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Safety of Acupuncture: Results of a Prospective Observational Study with 229,230 Patients and Introduction of a Medical Information and Consent Form

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Key Words
Acupuncture · Safety · Adverse effects · Adverse events · Informed consent · Information and consent forms

Summary
Background: To evaluate the safety of acupuncture in a large number of patients receiving conventional health care and, based on these results, to develop a new medical consent form for acupuncture. **Methods:** The prospective observational study included patients who received acupuncture treatment for chronic osteoarthritis pain of the knee or hip, low back pain, neck pain or headache, allergic rhinitis, asthma, or dysmenorrhoea. After treatment, all patients documented adverse events associated with acupuncture (defined as adverse effects). Patients who reported a need for treatment due to an adverse effect completed an additional standardised questionnaire on the most important adverse effect. Based on this data and considering ethical and legal aspects a new consent form was developed. **Results:** A total of 229,230 patients received on average 10.2 ± 3.0 acupuncture treatments. Altogether, 19,726 patients (8.6%) reported experiencing at least one adverse effect and 4,963 (2.2%) reported one which required treatment. Common adverse effects were bleedings or haematoma (6.1% of patients, 58% of all adverse effects), pain (1.7%) and vegetative symptoms (0.7%). Two patients experienced a pneumothorax (one needed hospital treatment, the other observation only). The longest duration of a side effect was 180 days (nerve lesion of the lower limb). The resulting medical consent form consists of five modules: Introduction to acupuncture and moxibustion, Risks of acupuncture treatment, Conditions which can increase the risk, Doctor's statement, and Consent. **Conclusion:** Acupuncture provided by physicians is a relatively safe treatment and the proposed consent form could support both patients and professionals in the process of obtaining informed consent.

Schlüsselwörter
Akupunktur · Sicherheit · Nebenwirkungen · Unerwünschte Ereignisse · Informierte Einwilligung · Aufklärungsbogen

Zusammenfassung
Hintergrund: Ziel der Studie war es, die Sicherheit von Akupunktur in einem großen Patientenkollektiv in der Normalversorgung zu untersuchen und auf Basis der resultierenden Daten einen Akupunkturaufklärungsbogen für die Normalversorgung zu entwickeln. **Methoden:** In eine prospektive Beobachtungsstudie wurden Patienten aufgenommen, die Akupunktur wegen folgender Diagnosen erhielten: chronische Schmerzen aufgrund von Osteoarthrose des Knies oder der Hüfte, Schmerzen der Lendenwirbelsäule, Kopfschmerzen und Schmerzen der Halswirbelsäule, allergische Rhinitis, Asthma und Dysmenorrhoe. Am Ende der Akupunkturbehandlung wurden alle Patienten nach Nebenwirkungen befragt, die sie mit der Akupunktur in Zusammenhang brachten. Patienten, die die Behandlungsbedürftigkeit einer Nebenwirkung berichteten, erhielten einen zusätzlichen Fragebogen zur bedeutendsten Nebenwirkung. Auf Grundlage dieser Daten und unter Beachtung von ethischen und juristischen Aspekten wurde ein Patientenaufklärungsbogen entwickelt. **Ergebnisse:** Insgesamt wurden 229 230 Patienten in die Studie eingeschlossen. Die Patienten erhielten im Durchschnitt 10,2 ± 3,0 Behandlungen. 19 726 Patienten (8,6%) berichteten von mindestens einer Nebenwirkung und 4963 (2,2%) benötigten deswegen eine Behandlung. 24 377 Nebenwirkungen wurden berichtet. Häufige Nebenwirkungen sind Blutungen oder Hämatome (6,1% der Patienten, 58% aller Nebenwirkungen) sowie Schmerz (1,7%), gefolgt von vegetativen Symptomen (0,7%). Bei 2 Patienten wurde ein Pneumothorax durch die Akupunktur verursacht. Ein Patient benötigte deswegen eine Krankenhausbehandlung, bei dem anderen genügte die weitere Beobachtung. Die mit 180 Tagen am längsten andauernde Nebenwirkung war eine Nervenläsion am Unterschenkel. Der resultierende Aufklärungsbogen umfasst fünf Module: Einführung in die Akupunktur und Moxibustion, Risiken der Akupunkturbehandlung, Bedingungen, die das Risiko erhöhen können, Ärztliche Anmerkungen und Einwilligung. **Schlussfolgerung:** Die von Ärzten durchgeführte Akupunktur ist eine relativ sichere Behandlungsform. Der vorgeschlagene Aufklärungsbogen könnte Patienten und Ärzte bei der Aufklärung vor der Einwilligung unterstützen.

