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Author J.E. van Hooft
Faculty Faculty of Medicine
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Chapter

8^a

Premature closure of the
Dutch Stent-in I study

J.E. van Hooft, P. Fockens, A.W. Marinelli, P.M. Bossuyt, W.A. Bemelman,
on behalf of the Dutch Stent-in study group

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We would like to draw your attention to the following. On Jan 18, 2006, the Dutch Stent-in I study (ISRCTN01790428) had to be terminated prematurely because of a high number of serious adverse events. This study was a multi-centre, prospective, randomised controlled trial to assess the potential benefit of endoluminal stenting with the WallFlex colonic stent (Boston Scientific, Natick, MA, USA) compared with surgery in patients with incurable colorectal cancer.

When the study was stopped on the advice of the Safety Monitoring Committee, 21 patients had been included. 11 patients were assigned stenting: of those, 10 were treated accordingly. During follow-up four patients had a stent perforation, respectively 12, 12, 44 and 106 days after stent placement. Three of these patients died as a result of this complication. This high number of late perforations was unexpected because published data revealed a much lower incidence (4%) of perforations, mostly early and associated with stent placement.^{1;2}



In one patient the perforation was located at the right side of the colon and was thought to be caused by a blowout due to stent obstruction. In three patients the perforation occurred at the site of the stent, apparently because of erosion of the stent through the bowel wall, since the pathology did not show malignant tissue at the site of perforation (Figure). In two of these, the perforation was at the proximal edge of the stent. In the fourth patient, who was on chemotherapy, the exact location remained unclear due to peritonitis at the outside of the colonic wall.

We cannot tell whether this high complication rate is caused by the design of this new enteral stent or is a chance phenomenon. There are no published data on the safety of this new stent. We can only point out that changes in the stent design could have contributed to the perforations: the stent has a larger diameter at the proximal end (30 mm), where the perforation occurred in two, and possibly three, of the four patients. Additionally, the stent is made from braided nitinol instead of stainless steel (as for the enteral Wallstent [also Boston Scientific]). This might affect the force applied to the colonic wall.³⁻⁵ As long as the cause of the high incidence of late perforations remains unclear, we feel that it is of paramount importance that patients being or having been treated with this new type of colonic stent are prospectively followed in a registry, since the WallFlex colonic stent is still commercially available.

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