Endocinch treatment for gastro-oesophageal reflux (GORD): retention of plications are essential to control GORD

We congratulate Schwartz *et al* for their first reported Endocinch sham control trial (*Gut* 2007;**56**:20–8). The results of this trial confirm those of earlier open-label studies[1–3] showing that in the short and intermediate term, endoscopic gastroplication improves gastro-oesophageal reflux disease symptoms and quality of life (QOL), and reduces the requirements of acid-inhibitory drugs. In their current study design, they only performed endoscopy/gastroplications in patients who have treatment failure in the active treatment group, and hence the actual proportion of patients who have retention of stitches (or judged to be functional) is unknown in the active treatment group. However, the retention of stitches seems to be a major problem reported with this technique.[4 5] In our group, we used only two plications 1 and 2 cm below the Z line along the lesser curve, and used the previous knot technique in comparison with a recent clip devise for anchoring sutures.[1] However, better outcomes with three plications have been shown by Thompson *et al*.[6] We have now completed a 5-year postprocedural study on our group of patients. Although the number is small (n = 22; 17 completed their 5-year follow-up for symptom scoring and usage of proton pump inhibitors (PPIs) and only 13 agreed for repeat endoscopy), it clearly showed potential to maintain significant control in gastro-oesophageal reflux disease symptoms and QOL, and reduction in the requirements of PPIs up to 5 years after the procedure.[7] To further determine whether retention of stitches is of significance, we further analysed our data. In our cohort, plications were intact in 70% of cases at 5 years after the procedure (confirmed by repeat endoscopy, which was performed by an independent blinded experienced endoscopist). It showed that the group of patients who retained plications showed significant improvement in symptom scoring ($p = 0.01$), regurgitation score ($p = 0.007$), QOL ($p = 0.02$) and 67% reduction in the requirement of PPIs at 5 years after the procedure as compared with the group of patients who lost plications.[8] Hence, long-term failure seems to be related with loss of plications. At this stage of development, it is also important that those who are performing or have performed these procedures should follow-up their cases to further assess the retention of plications and their durability. We believe that better sedation and increasing depth of sutures with increasing size of suction chamber may help in retention of sutures.[9] However, further modifications are needed to improve this technique, in particular to improve the retention of sutures for achieving maximum clinical benefit.

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Author's response

We thank Mahmood *et al* for their useful comments on our paper. We fully agree and want to reiterate that the long-term failure of Endocinch treatment in a large subset of patients is due to the loss of intact plications, as was also pointed out in the discussion section of our paper.

However, the present study was deliberately not designed to address the issue of durability of plications, because we decided that the potential gain of extra information from a second gastroscopy would not outweigh the extra burden for the patient.

As many authors had already defined the problem of lost plications (also outlined by Mahmood *et al*), our primary study goal was to compare active treatment with sham treatment. In this respect, it is also important to realise that determination of the patency or functionality of gastroplications is not always as simple as it may seem. In general, it is difficult to judge the functional characteristics endoscopically. An absent plication is easy and straightforward to judge, but how to judge a present plication as functional, non-functional or loose? A present but loose suture thread might theoretically still have functional capacities, as one report has shown that endoluminal suturing affects oesophageal sensitivity.[1] By contrast, an intact gastroplication might have no antireflux function at all. Also, even while one (or more) plication has clearly been lost, the remaining two may still have excellent antireflux capacities. As the exact working mechanisms of most endoluminal antireflux therapies are largely unknown, it is hard to judge the sufficiency of sutures or gastroplications. There is clearly a need for sharp definitions regarding these issues, but this subject was out of the scope of our study.

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Accuracy of a referral guideline for patients with chronic hepatitis B in primary care to select patients eligible for evaluation by a specialist

Practice guidelines have been developed to select patients with chronic hepatitis B who might benefit from antiviral treatment.[1–3] These sophisticated guidelines are directed at specialist care, and include the assessment of serum hepatitis B virus (HBV) DNA. However, most patients with chronic HBV are diagnosed in primary care where HBV DNA is usually not assessed. A simpler, less expensive guideline that can be used at the primary care level to select patients for referral to specialist care can reduce the number of patients referred who, after evaluation by a specialist, are ineligible for treatment. By preventing the referral of ineligible patients, the disappointment that patients with high expectations experience after referral to a specialist is avoided. Furthermore, it reduces the burden on the healthcare system.

A guideline for the referral of patients with chronic HBV in primary care, based on hepatitis B e-antigen (HBeAg) status and alanine aminotransferase (ALT) level, has been in use in Rotterdam since 2002.[4] We assessed the accuracy of this simple guideline to predict high HBV DNA levels, defined as $>10^5$ copies/ml as this cut-off point is recommended in clinical practice.[1 2]

The study population was an unselected population-based cohort of 464 newly diagnosed patients with chronic HBV in Rotterdam, The Netherlands. Half of the study population was female. The patients were aged 8–80 years and were from various ethnic backgrounds. Patients were considered eligible for referral if they were positive for HBeAg or had increased ALT levels. Patients not selected for referral were referred to their general practitioner for annual monitoring of their ALT level. The HBV DNA viral load was determined as described previously.[5] Positive predictive value, negative predictive value, sensitivity and specificity of the referral guideline and its components, HBeAg and ALT, were calculated with 95% CIs. The procedure is illustrated in a flow chart (fig 1), and table 1 summarises the results.

