

Defining Standard of Care for Acupuncture: The Case of Türkiye: Traditional Review

Akupunktur Bakım Standartlarını Tanımlamak: Türkiye Örneği: Geleneksel Derleme

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ABSTRACT Acupuncture with a history of 3,500 centuries is one of the most prevalent traditional and complementary medicine (TCM) practices. It is significant to prepare a care standard and checklist to avoid medical malpractice during acupuncture practice. The study is based on research in the literature and systematic analysis of data. The literature search was conducted using the words “malpractice in acupuncture” and “care standard for acupuncture between September 1, 2022” and April 30, 2023 in “Google Academic (Google, Kaliforniya, ABD)”. There is no generally accepted standard of care in Europe regarding malpractice in acupuncture practices. In Türkiye; the TCM Regulation regulates some subjects such as who can perform TCM applications including acupuncture, in which areas the application can be performed in the units and application centers, in which areas the practices cannot be performed under any circumstances, and which devices and materials must be kept in the units and application centers are determined. Acupuncture is based on trial and observation rather than scientific evidence like the other TCM practices. Thus, it is even more important to identify and analyze medical malpractice points in this field. It is significant to make the necessary legal regulations for acupuncture practices, just like in conventional medicine practices, and to establish care of standards, especially for informed consent and malpractices. The malpractice checklist and algorithm which was developed for acupuncture based on legal regulations and practices in Türkiye may be proposed as a best practice.

ÖZET Akupunktur 3,500 yıllık geçmişi olan, en yaygın geleneksel ve tamamlayıcı tıp (GETAT) uygulamalarından biridir. Akupunktur uygulaması sırasında tıbbi uygulama hatalarını önlemek için bakım standardı ve kontrol listesinin hazırlanması önemlidir. Bu çalışma, akupunktur uygulamalarında tıbbi uygulama hatalarını önlemek için bakım standardı ve kontrol listesi oluşturmayı hedeflemektedir. Çalışma literatürdeki araştırmalara ve verilerin sistematik analizine dayanmaktadır. Literatür taraması “Google Akademik”te 1 Eylül 2022 ile 30 Nisan 2023 tarihleri arasında “akupunkturda malpraktis” ve “akupunktur bakım standardı” kelimeleri kullanılarak yapılmıştır. Avrupa’da akupunktur uygulamalarında tıbbi uygulama hatalarına ilişkin genel kabul görmüş bir bakım standardı bulunmamaktadır. Türkiye’de GETAT Yönetmeliği, akupunktur da dâhil olmak üzere GETAT uygulamalarını kimlerin yapabileceği, ünite ve uygulama merkezlerinde hangi alanlarda uygulama yapılabileceği, hangi alanlarda hiçbir şekilde uygulama yapılamayacağı, hangi cihaz ve malzemelerin bulundurulması gerektiği gibi konuları düzenlemektedir. Akupunktur diğer GETAT uygulamaları gibi bilimsel kanıtlardan ziyade deneme ve gözleme dayanmaktadır. Bu nedenle bu alandaki tıbbi uygulama hatası noktalarının tespit edilmesi ve analiz edilmesi daha da önem kazanmaktadır. Akupunktur uygulamalarının da tıpkı modern tıp uygulamalarında olduğu gibi bilimsel boyutta düzenlenebilmesi için hatalı uygulamalara dair bakım standartlarının oluşturulması önemlidir. Türkiye’deki yasal düzenlemeler ve uygulamalar temel alınarak akupunktur tedavileri için geliştirilmiş olan malpraktis kontrol listesinin ve algoritmasının iyi uygulama örneği niteliğinde olduğu düşünülmektedir.

Keywords: Acupuncture; malpractice; standard of care

Anahtar Kelimeler: Akupunktur; malpraktis; bakım standardı

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The concepts of health and illness have continued to differ across cultures for centuries.¹ The World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being”.² This definition is still valid and accepted since 1948.³ People’s quest to achieve “well-being”, combined with their desire not to use medication all the time and their curiosity to try different methods, has led to an increase in the use of traditional and complementary medicine (TCM) practices.⁴ Acupuncture, which dates back more than 3,500 years, is one of the oldest and most common TCM practices.⁵⁻⁷

The WHO Traditional Medicine Strategy 2014-2023 found that TCM practices vary from country to country depending on culture, understanding and accessibility, with acupuncture showing the most significant improvement, and that acupuncture, originally a feature of traditional Chinese medicine, is now a globally accepted and used practice.

