DOI: https://doi.org/10.12700/btsz.2026.8.2.29

RISK ANALYSIS OF ELECTROTHERAPY TREATMENT FOR PATIENTS UNABLE TO PROVIDE FEEDBACK

VISSZAJELZÉSRE KÉPTELEN PÁCIENSEK ELEKTROTERÁPIÁS KEZELÉSÉNEK KOCKÁZATELEMZÉSE

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Abstract

Electrotherapy is a widely used, non-invasive physiotherapy method for pain relief, muscle and nerve stimulation, and inflammation reduction. Despite its benefits, it can be risky for those who are unable to provide feedback during treatment. The aim of the study was to identify, analyse, and develop measures to reduce the risks for this vulnerable group. We analysed the treatment protocol, current and pulse parameters, biophysical and histological characteristics, as well as the design and use of electrodes. Based on the reviewed literature and two decades of professional experience, the greatest dangers are thermal injury, abnormal muscle contraction, and infection, particularly in patients who are unconscious, sedated, or suffering from peripheral nerve damage. The risks were classified and ranked using an Ishikawa diagram and a risk matrix. As a result, recommendations were made regarding the management protocol, patient care, training, equipment supervision, infection control, fire safety, and data protection. The targeted measures reduced high and medium risks to a low or minimal level.

Keywords

electrotherapy, lack of feedback, risk assessment, patient safety, risk mitigation

Absztrakt

Az elektroterápia nem invazív fizioterápiás kezelési mód fájdalomcsillapításra, izom- és idegstimulációra és gyulladáscsökkentésre. Előnyei mellett kockázatos lehet azoknál, akik kezelés közben nem tudnak visszajelzést adni. A kutatásunk célja e sérülékeny csoport kockázatainak azonosítása, elemzése és a feltárt kockázatok csökkentésére vonatkozó intézkedések kidolgozása volt. Elemeztük a kezelési protokollt, az áram- és impulzusparamétereket, a biofizikai és szövettani jellemzőket, valamint az elektródák kialakítását és használatát. A szakirodalom és a két évtizedes szakmai tapasztalat alapján a legnagyobb veszélyt a termikus sérülés, a kóros izomkontrakció és a fertőzés jelenti, különösen eszméletlen, szedált vagy perifériás idegkárosodásban szenvedőknél. A kockázatokat Ishikawa-diagrammal és kockázati mátrixszal osztályoztuk, rangsoroltuk. Eredményként ajánlások készültek a kezelési protokollra, képzésre, eszközfelügyeletre, infekciókontrollra, tűzbiztonságra és adatvédelemre. A célzott intézkedések a magas és közepes kockázatokat alacsony vagy minimális szintre mérsékelték.

Kulcsszavak

elektroterápia, visszajelzés hiánya, kockázatértékelés, betegbiztonság, kockázatcsökkentés

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HIGHLIGHTS

- Risk of electrotherapy were mapped for patients unable to give feedback.
- Treatment failure emerged as the highest-priority hazard.
- Skin and muscle damage were identified as clinically relevant risks.
- Targeted risk controls reduced all hazards to low or minimal levels.
- Standardised safety guidance is needed for this vulnerable group.

INTRODUCTION

Electrotherapy is a widely applied modality in physiotherapy, utilising electrical currents to alleviate pain, stimulate muscles and nerves, and promote tissue regeneration. Its clinical relevance is largely attributable to its non-invasive nature and its capacity to complement pharmacological treatments. The currents triggered by the millivolt and microvolt level voltages used during the treatment exert a gentle and controlled effect on the cells, minimizing the risk of damage. By modulating cellular activity, electrotherapy enhances metabolic processes, improves oxygen and nutrient uptake, and facilitates tissue repair. The patient's mobility improves; increased blood flow and nutrient supply accelerate tissue regeneration and reduce inflammation. In addition, electrically induced muscle contractions may help prevent disuse atrophy associated with prolonged inactivity. [1]

