

## Malpractice in Oncology

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### Key Words

Malpractice · Quality assurance · Guidelines

### Summary

In oncology, as in all other medical disciplines, medical malpractice is assumed when the physician has not taken sufficient care in his treatment, and when he has not met the required standards of medical care. The physician is liable for damages when distinct harm has arisen from this. In oncology, accusations of malpractice arise especially when suspicion of a malignancy is not based on unequivocal substantive diagnostic criteria (for example, the appropriate appraisal of routine x-rays or screening scans), or in terms of organizational mistakes. Stringent safeguards in oncological diagnostics and therapy are usually based on approved and generally recognized guidelines. From the time that the malignancy is suspected, there is therefore little concrete danger that malpractice will be attested provided these guidelines are complied with. The tolerance accorded by experts in respect of intraoperative complications in oncological operations appears to be great amongst medical expert witnesses. If a malpractice is attested, the distinct damage resulting from this can only be appraised approximately, e.g. by comparing the statistical probability of survival in various tumor stages.

Medical malpractice is the breach by a physician of his/her duty to take appropriate care in the diagnosis and treatment of diseases. The physician is accused of malpractice when it can be proved that he/she has not taken sufficient care and it can be demonstrated that avoidable harm to the patient has

### Schlüsselwörter

Behandlungsfehler · Qualitätssicherung · Leitlinien

### Zusammenfassung

In der Onkologie – wie in allen anderen medizinischen Fächern – wird ein ärztlicher Behandlungsfehler dann angenommen, wenn sich der Arzt in seiner Behandlung nicht in ausreichendem Maße Mühe gegeben hat, und wenn er damit den jeweils geforderten Standard der ärztlichen Sorgfalt nicht gewahrt hat. Schadensersatzpflichtig wird der Arzt dann, wenn sich hieraus ein eigenständiger Schaden ergeben hat. In der Onkologie werden Fehlervorwürfe vor allem dann erhoben, wenn es um die diagnostische Abklärung bei noch nicht konkretem Malignomverdacht geht (z.B. bei der Beurteilung von Routineröntgenaufnahmen oder Screeninguntersuchungen), oder im Sinne von Organisationsfehlern. Aufgrund der hohen Absicherung onkologischer Diagnostik und Therapie durch konsenterte und allgemein anerkannte Leitlinien besteht – folgt man diesen Leitlinien – ab dem Zeitpunkt des Malignomverdachts nur eine geringe Gefahr, dass ein ärztlicher Behandlungsfehler attestiert wird. Die Toleranz gegenüber intraoperativen Komplikationen bei onkologischen Eingriffen scheint bei den Gutachtern groß zu sein. Ist ein Behandlungsfehler festgestellt, so kann der sich hieraus ergebende eigenständige Schaden oftmals nur approximativ abgeschätzt werden, so z.B. durch einen Vergleich der statistischen Überlebenschancen in verschiedenen Tumorstadien.

arisen from this insufficient action [1]. Malpractice would actually have to be attested the more frequently, the more difficult, the more complex and more susceptible to complications a treatment is. Accusations of malpractice should thus have arisen with considerable frequency in oncology.

Yet, this is not the case. In many sectors of oncology, the incidence of accusations of malpractice is infinitesimally low. The reason for this surprising finding might be that in Germany physicians engaged in surgical treatment are traditionally being accused of medical malpractice far more frequently than physicians not engaged in surgery [2]. Another reason might be that unfavorable clinical courses in oncology are accepted in the public perception mostly as 'naturally' occurring. Consequently, a layperson (who will potentially sue) much more rarely suspects malpractice in oncology than, for example, in orthopedic surgery. Finally, in oncology it may be difficult to appraise ostensible malpractice in terms of distinct harm that has arisen. Here, it would be necessary to delineate the spontaneous evolution of the cancer with sufficient precision in contrast to the course that takes place in the event of malpractice. Understandably the spontaneous clinical evolution of a diagnosed cancer will never be awaited and known.

