Supplementary file 5

RESEARCH PROTOCOL

Title: *Prevalence, characteristics and predictors of cancer patients presenting to emergency departments.*

Background and rationale for the study

Cancer is the second leading cause of mortality in developed countries, including Hungary, and the care of cancer patients places an extremely high burden on society. Within the healthcare system, in addition to oncologists, a number of health care professionals are involved in the care of cancer patients, and a significant proportion of patients present to emergency departments as a consequence of their cancer, its treatment or for completely unrelated medical reasons. Although some emergency department visits are justified and necessary, the literature suggests that 12% of presentations do not warrant emergency care and 56% of cases could be prevented.[1] The existing data suggest that patients who are undergoing or have undergone oncological treatment utilize emergency care between 1-83%, but is certainly more frequent than the average non-cancer population.[2] Previous studies in the United States have shown that cancer patients presenting to the emergency room while undergoing treatment have worse overall outcomes and hospital readmissions increase health care costs compared to patients with cancer but without emergency hospitalisation[3].

In our country (nor in the Central-Eastern European region), no study has been conducted to investigate the incidence, characteristics, and predictors of emergency care utilization of cancer patients presenting to emergency departments.

Objectives of the study

The aim of our study is:

-to describe and analyze the characteristics of cancer patients visiting the ED in a tertiary care hospital in Hungary

- identify predictive factors of multiple ED visits, hospitalization and potentially preventable ED visits made by cancer patients.

-to analyze the relationship between frequency of ED visits and the 3-year survival of patients with cancer.

Study design

Observational, retrospective study. Data collected cross-sectional, with follow-up of patients regarding survival.

Outcome measures

-clinical and demographic characteristics of cancer patients visiting the ED

-the predictors of multiple (≥2) ED visits within the study year

-admission to inpatient care following the ED visit (hospitalization)

-potentially preventable ED visits (defined as cases with a non-urgent triage category Triage level 5 plus not hospitalized plus who did not die within 30 days of the ED visit)

-death within 36 months after ED presentation

Target population (participants)

The study will include cancer patients, with an ICD-10 "C" code (C0000-C9670) who present to the emergency department from 01/01/2018 to 31/12/2018

It is a single-site study, conducted in one emergency centers, with a coverage area of the South Transdanubian region.

The site of the study/data collection is:

- The Emergency Care Centre of the Kaposvár Kaposi Mór Teaching Hospital

Sites of data analysis:

- The Emergency Care Centre of the Kaposvár Kaposi Mór Teaching Hospital

- The Department of Emergency Medicine of the University of Pécs Clinical Centre of Kaposi Mór Municipal Hospital

- The Department of Public Health Medicine, Faculty of General Medicine, University of Pécs

- The Department of Primary Care of the Faculty of General Medicine of the University of Pécs

Criteria for patient admission:

-Adult patients over 18 years of age

-who visited the ED between 1 January - 31 December 2018

-had received their diagnosis of cancer within 5 years of their first ED visit in 2018 or received their diagnosis of cancer latest within the study year.

-have an ICD-10 code "C", which has been documented electronically at least twice

- If a patient presented to the ED without a cancer diagnosis, but with symptoms indicative of cancer and which cancer was subsequently histologically confirmed (but within the study year), the patient is categorized as a “new cancer diagnosis-related ED visit”.

Investigated data

I. Demographic and (baseline) clinical data:

- sex and age distribution
- place of residence
- type of cancer
- presence of other diseases (comorbidity)
- smoking/alcohol consumption
- educational level

II. Variable data:

- stage of the tumor
- type and date of oncological treatment
- Hospice care admission (type and date, hospital, or home care)
- admission to palliative specialist care/BSC, type and date
- type of emergency referral (with/without GP referral)
- number of emergency department visits (1 or more) with dates
- complaints +symptoms the complaint(s) justifying the emergency department visit
- medical condition justifying the emergency department visit (emergency department diagnosis)
- the date of the emergency department visit
- the triage classification at the time of admission to the emergency department
- the number of patients discharged from the emergency department to in-patient admission (hospitalization)

- the number of days spent in hospital following admission

- the nature of the inpatient stay (active/chronic)

- the diagnosis justifying the inpatient stay

- mortality in the emergency department or in hospital following admission

-follow-up at 36 months

Planned methods

Data collection will be carried out by automated software system (specifically designed for the study) and reviewed by researchers appointed by the heads of the institutes or departments of the participating institutions, following receiving full ethical approval.