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Introduction

Today, acupuncture is often used [1–3] and increasingly integrated into conventional care. It is administered on the basis of positive evidence for pain-related conditions such as osteoarthritis of the knee [4–6] as well as postoperative and chemotherapy-induced nausea and vomiting [7, 8]. Despite the lack of positive scientific evidence, it is also used for other conditions such as asthma [9] and smoking cessation [10]. But side effects, even severe ones like pneumothorax, cardiac tamponade, and infections can occur [11–22] and a patient should be informed about these. Some authors, however, point out that many of these events may have been caused by malpractice or negligence [19, 23, 24] suggesting that they could be avoided.

An important part of health care (including acupuncture) consists of providing patient information and gaining informed consent. However, this is time consuming and therefore often neglected. Additionally, sometimes the scientific basis for this information is incomplete.

Informed consent is the legal basis for medical treatments. In Germany, any medical intervention is considered to contain the elements of the legal offence known as physical injury, as defined by §§ 223 et seqq. StGB (Strafgesetzbuch, Criminal Code); 823 BGB (Bürgerliches Gesetzbuch, German Civil Code). This position, espoused by the Imperial Court of Justice (Reichsgericht) in 1894 (RGSt 25, 375), has been consistently maintained by the German Federal Court of Justice (Bundesgerichtshof) (BGHSt 35, 246) [25]. Yet, in order to gain adequate informed consent before acupuncture treatments, detailed patient information and a discussion about possible treatment risks associated with acupuncture is important. However, for this purpose valid data on the side effects of acupuncture and their frequency of occurrence is necessary.

Until recently, most data available was based on anecdotal reports [16] or on practitioners' self reports [18, 26–29]. The aim of the Acupuncture Safety and Health Economics Study (ASH) was to investigate safety in German usual care including self-reports of a large number of patients. The ASH was part of a large research initiative supported by the health sickness funds. The additional aim of this article is to provide a consent form for acupuncture which uses these new data to inform patients about possible side effects.

Methods

Observational Study

The prospective observational study included all out-patients (age ≥ 18 years) from participating health sickness funds who received acupuncture treatment for chronic osteoarthritis pain of the knee or hip, low back pain, neck pain or headache, allergic rhinitis, asthma, or dysmenorrhoea between December 2000 and August 2004 [30, 31]. Acupuncture was provided by physicians with postgraduate acupuncture training of at least 140 h. At the end of each treatment cycle, all patients were asked to complete a standardised questionnaire and to document adverse events they associated with acupuncture (defined as adverse effects) in free text and, if necessary, the kind of treatment they had needed (self-treatment, medication/physician treatment, treatment in hospital). Adverse events without association to the acupuncture treatment were not documented. Patients who reported adverse effects which needed treatment, received from the study office an additional, more detailed standardised questionnaire concerning their most important adverse effect.

For analysis, adverse effects were categorised by specially trained staff using categories which were developed in a consensus process between MDs, acupuncturists, epidemiologists and psychologists.

Development of the Consent Form

The frequency of adverse effects was classified according to the guidelines of the European Commission used to describe adverse effects of medicinal products (very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to ≤1/100); rare (≥1/10,000 to ≤1/1,000); very rare (≤1/10,000), not known) [32].

