

**Diaphragmatic hernia as a rare complication after gynaecological oncological surgery. A case report and review of the literature.**

(Abstract ID: 19)

Dr. med. Sabine Schatz<sup>1</sup><sup>1</sup>Caritas Krankenhaus St. Josef, RegensburgIntroduction:

Symptomatic diaphragmatic hernias in adults are commonly acquired and therefore almost exclusively of post-traumatic nature. Delayed occurrence after abdominal surgery is a very rare complication. We present a case demonstrating the symptomatic progression of this resulting in acute abdomen.

Case presentation:

We present the case of a 58-year-old female with symptoms of an acute abdomen following debulking-surgery and peritonectomy for advanced serous-papillary ovarian carcinoma (FIGO IIIc). After initially uncomplicated postoperative course, adjuvant chemotherapy was performed with complete remission of the patient. Eight months after surgery she was admitted to our emergency unit due to signs of an acute abdomen with sudden abdominal and left shoulder pain. No complaints of dyspnea. In addition to inconspicuous laboratory results and ultrasound findings we initiated a computed tomography of the abdomen. Herein a diaphragmatic hernia on the left side with migration of parts of the stomach was revealed (Fig. 1). Due to signs of developing incarceration surgery was indicated. Because of massive intraabdominal adhesions a laparoscopic approach was not possible, so we had to perform open surgery.

Intraoperative findings: Left diaphragmatic hernia in the area of the trigonum lumbocostale, the diameter of the defect size was 3 cm (Fig. 2). After unproblematic reposition of the incarcerated gastric fundus the tissue showed a quick recovery. No ischaemic or necrotic areals were found. No pathological pulmonary affection, no chest drainage was necessary. Defect closure was performed by non-absorbable continuous suturing technique and augmented with bio-mesh (7 x 12 cm). The postoperative course was uneventful and the patient was released nine days after surgery.

Conclusion:

As prior mentioned, diaphragmatic hernia as a late complication after abdominal surgery is very rare. Due to management delays and misdiagnosis, they can become symptomatic as a life-threatening emergency. A conventional x-ray may be helpful, indeed computed tomography is the diagnostic gold standard. Only little data regarding the incidence and reports have been published on this subject. Here, we present a case report of a patient with a postoperative hernia who became acutely symptomatic eight months after surgery. The diaphragmatic hernia was managed successfully. Laparoscopic as well as open surgery are accepted as safe and promising procedures in hernia treatment. Late diagnosis of diaphragmatic hernias is frequent because of mostly non-specific symptoms; urgent surgery is indicated at the time of diagnosis.



