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● *Original Contribution*

IMPROVEMENT IN T-STAGING OF RECTAL CARCINOMA: USING A NOVEL ENDORECTAL ULTRASONOGRAPHY TECHNIQUE WITH STERILE COUPLING GEL FILLING THE RECTUM

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Abstract—Our purpose was to study the accuracy of using endorectal ultrasonography (ERUS) with sterile coupling gels filling the rectum in the preoperative T-staging of rectal carcinoma. A total of 189 patients with confirmed rectal carcinoma were recruited. All underwent ERUS and surgery within the week following sonography. EURS was performed by introducing sterile coupling gel into the rectum. Two radiologists looked at the images at the same time and agreed upon staging. Rectal carcinoma was staged from Tis to T4. The accuracy of T-staging by ERUS was 89.95%. The sensitivity, specificity, PPV and NPV for ERUS at different stages were calculated. For early stage (Tis and T1), these values were 93.62%, 97.89%, 93.62% and 97.89%, respectively. ERUS filling with sterile coupling gel in the rectum overcomes the pressure effect from a water bath and the restriction caused by tumor stenosis, thus, greatly improving the accuracy of T-staging. The examination is real-time, safe and inexpensive. (E-mail: leuyf2@gmail.com) © **2012 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Endorectal ultrasonography, Rectum, Cancer, T-staging, Coupling gel.**

INTRODUCTION

The treatment of rectal cancer has been greatly improved in recent years (Gerard et al. 2006; Wolpin et al. 2007; Lin et al. 2008; Korkolis et al. 2007; Tytherleigh et al. 2008). Surgery is still the primary treatment for Tis to T3 stage tumors (Tytherleigh et al. 2008; Middleton et al. 2005). Tumors of stages 2 to 4 require preoperative chemoradiotherapy to decrease their size and stage. Stage 4 tumors require follow-up with postoperative or palliative chemoradiotherapy (Lin et al. 2008; Gavioli et al. 2007). Therefore, an accurate assessment of invasion depth or staging is particularly important in guiding treatment and is the major factor in determining prognosis (Wolpin et al. 2007; Karantanas et al. 2007).

Currently, endorectal ultrasonography (ERUS), computer tomography (CT) and magnetic resonance imaging (MRI) are the three main techniques used in preoperative staging of rectal carcinoma (Reddy et al. 2008; Krajewski and Kane 2008; Halefoglu et al. 2008; Dinter et al. 2008; Chun et al. 2006). It has been widely demonstrated that ERUS can clearly visualize the five layers of the rectal wall and is an accurate modality in assessing the local depth of tumor invasion into different layers of the rectal wall (Hildebrandt and Feifel 1985; Beynon et al. 1986; Reddy et al. 2008; Krajewski and Kane 2008; Bianchi et al. 2006; Radovanovic et al. 2008).

Past studies have typically used the water bath technique to fill the gap between the probe and rectal wall. In addition to using a water balloon, some used gel on the probe to facilitate visualization of the rectal wall and tumor. However, we find that when the water bath expands, it may compress the tumor. Additionally, the water bath cannot pass through stenosis created by the tumor (Taylan and Yusuf 2010; Saranovic et al. 2007, Berton et al. 2008, Bipat et al. 2004).

The aim of this study was to investigate whether direct injection of sterile coupling gel into the rectum could improve visualization of the rectal wall and tumor. To the best of our knowledge, there are no prior

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publications reporting the use of coupling gel to fill the rectum for study. We also studied the accuracy of this technique in the T-staging of rectal carcinoma by correlating our visualization results with the histopathologic finding.

MATERIALS AND METHODS

Patient selection

Between May 2008 and October 2010, 189 consecutive patients who had rectal carcinoma that was verified by postsurgical histopathologic examination were recruited in this study. All patients had undergone surgery within 1 week after ERUS. The patients were referred from the Department of Abdominal Surgical Oncology, Cancer Hospital, China. None had undergone chemoradiation therapy before surgery. Informed consent was obtained from all patients, and this study was approved by the institutional review committee.

