Oral presentation 1

Levels of total cell free DNA in metastatic colorectal cancer is a prognostic marker for overall survival

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Background
Treatment strategies for incurable metastatic colorectal cancer is focused on prolonging survival and maintain quality of life. Prognostic and predictive markers are needed to guide treatment. The aim of this study was to analyze the relation between cell free DNA (cfDNA) levels and outcome in patients receiving systemic therapy for incurable metastatic colorectal cancer.

Materials and methods
The study was a prospective non-interventional biomarker study for patients receiving standard of systemic treatment for mCRC. Patients, who by standard guidelines were considered for treatment with EGFR inhibitors for mCRC, were included. The cfDNA levels in consecutive plasma samples were measured by a new approach; direct fluorescence assay.

Results
Forty-seven patients were included. Blood samples were available at baseline (n = 47); prior to the third treatment cycle (n = 31); the first (n = 33), second (n = 22) and third response evaluation during treatment (n = 17); and at progression (n = 22). The median cfDNA level was significantly higher at baseline compared to during treatment. The patients were divided into two groups based on baseline cfDNA levels. A group with high cfDNA levels (≥75th percentile of baseline cfDNA levels) and a group with low cfDNA levels (<75th percentile of baseline cfDNA levels). The disease control rate were 42% and 91% in patients with high and low cfDNA levels, respectively ($p < 0.001$). This translated in to a median progression free survival of 3.8 months and 8.5 months in patients with high and low cfDNA levels, respectively (hazard ratio = 3.03, 95% CI 1.46-6.29, $p < 0.01$), and a median overall survival of 5.0 months and 26.6 months in patients with high and low cfDNA levels, respectively (hazard ratio = 3.48, 95% CI 1.44-8.44, $p < 0.01$). In multivariate analysis, baseline cfDNA levels remained a significant predictor of progression free survival and overall survival. Early changes in cfDNA-levels also proved to be a predictor of progression free survival.

Conclusion
With a simple, fast, and inexpensive method to determine cfDNA levels we demonstrated that cfDNA is a promising prognostic tool, when personalizing the treatment of mCRC.

Kategori: Original forskning, aldrig præsenteret tidligere
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Midt
Tidligere præsenteret:

Oral presentation 2

Intensified induction chemotherapy for locally advanced squamous cell carcinoma of the anus

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Background
Treatment of locally advanced squamous cell carcinoma of the anus (LASCCA) remains a challenge. These patients have high risk of treatment failure and consequently a poor prognosis. To improve the outcome of this patient group, intensified treatment options are needed. With this study, we present long-term follow-up of a nation-wide cohort of LASCCA treated with intensified induction chemotherapy (ICT).

Materials and methods
Patients with LASCCA (T3-4N0 or T1-4N+), treated between 1998-2018 with at least one cycle of intensified ICT (cisplatin, ifosfamide, leucoverin and 5-flourouracil) were included. Patients were identified from the three National Centres (Aarhus, Vejle, Herlev), and data were retrospectively collected from medical records. Statistical analyses were computed using STATA 16.1 and survival analyses were performed using the Kaplan-Meier method.

Results
In total, 168 patients with LASCCA were identified. The majority of patients were female (80%) and in good performance status (PS) (PS 0-1 81%). Most tumours were T3 or T4 (81%) with 67% having regional lymph node metastases. The mean number of ICT cycles administered was three (range 1-5). The objective response rate after ICT was 77% including 13% (n=21) with complete response and 64% (n=100) with partial response. After completing ICT, 159 patients (95%) underwent curative treatment with either definitive radiotherapy (RT) (71%), chemoradiotherapy (CRT) (26%), or abdominal perineal resection (APR) (3%), whereas eight patients (5%) were treated with palliative intent after ICT. One potentially treatment related death was registered. After completing curative treatment, 127 patients (80%) achieved complete response. Persistent disease was confirmed in 30 patients, and of these 25 underwent salvage surgery. The median follow-up was six years (range 0.3-21.6). During follow-up, locoregional failure rate was 22%, and distant failure rate was 14%. Survival analysis showed a three- and five-year disease-free survival of 70% and 67%, and a three- and five-year overall survival of 76% and 67%, respectively.

