University of Groningen

Euricterus-practical applications using the european jaudice database and diagnostic electronic tool

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SUMMARY AND CONCLUSIONS

This thesis contains work on a large European Union project on (sub)clinical jaundice (bilirubin ≥20 µmol/l) in patients aged 16 years or over which was performed prospectively in 28 European countries both within- and outside the European Union, to include 10004 patients of which 8032 fulfilled the criteria to be part of the scientific database. Part of the project was the development of the electronic diagnostic tool Trial©.

Chapter 1 reviews the methods and assesses the systems in use for computer-based clinical decision aids. For diagnosis making and patient management, a large amount of information is exchanged between patient and physician. The computer has several inherent capabilities which are suitable for medical problem solving and can help in the formalization of medical knowledge. The different approaches on which the 'reasoning engine' is built are based on manipulation of information and advocate the use of knowledge to construct a solution to a medical problem. Evaluation of support systems should be made on the accuracy of the program, the nature of the system, the use of the data and the acceptance by the target users. Acceptance by physicians depends among other things on ease of use of the user interface. The rapid growth of on-line computer communication and the development of integrated clinical decision support systems and electronic medical records will induce profound changes in the delivery of health care. Still, computer aided decision making is in its infancy and real support in daily practice is not yet achieved.

Chapter 2 introduces the reader into the backgrounds and the purpose of the Euricterus project. The data obtained in this project provide a baseline for objective measurement of bedside clinical data to diagnose and sometimes prognosticate jaundiced patients, whatever the cause. This data is a source of realistic figures on the diagnostic importance and accuracy of different symptoms and signs. With this

database project as starting point, two further European Union successor projects, one aimed at the development of an electronic medical record for jaundiced patients (IDMR) and one on the contribution of technology to the diagnosis of jaundice (ICTEC) have been completed or are in progress.

In **chapter 3** the overall results of the Euricterus project are described for one European country, the Netherlands. Involved were four university and twenty general hospitals, delivering prospective data on 702 patients. Pancreatic or biliary carcinoma (20%), gallstone disease (13%) and alcoholic liver cirrhosis (10%) were the most frequent causes of hyperbilirubinaemia while pancreatitis (1.7%), fulminant liver failure (1.1%) and malaria (1.0%) were the least frequent. The most frequent symptoms were unwell feeling, dark urine and anorexia and the most frequent signs enlarged liver, looks ill and appears wasted. There were differences in symptoms and signs in patients under and above the median bilirubin of 83 μmol/l and also under and above the median age of 61 years. (Sub)jaundiced patients in general hospitals were older than in the university hospitals and the frequencies of symptoms and signs were different. Disease representation was also different and this in part was due to the referral practice of general practitioners.
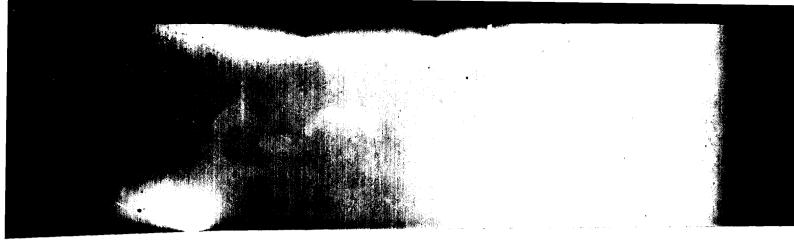
In **chapter 4** severity of disease was assessed in 1015 Euricterus cirrhosis patients with the Campbell-Child and Pugh-Child scores as well as with ascites presence and degree and a new ascites-nutritional state (ANS) score (based on two Child-Turcotte variables, no laboratory parameters). Ascites was found in 70% of the patients and poor nutritional state in nearly half. The median Campbell-Child and Pugh-Child scores (5-15) were both 11. Analysis of the variable limits, variable score ranges and classes A, B and C of the Campbell-Child and Pugh-Child classifications showed different class outcomes to be caused by design differences in score ranges. The ANS score correlated equally well with both the Campbell-Child and the Pugh-Child scores. The results of Campbell and Pugh-Child scores being equal (and

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correlated strongly (r=0.87)
Mayo risk score R and Pu
survival estimates could be a
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these results was stressed.

