous demand attended at the referral center for leprosy in Mossoró, northeastern Brazil, and who had leprosy reaction at the time of the study. Exclusion criteria were: patients who were being treated for leprosy but were not affected by the reaction conditions.

Study participants were recruited as follows: as the reference center attends individuals in reactive conditions and also some patients who have only leprosy, when patients were approached in the waiting room, the researcher talked to each one individually, informed them on the implementation of study and asked about which type of treatment were used, if only for leprosy, leprosy reactions or both.

Patients who met the inclusion criteria of the study were informed in more details about it, and subsequently invited to participate. The study was conducted with 61 individuals, as defined in the sample size calculation. We invited 69 individuals to participate, but eight individuals refused to participate.

The Research Ethics Committee (CEP[d]) of the *Universidade do Estado do Rio Grande do Norte* (UERN) on August 12th 2013 approved the study protocol under the CAAE Nº. 08099213.6.0000.5294, and from the Opinion Embodied CEP/UERN Nº. 356765, the data collection was carried out between the months of October 2013 and April 2014 in the reference center, in a closed room in order to ensure the privacy of patients, as recommended by Resolution 466/12[13] of the Brazilian National Health Council.

Data were obtained through an interview, the medical record analysis and physical examination. In the interview, simple questions about clinical, social and epidemiological aspects of the research subjects were asked. Through medical record analysis, we obtained some information about the date of diagnosis, beginning and end of leprosy treatment, the clinical classification of the disease, diagnostic data and early treatment of reactive condition, drugs used, and other information.

For the physical examination, we used a guiding script constructed from instruments validated by the Brazilian Ministry of Health (Form-A from the Primary Care System[14] and the Handbook for Monitoring Leprosy Cases[9]). The degree of patients disability was determined through a neurological assessment, which was guided by the Simplified Form of Neurological Assessment, available in the Handbook for Monitoring Leprosy Cases[9].

Data analysis was performed using SPSS (Statistical Package for Social Sciences), version 22.0. Data were expressed as mean, standard deviation, minimum and maximum values. The statistical test used was chi-square (χ^2), considering a significance level of 0.05 (5%). Among the categories that showed positive associations by Chi-square test, a residual analysis was conducted to identify where these associations were. The residual analysis allows the evaluation of the existence of bias and/or large estimates of errors[15]. The residual analysis values were standardized and adjusted for presenting greater statistical consistency.

This study was extracted from the monograph paper word entitled: "Leprosy- related reactions: a clinical and epidemiological picture", study conducted as prerequisite for the completion of the Nursing undergraduate course from the *Universidade do Estado do Rio Grande do Norte*[16].

RESULTS

Demographic and socioeconomic data

The study revealed that most patients were male (57.38%), declared to be white (52.46%), had between 30-59 years old (68.85%) and 75.41% of the individuals had incomplete primary education.

It was found that 50.82% of patients affected by leprosy-related reaction had family income of up to one minimum wage, 68.86% lived in homes that had up to five rooms, 59.02% lived with four or more people and 42.63% lived in areas of high population density and low economic status, in Santo Antonio (31.15%) and Barrocas (11.48%) neighborhood.

Clinical and epidemiological profile

With regard to the emergence of leprosy-related reactions, we found that 65.57% of the patients studied manifested it during treatment with polychemotherapy (PCT), followed by those who had had treatment before (26.23%) and after the treatment (8.20%).

The clinical classification, which reaction conditions occurred more frequently, were lepromatous (55.74%) and

[d] CEP is the acronym for *Comitê de Ética em Pesquisa* in Portuguese.

borderline (32.79%), followed by clinical classification tuberculoid (6.56%) and pure neural (4.92%), with no manifestation of indeterminate classification. There was a predominance of the reactions in patients classified as multibacillary, corresponding to 91.80% of the study participants.

Assessing the degree of disability presented by patients at the diagnosis moment, at the end of treatment with PCT and during the study, we observed that, during diagnosis, 52.45% of patients presented some degree of physical disability (Grade I: 37.70% and Grade II: 14.75%) and that at the time of the study, 70.49% of patients had some degree of physical disability (Grade I: 44.26% and Grade II: 26.23%). However, there was a lower incidence of physical disability when the assessment was conducted at the end of the treatment, being present in 40.98% of patients (Grade I: 22.95% and Grade II: 18.03%). Whereas 26.23% of patients had not performed the end of treatment assessment, as this had not yet been completed.

