non-inferiority of progression-free survival (PFS) obtained with IRIS in comparison with FOLFIRI.
Methods: IRI-naïve mCRC patients (pts) with one prior chemotherapy regimen, ECOG PS 0–1, and adequate organ function were randomized to receive either FOLFIRI (200 mg/m^2 of l-leucovorin given simultaneously with 150 mg/m^2 of IRI, followed by a 400 mg/m^2 bolus of 5-FU on day 1, and then 2,400 mg/m^2 of 5-FU over 46 h, every 2 weeks) or IRIS (125 mg/m^2 of IRI on days 1 and 15, and 40–60 mg/body of S-1 twice daily for 2 weeks, followed by a 2-week rest). Pts were stratified by institution, prior chemotherapy (with or without oxaliplatin), and PS. The primary endpoint was PFS. Secondary endpoints were overall survival, response, safety, and cost. A sample size of 200 pts per group was estimated to be necessary based on a median PFS of 4.0 months in each group and 80% power to demonstrate non-inferiority of IRIS with a 1-month margin (hazard ratio, HR = 1.333) and 1-sided alpha of 0.025.
Results: Between January 2006 and January 2008, 426 pts were enrolled. Baseline characteristics were well balanced. Pts received an average of 4.7 cycles (1 cycle = 4 weeks) of FOLFIRI (range: 0–20) and 4.9 cycles of IRIS (range: 0–23). The median relative dose intensity of IRI was 78.3% in both arms. Median PFS was 5.1 months (95% CI: 4.2–6.0) with FOLFIRI and 5.8 months (95% CI: 4.5–6.0) with IRIS. The adjusted HR for PFS was 1.077 (95% CI: 0.879–1.319) and the p value for non-inferiority was 0.039. The median survival time was 18.2 months (95% CI: 15.8–20.2) with FOLFIRI and 19.6 months (95% CI: 15.4–23.5) with IRIS (adjusted HR: 0.909; 95%CI: 0.699–1.181). The response rate (RECIST) was 16.7% (29/174) with FOLFIRI and 18.8% (34/181) with IRIS. The safety profile of IRIS was similar to that previously reported, with no unexpected toxicities. Grade 3/4 adverse events (FOLFIRI vs. IRIS) were neutropenia (52 vs. 36%), diarrhea (5 vs. 21%), vomiting (4 vs. 2%), mucositis/stomatitis (1 vs. 3%), fatigue (3 vs. 9%), and febrile neutropenia (1 vs. 5%). The average cost per cycle of chemotherapy (including supportive care) was significantly lower with IRIS.
Conclusion: IRIS was demonstrated to be non-inferior to FOLFIRI with respect to PFS as 2nd-line treatment of mCRC, thus it could replace FOLFIRI.

6013 ORAL

Quality assurance in rectal cancer treatment in the Netherlands: a catch up compared to colon cancer treatment

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Background: In the last two decades, treatment of rectal cancer has been substantially improved by the introduction of the Total Mesorectal Excision (TME) surgical technique together with effective neoadjuvant treatment regimens. In the Netherlands, TME surgery was implemented in a structural way within the framework of the TME trial (1996–1999). For the treatment of colon cancer, adjuvant chemotherapy was introduced in the late 1990's. Traditionally, survival after rectal cancer was inferior compared to colon cancer. The aim of this study is to examine the effects of the structural changes in rectal cancer care on survival compared to colon cancer for patients treated before, during and after the TME trial.
Material and Methods: We compared two-year overall survival of all patients with curatively resected colon (n = 15266) and rectal cancer (n = 5839) in the regions of Comprehensive Cancer Centres South and West between 1990 and 2005.
Results: Using a Cox proportional hazard model adjusting for age, gender and tumor stage, there was no difference in two-year survival between rectal cancer and colon cancer in the pre-trial period. However, in the post-trial period, two-year survival was higher for rectal cancer than for colon cancer. When comparing the pre-trial period with the post-trial period, two-year survival improved significantly for stage II and III colon cancer patients and for stage II and III rectal cancer patients.

