USE OF EXTRACORPOREAL SHOCK WAVES IN THE TREATMENT OF PSEUDARTHROSIS, TENDINOPATHY AND OTHER ORTHOPEDIC DISEASES

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ABSTRACT

Purpose: The use of shock waves in orthopedic diseases was reviewed with special regard to the clinical applications.

Materials and Methods: Findings in the literature and results from our own studies were analyzed and summarized.

Results: Extracorporeal shock waves induced osteoneogenesis in animal models with intact and fractured bones. Based on these findings shock waves were used for the treatment of pseudarthrosis in humans. Most patients had at least 1 unsuccessful operation before shock wave therapy. Complete reunion was noted in 62 to 91% of cases and shock waves are recommended by some as the first choice of treatment for hypertrophic pseudarthrosis.

After failed nonoperative therapy shock waves were used for the treatment of patients with various diseases as secondary treatment. The success rate for treatment of tendinopathies, such as tennis elbow, periarthritis humeroscapularis or calcaneal spur, was approximately 80%. For calcific tendinitis shock wave therapy seems to be superior to all other minimal or noninvasive techniques without compromising a potential later operation.

Conclusions: Shock waves have changed medical therapy substantially. Accounting for the epidemiology of the treated diseases, this new change may equal or even surpass the impact of extracorporeal shock wave lithotripsy.

KEY WORDS: extracorporeal shockwave lithotripsy, pseudarthrosis, tendinitis, calcaneus

With the use of shock waves for the treatment of urolithiasis, a new physical factor was introduced into medicine that allows one to achieve effects inside the body and permits surgery without using a blade. In the early 1970s Hausler and Kiefer noted experimental signs that shock waves were capable of disintegrating renal stones. Subsequent studies focused on further technical development, feasibility and side effects. In 1980 the first clinical extracorporeal shock wave lithotripsy (ESWL*) for a renal stone in a patient was performed. Since then ESWL has revolutionized the therapy of urolithiasis. Numerous studies have been done regarding effectiveness, side effects and the development of new lithotriptors.

After 1985 stones in other organs, such as the gallbladder, bile duct, pancreas or salivary glands, have been treated with shock waves. Within the last 10 years the understanding of shock waves has continuously improved. The physical principles as well as the tissue effects have been widely investigated. Regarding the action of shock waves on tissue, 4 phases have been postulated: 1) physical phase—extracellular cavitations, ionized molecules and an increase of membrane permeability are direct effects of the shock waves, 2) subsequent physical-chemical phase—diffusible radicals and interactions with biomolecules (in both phases mitochondrial lesions were observed), 3) chemical phase—may be accompanied by intracellular reactions and molecular changes, and 4) biological phase—note if these changes persist. Many of the shock wave tissue interactions are not yet completely understood. However, shock waves were introduced in the therapy of various orthopedic diseases.

WOUND HEALING

In 1986 shock waves were used to stimulate healing processes for the first time. Shock waves of various dosages were applied to split thickness wounds in pig skin. These experiments showed a dose dependency, that is with low energies wound healing was stimulated, while high dosages led to a prolonged recovery time. Irradiated skin, resembling a delayed healing model, showed similar effects. Although some clinical treatments have been performed successfully for a crural ulcer, these must be considered anecdotal, since clinical studies have not been reported to date. During the last 30 years there have been numerous investigations on physical factors involved in healing processes, most of which, such as electrical stimulation, electromagnetic fields, piezoelectricity, ultrasound or mechanical influences such as intermittent tension, immobilization and continuous passive motion and micromovement were tested in biological systems for their effects on bone growth or fracture healing.

