Part IV ANNEX TO CLINICAL DOCUMENTATION

Routes of Administration for Homoeopathic Drugs

Parenteral Administration

(Parenterale Anwendung homöopathischer Arzneimittel)

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The application of parenteralia in homoeopathy

1. Introduction

Homoeopathic drugs can be used in all traditional routes of administration in accordance with the experience and conceptions of homoeopathy. This also includes the parenteral means of application i.v., i.m. s.c. and i.c. Up till now there are no known risks that go beyond a general risk caused by the way of administration.

On the basis of their way of application injections firstly require certain medical knowledge and manual skills. For this reason the parenteral administration is not carried out by the patients themselves, but by physicians. The parenteral application offers the certainty in therapy, that the concerning remedies are actually administered at the right time in the designated dosage. This results in a clear improvement of the compliance. In addition it is known from therapeutic experience that the onset of parenteralia begins clearly faster than with the oral administration.

The following aspects can be set out as general advantages of the parenteral application in the therapeutic practice:

- An application can take place in local pain points
- Because of the various possibilities of the s.c., i.c., i.m. application the depth of the injection can vary each time according to the tissue area that needs to be treated.
- Because of the parenteral application the patient compliance is in any case guaranteed.

Homoeopathic remedies have been available in many European Union countries, and very much in Germany, and throughout the world since the nineteen sixties. Many physicians, including general practitioners, rheumatologists and orthopaedic surgeons share the advantages of giving injections with homoeopathic products for a variety of clinical medical problems.

2. What is the clinical importance of homoeopathic injections?

The clinical importance of homoeopathic injections has recently gained international recognition since the introduction of the term "**Biopuncture.**" (1, 3, 7). It is a new term in the field of natural medicine that describes any form of homoeopathic injections. This term will give this technique more exposure, both for the medical doctors as for the patient.

Biopuncture reflects the empiric knowledge of many medical doctors today in the field of homoeopathic so-called "**biotherapeutic**" injections. The basic principles, theoretic background, clinical research and practical application of this technique is described in "Biopuncture and Antihomotoxic Medicine" (8). In this textbook (250 p.), J. Kersschot (M.D., Belgium) describes the use of homoeopathic injections in very specific areas of the patient's body. Several presentations have been given on an international level regarding "biopuncture" (2, 4, 5, 6, 17).

Clinical practice all over the world is demonstrating that the local infiltration of one specific homoeopathic product has an additional effect that can not be achieved by giving the same remedy as an oral product or applying a topical preparation. The oral application does not give rise to the high tissue concentrations of the biotherapeutic product in the target area, and the application of that product in a topical way does not penetrate deep enough in most cases. Injecting the homoeopathic product right at the spot where the physician wants it, is the only solution here in order to have excellent and immediate results. This is especially clear when for example injecting Traumeel® or Zeel® (9, 10, 11, 12, 14) (both complex homoeopathic products) into the synovial cavity of the knee joint.
But there are more injection techniques possible besides the intra, articular application. Several other techniques are used in biopuncture, indeed. Biotherapeutic liquids are injected subcutaneously in organ reflex zones (segments) to treat the function of the organs involved. There are also specific techniques to treat musculoskeletal conditions: for the treatment of myofascial pain one can give intra-muscular injections of homoeopathic remedies in the pain zone, in pain points and in myofascial

trigger points (15, 16). Regarding orthopaedic problems, there is of course also the possibility of giving infiltrations in specific areas of the musculoskeletal system: infiltrations of ligaments, bursae, as well as peri-articular injections.

3. Why do physicians prefer parenteral application when tablets and drops are available?

3.1. Enhanced activity via injection

The physician can benefit from the knowledge that, when he injects in an acupuncture point as well as in the zones of Head (Segment therapy), each segment or acupuncture point on the respective meridian is classified and corresponds to a specific organ or tissue. By means of an injection (needle effect) the specific organ or tissue is being stimulated as well as from the injectable homeopathic solution. This homoeopathic injection can be a simple or a complex preparation. By this double stimulus – mechanical stimulus and the activity of the homoeopathic preparation - a synergistic therapeutic effect may result.

In a survey (18) conducted by Heel with 327 doctors in 1999/2000 evaluating the advantages of homoeopathic injectable therapy in daily practice as compared to the oral administration form the outcome yield the following opinions:

- improved effect (77.1%)
- improved tolerance (38.5%).
- improved therapeutic control (57.2%)
- improved possibility of focused administration (72.8%)
- improved biological availability (45%)

3.2. Better patient compliance

When a medical doctor doubts the patient's compliance regarding the medication he prescribes, injections give maximum therapeutic control. Indeed, the physician is 100% sure that the remedy prescribed is actually taken by the patient, because the doctor is injecting the remedy immediately during the visit in his or her practice.

3.3.No change of the homoeopathic drug component

The product is not passing the gastrointestinal system (stomach, intestinal tract), and is not subject to the enzymes of the mouth, the acidity of the stomach and the pancreatic enzymes in the duodenum. Furthermore, there is no first-pass effect in the liver. As a result, the physician can expect more clinical results because the biotherapeutic agent is reaching the tissues and the intercellular space unaltered.

3.4. When oral application is not possible

Medical doctors choose to give injections to those patients who have difficulty in swallowing drops or tablets. This is especially true for patients who are hospitalised. These injections are given iv, sc or im.

3.5. To avoid side effects of oral application

When a patient reports that the oral application of a biotherapeutic product shows side effects (e.g. gastrointestinal), the same product may be injected to avoid such side effects. These injections are given iv, sc or im.

4. Why do physicians choose to give *local* parenteral application?

There is a wide range of reasons why a physician can decide to give a specific *local* injection with a biotherapeutic product. In other words, the medical doctor judges the need to inject the product as close as possible to the target (zone, tissue) he or she wants to influence. It is clear that administering the product in the target area prevents that the active product will be diluted in the entire blood circulation which spreads the product through the whole body. In order to prevent that the product is 'spoiled' in those areas which do not need any treatment, a localised application is the only solution. From a clinical point of view, there are five major reasons to give a local injection:

4.1. A more rapid onset of therapeutic action

It is obvious that a local injection right at the spot will give rise to a more rapid onset of therapeutic action because the active product arrives right at the target (e.g. trauma, inflammation, trigger point). When treating tennis elbow, the physician injects in that specific region of the elbow, when treating low back pain, the physician will inject in that specific region of the low back, and so forth. This strategy allows the physician to respond directly to the patient's needs.

4.2. To reach those areas in the body which can not be reached through oral application

In order to reach those areas in the body which are not reached through oral application, direct application on the spot can only be attained through deep injection (several centimetres). This is a very common use of biotherapeutic injections, indeed. Especially the intra-articular injections show supplementary clinical effects which can not be reached when giving the same product orally (e.g. injection in the knee joint or shoulder joint).