Fig. 1

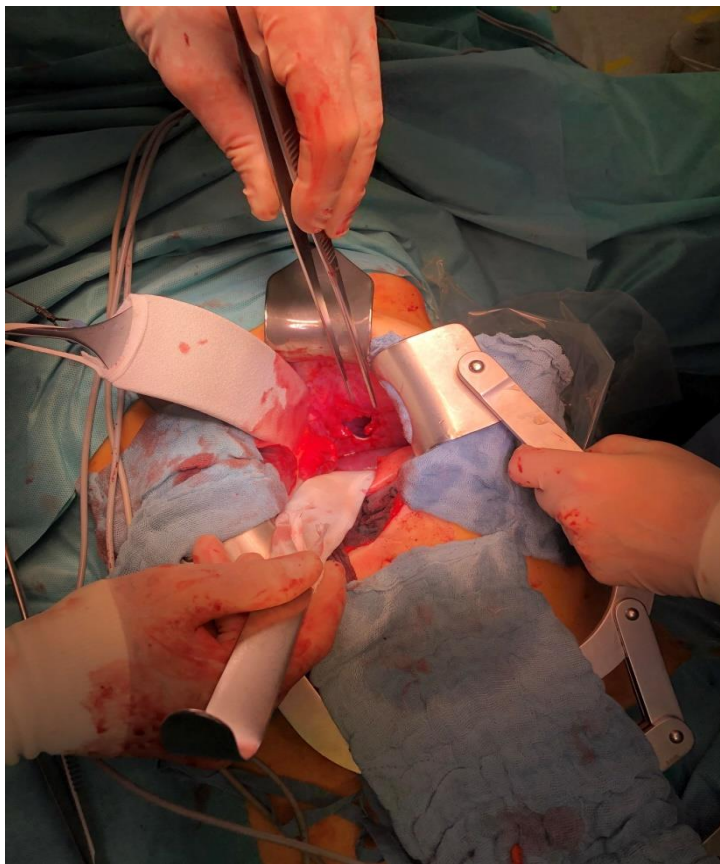


Fig. 2

**Extensive thoracic defect wound – preclinical management**  
(Abstract ID: 21)

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Report on 5 patients who had suffered a large thoracic defect wound due to massive violence. Two victims of the accident were hit by a train, one patient had fallen from a great height and one had been shot at close range with a shotgun. In the latter case, a broken flex disc had shattered the chest wall. The extensive tissue destruction, in one case with a traumatic arm amputation, and the massive bleeding, for example due to tearing of intercostal vessels, quickly led to a profound shock. Without aggressive preclinical care, victims usually die on the way to the clinic. In general, the following „damage control“ measures help to stabilize the seriously injured up to the emergency room. The destruction of the stabilizing bony structures and the resulting „paradoxically breathing“ quickly leads to hypoxia, which requires immediate intubation with controlled ventilation and an additional pleural drain. If heavy bleeding from the chest wall defect or from the pleural cavity forces a tamponade, this can provoke an „iatrogenic“ tension pneumothorax, which under certain circumstances leads to a circulatory breakdown in „seconds“. In this case, the immediate insertion of a large-lumen drainage is a „conditio sine qua non“. Foreign bodies should be left „in situ“ in order not to trigger mass bleeding by eliminating the tamponade effect. If large vessels (e.g. subclavian artery) are torn off, clamps are permitted as an exception („Life before limb“). In addition, accompanying measures should be used at an early stage, such as permissive hypotension to control bleeding, if craniocerebral trauma is excluded. To control trauma-induced fibrinolysis, intravenous administration of tranexamic acid (1 gram in 10 minutes) is recommended. Supported by the addition of warmth (emergency blanket, body warm infusions) to combat hypothermia, which leads to coagulation disorders. Due to the severe contamination of the wound, intravascular antibiotics should be administered preclinically. All trauma patients survived the transport to the hospital, unfortunately one of them died later (patient with the amputation). The remaining patients are able to work again.

**Abdominal compartment syndrome after transoesophageal echocardiography**  
(Abstract ID: 22)

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In a 77-year-old multimorbid patient (condition after multiple coronary stents), 2 mitralclips were inserted because of a high degree of mitral insufficiency using transesophageal echocardiography (TEE). Because of his poor general condition, monitoring was carried out in the intensive care unit. Fresh, partly coagulated blood was suddenly emptied via an inserted gastric tube, so that an emergency gastroscopy was carried out. A mucosal injury was found in the entire esophagus and a subcardiac perforation site covered with coagulum. When the surgical consilarius arrived, the patient was in a severe shock with a progressive bradycardia that was not controlled by medication with atropine. The clinical examination showed a monstrously inflated, bulging abdomen in the sense of an acute compartment syndrome. Because of the impending cardiac arrest, an emergency laparotomy was performed in bed under „semi-sterile“ conditions with explosive air evacuation. Immediately afterwards, the circulation had improved significantly. After transport to the operating room, the revision of the abdomen showed a long perforation of the anterior wall of the stomach (~ 20 cm) starting just below the cardia and extending to the lower third of the stomach. The heavily bleeding defect (anticoagulation!) could be securely closed with a two-layer suture. After prolonged intensive therapy, the patient was finally discharged after 3 weeks. An abdominal compartment syndrome with throttling of the venous return flow to the heart and massive impairment of the ventilation of the lungs due to a high level of the diaphragm can quickly develop into a life-threatening condition. The error in this case was that primarily symptoms such as bradycardia were treated with medication (e.g. atropine) without recognising the actual vital problem, the massive increase in abdominal pressure, because the clinical examination was not performed.

**Deficiency of the neuropeptide receptor activity modifying protein (RAMP)1 reduces liver regeneration by regulating YAP activity during acute or chronic liver injury**  
(Abstract ID: 24)

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**Background & Aims:** The high regenerative capacity of the liver allows for treatment of cancerous hepatic disorders by extensive surgery. High frequency of hepatocyte proliferation also takes place during chronic liver damage following liver fibrosis in patients, an essential mechanism to prevent liver failure. Sensory nerves innervating the liver release the neuropeptide calcitonin gene-related peptide (CGRP) which binds to the receptor activity-modifying protein (RAMP)1. Here, we investigate whether deficiency of the neuropeptide receptor RAMP1 affects liver regeneration upon partial hepatectomy and during hepatic fibrosis.

**Methods:** Wild type and RAMP1 deficient mice underwent either 70% partial hepatectomy (PH) or were injected biweekly with carbon tetrachloride (CCl<sub>4</sub>) for four weeks to induce liver injury. The amount of CGRP receptor components in liver tissues of both models was determined on the RNA-level by quantitative RT-PCR. Ki67- and BrdU-specific immunohistochemistry was used to quantify hepatocyte proliferation, and cell cycle regulatory components were analyzed on protein and RNA levels. Deposition of collagen fibers in the liver parenchyma was assessed by Sirius Red staining. Presence of fibrotic markers, including  $\alpha$ -SMA and collagen, was evaluated by western blot analysis. Influence of CGRP/RAMP1 on Hippo pathway was tested by the presence of global or active YAP, as well as active YAP-regulators LATS1/2 and MOB1 using western blot analysis. To test whether CGRP directly modulates YAP activity in hepatocytes or intact liver tissue, we stimulated primary hepatocytes or precision-cut liver slices with CGRP and analyzed global and phosphorylated YAP protein.