On the basis of the study results, existing material (*www.uni-essen/naturheilkunde*), and considering ethical and legal aspects of informed consent [20, 25, 33, 34], a consent form on medical acupuncture was developed. Besides information about the patient's ailment, the nature of the proposed treatment, the benefits of the treatment, and reasonable treatment alternatives we focused on detailed information about risks similar to the European medicinal product information [32] used in European patient information leaflets.

The ASH study was approved by the appropriate ethics committees and all patients provided written informed consent. SPSS 11.5 (SPSS Inc., Chicago, IL, USA) was used for data analysis.

Results

Observational Study

A total of 13,579 physicians (mean age 46.0 ± 7.4, 61.1% male) practising acupuncture in Germany participated in the present study. All physicians had at least 140 h of acupuncture training (German A diploma) and on average 6.9 ± 5.3 years of acupuncture practice, 15.4% had ≥350 h of training (German B diploma). Half of the physicians (48.3%) were general practitioners, 18.8% orthopaedists, 10.4% internists, 4.5% anaesthetists, 4.4% gynaecologists, and 13.6% had other specialisations. On average, they treated 11.7 ± 15.7% of their patients with acupuncture.

229,230 patients (mean age 51.0 ± 14.3 years (95% CI 51.0–51.1), 64.8% female) were enrolled and received on average 10.17 ± 3.0 (10.16–10.18) acupuncture treatments. The analysis is thus based on 2.2 million acupuncture sessions. Altogether, 19,726 patients (8.6%) reported experiencing at least 1 adverse effect. Adverse effects requiring treatment occurred in 2.2% of patients (n = 4,963). Overall, 24,377 adverse effects were reported. Common adverse effects were minor bleeding or haematoma (6.1%) and pain (1.7%) followed by vegetative symptoms (0.7%) (table 1). Bleeding or haematoma was the predominant adverse effect (58% of all adverse effects, fig. 1). Adverse effects which indicate negligence or malpractice (broken or forgotten needle, pneumothorax, burns after moxibustion) occurred in 0.1% of all adverse effects.

Of the adverse effects 39.4% occurred during and 60.6% after the treatment sessions. Two cases of pneumothorax occurred, both immediately after and caused by acupuncture;

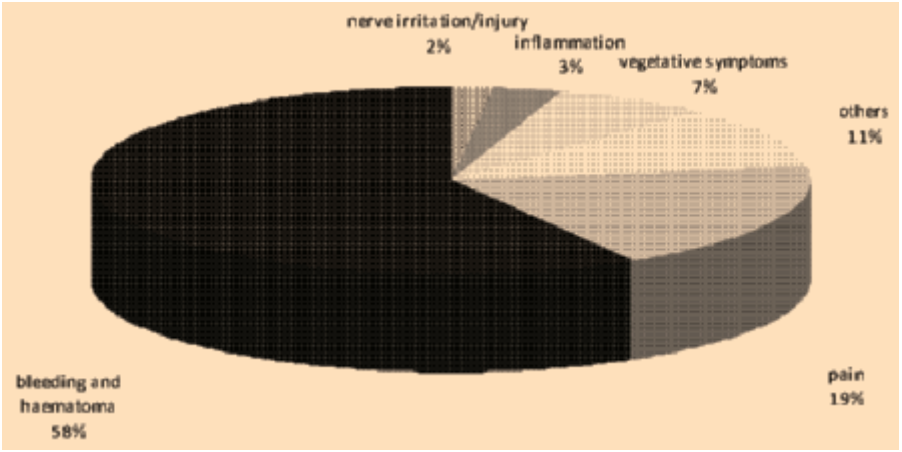

Fig. 1. ASH study: Most frequent adverse effects of acupuncture in condensed categories.