EFFECTS OF SHOCK WAVES ON BONE TISSUE

The positive results of the wound healing experiments led to the hypothesis that fracture healing might be enhanced with shock waves as well. The first treatments were performed using a fracture model in rats. Using 5 treatments...
with 100 shock waves generated by an experimental Dornier XL-1 lithotriptor, the osteogenetic potential was discovered in 1986. Radiological, histological and biochemical findings revealed that fracture healing was stimulated.\(^5\)\(^4\)\(^6\)\(^7\)

Graff et al investigated the effects of shock waves on all tissues through which the shock waves penetrate during ESWL.\(^5\)\(^7\)\(^8\)\(^9\) The first experiments in 1986 had 2 main purposes that is to investigate the shock wave transmission through bone and the effects on bone tissue. Thus, a series of in vivo and in vitro experiments was performed using pig, rabbit and beagle dogs. In 1 study 24 rabbits were treated with 5,500 shock waves on the left anterosuperior iliac spine and the left distal femur. Two groups with 12 animals each were treated with 20 and 25 kv. generating power, respectively, using a Dornier HM3 lithotriptor. A third of the animals was sacrificed after 48 hours, and after 2 and 3 weeks, respectively. Small hematomas and petechial bleeding similar to the findings after blunt trauma were noted. There were no macroscopic fractures. The experiments showed remarkable influence of shock waves on intact bone. Short-term effects with a healing and necrosis after 2 and 3 weeks, particularly with higher energies. Aseptic necrosis of bone marrow and damage to the osteocytes, as well as excess osteoneogenesis were observed. The 25 kv. group showed multidirectional building of new trabeculae, which can be considered the beginning of fracture healing without previous fracture.\(^5\)\(^7\)\(^8\)\(^9\)

The findings were confirmed by Johannes et al.\(^6\)\(^1\) In a canine nonunion model 4 of 5 shock wave treated animals but only 1 of 5 untreated animals showed bony union after 12 weeks.\(^6\)\(^2\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^8\)\(^9\) However, bone defects in a dose dependent manner using rabbit femur and tibia specimens were noted in ex vivo studies.\(^6\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^8\)\(^9\) Results of ex vivo models for shock wave treatment of bones\(^6\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^8\)\(^9\) often contrast with the in vivo results and, thus, they may not be helpful.

Although shock wave treatment for pseudarthrosis had already been performed successfully in humans in the late 1980s, there was no proof of an osteogenetic effect of shock waves in a standardized fracture model. We used 42, 1-year-old blackhead sheep and inflicted standardized fractures by osteotomy with an oscillating saw. The fractures were stabilized with a landing and external fixation. After 1 week 2 treatment groups were treated with 3,000 shock waves from 2 different angles with a generating voltage of 20 or 24 kv. using a modified Dornier HM3 lithotriptor. Group 3 underwent sham treatment and served as controls. Half of the animals were sacrificed 4 and 7 weeks after fracture infliction. The evaluated parameters were conventional x-ray, microangiography, computerized tomography, conventional histology, biomechanical testing (4-point bending), fluorescence microscopy (calcine green and reverin staining) and serum analyses (phosphate, calcium, albumin, alkaline phosphatase, total and bone isoenzyme). The radiological methods showed a smaller fracture gap and enhanced endosteal and periosteal osteoneogenesis in the treated animals. Enhanced osteogenesis and significant transformation into lamellar, stable bone were confirmed by histology and fluorescence microscopy. As expected, there were no changes in serum values. Biomechanical stability was achieved in all groups after 7 weeks. Clinically relevant side effects were not observed.\(^6\)\(^9\)\(^1\)

The application of 1,500 shock waves at 20 kv. with the high power experimental lithotriptor Dornier XL-1 unit to the epiphyseal region resulted in impaired longitudinal growth in 3 of 18 rats. In 8 animals growth plate dysplasias were reported, which were at least partly replaced by new bone spicules.\(^7\)\(^0\) However, using a larger animal model and lower energies (Dornier HM3, 1,000 shock waves, 18 kv.) Van Arsdale et al noted no differences in the femurs of treated and untreated rabbits.\(^7\)\(^1\) In another experiment fibula osteotomies and tibia defects showed no promoted healing after shock wave treatment with low dosages.\(^7\)\(^2\) In summary, the osteogenetic effect of high energy shock waves was demonstrated in the majority of studies.

