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Avoiding 'whoops' surgery in primary bone tumours in the spine: An intake protocol for all possibly involved caregivers in a tertiary hospital

B. Depreitere, MD, PhD[1], S. Schelfaut, MD[2], F. Sinnaeve, MD[2], H. Wafa, MD[2], M. Lambrecht, MD, PhD[3], M. Christiaens, MD, PhD[3], M. Delforge, MD, PhD[4], F.J. Sherida H. Woei-A-Jin, MD, PhD[5], P. Brys, MD[6], M. Renard, MD[7], R. Sciot, MD, PhD[8], J-F. Daisne, MD, PhD[3]

SUMMARY

Primary bone tumours of the spine are relatively rare when compared to metastatic lesions and haematopoietic neoplasms. This often results in misdiagnosis leading to a high incidence of inadvertent intralesional surgery, which is associated in many cases with worse progression-free survival and overall survival. Based on evidence and consensus, a protocol was designed at the University Hospitals Leuven, intended to guide all possibly involved caregivers in different clinical situations. The protocol raises awareness of potentially suspicious situations and provides expert input to avoid unfortunate decisions, even in situations with alarming neurological deficits.

(BELG J MED ONCOL 2023;17(1):4-10)

INTRODUCTION

At the end of the 20th century, new instrumentation possibilities introduced in spinal surgery re-established the role of surgery in the management of spinal metastases, whereas laminectomy alone previously resulted in poor outcomes.[1,2] This new evolution was particularly marked by the publication in 2005 of *Patchell, et al.* of a randomised trial in which surgical debulking and reconstruction followed by radiotherapy resulted in superior neurological and pain outcomes compared to radiotherapy alone.[3] This finding was also demonstrated in several other studies.[4-8] In surgical candidates with solid spinal metastases, operative management was demonstrated to improve and maintain quality of life when compared to preoperative functional status.[4,9] In parallel, *Tomita* in Japan, and *Boriani* in Europe developed radical tumour resection techniques, referred to as 'marginal/wide en bloc spondylectomy', that proved to be safe in experienced hands.[10,11] While the role of these radical surgeries in spinal metastases remains controversial, there is a tendency for less invasive surgical approaches in spinal metastatic disease, with early percutaneous stabilisation when the Spinal Instability Neoplastic Score (SINS) indicates instability, and minimally invasive debulking around the thecal sac to allow for early mobilisation and swift radiotherapy.[12-13]

The value of intralesional tumour surgery has been largely established in the management of spinal metastatic disease, in which the duration of local tumour control can be

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Keywords: En bloc surgery, primary bone tumour, spinal cord compression, spinal metastasis, spinal tumour surgery.

Real-world evidence for implementation of new drugs

N.A. de Glas, MD[1], M.G. Derks, MD[2], F. van den Bos, MD[3], M. Slingerland, MD[1], J.E. Portielje, MD, PhD[1]

SUMMARY

Randomised clinical trials are still the gold standard when it comes to the development of new drugs. There are, however, important limitations to trials. Such as, patients included in clinical trials are often not representative of the general population, which limits the applicability of trial results in clinical practice. In this article, the advantages and disadvantages of observational data are discussed. For example, observational data are generally more representative of the general population and can include large numbers of patients. However, there are important biases that should be considered when performing observational studies. Of these, so-called 'confounding by indication' is the most important form of bias, which means that reasons for certain treatment allocations are also associated with outcomes of treatment, which can disrupt the analyses. In summary, real-world data can add to clinical trials, but bias in these studies cannot be completely resolved. For this reason, clinical trials remain essential and should attempt to use less stringent inclusion criteria in order to improve the generalisability of their results.

(BELG J MED ONCOL 2023;17(1):11-4)

INTRODUCTION

Randomised phase III studies are the gold standard in the development of new medicines. However, randomised studies have a number of important limitations. This article discusses the advantages and disadvantages of real-world data as an alternative to randomised trials.

For example, the patients in randomised studies are by no means always representative of the population of patients in daily oncological practice. Elderly patients and patients with comorbid conditions are underrepresented in randomised studies.[1,2] Moreover, unfavourable oncological features (e.g. brain metastases) are often an exclusion criterion in these studies.[3] The differences between study and population are partly explained by the strict inclusion criteria of randomised studies. They are often financed by the pharmaceutical industry, which has an interest in including as homogeneous a population as possible with the greatest chance of a treatment response. This is partly understandable, because the inclusion of a population that is too heterogeneous can dilute a treatment effect or lead to the registration of a medicine for a group of patients for whom the treatment is not effective in practice. In current practice, however, results from selected study populations are often applied to a broader population of patients, for which there is not always evidence of the efficacy of the drug.

