



DGTHA

Deutsche Gesellschaft zur Förderung
der Therapien mit Hirudineen und
ihres Artenschutzes e.V.

Training Guidelines on the Use of Leech Therapy in Humans (DGTHA e.V.) Effective 21st June 2017

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Introduction

The German Association for the Promotion of Leech Therapy and the Protection of Leeches (DGTHA) has been founded in 2006 by circles of experts. The major target of this foundation was to promote “quality assurance systems on medicinal leech therapy by preparation of education directives and the qualified education and advanced training of leech therapists.” The preparation of the Training Guidelines has been delayed by the discussion on the appropriate scope and claims of the education directives in various user countries of leech therapy.

The ever-expanding use of leech therapy and the increasing regulatory demands of drug agencies require the necessity of providing a Training Guidelines for interested circles. The members of the DGTHA association possess the essential knowledge for the elaboration of a respective education directive.

The Training Guidelines follows the current legal position of medicinal leech therapy in Germany. This directive is scheduled to initiate a basic discussion on international minimum standards for leech therapists.

The Training Guidelines deliberately does not indicate the amount of time of the various training volumes. At least one seminar day is scheduled for a basic training on the section of main indications of leech therapy. The leech therapists advanced training can be extended by further indications of medicinal leech therapy.

The Training Guidelines is directed at stimulation of the discussion on the proper use of medicinal leech therapy. The DGTHA association welcomes any suggestions for further developments of the education directive. The topicality of the Training Guidelines should be checked and revised at manageable intervals. The DGTHA association invites every interested circle to contribute with commentaries to the further development of the education directive.

1 The Place of Medicinal Leech Therapy as Part of Medicine and Naturopathy

1.1 History

Teaching Content:

- Impact of medicinal leech therapy from ancient to mediaeval times
- Excessive use of leech therapy in France (Vampirism) in the 19th century
- Decline of leech therapy in the Western countries following the explorations of microbiology (Robert Koch and Louis Pasteur)
- Earliest scientific works on active ingredients of leech saliva (Detection of hirudin by Haycraft in 1884)
- First comprehensive medical handbook on medicinal leech therapy by Heinz Bottenberg (1935)
- Reduction of leech therapy into nicheness in Western Europe after the second world war
- Re-discovery of leech therapy in the indication „venous congestion“ by two Slovenian surgeons (Derganc, M & Zdravic, F from Ljubljana (British Journal of Plastic Surgery 1960)
- Continuous increase of the use of leech therapy within the scope of German speaking medical naturopathy, since the 1970ies.
- Pharmacological proof of several active ingredients in leech saliva
- Genetic and synthetic production of some active ingredients of leech saliva as approved and marketed drugs
- 2004: The Federal Drug Agency FDA grants US market approval for leech therapy in post-operative venous congestion
- 2008: Rating of medicinal leeches as pharmaceutical product according to legal approval standards in Germany

1.2 Regional and Cultural Varieties

Teaching Content:

- Western Europe, Russia, India
Focus indication areas, treatment procedure
- China
Route of administration (Powder, ointment)
- Turkey, Iran
Folk medicine, self-treatment

2 Leech Biology

Teaching Content:

- Leech species for medical use in Europe
- Habitat of leech species
- Leech protection according to Washington Convention on International Trade in Endangered Species
- Species characteristics
- Structure and function
- Food intake (Sucking procedure)
- Reproduction
- Inter-specific relationship between parasite and host

3 Leeches as Pharmaceutical Product

Teaching Content:

- Quality requirements on leeches used as pharmaceutical products
- Safety management in view of natural preconditions of medicinal leeches
- Supplementary measures of drug safety
- Unique features of living drugs (Pharmacological effects, blood withdrawal, energetic aspect)
- Effects of known active ingredients of leech saliva
- Clinical studies
- Mode of action, leech saliva, phlebotomy, stimulatory aspect
- Explanatory approach on mode of action

4 Legal Aspects of Leech Therapy

Teaching Content:

- Status of pharmaceutical legislation
- Professions obtaining license for leech therapy
- Obligatory education and advanced training for leech therapists
- Obligatory patient information
- Obligatory patient informed consent
- Accessibility and patient care in case of unwanted adverse reactions
- Animal and nature protection
- Handling of used medicinal leeches

5 Treatment Principles and Indication Areas of Leech Therapy

5.1 Treatment Principles

Teaching Content:

- Localised symptomatic treatment
- Systemic treatment

5.2 Indication Areas

Teaching Content:

- Surgery/Plastic Surgery
- Orthopaedics/Traumatology
- Rheumatology
- Phlebology
- Internal Medicine
- Dermatology
- Neurology
- Gynaecology/Andrology
- Otolaryngology
- Ophthalmology
- Stomatology

5.3 Major Indications of Leech Therapy

(Teaching Content: Selection of article 5.4, listed according to frequency of use in practice)

Comment on presentation of indications of leech therapy according to Diagnostic Code ICD-10	
Letter, number, number (M00)	= all sub-indications suitable for leech therapy
Letter, number, number.x (H66.x)	= some sub-indications suitable for leech therapy
Letter, number, number.number (H93.1)	= indication suitable for leech therapy without sub-indications

- Arthrosis, arthritis, gout (M00-M25)
- Backbone and back diseases (M40 - M54)
- Thrombosis, phlebitis and thrombophlebitis (I80)
- Varicose veins, ulcer varicosum (I83.x, I86.x)
- Soft tissue diseases (M60 - M79)
- Abscesse, furuncle, carbuncle (L02)
- Abscess in anal and rectal region (K61)
- Ulcer (L97, L98.x)
- Osteopathy and Chondropathy (M80 - M94)
- Suppurative and otitis media unspecified (H66.x)
- Hearing loss (H91.x)
- Tinnitus (H93.1)
- Bruise and contusion (T14)
- Haematoma (T14)
- Haemarthrosis (M25, T14)
- Distortions and strain (S33, S43, S53, S63, S73, S83, S93)
- Haemorrhoids (K64.x)

5.4 Indications of leech therapy pursuant to ICD 10 (not final)

Teaching Content:

- Certain infectious and parasitic diseases (A00 - B99)
 - Shingles (B02.x)
- Diseases of the blood and blood-forming organs (D50 - D90)
 - Polyglobulism/Polycythaemia (D75.x)
- Endocrine, nutritional and metabolic diseases (E00 - E90)
 - Haemochromatosis (E83.1)
- Diseases of the nervous system (G00 - G99)
 - Migraine (G43.x)
 - Other headaches (G44.x)
 - Diseases of nerves, nerve roots, and plexus (G50.x – G64.x)
- Diseases of the eye and adnexa (H00 - H59)
 - Diseases of eyelid (H01)
 - Glaucoma (H40 - H42)
- Diseases of the ear and mastoid processes (H60 - H95)
 - Hordeolum and Chalazion (H00)
 - Suppurative and other otitis media, unspecified (H66.x)
 - Diseases of vestibular function, Menière syndrome (H81.x, H82.x)
 - Hearing loss (H91.x)
 - Tinnitus (H93.1)
 - Diseases of ear, unspecified (H93)/Disturbed blood supply
- Diseases of the circulatory system (I00 - I99)
 - Hypertension (I10.x - I15.x)
 - Ischaemic heart diseases (I20.x – I25.x)
(Angina pectoris, subsequent myocardial infarction)
 - Cerebrovascular diseases (I60.x – I69.x)
 - Varicose veins, Ulcer varicosum (I83.x, I86.x)
 - Thrombosis, phlebitis and Thrombophlebitis (I80)
 - Other diseases of veins (I87)/Venous disturbed circulation
- Diseases of the respiratory system (J00 - J99)
 - Sinusitis, pharyngitis, tonsillitis (J01.x - J06.x)
- Diseases of the digestive system (K00 - K93)
 - Fissure and fistula of anal and rectal regions (K60.x)
 - Haemorrhoids (K64.x)
 - Biliary colic (K80.x)

