

and up scaled to have pT4. Accordingly, at least 2/3 of the MRI staged T4 tumours before treatment still were pT4 after multimodal treatment.

**Conclusions:** The tumours were downstaged, but to lesser amount downstaged. If cure is the goal of the treatment, extended TME as *en-bloc* resections has to be performed. It is necessary to remove tumour as shown in pre-treatment MRI, as well as tumour, fibrosis and mucus as shown in MRI after post neoadjuvant treatment. MRI assisted pathology is an important option for better T-stage classification in advanced tumours, and essential for planning the extent of the surgical resection.

6016

POSTER

# One hundred cases of delayed coloanal anastomoses: the end of diverting stoma following total mesorectal excision?

S. Evrard<sup>1</sup>, J. Jarry<sup>1</sup>, M. Isambert<sup>1</sup>, C. Bellera<sup>1</sup>, T. Razafindratsira<sup>1</sup>, J.L. Faucheron<sup>2</sup>. <sup>1</sup>Institut Bergonie, Digestive Tumours Unit, Bordeaux, France; <sup>2</sup>Hôpital Albert Michalon, Service de Chirurgie Digestive, Grenoble, France

**Background:** Anastomotic leakage is the main drawback from rectal cancer surgery. Coloanal anastomosis with a J-pouch is protected by a diverting stoma in case of preoperative radiotherapy. The leakage rate is between 4 and 20% in the literature. This study aimed to assess the results of a pull-through procedure after total mesorectal excision (TME) followed by delayed coloanal anastomosis (DCA) without diverting stoma for mid and low rectal cancer, in terms of oncologic results, postoperative morbidity and mortality, and functional outcomes.

**Methods:** From May 2000 to October 2008, patients with mid and low rectal cancer underwent pull-through procedure with TME followed by DCA in two university centres. Patients with T3, T4 or N+ disease were treated with preoperative radiotherapy. Patient's data were prospectively collected in a database which was retrospectively analysed.

**Results:** One hundred patients with tumours at a median distance of 5 cm (range 2–12) from the anal verge underwent this surgical procedure. Seventy-five patients (75%) underwent laparoscopy and twenty-five patients (25%) underwent open route surgery.

The rate of complete microscopic resection (R0) was 96.4%. The actuarial overall and disease-free survivals were 81% and 66% at five years respectively. The postoperative mortality rate was 3%. The overall postoperative morbidity rate was 39% with 22 surgical complications including 10 pelvic sepsis requiring 7 diverting stoma (4 temporary and 3 definitive). After the second postoperative year, more than 70% of the patients had good functional outcomes (Wexner score <10).

**Conclusion:** In view of the oncologic results, postoperative morbidity and mortality, and functional outcomes, we can conclude that the pull-through procedure with TME followed by DCA is a safe and effective sphincter-preserving procedure that avoids a preventive diverting stoma for patients with mid or low rectal cancer. A prospective multicentric phase 2 will be launched in a near future.

6017

POSTER

# Retrospective analysis of resected primary colorectal cancer revealed no correlation b/w node harvest and node involvement

K. Khan<sup>1</sup>, M. Rathore<sup>2</sup>, V. Loughlin<sup>3</sup>, T.C.K. Tham<sup>4</sup>, M.I. Bhatti<sup>5</sup>, D. Allen<sup>6</sup>, R. Wilson<sup>7</sup>. <sup>1</sup>Northern Ireland Cancer centre, Medical Oncology, Belfast N. Ireland, United Kingdom; <sup>2</sup>Lagan Valley Hospital, General Surgery, Lisburn N. Ireland, United Kingdom; <sup>3</sup>Lagan Valley Hospital, Colorectal Surgery, Lisburn N. Ireland, United Kingdom; <sup>4</sup>Ulster Hospital Dundonald, Gastroenterology, Dundonald N. Ireland, United Kingdom; <sup>5</sup>Lagan Valley Hospital, Surgery, Lisburn N. Ireland, United Kingdom; <sup>6</sup>Belfast City Hospital, Pathology, Lisburn N. Ireland, United Kingdom; <sup>7</sup>NI Cancer Centre, Medical Oncology, Belfast N. Ireland, United Kingdom

**Background:** Lymphadenectomy in colorectal cancer is believed to be a critical component concerning prognosis and survival of patients. The aim of this study was to analyze the relationship between the number of lymph nodes harvested (LNH) and the number of lymph nodes involved (LNI), at the histological examination of the specimens of resected primary colorectal cancer (CRC) at our unit.

