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Original articles

Site of local surgery in adenocarcinoma of the rectum T_2 N_0 M_0

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ARTICLE INFORMATION

Article history:
Received April 1, 2008.
Accepted September 5, 2008.

Keywords:
Ileal pouch-anal anastomosis
Crohn's disease
Inflammatory bowel diseaser

A B S T R A C T

Introduction: The local exeresis adenocarcinoma of the rectum T_2 N_0 M_0 (ADC-T2), using transanal endoscopic microsurgery (TEM), has the benefit of achieving lower morbidity with a better quality of life. However, local occurrence of the local exeresis is greater than 20%, which is unacceptable these days.

Patients and methods: Prospective, observational follow up study. The tumours committee agreed that those ADC-T2 patients could have the following treatments: total mesorectal excision (TME), simple TEM, TEM with postoperative chemo- and radiotherapy (Ct-Rt), preoperative Ct-Rt with subsequent TEM, and radical surgical rescue (TME) within at least 4 weeks.

Results: Of the 146 patients operated on using TEM, 75 had adenocarcinomas, 59 adenomas, 6 scarring wounds, 5 carcinoids, and 1 GIST. Of the adenocarcinomas 22 were ADC-T2.
Follow up: median of 16 months (range, 3–32 months). The overall local recurrence was 18% (4/22). According to the treatment strategy the local occurrence was: TEM as the only procedure, 20% (2/10). Radical surgical rescue was performed on 3 patients after TEM, with no local or systemic recurrences. TEM with Qt-Rt after surgery was performed on 6 patients, with a local recurrence of 33% (2/6). Ct-Rt and subsequent TEM in 3 patients, with no local or systemic recurrences.

Conclusions: Treatment of ADC-T2 using simple TEM is not effective. The combination of Ct-Rt after TEM, does not improve the results of TME. It is possible to rescue those patients without changing the overall survival. Preoperative Ct-Rt and TEM appears to be the approach that obtains a clinical and histological response, although a response is needed by clinical trials.

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Lugar de la cirugía local en el adenocarcinoma de recto $T_2N_0M_0$

Palabras clave:
Adenocarcinoma de recto T_2
Cirugía local cáncer de recto
Microcirugía endoscópica transanal
TEM
Cirugía local de tumores rectales

RESUMEN

Introducción: La exéresis local del adenocarcinoma de recto $T_2N_0M_0$ (ADC-T2), mediante microcirugía endoscópica transanal (TEM), se beneficia en conseguir una menor morbilidad con mejor calidad de vida. Sin embargo, la recidiva local de la exéresis local es superior al 20%, inaceptable en estos momentos.

Pacientes y método: Estudio observacional de seguimiento prospectivo. Los pacientes ADC-T2 son consensuados en el comité de tumores a las actuaciones terapéuticas: escisión total del mesorrecto (ETM), TEM simple, TEM con quimiorradioterapia (Qt-Rt) postoperatoria, Qt-Rt preoperatoria con posterior TEM y rescate a cirugía radical (ETM) en menos de 4 semanas.

Resultados: Se ha intervenido a 146 pacientes mediante TEM; 75 adenocarcinomas, 59 adenomas, 6 lesiones cicatriciales, 5 carcinoides y 1 GIST. De los adenocarcinomas, 22 fueron ADC-T2. Seguimiento: mediana, 16 (intervalo, 3-32) meses. La recidiva local total ha sido del 18% (4/22). Según la estrategia terapéutica la recidiva local fue: TEM como único procedimiento en el 20% (2/10). Se realizó en 3 pacientes rescate a cirugía radical tras TEM, sin recidiva local ni sistémica. TEM con Qt-Rt posterior a la cirugía se realizó en 6, con una recidiva local del 33% (2/6). Se practicó Qt-Rt y posteriormente TEM en 3 pacientes, sin recidiva local ni sistémica.

