

International Congress on Spa Therapy with Saline Waters in Health Resorts

Abstracts

DEAR FRIENDS OF THE BRINE-THERAPY!
DEAR CRITICS OF THE BRINE-THERAPY!

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PVA Bad Ischl

The use of brine-therapy at spa resorts shows a great diversity. The most common are brine baths, exercise baths, inhalation and drinking cures. As part of the treatments, salt is used alone or in combination with other local remedies. A special feature is thalassotherapy. The indications which are named by the spa resorts, are amazing diverse, e.g. skin and respiratory diseases, inflammatory and non-inflammatory rheumatic diseases, gynecological diseases and infertility, and general susceptibility to infection and psycho-fatigue.

Whilst the brine-treatment was called standard therapy in all previous textbooks of internal medicine and paediatric, dermatology, gynaecology, rheumatology and orthopaedics, many critical scientists only shake their head about it. But still nowadays there is great acceptance and support among the patients.

So what is really true about brine-therapy? What form of brine-therapy is scientifically proven for which symptoms or at least clearly supported by clinical experience? What can the doctor now recommend to his patient, with a good conscience when asked about the possibilities of a brine-therapy at a spa resort? Of course, he can expect a competent medical response.

The aim of the conference is to provide the best possible answers to relevant questions. What indication is useful, which is no longer to be represented nowadays? Physicians with broad clinical experience will present in surveys their position of the "classic" indications of brine-therapy. Sufficient time will be given for critical discussions. The poster presentation and discussion of new scientific work will be especially enthralling.

I hope for your interest in the conference and for lively discussions, with as dear as possible results, all this in the usual friendly atmosphere of the balneologists and in the welcoming surroundings of the spa town Bad Ischl

THE FUTURE SIGNIFICANCE OF LOCAL NATURAL REMEDIES IN HEALTH RESORT MEDICINE

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This topic affects numerous health resorts in the European Member States whose national spa associations are among the currently 20 members of the European Spas Association (ESPA). Under the title 'Natural remedies - the USP of spas and health resorts in Europe', local natural remedies were one of the main topics of the 15th ESP A Annual Congress 2010 in Romania.

Given the drastic changes and cuts for all those concerned in the health service, this topic is especially relevant at this present time and draws attention to the European dimension of this fundamental question regarding the future of health resorts. It should be remembered that ESPA's mission is "to maintain and develop the longstanding health resort culture in Central Europe and to align it within today's national medical systems and the European Union."

In his preface to the second edition of the German Health Resort Almanac, in November 2007 Prof. Christoph Kirschner recalled the origins of spas, which were always closely linked to local natural remedies. And he outlined the range of functions of health resorts: from purely experiential medicine used successfully for centuries to the treatment of chronic diseases, medical rehabilitation, prophylactic therapy at all stages, and encouraging a healthy lifestyle.

In order to open up new prospects for the use of traditional natural remedies, in March 2009 ESP A teamed up with the BBKV Brandenburg Spas Association to hold the first European Peloid Conference in Bad Saarow. The main topics addressed were economic issues, aspects of therapy, the ways in which various peloids can be used, and their effectiveness. Innovative types of future marketing were proposed by the international team of experts present.

The big response to this conference prompted ESP A to set up its own Peloid Division on 8 February 2010 in Bad Schwalbach (Germany). Experts from several member associations are now taking part in the work of the Peloid Division. This example could pave the way for the development of other local natural remedies in order to raise their profile and make health resorts more conscious of the 'treasure' they have.

World Water Day held annually on 22 March is another opportunity to make the general public aware of this natural resource and to generate advertising for the services offered by health resorts. Imagine the boost it would give their publicity if hundreds of health resorts all over Europe celebrated World Water Day by hosting open days, concerts, activities for families and so on!

The subject of 'medical wellness' will be discussed in the paper as an economic necessity and an innovative service in many health resorts - above all for direct payers. Once again, the use of local natural remedies in connection with this new development is essential. What else would distinguish health resorts from everyday tourist services?

The conclusion will be another quotation from Prof. Kirschner's preface: "Just as human physiology changes over time, the ways in which mankind deals with long-standing stimuli such as light and air, sun and wind, water and the climate, movement and calm are always in keeping with the times. Health resort medicine's methods of function and regulation therapy by various means of treatment to reinforce vitality are and will remain indispensable

Saline water and evidence based medicine

SPA THERAPY WITH SALINE WATER: EVIDENCE OF EFFECTIVENESS ?

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Evidence based medicine (EBM) is the current standard of medical clinical science. Originally developed as a tool for physicians, to generate and promote the optimum of medical care for individual patients, the criteria of EBM serve meanwhile as basement for clinical guidelines which combine evidence of effectiveness with weighted recommendations.

However, different systems for grading the evidence and strength of recommendations exist. These grading systems are not compatible, the classifications have not been comprehensively evaluated, reproducibility and discriminative power have been questioned. A new grading system was proposed which overcomes some limitations of the existing classifications, but is not yet applied in most clinical guidelines.

Saline water is defined as water that contains in 1 kg at least 5,5g sodium and 8,5g chloride ions (equal to 240mval per kg sodium or chloride ions respectively). Saline water is seldom applied as single treatment modality, but is often integrated in a bundle of therapies of spa treatment.

Dead Sea

The Dead Sea water has a salt content of about 320 g/L, of which potassium chloride, magnesium chloride, calcium chloride, and sodium chloride (with their respective bromides) are the major components, comprising 98% of the salts on a dry weight basis. As the average sodium content is 1.70% = 5,44 g and chloride is 7.80% = 24,96 g, Dead Sea water may be classified as saline. However, the effects of Dead Sea salt water cannot fully assigned to sodium chloride only.

