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REVIEW ARTICLE

## The Rectal Cancer Project of the Spanish Association of Surgeons



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### KEYWORDS

Rectal cancer;  
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**Abstract** The Spanish Rectal Cancer Project was established in 2006, inspired by the Norwegian Rectal Cancer Project. It consisted of an educational project aiming to introduce mesorectal excision surgery to surgeons, pathologists and radiologists to establish a network of the Spanish National Health Service in Spain.

**Methods:** All hospitals covering a population area of at least 300,000 inhabitants and operating on more than 12 patients per year were invited to participate. The project was carried out similarly to the Norwegian one. Several “hands on” workshops were arranged yearly between 2006 and 2012. A central registry measured the effectiveness of the project with feedback to participating institutions of their own results compared with the national average.

**Results:** The National Health System consists of 261 hospitals of which 103 were included in the project. Of these 23 were excluded due to non-compliance with data registration. Therefore, the analysis included results from 80 hospitals covering a geographical area with 19,329,992 inhabitants. From 2006 to 2015 a total of 14,815 patients had a curative resection. The postoperative mortality rate was 1.8%; postoperative complications were observed in 39.9% patients; 10% developed anastomotic leakage and 9% required reoperation. The outcomes observed in 3088 cancer patients who have completed a five-year follow-up were: 6.2% local recurrence, metastasis 18.8% and 73.5% overall survival.

**Conclusions:** This project shows that the results obtained in Scandinavia have been reproduced in a larger population in Spain applying a similar methodology focused on the spread of competence and auditing of results.

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**PALABRAS CLAVE**

Cáncer de recto;  
Base de datos  
multicéntrica;  
Docencia

**El Proyecto de cáncer de recto de la Asociación Española de Cirujanos**

**Resumen** La Asociación Española de Cirujanos inició en 2006 una iniciativa docente inspirada en el Norwegian Rectal Cancer Project con el objetivo de introducir la escisión del mesorrecto a: cirujanos, patólogos y radiólogos y constituir una red de hospitales para tratar el cáncer de recto en el Sistema Nacional de Salud Español.

**Métodos:** Todos los hospitales que cubrían una población de 300,000 o más habitantes y que realizaran, como mínimo, 12 resecciones de recto al año fueron invitados a participar. El proyecto, que imitó al noruego, consistió en cursos teórico-prácticos anuales entre los años 2006 y 2012. Para evaluar la eficacia del proyecto se creó un registro centralizado que enviaba a cada hospital sus resultados comparados con las tasas nacionales.

**Resultados:** El Sistema Nacional de Salud consta de 261 hospitales de los cuales 103 fueron incluidos en el proyecto. De ellos, 23 han dejado de participar por incumplimiento en el envío de datos. Por tanto, el análisis incluye los resultados de los 80 hospitales que atienden a una población de 19.329,992 habitantes. Entre 2006 y 2015, 14,815 pacientes fueron tratados con una resección del recto curativa. La tasa de efectos adversos han sido: mortalidad operatoria: 1.8%; complicaciones postoperatorias: 39.9%; dehiscencia anastomótica: 10%; y necesidad de una reintervención: 9.0%. Los resultados oncológicos observados en 3088 pacientes que han completado un seguimiento de cinco años han sido: recidiva local 6.2%, metástasis en el seguimiento 18.8% y supervivencia general 73.5%.

**Conclusiones:** Este proyecto muestra que los resultados conseguidos en Escandinavia se han alcanzado en España aplicando una metodología centrada en difundir el procedimiento y auditar los resultados.

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**Historical background**

Before the 1990s local recurrence rate of rectal cancer was offensively high in many countries, and percentages of 20–45% are found in the literature.<sup>1–3</sup> The poor results after radical surgery for rectal cancer, to a great extent caused by the detrimental effect of local recurrence, was regarded as an irrefutable fact. As a consequence professional bodies advocated adjuvant radiotherapy and adjuvant chemoradiotherapy as a standard treatment.<sup>4–5</sup>

However, in 1986 Heald and Ryall<sup>6</sup> reported a 4 per cent local recurrence rate using total mesorectal excision (TME) without adjuvant treatment. This result was held to be a consequence of optimized surgical technique and performance, emphasizing a meticulous dissection in the anatomical plane surrounding the mesorectal fascia, which is the landmark of total mesorectal excision. This technique ensures that the main pathway of cancer spread (i.e. the mesorectum) is dissected out, removing the lymph nodes in the drainage area of the rectum.

