

## ESGE Newsletter

### Current ESGE News

### Upcoming Events

European  
Society of  
Gastrointestinal  
Endoscopy



#### EURO-NOTES 2010

#### 4<sup>th</sup> joint European NOTES Workshop

#### September 9–11, 2010

#### Rome, Italy



The following ten abstracts were chosen for presentation at the upcoming EURO-NOTES 2010 Workshop, a combined activity of the European Association for Endoscopic Surgery (EAES) and ESGE.

For more information please visit  
[www.euro-notes-org/workshop](http://www.euro-notes-org/workshop)

#### Find more information on ESGE activities at [www.esge.com](http://www.esge.com)

or contact the ESGE Secretariat:

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#### Gastric emptying is delayed in transgastric NOTES compared with other NOTES approaches and laparoscopy: a randomized study in a survival porcine model

Córdova H, Rodríguez A, Guarnier-Argente C, Martínez-Pallí G, Navarro-Ripoll R, Rodríguez de Miguel C, Beltrán M, Comas J, Martínez MA, Delgado S, Lacy A, Ginès A, Pellisé M, Llach J, Fernández-Esparrach G  
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**Objective:** To evaluate the restoration of gastrointestinal motility after NOTES using capsule endoscopy (CE), after transgastric NOTES (TG), transrectal NOTES (TR), transvaginal NOTES (TV) and laparoscopy (Lap).

**Methods:** Adult Yorkshire pigs were randomly assigned to four groups. Animals were kept NPO for 24 hours prior to procedure and pre- and post-op antibiotics administered. Anti-septic technique was utilized in NOTES procedures whereas Lap was performed in sterile conditions. 30-min abdominal exploration was performed in all groups. At the end of surgery, an array of 8 receivers was attached to the abdominal wall of each subject and the recorder attached to a belt around the body. The CE was delivered into the gastric antrum with the help of an endoscope and a polypectomy snare. Animals survived for 14 days.

**Results:** Five animals were included in each group (n = 20). Median time for surgical procedure was larger in TG (56 minutes, 47–63) and TV (54 minutes, 44–79) than in Lap (32 minutes, 32–33; p < 0.05 and p < 0.01) and TR (45.5 minutes, 33–56; p = ns) and this increase was related to a larger incision and closure time. The CE was successfully delivered in all cases but one animal bit the sensors and the recorder and we could not retrieve any images. In the other 19 cases, the median CE operation time was 465 minutes (368–600). The CE was retained in the stomach for the entire recording period in all animals in TG (median time 459 minutes), but only in one animal in TR and TV and in none in Lap with a median gastric emptying time of 52, 43 and 31 minutes,

respectively. Animals in TG gained less weight than TV (1.7 kg, –1.98 to 4.5 vs 7.7 kg, 5.8 to 11.45; p < 0.01). Failure of CE transportation beyond the stomach was significantly associated with TG and longer time for incision closure.

**Conclusions:** Gastric emptying is delayed after TG peritoneoscopy compared to TR, TV and Lap and this is associated with less weight gain. More studies are necessary to assess the physiologic impact of NOTES before its implementation in humans.

#### Comparison of different over-the-scope devices for gastric incision closure post NOTES procedures

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**Objective of the study:** Over-the-clip (OTS) closure devices have been recently created. Objective: To compare 2 existing OTS devices for closure of the gastric wall incision after NOTES procedures.

**Methods and procedures:** We performed 48 survival experiments on 50-kg pigs. Standard transgastric approach to the peritoneal cavity was made using our proprietary needle knife puncture and dilation device followed by peritoneoscopy. Then the endoscope was withdrawn into the stomach and gastric incision closure was performed using either OVESCO OTS device (Group 1–25 animals) or Aponos OTS device (Group 2–23 animals). All animals survived for two weeks and then repeat endoscopy followed by necropsy were performed.