There is often reluctance among doctors and patients themselves to include elderly or more vulnerable patients in studies, because it is unclear how the risk of side effects should be estimated for relatively new medicines. For example, a study of patients in the international TEAM trial of adjuvant hormonal therapy in postmenopausal women with early-stage breast cancer examined the difference between patients in the population and the study. Even when the study's inclusion criteria were applied to the population-based cohort, the study showed that the patients in

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Keywords: Drugs, epidemiology, methodology, real-world data, research.

What are the treatment options for metastatic castration-resistant prostate cancer anno 2023?

D. Schrijvers, MD, PhD

SUMMARY

Patients developing metastatic castration-resistant prostate cancer are in most instances pre-treated with androgen deprivation treatment and a newer androgen receptor-targeting agent in the metastatic castration-sensitive setting.

In this article, I discuss the first- and second-line treatment options in this patient population.

(BELG J MED ONCOL 2023;17(1):15-8)

INTRODUCTION

Many new drugs have been developed in metastatic prostate cancer in the castration-resistant setting, but most of them are now being used in metastatic castration-sensitive prostate cancer (mCSPC). This is a natural life cycle of new cancer drugs, which are mainly developed in end-stage disease and are subsequently used in earlier disease stages preferentially when they have proven efficacy in terms of overall survival or patient-reported outcome measures, demonstrated in randomised studies in this setting.

In Belgium, androgen deprivation treatment (ADT) in combination with a new androgen receptor-targeting agent (ARTA) (reimbursed drugs in this setting are abiraterone acetate, apalutamide and enzalutamide) or with docetaxel are standard treatments for patients with mCSPC. Another ARTA such as darolutamide or triple therapy with docetaxel + ARTA +ADT have shown benefits in terms of overall survival in randomised trials and will be introduced in clinical practice after reimbursement in Belgium.[1,2]

Nowadays, most patients are treated with ADT + ARTA by their urologists and are referred to a medical oncologist when these treatments do not work anymore. This article focusses on which treatment options medical oncologists have for patients with metastatic castration-resistant prostate cancer (mCRPC).

TREATMENT APPROACH IN PATIENTS WITH MCRPC

When a patient develops mCRPC, several factors have to be taken into account.

Firstly, castration resistance should be confirmed by determining the testosterone level and if the level of testosterone is not < 50 ng/ml, biochemical or surgical castration should be re-initiated.

In addition, the determination of *BRCA* 1 or 2 mutations should be performed on tumoral tissue, because of the availability of poly ADP ribose polymerase (PARP) inhibitors if mutations are present. If a somatic mutation is present, a germ-line mutation analysis should be discussed because of the implications for the patient and his family. The quality of the stored prostate cancer tissue may be a problem to determine this somatic mutation and in some patients, a biopsy has to be performed, since the use of liquid biopsy of circulating tumour cells is limited to clinical studies.

Patients with mCRPC should be staged by conventional methods (bone scan, and computed tomography of the

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Keywords: ARTA, cabazitaxel, docetaxel, metastatic castration-resistant prostate cancer, PARP inhibitor, radium-223, 177-Lu-PSMA.

Audits in medical oncology

D. Schrijvers, MD, PhD

SUMMARY

The quality of oncological care can be ensured by different means, such as graduate and postgraduate education, guidelines, quality labels and audits. Audits in medical oncology departments are not routinely performed and are only used in case of problems. In this article, the introduction of audits in the medical oncology department is advocated, and a strategy to implement this quality improving tool is proposed.

(BELG J MED ONCOL 2023;17(1):19-26)

INTRODUCTION

The quality of oncological care provided by the different Belgian hospital does not undergo any specific quality control.

In the 'Koninklijk Besluit'(KB) related to the standards of basic oncology care and an oncology care program, a number of quality criteria have been included, such as a quality handbook with guidelines related to diagnosis, treatment and follow-up, and a multidisciplinary consultation.[1]

Also, the 'Vlaamse Overheid' publishes reports on indicators of the quality of care in Flemish hospitals. In the past, these reports focussed on certain tumour types (e.g. breast cancer, rectal cancer, lung cancer).[2]

In addition to these government-initiated quality initiatives, external audits have been performed in the Belgian hospitals by commercial companies (e.g. Nederlands Instituut voor Accreditatie in de Zorg (NIAZ) and Joint Commission International (JCI)) in relation to the functioning of these hospitals. Specific recommendations were given to improve the safety of the patient and the working environment. These audits did not solely focus on cancer care.