Conclusion
These results suggest that intensified ICT could be a relevant treatment option in the most advanced cases of LASCCA. To investigate this treatment possibility future prospective, randomised trials are needed.

Kategori: Pilot data (fra en institution) er tidligere, men ikke det fulde nationale datasæt
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Midt
Tidligere præsenteret: ESTRO 2012

Oral presentation 3

FDG-PET/CT in high-risk primary breast cancer—a prospective study of stage migration and clinical impact

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Background

Correct staging of breast cancer is of paramount importance in the planning of the optimal treatment for breast cancer, but FDG-PET/CT remains an optional modality in primary breast cancer guidelines. This study aimed to investigate the clinical impact of FDG-PET/CT for staging and treatment planning in high-risk primary breast cancer.

Materials and methods

Women with high-risk primary breast cancer were enrolled between September 2017 and August 2019 at Odense University Hospital, Denmark. Conventional mammography with/without MRI was performed before staging by FDG-PET/CT. We studied the accuracy of FDG-PET/CT for the detection of distant metastases, the effect on the change of treatment, and the prevalence of incidental findings. Biopsy and follow-up were used as a reference standard for the accuracy analysis.

Results

Of 103 women, 24 (23%) were diagnosed with distant metastases by FDG-PET/CT. Among these, breast surgery was omitted in 18 and could have been spared in six. Another sixteen (16%) patients were upstaged to more advanced locoregional disease, leading to more extensive radiotherapy. Sensitivity and specificity for diagnosing distant metastases were 1.00 (95% confidence interval: 0.86–1.00) and 0.95 (0.88–0.99), respectively. Twenty-nine incidental findings were detected in 24 women (23%), leading to further examinations in 22 and diagnosis of eight (8/22, 36%) synchronous diseases: cancer (n = 4), thyroiditis (n = 2), aorta aneurysm (n = 1), and meningioma (n = 1).

Conclusion

FDG-PET/CT had a substantial impact on staging and change of treatment in women with high-risk primary breast cancer, and further examination of incidental findings was considered clinically relevant. Our findings suggest that FDG-PET/CT should be considered for primary staging in high-risk primary breast cancer to improve treatment planning.

Kategori: Original forskning, præsenteret ved tidligere lejlighed det seneste år
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Syddanmark
Tidligere præsenteret: eposter ved ESMO 2020
Publiceret i Breast Cancer Research and Treatment, 2020
https://doi.org/10.1007/s10549-020-05929-3

Oral presentation 4

Combination of G-8 screening tool and hand-grip strength to predict long-term overall survival in NSCLC patients undergoing SBRT.

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(3) On behalf of the Academy of Geriatric Cancer Research (AgeCare), OUH, Odense, Denmark.

Background
Patients with localized non-small cell lung cancer (NSCLC) unfit for surgery are offered stereotactic body radiotherapy (SBRT). For these patients, age-related comorbidities, rather than lung cancer, are the leading cause of mortality. The Geriatric 8 (G-8) was developed to predict frailty in older patients with cancer and has been demonstrated to be a strong independent predictor of overall survival. However, the G-8 focuses on nutritional aspects, and a combination of G-8 and a geriatric functional assessment tool may be a better predictor of overall survival (OS). The aim of the study was to test if G-8 combined with HGST in patients with NSCLC treated with SBRT can predict long-term OS.

Materials and methods
From January 2015 to June 2016, 51 T1-T2N0M0 NSCLC patients treated with SBRT at OUH were enrolled in a randomized study investigating the impact of a comprehensive geriatric assessment. G-8 and hand-grip strength test (HGST) were assessed at the start of SBRT. G-8 scores ≤14 and HGST <21kg for men and <15kg for women were considered abnormal. Patients were divided into three groups: fit (normal G-8 and HGST), vulnerable (abnormal G-8 or abnormal HGST) and frail (abnormal G-8 and abnormal HGST).