**TREATMENT OF PSEUDARTHROSIS**

In humans 0.5 to 10% of the fractures show insufficient healing, resulting in pseudarthrosis.\(^7\)\(^3\) Delayed union is defined when a fracture is not healed completely within 4 months. Healing that does not appear within 6 months is called pseudarthrosis.\(^7\)\(^4\) Congenital forms of pseudarthrosis are known.\(^7\)\(^5\) According to radiological criteria pseudarthrosis can be hypertrophic or atrophic.\(^7\)\(^3\) A long surgical course of treatment is not uncommon among patients with pseudarthrosis. Schlieberger reported up to 40 operations with an average of 9 before shock wave treatment was performed in his patients.\(^7\)\(^6\)

Initial clinical data were reported by Valchanow et al, who began shock wave treatment of pseudarthrosis and delayed union in 1988.\(^7\)\(^7\) Of 82 treatments 70 were successful but, unfortunately, patient history, concomitant treatment and followup were not exactly specified.\(^7\)\(^8\) Although, results presented by Bürger,\(^7\)\(^9\)\(^-\)\(^1\)\(^2\)\(^1\)\(^3\) and Witzach\(^7\)\(^4\) et al showed a lower success rate, they still observed complete union in 35% and callus formation in 21% of 37 treated patients. Haist differentiated the results with respect to hypertrophic versus atrophic pseudarthrosis.\(^7\)\(^5\) While all patients with hypertrophic pseudarthrosis showed complete healing, only 3 of 13 with atrophic pseudarthrosis did so. Schlieberger and Senge postulated that pseudarthrosis should be stabilized after shock wave treatment but axial pressure has to be assured.\(^8\)\(^5\)\(^8\)\(^6\) Therefore an orthesis may be used to avoid bending, rotating or shear forces. Osteosynthetic material does not compromise safety or success of shock wave application.\(^7\)\(^8\)\(^9\)\(^1\)\(^0\)\(^1\)\(^1\)\(^2\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^8\)

Results support the data in the literature. With 2 different lithotriptors a success rate of 67% in 87 patients was observed. Disregarding patients who today are considered poor candidates because of atrophic or scaphoid pseudarthrosis with insufficient stabilization, the success rate increases to 76%.\(^8\)\(^7\)\(^8\)\(^9\)

The table summarizes the reported results of shock wave therapy for pseudarthrosis.\(^7\)\(^6\)\(^5\)\(^7\)\(^8\)\(^9\)\(^1\)\(^0\)\(^1\)\(^2\)\(^3\)\(^4\)\(^5\)\(^6\)\(^7\)\(^8\) Complications, such as transient pain and petechial or subcutaneous bleeding, occur in up to 4% of all treated patients.

**USE OF SHOCK WAVES IN ENDOPROSTHESIS**

The use of an endoprosthesis has gained great importance and today total hip arthroplasty is the standard treatment for patients with arthritis of the hip. Instability has been the major cause of failure during the years.\(^7\)\(^9\) The only definite treatment is surgical replacement of the prosthesis. If a cement stabilized prosthesis is used, the prosthesis and cement must be removed to replace the prosthesis. This procedure often is difficult. As a consequence, shock wave treatment was investigated with respect to mobilization of the cement and, thus, facilitating the replacement.\(^7\)\(^9\)\(^2\)\(^2\)\(^3\)

An acoustic interface was deemed responsible for the disintegration of kidney stones by shock waves.\(^5\) A similar

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**Shock wave treatment of pseudarthrosis**

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acoustic interface was believed to exist among bone, cement and prosthesis. Indeed, shock wave induced microfractures have been described in bone cement as well as cortical bone.\textsuperscript{92, 94-96} Decreases in tension stability of \textsuperscript{19}qg5 and in prosthesis. Indeed, shock wave induced microfractures were observed.\textsuperscript{84} Others reported no changes in stability after shock wave treatment.\textsuperscript{97} In human cadavers application of shock waves facilitated the removal of prostheses.\textsuperscript{98} In contrast, others found no effect of shock waves on bone cement regarding stability or morphology.\textsuperscript{64, 65} In 1 of these cadaver experiments intravasation of bone marrow was noted. Although the authors postulated the risk of fat embolism,\textsuperscript{65} this has never been seen clinically. Based on these controversial results Delius concluded that shock waves are unlikely to be used for removal of the arthroplasty.\textsuperscript{99}

Regarding current knowledge on the osteogenetic potential of shock waves another approach seems more promising. Shock wave induced osteogenesis could result in stabilizing the prosthesis, although to my knowledge this has not been investigated to date. Occasional clinical treatments have been performed with temporary success.\textsuperscript{100}

OSTEOCHONDROSIS

Osteochondrosis dissecans of the knee or talus was treated with shock waves by Schleberger, resulting in integration of the dissecating bone piece but success rates have not been reported yet.\textsuperscript{76} Few treatments with promising results have been performed in patients with Kohler's, Perthes' or Osgood-Schlatter's disease.\textsuperscript{101, 102} To date these therapies must be considered experimental.