Even though other institutions published similar results,<sup>7</sup> the usefulness of this technique was not considered proven until the Norwegian Rectal Cancer Project published its results in 2002.<sup>8</sup> This project aimed to improve rectal cancer care because Norwegian professional bodies considered the national results inadequate. They examined the outcome of rectal cancer surgery during implementation of TME on all the hospitals of Norway performing rectal cancer surgery. It was found that the risk of local recurrence decreased by a half (i.e. from 12% to 6%) using TME compared to conventional surgery. Furthermore, the marked

reduction of local recurrence was followed by a substantial increase of overall survival from 55% to 67%. As neither adjuvant nor neoadjuvant treatments were used, the improved oncologic outcomes could only be attributed to surgery. Furthermore, this project showed that this technique could be implemented nationwide.

The results of the Norwegian Rectal Cancer Project, that achieved national rates of local recurrence and survival comparable to many centres of excellence in the world, have been confirmed in other studies in Scandinavia,<sup>9,10</sup> the Netherlands,<sup>11</sup> and Great Britain.<sup>12</sup>

At the same time a national survey promoted by the Spanish Society of Surgeons (AEC) showed that total mesorectal excision was not routinely used in Spain.<sup>13</sup> Moreover, the Ministry of Health<sup>14</sup> commissioned the AEC a study on the outcomes of surgery for rectal cancer in Spain. The study concluded that the results were unknown.

Based on this amount of information the AEC decided in 2004 that TME should be recommended as the preferred technique for rectal resections. In 2006 the Spanish Society of Surgeons launched a project inspired by the Norwegian Rectal Cancer Project.<sup>8</sup> This initiative aimed to introduce total mesorectal excision (TME) to multidisciplinary teams of surgeons, pathologists, and radiologists to establish a network of hospitals in the National Health Service in Spain. The project was carried out similarly to the Norwegian one applying a similar methodology focused on the spread of competence and auditing of results. In the absence of previous data in Spain, in order to see if the results achieved by the MDTs with this initiative were adequate, it was decided to compare Spanish results with those achieved in

the Scandinavian countries, considering these as the gold standard.

## Organization

### Education and training

Training for the Multidisciplinary Teams (MDTs) of surgeons, pathologists and radiologists was organized on a yearly basis. All hospitals in Spain covering a population area of at least 300,000 inhabitants and operating on more than 12 patients per year were invited to participate.<sup>15</sup>

The project was carried out similarly to the Norwegian one where training of surgeons in TME principles was organized; several workshops based on live demonstrations and 'master classes' were arranged in four different health regions of Spain. The condition required to participate in the project was that the hospital have specialists with interest and dedication to rectal cancer (i.e. including surgeons, pathologist, radiologists and oncologists). Every year a limited number of hospitals were admitted to these courses. In addition, hospitals that wanted to repeat the course were readmitted to the next events.

Surgeons with dedication to coloproctology were taught the TME principles; pathologists were trained in the standardized handling and reporting of the specimen according to Quirke's principles,<sup>16</sup> with special emphasis on the importance of the circumferential resection margin and quality of the mesorectum; radiologists were trained in a standardized technique and reporting of the images of magnetic resonance.<sup>17</sup> The pro forma for colorectal cancer resections of the Royal College of Pathologists of the United Kingdom was used.

### Data registration

A centralised registry and a specific rectal cancer database was created and maintained by the Spanish Society of Surgeons. The staff of the project includes one director, one data manager and a part-time statistician. The annual budget of the register (50,737€/year) is financed by the participating hospitals using research grants. The director receives no money.

The registry includes all patients operated on for rectal cancer in the participating centres. Non-resectional operations (stoma, bypass or exploratory laparotomy), local excision and rectal resection, including subtotal or total proctocolectomy, anterior resection, abdominoperineal resection, pelvic exenteration and Hartmann's procedure, were registered.<sup>18</sup>

Each participating hospital designated a surgeon responsible for data registration and reporting. The registered data include patient characteristics, type of surgery, postoperative morbidity and mortality, details of adjuvant treatment and follow-up data on LR, metastasis and death. The Spanish Death Registry provided information on time of death. Consequently, survival data are given as overall survival.

