



Management of ulcerative proctitis by rectal route of drug administration: A case study

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ABSTRACT: Proctitis is inflammation of the rectum which commonly affects middle-aged who presents with increased defaecation frequency. Diarrhoea is often bloody stools mixed with mucous and has to be differentiated from colorectal carcinoma. Inflammation of proctitis is generally confined to the rectum and can ascend proximally to the colon termed as procto-colitis. Although after making a concrete diagnosis, treatment of procto-colitis is unpredictable with waxing and waning symptoms pertaining to lower gastrointestinal tract. Rarely, proctitis with ulcerations can also be presented with severe constipation.

In this study a female patient with ulcerative proctitis responded well to the targeted treatment of *gudavrana*. Mainline treatment was rectal instillation of medicated *ghrita* with internal medications having *vraṇa-sodhana* and *vraṇa-ropana* properties. Treatment further focused on *rasaayana* with the intention to reduce recurrence, minimize the risk of progression into ulcerative colitis / colo-rectal carcinoma and to improve the quality of life of the individual.

Keywords: Ulcerative proctitis, jatyadi ghrita, gudavrana, vraṇa-sodhana

INTRODUCTION

Ulcerative proctitis is a subcategory of ulcerative colitis which is an inflammatory bowel disease affecting rectum and colon with extra intestinal manifestations. Colonic inflammation is diffuse, confluent and superficial; primarily affecting mucosa and superficial submucosal layer of intestinal walls. Ulcerative colitis is common in USA and Western Europe but relatively rare in the far East and tropics. ^[1] The incidence and prevalence of ulcerative colitis is increasing day by day especially in Northern India, due to dietary habits including consumption of spicy, hot and fried foods and faulty lifestyle. Virtually in all cases, the disease starts in the rectum and extends proximally in continuity. Proctitis is present in most cases of ulcerative colitis. Aetiology of the ulcerative proctitis remains uncertain although environmental factors, intestinal flora, immune

dysregulation and genetic predisposition play their role in disease pathogenesis.

Clinical symptoms of *paaka* as expounded in *samhitas* show the involvement of *tridoshas* which are *rujaa* in *vaata*, *paaka* in *pitta* and *pooya* in case of *kapha-vrddhi*. Here *guda* is involved and thus the word is coined as *gudapaaka*. ^[2,3] This represents the inceptive inflammatory stage of ulcerative proctitis. Exploring the disease pathogenesis in light of *shatkriyaa-kaala*, manifestation of *guda-paaka* is at *sthaanasamśraya* phase. As a sequel, the condition progresses to ulceration of rectal mucosal layers, expressing true identity of the disease *gudavrana* at *vyaktibhaava* state. This is terminal phase for advising accurate treatment to impede its advancement to ulcerative colitis or colo-rectal carcinoma. Treatment principle is based on *dusta-vraṇa cikitsa*, applying

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appropriate treatments mentioned in *shashṭirupakrama*.

PATIENT INFORMATION

A female patient aged 52 years, diagnosed as having ulcerative proctitis reported at OP Department of Salyatantra (MRD No:261944), Vaidyaratnam Ayurveda College Hospital, Ollur, Thrissur on 2nd September 2024. She presented with lower GI symptoms of prolonged constipation, tenesmus and abdominal cramps for one year. Defecation was initiated only with the application of suppositories once in 4 days, stools being hard making the process painful. This was associated with bleeding per anum mostly clots and blood-stained brownish watery discharge, often mucous mixed. Over a period of time, local manifestations aggravated complicating with systemic involvement when the patient had severe weight loss, anaemia, dizziness and general weakness. Additionally, she was anguished due to recent demise of her son. Patient was afebrile throughout the course of disease.

The investigation reports of hematological, colonoscopic and histopathological study was thoroughly analysed. Colonoscopy report on 9/04/2024 shows diffuse ulcerations in distal rectum. Biopsy test detailed the histology of rectal mucosal bits with superficial ulceration, edematous lamina containing mixed inflammatory cells, focally with collections of neutrophils around ruptured crypt abscess, evidence of cryptitis, mucin depletion and architectural distortion of glands. The endoscopic and histopathological tests affirmed the diagnosis of ulcerative proctitis.

