Cover page

The prevalence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in patients suspected of hemorrhagic proctosigmoiditis (SOS Proctitis)

A quality improvement project in the Central Denmark Region

Initial internal protocol

Version 1., October 1st, 2024

Quality Assurance Project: Infectious Proctitis, Aarhus University Hospital

Updated on 01.10.2024

Application: Approval of quality assurance project and permission to access patient records and other electronic patient systems without patient consent.

Project Title:

Prevalence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in Patients Suspected of Hemorrhagic Proctosigmoiditis

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Background and Purpose:

It is known that *Chlamydia trachomatis* and *Neisseria gonorrhoeae* can cause infectious proctitis that is macroscopically indistinguishable from hemorrhagic proctosigmoiditis (HP), which is associated with the chronic inflammatory bowel disease ulcerative colitis.

Currently, it is not standard practice to inquire about sexual risk behaviour or test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* during the initial diagnostic workup of proctitis. This is despite the fact that these pathogens represent the most frequent causes of symptomatic sexually transmitted proctitis, with an increasing incidence in Denmark. Their inclusion in the standard diagnostic evaluation for proctitis therefore seems warranted.

As a result, we lack epidemiological insight into how many patients diagnosed with HP may, in fact, have infectious proctitis caused by a sexually transmitted infection with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*.

We aim to determine the proportion of patients with either newly diagnosed or treatment-refractory HP who have an underlying infection with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*. The objective is to evaluate whether routine screening for these pathogens should be implemented in the diagnostic workup of proctitis.

Materials:

All patients suspected of proctitis undergo endoscopy (either sigmoidoscopy or colonoscopy) to establish the diagnosis. In cases of inflammation up to 35 cm from the anal verge, an additional

swab for *Chlamydia* and *Gonorrhoea* will be collected during the examination. If this is not performed at the time of endoscopy, it will be conducted at a follow-up outpatient visit.

Patients who do not respond to standard therapy and continue to have disease limited to the proximal 35 cm will undergo re-testing.

Method:

Over a 24-month period, we will include all patients at Aarhus University Hospital diagnosed with proctosigmoiditis (i.e. endoscopic inflammation from the anal verge to 35 cm proximally) or with treatment-refractory disease (defined by escalation to biological therapy).

Staff responsible for microbiological test ordering for *Chlamydia* and *Gonorrhoea* will assign Dr. David Haldrup, Department of Hepatology and Gastroenterology, as the responsible physician in the EPJ system for test follow-up.

All patients with microbiological test orders under Dr. Haldrup's name will be recorded in the Region Midt REDCap database. These patients will follow standard clinical pathways in the Department of Hepatology and Gastroenterology at Aarhus University Hospital. Patients testing positive for *Chlamydia* or *Gonorrhoea* will be offered treatment through the Department of Dermatology and Venereology, where the responsible consultant is Dr. Line Kibsgaard.

The included patients will constitute a prospective cohort. Their disease course will be documented with respect to the extent of hemorrhagic proctitis and current pharmacological treatment.

Reporting:

Data will be processed by:

- David Haldrup
- Ditte Smed Kornum
- Line Kibsgaard
- Christian Lodberg Hvas
- Anders Kirch Dige

Results will be incorporated into a manuscript for publication, regardless of outcome. If *Chlamydia* and *Gonorrhoea* are found to be prevalent, routine screening will be implemented for all patients referred for proctitis evaluation and for those with treatment-refractory disease.

If patients improve following pathogen-directed treatment and avoid treatment-refractory disease, the project may yield cost savings in terms of reduced use of biological agents.