TENDINOPATHY (TENNIS ELBOW, PERIARTHRITIS HUMERO-SCAPULARIS, CALCANEAL SPUR)

Tendinopathies, such as the so-called tennis elbow (epicondylitis humeri radialis), golfer's elbow (epicondylitis humeri ulnaris) or the periartthritis humero-scapularis, have been well known for more than 100 years.\textsuperscript{101-103} However, the pathogenesis remains unclear. Some terms, such as periartthritis humero-scapularis, are now considered an incorrect subsumption of different diseases. Most frequently pathological findings in the rotary cuff and long head of the biceps muscle are found. Common symptoms are pain, limited movement and muscular atrophy.\textsuperscript{103} Most affected patients are 40 to 60 years old. The cumulated lifetime risk to develop periartthritis humero-scapularis is estimated to be \textsuperscript{29}c.\textsuperscript{104} Shoulder pain is increasing and ranks second among trauma illnesses, which are responsible for more than half of all occupational illnesses in the United States.\textsuperscript{105} Immobilization, physical therapy, radiotherapy and steroid injections are symptomatic treatments.\textsuperscript{104, 106} Arthroscopic or open surgery are restricted to patients with no response.

Tennis elbow was originally described as writer's cramp\textsuperscript{101} before Morris used the term "lawn tennis elbow."\textsuperscript{107} The disease has a prevalence of 1 to 2 %. In women 40 to 50 years old the prevalence increases to 10\%.\textsuperscript{106} Epicondylitis is associated with severe pain and limited movement. Half of the patients will present to a physician.\textsuperscript{109} Of the patients with medial and lateral epicondylitis of the elbow 12 and 4\%, respectively, need surgery.\textsuperscript{110} Of the patients with all other syndromes were treated. Dahmen et al reported an average of 9.6 repeat treatments, while others limited the number to a maximum of 5.\textsuperscript{129}

Haist and von Keitz-Steeger reported on 812 patients treated for enthesopathy 1 to 5 times with an average of 2.2 shock wave treatments per patient using a Siemens Lithostar \textsuperscript{v} overhead module.\textsuperscript{130} All patients had a long history of unsuccessful nonoperative treatment and 52\% suffered from radial epicondylitis, 11\% from pariarthritis humero-scapularis and 87\% from humeral epicondylitis. The others had insertion tendinosis of the major trochanter, calcaneal spur, achillodynias or phantom pain after amputation. A total of 468 patients (76.5\%) with epicondylitis was followed for at least 3 months and 86.1\% experienced a good treatment result, whereas only 7.1\% were unsatisfied. For patients with shoulder symptoms the success rate was 73.8\% with 2.4\% unsatisfactory results.\textsuperscript{84} Summarizing the studies, the success rate, defined as pain free or substantially improved, was 65 to 85\%. In 296 of 386 sportsmen very good or good results were achieved, while only 20 had an unsatisfactory treatment outcome.\textsuperscript{130}

Rompe et al treated 150 patients with epicondylitis after failed nonoperative therapy for a minimum of 3 months (average 15).\textsuperscript{131} An average of 5 nonoperative treatments (range 3 to 9) had been performed, for example 92\% of the patients received steroid injections without success. Before shock wave therapy a 3-week treatment pause was mandatory and all patients were originally planned for surgery. Using the Osteostar shock wave unit, 1,000 shock waves with an energy density of 0.06 mJ/mm\textsuperscript{2} were applied 3 times at weekly intervals. The parameters (such as night pain, pain with and without activity) evaluated showed significant improvement. The results were very good in 48 patients, good in 51, sufficient in 27 and unchanged in only 24 (15 of whom underwent surgery). In summary, the success rate was 84\% in patients who had otherwise been candidates for surgery.\textsuperscript{106, 116, 127, 128, 131} Higher energy units have also been used; the average success rate was 79%, a success rate with 14\% unchanged is described in 41 patients with calcific tendinitis (29\%), epicondylitis (10\%) and
achillodynia (2). This finding corresponds to results in 80 patients with success rates of 68 and 89% for epicondylitis and calcaneal spur, respectively (Diesch, R., personal communication). However, Richter et al reported disappointing results 6 months after treatment. Schleberger prefers the ultrasound guided MPL9000 instrument for shoulder treatments, while using the MPL5000 * device with x-ray localization for epicondylitis.