Skin disease

It is well established, that salt water influences the minimal erythema dose for Ultraviolet-B-light. The related clinical effect of immersion in saline water on psoriatic skin is small. Effectiveness of saline baths on other skin diseases including atopic dermatitis is not sufficiently supported by randomised controlled studies or due to contradictive results. The much discussed IQWiG report on photo-balneotherapy found more reduction of psoriatic skin lesions after saline water bath plus UVB irradiation compared UVB without immersion in saline water. Adding Psoralen to photo-balneotherapy resulted in an additional effect on skin clearance and less unwanted effects compared to photo-balneotherapy as a sole treatment

Back pain

Only one small study investigated the effect of immersion in saline water on back pain and tension of back muscles compared to tap water, but different effects were not found. None of the studies included in the systematic review by

Pittler et al. used mineral water with sufficient content of sodium and chlorine ions, although the study by Constant et al reported the effect of spa treatment in Saint-Nectaire where the total mineral content of the water is 8073 mg/l.

Osteoarthritis of the knee

Spa therapy for osteoarthritis induced knee pain is regarded as effective treatment. However, immersion in mineral water is in all studies only one of several treatment modalities. Only one study reported a mineral content of the spa water that met the required content of sodium and chlorine for saline water. This study compared bathing for 20min, twice a day, leisure activities and massage on request with the effect of non steroidal antirheumatic drugs and found superior reduction of pain and disability for spa therapy at 2, 12 and 24 weeks after treatment.

Floating

Floating REST (Restricted Environmental Stimulation Technique) is a relaxation technique. The patients are floating in a very big tank or floating room with water at body temperature and 30% Epsom salts (magnesium sulphate). 70 patients with stress-related muscle tension pain were randomly assigned in equal numbers to either in a total of 12 flotation-REST or control sessions. Results indicated that pain areas, stress, anxiety, and depression decreased more after floating rest, whereas sleep quality and, optimism increased. These results were confirmed in post hoc analysis of three combined studies previously published.

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Orthopaedics and Rheumatology

SPA THERAPY AND INFLAMMATORY RHEUMATIC DISEASES- STATE OF THE ART LECTURE

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Rheumatoid arthritis (RA), ankylosing spondylitis (AS), and psoriatic arthritis (PsA) are the most common inflammatory rheumatic diseases. The introduction of new disease modifying drugs, in particular the biologic agents, has improved the prognosis of patients significantly. In this lecture I shall review randomized prospective controlled studies that have been published in the English literature,

The lecture will focus on conclusions based on these studies, relating to the effectiveness of balneotherapy in the treatment of these diseases. Future studies that can help fortify these conclusions will be proposed.

Rheumatoid Arthritis

RA is the most common inflammatory arthritis, affecting approximately 1% of the adult population worldwide. This potentially crippling disease reduces survival and most importantly compromises quality of life in most patients.

The 5 prospective randomized controlled studies reported in the English literature are summarized in Table 1.

The most important conclusions that can be drawn from these studies are:

A. Clinical improvement lasting up to six months was observed in most of the clinical parameters assessed.

B. The number of patients in most studies is relatively small and the clinical parameters used to assess disease activity are outdated and unacceptable for present and future studies. None of the patients received any of the new biologic agents, which are the most effective medications available today for RA patients

C. There is no way to determine the preferred duration of therapy, the optimal treatment modality, or whether combination therapy is necessary to achieve a maximal effect.

D. Balneotherapy is safe and can be used even during periods of severe and active inflammation.

E. Clinical improvement is usually not associated with concomitant improvement in laboratory indices of inflammation such as ESR and CRP.

F. The mechanism/s of action of balneotherapy is basically unknown and there are no basic science studies that assess the effect of balneotherapy, or animal models of arthritis. Recently we have demonstrated amelioration of the severity of adjuvant arthritis in rats after bathing in Dead Sea water. The clinical improvement was associated with significant decrease of IL-1 and significant increase of IL-10 in splenocytes. Rats that have been treated in a similar way with tap water or did not improve and their IL-1 and IL-10 did not change significantly.

G. Cost effective studies comparing balneotherapy to therapy based on the new biologic agent are needed.

H. Clinical trials on patient populations with relatively early disease, before the occurrence of permanent damage, are needed. Early spa therapy may improve the outcomes.

Ankylosing Spondylitis

AS is a chronic inflammatory disorder that primarily affect the spine, the axial skeleton and the large proximal joints of the body. The prevalence of AS in the general population is between 0.1% and 0.6%. A distinctive feature of AS is its tendency for ossification and ankylosis of the spine and involved joints. The typical presentation is inflammatory back pain of insidious onset and morning stiffness that improves with physical activity. Until recently therapy was based on non-steroidal anti inflammatory drugs (NSAIDs) and old disease modifying anti rheumatic drugs (DMARDs) such as sulphasalazine. The introduction of biologic agents, espe-

Table 1
Rheumatoid arthritis: prospective randomized controlled studies.

Outcome	Primary end points	Follow-up (months)	Duration(days)	N	Mode of therapy	Author
Positive	VAS-pain AIMS Scale	6	15	60	Radon baths vs CO ₂ baths	Franke (5)
Positive	Richie index No active joints	3	14	30	Dead Sea salt vs table salt (NaCl)	Sukenik (2)
Positive	Richie index No active joints	3	14	40	Mud vs sulfur vs mud + sulfur	Sukenik (1)
Mild improvement	Richie index	6	14	41	Mineral baths + mud vs tap water	Elkayam (3)
Positive	Richie index No active joints	3	12	36	Dead Sea water vs sulfur vs Dead Sea + sulfur	Sukenik (4)
				199		

Table 2
Ankylosing spondylitis: randomized controlled studies

Outcome	Primary end points	Follow-up (months)	Duration (days)	N	Mode of therapy	Author
Positive	Functional ability Patients global wellbeing Pain, morning stiffness	10	21	120	Spa exercise	Van Tubergen (6)
Positive	ASAS core set	6	21	61	Balneotherapy vs balneotherapy + NSAIDS	Yurtkuran (7)
Weakly positive	BASDAI VAS pain, SF -36	3	14	28	Mud +sulfur vs tap water	Codish (8)
Positive	BASDAI ,BASFI, DFI, and others	6	21	60	Balneotherapy vs control	Altan (9)
Weakly positive	BASFI, Vas (EQ-5DVAS)	6	7	60	Etanercept vs etanercept + spa therapy	Colina (10)
				329		

cially anti-tumor necrosis factor (anti-TNF) agents has improved dramatically the prognosis of patients.

