SHORT REPORT

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Recommended Contraindications for the Use of Non-Medical WB-Electromyostimulation

Empfehlungen zu Kontraindikationen für Ganzkörper-Elektromyostimulation im kommerziellen, nicht-medizinischen Setting

Summary

- **Rare but regularly recurring complications** are leading to ongoing regulation of the commercial, non-medical whole-body electromyostimulation (WB-EMS) market. In addition to the revised German Radiation Protection Statutes (NiSV), the "Deutsche Industrie Norm" (DIN) 33961-5 was recently published with safety policies for WB-EMS application, anchoring both relative and absolute contraindications for WB-EMS for the first time. The purpose of this article is to justify the rationale of contraindications in a commercial setting and to support their consistent application.
- **While the relative contraindications** appear plausible and uncritical, absolute contraindications for WB-EMS are much more debatable. In fact, some absolute contraindications (e.g. diabetes mellitus) could be safely addressed by WB-EMS at least after careful medical anamnesis and competent, close supervision. However, this requires sound knowledge of WB-EMS on the part of physicians and instructors, low user-trainer ratios and prompt medical care in an emergency.
- **However,** considering the multitude of different settings of commercial WB-EMS, in extreme cases with hardly supervised, only video-guided WB-EMS sessions, the necessary accurateness and expertise for safe WB-EMS is not always guaranteed. That there is no mandatory licensing of WB-EMS instructors, the key players in WB-EMS, underscores the concern.
- **Whilst** acknowledging the multitude of high-quality suppliers, it is advised that the commercial, non-medical WB-EMS sector as a whole to be wary of indications with significantly increased complication potential. Lastly, the mandatory acceptance of the contraindications listed in DIN 33961-5 might be considered as an inevitable step towards preventing overregulation by official authorities.

KEY WORDS:
Whole-Body Electromyostimulation, DIN 33961-5, Commercial Application, Guideline

Zusammenfassung

- **Vereinzelte aber regelmäßig wiederkehrende** Komplikationen führen zu einer zunehmenden Regulation des kommerziellen, nicht-medizinischen Ganzkörper-Elektromyostimulation (WB-EMS) Marktes. Neben der Aufnahme u.a. der WB-EMS-Technologie in die novellierte Strahlenschutzverordnung (NiSV) adressiert auch die im Frühjahr 2019 herausgegebene Deutsche Industrie Norm (DIN) 33961-5 wichtige Sicherheitsaspekte. So werden erstmalig relative und absolute Kontraindikationen für ein WB-EMS Training in einer Norm verankert. Das Ziel des vorliegenden Beitrags ist es, die Rationale der Kontraindikationen in einem kommerziellen Setting zu begründen und ihre konsequente Anwendung zu unterstützen.
- **Während die relativen Kontraindikationen** plausibel und unproblematisch handhabbar erscheinen, ist um die absoluten Kontraindikationen der WB-EMS Anwendung eine heftige Kontroverse entbrannt. Tatsächlich ist bei einigen absoluten Kontraindikationen wie bspw. dem Diabetes Mellitus eine WB-EMS Anwendung nach ärztlicher Anamnese und fachkundiger Trainingsbegleitung sicher durchführbar und sinnvoll. Dies setzt jedoch ärztliche Kenntnisse über WB-EMS Anwendung und Wirkungsweise, fundiertes medizinisch-/trainingswissen-schaftliches Wissen des Fachpersonals, einen engen Betreuungsschlüssel sowie, im Notfall, eine rasche medizinische Versorgung voraus.
- **Angesicht der Vielzahl** der unterschiedlichen Settings des kommerziellen WB-EMS Marktes, im Extremfall mit kaum überwachter, lediglich noch videogeführter WB-EMS Anwendung, ist diese fachkundige Anamnese und Betreuung allerdings nicht in jedem Fall sichergestellt. Hinzu kommt, dass selbst die Lizensierung des WB-EMS Übungsleiters zumindest bis zur Einführung der NiSV nicht verbindlich vorgegeben wird.
- **Ohne die Vielzahl** gut aufgestellter, gesundheitsorientierter Einrichtungen diskreditieren zu wollen, erscheint somit im Grundsatz ein Verzicht auf Indikationen mit deutlich erhöhtem Komplikationspotential für den kommerziellen, nicht-medizinischen WB-EMS Bereich als gerechtfertigt. Insofern ist die verbindliche Akzeptanz der (absoluten) Kontraindikationen der DIN 33961-5 aus unserer Sicht ein wichtiger Schritt, einer behördlichen Überregulierung des WB-EMS vorzubeugen.

