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ORIGINAL RESEARCH

Pilot Study of a Clinical Pathway Implementation in Rectal Cancer

Esther Uña¹ and Francisco López-Lara²

¹Oncology Department Clinical University Hospital of Valladolid, 47005 Valladolid, Spain. ²Radiotherapy Department Clinical University Hospital of Valladolid, 47005 Valladolid, Spain. Corresponding author email: aunacid@hotmail.com

Abstract

Background: Rectal cancer is a highly prevalent disease which needs a multidisciplinary approach to be treated. The absence of specific protocols implies a significant and unjustifiable variability among the different professionals involved in this disease. The purpose is to develop a clinical pathway based on the analysis process and aims to reduce this variability and to reduce unnecessary costs.

Methods: We created a multidisciplinary team with contributors from every clinical area involved in the diagnosis and treatment in this disease. We held periodic meetings to agree on a protocol based on the best available clinical practice guidelines. Once we had agreed on the protocol, we implemented its use as a standard in our institution. Every patient older than 18 years who was diagnosed with rectal cancer was considered a candidate to be treated via the pathway.

Results: We evaluated 48 patients during the course of this study. Every parameter measured was improved after the implementation of the pathway, except the proportion of patients with 12 nodes or more analysed. The perception that our patients had about this project was very good.

Conclusions: Clinical pathways are needed to improve the quality of health care. This kind of project helps reduce hospital costs and optimizes the use of limited resources. On the other hand, unexplained variability is also reduced, with consequent benefits for the patients.

Keywords: clinical pathway, implementation of clinical pathways, quality of care, rectal cancer

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Introduction
One concern after rectal cancer surgery is the high local recurrence rate. It has also been recognised that 20%–40% of rectal cancer patients continue to develop distant metastases and die. The majority of patients with nonmetastatic rectal cancer are candidates for an aggressive multimodal approach with curative intent and in these cases, preoperative staging is critical in determining which patients should be offered neoadjuvant therapy.

The objective of treatment in rectal cancer is to decrease rate of recurrence, which is the most frequent cause of mortality in these patients, and also to increase the survival rate. In recent years, many papers have been published that show the relevance of neoadjuvant treatment, with chemoradiotherapy decreasing the rate of local recurrence and, in some cases, increasing survival.

Despite the fact that surgery is still an elective aspect of treating rectal cancer, the management of this disease should be performed by a multidisciplinary team, with contributions by surgeons, oncologists, pathologists, medical and radiation radiologists, and gastroenterologists. This is the only way to obtain the best results not just for survival but also for quality of life.

This has also been a way to achieve the goals established by the modern concept of quality in healthcare. But it is not always easy to create a work group composed of every specialist involved in patient care. Another difficulty is obtaining a consensus among the different specialists.

Clinical pathways are healthcare plans in which the whole process of the disease from the diagnosis is described, including the responsibilities every professional has with the patient.

Rectal cancer is one of the more complex tumoral diseases because of the need of multiple specialists to take part in its diagnosis and treatment. This means that coordination among different clinical units is necessary, which is often lacking. This fact requires us to develop a way to involve every specialist in a multidisciplinary team to avoid delays between different phases of the process and to avoid clinical variability among the different professionals involved. In this context, it seems to be relevant to create a clinical pathway and to implement it.

Our study aims to describe the results before and after the process of elaborating a clinical pathway and the improvements obtained in the patients’ care parameters six months after its implementation.

Methods
We carried out this project during the second half of 2009 and 2010 in our institution. The work consisted of developing, step by step, a clinical pathway in rectal cancer. We chose this disease because of the high unexplained clinical variability we detected in a previous project we had carried out. This project (analysing the process) consisted of a retrospective cross-sectional study of 44 patients consecutively diagnosed with rectal cancer. The data showed a significant variability in the process of diagnosis and treatment, related not only to the type of diagnostic tools but also to the waiting time to go on into the process, and to the treatments and sequence of treatments they received. On the other hand, we had also detected a high variability in the contents of pathological reports and the professional perception of poor information given to the patient and family about the process.

Once the schedule of activities and protocol of this project were approved by the local Ethical Committee, we began to schedule many multidisciplinary meetings with representative members from every clinical unit. Both authors coordinated the team and the progressive development of the clinical pathway.