4.3. Additional segmental reactions

Many physicians have experienced that specific zones on the surface of the body (the skin and the subcutaneous tissues) are related to internal functions related to specific organs (zones of Head). This observation has also lead to a lot of therapeutic measurements, where the application of heat, cold, pressure, needles and injections can influence the functions of the correlated organs (e.g. on the abdomen for the liver, on the thorax for the bronchi). Clinical practice has shown that giving injections with biotherapeutics into the segment of one specific organ can influence the healing capacities of the body in that area.

4.4. Additional neuromuscular reactions

A wide range of minor orthopaedic clinical disorders can be treated using biotherapeutic injections in myofascial trigger points. When injecting into myofascial trigger points, several mechanisms are observed which may explain the extra clinical effects observed (20):

- local muscle spasms are released
- there is a decrease in intramuscular pressure
- there is an inactivation of nociceptors in those muscles
- there is less release of algogenic neuropeptides by activation of nociceptors

As a result of these mechanisms, myofascial pain can be treated more effectively using injections. This is especially true for the treatment of for example low back pain and whiplash.

4.5. Additional neurological reactions

When injecting into or near peripheral nerves (or nerve endings), the physician can expect additional clinical effects, especially regarding neuropathic pain patterns (21). This technique is commonly used for the treatment of for example cervicobrachialgia, carpal tunnel syndrome and sciatic pain.

5. When is it interesting to go for local injections with homoeopathic products?

1. The physician can choose to give injections right away, because the clinical situation definitely needs this direct approach (see 4.2, 4.3, 4.4, 4.5).

2. The physician can conclude to give injections when other local treatments had to be stopped for major side effects (e.g. injections of corticosteroids)

3. The physician can decide to give injections when other local treatments like physiotherapy, injections of allopathic remedies, surgery, did not succeed

4. The physician can choose to give injections when an oral treatment with biotherapeutics has been unsuccessful for that particular patient.

Conclusion
Biopuncture is a technique in today's medicine which matches both the standards of mainstream medicine as well as natural medicine. It is acceptable in mainstream medicine because it respects the traditional medical diagnosis. Many physicians combine biopuncture with allopathic medicine, if necessary. On the other hand, biopuncture is a medical technique which also respects the laws of natural healing, and uses products which have less side effects than the allopathic remedies used in such cases.

6. Background and clinical proof of the efficacy of homoeopathic injectables

6.1. Animal studies

- Prof. Cazin (22), university of Lille (1987), demonstrated in a single blind study on 696 rats the therapeutic draining effect of injected C5-C15, D10-D30 Arsenicum. This is being confirmed in practice by Blostin (23) on the "International Congress for Veterinary Homoeopathy" in Zutphen, The Netherlands (1990). Doctor Blostin describes how fifty dogs and cats were treated with injections of Arsenicum 15CH after neurotoxic symptoms. The dog intoxicated by Arsenicum is normalized two hours after the first injection. Dr. Blostin reports that only 8% of the animals who were injected died, as opposed to traditional treatment with a death rate of 50%.

- Another research was conducted by Oberbaum et al. (24) at the Hebrew University Hadassah Medical School in Jerusalem (1997). Wounds induced at the auricle of female mice (C57B1/6, 12-16 weeks old) in 13 different groups of 10 mice each, were treated with various dilutions of Silicea (C5, C30 and C200). For the evaluation the procedure of 'image-analyser' was applied, which allows to objectify the influence of the medication on the healing of the induced wounds.
  The administration of the homoeopathic drugs was done by means of intra-peritoneal injections in groups 1 and 2 and orally in groups 3 to 13. In the preliminary study a significant difference can be observed between de mice being treated with homoeopathic injections and those who didn't receive any Silicea-injections. The initial difference stayed for the whole duration of the experiment (32 days).

- In a study on rats (DA-HAN) Reber et al. (25) demonstrate the effect of peritoneal injections of Cocculus (4CH, 7CH and 15CH) in induced horizontally optokinetic nystagmus and in vestibulo-ocular reflex by toxic doses of the plant extract Anamirta cocculine. The reflexes returned to normal after injection of Cocculus 4CH. A clear improvement was observed after the injection of Cocculus 7CH and 15CH.

- Conforti et al. (26) compared homoeopathic injections with the injection of a saline solution on the induced oedema of the paw of guinea pigs. They observed that the reduction of the oedema was clearly faster with the verum than with the placebo group ($p<0.05$ after 3 hours and $p<0.01$ after 5 hours), in spite of an identical oedema development during the first hour after oedema-induction in the verum- and the placebo-group. It was also demonstrated that the therapeutic activity of the homoeopathic complex was higher than that of its separate homoeopathic components. Besides a clear reduction of the oedema, also a significant reduction of IL-6 was observed. Both the

Pharmacological Institute of the University of Verona, Italy, as well as the Institute for Chemistry and Clinical Microscopy of the same university cooperated in this research.

6.2. Human pharmacology

- In two in vitro and one controlled prospective single blind study Wagner et al.(27) report in 1986 the increasing granulocytosis after the use of complex homoeopathic drugs, using i.v. injections. The aim was the difference in result between the use of 3 different complex homoeopathic drugs and a combination of the first and second complex in a third complex. Consequently 4 study designs were made in total. A granulocytosis rise of 41% was reached after five days with a combined injection of two homoeopathic complex drugs. A sustained administration of the homoeopathic drug caused after five days an accelerated decrease of the granulocytosis, according to the authors caused by an "exhaustion" of the defence system.

6.3. Clinical studies

6.3.1. Drug monitorings on Zeel® (complex homoeopathic product) injections for chronic knee-joint problems

Several drug monitorings have been performed with the purpose of gaining more knowledge with regard to the therapeutic application in the practice of the injectable solution Zeel® (ref. 10, 11, 30, 31).

- In the first study (10), no other patients have been included than those suffering from arthrosis of the knee. Zeel® was injected by the intra-articular route exclusively. A number of 190 orthopaedics participated in the drug monitoring, 1845 patients were treated with Zeel® and monitored during four months. The orthopaedic doctors recorded the results obtained on standardized form sheets, containing information about anamnestic data, adjuvant medications, additional non-drug therapies, scope of treatment, assessment of therapy, and tolerance. In this follow-up monitoring, physicians assessed the stiffness of the knee-joint and the intensity of pain found during each medical attendance. Within the scope of a series of intra-articular injections, the physicians found that the efficacy of the treatment was statistically evident. On an average, every patient was given 2 injections in a week, over a period of one month. A regression of the symptoms was statistically demonstrable after no more than two injections. Another important feature of the treatment was its safety: the tolerance of Zeel® injections was very good; side effects were reported in 0.45% of the cases. The side effects occurring were local inflammatory signs exclusively; all of the side effects were reversible.