Conclusiones: El tratamiento del ADC-T2 mediante TEM simple no es razonable. La asociación de Qt-Rt tras TEM, no consigue mejorar los resultados a la ETM. Es factible rescatar a los pacientes sin que altere la supervivencia total. La Qt-Rt preoperatoria y TEM parece ser la línea cuando se consiga una respuesta histológica y clínica, aunque es necesaria la respuesta por parte de ensayos clínicos.

Introduction

Treatment of adenocarcinoma of the rectum $T_2\ N_0\ M_0$ (ADC-T2),[1] in accordance with NCCN-2008,[2] consists of total mesorectal excision (TME), non adjuvant. As an alternative, the guide proposes the option of local surgery in cases of T_2N_X as an alternative with a degree of evidence of 2B, followed by chemo- and radiotherapy.

TME is the most effective treatment in these situations, with local recurrence rates of between 2% and 11% and a systemic recurrence rate of 2%–13%.[3] This surgery is costly, with postoperative morbidity and mortality rates being 30%–40% and 2% respectively[4] in addition to disorders arising from considerable genitourinary alterations (>30%) and the secondary effects of having a temporary or permanent ostomy.[5]

Local exeresis of ADC-T2 by means of transanal endoscopic microsurgery (TEM) has the advantage of low postoperative morbidity (10%–15%) and virtually zero mortality, without producing genitourinary alterations.[6] The main problem with ADC-T2 is that it is associated with potential lymph node disorders that may represent 12%–28%.[7]

Different therapeutic experiences after the use of local ADC-T2 surgery described in literature include simple local excision using either endoanal excision or TEM, local surgery (TEM or endoanal) with postoperative chemo- and radiotherapy (Cht-Rt) and preoperative Cht-Rt and local excision (TEM or endoanal.)[8-13]

After applying local surgery in the case of adenocarcinoma of the rectum, with T_1 preoperative stage and following the anatomo-pathological report, it is observed that this is a tumour with high risk of recurring[14] or, in case of developing to a more advanced state, that the treatment with radial surgery (TME) within a period of less than 4 weeks does not alter the cancer prognosis.[15]

We present our experience with ADC-T2 using TEM, following a protocol based on a preoperative study, surgical technique and prospective follow-up.

Patients and method

Observational prospective follow-up study. The study protocol for local surgery of rectal tumours by TEM at Parc Taulí Health Corporation is as follows: full clinical history, perianal examination, and rectal probe. A total colonoscopy was requested, with a multifocal biopsy of the lesion, application of the Wexner[16] incontinence severity scale and anorectal manometry. Classification of the tumour state was made by endorectal ecography and pelvic resonance (u,rm). In the event of differing diagnoses using these techniques, the highest is taken into account. In the case of tumours with a biopsy of the adenocarcinoma, an abdominal CAT scan was requested, with CEA and CA 19.9 tumour markers. The tumours were classified depending on their height with respect to the anal margin in tumours of the lower rectum

(<8 cm), middle (8 to <12 cm), and upper rectum (12–16 cm).[8] Following these studies, the patients were classified and divided into 4 preoperative therapeutic indication groups: I, for curative purposes, in state u,rmT_0, u,rmN_0 (benign tumours) adenoma; II, for curative purposes in state u,rmT_{0-1}, and N_0 adenomacarcinoma; III, for indication based on consensus, in state u,rmT_2 and u,rmN_0 adenomacarcinoma; and IV, palliative indication in adenocarcinoma in any state.[6]

Preoperative preparation and postoperative care were carried out as described above.[6] The local excision technique was applied using TEM,[17] with the difference that in all cases the wall was completely excised using an ultrasound scalpel (Ultracision, Ethicon, Endo-Surgery, Cincinnati, Ohio, USA), performing the dissection on the perirectal fat to treat the lesion with a margin of over 15 mm.[6] Once removed, the tumours were prepared on a cork surface and the resection margins were fixed in place with needles, to prevent retraction.

