ISSN: 1676-4285

OBJN Online Brazilian Journal of Nursing
ENGLISH
Federal Fluminense University
AURORA DE AFONSO COSTA NURSING SCHOOL
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Clinical and epidemiological profile of patients using biological therapy in a university polyclinic in Rio de Janeiro: a descriptive study

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ABSTRACT

Objective: to describe the socioeconomic, demographic and clinical conditions of patients on biological therapy in a secondary health care unit in the city of Rio de Janeiro. **Method:** a descriptive, cross-sectional study with a quantitative approach. **Results:** Most patients were female, aged ≥50 years, brown-skinned, married or living with a partner, without children and having concluded high school. 28.75% were declared disabled and had as their main source of income the social security pension from the National Institute of Social Security, amounting between 1 and 2 minimum wages, all of them contributing permanently to the total income of the families they were living with. As for clinical characteristics, 54% reported being followed up at the gastroenterology clinic, 55% of them taking Infleximab and having been on treatment for more than 24 months. **Conclusion:** Based on the knowledge of the characteristics of this clientele, we can provide an organizational support to the provision of care that may have direct influence on the quality of life and well-being of patients and professionals.

Descriptors: Health Profile; Chronic Disorder; Nursing; Biological Therapy; Secondary Healthcare.

Nunes AS, Reis NSP, Barreto CTG, Dias CS, Silva GB, Scherlowski HMLD. Clinical and epidemiological profile of patients using biological therapy in a university polyclinic in Rio de Janeiro: a descriptive study. Online Braz J Nurs [Internet]. 2020 [cited year month day];19(2):e20206136. Available from: https://doi.org/10.17665/1676-4285.20206136

INTRODUCTION

Over the past decades, Brazil has gone through demographic, epidemiological and nutritional transition processes which have led to changes in the population's morbidity and mortality patterns[1]. In this scenario, there is a significant increase in the incidence of chronic non transmissible diseases (NCDs) in view of the gradual reduction in the burden of infectious diseases. Such changes in the patterns of disease occurrence represent a major challenge to health management in the country, given the complexity in the management of these diseases[2].

The management of care in chronic situations has become more important to managers looking for interventions and strategies to reduce costs and hospitalization rates and to fight more capably disease worsening and even death[3]. Coping with these situations requires immediate strategies, articulating care management models with the guidelines established by the strategic action plan[4].

This health care model has been continuously adjusted in Brazil in order to provide comprehensive care to users. A result of this has been the inclusion and expansion of services. In order for such development to succeed, horizontal relations are sought between points of care articulating themselves both for health recovery and for preventive and promotional measures[5].

Based on the chronic condition model (MACC), a reference center in Minas Gerais developed tools for the management of users in a chronic situation. Such tools can be considered innovative, especially due to their focus on the users and their health needs and for including a multi-professional team as an assistance back-end[6].

The treatment of NTCDs, especially when related to the specialized services covered by this study, has gone through progressive improvement over time and has expanded upon the arrival of biological therapies. This whole process has led to the betterment of therapeutic results and of quality of life as well as to a reduction in patient morbidity and mortality[7].

Specialized care aims to provide the population with quality care and in a timely manner[8]. However, what we see is that the actions taken have been largely insufficient. Single Health System (SUS) managers, when considering how important this area is for the provision of comprehensive care, have been investing in training for this level of care[8].

Biological Therapy (BT) is further proof of the importance of qualifying this level of care, aiming at comprehensive and quality care. BT emerged after the use, for years, of medications for treatment of chronic inflammatory and self-immune diseases in patients with frequent disease relapse, particularly relating to diseases in the areas of gastroenterology, pneumology, rheumatology and dermatology[9]. When such relapses take place, the choice is often re-treatment with corticosteroids, which are excellent for inducing remission of disease. Over time, however, this might lead to complications of the same severity as those related to the original disease if not worse[3].

It is noteworthy that the recognition of the sociodemographic, socioeconomic and clinical profile of patients with NTCDs can provide important information for the development

of actions aiming at supporting health care management and increasing the quality of life of patients taking medium and high complexity medication, mostly administered parenterally.

In this context, it is important to have health technologies made available according to each person's unique needs and at different moments in life, aiming at the well-being, safety and autonomy of patients with NTCDs being given care in the field of secondary care.

