Efficacy of hydrostatic balloon dilatation of anastomotic Crohn’s disease strictures

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SUMMARY

Objectives — To estimate the efficacy of hydrostatic balloon dilatation (HD) of anastomotic strictures of Crohn’s disease and the impact of medical treatment on the duration of HD effects.

Methods — Sixteen patients with anastomotic stricture (average length 4.7 cm) were treated by HD and followed-up for a median duration of 24 months. Immunosuppressive treatment was given when a second HD was necessary.

Results — HD failed in 3 patients (19%). Thirty-two HD were performed in the other 13 (1 HD: 6, 2 HD: 2, > 2 HD: 5). No severe complication was observed. Eight patients received immunosuppressive treatment started before the first HD in 4 cases or following the second HD in 4 cases. Based on actuarial analysis, clinical and surgical recurrence rates were 39% and 0% at 1 year and 73% and 22% at 2 years, respectively. Time between the first and the second HD were not statistically different (P = 0.24) for HD performed with (11.5 ± 8.8 months, range: 5-30) or without (8.0 ± 6.9 months, range: 2-17) immunosuppressive treatment.

Conclusion — HD delays the surgical timing for anastomotic Crohn’s disease strictures. Medical treatment associated with HD does not seem to modify the duration of the clinical remission.

Between September 1997 and June 2002, 16 patients (8 men, 8 women, mean age 44 years) underwent at least one attempted HD of an anastomotic stricture of Crohn’s disease. Patient characteristics are summarized in Table 1. In 11 of the 16 patients, the indication for surgery was fistulizing Crohn’s disease. Initial resection of Crohn’s disease lesions was completed in all patients who all presented endoscopic signs of recurrence. Twelve of the 16 patients presented ulceration of the colonic portion of the anastomosis. Four patients free of colonic ulceration presented intestinal ulcerations distant from the anastomosis.

Hydrostatic dilatation technique

HD was performed under general anesthesia (Diprivan®) in all patients after preparation with polyethylene glycol given orally. The stricture was catheterized with a Microvasive Rapid Flex® balloon (Boston Scientific) measuring 15 or 20 mm in diameter. The balloon was inflated with water under manometric control. A guidewire was used to facilitate catheterization if needed. A 20-mm balloon measuring 5 to 8 mm in length was used for most of the patients. Maximal pressure was maintained for two periods with a total duration of 2 to 3 minutes. HD was considered successful if the balloon could be inserted and dilated to a diameter greater than or equal to 10 mm, whether the endoscope could pass through or not. If the stenosis could not be catheterized, HD was considered to have failed. The patient was discharged the evening of the procedure or the next morning unless there were complications.

Medical treatment associated with HD

Immunosuppressor treatment could be continued or instituted at the first HD in the event of early postoperative recurrence or steroid dependence if steroid resistance had developed since surgery. Immunosuppressor treatment was given systematically if the patient underwent a second HD; treatments were adapted to efficacy and tolerance of prior immunosuppressors. Corticosteroid treatment (prednisone, budesonide, or bethamethasone for patients with intestinal obstruction) was generally prescribed before the first HD and generally continued for 4 to 8 weeks after the first HD independently of the endoscopic findings. Corticosteroid treatment was not usually proposed in association with subsequent HD.

Patient follow-up

All patients were seen 1 to 2 months after HD, then as needed for routine care. HD was considered effective if the clinical signs of obstruction resolved. In the event of clinical recurrence, defined as resumption of the initial clinical signs after a symptom-free period, a new endoscopy
was proposed for a second HD procedure if the patient presented anastomotic stricture. We noted time to clinical recurrence and time to surgical recurrence. The effect of associated immunosuppressor treatment (azathioprine, N = 17). Time between the first and second HD procedures (mean 2.5 per patient, range 1-8). Among the five patients who were not given immunosuppressor treatment, four had had one HD and the fifth (n = 10) was given successively azathioprine, methotrexate, and ciclosporin, with no effect. Globally, 19 of the 32 HD were performed in association with immunosuppressor treatment (azathioprine, N = 17). Time between the first and second HD was statistically different (P = 0.24) between patients undergoing HD with or without immunosuppressor treatment (11.5 ± 8.8 months, range 5-30 versus 8.0 ± 6.9 months, range 2-17).

**Discussion**

With the exception of two studies [14, 16], all reports on HD of strictures in Crohn’s disease patients have been retrospective analyses. Like our study, most reports have included a small number of patients [11-21]. We limited our analysis to anastomotic strictures diagnosed in patients with symptoms suggestive of intestinal obstruction which did not respond to short-term corticosteroid therapy; this type of patient would appear to be the best candidate for HD [14]. We considered that Crohn’s disease was
Table II — Characteristics of patients treated by hydrostatic dilatation.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Length of stricture (cm)</th>
<th>Ulcerations of stricture</th>
<th>Time from surgery to first HD (months)</th>
<th>Medical treatment</th>
<th>Number of HD</th>
<th>Follow-up after HD (months)</th>
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we = data not available

