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# Effects of electrostimulation (Veinoplus1) on lower limbs venous insufficiency-related symptoms during pregnancy. Preliminary study

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## Abstract

Objective.– To assess if electrostimulation of lower limbs relieves lower limbs venous insufficiency-related symptoms during pregnancy.

Patients and methods.– A two-step study was conducted. First, a monocentric prospective preliminary study including 30 pregnant women wasconducted to assess the effects of electrostimulation on fetal monitoring and uterine contractions. Then, a multicentric prospective non-randomised study including 58 pregnant women with a gestational age between 23 and 33 weeks of amenorrhoea was conducted to evaluate the electrostimulation treatment. This evaluation was based on a clinical examination performed pre- and post-treatment, a CIVIQ questionnaire filled out pre- and post-treatment and a daily diary filled out by the patient during treatment duration. Treatment duration was 21 days including two daily treatment sequences of 20 min. Three groups of patients were identified based on initial intensity of venous insufficiency-related symptoms (group 1 minor symptoms, group 2 moderate symptoms, group 3 severe symptoms).

Results.– Preliminary study showed no interferences between electrostimulation and fetal cardiac rhythm, uterine contractions and maternal uterine and fetal umbilical arteries Doppler. Concerning the evaluation of the electrostimulation: in group 1, electrostimulation significantly reduced heavy legs sensation ( $p < 0,001$) and calves pain ( $p = 0,02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaire decreased after treatment and a significant reductionwas noted for generalised pain feeling ( $p = 0,04$) and psychological impact ( $p = 0,03$). In group 2, a significant decrease was noted for tiredness ( $p < 0,001$), heavy legs sensation ( $p < 0,001$), calves pain ( $p < 0,001$) and edema ( $p = 0,02$) between the beginning and the end of the treatment. The four scores calculated with the CIVIQ questionnaire significantly decrease after 21 days of treatment. In group 3, a significant decrease of heavy legs sensation ( $p = 0,03$) and calves and malleoli perimeters ( $p < 0,05$) was noted. After 21 days of treatment, the four scores calculated with the CIVIQ questionnaire significantly decrease ( $p < 0,05$). When comparing the three groups, beneficial effects of the treatment are mostmarked in group 2 regarding subjective symptoms, CIVIQ questionnaire scores and leg pain. According to the patients, effectiveness and tolerance of the treatment ranged from good to excellent in the three groups.

Discussion and conclusion.– Electrostimulation is an effective and well-tolerated treatment of lower limbs venous insufficiency-related symptoms in pregnant women. Its use during pregnancy did not show any effects on fetus and pregnancy.


Keywords: Pregnancy; Venous insufficiency; Electrostimulation

## 1. Introduction

Many women present symptoms of lower limbs venous insufficiency during pregnancy, such as heavy legs, painful legs, cramps, varicose veins, varices and oedema, generally occurring during the second half of pregnancy. These problems tend to increase with the number of pregnancies. The treatments currently used are phlebotonic agents and elastic hosiery. Rutoside has proven its efficacy on the symptoms of venous insufficiency in comparison to a placebo, but it is not recommended during pregnancy. Elastic hosiery also improves the symptoms of venous insufficiency [1]. Electrostimulation (EST) has proven its efficacy in the improvement of the symptoms of lower limbs venous insufficiency and in the quality of life of the patients during pregnancy [2]. This study was conducted in pregnant women in order to judge the use of the method during pregnancy and to verify its impact on quality of life. A preliminary study relating to 30 women showed the absence of interference of the EST with foetal monitoring (foetal cardiac rhythm [FCR] and tocography) and with foetal and uterine Doppler scans. This study was validated by the committee on the protection of individuals.

## 2. Patients and Methods

### *2.1 Preliminary study*

The objective of this first part of the study was to evaluate the effects of the EST on the FCR and the uterine contractile (UC) activity. It was a single centre prospective study covering 30 patients. Patients with an appointment or hospitalised in the maternity department of Bichat hospital were randomly offered the chance to test the EST equipment. During its use the FCR and the UC activity were recorded in 16 women, group A, and an echography with measurement of maternal uterine (UD) and foetal umbilical (OD) Dopplers in 14 women, group B. The inclusion criteria were pregnancy between 23 and 40 weeks of amenorrhoea (WA) and agreement to be included in the study. The pregnancies could be normal or pathological (threat of premature labour, retarded intra-uterine growth, pre-eclampsia, gestational diabetes).