- Diseases of the skin and subcutaneous tissue (L00 - L99)
 - Failure and rejection of transplanted organs and tissues (T86)/Venous congestion subsequent to skin- and tissue transplantation
 - Phlegmon (L03)
 - Cutaneous abscess, furuncle and carbuncle (L02)
 - Abscess of anal and rectal region (K61)
 - Ulcer (L97, L98.x)
- Diseases of the musculoskeletal system and connective system (M00 - M99)
 - Arthrosis, arthritis, gout (M00-M25)
 - Systemic connective tissue diseases (M30 - M36)
 - Dorsopathies vertebral and and back region (M40 - M54)
 - Diseases of connective tissue (M60 - M79)
(Periarthritis, bursitis, synovitis, tendinitis, tendovaginitis, myositis, fibromyalgia)
 - Osteopathies and chondropathies (M80 - M94)
- Diseases of the genitourinary system (ICD 10 Kapitel XIV: N00 - N99)
 - Premenstrual complaints (N94.3)
 - Oligomenorrhea. Dysmenorrhea, amenorrhea (N91.x, N92.x, N94.x)
 - Menopausal disorders (N95.x)
- Symptoms, not elsewhere classified (R00 - R99)
 - Dizziness and giddiness (R42)
- Injury and certain other consequences of external cause (S00 - T98)
 - Distortions and strain (S33, S43, S53, S63, S73, S83, S93)
 - Bruise and contusion (T14)
 - Haematoma (T14)
 - Haemarthrosis (M25, T14)

6 Contraindications

6.1 Absolute Contraindications

Teaching Content:

- Inherited or acquired bleeding disorders (haemophilia)
- Concomitant treatment with anticoagulant substances (oral and non-oral anticoagulants, NOAKs/DOAKs, oral thrombocytes aggregation inhibitors) as a preventive of thrombosis, embolism, and stroke – Exception low dose acetylsalicylic acid
- Anaemia or bone marrow suppression
- Erosive gastritis, gastrointestinal bleeding or stomach ulcers tending to bleed
- Infectious diseases during an acute stage or with fever
- Serious, unstable diseases of an organ
- Artificially induced (e.g. by medication) suppression of immune reactions or pronounced allergy diathesis and specific protein allergies
- Known allergies, such as to one of the ingredients in leech saliva
- Tendency to bleed (haemorrhage diathesis)
- General and localised wound healing disorders
- Excessive formation of scar tissue (keloid)

6.2 Relative Contraindications

Teaching Content:

- Pharmaceutical products containing low dose acetylsalicylic acid
- High dosages of enzyme preparations
- High dosages of fish oil
- Vitamin C infusions
- Immune system diseases

7 Leech Treatment Performance in Practice

7.1 Organisational Measures

Teaching Content:

- Individual therapy
- Group therapy/Simultaneous therapy

7.2 Quality Management of Leech Keeping in Practice before Treatment

Teaching Content:

- Short-term keeping
- Long-term keeping
- Minimum requirements of keeping quality
- Preparation of leeches for therapeutic use

7.3 Preventive Measures (Anamnesis)

Teaching Content:

- Clarification of proper indication and verification of justification of leech therapy
- Number of repeat treatments
- Check of current patient medication
- Inspection of current blood values to exclude for example anaemia, acute infection, thrombocytopenia, or other blood coagulation disorders
- Explanation which medication has to be discontinued in consultation with the treating physician
- Obligatory patient considerations
- Duration of treatment
- Patient perceptions of leech treatment
- Average number of leeches (4-8, depending on the indication and the general health condition of the patient)
- Organisational issues of treatment procedure
- Sitting, recumbent, visits to the toilet, way home, supply of supplementary dressing for the secondary haemorrhage
- Accessibility of the treating therapist
- Patient information with written informed consent of the patient

7.4 Treatment Performance

Teaching Content:

- Patient examination
- Definition and marking of the appropriate application sites
- Patient position
- Preparation and pin-pointed application of leeches
- Actions to be taken in case of insufficient leech biting
- Monitoring of treatment procedure
- Professional removal of leeches (only exceptional)

7.5 Follow-up

Teaching Content:

- Evidence of sufficient intake of fluids
- Follow-up next day including change of dressing
- Rest and immobilisation in particular in case of extremities treatment
- Personal hygiene and care
- Explanation on potential adverse reactions (Secondary haemorrhage, itching, redness, swelling, lymph node swelling)
- Adverse reactions necessitating the patient for immediate contacting of the therapist
- Accessibility of an experienced leech therapy physician in case of necessary medical treatment of adverse reactions (only valid for alternative practitioners)
- Handover of the package insert to the patient containing the practice seal of the leech therapist in case of treatment queries

8 Sequelae and Adverse Drug Events

8.1 Avoidance and Reduction of Sequelae

Teaching Content:

- Pay attention to sections 7.4 Treatment Performance and in particular section 7.5 follow-up
- Ensure accessibility of the therapist
- Use of itching alleviating ointments
- Cooling compresses
- Administration of an oral antihistamine
- Ensure emergency preparedness in the practice

8.2 Treatment of Adverse Drug Events

Teaching Content:

- Swelling of the three-forked wound brinks accompanied by localised feeling of tension, usually lasting 12 to 48 hours
Actions to be taken: Cooling or antihistamine as appropriate

- Red-purple stain of the wound brinks, later turning yellowish, up to 14 days
Actions to be taken: Cooling or antihistamine as appropriate
- Regional lymph node swelling
Actions to be taken: Drainage activating ointments, lymph drainage
- Intensified secondary haemorrhage with concomitant haemoglobin decrease, risk of blood loss with need for transfusion
Actions to be taken: compressing bandage, in case of emergency need for suturing or blood transfusion
- Tightly localised inflammations with partly papular tumescence at the bite sites, frequently accompanied by itching
Actions to be taken: Cooling or antihistamine and antibiotics as appropriate
- Limited localised allergic symptoms
Actions to be taken: Antihistamine
- Swelling of the treatment region for several days in case of leech application on extremities
Actions to be taken: Antihistamine, or drainage activating ointments, lymph drainage
- Pronounced blood pressure decrease (Circulatory depression and vasovagal syndrome)
Actions to be taken: Passive leg-raising or call for emergency physician
- Distinct localised inflammations, e.g. erysipelas, inflammation of lymph paths (lymphangitis)
Actions to be taken: 3rd generation cephalosporines or gyrase inhibitors
- Cutaneous B-cell-pseudo lymphoma (Formerly arthropod reaction)
Actions to be taken: Treatment options not known, watchful waiting, no further leech therapies
- Systemic infections with sepsis, e.g. caused by secondary wound infection (various pathogens possible), or by primary infection caused by *Aeromonas hydrophila* or *Aeromonas veronii biovar sobria*
Actions to be taken: 3rd generation cephalosporines or gyrase inhibitors
- Anaphylaxis (Stage I – IV)
Actions to be taken: Actions pursuant to the stage of anaphylaxis in line with the ERC-Guidelines (European Resuscitation Council)

9 Application of Medicinal Leeches

Teaching Content:

- Lavatory visit of the patient as appropriate
- Patient's position during treatment (Sitting, recumbent)
- Hygiene before and during treatment
- Selection of application sites
- Giving a shower to the leeches immediately before the application
- Handling of leeches in the course of application
- Patient care in the course of leech sucking
- Bandaging with sterile dressing and sufficient absorbant stuff for the secondary haemorrhage
- Whereabouts of the leeches after the treatment

10 Accounting System

Teaching Content:

- Accounting of the medical ambulant treatment according to the scale of charges for physicians (GOÄ in Germany)
- Accounting according to the scale of charges for alternative practitioners (GebüH in Germany)