Table 1
Hematological reports

S.No.	Hematological reports	Values Range	Normal
1	Hb	9.8gm/dl	12.3-15.3gm/dl
2	TSH	2.03uIU/ml	0.27-4.2uIU/ml

Anorectal examination

- Inspection: Errythmatous appearance on anal verge
- Palpation: No induration, no swelling and tenderness
- Digital examination: No palpable mass within anal canal lumen/ outside the canal wall; altered - blood on gloved finger
- Proctoscopy: Red coloured inflamed mucosa, ulcerations seen, discharge of blood clots and blood mixed with mucous were present on withdrawal of proctoscope.
- Vital Signs: Heart rate: 80bpm, Blood Pressure: 116/70 mmHg, Temperature: 98.6 F, Body weight: 45kg

Therapeutic intervention

Phase 1 (Target –*Vrana-sodhana* and *ropana*)

(Duration of treatment: 1 week)

1. Triphala guggulu Tab^[4] - 2-2-2 After food with warm water
2. Rasa sindhoora Capsule^[5] - 1-0-1 After food with warm water
3. Jatyadi ghrita^[6] - 50 ml per rectum for 7 days (Instillation)

Phase 2 (Target –*Samana cikitsa*)

(Duration of treatment: next 1 week)

1. Triphala guggulu Tab - 2-0-2 After food with warm water
2. *Rasa sindhoora* Capsule - 1-0-1 After food with warm water
3. Avipathy choorna^[7] - One tsp with honey, after food
4. Jatyadi ghrita - Local Application (Anal canal)
5. Phase 3 (Target –*Rasaayana*)

(Duration of treatment: For 1 month and thereafter)

1. Triphala guggulu Tab - 1-0-1 After food with warm water
2. Rasa sindhoora Capsule - 0-0-1 After food with warm water
3. Manasamitra tablet^[8] - 0-0-1 After food with milk

FOLLOW UP AND OUTCOME

Patient showed immediate symptomatic response

in a span of 2 weeks. Before ayurvedic intervention, bowel movement of the patient was constipated and suppository aided which improved to regular formed stools without tenesmus. Discharge of blood clots per rectum gradually reduced to minimal blood streak on stools, once in fortnight. Moderate weight gain was observed in another two months.

Table 2
Periodical assessment in patient

Methodology	Ano-rectal Examination on 2/09/2024	Ano-rectal Examination on 17/9/2024	Ano-rectal Examination on 29/10/2024
Inspection:	Erythematous lesions at anal verge	No lesions found at anal verge	No lesions found at anal verge
Digital examination:	Blood stains on gloved finger	No blood stains on gloved finger	No blood stains on gloved finger
Proctoscopic Examination:			
(i) Mucosa	Red inflamed mucosa	Pinkish mucosa	Pinkish mucosa
(ii) Anal canal	Anal canal and rectum filled with blood clots and blood mixed with mucous. Ulcerations found in distal rectum, anal canal. partially obscured due to presence of blood clots	No blood clots and mild blood mixed mucous in rectum. Healing ulcers found in rectum and anal canal.	No blood clots and no blood mixed mucous in anal canal.No ulcerations in anal canal Rectum, Anal canal: normal



Figure 1
Examination on 2/9/2024: Erythematous lesions at anal verge,blood mixed mucous discharge

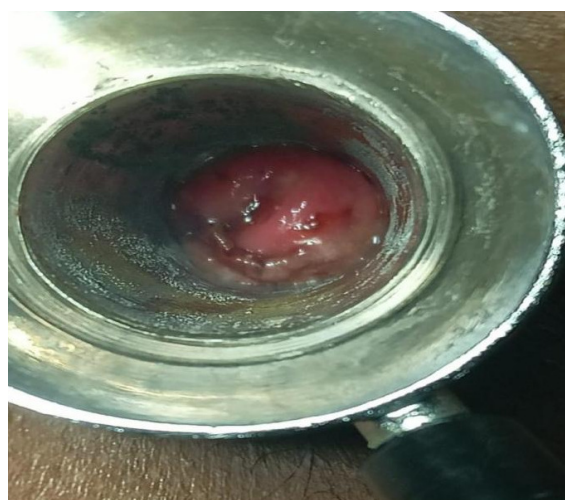


Figure 2
Examination on 17/9/2024: Pinkish mucosa with minimal blood mixed fluid discharge



Figure 3
Examination on 29/10/2024: Pinkish mucosa with no mucous discharge, No blood clots and ulcerations

DISCUSSION

Treatment of ulcerative proctitis was executed after thoroughly examining the patient, analysing the disease stage collaborating with investigation reports. Interpreting the condition as *guda-vrana* in ayurvedic purview, the disease was symptomatically put under control in a short period adopting principles of *vrana-cikitsa*. Crohn's and ulcerative colitis questionnaire [CUCQ-8]^[10] scoring system was applied to assess Quality of life of the subject before treatment and after 6 weeks of treatment, the graph of which shows improvement.

In this case, a female patient diagnosed with ulcerative proctitis showed improvement to the comprehensive ayurvedic intervention of *vrana-sodhana*, *vrana-ropana* and *rasaayana* therapy. The patient who showed minimal response to previous treatments done elsewhere was physically weak and malnourished, apart from typical features of lower gastrointestinal pathology. Systemic and local targeted therapy helped to be symptom-free and improve the subject's quality of life. Medication selected for ano-rectal instillation was Jatyadhi ghritha as the formulation possesses *vrana-sodhana* and *ropana* properties simultaneously. Alongside, oral

administration of Tab. Triphala guggulu and Cap. Rasa sindhoora was advised to address the inflamed bowels and associated local/ systemic complications.

