

Research Evidence Base for Anthroposophic Medicine

Clinical studies

A great number of research studies of all evidence levels is available for Anthroposophic Medicine (AM).

In a comprehensive Health Technology Assessment report, [1] the efficacy, efficiency and safety was assessed. The methodological quality of the systematically searched studies was critically assessed and only studies of higher quality were included. The HTA-assessment is based on one systematic review and 189 clinical studies. 39 of these studies are prospective with a control group, thereof 17 randomized and 5 blinded. The emphasis of the studies (50%) lays on mistletoe therapy in oncologic diseases (94 studies, thereof 14 RCTs). The other clinical studies are related to a great variety of indications analyzing AM as a system, non-pharmacological AM-therapies (5 studies) and the anthroposophic treatment of pain diseases and wounds (18 studies, thereof 3 RCTs).

Further studies are available for the following indications: chronic hepatitis B and C (10 studies), AM-treatment of neurologic and psychiatric disorders (7 studies), AM-treatment in gynaecology and obstetrics (6 studies), acute infections of the upper respiratory system, ears, eyes, GI-tract (16 studies), cardiovascular diseases (6 studies), thyroid diseases (4 studies) lung diseases (6 studies, thereof 2 concerning sarcoidosis), active ulcerative colitis (1 study) fatigue (1 study), hyperlipidemy (1 study), hyperuricemy (1 study), painful diseases (4 studies).

180 of the 189 evaluated studies show a similar or better result for AM than that of conventional medicine in at least one clinical parameter.

Among these studies the GCP conform study on anthroposophic treatment in various chronic diseases, the 'Anthroposophic Medicine Outcomes Study (AMOS)' is to be pointed out, which studied the outcome, efficacy, utility and efficiency of AM in realistic treatment situations. A clinically relevant and statistically significant improvement could be shown, which was stable

over 2 years. Health-care costs decreased simultaneously [2-5].

In 2004 a broad pharmacovigilance network was established to study the use and drug safety of anthroposophic remedies. Up to now over 1 million prescriptions of anthroposophic therapies are documented. By this means the tolerance, and safety and harmlessness of AM could be shown [6].

The studies on oncologic mistletoe therapy show a significant improvement of quality of life and a decrease of side effects under chemo- and radiotherapy and after surgery [7]. These results were shown in particular for breast cancer [8]. Several studies have shown a prolongation of survival or tumour remission for some tumour entities but the methodological quality of these studies varies.

Recent studies confirm the findings of the health technology assessment and give evidence for the efficacy of the oncologic mistletoe therapy also for pancreas carcinoma [9] and colorectal carcinoma [10].

Basic research

Fundamental research is carried out with emphasis on mistletoe. The biological and pharmacological properties of *Viscum album* L. extracts (VAE) have been subject to extended scientific investigations [11, 12]. Several pharmacologically active compounds have been isolated, such as mistletoe lectins (ML I, II and III) [13], viscotoxins oligo- and polysaccharides, lipophilic extracts and various others [11, 12]. The most prominent properties of VAE are their cytotoxic and growth-inhibiting effects, *in vitro*, on a variety of human tumour cell lines, lymphocytes and fibroblasts [11, 12]. The cytotoxic effects of VAE are mainly due to the apoptosis-inducing mistletoe lectins [14-16], while the viscotoxins induce necrotic cell death [15, 17]. VAE are also recognized for their immune-modulating activity: *In vitro* and *in vivo* studies have demonstrated activation of monocytes/ macrophages, granulocytes, natural killer (NK) cells, T-cells (especially T-helper-cells) and the induction of various cytokines [11, 12]. VAE also possess DNA stabilizing properties, they reduce chromosome damage and improve DNA repair [18-21]. In animals, VAE displays potent antitumoural effects when administered either

directly into the tumour or systemically [11, 12]. Currently, mistletoe lectin I, an important compound of mistletoe extract, is also being produced as a recombinant and being tested for application in clinical oncology.

Further emphasis of fundamental research lays on rhythm research [22-24] quality of life [25-27] and epistemeology [28].

Cost efficiency

The results of several studies considering cost efficiency of AM indicated a positive result during long-term observation compared to conventional therapies. Besides reduction of drug expenditure, patients had fewer hospital admissions and disability days [5].

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