Patient and coupling gel preparation

Before the ERUS examination, all outpatients were given senna (a Chinese herbal oral laxative) the day before. For all inpatients, pre-examination sigmoidoscopy was performed. The above procedures were to ensure that the rectal lumen was clear of debris. This allowed easier passage of the probe into the rectum and also optimized the images by freeing them of artifacts. Digital rectal examination was performed to document the presence of palpable masses, scars or stenotic lesions as well as to provide useful information about the anal canal anatomy.

As suggested by the AIUM Practice Guidelines, the instrument that was in direct contact with the mucous membranes underwent high-level disinfection rather than sterilization (AIUM 2009). However, since some patients in our study may have ulcers or internal wounds in the rectum, we needed to make sure that the gel introduced into the rectum did not cause infection in these wounds. We have chosen to use sterile gel in all cases. Therefore, the inner lining of the bottle is sterilized with hydrogen peroxide solution at room temperature. Then, commercially available sterile gel is squeezed into the sterilized bottle for use.

ERUS

All patients were studied in the left lateral decubitus position without sedation. The tip of the endorectal probe was covered with a latex condom, inserted into the anus and advanced into the rectum for preliminary evaluation of the tumor. The probe was then removed. We introduced 100 to 150 mL sterilized coupling gel into the rectum. The minimum length for the bottle nozzle must be 3.5 cm, and the bottle was discarded after use. The probe was reinserted to check the gel filling inside the rectum. If the filling was satisfactory, the five layers of the bowel wall and the tumor could be clearly seen. When there was stenosis, we waited for the gel to pass through the stenotic site before scanning. There was no need to pass the probe through the stenotic site. After the examination, patients expelled the coupling gel.

The ultrasound machine used in this study was the Philips iU22 unit (Philips, Bothell, WA, USA). An end-fire type endorectal probe (C5-9 sec) was utilized. The tumor position, size, morphology, echo pattern (mass or ulcer type) and internal vascularity as well as the localization of the rectal wall layers that were disrupted by the tumor were studied. The relative movements of the tumor with adjacent organs like the prostate, cervix or vagina was observed by applying pressure to the probe to confirm if there was any possible infiltration. All observations were recorded in our PACS system for offline evaluation. However, the presence of adenopathy in the perirectal space was not assessed.

Two radiologists (Y.W., Y.-Z.H.) who have over 10 years of experience in the preoperative staging of rectal carcinoma using ERUS performed the offline image interpretation simultaneously. They looked at the images at the same time. When there was discordance in staging, they reevaluated the images again and finally reached a consensus agreement. Before starting the study, the two radiologists received intensive training in ERUS using sterile coupling gel to fill the rectum in 10 cases during routine ERUS in our hospital (informed consent was obtained also).

The ultrasonographic staging of rectal carcinoma was based on the depth of tumor invasion and could be divided into five stages, from Tis to T4, according to the WHO classification (Taylan and Yusuf 2010; Hamilton and Aaltonen 2000). Tis is when the tumor invades the mucosa and muscularis mucosa only, leaving the submucosa intact. T1 tumors penetrate the submucosa layer. Tis and T1 are for early rectal cancer (Beynon et al. 1986; Radovanovic et al. 2008). T2 tumors penetrate the muscularis propria and merge with it. T3 tumors proceed beyond the muscularis propria and serosa, infiltrating the perirectal fat to a variable degree. In the last stage, T4, tumors infiltrate the adjacent organs such as the prostate or vagina and the adjacent levator ani muscle. The sonographic and histopathologic findings were compared.

Histopathology

The histopathologic findings were analyzed by two histopathologists (S.-M.L., X.-L.F.) who have more than 10 years of experience in gastrointestinal tumor analysis. The specimens were fixed by total immersion in buffered formalin for 48 h and were sliced transversely