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Intravenöse Laserblutbestrahlung bei Multipler Sklerose: ein neues Therapieverfahren mit signifikanter Verbesserung der Lebensqualität

Laser blood irradiation for multiple sclerosis: a new treatment procedure with significant improvement of the quality of life

Zusammenfassung

Hintergrund: Die Ätiologie der Multiplen Sklerose ist ungeklärt. Die Behandlung erfolgt heute in der Regel immunsuppressiv. Die intravenöse Laserblutbestrahlung (LB) mit einem Softlaser wirkt antiinflammatorisch und immunregulierend. Ziel der vorliegenden Studie war es zu ermitteln, welchen Einfluss eine intravenöse Laserblutbestrahlung auf die Lebensqualität von Patienten mit MS hat.

Methode: Bei 20 Patienten erfolgte eine intravenöse LB mit dem „weberneedle® blood System“ (HeNe-Dioden-laser mit einer Leistung von 5 mW und einer Wellenlänge von 658 nm). Eine vorexistierende immunmodulierende Therapie wurde unverändert parallel fortgesetzt. Der SF12 wurde als standardisiertes Instrument zur Erfassung der Lebensqualität bei MS herangezogen. **Ergebnisse:** Die Laserbehandlung ergab eine signifikante Verbesserung der körperlichen Summenskala von $38,2 \pm 5,8$ Punkte vor Therapie auf $43,4 \pm 8,1$ Punkte direkt nach der Therapie ($p=0,002$). Die psychische Summenskala verbesserte sich ebenfalls signifikant von $28,6 \pm 6,9$ auf $43,6 \pm 13,0$ Punkte ($p<0,001$). Im Langzeitverlauf konnte ein weiterer nicht signifikanter Trend zur weiteren Verbesserung beider Skalen beobachtet werden (körperliche Summenskala = $46,9 \pm 7,3$ Punkte; psychische Summenskala = $47,6 \pm 13,1$; p für beide Skalen im Vergleich zu den Skalen direkt nach Therapie = n.s.). **Schlussfolgerung:** Die Laserblutbestrahlung führt zu einer hochsignifikanten Verbesserung der Lebensqualität bei Patienten mit Multipler Sklerose. Weitere Untersuchungen sind erforderlich.

Schlüsselwörter

Multiple Sklerose, Laserblutbestrahlung, Lebensqualität, SF12

Summary

Background: Multiple sclerosis (MS) is a disease with a relapsing or chronically progressive course. As a general rule, the treatment performed today is immunosuppressive. Intravenous laser blood irradiation (LB) with a Softlaser (low level laser therapy) is anti-inflammatory, immune-regulating, rheologic and regenerative. Lately, studies on the efficacy of therapeutic measures are increasingly examining the change in the quality of life as a result of this treatment. The following study investigated the influence of intravenous LB on the quality of life of patients with MS.

Approach: Intravenous LB with the „weberneedle® blood system“ was used with 20 patients. A fiber optic HeNe diode laser with a power of 5 mW and a wavelength of 658 nm (red light) is used. SF12 was used as a standardized system to ascertain the physical and mental quality of life with MS.

Results: A significant improvement in the physical sum scale from 38.2 ± 5.8 before treatment to 43.4 ± 8.1 points directly after the treatment was achieved ($p=0.002$). The mental sum scale likewise improved significantly from 28.6 ± 6.9 to 43.6 ± 13.0 points ($p<0.001$). In the long-term course, a further non-significant trend towards continued improvement on both scales could be observed (physical sum scale = 46.9 ± 7.3 points; mental sum scale = 47.6 ± 13.1 ; p for both scales in comparison to the scales directly after treatment = n.s.). **Conclusions:** The laser blood irradiation led to a highly-significant improvement in the quality of life of patients with multiple sclerosis.