Several national and international oncological societies (e.g. European Society of Medical Oncology (ESMO), European Society of Surgical Oncology (ESSO) and European Society for Radiotherapy and Oncology (ESTRO)) developed initiatives to improve the quality of cancer care and treatment by the introduction of specific curricula, development, updating and distribution of guidelines for diagnosis, treatment and follow-up, educational programmes during educational events, continuous medical education programmes, and registries related to specific topics. Sometimes quality labels (e.g. breast cancer or palliative care) have been granted based on questionnaires. In the Netherlands, the Dutch Gynaecological Oncology Audit (DGOA) initiated in 2014 a nationwide audit by collecting information about gynaecological cancers through a web-based registration system with a set of predefined quality indicators. The results of these quality indicators are reported, and benchmarked information is given back to the users. Data related to ovarian cancer showed a variation between the hospitals with regard to pre-determined quality indicators. The aim of DGOA is to share best practices with all participants with the goal of improving the quality of care nationwide.[3]

The International Atomic Energy Agency (IAEA) has developed a program to improve the quality of radiotherapy units worldwide though audits (Quality Assurance Team for Radiation Oncology, QUATRO). This program defines a number of criteria to be evaluated and to improve the quality of radiotherapy departments, which are visited by auditors.[4]

The outcome of the QUATRO program after ten years in the IAEA Europe Region showed that eight centres were recognised as centres of competence, which differed from other centres mostly because they operated complete quality management systems and were adequately staffed. Other centres had excessive staff workloads and many gaps

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Keywords: Audit development, quality assurance, medical oncology.

Cyclophosphamide-induced hyponatremia leading to status epilepticus in a breast cancer patient

E. Cassiers, MD[1], N. Blockx, MD[2], W. Teurfs, MD[2]

SUMMARY

Cyclophosphamide (CP) is a well-known and extensively used immunosuppressive and antineoplastic agent. CP-induced hyponatremia remains an underestimated adverse event, although it can lead to severe complications and death. This case report describes the occurrence of life-threatening status epilepticus in a 74-year-old breast cancer patient due to CP-induced hyponatremia. The primary underlying mechanism seems to be impaired free water clearance, which is not influenced by ADH, but rather a direct effect of CP alkylating metabolites on the distal renal tubule. Future research is needed to further clarify the underlying pathophysiology and possible predisposing factors. Thorough monitoring of the patient's hydration status and electrolytes until 48 hours after the first administration of CP seems strongly advisable.

(BELG J MED ONCOL 2023;17(1):27-30)

INTRODUCTION

Cyclophosphamide (CP) is an alkylating agent that has extensively been used in immunosuppressive and antineoplastic therapies during the last decades.[1-3] Years of experience have led to the identification of several important and well-known side effects, such as bone marrow suppression, alopecia and haemorrhagic cystitis.[2,3] CP-induced symptomatic hyponatremia, however, remains an underestimated but potentially lethal adverse event.

This article reports the case of a patient with breast cancer who developed life-threatening hyponatremia after the first cycle of adjuvant chemotherapy containing low-dose CP.

CASE DESCRIPTION

A 74-year-old woman was diagnosed with a ductal adenocarcinoma of the right breast after biopsy. She underwent a tumorectomy and sentinel lymph node biopsy, after which the diagnosis of a grade III, invasive, ductal adenocarcinoma was confirmed. Resection margins and sentinel nodes were tumour-free (pT2N0(i-)(sn), ER +, PR +, Her2-Neu score 0). Two months after, she was scheduled to receive three cycles of adjuvant chemotherapy containing fluorouracil 500 mg/m², epirubicin 100 mg/m² and CP 500 mg/m², by a regimen of one cycle every three weeks, followed by three cycles of docetaxel 100 mg/m² (according to the FEC-D scheme).[4] She had no prior medical history, except for hypothyroidism and minor surgery. For her thyroid condition, she was treated with levothyroxine sodium 150 µg each day. Other habitual medication included bisoprolol/hydrochlorothiazide 5/12.5 mg per day, perindopril 5 mg per day and simvastatin 20 mg per day. At the start of her chemotherapy, there were no laboratory abnormalities, and the patient was euthyroid.

The patient received the first cycle of chemotherapy without complications or events. Standard supportive medication under the form of alizapride 50mg and methylprednisolone 40 mg was administered intravenously. She was discharged home afterwards with the addition of oral alizapride 50 mg for a maximum of six times per day (in case of nausea and/or

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Keywords: Cyclophosphamide, hyponatremia, syndrome of inappropriate antidiuresis.

Patient selection strategies throughout the renal cell carcinoma disease spectrum

E. Roussel, MD, PhD

SUMMARY

The present doctoral thesis manuscript aims to inform disease prognosis and guide therapeutic decision-making at all stages of the renal cell carcinoma disease spectrum. Novel imaging methods to improve pre-surgical characterisation of renal masses were developed, as well as prediction models for the estimation of postoperative renal function. Next, four molecular subtypes of clear cell renal cell carcinoma were described, their underlying disease biology and their implications in both the localised and metastatic settings. Moreover, the potential candidates for cytoreductive surgery were described, as well as the morbidity accompanying such procedures in the metastatic setting.