- Another drug monitoring on 446 patients has been performed with the purpose of gaining more knowledge with regard to the intra-articular application of "Zeel® comp." (11). Thirty-two orthopaedic surgeons took part in this study to collect the data with regard to the therapeutic application as well as to the efficiency and tolerance of Zeel® comp. in the treatment of chronic arthritis of the knee joint. The orthopaedic doctors gave an intra-articular injection of one ampoule of Zeel® comp. twice a week, and recorded the results obtained on standardized form sheets, containing information about anamnestic data, adjuvant medications, additional non-drug therapies, scope of treatment, assessment of therapy, and tolerance. They observed that after one month of treatment 90% of the patients achieved a positive therapeutic result (pain, stiffness in the joint). This efficacy was statistically obvious (11, p.118). Another important conclusion of the orthopaedic surgeons was that the tolerance of the injection was good; no aggravating adverse events occurred.

- Another drug monitoring was published about the use of peri-articular applications of Zeel® comp by German orthopaedic surgeons (31). In total 643 patients suffering from osteoarthritis of the knee got a peri-articular injection of Zeel® comp, with (51%) or without (49%) another additional therapeutic strategy. In the course of the treatment initial pain, pain following exercise, continuous pain as well as joint stiffness were decreasing linearly in the majority of patients (31, p.159). In 46% of the cases, a local anaesthetic was added. The tolerance of the injections was good; only 5

(0.8%) of the patients showed minor complications (in the whole study, 5531 injections were given).

- A multi-centre, randomised, single blind controlled study (30 = German publication, 32 = English publication) compared the efficacy and tolerance of intra-articular injections of Zeel® comp (only available in Germany) with intra-articular injections of Hyalart® (hyaluronic acid); (34). Out of 121 patients, 114 patients were accepted in the clinical study; each group got 2 intra-articular injections of 2 ml, twice a week during 5 weeks. The key parameters were intensity of pain during exercise, and global assessment of tolerance; both groups gave similar results (54% in the Zeel® comp group and 59% in the Hyalart® group), except for the reported concomitant effects (11% in the Zeel® comp group and 23% in the Hyalart® group). In both treatment groups, the most frequently reported side effects were signs of local inflammation or irritation after the i.a. injections (32, p.186).

6.3.2. Drug monitoring on Traumeel® (complex homoeopathic product) injections in musculoskeletal disorders

A multicentric drug monitoring trial (9) conducted on 3,241 patients investigated the effectiveness, the mode of application and the patient tolerance of this ampoule preparation. Most of the patients were suffering from gonarthrosis, coxarthrosis, periarthritis humeroscapularis, epicondylitis, and were treated with an intra-articular or peri-articular injection. Of all patients, 47% received adjuvant medicamentous therapy, and 65% obtained non-medicamentous therapy which included massage, applications of heat and cold, and electrotherapy. In 78.6% of the treated patients, the results were formally assessed as "very good" or "good". The tolerance to the preparation was good. So, we can concur with the authors, that the ampoule preparation may be considered as a low-risk therapeutic agent for treatment of the consequences of traumata, as well as for therapy of inflammatory and degenerative processes concerning the musculoskeletal system (9).

6.3.3. Double blind test on Traumeel® S (complex homoeopathic product) injections in traumatic hemarthrosis of the knee joint

- In 1991, W. Thiel (M.D.) and B. Borho (M.D.) published a randomised, placebo-controlled double-blind test (36 = German publication, 37 = English publication). Since Traumeel® had already been tested in a double blind placebo controlled study as an ointment, they tried to check on Traumeel® injections. They treated 73 patients with traumatic haemarthrosis of the knee by intra-articular injection of either Traumeel® (as drug therapy) or isotonic saline solution (as placebo). These injections were given 3 times in 8 days. The evaluation of the treatment was checked by the movement restrictions, the circumference of the joint, and the need for further puncture and therapy.
  The Traumeel® group scored better in every aspect, and not one patient in the Traumeel® group experienced major side effects along with their therapy.

6.3.4. Double blind testing on Engystol® (complex homoeopathic product) injections

- Engystol® is a non-specific immunostimulator, and used mainly for the treatment of flu, pertussis, stomatitis, herpes zoster, asthma, etc. (38) Wagner (University of Munich) investigated the in-vitro phagocytosis increase due to Engystol® and found considerable increases in the rates of phagocytosis with the granulocyte test (39).

- In 1992, A. Heilman (M.D.) published a randomised, placebo-controlled double-blind test with Engystol® on 102 influenza-patients (40 = German publication, 41 = English publication). A comparison was made between the effectiveness of intravenous administration of Engystol® and of isotonic saline for prophylaxis of flu and common colds. The Engystol® group scored better, especially for the clinical parameters.

- A similar study was done in Warschau for the treatment of 128 infants hospitalised for RSV or Respiratory Syncytial Virus infection (42); differences in clinical parameters (faster regression of

symptoms like dyspnoea and cough) and in laboratory tests (increase of phagocytosis activity: ref. 42, figure 3) were registered in the verum group.

- In 1995, Prof. Ryszard Matusiewicz published a randomised, placebo-controlled double-blind test on Engystol® (43 = German publication, 44 = English publication). Engystol® is indicated to activate the non-specific defensive mechanism, particularly in the case of viral diseases. In the summary of his article, Matusiewicz states: "In the search for less harmful methods in the treatment of corticoid-dependent bronchial asthma, a double blind randomised study was carried out in 40 patients. All of them were taking triamcinolone for more than 5 years, 4 to 8 mg. a day. Twenty patients received one ampoule Engystol® subcutaneously at intervals of 5 to 7 days, the remaining 20 patients received placebo." The following was measured for each patient: spirometry, granulocyte function and several clinical parameters.

- The results show that Engystol® is able to improve various clinical parameters in steroid-dependent bronchial asthma and allows for a reduction of the steroid doses. Therefore, the author concludes that Engystol® can be an effective and side-effect free drug in the therapy of bronchial asthma (43, p.242). The explanation for the clinical improvement after the administration of Engystol® may be associated with the non-specific, anti-inflammatory action of the preparation on the respiratory system (44, p.73); other possible mechanisms are: inhibition of the release of peroxide aminoradicals in granulocytes of peripheral blood (44, p.73), decreased release of peroxide aminoradicals by granulocytes (44, p.74) or stimulation of the migration ability of the granulocytes (44, p.74); the latter is especially disturbed among steroid-dependent asthma patients (45).

