



## ORIGINAL ARTICLE

# Therapeutic requirements in active ulcerative proctitis: A single-centre study



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### KEYWORDS

Ulcerative proctitis;  
Mesalazine;  
Suppositories;  
Topical treatment

### Abstract

**Background:** Ulcerative proctitis (UP) presents distinctive clinical characteristics, outcomes and therapeutic approaches as compared to left-sided and extensive ulcerative colitis (UC).

**Aim:** To describe the current therapeutic requirements and clinical outcomes in patients with active UP.

**Methods:** Retrospective observational study conducted in a referral IBD centre. Patients with UP in follow-up between 1989 and 2014 were included. The clinical characteristics, as well as the different treatments and drug formulations administered to treat flares, were recorded.

**Results:** Out of 687 UC patients, 101 patients (15%) with UP were included. Median follow-up was 8 years (IQR 3–14) and 49% of patients presented disease activity during the study period. Topical mesalazine monotherapy (90%) was the most commonly administered treatment for disease activity (mostly as suppositories), followed by topical steroids (47%) and oral mesalazine (56%) in monotherapy or combination therapy. Only 14% and 16% of patients required oral prednisone and beclomethasone, respectively.

**Conclusions:** In clinical practice, active UP presents mostly favourable outcomes. Mesalazine suppositories are by far the most used treatment for these patients.

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**PALABRAS CLAVE**

Proctitis ulcerosa;  
Mesalazina;  
Supositorios;  
Tratamiento tópico

## Requerimientos terapéuticos en el tratamiento de los brotes de la proctitis ulcerosa. Estudio unicéntrico

**Resumen**

*Antecedentes:* La proctitis ulcerosa (PU) presenta unas características clínicas, evolutivas y terapéuticas distintas con respecto a la colitis ulcerosa izquierda o extensa.

*Objetivo:* Describir los requerimientos terapéuticos y la evolución clínica en pacientes con PU activa.

*Métodos:* Estudio observacional retrospectivo realizado en un centro de referencia en EII, en el que se incluyeron pacientes en seguimiento entre 1989 y 2014 con PU. Se registraron las características clínicas, así como los diferentes tratamientos y galénicas utilizados para tratar el brote de actividad.

*Resultados:* De un total de 687 pacientes con colitis ulcerosa se incluyeron 101 (15%) con PU. La mediana de seguimiento fue de 8 años (RIC 3-14). El 49% de los pacientes presentó actividad de la enfermedad durante el período a estudio. La monoterapia con mesalazina tópica (90%) fue el tratamiento más utilizado para la actividad de la enfermedad (predominantemente en forma de supositorios), seguida de los esteroides tópicos (47%) y la mesalazina oral (56%) en monoterapia o en terapia combinada. Solo el 14 y el 16% de los pacientes requirieron prednisona oral y beclometasona, respectivamente.

*Conclusiones:* En la práctica clínica, los supositorios de mesalazina son el tratamiento más utilizado en pacientes con PU activa, presentando la mayoría de ellos una evolución clínica favorable.

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**Introduction**

Ulcerative colitis (UC) is a chronic, inflammatory, relapsing-remitting disease. The rectum and colon are continuously involved proximally from the anal verge. UC is classified, according to the extent of inflammation, into ulcerative proctitis (UP) when the inflammation is limited to the rectum, left-sided colitis (when it reaches up to splenic flexure), and extensive colitis (when inflammation extends beyond the splenic flexure of the colon).<sup>1</sup> The reason for this classification relies on that disease extent determines a different disease course and prognosis. Moreover, distal forms of UC can be managed with only rectal therapies. Finally, UP has not an increased risk for colorectal cancer, allowing a less intensive disease monitoring.<sup>2</sup>

In population-based studies, UP accounts for more than a quarter of UC patients.<sup>3,4</sup> UP usually runs a milder course as compared to more extensive disease (in terms of requirement for hospitalization, intravenous therapy, and colectomy),<sup>5</sup> and that is the reason why medical literature has paid less attention to this minor form of UC. However, symptoms in UP (particularly, tenesmus, urgency, and incontinence) impact deeply on the patients' health-related quality of life.

Rectal formulations, particularly mesalazine suppositories, are the first line therapy in UP since they achieve higher concentrations of active drug into the rectum and act directly to the inflamed mucosa providing better results as compared to oral formulations.<sup>6-8</sup> Moreover, rectal formulations show a better safety profile as compared to oral treatments. However, rectal therapies are

often inconvenient for the patients because of limited tolerance (particularly when the rectal mucosa is severely inflamed), or even because of the impossibility to be self-administered. These drawbacks may be relevant in some circumstances such as in elderly patients (with less anal continence and physical agility) or in patients living alone.

Although there are evidence-based arguments supporting the superiority of rectal mesalazine over rectal steroids for inducing symptomatic improvement and remission in distal UC,<sup>9</sup> there is the belief among patients and even some physicians that steroids are more powerful (and efficient) than mesalazine.<sup>10</sup>

In addition, topical mesalazine was available later than topical steroids. In Spain, the availability of different galenical formulations and dosages for topical mesalazine (suppositories, foams, and enemas) has considerably increased within the last decade, offering a wide variety of treatment options, while topical steroids are limited to two presentations, in foam and enema.

Although the combination therapy of oral and topical mesalazine is more effective than any of them alone, there are few data reporting the efficacy of topical mesalazine and topical steroids to treat active UP.

Despite the above-mentioned literature, studies performed in real-life clinical practice and specifically in patients with UP are scarce. Therefore, the aim of the present study was to assess the different treatment options and galenical formulations used in daily clinical practice for our cohort of UP patients with active disease. As a secondary aim, the use of clinical resources and disease course were also evaluated.

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