The importance of electrotherapy in rehabilitation is further underscored by the high incidence of injuries particularly in combat actions and sports. According to data from the Rugby Football Union (RFU) in England, during the twenty seasons examined between 2002 and 2023, a total of 13,193 male professional rugby players sustained injuries during matches, which averages to 660 injuries per season. [2] According to the International Ski Federation (FIS), between the 2006 and 2019 seasons, a total of 3,950 injuries occurred, which averages to 790 injuries per year. [3] Hospitalisation data related to musculoskeletal and connective tissue disorders demonstrate a considerable and variable burden on healthcare systems across Europe. In 2021, Austria had the highest number of discharges following musculoskeletal diseases, with 2,403 discharges per 100,000 inhabitants. On the other hand, the same figure was the lowest in Malta, with fewer than 300 per 100,000 inhabitants. A discharge occurs when a patient leaves the hospital due to the completion of treatment, leaves against medical advice, is transferred to another healthcare facility, or passes away. [4]

Despite its therapeutic advantages, electrotherapy is not without risk. The application of electrical currents to biological tissues may induce thermal, chemical, and physiological effects, which, under inappropriate conditions, can result in adverse outcomes such as burns, tissue damage, or excessive muscle contraction. [1] According to a finite element (FEM: Finite Element Method) bioheat-technical model, with a flat electrode, the peak temperature of the skin tissue can reach up to 51.6 °C, which can already cause tissue damage. Heat generation at the electrode–skin interface, influenced by factors such as electrode design, current intensity, and environmental conditions, represents a particularly important risk factor. [5] In addition, inappropriate stimulation parameters may lead to pathological neuromuscular responses or, in extreme cases, tissue necrosis. According to research, alternating current of 30 milliampere or direct current of 150 milliampere passing through the human body already poses a health risk. [6] Environmental temperature and humidity affect the skin's conductivity and heat regulation, which means these two parameters also influence heat generation during electrotherapy. According to a numerical model, an increase of 4 °C in environmental temperature raises the voltage experienced by neural tissues at the boundary of the epidermis (outer layer) and dermis (inner layer) by about 0.8 Volt, while a 12.5% rise in relative humidity increases it by approximately 1 Volt. Therefore, in a warm, humid environment, the skin's resistance decreases, allowing the current to penetrate deeper into the body, which increases the amount of heat generated. [7]

The muscle contractions that occur during electrotherapy can be traced back to two main causes. The treatment stimulates the peripheral nerves, which triggers the activation of motor neurons, resulting in muscle contraction. [8] In addition, the electric current also affects the spinal cord, modulating the activity of the central nervous system, which causes increased spontaneous muscle contractions. [9] The extent of these responses is strongly dependent on treatment parameters, including frequency, current intensity, and duration. Higher frequencies (e.g., 100 Hz) trigger more intense contractions, while low-frequency (e.g., 5 Hz) TENS (Transcutaneous Electrical Nerve Stimulation) can also enhance muscle activity, but requires longer treatment duration. A longer treatment duration (from 20 minutes to 1 hour) results in increased muscle activity. [10]

In routine clinical practice, the safe application of electrotherapy relies heavily on patient feedback, which allows the therapist to adjust treatment parameters in real time. However, there exists a clinically significant subgroup of patients who are unable to provide such feedback. Loss of consciousness in patients with severe injuries is most often a result of cranial trauma, hypovolemic shock (significant blood loss), or hypoxia (lack of oxygen). Due to the temporary or permanent loss of brain functions, the patient is unable to process sensory stimuli and respond motorically. [11] Confused states can be the result of diffuse brain damage, anoxia (cessation of oxygen supply), or metabolic disorders. Due to dysfunction of the cerebral cortex and the reticular (neuron network) activating system, the patient does not perceive peripheral sensory stimuli. [12] Sedative (tranquilizing or anaesthetic) and analgesic (pain-relieving) drugs commonly used in intensive care (e.g., midazolam, propofol, fentanyl) significantly reduce consciousness and sensation. Additionally, changes in blood circulation and skin temperature can distort the sense of heat, so there is an increased risk of burns during electrical stimulation. [13] The nervous system of infants is not yet fully developed. Although the nociceptive (sensory nerve) pathways are functioning, due to the lack of cognitive processing and communication abilities, the therapist do not receive reliable feedback about excessive stimulus intensity. [14] In severe forms of disorders, like intellectual, perceptional, or attentional, communication is simultaneously or individually limited. Such patients are often unable to accurately localize or interpret thermal and pain stimuli. [15] Due to damage to the peripheral nerves, patients have reduced or absent heat and pain sensation. This is because the small-diameter C and A-delta fibres that transmit heat and pain degenerate. [16]