SCHLÜSSELWÖRTER:
WB-EMS, DIN 33961-5, nicht-medizinische Anwendung, Richtlinie

Introduction

Due to its ability to simultaneously stimulate large muscle areas with dedicated (in excess supra-maximum) impulse intensity for each region, whole-body electromyostimulation (WB-EMS) is a very time-efficient training method for affecting many fitness- and health-related outcomes (8, 18, 19). This unique feature, however, carries the inherent risk of over-straining that could even lead to severe

rhabdomyolysis (14). Indeed, the finding that this has already been reported after local transcutaneous electrical nerve stimulation (TENS)/EMS application of a single leg (e.g. (3)) might indicate the potential risk of WB-EMS (10, 14), at least after improper WB-EMS application (7, 16). Recently, the WB-EMS Round Table Germany, a national consortium of scientific and educational institutions or organizations, published its "guidelines for safe and effective (WB-EMS) training" (6). This guideline predominately addresses safety (and effectivity) aspects during application, preparing and follow up of WB-EMS sessions. The most prominent demand of the guideline (6) is the consistent and close (1 instructor – 2 trainees) supervision by the certified WB-EMS trainer and the careful conditioning of the WB-EMS novice during the first weeks of WB-EMS. However, the guideline "for safe and effective (WB-EMS) training" is not mandatory, and in the wake of further negative side effects leading to a temporary ban of WB-EMS in Israel, the (mandatory) institutional regulation of WB-EMS application in Germany is now being addressed with more emphasis.

Regulations and Standards for WB-EMS in Germany

In 2018, the German Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit (BMU) included WB-EMS and other types of "applications of non-ionizing radiation to humans which are commercially used for cosmetic or other non-medical purposes" (Directive on protection against harmful effects of non-ionising radiation: NiSV) in the German Radiation Protection Statutes. This act will come into force in January 2021 and standardize areas of regulation, i.e. general requirements for operation, documentation of training sessions and qualifications of instructors or practitioners. However, the NiSV did not include specific aspects or detailed provisions related to unintended side effects, namely supervision, application and contraindications. Practically at the same time as the NiSV, DIN 33961-5 that also addressed non-medical, commercial WB-EMS facilities was launched in March 2019. In contrast to the mandatory NiSV, the DIN 33961-5 concentrates on practical aspects of supervision and application and, for the first time, prescribes dedicated relative and absolute contraindications for WB-EMS application.

Contraindications for WB-EMS Application

In general, most contraindications for WB-EMS are based on corresponding "recommendations" given for local electrical stimulation therapy (e.g. TENS, Neuromuscular Electrical Stimulation (NMES), High Voltage Pulsed Current (HVPC; (1)). However, due to the comprehensive total body approach of WB-EMS, systemic conditions (e.g. diabetes mellitus) also have to be addressed.

While relative contraindications in DIN 33961-5 (Tab. 1) can be considered plausible and highly applicable, the absolute WB-EMS contraindications listed in Table 2 are much more controversial.

Apart from absolute indications that should generally prevent participation in vigorous physical activity and exercise (e.g. acute alcoholic and narcotic intoxication, viral and bacterial infections, inflammatory processes or neuronal conditions (epilepsy, severe sensitivity disorder), all other contraindications for the application of WB-EMS are debatable.

Primarily, all relevant WB-EMS systems enable a limited stimulation of a few muscle areas with low impulse intensity. Thus, contraindications predominately based on limitations

Table 1

Relative contraindication for WB-EMS according to DIN 33961-5.