NTCD surveillance differs from that of transmissible disease as it is not centered on the need for compulsory and immediate notification of suspected cases, but rather uses multi-causal chains of determination. The prevention and health promotion measures are of population scope[2]. That is why building the profile of patients with NTCDs being provided secondary care contributes to building more effective care, prevention and health promotion strategies.

By mapping the population profile, managers are able to identify critical points of care and propose actions aligned with the demands of this population group, thus contributing to improving quality of care.

Given the above, the present study aimed to describe the socioeconomic, demographic and clinical conditions of patients using biological therapy in a secondary health care unit in the city of Rio de Janeiro.

METHOD

Descriptive, cross-sectional study with a quantitative approach, profiling patients on biological therapy from July to December 2016. Research was carried out at the biological therapy infusion laboratory of a secondary health care unit in the city of Rio de Janeiro. Authors of study created a form with questions of interest and a pre-test was performed with a sample of 10 patients in order to evaluate to what extent questions could be difficult to understand or ambiguous.

The final form was filled out by a project grantee interviewer who is also co-author of this article and was based on answers given by participants who filled out previous forms manually or who were interviewed either face-to-face or through phone calls lasting 10 minutes.

The target audience was of 101 patients meeting the following inclusion criteria: over 18 of age; bearing conditions justifying the use of biological therapy; being followed-up in the specialties of rheumatology, gastroenterology, allergy and pneumology; having undergone treatment for at least six months at the Biological Therapy Unit (BTU) of the Piquet Carneiro Polyclinic; having taken at least 4 infusions at the BTU. The exclusion criteria were as follows: loss of follow-up due to discharge or transfer within a period of six months.

A total number of 80 patients was interviewed, with a loss rate of 20.0%. All losses were due to patients not attending the infusion center during this period and not being able to be contacted by phone to clarify this non-attendance. All participants agreed to be part of the research, signing the Informed Consent Form. It is noteworthy that the ethical aspects related to resolution 466/2012[10] were obeyed and that the study was analyzed and approved by the Research Ethics Committee of the State University of Rio de Janeiro which, on this matter, issued the Certificate of

Ethical Evaluation # 70596017.0.0000.5282 and the opinion # 2,250,579.

RESULTS

The collected data were tabulated in a database created using the Version 7.0 of the Epi info 7.0 program. The simple and relative frequencies of the variables of interest were calculated and can be seen on the tables below.

As for sociodemographic characteristics, the majority was female (68.75%) and declared themselves to be brown-skinned (40%). More than half of the patients (62.50%) were over 40 years of age and 18.75% had completed primary education. Almost half of patients (48.75%) declared themselves to be married or to live with a partner; however, approximately one third had no children (Table 1).

Table 2 shows the socioeconomic characteristics of patients on treatment at the biological therapy unit. It stands out how almost 30% of them declare to be disabled. Coming next, we have 21.25% of workers with a formal work contract, around 20% of self-employed workers or workers without a formal contract, nearly 19% of unemployed workers and 10% of retired workers, whereas one patient reported another type of professional situation.

Most patients (38.75%) declared having the pension received from the National Social Security Institute as their main source of income.

Almost half the population (41.25%) lives on a family income of up to 2 minimum wages and the majority (76.25%) contributes regularly to the family income, 50% of them having their own as the main income in the family (Table 2).

Most patients live with their families (88.75%) and 9 (11.25%) live on their own. However, 4 (5.00%) reported not having a family reference, even when living with family members at home (3 patients).

Although the study was carried out in a public university health unit, 25 (38.25%) patients reported having some type of private health insurance.

By observing Table 3, one can see, in relation to the clinical characteristics, that more than half of the patients have gastroenterology (54%) as their outpatient clinic of origin. The most widely used medication is Infleximab (55%) and 60% of patients have been on treatment for more than 24 months. Regarding how the medication is transported, all of them make use of a dedicated thermal bag. As for storage, only one patient stores his medication in the freezer, whereas the others do it in the refrigerator, with 61 (81.34%) storing its shelf, 7 (9.34%) on the door and 6 (8.00%) in the drawer for vegetables (data not tabulated).