Key words

multiple sclerosis, laser blood irradiation, quality of life, SF12

Introduction

Multiple sclerosis (MS) is an isolated central nervous system disorder of unclear origin. Initially inflammatory processes predominate, degenerative developments ensue during the following progress. Disturbances of the motor and sensitive system come to the fore of symptomatology, culminating in restrictions of visual capacity due to inflammatory processes of the central nervous system. A massive chronic exhaustion subsequently often ensues, which may cause inability to work and for which no effective therapy is known. Concordance with the HLA system is known, affecting the autoimmune and inflammatory processes. In terms of aetiology, an autoimmune, neurodegenerative and inflammatory origin is being discussed [12]. The current prevailing doctrine assumes that a T-cell-dependent disorder with initial secondary macrophage activity and myelin sheath destruction is concerned. An immunosuppressive treatment is normally carried out nowadays.

Effects of the intravenous laser blood irradiation

The intravenous laser blood irradiation (LB) using a soft laser (low level laser therapy) has an anti-inflammatory, immune-regulating, rheological and regenerative effect [4]. Under a LB, an increase of immunoglobulins in the blood [5] and a CRP reduction in the peripheral blood could be observed [2]. A positive effect was also described in the B and T-cell populations [3, 6, 9]. On account of the LB, this leads to striking improvements in the rheological blood parameters with resulting elimination of hypoxia, improvement of ATP synthesis and, therefore, to a positive influence exertion on cellular metabolism [8]. Based on these data, a potential therapeutic effect on chronic inflammatory disorders of the central nervous system, which belong to the category of encephalomyelitis disseminata, is produced. In clinical studies, positive LB effects during the treatment of chronic diseases such as hypertonicity, hypercholesterinaemia, arterosclerosis and diabetes mellitus have been described [10].



Fig.1: Intravenous laser blood irradiation using the “weberneedle® blood”

Studies on the efficacy of therapeutic measures in chronic diseases are increasingly supported nowadays in their statement concerning the modification of the quality of life by means of treatment. The current work investigates the influence of an intravenous photo-laser therapy on the quality of life of patients with MS.

The questionnaire on the general health condition presents a validated instrument that compiles the quality of life [1]. It is deduced from the SF 36 applied mostly worldwide for the compilation of the quality of life. The applicability of such questionnaires to determine the modification in the quality of life of MS patients has been presented in depth by Pöllmann et al. [7].

Methode

The “weberneedle® blood” tool, manufactured by the Webermedical Sohnreistr. 6, D-37697 Lauenförde, were used.

Questionnaire on General Health Condition SF 12

Patient: _____ Date: _____ Time frame: _____ Week(s)

Diagnosis: _____

1. How would you generally describe your health condition?	excellent	very good	good	slightly good	bad
	1	2	3	4	5

How are you restricted in these activities on account of your health condition?	severely restricted	somewhat restricted	not at all restricted
2. ... moderately difficult activities, e.g. moving a table, vacuuming, bowling, playing golf	1	2	3
3. ... climbing several stair flights	1	2	3

4. in the past ... few weeks, have you worked less than you wanted to because of your <u>physical health</u> ?	yes	no
	1	2
5. in the past ... few weeks, could you only do certain things because of your <u>physical health</u> ?	1	2
6. in the past ... few weeks, have you worked less than you worked to because of <u>mental problems</u> , e.g. because you appeared or felt anxious?	1	2
7. in the past ... few weeks, were you unable to work as carefully as usual because of <u>mental problems</u> , e.g. because you appeared or felt anxious?	1	2

8. So far, have the pains hindered you in carrying out your daily home and professional activities during the past few weeks?	not at all	a bit	moderately	fairly	highly
	1	2	3	4	5

9. How often were you <u>calm and composed</u> during the past few weeks?	always	mostly	fairly often	sometimes	rarely	never
	1	2	3	4	5	6
10. How often were you... <u>full of energy</u> during the past few weeks?	1	2	3	4	5	6
11. How often were you... <u>depressed and unhappy</u> during the past few weeks?	1	2	3	4	5	6

12. How frequent has your physical health or mental problems affected <u>your contact with other people</u> during the past few weeks?	always	mostly	sometimes	rarely	never
	1	2	3	4	5

Fig. 2: The SF12 questionnaire

This tool uses a HeNe diode laser at the end of the fiber optics, with a power output of 5 mW. It emits multichromatic laser light. A red laser with a wavelength of 658 nm and 5 mW was used for the current study.

