EDITORIAL

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Clinical Trial IBD Unit: The Role of the Study Nurse in Conduction of Trials and Patients' Care

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The incidence of inflammatory bowel diseases (IBD), multifactorial chronic diseases, has been increasing worldwide in the last decades [1]. Crohn's disease and ulcerative colitis are the main diseases of this group. These are characterized by chronic or recurrent ailments, focal symptoms can be diarrhea, abdominal pain, rectal bleeding, weight loss tied to malabsorption as well as extraintestinal manifestation frequently presenting as joint pain, skin, and eye problems [2].

Inflammatory bowel diseases constitutes a challenge for hospitals and the health care system because the management of these diseases is, by default, multidisciplinary. Taking charge of these patients demands all-round approaches with high-quality care not only in regards to drugs and surgeries that require medical and surgical competencies that are highly specialized but even other health care professionals such as dietitians, psychologists, rheumatologists, dermatologists, and, especially, nurses [3]. In the management of these chronic diseases, patients are in need during their lifetime and their course of treatment, of a figure that facilitates access to care, depending on the needs and urgency of the moment, that can allow space and time for the educational moments and that is a fixed point of references easily reachable.

In tertiary IBD centers with a high number of patients, this role is often played by nurses highly specialized with a specific education in IBD and who are responsible for the clinical-care path of these patients and are, therefore, their main point of reference: care managers [4] and clinical trial nurses or study nurses. Care managers know in depth the personal needs of patients and support the medical personnel in choosing the appropriate and personalized course of treatment. They work closely with the study nurses who have a deep understanding of clinical research so these roles are particularly important in those centers that offer experimental drugs and research options and in which the therapeutic opportunities are surely multiplied as well as the complexity of the offer and, sometimes, the access to care.

In the last decades, the research on IBD had an explosive development and in just a few years the range of options have widened and today it counts several molecules with different mechanisms of action. Multiple programs of research, of which many are still ongoing, support the development of new therapies. These programs aim to evaluate the efficacy and safety of new drugs for IBD: sponsored clinical trials. Access to an experimental drug is often a unique opportunity of care for patients who have no other options in standard care drugs. Access to a clinical trial can be a strategy choice to broaden the therapy options for those patients who, in standard care, have not been able to find a therapy that reflects their demand in terms of efficacy, safety or administration comfort. The access to these therapies though, is limited to strict inclusion and exclusion criteria, and sometimes the complexity of study designs, study procedures that require multiple close-range visits, and the need for compliance with the recording of diaries data can be limiting for the patients [5]. Furthermore, the presence of the placebo [6] as a control arm and the double-blind design of the trial (meaning neither the physician nor the patient is aware of the treatment in which the patient is randomized) can be scary for the patients and can result in the patient giving up on a care path that could be convenient for them. In this scenario, it is fundamental that experimental drugs are proposed relying on the profile of the individual that is being considered and to make them an integral part of a personalized path of care designed by the treating gastroenterologist, the care managers, and the study nurse. Moreover, the patients need to be guided and

accompanied in the trial, to not feel abandoned in the transition from standard care to research where they will be meeting a new medical and nursing staff. Even in clinical trials, nurses still are key figures for patients, to ensure therapy adherence and, ultimately, for the success of their care.

As previously stated, IBD chronic and floating trends give ample chances to research since standard care can fail or patients can go through reactivation of the disease where a new therapy has to be considered.

Research gives these patients the option to take medications years in advance to the health care system and can give hope towards clinical remission to prevent surgical therapies that are irreversible.

Even from an economic point of view, research gives strong benefits as all the activities required in sponsored clinical trials are paid for by the pharmaceutical company that promotes the new molecule, formulation, or administration route [7].

For these reasons, many IBD centers are taking on the task of managing clinical trials to offer more therapeutical options to patients. To have an organized organigram should be central to the course and conduction of experimentation safely and transparently.

