



## Research paper

## Effects of neural therapy on quality of life in patients suffering from Raynaud syndrome

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## ARTICLE INFO

Present scientific contribution is dedicated to the 650th anniversary of the foundation of the University of Pécs, Hungary.

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## ABSTRACT

**Introduction:** Arterial circulatory deficiency in the upper limbs with repeated vasomotor contraction can cause serious tissue hypoperfusion functional deficiency and trophic abnormality, deformation in the distal area of the hands. This pathogenesis limits the ability to work, inhibits patients' self-management, and significantly reduces their quality of life (QoL). In our outpatient pain-clinic we mainly see patients suffering from primary and secondary Raynaud syndrome in all three stages after standard immunological, angiological and vascular-surgical investigations and treatments showed up to be ineffective.

**Method:** We applied stellate ganglion block (SGB) described first by Leriche and La Fontaine, adapted by Dosch as a special form of neural therapy (according to Hunecke) with para-tracheal technique on the effected side and conducted a prospective non-randomised case series. The treatment period took three weeks with the intervention repeated twice a week. To assess the effects of SGB on the arterial circulation of the hands, the consecutive ischaemic pain, the changes in trophic disturbances and patient's quality of life – using validated objective and subjective measurements.

**Results:** From the data of 12 examined and treated patients were collected. The average follow up time was 35 days after treatment. Aggregated changes in the skin temperature of the fingers showed significant improvement ( $p = 0.002$ ). Out of the 3 parameters of trophic disorder of the II-IIIrd fingers the aggregated changes showed significant improvement ( $p < 0.05$ ). Correlating with these objective parameters, subjective parameters as VAS values ( $p = 0.001$ ) and aggregated change of SF-36 questionnaire ( $p = 0.005$ ) showed a significant improvement.

No lasting complications were detected.

**Conclusion:** Our study is the first to evaluate SGB as a complementary treatment in addition to conventional standard care and employ subjective and objective outcome measurements, in a group of patients with Raynaud syndrome. These promising findings are an indicator for further research.

## 1. Introduction

Arterial circulatory deficiency in the upper limbs can occur by traumatic and non-traumatic, endogene and exogene causes. In our outpatient clinic within a hospital we mainly see patients suffering from primary and secondary Raynaud syndrome [1,2,3] in all three stages.

In these cases the repeated vasomotor contraction can cause serious tissue hypoperfusion in the distal area of the vessels of the hands [4,5,6,7]. This results severe ischaemic pain, functional deficiency and trophic abnormality, deformation of the fingers. Furthermore aggravation of the disease can cause necrosis and serious damage of the tissues, that may lead to losing parts of or entire fingers [8,9,10]. This pathogenesis limits the ability to work, inhibits patients' self-

management, and significantly reduces their quality of life (QoL). Neural therapy according to Hunecke is one of the CAM methods used in many European countries [11,14], applying stellate ganglion block (SGB) is also one of its advanced methods [12,13,17,20–25]. In some countries (Austria, Germany, Hungary, Greece) it is accepted as an official CAM method licensed exclusively for medical doctors [26].

## 2. Objectives

The aim of the investigation was, to assess the effects of SGB on the arterial circulation of the hands, the consecutive ischaemic pain, the changes in trophic disturbances and patient's quality of life – using validated objective and subjective measurements. Our aim was to

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observe possible complications and adverse reactions caused by the elimination of sympathetic innervation, to compare our results with similar, previously published studies, to conclude on the applicability of this neural therapeutic method on patients with Raynaud syndrome.

### 3. Study design

A prospective non-randomised case series was conducted in our outpatient pain-clinic over 6 months in Pándy Kálmán Hospital, Gyula, Hungary. Patients received a detailed and clear explanation of the stellate ganglion block and the preceding tests necessary before commencement of the study and provided signed written informed consent. The study was following the principles of the Declaration of Helsinki, with the written approval of the local research ethics committee (Békés Megyei Központi Kórház Pándy Kálmán Tagkórház, Gyula Intézményi Humán Kutatásetikai Bizottsága) under registration number: 244/2016.

### 4. Method – patients

#### 4.1. Selection of patients

All patients attending the clinic were able to take part in the study. So this was a pragmatic study where patients were treated in a 'real life' situation. All self selected patients were included, if they fulfilled the study's inclusion criteria and provided signed informed consent.

