

# The effectiveness of analgesic electrotherapy in the control of pain associated with diabetic neuropathy

Jan Szopinski

4th Department of Internal Medicine, Silesian Medical Academy, ul. Edukacji 102, 43-100 Tychy, Poland

Georg Lochner

Department of Bioengineering, University of Pretoria, South Africa

Hanna Szopinska

Pain Clinic, Mayo Medical Centre of South Africa, Constantia Kloof, University of the Witwatersrand, Johannesburg, South Africa

**KEY WORDS:** diabetic neuropathy, electrotherapy, TENS, electroacupuncture

## Abstract

**Objective:** To investigate the usefulness of transcutaneous electrical nerve stimulation (TENS) and electroacupuncture in managing the pain associated with diabetic neuropathy.

**Research Design and Methods:** A randomized, comparative, placebo controlled study was performed on a group of 100 patients diagnosed with diabetic neuropathy, at the 4th Department of Internal Medicine, Silesian Medical Academy, Katowice, Poland and the Pain Clinic, Mayo Medical Centre of South Africa, Johannesburg. The change in pain perceived was assessed after a course of analgesic electrotherapy using a visual analogue scale as well as changes in use of analgesics and walking ability.

**Results:** The level of pain reported and use of analgesics dropped significantly after the electrotherapy course, compared to the control group. Walking ability improved significantly in patients reporting pain relief. There was no statistically significant difference between the results obtained in the Type 1 and Type 2 patients. Electrotherapy did not produce any side effects.

**Conclusions:** Analgesic electrotherapy, which includes electroacupuncture and TENS, is an effective, affordable and convenient treatment of pain associated with diabetic neuropathy. If correctly applied, analgesic electrotherapy does not produce any side effects.

Diabetic sufferers are susceptible to a series of complications that not only cause morbidity and premature mortality but may also detract from their quality of life. Although diabetic neuropathy is rarely a direct cause of death, it can become a major source of suffering. It may affect every part of the nervous system with the possible exception of the brain.<sup>1</sup> Distinct symptoms can be recognized and several different types of neuropathy may be present in the same patient. The most common picture is that of peripheral polyneuropathy. Usually bilateral, the symptoms include numbness, paresthesias, severe hyperaesthesias and pain. The pain which may be deep-seated and severe, is typically worse at night. It is often lancinating or lightning in type. If not dealt with correctly, the condition can lead to foot ulcers and ultimately amputation of the feet.

Current treatment of diabetic neuropathy is unsatisfactory in most respects.<sup>1-7</sup> When pain is severe, it is easy for the patient to become habituated or addicted to narcotics or powerful non-narcotic analgesics. If the pain requires something stronger than aspirin, acetaminophen, or other non-steroidal anti-inflammatory agents, codeine is often the drug of choice. Antiepileptics such as phenytoin or gabapentin are used by some physicians, but others have not found it helpful. Combination therapy with amitriptyline and fluphenazine causes relief of the pain only in some patients.

Little information is available about the use of physical therapies in diabetic neuropathy.<sup>2-7</sup> These therapies are known to be effective in the management of many chronic pain syndromes, generally without side effects. This study was there-

## Correspondence:

Dr. J.Z. Szopinski.

P.O.Box 1042, Fontainebleau 2032, South Africa

fore undertaken to investigate their usefulness in diabetic neuropathy. Among the various physical therapies, analgesic electrotherapies such as electroacupuncture and transcutaneous electrical nerve stimulation (TENS) are known to be particularly effective, convenient and safe (under certain restrictions).

### Patients & Methods

This randomized, comparative, placebo controlled study was performed on a group of 100 patients diagnosed with diabetic neuropathy and referred to the 4th Department of Internal Medicine, Silesian Medical Academy, Katowice, Poland or the Pain Clinic, Mayo Medical Centre of South Africa, Johannesburg. The group consisted of 38 men and 62 women, mean age 63 (SD = 9). 59 patients were diagnosed with Type 1 diabetes mellitus and 41 with Type 2. All patients presented with painful feet, numbness, paraesthesias, hyperaesthesias, weakness of muscles of lower extremities, absent or delayed reflexes from lower limbs as well as loss of vibratory sense. Every fifth patient admitted was allocated to the control group which subsequently consisted of 8 men and 12 women. Eleven control group patients were diagnosed with Type 1 and 9 with Type 2 diabetes mellitus. Consent for participation in the study was obtained from each patient after the nature of the study was explained using a written information sheet.

