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Original article

What's New in Rectal Cancer Research?☆



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ABSTRACT

Introduction: Clinical evidence has a more significant role in medical specialties than in surgery. Rectal cancer (CR) is no exception. This paper explores what CR-related subjects are being investigated at the present time in a quantitative and qualitative way and analyses this information to know what possible answers clinical research could give us in the future.

Methods: The data collection was carried out in April 2014 and was based on 3 sources: 2 institutional clinical trials registries – American (clinicaltrials.gov) and European (EU Clinical Trials Register) – and a survey given to members of the Asociación Española de Coloproctología (AECOP). The obtained studies were exported to a database designed especially for this review, which included a number of descriptive elements that would allow the cataloguing of the different studies. The AECOP survey results were analysed separately.

Results: There are currently 216 clinical trials ongoing related to CR. Two-thirds are primarily conducted by oncologists. Nearly a third are surgical. The research focuses on improving preoperative treatment: new drugs, new schemes of chemo-radiotherapy (usually induction or consolidation schemes), or optimisation of radiotherapy and its effects. Surgical clinical trials are related to robotics, laparoscopy, stoma, low colorectal anastomosis, distal CR, and local treatment.

Conclusion: Most of the current clinical trials ongoing on CR are analysing aspects of chemo-radiotherapy and its effects. A third focus on purely surgical issues.

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¿Qué se investiga en cáncer de recto?

RESUMEN

Introducción: La evidencia clínica tiene más peso en las especialidades médicas que en las quirúrgicas. El cáncer de recto (CR) no es una excepción. En este artículo, nos hemos planteado explorar de forma cuantitativa y cualitativa, qué cuestiones y materias relacionadas con el CR están siendo investigadas en el momento actual y, posteriormente, analizar

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esta información para conocer qué respuestas podrá darnos la investigación clínica en el futuro.

Métodos: La obtención de datos se realizó en abril de 2014 y se basó en 3 fuentes: 2 registros institucionales de ensayos clínicos, –el registro americano (clinicaltrials.gov) y el registro europeo (EU Clinical Trials Register)– y una encuesta realizada a través de la Asociación Española de Coloproctología (AECOP). Los estudios obtenidos fueron exportados a una base de datos diseñada especialmente para esta revisión, en la que se incluyeron además una serie de elementos descriptivos que permitieran la catalogación de los estudios. Los resultados de la encuesta AECOP fueron analizados de forma separada.

Resultados: Hay actualmente en marcha 216 estudios referidos al CR. Dos tercios son fundamentalmente oncológicos. Casi un tercio son quirúrgicos. Las líneas de investigación se centran en la mejora del tratamiento preoperatorio: nuevos fármacos, nuevos esquemas de quimiorradioterapia (generalmente de inducción o consolidación) u optimización de la radioterapia y sus efectos. Los ensayos clínicos quirúrgicos estudian aspectos relacionados con robótica, laparoscopia, estomas, anastomosis bajas, CR distal y tratamiento local.

Conclusiones: La mayoría de los estudios actuales sobre CR analizan aspectos relacionados con la quimiorradioterapia y sus efectos. Un tercio se centran en temas especialmente quirúrgicos.

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Introduction

There is a perception that clinical studies do not represent a relevant role in surgery, and the surgeon does not represent a relevant role in the design of clinical studies.¹ Such perception can fit reality only if we take into account the percentage of the surgical clinical practice that is based on clinical trials, especially if we focus on randomised and controlled trials (RCT). Howes et al.² considered that, in surgical departments, only 24% of the medical procedures in admitted patients were supported by RCT, while this percentage increased up to 53% in the case of general medicine. Therefore, it is unquestionable that, from a strictly *quantitative* point of view, the clinical evidence is stronger in medical specialities than in surgical specialities. However, this fact should not be surprising, since there are some obstacles inherent to the surgical practice that hamper the performance of methodologically correct RCTs, especially if we analyse surgical techniques. The difficulty in the randomisation of patients, the variability in the surgical practice (particularly regarding new techniques and the learning curve), the assessment of surgical treatments against non-surgical treatments, and the difficulties to design trials, among other factors, make it especially hard for surgeons to pose methodologically flawless clinical studies.³

Rectal cancer (RC) is not an exception to these considerations. Until the decade of 1970s of the last century, RC treatment was not included in clinical studies. In the decade of 1980s and, mainly, 1990s, RC treatment started to provide a stronger scientific framework,^{1,4} with the development of adjuvant/neoadjuvant treatment and a standardised surgical technique, such as total mesorectal excision (TME). In more recent times, with the development of the laparoscopic approach⁵ and better technical options for local treatment, surgeons have gained a more active participation in the design and development of RCTs related to RC.

This article has 2 objectives: first of all, to quantitatively and qualitatively explore which facts and subjects related to RC are *currently* being investigated; and secondly, to analyse and compress this in principle heterogeneous information in order to know, based on evidence, which answers can be brought by clinical investigation in the more or less near future.

Materials and Methods

The data collection was carried out in April 2014, and was based on 3 sources: 2 institutional registries of clinical trials—the American registry (NCT)⁶ and the European registry (EUDRACT)⁷—and a survey designed by the Spanish Association of Coloproctology (Asociación Española de Coloproctología, AECOP) with which we attempted to perform an assessment of our closest environment.

The NCT registry includes world-wide studies. At the moment of the search, 51% out of the total amount of registered studies were outside U.S.A., 43% were only American studies, and 6% included other countries. The search was performed with the words “rectal neoplasm”, and afterwards the box “include only open studies” was clicked. The obtained studies were exported to a Microsoft Office Excel[®] 2003 page and, from there, to a FileMaker pro[®] 6 database, specially designed for this revision, in which, besides the fields referred to the exported data, a series of descriptive elements (Table 1) were included. Such descriptive elements allowed the classification of various studies, as well as the exclusion of those that were not specifically referred to RC.

The EUDRACT registry includes studies of the whole European continent. The search was also performed with the words “rectal neoplasm”, and the box “only open studies” was checked. In EUDRACT, there are studies already registered

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