**Results:** During liver injury induced either by partial hepatectomy or CCl<sub>4</sub>-injection, expression of hepatic CGRP mRNA and RAMP1 mRNA were significantly increased. Acute and chronic liver damage caused prominent hepatocyte proliferation and induction of cell cycle proteins known to drive cell cycle progression. In absence of RAMP1, hepatocyte proliferation and expression of essential cell cycle regulators were severely reduced. During liver fibrosis, absence of RAMP1 impairs collagen deposition around liver lobules as well as hepatic stellate cell activation. Mechanistically, expression of the transcriptional coactivator YAP was found to be decreased in livers of RAMP1-deficient mice following either partial hepatectomy or 4-weeks' CCl<sub>4</sub> injection. In concordance, RAMP1 deficiency impaired the de novo synthesis of YAP target genes in regenerating livers. Phosphorylation of YAP on Ser127 and Ser397, which promotes YAP inactivation by its cytoplasmic retention and extranuclear degradation, was found to be elevated in RAMP1-deficient livers in both models. Consistently, phosphorylation of the YAP kinases LATS1/2 as well as MOB1 was upregulated. In vitro, stimulation of primary hepatocytes or precision-cut liver slices with the neuropeptide CGRP supports our in vivo results and identifies the CGRP/RAMP1 signaling axis as a previously unrecognized positive regulator of YAP activity.

**Conclusion:** Our study demonstrates that the neuropeptide CGRP via signaling to its receptor RAMP1 promotes liver regeneration through controlling YAP activity. This previously unknown signaling pathway might be highly relevant for patients with liver diseases.

**Keywords:** liver injury, calcitonin gene-related peptide (CGRP), Yes-associated protein (YAP)

**Analysis of vasodilative effects of endothelin-1 receptor antagonists and phosphodiesterase 5 inhibitors in normal vs pathological human pulmonary arteries in ex vivo organ bath model**  
(Abstract ID: 29)

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**Objective:** Proliferation and remodeling of pulmonary vessels are histological characteristic of pulmonary arterial hypertension and lead to right heart failure. Considering limitations of medical monotherapy we analyzed the combination of endothelin-1 (ET-1) receptor antagonists (ERA) and phosphodiesterase-5 (PDE-5) inhibitor in an ex-vivo model with human pulmonary arteries.

**Methods:** Segments of the pulmonary vessels were harvested from either lobectomy specimens of patients without diagnosed PAH (normal vessels) or resected lungs of patients undergoing lung transplantation (pathological). Contractile forces of pulmonary arteries were determined isometrically in an organ bath following the ascending dose-response curves of ET-1 and norepinephrine after pre-incubation with vasodilator drugs. Bosentan, macitentan, and its metabolite ACT-132577 were used as ERA, and vardenafil as a PDE-5 inhibitor.

**Results:** Combination of bosentan (1e-7 M) and vardenafil (1e-5 M) significantly reduced ET-1- and norepinephrine-induced vasoconstriction in normal pulmonary arteries, better than vardenafil or bosentan alone. Bosentan with 1e-6 M vardenafil and bosentan alone also showed significant effects compared to control. In pathological vessels combination of bosentan with 1e-5 M or 1e-6 M vardenafil significantly affected ET-1-induced contraction and bosentan and 1e-6 M vardenafil abated norepinephrine-induced contraction. Combination of bosentan and 3e-6 M vardenafil showed stronger inhibition of vasoconstriction than substances alone. Combination of macitentan 1e-7 M and vardenafil significantly inhibited vasoconstriction in normal arteries than either compound alone. Series with 3e-8 M or 1e-7 M macitentan and all series with ACT-132577 combined with vardenafil showed no additional effects of vardenafil. In pathological arteries vardenafil enhanced the effect of macitentan to reduce vasoconstriction only in combination with 3e-8 M macitentan.

**Conclusions:** Best possible inhibition of vasoconstriction was obtained by lower ERA levels if PDE-5 was inhibited concomitantly. Effects were similar but not identical in terms of drug doses in normal and pathological pulmonary arteries that may require in vivo careful dose adjustments.



**Results of oral/local antibiotic bowel decontamination in elective rectal surgery: A bicentric analysis of certified colorectal centers**

(Abstract ID: 49)

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**Background:** Randomized studies and registry data have shown that combined mechanical bowel preparation (MBP) and oral/local antibiotic decontamination (OAD) in colorectal surgery significantly decreases the risk of anastomotic leakage (AL) and surgical site infection (SSI). The relationship between AL and pathogenic bacteria was shown in experimental studies, which substantiated the potential benefit of OAD. However, OAD still has not reached general acceptance. Currently, rates of AL range between 11 to 19% after rectal resections for cancer in registry data in Germany. In the present study we aimed to address the effect of OAD on the incidence of AL and SSI in rectal cancer surgery in a routine setting.