Table 1. Acupuncture adverse effects; total study population: n = 229,230

	Frequency		No need for treatment		Need for treatment		Frequency in text form[a]
	N	%	n	%	n	%	
Bleeding/haematoma	14083	6.144	11468	5.00	2615	1.14	common
Inflammation	711	0.310	382	0.17	329	0.14	uncommon
Inflammation at application site	680	0.297	375	0.16	305	0.13	uncommon
Local infection	31	0.014	7	0.003	24	0.01	rare
Pain	4681	2.042	2209	0.96	2472	1.08	common
Headache	1200	0.523	462	0.20	738	0.32	uncommon
Aggravation of symptoms, symptomatology	712	0.311	384	0.17	328	0.14	uncommon
Local muscle pain	548	0.239	261	0.11	287	0.13	uncommon
Strong pain during needling	490	0.214	283	0.12	207	0.09	uncommon
Generalised muscle pain	73	0.032	23	0.01	50	0.02	rare
Other pain	1658	0.723	796	0.35	862	0.38	uncommon
Vegetative symptoms	1663	0.725	873	0.38	790	0.34	uncommon
Vertigo	514	0.224	256	0.11	258	0.11	uncommon
Nausea	332	0.145	177	0.08	155	0.07	uncommon
Sweating	96	0.042	56	0.02	40	0.02	rare
Depression of blood pressure	86	0.038	42	0.02	44	0.02	rare
Unconsciousness	62	0.027	35	0.02	27	0.01	rare
Tachycardia	47	0.021	24	0.01	23	0.01	rare
Breathing difficulties	35	0.015	22	0.01	13	0.01	rare
Increase in blood pressure	30	0.013	11	0.005	19	0.01	rare
Constipation	8	0.003	0	0.00	8	0.003	very rare
Palpitations	6	0.003	6	0.003	0	0.00	very rare
Enterospasm	4	0.002	4	0.002	0	0.00	very rare
Weight reduction	2	0.001	2	0.0009	0	0.00	very rare
Circulatory disturbance	1	0.0004	1	0.0004	0	0.00	very rare
Other cardiac or circulatory disturbance	440	0.192	237	0.10	203	0.09	uncommon
Nerve irritation/injuries	601	0.262	350	0.15	251	0.11	uncommon
Paraesthesia	221	0.096	125	0.05	96	0.04	rare
Hypaesthesia	181	0.079	124	0.05	57	0.02	rare
Nerve irritation	130	0.057	74	0.03	56	0.02	rare
Paresis	38	0.017	14	0.01	24	0.01	rare
Nerve injury	31	0.014	13	0.01	18	0.01	rare
Others	2638	1.151	1302	0.57	1336	0.58	common
Fatigue	491	0.214	315	0.14	176	0.08	uncommon
Swelling	346	0.151	145	0.06	201	0.09	uncommon
Worsening health state	209	0.091	112	0.05	97	0.04	rare

Other dermal phenomena	205	0.089	92	0.04	113	0.05	rare
Itching	174	0.076	98	0.04	76	0.03	rare
Other neurological complaints	159	0.069	66	0.03	93	0.04	rare
Redness	147	0.064	102	0.04	45	0.02	rare
Restricted movement	117	0.051	52	0.02	65	0.03	rare
Sleep disturbance	97	0.042	40	0.02	57	0.02	rare
Joint problems	71	0.031	35	0.02	36	0.02	rare
Other mood swings	71	0.031	25	0.01	46	0.02	rare
Anxiety	55	0.024	22	0.01	33	0.01	rare
Vomiting	49	0.021	11	0.005	38	0.02	rare
Restlessness/nervousness	45	0.020	28	0.01	17	0.01	rare
Disturbed vision	45	0.020	19	0.01	26	0.01	rare
Other gastrointestinal complaints	45	0.020	15	0.01	30	0.01	rare
Feeling of coldness	36	0.016	14	0.01	22	0.01	rare
Depressive mood	35	0.015	9	0.004	26	0.01	rare
Menstrual problems	32	0.014	17	0.01	15	0.01	rare
Tinnitus	23	0.010	7	0.003	16	0.01	rare
Gastrospasm	19	0.008	8	0.003	11	0.005	very rare
Diarrhoea	16	0.007	4	0.002	12	0.01	very rare
Imbalance	15	0.007	6	0.003	9	0.004	very rare
Burns after moxibustion	14	0.006	4	0.002	10	0.004	very rare
Shivering	13	0.006	9	0.004	4	0.002	very rare
Needle forgotten	12	0.005	8	0.003	4	0.002	very rare
Poor concentration	9	0.004	3	0.001	6	0.003	very rare
Eye irritation	6	0.003	2	0.001	4	0.002	very rare
Lesion of blood vessels	5	0.002	3	0.001	2	0.001	very rare
Systemic infection	5	0.002	2	0.001	3	0.001	very rare
Nightmares	4	0.002	2	0.001	2	0.001	very rare
Euphoria	3	0.001	1	0.0004	2	0.001	very rare
Disturbance of speech	3	0.001	1	0.0004	2	0.001	very rare
Needle broken	2	0.001	0	0.00	2	0.001	very rare
Pneumothorax	2	0.001	0	0.00	2	0.001	very rare
Disorientation	2	0.001	2	0.001	0	0.00	very rare
Other adverse events	56	0.024	23	0.01	33	0.01	rare