In all cases, the pathological anatomy report was written by the same specialised pathologist, who described the characteristics of the resection based on the presence of the free margins with the minimum distance to the lateral edge and depth; differentiates the types of resections: R0, excision with the nearest margin being >1 mm; R≤1, margin ≤1 mm; Rx, fragmentation of the section with non-defined margins and R1, margins affected [8]; and reports about the diagnosis of the section with its characteristics in terms of high or low risk.[14]

Following the intervention, and based on the pathological anatomy report, the cases were discussed at the TEM tumours committee, formed by gastroenterology and ultrasound experts, radiologists, anaesthesiologists, anatomo-pathologists, cancer specialists, and colorectal surgeons. In the case of patients with high-risk pT_1 state tumours, the committee's decision was based on consensus, evaluating the characteristics and wish of the patient with respect to the following options: simple TEM, TEM with postoperative chemo- and radio therapy (Cht-Rt), and radical surgery (TME) within 4 weeks.

In patients undergoing Cht-Rt, the chemotherapy applied was a continuous infusion of 5-fluorouracyl at a dose of between 225 and 300 mg/m^2 a day, 5 days a week for 5 weeks. Radio therapy consisted of 50.4 Gy.

Until the end of 2006, the therapeutic intention for patients not agreeing to radical surgery (TME) at the outset was decided by consensus, using postoperative Cht-Rt after anatomo-pathological confirmation. However, only TEM was performed if there was a contraindication for Cht-Rt due to co-morbidity in the patient.

From the end of 2006, and in relation to the poor results with Cht-Rt following TEM, it was decided that patients refusing to undergo TME would start a preoperative Cht-Rt treatment protocol at the doses commented on above, and TEM after 7-8 weeks. TEM alone was also performed during this period, if there was a contraindication for Cht-Rt due to co-morbidity in the patient.

Follow-up of these patients was carried out exhaustively by means of endorectal ecography and rectosigmoidoscopy with a multifocal biopsy of the scar every 4 months for the first 2 years. From year 3 to year 5, these controls were performed every 6 months and then the habitual controls. Abdominal CAT scan and tumour markers every 6 months, and total colonoscopy every year.

With respect to the description of variables, version 12 of the SPSS programme was used. The quantitative variables description was made giving average and standard deviation values, provided that the distributions were considered to be normal. If not, the median and interval were determined. Categoric variables were described in absolute values and percentages.

Results

From July 2004 to February 2008, a total of 146 patients with rectal tumours were operated on in our centre using the TEM technique, from 37 hospitals; 47 were from Sabadell area (31.8%). Figure 1 shows the distribution of patients with rectal tumours considered eligible for TEM by preoperative therapeutic indication groups.

It is essential to ascertain the diagnostic accuracy using self-critical methods, for which reason Figure 1 shows that in group 1, in which the objective was to operate on benign rectal tumours considering the adenocarcinoma in situ as non-invasive, a preoperative diagnostic error was obtained in 3/66 (4.5%). In group II, a preoperative diagnostic error was obtained in 3/54 (5.5%), with 2 patients having a T_2 and 1 a T3. If we consider that the purpose was for the candidate patients to be operated using the TEM technique, taking group I and II jointly, out of 120 (66+54) patients, an error was found in 5 (4.2%) patients.

Figure 2 shows the classification by diseases following the anatomo-pathological diagnosis. Of the 21 ADC-T2 patients, 17 came from group III, 1 from group I, and 3 from group II. One patient had 2 tumours of the rectum 2.5 and 10 cm from the anal margin, both of which were ADC-T2, and so our case studies consisted of 22 ADC-T2.

Of the 21 patients with ADC-T2, 15 (71.4%) were male and 6 (28.6%) female, with an average age of 77 (55-87) years. The average size of the lesions was 4 cm (2.5–12). The average location with respect to the anal margin was 8 cm (2–18). The distribution of the tumours with respect to the anal margin height was 12 in the lower rectum, 6 in the middle part of the rectum, and 4 in the upper rectum.

