SECOND VIENNA SHOCK FORUM
Vienna Shock Forum Series
Series Editors: Günther Schlag and
Heinz Redl

First Vienna Shock Forum
Part A: Pathophysiological Role of Mediators and
Mediator Inhibitors in Shock

First Vienna Shock Forum
Part B: Monitoring and Treatment of Shock

Second Vienna Shock Forum
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Validity of the Elastase Assay in Intensive Care Medicine

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Introduction
The role in the so called inflammatory response of the polymorphonuclear granulocyte (neutrophil) has been well established (Lang and Fritz, 1986). Excessive neutrophil stimulation in traumatic or infectious foci may cause deleterious effects to the organism, manifested by the failure of shock sensitive organs. The pathogenetic agents responsible for those actions mainly are lysosomal proteinases and oxidative molecules released by the neutrophil. Therefore, the possible use of neutrophil elastase (PMN Elastase) as a biochemical marker for pathologic granulocyte stimulation has been investigated during recent years (Jochum et. al., 1986).

In this paper, data on the validity of plasma PMN Elastase measurements as a prognostic marker for clinical complications in postoperative and posttraumatic intensive care patients are presented.

Methods
For PMN Elastase measurements, in recent years a heterogeneous sandwich ELISA assay (Neumann et. al. 1984) has been used. Now, a homogenous "Immuno Activation" (IMAC) assay is available (Figure 1). This assay can be used for routine measurements of plasma elastase (inhibitor complex) levels. The characteristics of this assay are presented on page 708. The IMAC assay has been positively correlated to the ELISA assay. Due to improved protein purification techniques,
the elastase calibrator used in the IMAC assay (in form of
the elastase-α₁-proteinase inhibitor complex) has a 3 times
higher purity than the calibrator of 1984. The elastase
values of the IMAC assay, therefore, are lower than the
values of the ELISA assay by the factor of 3.0. All raw
data of the studies presented below have been recalibrated
to the new calibrator before evaluation.

1. ELISA TEST
   **PRINCIPLE**

   ![ELISA Test Diagram](image)

   **CHARACTERISTICS**
   HETEROGENOUS, SOLID PHASE SANDWICH ASSAY
   TIME REQUIREMENT: 4 resp. 2 HOURS

2. IMAC TEST ("IMMUNO ACTIVATION" TEST)
   **PRINCIPLE**

   ![IMAC Test Diagram](image)

   **CHARACTERISTICS**
   HOMOGENOUS ASSAY, SUITED FOR MECHANIZED ANALYZERS
   TIME REQUIREMENT: MANUAL 25 min., MECHANIZED 10 min.

   E ELASTASE  I α₁-PI  INDICATOR ENZYME

**Patients**

The studies evaluated in this paper are listed in **Figure 2**. The results of the different studies will be published in
detail by the authors separately.

<table>
<thead>
<tr>
<th>STUDY CENTER</th>
<th>PATIENTS</th>
<th>NUMBER</th>
</tr>
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<tbody>
<tr>
<td>1 INTHORN</td>
<td>POSTOPERATIVE</td>
<td>47</td>
</tr>
<tr>
<td>2 NAST-KOLB</td>
<td>POSTTRAUMATIC</td>
<td>33</td>
</tr>
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</tr>
<tr>
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<td>POSTOPERATIVE</td>
<td>12</td>
</tr>
<tr>
<td>5 SANDTNER</td>
<td>POSTTRAUMATIC</td>
<td>11</td>
</tr>
<tr>
<td>6 DITTMER</td>
<td>POSTTRAUMATIC</td>
<td>8</td>
</tr>
<tr>
<td><strong>TOTAL OF PATIENTS</strong></td>
<td></td>
<td><strong>125</strong></td>
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**Figure 1. Assays for measurement of plasma concentrations of the elastase-α₁-PI complex**

**Figure 2. Study centers and patients included in the evaluation**
Results

The hypothesis to be tested was the question, whether or not plasma elastase measurements in postoperative and posttraumatic patients will yield prognostic information about eventually forthcoming complications in these patients. Daily plasma elastase values (daily mean from 1 to 6 measurements) were correlated, therefore, to the course of the disease on subsequent days.

1. Correlation to Physician's Classification

Plasma elastase values were correlated to the physicians classification, whether or not the patient had suffered complications on the subsequent days. 114 patient reports were accepted as adequately documented for the evaluation. The results of this semi-subjective evaluation are shown in Figure 3: The plasma elastase levels differentiate well between the two groups classified "Complications" vs. "No Complications" during the postoperative/posttraumatic period. A window exists from day 3 to day 7, where the elastase level has predictive quality.

Figure 3. Mean plasma elastase levels from day 1 to 14 of patient groups.
"C = Complications between days 6 and 12", N = 62
"NC = No Complications from days 6 to 12", N = 52
The plasma elastase level on day 5 predicts whether or not a patient will suffer from complications within days 6 to 12, see Figure 4. An elastase discrimination level of 85 μg/l yields the following validity data: Diagnostic sensitivity = 94 %, diagnostic specificity = 79 %, predictive value of the positive test = 84 %, predictive value of the negative test = 91 %.

![Figure 4](image)

**Figure 4.** Discrimination on day 5 between the patient groups "Complications" (C) vs. "No Complications" (NC). Discriminatory plasma elastase level = 85 μg/l.

2. Correlation to the Multi Organ Failure (MOF) Score

To test fully objective criteria, the plasma elastase values were correlated against the MOF Score of Goris (1). In accordance to the work of Goris, a MOF Score of 5 was selected as discriminator between non critically ill vs. critically ill patients. 86 patient reports were accepted as adequately documented for the evaluation. The results are shown in Figure 5. The elastase value on day 5 discriminates between the patient groups "MOF ≥ 5 on days 7 to 12" vs. MOF < 5 on days 7 to 12. An elastase discrimination level of 135 μg/l (405 μg/l in the sandwich assay) yields the following validity data: Diagnostic sensitivity = 83 %, diagnostic specificity = 84 %, predictive value of the positive test = 66 %, predictive value of the negative test = 93 %.


Discussion

This exploratory data analysis is being followed up by a transnational multicenter study. Nevertheless, the data presented already document the diagnostic validity of plasma elastase measurements as a prognostic marker for postoperative/posttraumatic complications. The clinician's classification of a patient's situation is a more sensitive criterion (discriminatory elastase level 85 μg/l) than the MOF Score of 5 (discriminatory elastase level 135 μg/l). Intensive care patients at risk for complications (e.g. organ failure, septicemia) can be identified from day 5 (4th postoperative/posttraumatic day) on for a period of 1 to 6 days in advance. By selecting a suitable discriminatory elastase level, a predictive value of the positive test of 90% can be achieved. Using a discriminatory elastase level of 85 μg/l, no risk patients can equally be identified with a security of over 90% (predictive value of the negative test).
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