resection procedures. The majority of postoperative complications after pancreatoduodenectomy (PD) arise from pancreatic leakage by the pancreatic stump. The optimal management of the pancreatic remnant after PD remains a challenge. An interesting alternative option is the pancreatic stump occlusion technique with various methods. Our institution's eight-year experience using this approach in a selected group of patients is presented herein.
Materials and Methods: A retrospective study was performed in a nonselected series of 93 patients treated between 2002−09 with suspected pancreatic and periampullary cancer or chronic pancreatitis and were managed with Whipple's procedure. In 37 patients the pancreatic duct was occluded without anastomosis of the pancreatic remnant by stenting and a running 3−0 polypropylene suture, and in 56 patients a pancreaticojejunostomy was performed after PD. All patients were operated by the same surgical team.
Results: From the 37 patients two were treated for chronic pancreatitis whereas the rest of them for periampulla malignancies (including cancer of the pancreatic head). On the other group, from the 56 patients 9 were treated for chronic pancreatitis and the others for malignancies as well. The mean operative time for the occlusion group was 180 minutes versus 210 minutes in the anastomosis group. Mean hospitalization time was 6 days (4−11 days) for both groups. The mortality rate was 0% for the first group, and 3% (1 patient died of myocardial infraction and one of postoperative hemorrhage) for the anastomotic one. The morbidity rate was 24% in the occlusion group versus 32% in the latter one. From the postoperative complications a slightly higher incidence of pancreatic fistulas was observed at the anastomosis group of patients. Finally, there was no difference in one year survival rate among both populations. According to the literature the function of the islets of Langerhans is not affected by pancreatic duct occlusion. In our series there was no difference between the two groups neither to the patient needs of pancreatic enzymes replacement nor the diabetes incidence postoperatively. The decision for occlusion of the pancreatic remnant is directed by the pancreatic duct preoperative imaging (either ERCP or MRCP featuring an already occluded duct) or the intraoperative appearance of the duct.
Conclusions: Pancreatic remnant occlusion is a safe, time consuming and less complicated alternative management of the pancreatic stump during Whipple's procedure. Additionally, it does not affect the oncologic principles and long term survival of patients treated for cancer of the head of the pancreas.

2515 POSTER

Clinical Prediction of Survival by Surgeons for Patients With Incurable Malignant Disease

T. Hølmebakk[1], A. Solbakken[1], T. Mala[1], A. Nesbakken[2]. [1]*Oslo University Hospital, Department of Surgical Gastroenterology, Oslo, Norway;* [2]*University of Oslo, Faculty of Medicine, Oslo, Norway*

Background: Accurate prognosis facilitates decision-making and councelling in incurable cancer. However, predictions of survival are frequently inaccurate and survival is consistently overestimated. The prognostic skills of surgeons are sparsely documented, and the present study was undertaken to assess their prognostic accuracy for patients with advanced abdominal malignancy.
Patients and Methods: Clinical predictions of survival were made by three consultant surgeons independently in consecutive patients with incurable abdominal cancer. Survival was predicted in intervals ranging from <1 week to 18−24 months. Prognoses were considered accurate when actual survival fell within the expected range. Performance status was classified according to the Eastern Cooperative Oncology Group (ECOG).
Results: 243 assessments were made in 178 patients. Prognoses were accurate in 27%, over-optimistic in 42% and over-pessimistic in 31%. Accuracy was inversely related to lenght of survival and did not differ between surgeons ($P = 0.466$). The proportion of over-optimistic prognoses differed significantly between surgeons ($P < 0.001$). Prognostic accuracy was 44% in gastric cancer patients, 29% in pancreatic cancer patients and 22% in colorectal cancer patients ($P = 0.052$). ECOG performance status correlated well with survival.
Conclusions: Surgeons' accuracy in determining prognosis is poor. There are considerable individual differences between surgeons, and accuracy is reduced in cases with prolonged life expectancy.
Accepted for publication (in press) in the *European Journal of Surgical Oncology*, Eur J Surg Oncol (2011), doi:10.1016/j.ejso.2011.02.009.

