Diagnostic accuracy of MR vs rigid rectoscopy in assessing the extraperitoneal location of rectal cancers

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Purpose

From a medical oncologist's viewpoint, the discrimination between intra- and extraperitoneal rectal cancers has important treatment implications, since the risk of local recurrence increases, and overall prognosis worsens, moving towards the ano-rectal junction [1]. In fact, the anterolateral wall of the upper third of the rectum is lined by peritoneum and tumors located above the peritoneal reflection have the same clinical behaviour and, therefore, clinical management of colon cancer. Therefore, chemotherapy is administered as standard adjuvant treatment for radically resected colon cancer with involved regional lymph nodes, while combined chemoradiation is commonly employed for locally advanced (>T3a or N+) extraperitoneal rectal tumors, and preferentially administered before surgery (i.e. neoadjuvant chemoradiation). From a purely anatomical viewpoint, the upper boundary of the rectum is located at the rectosigmoid junction, slightly below the sacral promontory, but the peritoneal reflection is the true anatomical landmark to distinguish between extra- and intraperitoneal rectal cancers. This distinction can be made in the post-operative setting as the location of the rectal cancer relative to the peritoneal reflection is part of the surgical and pathological reports. However, preoperative identification of extra- vs intraperitoneal tumors is mandatory for individual treatment planning, and this information can be obtained prior to surgery with different modalities, each one characterized by peculiar advantages and limitations. Conventional methods. With rigid rectoscopy, it is possible to measure the distance between the inferior edge of the tumor and the anal verge, but the optimal cut-off distance to discriminate extra- vs intraperitoneal tumors remains to be defined. In fact, many constitutional factors may influence the distance of the peritoneal reflection from the anal verge, including age, sex, height, weight and parity. Thin-section rectal Magnetic Resonance Imaging may overcome the limitations of rigid rectoscopy and other techniques, directly showing the relationship between the anterior peritoneal reflection and the tumor on high resolution images. The main objective of the study was to compare the diagnostic performance of MRI with other two well-established methods (i.e. rigid rectoscopy and a bony landmark - the interface between S2-S3 sacral vertebrae -) to determine the extra- or intraperitoneal location of rectal cancers, using surgical exploration as reference standard. Furthermore, the degree of agreement between MRI and rectoscopy measurements of the distance between the inferior edge of tumors and the anal verge was assessed.
Methods and materials

Inclusion of patients

The study was approved by the ethics committee of the institution E.O. Ospedali Galliera. Patient recruitment of this prospective monocentric study began in January 2010 and ended December 2012. In this time interval all patients with a recent diagnosis of rectal carcinoma (any T and N stage), and scheduled for surgery (i.e. anterior resection, total mesorectal excision - TME -), with or without neoadjuvant therapy, were enrolled after giving written informed consent. Exclusion criteria were general contraindications to MRI (e.g. claustrophobia, metal fragments, pace-maker or implanted metal devices in the body). Renal insufficiency (GFR <30ml/min) was not considered as an exclusion criteria since rectal MRI is commonly performed without intravenous injection of paramagnetic contrast media. An additional exclusion criteria among patients who underwent neoadjuvant therapy was the complete response to chemoradiation (see following paragraph).

Preoperative assessment

Initial clinical assessment was carried out by a single specialist colorectal surgeon, who further performed all surgical procedures. All patients underwent rigid rectoscopy and thin-section rectal MRI for local tumor staging. Contrast enhanced computed tomography (CT) was used to stage distant metastases. Since surgical exploration was used as reference standard to assess the exact position of the inferior margin of tumors with respect to the PR, patients with a complete response to preoperative chemoradiation were excluded. In fact, in this subgroup of patients, it is impossible to detect the tumor's inferior margin (failure of reference standard). As a common practice of our institution to assess patient's response to chemoradiation, both rigid rectoscopy and rectal MRI were repeated after 6 weeks from the end of neoadjuvant therapy for purposes of tumor restaging. Complete responders were defined by the complete regression of the tumor mass at both rigid rectoscopy and MRI.