The postoperative mortality rate was 0 and morbidity, 4.7% (1/21), one postoperative perianal abscess. The average hospitalisation period was 4 (2–15) days. The type of therapeutic strategy applied in these patients is shown in Figure 2.

Follow-up was carried out for an average of 16 (3–32) months, with total recurrence ADC-T2 being 18% (4/22). In the group in which only TEM was performed, local recurrence was 20% (2/10), with 1 death during follow-up due to another type of disease. Table 1 shows the characteristics of these 2 patients with local recurrence. To date, the 3 patients submitted to radical surgery following TEM within 4 weeks have not shown any local or systemic recurrence. Table 2 describes the characteristics of the 6 patients submitted to TEM and then to Cht-Rt, in whom there were 2 recurrences

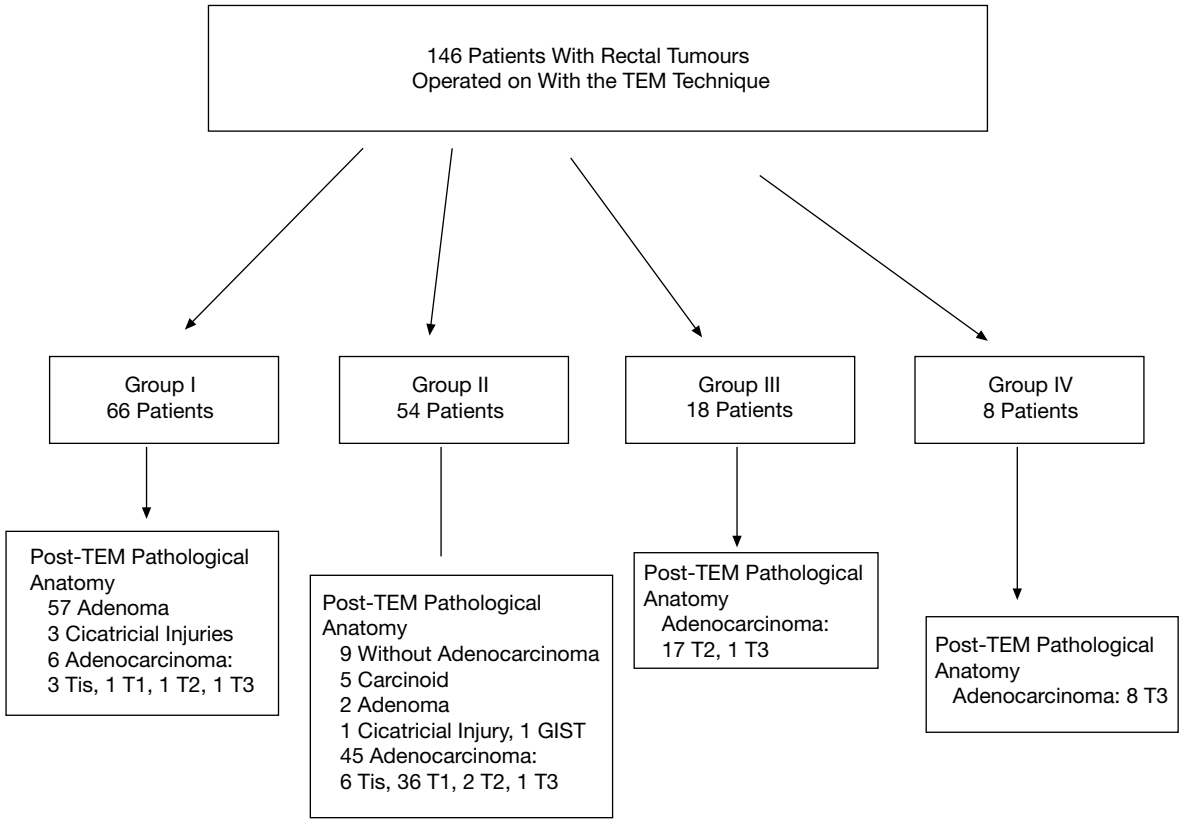

Figure 1 – Distribution of patients operated on with transanal endoscopic microsurgery (TEM) by preoperative therapeutic indication groups. GIST indicates gastrointestinal stromal tumour.