Once the pathway was drafted, we tried to implement it with contributions from the leaders of our institution. Every patient older than 18 years diagnosed with rectal cancer after drafting the pathway was included in it.

To analyse the results, we used specific indicators created for this clinical pathway and our results were compared to a previous series of patients analyzed before the implementation of this pathway.

We hypothesized that the application of our project would obtain at least a 20% reduction in the clinical variability after six months of implementation and, on the other hand, would provide a high level of patient satisfaction and a good perception of quality of care, or an increase of 20% in the diagnostic procedures performed.

We analyzed the clinical effectiveness, real compliance with the agreed goals and patient satisfaction once had been included in the clinical pathway.

We did a comparison of the evaluated parameters between the periods before and after implementation of this clinical pathway. We applied statistical analyses.
using the Mann–Whitney U-test and considered $P < 0.05$ as statistically significant.

**Results**

Before clinical pathway was implemented, we observed and identified several areas candidates to be improved, as shown in Table 1.

Six months after the implementation, we had recruited 48 patients according to selection criteria. The aim of our study was not the evaluation of the patient characteristics so we have not evaluated these in our study.

The pathological reports were improved by taking the information we agreed upon at the multidisciplinary meetings into account (see Table 2). The greatest benefits were seen in the information related to TNM (tumor, nodes, metastases) classification classification and about vascular invasion (see Table 3). Both parameters were clearly improved and we have demonstrated a clear statistical significance ($P < 0.05$).

Before our project was implemented, many pathologists used to write the Dukes classification in their reports and the others used TNM. But after several meetings, the consensus was clear: TNM would be the only classification to use in our institution and this decision was complied with totally.

A similar process was followed and a similar result has been obtained in the area of vascular invasion. However, we did not manage to make any improvements before and after implementing the new protocol regarding rate of mention of number of nodes analysed or isolated.

Another relevant change has been the growing use of chemoradiotherapy as a neoadjuvant treatment. Before the new pathway, this therapy was applied for just 2% of the patients but after the implementation, the percentage was 71%. Meanwhile, short courses of radiotherapy have been eliminated from our protocol. Both results were statistically significant.

Practically all time intervals between different phases of the process have considerably improved and shortened, mainly in the parameters related to the time between first diagnostic tool and results, and also time to treatment.

One of the most important results we obtained was that the use of MRI during the preoperative stage of the disease has increased greatly, 10 times higher than previous use ($P = 0.002$).

Finally, anal sphincter preservation has increased and translates into surgeons being aware about the benefits of the neoadjuvant and treatment by multidisciplinary teams, though this difference was not statistically significant. Indirectly, this point may increase the quality of life of rectal cancer patients.

Two patients were evaluated but not included in this study because of avoidable causes. These were ignorance about the clinical pathway, although it was presented in a multidisciplinary meeting, or because many doctors did not want to participate in this project.

One notable finding highlighted an aspect of care that appeared to deteriorate after implementation of the pathway. This is the proportion of the patients with

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### Table 1. Standards of quality determined by the clinical pathway committee members.

| Aspect of care          | % of cases with this data missing |
|-------------------------|----------------------------------|
| **Information**         |                                   |
| Pathological report     |                                   |
| Histological grade      | 3%                                |
| Size                    | 38%                               |
| Margins                 | 21%                               |
| TNM classification       | 49%                               |
| Nodes analysed          |                                   |
| Not mentioned           | 0%                                |
| Isolated                | 0%                                |
| <12                     | 67%                               |
| <4                      | 11%                               |
| **Neoadjuvant treatment** |                                 |
| Hypofractionated radiotherapy | 1%                             |
| Chemoradiotherapy       | 0%                                |

### Table 2. Appropriate interval time for procedures, as agreed upon by the workgroup.

| Procedures                                             | Expected time |
|--------------------------------------------------------|---------------|
| Time from the first visit to colonoscopy               | 15 days       |
| Time interval from colonoscopy to receiving pathological results | 7 days        |
| Time from pathological diagnosis to first treatment    | 15 days       |
| Time from the end of preoperative treatment to surgery | 4–6 weeks     |
| Time from colonoscopy to the end of diagnostic tests   | 15 days       |
| MRI is performed                                       | 30%           |
| Anal sphincter-saving procedure is performed           | 60%           |
rectal cancer but with less than 12 nodes analysed. We do not have a reasonable explanation for this fact but it may be related to the small number of patients included in the study when we were writing the research.