**Results:** Transgastric access in both groups was made without complications. Gastric closures in all 48 animals were easily achieved. Closure of the gastric wall incision with OVESCO device required 12.2 ± 2.9 minutes, and closure with Aponos device required only 8.0 ± 2.3 minutes (P < 0.0001). Repeat endoscopy demonstrated complete healing of the gastric wall incision in both groups. All OVESCO devices (100%) were still attached to the gastric wall after two weeks, while 22 Aponos devices (95.7%) had been already separated from the gastric wall after two weeks. Necropsy confirmed complete healing of the gastric wall incision in both groups. There were no visible signs of bleeding, infec-

tion, damage to adjacent organs or other complication inside the peritoneal cavity.

**Conclusion:** Although both available OTS devices provided clinically adequate closure of the gastric wall incision, Aponos device application was significantly faster and most of the Aponos devices spontaneously separated from the gastric wall within two weeks.

### Transgastric peritoneoscopy: low-pressure pneumoperitoneum is sufficient and associated with an improved cardiopulmonary response (pressurepig study)

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**Introduction:** Natural Orifice Transluminal Endoscopic Surgery (NOTES) is supposed to be less invasive than standard laparoscopy, but concrete evidence is lacking. Amongst other things, it has been speculated that lower intraabdominal pressures for the maintenance of pneumoperitoneum during transluminal endoscopy might be sufficient. The aim of this randomized, controlled trial in the acute porcine model was to compare the quality of transgastric peritoneoscopy with the use of low-pressure versus standard-pressure pneumoperitoneum and to evaluate the respective associated cardiopulmonary changes.

**Methods** For transgastric peritoneoscopy carbon dioxide was insufflated via the endoscope for constant intraperitoneal pressures of 6 mmHg or 12 mmHg in 18 pigs. The quality of transgastric peritoneoscopy was rated on a visual analogue scale (0 mm, min; 100 mm, max) by the blinded endoscopist. The cardiac index (CI) and global end-diastolic volume index (GEDVI; reflecting preload) were measured every three minutes by transpulmonary thermodilution. The following parameters were also recorded: heart rate (HR), mean arterial pressure (MAP), systemic vascular resistance index (SVRI; reflecting afterload), peak inspiratory pressure (PIP), pH, pCO<sub>2</sub>, and pO<sub>2</sub>.

**Results:** The quality of transgastric peritoneoscopy with the use of low-pressure pneumoperitoneum was non-inferior compared to the use of standard-pressure pneumoperitoneum (87 mm versus 87 mm;  $P < 0,05$ ). In both groups we observed a statistically significant rise in MAP and SVRI. The increase of SVRI was less pronounced during low-pressure pneumoperitoneum ( $P = 0,042$ ), thus indicating a reduced stress response in comparison to standard-pressure peritoneum. There were no differences between the groups regarding CI, GEDVI and HR. An intraabdominal pressure level of 6 mmHg also led to a better oxygenation ( $P = 0,031$  for difference in pO<sub>2</sub> between both groups) due to lower PIP ( $P = 0,001$  for difference). There were only slight differences between the groups regarding pH and pCO<sub>2</sub>. **Conclusions:** A pneumoperitoneum of 12 to 16 mmHg is used for laparoscopy. For NOTES a low-pressure pneumoperitoneum with an intraabdominal pressure of 6 mmHg is sufficient, but is associated with an improved cardiopulmonary response when compared to standard-pressure pneumoperitoneum.

### Transanal rectosigmoid resection and endolumenal colo-rectal anastomosis

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**Background:** In the context of Natural Orifice Transluminal Endoscopic Surgery (NOTES) we developed a new set of rigid instruments according to the principles of Transanal Endoscopic Microsurgery (TEM). These instruments are long, curved and in addition, steerable by rotating two wheels near its handle. Our success in transvaginal cholecystectomy in human with these instruments motivated us to explore the feasibility of transanal rectosigmoid resection.