On a yearly basis, every participating hospital received a report of its results compared with the Rectal Cancer Project average.

## Definitions and standards

**Rectal tumour:** Tumours at or below 15 cm from the anal verge, measured by rigid rectoscopy during withdrawal. Low rectal cancer was defined as a tumour 6 cm or less from the anal verge measured by magnetic resonance imaging (MRI).

**Postoperative mortality:** a death within the first 30 days of surgery, or in-hospital death irrespective of the time elapsed after surgery.

**Anastomotic leakage:** an event involving the anastomosis that required a postoperative interventional radiology procedure or surgical intervention, including pelvic abscesses without radiologic evidence of dehiscence and early rectovaginal fistulas. Subclinical leaks detected on water-soluble enemas before stoma reversal were not considered as leakages.

**Intraoperative tumour perforation:** any surgically induced defect in the rectal lumen.

**Postoperative overall morbidity rate including:** surgical-site infection, perineal wound problems, respiratory and heart complications.

The CRM was considered involved if cancer cells were found 1 mm or less from the margin.

**Local recurrence:** a recurrent disease in the pelvis, including recurrence at the site of the anastomosis and in the perineal wound. Isolated recurrence in the ovaries was recorded as distant metastasis.

**Curative resection:** a local radical procedure (R0 and R1) with negative or with microscopic invasion margins in the absence of distant metastases.

**Palliative resection:** a resection in a patient with distant metastases diagnosed in the preoperative study or an operation associated with macroscopic residual tumour in the pelvis (R2).

Stage classification for pathological specimens followed the tumour node metastasis (TNM) classification from the American Joint Committee on Cancer (stages I–IV; 5th edition).

## Quality control

Most of the patients with rectal cancer are managed in the hospitals of the National Health Service and are compulsorily referred to the local hospital. Therefore, within the geographic area and centres participating in the study, there is no selection of patients.

In order to control selection bias during the process of acceptance in the project, each candidate hospital is asked to provide data on their rectal cancer operations from the previous 5 years. The presence of a deviation of 10% in annual caseload was reviewed with the surgeon responsible for each hospital.

If there was no satisfactory explanation for this reduction in the number of cases, the hospital was excluded from the project. Moreover, several actions have been set up to guarantee the validity of registered data,<sup>19</sup> including the audit of results by the health authorities.<sup>20</sup>

## Results

Spain has a population of 46,700,000 million inhabitants, all of who were covered by the Spanish National Health

Service, which includes 261 public hospitals. From these 103 hospitals university and district general were included in the Spanish Rectal Cancer Project. The remaining 158 hospitals in the National Health Service, nearly all county hospitals, were not included in the project because their low case loads.

Twenty-three hospitals were excluded from the analysis due to non-compliance with data registration. Therefore the analysis included results from 80 university and district general hospitals. Hospitals included in the project treated patients from a geographical area with 19,329,992 inhabitants, representing 42% of the population of Spain.

### Short-term outcomes

From March 2006 to December 2015, a total of 14,815 consecutive patients underwent a curative resection. 66.8% had an Anterior resection, 23.5% an abdominoperineal resection, and 9.7% a Hartmann's procedure. These data are in the ranges of the Scandinavian registries. Rates of sphincter preservation vary from 68% in Norway<sup>21</sup> to 50% in Sweden,<sup>22</sup> and for Hartmann's procedure from 6% in Norway<sup>21</sup> to 16% in Denmark.<sup>23</sup>

The postoperative mortality rate was 1.8%; postoperative complications were observed in 39.9% patients; 10% developed anastomotic leakage and 9% required reoperation.

The mortality rate observed in this study is in the ranges of the national registries of Norway<sup>21</sup> (1.6%), Sweden<sup>22</sup> (2.3%) as well as Denmark<sup>23</sup> (1.7%), which give the crude rates for colorectal surgery. Moreover, rates of anastomotic leakage are also in the ranges of the Scandinavian registries: Norway<sup>21</sup> (7%), Sweden<sup>22</sup> (8.7%) and Denmark<sup>23</sup> (12.7%). Furthermore, the reoperation rate is similar to that reported in the Swedish registry (10.8%).<sup>22</sup>

### Long-term outcomes

From the 14,815 patients, 3088 have been followed up for at least five years. Invasion of the circumferential resection margin (CRM) occurred in 9.7% of the specimens. The rates of local recurrence, metastases during follow-up and overall survival were: 6.2%, 18.8% and 73.5% respectively.

