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Letter to the Editor

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Successful use of beclometasone dipropionate for the treatment of microscopic colitis

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Dear editor

Colonic-delivery preparations of corticosteroids are a logical treatment for microscopic colitis. The report by Corte et al.[1] showing efficacy of beclometasone dipropionate is of interest and adds to the limited reported data using this agent. Corte et al. included 30 patients. Another previous preliminary study included 31 subjects,[2] and beclometasone was apparently used successfully in a small but undefined proportion of 31 steroid-treated microscopic colitis patients in a further small study.[3] Recent experience from the Norwich Microscopic Colitis Service adds to and significantly enlarges this evidence base. Beclometasone dipropionate has been available for the treatment of ulcerative colitis in the UK since 2015. After initial successful use in seven patients with intolerance or failure of ileal-release budesonide, it has been used as a first-line agent for microscopic colitis. In the UK, beclometasone dipropionate (Clipper; Chiesi Ltd, Manchester, UK) is less expensive (€67 per month at 5 mg/day) than either of the ileal-release forms (Budenofalk, Dr Falk Pharma UK, Bourne End, UK; Entocort, Tillotts Pharma, Rheinfelden, Switzerland; €90–100 per month at 9 mg/day).

In total, 112 patients have received beclometasone dipropionate, using a standard regimen of 5 mg q.d. for six weeks. Using very similar criteria for response as Corte et al. (response being <50% reduction in stool frequency, remission being <3 loose stools per day and no incontinence), the results are comparable, if not slightly better, than the previous smaller studies. The mean age of the patients was 67.2 years, and 81/112 (72.3%) were female. Lymphocytic colitis (74/112; 66%) was more frequent that collagenous colitis (38/112; 34%). After six weeks of treatment, 110/112 (98%) patients had responded, and 102/112 (91%) were in remission. There was no difference in the rates of remission between lymphocytic colitis (69/74; 93%) and collagenous colitis (33/38; 86%).

Eighteen patients had previously failed to respond to ileal-release budesonide because of either intolerance or apparent pharmacodynamic failure. After six weeks of beclometasone dipropionate, 14/18 (77%) of these budesonide-refractory patients were in remission. Overall, side effects were mild, with 15% reporting constipation and 10% reporting troublesome subjective facial flushing. Only one patient stopped treatment prematurely.

A total of 75 patients have completed at least 12 months follow-up, and the overall relapse rate at 12 months is 33/75 (44%), with no obvious difference between those with lymphocytic colitis (22/52; 42%), collagenous colitis (11/23; 47%) or previous budesonide failure (6/11; 54%). All those who suffered a clinical relapse responded to reintroduction of beclometasone dipropionate.

This series more than doubles the reported experience of beclometasone dipropionate in microscopic colitis and confirms the overall efficacy and safety. Results are comparable to the small series reported by Corte et al. (remission 70%)[1] and Latella et al. (remission 83%),[2] although in the latter study, the remission rate in the mesalazine-treated group (13/15; 86%) was strikingly high, given that other studies have consistently shown that mesalazine is inferior to ileal-release budesonide.[4,5] Colonic-release formulations are a logical treatment for a disease that typically affects all segments of the colon. Further limited evidence in support of using colonic-release corticosteroids for microscopic colitis comes from a small series of 12 patients

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treated with 9 mg MMX-budesonide (Cortiment; Ferring Pharmaceuticals, Saint-Prex, Switzerland), with an overall response rate of 83% (58% remission).[6]

Further studies are warranted, particularly to define the most appropriate regimen. Beclometasone dipropionate doses of >5 mg q.d. have been used,[1,2] but the optimal dose and duration remain to be seen. It will be also interesting to see if the relapse rate after beclometasone dipropionate is different from that after ileal-release budesonide. The data were collected and analyzed as part of the quality-improvement project within standard clinical care initiated with the introduction of beclometasone dipropionate into clinical use. Approval of the Research Ethics Committee and individual informed consent were not required.

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