DRAINAGE AND FLUSHING THERAPY IN NECROTISING PANCREATITIS – A RETROSPECTIVE, MULTICENTRIC STUDY

Munich, April 2023

Dear colleagues,

We all know how challenging the drainage therapy of necrotizing acute pancreatitis can be. Drainage and irrigation regimes seem to vary greatly between centres and literature confirms this impression. For this reason, we would like to investigate the current practice of drainage and irrigation therapy of necrotising pancreatitis in a multicentre retrospective study (DRACULA Trial).

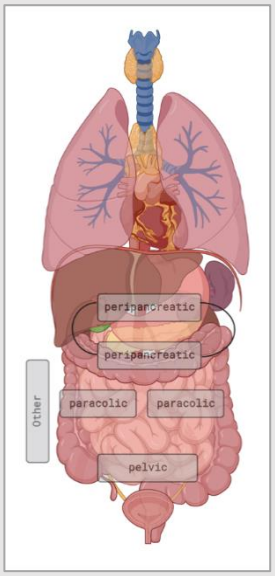
Background

Although a relevant proportion of necrotic lesions in necrotising pancreatitis resolve spontaneously, superinfected necrosis can lead to a septic course and even death [1,2]. In addition to antibiotic therapy, interventional treatment of necrotic collections is therefore often indicated. While in the past such necroses treated by means of open surgery, the superiority of a minimally invasive approaches has been demonstrated in recent years [3]. Such approach usually follows a step-up paradigm escalating from drainage only to drainage and irrigation and eventually necrosectomy, if need. If possible, endoscopy should be chosen as the primary route of access [4, 5]. But not all necroses are amenable to endoscopic therapy due to their anatomical location or the lack of defined wall; some still require the placement of percutaneous drains. Current guidelines do not specify recommendations on which drains should be selected for minimally invasive drainage therapy and which irrigation regime should be chosen with regard to the type of irrigation and flushing volume [1,6].

Method

The DRACULA trial aims to systematically investigate the drainage and irrigation therapy of pancreatic necrosis. It will be investigated whether there are differences in the morbidity, mortality or duration of stay of the patients due to the number or type of drains as well as the type of irrigation regimen. Patients who were treated as inpatients for necrotising acute pancreatitis between 01.01.2016 and 31.12.2022 will be included (data entry via eCRF).

For the first time, systematic data will be collected specifically with regard to drainage therapy of necrotizing pancreatitis:



Necrotic collection:
1) Location (peripancreatic, paracolic, small pelvis, other)
2) Size extension

Drains:
1) Quantity
2) Direction (external vs internal)
3) Diameter [Fr] and length [cm] of drains
4) Time of installation (days after initial diagnosis of pancreatitis), time of removal of last drainage

Flushing:
1) Type of flushing fluid and flushing regimen
2) Number of days with flushing

Objectives

The characteristics of collection are considered as independent variables.
The general parameters on epidemiological data as well as pancreatitis specifications are used for stratification. The following endpoints will be analysed:

Primary endpoint:

- Length of hospital stay

Secondary endpoints:

- Mortality during hospital stay
- Morbidity during hospital stay
- Length of antibiotic therapy
- ICU/IMC therapy

Publication Policy

Based on the number of patients, you and your colleagues can be co-authors in the paper (≥ 10 patients: **1 authorship**, ≥ 20: **2 authorships**, ≥ 50 patients: **3 authorships**).

Possibility to participate

We would be very happy about your participation in the DRACULA trial. Please send us an email with your request to participate in the study. You will receive the study protocol, the LMU ethics vote for submission to your ethics committee, and access to the eCRF system (including declaration). Please send the corresponding e-mail with your request for participation in the study at any time to:

simon.sirtl@med.uni-muenchen.de or marlies.vornhuelz@med.uni-muenchen.de

We would be very happy to hear from you
and are looking forward to generating evidence together with you in the DRACULA trial!

Best regards from Munich,

Marlies Vornhülz, Simon Sirtl
Georg Beyer, Julia Mayerle

References

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