2516 POSTER

Results of Surgical Reinterventions Following Colorectal Cancer Surgery: Open Versus Laparoscopic Reinterventions

D. Lips[1], R. Abegg[1], W. Brokelman[1], M. Ernst[1], K. Bosscha[1], H. Prins[1]. [1]*Jeroen Bosch Ziekenhuis, General Surgery and Surgical Oncology, Den Bosch, The Netherlands*

Background: Colorectal cancer surgery is performed frequently through both open and laparoscopic procedures. In as much as 15% cases a surgical reintervention is necessary. Although increasing data arises about primary laparoscopic colorectal surgery, less is known about the results of open and/or laparoscopic surgical reinterventions in case of complications. This study aims to investigate the morbidity and mortality derived from open and/or laparoscopic surgical reinterventions.
Materials and Methods: Retrospectively 87 consecutive patients operated upon between January 2008 and December 2010 were enrolled in the study. All patients underwent complicated colorectal cancer surgery, of which 58 patients were initially operated open followed by an open reintervention (open-open), 21 patients initially laparoscopic followed by an open reintervention (lap-open) and 8 patients with both laparoscopic procedures (lap-lap).
Primary endpoint was mortality. Secundary endpoints were complications classified according to the modified Clavien-Dindo scale, amount of reinterventions, total hospital stay, intensive care admissions and extent of stay, division rate and amount of radiological examinations.
Results: The three patient groups were comparable according to age, ASA-classification and comorbidity. Significant more Dukes D stage carcinomas and more acute initial presentations were observed in the open-open group.
A significant decrease in in-hospital mortality was seen in the total laparoscopic group (lap-open and lap-lap), independent of reintervention method (open-open 22.4%, lap-open 4.8% and lap-lap 0%). No significant differences were found in the secondary endpoints (total hospital stay, intensive care stay, amount of reinterventions, division rate and radiological examinations), although there was a trend towards decreased intensive care admissions and stay, total hospital stay and radiological examinations in the laparoscopic reintervention group.
Conclusion: Initial laparoscopic colorectal cancer surgery is related to less mortality and morbidity when complications arise, irrespective of the reintervention method. Best results seem to be reached when both primary and reintervention surgery is laparoscopic (lap-lap), although the presented study is biased by selection-bias and its retrospective character. However, these results should initiate prospective studies focussed on the precise role of laparoscopic surgery following colorectal cancer surgical complications.

Poster Discussion Presentations (Mon, 26 Sep, 13:15−14:15)

Symptom Science

3000 POSTER DISCUSSION

Effectiveness and Tolerability of Ferric Carboxymaltose in the Correction of Cancer − and Chemotherapy-associated Anaemia − a Multicenter Observational Study

H. Steinmetz[1], B. Tschechne[2], G. Virgin[3], B. Klement[4], B. Rzychon[5], M. Franzem[6], J. Wamhoff[7], H. Tesch[8], R. Rohrberg[9], N. Marschner[10]. [1]*Gemeinschaftspraxis für Onkologie und Hämatologie, Cologne, Germany;* [2]*Onkologische Gemeinschaftspraxis, Lehrte, Germany;* [3]*Vifor Pharma Deutschland GmbH, Munich, Germany;* [4]*Vifor Pharma Ltd, Glattbrugg, Switzerland;* [5]*Vifor Pharma Ltd, Freiburg, Germany;* [6]*iOMEDICO AG, Freiburg, Germany;* [7]*Onkologische Schwerpunktpraxis, Osnabrück, Germany;* [8]*Fachpraxis für Onkologie Hämatologie und Immunologie, Frankfurt, Germany;* [9]*Gemeinschaftspraxis und Tagesklinik für Hämatologie Onkologie und Gastroenterologie, Halle, Germany;* [10]*Praxis für Interdisziplinäre Onkologie und Hämatologie, Freiburg, Germany*

Background: Functional iron deficiency (FID; transferrin saturation [TSAT] <20% and ferritin >100 ng/mL) can cause low response to erythropoiesis-stimulating agents (ESAs). In different disease areas including oncology, intravenous (I.V.) but not oral iron enhances erythropoiesis in ESA-treated anaemic patients. This 12-week observational study evaluated the effectiveness and tolerability of ferric carboxymaltose (FCM) in routine treatment of unselected anaemic cancer patients.
Materials and Methods: 639 patients were enrolled and treated without restrictions at 68 haematology/oncology practices in Germany. 619