The present text reviews accusations of malpractice in oncology and enunciates criteria for expert reports and for the prevention of mistakes. The following materials will be discussed: the pertinent jurisprudence since 1949, as reflected in the compilation '*Arzthaftpflicht – Rechtsprechung*' (Medical Liability – Jurisprudence) [3] as well as a literature research (date: July 22, 2003, data bank: Medline, total: 12.4 mio hits) with the search term 'oncology and malpractice', publications from 1997 to 2003 (32 hits).

Court judgements on allegations of medical malpractice in oncology are essentially focused on four sectors: early diagnostics (e.g. in terms of screening) without concrete suspicion of an oncological disease, comprehensive diagnostic clarification in case of concrete suspicion of malignancy, problems of surgical techniques, and organizational inefficiencies.

#### *Diagnostics without Concrete Suspicion of Malignancy*

Allegations about an inappropriate diagnostic workup without sufficient concrete suspicion of carcinoma takes first place by far amongst all allegations of medical malpractice.

– On several occasions, there have been court judgements as to whether the misinterpretation of a mammography is an error, or whether it is inexcusable (gross) medical malpractice [4]. There was agreement in the literature that misinterpretation of a mammography is an avoidable mistake, but not completely incomprehensible (so that there is no gross medical malpractice). These decisions are noteworthy to the extent that the misinterpretation of a finding (and thus also the misinterpretation of an x-ray) is by no means regularly considered to be medical malpractice and not in all medical disciplines. The readiness to concede that the physician may have made a 'diagnostic error' without immediately alleging medical malpractice is otherwise relatively great. However, it is clear that the court judgements (or the experts advising the courts) assure that a mammography will not be misinterpreted if the physician is sufficiently careful.

– Comparable observations have been made when a chest x-

ray was taken for example for routine reasons and where a shadow giving rise to a suspicion of carcinoma was overlooked on this routine chest x-ray. This is also rated as an error, but not as 'gross medical malpractice' [5].

– Accordingly, there are references in the literature to the importance of early diagnostics of malignancies [6].

#### *Mistakes in Clinical Diagnosis in Malignancy*

Mistakes in clinical diagnosis in malignancy are evidently often regarded by the experts advising courts as 'not avoidable from the start'. In the compilation of court judgements over a period of 50 years, there is no single decision on a diagnostic mistake by a dermatologist in suspicion of melanoma. Nor is there any judgement on a misinterpretation of an x-ray under the heading 'diagnostic mistakes of radiologists', apart from the misinterpretation in mammography or allegations with regard to inadequate x-ray techniques.

#### *Diagnostics in Existing Concrete Suspicion of Malignancy*

Once the putative diagnosis of a malignant disease has been made, all necessary diagnostic measures must be used. A conspicuous digital examination of the rectum must be followed by extensive endoscopic diagnostics, and a palpable breast tumor must be histologically verified [7]. Uterine bleeding in the menopause must be clarified [8], mistakes in surgical staging resulting from insufficiently exhaustive diagnostic measures are not accepted, etc.

#### *Problems of the Surgical/Chemotherapeutic Technique*

Naturally, intraoperative complications such as injuries to the ureter in hysterectomy, difficulties at the biliodigestive anastomosis after partial liver resection etc. are bound to occur in oncological operations. However, as far as can be appraised synoptically no error is seen in this. The experts advising the courts are clearly very tolerant, especially with regard to oncological operations [9]. Allegations of medical malpractice pertaining to cytostatic treatment chiefly involve technical implementation, e.g. meticulous handling to avoid paravasations [10].

#### *Horizontal Division of Responsibilities*

Oncology is typically interdisciplinary, which can also lead to difficulties in establishing agreement and coordination between colleagues in the horizontal division of responsibilities. The same principles as those for all other clinical disciplines apply. The principle of trust holds: a physician (e.g. the treating surgeon) may trust that the recommendations or findings of a colleague of another specialty (e.g. radiology) are correct. Nevertheless, he must recognize when the advice or findings received from the consulted colleague are evidently wrong, and must then insist that these are clarified: If there is a striking discrepancy between the result of the histological examination and the visual finding of the physician after tissue specimens have been taken from two patients on the same day, it

must occur to the physician that the tissue samples may have been confused and he must investigate this possibility further [11].