CONTRAINDICATION
Acute back pain without diagnosis
Acute neuralgia, herniated discs
Implants older than 6 months
Diseases of the internal organs particularly kidney diseases
Cardiovascular diseases
Movement kinetosis
Greater fluid retention, oedema
Open skin injuries, wounds, eczema, burns
Corresponding medication for conditions mentioned above

of local origin (i.e. recent surgical operation, abdominal/inguinal hernia, but also pregnancy) could be managed by addressing non-problematic areas only (1). This means that electrodes for the stimulation of body regions with contraindication are switched off and only non-affected areas are stimulated. Further, although negative side effects should be addressed by more dedicated studies, clinical trials that focus particularly on patients with diabetes (18), cancer (12, 13), cardiovascular (2, 19) and cardiometabolic (5) conditions have so far not reported any negative side effects of WB-EMS application in these vulnerable cohorts. Other contraindications (e.g. arteriosclerosis, hemophilia) have not yet been evaluated by clinical WB-EMS studies and corresponding contraindications are lacking due to the want of evidence.

Diabetes Mellitus as a Contraindication for WB-EMS?

Diabetes Mellitus Type II (T2DM) might be a good example for the discrepancy between safety aspects, feasibility and effectiveness of WB-EMS application in a vulnerable cohort. T2DM and its complications generate pronounced negative individual and socioeconomic impacts (4, 17). Apart from cardiomyopathy, cardiac insufficiency, cardiac arrhythmia and peripheral arterial occlusive diseases, frequent complications of T2DM are hypoglycemia, eye, joint and tumor diseases, gangrene, polyneuropathy and nephropathy (4, 9). Physical activity and exercise are key agents in the prevention and rehabilitation of T2DM (11). However, due to the limited exercise affinity of the majority of older people, the cohort predominately affected by T2DM, enthusiasm for frequent exercise might be particularly low in Diabetes Mellitus II sufferers.

Thus, time-efficient WB-EMS technology with its validated positive effects on body composition (8), energy consumption, carbohydrate oxidation (15), glucose metabolism (18) and physical function (8) might be a feasible alternative to the recognized, but time-consuming endurance/resistance exercise protocols presently recommended (11). Vice versa, particularly high acute energy demands (15) and the regulation of impulse intensity by rates of perceived exertion in WB-EMS might be a problem, considering T2DM complications such as hypoglycemia and deficits in neuronal sensitivity. Without doubt, these challenges can be managed in a medically supervised clinical setting by experienced, well-trained instructors. However, is this the common setting of commercial, non-medical WB-EMS application at present? ›

Table 2

Absolute contraindication for WB-EMS according to DIN 33961-5.

CONTRAINDICATION
Acute diseases, bacterial infections, inflammatory processes
Recently performed operations in stimulation areas
Arteriosclerosis, arterial circulation disorders
Stents and bypasses active for less than 6 months
Untreated hypertension
Diabetes mellitus
Pregnancy
Electric implants, cardiac pacemakers
Heart arrhythmia
Tumor and cancer
Bleeding disorders, tendency of bleeding (hemophilia)
Neuronal diseases, neuronal disorders, epilepsy
Abdominal wall and inguinal hernia
Acute influence of alcohol, drugs and intoxicants

Aspects and Arguments for a Strict Specification of Contraindications in Commercial, Non-Medical WB-EMS Application According to DIN 33961-5

To answer the question raised above: "no" – we think there are evident differences between scientific or medical settings and the WB-EMS practice of commercial, non-medical suppliers. Anamnesis, supervision and counseling are more elaborate and reliable in a clinical setting compared to WB-EMS studios with their limited time and personal resources and, usually, lower medical qualifications. Despite their efforts to enhance safety and standardization, cost and revenue structures mainly based on 150-200 clients/institution/week ideally stimulated in parallel on two WB-EMS devices supervised by one instructor may well make it hard for commercial WB-EMS suppliers to compete with funded clinical trials or medical settings with their higher revenues. Another argument might be that due to eligibility criteria or focus on specific conditions, clinical settings or medical applications are more homogeneous, and thus easier to handle. However, the most striking argument focuses on educational aspects. Currently, the licensing of WB-EMS instructors is unfortunately not mandatory. One could assume that the NiSV launched in December 2020 might cure this limitation. However, reviewing the "EMF curriculum" in its present form – its unspecific contents, lack of obligatory access qualification, absence of official monitoring and control –the NiSV "EMF-Fachkunde" curriculum fall short of the more elaborate educational requirements of the non-mandatory DIN 33961-5. However, keeping in mind that DIN 33961-5 addresses both instructors' qualification and contraindications, it can be interpreted in a way that the DIN committee doubted whether the basic qualification prescribed would enable safe, feasible and effective WB-EMS application of the conditions listed in table 2. In this context, it might be of interest that the educational fraction of the WB-EMS round table (Glucker Kolleg, Berufskolleg Waldenburg, DHfPG), i.e. that part of our consortium particularly aware of instructor qualification and prerequisites, pleaded most decisively for strict application of the contraindications listed in the DIN 33961-5.