Results
Potential median follow-up time was 60 months (50.4-67.7 months). 33 patients had died at follow-up (October 2020). 46 patients had both G-8 and HGS assessments at baseline. The 4-year OS for the normal vs. abnormal G-8 groups were 69% vs 39%. For the fit vs. vulnerable vs. frail groups 4-year OS was 70%, 46% and 25%, respectively (p=0.038). In a multivariate analysis of OS being vulnerable with a hazard ratio (HR) 2.03 (95% CI: 0.50-8.12, p=0.32) and frail with a HR 3.80 (95% CI 0.80-18.01, p=0.09) indicated poorer OS.

Conclusion
The combination of G-8 and HGST may predict OS more precisely than G-8 alone in SBRT treated NSCLC patients, making the combination a valuable tool to predict prognosis helping the clinician and patient in the shared decision-making process of treatment strategies.

Kategori: Original forskning, aldrig præsenteret tidligere
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Syddanmark
Tidligere præsenteret:

5

Oncology patients support the cardiopulmonary resuscitation (CPR) “talk”: an exploratory mixed method study of CPR preferences

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Background
Often, health care professionals struggle to discuss CPR preferences with advanced cancer patients. We aimed to study the views of oncology patients on the subject of CPR as well as the timing of a CPR conversation.

Materials and methods
We performed an exploratory qualitative study in the emergency function at the department of Oncology. All admitted patients were presented with a questionnaire concerning their views and thoughts on CPR. The association between patient characteristics and responses were analysed using multivariable multinomial logistic regression. After discharge from the hospital, semi-structured telephone interviews were conducted with a random subset of the study population, and the interviews were analysed using qualitative descriptive method.

Results
114 patients completed the questionnaire. 73 patients (64%) had considered whether they wanted CPR in case of cardiac arrest. Specifically, 30 patients (26%) did not want CPR performed. Of these, six patients (20%) had a recorded do-not-resuscitate (DNR) order. 13 patients (11%) had made a living will. 53 patients (47%) had discussed CPR with others. 15 patients participated in the telephone interviews. The vast majority of the interviewees (14 patients) stated that the CPR conversation was important and natural. Regarding the timing of the discussion both early and late in the course of treatment were suggested. Some patients preferred a continuous discussion. Five patients stated that they preferred to talk to a physician they felt familiar with.

Conclusion
Most patients had contemplated CPR, but few patients had made a living will. Most interviewees supported a CPR conversation, however, the majority of patients who refused CPR, did not have a recorded DNR order. This indicates that the subject had not been discussed during admission. Further studies on the individualization and timing of the CPR discussion as well as the barriers of the health care professionals are needed.

Kategori: Kandidatspeciale på medicinuddannelse, kun præsenteret til eksamen og på afdelingen
Forfatters position: Nu KBU-læge (studerende, da forskningen blev lavet)
Ansættelsesregion: Nord
Tidligere præsenteret: Kun til afsluttende specialeeksamen på 11. semester og internt på Onkologisk Afdeling, AAUH

6

Learning from patient involvement in a clinical study analyzing PET/CT in women with advanced breast cancer

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(5) Patient and public representative, Danish Breast Cancer Patient Organization (DBO), Odense, Denmark
(6) Department of Public Health, University of Southern Denmark, Odense, Denmark
(7) Centre for Innovative Medical Technology, CIMT, Odense University Hospital, Odense, Denmark

Background
Despite increasing interest in patient involvement in health care research, researchers may be uncertain about the benefits of involving patients in the design and conduction of clinical studies. We aimed to evaluate the impact of patient involvement on patient recruitment and retention in a clinical study of PET/CT in women with advanced breast cancer. Further, we report our experience regarding the researchers' attitudes towards involving patients as partners in the research process.

Materials and methods
Two patient representatives from the Danish Breast Cancer Organization were invited as partners in the research team. These patient partners were asked to contribute in particular to participator information material and evaluation of ethical aspects of the study. The mpact of patient involvement on patient recruitment was evaluated by comparing expected versus actual number of patients recruited, and then relating it to patient recruitment in a
similar study at the same institution that did not involve patients as research partners.