Since acupuncture practice is based on trial and observation rather than evidence, it is even more important to identify and analyze medical malpractice in this field. This study aims to develop a methodology for the detection of possible medical malpractice in acupuncture practices based on legal regulations and practices in Türkiye and to develop a scientific, objective and reference-based standard of care proposal.

ACUPUNCTURE PRACTICE IN TÜRKIYE

IS IT LEGALLY REGULATED?

The word acupuncture is of Latin origin and derives from the words “acus” (“needle”) and “pungere” (“to pierce”).^{8,9} In the West, it is used in combination with conventional medicine.⁸ In 1979, the WHO recognized acupuncture as a “scientific method” and published a list of medical conditions for which it is effective. The main philosophy of acupuncture is to ensure “unity, balance and harmony between the energy currents in the organism”. Especially in the last thirty years, interest in acupuncture has increased in Türkiye in parallel with the western world and it has started to be applied in various fields.¹⁰

In Türkiye, acupuncture has a more special place than other TCM practices. This is because there were

legal regulations for acupuncture even when there were no legal regulations for other TCM practices. The first regulation in the field of TCM in Türkiye is the “Acupuncture Treatment Regulation” issued in 1991.¹¹ Other TCM practices were legally regulated in 2014 with the “Regulation on Traditional and Complementary Medicine Practices” (“TCM Regulation”).¹²

WHO PRACTICES IT?

According to the legal TCM Regulation valid in Türkiye, acupuncture is defined as “the practice of acupuncture by a certified physician or dentist who has received training in the relevant field of practice or by a dentist to practice in his/her field by stimulating special points on the body with stimulation methods such as needles, laser beams, electrical stimulation, cups, in-ear seeds, needles or magnetic balls, thermal stimulation, acupressure and sound or electrical or magnetic vibrations”.

MALPRACTICE IN ACUPUNCTURE

FROM THE VIEWPOINT OF INFORMED CONSENT

In General

For medical practice not to be considered malpractice, it must meet the conditions of compliance with laws. For this, 3 basic conditions must be met: the person who performs the medical practice, i.e. the intervention, must be a physician (relevant healthcare personnel), the patient’s informed consent must be obtained, and the medical intervention must be necessary and appropriate according to the rules of medical science.¹³ One of the conditions that render the medical practice lawful is the patient’s enlightenment and consent. Patient enlightenment is important to ensure the patient’s right to make decisions about his/her own future.¹⁴ The obligation to inform is a natural extension of the principle of patient autonomy, one of the principles of medical ethics.

The acupuncture practitioner’s duty of disclosure is particularly important. Since the evidence-based aspect is not as strong as in conventional medicine, patient enlightenment may be much more important in acupuncture practices. The acupuncture practitioner should advise the patient about the pos-

sible side effects of the treatment and advise the patient about alternative treatments and possible side effects, enabling the patient to make an informed decision before treatment.¹⁵ In acupuncture practices, since the side effects are not sufficiently known, the benefits are emphasized, and patients can sometimes be put into unrealistic expectations and hopes. In this case, the legal validity of the informed consent may be a matter of debate.^{16,17} It is precisely because of this character that acupuncture practices should be one of the areas where the obligation to disclose should be applied quite broadly. Although it is accepted that the acupuncture practitioner should provide information about alternative conventional treatments, it is also debated whether the physician who treats conventional medicine should also provide information about acupuncture practices that may be an alternative to the current treatment.¹⁷⁻¹⁹

In Türkiye

Pursuant to Article 10/4 of the TCM Regulation, an “Information and Consent Form” must be prepared for TCM practices in accordance with the Patient Rights Regulation and consent must be obtained from all patients to be treated.²⁰

The physician should not make statements and expressions that acupuncture will eliminate the disease or treat it alone or that may cause this perception. Pursuant to Article 8/4 of the TCM Regulation, it must be clearly explained to the patient and stated in the approved consent form that the TCM practice (which includes acupuncture) will not replace the standard treatment of the disease and cannot be performed in a way that will disrupt the ongoing treatment. As per the TCM Regulation the written consent is regulated as a condition of validity for acupuncture practices beyond the requirement of proof.