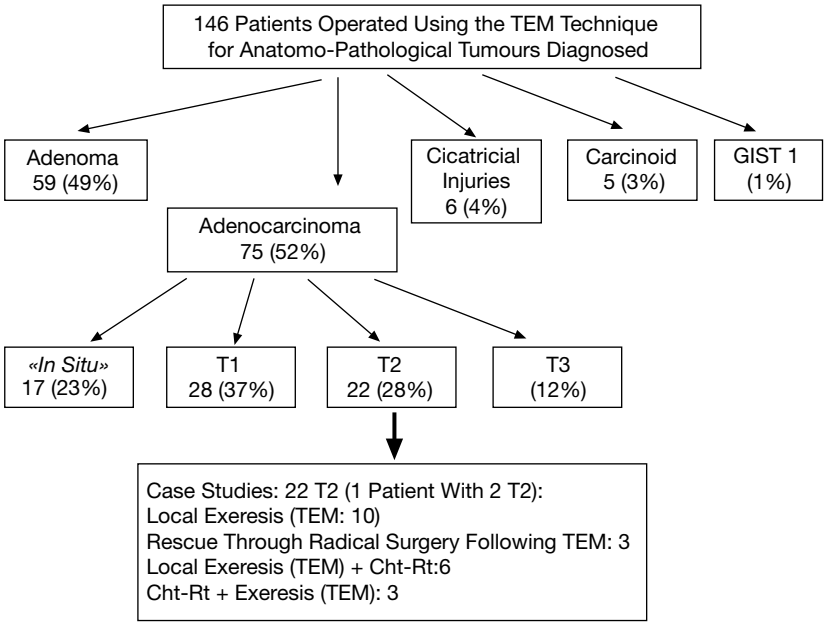

Figure 2 – Classification of patients with rectal tumours operated on with the transanal endoscopic technique (TEM) following an anatomo-pathological diagnosis. GIST indicates gastrointestinal stromal tumour.

(33%) which were treated by abdominal-perineal resection and are currently free from the disease.

Three patients entered the Cht-Rt and TEM group. Table 3 describes the characteristics of the 3 patients; the most important complication following Cht-Rt was the presence of perianal dermatitis in 1 patient. To date they are free from disease and with no local or systemic recurrence.

Table 1 – Local Recurrence Rate Following TEM as the Only Procedure (2/10 Patients)

Patient	Location in Rectum	AP Risk	Surgical Resection	Recurrence	Type of Surgery
Woman aged 75 years	Upper	Low	R0	13 months	LAR
Woman aged 77 years	Middle	High	R0	6 months	LAR

AP risk indicates anatomo-pathological risk of recurrence[14]; LAR, lower anterior resection.

Table 2 – Local Excision (TEM) and Subsequent Cht-Rt

Patient	Location in Rectum	AP Risk	Surgical Resection	Recurrence	Recurrence Time	Type of Rescue Surgery
1	Lower	Low	R0	Yes	6 months	APR
2	Middle-upper	Low	R0	No		
3	Lower	Low	R0	Yes	13 months	APR
4	Middle-upper	Low	R0	No		
5	Lower	High	R0	No		
6	Lower	Low	R0	No		

APR indicates abdominal-perineal resection; AP risk, anatomo-pathological risk of recurrence.[14]

Table 3 – Cht-Rt + Local Exeresis (TEM)

Preoperative State	Location in Rectum	Evaluation After Clinical Response	Surgical Resection	Complications Following Cht-Rt	ypT	AP Risk	Local Recurrence	Systemic Recurrence
u,rm T_2 N0	Lower	>50%[a]	R0	No	ypT2	Low	No	No
u,rm T_2 N0	Lower	>50%[a]	R0	Perianal dermatitis	ypT2	Low	No	No
u,rm T_3 N0	Middle	>50%[a]	Rx	No	ypT3	Low	No	No

u,rm indicates state according to the ecography and pelvic resonance; yPT, anatomo-pathological state following Cht-Rt and TEM.
[a]Reduction of lesion following Cht-Rt (clinical response).