**Methods:** We included 271 patients with rectal cancer undergoing oncologic resection with colorectal anastomoses in two certified colorectal cancer centers. Data collection was both retro- and prospective. In addition to mechanical bowel preparation (MBP) all patients received OAD, comprising Gentamicin 80 mg, Polymyxin B 100 mg, Amphotericin B 500 mg, and Vancomycin 125 mg over 7 days. Decontamination was started the evening before surgery and continued until day 7 postoperatively. Primary endpoint was the incidence of clinical relevant AL, secondary endpoints were all other surgical and general complications. In addition, complete application of OAD and side effects were recorded.

**Results:** Out of 271 patients included 165 were male (60.9%) and 106 female (39.1%), average age was  $68.1 \pm 10.3$  years. In 4.8% of the patients histology revealed no malignancy (adenoma or complete response after neoadjuvant treatment), in 20.3% we found stage I, in 18.5% stage II, in 16.6% stage III, and in 9.9% stage IV rectal cancer. There were 64 anterior rectum resections (AR) and 207 low anterior rectum resections (LAR); 196 patients received defunctioning loop ileostomy (72.3%). Laparoscopic resections were performed in 68 (25.1%) patients. Postoperatively, 15 AL (5.5%), 29 wound infections (10.7%), of which 14 were superficial, 6 deep and 9 were surgical site infections, as well as 2 wound hematomas (0.7%) were observed. Three patients developed pneumonia (1.1%), two patients had urinary tract infections (0.7%) and another two patients had cardiac events (0.7%). The total rate of infectious complications was 18.1%. One patient died as a result of AL (0.4%). In eight patients OAD was terminated prematurely (3.0%). Except for one unclear allergic exanthema (0.4%), no other side effects were observed. In seven patients clostridium difficile colitis was diagnosed (2.6%).

No AL (0%) and only four (6.3%) wound infections occurred after AR, while 15 (7.2%) AL and 25 (12.1%) wound infections developed after LAR.

**Conclusion:** Oral/local antibiotic bowel decontamination (OAB) is safe and effective in reducing infectious complications in rectal surgery. Our overall AL-rate of 5.5% and 0.4% mortality are considerably lower than results released from national registries of colorectal cancer centers.



# Mechanical failure of vertebro- (VP) and kyphoplasty (KP) in pathological osteoporotic vertebral fractures (OF) of the thoracic and lumbar spine - a 4-years follow up of the registry trial REPAOVERA

(Abstract ID: 55)

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**Introduction** A german multicenter study in A1 and A3 fractures showed an initial correction of the kyphotic angle of 12°-15°. Nevertheless, following dorsal instrumentation only, 6 months after hardware removal 7° were lost. Thus two operative procedures were performed for an average gain of 5 to 7° over the initial traumatic kyphosis. There is sparse information on the longterm results of OF either treated conservatively or by vertebro- or kyphoplasty.

