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viding the patients according to the criteria of Colon-Jones gave very small groups and offered no further information. The effects of the drug on individual symptoms, likewise, did not reach significance.

Conclusion: Our results do not support a role for gastric acid production in the generation of functional upper dyspepsia and do not warrant prescription of Omeprazole to patients suffering from non-ulcer dyspepsia.

33 Effects of Fedotizone in Chronic Idiopathic Dyspepsia: A Double Blind, Placebo Controlled Multicentre Study

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Safety and efficacy of fedotizone (F), a peripheral µ agonist, were assessed versus placebo (P), in a double blind multicentre study conducted in France by hospital and private gastroenterologists. Methods. 367 dyspeptic patients were entered in the study. They were defined by the presence, in the last 3 months and at least 3 times a week, of 2 or more post-prandial symptoms: early satiety, fullness/epigastric distension, nausea/vomiting, impression of slow digestion for more than 2 hours after meals, epigastric pain. An underlying organic disease was ruled out through medical examination, gastrodupancreato-duodenoscopy, upper abdominal ultrasound and routine blood biochemistry and hematology. At the end of a run-in period where all patients received placebo for 1 to 2 weeks, 305 were found to have persistent dyspeptic symptoms and were randomized in 2 parallel groups: F 30 mg or P 1 tablet tid for 6 weeks. Patients completed a diary card daily. Using a fixed point scale with 5 possibilities they were asked to rate the overall intensity of their symptoms (main efficacy end-point) and the intensity of each individual symptom. They also rated their quality of life (QoL) before and after treatment using the Subjective Quality of Life Profile questionnaire. [1] The protocol was approved by the Nantes academic hospital ethics committee and written informed consent was systematically obtained. The mean over the 6 week treatment period for each self-assessed parameter was evaluated using covariance analysis, the covariates being the mean of the 6 weeks. The improvement with F was greater than with P after analysis of the 163 patients who complied with the protocol. This beneficial effect was significant for the main efficacy end-point (overall intensity, p = 0.017), for the 2 most frequently reported symptoms (slow digestion p = 0.031, post-prandial fullness p = 0.027) and for nausea (p = 0.038). For the patients having completed both questionnaires, F significantly improved also the QoL compared to P (p = 0.01, discriminant analysis). Safety profile was very good. Conclusion: Fedotizone had a significantly greater beneficial effect than placebo with regard to the self-assessed overall dyspeptic syndrome and some individual symptoms in those patients who complied with the protocol. Quality of life was also significantly improved. Fedotizone had an excellent safety profile.


34 Placebo-Controlled Trial of Casiprade and Nizatidine in Unselected Patients with Non-Ulcer Dyspepsia


Patients in most trials of medical treatment of non-ulcer dyspepsia (NUD) have been selected groups referred for endoscopy. This could have lead to a selection-bias of non-responders explaining the negative outcome of most controlled treatment trials in NUD.

Aim: to assess the effect of casipride (CIS) and nizatidine (NIZ) in an unselected group of patients with NUD who consult their general practitioners (GP) and to determine whether symptom subgrouping provides a useful basis for choice of medical therapy in this patient group.

Design: Consecutive patients who consulted their GP with dyspepsia were invited to an interview and endoscopy. Patients with no abnormalities at endoscopy were eligible. Patients with a history of peptic ulcer, NSAID use and use of ulcer drugs except antacids within 4 weeks were excluded. Prior to endoscopy symptoms were classified by the clinician as: reflux-like (R), dysmotility-like (D), ulcer-like (U) or idiopathic/unclassifiable (I). 330 patients were randomized to double-blind treatment with CIS 10 mg tid, NIZ 300 mg at night or placebo (PLA) for two weeks. Randomization was stratified in accordance to symptom groups. Symptoms were assessed at entry and at day 14.

Results: 109 patients received CIS, 111 NIZ and 110 MLA. 20, 15 and 16 patients were excluded because of poor compliance or side effects. At entry the groups were comparable with regard to clinical variables and symptoms. 23% of patients were classified as R, 46% as D, 13% as U and 18% as I. Symptomatic response (symptoms resolved/improved) was found in 55 (62%) of patients on CIS (therapeutic gain CIS vs PLA: 0.1%, 95% CI = -14% to +14%) and in 52 (54%) of patients on NIZ (therapeutic gain NIZ vs PLA: -8%, 95% CI = -22% to +7%). The response was unrelated to subgroups of dyspepsia: effects of CIS, NIZ and PLA, respectively, in R: 57%, 60%, and 74%; in D: 61%, 55%, and 55%; in U: 67%, 50%, and 60% and in I: 67%, 50%, and 64%.