6.3.5. Double blind test on Traumeel® (complex homoeopathic product) in steroid-dependent bronchial asthma

- Asthma can be considered as a chronic inflammatory disorder of the respiratory tract. Many cells play a role in these phenomena, including neutrophils, basophils, eosinophils, macrophages and lymphocytes (46, p.107). In allopathic medicine, the therapy is focused upon anti-inflammatory medication, particularly inhalation of corticosteroids. Large-scale clinical studies have shown the positive effect of this treatment. Those doctors who look for a similar approach, but who want to avoid the possible side effects of corticosteroids, can administer subcutaneuos injections (46) of a product such as Traumeel®.

- In 1996, Prof. R. Matusiewicz published a randomised, placebo-controlled double-blind test on Traumeel® S (46). In the search for less harmful methods in the treatment of corticoid-dependent bronchial asthma, a double blind randomised study was carried out in 103 patients. A control group of 20 healthy persons was used to compare them with the patients in the testing period. All the patients were taking triamcinolone for more than 5 years, 4 to 8 mg a day. The "verum" patients received one ampoule Traumeel® S subcutaneously at intervals of 5 to 7 days, the other patients received placebo. The following was measured for each patient: spirometry, serum immunoglobulines (IgE, IgA, IgG, IgM), Clausen-Test (46, p.108), Park-Test (46, p.109), Bellavite-Test (46, p.109) and the daily dosis of corticosteroids. The results show that Traumeel® S is able to improve various parameters in steroid-dependent bronchial asthma and allows for a reduction of the daily steroid doses (46, p.111: figure 4).

- In 1997, Prof. Matusiewicz published a randomised, placebo-controlled double-blind test on i.m. injections of Traumeel® S *and* Engystol® N (48). In this study, he treated 50 patients with corticosteroid-dependent bronchial asthma with the immunosuppresive agents methotrexate (group 1) or ciclosporin (group 3) in combination with Traumeel® S and Engystol® N (group 2a and 4a) or placebo (group 2b and 4b). The i.m. injections were given every 3 or 4 days. All the patients were taking triamcinolone since more than 1 year. After six weeks, an important reduction of the cortisone intake could be realised in the Traumeel® + Engystol® groups (group 2a and 4a), without affecting the spirometric results (48: tab 1-6).

6.3.6. Miscellaneous

- In 1998 Timmermann et al. (49) published the results of a study (N=76) conducted over three years. It was an observational study of patients with complaints about the spinal column. An injection therapy with a complex homoeopathic therapy was followed. Although in the majority of the patients a clear improvement occurred already after four weeks, the result was remarkably better after 16 weeks.

- Hieber (47) reports an investigation of 100 patients with degenerative changes of the large joints that had been demonstrated with X-rays. Four different suis-organ preparations (homoeopathic preparations of organ tissue of porcine origin) are injected 6 times intra-articularly in the first four groups, leaving each time one day without therapy between each injection day. Group five received at the same rate a mixture of the four different homoeopathic organ preparations from the four earlier groups. Although the four separate groups already achieved good results, the results of group 5 (mixed injection) are distinctly better. The mixed injection obtains the evaluation "very good" to "good" in 21/22 as opposed to 24/28 for group 1, 12/17 for group 2, 15/19 for group 3, 13/14 for group 4. This study once more confirms the surplus value of a mixed injection (or complex homoeopathic formula) as opposed to the single use of homoeopathic drugs.

- Finally we would like to refer to the numerous scientific studies that have been conducted with regards to the injection of homoeopathic remedies. An investigation was done with 190 clinical investigators, all orthopaedists, on 1845 patients with gonarthrosis. A complex homoeopathic remedy was repeatedly injected intra-articularly. Approximately 18,000 intra-articular injections were administrated and evaluated – Weiser (28) (1993).

7. Review of parenteral administration of various homoeopathic substances

Homoeopathic drugs are often injected in the so-called skin points (points of Weihe, acupuncture points, homeosiniatry points) (19) (Zimmerman & Csallner 1985 (58); Schoeler 1952 (59); De La Fuye & Schmidt 1975 (29, 35, 60); Ebert 1992 (61); Veith 1979 (62); Schrecke & Wertsch 1992 (63); Pothmann 1992 (64); Geyer 1994 (57); Finkel, 2000 (13)). In many cases the i.c. quaddling is preferred to the s.c. application.

Around 1875 August WEIHE, a homoeopathic physician, discovered that certain (painful) pressure points on the body correspond to certain homoeopathic products. Weihe found 195 of such points (which show distinct similarities to the segmental zones named after HEAD, published in 1957) (28).

However, it was De la Fuye who discovered in the 1930-s that the 105 Weihe points correspond to the localised points of classical Chinese acupuncture (Weihe himself was not familiar with acupuncture). After many years of experience De la Fuye increased this number with another 129 corresponding pressure points (corresponding to acupuncture points and homoeopathic remedies) which he called very appropriately "homeosiniatric" points (homeo = similar, siniazio = to puncture).

Over the years quite a number of variants on homeosiniatry have developed. Zulla (56) describes on page 19 of his book "Akupunktur und Hoömopathie" (1977) a modified form of homeosiniatry. Zulla wheals or quaddles (intra-dermal injections with vesicles) with a complex or single homoeopathic remedy. He primarily uses this method when either the applied homeopathic simillimum or the acupuncture treatment did not achieve the desired results. The injection of the homoeopathic remedy in the acupuncture points was felt to offer a "synergetic" action superior to either applied alone.

The practice of applying homoeopathic drugs in these points has to be seen independently from the indication. At the most, different areas of application are chosen, as is the case with different points of Weihe or acupuncture points.

The practice of the intracutaneous (or i.c.) application of the components of the below-mentioned remedies are documented by the following literature sources:

