

Medical Liability and Patient Law in Germany: Main Features with Particular Focus on Treatments in the Field of Interventional Radiology.

Arzthaftung und Patientenrechtegesetz in Deutschland: Die Grundzüge unter besonderer Berücksichtigung von Behandlungen auf dem Gebiet der Interventionellen Radiologie.

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Key words

- law
- medical
- embolization
- chemoembolization
- interventional radiology

Abstract

On February 26th, 2013 the patient law became effective in Germany. Goal of the law-makers was a most authoritative case law for liability of malpractice and to improve enforcement of the rights of the patients. The following article contains several examples detailing legal situation. By no means should these discourage those persons who treat patients. Rather should they be sensitized to various aspects of this increasingly important field of law. To identify relevant sources according to judicial standard research was conducted including first- and second selection. Goal was the identification of jurisdiction, literature and other various analyses that all deal with liability of malpractice and patient law within the field of Interventional Radiology – with particular focus on transarterial chemoembolization of the liver and related procedures. In summary, 89 different sources were included and analyzed. The individual who treats a patient is liable for an error in treatment if it causes injury to life, the body or the patient's health. Independent of the error in treatment the individual providing medical care is liable for mistakes made in the context of obtaining informed consent. Prerequisite is the presence of an error made when obtaining informed consent and its causality for the patient's consent for the treatment. Without an effective consent the treatment is considered illegal whether it was free of treatment error or not. The new patient law does not cause material change of the German liability of malpractice law.

Key points:

- ▶ On February 26th, 2013 the new patient law came into effect. Materially, there was no fundamental remodeling of the German liability for medical malpractice.
- ▶ Regarding a physician's liability for medical malpractice two different elements of an offence come into consideration: for one the liability for malpractice and, in turn, liability for errors made during medical consultation in the process of obtaining informed consent.
- ▶ Forensic practice shows that patients frequently enforce both offences concurrently.

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Zusammenfassung

Am 26.2.2013 trat in Deutschland das „Patientenrechtegesetz“ in Kraft. Erklärtes Ziel des Gesetzgebers war es im Wesentlichen, die höchstrichterliche Rechtsprechung zur Arzthaftung in Form eines Gesetzes zu kodifizieren und für die Patienten die Durchsetzung ihrer Rechte zu verbessern. In dem vorliegenden Artikel soll anhand von Beispielen eine Orientierung über die Rechtslage gewonnen werden. Keinesfalls soll dies eine Demotivation der Behandelnden bewirken. Vielmehr sollen diese hinsichtlich verschiedener Aspekte, dieses immer wichtiger werden Rechtsgebiets, sensibilisiert werden. Für die Definition relevanter Quellen entsprechend juristischem Standard erfolgte eine Recherche mit Erst- und Zweitselektion. Ziel war die Identifikation von Rechtsprechung, Literatur und sonstiger

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Nachweise, die sich mit Arzthaftung und Patientenrechtegesetz auf dem Gebiet der Interventionellen Radiologie – unter besonderer Berücksichtigung der transarteriellen Chemoembolisation der Leber bzw. verwandter Verfahren – befassen. Insgesamt wurden 89 Quellen eingeschlossen und ausgewertet. Der Behandelnde haftet für einen Behandlungsfehler, wenn dieser für die Verletzung des Lebens, des Körpers oder der Gesundheit des Patienten ursächlich (kausal) ist. Unabhängig von einem Behandlungsfehler haftet der Behandelnde für einen Aufklärungsfehler. Voraussetzung hierfür ist das Vorliegen eines Aufklärungsfehlers und dessen Ursächlichkeit für die Einwilligung des Patienten in die Behandlung. Ohne eine wirksame Einwilligung ist die Behandlung, sei sie behandlungsfehlerhaft oder frei von einem Behandlungsfehler, als rechtswidrige Körperverletzung zu werten. Durch das „Patientenrechtegesetz“ erfolgt materiell – also in der Sache – keine grundlegende Umgestaltung des deutschen Arzthaftungsrechts.