In addition to their regular medication, each patient was treated with TENS 2-3 times per day, 20-40 minutes, up to 6 months (minimum 1 month). The multipurpose, dual channel (4 electrodes) electrotherapist 6-in-1 device, was used. The 'Chronic Disorder Therapy' mode, which produces preprogrammed chains of voltage pulses was selected. The frequency is cycled between 20Hz, 30Hz, 50Hz and 90Hz. Each frequency is applied 4 seconds on, 2 seconds off for 60 seconds. The intensity could be adjusted between 0V and 160V peak to peak. One electrode was placed just above the internal malleolus while the second electrode was placed on the metatarsus of the same leg (Fig. 1). The intensity was individually set between the patient's perception and pain thresholds, giving sensations of "tingling" or "pulsation". Since the device is easy to use, patients could perform the procedure themselves.

In 34 more cases electroacupuncture was applied, in addition to the TENS treatment. This consisted of three 30 minute sessions per week, for a maximum of 20 sessions. Selected classical acupuncture points of the lower legs were used, with locations as defined in classical acupuncture manuals: SP6, ST36, BL62, BL58, GB43 and LR2. All displayed increased

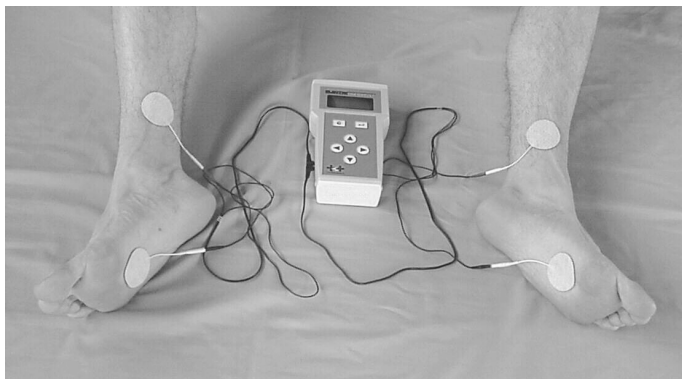


Fig 1. Electrotherapy of diabetic neuropathy using the ELECTROTHERAPIST 6-IN-1 device.

sensitivity to physical pressure and a high degree of electrical rectification.<sup>8-12</sup> They were stimulated with needles and electrical currents (parameters as above with reduced voltage).

After patients reported satisfactory pain relief over 24 hours and a reduction in the use of analgesics, they were discharged from the trial and advised to continue with home electrotherapy, at least one session every three days.

Patients in control group were treated over one month with a modified electrotherapist unit that did not produce any output current, but was otherwise unchanged.

Pain intensity was assessed before the first electrotherapy session and one week after completion of the treatment course, using the following methods:

- 1) Visual analogue scale (0% = no pain, 100% maximum imaginable pain). The Student's T test was used to calculate statistical significance.
- 2) Use of analgesics: \*\*\* - extensive use (highest allowed dosages on regular basis and narcotics occasionally), \*\* - moderate use (average dosages used on regular basis, no narcotics), \* - occasional use (low dosages used intermittently). The  $\chi^2$ -test was used to calculate statistical significance.
- 3) Walking ability : \*\*\* - not walking, \*\* - walk with difficulty, \* - normal walking. The  $\chi^2$ -test was used to calculate statistical significance..

$P < 0.05$  was accepted as the statistically significant difference.