FROM THE VIEWPOINT OF “STANDARD OF CARE”

In 1992, the World Medical Association defined medical malpractice as “harm caused by the physician’s failure to perform standard practice during treatment, lack of skill or failure to treat the patient” in its declaration on “Medical Malpractice” adopted at its 44th General Assembly.²¹⁻²⁵ In order for a medical practice to be lawful and not erroneous, it must be

carried out in accordance with the generally accepted principles and rules of medical science and profession.^{14,26-30} In order for a medical practice not to be faulty and to be lawful, it must comply with the principles and rules of medical science and profession.²⁶⁻³¹

Medical experts objectively evaluate if there is a legal causal connection between the act or omission of the physician and the damage inflicted to the patient; and if the medical practice may be considered as medical malpractice. The medical expert evaluate whether the physician is legally “authorized” to care for the patient, whether the physician is professionally “competent”, whether the physician acts in accordance with standard of care, and whether the informed of the patient consent has been obtained.^{14,23,32} Medical expert determine and evaluate whether there has been a violation of the standard of care, whether it was obvious by the standard of an average physician on a similar case. The physician's practice needs to be evaluated in terms of the existing medical knowledge, skills and experience considering the current situation.^{14,23}

The most unique and thorny area of medical malpractice in acupuncture practice is the issue of non-compliance with standards. The acupuncture practice may become quackery, fraud and promises not kept in case of it is practiced by unauthorised and untrained persons.

ESTABLISHING STANDARD OF CARE FOR ACUPUNCTURE: CASE OF TÜRKIYE

DEFINITION OF STANDARD OF CARE

The answer to the question of whether the medical practice is in compliance with the rules of medical science, the requirements of medical science, the principles and rules generally accepted by medical science, and whether the undesirable result subject to the dispute is a permitted risk, i.e. a complication or medical malpractice, is the most fundamental criterion that will clarify the issue. In order to answer this question, the most decisive and specific concept to consider is the concept of standard of care. Considering the current scientific and technical level of med-

ical science, the conditions of the environment in which the practice is performed, and the level of education of the practitioner; the care required by a physician to perform at the same level of competence in the same environment is named as standard of care, standard operating procedure and medical standard.^{14,23,31,33-35} Considering the current scientific and technical level of medical science, the conditions of the environment in which the practice is performed, and the level of education of the practitioner; if the care required by a physician at the same level of competence in the same environment is not shown, it can be said that there is medical malpractice and the physician will be responsible for this.

The concept of “Medical Standard” is defined in the decisions of the Turkish Supreme Court, as “the basic professional rules that are necessary for the physician to achieve the purpose of the treatment, which have been tried and proven, which express the level reached by the physician’s experience and natural sciences at that moment, and which have been tried and known”.³⁶⁻⁴¹

As can be seen, both doctrine and consistent judicial decisions agree that the physician must follow the standard of care, in other words, medical standards, in other words, standard operational procedures. The problem does not arise on this point, but on what the medical standard is. Especially when it is taken into consideration that the concept of medical standards is a dynamic concept and that it is capable of encompassing the current developments at the time, it is seen how the evaluation of medical standards plays a key role, especially in the criminal liability of the physician.

When medical standards are taken into consideration, “the scientific and technical level that medical science has reached today, the conditions of the environment in which the practice is carried out, the level of education of the practitioner, the care that a physician with the same level of competence should show under the same environmental conditions should be taken into consideration”.^{14,23} Here, “the care required by a physician at the same level of competence” should be considered as objective care. In this context, when assessing compliance with medical standards, the behavior of a reasonable/average

physician under the same circumstances should be taken into account.^{42,43} The physician is not expected to perform as well as the most knowledgeable, skilled and attentive colleague, but rather as an average colleague in the same specialty would perform under the same conditions.⁴⁴ In other words, the physician is expected to demonstrate the average behavior expected of an average person (physician) in the same circumstances, not above average or excellent skill and care.^{31,45,46}

DEFINING AN APPROACH ALGORITHM FOR ACUPUNCTURE PRACTICES

Creating a general flow diagram based on the articles of legislation is important in terms of revealing the rights and responsibilities of acupuncture practitioners.