Introduction

The Patient's Rights Law was enacted in Germany on February 26, 2013. The stated goal of the lawmakers was essentially to codify the existing case law of the highest court regarding medical liability in the form of a written law and improve enforcement of patients' rights. Detailed legal standards for regulating this increasingly important area of the law are thus now available. This article seeks to serve as a primer on liability matters using examples, whenever possible from the field of interventional radiology [1, 2]. The basics of medical malpractice liability are presented below on the basis of German civil law – albeit in a cursory manner given the limited space available. This article is by no means intended to discourage those who treat patients, but rather to sensitize them to different aspects of this increasingly important area of the law [3–5]. In this process, attention shall be given in particular to the Patient's Rights Law enacted on February 26, 2013 [6].

Methodology

Research was conducted to define relevant sources reflecting the legal standard. This research employed a three-pronged approach: (I) research at court, university and state libraries (in particular through online catalogues), (II) research conducted using the electronic medical database MEDLINE as well as (III) research using the internet. Sources were selected on the basis of defined inclusion and exclusion criteria. The goal was to identify case law, literature and other information concerning medical malpractice liability and the Patient's Rights Law in the field of interventional radiology – with special focus on transarterial chemoembolization of the liver as well as related procedures. The nature of the sources did not permit a standardized data extraction. Data was extracted in a multi-step process, the first step being a general categorization of sources and the second step being special examination of aspects of transarterial embolization or these related procedures. Source selection and data extraction were managed jointly by S.A.S. and C.M.S. through consensus and were concluded in January of 2014. Detailed information on the conducting of research as well as on the

definition and specific necessity of citation method can be obtained from the corresponding author.

Results

Following the process of initial and second selection, a total of 89 sources were included: 71 sources as a result of (I) research at court, university and state libraries, 12 sources as a result of (II) research conducted using the electronic medical database “MEDLINE” as well as 6 sources as a result of (III) research using the internet.

The liability of persons treating patients is based primarily two independent aspects, one being a treatment error and the other being error in obtaining informed consent. Both errors can each involve a contractual liability based on a treatment contract pursuant to § 280 paragraph 1 sentence 1 German Civil Code (“If the obligor breaches a duty arising from the obligation, the obligee may demand damages for the damage caused thereby.”) as well of a *tortious* liability independent of such a contract in particular pursuant to § 823 paragraph 1 of the German Civil Code (“A person who, intentionally or negligently, unlawfully injures the life, body, health [...] or another right of another person is liable to make compensation to the other party for the damage arising from this.”). Disregarding the details roughly concerning the use of auxiliary persons, both definitions of liability essentially deliver the same results [7, 8]. Therefore, no distinction is made between contractual and tortious liability when it comes to treatment errors or errors in obtaining consent.

Liability for treatment errors

The person providing treatment is liable to a patient for any treatment error responsible (causal) for injury to the life, body or health of the patient.

Treatment errors

A treatment error has been committed if the person providing treatment fails to perform treatment in accordance with § 630a paragraph 2 of the German Civil code, which stipulates that “unless agreed otherwise, the treatment must take place according to the medical standards that are generally recognized at the time of the treatment” [8, 9]. Types of treatment errors include, in particular, fault by assumption (roughly the rendering of treatment by a doctor without sufficient qualification due to a lack of advanced training), organizational or administrative fault (roughly a violation of the standards for hygiene, provision of medications or equipment safety), a diagnostic error, improper selection of therapy, an error regarding the specific – proper – therapy, failure to perform follow-up, or an error in providing information about therapy [8, 10]. The latter, which is distinct from “explanation in the process of obtaining informed consent” addressed under Item 2.2, is also referred to as “safeguarding explanation” and is regulated in § 630c paragraph 2 sentence 1 of the German Civil Code (“The treating party is obliged to explain to the patient in a comprehensible manner at the beginning of the treatment, and where necessary during the same, all and any circumstances that are relevant to the

treatment, in particular the diagnosis, the anticipated health development, the therapy and the measures to be taken on the occasion of and subsequent to the therapy.”) [7, 9]. In addition, § 630c paragraph 3 sentence 1 of the German Civil Code (“If the treating party knows that the complete assumption of the treatment costs by a third party is not secured, or if sufficient indications of this emerge under the circumstances, he/she must inform the patient in text form prior to commencing the treatment of the likely costs of the treatment”) mandates that persons providing treatment have a duty to inform regarding economic aspects.

