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Side-effects of extracorporeal shock wave therapy (ESWT) in the treatment of tennis elbow

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Abstract Apart from a few observational reports, there are no studies on the side-effects of extracorporeal shock wave therapy (ESWT) in the treatment of insertion tendopathies. Within the framework of a randomised, placebo-controlled, single-blind, multicentre study to test the effectiveness of ESWT in the case of lateral epicondylitis (LE), side-effects were systematically recorded. A total of 272 patients from 15 centres was allocated at random to active ESWT (3×2000 pulses, energy flux density ED₊ 0.04 to 0.22 mJ/mm² under local anaesthesia) or placebo ESWT. In all, 399 ESWT and 402 placebo treatments were analysed. More side-effects were documented in the ESWT group (OR=4.3, CI=[2.9; 6.3]) than in the placebo group. Most frequently, transitory reddening of the skin (21.1%), pain (4.8%) and small haematomas (3.0%) were found. Migraine was registered in four and syncopes in three instances after ESWT. ESWT for LE with an energy flux density of ED₊ 0.04 to 0.22 mJ/mm² is a treatment method which has very few side-effects. The possibility of migraine being triggered by ESWT and the risk of a syncope should be taken into account in the future. No physical shock wave parameters could be definitely identified as the cause of the side-effects observed.

Keywords Extracorporeal shock wave therapy · Side-effect · Tennis elbow · Lateral epicondylitis

Introduction

After extracorporeal shock wave lithotripsy (ESWL) established itself as the standard treatment for disintegrating kidney stones [1], it was clinically applied as extracorporeal shock wave therapy (ESWT) in the area of ortho-

paedics for the first time as a treatment of pseudarthrosis [18]. A secondary finding here was an intense analgesia [2] of the treated region, and ESWT was recommended by numerous authors [7, 10, 13, 14] for treating chronic insertion tendopathies such as tennis elbow (= lateral epicondylitis of the elbow, LE).

Despite this recommendation, up to now the side-effects of the therapy have not been systematically recorded. Richter et al. [10] reported localised reddening of the skin and small haematomas in 10 of 14 patients during treatment of epicondylitis. Rompe et al. [11] observed no side-effects at all in a verum group of 15 patients with plantar fasciitis and in an uncontrolled study group of 75 patients [12] when treating LE. The frequency with which haematomas occur appears to depend on the energy used, as was noticed when using a Dornier Compact lithotripter [1]. Using magnetic resonance image tomography, Loew et al. [8] were unable to establish any changes in muscular tissue in patients after ESWT applied to the shoulder using an energy flux density of 0.28 mJ/mm². In one case a transient oedema of the bone could be seen.

The only systematic recording of side-effects of ESWT [15] includes a group of 34 patients with LE, but the findings of all indications and energy levels are summarized. The type and frequency of the side-effects were not analysed with respect to the energy and number of pulses applied.

Considering the numerous side-effects that can be triggered experimentally [5], the number of isolated clinical reports on side-effects in the clinical application of the therapy is surprisingly low. Therefore, our work aims at closing this apparent gap for LE. This seems all the more urgent as application of this new therapy method has rapidly increased over the last few years.

Within the framework of a multicentre study [6] testing the effectiveness of ESWT, all side-effects which occurred were systematically recorded during the 'low-energy' ESWT of the LE. The objective was to find out which side-effects occur during therapy and to describe the frequency of side-effects according to various treatment parameters. These parameters are identified separately for the shock wave devices used in the study.

Patients and methods

The study was carried out as a blind, randomised, placebo-controlled study with two types of treatment, so the patients did not know which of the two types of treatment they were allocated to. The inclusion and exclusion criteria listed in Table 1 were applied. Only patients with chronic LE were accepted into the study, for whom at least 6 months of conservative therapy had led to no improvement. Before the first treatment a therapy-free period of at least 2 weeks was required. Patients were allocated to the active or control therapy randomly by telephone just before the first treatment. The randomisation and monitoring were carried out by the Institute of Medical Biometry and Epidemiology in Marburg.