We analysed also the patient’s satisfaction with the process and we achieved good results that showed a very high satisfaction rate with every parameter evaluated (see Table 4).

**Discussion and Conclusions**

Rectal cancer remains a frequent disease with variable clinical results. Improving these results is a very important challenge at the moment. With this aim, we performed a pilot study to evaluate the improvements obtained after implementing a clinical pathway in our institution.

We obtained positive results from the pilot study, so we planned to complete the project with the development of different clinical pathways related to every subprocess in this disease, such as surgery protocols or care after surgery. We also intend to complete the study by including survival data once a reasonable period of time has passed after the implementation.

We have been continuing to recruit patients to obtain more confident results after a great number of patients have been studied.

Although we would have liked to have a previous study of patient satisfaction before the implementation of our institutional pathway, unfortunately, we had not performed one before. Because of this, we cannot know if our new clinical pathway can improve

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**Table 3.** Improvement in the evaluated parameters after implementing clinical pathway.

| Parameter                                           | Before pathway n = 44 (%) | After pathway n = 48 (%) | P       |
|-----------------------------------------------------|---------------------------|--------------------------|---------|
| Pathology report poor in                            |                           |                          |         |
| Histological grade                                  | 23                        | 0                        | NS      |
| Size                                                | 58                        | 0                        | 0.011   |
| Margins                                             | 41                        | 0                        | 0.030   |
| TNM                                                 | 69                        | 0                        | 0.003   |
| Vascular invasion                                   | 79                        | 0                        | 0.001   |
| Nodes analysed not mentioned                        | 16                        | 0                        | NS      |
| Nodes isolated                                      | 19                        | 0                        | NS      |
| Nodes <12 analysed                                   | 87                        | 90                       | NS      |
| Nodes <4                                             | 31                        | 0                        | 0.030   |
| Neoadjuvant treatment                               |                           |                          |         |
| Hypofractionated radiotherapy                       | 31                        | 0                        | 0.03    |
| Chemoradiotherapy                                   | 2                         | 71                       | 0.003   |
| Appropriate interval between procedures             |                           |                          |         |
| Time to colonoscopy                                 | 20                        | 100                      | 0.003   |
| Time to results after biopsy                        | 18                        | 100                      | 0.005   |
| Time to first treatment                             | 27                        | 100                      | 0.026   |
| Time to surgery after the end of treatment          | 43                        | 100                      | NS      |
| Time to end of diagnostic tests                     | 23                        | 44                       | 0.002   |
| MRI performed as preoperative staging tool          | 9                         | 90                       | NS      |
| Anal sphincter preservation                         | 40                        | 65                       | NS      |

**Abbreviation:** NS, not significant.

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**Table 4.** Patients’ satisfaction after the implementation of this clinical pathway.

| Survey n = 48 | % of patients answering yes |
|---------------|-----------------------------|
| Do you think that the time to first treatment is adequate? | 80% |
| Are you satisfied with the information you received during the process? | 60% |
| Do you consider the length of hospital stay to be adequate? | 100% |
| Do you think that the care and assistance you received was of high quality? | 80% |
| Are you satisfied with the clinical attention you received? | 80% |
patient satisfaction, as we have no way of comparing satisfaction before and after implementation.

We can conclude that this clinical pathway has been positive to our patients and our institution, based on the improvements it has brought.

The development of a clinical pathway is a privilege and it is only possible in hospitals with a high degree of knowledge about clinical management and with professionals who are aware of the relevance of multidisciplinary teams. This is also the only way to achieve the highest levels of excellence in clinical cancer care.

Although cost has not been analyzed the perception we have so far since the implementation of this pathway is that it could reduce the costs associated with the clinical variability demonstrated before the implementation. These costs related to the high rate of diagnostic tools used without any clinical significance, the absence of a protocol which could regulate the number and type of analyses performed, or the length of hospital stay, or the different surgical procedures or chemotherapy and radiotherapy treatment given to the patients. This point is highly significant, given the current economic crisis and the lack of resources. This justifies a second project aimed towards obtaining a solid conclusion.

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Disclosure
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