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Nutritional risk in major abdominal surgery: NURIMAS Liver (DRKS00010923) – protocol of a prospective observational trial to evaluate the prognostic value of different nutritional scores in hepatic surgery

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ABSTRACT

Background: Malnutrition is commonly known as a risk factor in surgical procedures. The nutritional status seems particularly relevant to the clinical outcome of patients undergoing hepatic resection. Thus, identifying affected individuals and taking preventive therapeutic actions before surgery is an important task. However, there are only very few studies, that investigate which existing nutritional assessment score (NAS) is suited best to predict the postoperative outcome in liver surgery.
Objective: Nutritional Risk in Major Abdominal Surgery (NURIMAS) Liver is a prospective observational trial that analyses the predictive value of 12 different NAS for postoperative morbidity and mortality after liver resection.
Methods: After admission to the surgical department of the University Hospital in Heidelberg or the municipal hospital of Karlsruhe, all patients scheduled for elective liver resection will be screened for eligibility. Participants will fill in a questionnaire and undergo a physical examination in order to evaluate nutritional status according to Nutritional Risk Index, Nutritional Risk Screening Score, Subjective Global Assessment, Malnutrition Universal Screening Tool, Mini Nutritional Assessment, Short Nutritional Assessment Questionnaire, Imperial Nutritional Screening System, Imperial Nutritional Screening System II, Nutritional Risk Classification and the ESPEN malnutrition criteria. Postoperative morbidity and mortality will be tracked prospectively throughout the postoperative course. The association of malnutrition according to each score and occurrence of at least one major complication will be analysed using both chi-squared tests and a multivariable logistic regression analysis. Already established risk factors in liver surgery will be added as covariates.
Discussion: NURIMAS Liver is a bicentric, prospective observational trial. The aim of this study is to investigate the predictive value of clinical nutritional assessment scores on postoperative morbidity and mortality after hepatic resection. This is necessary, as only a validated identification of malnourished patients at high risk for postoperative complications, enables targeted preventive action.

1. Introduction

Malnutrition is frequently observed among surgical patients. Between 16 and 67 per cent of surgical patients are malnourished before their operation [1–7]. The estimates vary depending on the population examined and the diagnostic instruments used. Patients scheduled for liver resection are a particularly affected group: in a study at the National Cancer Centre in Korea patients with cancerous diseases of the liver had the highest prevalence

Abbreviations: NAS, nutritional assessment score; POD, postoperative day; PLF, postresectional liver failure.

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of malnutrition with a rate of 86.6%. In the total sample of 8895 patients 61% were malnourished [8].

Several studies have identified poor nutritional status as an independent risk factor for postoperative morbidity and mortality in certain patient populations [6,9–11]. However, different instruments for diagnosing malnutrition often show varying and sometimes even contradicting results [12]. In a meta-analysis van Bokhorst-de van der Schueren et al. [12] compared construct/criterion validity and predictive value on clinical outcome of 32 NAS. The authors come to the conclusion that only a few scores are suited to assess nutritional status and accurate in predicting the clinical outcome. Nevertheless, they argue that the development of new scores would be redundant and not likely to achieve higher sensitivity and specificity. Instead, the authors call for trials that analyse different NAS in specific patient populations. This would allow for a better comparison of the diagnostic instruments and could further validate the scores with regard to their predictive value on the clinical outcome.

For patients undergoing hepatic resection, the nutritional status is particularly relevant [13,14]. One of the predictive variables for successful outcome after liver resection, is the remnant liver's ability to regenerate and hence its capacity to sustain metabolic, synthesizing and detoxifying functions [13,15]. Nutritional status before surgery is regarded as one of the key factors that influence this process [2,16]. Yet, there are only few studies that investigate which nutritional markers and screening instruments for malnutrition are suited to predict postoperative liver failure (PLF) and other complications after hepatic resection. Bo et al. investigated the predictive value of the Nutritional Risk Index (NRI) on postoperative survival time after liver resection in patients with primary liver cancer [2]. They showed that patients suffering from malnutrition according to the NRI (values ≤ 100) had a significantly shorter postoperative survival time compared to patients with NRI values > 100. Huang et al. identified low preoperative prealbumin values as an independent risk factor for PLF after resection for primary liver cancer [17]. In a database analysis of 2313 hepatectomies, Aloia et al. identified low preoperative serum albumin levels as major risk factor for poor outcome [18]. They defined albumin levels as a marker for nutritional status.