##### 4.1.1. Inclusion criteria

- Raynaud syndrome i.e. circulatory disorder when standard immunological,
- angiological and vascular-surgical investigations and treatments showed up to be ineffective, ischaemic pain and trophic disturbances of the fingers persisted,
- three positive signs (regarding internationally accepted criteria) of severe trophic
  - disturbance,
  - age over 18 years,
  - clear consciousness,
  - balanced cardio-pulmonary state.

##### 4.1.2. Exclusion criteria

- contraindications (listed above),
- blood clotting disorder.

### 5. Outcomes

#### 5.1. Objective outcomes

- 1) Measurement of the skin temperature on the medial surface of the II<sup>nd</sup> – V<sup>th</sup> fingers of the hand to be treated, before treatment and on day 35.
- 2) We measured 3 different parameters of the trophic disorder of the II<sup>nd</sup> – III<sup>rd</sup> fingers of the effected hand
  - thickness (radius in mm)
  - livid skin colour (yes or no)
  - gangrene (yes or no)

before treatment and on day 35.

#### 5.2. Subjective outcomes

(Self-evaluation of the patients)

- (1) VAS was used for defining the intensity of pain on scale 0–10:

- 0 = no pain
  - 1 to 3 = mild pain: barely affecting everyday life;
  - 8 to 6 = moderate pain: significantly affecting every-day life
  - 9 to 10 = severe pain: paralyzing, hinders everyday life
- (2) SF-36 questionnaire for monitoring changes in quality of life.

### 6. Background/description of the investigated therapy

#### 6.1. Topographical anatomy and neural connection

There are three important thickenings (ganglion) of the border chain in the neck. These are ggl. cervicale superius, ggl. cervicale medium and ggl. cervicale inferius. This last one often fuses with the first thoracic ganglion, thus it can reach the length of 1–3 cm. Its trunk is at the height of C7 vertebra's transverse projection. The stellate ganglion controls the upper third of the body's vegetative mechanism, so it has an influence on all the organs of the head, neck, lungs, heart and upper limbs. (see [Picture 3](#)).

#### 6.2. Indications

Injection at the stellate ganglion causes sympathicolysis and vasodilatation in the treated area. Many indication of this therapy can be related to this effect: post-apoplectic conditions, thrombosis occurring in the treated area, brachialgia, eclampsia, erysipelas of the face and upper limbs, fracture-pain, insufficient callus-formation, algo-neuro-dystrophies, Sudeck-syndrome, causalgia, phantom pain, neuralgia occurring in the area of the head and upper limbs, conditions after surgery (stomatoplastics etc.), complementary treatment of various lung diseases, pulmonary embolism, lymphoedema, mastitis and milk stasis during breast-feeding, migraine, nasal diseases, nasolabial furuncle, chronic otitis, shoulder-arm syndrome, posttraumatic epilepsy, cerebral insufficiency, herpes zoster, herpes ophthalmicus, post-zoster neuralgias of the n. trigeminus and the C2–C3 spinal segments.

#### 6.3. Contraindications

Besides the general contraindications of neural therapy:

- oral anticoagulant therapy,
- hearth attack in previous medical history,
- AV block 2<sup>nd</sup> and 3<sup>rd</sup> degree.

*Effects and light adverse reactions (AR)* as Horner-trias, facial anhidrosis, hoarseness (recurrent laryngeal nerve), elevated hemidiaphragm (phrenic nerve), conjunctival vasodilatation, Guttman-sign show up transiently in 70–80% of all cases and are parts of the therapy.

*Severe complications* as in the injury of local anatomical structures; intravascular-, epidural-, intrathecal or intraneural injection (neuro- and cardiotoxicity); soft tissue infection, meningitis, osteitis can occur. With sufficient anatomical knowledge and experience complications are rare. Possible complications can be decreased by determining anatomical structures with ultrasound.

We applied SGB described first by Leriche and La Fontaine, adapted by Dosch as a special form of neural therapy (according to Hunecke) suggested by the German Association of Acupuncture and Neural therapy [14]. (see [Pictures 1. and 2](#))

#### 6.4. Clinical setting/treatment

Diagnostics were performed before entering the study: typical complaints and symptoms of the disease. Instrumental investigations such as plethysmography, capillaroscopy, angiography, hand perfusion scintigraphy, laser scanners and Doppler-flowmetry were performed during the previous conventional angiological treatment. The treatment period took three weeks with the intervention repeated twice a week. In

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