Given these considerations, there is a clear need for a structured and systematic approach to risk identification and management in electrotherapy, specifically tailored to patients who are unable to provide feedback. The aim of this study is therefore to identify and analyse the risks associated with this vulnerable patient population, and to develop evidence-based recommendations to enhance treatment safety.

METHODS

It was hypothesised that the reduction of risks identified within the electrotherapy treatment protocol would significantly enhance the safety of patients unable to provide feedback, while maintaining therapeutic effectiveness.

As an initial step, the individual stages of the electrotherapy treatment process were systematically identified and arranged in chronological order. Potential patients were categorised into three groups: (i) outpatients capable of providing feedback, (ii) outpatients unable to provide feedback, and (iii) unconscious inpatients unable to provide feedback. (The resulting process flow is presented in Figure 1.) The subsequent risk analysis focused specifically on patients unable to provide feedback.

A detailed risk analysis was conducted in accordance with the principles outlined in Chapter 6 of ISO 31000:2018, Risk Management - Guidelines. [17] Relevant standards and regulatory frameworks applicable in the United States, the United Kingdom, and the European Union were also taken into consideration.

Potential hazards were identified based on the defined therapeutic protocol and systematically assigned to the individual steps of the treatment process. This enabled the compilation of a comprehensive hazard inventory (Table 3.) Subsequently, the possible causes associated with each identified hazard were analysed. In cases where multiple contributing factors were identified, emphasis was placed on determining the underlying root causes (Table 4). Following hazard identification and causal analysis, a structured hazard evaluation was performed. Cause–effect relationships were visualised using an Ishikawa (fishbone) diagram (Figure 2), which provided a conceptual framework for the subsequent risk assessment. Risk assessment was carried out using a risk matrix incorporating both the severity of potential consequences and the likelihood of occurrence. Hazard severity was classified into four categories: catastrophic, critical, minor, negligible. The probability of occurrence was categorised as frequent, probable, occasional, rare, or unlikely. Based on these parameters, overall risk levels were defined as high, medium, low, or minimal, drawing on both established risk assessment principles and practical experience in electrotherapy applications. [18]