As active therapy 'low-energy' ESWT with 3×2000 pulses under local anaesthesia was applied within an interval of 1 week plus/minus 1 day using a device-dependent energy flux density ED₊ between 0.04 and 0.22 mJ/mm². The appropriate device setting was checked by the manufacturers for each centre. Positioning

Table 1 Inclusion and exclusion criteria

Inclusion criteria	<ul style="list-style-type: none"> - Epicondylitis of the radial humerus (at least two positive provocative tests: tenderness on the epicondyle, Thomson test, middle finger extension test, Bowden test, Mill test) - Availability of written informed consent - At least 6 months unsuccessful conservative therapy before entering the study with at least three local injections plus at least 10 individual treatments with physiotherapy plus at least 10 individual treatments of physical forms of therapy - At least 2-week interval since the last conservative therapy
Exclusion criteria	<ul style="list-style-type: none"> - Local arthrosis/arthritis or rheumatoid arthritis - Pathological neurological findings of the extremity to be treated - Preliminary operation on the epicondyle to be treated or bilateral symptoms - Under 18 years of age or pregnancy - Thrombopathy, anticoagulant therapy or manifest hyperthyroidosis - Infection of the upper extremity to be treated - Suffering from tumour of the upper extremity to be treated - Known allergy to local anaesthetic mepivacain/scandicain

was to be performed using ultrasound imaging. Patients in the control group received the same regimen of placebo ESWT under local anaesthesia. To do this, a PE-foil filled with air was fixed with ultrasound gel in front of the coupling cushion.

The lithotripter manufacturers worked out a set of shock wave parameters with which the equipment used can be compared. The set of shock wave parameters used (Table 2) was determined in the consensus report by the technical working group of the German Association for Shock Wave Lithotripsy [19]. The symbols and definition of the parameters stated follow the lines of this publication. The shock wave parameters were measured either with a fibre-optic probe for the specified energy setting or obtained by interpolation of corresponding adjacent values. Measuring was carried out in accordance with IEC 61846. All fibre-optic probes used were built according to the same design [17].

Side-effects were recorded on standardised forms by the attendant doctors during each of the three therapy sessions. It was explicitly asked whether reddening of the skin, swelling, petechia, allergy to the anaesthetic used, bleeding or a syncope occurred during the therapy. In addition, patients were also asked whether they had suffered any other side-effects. Unexpected adverse effects were to be reported separately.

Statistical methods

Descriptive statistics were used to characterise the patient sample, with means and standard deviations (SD) given where appropriate. Absolute and relative frequencies of the reported side-effects were calculated for each treatment in both groups. In order to state possible differences in frequencies between the two groups more clearly, odds ratios (OR) with 95% confidence intervals (CI) were determined. The exact Fisher's test was carried out on the differences to check for exploratory significance. For a discussion of possible dependencies of reported side-effects on the physical parameters of the equipment used, the devices were ranked with regard to each parameter, and the relative frequency of the individual side-effects was studied according to this ranking. Because

Table 2 Shock wave parameters for the equipment used in accordance with the consensus report of the technical working group of the German Association for Shock Wave Lithotripsy

Physical parameter	Unit	Dornier Epos Ultra, Level 2	Dornier Epos Ultra, Level 3	Dornier Epos Fluoro, Level 3	Dornier Compact S, Level 1	Siemens Sonocur, Level 2	Siemens Sonocur, Level 3	Storz Minilith SL1, Level 3	Wolf Piezoston 300, Level 5
P_+	Mpa	10.6	13.7	16.0	29	7.9	11	20	40
$f_{x(-6\text{ dB})}$	mm	7.4	6.0	9	3.0	5.7	5.5	4.75	3
$f_{y(-6\text{ dB})}$	mm	7.4	6.0	9	3.0	5.7	5.5	4.75	3
$f_{z(-6\text{ dB})}$	mm	34	33	90	38	57	56	30	20
$f_{x(5\text{ Mpa})}$	mm	8.2	6.3	18	11	3	5	14	10
$f_{y(5\text{ Mpa})}$	mm	8.2	6.3	18	11	3	5	14	10
ED_+	mJ/mm ²	0.06	0.08	0.07	0.09	0.04	0.07	0.22	0.08
ED	mJ/mm ²	0.11	0.22	0.11	0.12	0.09	0.16	0.32	0.20
$E_{+(-6\text{ dB})}$	mJ	1.5	1.6	3.2	0.6	0.7	1.1	1.65	0.6
$E_{(-6\text{ dB})}$	mJ	2.7	2.9	4.5	0.75	2	3	4.9	1.4
$E_{+(5\text{ MPa})}$	mJ	1.9	8.5	7.0	4.2	0.5	1	3.1	6.3
$E_{(5\text{ MPa})}$	mJ	3.4	15	11	6	2	3	22	15.8
$E_{+(5\text{ mm})}$	mJ	0.9	1.4	1.1	1.4	0.5	0.9	1.4	1.6
$E_{(5\text{ mm})}$	mJ	2.0	2.6	1.9	1.7	1.3	2	5.3	3.9

side-effects were not the primary criteria of the study, the reported values are to be regarded as exploratory.