Patient Collective

20 subjects were included in this study. 10 patients in this group showed an exacerbated form of clinical course, whereas the remaining 10 patients showed a chronic progressive course. The mean age of the patient group investigated was 34 ± 12 years. Amongst the subjects studied, 16 patients (80%) were female.

Implementation of laser therapy

An initial therapeutic cycle of ten treatments was designed for each proband. The therapy was to be carried out on a daily basis, except during the weekend. On average, the initial treatment comprised of 9 ± 2 individual treatments. Such a cycle spanned over an average period of 21 ± 9 days. The dosage was carried out in a concealed manner. The first-cycle treatment was performed in all 20 patients on the first day, using 50% of the laser capacity for 20 minutes. On the next day, 75% of the laser capacity was used over

25 minutes and, subsequently, with 100% of the laser capacity over 40 minutes. The following cycles are orientated in each individual clinical progress. If it led to deterioration, other treatments would be performed. A second cycle with an average of three treatments was required in four subjects (20%) after an average of 2.5 months. The treatment was implemented until deterioration was averted and a subjective improvement occurred. Two subjects received a third cycle with an average of 2.5 treatments after another two months. In one of these two patients, a fourth cycle of only one treatment was carried out after another two months. The average follow-up of all subjects under study was 8 ± 3 months.

A preexisting immunomodulating therapy using interferones in eight subjects (40%) was continued unchanged in parallel. This immunomodulating therapy already existed for more than two years before the study in these eight subjects and was not changed before nor during the study as well as during the follow-up period.

Data survey and statistics

The data survey on quality of life was carried out using the "SF12 questionnaire on the general health condition" [1]. This questionnaire is also a

standardized system for the compilation of physical and psychological quality of life in MS. The SF12 was completed by the subjects before commencing and after terminating the first cycle. Another self-assessment was practiced every four weeks within the scope of normal consultations. A survey was carried out in turn during the treatment before and after the repeated therapy. By using this procedure, statements concerning the therapeutic effect are required to be facilitated directly after the treatment as well as during the long-term process. The statistical evaluation was performed by means of SPSS for Windows, Version 15.0 (SPSS Inc., USA). The continuous variables are shown as mean values, and the standard deviation was selected as a measure of variation.

The continuous variables were validated by means of the Kolmogorov-Smirnov test with respect to their normal distribution. None of the tested variables demonstrated a normal distribution (Kolmogorov-Smirnov test: $p < 0.05$). Therefore, the t-test for paired random samples was used as a non-parametric test by comparing the means.

In contrast, the categorized data were evaluated by using the chi-square test and/or the exact Fisher test.

A two-sided significance testing was carried out in all tests, in which a p-value < 0.05 was considered as statistically significant for all statistical tests.

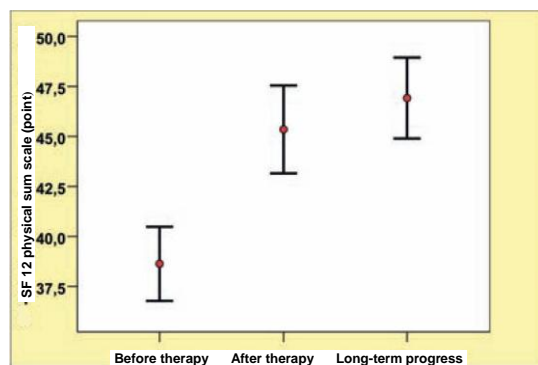


Fig. 3: Physical sum scale before and after the therapy. The mean as well as standard deviation is shown.