Conclusion: effects of a 2-week course of CIS or NIZ in unselected patients with NUD were not superior to effects of PLA. Symptom grouping was not predictive of response to therapy.

35 Endoscopic Ultrasonography and Computed Tomography in Diagnosis and Staging of Pancreatic Tumors: Comparison with Surgery


Purpose: The aim of this prospective study was to compare the effectiveness of endoscopic ultrasonography (EUS) and computed tomography (CT) in diagnosis and staging of malignant pancreatic tumors (MPT).

Patients and methods: From January 1990 to May 1993, EUS or CT suspected 67 MPT. Among them, 38 underwent surgery. The procedure included tumor diagnosis (D), lymph node metastases (LNM) and vascular involvement study. The final results, surgically and histologically assessed, were: pancreatic carcinoma: n = 29, ampullary carcinoma: n = 4, pancreatic metastasis: n = 1, cystadenocarcinoma: n = 1, malignant endocrine tumor: n = 6, cholangiocarcinoma with pancreatic involvement: n = 1. There were 23 LNM, 19 venous involvement (VI), and 9 arterial involvement (AI).

Results: EUS and CT sensitivity (Se) and specificity (Sp) were determined by reference to operative and histological findings.

<table>
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<tr>
<th>D</th>
<th>LNM</th>
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<td>EUS</td>
<td>Se %</td>
<td>95</td>
<td>57</td>
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<tr>
<td>Sp %</td>
<td>97</td>
<td>86</td>
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<tr>
<td>CT</td>
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<td>65</td>
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<td>Sp %</td>
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In MPT diagnosis, there was one false-positive in both techniques. In LNM diagnosis, there were 10 false-negative EUS findings explained by micrometastases in 6 cases. In VI diagnosis, there were respectively 6 and 14 EUS and CT false-negative findings. In AI diagnosis, there were respectively 4 and 3 EUS and CT false-negative findings.

Conclusion: (1) EUS is more accurate than CT in MPT diagnosis, detection of metastatic lymph nodes and venous involvement. (2) Results of EUS and CT are similar in detection of arterial involvement.

36 Safety of Linear Array Endoscopic Ultrasonography in Upper Gastrointestinal Malignancies

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Endoscopic ultrasonography (EUS) has been performed for almost a decade with increasing evidence of its capacity in the pretherapeutic staging and assessment of resectability in upper gastrointestinal malignancies (UGIM). Despite the widespread use of EUS only estimates of the risk related to the EUS examination has been reported and most materials are based upon retrospective series. Therefore, prospectively we recorded the number of complications during or immediately after EUS examination of patients with UGIM.

Materials and results: One hundred thirty-two consecutive patients with UGIM were referred for pretherapeutic staging and assessment of resectability. Forty-six patients had esophageal cancer, 56 patients had gastric cancer and 30 patients had pancreatic cancer. EUS was performed using a forward oblique linear array endoscopic echosounder. The examination time varied from 4 to 55 minutes (median 25 minutes). Five to 15 mg (median 10 mg) of diazepam was used during the examinations. Analgesic (Pethidine), 20 to 40 mg (median 25 mg), was administered together with sedatives when dilatations were performed. In 13 patients (37%) a complete EUS examination was performed without any complications at all. Twenty patients (15%) presented with a non-traversable tumor stenosis. EUS of the area oral to the stenosis gave sufficient information in 7 cases, but in 13 patients EUS of this area was inconclusive and dilatation was attempted. All patients were dilated using the balloon method, but three patients needed bougienage in general anaesthesia in order to perform a complete dilatation. No complications were seen during or after EUS following balloon dilatation, but two patients with severe tumor stenosis in the esophagus suffered a small perforation related to the dilatation and EUS performance. Both patients, however, recovered uneventful on a conservative regimen. In 8 patients the water-filled-stomach method was necessary in order to obtain a reliable EUS image of the tumor and in two of these cases (25%) a combination of overfilling and tumor stenosis resulted in nausea and vomiting. The examination was completed in both
patients and the incidents caused no late complications. In summary, two minor esophageal perforations occurred following dilation and two cases of vomiting were observed in connection with EUS of UGIM.