[a]According to the guidelines of the European Commission used to describe adverse effects of medicinal products (very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to ≤1/100); rare (≥1/10,000 to ≤1/1,000); very rare (≤1/10,000), not known) [32].

one patient required hospital treatment, the other was less seriously affected and required observation, only. The longest duration of a side effect was 180 days (nerve lesion of the lower limb). There were no acupuncture-associated deaths or permanent injuries associated with the acupuncture treatments.

Development of the Consent Form

The medical acupuncture consent form that has been developed consists of five modules: Introduction into acupuncture and moxibustion, Risks of acupuncture treatment, Conditions which can increase the risk, Doctor's statement, and Consent.

We decided to provide modules in order to allow that parts can be included in existing consent forms. Risks are shown in English (fig. 2), since they are relatively independent of country-specific influences. There is a free download of the full German version at *www.karger.com/doi/10.1159/000209315* and *www.charite.de/cam*). The authors regret that they cannot assume liability for errors or omissions. Ideally, patients should be informed 24 h prior to the first acupuncture session.

Discussion

The data from the observational study presented here show a variety of adverse effects accompanying acupuncture provided by German physicians. These adverse effects were not rare and occurred in 8.6% of the sampled patients. However, most of them were only minor events, like bleedings or haematoma, pain or vegetative symptoms. However, very severe side effects such as pneumothorax or nerve lesions do occur and patients should be made aware of them. The medical consent form for acupuncture made up of five modules, including information on possible side effects, is the first to provide information for the patient similar to instruction leaflets enclosed in any European box of medication.

The analysis is based on a large sample of 229,230 patients with more than 2 million acupuncture sessions in usual care setting. Moreover, in this study all patients from participating health sickness funds who received acupuncture treatment reported adverse effects directly. This study setting allows to

Risks of acupuncture treatment

Like all treatments, acupuncture can cause side effects. The following ranking is used:

Very common: more than 1 out of 10 treated people

Common: 1 to 10 out of 100 treated people

Uncommon: 1 to 10 out of 1,000 treated people

Rare: 1 to 10 out of 10,000 treated people

Very rare: less than 1 out of 10,000 treated people, including singular incidents

The character of possible side effects also depends on the acupuncture points which were chosen for treatment. Please ask your doctor which points he or she will use. The following symptoms were experienced by patients treated with acupuncture:

Common: 1 to 10 out of 100 people treated
Common side effects are bleeding and haematoma because of the lesion of small vessels. Sometimes, small bleedings are a desired part of Chinese acupuncture treatment.

Uncommon: 1 to 10 of 1,000 treated people
Uncommon side effects observed in the context of acupuncture treatment include: inflammation at the application site, swelling, strong pain during needling, and local muscle pain. Nerve irritation or nerve injury is also possible. This can cause sensation difficulties or a temporary weakness in the associated musculature. Furthermore, headache, fatigue, and vegetative symptoms like vertigo and nausea were experienced. An initial aggravation of the symptoms which lead to the treatment is possible.

