MISTLETOE IN TUMOUR THERAPY – a General Survey

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SUMMARY

The use of mistletoe in tumour therapy dates to Rudolf Steiner (1861 – 1925) and Ita Wegman (1876 – 1943). Today mistletoe is one of the best-studied medicinal plants. Mistletoe preparations are among the best known and most widely used medicines in complementary oncology in Germany. Mistletoe preparations from five manufacturers are approved for this application in Germany. Patients benefit from mistletoe therapy in all phases of cancer. Mistletoe therapy is used individually and mostly as a supplement within the framework of an integrative oncological therapy concept, confirmed by a wide range of therapeutic experience and numerous preclinical and clinical studies. The intention of mistletoe therapy is to support conventional therapies as well as their tolerability, tumour control, strengthening of the entire organism and improvement of quality of life.

Based on the position of mistletoe in oncology, this survey provides an overview, starting with the mistletoe preparations available in Germany, the main features of their production and application, their effects and clinical research and the results. For some time now, the entire field of oncology has been undergoing major changes, within which mistletoe therapy is continuing to develop. Basic and applied research in all the areas mentioned here is in progress. In this way, mistletoe therapy will continue to have its place and contribution to oncological therapy and for the benefit of patients in the future.

Keywords: Mistletoe, Viscum album L., integrative oncology, clinical studies

The more detailed version of this overview of mistletoe therapy, which also contains information on the biology of mistletoe and its ingredients, can be found at *https://www.naturundmedizin.de/die-mistel-in-der-tumortherapie* [1; article in German].

Introduction

According to the Robert Koch Institute, more than 500,000 people in Germany are diagnosed with cancer every year, and the trend is rising due to the ageing of our society [2]. The treatment is exhausting and often results in injury, organ loss, restrictions and stress. In this situation, many patients want to do something themselves and take the initiative to contribute to their recovery and are therefore looking for supplementary, complementary offers. A large proportion of the population in Germany makes use of these services.

A bridge to conventional medicine is integrative oncology [3], which uses complementary medical treatments to supplement conventional oncology to provide patients with the best possible care. It is a sensible overall concept that encompasses the whole person and the therapeutic relationship between doctor or therapist and patient. As part of such holistic cancer treatment, which, in addition to conventional oncology, includes, for example, psychologically supportive procedures, nutritional, exercise, artistic and care therapies, mistletoe is also used alongside various concomitant medications. The details of the treatment vary from patient to patient and are determined together with the patient depending on the disease and the resulting needs. Since mid-2021, there has been an S3 guideline on complementary medicine in cancer therapy that supports this integrative approach in oncology [4].

In addition, the entire field of oncology is undergoing rapid change. There are new successful therapies, such as the new immunological therapies (e.g. checkpoint inhibitors), which raise hopes of further improvements. As oncology changes, the contribution of mistletoe therapy will, indeed must, continue to develop and redefine its place.

The mistletoe symposia *(**https://www.mistelsymposium.de/english/**)*, which have been organised for almost three decades by various medical and pharmaceutical societies and run by the author of this article together with a group of scientists and doctors, play an important role here. Every

four years, experts from biology, pharmacy and medicine and related scientific fields come together to present and discuss the latest research and clinical findings on mistletoe in tumour therapy. The aim is to provide a comprehensive picture of the current state of scientific knowledge. This interdisciplinary dialogue recently took place at the 8th Mistletoe Symposium at the European Academy Otzenhausen in Nonnweiler (Saarland) from 9 to 11 November 2023 [5] and is to be continued with the 9th Mistletoe Symposium in November 2027. All abstracts from the 8th Mistletoe Symposium have been published in a special volume of the Journal of Integrative and Complementary Medicine and are freely accessible (until October 2026) [6]. The detailed contributions were published in a book that appeared in November 2024 [7].

Mistletoe preparations in Germany, basic features of their production

Mistletoe preparations for tumour therapy are aqueous total extracts from the mistletoe plant (→ **Fig. 1**). They are used as injectables. In Germany, they are available **from 5 manufacturers**, 4 of them from anthroposophic medicine, one from phytotherapy.