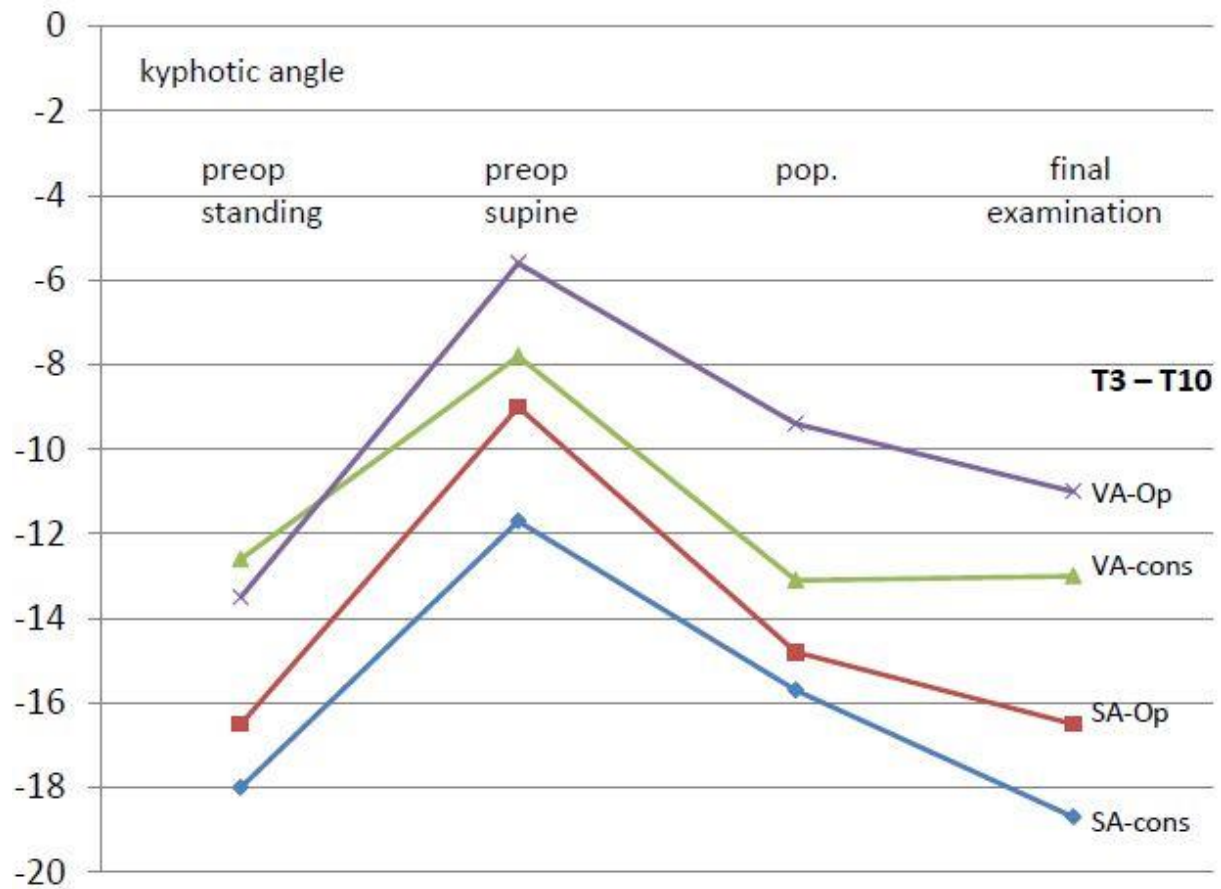
**Material and Methods** A prospective registry on pathological osteoporotic vertebral fractures (REPAOVERA), based on routine clinical parameters only, includes all OF patients presenting to the department for trauma and orthopedic surgery between 01.02.2006 and 31.10.2018. Data were collected by reviews of the clinical information system in 2 years intervals. No outpatient visit and not one x-ray examination were performed for study reasons only. Vertebral kyphotic angle (VA) and monosegmental kyphotic angle (SA) were measured in 49 lumbar (L3-5) and 46 thoracic (T3-10) fractures, on average 4 years p.op. (10-90%ile 21,4 - 134,3 months). Results were stratified according to conservative treatment (pain medication and physiotherapy, n=56) or operative treatment (VP / KP, n=39).

**Results** The theoretical difference between x-rays in standing or supine position is true for thoracic OF: the average difference of the kyphotic angle between standing and supine position (conventional x-ray vs. CT/MRI) is -6,7° for SA and -5,7° for VA. the respective numbers for L3- L5 are +1,1° and +1,6°, thus within measurement accuracy there is no difference. The figure demonstrates the longitudinal time axis analysis for the measurement time points "preoperative standing", preoperative supine position", "postoperative x-ray control" and "x-ray control at last follow-up" - on average 4 years postoperatively. Not only in the lumbar but also in the thoracic spine vertebral kyphotic angles 4 years p.op. come back to point zero, there is a difference of less than 2° in relation to the initial "trauma" situation. Even the monosegmental kyphotic angle shows no mechanical stability and returns to the pretherapeutic vertebral geometry. Especially bad result are found in the lumbar column, where the collapse of the posterior wall increased lordotic angles by +6.5° on average. None of the 55 routine parameters used in this registry allows for a prognosis related to the occurrence of vertebral collapse (M. Kümmel) or morphological stability.

**Discussion** Without doubt vertebroplasty or kyphoplasty are capable to reduce "posttraumatic" pain sensation, pain levels and pain duration. In this patient population operative treatment is ineffective regarding the reconstitution of normal local spinal alignment and profil. There is no difference between the results of vertebroplasty and kyphoplasty regarding structural stability. The development of secondary arthrotic deformity is not influenced. Looking at the possible complications of these procedures - a letality of 0,5 - 1% and the incidence of postoperative delir in 10-30% - the indication to perform these procedures should be scrutinised.

Fig. 1: Pre- and postoperative vertebral alignment in the thoracic spine. Kyphotic angles, stratified into VA-Op = vertebral angle, operative treatment, VA-cons = vertebral angle, conservative treatment and SA = monosegmental angle, either -Op, operative treatment or -cons, conservative treatment. Preop standing and supine respectively: Position in which the lateral x-ray was taken. P.op. = x-ray

within 2 weeks following the hospital admission. Final examination = x-ray in standing position, on average 4 years p.op.