### Results

The level of pain reported by patients according to the visual analogue scale, was significantly reduced after the electrotherapy course in the combined Type 1 and Type 2 group from  $75 \pm 10.5\%$  to  $22 \pm 6.0\%$  (Fig 2). There was no statistically

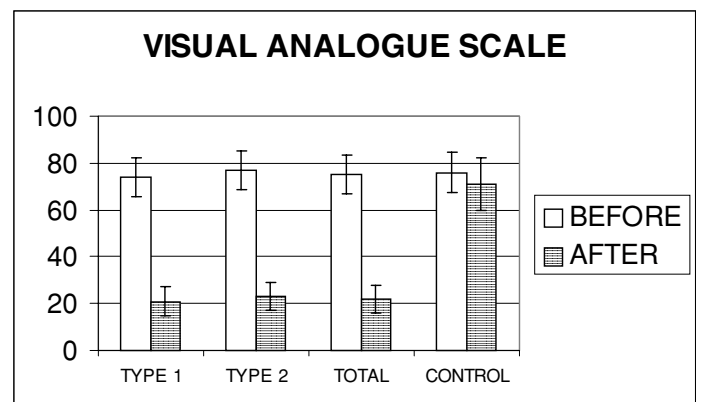


Fig 2. Comparison of pain levels in different patient groups before and after the electrotherapy course (according to analogue scale).

x - Statistically significant difference compared to control,  $P < 0.01$

y - Statistically significant difference compared to control,  $P < 0.05$

No statistically significant differences between Type 1 and Type 2 results.

significant difference between the results obtained for the Type 1 and Type 2 groups. In the control group the level of pain assessed in this way did not change significantly. It was generally observed that initial therapy sessions produced an immediate analgesic effect lasting 30-90 minutes: the duration of this analgesic effect gradually increased as the therapy course progressed.

**Table 1. Use of analgesics in different patient groups before and after the electrotherapy course**

| Group   | Before Treatment |    |     | After completion of treatment |                 |                |
|---------|------------------|----|-----|-------------------------------|-----------------|----------------|
|         | *                | ** | *** | *                             | **              | ***            |
| Type 1  | 0                | 29 | 18  | 31 <sup>y</sup>               | 16 <sup>y</sup> | 0 <sup>y</sup> |
| Type 2  | 0                | 21 | 12  | 23 <sup>y</sup>               | 10 <sup>y</sup> | 0 <sup>y</sup> |
| Total   | 0                | 50 | 30  | 54 <sup>x</sup>               | 26 <sup>x</sup> | 0 <sup>x</sup> |
| Control | 0                | 12 | 8   | 0                             | 13              | 7              |

x – Statistically significant difference in frequencies of \*, \*\* and \*\*\* compared with Control, P < 0.001.

y – Statistically significant difference in frequencies of \*, \*\* and \*\*\* compared with Control, P < 0.05.

No statistically significant differences between Type 1 and Type 2 results.

The use of analgesics dropped significantly after the electrotherapy course in the combined Type 1 and Type 2 group (Table 1). There was no statistically significant difference between the results obtained for the Type 1 and Type 2 groups. Extensive use of analgesics was eliminated and in 67% of patients only occasional use was required (Fig 3). In the control group the use of analgesics did not change significantly.

Walking ability improved significantly in patients treated with electrotherapy who reported pain relief (Table 2). There was no statistically significant difference between the results obtained for the Type 1 and Type 2 groups. All immobile patients regained their ability to walk and the group of patients with normal walking ability increased from 40% to 66% (Fig.4). In the control group mobility was not improved.

In patients reporting pain relief improvement of muscle strength and normalization of reflexes from lower extremities were observed (but not researched). Dermal perception and colour of lower legs were also normalized.

No negative side effects of the described electrotherapy were observed.