For example, according to case law, a continuation of the embolization following successfully conducted embolization of the left meningial artery must be qualified as a treatment error, if, during the probing of the right meningial artery the dangerous combination of excessively proximal placement of catheter, hazardous anastomoses and excessively small embolization particles appears [11]. In addition, case law requires that a “strictly defined medical indication” be present before “any invasive contrast-enhanced examination” can be performed [12]. On the other hand, case law viewed coronary angiography and a heart catheter examination as indicated and thus denied the presence of a treatment error in a specific case involving a history of coronary disease (two heart attacks and bypass) and the appearance of dyspnea [13].

In a civil medical malpractice trial (the patient files a lawsuit against the treating party for payment for pain and suffering and seeks compensation for future damage) the issue of burden of proof is of central importance. The burden of proof decides which party shall bear the consequences, should a fact relevant to the case – in this context the presence of a treatment error – remain unproven, i.e., which party bears the risk of failure to provide proof and therefore loses the trial [14]. While in principle the burden of proof is on the suing patient to demonstrate the presence of a treatment error [8, 9], the shifting of the burden of proof favors the patient at the treating party’s expense. Thus, according to § 630h paragraph 1 of the German Civil Code, a treatment error is “presumed to have been committed by the treating party if a general treatment risk has materialized which was fully manageable for the treating party and which led to the injury to the life, limb or health of the patient.” Such a risk could be, for example, an error in positioning the patient, deficient hygiene or insufficient equipment safety [9, 10]. In addition, the assumptions of § 630h paragraph 3 of the German Civil Code favor the patient: “If the treating party has not recorded a medically-necessary major measure and its result [...] in the medical records or he/she has not retained the medical records [...], it is to be presumed that he/she has not carried out this measure” [7, 9].

Causality of the treatment error for injury to the patient’s life, body or health

Furthermore, the prerequisite for liability of the treating party is that the treatment error has causality for the injury to the patient’s life, body or health. This is the case if the injury to the patient’s legally protected rights would not have occurred without the treatment error (“if not for”) [10].

While in principle the burden of proof is also on the patient to demonstrate the aforementioned causality, it has likewise been shifted in this context in the patient’s favor at the ex-

pense of the treating party. On the one hand, § 630h paragraph 4 of the German Civil code mandates that “If a treating party was not qualified to carry out the treatment which he/she performed, it is to be presumed that the lack of qualification was the cause of the occurrence of the injury to the life, limb or health.” This encompasses, in particular, cases of “beginner’s errors”, i.e. errors due to lack of qualification on the part of the treating party [8, 9]. On the other hand, § 630h paragraph 5 sentence 1 of the German Civil Code states that “If gross malpractice has been committed, and if this is capable as a matter of principle to cause an injury to life, limb or health of the nature which in fact took place, it is to be presumed that the malpractice was the cause of this injury” (the same applies accordingly pursuant to § 630h paragraph 5 sentence 2 of the German Civil Code: “This is also to apply if the treating party omitted to take or record a medically-necessary finding in good time where the finding would with sufficient certainty have led to a result which would have given rise to further measures, and if failure to carry out such measures would have constituted gross malpractice”). Gross malpractice has then occurred, if the physician clearly violated established medical treatment regulations or trusted medical knowledge and thereby committed an error, which no longer appears to be justifiable from a medical perspective, because such an error “must by all means not be committed” by a doctor [9, 10, 15].

For example, case law viewed a faulty embolization with microparticles as this type of gross malpractice. However, for the material elements of the offence, the causality of this gross malpractice for the injury to legally protected interests was, as an exception, denied given that causality was entirely unlikely [10, 11]. Furthermore, case law denied gross (!) malpractice and thus a shifting of the burden of proof in the aforementioned sense solely based on the situation that moving the patient to another bed was undertaken solely by the “radiology assistant” [16].