**Spleen tumor 6 months after birth**  
(Abstract ID: 62)

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A 28 year old patient was admitted to hospital due to increasing abdominal pain with a feeling of fullness. She had given birth to a healthy girl 6 months earlier. The course of the pregnancy was without any abnormalities. The MRI showed a large, palpable mass in the left upper abdomen with suspected splenic cyst. The laboratory values were normal except for a slightly reduced hemoglobin (11,9 g/dl). Due to the increasing pain symptoms, a median laparotomy was performed, which revealed a monstrous tumor (20 cm in diameter), which, among other things, had caused the left kidney to displace and had caused a massive vascular congestion in the omentum. Because of the size of the tumor, the spleen could only be mobilized and extirpated after the splenic vessels had been ligated. Macroscopically a blood-filled cyst was found which had taken up about half of the spleen. The histological assessment identified a benign pseudocyst with a central necrosis, as well as abundant granulocytes, mesothelia and numerous erythrocytes. After evaluating all the findings, there was a pseudocyst in our case that was caused by hematoma resorption. After the patient denied any previous trauma, a birth trauma must be assumed, especially since the sonographic checks carried out during the pregnancy abuse were always unremarkable. Ultimately, the patient was able to be discharged home symptom-free. Criticism: The increasing pain was primarily not taken seriously and underestimated as a "pregnancy-related" problem. A simple upper abdominal sonography would have been sufficient to clarify the symptoms at an early stage. In the worst case, the rupture of the spleen could have been fatal !

**Influence of the gut microbiome on liver regeneration**

(Abstract ID: 86)

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**Aims**

The adult liver has a high regenerative capacity, enabling extensive partial resections of up to 75%, if the remaining liver parenchyma is functional. The cellular programs involved in liver regeneration, notably control of hepatocyte proliferation, are still incompletely understood. However, postoperative liver failure leads to considerable morbidity and mortality. Recently, liver-extrinsic factors, such as the gut microbiome and microbial-derived metabolites, were proposed as crucial contributors to liver regeneration. In our preliminary investigations on mouse models, we found that a large part of the lipid synthesis in hepatocytes relies on microbial metabolites (short chain fatty acids). We therefore postulate that the gut microbiome provides factors via the portal vein that are necessary for the proliferation and growth of hepatocytes, such as precursors for lipid synthesis. The aim of this study was to test the importance of the gut-liver-axis, and in particular the intestinal microbiome, in a preclinical model.

**Methods:** A partial liver resection (PHx) was carried out in C57Bl/6 mice, whereby conventionally kept control animals (SPF) were compared with mice treated with germ-free animals and with animals that were re-colonized with an established minimal microbial consortium. The expression of proliferation marker genes was examined with qPCR, the lipid synthesis using mass spectrometry, histology by immunohistochemistry on fixed tissue sections. All animals used were of the same age, sex, genetic background and feeding.

**Result:** While conventionally kept animals, as well as animals with defined microbial minimal flora, tolerated the PHx well without mortality, the germ-free mice from a gnotobiotic facility showed a significantly worse course after the intervention. The expression of enzymes in lipid synthesis and cell cycle markers was significantly reduced in the liver parenchyma of germ-free animals.

**Conclusion:** The intestinal microbiome may have a pronounced positive effect on liver regeneration in the preclinical animal model, presumably mediated by soluble microbial factors that enter the liver via the portal vein.

**Therapy of metastasised primary liposarcoma of the pancreas**

(Abstract ID: 126)

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**Introduction:** Liposarcoma are most frequent in soft-tissue sarcomas covering 15-20% of all mesenchymal tumors. They are mostly located at limbs and in the retroperitoneal space. Visceral liposarcomas are very rare and primary location in the pancreas is seen as a rarity. We report the treatment of metachronic metastases of a primary liposarcoma of the pancreas.

**Case report:** A 66-years old patient underwent left-sided pancreatectomy and splenectomy due to diffuse lesion. Histology showed primary liposarcoma of the pancreas, so adjuvant radiation with 54 Gy was added. Tumor after-care was uneventful until 2017, when livermetastasis occurred. This was cured by resection of the left-lateral lobe. 12/2018 suspicious nodules were found bipulmonary, which were wedge- resected after neoadjuvant chemotherapy (adriamycin and ifosfamide). They also turned out to be metastasis of the liposarcoma. In the further course, we found new pulmonary nodules as well as bony metastasis in 9<sup>th</sup> rib. This lesion could also be resected in sano and histology showed again metastasis of the pancreatic liposarcoma. Local relapse never occurred surprisingly, although sarcoma was meanwhile completely dedifferentiated and classified as high-grade sarcoma. These sarcomas show local relapse- rates of more than 40%. Further treatment was recommended as chemotherapy again due to residual filiae of the lung, followed by resection again, to achieve R0-stage. The patient is in good condition and symptom-free.

**Summary:** Primary liposarcoma of the pancreas are rare. In literature only seven cases are reported since 1979, in only one case the tumor was dedifferentiated and was treated with radiochemotherapy. Reports on therapy algorithms in metastatic stages are missing. The course of our case shows that multimodal therapy can lead to long-term survival also in advanced disease. An aggressive surgical/ systemic treatment seems to be indicated in motivated and otherwise healthy patients.

**Multicenter prospective cohort study of PATient-Reported Outcomes and complications following major abdominal Neoplastic Surgery (PATRONUS) - a CHIR-Net SIGMA trial**  
(Abstract ID: 132)

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**Background:** SIGMA (Student-Initiated German Medical Audit) is the first national wide student research network in Germany and part of the CHIR-Net. The project introduces young medical students to clinical studies by making them responsible for planning, organization, execution, assessment, and publication – accompanied by experienced doctors (<https://www.sigma-studies.org>). SIGMA also regularly offers Clinical Investigator Training sessions to instruct participants and therefore ensure the highest quality of study.