Results

A total of 135 patients was randomised to the ESWT group and 137 patients to the placebo group. Of these, 53.7% and 51.8% were women, and their average age was 46.9 (SD 8.5) and 46.3 (SD 9.6) years, respectively. The epicondylitis had lasted 27.6 (SD 35.5) and 22.8 (SD 21.4) months, and the duration of the conservative therapy was 22.3 (SD 23.3) and 20.2 (SD 19.7) months.

Each of the 135 randomised patients in the ESWT group should have undergone three treatments. One patient withdrew his consent after the randomisation, another stopped after the first treatment due to another illness, and 1 patient did not turn up for the third treatment. This left a total of 399 ESWT treatments which are described here.

The documentation was missing for 2 of the 137 randomised patients in the placebo group, 1 patient rejected the second treatment, and a further patient did not turn up for the third treatment, so that in total 402 placebo treatments were carried out and documented.

Energy flux density

The centres adhered to the 'low energy' ESWT device setting determined by the manufacturers. The applied energy flux density ED_+ varied from 0.04 to 0.07 mJ/mm² (Storz Minilith 0.22 mJ/mm² measured with laser hydrophone). This bandwidth results from the new measuring methodology only recently available and now standardised for all equipment.

Pulse frequency

The required pulse frequency was inadvertently adjusted to 240 pulses per minute in 24 of 801 treatments; for all the rest, a frequency of 120 pulses per minute was adhered to.

The required number of pulses (2000 pulses) per treatment was adhered to in all cases.

Side-effects

The frequency with which side-effects and undesirable events occurred during and after the treatment is listed for each treatment in Table 3. The following side-effects were not listed in the forms but were often quoted and explic-

Table 3 Absolute and relative frequencies of observed side-effects and undesirable events in each group across all equipment used

Side-effects/undesirable events	Number of ESWT (%)	Number of placebo (%)
Reddening of the skin	84 (21.1)	19 (4.7)
Pains	19 (4.8)	7 (1.7)
Petechiae/bleeding/haematomas	18 (4.5)	7 (1.7)
Swelling	10 (2.5)	11 (2.7)
Other	5 (1.3)	3 (0.8)
Migraine attack	4 (1.0)	0
Syncope	3 (0.8)	0
Feeling unwell/nausea/dizziness	3 (0.8)	1 (0.3)
Cold/influenza/bronchitis	2 (0.5)	1 (0.3)
Allergy to local anaesthetic	2 (0.5)	0
Elbow irritated/sensitive	1 (0.3)	1 (0.3)
Cardiac failure (SAE)	1 (0.3)	0
Total	152 (38.1)	50 (12.4)

Table 4 Percentage of treatments with side-effects or undesirable events per device in treatments carried out with one device