MRI protocol

High-spatial-resolution pelvic MRI was performed with a 1.5T MRI scanner and a pelvic phased-array coil. High-resolution oblique axial and coronal scans (slice thickness 3-3.5 mm, interslice gap 0.3 mm) were oriented perpendicular and parallel to the long axis of the tumor, in order to avoid misinterpretation due to partial volume effects. In the case of low rectal cancers, high-spatial-resolution coronal images are performed to optimally show the levator muscles, the sphincter complex, as well as the intersphincteric plane. A Diffusion-Weighted Imaging (DWI) sequence (b 1000 s/m²) was performed in the axial
plane for aiding the identification of the inferior edge of tumors (Figure 1). Patients did not receive bowel preparation or spasmolytic agents.

Image analysis

All MRI studies were reviewed in consensus by two abdominal radiologists with 7 and 12 years of experience in rectal MRI, respectively, blinded to the location of the mass. They had to define the extra- or intraperitoneal location of tumor’s inferior edge with respect to the anterior peritoneal reflection. This anatomical structure was defined according to Brown et al. [2]. In the midsagittal plane, the peritoneum was identified as a thin hypointense linear structure which courses along the superior aspect of bladder (men) or uterus (women), following the cul-de-sac of the pelvis in women and approximately the tip of the seminal vesicles in men, to reach its attachment onto the anterior rectal wall. Specifically, the anterior peritoneal reflection was considered as the insertion site onto the anterior rectal wall (Figure 2a). On FSE T2-weighted axial images, the peritoneum attaches in a V-shaped manner onto the anterior aspect of the rectum, an appearance that has been defined the "seagull" sign (Figure 2b). One pitfall to avoid is visualization off-midline, where the peritoneal reflection is higher as it proceeds laterally and superiorly. FSE T2-weighted sagittal and axial images enable the detection of the anterior peritoneal reflection, while the diffusion weighted axial sequence is helpful to confirm the level of the inferior edge of tumors. The two readers had to define the quality of identification of the anterior peritoneal reflection according to a 4-point confidence scale: 0, not visible; 1, poor; 2, good; 3, excellent. The distance of the inferior edge of tumors from the anal verge was measured in millimeters by means of an electronic digital caliper. This measurement necessitated two or more interconnecting angulated lines, sometimes on two or more adjacent sagittal slices for an approximate summated total length (Figure 3).

Furthermore, the readers had to define the position of the inferior tumor's margin with respect to a bony landmark of the sacrum, the passage between sacral vertebrae S2-S3. This analysis was performed drawing a line parallel to the interspace between S2 and S3 sacral vertebrae, which commonly intersects anteriorly the upper third of rectum (Figure 3).

Different other measurements were taken by the two readers on the FSE T2-weighted sagittal image of each MRI examination: the distance from the anal verge to the anorectal junction (ARJ), which corresponds to the mean length of the anal canal; the distance from the ARJ to the APR; the distance from the anal verge to the APR.

From a clinical viewpoint, the anal verge marks the lowermost portion of the anal canal and begins where the skin stops and the anal mucosa (i.e. anoderm) starts. On sagittal FSE T2-weighted images, the anal verge is defined as the lowermost portion of the anal sphincter complex, where the external sphincter merges toward the midline. On FSE T2-weighted sagittal images, the ARJ was considered the point of posterior angulation of the
rectum with respect to the anal canal, which represents the passage from the superior border of the sphincter and puborectalis complex to the rectum.

**Rigid rectoscopy**

Rigid rectoscopy was performed by a single operator in all included patients, before surgery, using a rigid instrument with centimetric markers on its surface. The distance of the inferior margin of the tumor corresponded to the value in centimeters read on the surface of the rectoscope at the level of the anal margin.

**Standard of reference**

As conventionally described, the upper third of the rectum is invested with peritoneum anteriorly and laterally, the middle third is partially invested anteriorly, and the lower third is completely extraperitoneal. Posteriorly, there is no peritoneal investment. Intraoperatively the limit among intra and extra-peritoneal rectum has been identified with the peritoneal reflection sited where the peritoneum, that cover the anterior and the lateral side of the rectum, leave the lateral sides and become only anterior. At this level, posteriorly, begin the mesorectal fat that cover the posterior and lateral rectal faces up to the plane of the levator muscles.