Discussion

The temptation to practise treatment options with low postoperative morbidity and mortality and a lack of deterioration in the quality of life may involve the risk of not controlling the disease and cost the patient his/her life.[18] However, the particular conditions of each patient must be considered, many of whom are elderly and have many concomitant ailments, and the benefit of treating them of the cancer may cause mortality due to causes not related with cancer, and a considerable reduction in their quality of life.[19] For this reason it is important to know the current results obtained in each situation of adenocarcinoma of the rectum and establish the most appropriate balance.

In low-risk T1 adenocarcinoma, the latest studies published consider local excision using TEM as the preferred technique.[20-23]

With respect to ADC-T2, the response is more complex, due to the fact that the therapeutic options associated with local surgery give different results. Thus, in literature it can be seen that there are references to local recurrences of between 0% and 67%.[8] The discrepancy is due to a lack of homogeneity in the design, the fact that they are retrospective studies with no follow-up, the use of different therapeutic concepts in local treatment and the divergence in patient selection.

Focusing on excision of ADC-T2 as the only procedure with TEM, Borschitz et al[8] describe their experience with 20 patients, analysing their general experience of a local recurrence rate of 35%. In our series of 11 patients with ADC-T2,[9] published jointly with another centre, with an average follow-up of 59 months and a minimum of 24, a local recurrence rate of 22.2% was observed, with a probability of non-recurrence of 81.8%. Based on our current experience, local recurrence was 20% despite treating the lesions with resections with negative margins and with a relatively short follow-up period. As a result of all these data, we think that local surgery alone, either with TEM or endoanal excision, obtains results that are unacceptable compared to radical surgery (ETM). It is not a curative therapy, regardless of the location, histological risk and type of resection (R0).

In view of the difficult situation when performing a TEM with a preoperative I or II group state in which the anatomo-pathological report shows an ADC-T2 or high-risk T1, rescue using radical conventional surgery offers acceptable results in terms of recurrence and survival from the oncological perspective.[8,15] Our current and previous experience also follows this line,[9] and no decline in the prognosis was observed in these patients following rescue surgery. In our opinion, in the face of adenocarcinoma of the rectum that is difficult to evaluate preoperatively in T_{1-2}, with N_0 by endorectal ultrasound and pelvic resonance, the option of performing a TEM while waiting for the final histological result may bring considerable benefit to the patient in the case of obtaining favourable results. In a contrary situation, rescue would not reduce the probability of survival.

During recent years, great expectations have arisen with respect to postoperative auxiliary treatments. This situation was logical, due to the fact that the lesion could be correctly diagnosed in anatomo-pathological terms (with no problem of infra-classification or over-classification) and in relation to this, auxiliary therapy would eventually control the disease with a lower cost than radical surgery.

A review of literature on Cht-Rt following local surgery also gives disconcerting results of local recurrence of between 0 and 45%.[24] Our experience was unfavourable in 2 of the 6 patients. Despite performing a correct surgical resection (R0) and the tumours being low risk in histological terms, the tumours developed again after 6 and 13 months, representing a local recurrence rate of 33%. We think, in agreement with Baxter et al,[24] that although the results of the different studies indicate an improvement in controlling local recurrence when compared to solely local excision, this is still evident in high proportions.

In referring to experience of Cht-Rt prior to ADC-T2, we should mention the study conducted by Habr-Gama et al.[25] It describes how preoperative Cht-Rt leads to a high percentage of clinical and histological response (26.8%) for distal adenocarcinoma of the rectum in state 0 (with a full clinical and histological response.) This state 0 is associated with an excellent result of control of local recurrence and long-term survival.