Type of device:	Dornier			Siemens			Storz		Wolf		Total
	Compact S	Epos Ultra Level 2	Epos Ultra Level 3	Epos fluoro	Sonocur/~ Level 2	Sonocur/~ plus Level 3	Lithostar	Minilith SL1	Piezoson 300		
Number of treatments	9/15	64/63	72/72	27/27	87/87	24/27	0/3	101/98	15/10	399/402	
Side-effect (%)											
Reddening of the skin	0/0	3.1/0	23.6/6.9	3.7/0	1.2/0	4.2/0	0/0	54.5/10.2	46.7/40.0	84/19	
Petechiae/bleeding/haematomas	11.1/0	4.7/4.8	9.7/2.8	0/0	1.15/0	4.2/0	0/0	5.0/2.0	0/0	18/7	
Swelling	0/0	12.5/12.7	1.4/1.4	3.7/0	0/0	0/0	0/0	0/2.0	0/0	10/11	
Allergy to local anaesthetic	0/0	0/0	0/0	0/0	1.2/0	0/0	0/0	1.0/0	0/0	2/0	
Syncope	0/0	0/0	0/0	11.1/0	0/0	0/0	0/0	0/0	0/0	3/0	
Pains	22.2/13.3	0/0	0/1.4	7.4/3.7	8.1/2.3	16.7/0	0/0	4.0/1.0	0/0	19/7	
Nausea/dizziness	0/0	0/0	0/0	0/0	0/0	8.3/0	0/0	1.0/1.0	0/0	3/1	
Migraine attack	0/0	0/0	0/0	0/0	4.6/0	0/0	0/0	0/0	0/0	4/0	
Elbow irritated	0/0	0/0	0/1.4	0/0	0/0	0/0	0/0	1.0/0	0/0	1/1	
Cold/influenza/bronchitis	0/0	0/0	1.4/0	0/3.7	1.2/0	0/0	0/0	0/0	0/0	2/1	
Other	0/0	0/0	0/0	3.7/0	3.5/1.2	0/3.7	0/0	1.0/1.0	0/0	6/3	

ity cited: pain, haematoma, migraine attacks, feeling unwell/nausea/dizziness, cold/influenza/bronchitis, and sensitivity and irritation of the elbow. In addition, petechiae, bleeding and haematomas have been put into one category. Overall more side-effects were reported for treatments in the ESWT group than in the placebo group (OR=4.3, CI=[2.9; 6.3], descriptive $p=0.0001$). This can be attributed for the most part to the frequently reported reddening of the skin (OR=5.4, CI=[3.1; 9.6], descriptive $p=0.0001$). Furthermore, pains and petechiae/bleeding/haematomas were reported more frequently in the ESWT group (OR=2.8 and 2.7, CI=[1.1; 8.0] and [1.0; 7.6], descriptive $p=0.017$ and 0.0261). In the ESWT group there was one death due to cardiac failure, but this was not causally linked to the shock wave therapy.