Results
Having patients as partners in the research team led to a major revision of the participator information material and improved patient recruitment. The expected number of patients was 260, but 380 were actually enrolled within the planned study period, thus 146% of the expected patient recruitment. In the previous study, only 100 of the expected 150 patients were enrolled during a 10-month extended study period, i.e. 67% of the expected number. Patient retention in the current study was high, with 86% of eligible patients attending follow-up scans. We observed initial resistance amongst researchers against inviting patients as team partners. This resistance gradually lessened during the study, and the most reluctant researchers at the beginning of the study later applauded the collaboration and the ideas generated by the patient representatives.

Conclusion
Involving patients as partners in the research team resulted in major changes to the participator information material and contributed to higher than expected patient recruitment and retention. Furthermore, we observed a positive change of attitude amongst the researchers towards patient involvement in the research process.

Kategori: Original forskning, præsenteret ved tidligere lejlighed det seneste år
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Syddanmark
Tidligere præsenteret: Publiceret i Research Involvement and Engagement, 2020
https://doi.org/10.1186/s40900-019-0174-y

7

A national survey on oligometastatic disease - perspectives from the clinically working physicians

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Background
Results from recent randomized, phase 2 trials, examining ablative radiotherapy as a strategy for patients with oligometastatic disease (OMD), have been encouraging and renewed our hopes of prolonged disease control and survival. However, the selection of patients eligible for an ablative treatment strategy is a challenge. Consensus reports for the definition and patient selection have been published, but no correlation to clinical outcome are yet reported.
We conducted a nationwide survey to evaluate the practice patterns among clinically physicians working in the Danish Oncology Departments. The aim was to explore the current pattern of care and use of ablative strategies for OMD in Denmark as well as to assess the clinically working physician's perception of the OMD concept.

Materials and methods
An 18-items questionnaire was prepared using an online survey tool. Mails with invitation to complete the online questionnaire, were send out in early spring 2020. Invitations to participate in the survey was sent to 461 physicians working at 10 different centers, seven with radiotherapy (RT) facilities. Answers were analyzed using basic descriptive statistics.

Results
A total of 102 physicians completed the survey (response rate of 22%); response was received from seven different centers. Fifty-three percent of the responders worked with RT on a weekly basis. Most responders were specialists in clinical oncology (64%), 30% were clinical oncology trainees and 2% were specialists in medical oncology. The remaining 4% were specialist in palliative medicine or in unclassified positions. Treatment of up to three metastases was the preferred limit (43%). Only 7% would consider treating up to five metastases. There was no apparent disagreement between responders working with RT and those only referring to RT. Among different cancer types, the responders found that patients with colorectal-, breast-, lung-, prostate-, and renal cell cancers were most suitable for an ablative treatment strategy.

Conclusion
In general, the responders had confidence in an ablative treatment strategy for selected patients with OMD. The preferred selection parameters regarding primary tumors and number of metastases match the clinical setting most often studied and reported in the literature. The results from this survey will be used as basis to reach a national concensus.

Kategori: National Survey
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Hovedstaden
Tidligere præsenteret: Nej - Indsendt til ESTRO

8

Clinical outcomes after stereotactic ablative radiotherapy in locally advanced cholangiocarcinoma

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Background
Cholangiocarcinoma (CC) is a rare malignancy with a poor prognosis. The only curative treatment is surgical resection, however most patients (70%) are unresectable at time of diagnosis. Stereotactic Ablative Body Radiotherapy (SABR) is feasible in carefully selected patients.

Materials and methods
Between 2009-2018, 41 patients with unresectable CCs were treated with SABR at our institution and retrospectively analyzed. Data were obtained from patient files and the treatment planning system. The primary endpoint was overall survival and secondary endpoints were local control, progression-free survival and toxicity.

Results
The study included 41 patients with a mean age of 69 years (39-82); 63% were male. 17% had a Charlson comorbidity score ≥3 and 27% a PS ≥2. The median CTV diameter was 3.6 cm (2-7.4 cm). The most frequently used radiotherapy schedule was 48 Gy in 6 fractions (11 patients=27%) and only 7 patients (17%) received chemotherapy.
Median follow-up time was 9.5 months and 32 patients (78%) were followed for at least 3 months after SABR. Median overall survival was 11.8 months, median time to progression 5.7 months and 1-year local control rate 67.7%. In univariate analysis, shorter overall survival was associated with extrahepatic disease (p=0,049) and presence of any grade of toxicity (p=0,011). No deaths due to toxicity were observed.
Toxicity was only evaluated in patients followed for at least 3 months. Seven patients (22%) experienced no toxicity at all. Acute and late toxicity (any grade) was found in 66 % and 44 % of patients, respectively. The most common toxicity was cholangitis.

