

software. Using traditional endoscopy as the gold standard, the pilot study showed that the PillCam method had a sensitivity of 100% and a specificity of 80%. No patients experienced difficulties in ingesting the capsule and there were no adverse events. The majority (73%) of patients preferred capsule endoscopy over traditional endoscopy.

Since this pilot study was published, the capsule has been approved for use by the FDA.

Original article Eliakim R *et al.* (2004) A novel diagnostic tool for detecting oesophageal pathology: the PillCam oesophageal video capsule. *Aliment Pharmacol Ther* **20**: 1083–1089

Risk of gallstone disease reduced by high intake of *cis* unsaturated fats

New results from a long-term, population-based study have shown that energy-balanced diets rich in polyunsaturated and monounsaturated fats may help to reduce the risk of gallstone disease in men older than 40 years.

The Health Professionals Follow-up Study included 45,756 men who were free of gallstone disease at the time of enrollment. Participants were asked to provide details of their food intake by completing a semi-quantitative questionnaire at baseline and every two years during the 14-year follow-up.

A total of 2,323 incident cases of gallstone disease were recorded during the study and cholecystectomy was required in 1,279 of these. The median daily intake of both polyunsaturated and monounsaturated fats among the study population varied by approximately two-fold. In an analysis adjusting for age, multiple potential confounding factors and intake of saturated and *trans* fat, men in the highest quintile for intake of total *cis* unsaturated fats were at an approximately 20% lower risk of developing gallstone disease than those in the lowest quintile (relative risk 0.82, 95% CI 0.69–0.96, $P=0.006$). This trend was also observed when polyunsaturated and monounsaturated fats were considered separately.

These results reflect earlier, experimental studies demonstrating that *cis* unsaturated fats

can inhibit gallstone formation. The authors conclude that the findings might be relevant in epidemiological and clinical research as well as in the study of disease mechanisms.

Original article Tsai C-J *et al.* (2004) The effect of long-term intake of *cis* unsaturated fats on the risk for gallstone disease in men. *Ann Intern Med* **141**: 514–522

Severe toxicity with erlotinib and FOLFIRI

Combinations of EGFR-targeting agents and conventional chemotherapy have shown promise in the treatment of colorectal cancer, and their safety profile has been satisfactory. A recent trial has revealed excessive toxicity, however, in patients receiving a combination of erlotinib (an oral EGFR tyrosine kinase inhibitor) and the standard FOLFIRI chemotherapy regimen.

This phase I study was designed to assess escalating doses of the combination in individual cohorts of six patients with advanced colorectal cancer. The trial was terminated after the first cohort developed severe toxicities at the lowest dose level (100 mg/day erlotinib continuously and FOLFIRI at ~80% of the standard doses). Toxicities included grade 3 vomiting (one patient) grade 3 diarrhea (four patients), grade 3 or 4 neutropenia (three patients) and grade 4 pulmonary embolism (one patient). Four subjects also developed a disfiguring, acneiform rash on the face and upper chest or back. It was necessary to discontinue, interrupt or reduce the dose of erlotinib and/or FOLFIRI in all six patients, and no patient received more than two 6-week cycles of therapy. After one cycle, five patients had stable disease and one patient had a partial response.

Concluding that the combination of erlotinib with FOLFIRI caused severe toxicity in this study, authors Messersmith *et al.* stress that the safety of any such combinations should be tested.

Original article Messersmith WA *et al.* (2004) Phase I trial of irinotecan, infusional 5-fluorouracil, and leucovorin (FOLFIRI) with erlotinib (OSI-774): early termination due to increased toxicities. *Clin Cancer Res* **10**: 6522–6527

GLOSSARY

EGFR

Epidermal growth factor receptor

FOLFIRI

A standard chemotherapy regimen of irinotecan, infusional 5-fluorouracil and leucovorin