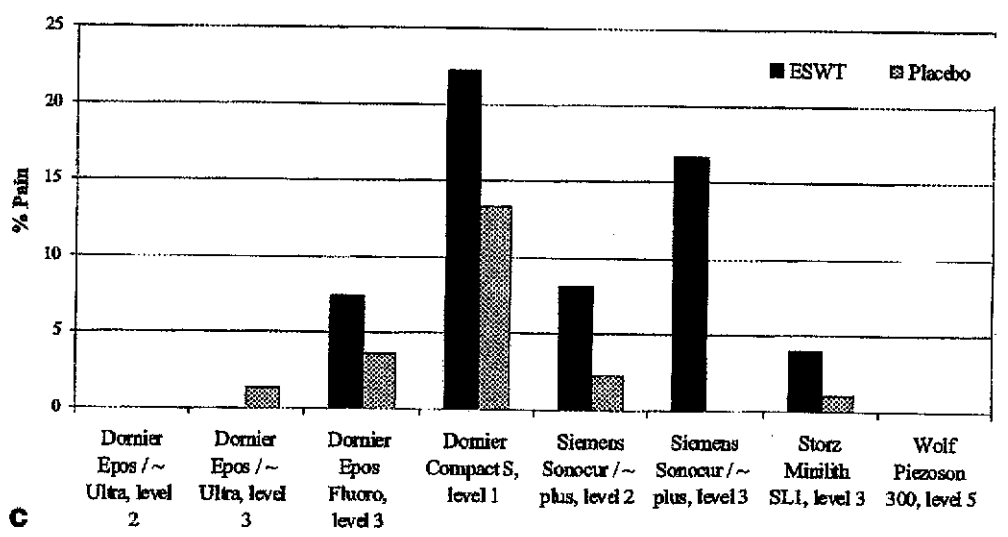
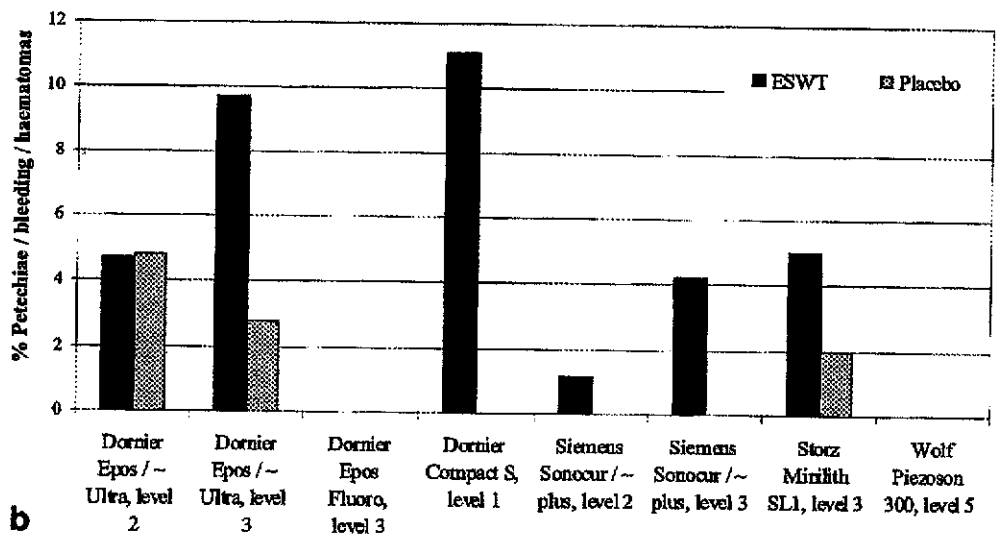
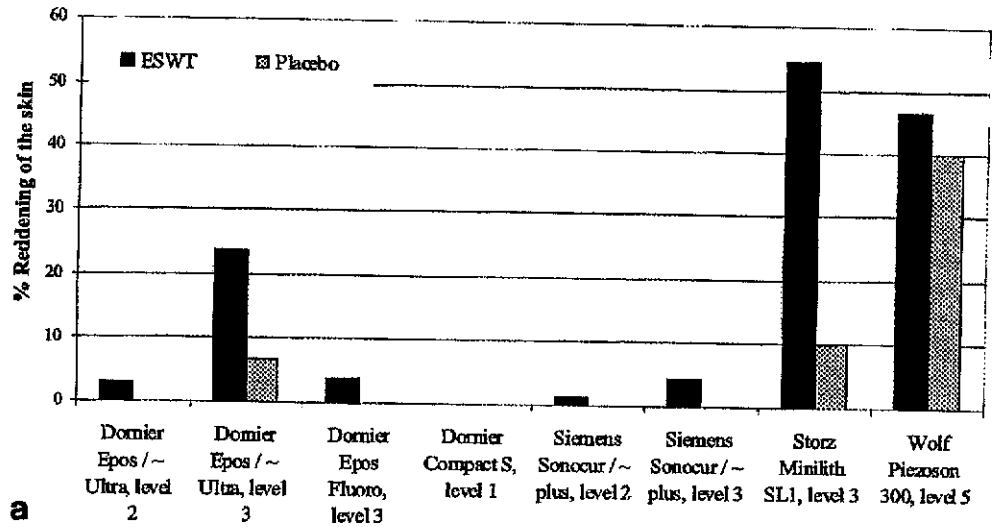
Side-effects related to equipment: Table 4 shows the number of treatments with each device for both groups. In addition, the relative proportion of treatments with side-effects and undesirable incidents is depicted for every device. Reddening of the skin is found more frequently with Wolf Piezoson and Storz Minilith SL than with other devices (Fig. 1a), but a difference between ESWT and placebo could be seen only with Storz. With Dornier Epos Ultra Level 2, there were more swellings than with other devices. The Dornier Compact and Dornier Epos Ultra Level 3 produced large numbers of haematomas/bleeding/petechiae in the ESWT group, but not in the placebo group (Fig. 1b). Pain was documented for the Dornier Compact in both groups and for the Siemens Sonocur Level 3 in the ESWT group (Fig. 1c). The four migraine attacks reported occurred in three different patients 1-4 days after ESWT with the Siemens Sonocur Level 2. There were three instances of syncope, each time during the first treatment with the Dornier Epos Fluoro.

Discussion

In this study the side-effects of ESWT in the treatment of LE were systematically identified for the first time in a large patient population and described with regard to the equipment used.