The only prospective study on preoperative Cht-Rt and TEM in $T_{2-3}N0$ adenocarcinoma of the rectum have been analysed by Lezoche et al.[12] They conclude that TEM combined with preoperative Cht-Rt can be considered the only effective minimally invasive treatments for treating small T_2 and T_3 N_0 tumours of the rectum.

Recently, Borschitz et al[13] have published a review of literature on their experience published with preoperative Cht-Rt and local surgery in ADC T_{2-3}. They observe that when the tumour is classified as having a lower state following Cht-Rt in resection pieces at ypT0, local recurrence is 0% and systemic, 4%. When it is a ypT1, the local recurrence is 2% and systemic, 7%. In ypT2 it rises to an RL of 7% and systemic RL also of 7%. However, when there is no lowering of the tumour classification, in ypT3, the results are a local recurrence of 21% and systemic recurrence of 12%. In our cases, we apply the same guideline of new auxiliary techniques with clinical response results higher than 50%, but without succeeding in lower the histological classification.

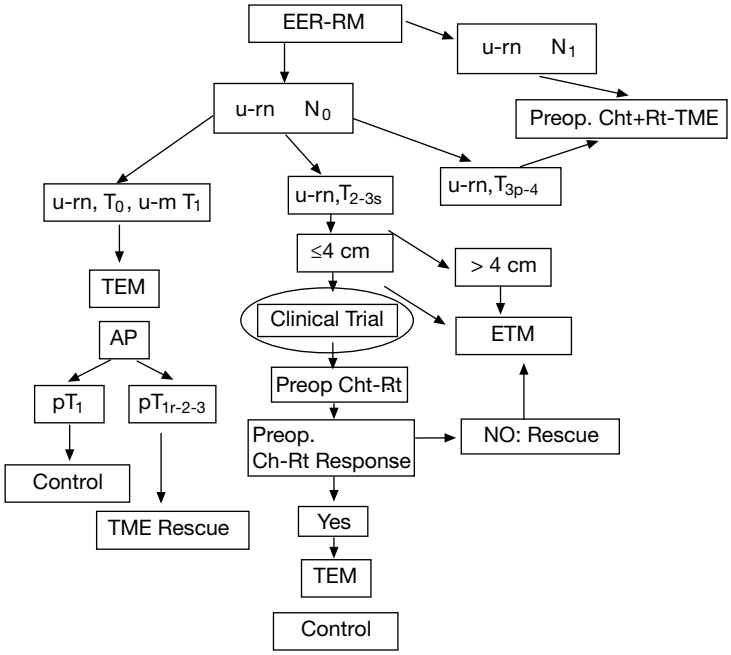

Figure 3 – Therapeutic diagram of rectal adenocarcinoma based on the pT classification state. EER indicates endorectal ecography; pT, tumour state following anatomo-pathological analysis; pT1r, pT1 with high anatomo-pathological risk of recurrence[14]; RM, pelvic magnetic resonance

Based on the current experience published, the only way to provide a final response is through clinical trials, as recently indicated by Suppiah et al.[19] Our group is currently developing this type of prospective, controlled, multi-centre, randomised study to provide a solution to the above questions. In the current situation, our therapeutic attitude regarding adenocarcinoma of the rectum is summarised in the chart shown in Figure 3, after ruling out remote metastasis. In the preoperative state of ADC-T3, we make a distinction between a surface and depth endorectal ecography and pelvic resonance, after observing that from the oncological point of view, the first behaves like an ADC-T2.[26,27]

In the case of it being proved that this line is effective, we must ascertain the price of morbidity, mortality and quality of life that determines preoperative Cht-Rt, and try to verify and identify the percentage of patients who can benefit from a separate clinical and histological lowering of the classification and their relation with local and systemic recurrence. In the future, the incorporation of new chemotherapy techniques will certainly help to favour the results achieved using this approach.

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