The majority of studies that need the application of new techniques or the administration of new drugs require the application of nursing skills that ensure the involved patients receive quality care.

Some of the activities required could be defined as "basic skills"; these involve the execution of blood sampling as well as taking urinary, fecal, or bioptical samples which are activities that nurses acquire during university as well as preparation and administration of drugs and the delivery of health education to patients and caregiver based on guidelines.

Though, the nurses involved in clinical research, study nurses, acquire advanced skills. The role implies a deep understanding of the IBD unit in which the nurse works and the skill to conduct all ambulatorial activities knowing all commercialized drugs, their mechanism of action, modalities, doses, and timing of administration [8].

Study nurses are capable of dissecting a clinical protocol to identify the activities that are within their competencies and can examine them in depth to carry them out as per the protocol's strict indications [9].

Often, the requirements of the protocol to take biological samples are enriched with specific information regarding the timing of collection, before or after the administration of the study drug, or regarding the location of the biopsies during endoscopy for IBD patients.

Study nurses need specific skills especially when working with specific diseases such as IBD, the detailed study of the key aspects of these pathologies is fundamental for the role. The knowledge of the endoscopic scores, the evaluation scales of the disease, and of questionnaire on health and wellness perceived by patients are crucial to the correct conduct of the protocol.

Moreover, regarding the drugs to be administered, these are often new molecules or formulations never applied to the IBD population and require an in-depth study of the modalities of preparation, administration, and possible adverse events drug-related. For transparency of results, the nurse is often asked to work as part of the blind team. This means administering therapies that are prepared by a third unblind party and not knowing what the formulation administered contains. On the other side of the coin, the nurse involved in the unblind team that has access to specific information on the preparation of the drug compiles specific modules with information about conservation, and preparation and, sometimes, when randomization requires, gives to the nurse in the blind group a placebo solution.

It is important to underline and understand that study nurses are demanded to participate and manage autonomously activities such as: coordination of follow-up visits, request of specialized consultation as per protocol, participation in endoscopic activities in the endoscopy room as a second operator, and are involved in the recruitment of new patients and are present to combined visits with the gastroenterologist.

Study nurses must be an integral part of the multidisciplinary team as their presence is becoming more and more necessary.

Study nurses take charge of the patient, and collaborate with the physician (principal investigator or, more often, sub-investigator) so that the patient can access to active protocol of the center. This role is the bridge between physician and patients, sub-investigator and study coordinator, between the site research team and the clinical research organizations (CRO) that are involved in the verification of the correct conduct of the research activities.

With the patient, study nurses create an empathic bond trying to allow space for harmony and offering support as well as be advocates for the patient's health rights.

Activities of collaboration with the study coordinator are fundamental since the study nurses take charge of the patient and are required to verify with the study coordinator that the data collected during experimentation are accurate and correctly added in the case report forms (CRF) [10]. The study nurses can answer the request of the clinical research associate (CRA), this often requires coordinating the patient's activities observing the protocol's requests, being able to understand and resolve issues caused by devices used and given by the sponsor as well as taking into the account the specific window allowed for the visits and the need to organize possible repeat of exams and inspection because of not available tests.

Study nurses have the responsibility of taking care of the helpline email, answering autonomously to issues regarding protocol timing, and appointments or giving specific information regarding visits, preparation for examinations, or activating the sub-investigators for medical needs [11].

The constant collaboration with IBD nurses, care managers, and physicians of the IBD unit are key points for the individuation of potential patients that could be included in the active protocols of the site.

The study nurse's role in the IBD research center is fundamental and inescapable to deliver quality care, to answer chronic patients' needs, and to manage the complex flow of information that derives from different figures both internal and external to the hospital.

The clarification and legal identification of this role would benefit not only the nurses who would finally feel acknowledged for their role with a job description both accurate and defined, but even the hospital would benefit economically and in reputation by the presence of a competent, autonomous, capable and recognized professionals able to better the public health care [12].

Conflicts of interest: None to declare.

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