Liability for errors in obtaining informed consent



The treating party is liable in the event of an error in obtaining consent independently of a treatment error. The perquisite for this liability is the presence of an error in obtaining consent which resulted in the patient consenting to the treatment as well as the existence of a risk that must be disclosed. Thus according to § 630d paragraph 2 of the German Civil Code, the “effectiveness of the consent is contingent on the patient” [...] having been properly “informed [...] prior to giving consent”. Without effective consent, any treatment, regardless of whether it involves malpractice or not, must be viewed as illegal bodily injury [8, 10].

Error in obtaining informed consent

An error in obtaining consent is present particularly if the treating party does not satisfy the obligations to provide information specified in § 630e paragraph 1 through 3 of the German Civil Code. The aforementioned standard, also known as the “Magna Charta” of obligations to provide information states the following:

“(1) The treating party is obligated to inform the patients of all circumstances material to consent. This includes, in particular, the nature, scope, execution, expected conse-

quences and risks of the measure as well as its necessity, urgency, suitability prospects for success with regard to the diagnosis and therapy. During the process of informing the patient, alternatives to the measure must also be noted if multiple medically equivalent indicated and usual methods can lead to significantly different burdens, risks or chances of being healed or cured.

(2) The patient must be informed

1. orally by the treating party or by a person possessing the necessary training for conducting the measure. This can be supplemented by reference to documents that the patient receives in printed form.
2. in a timely manner that allows him or her to make a decision on giving consent following sufficient consideration.
3. in a manner that he or she can understand.

The patient must be provided with documents which he or she signed upon being informed or giving his or her consent.

(3) Informing the patient is not required provided that special circumstances render it unnecessary in exceptional cases, particularly if the measure cannot be delayed or the patient expressly waived being informed."

On a supplemental basis, § 630e paragraph 4 of the German Civil Code states that if, in accordance with § 630d paragraph 1 sentence 2 of the German Civil Code, a patient is unable to consent and thus consent is to be obtained from the appropriate "entitled party", e.g., the legal guardian, caregiver, legal representative or authorized agent, the entitled party is to be informed according to the principles specified above [7, 9]. In addition, § 630e paragraph 5 of the German Civil Code states that the "major circumstances" according to § 630e paragraph 1 of the German Civil Code "shall also be explained to the patient in a manner that he/she is able to understand, where the latter is capable of absorbing the explanation on the basis of his/her state of development and ability to understand and unless it is inconsistent with his/her well-being".

Consistent with case law, the following rule can be used as a rough general standard for the scope and degree of accuracy of the information: the scope and level of detail of the information are inversely proportional to the urgency and the prospects of success of the intervention. The burden of information thus increases as the urgency of the medical intervention and its prospects of success decrease and vice versa [17].

With regard to the particulars of providing information in the process of obtaining consent, it is necessary specifically to satisfy the requirements for those required to inform, those being informed, the time at which information is provided, the form in which information is provided and the documentation of the process of informing [8, 10, 18–21].

Concerning digital subtraction angiography, the body of professional literature specifies the following "as general complications" of which the treating party must advise the patient when informing him or her of the following particular risks: skin irritation due to radiation exposure, inducement of a cancerous disease ("highly unlikely"), pain ("common"), severe allergic reactions with difficulty breathing, cardiovascular failure, necessity of internal medicine and permanent organ damage (probably 0.05 to 0.1% of patients), moderate – not life-threatening – allergic reactions (occurring in 1 to 2% of patients), worsening of already impaired kidney function up to kidney failure (occurring in 2 to 30% of patients), hyperthyroidism up to thyrotoxic crisis

("minimal risk" for patients with normal thyroid function and normal TSH), exacerbation of hyperthyroidism or an iodine-induced hyperthyroidism (in principle, patients with latent hyperthyroidism or a functional autonomy at risk), hemorrhages following vascular or tissue injuries ("occasional"), pseudoaneurysms following femoral puncture (in up to 7.7% of patients), thromboses at the puncture site ("occasional"), embolisms with vascular occlusion as well as disturbances of blood perfusion in organs and limbs as a result of a migration of a thrombosis, the loss of a stent in the bloodstream as a result of an inflammation, vascular occlusion and the necessity of stent recovery ("rare"), infection of the punctured site with migration into the bloodstream (sepsis) or inflammation of the endocardium ("very rare") as well as the injury of skin and soft tissue with tissue and nerve damage ("occasional") [22].