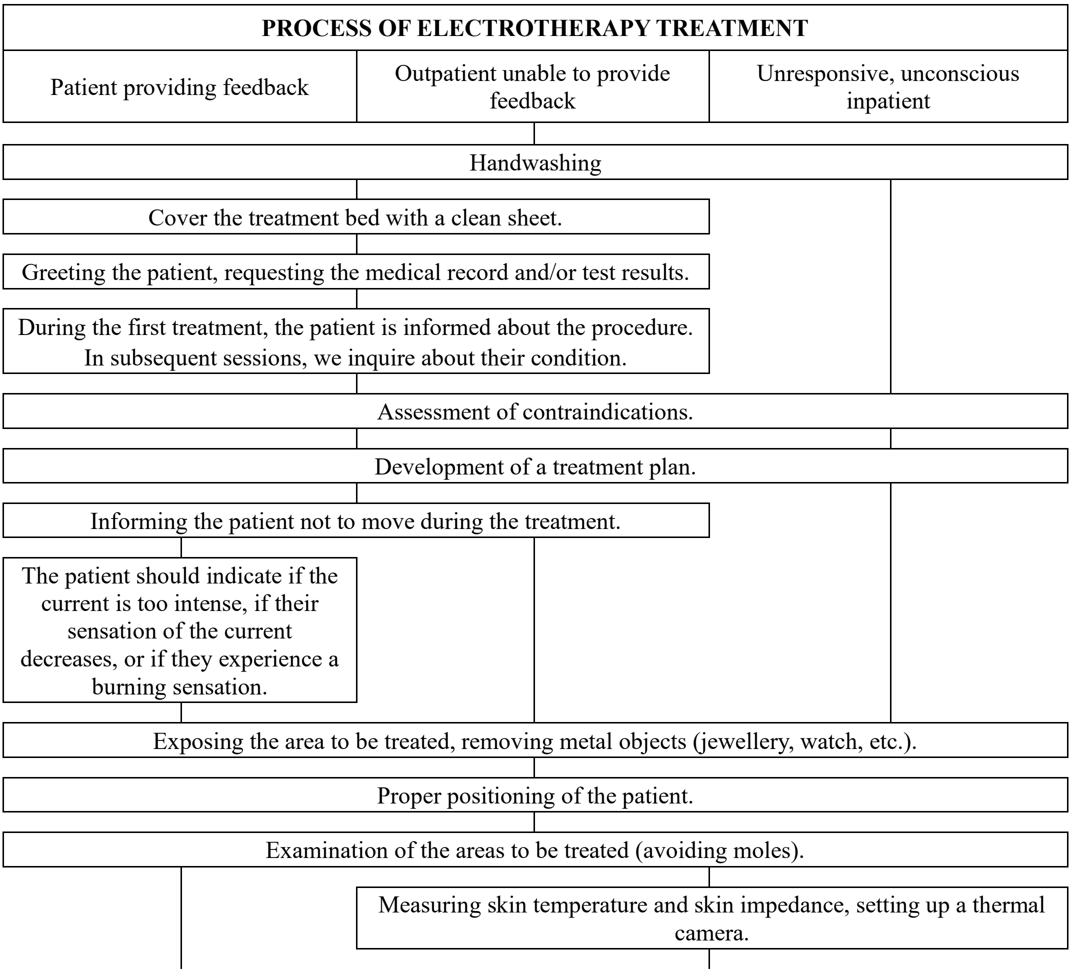
RISK ASSESSMENT MATRIX		**PROBABILITY**				
		Common (5)	Probable (4)	Occasional (3)	Rare (2)	Unlikely (1)
SEVERITY	Disastrous (4)	20	16	12	8	4
	Critical (3)	15	12	9	6	3
	Minimal (2)	10	8	6	4	2
	Negligible (1)	5	4	3	2	1
Evaluation	1-3 small	Acceptable (no action needed)				
	4-6 low	Examination required (action depends on the result)				
	8-10 medium	After the examination, risk reduction is necessary!				
	12-20 high	Avoid, immediate risk reduction is necessary!				