The disparity of markers and definitions used in the mentioned studies mirrors the lack of validated instruments for identifying malnourished patients that have a higher risk for complications and need additional treatment. There are no studies that compare different nutritional screening tools in terms of their predictive value on postoperative complications in liver surgery.

This trial is part of a series of studies on nutritional risk in major abdominal surgery (NURIMAS), that aims at testing different NAS for their predictive value on postoperative complications in certain patient populations. Trials with patients undergoing upper gastrointestinal and colorectal surgery are planned for the future. Recently published results of the first study, "NURIMAS Pancreas", suggest that none of the tested nutritional scores adequately predicts the clinical outcome for patients undergoing pancreatic surgery [19].

2. Aim of the trial

With the NURIMAS Liver trial we want to investigate whether commonly used NAS are suited to predict postoperative complications after hepatic resection.

Validation of these tools is necessary, since a screening for malnutrition and possible preventive therapeutic actions are only beneficial, if those individuals can be identified, who have a higher operative risk due to their poor nutritional status. Based on a validated screening method in a certain population, measures like peri-operative parenteral nutrition or immunonutrition could be taken effectively.

3. Methods

Study design, measures and statistical analyses of NURIMAS Liver are based on the structure of NURIMAS Pancreas (DRKS00006340) [20].

3.1. Study population

All patients that are scheduled for elective liver resections at the surgical department of the University Hospital Heidelberg and of the municipal hospital in Karlsruhe, will be included. The following criteria will be applied for eligibility (Table 1):

The study population comprises patients with all diseases that result in a hepatic resection. This includes malign oncologic diseases (HCC, CCC, metastasis), as well as benign ones, for example symptomatic cysts, echinococcosis or haemangiomas. Thus, collected data will allow analyses of a representative population, with patients at different ages and health status.

3.2. Diagnostic intervention (Nutritional assessment scores)

Before surgery, information for a total of 12 NAS will be gathered. 11 scores were chosen based on the systematic review by Van Bokhorst-de van der Schueren et al. [12]. In a meta-analysis, they looked at construct and predictive validity of 32 NAS. 11 scores were chosen, that seemed most suitable or promising in a surgical context. In addition, the malnutrition criteria defined by the European Society of clinical nutrition and metabolism (ESPEN) [21] is included. Table 2 gives an overview of the 12 NAS that will be analysed.

3.3. Outcome measures

The association between nutritional risk, as evaluated by the NAS, and complications after liver resection, will be analysed. Thus, postoperative morbidity and mortality is the primary endpoint in this study. Secondary endpoints are comprehensive complication index [32], length of stay in hospital, length of stay in intensive care unit, administration of postoperative enteral or parenteral nutrition and place of discharge (to home, rehabilitation or care facility).

3.4. Trial site and sample size calculation

The trial will be conducted at the department of general, visceral and transplantation surgery of the University Hospital Heidelberg and the department of general and visceral surgery of the municipal hospital of Karlsruhe.

The sample size calculation is based on nomograms for diagnostic studies [33]. Prevalence of malnutrition in liver surgery patients is known to be about 56% [34]. For the sample size a prevalence of 60% was assumed. With a specificity and sensitivity of 95% and a confidence interval of 0.05, according to the nomograms a total of 180 patients will be needed. Taken into account a drop-out of

Table 1
Eligibility criteria.

Inclusion criteria	Exclusion criteria
Age ≥ 18 and ≤ 90 years	Language problems
Elective liver resection	Inability to understand the trial
Written informed consent	