Prospective Clinical Study on the Use of a New Reopenable Endoclip in Comparison with Traditional Clipping Systems.

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Introduction

Hemoclipping is one of the methods of first choice for stopping ulcer bleeding, along with injection therapy and coagulation. Closing fistulas or leakages with endoclips is part of everyday clinical practice. Comparisons of various clipping systems have so far only existed in the form of experimental studies, since comparable study conditions in clinical use can be produced only to a limited extent.

Aim

Evaluation of a new reopenable hemoclip by comparison with other established clipping systems in regard to success of hemostasis in bleeding and effectiveness of closure of dehiscent wounds.

Patients and Methods

A new reopenable one-time clip applicator (Resolution clip, Boston Scientific Medical Technology, Ratingen) was compared on a randomized, prospective basis with various reusable clip applicators (HX-610, Olympus Co., Hamburg), the Quickclip single-use system (Olympus Co., Hamburg), and the Triclip (Wilson and Cook, Mönchengladbach) in clinical use. Various lengths were available for use in the upper and lower GI tracts respectively. In the period between December 06 and December 07, hemoclips were the primary treatment in 197 of 395 patients with ulcer bleeding in Forrest stage IA, IB, or IIA. Of these, 99 were treated with the reopenable clip and 98 with the other systems. 8 physicians participated in these emergency endoscopic procedures.

In the same period, dehiscences such as Mallory-Weiss lesions, fistulas, anastomosis insufficiencies and perforations were clipped in 47 patients, 26 of them with the reopenable clip and 21 with the other systems.

The patient groups were similarly distributed with regard to age and sex (59 vs. 57 years, M: 101 vs. F: 96).

Results

The reopenable clip was used as the primary hemostatic procedure in 89 patients. Bleeding was stopped effectively after application of an average of 1.4 (minimum 1, maximum 5) clips. Of these 85 were for ulcer bleeding, 2 for post-polypectomy bleeding and 2 for Dieulafoy bleeding. In 64 patients (72%), a single clip was sufficient; 2 were required in 17, 3 in 4, 4 in 3 and 5 in 1 patient.

To achieve effective closure of comparable Mallory-Weiss tears (13 vs. 12), fistulas (5 vs. 3), Anastomosis insufficiencies (3 vs. 2), and perforations (5 vs. 4) an average of 2.2 (minimum 1, maximum 6) applications of the reopenable clip were required in 26 patients. With the other systems, in 21 patients, an average of 4.6 (minimum 2, maximum 12) applications were required.

With the other systems, in 92 patients, an average of 3.0 (minimum 1, maximum 7) clips were required. 89 of these were for ulcer bleeding, 2 for post-polypectomy bleeding and 1 for Dieulafoy bleeding. In 20 patients (22%), a single clip was sufficient; 2 were required in 14, 3 in 19, 4 in 28, 5 in 9 patients, and 6 and 7 in 1 patient each.

The failure rate for primary clipping, resulting in changing to another hemostatic procedure, was 10 patients for the reopenable clip and 6 for the other systems. The reintervention rate in follow-up checkups was almost the same (9 vs. 10 patients or 10.1 vs. 10.9%).

The Resolution clip remained on the lesions significantly longer than did the clips from the other systems (68% vs. 27% after 10 days).

Discussion

The lower number of clips was caused primarily by the possibility of correction during the placement process as a result of their forceps-like functionality. Another reason was the deeper penetration into the tissue portion of the lesions. Because of the jaw lengths (10 mm vs. 8 or 6 mm), however, lesions with anatomically difficult access such as directly post-pyloric or post-bulbar duodenal-tissue stumps were more difficult to grasp with the Resolution clip. The same applies to the Triclip (12 mm). For assisting staff the one-time clip system was clearly more convenient and quicker to use than the multiple-use clip systems, in which clips are occasionally released erroneously during the application process.

References