**Statistical analysis**

Categorical variables were expressed as number and percentage, while continuous variables as mean and standard deviation (SD). The normal distribution of rectoscopy and MRI measurements was assessed by means of the D'Agostino-Pearson test. Since some datasets did not follow the normal distribution, non-parametric tests were used instead of parametric ones. Mann-Whitney test was used to assess the presence of a significant difference between rectoscopy and MRI measurements, while their degree of correlation was assessed by the Spearman's rank test. Bland-Altman analysis was applied to compare rectoscopy and MRI measurements. In this graphical method the differences between the two techniques are plotted against their average values. The diagnostic performance of MRI and bony landmark (S2-S3 interface) in determining the extra- vs intraperitoneal location of rectal cancers was calculated using 2x2 tables with positive cases corresponding to the extraperitoneal location and negative cases to intraperitoneal location. Different characteristics such as sensitivity, specificity, positive and negative likelihood ratio, disease prevalence as well as positive and negative predictive values were calculated. Since rectoscopy provides a measurement of the distance of the tumor's inferior edge from the anal verge (continuous variable expressed in millimeters), its diagnostic performance was assessed analyzing the area under the ROC curve. In a ROC curve the true positive rate (sensitivity) is plotted in function of the false positive rate (100-specificity) for different cut-off points of a parameter. Each point on the ROC curve represents a sensitivity/specificity pair corresponding to a peculiar measurement.
threshold. In this study, the area under the ROC curve was used to assess how precisely the rectoscopy measurements can distinguish between the two diagnostic groups (1= extraperitoneal/0= intraperitoneal location). The cut-off value <10 cm was considered the most suitable from a clinical viewpoint, since it was the lowest one to reach a 100% sensitivity, and it was further used to compare the diagnostic performance of rectoscopy with the other two modalities.
**Fig. 1:** Value of Diffusion Weighted Imaging (DWI) in the correct localization of tumor’s inferior edge. FSE T2-weighted sagittal image (A) demonstrates uneven mural thickening of the middle third of rectum, which is more evident in correspondence to the posterior wall (asterisk). The dotted line is drawn through the inferior edge of the rectal cancer, at the same level of the two axial images (B and C). FSE T2-weighted axial image (B), obtained at the level of the inferior tumor’s edge, shows thickening of the posterior rectal wall. The pathological tissue within the rectal wall appears as a clearly hyperintense area on the corresponding axial DWI sequence due to its high cellular content determining a notably restriction in the diffusion of water molecules (C). Below this level, the DWI sequence did not show any significant restriction in water diffusion within the rectal wall, thus confirming the exact position of tumor’s inferior edge.

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**Fig. 2:** FSE T2-weighted sagittal image (A) shows an extraperitoneal semi-circumferential rectal tumor (asterisks) in a 70 year-old woman who previously underwent hysteroanessiectomy. The anterior peritoneal reflection (arrowheads) is well appreciable as a thin hypointense linear structure that extends from the roof of the urinary bladder to its posterior attachment site on the anterior rectal wall (large arrow). FSE T2-weighted axial image (B) demonstrates the left and right aspects of the anterior peritoneal reflection (arrowheads in B) merging toward the midline to reach the anterior rectal wall (thin arrow).

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Fig. 3: Method of measurement of the distance between the anal verge and the tumor’s inferior edge. FSE T2-weighted sagittal image demonstrates an extraperitoneal tumor in the middle third of the rectum (asterisk). The anterior peritoneal reflection is well appreciable as a thin, hypointense linear structure that attaches posteriorly onto the anterior rectal wall (arrow). The two continuous lines were drawn to measure the distance between tumor’s inferior edge and anal verge. The dotted line in drawn through the S2/3 interspace.

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Results

Characteristics of patients

Sixty-six patients were included: 39 (59%) men and 27 (41%) women with a mean age of 69.4±9.6 years (range: 41-87 years). The mean height and weight of male patient were 174.5±10.1 cm and 73.7±8.4 kg, respectively, and the mean BMI was 23.9±3.2. The mean height and weight of female patient were 162.8±10.2 cm and 62.5±7.2 kg, respectively, and the mean BMI was 24.2±3.7. Three patients had a stage I (T1/2, N0, M0) rectal cancer, 11 patients had a stage II (T3 or T4, N0, M0) rectal cancer, and tumors belonging to stage III (T1/2, T3, T4, N1 or N2, M0) were present in 52 cases. The prevalence of extraperitoneal cancers was 53/66 (80.3%), while that of intraperitoneal cancers was 13/66 (19.7%). 30 patients (45.5%) underwent primary surgery, and 36 patients (54.5%) underwent surgery after fluoropyrimidine-based combined chemoradiation. After neoadjuvant therapy, no patient had a complete response; consequently, no patient was further excluded from the study. Anterior resection was performed in 13 patients (19.7%), TME in 51 (77.3%) cases, and transanal resection in only 2 patients (3%).