(BELG J MED ONCOL 2023;17(1):31-2)

INTRODUCTION

This thesis project aimed to inform disease prognosis and guide patient selection strategies throughout the renal cell carcinoma (RCC) disease spectrum. To do so, diverse clinical and translational research projects were conducted in both the localised and the metastatic settings.

In the localised setting, several novel-imaging methods were identified through a collaborative review of the literature. These methods were capable of non-invasively characterising renal masses and potentially altering therapeutic strategies.[1] Furthermore, a user-friendly prediction tool for the estimation of postoperative renal function in patients undergoing surgery for localised disease was developed, which provides a useful tool for clinical decision-making when balancing the risks and benefits of partial *vs.* radical nephrectomy.[2]

Next, for the first time, a pipeline for the determination of the four clear cell RCC (ccRCC) molecular subtypes was successfully developed and implemented on formalin-fixed paraffin-embedded tissue through unsupervised clustering of whole transcriptome sequencing data. This allowed to further explore the underlying disease biology represented by this biomarker and to provide the basis for the ongoing research in this research group. While the prognostic impact of these subtypes in the setting of metastatic RCC was established, it was hypothesised that these subtypes could also have a prognostic value in other clinical settings. This thesis has shown that the ccRCC molecular subtypes are also prognostic for localised disease.[3] These findings put forward a potential explanation for why trials with adjuvant anti-angiogenic agents have failed, and are of specific interest in light of the recent studies on adjuvant immunotherapy, which might not optimally select patients who will benefit from such therapies.

In the setting of metastatic RCC, treatment paradigms have been changing at an unprecedented pace. The role of cytoreductive surgery has been a topic of heavy debate, following the results of the CARMENA and SURTIME trials. While there is consensus that a subset of patients would still benefit from the continued role of upfront cytoreductive nephrectomy, it is unclear who these patients are. In the present work, patients with low-volume disease and few adverse risk factors have been identified as those who experience long systemic therapy-free intervals following cytoreductive nephrectomy.[4,5]

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Keywords: Patient selection, personalised medicine, renal cancer, renal cell carcinoma.

New oncology reimbursements in Belgium

T. Feys, MSc, MBA

OVERVIEW OF BELGIAN REIMBURSEMENT NEWS

(BELG J MED ONCOL 2023;17(1):33)

SACITUZUMAB GOVITECAN (TRODELVY®)

From January 1st onwards, the antibody-drug conjugate (ADC) Sacituzumab Govitecan is reimbursed as monotherapy for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) who received two or more prior lines of systemic therapy, including one in the metastatic setting.

The reimbursement of Sacituzumab Govitecan in this setting is based on the results of the randomised phase III ASCENT trial, in which this Trop-2 directed ADC proved to be superior to single-agent chemotherapy (i.e., eribulin, vinorelbine, capecitabine, or gemcitabine).[1] Sacituzumab Govitecan significantly delayed the disease progression compared to chemotherapy (median progression-free survival: 5.6 *vs.* 1.7 months; HR[95%CI]: 0.41[0.32-0.52]; p< 0.001), translating into a significant benefit in overall survival of almost half a year (median: 12.1 *vs.* 6.7 months; HR[95%CI]: 0.48[0.38-0.59]; p< 0.001). The percentage of patients reaching an objective response to Sacituzumab Govitecan was reported at 35% as compared to only 5% with chemotherapy. The most common treatment-related adverse events of grade ≥3 included neutropenia (51% with Sacituzumab Govitecan *vs.* 33% with chemotherapy), leukopenia (10% and 5%), diarrhoea (10% and <1%), anaemia (8% and 5%), and febrile neutropenia (6% and 2%).[1]

REFERENCES

1. Bardia A, et al. N Engl J Med. 2021;384:1529-41.

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Keywords: Sacituzumab Govitecan, Trodelvy®.

INTERNATIONAL & NATIONAL CONGRESSES 2022

Mayo Clinic Radiation Oncology: Current Practice and Future Direction 2023
9-13 January 2023
Kohala Coast, HI, United States

25th Post-ASH meeting
13 January 2023
Sheraton Brussels Airport, Belgium

Breast-Gynaecological & Immunooncology International Cancer Conference (BGICC)
19-20 January 2023
Cairo, Egypt

HYBRID - ASCO Gastrointestinal Cancers Symposium
19-21 January 2023
San Francisco, CA, United States

SIO2023
19-23 January 2023
Washington, DC, United States

24ste Nationale Longkanker Symposium 2023
20 January 2023
Amsterdam, the Netherlands

Melanoma 2023: 33rd Annual Cutaneous Malignancy Update
20-22 January 2023
San Diego, CA, United States

19th Winter Thoracic Oncology Symposium
21 January 2023
Gent, Belgium

33rd Annual International Prostate Cancer Update
22-25 January 2023
Vail, CO, United States

25th Annual BSMO meeting
3-4 February 2023
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