PATRONUS is the pilot project and concentrates on the following subject:

Modern and personalized medicine have increased complication-free procedures and survival rates. By that, the relevance of patient satisfaction and their quality of life have become a highly relevant factor in medical care. These subjective values can be objectified by Patient Reported Outcomes (PRO). By being evaluated by the patients themselves they are based on their personal perception of disease and treatment. Still, the objective clinical outcome will remain an important measure for treatment success. These important relations and correlations yet remain unclear, PATONUS aims to investigate correlations between objective and subjective outcomes and examines the value of currently established PROs in oncological patients undergoing abdominal surgery.

**Material and methods:** PATRONUS is a multicenter prospective observational cohort study. The chosen endpoints are: The clinical outcome including complications up to 30 days post-surgery (short term outcome) as well as the six-month overall survival (long term outcome). Two sets of PROs for quality of life were evaluated: a) the cancer- specific EORTC QLQ-C30-questionnaires and b) the PRO-CTCAE, including 12 cancer associated symptoms. The follow-up included eight clinical visits altogether within six months. The obtained information was recorded using an electronic case report form. Statistical planning and analyses are performed by the IMBI Heidelberg. Data is analyzed on correlation and regression to determine associations or rather differences between complications, clinical findings, PROs as well as different tumor entities.

**Results:** 351 patients were recruited and regularly visited. The study simultaneously evaluates the students' and young doctors' ability to conduct clinical trials. Altogether, 148 trained medical students in 15 active SIGMA sites (with the respective agreement of their ethics commission) across Germany were part of the data gathering. SIGMA was successfully established as the first German-wide student research network. A draft for data analysis was created in a SIGMA-organized "Student Workshop for Analysis and General Statistics" by the students (SWAG) and is currently reviewed by the Institute for Medical Biometrics and Informatics (IMBI) Heidelberg and a manuscript for publication is prepared.

The study is conducted and organized by the student-led German Clinical Trial Network SIGMA.

Trial registration: Deutsches Register Klinischer Studien (DRKS, German Clinical Trials Register): DRKS00013035, UTM U1111-1202-8863. Registered on 26.10.2017.

**Multicenter randomized controlled trial exploring postoperative complications and mobilization following major abdominal surgery with vs. without fitness tracker-based feedback (EXPELLIARMUS) - a CHIR-Net SIGMA trial (O)**  
(Abstract ID: 133)

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**Background:**

Early mobilization following major abdominal surgery (>500 ml blood loss or >2 h planned operation time) not only is an important step in recovery but also has been advocated to reduce postoperative complications. Thrombosis, associated embolisms, pneumonia, bedriddenness and therefore lack of independence are frequent and considered to be connected to a lack of physical activity. Early and enhanced postoperative mobilization has been advocated to reduce postoperative complications. /However, it is still unclear whether and to which extent it can independently improve the outcome after major surgery. Fitness trackers (FTs) are a promising tool to improve postoperative mobilization, but their effect on postoperative complications and recovery yet has to be further investigated in clinical trials.

**Materials and methods:**

EXPELLIARMUS is a multicentre randomized controlled trial conducted by the SIGMA (Student-Initiated German Medical Audit) study group. Associated to the CHIR-Net trial network it is carried out by medical students from 15 German university hospitals and is the first interventional multicentre student-initiated randomized controlled trial (RCT) in Germany.

The Aim of this study is to investigate, whether the implementation of a simple mobilization protocol in combination with FT-based feedback can reduce postoperative morbidity in patients undergoing major abdominal surgery and therefore improve the postoperative outcome.

Patients receiving major visceral surgery will be screened for eligibility and then assigned randomly to either the interventional or control group, both receiving a FT device for the length of their stay in the clinic or for a maximum of 30 days. The interventional arm is receiving step goals and FT-feedback about daily steps done. The control group, however, is mobilized according to hospital standards and receives a FT with a blackened screen; thus, no feedback regarding physical activity is given. A total of 348 patients will be included. The data is saved using an electronic case report form. Statistical planning and analysis are performed by statisticians from the IMBI (institute for medical biometry and informatics, Heidelberg).

**Results:**

Primary endpoint of the study is to determine whether daily postoperative step goals and feedback via a fitness tracker significantly reduces the rate of postoperative complications following elective major abdominal surgery by comparing postoperative morbidity within 30 days measured via the Comprehensive Complication Index.

Secondary endpoints include number of steps, a set of functional, morbidity and safety parameters as well as the evaluation of feasibility and performance of student-initiated and student-conducted multicentre RCTs measured by the completeness and accuracy of the data.

Heretofore 232 patients have been included in the prospective multicentre randomized controlled trial in ten centres. The great effort and thorough preparation of involved medical students are reflected in a data completion rate of 90,4%.