It all began more than 100 years ago: The philosopher and founder of anthroposophic medicine, Dr Rudolf Steiner (1861 – 1925), wanted to bring the organism into a new, healthy balance by „healing from within" through a specific stimulation of creative forces, in contrast to the oncology established at that time, which tended to view the tumour as a spreading local disease and treated it as such. Based on spiritual-scientific findings, he introduced mistletoe, which was previously unknown in this indication, preparation and method of application, into cancer therapy and gave corresponding suggestions and advice. These were implemented by the physician Dr Ita Wegman (1876 – 1943). They led to the first mistletoe preparations and their successful use in cancer patients in 1917 [8].

What all mistletoe preparations of the **anthroposophical therapeutic approach** have in common is that the mistletoe is harvested at different times of the year, predominantly from wild collection. Rudolf Steiner suggested producing a summer juice and a winter juice and then mixing the two in a suitable way to achieve a new state of substance and thus improved efficacy [9].

Fig. 1: Female mistletoe in winter, with ripe berries. Photo: Rainer Scheer

Tab. 1: Mistletoe preparations available in Germany for tumour therapy.
Information on all anthroposophical mistletoe preparations:
https://www.mistletoe-therapy.org/information-for-patients/preparations

Name	Manufacturer	Ampoule size; available strengths or potency levels	Host trees*
Anthroposophic medicines			
Abnobaviscum	Abnoba GmbH, 75223 Niefern-Öschelbronn, Germany	1 ml: 20 mg, 2 mg, 0.2 mg, 0.02 mg, D6, D10, D20, D30 according to HAB** prescription 32	A, Ac, Am, B, C, F, M, P, Q
Helixor	Helixor Heilmittel GmbH, 72348 Rosenfeld, Germany	2 ml: 100 mg; 1 ml: 50 mg, 30 mg, 20 mg, 10 mg, 5 mg, 1 mg, 0.1 mg, 0.01 mg	A, M, P
Iscador	Iscador AG, 4144 Arlesheim, Switzerland	1 ml: 20 mg, 10 mg, 1mg, 0.1mg, 0.01mg, 0.001mg, 0.0001mg	M, P, Q, (U)***
Iscador special	Iscador AG, 4144 Arlesheim, Switzerland	1 ml: 5 mg	M, Q
Iscucin	WALA Heilmittel GmbH, 73087 Bad Boll/Eckwälden, Germany	1 ml: each potentised 1:20 according to HAB** prescription 38 starting with strength H (=50 mg), then G, F, E, D, C, B, A; exception Quercus: only the strengths F-A are available.	A, C, M, P, Po, S, Q, T
Phytotherapeutic medicinal products			
Lectinol Madaus****	Viatris Healthcare GmbH, 53842 Troisdorf, Germany	0.5 ml: 0.02-0.07 mg normalised to 15 ng active mistletoe lectin (ML), determined as ML I	Host tree not mentioned in the product information

* A: Abietis = fir, Ac: Aceris = maple, Am: Amygdali = almond, B: Betulae = birch, C: Crataegi = hawthorn, F: Fraxini = ash, M: Mali = apple, P: Pini = pine, Po: Populi = poplar, Q: Quercus = oak, S: = Salicis = willow, T: = Tiliae = lime, U: Ulmi = elm.

** HAB: (German) Homeopathic Pharmacopoeia.

*** The majority of Iscador preparations are also offered as a composition with metal salt additives in D8. Iscador U is only available with added metal salts.

**** At the time of writing this article in November 2024, Lektinol Madaus was no longer listed on the Viatris website, but it was still listed in the Pharm-Net Bund drug information system. It has therefore been included in this table. Lektinol Madaus is now off the market (as of 5/2025) and is no longer listed in the PharmNet Bund directory.

Subsequently, these impulses from Steiner were realised differently by the various research groups over time. This led to different developments from manufacturer to manufacturer and ultimately to different medicinal products.