Accordingly, with an algorithm that answers the following questions, it will be possible to approach TCM practices and determine whether one is at the point of medical malpractice or whether one is in a safe area.¹³

1. Was the TCM practice performed in a licensed practice center or unit? (*If no, Medical Malpractice*)
2. Is the TCM practice applied in the unit one of the practices that can be applied in the unit? (See: TCM Regulation Annex-3) (*If no, Medical Malpractice*)
3. Is the TCM practitioner under the supervision and control of a physician or dentist? (*If no, Medical Malpractice*)
4. Does the TCM practitioner have a certificate related to the field of practice? (*If no, Medical Malpractice*)
5. Has the TCM practitioner enlightened the patient about “the possible causes of the disease and how it will progress, who, where, how and how the medical intervention will be performed and its estimated duration, other diagnostic and treatment options and the benefits and risks of these options and their possible effects on the patient’s health, the possible benefits and risks that may arise in case of refusal of possible complications, the important features of the drugs to be used, lifestyle recommen-

datations that are critical for his/her health, and how he/she can access medical assistance on the same subject when necessary”? (If no, Medical Malpractice)

6. Did the TCM practitioner have the patient sign the Information and Consent Form specified in the legislation? (See: TCM regulation article 12) (If no, Medical Malpractice)

7. Has the patient been informed about alternative treatments within the scope of conventional medicine? (If no, Medical Malpractice)

8. Did the TCM practitioner give information that TCM practice would eliminate the disease or treat the disease alone? (If no, Medical Malpractice)

9. Has the patient been referred for conventional medicine if the patient’s condition warrants conventional treatment, or has conventional treatment been recommended if the practitioner is in the area of expertise? (If no, Medical Malpractice)

10. Is the TCM practice within the scope of the areas where the practice can be performed? (If no, Medical Malpractice)

11. Is the TCM practice to be performed within the scope of areas where the practice cannot be performed? (If no, Medical Malpractice)

12. Are there devices and materials that should be kept in the unit or practice center where TCM practice will be made, are they used? (If no, Medical Malpractice)

13. Was TCM practice carried out in accordance with certified training standards? (This is the most challenging stage and this can be clarified with the opinion of a medical expert/expert opinion for each specific practice.) (If no, Medical Malpractice)

14. If complications developed after TCM, was the complication managed timely and correctly? (If no, Medical Malpractice)

15. Did the physician exercise due care to prevent harm while instructing, supervising and controlling the practitioner under his/her supervision and control? (If no, Medical Malpractice)

It would be possible to specify an algorithm that includes the most basic steps of the above questions as follows (Figure 1).¹³