Transitory reddening of the skin in the coupling area of the equipment represented the majority of the side-effects observed. The difference between the verum and the placebo therapy was statistically noticeable here. Nevertheless, changes in skin pigment or trophic disturbances above the epicondyle of the radial humerus resulting from this were not reported at the follow-up examinations after 12 weeks. The high incidence of reddening of the skin in the case of two devices may have been caused in one instance by using a device with the highest energy flux density within the framework of the study; in the other case, however, an ESWT-independent centre effect may be possible because of the high portion in the placebo group also. We consider reddening of the skin as a harmless concomitant side-effect, which in no case forced the treatment to be discontinued or the dose to be reduced during the study.

Fig. 1a-c Percentage frequency of reddening of the skin (a), petechiae, haematomas, bleeding (b) and pain (c) in the study for each device and energy setting used for extracorporeal shock wave therapy (ESWT) and placebo treatments



Petechiae, haematomas and small bleedings from the skin occurred substantially less often in our study in comparison with the observations of Sistermann and Katthagen [15]. It remains speculation whether the use of a urological device there was the cause, as it has no CE certification for applications to the musculoskeletal system. The frequency of petechiae varied for different devices within our study, but we were unable to find that any specific technical parameter was responsible for this.

The painfulness of ESWT is the second most frequent side-effect in the verum group despite local anaesthesia, but this did not force any dose reduction. The peak pressure (P_+) seems to have as equally small an influence on triggering the pain as other energy parameters (P_+ , E 5 mm, E 5 Mpa, ED, ED₊), although the physical effects of disintegrating kidney stones are linearly dependent on the effective energy [4]. Surprisingly, patients do not complain about more pain even when the energy is increased. This finding is independent of the device. When analysing the technical parameters, it was noticeable that a larger axial focal extension (fz-6dB) seems more likely to be linked with greater painfulness. A larger axial focus extension leads to the delivery of energy to a larger area of bone below the insertion of the tendon even though otherwise the device setting is the same. The energy released there due to the large difference in impedance between the tendon and bone could be the cause of increased painfulness.

Migraine attacks occurred after four treatments (in three different patients) in the ESWT group after 1-4 days. This number is low (approx. 1% of the ESWT treatments), but because there were no such cases in the placebo group, in the future it should be pointed out that ESWT treatment could possibly trigger such attacks. To date, there are no reports of migraines being triggered in the extensive literature on lithotripsy of kidney stones (ESWL). On the other hand, headaches were reported after ESWL, which were blamed on the spinal anaesthesia [16]. Within the framework of this study, migraines only occurred in the case of ESWT patients who were treated with the same device.

Vasovagal syncope occurred in three instances and with only one device during the first therapy session for patients who had never before reported this incident. It is generally recommended that treatment with ESWT applications is carried out with the patient lying down, provided the device being used makes this possible.

The reported differences between the devices can have various causes. Firstly, due to the small number of treatments conducted with each device, differences observed might merely reflect random variation. Secondly, it is possible that the properties of the different devices actually cause side-effects to a varying extent. It should be noted here that in principle all the parameter values used in the study with the exception of the peak pressure can be achieved by all of the devices used in the study, if the energy settings are performed accordingly.

Additionally, it should be considered that in this study the variables of centre and device are very often confounded.

Currently, we cannot causally link the observed side-effects to the existing device parameters, we can only make suggestions. When comparing devices, we must also take into account that the measured physical parameters are subject to large measurement errors due to basic technical measuring problems. The size of this measurement error was estimated to be 31% at peak pressure P_+ [2]. The measurement error for measurements with the fibre-optic probe is estimated to be 20% at peak pressure by the manufacturers.

In our opinion, comparisons with earlier studies [e.g. 12] is not permitted because these were obtained with experimental lithotriptors, for which the measuring parameters available today were either not determined or determined in a different way.

We must take into account that in the study the total number of pulses and their frequency were strictly fixed, so that a comparison of the devices within the study provides only information on the dependence of ESWT side-effects on the same number of pulses, same frequency and varying energy values. A therapy regimen other than the one used here could therefore lead to other side-effects.

In conclusion, ESWT with an energy flux density of ED₊ 0.04 to 0.22 mJ/mm² (measured with glass fibre hydrophone) is a treatment method for LE which has very few side-effects. Patients should be advised on the possibility of migraine being triggered in the future, and the treatments should take place with the patient lying down due to the risk of a syncope. No physical shock wave parameters could be definitely identified as the cause of the side-effects observed.

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