CASE STUDY 1

The diagnostic value of troponin T testing in the community setting

Applicable Regulation and Category
ClinO-MD Art. 6*a*: interventional performance study; category A and subcategory A1

BACKGROUND

Many patients presenting with chest pain to their family physician are referred to the emergency room, in part, due to lack of accurate objective diagnostic tools. This study aimed to assess the diagnostic accuracy of troponin T kit testing for the diagnosis of acute myocardial infarction in patients presenting with chest pain.

METHODS

Consecutive subjects with chest pain presenting to community clinics were recruited. Family physicians performed a first clinical assessment of the patients. Subsequently, a venous blood sample was taken from patients to perform a qualitative troponin T testing. Troponin T testing was performed with a conformity-marked kit that is not prohibited in Switzerland and that was used according to manufacturer's instructions respecting the conformity-marked indications. Patients with both a negative clinical assessment and negative troponin kit were sent home and all others were referred to the emergency room. The validity of the troponin kit test at the family physician's office for the diagnosis of acute myocardial infarction was calculated using sensitivity, specificity, positive and negative predictive values. The result of the troponin T test at the emergency room was considered to be the reference standard.

CASE STUDY 2

Accuracy of different non-invasive tests for the diagnosis of *Helicobacter pylori* infection

Applicable Regulation and Category
ClinO-MD Art. 6*a*: non-interventional performance study not according to Art. 2a paragraphs 1-3; category A and subcategory A2

BACKGROUND

Diagnosis of *Helicobacter (H.) pylori* infection is typically made via an invasive test (endoscopy = reference standard). The aim was to evaluate the accuracy of a non-invasive urea breath test to diagnose *H. pylori* infection.

METHODS

Patients (n=178) presenting for elective upper endoscopy for any reason (including suspected *H. pylori* infection) were enrolled in this study. Patients provided written informed consent and underwent endoscopy of the upper gastrointestinal tract. During endoscopy, in addition to biopsies of any lesion, two sets of gastric tissue biopsies were obtained using large capacity (“jumbo”) forceps. The biopsies were used to detect *H. pylori* on histological staining and in bacterial cultures (reference standard). For the urea breath test, a single baseline breath sample was obtained from study participants shortly after the endoscopy. Subsequently, participants ingested a tagged urea solution and breath samples were obtained 30 and 40 minutes following ingestion of the tagged urea solution. Sensitivity, specificity and accuracy of the urea breath test to diagnose a *H. pylori* infection compared to the reference standard were calculated. Patients and their treating physician were only informed about the results of the reference standard test and not about the results from the urea breath test. Any treatment decisions were based on the results of the reference standard test.