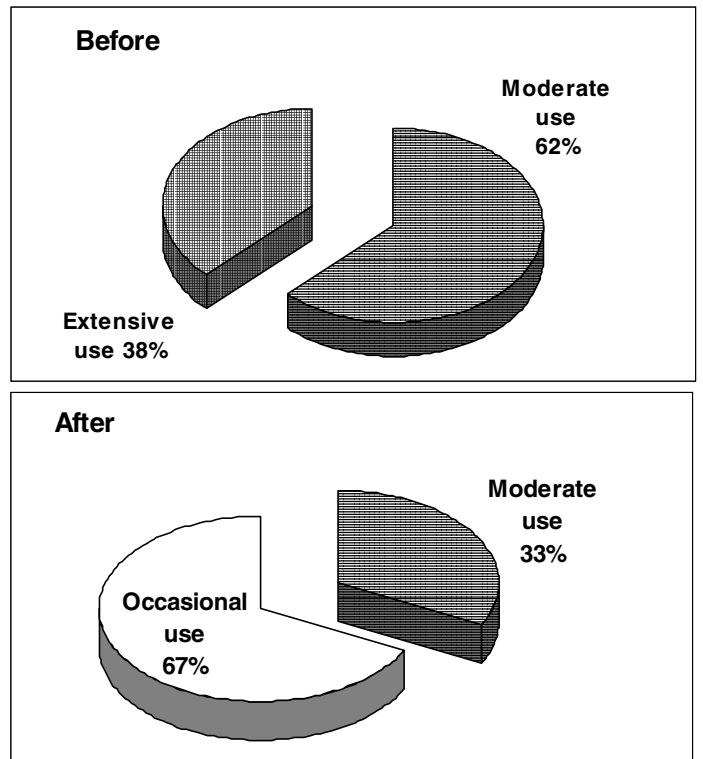
**Table 2. Walking ability in different patient groups before and after the electrotherapy course**

| Group   | Before Treatment |    |     | After completion of treatment |                 |                |
|---------|------------------|----|-----|-------------------------------|-----------------|----------------|
|         | *                | ** | *** | *                             | **              | ***            |
| Type 1  | 19               | 22 | 6   | 31 <sup>y</sup>               | 16 <sup>y</sup> | 0 <sup>y</sup> |
| Type 2  | 14               | 14 | 5   | 22 <sup>y</sup>               | 11 <sup>y</sup> | 0 <sup>y</sup> |
| Total   | 32               | 37 | 11  | 53 <sup>x</sup>               | 27 <sup>x</sup> | 0 <sup>x</sup> |
| Control | 8                | 9  | 3   | 8                             | 9               | 3              |

x – Statistically significant difference in frequencies of \*, \*\* and \*\*\* compared with Control, P < 0.001.

y – Statistically significant difference in frequencies of \*, \*\* and \*\*\* compared with Control, P < 0.05.

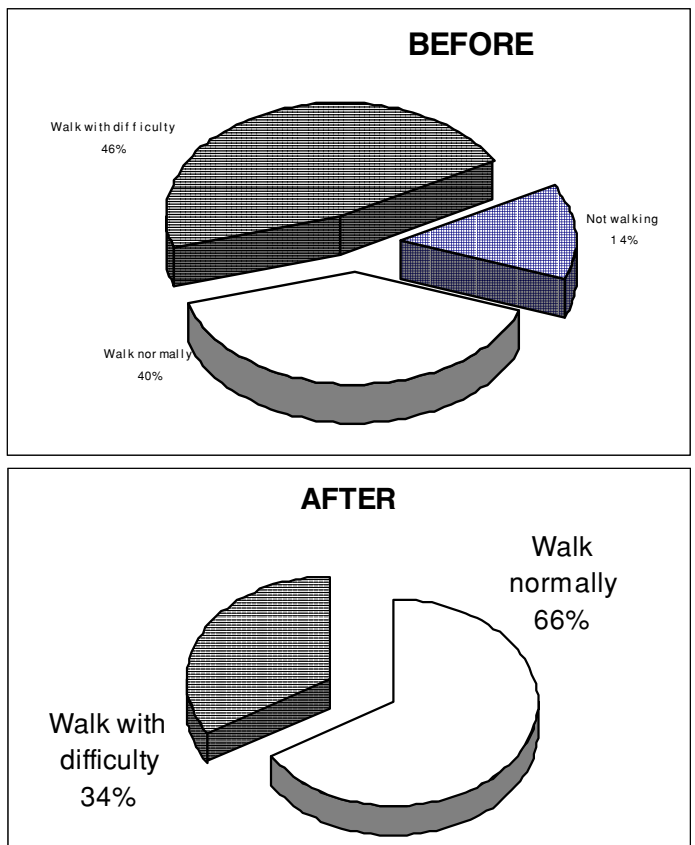
No statistically significant differences between Type 1 and Type 2 results.