1. Table: Risk assessment matrix [18]

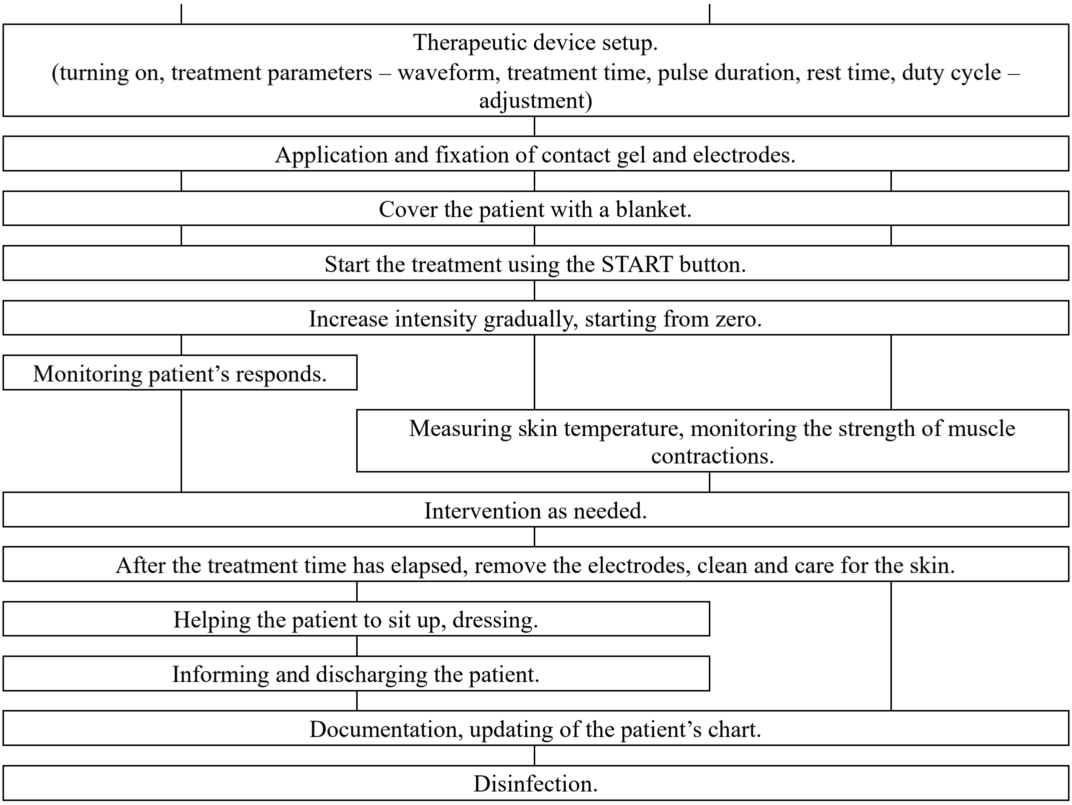
To support the development of targeted risk mitigation measures, the identified hazards were prioritised according to their risk classification (Table 5). The risk classification framework was informed by practical experience derived from electrotherapy treatments conducted over a five-year period in a private physiotherapy practice of one of the authors. Focused on patients who are unable to provide feedback, particular attention was given to risks associated with treatment failure and patient injury, which were considered critical and requiring immediate intervention. Additional focus was placed on risks related to incorrect treatment planning, the application of excessive therapeutic parameters, and infection.

RESULTS

Following the identification and systematic organization of the electrotherapy treatment steps across the three predefined patient groups, a comprehensive process flow diagram was developed (Figure 1).



1. Figure Electrotherapy treatment protocol (continued on the next page)



1. Figure: Electrotherapy treatment protocol (continuation of the previous page)

Safety considerations

Electrotherapy devices operate by converting mains voltage into low-intensity currents in the milliampere and microampere range suitable for therapeutic application. (typically ~230 Volts / 50 Hz in Europe, 117 Volts / 60 Hz in the United States). Accordingly, compliance with relevant electrical safety, technical, and clinical standards is required.The applicable regulatory frameworks in Hungary (EU), the United Kingdom, and the United States are summarised in Table 2.

Area	Hungarian / EU	United Kingdom	USA (standard / law)
Safety of Machinery	MSZ EN 60204-1:2018/A1	BS EN 60204-1	NFPA 79 – Electrical Standard for Industrial Machinery
Medical electrical equipment (Electromagnetic disturbances)	MSZ EN 60601-1-2:2015/A1:2021	BS EN IEC 60601-1-2	ANSI/AAMI IEC 60601-1-2 (FDA-approved consensus standard)
General occupational safety and health (framework law)	Act XCIII of 1993 on Labor Safety	Health and Safety at Work etc. Act 1974	Occupational Safety and Health Act (OSH Act, 1970)
Occupational health / work fitness / occupational medicine	Decree 20/2009 (VI. 18.) of the Ministry of Health	Management of Health and Safety at Work Regulations 1999 + related HSE regulations	OSHA 29 CFR (pl. 1910 Subpart Z, medical surveillance)

2. Table: Standards and regulations related to electrotherapy in the EU, UK, and USA

List of hazards

The identified hazards associated with the electrotherapy treatment process are presented in Table 3.

Tasks	Hazards
Ensuring hygienic conditions	Infection.
Assessment of the patient's condition	Lack of medical history. Incorrect measurement of parameters. Ignoring contraindications. Faulty treatment plan.
Ensuring the technical conditions of the treatment	Treatment failure. Under- or overtreatment.
Treatment	Exceeding the treatment limits. Damage to muscle fibres. Skin burns. Malfunction of electrodes or their connections. Damage to the therapeutic device.
Post-treatment procedures	Unauthorized use. Risk of infection. Data protection incident.