Image analysis

The APR was appreciable on all MRI examinations. The quality of individuation of the APR was defined excellent by the two readers in 25 (37.88%) MRI examinations, good in (50%) and poor in 8 (12.12%) cases. The mean distance from the anal verge to the ARJ on MRI examinations (mean length of the anal canal) was 30±7 mm, the mean distance from the anorectal junction to the APR was 66±16 mm, and the mean distance from the anal verge to the anterior peritoneal reflection on MRI examinations was 106±76 mm.

Comparison between of diagnostic performance of MRI, rectoscopy and bony landmark of the sacrum

MRI was characterized by an excellent diagnostic performance: sensitivity 98.15% (90.11% to 99.95%), specificity 100.00% (73.54% to 100.00%), positive predictive value 100.00% (93.28% to 100.00%), negative predictive value 92.31% (63.97% to 99.81%).

The value of the area under the ROC curve for RRS was 0.985 (standard error: 0.0112, 95%CI 0.919 to 1.000). Criterion values and coordinates of the ROC curve are reported in Table 1.

At a cut-off value <10mm the diagnostic performance of rigid rectoscopy was: sensitivity 100.00% (93.28% to 100.00%), specificity 76.92% (46.19% to 94.96%), positive predictive value 94.64% (85.13% to 98.88%), negative predictive value 100.00% (69.15% to 100.00%). The diagnostic performance of the bony landmark (interface between sacral

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vertebrae S2-S3) was: sensitivity 100.00% (93.28% to 100.00%), specificity 38.46% (13.86% to 68.42%), positive predictive value 86.89% (75.78% to 94.16%), negative predictive value 100.00% (47.82% to 100.00%) (Table 2).

Comparison between MRI and rectoscopy measurements of the distance between the inferior edge of tumors and anal verge

The mean distance of the inferior edge of tumors from the anal verge at rectoscopy (68±44.3 mm) was not significantly different from that obtained on MR images (73.5±42.4 mm) (p=0.25 Mann-Whitney test for independent samples). The two measurements were strongly correlated (Spearman’s coefficient of rank correlation (rho): 0.928; 95%CI for rho: 0.884 to 0.955; P<0.0001).

At Bland-Altman analysis, the arithmetic mean of differences (rectoscopy - MRI measurements) was -5.52 (95%CI -6.8 to 4.23) with a standard deviation of 5.22 (limits of agreement: -15.74 [95% CI -17.95 to -13.54] to 4.71 [95%CI 2.51 to 6.92]) (Figure 4), thus underscoring a trend of overestimation of MRI.
Table 1: Criterion values and coordinates of the ROC curve for rigid rectoscopy in assessing the location of tumors above or below the anterior peritoneal reflection. Legend: +LR, positive likelihood ratio; -LR, negative likelihood ratio.

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<table>
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<th>Criterion</th>
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<th>Specificity</th>
<th>95% CI</th>
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<th>-LR</th>
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<td>≤10</td>
<td>3.77</td>
<td>0.5 - 13.0</td>
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<td>0.64</td>
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<td>≤45</td>
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<td>26.5 - 54.0</td>
<td>100.00</td>
<td>75.3 - 100.0</td>
<td>0.60</td>
<td>0.53</td>
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<td>≤50</td>
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<td>33.3 - 61.4</td>
<td>100.00</td>
<td>75.3 - 100.0</td>
<td>0.53</td>
<td>0.30</td>
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<td>≤60</td>
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<td>53.7 - 80.1</td>
<td>100.00</td>
<td>75.3 - 100.0</td>
<td>0.32</td>
<td>0.15</td>
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<td>72.4 - 93.3</td>
<td>100.00</td>
<td>75.3 - 100.0</td>
<td>11.77</td>
<td>0.10</td>
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<tr>
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<td>79.3 - 96.9</td>
<td>92.31</td>
<td>64.0 - 99.8</td>
<td>12.26</td>
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<td>84.3 - 98.8</td>
<td>92.31</td>
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<td>12.26</td>
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<td>46.2 - 95.0</td>
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<td>25.1 - 80.8</td>
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<td>≤200</td>
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<td>0.00</td>
<td>0.0 - 24.7</td>
<td>1.00</td>
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Table 2: Diagnostic performance of MRI, rigid rectoscopy at the cut-off value <10mm and the bony landmark (S2/3 interface). Legend: PPV, positive predictive value; NPV, negative predictive value.