**Materials and Methods:** The study period is Jan 2002 – Dec 2006 inclusive (5 years). The data was obtained from medical records, pathology and radiology. The patient inclusion criteria were resection of primary CRC (curative or palliative intent) including synchronous or metachronous cancer. Exclusion criteria were recurrent CRC, cancer not operated, cancer not resected (stoma-only, open-close) and endomucosal resection. LNH and LNI were obtained. The data were analyzed and also compared with the literature and the national audit.

**Results:** Over the five-year study period, 142 resections for primary CRC were performed on 141 patients (one metachronous). Mean number

of resections per annum was 28. There were 86 (60.5%) colonic and 56 (39.5%) rectal cancers. There were 70 (49.3%) anterior resections. M:F ratio was 0.97:1. Median age was 71 years for colonic and 69.5 years for rectal cancers. Eighty eight percent of resections were elective (OR = 2.2 RR = 1.14 p = 0.003 compared to the national audit). Adenocarcinoma NOS constituted 94% of all histology results (5% mucinous and 1% signet ring). Median CRM was 7.5 mm (mean = 8.8 mm). The CRM involvement was 12.7% for all CRC and 16% for rectal cancers. The LRM involvement was 1.5%. Median overall LNH was 12, (mean = 13 p = 0.08 when compared to the recommended LNH of 12). Median LNH for rectal cancers = 11 and for colonic cancer = 13. There were 11 (14%) APRs compared to 70 (86%) sphincter-saving operations from a total of 83 rectal resections. 84% of resections were R<sub>0</sub>. The 30-day all-cause mortality was 4.3%. Actuarial survival curve demonstrated 17.6% chance of metastasis at presentation, all-stage 3-year disease-free survival (DFS) of 67% and of 82% for stages I-III (T<sub>any</sub> N<sub>any</sub> M<sub>0</sub>). CEA relapse as a marker of disease recurrence (available for n = 125) revealed 3-year DFS = 71%. When correlation was determined between LNH and lymph node involvement, it revealed a low correlation (r = 0.159 p = 0.06) which was statistically insignificant. When the national audit calculated the same relationship among its much larger sample the results were the same (r = 0.152 p = 0.001) and had achieved statistical significance.

**Conclusions:** LNI as a function of tumour and host behaviour is of prognostic significance whereas LNH may be a marker of 'pathologist's diligence' at the histological examination and therefore a quality assurance (QA) tool.

6018

POSTER

# Multimodal preoperative evaluation in surgical decision-making for rectal cancer: a randomized controlled trial

D. Lv<sup>1</sup>, X. Wang<sup>2</sup>, H. Song<sup>1</sup>, Q. Gao<sup>1</sup>, L. Yan<sup>1</sup>, J. Wu<sup>3</sup>, Y. Shi<sup>4</sup>, Z. Li<sup>5</sup>, L. Li<sup>2</sup>. <sup>1</sup>Sichuan University, West China School of Medicine, Chengdu Sichuan, China; <sup>2</sup>West China Hospital, Department of Anal-Colorectal Surgery, Chengdu Sichuan, China; <sup>3</sup>West China Hospital, Department of Radiology, Chengdu Sichuan, China; <sup>4</sup>West China Hospital, Department of Sonography, Chengdu Sichuan, China; <sup>5</sup>West China Hospital, Department of Laboratory Medicine, Chengdu Sichuan, China

**Background:** Multimodal preoperative evaluation (MPE) is a novel strategy for surgical decision-making, incorporating the transrectal ultrasound (TRUS), 64 multi-slice spiral computer tomography (MSCT) and serum amyloid A protein (SAA) for rectal cancer. The MPE system uses TRUS for T staging, MSCT for M staging, and assesses N stage based on MSCT with SAA for identification. This trial is to determine the accuracy of MPE in preoperative staging and role in surgical decision-making for rectal cancer.