Conclusion
SABR for patients with CC is a promising treatment option especially in fragile patients with the benefit of short treatment time and acceptable toxicity. Our study adds knowledge to the retrospective evaluation of SABR-treated patients while larger prospective trials are warranted. The impact of chemotherapy and patient reported Quality of Life needs further investigation.

Kategori: Foreløbige resultater
Forfatters position: Forskningstræning
Ansættelsesregion: Midt
Tidligere præsenteret:

9

ESO-SPARE: Esophagus sparing radiotherapy for thoracic and cervical metastatic spinal cord compression. A randomized phase III study.

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Background
Metastatic spinal cord compression (MSCC) is a feared and potentially disabling complication of metastases to the vertebra. When MSCC is diagnosed, life expectancy is short, and treatment is palliative. There are no systematic reports in the literature of early esophageal toxicity after radiotherapy for MSCC. In a small prospective study (Gram et al. 2019) , 11 of 14 MCSS patients treated at Th8 or above reported esophageal discomfort lasting for an average of 11 days. A significant correlation between dose to the esophagus and toxicity was reported, indicating a high incidence of early esophageal toxicity. The use of volumetric arc therapy (VMAT) and precise setup with Cone-Beam Computed Tomography (CBCT) enables delivery of treatment with tight safety margins and reduced dose to the esophagus. Due to the close proximity to the spine, sparing of the esophagus can only be achieved by compromising dose to the vertebrae and/or increasing entrance dose through other anatomical structures.
We will investigate whether: a) esophagus sparring radiotherapy can significantly decrease patient reported esophageal toxicity in patients with MSCC without compromising their ambulatory function. b) esophagus sparring radiotherapy will lead to an increase in other toxicities compared to standard radiotherapy.

Materials and methods
200 patients from Herlev hospital and Rigshospitalet referred for radiotherapy, with any fractionation scheme, of MSCC in the thoracic or cervical spine will be randomized to either standard treatment or esophagus sparing radiotherapy. Patients will report esophageal toxicity and pain from treatment site using daily PRO(patient reported outcome)-CTCAE questionnaires for 5 weeks and here after weekly for 4 weeks. Changes in analgesic consumption, quality of life, physical function (EQD5 and EORTC-C30) will be registered on a weekly basis.

Results
Primary outcome is patient reported esophageal toxicity measured as peak score within the first 5 weeks after treatment start measured by PRO-CTCAE. Secondary outcomes include duration of esophageal toxicity, ambulatory function, reirradiation rate, quality of life, change in weight, pain reduction, change in analgesic consumption and overall survival.

Conclusion
The ESO-SPARE protocol is awaiting approval from the National Ethical Committee and estimated to start accrual in Q2 2021.

Kategori: Projektbeskrivelse, planlagt projekt
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Hovedstaden
Tidligere præsenteret:

10

Glucocorticoid induced diabetes in patients treated for metastatic spinal cord compression (MSCC). A prospective observational study.

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Background
High-dose glucocorticoid treatment used in MSCC, before and during radiotherapy (RT), to decrease inflammation and edema can induce hyperglycemia and diabetes.
In 2014 Schultz et al. systematically measured blood-glucose (BG) in 131 patients treated with glucocorticoid during palliative (RT) for MSCC. 43% developed BG values diagnostic of diabetes and 12% were treated with insulin. A HbA1c-value <39 mmol/mol was a negative predictor for the development of insulin demanding diabetes.
There are no international guidelines on the handling of glucocorticoid-induced diabetes in patients with late stage cancer and no studies describing the spontaneous course of plasma-glucose levels in patients treated with high-dose glucocorticoids.
Generally, the focus of modern diabetes care is to avoid long term complications. When MSCC is diagnosed, life expectancy is short, and treatment should focus on immediate palliation of symptoms impacting quality of life.
We hypothesize, that glucocorticoid induced hyperglycemia and diabetes is symptomless in most patients and self-limiting when glucocorticoids are discontinued after radiotherapy.
The purpose of this study is 1) to characterize the spontaneous course of PG during and after high-dose glucocorticoid treatment using Flash glucose measurements. 2) to validate the use of HbA1c < 39 mmol/mol as a cut-off to identify the patients at low risk of developing insulin demanding diabetes.