According to literature, the patient must be informed of the following "special complications" before undergoing "local chemoembolization (vascular occlusion with injection of cytostatics for treating liver tumors)":

"Pain, fever, nausea and vomiting (also referred to collectively as "post-embolization syndrome") can occur as side effects of cytostatics in nearly any patient [with additional reference]. Gallbladder or pancreatic inflammation can possibly appear as a consequence of treatment being performed on or around the liver (occurring in 0.7% of cases [with additional reference], as can pain, hemorrhage, infection, thrombosis/embolism, skin and nerve damage [...] and an allergic reaction to the cytostatics or to the substances used for embolization. In rare cases, a general coagulation disturbance (consumption coagulopathy) is observed that is brought on by severe tumor decomposition following suppression of blood supply and an inflammation in the embolized organs, which potentially develops into an abscess requiring surgical treatment"[22].

In addition, case law states the following obligations to provide information in the form of examples: If a patient undergoes a three-stage diagnostic intervention, specifically angiography, embolization and occlusion test for which there is a cumulative risk, the patient is to be informed of the risk for each stage of the intervention. In the case of selective angiography, the patient is to be advised of an elevated risk of vascular injury [23]. The patient is to be informed of the possibility of vascular injury occurring with arterial puncture. The use of medical jargon is not sufficient for indicating the risks of diagnostic interventions, since they do not adequately reflect the potential burden to laypersons. The information provided must clearly convey that a heart catheter examination can not only lead to heart problems and temporary bleeding, but also permanent damage to entirely different parts of the body [24]. Prior to a heart catheter examination, the risk of dissection of iliac arteries and the aorta must be explained. It is not sufficient to describe the risk using jargon such as "vascular damage" or "hemorrhage". [25]. Patients with kidney dysfunction, regardless of how minor, must be informed of the risk of kidney failure as a consequence of an arterial heart catheter examination and coronary angiography. In this case, the patient must also be advised that he or she suffers from such a problem [26]. A patient scheduled to undergo cranial digital subtraction angiography must be thoroughly informed of the associated risk of stroke. The patient must be advised

especially if there is an elevated risk for this condition given his or her medical history [27, 28]. The patient must be informed of the risks of arterial angiography, even if he or she has already been informed by another doctor about the risks of venous angiography when having undergone such procedure and those of subsequent possible arterial angiography [29]. In general, “diagnostic interventions without direct therapeutic value” are subject to stricter requirements when it comes to informing the patient [23, 26, 30–32]. In severe cases of cancer, it must be explained that not only is the chemotherapy merely palliative in nature, but also fails to achieve the intended goal in the majority of patients [33]. If a patient is handed a “Perimed sheet” when being informed of a risk, he must also have the opportunity to quietly read the informational form. If the form consists of four two-column pages of text, then the informational discussion to obtain informed consent must be postponed until the day of the coronary angiography [34].

It must then be established that the burden of proof is on the treating party to demonstrate that effective consent was obtained and the patient was duly informed. As § 630 h paragraph 2 sentence 1 of the German Civil Code stipulates: “The treating party is to prove that he/she has acquired consent in accordance with section 630 d [German Civil Code] and provided information in accordance with the requirements of section 630e [German Civil Code]” [7–9]. In particular, the treating party must prove that he or she furnished the patient with copies of documents related to patient information and consent in accordance with § 630e paragraph 2 sentence 2 of the German Civil Code. The treating party should therefore obtain written acknowledgement from the patient that these documents were distributed.