**Methods:** According to our experience in colorectal surgery, TEM and NOTES, the concept for transanal rectosigmoid resection was developed and after more than 100 experiments in an ex-vivo experimental model, the technical details of the procedure were standardized. The technique comprises the following: 1. Closure of the rectal lumen by an endolumenal purse string suture. 2. Transection of the rectal wall 1 cm distal to the purse string suture and continuation of the dissection

towards the fascia and upward excising the mesorectal tissue. 3. Inferior mesenteric artery is divided near its origin. 4. The colon is mobilized up to the splenic flexure. 5. The mobilized colon is brought down to the pelvis; ligated twice at the intended proximal resection site and divided between the ligatures. 6. The specimen is delivered transanally. 7. Intestinal continuity is restored by either stapled or endolumenal hand-sutured anastomosis. The standardized technique was then objectively evaluated in a prospective experimental trial. Once experimental results were satisfactory, we performed the procedure on human cadaver.

**Results:** In the experimental part, twelve recto-sigmoid resections, 20 stapled and 27 hand-sutured anastomoses were performed. Mean operation time for the resection part was 78.6 min (SD = 9.9). The average specimen length was 37.2 cm. During the dissection in the pelvis, as the specimen was pushed upward and toward abdomen, an "empty pelvis" view of the working field was achieved facilitating dissection. In the cadaver experiment, the procedural details could be reproduced well in human anatomy. Due to the inline position of TEM optic, the dissection plane in the deep pelvis could be developed with good visualization and a precise mesorectal resection was executed.

**Conclusions:** Transanal access by virtue of better visualizations of the operative site in the deep pelvis, stereoscopic vision from TEM optic and the reduced access-related trauma might influence the outcome following colorectal surgery.

### Transgastric endoscopic gastrojejunostomy for treatment of duodenal obstruction

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**Objective:** Open or laparoscopic gastrojejunostomy is an established treatment for malignant duodenal obstruction but associated with significant morbidity and mortality. The purpose of this study was to develop a model for a pure endoscopic gastrojejunostomy, with duodenal occlusion, and to compare it to the laparoscopic technique.

**Methods:** During the first part of the study the model for pure endoscopic gastrojejunostomy was developed and tested in porcine non-survival and survival experiments (n=12). During the second part of the study (n=10) endoscopic gastrojejunostomy (EG) was compared with laparoscopic gastrojejunostomy (LG) in a randomized controlled survival trial. LG was performed with four ports and a 45 mm endoscopic stapler followed by a continuous suture to close the defect. EG was performed with a double channel endoscope and novel dedicated endo-surgical prototype instruments. The distal duodenum was divided using a stapler in all animals.

**Results:** In the randomized controlled trial the median time in minutes for LG was 70 (IQR 65–75) compared to EG, which was 210 (IQR 197–220); p=0.01. There was a trend towards increased anastomosis diameter (cm) in the LG group 2 (IQR 2–3) compared to the EG group at the time of necropsy 1.8 (IQR 1.6–1.8; p=0.06). One animal in the EG group died secondary to bowel ischemia from volvulus of the jejunal loop. One animal in the LG group was prematurely sacrificed due to extensive pulmonary congestion and edema. All anastomoses were intact and patent.

**Conclusions:** Pure endoscopic gastrojejunostomy using the developed technique and the novel devices is feasible and results in an adequate anastomosis for relief of duodenal obstruction.

### Less versus standard laparoscopic cholecystectomy: results of the first pilot RCT

Lirici MM, Corcione F, Kamei A, Angelini P, Califano AD

**Introduction:** In the last years new designed devices provided with multiple channels made the accomplishment of laparoscopic cholecystectomy through a single access not only feasible but much easier. The potential benefits of laparoscopic single site cholecystectomy (LESS cholecystectomy) may consist in: undergoing scar-less surgery, reduced postoperative pain, reduced postoperative length of stay, improved postoperative quality of life. There are no comparative data between LESS cholecystectomy and standard laparoscopic cholecystectomy available at present, that can show the actual weight of the above mentioned benefits.

**Methods:** This study was a prospective, randomized, dual-institutional pilot trial comparing laparo-endoscopic single-site (LESS) cholecystectomy to standard laparoscopic cholecystectomy. Primary endpoint was: postoperative Quality of Life (QoL) measured as length of hospital stay (LoS), postoperative pain, cosmetics and by the SF 36 questionnaire. Secondary endpoints included: operative time, conversion to standard LC, difficulty of exposure, difficulty of dissection, and complication rate.