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<table>
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<th>Sensitivity</th>
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<th>NPV</th>
<th>Accuracy</th>
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<td>MRI</td>
<td>52/53 (98.15%)</td>
<td>13/13 (100%)</td>
<td>52/52 (100%)</td>
<td>13/14 (92.86%)</td>
<td>65/66 (98.48%)</td>
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<tr>
<td>Rectoscopy</td>
<td>53/53 (100%)</td>
<td>10/13 (76.92%)</td>
<td>53/56</td>
<td>10/10 (100%)</td>
<td>63/66 (95.45%)</td>
</tr>
<tr>
<td>S2-S3</td>
<td>53/53 (100%)</td>
<td>5/13 (38.46%)</td>
<td>53/61</td>
<td>5/5 (100%)</td>
<td>58/66 (87.88%)</td>
</tr>
</tbody>
</table>
Fig. 4: In this graphical method, the differences between the two techniques are plotted against the averages of the two techniques. Horizontal lines are drawn at the mean difference, and at the limits of agreement, which are defined as the mean difference plus and minus 1.96 times the standard deviation of the differences. The scatter diagram shows a trend of overestimation of MRI over rectoscopy measurements.

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Conclusion

The location of a rectal tumor above or below the PR has important treatment implications, since the different behavior of extra- and intraperitoneal cancers is mainly due to peculiar pathways of tumor spread, which are specific for each location [3]. From an anatomical viewpoint, the APR is a well-defined anatomic landmark at laparotomy, but the accurate preoperative identification of this structure is still a challenge. On clinical grounds, there is increasing clinical evidence that neoadjuvant therapy, consisting of combined chemoradiation, is not useful for intraperitoneal cancers. In addition, rectal cancers above the PR are often surrounded by loops of the small bowel, with an increased risk of morbidity from radiation enteritis. On the other hand, there is a risk of undertreatment and local failure, if a tumor with a prominent intraperitoneal location, but with its inferior edge below the PR, is treated as a pure sigmoid cancer. In this case, the lateral drainage of the extraperitoneal portion of the tumor to the internal iliac nodes, through the middle or inferior rectal lymphatics, is considered the primary cause of the high rate of pelvic recurrence. Therefore, choosing the optimal treatment for each patient is not easy in relation to the risk of under- or overtreatment. An immediate way to assess the location of a rectal tumor is digital exploration; with this method, all palpable tumors are considered to have an extraperitoneal location and, consequently, have to be treated by preoperative chemoradiation. Rigid rectoscopy provides a measurement of the distance of the inferior edge of tumors from the anal verge, eliminating the variability due to the possible folding of a flexible scope. Different trials of pre-operative radiation have enrolled patients with tumors located up to 16 cm from the anal verge. Using this cut-off measure, there is a concrete risk of overtreatment. In fact, according to our results, in front of a 100% sensitivity in detecting extraperitoneal cancers, the specificity drops down to 38.46%, potentially resulting in the inclusion of intraperitoneal tumours that would not benefit from unnecessary radiotherapy. A lower 12 cm cut-off value has been used in other trials [4]. In our study cohort, we found that a cut-off measure <10 cm is sufficient to reach a 100% sensitivity in detecting extraperitoneal cancers, preserving an acceptable specificity (i.e. 76.92%). This observation, despite the relatively low number of patients included in our study, is confirmed by the results of the Dutch TME trial, which showed no beneficial effect of radiotherapy for tumors above 10 cm [5]. In addition, we found that the mean distance of the PR from the anal verge corresponded to 10.6 cm. It seems straightforward that the greatest limitation of endoscopy relies on the lack of an optimal cut-off measure to distinguish extra- from intraperitoneal cancers, since the position of the APR varies significantly among individuals. The use of the anatomical bony landmark (i.e. S2/3 interface) on MRI sagittal images resulted in a high rate of false negatives (i.e. intraperitoneal cancers erroneously classified as extraperitoneal), since the straight line drawn parallel to the S2/3 interspace intersects the upper third of rectum near the recto-sigmoid junction, almost always above the APR. MRI is a well-established method for the loco-regional staging of rectal cancers, and a recent retrospective study has shown that expert abdominal radiologists can reliably appreciate APR on thin-section rectal MRI examinations. In our study, consensus reading of MRIs by
means of sagittal and axial sequences resulted in a consistent preoperative visualization of APR, assisting the clinical team in individualizing therapy. According to Gollub et al. [6], the tip of the seminal vesicles was an affordable landmark to assess the location of the most inferior aspect of the peritoneal membrane in men, while, in women, this thin hypointense anatomical structure was often appreciable in correspondence to the uterocervical angle in its posterior course toward to the anterior rectal wall. Poor image quality, motion artifacts, paucity of pelvic fat planes, retroversion of the uterus, and large exophytic rectal tumors are all causes that may hinder detection of the APR, which, on the contrary, can be easily recognized when a trace amount of fluid was present in the pelvic cul-de-sac of the peritoneal membrane. The diagnostic performance of MRI in distinguishing extra- vs intraperitoneal tumors was superior to both rigid rectoscopy and S2/3 interspace landmark.