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Abrotanum	X	X	X	X	X	X
Absinthium	X	-	-	-	-	-
Aceton	-	-	X	-	-	-
Acetylcholin-chlorid-Injeel	-	-	-	-	X	-
Acetylsalicylsäure	-	-	-	-	X	-
Acidum benzoicum	X	X	X	X	-	X
Acidum carbolicum	-	-	X	-	-	-
Acidum fluoratum	-	X	-	X	-	-
Acidum fluoricum	X	-	X	-	-	X
Acidum formicicum	X	-	-	X	-	-
Acidum hydrocyni	-	-	X	-	-	-
Acidum muriaticum	-	X	X	-	-	-
Acidum nitricum	X	X	X	X	X	X
Acidum oxalicum	X	-	X	-	-	-
Acidum phosphoricum	-	X	X	X	X	X
Acidum picrinicum	X	X	X	X	X	X
Acidum salicylicum	-	X	X	-	-	-
Acidum succinicum	-	-	X	-	-	-
Acidum sulfuricum	-	-	X	-	-	-
Aconitum napellus (Aconitum)	X	X	X	X	X	X
Actaea racemosa	-	X	X	-	-	-
Adonis vernalis	X	X	X	X	-	X
Aesculus hippocastanum	X	X	X	X	-	X
Aethusa cynapium (Aethusa)	X	X	-	X	X	X
Agaricus muscarius	X	X	X	X	X	X
Agnus castus	X	-	-	X	-	-
Agrostemma githago	-	-	X	-	-	-
Aletris farinosa	X	-	-	X	-	-
Alkohol	-	-	-	-	X	-
Allium sativum	X	-	-	-	-	-
Aloe socotrina (Aloe)	X	X	X	X	X	X
Alumina	X	X	X	X	X	X
Ambra grisea	-	-	X	-	-	-
Amidopyrin	-	-	-	-	X	-
Ammonium carbonicum	X	X	X	X	X	X
Ammonium muriaticum	X	-	-	-	-	-
Anacardium	X	-	-	-	-	-
Anacardium orientale	X	X	X	X	-	-
Angusta vera	-	-	X	-	-	-
Anhalonium	X	-	-	-	-	-
Antimonium arsenicosum	-	-	-	X	-	-
Antimonium crudum	X	X	X	X	X	X
Antimonium jodatum	X	-	-	-	-	-
Antimonium sufuratum	X	-	-	-	-	-
Antimonium tartaricum	X	X	-	X	X	X
Apis mellifica (Apis)	X	X	X	X	X	X
Apocynum cannabinum	X	-	-	X	-	-
Apomorphinum hydrochloricum	X	-	-	X	-	-
Aqua formicarum	-	-	X	-	-	-
Aralia racemosa	-	-	X	X	-	-
Aranea diadema	X	X	X	X	X	X
Argentum foliatum	-	-	X	-	-	-
Argentum metallicum	-	X	-	-	-	X
Argentum nitricum	X	X	X	X	X	X

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Aristolochia clematitis	X	-	-	X	-	-
Arnica	X	X	X	X	X	X
Arsenicum album	X	X	X	X	X	X
Arsenicum jodatum	X	X	X	X	-	X
Asa foetida	X	-	X	X	-	-
Asarum	-	-	X		-	-
Asclepias tuberosa	-	-	X	-	-	-
Atropinum	X	-	-	X	-	-
Aurum metallicum (Aurum)	X	X	X	X	X	X
Avena sativa	X	-	-	X	-	-
Bacterium coli-Injeel	-	-	-	-	X	-
Badiaga	-	-	X	-	-	-
Balsamum peruvianum	-	X	X	-	-	-
Baptisia tinctoria	X	X	X	X	-	-
Baryta jodata	-	-	X	-	-	-
Baryum carbonicum	X	-	X	-	X	-
Belladonna	X	X	X	X	X	X
Berberis vulgaris (Berberis)	X	X	X	X	X	X
Bismutum subnitricum	X	-	X	X	-	-
Borax	-	-	X	-	-	-
Bovista	-	-	X	-	-	-
Bromum	-	X	X	-	X	X
Bryonia	X	X	X	X	X	X
Bufo rana	X	X	X	X	X	X
Cactus grandiflorus (Cactus)	X	X	X	X	X	X
Cadmium sulfuricum	-	-	X	-	X	-
Caladium seguinum	X	-	X	X	-	-
Calcarea arsenicosa	-	-	X	-	-	-
Calcium carbonicum	X	X	X	X	X	X
Calcium fluoratum	X	X	X	X	X	X
Calcium jodatum	-	X	X	-	X	X
Calcium phosphoricum	X	-	X	-	X	-
Calcium sulfuricum	X	X	X	X	-	-
Calendula officinales	-	-	X	-	-	-
Camphora	X	-	X	X	-	-
Cannabis sativa	-	-	X	-	-	-
Cantharis	X	-	X	X	X	X
Capsicum	-	X	X	X	X	X
Carbo vegetabilis	X	X	X	X	X	X
Carboneum sulfuratum	X	X	X	-	-	X
Cardiospermum	X	-	-	-	-	-
Cardiospermum	X	-	-	-	-	-
Carduus marianus	X	X	X	X	-	X
Caulophyllum	-	-	X	-	-	-
Causticum	X	X	X	X	X	X
Ceanothus	X	X	X	X	X	X
Cedron	-	-	X	-	X	-
Cepa	X	-	X	-	-	-
Chamomilla	X	X	X	X	-	X
Chelidonium majus (Chelidonium)	X	X	X	X	X	X
Chenopodium	-	-	X	-	-	-
China	X	X	X	X	X	X
Chininum arsenicosum	X	-	-	X	-	-
Chininum sulfuricum	X	X	-	X	-	-
Chloralum	X	-	-	-	-	-

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Cholesterinum	X	-	-	X	-	-
Cicuta virosa	-	-	X	X	-	-
Cimicifuga	X	-	X	X	-	X
Cina	-	X	X	-X	-	-
Cinnabaris	X	-	-	X	-	-
Cistus canadensis	X	X	X	X	-	-
Clematis erecta	X	-	X	-	-	-
Cobalt metallicum	-	-	X	-	-	-
Cobaltum nitricum	-	-	-	X	-	-
Coca	-	X	X	-	-	X
Cocculus	X	X	X	X	-	-
Coccus cacti	X	X	X	X	-	X
Coffea	X	-	X	-	-	-
Colchicum autumnale	X	-	X	X	-	-
Collinsonia canadensis	-	X	X	X	-	-
Colocynthis	X	X	X	X	X	X
Condurango	X	-	X	X	-	-
Conium maculatum (Conium)	X	X	X	X	-	X
Convallaria majalis	X	-	X	X	-	-
Corallium rubrum	-	X	X	X	X	X
Corrosivus	-	X	-	-	-	-
Cortison	-	-	-	-	X	-
Crataegus	X	X	X	X	X	X
Crocus sativus	X	-	X	-	-	-
Crotalus horridus	-	-	X	-	-	-
Croton tiglium	-	-	X	-	-	-
Cumarin	-	-	X	-	-	-
Cuprum aceticum	X	-	-	X	-	-
Cuprum arsenicosum	X	X	X	-	X	X
Cuprum metallicum (Cuprum)	X	-	X	X	X	X
Cyanocobalaminum	-	-	-	-	X	-
Cyclamen europaeum	-	-	X	X	-	-
Cystisus laburbum	-	-	X	-	-	-
Damiana	X	-	-	X	-	-
Digitalis purpurea	-	X	X	X	X	X
Dolichos	X	-	-	-	-	-
Drosera rotundifolia (Drosera)	-	X	X	X	X	X
Dulcamara	X	X	X	X	X	-
Echinacea angustifolia	X	-	-	X	-	-
Engystol®	-	-	-	-	X	-
Equisetum arvense	X	-	-	-	X	X
Erigeron canadensis	X	-	-	-	-	-
Eucalyptus	X	-	-	-	-	-
Eupatorium perfoliatum	-	X	X	-	-	-
Euphorbium officinalis	-	-	X	-	-	-
Euphrasia	-	X	X	X	-	X
Evonymus	-	-	X	-	-	-
Eyuisetum hiemale	-	X	-	X	-	-
Fabiana imbricata (Pichi-Pichi)	X	X	-	-	-	X
Ferrum arsenicosum	-	-	-	X	-	-
Ferrum jodatum	X	X	X	X	X	X
Ferrum metallicum	X	X	X	X	-	X
Ferrum phosphoricum	X	X	-	X	X	X
Ferrum picrinicum	-	-	X	-	-	-
Formica rufa	-	-	-	X	-	-