Discussion & Conclusion: Most EUS examinations in UGIM can be performed within 25 minutes, without any complications and using only limited medication. Non-traversable tumor stenosis constitutes not only a time consuming problem but also a potential risk of perforation. If dilatation is necessary to complete the EUS examination, the balloon dilation method seems to carry only little (if any) risk of perforation. However, this method might not be sufficient and the employment of rigid bougieurage carries a high risk of perforation. The water-filled-stomach method might cause nausea and vomiting but reduced water installation (< 400 ml) and correct left lateral positioning of the patient seems to reduce the discomfort and risk of complications. It is our impression that EUS of UGIM is a safe procedure, even when examining patients with tumor stenosis and when a balloon dilation is necessary prior to EUS. Attempts to bougieurage tight malignant strictures should only be considered in a few selected patients.

37 Use of New Ultrasonic Probes for Determining the Depth of Superficial Cancer Invasion in Gl Tract
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Recently, new small-sized ultrasonic probes (radial/linear type, 15 or 20 MHz, 2.6 mm in diameter) has been developed, the probes allowed that not only examination can be possible under the direct view but also a resolution became better. The aim of this study is how accurate mucosal cancer is determined by the new probes. Mucosal cancer was delineated as tumor limited in the muscularis mucosa which was the 4th hypoechogenic layer. Patients with diagnosed mucosal cancer were candidate in mucosal resection under the endoscopy. Of 116 patients with superficial cancer who were examined by these probes and were selected treatments, out of 34 patients underwent mucosal resection under the endoscopy, while 82 patients underwent surgery, resected specimens were compared with ultrasonographic findings. In esophageal cancer, distinction between mucosal cancer and submucosal cancer was accurately diagnosed 81%. In gastric cancer, mucosal cancer was accurately diagnosed in 59%, submucosal cancer in 75%. The low accuracy was due to cases of cancer concomitant with ulcer. So accuracy of cases of cancer without ulcer was 83%. In colon cancer, mucosal cancer was correctly diagnosed in 93% and submucosal cancer in 100%, an overall accuracy rate in 95%. The high frequency ultrasonography provides precise diagnosis between mucosal and submucosal cancer.

38 Radial Type Ultrasonic Probe (20, 15 MHz) for the Pre-operative Evaluation of Gastric Cancer
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Previous studies have reported that the prognosis of patients with gastric cancer is mainly related to the infiltration depth. Endoscopic mucosal resection (EMR) has been attempted in patient with small (≤ 2 cm) cancer suspected to be limited to the mucosal invasion. We have already reported that endoscopic ultrasonography (EUS) is the most accurate diagnostic method presently available to determine the depth of cancer invasion, but it is sometime difficult to visualize small and flat cancers. Recently we have used two prototype ultrasonic probes (USP) with a high frequency transducer and report its usefulness for the pre-operative evaluation of gastric cancer.

Subject and Method: 920 lesions of gastric cancer were evaluated with EUS before operation (730 lesions) and chemotherapy for the last 7 years. From December 1992 to June 1993, we also performed pre-operative staging with a radial type ultrasonic probe (Olympus-prototype 20 MHz 2.5 mm in diameter, Aloka-prototype 15, 20 MHz 2.4 mm in diameter), especially in 11 patients with small cancer.

Results: According the analysis of 920 EUS examination, lesions could not be visualized because they were small and flat (22), difficult location (1), stenosis of cardia (13) and non-cooperative patient (1). 22 of 23 non-visualized lesions were less than 4 cm. USP was able to pass through the channel of a normalendoscope (2.8 mm). Image of USP was more fine and clearer than that of EUS within 3 or 4 cm from the transducer and the gastric wall was revealed a 9-layer structure (Skin and border of mm, mucosa, border between inner and outer muscle). All small lesions were visualized easily by USP with endoscopic guidance. Diagnostic accuracy in the diagnosis of cancer invasion with USP, EUS was 81.8% (9/11), 82.5% (602/730) and in the group of small cancer (less than 4 cm) 87.5% (78), 81.3% (313/385) respectively. Using USP, celiac trunk, common hepatic and splenic artery were visualized in 7 of 11 patients. 2 of 11 had lymph node metastasis and 1 of 2 detected by USP.