Their production is specific to the host tree. The tree from which the extract originates can be recognised by the medicinal product name, which also contains the genus name of the mistletoe host tree (➔ **Tab. 1**). Furthermore, different concentrations of each preparation or variety are offered. This means that there is a whole range of different anthroposophic mistletoe preparations on the market with different compositions and strengths. This enables individual dosage depending on the type, stage and course of the tumour. When selecting the host tree and the dosage, the recommendations of the respective manufacturers of mistletoe preparations should be observed.

The mistletoe preparation used in **phytotherapeutic therapy**, on the other hand, is harvested from one host tree species at one time and is only available in one strength.

Some (a few) mistletoe preparations are standardised to mistletoe lectins, although these are not the sole determinants of efficacy, but are only one group of numerous relevant ingredients that contribute to efficacy.

Mistletoe preparations from all manufacturers are filled into glass ampoules **under aseptic conditions after sterile filtration**, as mistletoe lectins and viscotoxins are **heat-labile** and therefore cannot be autoclaved. Further details on the production of all anthroposophical mistletoe preparations are published in the journal Der Merkurstab in issue 3 from 2021 [10].

On the use of mistletoe preparations

Mistletoe preparations are authorised in Germany (depending on the manufacturer also in other countries) for the treatment of oncological diseases in adults. The anthroposophic mistletoe preparations have a common product information and package leaflets [11] with only a few preparation-specific, i.e. different, contents.

Mistletoe preparations are used – according to the instructions for use – in adults for the treatment of all malignant tumours, including those with accompanying disorders of the blood-forming organs, benign tumours, for recurrence prophylaxis after tumour operations and for defined precancerous conditions. Mistletoe preparations are usually administered subcutaneously. Intravenous use is only authorised for Lektinol Madaus (off the market, ➔ **Tab. 1**) and for some so-called potentised preparations, e.g. from D10, but is also practised with higher dosages in the context of studies or in so-called off-label use after the patient has been informed by the treating physicians.

Each mistletoe therapy is individualised. Details are described in the respective product information and instructions for use. Detailed brochures on mistletoe therapy can also be requested from each manufacturer (➔ **Tab. 1**).

Off-label use

Off-label is understood to mean applications outside of the approved authorisation. In the case of mistletoe therapy, there are other types of application than the authorised subcutaneous application (see above), such as intravenous, intravesical (e.g. instillation into the urinary bladder), intrapleural or intratumoral. This also includes a dosage regimen other than the authorised one, for example starting directly with high doses. Scientific data on off-label use is available [12 – 15].

Although not the rule, remissions or impressive disease stabilisation have been observed in individual cases with mistletoe therapy alone – especially when given intratumorally in high doses (e.g. [16, 17]). In addition to the immunomodulating properties, the cytotoxic, apoptosis-inducing properties of mistletoe preparations also come into play.

Such off-label applications should only be carried out by specialists already familiar with mistletoe therapy under close clinical supervision. Off-label applications of mistletoe that exceed the authorisation are also generally considered safe in the hands of experienced physicians (see also the following section on efficacy). They require the patient's written consent.

The effectiveness of mistletoe

Study situation

The effects of mistletoe preparations have been proven by a wide range of therapeutic experience and numerous clinical studies. It began as early as 1921 with the first case reports by Dr. Ita Wegman. There was talk of improvement in subjective well-being, sleep, appetite, reduction in pain and no further weight loss in advanced tumour disease [18]. Subsequently, there were more and more such reports. The first studies were carried out by committed doctors with the aim of reviewing their practical experience and placing it in the context of the relevant knowledge. Well over 150 clinical studies have now been published: on various cancers – e.g. breast and lung cancer, gastrointestinal tumours (e.g. colon, liver and pancreatic cancer) and many more – at different stages and with different questions and objectives, such as the influence of mistletoe therapy on survival time, quality of life and tumour growth. One third of these studies are prospective comparative studies.