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Galphimia glauca	X	-	-	-	-	-
Gamma globulin Injeel	-	-	-	-	X	-
Gelsemium sempervirens (Gelsemium)	X	X	X	X	X	X
Ginseng	X	X	-	X	X	X
Glonoinum	X	X	X	X	-	X
Gnaphalium polycephalum	X	-	-	X	-	-
Graphites	X	X	X	X	X	X
Gratiola	-	X	X	-	-	-
Grindelia	X	-	-	X	-	-
Guajacum	-	-	X	-	-	-
Gummi gutti	-	-	X	-	-	-
Hamamelis virgincum	-	-	X	-	-	-
Harpagophytum	X	-	-	-	-	-
Hedera helix	-	-	-	X	-	-
Helleborus niger	X	X	X	X	-	-
Helonias dioica	-	X	-	X	-	X
Hepar sulfuris	X	X	X	X	X	X
Histamin	-	-	X	-	X	-
Hydrastis canadensis (Hydrastis)	X	X	-	X	X	X
Hydrophobinum	-	X	-	-	-	X
Hyoscyamus	X	X	X	X	X	X
Hypericum	X	X	-	-	X	X
Hypericum perforicum	-	-	X	-	-	-
Iberis amara	X	-	-	X	-	-
Ignatia	X	X	X	X	X	X
Ipecacuanha	X	X	X	X	X	X
Iridium metallicum	-	-	X	-	-	-
Iris versicolor	X	X	X	X	X	X
Jacaranda	-	-	X	-	-	-
Jalappa	-	-	X	-	-	-
Jatrophacurcas	-	-	X	-	-	-
Jodoformium	-	-	X	-	-	-
Jodum	X	X	X	X	X	-
Juglans regia	-	-	X	X	-	-
Juniperus	-	-	-	-	-	X
Juniperus communis	X	X	-	X	X	-
Kalium arsenicosum	-	-	X	-	-	-
Kalium bichromicum	X	X	X	X	X	X
Kalium bromatum	-	-	X	-	-	-
Kalium carbonicum	X	X	X	X	X	X
Kalium chloricum	X	-	X	-	-	-
Kalium jodatum	X	-	X	X	-	-
Kalium muriaticum	X	X	-	X	-	X
Kalium phosphoricum	X	X	X	X	-	X
Kalium sulfuricum	X	-	X	-	-	-
Kalmia	X	X	X	X	-	-
Kreosotum	X	-	X	X	-	-
Laburnum	X	-	-	-	-	-
Lachesis	X	X	X	X	-	X
Lactuca virosa	-	-	X	-	-	-
Lathyrus sativus	-	X	-	-	X	X
Latrodectus mactans	X	-	-	X	X	-
Laurocerasus	-	-	-	X	X	-
Ledum palustre	-	X	X	-	X	-
Lilium tigrinum	X	-	X	-	-	-

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Lithium carbonicum	X	-	X	X	X	-
Lobelia inflata	X	X	X	X	-	-
Lolium temulentum	X	-	-	-	-	-
Luesinum	-	X	-	-	X	X
Luffa	X	-	-	X	-	-
Lycopodium clavatum (Lycopodium)	X	X	X	X	X	X
Lycopus virginicus	X	-	-	X	-	-
Lyssinum	-	-	-	-	X	-
Magnesium carbonicum	X	X	X	X	-	X
Magnesium chloratum	-	-	-	X	-	-
Magnesium muriaticum	X	-	-	-	-	-
Magnesium phosphoricum	X	X	X	X	-	X
Magnesium sulfuricum	-	-	-	X	-	-
Manganum aceticum	-	X	X	-	-	-
Manganum metallicum	-	-	-	-	X	-
Mangnolia	X	-	-	-	-	-
Marmoreck	X	X	-	-	-	X
Marum verum	-	-	-	X	-	-
Medorrhinum	X	X	-	-	X	X
Melilotus	-	-	-	-	-	-
Menyanthes	-	X	X	-	-	X
Mephitis putorius	X	-	X	X	-	-
Mercurius bijodatum	-	-	-	-	-	X
Mercurius cyanatus	-	-	X	-	-	-
Mercurius dulci	-	-	X	-	-	-
Mercurius jodatum ruber	-	X	X	X	-	-
Mercurius jodatus flavus	-	X	X	-	-	-
Mercurius praecibitatus ruber	-	-	-	-	X	-
Mercurius solubilis	X	X	X	X	X	X
Mercurius sublimatus corrosivus (Mercurius corrosivus)	-	-	X	X	-	X
Mercurius vivus	-	-	X	-	-	-
Mezereum	X	X	X	X	X	X
Millefolium	-	X	X	X	-	X
Mormordica balsamina	X	-	-	X	-	-
Moschus moschiferus (Moschus)	-	X	-	X	-	X
Muira puama	X	-	-	-	-	-
Murex purpureus (Murex)	X	X	X	X	X	X
Myrica cerifera	X	X	-	X	-	X
Naja tripudians	X	X	X	X	X	X
Natrium arsenicosum	-	-	X	-	-	-
Natrium carbonicum	-	-	X	X	-	-
Natrium chloratum	-	-	-	X	-	-
Natrium hypochlorosum	-	-	X	-	-	-
Natrium hypophosphorosum	-	-	X	-	-	-
Natrium muriaticum	-	X	X	X	-	-
Natrium nitricum	-	-	X	-	-	-
Natrium phosphoricum	X	-	X	-	-	-
Natrium sulfuricum	X	X	X	X	-	X
Niccolum metallicum	-	X	X	-	-	-
Nux moschata	X	X	X	X	X	X
Nux vomica	X	X	X	X	-	X
Oenanthe crocata	X	X	-	X	-	X
Okoubaka	X	-	-	-	-	-
Oleander	-	X	X	-	X	-