In anatomy texts the level of the peritoneal reflection has been described as 7.5 cm from the anal verge in males and 5.5 cm in females. Some anatomic studies located the anterior peritoneal reflection approximately 8 cm and 6 cm from the anal verge in men and in women respectively, but all the measurements were performed in cadavers, so there was a difference to the rectum lengths of live humans. According to other authors [7] the peritoneal reflection, determined in living patients using intraoperative proctoscopy, is located higher on the rectum than reported in autopsy studies (9 cm for females, and 9.7 cm for males). Memon et al. determined the distance from the anal verge to the anterior peritoneal reflection in vivo by using intraoperative rigid sigmoidoscope: they found that the mean distance from the anal verge to the anterior peritoneal reflection was 11.9 cm in men and 10 cm in women [8]. Also Yun et al. [9] measured the pelvic anatomy in detail. They evaluate the surgical length of the peritoneal reflections from the anal verge by rigid sigmoidoscope during operation with a mean length of 8.8±2.2 cm, 8.1±1.7 cm in males and females, respectively.

Interestingly, the mean distance from ARJ to APR measured on sagittal MR images by our two readers (i.e. 6.6±1.6 cm) was similar to that reported by Gollub et al. (i.e. 6.7-6.9 cm). Also for the mean length of the anal canal, we obtained a value comparable to that retrieved by the previously mentioned authors (3±0.7 mm vs 3.6-4.1 cm) [6].

The major limitation of the present work relies on the relatively low prevalence of intraperitoneal cancers (19.7%) vs that of extraperitoneal ones (80.3%), but this is otherwise coherent with the common clinical practice and with previously reported series. In addition, the inclusion of patients who underwent preoperative chemoradiation may arise questions about the precision of the reference standard, since tumor’s shrinkage may have altered the position of the tumor’s inferior edge with respect to the APR. In particular, some extraperitoneal cancers with an intraperitoneal component may have erroneously been classified as purely intraperitoneal due to tissue shrinkage with elevation of their inferior edge above the APR. However, we checked all the extraperitoneal cancers with a component above the peritoneal reflection, finding that they were correctly classified as extraperitoneal at both preoperative MRI and surgical exploration. So, our reference standard can really be considered valid. Another minor
methodological limitation is that we used the anal verge as an imaging landmark, corresponding to the lower part of the external sphincter merging toward the midline. On clinical grounds, the anal verge corresponds to the junction of hair-bearing to non-hairbearing skin of the anus, and, indeed, some discrepancies may arise the MRI definition of this anatomical region. However, we found excellent correlation of MRI with rectoscopy measurements, concluding that the anal verge can reliably be assessed on sagittal MRI sequences, even if what is seen on MRI is not exactly what the surgeon can examine separating the patient's buttocks.

Conclusions

The results of our study confirm the great clinical value of MRI in determining the extra- vs intraperitoneal location of rectal cancers by the direct visualization of APR in a preoperative setting. MRI measurements of the distance between the tumor's inferior edge and the anal verge are optimally correlated with rectoscopy, with a trend of overestimation by MRI.
References