The data will be collected from the electronic databases of the Clinical Centre of the University of Pécs and the eMedSol software of the Kaposi Mór Teaching Hospital.

Patient data are collected in Excel spreadsheets (see Annex 1).

The same patient may present to the emergency department several times after the same oncological treatment. In this case, variable data for the same patient are collected in separate rows in the spreadsheet. If the patient undergoes repeated oncological treatment, the next time of emergency department attendance is counted from the date of the latter. The demographic (baseline) data are recorded according to the documentation of the first emergency department visit, while the other (variable) data depend on the frequency and type of emergency department visit.

The Charlson Comorbidity Index (CCI) is defined as a predictor of 1-year mortality based on a patient's comorbidities. The medical conditions listed in the CCI will be registered as comorbidities besides the cancer diagnosis.

Categories will be made, based on raw data, regarding, symptoms, medical diagnosis at the ED, cancer types, type of hospital admission.

Patients will be followed up for 36 months to determine if they died or not (time and date of death shall be registered.

Processing of data

Statistical processing of the data will be performed using Jamovi 2.2.5. Both descriptive and exploratory approaches will be used. Two data sets will be created for ED patients and ED cases, separately, since one patient may present themselves more than one time within the study year. Standard descriptive statistics, frequency tables, log-rank test (for Kaplan-Meier survival analysis) and mixed effects as well as binary logistic regression analysis will used for data analysis. Multicollinearity will be checked. For statistical tests (t test, Chi-square test or Fisher exact test), $p < 0.05$ is considered significant.

Expected results (benefits of the research)

Patients with cancer visit emergency care more frequently than noncancer patients of the same age and sex. 58% of cancer patients are admitted to an inpatient facility, in contrast to 12.5% of their noncancer counterparts who are hospitalized, although a national study suggests that this figure may be as high as 22.2% in our country.[4,5] Our research aims to identify the risk factors that make cancer patients more likely to visit the emergency department. Such a study of cancer patients in large regional emergency centres has not been conducted in Hungary so far. A novel approach to the problem, also in comparison to foreign literature, is to study the different aspects of the cancer patients' ED visits in one comprehensive study.

By obtaining information on the emergency room attendance of cancer patients, it is possible to highlight high-risk groups, target patient education, and other planned (non-emergency) care. This is expected to increase patient satisfaction and reduce the burden on emergency department staff and improve the quality of patient care.

Planned time of the study

The total duration of the data collection period is expected to be 18 months. Data analysis and preparation of planned publications: 6 months.

Arrangements for handling personal and health data of participants

In the study, patients' data will be treated anonymously, using a unique identifier. Personal and health data will be processed in accordance with the legislation in force.

Ethical permission from the Regional Ethical Committee of the University of Pécs Medical School will be applied for. All methods will be carried out in accordance with the Declaration of Helsinki and the relevant guidelines and regulations

Planned costs

The administrative tasks will be carried out by the staff of the institutions participating in the study and will require a computer system. A dedicated software for screening of data will be developed.

Sincerely,

Eva Pozsgai MD, PhD

Lead Researcher

Department of Public Health Medicine

Department of Primary Health care

University of Pécs Medical School

+36 30 6248 176

pozsgay83@gmail.com

Sources

[1] Weinick RM, Billings J, ThorpeJM. Ambulatory care sensitive emergency department visits: a national perspective. Acad Emerg Med 10(5):525–6.

[2] Lash SR, Bell JF, Reed CS, Poghosyan H, Rodgers J, KK, Bold RJ, Joseph JGA Systematic Review of Emergency Department Use Among Cancer Patients. Cancer Nurs. 2017; 40(2): 135–144.

[3] Dufton P.H. , Drosdowsky A, Gerdtz MF, Krishnasamy M. Socio-demographic and disease related characteristics associated with unplanned emergency department visits by cancer patients: a retrospective cohort study. BMC Health Services Research (2019) 19:647

[4] Lochner KA, Goodman RA, Posner S, Parekh A. Multiple chronic conditions among Medicare beneficiaries: state-level variations in prevalence, utilization, and cost, 2011. Medicare Medicaid Res Rev. 2013 Jul 23;3(3).

[5] Varga Cs, Lelovics Zs, Soós V, Oláh T Betegforgalmi trendek multidiszciplináris sürgősségi osztályon. 2017 158. évfolyam, 21. szám 811–822.