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Case Reports on Cancer Therapies: The Urgent Need to Improve the Reporting Quality

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Current guidelines for certain cancer therapies mainly provide recommendations for therapy options treating the primary tumors. However, first-choice treatments for advanced or metastasizing tumors are described only rarely if at all. In such cases, one or more individual treatment options are chosen by the physician depending on the medical need of the patient and considering the acceptance of this treatment by the patient. Often, well-known drugs are selected with a different dosing than is indicated in the drug information leaflet. In other cases, drugs not yet approved for this particular type of cancer are used off label or certain therapies are used in combination or consecutively in a manner not reported before. With the increasing research on personalized medicine, particularly in treating cancer, case reports on innovative drug therapies or newly developed surgical interventions may provide extremely valuable information in instances where randomized controlled trials may not be feasible (eg, because of a low patient number or ethical considerations). Moreover, they may support the identification and selection for further clinical research of a special subpopulation of people who respond to a certain treatment.

There is already a significant source of information available in the physician's patient records for individualized treatments adjusted to an individual patient, and numerous cases have been reported as single case reports or case series in the scientific literature. The goal of individual case reports thus should be to inform healthcare providers and decision makers in health authorities and insurance companies about the effectiveness of an exceptional and potentially innovative treatment option, in a positive or negative sense (ie, both successes and failures should be described). Thus, to be of value, case reports should provide as much information as possible and consider as many items of the CONSORT statement as possible.[1,2] To support this effort, an article by Cohen provides guidelines for writing patient case reports, with a focus on medication-related reports.[3] At the point of care, the use of a data collection sheet, an example of which is illustrated in the Figure, may be useful.

However, the reality looks different and the quality of case reports leaves a lot to be desired. As an example, more than 150 case reports describing different surgical, radiological, and drug therapies for metastasizing basal cell carcinoma could be found with a systematic literature search in the databases Medline and Embase. When collecting the data from these case reports in a systematic manner—eg, in a spreadsheet detailing demographic data, baseline characteristics, and details about the therapies and treatment outcomes—several gaps with essential information missing were identified.

Here are some observations made during the screening of case reports on therapies for patients with metastasizing basal cell carcinoma. This screening was undertaken to identify effective therapies from daily practice for this particular type of cancer.

In several case reports, no description of the patient's medical history, concomitant diseases and medications, or previous treatments for the primary tumor(s) is given. More than once, no dosage for drugs used for chemotherapy was reported and no indication of treatment cycles or duration of treatment was given. In a report presenting a patient with pulmonary metastasis from a giant polypoid basal cell carcinoma in the lumbosacral area, resection and chemotherapy were applied with a negative outcome, as the patient died 12 months after tumor resection because of tumor progression. However, the report does not even specify which drug(s) for chemotherapy was given, report the dosage and duration of treatment, or offer a conclusion regarding the negative clinical outcome.[4] It was also found that the drugs (carboplatin and docetaxel, 5-fluorouracil and cisplatin) were described without mentioning the dosages.[5,6]

Radiotherapy is another highly effective option for palliation and symptom control in many cases of advanced or recurrent cancers; however, there are large variations among different countries and within countries for the provision of radiotherapy.[7] No standardized protocols for radiotherapy have been reported, and the radiation dose and length of treatment published in several case reports are rather heterogeneous. Mostly, the treatment is reported simply as standard radiation therapy, meaning the default setting at a specific clinic, which might vary substantially between clinics. In only a few reports, information about the radiation dose is provided, such as 60 Gy, external beam radiation therapy in one case report,[8] or even more detailed in another, 50 Gy in 25 fractions by 6 McV photons followed by a boost of 10 Gy in 5 fractions.[9] However, whether these dosages are considered standard or are specific to a particular patient is not explained.

Regarding the clinical outcome, in many cases no information about follow-up observations, adverse

Figure Sample Data Collection Sheet for Case Reports

		Case Reports Reporting the Item
Study Identification	Study group/healthcare practitioner/clinic, other	
Treatment	Medication/medical device/measure	
	Dose	
	Length of treatment	
	Route of administration	
	Administration schedule	
	Comparator drug or measure (if applicable)	
Study Design	Study year	
	Study design	
	Written consent from the patient(s)	
	Objective	
	Endpoint parameters for efficacy, safety, tolerability, quality of life, using validated questionnaires	
	Inclusion criteria	
	Exclusion criteria (if applicable)	
	Description of planned follow-up (d, m, y)	
Demographic Data and Baseline Characteristics	Description of included subject(s)	
	Gender (male, female) in number (if more than 1 subject)	
	Age (y)	
	Previous and concomitant disease(s) and medication(s)	
	Group differences (if applicable)	
Clinical Results for Efficacy	Description of results for each efficacy parameter	
	Discussion of the clinical outcome Comments, if treatment was assessed as being more or less successful in comparison with other treatments known from the literature Recommendation for future treatments	
Clinical Results for Safety	Adverse events (AEs)	
	Serious AEs	
	Intensity of AEs	
	Relation to treatment	
	Duration of AEs and outcome (follow-up of AEs) Other safety parameters	
	(eg, blood pressure, liver enzymes, etc)	
Total Number of Case Reports Analyzed		

events, or effects on quality of life (QOL) using validated QOL questionnaires has been described, which would be extremely helpful to assess the effectiveness, safety, and tolerability of a particular therapy. Often, the message gleaned from the report is enthusiastic but without sufficient detail regarding the patient-related outcome. For instance, one report mentioned as outcome after radiotherapy and tomotherapy that "the tumor showed an excellent response" without further elaboration.[10]

Often, follow-up information is not available as the patient did not visit the physician again or died because of progressive disease. One reason for lack of information is that in most cases, physicians try to compile the patient's data retrospectively, whereas a prospective recording of the data with the intention to publish the case was not taken into account when the patient appeared at the clinic for therapy. Thus, as soon as an interesting case is identified in the clinical practice and thought to be of value to be reported to the medical community, the patient's written informed consent should be obtained to prospectively collect as much clinical data of the treatment as possible for reporting the case.

Certain therapies repeatedly described in a thorough way for a specific type of disease in individual patients may be summarized in a meta-analysis in a similar manner as randomized controlled trials, and as potential treatment recommendations, they may finally find their way into guidelines of medical societies.

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