**Fig 3. Changes in use of analgesics before and after the electrotherapy course**

**Discussion**

Little research has been reported in literature regarding the use of electrotherapy in the treatment of diabetic neuropathy. However, the limited evidence<sup>2,4-7</sup> indicates that this kind of treatment can potentially play an important role in the man-



**Fig 4. Changes in walking ability before and after the electrotherapy course**

agement of this condition. Electroacupuncture and TENS were even shown to be effective in treating experimentally induced diabetic neuropathy in rats.<sup>5</sup> Most authors suggest that the beneficial influence of electrotherapy on diabetic neuropathy is due to improved local blood circulation<sup>2,4,6,13,14</sup> probably through axon reflex vasodilatation. Various electrode placements have been described, including local acupuncture points, the lumbo-sacral region and spinal cord stimulation.

This study confirmed the high effectiveness of electrotherapy in the control of pain associated with diabetic neuropathy. In contrary to pharmacotherapy, no side-effects were observed. According to our investigations using radioisotopes<sup>2</sup>, both electroacupuncture and TENS improved local blood circulation in the lower legs for several hours after each treatment. Improved microcirculation could facilitate recovery of damaged nerves. This could explain the long-term clinical improvement generally observed after the course of electrotherapy.

There are many hypotheses which try to explain the immediate analgesic effect produced by electroacupuncture and TENS.<sup>15-26</sup> However, even the most well known theories adopted for this purpose e.g. Melzack and Wall's 'gate control' theory<sup>20</sup> (Zimmermann modification)<sup>26</sup> and the endorphinic theory<sup>17,19,21-23</sup> show significant drawbacks in this sphere. The 'gate control' mechanism may simply lead to self-blocking, it also eliminates superficial dermal pain perception, which is always observed during acupuncture and electrotherapeutic procedures.

Electroacupuncture stimulates both nociceptive and non-nociceptive nervous receptors and in this way can elevate the level of endorphins in blood serum, especially when applied to healthy parts of the body (for experimental purposes). TENS stimulates non-nociceptive receptors and decreases the level of endorphins when applied to pain sufferers for therapeutic purposes.<sup>27</sup> This clearly indicates that electroanalgesia does not rely on the release of endorphins. In addition, the therapeutic specificity of acupuncture points as well as the utilisation of these points for organ diagnostics<sup>8,10,11,28-32</sup> cannot be explained by the release of endorphins or other chemicals.

Pain is basically a signal sent from damaged tissue to decision making centers of the central nervous system. As a basic protective mechanism, the pain induces contraction of related muscles in a reflexive way, including muscles of local arteries. Therefore, by blocking pain signals, at the level of the local reflex arc, improvement in local circulation can be expected.

There is a lot of evidence<sup>12</sup> that so-called reflexive therapies can block pain signals at the level of the local reflex arc. The term reflexive therapies describes physical methods which stimulate certain skin areas in order to improve the condition of particular internal organs. They include not only electroacupuncture and TENS but also classical acupuncture, pressopuncture, thermotherapy (reflexive cryotherapy, moxa), soft laser therapy etc. There are specific neurophysiological mechanisms<sup>12</sup> which filter information directed to the central nervous system (neural convergence principle), because the brain cannot process all available information at the same time. These mechanisms give higher priority to signals resulting from external stimuli (skin) than to messages coming

from internal organs. Information coming from sensory organs, including the skin, is more important for the organism's self defense and survival. This is why painful sensations originating from various parts of the body can be blocked at the convergence point even by mild stimulation of the relevant skin areas. In addition, by breaking the relevant reflex arc, chronically contracted muscles can be relaxed, local blood circulation improved and adequate changes can even be induced in hormonal levels. In this way both the immediate analgesic effect and the vasodilatation phenomenon of electrotherapy can be explained.

Stronger signals from the skin have a greater probability of eliminating pain signals at the convergence point.<sup>12</sup> That is why electroacupuncture, as more irritative in general, produces quicker results than TENS. For the same reason our therapeutic current parameters were selected to produce maximal irritation, while ensuring safety.<sup>33</sup> Modulation of frequency and amplitude prevents adaptation of dermal nervous receptors and eliminates the need to adjust intensity during the procedure. Any injury to the diabetic foot poses a risk of ulceration which could even result in amputation. Therefore any electrostimulation which contains a direct current component is contraindicated since it could lead to ulcers. Our electrode placement was empirically determined, over several years of experimentation.