3. Table List of hazards

Causes of hazards

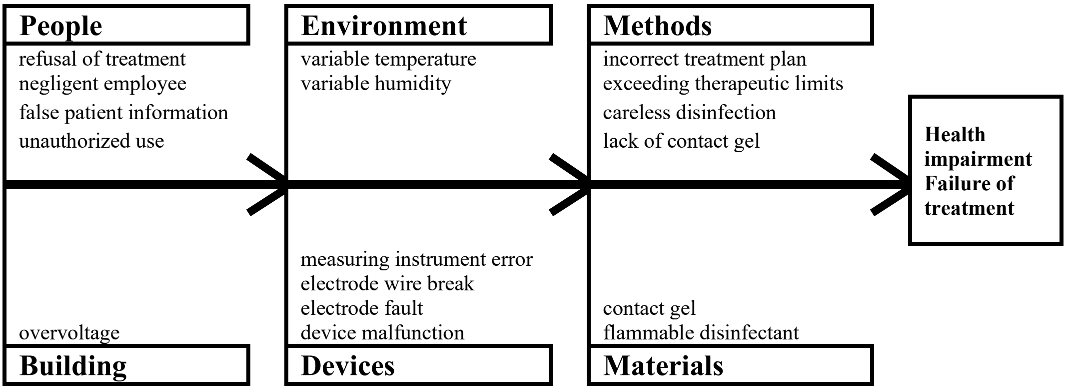
The potential causes associated with these hazards are summarised in Table 4.

Hazards	Potential causes
Treatment failure	The patient is uncooperative and refuses treatment. Malfunction of the therapeutic device. The area to be treated is not suitable for electrode placement.
Incorrect treatment plan	The patient provides incomplete and/or misleading information. Undocumented medical history. Incorrect environmental and biological measurement data.
The use of therapeutic parameters higher than permitted	Calculations based on incorrect initial data. Incorrect settings of the therapeutic device. Tired, careless employee.
Risk of infection	Treatment beds, measuring instruments, therapeutic electrodes, or objects in common areas not properly disinfected. A patient or medical staff hiding their illness.
Damage to the skin surface and/or muscle fibres	The patient conceals their actual condition. Due to an incorrect treatment plan, the therapy may be of too high intensity, have the wrong waveform, or last too long. Use of inappropriate therapeutic electrodes. Too little or missing contact gel. Malfunction of the therapeutic device.
Fire hazard	Improper storage of chemicals used for disinfection.
Damage to the therapeutic device	The chemical used for disinfection flows into the device. Due to incorrect use, the connection between the device and the electrodes is lost (wire breakage). Mains overvoltage.
Unauthorized use	Failure to lock the therapeutic device.
Data protection incident	Improper storage of medical records.

4. Table Causes of Hazards

Ishikawa (cause-and-effect) diagram

The relationships between hazards and their underlying causes were further analysed using an Ishikawa diagram (Figure 2). The hazards were assigned to six different groups depending on what causes the occurrence of each hazard. The possible causes were assigned to the persons involved in the treatment, the treatment environment, the methods applied, the building, the equipment, and the materials used in the treatment. Each of the possible causes leads to the two highlighted outcomes: health impairment and treatment failure.



2. Figure Cause-and-effect diagram of hazards

Risk classification of hazards

Based on the defined risk assessment matrix (Table 1), the identified hazards were classified according to their severity and probability (Table 5). Treatment failure was categorised as a high-risk hazard due to its potentially severe consequences and moderate likelihood of occurrence. Damage to the skin surface and muscle fibres was classified as a medium-level risk. Other hazards, including incorrect treatment planning, excessive therapeutic parameters, infection, fire hazard, equipment damage, unauthorised use, and data protection breaches, were predominantly classified as low or minimal risks.