**Results:** No significant differences in postoperative LoS were found in the two groups. Postoperative pain evaluation by visual analogue scale (VAS) showed a significant better outcome in the standard LC arm on the same day of surgery (p=0.041). No differences in postoperative pain were found at the next VAS evaluations, nor in postoperative administration of pain relieving medications. Cosmetics satisfaction was significantly higher in the LESS group at one month follow-up (mean 94.5% ± 9.4 vs. 86% ± 22.3, median 100% vs. 90%, p=0.025). Among the eight scales of the SF36 assessing the patient's physical and mental health, the "role emotional" scale results were significantly better in the LESS group (mean 80.05 ± 29.42 vs. 68.33 ± 25.31, median 100 vs. 66.67, p < 0.0001).

**Conclusions:** This pilot RCT showed that single site endoscopic cholecystectomy is feasible, safe and has better results in term of cosmetics and postoperative QoL, as compared to standard laparoscopic cholecystectomy. A larger multicenter

RCT is needed to confirm and further investigate these results.

### Natural orifice endoscopic full-thickness colon-wedge resection: a novel "no-touch" technique complies with important requirements in surgical oncology

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**Objective:** Natural orifice endoscopic full-thickness colon-wedge resection attempts to overcome the need of conventional surgery for colorectal polyps, not resectable by standard endoscopic interventions. Although up to 25% of colorectal polyps with benign initial biopsy, might harbor invasive adenocarcinoma, recently proposed techniques do not meet fundamental oncological principles. Important aspects such as a pre-determined safety margin, no technique-related damage of the potential malign tissue together with pre-resection tissue-closure to avoid infectious complications, have not been demonstrated so far. This study aimed to evaluate the feasibility and safety of a novel endoscopic "no-touch" technique for colon-wedge resection addressing crucial standards of surgical oncology.

**Methods:** One human cadaver model, ten explanted porcine colon stumps and two acute pig models were used. T-type suture-anchors were applied around the circumference of a hypothesized colon lesion using a standard colonoscope. The endoscope together with a mounted over-the-scope clip-closure system (ECCS) was subsequently placed in front of the marked lesion. The colon wall was then retracted into the ECCS with the clip attached by gently pulling the sutures backwards. Consecutively, the clip was fired for pre-resection tissue closure. The retracted pseudo-polyp was then excised by snare-resection and harvested by withdrawing the sutures still attached to the specimen. Air leak-pressure of tissue-closure was tested and compared to open hand-sewn colon-wedge resection.

**Results:** Full-thickness colon wedge resection was achieved in all (13/13) experiments. The mean diameter of the resected specimen was 27 ± 2 mm. As in all experiments the tissue anchors were still attached to the outer edge of the specimen, a pre-determined safety margin was also excised. The hypothesized center of the lesion was neither touched nor compro-

mised by puncturing. Mean intervention time was  $32 \pm 9$  min. Leak-pressure tests revealed, that pre-resection ECCS closure (mean:  $60 \pm 5$  mmHg) provided a significantly higher air-pressure resistance compared to the hand-sewn control ( $25 \pm 6$  mmHg,  $p < 0.01$ ).

**Discussion:** This novel endoscopic “no-touch” technique for colon-wedge resection appears to be safe and meets fundamental requirements in surgical oncology, not demonstrated so far. Clinical trials are mandatory to further evaluate this natural orifice endoluminal procedure.

### Transgastric NOTES surgery is less traumatic causing a less pronounced postoperative stress response despite longer operating time

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**Introduction:** NOTES have been suggested to be even less invasive than laparoscopic surgery. The aim of this study was to compare postoperative stress response and recovery after NOTES transgastric, laparoscopic and open uterine horn resection.

**Methods & Procedures:** 30 pigs were randomized to open, laparoscopic or NOTES (transgastric) uterine horn resection with four weeks survival. All animals were equally prepared with liquid diet prior to surgery and received prophylactic antibiotics. No washing of stomachs was performed. Open and laparoscopic surgery was performed using standard techniques. Transgastric surgery was performed using the Olympus R-scope and conventional accessories. The gastric access site was closed using TAS T-tags. Operating time and postop time till standing up and eating were recorded as well as daily temperature and weight. During the first postop week blood samples were taken every other day during one week and then every week until post mortem. CRP and TNF- $\alpha$  were analysed using porcine specific ELISA.