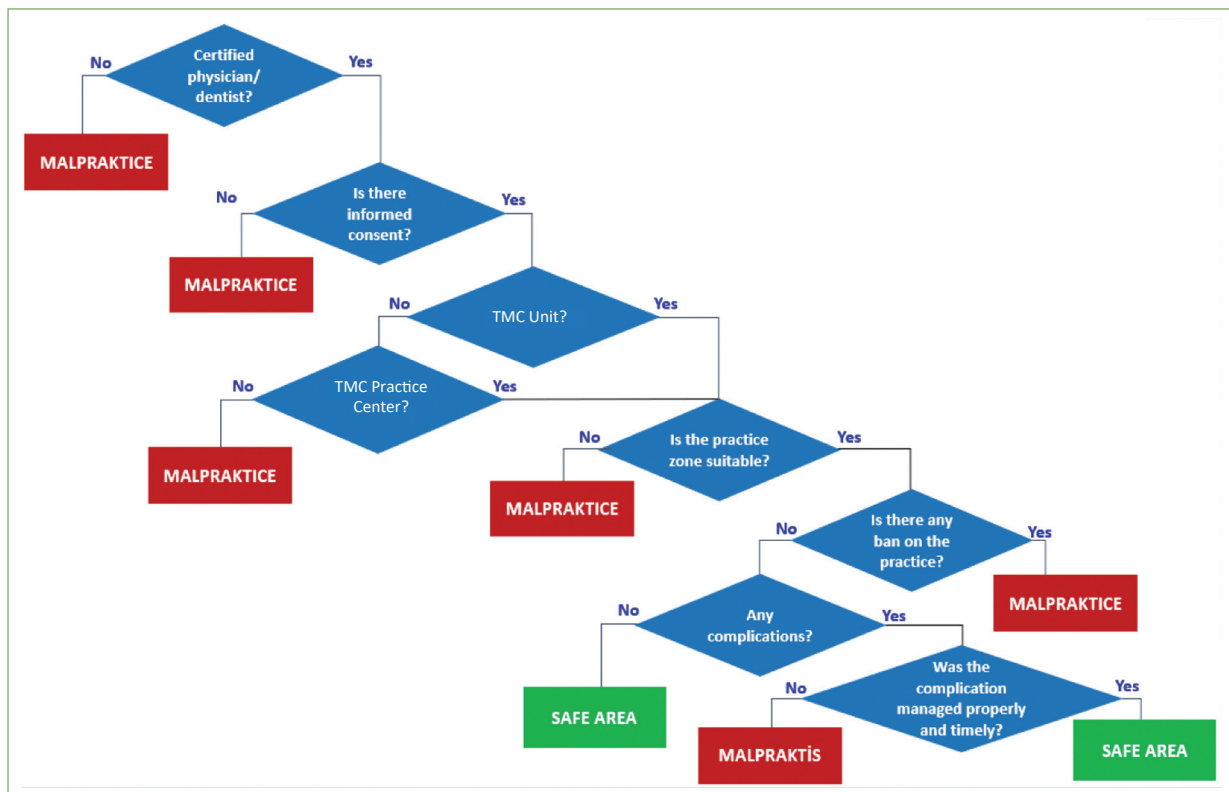


FIGURE 1: Approach algorithm for TCM practices. TCM: Traditional and complementary medicine.

TABLE 1: Acupuncture practice checklist.¹³























| ACUPUNCTURE PRACTICE CHECKLIST | | |
|--------------------------------|---|---|
| NO | CHECKPOINT | CONCLUSION |
| I | Authorization Related Checkpoint | Result |
| | | Yes No |
| 1 | Was acupuncture performed in a licensed practice center or unit? |   |
| 2 | Is the acupuncture practice applied in the unit one of the practices that can be applied in the unit? |   |
| 3 | Is the person practicing acupuncture a certified physician trained in the relevant field or a dentist practicing in his/her field? |   |
| 4 | Does the acupuncture practitioner have a certificate in the field of acupuncture? |   |
| II | Lighting Related Control Point | Result |
| | | Yes No |
| 5 | "Possible causes of the disease and how it will progress, where, by whom, how and how the medical intervention will be performed and its estimated duration, other diagnostic and treatment options and the benefits and risks of these options and their possible effects on the patient's health, possible benefits and risks that may arise in case of refusal of possible complications, important features of the medicines to be used, lifestyle recommendations that are critical for his/her health and how he/she can access medical assistance on the same subject when necessary". |   |
| 7 | Has the patient signed the Information and Consent Form specified in Article 12 of the TMC regulation? |   |
| 8 | If the patient is a child or restricted, has his/her legal representative signed the Information and Consent Form specified in Article 12 of the TMC regulation? |   |
| 9 | Did the acupuncture practitioner inform you that acupuncture would eliminate the disease or treat the disease on its own? |   |
| 10 | Has the patient been informed about alternative treatments within the scope of conventional medicine that may be an alternative to acupuncture? |   |
| III | Control Point for Patient Referral | Result |
| | | Yes No |
| 11 | Does the patient's current condition require referral to conventional medicine? |   |
| 12 | If the patient's current condition requires referral to conventional medicine, was a referral made? |   |