Special efforts will have to be made to avoid organizational deficits in other respects in oncological treatment [12, 13], not least because in principle organizational requirements are regarded as controllable. For this reason the attestation of an organizational shortcoming can make it easier for the patient to prove his case [1]. This can also apply to purely technical problems involving instruments. It is self-evident that giving detailed information about potential benefits and risks of a treatment as well as giving sufficient information about alternative treatments, play a central role in oncology [1, 14]. Failure to obtain and document appropriate informed consent implies liability.

### *Consequences of Errors*

After attesting malpractice, the question regularly follows as to what extent the error established has given rise to distinct and avoidable clinical consequences, i.e. consequences going above and beyond the actual manifestation of the disease. As a rule, the medical experts say that the spontaneous course of a malignant disease is never individually predictable. This is also taken into account in court judgements [15].

If the pattern of allegations of medical malpractice in oncology is reviewed, it is apparent that the essential risk of a 'culpable error' in consequence of a lack of care is inherently present when the concrete putative diagnosis of malignant disease has not yet been made, i.e. in preventative investigations. If a suspicion of carcinoma has been expressed, the diagnostics and therapeutics evidently tend to aim in one direction. Traditionally, evidence-based guidelines that are consented to within the specialist society and generally accepted guidelines play a pre-eminent role in oncology. If the diagnostic and therapeutic procedures inherent in the rationale of a guideline are followed, a medical malpractice cannot usually be attested. This is confirmed by the repeated observation that it is necessary not only to safeguard the patients, but in particular also the doctors themselves (especially in fields of highly complex medicine that are inherently subject to risks) by means of 'consented guidelines' – not to suppress diagnostic and therapeutic diversity, on the contrary in order to counter fortuitous reporting on the part of medical expert witnesses in allegations of medical malpractice. A physician who sticks to the consented and up-to-date guidelines in the diagnostics or treatment of oncological disease can reasonably be certain that in the case of an accusation of an error, the medical expert witness reporting will also apply the same yardstick, regardless who has been appointed. If an oncological medical

expert failed to do so, the credibility of his report would be zero from the start.

This situation is quite different in many other specialties of medicine. Even in the classical surgical disciplines (e.g., visceral surgery, accident surgery, orthopedic surgery), observations of divergent diagnostic and in particular therapeutic principles are part of clinical and scientific routine. This does not mean that the multiplicity of approaches are normally expressly accepted formally on an equal footing. In consequence, in the event of an accusation of medical malpractice, the appraisal of the medical expert witness will very largely depend on the individual 'school' he/she belongs to or at least on whether the medical expert witness admits to the court that there is multiplicity of opinions. The fortuitous situations in the field of hospital hygiene are even more manifest: in this area, legal certainty probably no longer exists in many respects in view of a discrepancy of opinions which has been meticulously fostered for more than 10 years.

The weight of guidelines in oncology is consequently an excellent example of how a consensus within a specialty does not only contribute to quality assurance in the field of clinical treatment, but also very largely to quality assurance of medical expert reporting in the case of accusation of medical malpractice.

It is in accordance with the spirit of our times that the claims to diagnostic certainty in the absence of suspicion of carcinoma (in routine investigations or screening investigations) are high and tend not to admit any probability of error. It remains an open question as to whether it will be possible some day to argue that even with excellent postgraduate training and standardized quality assurance a diagnostic error may be acceptable to a certain extent, e.g. in mammography screening, so that a diagnostic error does not automatically imply lack of care.

In attempting to establish whether a causality meeting the criteria of liability (in the question to what extent an attested medical malpractice has given rise to distinct consequences), a qualified medical expert witness will in the future probably have to go by statistically verified data, e.g. statistically verified probabilities of survival. For example, if a broad-based tubular adenoma of the colon is not resected completely and develops into a carcinoma (this can engender allegations of medical malpractice), a serious medical expert witness will have to present the relevant statistical rates of cure and survival of the respective tumor form, always pointing out that this does not constitute an appraisal of the individual (hypothetical) prognosis. The extent to which these appraisals become part and parcel of a judgement will be a matter for the court to decide.

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### IMPORTANT DATES

17 May 2004	Abstracts, paper submission
24 May 2004	Abstracts, online submission
19 July 2004	Early registration closure
20 September 2004	Late registration closure
27 September 2004	Hotel reservation deadline

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