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Oleum	-	-	X	-	-	-
Opium	X	X	X	-	-	X
Origanum	X	X	-	-	X	X
Origanum majorana	-	-	-	-	-	X
Osmium	-	X	X	-	-	X
Paeonia officinalis	X	-	-	X	-	-
Palladium	-	X	X	-	-	-
Para benzochinon	-	-	-	-	X	-
Pareira brava	X	X	X	X	-	X
Paris quadrifolia	X	X	X	-	-	X
Passiflora incarnata	X	-	X	X	-	-
Petroleum	X	X	X	X	X	X
Phellandrium	X	X	-	-	-	X
Phenatecin	-	-	X	-	-	-
Phosphorus	X	X	X	X	X	X
Phytolacca decandra (Phytolacca)	-	X	X	X	-	X
Piper methystic	-	-	X	-	-	-
Plantago major	X	X	X	X	-	X
Platina	-	X	X	-	-	-
Plumbum aceticum	X	-	-	X	-	-
Plumbum jodatum	X	-	-	-	-	-
Plumbum metallicum (Plumbum)	X	X	X	X	X	X
Podophyllum peltatum (Podophyllum)	X	X	X	X	-	X
Prunus spinosa	X	-	-	X	-	-
Psorinum	X	X	-	X	X	X
Ptelea trifoliata	X	-	-	-	-	-
Ptelea trifoliata	-	X	-	X	-	-
Pulsatilla pratensis (Pulsatilla)	X	X	X	X	-	X
Pyrogenium	X	-	-	X	-	-
Quassia amara	X	-	X	X	-	-
Quercus robur	-	-	X	-	-	-
Ranunculus bulbosus	X	-	X	X	-	-
Ranunculus sceleratus	-	-	X	-	-	-
Raphanus sativus	X	X	X	X	X	X
Ratanhia	-	-	X	X	-	-
Rheum	-	-	X	-	-	-
Rhododendron chrysanthum	X	-	X	X	-	-
Rhus radicans	-	X	X	-	X	X
Rhus toxicodendron	X	X	X	X	X	X
Robinia pseudoacadia	-	-	-	X	-	-
Rumex crispus (Rumex)	-	X	X	X	X	X
Ruta graveolens	-	-	X	X	-	-
Sabadilla	-	-	X	-	-	-
Sabal serrulatum	X	-	X	-	-	-
Sabina	-	-	X	-	-	-
Sambucus nigra	X	-	X	X	-	-
Sanguinaria	X	X	X	X	X	X
Sarothamnus scoparius	-	-	-	X	-	-
Sarsaprilla	X	-	X	-	-	-
Scrofularia nodosa	-	-	X	-	-	-
Secale cornutum	X	X	X	X	X	X
Selenium	X	X	X	X	X	X
Senecio aurea	-	-	X	-	-	-
Senega polygala	-	X	X	X	-	-
Sepia	X	X	X	X	X	X

Single remedies	Geyer	De La Fuye / Schmidt	Schoeler	Schrecke / Wertsch	Veith	Finkel
Silicea	X	X	X	X	X	X
Sinapis alba	-	-	X	-	-	-
Solidago virgaurea	X	X	X	X	X	X
Spigelia anthelmia (Spigelia)	X	X	X	X	X	X
Spiraea ulmaria	-	-	-	X	-	-
Spongia	-	-	X	-	-	-
Squilla	-	-	X	-	-	-
Stannum metallicum	X	-	X	X	X	-
Staphisagria	X	X	X	X	X	X
Staphylococus	-	-	-	-	X	-
Stibium arsenicosum	-	-	X	-	-	-
Sticta pulmonaria	-	-	X	X	-	-
Stramonium	X	X	X	X	X	X
Streptococcus haemolyticus	-	-	-	-	X	-
Strontium carbonicum	X	X	X	-	-	-
Strophantus gratus (Strophantus)	X	X	X	X	-	X
Sulfur	X	X	X	X	X	X
Sulfur jodatum	-	-	X	X	-	-
Sumbul	-	-	X	-	-	-
Symphytum officinalis	-	-	X	-	-	-
Szygium jambolan	-	-	X	-	-	-
Tabacum	X	X	X	X	X	X
Taraxacum	-	-	X	X	-	-
Tartarus emeticus	X	-	-	-	-	-
Tartarus stibiatus	X	-	X	-	-	-
Tellurium (Tellurium metallicum)	-	X	X	-	-	X
Terebinthina	X	X	-	X	X	X
Teucrium scorodonia	-	-	X	X	-	-
Theridion	X	X	-	-	-	X
Thlaspi bursa pastoris	-	-	X	-	-	-
Thuja occidentalis (Thuja)	X	X	X	X	X	X
Tonca	-	-	X	-	-	-
Tongo	-	X	-	-	-	-
Tuberculinum	-	-	-	-	X	-
Uranium nitricum	-	X	X	-	-	X
Ustilago	-	-	X	-	-	-
Valeriana	-	-	X	-	-	-
Vanadium metallicum	-	-	X	-	-	-
Veratrum album	X	X	X	X	X	X
Verbascum thapsiforme	X	-	X	X	-	-
Viburnum opulus	X	-	X	X	-	-
Viola tricolor	-	-	X	-	-	-
Viperus berus	X	-	-	-	-	-
Viscum album	X	-	X	X	-	-
Zincum metallicum (Zincum)	-	X	X	X	-	X
Zincum sulfuricum	-	X	-	-	X	X
Zincum valerianicum	X	-	-	-	-	-

This table reflects the parenteral use of homoeopathic drugs within the field of e.g. acupuncture or homeosiniatry (19), as referenced in the specialist literature.

However, from the absence of certain remedies in monographies on this subject we certainly cannot draw the conclusion that these remedies are not used, resp. cannot be used in the form of parenteralia.

8. Safety

Parenteralia have been manufactured and distributed by the pharmaceutical company HEEL since many decades. The first injection solutions have been on the market since at least 1959. Experience has shown that except for the general risk resulting from the way of application, no other risks have to be expected from this way of administration in the case of homoeopathic remedies.

The vast experience of the applicant with parenteral homoeopathic drugs is reflected in the produced and distributed number of ampoule preparations.

During the years 1995 to 2001 at least 420 million ampoules from the manufacturer HEEL GmbH (Baden-Baden, Germany) have been distributed world-wide, of which the majority was distributed in Germany and in total 3,358,000 ampoules in the Netherlands.