Preliminary treatment line was on the basis of *vrana adhisthaana* and the *dosha* involved, thereby applying *raktapitta-hara* medications. Owing to the high probability of infection in rectal ulcerations as it essentially functions as a reservoir and conduit for faeces, *vrana-sodhana* drugs were considered in the first phase. Jatyadi ghritha was instilled at distal rectum, directly to the ulcerations. Later *samana-cikitsa* (systemic internal medicines) and *rasaayana cikitsa* (systemic internal medicines and rejuvenators) were adopted. Drugs were carefully chosen and doses were attenuated according to symptomatic response. It was also noted that patient's haemoglobin value increased to 11.4gm/dl in a period of 3 months.

(i) Rectal route of drug administration:^[9]

Drug absorption following rectal administration is determined by a combination of

- a. formulation-related factors
- b. drug-related factors
- c. physiology-related factors.

For drug absorption to occur it must be released from the formulation and then be solubilized in the low volume of rectal fluid before crossing the mucus layer and epithelium. This is highly dependent on the type of formulation with liquid dosage forms having faster absorption rates.

The physicochemical characteristics of the drug will also affect its ability to be absorbed via the rectal route. This includes

- a. solubility
- b. degree of ionization
- c. partition coefficient
- d. particle size

The solubility of the drug in the rectal fluid will determine the maximum concentration available

for absorption. In general, higher drug solubility is associated with faster dissolution rates and more rapid absorption. Transcellular route is the main mechanism for drug absorption in the rectum. Ideally, drugs should have adequate hydrophilic properties to be soluble in the rectal fluid and be lipophilic enough to cross the epithelium. Smaller particle surface area has a better chance for faster absorption due to higher dissolution rates.

Retention of the formulation is also important for absorption as this will influence its bioavailability and efficacy. For absorption to occur, drugs need to be able to penetrate the mucus layer in order to reach the epithelial cells lining the rectum. Early expulsion of the drug, including following defecation, will also affect the concentration available to undergo passive absorption. Hence, it is important to consider the time of dosing with respect to an individual's bowel movements.

The volume administered can affect drug retention in the rectum. The smaller volumes have shown to have greater retention, while volumes higher than 80 ml can stimulate defecation.^[9] All conventional liquid dosage forms can suffer from various degrees of leakage, which can lead to irregular drug absorption. Positioning the patient preferably in left lateral or dorsal positions after rectal instillation is hereby significant.

(ii) Rationality for selecting Jatyadi ghrita for rectal instillation:^[9]

Jatyadi ghrita is indicated in ulcers which fail to heal easily which can be inferred from the indications quoted in the reference. The synergistic effect of individual drugs proved to have *pitta-raktahara* and *seeta-veerya* properties in general. The drug acts by its concurrent action of *vraṇa-śodhana* and *vraṇa-ropaṇa* which is barely seen in other formulations.

Drugs with a high partition coefficient will be more lipophilic. This may lead to slow release of the drug from formulations that have fatty bases in comparison to more hydrophilic bases. An

optimal balance between hydrophilicity and lipophilicity is important for effective rectal drug delivery which is seen in classical *ghṛta* preparations. Moreover, the formulation incorporates drugs having water soluble components such as phenolics and lipid soluble components as alkaloids and terpenoids.

The viscous consistency of *ghṛta* (ghee) promotes improved retention of formulation. In this case, 50ml of Jatyadi ghrita was retained in the rectum for 3 hours consecutively for a period of one week. To ensure proper retainment of the medicine within rectum, bowel clearance prior instillation of drug and appropriate positioning of the patient after procedure was done. Direct application of Jatyadi ghrita on the epithelium and rectal mucosa for a constant period of time proved to be beneficial.

At relatively neutral pH 7-8 of the rectum and with minimum buffering capacity, basic drugs with an acid dissociation constant (pKa) near or above the physiologic range tend to be more readily absorbed, as they will predominantly be in their non-ionized form. Jatyadi ghrita, inclined towards acidic nature has helped to heal ulcers faster.

Self-emulsifying drug delivery systems (SEDDS) is a recently developed method to enhance bioavailability of poorly soluble drugs. This is attained by enhancing drug solubility and improving membrane permeability. In general, SEDDS are composed of an oily base and a surfactant, with or without a hydrophilic co-solvent or cosurfactant. This creates a liquid dosage form that alters to an oil-in-water emulsion once in contact with the aqueous phase at the site of administration. Jatyadi ghrita itself probably act by the mode of SEDDS, when applied locally to heal the rectal ulcers.

