

Early treatment and prevention of the radiation proctitis—composite enemas containing sodium butyrate

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Dear Editor:

With interest, we read the paper by Pironi et al. “Chronic radiation-induced proctitis: the 4 % formalin application as non-surgical treatment” considering the problem of proctitis induced by chronic radiation.

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Radiation-induced proctitis is a very important problem in irradiated patients. The frequency of radiation proctitis, presented in publications, mostly affects severe cases with clear clinical symptoms. It is estimated from 5 % to more than 50 %, and depends on knowledge of doctors treating patients and criteria used for evaluation the symptoms. Main factors determining those criteria are different radiation protocols, observation period, and standard of diagnosis.

Evaluation of proctitis starts from some mucosal lesions, which are mostly asymptomatic and can be detected only in proctoscopy and histological examination of the mucosal specimen. This phase, called acute endoscopic proctitis, can lead, in most cases, into acute clinical proctitis with diarrhea, rectal bleeding, mucoid discharge, rectal pain, tenesmus, changes in bowel movements frequency, urgency, and continence problems. Severe symptoms, with bleeding leading to anemia, occur in patients with chronic clinical proctitis. Surgery is avoided in most of the cases so the nonsurgical treatment in those patients is indicated. Effective and popular methods are endoscopic treatment with argon plasma coagulation, laser therapy, application of the low concentration of formalin, or hyperbaric oxygen therapy. These techniques may cause some complications and side effects. Their effectiveness, as well as time of recurrence of symptoms, varied in different publications.

Multiple experiments confirmed indication and effectiveness for the prevention of radiation proctitis. In our opinion, there are three main steps to reduce the frequency and severity of the proctopathy after radiation:

1. Early prevention of proctitis starting even before radiation: This may be achieved by anti-inflammatory treatment, usage of the physiological agents and promotion of colonocytes renewal. The therapy can be administered

orally, using probiotics or short chain fatty acids (SCFA). Laxatives in low doses, fiber supplementation, as well as sufficient water intake can improve bowel movements and reduce the risk of mechanical injury. Administration of laxatives requires caution and a control of clinical condition as a diarrhea prevalence. Very effective way of prevention of proctitis is a topical treatment using enemas. Prophylaxis should be administered as soon as possible. In some studies, authors started enema with steroids as the prevention even before radiation.

2. Early diagnosis of the acute radiation proctitis using proctoscopy and clinical evaluation: Patients need to be informed about the risk of radiation proctitis. Clinical follow-up should be started immediately after radiation. Proctoscopy is necessary as an effective method of the proctitis detection. Clinical evaluation has to follow one of the common scoring algorithms as well as their adaptations.
3. Pharmacotherapy of the chronic proctitis: Topical treatment is indicated. In mild or moderate clinical course SCFA or probiotics can be used. Therapy of the severe courses is mostly based on topical treatment using steroids, 5-ASA, mesalazine, or other substances. In cases with severe bleeding and ineffective pharmacological therapy other procedures such as endoscopic intervention, formaline enemas, or oxygen therapy can be considered.

Our experiences based on observations during a pilot study focused on early prevention and treatment of radiation proctitis. In our study, we are using composite enema. Due to early stage of our investigation we cannot describe technical details of the enema composition. Capacity of 150 ml enema contains sodium butyrate and specified nonorganic nanostructure with high absorption capability and antibacterial characteristic. Sodium butyrate has an anti-inflammatory effect on the bowel mucosa. Butyrate is an important energy source for

colonocytes. It can induce regeneration and improve condition of mucosa. Enemas were used in two groups of irradiated patients: in group I as prevention of radiation proctitis (nine patients) and in group II as a treatment of acute proctitis (ten patients). The study is a randomized prospective placebo controlled investigation for 100 patients (50 patients in prophylactic group and 50 patients in treatment group). In this pilot study, the mean observation time was 6 months.

In group I—prevention of proctitis—enemas were applied by the patient once a week during 3 months, started 2–14 days after radiation due to the prostate or cervical cancer. During control examination, we observed six patients with early endoscopic proctitis. In one case, acute clinical proctitis with mild clinical manifestation occurred. During the observation period until now (4–7 months), no severe radiation proctitis, bleeding, or indication for more advanced treatment were observed.

In group II—patients with mild or moderate radiation proctitis (without active bleeding)—we used the enema in the same dose and frequency. During the observation (6 months) in six patients, a decrease of clinical symptoms and endoscopical signs was observed; in four patients, there were no differences before and after enema. During the observation period until now, no patients required more intensive treatment, no patients reported bleeding, or increase of clinical symptoms.

In our opinion, prevention is very important to reduce severity and frequency of radiation proctitis. Enemas under investigation, containing sodium butyrate, can be very effective in proctitis prophylaxis. Small number of patients with severe complications may require more aggressive treatment, including argon coagulation, formaline enemas or oxygen therapy.

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