Five randomized controlled studies will be included in my lecture and are summarized in Table 2.

The most important conclusions from these studies are:

A.Clinical improvement lasting 3-6 months was achieved in only 3 of these studies.

A.Van Tubergen showed, for the first time, that balneo-therapy is not only effective but also cost-effective.

B.The study of Colina (10) is the first one that compared the efficacy of combination therapy (balneotherapy plus biologic therapy) versus monotherapy (biologic agent alone). No definite conclusions can be drawn from this study because of the very short duration (one week) of the spa therapy.

Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic inflammatory arthritis that occurs in approximately 26% of patients with psoriasis, leading to a prevalence rate in the population of 0.3% to 1%. There are a few clinical subsets of PsA including oligoarthritis (the most common subset), distal joint disease, arthritis mutilans, rheumatoid arthritis like (symmetrical polyarthritis), and spondylitis. The diagnosis is made on clinical grounds in patients with psoriasis who have skin, scalp or nail changes.

The only two studies evaluating the effect of balneotherapy on patients with PsA were conducted in Israel (Table 3). Treatment for psoriasis at the Dead Sea has been proven in many studies to be highly efficacious. The treatment regimen is based mainly on exposure of the skin to both Dead Sea water and the sun's ultraviolet rays.

The main conclusions of these two studies are that bathing in Dead Sea water and exposure of the skin to the unique ultraviolet rays at the Dead Sea area have a beneficial effect on both the skin and the peripheral joints. The addition of mud and sulfur therapy reduces spinal pain and improves spinal mobility.

Further studies are needed to clarify which of the modalities have a greater effect, balneotherapy or climatotherapy.

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Table 3
Randomized controlled studies

Outcome	Primary end points	Follow-up (months)	Duration (days)	N	Mode of therapy	Author
Positive for peripheral joints, spine pain and mobility	Richie index VAS pain Spine mobility	No follow up	21	166	Dead sea + sun vs Dead Sea + sun + mud + sulfur	Sukenik (11)
Positive for peripheral joints, spinal pain and mobility	Tender & swollen joints Schober test, VAS for pain	6	28	42	Dead Sea + sun vs Dead Sea + sun + mud + sulfur	Elkayam (12)
				208		

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EXPERIMENTAL, PHYSIOLOGICAL AND CLINICAL BALNEOLOGY STUDIES WITH SALT OR SALINE WATERS

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Brine baths are used in treatment of various diseases of the musculoskeletal system. We investigated the effectiveness and some beneficial effects of balneotherapy with NaCl mineral water in clinical trials and in experimental studies. We present a summary of these studies.

We have shown that experimental paw edema in animals (Vistar Albino rats) with adjuvant arthritis diminished with NaCl baths. We reported that at the end of 30-day NaCl bath cure, edema in acute arthritic paw decreased predominantly and significantly in comparison to the control (without bath therapy) and tap water therapy groups.

To examine the effects of brine baths on pain and muscle functions in patients with chronic low back pain (CLBP) we conducted a controlled study. The results showed that the whole body immersion leads to a significant reduction of muscle tension and pain intensity in patients suffering from CLBP. Similarly we found in a physiological study that single hyper-thermal salt water baths increases pressure pain threshold in healthy young adults.

In a 2 year cross over randomized clinical study, we aimed to investigate the effects of spa therapy consisting of NaCl water balneotherapy and rest at a thermal spa hotel in patients with rheumatoid arthritis. The quality of life parameters were improved, tender and swollen joint counts, patient's and physician's global assessment of disease and pain scores were decreased just after 2 week NaCl balneotherapy and at 6 month follow- up period. Concomitantly antioxidant effect of this type of spa therapy was investigated in same study group. It has been found that some parameters of antioxidant system (NSSA, AOP) were improved after 2 weeks salt water balneotherapy course.

Very recently, we published a pilot study on the beneficial effects of spa therapy course with brine (sole) baths on osteoarthritis the most common degenerative joint diseases of our times. We reported that a 10- day course of spa therapy is beneficial in short- and medium-term up to 24 weeks by reducing pain and improving functional status (Lequesne Algo-Functional Index) and overall well-being in patients with severe knee OA.

SALINE WATER IN OSTEOARTHRITIS: CLINICAL ISSUES

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The main balneotherapeutic indications for saline or salt water are dermatological conditions such as psoriasis and Atopic dermatitis and painful and arthritic conditions of musculoskeletal system such as osteoarthritis, rheumatoid arthritis, low back pain and fibromyalgia. Even though a meta-analysis is missing so far, published clinical studies evaluating efficacy and effectiveness of saline water balneotherapy in dermatology and rheumatology reported mostly positive results. Spa therapy at Dead Sea Area including Dead Sea water baths combined with heliotherapy or mud pack therapy or salt water (Dead Sea salts or 3-4% NaCl) balneotherapy plus UV radiation at clinical settings (balneophototherapy) are the most common forms of balneological treatments with saline water.

We conducted clinical trials investigating the therapeutic effects of saline or salt water balneotherapy at spa resorts and salt water balneotherapy plus mud pack therapy at our outpatient clinic in patients with rheumatoid arthritis, low back pain, and fibromyalgia and knee osteoarthritis. 3 of these clinical trials were planned to investigate the effects of saline ater and salt water plus mud pack therapy (prepared by mixing clay with salt water) in patients with knee osteoarthritis. Results of these studies confirmed the observed therapeutic effects of saline water and mud in short and medium term that have been shown in the improvements of the scores of pain measured on visual analog scale (VAS), functional status assessed with Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) and general well being measured as patient's global assessment of disease activity on VAS.

Recently, it has been criticized if such improvements reported as mean and standard deviation of the change in score in clinical trials, at the group level are clinically important. Do they reflect a meaningful improvement for the patient? In an attempt to evaluate the clinical relevance of reported results, the concept of the minimal clinically important difference (MCID) has been developed which can reflect either an improvement or a worsening. In fact we are always interested in improvement and not worsening. Starting from this argument, a group of authors suggested the minimal clinically important improvement (MCII) concept, defined as “the smallest change in measurement that signifies an important improvement in a patient's symptom”.