Hazards	Severity	Probability	Risk classification
Treatment failure	disastrous	occasional	high
Incorrect treatment plan	critical	rare	low
The use of therapeutic parameters higher than permitted	critical	rare	low
Risk of infection	minimal	rare	low
Damage to the skin surface and/or muscle fibres	disastrous	rare	medium
Fire hazard	critical	unlikely	small
Damage to the therapeutic device	minimal	unlikely	small
Unauthorized use	minimal	unlikely	small
Data protection incident	minimal	rare	small

5. Table Risk classification of hazards

Following the implementation of risk mitigation measures, a revised risk classification was established (Table 6). The results indicate a reduction in risk levels across all categories, with previously high- and medium-level risks being reduced to low or minimal levels.

Hazards	Severity	Probability	Risk classification
Treatment failure	disastrous	unlikely	low
Incorrect treatment plan	critical	unlikely	small
The use of therapeutic parameters higher than permitted	critical	unlikely	small
Risk of infection	minimal	unlikely	small
Damage to the skin surface and/or muscle fibres	disastrous	unlikely	low
Fire hazard	critical	unlikely	small
Damage to the therapeutic device	minimal	unlikely	small
Unauthorized use	minimal	unlikely	small
Data protection incident	minimal	unlikely	small

6. Table Effects of risk-reducing measures

DISCUSSION

The present study aimed to identify and systematically evaluate the risks associated with electrotherapy for patients unable to provide feedback, and to develop targeted risk mitigation strategies. The findings highlight that, although electrotherapy is generally considered a safe and effective therapeutic modality, its application in this vulnerable patient population requires enhanced precautionary measures.

One of the most critical risks identified was treatment failure, which may arise from multiple factors, including patient non-cooperation or inadequate communication. In particular, insufficient patient information and suboptimal staff–patient interaction may lead to refusal of treatment, thereby compromising therapeutic outcomes. These findings underline the importance of effective communication strategies and continuous professional training of healthcare personnels. The treatment may also fail due to a malfunction of the therapeutic device or a break in the electrode wires. In this case, the faulty device or electrode must be promptly sent to a professional service centre. The failure of the treatment can be prevented by using a replacement device with similar parameters or by using spare electrodes.

Tissue damage, including skin injury and muscle fibre damage, was also identified as a significant risk. This may result from inappropriate treatment parameters, inadequate electrode application, or insufficient use of contact gel. Due to inaccurate treatment plan, therapy of too high intensity, incorrect waveform, or prolonged duration may be occurred, which in milder cases can result in ineffective treatment, in more severe cases can cause damage to the skin or muscle fibres. In patients unable to provide feedback, such adverse effects may remain undetected until significant damage has occurred. Therefore, the implementation of objective monitoring methods, such as skin temperature measurement, is essential to ensure patient safety. In case of injury, the patient must receive medical care. Coverage for any significant monetary claims resulting from the patient's potential damages can be provided through an appropriate level of professional liability insurance. If the injury occurs due to electrodes of inadequate size or quality, or due to insufficient contact gel, the activities of the attending staff and the content of the therapeutic protocol must be reviewed. In case of faulty electrodes, the electrode must be replaced, and the defective electrode must be sent to a professional service centre.

The analysis further demonstrated that incorrect treatment planning constitutes an important contributory factor to several identified hazards. This is particularly relevant in cases where patient-related information is incomplete or unreliable. For patients unable to provide feedback, reliance on accurate medical documentation and objective diagnostic measurements becomes crucial. In this context, the involvement of a physician in prescribing and supervising electrotherapy may significantly reduce associated risks.

Although less frequent, fire hazards and technical failures were also identified as potential risks associated with electrotherapy. These risks are primarily linked to improper storage of flammable materials, inadequate maintenance of devices, and electrical faults. Appropriate storage practices, routine equipment inspection, and the availability of suitable fire extinguishing equipment (Class ABC) are therefore necessary components of safe clinical practice.