According to the referral guideline, 43% (181/420) of the patients were eligible for referral to specialist care. The positive predictive value of the referral guideline was 45%, as 82 of 181 patients selected for referral had high viral loads. The negative predictive value was 95%, as 227 of 239 patients not selected for referral had low viral loads. The patients selected for referral included 82 of 94 patients

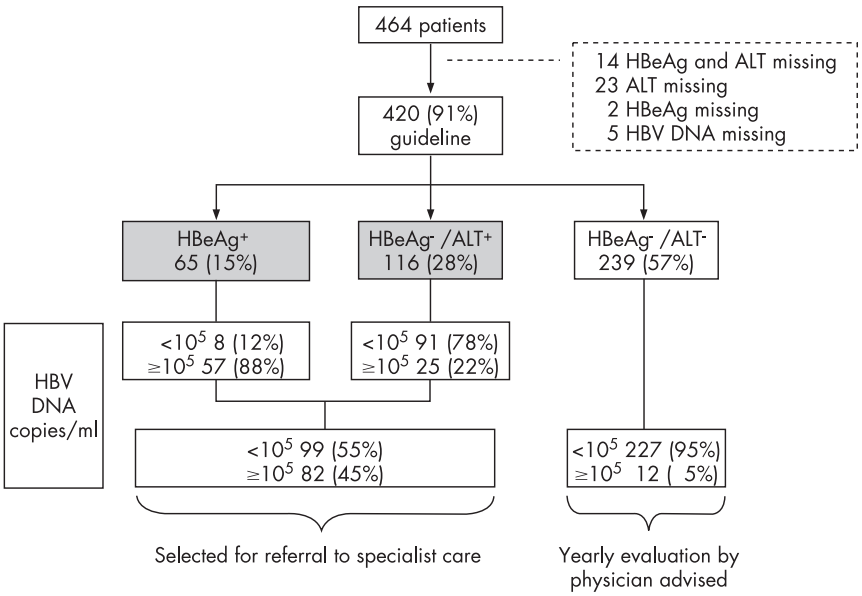

Figure 1 Flow chart of patients by hepatitis B e-antigen (HBeAg) status, alanine aminotransferase (ALT) level and serum hepatitis B virus (HBV) DNA level.

Table 1 Characteristics of different determinants for selection for referral

	Determinant for selection for referral (% and 95% CI)		
	HBeAg+ or ALT+	HBeAg+	ALT+ in HBeAg−
Prevalence of determinant	43 (38 to 48)	15 (12 to 19)	33 (28 to 38)
Positive predictive value*	45 (38 to 53)	88 (78 to 94)	22 (15 to 30)
Negative predictive value†	95 (91 to 97)	90 (86 to 92)	95 (91 to 97)
Sensitivity‡	87 (80 to 93)	61 (51 to 70)	68 (51 to 80)
Specificity§	70 (64 to 74)	98 (95 to 99)	71 (66 to 76)

ALT, alanine aminotransferase; HBeAg, hepatitis B e-antigen; −, negative; +, positive.
*Proportion of patients selected for referral who had high viral loads.
†Proportion of patients not selected for referral who had low viral loads.
‡Proportion of patients with high viral loads who were selected for referral.
§Proportion of patients with low viral loads who were not selected for referral.

with high serum HBV DNA, which corresponded to a sensitivity of 87%. When only patients with a positive HBeAg test were referred, the number eligible for referral could be reduced to the 15% of patients who were HBeAg positive. However, although the predictive value of a positive HBeAg test was high at 88%, the sensitivity was unacceptably low, and almost 40% of patients with a high viral load would have been missed. The sensitivity of an increased ALT level in patients who were HBeAg negative was also low at 68%, but the combination of both test results in the guideline improved the sensitivity to an acceptable 87%.

Of 12 patients with high viral loads who were not selected for referral by the guideline, 11 had a viral load of 10^5–10^6 copies/ml. We checked whether these patients had, in one way or another, been seen by a specialist at the Department of Gastroenterology and Hepatology of Erasmus Medical Center, Rotterdam, The Netherlands, which was the case for three of them. All three were referred back to their general practitioner after exclusion of significant liver disease. Another patient had an extremely high viral load of 2×10^{10} copies/ml. He was a 65-year-old Dutch man who was tested because of dialysis, and was already under the care of a specialist.

We conclude that a guideline based on HBeAg and a single ALT determination can successfully predict viral load in patients with chronic HBV and can be used in primary care to select patients for referral to specialist care.

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Delayed healing of percutaneous endoscopic gastrostomy site during chemotherapy

Many patients with head and neck cancer experience altered deglutition, weight loss and malnutrition as a consequence of their disease. Surgery, radiotherapy and chemotherapy frequently compound these problems. The use of percutaneous endoscopic gastrostomy (PEG) for nutritional support has been found to be effective, acceptable to patients and has a low rate of complications. We describe two cases of delayed healing and peristomal leakage in patients whose PEG was inserted during chemotherapy.

Case 1

A 59-year-old man with a T3N1M0 laryngeal carcinoma began weekly cisplatin chemotherapy and radiotherapy 2 weeks before insertion of a 9 Fr Freka PEG. There was no initial complication and the patient received his third dose of chemotherapy the next day. One week later, he presented with significant peristomal leakage of gastric juices and feeding liquid such that it had become necessary to change both his shirt and underpants frequently. There was redness of the surrounding skin extending below the umbilicus. He received a fourth dose of cisplatin as planned the next day. After review by the gastrointestinal team, the PEG was tightened at the external fixation plate in an attempt to improve the seal formed by the internal bumper on the anterior gastric wall and between the gastric and abdominal walls, and the site was kept clean and lightly dressed. Swabs grew mixed coliforms thought to be skin contaminants. No clinical or laboratory evidence of infection or peritonitis was seen. He was fed continuously through the PEG at a low rate and was given omeprazole intravenously to reduce the caustic effect of gastric juice on the skin. Leakage diminished after 2 days on this management and ceased after 5 days. The fifth dose of chemotherapy was postponed for 1 week. There was no further problem.