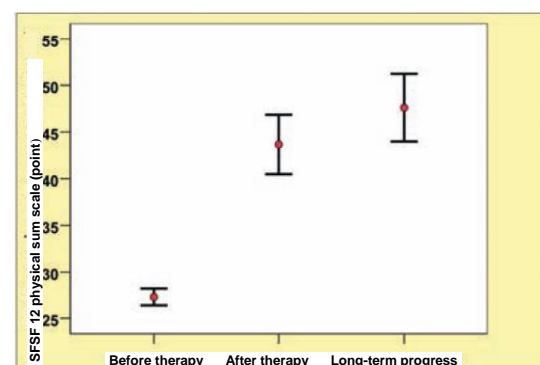


Fig. 4: Psychological sum scale before and after the therapy. The mean as well as standard deviation is shown.

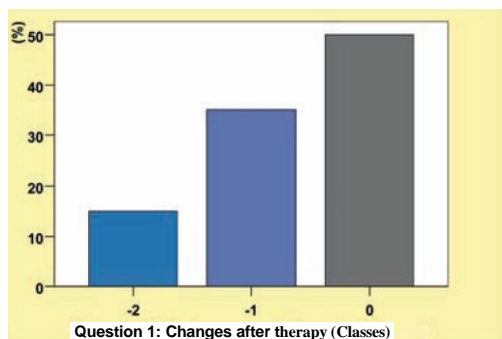


Fig. 5: Question 1 in SF12 – directly after therapy: “How would you generally describe your health condition?” The number of categories, in which the energy condition has changed, is shown.

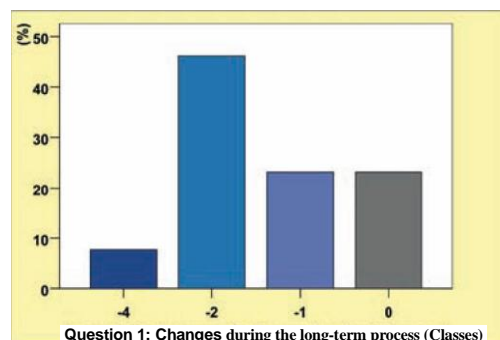


Fig. 6: Question 1 over a long-term process

Results

A significant improvement of the physical sum scale from 38.2 ± 5.8 points before the therapy to 43.4 ± 8.1 points could be obtained directly after the therapy ($p=0.002$) by means of laser treatment.

The psychological sum scale was also significantly improved from 28.6 ± 6.9 to 43.6 ± 13.0 points ($p<0.001$).

A non-significant trend for further improvement of both scales could be observed during the long-term progress of both physical as well as psychological sum scales (physical sum scale= 46.9 ± 7.3 points; psychological sum scale= 47.6 ± 13.1 ; the p value was insignificant for both scales when compared to the scales directly after the therapy).

The evaluation of question 1 in SF12 according to the “general health condition” directly after the intravenous LB is shown in Fig. 5. Possible answers were “excellent” (Class 1), “very good” (Class 2), “good” (Class 3), “less good” (Class 4) and “bad” (Class 5). 15% of the subjects reported improvement at two classes directly after the intravenous LB cycles. In 35% of the patients, the condition improved in one class. No improvement existed when determining the general health condition in 50% of the patients.

Figure 6 is a survey of question 1 on the long-term progress in the determination of the general health condition after the observation period has terminated. Improvement in four classes were reported in 10% of the patients (two subjects), a 50% improvement in two classes (ten subjects) and an improvement in one category of 20% of those treated (four subjects).

20% of the patients (four subjects) experienced no modification.

Question 10 of SF12 is: “How often were you full of energy in the last few weeks?” A possible answer was in the categories “always” (Category 1), “mostly” (Category 2), “fairly often” (Category 3), “sometimes” (Category 4), “rarely” (Category 5) and “never” (Category 6). In the evaluation of this question, Fig. 7 shows the LB influence directly after treatment.