TABLE 1: Acupuncture practice checklist (continuing).¹³

| Checkpoint on Areas for Acupuncture Practice | | Result | |
|---|---|---------------|-----------|
| IV | Was the acupuncture treatment in the following area performed in the TMC Unit or TMC Practice Center? | Yes | No |
| 13 | Was it applied for mechanical pain of the musculoskeletal system? | | |
| 14 | Was it applied for joint pain? | | |
| 15 | Was it applied for migraine, tension-type and other non-organic headaches? | | |
| 16 | Was it applied for toothache? | | |
| 17 | Was it for neuropathic pain? | | |
| 18 | Was it applied for muscle spasm, herniated disc acute conservative period and chronic period low back pain? | | |
| 19 | Was it applied for nausea and vomiting due to medication side effects, motion sickness and pregnancy-related nausea and vomiting? | | |
| 20 | Functional gastrointestinal disorders; constipation, motility disorders, reflux? | | |
| 21 | Was it applied for allergic rhinitis symptoms? | | |
| 22 | Applied for dysmenorrhea, infertility, polycystic ovary syndrome and premenstrual syndrome, labor pain? | | |
| 23 | Was it administered for sleep disturbance with no organic cause? | | |
| 24 | Was it performed for diet compliance in a patient diagnosed with exogenous obesity? | | |
| 25 | Was it applied for itching due to allergies, eczema and dry skin? | | |
| 26 | Was it applied for anxiety during smoking cessation? | | |
| 27 | Was it applied for anxiety? | | |
| 28 | Was it applied for nocturnal micturition without an organic cause? | | |
| 29 | Was it applied for nausea, vomiting, pain, dry mouth due to chemotherapy and radiotherapy? | | |
| 30 | Was it performed for vertigo with no organic cause? | | |
| 31 | Was it performed in geriatric patients? | | |
| 32 | Was it applied to improve the quality of daily life in chronic diseases of the respiratory system? | | |
| 33 | Was it intended to help establish and maintain general well-being? | | |
| V | Was the acupuncture treatment in the following area performed at the TMC Practice Center? | Yes | No |
| 34 | Was it applied for nerve root irritations without progressive neurologic deficit and cauda equina? | | |
| 35 | Was it applied to reduce the difficulties in the treatment of alcohol addiction? | | |
| 36 | Was it performed for respiratory distress after extubation in a child? | | |
| 37 | Was it applied to improve patient compliance with treatment in chronic eye diseases? | | |
| 38 | Was it applied to improve quality of life in cases of forgetfulness and memory problems? | | |
| 39 | Was it applied for attention deficit and hyperactivity disorders? | | |
| 40 | Was it applied for dry eye due to idiopathic and/or Sjögren's disease? | | |
| 41 | Was it applied for muscle contractures or weakness in partial paralysis due to stroke? | | |

TABLE 1: Acupuncture practice checklist (continuing).¹³

| | | Result | |
|---|---|--------|-------|
| VI | Checkpoint on zones where acupuncture cannot be applied | Yes | No |
| 42 | Was it applied in emergencies? | Red | Green |
| 43 | Was it performed in patients with bleeding diathesis? | Red | Green |
| 44 | Was it applied in the lower abdomen in the first three catches during pregnancy? | Red | Green |
| 45 | Was it applied to the upper abdomen and lumbosacral regions in the 2nd and 3rd trimesters of pregnancy? | Red | Green |
| 46 | Was it applied to intensely stimulating points of the pregnant woman? | Red | Green |
| VII | Checkpoint for Devices and Materials that must be present | Result | |
| | | Yes | No |
| 47 | Is a sterile disposable steel needle available? | Green | Red |
| VIII. | Checkpoint on the Compliance of Acupuncture Practice with Standards | Result | |
| | | Yes | No |
| 48 | Was acupuncture treatment performed in accordance with certified training standards? (This is the most challenging stage and will be clarified by medical expert opinion/expert opinion for each specific practice). The following sampling was made according to the training titles in the certified training standards: | Green | Red |
| 49 | Was an appropriate anamnesis taken from the patient? | Green | Red |
| 50 | Were the punctuation places correctly determined? | Green | Red |
| 51 | Was the acupuncture practice applied to the right points? | Green | Red |
| 52 | Is the needling method applied correctly? | Green | Red |
| 53 | Was the correct needle used? | Green | Red |
| 54 | Was the needle entry depth applied correctly? | Green | Red |
| 55 | Has a needle been made where the needle will not be made? | Red | Green |
| 56 | Has sterilization been performed? | Green | Red |
| 57 | Was the acupuncture technique selected and applied correctly? | Green | Red |
| 58 | If complications developed after acupuncture practice , was the complication managed on time and correctly? | Green | Red |
| (*) Any marking in the red area indicates medical malpractice, and the green areas indicate that the TMC practitioner and more importantly the patient is in a safe area. | | | |

DEFINING A CHECKLIST FOR ACUPUNCTURE PRACTICES

When Annex-3 of the TCM Regulation and Certified Acupuncture Training Standards are examined, it is seen that some conditions and prin-

ciples have been introduced.⁴⁷ Violation of these conditions and principles constitutes medical malpractice. By collating these regulations, it is possible to create a checklist as followings (Table 1).¹³