We checked the scores of pain, WOMAC and patient's global assessment of the 3 knee osteoarthritis studies with salt water therapy and estimated MCII values for each study for each assessment time point. MCII was defined as the ab-

solute change of = 19.9 mm on pain VAS score and/or = 9.1 points on WOMAC function subscale normalized to 0-100 score and = 18.3 mm patient's global assessment VAS score. Obtained number and percentage of improved patients achieving MCII at the end of the therapy period and at follow-up (3 to 6 months) provided additional and meaningful information on the effect size of spa therapy with saline water baths and salt water balneotherapy in combination with mud pack therapy. We think that using MCII in clinical trials of balneology seems more appropriate and facilitates the readers in interpreting the results in accordance with their clinical relevance.

SALINE WATER AND BACK PAIN

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Balneotherapy is the oldest form of medical treatment that has been handed down to us. It is probably even older than the written word, which dates back more than 6000 years. It was, however, rarely applied as a monotherapy, but rather in combination with movement therapy, diet and instruction to achieve a balanced way of life, which the Greeks called Diataia. Almost 2000 years later, Sebastian Kneipp would develop from this his form of treatment. Unfortunately, only a part of his body of thought is known, namely the use of Kneipp Baths as a specific form of hydrotherapy.

Within the scope of curative water and medical springs, the brine bath is among the most widely used balneological applications. They were originally believed to be an inland substitute for sea resorts. In general, 1.5 to 6% brine baths are used. It was also attempted to apply brine concentrations of up to 25%. Brine baths represent the most highly concentrated applications in balneotherapy. The resulting osmotic effect changes the composition of the skin through increased elution, proven by skin affected by psoriasis. The skin's resorption of sodium and chloride takes place almost independently of the brine concentration. There also occurs an additional postsorption, which stretches to over 100 hours. The vegetal concurring reactions that can be observed are detectable in numerous functional systems, and are labelled "unspecific". The few comparative studies with different treatments at the same spa facility could find no evidence that brine bath treatments caused a specific reactive pattern in contrast to other spa treatments.

In the treatment of rheumatological disorders, the influence of the vegetative systems and the pituitary- adrenocortical system are used to explain the success of therapies. Thus, there are improvements in the often impaired local circulatory response and in the reduced hyperergic response. There also occurs a correction of disturbances in the regulation of the pituitary-adrenocortical system.

Controlled studies on rheumatoid arthritis and degenerative joint diseases (osteoarthritis) are available in which improvements in muscle strength, increased joint mobility and reduction of pain were achieved. However, wide ranging literature research has not uncovered any controlled studies on the treatment of low back pain with halotherapy. An abstract of a study has been published which attempts to examine the influence of brine baths on pain and muscle tone in comparison to mains water (Bothmann O. et al. 2003).

There have also been studies on the treatment of patients with ankylosing spondylitis at the Dead Sea (Codish S. et al. 2005), likewise, studies of thalasso therapy as a treatment of fibromyalgia (de Andrade et al. 2008, Skenik, S. et al. 2001). A study using medical bath salt from the Dead Sea on diverse spinal problems without a control group was published in 1982 (Engel P).

If one is aware of the socio-economic significance that low back pain has today, then it is astonishing that almost no controlled studies of halotherapy have been carried out for publication.

SALINE MUD THERAPY FOR HEADACHE SECONDARY TO CERVICAL OSTEOARTHRITIS

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OBJECTIVE. To investigate the effect of a series of local treatments with saline mud combined with bathing in mineral water in patients suffering from headache secondary to cervical osteoarthritis.

DESIGN: Open uncontrolled case series with pre-post comparison

SETTING: Edipsos Spa Center in Evia, Greece.

PATIENTS: 32 patients(12 male, 20 female) which fulfilled the diagnostic criteria for cervicogenic headache according to the International Classification of Headache (ICHD-II 2004).

OUTCOME MEASURES: Range of motion (ROM) of the cervical spine in all planes: extension-flexion; lateral bending, rotation; headache diary, pain (VAS), number of analgetic drugs, SF-36.

TREATMENT: The treatment lasted for 2 weeks (6 therapy session/week). Mud was mixed with the Edipsos water, which has a mineral content of 2 9,6 g; 77,3% of the minerals are sodium chloride, defining the Epidipsos water as saline water. These mud packs were applied with a layer thickness of 7-10 cm and a surface temperature between 47 and 50° once a day for 15 to 30 minutes on the dorsal neck and the upper back: After the mud pack all patients took a bath in the mineral water (temperature between 34 and 38°C) followed by rest for 30 to 40 minutes.

RESULTS: 23 of 32 patients (73,6%) reported that they were totally cured after the series of therapy. 8 of 32 patients (25,6%) reported total well-being by the end of the treatment. Only 1 patient did not show any signs of improvement or cure and stopped the therapy at his 5th appointment (3,2%). The number of days with headache was reduced compared to the pre-treatment period. Pain decreased from a 75±18 (mean ± SEM) prior to treatment to 22±14 after treatment. SF-36 scores improves and a significant reduction of drug use was also observed (pre-SPA treatment 124.7±11.6 vs post SPA treatment 15.2±4.1)

CONCLUSION: The observed reduction in pain and disability after Spa therapy with saline mud packs and mineral water baths warrants further controlled investigations.

Dermatology

SALTS AND THE SKIN

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The human skin is protected against penetration by foreign substances and against the loss of body substances by a protective horny layer only 10 microns thick, the stratum corneum. The composition of this layer is about 50% protein, 32% water-soluble salts, 10% water and 8% lipids. These substances are being formed by the differentiation of the epidermal squamous epithelium. More than 50% of water-soluble substances are salts of amino acids, the rest are lactates and inorganic. It takes fourteen days for the stratum corneum to regenerate the daily loss of dead cell debris being shed as a result of desquamation.