Conclusion: We conclude that USP is more useful and easy than EUS, especially in cases with small and flat lesion.

39 “Second Look” Transabdominal Ultrasound vs Echoendoscopy for Bilipancreatic Explorations: A Prospective Comparative Study of 76 Patients
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Echoendoscopy (EUS) is now considered as the best method for the study of the biliary duct and the pancreas. However in previous comparative studies, US was often performed early in patients' examination without all the informations available for EUS examinations. Here was studied the capacity of US in practiced in good conditions to reach the same conclusions than EUS.

76 consecutive patients, referred for biliary or pancreatic EUS with previous non-informative US, were systematically re-examined by US and EUS were performed independently, the same day with the same level of informations by experienced operators. Operators were asked to give their final diagnosis and their advice on patients’ management thereafter. When EUS and US reached different conclusions, EUS was considered as the gold standard. With similar conclusions, EUS was considered as more informative when US was not of perfect quality.

EUS diagnosis were no abnormality (n = 40), pancreatic (n = 10) or ampullary tumor (n = 4), pancreatic cyst either serous (n = 2) or mucinous (n = 3), chronic pancreatitis (n = 8), lithiasis of the biliary duct (n = 8), sclerosing cholangitis (n = 1). There was a technical failure at US in 6 cases. US gave the same diagnosis in 48 cases (63%). US conclusions were different or similar but uncertain in 22. Noteworthy US was inferior for biliary duct lithiasis (missing 2 of the 8 cases), ampullary disease (missing 2 of 4) and chronic pancreatitis (missing 2 of 8). For patient's management after EUS or US, US gave the same advice in 63 cases (83%).

Second look US performed with similar conditions, gave the same informations than EUS in about 60% of cases where EUS could thus be avoided. However, US liability for diagnosis such as biliary lithiasis, ampulloma, mild chronic pancreatitis is less than that of EUS and EUS will have to be performed in case of disagreement between US and the clinical background.

40 MRI-imaging with Endoscopically Placed Endocoil in Adenoma and Carcinoma of the Rectum – First Clinical Results
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Introduction: The determination of infiltration in width and depth in the wall layers in rectal adenoma and carcinoma is in several cases with the usually applied endoscopic and x-ray procedures (x-ray contrast, endosonography, CT, extracorporeal MRI) difficult. From these diagnoses often depend severe therapeutic consequences (endoscopic versus surgical resection procedures, palliative therapy, radiation). In this study we made first experiences with the MRI-diagnostic with a new endoluminal MRI-coil with relevance in the diagnosis of the mentioned rectal processes should be discussed.

Methods: All examinations were performed with a 1.5 Tesla SP 63 Magnet under application of an experimental rectal endocol. This high resoltuting magnetic resonance coil (MEDRAD inc. WI, USA) was placed under endoscopic guidance in left sided position of the pt. in his rectum ampulla and stabilized with a balloon. For technical application we used sphincto as gradient echo sequences.

Results: We performed the examination until now in n = 7 pts. (n = 4 female, n = 3 male, mean age: 59.6 years). N = 3 pts. had non stenosing rectal carcinoma, n = 3 pts. non stenosing rectal adenoma, two of them with severe, one with middle grade epithelial dysplasias in the WHO-classification, one patient had a choroma. We compared the results of endoluminal MRI with those of endoscopy, of endosonography and the histology, in all pts. with endoluminal MRI the exact infiltration in the layers of rectal wall could be defined. The visual resolution was higher compared to the reference methods. In n = 2 pts. we could apply the method in the follow-up before and after endoscop-dexter-laser resection of big rectal adenoma and we could prove the absence of adenoma after therapy also in the deeper layers of the rectal wall.

Conclusions: Our first experiences with the application of the new endoluminal MRI-coil in rectal neoplasias show the outstanding visual reproduction of wall layers with definition of infiltration depth. This method is superior to comparable procedures in quality of imaging and details of the anatomy and wall structure. Due to endoscopic guidance the device is applicable without any complications. It suits for primary diagnosis and follow-up of large col- rectal adenoma before and after endoscopic electrocautery resection.