received at least one FCM dose (safety population), 420 had baseline Hb measurements within 10 days of first FCM dose (BL; effectiveness population), and 364 also had at least one follow-up measurement to assess Hb increase (primary endpoint). Transfused patients were censored from analysis prior to the transfusion. Data are shown as median (Q1, Q3).
Results: 91.2% of the effectiveness population (54.8% female, 67 years [58, 73]) presented with solid tumours (61.0% metastatic). BL Hb was 10.0 g/dL (9.1, 10.6), 75.6% had a TSAT <20% but 62.5% had a ferritin >100 ng/mL. Median total iron dose per patient was 1000 mg (600, 1500). Hb increase was comparable (1.4−1.6 g/dL) and significant vs. baseline ($p \leqslant 0.0001$) for transfused and not transfused patients with or without ESA supplementation. Patients with BL ferritin levels <100 ng/mL rapidly achieved median Hb levels ⩾11 g/dL (in 3−4 weeks, Tab.). Patients with BL ferritin 100–500 ng/mL also achieved Hb ⩾11 g/dL but slower (from week 7 onwards). FCM was well tolerated, 2.3% reported possibly or probably drug-related adverse events (AEs). One fatal case occurred after a possibly related respiratory failure. Two serious AEs of tachycardia and dyspnoea were unlikely related.
Conclusions: FCM significantly increased and stabilised Hb levels at 11−12 g/dL after week 5. This observational study suggests a role for I.V. iron alone in the correction of anaemia in cancer patients with absolute or functional iron deficiency.

	Median Hb			
	BL	Wk 5	Wk 7	Wk 12 or end of study
All uncensored (420)	10.0	11.1	11.3	11.5
All* (328)	10.0	11.1	11.6	11.9
Hb*				
<10 g/dL (152)	9.2	11.0	11.0	11.6
10−11 g/dL (128)	10.4	11.4	11.8	11.1
Ferritin*				
⩽30 ng/mL (65)	10.0	11.6	12.0	11.0
30-<100 ng/mL (29)	10.4	12.1	11.8	12.2
100–500 ng/mL (92)	10.1	11.0	11.7	11.6
TSAT*				
<20% (131)	10.0	11.3	11.6	11.4
⩾20% (39)	9.8	10.4	10.7	11.4
FCM*				
FCM no ESA (277)	10.0	11.1	11.5	11.9
FCM + ESA (51)	9.6	11.2	11.9	11.1

*Censored for transfusions.

3001 POSTER DISCUSSION

Ultra-low-molecular-weight Heparin (ULMWH) Semuloparin for Prevention of Venous Thromboembolism (VTE) in Cancer Patients Receiving Chemotherapy: Consistent Beneficial Effect Across Cancer Stage and Location Subgroups

G. Agnelli[1], D. George[2], W.D. Fisher[3], A.K. Kakkar[4], M.R. Lassen[5], P. Mismetti[6], P. Mouret[7], F. Lawson[8], A.G.G. Turpie[9]. *[1]University of Perugia, Perugia, Italy; [2]Duke University Medical Center, Divisions of Medical Oncology and Urology, Durham, USA; [3]McGill University Health Centre, Department of Orthopaedic Surgery, Montreal, Canada; [4]Thrombosis Research Institute and University College London, London, United Kingdom; [5]Glostrup Hospital, Glostrup, Denmark; [6]University Jean Monnet, Clinical Pharmacology Unit, Saint-Etienne, France; [7]Klinikum Frankfurt, Höchst, Germany; [8]Sanofi-Aventis, R&D, Bridgewater, USA; [9]McMaster University, Hamilton, Canada*

Background: VTE is a serious complication for cancer patients receiving chemotherapy. Semuloparin is a novel ULMWH with high anti-factor Xa and residual anti-factor IIa activities. We recently completed a multinational, randomized, placebo-controlled trial (SAVE-ONCO, NCT00694382, sanofi-aventis) to assess the efficacy and safety of semuloparin for thromboprophylaxis in cancer patients receiving chemotherapy.
Materials and Methods: Patients were eligible for inclusion in this double-blind study if they had metastatic or locally advanced solid tumours and were initiating a new chemotherapy regimen. Patients with creatinine clearance <30mL/min and requirement for/contraindication to anticoagulation were excluded. Patients were randomized to subcutaneous once-daily semuloparin 20 mg or placebo until change of chemotherapy regimen. The primary efficacy outcome was the composite of any symptomatic deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE) and VTE-related death. Any clinically relevant bleeding and major bleeding were the main safety outcomes.
Results: Of the 3212 patients randomized, 68% had metastatic cancer; 37% had lung, 29% colon-rectum, 13% stomach, 12% ovary, 8% pancreas, and 2% bladder cancer. Median treatment duration was 3.5 months. In an intent-to-treat analysis, treatment with semuloparin resulted in a 64% risk reduction in the incidence of the primary efficacy outcome versus placebo: 1.2% vs 3.4%; hazard ratio (HR) 0.36 [95% confidence interval (CI) 0.21–0.60], $p < 0.0001$. Treatment effect was consistent across DVT and PE with a 59% reduction in PE incidence; HR 0.41 [0.20–0.86]. No heterogeneity of treatment effect was detected for cancer stage (interaction p-value=0.3236) or location (interaction p-value = 0.7994): lung HR 0.36 [0.17–0.77]; colon/rectum HR 0.54 [0.18–1.60]; stomach HR 0.25 [0.03–2.20]; ovary (HR not applicable, 0 VTE in placebo, 1 in semuloparin); pancreas HR 0.22 [0.06–0.76]; bladder HR 0.30 [0.03–2.95]. Incidence of any clinically relevant bleeding was 2.8% with semuloparin vs 2.0% with placebo; HR 1.40 [0.89–2.21] and the incidence of major bleeding was similar: 1.2 vs 1.1%; HR 1.05 [0.55–1.99].
Conclusions: In cancer patients receiving chemotherapy, semuloparin significantly reduced the risk of VTE without increasing the incidence of major bleeding. No heterogeneity of treatment effect was detected across cancer stage and location. Thromboprophylaxis should be considered in cancer patients receiving chemotherapy.

