Pancreatic Cancer Registry
Registry supervisor: Dr. Gábor Lakatos
HPSG Chair: Prof. Dr. Péter Hegyi

Andrea Szentesi
PancreOS Kick-off meeting, 17th March 2016, Madrid
Pancreas cancer worldwide

- 338,000 new cases in 2012
- 7th among cancer deaths worldwide
- 4% of all cancers diagnosed
- 5 year survival less than 5%
- Higher incidence in more developed countries

Source: GLOBOCAN 2012

Pancreas cancer in Hungary

- 2,545 new cases in 2012
- 5th among cancer deaths in Hungary
- Increasing incidence
- 5 year survival less than 5%

Source: National Cancer Registry
Eastern and Central Europe

- Worse prognosis compared to western countries
- Increasing incidence and mortality (Hungary, Romania, Albania, Croatia, Serbia) (1,2)

Possible reasons

- Limited access of diagnostic tools and treatment modalities (long waiting lists for CT and MRI)
- Lack of evidence based guidelines
- Financing problems

Aim

- Prospectively collect and analyse data in the Hungarian (and Central and Eastern European) population that can serve as a basis for evidence based guidelines and further trials

(1.) National Cancer Registry, Hungary
(2.) Hariharan D et al.
Starting the Registry – 2011-2012

- Research plan
- Financing (sponsors, grants)
- Ethical approval
- Biobank permission and set up
- CRF discussion
- Informatics (eCRF)
- Involving centres
  - Who is going to fill the forms (doctor, study nurse, administrator-partly?)
    - Motivation (financing, authorship)
- Data management and quality control
  - Administrative and professional control
  - Trainings
Data handling and analysis

Secrecy

- Everyone can see only his/her own data unless otherwise agreed among participants
- In case of research projects permission is asked for using data (co-authorships)

Transparency

- The registry head has the right to publish the first cohort
- Anyone may propose a research plan based on the registry data
  - The research plan is approved by the HPSG (to avoid duplication)
  - The researcher defines the first and last author
  - The HPSG may ask to name further co-authors and sponsors in the acknowledgement
Registry and Biobank for Pancreatic Patients

- started in 2012
- prospectively collected clinical data and blood samples
- web-based electronic data administration system
- acute pancreatitis (AP), chronic pancreatitis (CP), pancreatic cancer (PC), autoimmun pancreatitis (AIP)
- observational clinical trials in AP from 2015
Published genetic studies

- Genetic analysis of the bicarbonate secreting anion exchanger SLC26A6 in chronic pancreatitis
- SPINK1 Promoter Variants in Chronic Pancreatitis
- A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohorts

- Pancreatic cancer. Multicenter prospective data collection and analysis by the Hungarian Pancreatic Study Group. – accepted in JGLD
- Prospective, multicentric, nationwide clinical data from 600 cases of acute pancreatitis – submitted
- Cohort in CP – under development
Observational Clinical Trials in AP

- Early Achievable Severity Index
  Pre-study article: J Gastrointestin Liver Dis, June 2015 Vol. 24 No 2

- Pain in Early Phase of Pediatric Pancreatitis

- Analysis of Pediatric Pancreatitis
  Pre-study article: Digestion. 2016;93(2):105-10. doi: 10.1159/000441353.

Under development:
- PREPAST - The role of preventive pancreatic stents in acute biliary pancreatitis - eCRF being developed

Planned in 2016:
- Interventional trials in AP
- 2 observational trials in CP
Pancreatic cancer registry – Content

- Date of birth, gender, race, date of interview
- Details from the medical history
- Symptoms and signs
- Patient related data
- Tumor-related data
- Oncological therapy
- Supportive treatment
2. Details from the medical history

- Alcohol consumption
- Smoking
- Drug abuse
- History of infectious disease
- Diabetes mellitus
- Lipid metabolism disorder
- Familial pancreatic disease
- Medication taken
- Diet
- Weight/height
- BMI

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<td>for how many years:</td>
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<td>for how many years:</td>
<td>None</td>
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Guide for estimation of the amount:
1 dl beer (4.5 vol.%) = ~3.5 g alcohol
1 dl wine (12.5 vol.%) = ~10 g alcohol
1 dl hard drink (60 vol.%) = ~40 g alcohol
3. Symptoms and signs

- Abdominal pain
- Nausea
- Vomiting
- Fever
- Loss of appetite
- Weight loss
- Jaundice
4. Patient related data

Diagnosis
- clinical
- histological

Survival status
- (Overall survival time)

**ECOG PS status**
- Tumor markers: CA 19-9, CEA
5. Tumor related data

Staging
- clinical
- pathological

Surgical treatment
- resectability
- type of surgical intervention

Endoscopic treatment

Radiological intervention
## 6. Oncological therapy

- Chemotherapy
- Radiotherapy
- Molecular targeted agents
- Somatostatin analogue
- Peptid receptor radionuclide Tx.

- Progression free survival
- Best response
7. Supportive treatment

- **Pain management**
- **Pancreas enzyme substitution**
- **Nutritional supplements**
Pancreatic Cancer Registry

Patient Enrollment

- Informing the patient, signed informed consent form
- Completing the patient questionnaire
- Collecting blood sample
- Uploading data to the electronic data administration system

Source of data
- Patient questionnaire
- Electronic medical records
- Therapy information – usually paper-based
# Data Quality Control

## In the electronic system

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1. administrator or doctor
2. local doctor
3. central admin control
4. head of the registry

- approved
- rejected with a note

**Informed consent forms, medical records – on site**

**Trainings – on site, on the HPSG conference**
Results

**Genetic study**
“A Common CCK-B Receptor Intronic Variant in Pancreatic Adenocarcinoma in a Hungarian Cohort” – Anita Balázs et al.

**First Hungarian cohort for PC**
“Pancreatic cancer. Multicenter prospective data collection and analysis by the Hungarian Pancreatic Study Group.” – Gábor Lakatos et al.

- Study period: 2012-2014
- 354 patients, 14 centers
- Manuscript accepted in *Journal of Gastrointestinal and Liver Diseases*

**Current patient and sample numbers**
- 513 patients
- 420 blood samples
What we have done recently

In 2015, the registry has been completely renewed

- Improvement of the electronic system
- The content of the questionnaire was fully updated
- The registry is available in Hungarian and in English

Plans

- Need to further improve the quality of data collection
- Need to build up the co-operation along the patient’s route in treatment (diagnosis, surgical treatment, oncological treatment)
- Need to extend the database to other Central and Eastern European countries.
Thank you for your attention!

THE HUNGARIAN PANCREATIC STUDY GROUP IS COMMITTED TO IMPROVING THE LIVES OF PATIENTS SUFFERING FROM PANCREATIC DISEASES!