Causality of the error in obtaining consent for the patient's consent to treatment

For the treating party to be held liable for an error in obtaining consent, it must furthermore be established that this error was the cause of the patient consenting to the treatment [8–10]. In this regard, the issue of hypothetical consent on the part of the patient, i. e. the patient's consent in the event of his being properly informed, is relevant. If this hypothetical consent can be affirmed, then causality can be denied. If, conversely, the existence of this hypothetical consent is denied, then causality is present. In this respect § 630 h paragraph 2 sentence 2 of the German Civil Code stipulates: “If the information does not comply with the requirements of section 630e, the treating party may assert that the patient would also have consented to the measure had proper information been provided”. The burden of proof to demonstrate the patient's hypothetical consent is thus on the treating party [8, 9]. The treating party must therefore prove that the patient would have resolved his potential decision-making conflict in favor of undergoing the treatment had he also been properly informed.

Commentary

This article seeks to build an interdisciplinary bridge between law and radiology in Germany. The fundamentals of medical liability and the patient's rights law are presented with special focus on treatments in the field of interventional

radiology. The article consciously foregoes examining specific clinical issues more closely and providing practical advice, such as when it comes to informing patients who do not speak German or the role of living wills held by patients who are capable of providing consent. For these issues, the authors refer the reader to the relevant publications and expert opinions.

To our knowledge, no comprehensive high court case law has been published to date regarding the “Patient's Rights Law” enacted on February 26, 2013, specifically regarding sections 630a ff. appended to the German Civil Code concerning the “Treatment Contract”. However, prior case law and literature are generally applicable in this regard, given that the aforementioned new act brought about no *fundamental* changes to the German medical liability law in a material sense. Rather, the stated goal of the law makers was essentially to codify the existing case law of the highest court regarding medical liability in the form of a written law. Therefore, prior jurisprudence and professional knowledge are in no way obsolete following the enacting of the “Patient's Rights Law”, thus making the aforementioned sources still relevant. Two different elements of offense therefore continue to be considered with regard to a physician's liability in Germany: Liability can be based either on a treatment error or on an error in obtaining consent in the process of obtaining informed consent. Of course, both errors are frequently claimed concurrently by patients filing suit, as the damaged parties or allegedly damaged parties seek to give their lawsuits an increased chance of success. Because of the vast number of conceivable treatment errors possible in diagnostic and interventional radiology and the complexity of the aspects to be explained in this field, this article in any case presents as examples typical liability cases such as the absence of a “strictly defined medical indication” in the event of a contrast-enhanced examination (treatment error) or failure to inform the patient of general and specific complications when performing a local chemoembolization (error in obtaining consent). Potential limitations of this methodological-theoretical presentation include the overlooking of relevant sources, which can result from the absence of a standardized vocabulary, from the interdisciplinary subject as well as from the limited number of databases employed. However, the authors consider the exclusion of key publications to be “unlikely”, since these would have been identified through cross-reference at the time of research.

Adherence to ethical standards

The corresponding author declares for himself and on behalf of his colleagues that there are no conflicts of interest. This article does not involve any studies on humans or animals.

Remarks

This article shall additionally appear in similar form, particularly with more in-depth information, as Chapter 3 “Rechtliche Aspekte” [Legal Aspects] of the monograph titled “Moderne Praxis der transarteriellen Tumorthherapie der Leber” [Contemporary Use of Transarterial Tumor Ther-

apy in the Liver], which is slated to be published in 2015 by UNI-MED Verlag, Bremen, Germany.

Abbreviations

AHRS	Arzthaftpflicht-Rechtsprechung [Medical malpractice liability case law]
BGHZ	Entscheidungen des Bundesgerichtshofs in Zivilsachen [Rulings of the Federal Court of Justice in civil matters]
GesR	Zeitschrift für Arztrecht, Krankenhausrecht, Apotheken- und Arzneimittelrecht [journal]
MDK	Medizinischer Dienst der Krankenversicherung [Health Insurance Medical Services]
MedR	Medizinrecht [journal]
NJW	Neue Juristische Wochenschrift [journal]
NJW-RR	Neue Juristische Wochenschrift – Rechtsprechungs-Report Zivilrecht [journal]
RöFo	Fortschritte auf dem Gebiet der Röntgenstrahlen und der bildgebenden Verfahren [journal]
VersR	Zeitschrift für Versicherungsrecht, Haftungs- und Schadensrecht [journal]

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