		1990–1995	2000–2005	P
Rectal vs Colon	Hazard Ratio[1]	1.088		0.14
	Hazard Ratio[2]		0.844	0.003
Colon cancer	2 yr surv stage II	77.7%	80.1%	0.029
	2 yr surv stage III	62.3%	69.1%	<0.001
Rectal cancer	2 yr surv stage II	77.6%	85.1%	<0.001
	2 yr surv stage III	64.0%	78.6%	<0.001

[1]Compared to colon cancer 1990–1995. [2]Compared to colon cancer 2000–2005.

Conclusion: In the past 15 years, survival improved significantly for both colon and rectal cancer. Remarkably, the traditional survival backlog for rectal cancer compared to colon cancer has changed to a lead in the most recent years. This study shows the lasting effects that structural surgical training and quality assurance can have on survival outcome.

Poster presentations (Wed, 23 Sep, 09:00–12:00)
Gastro-intestinal malignancies – Colorectal cancer

6014 POSTER

Transanal Endoscopic Microsurgery (TEM) in Tubulovillous Adenoma and T1 rectal lesions

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Background: Transanal Endoscopic Microsurgery (TEM) is a minimal invasive technique for the local resection of Tubulovillous Adenoma and stage T1 rectal carcinomas in selected patients, associated with lower morbidity and mortality rates than open surgery. We report our initial results using TEM.
Methods: In 2002, TEM was introduced in our clinic. All patients undergoing TEM for tubulovillous adenoma or carcinoma between May 2002 and December 2007 were included in a prospective database.
Results: We included 105 patients: 54 men and 51 women. The median age was 68 years (range 46–94 years). The procedure was performed in 104 patients with curative intention and in 1 patient in a palliative setting. The median distance from the tumour to the anal verge was 7.0 centimetres and the median operating time was 90 minutes.
Peroperatively, 10 perforations occurred, all in high ventral or lateral situated tumours. In 2 of those 10 patients TEM was converted to (low) anterior resection. As a result of difficult access to the lesion or size of the lesion, but with an intact peritoneum, conversion to (low) anterior resection was also performed in 4 other patients (total conversion rate 5.7%).
Postoperative staging revealed 77 stage T0 tumours, 22 stage T1 tumours, 5 stage T2 tumours and 1 stage T3 carcinoma. In 89% of patients tumour resection was radical. In 6 patients an additional open resection was performed.
8 patients suffered from one of the following postoperative complications; urinary infection, urinary retention, pneumonia, atrial fibrillation, rectal bleeding or late perforation. (postoperative complication rate 7.6%).
Median length of stay in our hospital was 4 days. At this moment 8 recurrences occurred after a follow up ranging from 3 to 59 months (median follow up 27 months; recurrence rate 7.6%).
Conclusion: TEM is a safe curative operating technique, with low morbidity and recurrence rates. As such, TEM is the treatment of choice for tubulovillous adenoma and selected stage T1 rectal tumours.

6015 POSTER

Extended TME and MRI assisted pathology show high incidence of pT4 after neoadjuvant treatment

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Background: The clinical ability of pre- and post neoadjuvant magnetic resonace imaging (MRI) to predict the necessary extension of total mesorectal excision (ETME) in evaluation of the areas at risk in locally advanced rectal cancer. Evaluation of treatment response to chemoradiotherapy/radiation therapy in T4 stage tumours is difficult. MRI cannot detect small islets of tumour within fibrosis or mucin and not discriminate between different tissue components within a voxel. Increasing rate of late local relapses, also later than five years after treatment, have been reported from different studies.
Material and Methods: Prospective registration of 92 MRI evaluated T4a cancers undergoing multimodal treatment for rectal cancer between 2002 and 2007 in a Norwegian tertiary referral cancer centre. MRI was found to predict T-downstaging in 10% after neoadjuvant treatment. In 35% both MRI and histopathological examination staged the patients as T4 after treatment. Fifty-five percent (n = 51) of the patients were downstaged after the routine postoperative pathology work-up. A new technique with MRI-based sampling of areas of infiltration was introduced and dedicated histopathological evaluation of these threatened areas was performed.
Results: ETME was performed in 95% of the patients, mostly as en-bloc resections. After MRI focused pathology 50% of these 51were reclassified

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 downsized, 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?

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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 universitary 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 reveled no correlation b/w node harvest and node involvement

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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_0. 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_{any} N_{any} M_0). 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

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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