Regarding lesions, we found 32.79% of patients with hypopigmented spots or hyperemia in the body and 16.39% showed multiple conditions, being considered as situations where the patient has three or more different types of lesions.

The chi-square test identified significant associations ($p<0.05$) between clinical observed classification and the time of manifestation of leprosy-related reactions ($p=0.034$) and between the clinical classification and lesion type ($p=0.018$). The residual analysis found that pure neural classification was associated with a manifestation before treatment with PCT and that borderline was associated with manifestations during treatment with PCT. Tuberculoid and lepromatous classifications were not associated to any moment of manifestation and reactions to treatment with PCT.

Regarding the association between the clinical presentation and major lesions presented by patients, we observed that the pure neural classification has been associated to mobility problems, foot drop and dry skin and tuberculoid was associated with spots or absence of lesions. Other clinical classifications were not associated with any type of lesion.

DISCUSSION

Similarly to what we stated in this study, other authors have also identified that there is a higher incidence of leprosy-related reactions in males[11]. The prevalence of reactive conditions among men may be associated with a low demand for health services, which is a barrier for the development of prevention and early diagnosis actions.

When analyzing the education level of the sample, it was noticed that 75.41% of the subjects had not finished elementary school and 9.84% were not formally educated, which may have directly influenced the understanding of the orientations introduced by the professionals and performing self-care.

In patients affected by leprosy, self-care actions correspond to exercises and procedures on the nose, eyes, hands and/or feet, where the disease causes a greater nervous impairment, and are designed to prevent the occurrence of physical disabilities or prevent complications when disabilities are already established[9].

Patients who have loss of protective sensitivity in the eyes, hands and/or feet and disabilities should be guided by health professionals to perform specific daily self-care; patients without neural impairment or disabilities, on the other hand, should be alerted to the possibility of such symptoms, being advised to perform daily self-observation and seek the health service to check any neurological changes[9].

In this sense, the orientations regarding self-care are constituted as one of the tools that enable the prevention of disabilities. Thus, when patients have some difficulty in understanding and/or performing it, it is essential for professionals to make appropriate orientations crystal clear to their level of understanding.

Using epidemiological data obtained in the study, we can infer that low socioeconomic conditions are a reality in our sample. Thus, attention to individuals with leprosy and/or reactive conditions should not be restricted to the health sector, requiring an inter-sectoral action involving political, economic and social aspects with a view to promoting the health of the population through the needs supply which focus directly on the health/disease process, which are not considered in the health sector.

Health promotion represents a cross-sectional joint strategy that seeks to act on the factors that affect the health of the population and develop mechanisms or actions that reduce vulnerabilities, defend equity and incorporate the participation and social control in public policy management[17].

In order to offer effective responses to the health needs of patients with leprosy, it is necessary that health teams in primary care and other levels of care are committed to the development of actions to promote health, among which we can mention: the identification of environmental, socioeconomic and cultural factors that affect the health of individuals; developing partnerships with the government and non-governmental institutions or organizations present in the community; helping the healthcare team to develop

strategies that contribute to improving the population quality of life; as well as conducting targeted educational activities for the family and the community in order to empower individuals so they can act on improving their own quality of life and health[9].

Regarding the manifestation of reactive conditions, other authors also found that there was a prevalence of leprosy reactions during treatment with PCT[11]. In this sense, during first doctor visit, practitioners need to alert patients regarding the possible occurrence of these reactions, advising them on how it occurs and what are the complications that can happen, so that through the presentation of a complication, the individual may have clarity of their status of health and will not associate it with polychemotherapy treatment for worsening their clinical condition.

Leprosy patients can also present the reactive condition after high PCT. This is a significant finding, although it happened in just 8.20% of the sample, due to the fact some patients who have reaction after treatment have an increased risk of developing disabilities, so they cease to be followed up by the health service and there are difficulties in recognizing the signs and symptoms of reactive condition, seeking for health service when it is already late[18].

According to data obtained in this study, many patients already had some kind of physical disability at the moment of leprosy diagnosis, which is very serious because it shows that, in the city, the diagnosis has been delayed and that there are still major obstacles for control of the disease and prevention of disabilities.