The protective function of this layer depends on retained moisture which results from the hygroscopic properties of contained salts. The inorganic salts in the stratum corneum originate from the intracellular and extracellular inorganic salts of the living epidermis, but because of the much lower water content in the top layer its salt concentration is about 6.5 times higher than in living tissue. For an isotonic concentration of aqueous solutions with skin contact this corresponds to a 6% solution of sodium chloride. Only higher salt concentrations will lead to an outflow or loss of water. Therefore, because of the lower concentrations in Balneology, we always have water influx.

At contact water penetrates about 3 microns into the undamaged stratum corneum. Because of increasing density dissolved substances penetrate deeper layers of the stratum corneum only in logarithmically decreasing concentrations per mass of horny cells. This limits the transcutaneous transport of exogenous substances to a minimum.

With dry skin the packed density of horny cells decreases and that favours the penetration of exogenous substances. During occlusion the water content of the stratum corneum rises which can then act as a lubricant for the diffusion of exogenous substances.

With a bathing time of 20 minutes the maximal flow rate will not be reached because the through-flow compartments are not yet in a steady state. The transcutaneous transport of substances follows the laws of dialysis. This means substances need to dissolve through the stratum corneum. This causes different substance-dependent diffusion and permeation speeds. With the concentrations used in Balneology this speed is proportional to the corresponding substance concentration. Gases such as Radon, CO₂ and H₂S have the highest permeation speeds, and inorganic ions the lowest values. Substances that dissolve to some degree in water as well as lipids have intermediate values.

A special situation exists when identical substances are in the bath and in the skin. This can lead to more salts being lost than absorbed. For instance the steady-state of sodium chloride is close to the concentration in the Atlantic Ocean with about 3.5% of NaCl. Therefore with a lower salt concentration we will find more salt in a bath afterwards than before.

During washing and bathing endogenous salts are rinsed out the skin. With repeated rinsing this loss cannot be compensated through regeneration of the stratum corneum. One bath will cause about as much salt loss as can normally be regenerated in one week. Too much salt loss can damage the skin and impair the protective function of the stratum corneum. Such skin damage may reveal itself in hypertonic salt baths through an osmotic response leading to a feeling of burning or itching after the bath.

SALINE WATER AND UV EXPOSURE IN PSORIASIS: RANDOMIZED CONTROLLED TRIALS

Franke A for the balneo-phototherapy study group

(Brockow T, Franke A, Resch KL from FBK Spa Medicine Research Institute Bad Elster, Germany, and Schiener R, Peter RU from Department of Dermatology, University of Ulm, Germany)

In 1999 the German authority Bundesausschuss Ärzte und Krankenkassen (BAAK) decided to take the non-synchronous balneo-phototherapy off the list of treatments in ambulant settings and in spas because no large trials existed on its superiority over UVB irradiation alone in psoriasis. The latter was regarded sufficiently effective and was exclusively financed by public health insurances in Germany. Sponsored by German Spa Association (DHV) and Professional Association of German dermatologists (BVDD) the FBK and the Ulm dermatological Department performed 3 randomized trials in 2000 to 2003 (BVDD-) resp. 2005 (DHV-Studies which were terminated prematurely due to missing recruitment after about half of the sample sizes).

Aim of all studies was to compare non-synchronous balneo-phototherapy with UVB alone. Upon requests of DHV and with regard to different saline concentrations two 2-armed studies were performed - one investigating highly concentrated (HC: 25% to 27%) saline water (SW) baths (in 4 spas), the other low concentrated (LC: 4.5% to 12%) SW baths (in 5 spas) followed by UVB exposure compared to UVB alone.

The BVDD - after various discussions with BAAK - requested an extended 4-armed study design. Within this, at first the superior reference treatment (tap water-TW+UVB or UVB alone) should be detected and secondly, SW-UVB and bath-PUVA should be compared to this and between each other.

In the BVDD study 1241 outpatients with stable psoriasis vulgaris, a Psoriasis Area and Severity Index (PASI) ≥ 7 and/or an affected body surface $\geq 5\%$ from 102 clinics were randomly allocated to UVB, TW-UVB, SW-UVB or bath-PUVA. Baths preceded UV irradiation. UV dose was adapted to erythematous response. Intervention period with 4 treatment sessions per week lasted for a maximum of 8 weeks.

In the DHV-HC resp. DHV-LC study 160 resp. 143 patients were recruited, however with initial PASI > 10 , intervention periods of maximally 6 weeks and interventions (SW-UVB or UVB alone) thrice weekly. In all trials randomisation ratios were balanced, observer-blinding was performed, and intervention was stopped in case of remission (PASI < 5).

Primary end point was therapeutic success defined as reduction of PASI and/or affected body surface $\sim 50\%$ at the end of treatment. Fisher's exact test was performed

within the 'full analysis set' of patients (using adjusted significance levels according to the Holm-Shaffer procedure due to multiple testing in the BVDD study). Patients' self-administered PASI was used to prove long-term benefit after 3 and 6 months.

In the BVDD study the TW-UVB group proved to be superior to UVB alone (61 % vs. 43%; $P=0.0$). The 2 active treatment arms demonstrated even higher success rates compared to TW-UVB (75% vs. 61 %; $P=0.0$ for SW-UVB, 78% vs. 61 %; $P=0.0$ for bath-PUVA). Bath-PUVA was not superior to SW-UVB (78% vs. 75%; $P=0.3$). No causally related serious adverse events (SAE) were observed, but 11 major, yet reversible, phototoxic reactions).

In both DRV studies SW-UVB attained higher success rates, too, with 86% vs. 54% ($P<0.001$ in He-SW) and 73% vs. 50% ($P=0.005$ in LC-SW). In the BVDD and DRV-LC studies benefit persisted until 6 months.

As SW-UVB and Bath-PUVA are comparably effective treatments in psoriasis and superior to UVB alone or TW-UVB the BAAK recognized this superiority and recommended to put the non-synchronic balneo-phototherapy back to the list treatment options financed by public health-insurances in ambulant settings in 2008.

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TREATMENT OF SKIN DISEASES WITH SALINE WATERS: CLINICAL ISSUES

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Saline balneophototherapy was introduced in several German centres in the late 1970s after encouraging reports of the efficacy of Death-Sea bathing combined with UV-radiation in Israel. The positive effects of saline balneotherapy in combination with UV-radiation are well known for the treatment of psoriasis vulgaris and atopic dermatitis.