In the survey of question 10, 35% of the subjects reported improvement of three categories directly after the laser cycle. An improvement in two categories was reported in 25% of the patients and an improvement in a category of 10% (two subjects). In 30% of those under study (six subjects), this led to no change in the energy condition.

Fig. 8 shows the influence of the intravenous LB on the survey of question 10 in the long-term progress. 55% of those surveyed (eleven subjects) reported improvement in three categories in the long-term progress, whereas improvement in two categories was in 15% of the patients

. 30% (six subjects) reported no modification of their energy condition

Discussion

The laser blood irradiation leads to a highly significant improvement in the quality of life in patients with multiple sclerosis. This concerns both the physical as well as the psychological sensitivity. A highly significant improvement was produced in both sum scales directly after terminating the laser cycles. Side effects were not observed. Side effects were also not observed by Gasparian [2] and Siposan et al. [8].

The SF12 was used in the current study because both the physical condition as well as the psychological well-being could be determined by employing it. Approximately 70% of those afflicted with MS suffer excruciating and continuous exhaustion condition (fatigue syndrome). The LB effect on this symptom could be evidenced in the current study using the deliberate representation of the changes in the evaluation of question 10 in SF12. After the first laser cycle of an average of nine treatments was terminated, other treatments were carried out when a clinical deterioration reappeared. Fewer treatments were required to produce improvement in the subsequent cycle than in the first cycle.

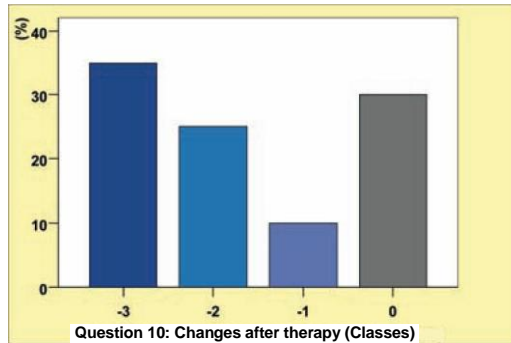


Fig. 7: Question 10 in SF12 – directly after therapy: “How often were you full of energy in the last few weeks?” The number of categories, in which the energy condition has changed, is shown.

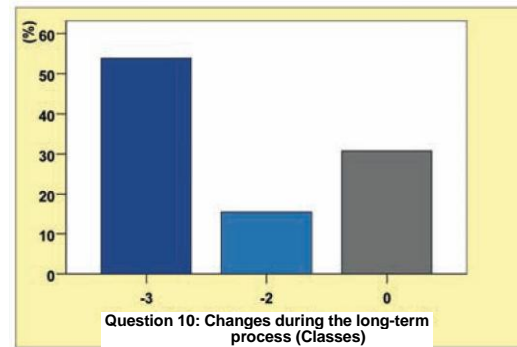


Fig. 8: Question 10 over a long-term process

The dosage of the following laser cycles must be performed individually depending on the experiments of the author. On a temporal basis, the patients specifically report a decreasing effect and this is noticed in their reduced physical and mental capacity and/or deteriorating quality of life. In the current study, the repeated treatment was always first performed after deterioration. Use of laser therapy is, however, already reasonable prior to the reduced effect. This point in time is individually easy to determine in any patient from the clinical process. Then a long-term improvement in the quality of life might be possible using a regular treatment.

Conclusion

According to the experiments of the author, there is no established therapy that is capable of being accomplished when treating fatigue syndrome in MS-like conditions like intravenous LB. An interesting question in the future is whether the effect could still be elevated by using a different chromatic laser and simultaneous laser irradiation of head zones or in simultaneous laser acupuncture. Studies observing the exclusive LB use without accompanying immunomodulating treatment are also meaningful. The current results within this context are expected to initiate further studies on large numbers of patients with a longer observation time

. Thus, a compilation of the changes in the relapse rate and EDSS (Expanded Disability Status Score) is also possible.

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