**Material and Methods:** 225 participants histologically proved rectal cancer with tumor height (proximal from dentate line) less than 10 cm were randomly assigned into three arms in the ratio 1:1:1, according to a computer-generated randomisation list. Arm A (MPE) was multimodal staged by the combination of MSCT, TRUS and SAA. Arm B (MSCT+SAA) was staged by MSCT and SAA. Arm C (MSCT) was staged only by MSCT. The primary endpoints were the accuracy of preoperative staging and expected surgical procedures. The secondary endpoint was correlation between final surgical procedures and clinicopathological factors.

Table 1: The primary endpoints of three arms

Endpoints	Arm A n = 74	Arm B n = 72	Arm C n = 72	Arm A vs. B	Arm A vs. C	Arm B vs. C
Accuracy of preoperative T staging	94.6%	77.8%	80.6%	P = 0.003	P = 0.010	P = 0.682
Accuracy of preoperative N staging	85.1%	84.7%	69.4%	P = 0.944	P = 0.023	P = 0.029
Accuracy of preoperative M staging	100%	100%	100%	P = 1.000	P = 1.000	P = 1.000
Accuracy of preoperative TNM staging	82.4%	81.9%	70.8%	P = 0.939	P = 0.097	P = 0.116
Accuracy of surgical decision-making	96.2%	88.9%	80.6%	P = 0.106	P = 0.001	P = 0.087

**Results:** The accuracies of preoperative T, N, M and TNM staging were 94.6%, 85.1%, 100% and 82.4% in arm A, respectively; 77.8%, 84.7%, 100% and 81.9% in arm B; 80.6%, 69.4%, 100% and 70.8% in arm C. The analysis showed statistical difference in the accuracy of T staging between arm A and B (P = 0.003), arm A and C (P = 0.010). Accuracy of preoperative

N staging were significant different between arm A and C ( $P = 0.023$ ), arm A and B ( $P = 0.029$ ). Surgical decision-making in arm A was more accurate than that in arm C (96.2% vs. 80.6%,  $P = 0.001$ ). Pathological T stage ( $P < 0.001$ ), N stage ( $P < 0.001$ ), TNM stage ( $P < 0.001$ ), serum level of SAA ( $P = 0.002$ ) and tumor height ( $P = 0.030$ ) were significantly associated with final surgical procedures.

**Conclusions:** MPE is a powerful strategy in preoperative staging and more accurate than other available strategies in surgical decision-making for rectal cancer. The final surgical procedures are associated with pathological T, N, TNM stages, which MPE could dependably provide for surgical practice.

6019

POSTER

# Phase II XERT trial: Neoadjuvant cetuximab, capecitabine and radiotherapy (RT) in locally advanced resectable rectal cancer

V. Velenik<sup>1</sup>, J. Ocirk<sup>2</sup>, I. Oblak<sup>1</sup>, F. Anderluh<sup>1</sup>. <sup>1</sup>Oncology Institute, Radiotherapy, Ljubljana, Slovenia; <sup>2</sup>Oncology Institute, Medical Oncology, Ljubljana, Slovenia

**Background:** Preoperative chemoradiotherapy (CRT) with capecitabine is a widely accepted treatment for locally advanced rectal cancer. Tumor response may be further enhanced by the radiosensitizing effect of the EGFR-targeting monoclonal antibody, cetuximab. This prospective, non-randomized, open-label phase II study evaluated the efficacy and safety of cetuximab combined with capecitabine and concurrent RT for locally advanced resectable rectal cancer.

**Materials and Methods:** Enrolled patients (pts) with MRI-confirmed stage II/III rectal cancer received capecitabine 1250 mg/m<sup>2</sup> twice daily for 2 wks, followed by IV cetuximab 400 mg/m<sup>2</sup> at wk 3, then cetuximab 250 mg/m<sup>2</sup>/wk and capecitabine 825 mg/m<sup>2</sup> twice daily (including week-ends during RT). RT was started at wk 4 at a 45 Gy dose (25 × 1.8 Gy, 3D conformal technique). Total mesorectal excision was scheduled 4–6 wks after CRT completion with tumor regression grades (TRG) assessed using the Dworak system. The primary endpoint was complete pathologic response (pCR; TRG 4).