However, there are only few single case reports on the treatment of other skin diseases like ichthyosis or vitiligo. Due to the effects of saline solution baths on the skin like elution of inflammatory mediators such as leucocyte elastase and cytokines, inhibition of cell proliferation and increasing erythema sensitivity there might be additionally positive effects for the treatment of other inflammatory skin diseases.

However highly concentrated saline baths might be not well tolerated by patients with acute and severe inflammatory diseases due to extensive burning sensations. Therefore further clinical trials have to be performed.

ENT and Airways Diseases

CLINICAL IMPACT OF SALINE WATER IN ENT

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For centuries endonasal irrigations using salt solutions have been prescribed for the treatment of paranasal sinus diseases without the efficacy having been determined by scientific data. In 1895, the civilised nose was described in an Editorial in *The British Medical Journal* as: "... one of the dirtiest organs in the body" and for washing it, one was "to plunge the face into a basin of clean water, cold or tepid, and take slight sniffs, in and out, while under water". Since then – beginning in the late '50s of the last century a plethora of investigations have been published.

Messerklinger in Graz/Austria was first to describe in detail the ciliary movement of the mucosal layer in the paranasal sinuses in the early '60s. He found that the mucosal layer existant in the nose, the sinusses, the larynx and the trachea as well in the middle ear is the "binding link" in the speciality of ear-nose-and-throat (otorhinolaryngology). Nevertheless, its physiological function is of utmost importance to maintain a healthy condition in the upper airways.

The cilia are covered by a blanket of mucus, which is constantly being moved to the sinus ostia and the nasopharynx

and than swallowed. This blanket of mucus - often referred to as "tapis roulant" - binds bacteria, viruses, dust and other particles. On the other hand it helps to humidify and warm the streaming air. Endonasal irrigations and inhalation with brine aerosols aid the clearance of secretion, debris and intranasal crusts. It has to be mentioned that an isotonic solution equivalent to 0,9% sodium chloride solution or with a little higher concentration up to 2,5-3% improves ciliary function and is found "indifferent" when also the temperature is the same as within the body.

In a very first randomized, controlled trial (RCT) the effect of endonasal irrigation as adjuvant postoperative care in endoscopic sinus surgery could be proven by our study group in the early '90s. Later in an investigative trial we evaluated the effect of endonasal irrigation carried out twice daily using isotonic Ems salt solution over a period of seven days on patients with chronic sinusitis. Endonasal irrigations were significantly effective and both the subjective as well as the objective parameters improved.

In children we could prove by a RCT study the efficacy of brine nose drops compared to xylometazoline, a strong decongestive agent.

Also other authors and study group contributed to the scientific evaluation of saltwater inhalation or rinsing. Nowadays brine rinsing is part of the recommendation for the

treatment of chronic rhinosinusitis and found in the guidelines with a high grade of evidence. In 2007, Cochrane review about nasal irrigations for the symptoms of chronic rhinosinusitis (CRS) came to the conclusion that "the addition of topical nasal saline is likely to improve symptom control in patients with persistent sino-nasal disease".

In summary, in upper airway diseases salt water has found a scientific and evidence based place in daily ENT treatment of the nose and the paranasal sinuses in many important indications for children and adults.

SALINE WATER AEROSOLS IN AIRWAY DISEASES

J. Fischer

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The inhalation of salt can be done in different aggregate states. The most common mode is the inhalation of saline water aerosols. The concentrations of salt solutions can be hypotonic, isotonic or hypertonic. The osmotic pressure in these different concentrations is lower, the same or higher than the osmotic pressure of blood.

The salt solutions are often used as an approach of treatment of acute and chronic airway diseases. The saline water aerosols are used for inhalation therapy mainly in rhinitis, bronchitis, bronchial asthma of different origin, bronchiectasis and cystic fibrosis.

It has been shown that the inhalation of hypotonic saline solution can lead to hyperreactive reactions of the smaller airways. The inhalation of isotonic solution is mostly propagated by the manufacturers of industrial made solutions. Naturally occurring saline water aerosols are mostly hypertonic, as e.g. the seawater. Solutions with a salt concentration of more than 5% can as well lead to hyperreactive reactions as cough or bronchospasm. This can happen especially in patients with bronchial asthma.

The deposition of the inhaled saline water aerosols is of particular importance for the therapeutic effects. Deposition depends on particle size, the volume of nebulized solution per time interval, and in case of naturally occurring saline water aerosols on distance to the location of aerosol production of the natural source. It has to be taken into account that salt aerosols dependent of air humidity are growing because of their hygroscopic properties.

The expected effects of inhalation of saline water aerosols are improvement of the viscosity of epithelial secretions, improvement of immune defense, normalizing of the surface layer of the bronchial epithelium and improvement of the ciliary function. The improvement of lung function, measured by the forced expired volume after 1 second (FEV1), often is the primary outcome parameter in studies. The number of exacerbations and changes in quality of life are as well used as outcome parameters. The measurement of the effect of the inhaled salt solution on the integral system of mucociliary transport with radioactive labeled inhaled particles is expensive and difficult.

In different studies it is shown that the inhalation of higher concentrations of salt solutions in asthmatic patients leads to cough and bronchospasm. In own investigations this could be shown in patients with bronchial asthma who had a highly significant reaction on Carbachol provocation but no significant reaction after inhalation of seawater (3,6%).

Patients with bronchial asthma and allergic rhinitis showed after nasal provocation with specific allergens dramatic nasal obstruction. The reaction was the same after 7 days of nasal inhalation of physiological saline inhalation (0,9%). After nasal inhalation of seawater (3,6%) for 7 days the nasal obstruction after specific provocation could not be found in 60% of the patients.

In a recent published paper of the Cochrane Collaboration it is stated that there is enough evidence to recommend the inhalation of salt water (3% or more salt) through a mask or mouthpiece in patients with cystic fibrosis.