Three extensive Clinical Investigator Training (CIT) were held in order to train and brief students, mediating knowledge and skills in order to empower medical students to self-reliantly participate in clinical research. So far over 60 medical students have been educated and trained, who then taught their peers (student-teaching-students) to become competent clinician scientists.

The study is conducted and organized by the student-led German Clinical Trial Network SIGMA. Trial registration: Deutsches Register Klinischer Studien (DRKS, German Clinical Trials Register): DRKS00016755, UTN U1111-1228-3320. Registered on 06.03.2019.



**Perioperative Selective Intestinal Decontamination (SID) in patients with Hinchey 2b perforated Sigmoid Diverticulitis**  
(Abstract ID: 135)

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**Background:** Surgical site infections (SSIs) and anastomotic leakage (AL) are common complications in acute colorectal surgery and not only cause prolonged hospitalization but also increased patient mortality. Shogan et al. showed that the bacterium *Enterococcus faecalis* contributes to the pathogenesis of anastomotic leakage through its capacity to degrade collagen and to activate tissue matrix metalloproteinase 9 (MMP9) in intestinal tissues. This effect can be substantially decreased by perioperative selective intestinal decontamination (SID). Recent reports reveal that SID has a positive effect on healing of the colonic anastomosis in elective surgery. The aim of this analysis is to evaluate the impact of SID on patients with Hinchey 2b perforated sigmoid diverticulitis.

**Methods:** Between January 2015 and January 2020, we performed 617 colorectal surgeries with primary anastomosis at our clinic. 214 patients with Hinchey 2b perforated sigmoid diverticulitis underwent a primary descendrectostomy with no protective ileostomy. In the period from September 2018 to January 2020, 67 of these patients received a preoperative SID consisting of Neomycin (capsules) and Metronidazole according to the following scheme: the day before surgery, a colon cleansing with osmotic laxatives was performed, followed by oral application of 1 g Neomycin and 0,8 g Metronidazole at 19:00 h and 23:00 h. 30 min before the surgical intervention, patients received 500 mg Neomycin oral and 400 mg Metronidazole intravenously. After surgery, 400 mg Metronidazole were given orally twice a day for another 5 days.

**Results:** 62 patients (92,5 %) completed SID, 5 patients (7,5 %) discontinued SID due to side effects like nausea and vomiting. Of the patients who underwent surgery after SID, 2 (2,9 %) patients developed an AL and 5 patients (7,5 %) developed SSIs. Compared to patients who underwent surgery with no SID, matched-pair analysis of patients during the time period of 2015 to 2018 (n = 147), the postoperative complication rates were noticeably higher (AL 4,1 % (n = 6), SSI 9 % (n = 13)).

**Conclusion:** First results after introduction of SID in patients suffering Hinchey 2b perforated sigmoid diverticulitis indicate that SID may help to reduce anastomotic leakage and surgical site infections.

**Success rate of percutaneous transhepatic cholangiodrainage (PTCD) placement in patients with leakage of the biliodigestive anastomosis after pancreaticoduodenectomy**  
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**Aim:** The aim of this work was to determine the success rate of interventional transhepatic treatment of patients with leakage of the biliodigestive anastomosis (BDA) after complex pancreaticoduodenectomy.

**Methods:** During the time period of January 2017 to December 2019, 96 complex pancreatic resections for either tumors or chronic pancreatitis were performed. As part of this analysis, the clinical course of patients with percutaneous transhepatic cholangiodrainage (PTCD) and the indication for surgical revision were evaluated. Furthermore, we analyzed the duration and outcome of BDA leakage after treatment with PTCD.

**Results:** 64 out of 96 patients received a BDA after pancreaticoduodenal resection or pancreatectomy. 8 patients (12,5 %) developed anastomotic leakage. Bile leakage was identified by elevated bilirubin concentration measured in abdominal drainages, typically 3-4 days after surgery. 2 patients (3,1 %) with less than 100 ml drainage secretion per day, did not need any further interventions and bile leakage stopped spontaneously. 6 patients (9,4 %) received PTCD placement via not dilated intrahepatic bile ducts. In an average of 49 days after PTCD placement, BDA leakage was successfully treated in all cases.

Because of complete necrosis of the bile duct, surgical revision was necessary in 1 patient to subtotally resect the necrotic bile duct and a Roux-en-Y anastomosis to jejunum was performed, followed by placement of a transhepatic Neuhaus drainage.

In a second patient (BMI 57) reanastomosis of the BDA was necessary after spontaneous aneurysmatic rupture of the right hepatic artery and unsuccessful endovascular embolization.

The 90-day mortality rate of all patients was 0 %.

**Conclusion:** PTCD placement in patients with BDA leakage is technically demanding since most patients do not show any dilation of the intrahepatic bile system. If PTCD placement has been performed successfully, complete healing of BDA insufficiencies was possible in all cases. Using this interventional radiological technique, postoperative surgical revisions and mortality rates can substantially be reduced.