**Results:** A total of 37 pts were evaluable for efficacy and safety; 81% male; median age 55 (range 33–72) yrs. Four pts (10.8%) had T4N2 tumors, 15 pts (40.5%) T3N2, 1 pt (2.7%) T2N2, 13 pts (35.1%) T3N1, 1 pt (2.7%) T2N1, and 3 pts (8.1%) T3N0. The median tumor distance from the anal verge was 6 (range 1–11) cm. A pCR (TRG 4) was reported in 3 pts (8.1%), TRG 3 in 7 pts (18.9%), and T-, N-, and overall downstaging rates were 56.8%, 81.1%, and 73.0%, respectively. The total sphincter preservation rates were 75.7% and 53.0% in 17 pts whose tumors were located ≤ 5 cm from the anal verge. All pts received 45 Gy RT. Dose reduction or treatment interruption was required for 9 pts (24.3%) due to hypersensitivity reaction ( $n = 4$ ), grade 3 diarrhea ( $n = 4$ ), and grade 3 hepatotoxicity ( $n = 1$ ). Other grade 3 toxicities included dermatitis ( $n = 6$ , 16.2%), infection and anorexia (each  $n = 1$ , 2.7%). Eleven pts (29.7%) experienced non-fatal perioperative complications; 6 of whom had wound healing problems. One pt (2.7%) with anastomotic leakage and abdominal abscess and 1 pt (2.7%) with incarceration of transversostoma required reoperation, and 34 pts (91.9%) received postoperative chemotherapy. One pt died from sepsis after colonic necrosis and perforation.

**Conclusions:** Preoperative CRT with cetuximab and capecitabine is safe and feasible. While the pCR rate was in the range previously reported for CRT with capecitabine, a high pathologic downstaging rate was achieved.

6020

POSTER

# Large variation between hospital types and pathology laboratories in lymph node evaluation in colon cancer in the Netherlands and its impact on survival, a national population-based study

M. Elferink<sup>1</sup>, S. Siesling<sup>1</sup>, O. Visser<sup>2</sup>, H.J. Rutten<sup>3</sup>, J.H.J.M. van Krieken<sup>4</sup>, R.A.E.M. Tollenaar<sup>5</sup>, V.E.P.P. Lemmens<sup>6</sup>. <sup>1</sup>Comprehensive Cancer Centre North East, Department of Research, Enschede, The Netherlands; <sup>2</sup>Comprehensive Cancer Centre Amsterdam, Department of Research, Amsterdam, The Netherlands; <sup>3</sup>Catharina Hospital, Department of Surgery, Eindhoven, The Netherlands; <sup>4</sup>Radboud University Nijmegen Medical Centre, Department of Pathology, Nijmegen, The Netherlands; <sup>5</sup>Leiden University Medical Centre, Department of Surgery, Leiden, The Netherlands; <sup>6</sup>Comprehensive Cancer Centre South, Department of Research, Eindhoven, The Netherlands

**Background:** Adequate lymph node evaluation is important for staging and subsequent planning of treatment in patients with colon cancer. Adjuvant chemotherapy should be considered for patients with lymph nodes metastasis. A large variation in the number of evaluated lymph nodes exists. The aim of this study was to describe the influence of patient and tumour characteristics, hospital type and pathology laboratory on adequacy of

nodal examination, and to determine its relationship with stage distribution and survival.

**Methods:** Data from all patients with colon carcinoma stage I–III (pT1–4NanyM0) who underwent surgical treatment, diagnosed in the period 2000–2006 were retrieved from the Netherlands Cancer Registry. Multilevel logistic analysis was performed to examine the influence of relevant factors on the number of evaluated lymph nodes. The relation between pathology laboratories and stage distribution was assessed. Cox regression analysis was performed to analyse the association between the number of examined lymph nodes, the lymph node ratio and survival.