Gynaekology

VAGINAL SOLE APPLICATIONS IN GYNECOLOGICAL MEDICAL HYDROLOGY

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This presentation will provide an overview of the treatment options presented by medical hydrology in gynecology and will serve to discuss the possibilities and limits of vaginal sole applications in female disorders. Many indications are no longer considered up-to-date and practicable and need to be reassessed, which will be addressed in the presentation. A special clinic for medical hydrology in gynecology opened in Bad Kissingen in 1996. The data of the patients was reviewed with regard to vaginal sole therapy and the results are summarized.

Medical hydrology in gynecology is the application of natural, primarily local remedies, such as sole, to prevent, treat and rehabilitate female disorders.

As a rule, 4 percent sole concentrations are used. Sole baths are administered as hip, half or full baths at temperatures of

36 to 40 degrees Celsius for 10 to 20 minutes. Important gynecological mechanisms observed here are trophotropic neurovegetative change, relaxation, spasmolysis, resorption of exudates, and loosening of connective tissue. Sole baths are generally considered to be indicated for sterility, neurovegetative dystonia, menopausal complaints, and age-related atrophy.

Hot vaginal sole irrigations are conducted with glass bulbs (Pinkus bulbs) containing 2 to 4 percent sole at a temperature of 40 to 44 degrees Celsius and falling from a height of 2 meters, which requires up to 15 liters of sole within 15 minutes. However, the total number of sole irrigations should not exceed 10 to 15, especially in pessary users. Experience has shown sole irrigations to be clearly effective in sterility, chronic salpingitis, postoperative infiltrates, post-hysterectomy syndrome, incipient ovarian insufficiency, acnuresis, atonic paraurethral tissue, pressure-induced damage in pessary users, age-related atrophy, adhesion-related complaints, pelveopathia spastica, osteoporosis, vegetative regulatory disorders during pregnancy and in childbed, and in the gerontogynecological treatment of pelvic congestion.

There are differences between hot sole full baths and vaginal sole heat applications regarding thermoregulation and compliance. A hot full bath is stressful. The thermal energy applied via a full bath needs to penetrate and warm the cold periphery before reaching the inner body in weakened form. In contrast, the heat gradient of vaginal sole applications runs from the lesser pelvis to the skin and not vice versa. Thus much higher temperatures can be achieved in the lesser pelvis for a much longer time and in a much more agreeable way than would be possible in a hot full bath.

The advantage of vaginal sole applications lies in their highly intensive local mechanisms directly in the lesser pelvis while circumventing the normal systemic thermoregulation.

tory defense mechanisms. Their disadvantage is the impossibility of influencing the greater systemic neuro-vegetative situation, which in turn is the strength of systemic sole baths.

Experience has shown that sole baths and vaginal sole applications enable differentiated thermal treatment of female disorders. The mechanisms and indications of both methods are partially identical, but also in part considerably different.

(Further information on medical hydrology in gynecology can be found under www.balneologie-dggg.de.)

Applied Physiology and Psychology

IMPACT OF SALT IN BALNEO- AND THALASSOTHERAPY IN JAPAN

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Japan is situated at the far eastern part of Asia and consists of about 6,900 islands, known as the Japanese archipelago, stretching in a long curve in the north-western corner of the Pacific Ocean. The length is 3,000 km from the subarctic zone to the subtropical zone, providing various climatic and terrain characteristics.

Due to the topographical nature of the country and the prevalence of volcanoes, there exists approximately 30,000 mineral springs all over the country. About 30 % of them are sodium-chloride thermal springs. There is almost none halite.

The salt has been used in religious services as offering, sea water and hot spring water bathing for purgation since ancient time in Shinto and Buddhism. In Sumo wrestling of national game, the wrestler scatters salt before game for purification ceremony.

In this paper, some physiological and clinical studies on balneo- and thalassotherapy, especially the salt and water bathing are presented.

The different salinity of sea water caused concentration-dependent increment of both rectal and mean body temperature in total body water bathing. The sea water bathing with flow motion showed significant increase of rectal temperature compared with that in plain water and without flow motion.

We studied on psychological effects of water bathing using "Emotion Spectrum Analysis Method" by EEG. In this method, 4 emotional elements, that is, stress/anger, joy/vigor, sadness/depression and relaxation can be displayed numerically. Ordinary water bathing causes decrease in the stress index level and increase of relaxation level after bathing.

Clinical investigation of balneotherapy and thalassotherapy:

There are many reports on immunological studies. However the results were variable, presumably due mainly to the different treatment conditions.

We studied on humoral and cellular immune activities for 4-weeks balneo-thalasso therapy in diabetic patients. A significant increase in cellular immune activity measured by Regression Assay method for Epstein-Bar Virus (EBV) specific Killer-T cell activity.

Chronological studies were also undertaken in these therapies. It was shown that many physiological parameters such as blood glucose, endocrine functions, were improved with circaseptan periodicity during 4-week balneotherapy. We are now using handy wrist watch type apparatus (ACTIGRAPH) for measuring especially the changes of circadian rhythm of body movement, sleep, fatigue state in long term balneotherapy with strong sodium-chloride thermal spring (Matsusiro Onsen).

Recently, thalassotherapy facilities with Deep Sea Water (DSW) has been rapidly developing. Some basic and clinical studies DSW thalassotherapy will be discussed.

PHYSIOLOGICAL EFFECTS OF SALT SPRING WATER BATHING AFTER INTENSIVE EXERCISE

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In order to investigate the physiological effects of different quality of constituents of bathing water after exercise, bathing was taken in plain and salt spring water after intensive exercise load.

SUBJECTS AND PROCEDURES: Sixteen healthy male adults (30-50 years of age) were subjected in this study after concrete explanation and agreement. Before the experiment, the sub-maximal aerobic capacity was determined by bicycle ergometer exercise in each subject. The intensive exercise load was performed for 30 minutes by incremental exercise method in which 70% $\dot{V}O_{2max}$ was reached within 25-30 minutes in each case.

This procedure was taken in each subject at long enough interval time of day for 3 different bathing, that is, in plain water, in salt spring water and in air as sham control.

The constituents of thermal spring was Fe(?) - Sodium - Calcium-Chloride containing ca. 16g/kg salt at Matsushiro Onsen, Nagano Prefecture).