Materials and methods
150 patients referred for RT of MSCC, with no prior history of diabetes and HbA1c < 48 mmol/mol, will be followed with Flash glucose measurements for 28 days from RT start. Baseline HbA1c will be obtained. Glucose measurements are blinded and there will be no other glucose measurements. Patients are followed with daily online self-assessed measures and will be instructed to contact the study PI if symptoms of hyperglycemia should occur. All in-hospital patients will be treated according to local guidelines.

Results
Primary outcome is incidence of glucocorticoid-induced diabetes. Secondary outcomes are incidence of insulin demanding diabetes, incidence of hospital contacts requiring regulation of hyperglycemia, characterization of plasma-glucose: time in range, time above range, mean glucose and coefficient of variation.

Conclusion
This study is awaiting approval from the National Ethical Committee and estimated to start accrual in Q2 2021.

Kategori: Projektbeskrivelse, planlagt projekt
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Hovedstaden
Tidligere præsenteret:

11

Prognostic Relevance of Geriatric assessment and Onco-geriatric Screening In cancer patients age Seventy or more: A prospective cohort protocol abstract (PROGNOSIS-G8)

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Background
Older patients with cancer constitute a heterogeneous group with varying comorbidity; therefore, geriatric assessment with initial screening is recommended. The Geriatric 8 (G8) and the modified Geriatric 8 (mG8) are promising screening tools with high diagnostic accuracy and are associated with survival, however, evidence is sparse concerning patient-centered outcomes. This study aims to address the prognostic value of the G8 and mG8 with quality of life (QoL) as the primary outcome

Materials and methods
In this single-center, prospective cohort, solid carcinoma cancer patients, age 70 years or more, will be screened with the G8 and mG8 prior to first-line antineoplastic treatment. Patients will contribute medical record data and fill out the EORTC QlQ-C30 and ELD-14 QoL questionnaires at baseline, 3, 6, 9, and 12-month follow-up. Two functional measurements, the 30-second chair stand test, and the handgrip strength test, will be conducted at baseline to assess the added prognostic and diagnostic value. Medical record data will be recorded on performance status, Charlson's comorbidity index, diagnosis, and cancer-directed treatment at baseline, and treatment adherence, overall survival, and cancer-specific survival at 1-year follow-up. Differences in QoL between frail (G8 score ≤14; mG8≥6) and non-frail participants will be tested using the Wilcoxon rank-sum test (median differences) or the Student's t-test (mean differences) depending on the distribution. Overall survival and cancer-specific survival will be assessed using the Kaplan Meier analysis and Cox proportional hazard models. Potentially confounding variables will be included in multivariable analysis. Performance analysis of the G8, including cut-off analysis, will be conducted in reference to comprehensive geriatric assessment findings.

Results
Study inclusion began June 1, 2020, and is expected to conclude November 30, 2021. Currently (15-03-21), 676 participants have been recruited, of which 334 have contributed with baseline QoL data.

Conclusion
This study will generate new knowledge on how to distinguish between subgroups of older cancer patients, identifying those who can receive standard treatment and those who are too frail and may need additional support or treatment modification. It is our hope that such knowledge will be constructive in establishing national guidelines for the treatment of these patients in Denmark.

Kategori: Projektbeskrivelse, planlagt projekt
Forfatters position: Ph.d.-studerende
Ansættelsesregion: Syddanmark
Tidligere præsenteret:

12

Impact of Comorbidity and Venous Thromboembolism on Outcome in Real-life Non-Small Cell Lung Cancer (NSCLC) Patients Treated with Immune Checkpoint Inhibition (ICI).