**Results:** 27 animals survived until four weeks. One animal from each group was euthanized earlier due to: hoof infection, omental bleeding and abdominal wound-dehiscence. Operating time was significantly longer in the NOTES-group, mean 124 min versus laparoscopy 35 min and open surgery 23 min. The groups did not differ concerning postop temperature, or

postop time to standing up or eating, NOTES-animals increased significantly in weight during the first postoperative week. The other animals did not gain weight during this week. CRP did not differ between the groups at the end of the procedures. At postop day one the NOTES group had a significantly lower CRP ( $p = 0.04$ ) and did not show the same peak as the other groups. TNF- $\alpha$  peaked at day three and five in the open group showing significantly higher levels than the other two groups ( $p = 0.016$ ). At post mortem 3/9 animals in the open surgery group had wound infections and 2/9 in the laparoscopic group. No intra-abdominal infections were recorded in either group.

**Conclusion:** Transgastric NOTES surgery seems to be less traumatic than both open and laparoscopic surgery inducing less stress response and a better recovery despite longer operating time.

### Endoscopic closure of iatrogenic perforations of the gastrointestinal tract using the over-the-scope-clip: a prospective multicenter human trial

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**Background and aims:** Iatrogenic perforations of the gastrointestinal tract are rare but severe complications of endoscopy with relatively high morbidity and even mortality. Surgical repair is usually indicated. Secure endoluminal repair of perforations would obviate the need for a surgical intervention. Aim was to evaluate safety and reliability of endoscopic closure of iatrogenic perforations of the gastrointestinal tract using the Over-the-Scope-Clip (OTSC; Ovesco).

**Methods:** We conducted a prospective international multicenter trial in which all consecutive patients from March 2009 with acute iatrogenic perforations were included. Closure was performed according to a standard operating procedure, which could be divided in three steps: 1. Approximation of deep layers using a twin grasper; 2. Pulling the tissue into the OTSC-cap; 3. Releasing the clip. Primary endpoint was successful closure, determined as macroscopic adequate closure and no leakage on water soluble contrast X-ray within 24 hours. Secondary endpoints included closure time (starting from introduction of the OTSC-system until adequate closure), adverse events and additional interventions needed.

**Results:** Thirty-one patients (ten male) were included until July 2010. Four esophageal, seven gastric, nine duodenal and ten colonic perforations were included. Twenty-four patients (46%) suffered from a perforation after a therapeutic and seven during a diagnostic endoscopy. In six cases there was another cause. In one patient with a duodenal perforation a deep esophageal laceration occurred while introducing the OTSC-cap and in another case adequate closure using the OTSC failed. Both perforations were closed surgically. Endoluminal closure was macroscopically successful in all 22 remaining patients in a median of 5:04 minutes (SD 2:50). In none of the patients there was leakage of soluble contrast on X-ray or CT within 24 hours after closure. One patient in whom a colonic perforation appeared to be successfully closed, deteriorated within 24 hours and was referred for surgery which showed a detached clip at the perforation site. Within 24 hours after successful surgery the patient deceased of unknown cause. Post-mortem necropsy did not show an abdominal catastrophe. Twenty-one patients did clinically well and resumed oral intake within a median of one day.

**Conclusions:** Endoluminal closure with the OTSC for closure of large iatrogenic perforations was shown to be relatively easy and resulted in adequate closure in 88% of patients in this multicenter prospective human trial.

### Endoscopic anchoring device used in NOTES gastric restriction

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**Objective of the study:** To study a flexible anchoring device used to effect gastric restriction in the ex-vivo swine stomach model.

**The device:** A flexible endoscopic fastening assembly having a diameter sufficiently small to be slidably insertable into a working channel of a flexible endoscope comprises one or more surgical anchors loaded inside a catheter. The catheter, terminating in a sharp needle tip, is configured for delivery of the anchors into tissue. The temperature biased Nitinol anchor comprises four outwardly hooked spines that splay out to enhance tissue grasping, and an eyelet for suture thread coupling is positioned at a proximal end thereof. The anchors are disposed inside the flexible needle in a closed pre-deployment configuration.