In experiment, each subject took at first 20 minutes rest period, followed by the intensive ergometer exercise load for 30 minutes, then 30 minutes rest. After that, he took a water bath for 15 minutes at 41.5 °C in sitting position, followed by 30 minutes rest.

RESULTS: Sublingual temperature increased with the same manner in all 3 groups. The decrease tendency was much slower in spring water group after bathing compared with others.

Change of heart rate showed no difference in water bathing among 3 groups. Blood lactic acid level which elevated by the intensive exercise load decreased significantly in salt spring bathing group compared with other groups. It is assumed that the turn-over rate of blood lactic acid in blood is promoted due to peripheral circulatory increment by bathing in thermal salt spring.

A STUDY OF IMMEDIATE EFFECTS OF HOT SPRING POOL THERAPY ON PHYSICAL FUNCTION FOR HEALTHY ADULTS GROUP AND PATIENT GROUP

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METHODS: Study subjects were healthy adults group and patient group (cerebral apoplexy or orthopedic diseases) who took hot spring pool therapy at Shiobara Hot-Spring Hospital. Eight items were measured: two-point discrimination, superficial perception, deep sensation, a rate of loading the lower limb, time to maintain standing in a tandem gait posture, timed up and go test (TUG), functional reach test (FRT), and 30-sec chair stand test (CS30). Exercises performed in the rehabilitation room (ground exercises) and spa pool exercises (underwater exercises) each consisted of 2 sets of 20 repeats per set of high knee movements, squats, hip joint abduction, hip joint extension, and heel raises. In each study groups, above items were measured before and after two categories of exercises, i.e. ground and underwater exercises, to compare statistically their changes from before to after exercises between the two exercise categories.

RESULTS: Superficial perception was significantly enhanced in the healthy adult group after underwater exercises, while it was improved only after ground exercises in the patient group.

The patient group did not improve CS30 after either category of exercises. Time to keep standing in a tandem gait posture was improved in the patient group after any category of exercises in the patient group. The subgroup of apoplexy patients improved in TUG after underwater exercises, while the counterpart group did not.

DISCUSSION: As a whole, it was shown that both healthy adults and patients were benefited by hot spring pool therapy utilizing the Shiogama hot springs that was rich in salt. We considered that especially the patient group was very efficiently trained for body balance control utilizing these salt-rich hot springs that elevated the deep body temperature through hot springs-induced better thermal conductiv-

ity and through their higher levels of buoyancy as well as viscosity.

EFFECTS OF BATHING FOR TWO WEEKS WITH SALT SPRING ON SLEEP QUALITY

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BACKGROUND AND PURPOSE: Sleep disorder is one of the most significant issues for Japanese. Daily bathing in hot spring is expected to improve Sleep quality in Japanese society. The purpose of this study was to define the effect to sleep quality by bathing in salt spring.

SUBJECTS AND METHODS: The subjects of this study are healthy 32 adults residents (41.5±11.2) who have the custom of bathing every day. After two weeks wash out period Bathing in Salt spring Group (SG) taken bathing with salt spring (1.5%, 42°C) in bathing facility everyday for two weeks and Control Group (CG) continued bathing at home. PSQI (Pittsburg sleep quality index) was used for subjective sleep quality assessment before washout period (BWP), after washout period (AWP) and after intervention period (AIP). Actigraph (Ambulatory Monitoring Inc. U.S.A.) was used for objective assessment from the washout period to bathing period. Chi-square test was used for analysis between groups and one-way repeated measures ANOVA was used for statistical analysis for time-series data.

RESULTS: PSQI scores on BWP were 4.4(2.6) in SG and 4.2(1.8) in CG and there was no significant difference. (P=0.954) On time-series analysis among BWP, AWP and AIP no significant difference was shown on PSQI score in SG nor CG. Low sleep quality group (LSQG) and High sleep quality group (HSQG) were made divided at cutoff of the median on PSQI score at 4.0. Although in CG there was no significant difference on statistical test among BWP, AWP and AIP (P=0.267), in SG significant difference was shown among these period. (P=0.015)

DISCUSSION: Two weeks daily bathing in salt spring with 42°C may improve sleep quality. Further case control study is necessary regarding timing of bathing before sleep.

SALINE WATER IMMERSION IN REHABILITATION: THE PATIENTS' VIEW

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INTRODUCTION: Most rehabilitation centers in Central Europe are located in health resorts, which are traditionally characterized by their local natural mineral waters. Repetitive immersion in bath tubs is still part of the comprehensive rehabilitation scheme in many facilities, although some rehabilitation specialists have reservations regarding the medicinal benefit. What about the patients' view on medicinal baths in the context of the rehabilitation scheme? In Bad Ischl the local natural remedy is saline water, all other waters are artificial.

METHOD: In the last week of a three-week rehabilitation course in the Sonderkrankenanstalt Bad Ischl-Lindau a

group of 368 patients (all suffering from orthopedic or pulmonary diseases) were asked to fill out a standardized questionnaire. They were asked about their own view on the impact of every therapeutic measure they had taken. Possible answers: very important, rather important, not very important, not important. The questionnaire was completed by 322 patients (m143, f 179) aged between 24 and 88 years (mean 56 yrs.). The impact of bath tub immersion in different waters was compared. 208 had taken medicinal baths.

RESULTS: Saline baths (n=71) were valued as very important by 62% of the patients, fizzy water bath (n=66) by 52%, CO₂-baths (n=28) by 48%, hey-baths (n=26) by 44% and cream-bath (balneum, soja, n=17) by 27%.

DISCUSSION: Evidently, immersion in natural mineral water as part of the rehabilitation process is still important for many patients. It remains speculative whether this quite positive assessment of immersion in bath tubs (with its evident subjective bias) results from the fulfillment of the patient's expectation when coming to a health resort, the feeling of well-being during or after immersion or the perceived improvement in body function after rehabilitation. Only controlled clinical trials on the benefit of rehabilitation procedures (with or without taking medicinal baths) can contribute to a better understanding of the benefit of immersion in a bath tub within the rehabilitation process.

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