In a prospective randomized trial of 61 patients with persistent severe heel pain due to calcaneal spur 68% showed improvement after shock wave therapy, compared to only 16 controls, while 48% had become completely pain-free and 12% of the treated patients still reported severe pain. The involved mechanisms remain unclear. Stimulation of the obturator nerve by shock waves during lithotripsy of a lower third ureteral stone was described in 1 case. Schelling et al showed the stimulation of frog sciatic nerves via a cavitation mediated mechanism. Haist and von Keist-Stegger postulated 3 hypotheses regarding the mechanisms: 1) shock waves damage cell membranes and thus, nociceptors cannot build up a potential to transmit pain signals, 2) stimulated by shock waves the nociceptors send a high frequency of impulses, which are suppressed due to a gate control mechanism and 3) shock wave induced pericellular free radicals change the chemical milieu and pain suppressing substances are released.

CALCIFIC TENDINITIS

Calcific tendinitis is a common event. The literature notes 2 to 20% of such calcifications in the shoulder of asymptomatic persons and up to 50% in patients with shoulder pain. Spontaneous remission of these calcifications is seen in up to 100% of patients with acute pain. However, chronic pain may lead to rest pain and kinesalgia. In such patients only 9% of the calcifications will resolve spontaneously within 3 years. Nonoperative therapeutic options are physical treatment, antiinflammatories, local x-ray radiation, steroid infiltration and needling. X-ray is without therapeutic effect, while needling is successful in 40 to 60% of cases. Open surgery removing the calcifications has a high success rate, while arthroscopic procedures succeed in 50% only.

The first treatment of calcific tendinitis with shock waves with the goal to disintegrate the calcification was reported by Loew and Jurgowski et al in 1993. A total of 15 patients with a long history of calcific tendinitis (mean 5.5 years) had been treated in 1 or 2 sessions with 1,500 to 2,000 shock waves. Of the 5 patients treated with a Dornier compact lithotriptor 4 had complete disintegration of the calcification and marked clinical improvement. Interestingly, only 2 of the 8 patients treated with the MFL 5000 device showed partial disintegration and none had clinical improvements. The different results could be due to the differing shock wave generation of the devices (electromagnetic versus hydraulic). However, newer studies indicate that localization problems were more likely to explain the difference.

Loew et al also reported a prospective study of 20 patients with severe symptoms, whose calcifications were at least 1 cm. in diameter. The minimum history was 12 months and the last treatment was not done within the last 2 months. A total of 2,000 shock waves at 18 to 22 kV. generating voltage was applied in 2 sessions 14 days apart. Local anesthesia with subcutaneous bupivacaine infiltration was used. After 12 weeks 7 patients had radiologically complete resolution of the calcification and 5 had partial disintegration. Magnetic resonance tomography revealed no bone or soft tissue damage. Six patients were completely symptom-free after 12 weeks, 8 were significantly improved and only 1 experienced symptom deterioration. Using a 100 point score to evaluate shoulder disabilities according to pain, daily life activities, active pain-free motion and force, an average improvement of 25 points was noted with 13 patients reaching success values (more than 80%). Petechial skin bleeding in 14 patients and superficial hematomas in 4 were the only side effects.