Rare: 1 to 10 out of 10,000 people treated
Rare side effects include: local infection, redness, itching, sweating, decrease of blood pressure, increase in blood pressure, unconsciousness, tachycardia, breathing difficulties, vomiting, worsening health state, generalized muscle pain, restricted movement, joint problems, feeling of coldness, menstrual problems, depressive mood, anxiety, sleep disturbance, restlessness/ nervousness, disturbed vision and tinnitus.

Very rare: less than 1 out of 10,000 treated people, including singular incidents
Side effects observed in the context of acupuncture treatment include: palpitations, constipation, diarrhoea, gastrospasm, enterospasm, weight loss, circulatory disturbance, lesion of blood vessels, systemic infection, euphoria, nightmares, poor concentration, imbalance, disturbance of speech, disorientation, shivering, and eye irritation. Very rarely acupuncture needles can be forgotten or break. During treatment on the thorax a too deep insertion of an acupuncture needle can cause accumulation of air in the pleural cavity (pneumothorax). In the scientific literature injuries of the central nervous system and the pericardium have been reported.

The application of heat through burning mugwort (moxibustion) can cause burns.

Some of the side effects mentioned above can influence your fitness to drive!

If side effects occur during or after treatment, please inform your doctor.

Fig. 2. Risks of acupuncture treatment.

recognise very rare complications, reflects acupuncture performed by physicians in Germany, and helps minimise underreporting [35] and selection bias. Nonetheless, direct patient reports do have certain limitations – e.g. recall bias, overreporting, coincidence of acupuncture and undesirable effects, or vague causality – and there was no control group. Furthermore, only patients with chronic osteoarthritis pain of the knee or hip, low back pain, neck pain or headache, allergic rhinitis, asthma, or dysmenorrhoea were included in the study and auricular acupuncture or electro-stimulation were not performed. Nevertheless, these patients represent most of the patients treated with acupuncture in Germany.

The type and frequency of adverse effects are difficult to compare between the various studies which evaluate acupuncture adverse effects [12]. Studies can vary in many ways including, among others, in the observed acupuncture technique, the number and type of patients included, the number of reported sessions, the training of the acupuncturist (MD vs. non-MD) and the conditions treated with acupuncture. Moreover, the methods used to define and document adverse effects differ. Both, physician and/or patient information are used to report adverse effects, after every session, after a treatment cycle, or, irrespective of the individual patient, all adverse effects in a certain time frame. Therefore, the incidence of adverse effects can be described per patient or per treatment session. However, we think two studies are comparable [28, 35] to our study, because they used either direct reports from patients of a large sample or included a comparably large sample of patients.

In 2002, MacPherson et al. [35] conducted a survey on the adverse events of acupuncture and also used direct reports of a large sample of patients. Of 9,408 recruited acupuncture

patients, 6,348 completed a questionnaire concerning adverse events after 3 months. The achieved sample reported an average of 4.8 acupuncture visits over the 3 months corresponding to a total of 30,196 consultations for the whole sample. 682 patients (10.7%) reported a total of 1,044 adverse events caused directly by the acupuncture treatment, with severe tiredness or exhaustion and prolonged or unacceptable pain at the site of needling as the most frequent adverse events. Less than 10 visits, which was the average number of visits in our study, were reported. The percentage of patients reporting adverse effects was about 20% higher than the 8.6% (19,726) we found. In terms of the guidelines of the European Commission, used to describe adverse effects of medicinal products, MacPherson's data would rate acupuncture adverse effects as 'very common' whereas our results suggest them to be 'common'. The frequency of specific adverse effects like fatigue or headache was different compared to our data. One possible explanation for the differences is that MacPherson et al. used checklists with tick boxes, which may have produced a higher reporting compared to the free text form we used. An interesting question is whether the difference between our results and those of MacPherson can be explainded by the different type of provider. MacPherson et al. included non-physician acupuncturists whereas in our study, only physicians were included. Another study by MacPherson et al. [18], however, showed that the frequency of significant adverse events was comparable to that observed in a study by White et al. [36] which included doctors and physiotherapists (MacPherson: 1.3 per 1,000 treatments vs. White: 14 per 10,000 consultations).