Infection risk remains a fundamental concern in all physiotherapeutic interventions. The findings emphasise that adherence to established infection control protocols, including regular disinfection of equipment and treatment environments, is essential. In the European Union, the regulation is uniform. In Hungary, the current regulation in force is Decree 20/2009 (VI.18.) of the Ministry of Health, concerning the prevention of healthcare-associated infections, the professional minimum requirements for these activities, and their supervision. The decree requires the existence of infection control, whose purpose is to prevent avoidable infections associated with healthcare. The regulation mandates that healthcare providers must have an infection control manual. The content of the manual must be reviewed at least every two years based on experience, and any amendments must be recorded. The provisions contained in the manual are binding for all employees and contracted personnel of the healthcare provider. [19]

Data protection represents an additional, non-clinical risk factor. Improper handling or storage of patient records may result in data protection breaches. Ensuring secure storage systems and restricting access to authorized personnel are essential measures to mitigate such risks. The risk of data protection incidents can be reduced by storing patient records away from the treatment room, in a physically separate, lockable cabinet. It is the responsibility of the medical staff to ensure that only the records of the currently treated patient are accessible in the room during the treatment session. The compliance with the new protocol established based on measures taken to reduce risk must be regularly monitored. According to Section 54 (3) of Act XCIII of 1993 on Occupational Safety, in force in Hungary, "the employer is obliged to carry out risk assessments, risk management, and the determination of preventive measures – in the absence of other legal provisions – before starting the activity, afterwards if justified, but at least every 5 years." [20]

The risk assessment must be documented in every case, even if it is determined during this process that there has been no change in the risks and the measures applied continue to be adequate. The employer must prove that they have taken all necessary measures to assess and eliminate the risks, or to minimize them. Proper documentation of the results includes the process followed during the risk assessment and the goals achieved.

The documentation prepared as a result of the risk assessment has no prescribed form, however, at least the following must be recorded:

- the date, place, and subject of the risk assessment,
- the identifying data of the person conducting the assessment;
- identification of hazards;
- identification of those at risk and the number of people affected;
- factors that exacerbate the risk;
- qualitative and/or quantitative evaluation of the risks and the determination of whether the conditions comply with occupational safety regulations and whether the risks are maintained at an acceptable level;
- necessary preventive measures, their deadlines, and the persons responsible;
- the planned next date for preparing the risk assessment;
- the date of the previous risk assessment.

The employer must keep the document for at least 5 years. [20]

From a broader perspective, the findings of this study highlight the importance of integrating risk management into routine clinical practice in physiotherapy. Continuous monitoring, regular updating of treatment protocols, and the incorporation of risk assessment into institutional procedures are essential to ensure patient safety. A key contribution of this study is the identification of the lack of a unified, widely accepted professional protocol for the electrotherapy of patients unable to provide feedback. This gap in clinical practice underscores the need for the development of standardized guidelines and evidence-based recommendations.

LIMITATIONS

The risk assessment was primarily based on qualitative analysis and practical experience, which may limit the generalisability of the findings. Future research should aim to validate the proposed risk classification and mitigation strategies through quantitative studies and clinical data.

Overall, the findings support the implementation of a comprehensive, multidisciplinary approach to risk management in electrotherapy, particularly in the treatment of patients who are unable to provide feedback.

CONCLUSIONS, RECOMMENDATIONS

Electrotherapy in patients unable to provide feedback is associated with a range of potentially underestimated risks arising from patient-related, human, and technical factors. The absence of reliable sensory feedback significantly increases the likelihood of undetected adverse events, including tissue damage and ineffective treatment. This study demonstrates that the application of a structured risk assessment framework enables the systematic identification and effective mitigation of these risks. The implementation of targeted measures—particularly in relation to treatment planning, objective patient monitoring, staff training, equipment maintenance, and infection control—can substantially improve patient safety. The findings emphasize the necessity of regularly updating treatment protocols and integrating risk management into routine clinical practice. Strengthening both physical and data security within the therapeutic environment is also essential. Importantly, the absence of a unified professional protocol for the electrotherapy of patients unable to provide feedback highlights a critical gap in current practice. The development of standardized, evidence-based guidelines is therefore strongly recommended.

Overall, a comprehensive and proactive approach to risk management is essential to ensure the safe and effective application of electrotherapy in this vulnerable patient population.

FUNDING STATEMENT

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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