With regard to leprosy, the main strategies adopted by the Brazilian Ministry of Health to achieve the sixth MDG in Brazil were increasing early detection and cure of diagnosed cases[7]. One study[19] that sought to assess whether the elimination of leprosy, defined as less than 10 new cases per 100000 inhabitants, will be achieved by 2020 in India, Brazil and Indonesia, which together account for over 80% of leprosy cases around the world, has identified that early detection strategies and cure of diagnosed cases is possible in the near future, to reach that goal at the country level. However, in endemic regions, this goal will not be achieved by 2020.

The study also showed that there is a continuous decline in the detection of new cases of the disease in these countries, demonstrating that these control strategies, if applied consistently, reduce disease transmission, thus contributing to their gradual elimination[19].

Thus, increased investment is needed from managers and health professionals in the development of actions that contribute to the early diagnosis and treatment of leprosy, such as conducting an active search for new cases and health education in the community to clarify signs and symptoms of the disease.

In this context, the nurse, among other competencies, is responsible for identifying the signs and symptoms of leprosy, dealing with treatment and monitoring of cases, the prevention and treatment of disabilities and for carrying out health education activities with patients and the community[9], therefore, these professionals are of great importance for control and consequently to achieve the goals of eliminating the disease.

The association between pure neural clinical leprosy and the difficulty of movement and foot drop can be explained by the fact that in this clinical classification there is no presence of skin lesions, there is only nervous impairment. The diagnosis in these cases is hindered or delayed by lack of leprosy knowledge by the healthcare professionals which leads patients to arrive at the moment of diagnosis with some degree of physical disability already installed.

The association between Borderline leprosy and its manifestation during treatment with PCT can be explained by the bactericidal action of treatment that also eliminates the secretion of lipoarabinomanana immunosuppressants (LAM) and glycolipid-phenolic-1 (PGL-1), which given the borderline partial immunity, these reductions of suppressor factors can trigger an imbalance in the response of T-helper-1 cells, leading to hypersensitivity reactions to antigens in tissues and therefore the reaction conditions[20].

CONCLUSION

From this study we found that leprosy reactions occurred more frequently in individuals with low socioeconomic conditions, which strengthened the association between poverty and leprosy and the need to promote an interweaving of actions that will achieve more than one of the millennium goals.

Regarding clinical characteristics, the research showed that the reaction conditions were manifested more frequently during the course of treatment with PCT and that most of the patients had some degree of physical disability established at leprosy diagnosis and during the study, showing to seek health services at an advanced stage of the disease. Neural pure leprosy was associated with reactions manifestations before treatment and Borderline to manifestations during treatment with PCT.

From this, it was possible to infer that the leprosy diagnosis has been done late, considering that many patients

start treatment of leprosy or reactive conditions with some degree of disability established, as well as observed the need for patients are informed about the possible occurrence of reactional states since the beginning of treatment and thus seek the health service after its manifestation.

The goal of eradicating leprosy cannot be achieved without the public be informed about the disease and without a greater commitment to the development of detection and early treatment strategies. Thus, the nurse as health professionals who are directly involved in the identification of signs and symptoms of disease, treatment and monitoring of cases and carrying out educational activities, can contribute significantly to the fight against leprosy, as proposed by the sixth MDG.

There is also the need for nurses and other health professionals to inform people of the pure neural leprosy and its manifestations, as these professionals often, believing that the population is not able to understand the disease, only emphasize the insensitive spots like leprosy symptoms, not informing them about the other symptoms and the clinical conditions that has no skin manifestations. On the reduction of illiteracy and increased education of the Brazilian people in recent years, a change of attitude is possible for professionals to include the person with leprosy in the co-management of their treatment by promoting health, independence and quality of life.

The data also showed that the problem of leprosy and reactive conditions require investments not only in actions that enable early diagnosis, treatment and cure, essential for the elimination of the disease, but also in continuing education to professionals in order to encourage an effective service and monitoring of patients during treatment and after discharge by cure.

We found a relatively small number of leprosy reactions affected individuals treated at the research site, whose municipality is a medium sized city. Also, due to the data sample size this study cannot be generalized.

Similar studies should be carried out in other referral centers and basic health units working with leprosy reactions, since there is little research in Brazil focused on the treatment and management of reactional conditions. These researches would allow us to deepen our knowledge of the clinical and epidemiological profile of these patients in different regions of the country.

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