DISCUSSION

Patients were mostly women aged ≥50 years, and the results resembled those of a study by the Ministry of Health[11] making evident that in all regions of Brazil there is a higher prevalence of women with chronic diseases than of men. This data is in line with data from a study carried out in Portugal[12] making clear and quite prominent that women are more susceptible to self-immune diseases. According to this study, 78% of self-immune disease cases affect women and have their onset at reproductive age. Hormonal changes like the ones observed during pregnancy and

Table 1 - Sociodemographic characterization of patients seen for infusion of biological therapy in a Polyclinic in the city of Rio de Janeiro from July to December 2016. Rio de Janeiro, RJ, Brazil, 2016 (n = 80)

SOCIODEMOGRAPHIC CHARACTERIZATION OF PATIENTS SEEN FOR BIOLOGICAL THERAPY INFUSION		
VARIABLES	**PATIENTS SEEN**	
	N	**(%)**
GENDER		
FEMALE	55	68,75
MALE	25	32,25
AGE BRACKET		
15-20 YEARS	07	8,75
21-30 YEARS	11	13,75
31-40 YEARS	12	15,00
41-50 YEARS	19	23,75
>50 YEARS	31	38,75
RACE/ETHNICITY		
WHITE	31	38,75
BLACK	17	21,25
BROWN	32	40,00
LEVEL OF SCHOOLING		
INCOMPLETE B.E.	06	7,50
COMPLETE B.E	09	11,25
INCOMPLETE S.E	07	8,75
COMPLETE S.E	32	40,00
INCOMPLETE H.E	10	12,50
COMPLETE H.E	14	17,50
NONE	02	2,50
MARITAL STATUS		
BACHELOR/BACHELORETTE	30	37,50
MARRIED/LIVING WITH A PARTNER	39	48,75
DIVORCED	07	8,75
WIDOWER/WIDOW	04	5,00
NUMBER OF CHILDREN		
WITHOUT CHILDREN	27	33,75
01	22	27,50
02	13	16,25
03	14	17,50
04	03	3,75
MORE THAN 05	01	1,25
TOTAL	80	100

Source: Prepared by the authors, 2016.

Table 2 - Socioeconomic Characteristics of patients being provided biological therapy infusion at a Polyclinic in the municipality of Rio de Janeiro in the period from July to December 2016. Rio de Janeiro, RJ, Brazil, 2016 (n=80)

SOCIOECONOMIC PROFILE OF PATIENTS BEING PROVIDED CARE FOR BIOLOGICAL THERAPY INFUSION		
VARIABLES	**PATIENTS SEEN**	
	N	**(%)**
PROFESSIONAL SITUATION		
RETIRED/PENSIONER	08	10,00
SELF-EMPLOYED	10	12,50
UNEMPLOYED	15	18,75
DISABLED	23	28,75
FORMAL WORK CONTRACT	17	21,25
NO WORK CONTRACT	06	7,50
OTHER	01	1,25
FAMILY INCOME (IN MINIMUM WAGES)		
LESS THAN 1	04	5,00
1-2	29	36,25
2-3	23	28,75
3-5	09	11,25
5-10	06	7,50
10-20	02	2,50
ABOVE 20	01	1,25
COULD NOT INFORM	06	7,50
MAIN SOURCE OF INCOME		
REGULAR EMPLOYMENT	21	26,25
SELF-EMPLOYED	11	13,75
PENSIONER	31	38,75
NO INCOME	17	21,25
MAIN INCOME IN THE FAMILY IS HIS/HERS		
YES	40	50,00
NO	40	50,00
FINANCIALLY CONTRIBUTES TO FAMILY INCOME		
YES-PERMANENTLY	61	76,25
YES-NOW AND THEN	08	10,00
NO	11	13,75
Nº OF PEOPLE DEPENDING ON PATIENT'S INCOME		
ONE	09	11,25
TWO	23	28,75
THREE	31	38,75
FOUR	10	12,50
FIVE	06	7,50
MORE THAN SIX	01	1,25
HEALTH INSURANCE PLAN		
YES	25	31,25
NO	55	68,75
TOTAL	80	100

Source: Prepared by the authors, 2016.