Since every substance for injection in the EU has to meet the sterility requirements of the official pharmacopoeia as stated in the "Parenterals" monograph of Ph. Eur. 1997, a risk of infection from this dosage form can be excluded (50). In accordance with Method 11, HAB 2001, the same requirements also apply to homoeopathic liquid dilutions for injection (51).

8.1. Pharmacovigilance

It is undoubtedly right that any invasive use of a drug, such as parenteral administration, should carry some degree of risk. This is equally true for homoeopathic and non-homoeopathic medicines.

So as to formally establish whether and to what extent a risk exists in the use of a drug, the legislators introduced a legal requirement for pharmaceutical manufacturers to document drug risks. Today, thanks to the statutory provisions and the principles of GOOD MANUFACTURING PRACTICE, it is standard international practice to document all suspected cases of risk associated with a drug and to make a medical assessment of every suspected case which comes to light. Each instance must be reported to the competent authority. Specialist committees at the competent authority check all reported cases and take the action appropriate to the degree of risk, which might even result in the product in question being withdrawn from the market.

The data given below are taken from the risk reporting databases of one homoeopathic and two anthroposophic manufacturers in Germany. It should be mentioned that German homoeopathic manufacturers alone account for more than 80% of the homoeopathic parenterals manufactured in the EU. The figure for the anthroposophic manufacturers is similarly high.

8.2. Type of adverse reactions reported

The risk reports recorded in connection with the injection of homoeopathic and anthroposophic injection solutions concerned:

1. Local swelling and/or redness (> 90% of reports)
2. Local pain (about 8% of reports)
3. Allergic reactions (about 2% of reports)
4. Severe, life-threatening side effects (e.g. anaphylactic shock) (< 0.1% of reports)
5. Nausea (< 0.1% of reports)
6. Abdominal pain/colic (< 0.1% of reports).

8.3. Adverse reactions recorded in manufacturers' databases

The following table shows the adverse reactions recorded in the side effect databases of two German anthroposophic manufacturers and the largest German homoeopathic manufacturer of parenteral dosage forms. The 10-year data cover the period 1990-1999, the 5-year data the period 1995-1999.

Manufacturer	Number of ampoules sold	Ampoule volume	Mode of administration	Number of adverse reactions
1st anthroposophical manufacturer	105 million in 10 years	1 ml and 10 ml	s.c. (98%), i.m. and i.v. (2%)	13
2nd anthroposophical manufacturer	80 million in 10 years	1 ml	s.c. (98%), i.c., i.v., i.m. (2%)	23
Homoeopathic manufacturer	350 million in 5 years	1 ml and 2 ml	s.c. (ca. 60%), i.v., i.c., i.m., intra-articular and peri-articular (about 40%)	22, of which s.c. 6 times i.v. 2 times i.m. 8 times intra-artic. 3 times peri-artic. 3 times

The number of side effect risks recorded for the three manufacturers shown above is extremely small if the number of adverse reactions is compared with the number of ampoules used.

The percentage proportion of adverse reactions for the homoeopathic manufacturer is 0.000036%. It should also be borne in mind that the adverse reactions included in the table relate only to 21 homoeopathic combination products, which account for 61.5 million ampoules. However, this manufacturer produces about 70 million ampoules *every year*, i.e. about 350 million ampoules in 5 years; the full ampoule range of this manufacturer covers more than 800 different parenteral homoeopathic combination products. There is however not a single side effect report for the remaining 290 million or so ampoules produced in the above-mentioned 5-year period.

Similarly small numbers of side effect reports can also be found for the two anthroposophic manufacturers.

- In a prospective post-marketing surveillance exercise with a homoeopathic injection product for the treatment of gonarthrosis (28), a side effect rate of 0.45% was found after intra-articular administration in 1845 patients with knee disorders. The side effects were all mild and reversible; thus, no treatment of the side effect was required in 24 cases, and in 15 cases conservative treatment was sufficient, e.g. in the form of ice packs; in a further 29 patients allopathic drugs such as diclofenac, ibuprofen and dexamethasone were also used.

- The medical literature describes the intra-articular method of administration in particular as being relatively risky, as has been reported by various authors. The risk of infection after intra-articular administration is, according to Bienvenido et al. (52), 1:7000. Other authors such as Anders (53) give a complication rate of 0.034% after a retrospective study of more than 650,000 doses given in 99 outpatient orthopaedic indications. Bernau and Köpcke (54) report an incidence of three infections in 105,000 intra-articular injections (about 1:35,000).

- In another publication by Weiser in 1997 (31), a prospective post-marketing surveillance study investigated tolerability in the peri-articular treatment of gonarthrosis using a homoeopathic, parenteral drug with a complex composition. 48 orthopaedists in private practice took part in the study; they treated a total of 643 gonarthrosis patients with the product. Overall, 5 patients (0.8%) showed adverse reactions. Referred to the total number of injections given (n = 5531), this corresponds to a side effect rate of 0.09%.
  The adverse reactions recorded were exclusively local signs of inflammation in the knee region, with 5 cases each of heat and pain, 2 cases of redness, and one case with joint exudate. In 4 of the 5 cases of side effects, anti-inflammatories and analgesics plus conservative ice treatment were used to treat the symptoms. All side effects were completely reversible.

8.4. Summary

The data currently available demonstrate that homoeopathic parenteral products have a very low risk of side effects. The parenteral administration of homoeopathically potentized drugs thus has an extraordinarily low risk potential when administered properly, as is shown by the literature (10, 31, 55) and by risk reporting data from major homoeopathic/anthroposophic manufacturers (see 8.3.).

By contrast, the side effect risk for allopathic parenterals is much more important (52). It is therefore justified for homoeopathic parenterals to be considered practically hazard-free in current risk assessments, particularly in subcutaneous administration.

The parenteral form of administration has clear therapeutic advantages over the oral form, such as the fact that the drug is not altered by the influence of the gastric acid and enzymes in the gastrointestinal tract. Since parenteral administration is generally performed by the physycian, patient compliance is high. In addition, the action of the homoeopathic parenteral medicine in question can be improved by administration to trigger points, acupuncture points or the "loco dolenti".

The parenteral method of administering homoeopathic/anthroposophic medicines has no increased risk compared to oral administration when given properly by the therapist, as demonstrated in the outcomes study by Riley et al. (33).

9. Conclusion

The homoeopathic literature shows that the parenteral administration of homoeopathic drugs is not only common, but that in certain therapy forms, e.g. in homeosiniatry (19) or in the combination of acupuncture and homoeopathy or in biopuncture, only the parenteral application can achieve the desired therapeutic effect, because with oral therapeutics the well-directed application in certain skin-energy points is not possible.
Heel as a pharmaceutical company can look back at more than 40 years of experience in producing, according to GMP guidelines, and distributing homoeopathic parenteralia.

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