**The procedure:** In eight ex-vivo swine stomachs, gastric restriction was performed as follows: the endoscope was introduced into the stomach, the flexible needle was passed through the endoscope's working channel, the needle was plunged into the gastric wall, and the anchor was deployed and implanted. The anchors were either delivered in tandem – threaded onto a single suture thread, or each anchor was delivered separately, adjoined to its respective suture thread. After the anchors were implanted into the gastric wall, the suture threads were synched together, approximating the anchors and respective gastric folds.

**Results:** Eight gastric restrictions with three to five anchors implanted in various parts of the stomach were performed in the x-vivo swine stomach model. The anchors and respective gastric folds were successfully synched together in all eight stomachs.

**Conclusions based on results:** The endoscopic anchoring device was successfully used to effect gastric restriction in the ex-vivo swine stomach model. Similar studies performed on live non-survival and survival animals are necessary to explore whether this device may be considered for tissue approximation in humans.

### APDW 2010 Asian Pacific Digestive Disease week

▼  
Malaysia, Kuala Lumpur  
September 19–22, 2010  
ESGE will be present this year at APDW  
*Please visit us at the booth Nr 91 and find out more about ESGE activities in Europe and beyond. Ask about benefits for ESGE members and get to know the society!*

### ESGE Endorsed Events

▼  
*ESGE individual members receive a 20% discount at ESGE endorsed events.*

**9th Erasmus Endoscopy Days**  
September 9–10, 2010  
The Netherlands, Rotterdam  
Information: Ms Karla Rutten  
k.rutten@congresscompany.com

**The 4th meeting of the Society of Gastrointestinal Intervention (SGI)**  
October 8–9, 2010  
Korea, Seoul  
Information: Ms Violet Chae  
violet@insession.co.kr

**First Digestive Endoscopy Symposium and Second Capsule Endoscopy Course**  
October 8–10, 2010  
Koweit, Salmiya  
Information: Dr. Mahmoud Omar  
mmmmomar@hotmail.com

**Endoscopic Ultrasonography Live**  
October 8–10, 2010  
USA, Chicago  
Information: Ms Mahira Bonomo  
mbonomo@bsd.uchicago.edu

**Gazi University Therapeutic Endoscopy Workshop**  
October 15–16, 2010  
Turkey, Ankara  
Information: Prof Tarkan Karakan  
tkarakan@gmail.com

**The 4th libyan Endoscopy workshop**  
November 6, 2010  
Libya, Tripoli  
Information: Prof. A. Shaban  
dr.bisheya@yahoo.com

**The 17th International Symposium on Endoscopic Ultrasonography**  
November 12–14, 2010  
China, Shangai  
Information: Dr Liuyan  
liuyan80@263.net  
www.eus2010.org

**12th International Workshop on Therapeutic Endoscopy**  
December 12–13, 2010  
Egypt, Cairo  
Information: Prof. I. Mostafa  
ibrahimmostafa@egyptgastrohep.com  
*Please visit us at the booth!*

**Amsterdam Live Endoscopy 2010**  
December 13–14, 2010  
The Netherlands, Amsterdam  
Information: Joy Goedkoop  
epgs@amc.uva.nl  
www.amsterdamendoscopy.com  
*Please visit us at the booth!*

**13th Düsseldorf International Endoscopy Symposium**  
Germany, Düsseldorf  
February 4–5, 2011  
Information: Sandra Reber  
sandra.reber@cocs.de  
*Please visit us at the booth!*

**Fourth Congress of Gastroenterology Association of Bosnia and Herzegovina**  
May 25–28, 2011  
Bosnia and Herzegovina, Sarajevo  
Information: Ms Aida Pilav  
a.pilav@bih.net.ba

**Second International Symposium on complications in GI**  
June 16–18, 2011  
Germany, Hannover  
Information: Ms Gabriele Krupp  
gabriele.krupp@ddh-gruppe.de