(1) or (2): treatment given during first or second hydrostatic dilatation (HD)

active in all of our patients at the time of HD and that the anastomotic strictures signaled disease recurrence [6]. The goal was a high rate of technical success of HD, in terms of preventing surgical recurrence, which reached 100% at one year and 88% at two years in our patients. Success rates reported by others are difficult to compare with ours due to technical differences: reports of HD for anastomotic and spontaneous stricture without distinguishing the results, imprecision of failure criteria (particularly surgery after one or two HDs), variable associated medical treatment (systemic or local corticosteroids, immunosuppressors), expression of the results. Three studies have reported actuarial survival curves taking surgical recurrence as the end point. For Sabate et al. [20], the rate of successful HD in terms of prevention of surgical recurrence was 71% and 63% at one and two years respectively. Couckuyt et al. [14] reported corresponding figures of 75% and 43%. In their controlled study, Raedler et al. [16] found a 20% rate of surgical recurrence at one year when HD was associated with azathioprine and budenoside and 33% when associated with placebo (p = 0.02). The patients in these three studies, like ours, required repeated HD to delay surgery. The rate of clinical recurrence after a single HD was 39% and 73% at one and two years respectively. The mean duration of clinical remission after one HD was about one year. This relatively short remission, particularly in comparison with that obtained after surgical treatment, is the main limitation of the method. It would however be rational to propose repeated HD when the treatment is effective in patients with a high risk of short bowel and for patients who develop early postoperative recurrence. For other patients requiring several repeated HDs in a short period of time, surgical treatment should probably be proposed since remission is usually longer. The number of HD procedures has varied from 1 to 18 in published series [21]. In the two largest series, only 26% [19] and 33% [14] of patients had more than one HD. In our series, 54% of patients had one HD, a possible expression of better results in terms of preventing surgical recurrence.

We did not find that associated medical treatment with HD significantly affected the duration of clinical remission. Unlike the results reported by Raedler et al. [16], our data did not show longer clinical remission after HD in patients given immunosuppressors. Nevertheless, they reported retrospective results which may have included patients with more severe Crohn’s disease and possibly higher risk of early recurrence. It would be of interest to assess the usefulness of early recurrence. It would be of interest to assess the usefulness.
of giving azathioprine, which has a demonstrated beneficial effect in Crohn’s disease, in association with HD in a prospective study. The report by Raedler et al. [16] is still not available in full article form five years after publication of the abstract. Azathioprine and its derivatives are generally considered as effective treatment for the prevention of postoperative recurrence. In a controlled therapeutic trial enrolling 131 operated patients followed for two years, the efficacy of desonide [50 mg/d] was significantly superior to that of placebo for the prevention of endoscopic and clinical recurrence [22]. In a recent retrospective study [23], 38 patients with Crohn’s disease were treated with azathioprine for the prevention of postoperative recurrence. The probability of clinical relapse was 9%, 16% and 28% at 1, 2 and 3 years respectively. These relapse rates are lower than usually reported [7-10]. Our study does not provide any evidence in favor of a beneficial effect of systemic corticosteroids in this indication. We have been unable to find any data concerning a possible beneficial effect of systemic corticosteroids after HD. The only data available concern local injections [15, 17-19]. These studies reported results for 6 to 13 patients followed for 3 to 73 months and found a long-term success rate of 100%. Nevertheless, the superiority of this technique over simple HD is not established because none of these studies included a control group.

The technical aspects of HD have not been standardized, particularly the duration of the dilatation and the minimal diameter necessary for successful HD. Passing a colonoscope through the stricture after HD is probably a good way to determine the efficacy of the HD. Couckuyt et al. [14] observed that for other reasons, the duration of the dilatation was significantly longer (P = 0.007). We were able to pass through the stenosis in 93.7% of our patients. For other reports, the rates varied from 45% to 73% [14, 20, 21]. The rate of technical failure has ranged from 0 to 29% and, as in our series, has generally been due to inability to catheterize a very tight stenosis or to an angle preventing introduction of the balloon. The length of the stricture was not a cause of failure but most of our anastomotic strictures were relatively short (4.7 cm on average). Longer strictures to the order of 20 cm have been dilated successfully by others [14, 17]. All of our failures were observed in our first HD procedures (19% of patients). We did not note any particular technical problem for repeated HD. In our patients, the presence or absence of ulcerations at the level of the stricture did not appear to be a cause of failure. Similarly, there is no evidence of relationship between disease activity and long-term success of HD [14].

The risk of complications appears to be limited. In series reporting more than 10 patients [13, 14, 20, 21] the complication rate has varied from 0% to 16%. The most common complications are perforation (about 5%) [13, 14, 20], which requires surgery in about one out of two cases. Digestive bleeding is usually benign and has been observed in 0 to 7.5% of patients [14, 20].

In conclusion, hydrostatic dilatation of anastomotic strictures in patients with Crohn’s disease is a safe and effective method. It can retard the need for surgery which can be avoided in the mid term. The procedure must be repeated in most patients to obtain sustained results. The supplementary benefit of associating immunosuppressive treatment remains a question of debate. HD can be recommended for the first-intention treatment of anastomotic strictures in Crohn’s disease, particularly in patients who do not respond to corticosteroid treatment and who have a risk of short bowel syndrome.

REFERENCES