The quality of these studies varies. Sometimes a downgrading of the quality in the study assessment is also due to the fact that very few comparative studies in the mistletoe group are blinded [19]. The quality of studies has improved over the years, but the requirements have also increased. Today, the requirements for modern clinical trials are very high due to organisational, infrastructural, bureaucratic and legal hurdles, as are the costs, which can be in the 7- to 8-digit range depending on the effort involved.

There are also numerous reviews assessing the clinical efficacy of mistletoe preparations in the treatment of cancer [20 – 28, 30 – 35]. However, even these are of varying quality and are unfortunately also partly characterised by the dispute between representatives of conventional and complementary medicine [29].

Results of the studies

Clinical studies with mistletoe preparations consistently report that mistletoe therapy in cancer patients primarily leads to a better quality of life and to an improvement in the tolerance of chemotherapy. The general state of health improves, as do energy and joie de vivre, emotional well-being, concentration, sleep and appetite. Patients also suffer less from exhaustion, nausea, vomiting, pain and shortness of breath, and they are less burdened by sadness, anxiety, depression, irritability and worry. They also show improved self-regulation, i.e. autonomy and self-activity, which enables them to achieve an inner balance and a feeling of competence and security in stressful situations, for example.

There is good evidence that subcutaneous mistletoe therapy prolongs the survival time of tumour patients. A prospective randomised study conducted in Serbia with patients with advanced pancreatic cancer and published in 2013 should be highlighted here [36]. Here, a statistically significant advantage was shown for overall survival with mistletoe therapy with a significantly better quality of life. However, this result could not be confirmed in a follow-up study conducted in Sweden [37].

The question of whether mistletoe preparations have a direct effect on the tumour has not yet been answered in the above-mentioned controlled clinical trials. There are only a number of smaller studies on this question: a phase I/ II study on dose finding, safety and efficacy in bladder cancer [14], observational studies or case series and a number of very well documented case reports showing tumour regression under mistletoe therapy. Mistletoe preparations were usually administered in high doses and close to the tumour. Overall, however, such tumour regressions are rarely observed with mistletoe therapy.

Furthermore, the safety of mistletoe therapy has been investigated in clinical studies, systematic reviews and health outcome research studies, with the result that mistletoe therapy is considered safe. It is characterised by good tolerability with only mild side effects; there is usually a localised inflammatory reaction around the injection site of the subcutaneous injection at the beginning of the therapy, possibly also a slight increase in body temperature. Serious or life-threatening events have not been observed [38 – 41].

Health outcome research

Clinical studies generally only depict specific, narrowly defined clinical situations set out in a study protocol with inclusion and exclusion criteria, but not the reality of everyday therapy. Health outcome research is there to answer all other questions, for example when it comes to the implementation of findings from clinical research in everyday therapeutic practice, or to the comparison between therapy concepts and their efficiency, also from a cost perspective. This requires instruments such as databases, registry data (cancer registries) or forms of study that do not intervene in a therapy, but only observe it and collect the necessary data. These are the long-established observational studies (non-interventional studies), a form of study that is suitable for investigating the safety of drugs after they have been authorised and launched on the market. Regulatory authorities are increasingly allowing such data to support clinical questions about efficacy (e.g. in the case of indication extensions) [42].

One such large database is the so-called "Network Oncology", set up and operated by the Havelhöhe Research Institute (FIH). It is used to collect diagnostic and treatment data from cancer patients in a structured manner following their consent to research integrative oncology concepts, their implementation and results, and to compare them with other concepts and thus contribute to improved patient care. In this context, the above-mentioned studies on the safety of mistletoe therapy [38-41] were conducted, as well as studies on interactions with other drugs. Mistletoe preparations do not have a negative effect on other cancer therapies. This has been shown for anti-hormonal substances that are mainly used for breast cancer (e.g. tamoxifen, anastrozole) and some antibody therapies (e.g. trastuzumab, pertuzumab). However, no negative effects were found with immune checkpoint inhibitors (e.g. ipilimumab and nivolumab) either. The side effect profile of modern immunotherapeutics was not intensified or extended [43 – 46]. An initial positive effect of mistletoe in this context was shown in a study from health outcome research, in which additional mistletoe therapy was able to significantly reduce treatment discontinuations in the context of targeted therapy, including with immune checkpoint inhibitors, by half [45].