Electroacupuncture, although effective, can be uncomfortable and requires a qualified operator and a sterile environment. TENS is safe, convenient and very cost effective and can be performed by the patient himself on a regular basis, at home or even at the workplace.

## Conclusions

- 1) Analgesic electrotherapy, which includes electroacupuncture and TENS, is effective in controlling pain associated with diabetic neuropathy.
- 2) If correctly applied, analgesic electrotherapy does not produce any side effects.
- 3) Any electrostimulation involving a direct current component is contraindicated in diabetic neuropathy, since it could cause serious complications.

## Acknowledgement

The authors express their gratitude towards Prof. G. Jonderko, former Head: 4<sup>th</sup> Department of Internal Medicine, Silesian Medical Academy, Katowice, Poland for his much appreciated advice and support.

## References

1. Foster DW, *Diabetes Mellitus*, Isselbacher KJ, Braunwald E, Wilson JD, Martin JB, Fauci AS, Kasper DL, editors, *Harrison's principles of internal medicine*. United States, McGraw-Hill, 1994, 1979-2000
2. Jonderko, G., Szopinski, J., Miarka, J.: *Reflexive therapy in diabetic polyneuropathy (Polish)*, *Anest. Inten. Ter.* 14:339, 1982.
3. Forst T, Pfutzner A, Bauersachs R, Arin M, Bach B, Biehlmaier H, Kustner E, Beyer J: *Comparison of the micro vascular response to transcutaneous electrical nerve stimulation and postocclusive ischemia in the diabetic foot*. *Journal of Diabetes & its Complications*, 11(5):291-7, 1997
4. Gilcreast DM, Stotts NA, Froelicher ES, Baker LL, Moss KM: *Effect of electrical stimulation on foot skin perfusion in per-*