THE ROLE OF FORENSIC EXPERTISE IN DETECTION OF MEDICAL MALPRACTICE IN ACUPUNCTURE PRACTICES

According to a World Bank study published in 2009, which comparatively analyzed the problems of the expert witness institution in four countries, an expert opinion is defined as “any testimony (written or oral) on a professional, scientific or technical matter that can be presented as evidence in legal proceedings”.¹⁴

The expert opinion must be “objective”, “measurable” and “based on scientific values and standards”.^{14,23} The expert opinion must assist the court in determining evidence or the truth, be based on appropriate facts and reasons, be the product of reliable principles and methods, and be applicable to the facts of the case.⁴⁸ The first condition is that the persons who will act as experts in medical malpractice cases are medical experts. Especially in cases of medical malpractice, the expert opinion formed by the forensic medicine specialist and the expert of the relevant subject will give the most efficient result.^{13,14} The opinion of the medical expert has a key role in medical malpractice. When giving an opinion on whether there is a medical malpractice, the medical expert’s opinion must be “objective, measurable and based on scientific values and standards”.

The same will be true for TCM practices. If an undesirable situation has occurred in the patient as a result of the TCM practice, the medical expert will be able to clarify whether there is a causal link between this undesirable situation and the practice of the TCM practitioner, and also whether this situation is a complication or a medical malpractice. Since TCM practices are based on practice and observation rather than scientific evidence, and their ethics can sometimes be seen in personal terms, there may be problems in terms of objectivity, measurability, and the criteria of being based on scientific values and standards. However, this weakness of TCM practices has been strengthened by the TCM Regulation and Annex-3, which includes comprehensive regulations on the practices that can be performed in units and practice centers. This is because the list of

who can perform TCM practices, in which cases the practice can be performed in the unit, in which cases the practice can be performed in the practice center, in which cases TCM practices cannot be performed under any circumstances, and the list of devices and materials that must be kept in the units and practice centers are determined one by one for each TCM practice.

To give an example in acupuncture practices;

- Whether the punctuation is correct,
- Whether acupuncture is applied to the right points,
- Whether the needling procedure is applied correctly,
- Whether the right needle is used according to the case,
- Whether the needle insertion depth is applied correctly,
- Which places are not places where injections cannot be made,
- Whether the process is performed in accordance with sterilization,
- Whether the acupuncture technique was chosen correctly,
- If there is a complication after acupuncture, the answer to the question of whether the complication was intervened in a timely and correct manner can only be clarified by the opinion of an experienced medical expert in the field.

CONCLUSION

In a world where the patient’s right to self-determination comes to the fore, it is a fundamental extension of the principle of patient autonomy to be able to benefit from acupuncture practices provided that the patient is properly informed and complies with all legal criteria on the subject. In this context, not ignoring acupuncture practices on the grounds that they are based on practice and observation rather than scientific evidence and regulating them within the framework of a broad disclosure obligation will prevent erroneous results. If TCM practices, which pa-

tients prefer to use in one way or another, are not legally regulated, these practices will be applied indiscriminately by untrained people who are not subject to regulation in any way, and public health will be threatened.

With the TCM Regulation, issues such as who can perform TCM practices, in which areas practices can be performed in units and practice centers, in which areas no practice can be performed under any circumstances, which devices and materials must be available in units and practice centers have been determined. Thus, a standard has been established in terms of acupuncture practices regulated by the TCM Regulation. The practices regulated by the TCM Regulation are qualified as medical practices, and acupuncture practitioners who perform these practices will have legal and criminal liability. This study is a preliminary study to create a checklist for each practice based on the regulations in the current legislation and training standards and to conduct a standard of care/SOP study specific to TCM practices. It is thought that the draft checklists prepared for Türkiye based on the TCM Regulation and the regulations in certified training standards will be a starting point in this context and can serve as an example of good practice.¹³

It is very important to make the necessary legal regulations in order to regulate acupuncture practices in a scientific dimension just like conventional medical practices, especially to establish standards of care regarding informed consent and malpractice.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Zeynep Reva; **Design:** Zeynep Reva; **Control/Supervision:** Zeynep Reva, Oğuz Polat; **Analysis and/or Interpretation:** Zeynep Reva; **Literature Review:** Zeynep Reva; **Writing the Article:** Zeynep Reva; **Critical Review:** Zeynep Reva, Oğuz Polat.

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