Furthermore, a reduction in pain, nausea and vomiting was observed when mistletoe therapy was combined with radiotherapy [47].

Future developments in mistletoe therapy

The future of mistletoe therapy is taking place within a changing oncology with a multitude of promising new therapies and numerous new oncological drugs. Targeted therapies and personalised medicine are also part of the new tools in oncology and not only there. Added to this is the development of vaccines, in particular mRNA-based vaccines, which are said to have great potential to generate immune responses. Currently, therapy with the so-called new immunotherapeutic agents (e.g. checkpoint inhibitors) is being developed. These do not act directly on the tumour but instead enable the body's own immune system to attack the tumour cells efficiently by blocking important checkpoints. However, they can also lead to significant side effects, meaning that not all patients can benefit from these therapies. In this environment, mistletoe therapy must continue to prove itself and possibly redefine itself.

That means,

a) the existing therapeutic options for **mistletoe in combination with modern immunotherapeutics** in particular must be further investigated both preclinically and clinically. This will not only improve the safety of these combination therapies, but the additional benefits and limitations of mistletoe will also become clearer. Concepts from **health outcome research** are initially ideally suited for this purpose. However, good **randomised clinical trials (RCTs)** should follow whenever possible. For example, an observational study is currently being conducted in patients with advanced non-small cell lung cancer under routine joint therapy with immune checkpoint inhibitors (nivolumab, pembrolizumab) and mistletoe preparations [48].

b) gain further insights into **off-label applications** to utilise the cytotoxic and immunomodulatory properties present in mistletoe. This is precisely one of the strengths of mistletoe preparations, combining broad immunological with specific antitumour properties with high sensitivity. As a result, permanent remissions and impressive disease stabilisation have repeatedly been achieved in the past. Based on further successful applications, it is possible to increase knowledge about this and, on this basis, to conduct studies and seek marketing authorisations. Projects that are a-l ready being implemented include **intra-vesical** high-dose instillation into the bladder for superficial non-invasive bladder cancer, which is currently being tested in an RCT [49] and **intravenous application** [12].

c) to open new application possibilities for mistletoe with **innovations**, for example for **targeted therapy using new liposomal preparations**. A corresponding research project has been launched [50].

d) to conduct **basic research**, for example to further investigate the **biology of mistletoe** to better understand its properties and special features and to derive new therapeutic concepts and develop **new applications**. Work is already underway on the triterpenes [1].

In addition to the influence of changing oncology, the influence of requirements from the regulatory environment to maintain mistletoe preparations on the market, for example due to official and legislative requirements and conditions, must not go unmentioned in the future scenario described. Increasing regulatory requirements in all areas are also tying up more and more resources. As mentioned above, the costs for a clinical trial are in the millions and often exceed the annual turnover of medium-sized mistletoe preparation manufacturers. On the other hand, the implementation of research into clinical issues is becoming increasingly complex, for example due to regulatory requirements, marketing authorisation, drug safety or even therapy research initiated by doctors. As a result, medium-sized manufacturers have reached the limits of their economic possibilities, and the question must be asked as to whether there is not also a social responsibility here to ensure the supply of patients with effective and tested herbal medicinal products such as mistletoe preparations and to carry out manufacturer-independent clinical research with public funds.

All in all, this scenario shows that there are still many uncertainties and risks, and some future developments are still unimaginable today. But the fact is that mistletoe is used to produce effective, high-quality, safe and harmless medicines that help cancer patients, usually as part of integrative therapy concepts. Furthermore, the potential of mistletoe therapy is far from exhausting.

Conflict of interest

The author is employed part-time as a Qualified Person (QP) at Abnoba GmbH.

Translation

The translation into English was done by the author of this article.

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The original article is published in German in Zeitschrift für Phytotherapie 2024; 45: 267-274; DOI 10.1055/a-2346-8163, ISSN 0722-348X.