- sons with or at risk for diabetic foot ulcers, *Wound Repair Regeneration*, 6(5):434-41, 1998
5. Mo X, Chen D, Ji C, Zhang. J, Liu C, Zhu L: Effect of electroacupuncture and transcutaneous electric nerve stimulation on experimental diabetes and its neuropathy [Chinese], *Chen Tzu Yen Chiu Acupuncture Research*, 21(3):55-9,1996
  6. Petrakis BE, Sciacca V: Spinal cord stimulation in diabetic lower limb critical ischaemia: transcutaneous oxygen measurement as predictor for treatment success, *European Journal of Vascular & Endovascular Surgery*, 19(6):5 87-92, 2000
  7. Somers DL, Somers MF: Treatment of neuropathic pain in a patient with diabetic neuropathy using transcutaneous electrical nerve stimulation applied to the skin of the lumbar region. *Physical Therapy*, 79(8):767-75, 1999
  8. Szopinski, J., Sierak, T., Kaniewski, M., Niezbecki, A: Der Einfluss ausgewählter Krankheiten auf die Bioelektrischen Eigenschaften der Akupunkturpunkte, *Dtsch. Z.Akup.* 3,51,1988.
  9. Szopinski, J., Sierak, T., Gabryel, A.: Die Erforschung der bioenergetischen Eigenschaften der Akupunkturmeridiane, *Dtsch. Zschr. Akup.* 2: 31-35,1988.
  10. Szopinski, J., Pantanowitz, J., Jaros, G.G, Diagnostic accuracy of organ electrodermal diagnostics, *S.A.M.J.* 88: 146 1998.
  11. Jan Szopinski, Tadeusz Sierak, Georg Lochner: Organ Electrodermal Diagnostics: New Direction of Noninvasive Organ Diagnostics, *Am. J. Phys. Med. Rehab.*, submitted
  12. Szopinski J, Sierak T, Lochner G: Neurophysiological Foundations of Organ Electrodermal Diagnostics, *Acupuncture, TENS and Other Reflexive Therapies*, *Am. J. Phys. Med. Rehab.*, submitted.
  13. Westerman RA, Delaney C, Ivamy-Phillips A, Horowitz M, Roberts A: Concordance between different measures of small sensory and autonomic fibre neuropathy in diabetes mellitus. *Clinical & Experimental Neurology*, 26:51-63,1989
  14. Westerman RA, Widdop RE, Hogan C, Zimmet P: Non-invasive tests of neurovascular function: reduced responses in diabetes mellitus, *Neuroscience Letters*, 81(1-2):177-82, 1987
  15. Bischko, J., *An Introduction to Acupuncture*, HaugVerlag, Heidelberg, 1978.
  16. Bong-Han, K., *On the Kyungrak System*, Foreign Languages Publishing House, DPRK, 1964.
  17. Domzal, T., *Pam (Polish)*. W.P, Warsaw, 1980.
  18. Durinyan, R, *Physiological Basis of Auricular Reflex Therapy (Russian)*, Ayastan Publishing House, Erevan, 1983.
  19. Gamuszewski, Z., *Acupuncture in Contemporary Medicine*, (Polish), Amber, Warsaw, 1997.
  20. Melzack, R, Wall, P.D: Pain mechanisms: a new theory. *Science* 150: 45, 1965.
  21. Pauser, G., Gilly, H.: *Neurophysiologische und neurohumorale Mechanismen der Akupunkturalgesie*, *mHandbuch der Akupunktur und Aurikulotherapie*, Part 25.2.0, Bischko, J., Ed., HaugVerlag, Heidelberg, 1985, p. 7
  22. Portnov, F., *Electropuncture Reflexotherapy (Russian)*, Zinatne Publishing House, Riga, 1982.
  23. Tabeyeva, D., *Manual of Acupuncture Reflexotherapy (Russian)*, Meditsina, Moscow, 1980.
  24. Umlauf, R, *Zu den wissenschaftlichen Grundlagen der Aurikulotherapie*, *Dtsch. Zschr. Akup.* 3:59,1988.
  25. Umlauf, R, *Zu den Grundmechanismen der Akupunkturwirkung und Möglichkeiten ihrer Beeinflussung*, Haug Verlag, Heidelberg, 1988.
  26. Zimmermann, M., *Physiologische Mechanismen von Schmerz und Schmerztherapie: TriangellQ*: 7,1981.
  27. de Wet, E.H., Oosthuizen, J.M.C., Odendaal, S.L., Shipton, E.A: Neurochemical mechanisms that may underlay the clinical efficiency of AP simulation therapy in chronic pain management.. *South Afr. J. Anaest. Analg.*, 5: 33 ,1999
  28. Sierak, T., Szopinski, J.: *Universelles elektronisches Gerat fur die automatische Elektropunkturdiagnostik und Elektroreflextherapie*, *Dtsch. Z. Akup.* 5: 112, 1988.
  29. Sierak, T, Szopinski, J.: *Universal device for Electrodermal Organ Diagnostics and electrotherapy (Polish)*, *Probl. Tech. Med.* 18: 255, 1987.
  30. Szopinski, J., Sierak, T., Szopinska, H., Cizek, M.: *Bioelektrische und bionergetische Eigenschaften und morphologische Strukturen der Akupunkturpunkte und Akupunkturmeridiane*, *mHandbuch der Akupunktur und Aurikulotherapie*, Part 25.2.0 Bischko, J., Ed. Haug Veriag, Heidelberg, 1985, p. 105.
  31. Szopinski, J.: *Application of the Organ Electrodermal Diagnostics own method in chosen internal diseases (Polish)*, PhD thesis, Silesian Medical Academy, Katowice, 1985.
  32. Szopinski, J., Sierak, T., Niezbecki, A., Kaniewski, M.: *Influence of selected internal diseases on electrical parameters of acupuncture points (Polish)*, *Diary of 1st National Conference on Acupuncture*, 23-24 September, Warsaw, Sapinski.W., Ed., WSZ, Kalisz, 1982, p. 54.
  33. Szopinski J, Sierak T, Kaniewski M, Niezbecki A: *Investigations into the effects of electrical current parameters on acupuncture points in order to determine the optimal parameters for reflexive electrotherapy (Polish)*, *Akup. Pol.* 1:17-27, 1983 