The CRM is an extensive surgically created plane of dissection produced during the removal of the rectum from its surroundings. The largest area is posterior, and a full 360° circumferential margin appears below the peritoneal reflection. The frequency of histological involvement of the CRM is strongly associated with local recurrence and poor survival. Therefore it is an excellent proxy of the long-term outcomes allowing comparison of surgical performance between hospitals. Involvement rates 10% or higher imply a high probability of poor outcome.<sup>24</sup> National registries of Norway,<sup>21</sup> Sweden<sup>22</sup> as well as Denmark<sup>23</sup> report a 8–9% rate for invaded CRM which are comparable with those of this project.

The rate of local recurrence in this project is almost similar to those in the latest reports from the Norwegian<sup>21</sup> (4.3%) and Swedish<sup>22</sup> (5%) national registries. The Danish registry<sup>23</sup> does not evaluate this indicator. Moreover, the rates of local recurrence have improved over the years,

as it happened in the Norwegian<sup>21</sup> and Swedish<sup>22</sup> national registries. In the Spanish Rectal Cancer Project the rate dropped from 8% in the first evaluation performed in 2012 to 7% in 2014, and 6.2% in 2015. Five-year overall survival in this project (73.5%) is similar to those published by the Norwegian<sup>21</sup> (76%) and Swedish<sup>22</sup> (75.8%) registries and slightly higher than that published for the Danish registry<sup>23</sup> (68%).

It is difficult to explain the almost similar local recurrence and overall survival reported by the Scandinavian registries and the observed one in this project because the use of neoadjuvant treatment differed considerably. In the Norwegian<sup>21</sup> and Danish<sup>23</sup> registries, 33% of patients underwent neoadjuvant treatment compared with 66% in the Swedish registry<sup>22</sup> and 55% in the Spanish Rectal Cancer Project.<sup>19</sup> Furthermore, whereas in Sweden<sup>22</sup> neoadjuvant treatment consists mainly of short-course radiotherapy in Denmark,<sup>23</sup> Norway<sup>21</sup> and Spain<sup>19</sup> chemoradiotherapy is the predominant regimen.

A large body of research has focused on investigating the effects of healthcare provider volume and specialization on patient outcomes. In this project multivariable studies have shown that the caseload of the participant hospitals does not influence short-term outcomes (i.e. operative mortality<sup>25</sup> and anastomotic leakage<sup>26</sup>). However, long-term outcomes (i.e. local recurrence and overall survival) were influenced by lower case load as it was shown in the registries of the Scandinavian countries.<sup>22,27</sup>

In a society like the Spanish one, with free and equal access to the health care system, there should be equally high standards of treatment with limited variation in quality between hospitals. To address whether this aim was achieved in this project several multilevel studies have been performed. These studies show variability among the hospitals participating in the project in operative mortality<sup>25</sup> and in anastomotic dehiscence.<sup>26</sup> However, there were no statistical differences between hospitals in the long-term outcomes.

The most important result of this project is the improvement of rectal cancer surgery after introduction of an educational project and a centralized registry. Since the beginning of this project ten years ago, the best parameter of surgical performance, the rate of local recurrence, has continuously declined. Therefore, the regular feedback of results to each surgical department implies that a continuous focus on outcome can lead to a better outcome with time. However, this project has not entirely eliminated the problem of variation of results. Thus it is still a potential for enhancement treatment standards.

Educational programmes and national registries either compulsory or voluntary have been settled down in other European countries (i.e. Belgium,<sup>28</sup> Holland,<sup>29</sup> Ireland<sup>30</sup> and United Kingdom<sup>31</sup>). This initiative has not yet convinced the healthcare authorities to create a national registry in Spain, even though the strategy of auditing and registration of rectal cancer has clearly improved the outcome of treatment in Spain and several other European countries. Therefore the project continues in a voluntary basis.

In conclusion this project shows that the results obtained in Scandinavia can be reproduced in a larger population,

implementing a MDTs educational programme focused on the spread of competence and auditing of results.

## Conflict of interest

The authors declare that they have no conflict of interests.

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