The study by Melchart et al. [28] included 9,429 German physician acupuncturists of whom 7,050 reported adverse effects from 97,733 patients and approximately 760,000 sessions with an average of 7.8 acupuncture sessions per patient. They observed mild adverse effects in 7.1% of the patients, with needling pain and haematoma as the predominant effects. About 15% less adverse effects than in our study were observed, possibly because of underreporting by physicians. Needling pain (3,202, 3.28%), however, was much more often reported than in our study (490, 0.21%). One possible explanation for this difference is the use of a tick box for needling pain.

Most of the very severe complications mentioned in the literature, e.g. cardiac tamponade or spinal cord injury [19, 21, 37], were not reported in our study. On the other hand, pneumothorax was observed both in our study and in that of Melchart [28]. It is a possible complication which can be caused by the care provider, but also by the patients who can accidentally push a punctured needle deeper into the thorax with a blanket or towel used to keep them warm. Nerve lesions are also known significant complications [14, 15, 21, 38] which were also observed in our study, however, these were not permanent injuries. Skin infections are adverse effects [15, 35] which might be avoidable. Tiredness or drowsiness, which was less observed in our study than it that by MacPherson et al. [35], is also a relevant adverse effect, because it affects the fitness to drive. In order to avoid unconsciousness or needle fainting, special care should be taken when inserting needles in a standing or sitting position or when a patient stands or sits up quickly after a treatment if the patient has little or no experience receiving acupuncture [19].

For the interpretation of events which we did not observe in our study but which are known from the literature, we can use a formula from Hanley and Lippman-Hand [39, 40]. According to this formula, a sample size needs to be 3 times n to have a 95% probability that no severe complication occurs in n treatments [18, 39, 40]. This shows that even with the high number of patients in our study, it is difficult to draw conclusions for extremely rare events. But we can state that the highest risk of experiencing an adverse effect which we did not observe in our study is about 1 in 76,000 patients, with 95% probability. We think, very severe complications should not be overestimated but nonetheless, physicians and patients should be aware of them.

In out-patient care, the use of medical consent forms is especially difficult, because it is not an established practice; it is time consuming and seems impersonal. However, we want to motivate hospital and practice physicians to use an acupuncture consent form to standardise patient information.

Balancing the patients' needs for information and the legal aspects while avoiding information overload, was a difficult task in the process of developing the medical consent form. On the one hand the information should be clear and easy to understand for patients and doctors, but on the other hand, it should be detailed enough to fulfil all criteria in terms of content and legal aspects [25, 34]. Consequently, the present consent form is a compromise. We decided to use the data from the ASH study as a basis. This data should represent the risk profile of most German patients treated with acupuncture in Germany and can help patients and physicians estimate the risk of adverse effects more accurately.

It is interesting to note that similar conventional interventions such as blood taking, injections or inserting peripheral intravenous lines are mostly performed without written informed consent, i.e. only verbal consent is obtained. One explanation might be that in most Western countries, acupuncture is not yet part of conventional university medical education or medical care, although it is becoming more and more common and increasingly integrated. Acupuncture is also used for the treatment of conditions although there is no clear scientific evidence of its efficacy in this context. A comprehensible process of gaining informed consent could improve patient information and help avoid legal disputes. The presented data and the proposed consent form may help achieve this aim.

However, the process of gaining informed consent does take time which could otherwise be used for a more intense patient-doctor interaction. And the question has to be answered what better helps to improve treatment safety: more bureaucracy or more time for intensive doctor-patient interactions? In order to allow flexible use of the information and

consent form we propose a framework consisting of five modules which can be adapted according to condition and the individual patient. The modules or parts of them can also be included in existing consent forms. Routine reporting of severe adverse effects could help to keep the data up-to-date.

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Conflict of Interest: None

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