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Background

Optimizing selection of real-life NSCLC patients for ICI is necessary in order to get more patients to obtain long-term effect. Many NSCLC patients are ≥ 75 years old with tobacco-related comorbidity, poor performance status (PS) and widespread metastatic disease. These factors may increase the risk of cancer-associated venous thromboembolism (VTE), which may lead to premature termination of ICI and affect outcome. Studies on VTE and impact on outcome in real-life NSCLC patients undergoing ICI are lacking but warranted.

Materials and methods
Retrospective data of 367 incurable stage III-IV NSCLC patients treated with ICI at three different Danish Oncologic Departments from 2015-2019 was gathered. Comorbidity, a history of prior known VTE (P-VTE), development of VTE from first ICI until two months after last ICI (D-VTE) and from first ICI until end of follow-up (F-VTE) were registered. For survival analysis Kaplan Meier and cox regression were performed.

Results
Median follow-up time was 29.1 months. D-VTE for first line ICI: 8% and ≥ 2. Line: 4%. Of F-VTEs 82 % were pulmonary embolisms. Of those with P-VTE, 15% had D-VTE and 24% had F-VTE despite use of guideline prescribes anticoagulants. PD-L1 ≥ 50% correlated to radiologic response (RR) ($r=0.25$, $p<0.0009$), but D-VTE and F-VTE did not. Precise PD-L1 status was obtained for 55% and D-VTE correlated to PD-L1 level ≥ 80 % ($r=0.2$, $p=0.024$). In multivariate analysis hypertension (HT), peptic ulcer (PU) and PS ≥2 were significantly associated to impaired OS and PFS.

Conclusion
Real life NSCLC patients eligible for palliative ICI have substantial comorbidity. Having a P-VTE prior to ICI increases the risk of recurrent VTE considerably. PU and HT seem to increase the risk of impaired outcome from ICI. VTE development during ICI in NSCLC real life patients might be associated to PD-L1 level. Future prospective studies need to explore this and the impact of VTE and comorbidity on outcome.

Kategori: Original forskning, præsenteret ved tidligere lejlighed det seneste år
Forfatters position: Ph.d.-studerende, Speciallæge
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Shared decision making in the care for the prostate cancer patient

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Background
The addition of docetaxel or second-generation antiandrogen to early hormonal therapy has demonstrated impact on survival and time to progression in metastatic castration-sensitive prostate cancer (mCSPC) patients with high-volume disease and with good performance status and adequate organ function. In Denmark, docetaxel is the standard offer, whereas abiraterone can be considered in patients who are not expected to tolerate docetaxel. As in many other treatment situations, there is a trade-off between efficacy and toxicity.
In daily practice a significant fraction of patients with mCSPC are old and/or suffer from comorbidity, which makes a shared treatment decision with the patient important.
The aim of this project was to develop, test, and implement a patient decision aid (PDA) to facilitate shared decision-making (SDM) in treatment planning of high-volume mCSPC patients.

Materials and methods
Patients, relatives, nurses, and clinicians have together developed a patient decision aid based on an existing generic template. At the second step, we will perform an alpha test with the use of questionnaires presented to patients and clinicians in order to assess whether the PDA will prepare the patient to make a decision. Validated outcome measures, SDM-Q9 and SDM-Q-DOC, are used in beta testing where the patients´ and the doctors´ experiences of SDM will be assessed before and after the implementation of the PDA.

Results
The PDA used in the patient-clinician conversation includes five steps; 1) The purpose of the PDA 2) Information of available treatment possibilities, 3) Clarification of the patients´ personal preferences, 4) The patients´ options and harms/benefits of each option 5) A shared treatment decision made with the patient.

Conclusion
We have developed a PDA to facilitate the treatment decisions of docetaxel plus hormonal therapy versus hormonal therapy alone for patients with mCSPC. Furthermore, we have also developed another PDA comparing two other treatment options: Abiraterone plus hormonal therapy versus hormonal therapy alone for patients who are not expected to tolerate docetaxel. The PDAs developed will be presented.Test and implementation are ongoing.