Table 3 - Clinical characteristics of patients seen for biological infusion therapy at a Polyclinic in the municipality of Rio de Janeiro in the period between July and December 2016. Rio de Janeiro, RJ, Brazil, 2016 (n=80)

CLINICAL CHARACTERISTICS OF PATIENTS SEEN FOR BIOLOGICAL THERAPY INFUSION		
VARIABLES	**PATIENTS SEEN**	
	N	**(%)**
OUTPATIENT HOSPITAL FOLLOW-UPO		
ALERGY	06	7,50
GASTROENTEROLOGY	43	54,00
PNEUMOLOGY	09	11,00
RHEUMATOLOGY	22	27,50
MEDICATION		
TOCILIZUMABE	10	12,50
INFLEXIMABE	44	55,00
IGH	04	5,00
XOLAIR	06	7,50
ALFA 1	06	7,50
ABATACEPT	09	11,25
HUMIRA	01	1,25
BEGINNING OF TREATMENT		
<6 MONTHS	07	8,75
06-11 MONTHS	07	8,75
12-24 MONTHS	18	22,50
>24 MONTHS	48	60,00
TOTAL	80	100

Source: Prepared by the authors, 2016.

menopause are inductors of clinical changes affecting women with such kinds of pathology, leading to either clinical improvement or worsening.

Likewise, a study carried out in Ribeirão Preto[13] into the search for health services observed that women sought health services 1.9 times more than men and that this can facilitate making an early diagnosis of a possible chronic disease.

Regarding the age group ≥50 years, the ELSA-Brazil multicenter cohort study presented a profile very close to that of the participants in this study when addressing NTCDs in Brazil. Its age bracket ranged between 45 and 64 years (67.3%), already displaying a 10% amount of participants ranging from 65 to 74 years of age[14].

Despite being in a productive age, the negative impact of chronic diseases is made evident when we observe that most of the population is described as disabled. A high percentage of early retirements may explain how low income is predominant among this population, given how the pensions received are of low amount[15].

The difficulties faced by chronic patients can range from the shock caused by the diagnosis, a disease with no cure, to beginning treatment and noticing the side effects that come along. In one way or another, these patients undergo several moments of disruption in

their lives, caused both by physical discomfort and by considerable changes in their daily routine, something that demonstrates the importance of providing social support and to have it linked to a support network as a means to increase the adherence to treatment and provide a more positive perspective regarding the future and the difficulties resulting from a chronic disease[16].

This way, there is no doubt that the health care provided to chronic patients requires implementing more effective guidelines and redesigning processes and systems to offer actions and services. Referral of patients to specialized care is a key component to the health system's function and we are aware of the need to improve it in the Brazilian public system[17].

Most patients are followed up at the Gastroenterology outpatient clinic, suggesting that those are majorly cases of chronic inflammatory bowel disease (IBD) with a prevalence of Crohn's disease and ulcerative colitis in their chronic form and with frequent relapses as they evolve. IBDs take on severe clinical forms and can largely compromise quality of life, leading to absenteeism from work, high treatment costs and frequent hospitalizations[18].

The use of Infleximab for a period> 24 months is justified when we observe how IBDs are characterized by different periods of relapse, sometimes requiring ever more treatment through the infusion of immunobiological agents, given that the conventional immunosuppressive treatment might have failed by then and there is a need to start the infusion of immunobiological medication such as the anti-necrosis factor monoclonal antibody known as Infleximab[19; 20].

It is recommended that these medications be stored at 2 to 8º C. At home, they should be stored in the refrigerator in a plastic bag to prevent the packaging from getting wet and should be put on the shelf without touching the bottom. It is not recommended to place them on the refrigerator door due to a larger possibility of temperature changes, neither should the freezer or freezing compartment be used as this might lead to having to discard the medication in case it freezes[21].

As for transportation to the residence, it is recommended to carry it in a thermally insulated bag (styrofoam box or thermal bag with an ice pack), capable of keeping the temperature cool throughout the journey[21].

The nurse plays a strategic role in this scenario as a care coordinator helping the patient to understand the importance of correctly storing and transporting the high-cost medications administered, in addition to the role in preventing and making an early identification of adverse reactions and of the need for a long-term continuous treatment.

CONCLUSION

By identifying the profile of patients, the study may contribute to a better integrated management of the care provided by nurses. Given that the levels of income and education of the population encompassed are low, this may hinder the understanding of disease and treatment. The knowledge of the characteristics of this clientele allows having an organizational support for providing care which will have a direct influence over the quality of life and the fulfillment of both patients and professionals.

That said, the findings of this study will help us update care practices of the multiprofessional team in what relates to chronic disease and its usually difficult management. This may have an influence on the safety of the medicine most commonly provided, improving the quality of clinical knowledge and practice, with a large potential to improve the evolution and prognosis of the disease, besides changing significantly the quality of life of patients.

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Received: 07/18/2018

Revised: 01/25/2020

Approved: 02/23/2020