Conclusion

After extensive discussions on applicability, effectiveness, socioeconomic impact and safety, the WB-EMS round table finally decided unanimously to support strict application of the absolute contraindications listed in DIN 33961-5 (Tab. 2). In accordance with DIN 33961-5, we direct this recommendation exclusively to commercial, non-medical WB-EMS-studios. We understand the criticism that such a generalization of WB-EMS studios might be considered as undifferentiated and unfair, at least with respect to WB-EMS studios with higher standards. Nevertheless, based on our experience, we believe that the vast majority of commercial WB-EMS studios might have enormous problems in appropriately handling patients with conditions listed in table 2. The reader may feel that the non-mandatory character of DIN 33961-5 prevents a broad application of the contraindications in commercial settings. However, one should be conscious that in the absence of other regulatory norms, in cases of relevant adverse effects related to clinical conditions, authorities might base their decision on this DIN. We are aware that many WB-EMS facilities will not like the idea of losing target groups now excluded by DIN 33591-5. Nevertheless, we are convinced that a reasonable and responsible limitation is essential to prevent further negative side effects and thus avoid much more painful official regulations. Further, one has to bear in mind that DIN 33961-5 and NiSV focus entirely on commercial, non-medical WB-EMS studios. Cooperation with physicians, physiotherapists and other qualified medical staff will contribute to a more dedicated medical supervision, an aspect very important in the context of WB-EMS contraindications. Combining even more personalized WB-EMS (1 instructor – 1 client) with the use of WB-EMS tools with medical device approval will enable a safe and effective WB-EMS application even with vulnerable cohorts; albeit with a different cost and revenue structure and the possibility of funding or co-funding by the health care system. Reviewing the present composition and orientation of WB-EMS application in Germany, the limited diversification and specialization of WB-EMS suppliers in reaching promising target groups (e.g. seniors) is amazing and calls for review. We think DIN 33961 and NiSV can be a stimulus for a corresponding diversification of the market with more dedicated WB-EMS offerings.

However, one important aspect with relevance for safety and effectiveness still has to be addressed here. With respect to the "Fachkunde" or specialist training for medical staff (i.e. physiotherapists, neurologists or sports physicians), we do not share the opinion that (local) electrotherapy schooling as it stands, and moreover as it varies considerably between the different federal states adequately, qualifies these cohorts to properly estimate, apply or supervise WB-EMS applications. Specified mandatory training courses for WB-EMS implemented in the corresponding schooling curriculum or outsourced to specific WB-EMS educational institutions should enable this group to generate a safe and effective WB-EMS application.

In summary, the publication of official contraindications for WB-EMS application has long been overdue (10, 14). Without doubt, some of the absolute contraindications are debatable and might be downgraded to relative contraindications or even revised as contraindications in future recommendations. This process however, should include more evidence-based EB-EMS research and a mandatory (more) profound education of instructors and other responsible subjects (e.g. EMS studio staff) involved in the application of WB-EMS. Although this contribution focus on DIN 33961-5 that addresses

the commercial, non-medical WB-EMS market, we do not support the specification in the (mandatory) NiSV that physicians and physiotherapists be completely exempt from specific WB-EMS education. However to date and considering the present situation, it might sound strange and disrespectful at first, but we feel that it might be necessary to address conditions with a high potential of complications so as to protect commercial, non-medical WB-EMS institutions from their own ambitions.

Conflict of Interest

The authors have no conflict of interest.

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