Kategori: Projektbeskrivelse, planlagt projekt
Forfatters position: Speciallæge
Ansættelsesregion: Syddanmark
Tidligere præsenteret:

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Outcomes of prophylactic cranial irradiation in patients with small cell lung cancer after the introduction of baseline magnetic resonance imaging of the brain

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Background
Improved treatment for patients with small cell lung cancer (SCLC) has led to improved survival with up to 80% of patients who will develop brain metastases (BM). International guidelines recommend Prophylactic Cerebral Irradiation (PCI) to prevent brain metastases. A randomized study has suggested that PCI may not be beneficial for patients with SCLC if patients were examined with brain MRI after chemotherapy prior to PCI. This retrospective study compares PCI outcomes in patients with SCLC with and without baseline brain MRI performed prior to chemotherapy.

Materials and methods
The study included 221 patients diagnosed SCLC/mixed NSCLC-SCLC treated in the Region of Southern Denmark from 2012 to 2018. The population analyzed separately in patients with limited disease (SCLC-LD) and with extensive disease (SCLC-ED). The primary outcome of PCI was time to BM. Secondary outcomes were overall survival (OS), and progression-free survival (PFS). The analyses included information on PCI and baseline brain MRI (PCI+MRI, PCI-MRI, control+MRI, and control-MRI groups).

Results
In patients with SCLC-LD the probability of developing BM at 1 year was 6% vs. 14% (p=0.09), the median OS (mOS) was 55 months vs. 27 months (p<0.05), and the median PFS (mPFS) was not reached vs. 11 months (p<0.05) in the PCI+MRI group and PCI-MRI group, respectively.
No statistically significant differences were observed for patients with SCLC-ED. The probability of developing BM was 0% vs. 27% (p=0.11), the mOS was 12 months vs. 12 months (p=0.49), and the mPFS 8 months and 7 months (p=0.78) in the PCI+MRI group and PCI-MRI groups, respectively.
In a multivariate cox regression analysis of time to BM for patients with SCLC-LD, no variables were statistically significant associated with the risk of developing BM. For patients with SCLC-ED, baseline brain MRI was associated with a decreased risk of developing BM (HR=0.25, CI; 0.00-1.02, p=0.05).

Conclusion
This study found better PCI-outcomes for patients with SCLC-LD if a baseline brain MRI was performed prior to initial chemotherapy. The same differences were not found for patients with SCLC-ED.

Kategori: Original forskning, aldrig præsenteret tidligere
Forfatters position: Yngre forsker uden ph.d., dr. med. el. lign.
Ansættelsesregion: Syddanmark
Tidligere præsenteret:

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^{68}Ga-PSMA PET/CT for patients with PSA relapse after radical prostatectomy or external beam radiotherapy

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Background
The study aimed to summarize clinical characteristics associated with Gallium-68-prostate-specific membrane antigen (PSMA) positron emission tomography/computed tomography (^{68}-Ga-PSMA PET/CT) scans as patients were restaged for prostate-specific antigen (PSA) relapse after radical prostatectomy (RP) or external beam radiotherapy (EBRT).

Materials and methods
Our analyses included multiple cox regression analyses.

Results
The study evaluated 95 patients with rising values of PSA after RP and after EBRT. Sixty (63 %) patients had a positive ^{68}-Ga-PSMA PET/CT scan. Twelve patients (13 %) had a positive site in the prostate bed, 29 patients (30 %) had a positive site in regional lymph nodes, and 19 (20 %) had positive sites in distant organs. For 4 years follow-up, 21 patients (22 %) died.
In multiple Cox regression analyses, the number of positive sites on ^{68}-Ga-PSMA PET/CT significantly predicted OS (p = 0.0001) whereas risk score and regional locations of the positive sites were not significant in the multiple Cox regression analyses.

Conclusion
Our study indicates that the reporting of ^{68}-Ga-PSMA PET/CT is important for the ability of the scans to predict the outcome after ^{68}-Ga-PSMA PET/CT of treatment of patients with PSA relapse.

Kategori: Original forskning, aldrig præsenteret tidligere
Forfatters position: Speciallæge
Ansættelsesregion: Privat virksomhed
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