**Results:** The number of examined lymph nodes was determined for 29,551 (89%) of the 33,206 tumours. The median number of evaluated lymph nodes was 8, varying from 4 to 15 lymph nodes between pathology laboratories. Median number of lymph node count was negatively associated with volume of pathology laboratory and positively associated with volume of hospital. Females, younger patients, right-sided tumours, tumours with larger depth of invasion, tumours with nodal involvement and patients treated and evaluated in a university medical centre were less likely to have 9 or less lymph nodes evaluated. After adding these factors to the multilevel model, an unexplained variation between the pathology laboratories remained. This variation led to differences in stage distribution between the pathology laboratories, correlating with the median number of evaluated lymph nodes ( $p < 0.001$ ). With increasing number of evaluated lymph nodes, the risk of death decreased, both in patients with positive lymph nodes and in patients with negative lymph nodes. The risk of death increased with rising lymph node ratio in patients with lymph node metastasis.

**Conclusion:** There was a large diversity in lymph node evaluation among patients with colon cancer, with variation between pathology laboratories, leading to differences in stage distribution and being associated with survival. These results indicate that improvement in nodal sampling is needed in many pathology laboratories.

6021

POSTER

# Efficacy of chemoradiotherapy for the treatment of locally advanced squamous cell carcinoma of the rectum

M.C. Tronconi<sup>1</sup>, R. Doci<sup>2</sup>, M. Bignardi<sup>3</sup>, F. Sclafani<sup>1</sup>, N. Personeni<sup>1</sup>, S. Bozzarelli<sup>1</sup>, L. Rimassa<sup>1</sup>, M. Di Rocco<sup>4</sup>, A. Santoro<sup>1</sup>, C. Carnaghi<sup>1</sup>.

<sup>1</sup>Istituto Clinico Humanitas, Department of Oncology and Hematology, Rozzano Milano, Italy; <sup>2</sup>Istituto Clinico Humanitas, Surgical Oncology Unit, Rozzano Milano, Italy; <sup>3</sup>Istituto Clinico Humanitas, Radiotherapy and Radiosurgery Unit, Rozzano Milano, Italy; <sup>4</sup>Istituto Clinico Humanitas, Department of Pathology, Rozzano Milano, Italy

**Summary background data:** Squamous cell carcinoma (SCC) of the rectum is a rare pathologic entity, accounting for only 0.1% to 0.25% of all rectal cancers. Only 57 cases of colorectal SCC having been reported over a period of more than 60 years. From June 2006 to August 2008, six consecutive patients with squamous cell carcinoma (SCC) of the rectum were treated at the same Institution, according to protocols used for anal SCC.

**Methods:** All tumours were locally advanced and the clinical stage was T3N0M0 in 2 cases, T3N1M0 in 1, T4N1M0 in 2 and T3N2M1 in 1 case (lung metastases). Five patients received primary chemoradiotherapy and one received chemotherapy only due to previous pelvic irradiation. Radiotherapy was delivered to a target volume including primary tumor, internal and external iliac nodes and mesorectum. The minimum dose was 5.040 cGy; a boost dose to the primary tumor up to 5.940 cGy was given to three patients. Radiotherapy was associated with these chemotherapy schedules: 4 patients received 3 cycles of 5-fluorouracil (5-FU) (1000 mg/m<sup>2</sup>/day continuous infusion on days 1–4) and cisplatin (CDDP) (80 mg/m<sup>2</sup> on day 1) repeated every 3 weeks; 1 patient received 6 weeks of continuous infusion of 5-FU (225 mg/m<sup>2</sup> daily). One patient received 2 cycles of 5-FU (1000 mg/m<sup>2</sup>/day continuous infusion for 4 consecutive days) in combination with mitomycin-c (10 mg/m<sup>2</sup> on day 1) every 4 weeks; this patient received 2 additional cycles of chemotherapy at the end of radiotherapy because of the presence of metastases. The patient treated with chemotherapy alone received 2 preoperative cycles of 5-FU and CDDP repeated every 3 weeks. All patients concluded their treatment without a diverting enterostomy.

**Results:** Complete clinical response (CR) was achieved in 3 patients and partial response (PR) in 2. Disease stabilization (SD) was obtained in 1 case and no patients showed progressive disease (PD). Surgery was performed in 1 patient with PR and in 1 with SD. The patient with lung metastases received 4 courses of systemic chemotherapy. As of the last follow-up (FU) patients with CR were free of recurrence at 17 (cT4N1), 31 and 28 months (cT3N0). At a median FU of 18 months all patients are alive and all but the patient with metastasis are disease free.