In **chapter 7** the Euricterus pro
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exchangeable), gives Campbell the advantage that the only laboratory parameters needed are albumin and bilirubin, omitting prothrombin time determination which is not universally available.

Chapter 5 deals with the relation of the protocol laboratory findings in the 1015 Euricterus cirrhosis patients (chapter 4) to the severity assessments of ascites absence or presence (ANY), ascites degree (ADeg), ascites-nutritional state (ANS), Campbell-Child and Pugh-Child scores. Albumin had the strongest correlation with all five severity assessment methods, followed by prothrombin time, plasma water/total protein, whole blood water (males), AST/ALT ratio, white blood cell corpuscles and bilirubin. Also after division of the patients in the liver cirrhosis categories alcoholic, non-alcoholic and with hepatocellular carcinoma, albumin appeared (of the variables tested) to be the prime laboratory parameter in cirrhosis severity assessment.

In **chapter 6** the Mayo clinic prognostic model risk scores and survival estimates and the Pugh-Child-PBC scores and classes were calculated in 143 Euricterus primary biliary cirrhosis (PBC) patients. The median estimated survival of this PBC population (Mayo) was 14% at 5 years. Pugh-Child-PBC and Mayo Clinic scores correlated strongly (r=0.87) and all Mayo and Pugh variables correlated with both Mayo risk score R and Pugh score P. The conclusion was that Mayo 1-7 year survival estimates could be affixed to Pugh scores, delivering an easy assessment method for the most important period for therapeutic decisions. The need to validate these results was stressed.

In **chapter 7** the Euricterus protocol laboratory parameters in 143 PBC patients were related to the Pugh-Child-PBC and Mayo model scores (chapter 6). A significant correlation was found between both Mayo and Pugh scores and total protein/plasma water and AST/ALT ratio and the Mayo and Pugh laboratory variables albumin,

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bilirubin and prothrombin time. The peak values of ALT, AST, ALP and LDH all were in Pugh scores 7 to 9 and Mayo scores 6.1 to 7.8. The six patients with white blood cell corpuscles above 12 x10^9/l all had ascites. The conclusion was that in this PBC population albumin, bilirubin, prothrombin time, total protein/plasma water and AST/ALT ratio were all related to the severity of disease and prognosis.

In **chapter 8** the use of the Euricterus electronic diagnostic tool Trial©, which is based on data derived from the Euricterus database, is exemplified with the 143 Euricterus PBC patients (chapters 6 and 7). Trial© delivers diagnostic probabilities based on Bayes' theorem and Trial Algorithm. The diagnostic probability of PBC was mentioned with Bayes in 86% and with Trial Algorithm in 91% of the patients. In the patients who did not have PBC as sole diagnosis, non-alcoholic active liver disease and pancreatic or biliary carcinoma were the leading other first diagnoses. PBC was mentioned by the tool in all patients with a Pugh-Child-PBC score 10 or higher (advanced disease). The conclusion was that the electronic tool Trial© was able to identify PBC as a diagnostic probability in the vast majority of this PBC patient group.

In **chapter 9** the diagnostic accuracy of the physicians' working diagnosis (PWD) was compared with the Euricterus electronic diagnostic tool Trial© in a random sample of the Dutch Euricterus patients (chapter 3), in an independent prospective database derived from patients in three general hospitals in the Netherlands and in an independent retrospective database from one Dutch hospital. The accuracies of both PWD and Trial© showed no differences between the three databases and pooled results of 416 patients were presented. The accuracy of PWD was about 80% and for Bayes and Trial Algorithm (chapter 8) only slightly less. The conclusion was that Trial© can strengthen the physician's judgment and that it delivers a (sub)icterus diagnostic disease probability at nearly consultant level.