Haupt and Katzmeier treated 29 patients with the Ossa-tron unit, of whom 14 became pain-free and 10 were substantially improved. No patient experienced deterioration. In a larger series of more than 100 patients 70% were pain-free or substantially improved and 16% were primarily improved (Diesch, R., personal communication). Rompe et al treated 40 patients with 1,500 shock waves and an energy density of 0.28 mJ/mm² using plexus anesthesia. Of the patients 62.5% showed partial or complete radiological disintegration of the calcification, 72.5% had no or only occasional discomfort and after 24 weeks only 6 reported no improvement of the symptoms. The same investigators performed a controlled, prospective and randomized study of 100 patients with symptoms at least 12 months in duration. Clinical evaluation and pain level were assessed in a standardized manner, and the patients were followed for 24 weeks. One group of patients received 3,000 shock waves, while the other group had only 30 shock waves. In all 6 tested parameters the group with 3,000 shock waves showed statistically significant superior results. The overall outcome was good or excellent in 48% of cases and acceptable in 42% in this group, compared to 6 and 24%, respectively, in the 30 shock wave group.

The mechanism of action remains unknown. Resorption of the calcification in the tendon and reactive hypervascularization have been discussed. Dahmen et al used low energies and reported an increased repeat treatment rate of up to 20. Using this regimen 48 of 76 patients had good and 19 had improved results, and 9 remained unchanged.

Loew et al conducted a prospective randomized study of 20 patients in an untreated control group and 20 in a shock wave treated group (2 treatments with 2,000 shock waves at 21 kv., MFL 5000 device). Of the treated patients 14 had a successful result compared to only 1 control. Radiological and clinical differences were statistically significant. In a second study they compared single treatments (2,000 shock waves and 21 versus 18 kV.). The 21 kv. group showed statistically significantly better results. One treatment at 21 kv. was as successful as the aforementioned double treatment.

To date the results of shock wave therapy for calcific tendinitis have been superior to those of the spontaneous course and to physical or minimal invasive treatment. Treatment with greater success, open surgery, will not be compromised in case of shock wave treatment failure.

CONCLUSIONS

Several studies of shock waves for orthopedic diseases have been reported but randomized trials are still rare and needed. However, some points have been clarified. To my knowledge no severe deterioration or complication has been described to date. Of course, the general contraindications for shock wave therapy still apply, for example pregnancy, coagulation disorders or lung tissue in the shock wave path. To date shock wave therapy has been limited in almost every study to patients who had unsuccessful nonoperative treatment, and for pseudarthrosis to those who also underwent unsuccessful surgery. Alternative therapy, such as surgery, has not been compromised by shock wave therapy. Thus, the orthopedic group of the German Lithotripsy Society at the consensus meeting in 1995 recommended shock wave therapy for various indications including pseudarthrosis and delayed union of bones, enthesopathy (tennis elbow, shoulder syndromes, calcaneal spurs) and pain in soft tissue in prox-

* Dornier, Germering, Germany.
imity to bones, and tendopathies with extraneous calcification. For pseudarthrosis shock wave therapy is referred to as the treatment of first choice.16o

Until 1992, we were the only center in Germany (and to our knowledge 1 of 2 centers worldwide) to perform shock wave therapy for orthopedic diseases. An overview in 1993 revealed that already every sixth German urological shock wave unit was also used for such treatments.90 Meanwhile a number of other European departments have started to use this therapy. At some departments it has outnumbered the urological applications by far. The total number of orthopedic shock wave treatments in Germany is estimated at 66,000 in 1996, while ESWL for urolithiasis was performed 70,000 times.161 Even during the Olympic Games in Atlanta shock wave therapy was used for the treatment of athletes (Wess, O., personal communication).

Several shock wave parameters exist, such as rise time, peak pressure, negative pressure, pulse width, intensity and focal energy. The geometry of the focus may also influence the treatment. Considering the long-lasting and often invasive treatment, and the socioeconomic importance of these diseases, it seems reasonable to enable our colleagues the access to the new therapies.

Regarding the large population afflicted with these diseases, considering the long-lasting and often invasive treatment, and the socioeconomic importance of these diseases, it is realistic to expect an even greater importance of shock waves in this field than in urology. Urologists know how to use shock waves for the treatment of urolithiasis. We should enable our colleagues the access to new treatments and support them with the experience we gained in 15 years of using ESWL.

Dr. Rupert Diesch provided information about pathogenesis, symptoms and treatment alternatives of the orthopedic diseases. Dr. J. Miguel Garcia Schirmann provided assistance in the review.

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