3002 POSTER DISCUSSION

Venous Thromboembolism (VTE) in Cancer Patients Receiving Chemotherapy: a Real-world Analysis of VTE Risk and the Impact of VTE on Healthcare Expenditure

G.H. Lyman[1], Y. Wang[2], H. Wang[3], A.T. Cohen[4]. *[1]Duke University, Medicine, Durham, USA; [2]eTeam Inc, Bridgewater, USA; [3]Sanofi-Aventis, R&D, Bridgewater, USA; [4]King's College Hospital, Department of Surgery and Vascular Medicine, London, United Kingdom*

Background: VTE is an important complication in cancer patients receiving chemotherapy. The aim of this analysis was to determine VTE risk in cancer patients initiating chemotherapy and assess the economic impact of VTE occurrence.
Materials and Methods: The InVision™ Data Mart Multiplan database (US) was used to retrospectively identify patients with lung, pancreatic, stomach, colon/rectum, bladder or ovarian cancer initiating chemotherapy between 1/1/2005−12/31/2008; the first day of chemotherapy after cancer diagnosis was defined as the index date. Patients with ⩾12 months of continuous medical coverage prior to the index date and ⩾3.5 months during follow-up, and without prior VTE within 12 months, major bleeding within 3 months, or anticoagulant treatment within 2 weeks of the index date were included. The incidence of VTE was assessed at 3.5 and 12 months post-index. Healthcare costs (i.e. pharmacy, inpatient, emergency room, and outpatient costs) were assessed 1 year pre- and post-index.
Results: 30,552 eligible patients were identified. Patient baseline characteristics and VTE incidence by cancer location are summarized in the Table. Patients who developed VTE within 3.5 months post-index had comparable healthcare costs during 1 year pre-index ($37,542) to those without VTE ($35,342). However, during 1 year post-index, costs in patients with VTE were significantly higher ($110,362) than in those without VTE ($77,984), primarily driven by higher inpatient ($34,875 vs $16,834) and outpatient costs ($70,310 vs $57,397). These results were consistent when VTE was assessed 12 months post-index.

	3.5 months		12 months	
	Patients with VTE	Patients without VTE	Patients with VTE	Patients without VTE
Age, mean±SD, years	63.9±10.4	63.1±11.1	63.6±10.5	63.1±11.1
Female, n (%)	1100 (48.9)	13,524 (47.8)	2015 (48.6)	12,609 (47.8)
Charlson Comorbidity Index, mean±SD	6.98±3.22	6.25±3.26	6.30±3.20	6.30±3.27
n (%)				
Total	2248 (7.4)	28,304	4147 (13.6)	26,405
Bladder	130 (4.8)	2559	267 (9.9)	2422
Colon/rectum	683 (6.1)	10,462	1326 (11.9)	9819
Ovary	152 (6.2)	2299	279 (11.4)	2172
Lung	942 (8.5)	10,129	1642 (14.8)	9429
Stomach	97 (8.5)	1047	191 (16.7)	953
Pancreas	244 (11.9)	1808	442 (21.5)	1610

Conclusions: The risk of VTE in cancer patients 3.5 months after chemotherapy initiation ranges 4.8–11.9%; the highest risk is observed in patients with pancreatic, stomach, and lung cancer. The VTE risk continues to increase over a 1-year period. In addition, VTE is associated with a significant economic burden.