(iii) Discussion on systemic internal medicines and rejuvenators

Tab. Triphalaguggulu: This formulation consists of *aamalaki* (*Embilica officinalis*), *hareetakee*

(*Terminalia chebula*), *vibheetaki* (*Terminalia bellerica*), *krshnaa* (*Piper longum*) and *guggulu* (*Commifora mukul*). It is indicated to relieve constipation and to heal ulcers. The drug was given in a dose of 2 tablet each of 125mg, thrice daily and tapered in subsequent phases of treatment.

Cap. Rasa sindhoora: It is a herbo-mineral formulation prepared by *kooppeepakva* technique. The medicine can be administered in patients having general weakness, abdominal pain, non-healing wounds and inflammatory conditions which were rightly selected for this condition.

Avipathy choorna: Main ingredients of the formulation are *sunthi* (*Zingiber officinale*), *pippali* (*Piper longum*), *marica* (*Piper nigrum*), *elaai* (*Elettaria cardamomum*) et.al which acts as a safe purgative in habitual constipation. It is indicated for *pitta-samana*, *alpagni* and *paandu*.

For local or systemic drug absorption to occur, any formulation needs to be retained in the rectum for an adequate period of time. Increased colonic motility can lead to reduced retention of rectal dosage forms and incomplete drug release. Early expulsion of the drug, including following defecation, will also affect the concentration available to undergo passive absorption. Frequency of bowel movements can be increased in patients administered with avipathy choorna, the reason why the drug was selected only in second phase of treatment.

Manasamitra tablet: The medicine helps to reduce stress, tension and other psychosomatic condition. Thus the drug was selected in the third phase of treatment .

Patient perspective

The patient’s quality of life improved [based on QOL assessment tool for ulcerative colitis: CUCQ-8^[10]] and is symptomatically better.

Crohn's and ulcerative colitis questionnaire-8 modified (CUCQ-8)
 Date: 02/09/24 52 year female OP No: 60144 MRD No: 261944

- On how many days over the last two weeks have you felt tired?
 19...days
- In the last two weeks did your bowel condition prevent you from going out socially?
 a) No, not at all
 b) Yes, some of the time
 c) Yes, most of the time
 d) Yes, all of the time
- On how many days over the last two weeks have you felt generally unwell?
 Most of the days
- On how many days over the last two weeks have you felt pain in your abdomen?
 2-3... days
- On how many nights in the last two weeks have you had to get up to use the toilet because of your bowel condition after you have gone to bed?
 10...nights
- On how many days over the last two weeks has your abdomen felt bloated?
 10...days
- In the last two weeks have you felt upset?
 a) No, not at all
 b) Yes, some of the time
 c) Yes, most of the time
 d) Yes, all of the time
- On how many days over the last two weeks have you had to rush to the toilet?
 10...days

Figure 4
CUCQ-8 Assessment score:19 (Before treatment)

Crohn's and ulcerative colitis questionnaire-8 modified (CUCQ-8)
 Date: 24/10/24 52 year female OP No: 60144 MRD No: 261944

- On how many days over the last two weeks have you felt tired?
 2...days
- In the last two weeks did your bowel condition prevent you from going out socially?
 a) No, not at all
 b) Yes, some of the time
 c) Yes, most of the time
 d) Yes, all of the time
- On how many days over the last two weeks have you felt generally unwell?
 1-2... days
- On how many days over the last two weeks have you felt pain in your abdomen?
 2-3... days
- On how many nights in the last two weeks have you had to get up to use the toilet because of your bowel condition after you have gone to bed?
 2-3...nights
- On how many days over the last two weeks has your abdomen felt bloated?
 2-3... days
- In the last two weeks have you felt upset?
 a) No, not at all
 b) Yes, some of the time
 c) Yes, most of the time
 d) Yes, all of the time
- On how many days over the last two weeks have you had to rush to the toilet?
 1-2... days

Figure 5
CUCQ-8 Assessment score:03 (After 6 weeks of intervention)

CONCLUSION

Ulcerative proctitis is an anatomically limited form of ulcerative colitis. The case study is an example of proper planning and execution of ayurvedic medications in the management of ulcerative proctitis. This was challenging as the patient did not respond symptomatically to a yearlong advanced medical treatment sought elsewhere, with standard drug of prescription for the condition. Minimal medical interventions in minimal duration of time helped the patient recuperate from ulcerative proctitis, a progressive gastro-intestinal pathology. The patient is being monitored and screened at fixed intervals to check for recurrence. Further researches can be carried out to validate the selected drugs and treatment protocol in disease-specific aspect. Research on 'nanoparticulate rectal drug delivery' and its dosage forms can be improvised and investigated to improve therapeutic effectiveness of the prescribed drug for local therapy.

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