### *2.2 Efficacy study*

Non-randomised multi-centre prospective study including 58 pregnant patients between 1st December 2004 and 31 June 2006. The criteria for inclusion in the study were: pregnancy, between 23 and 33 WA, age upon inclusion of at least 18, normal foetal morphological scan, normal pregnancy, agreement to fill in the surveillance diary, agreement to come for final consultation, written consent, not having sciatalgia, not having a history of deep vein thrombosis, not taking anticoagulant treatment, not having a psychiatric condition, participating in the whole duration of the study, and not being subject to legal protection.

Upon the inclusion visit the interview and the examination collected the anthropometric data of the ankles and calves and the circulatory, medical and surgical history. Circulatory problems of the lower limbs were evaluated (intensity of the pain of venous origin felt in the last seven days on a scale of 0 to 100, existence or otherwise of heavy legs, cramps, primo-decubitus restless legs) and the patients filled in a quality of life evaluation questionnaire, the ChronIc Venous Insufficiency Questionnaire (CIVIQ) [3]. The CIVIQ questionnaire enabled calculation of a score from 0 (best quality of life possible) to 100% (quality of life as impaired as it can possibly be). A venous echo-Doppler scan of the lower limbs was performed in order to eliminate vein thrombosis. The patients were distributed into three groups according to the intensity of their circulatory problems: group 1 (G1) patients with minor circulatory problems, group 2 (G2) patients with moderate problems, such as cramps and/or oedema, and group 3 (G3) patients with significant problems and presenting with varices and varicose veins. At the end of the consultation the patients received an EST device and instructions for use.

The Veinoplus® EST device is the size of a Walkman and is powered by a 9V battery. Its function is to stimulate the muscles of the calf by EST in order to entail compression of the deep veins of the leg to improve the venous blood return. The current is applied via two oval electrodes of 8 x 13cm placed symmetrically on the skin of the central part of the calf on each of the legs. This stimulator is European medical certificate (EC) certified. It produces a series of pulses of low energy and low voltage of rectangular shape. The shape of the current wave is symmetrical and two-phase for each pulse, entailing contractions of the muscles of the calf that are almost symmetrical in each leg. The intensity of the current can be adjusted by the patient, according to the tolerance and sensitivity of each patient. The rate of the pulses is pre-programmed in the device's microchip. This rate is defined so that the pulses are delivered in bursts. These bursts of pulses produce painless muscular contractions similar to the heart rate. The time between each burst changes automatically every five minutes. This corresponds to one second for the first five minutes, 0.8 seconds for the next five minutes, 0.7 seconds for the next five minutes, and 0.6 seconds for the last five minutes. Each treatment sequence lasts 20 minutes and produces 1,600 bursts of stimulation, resulting in at least 1,500 effective contractions of the muscles of each calf.

The treatment protocol consisted of 20 minutes of EST morning and evening every day for 21 days. The patients had to fill in the monitoring diary after the EST session in the morning, and in the evening before and one hour after the sequence. The parameters used in the diary related to fatigue, heavy legs, pain in the calves and oedema. These subjective evaluations were measured by scales later coded from 0 to 100 arbitrary units enabling monitoring of the evolution of the symptoms on a day-to-day basis. The intensity of the EST was indicated for the treatment practised in the evening.

At the final visit, the women returned the device, underwent an interview and a clinical examination identical to those of the inclusion visit, filled in an end of treatment CIVIQ questionnaire, and gave their point of view and their assessment of the treatment.

For all variables of the questionnaire and the diary, the average values were compared to the average of the statistical tests such as the repeated measures analysis of variance or paired Student's t test. For the comparison of the three groups, the single factor analysis of variance test or unpaired Student's t test was used.

Correlations and comparisons of populations were also realised using the $Chi^2$ test.

## 3. Results

### *3.1 Preliminary study*

The results of the foetal and maternal examinations during use of the EST device showed the absence of any interference of the device on the FCR, on the UC activity or on the maternal uterine and OD Dopplers under normal conditions of use. These results are presented in Table 1.

### *3.2 Efficacy study*

Statistical analysis of the CIVIQ questionnaires related to the 58 patients of the second step of the study. Analysis of the diaries only related to 56 patients. The diaries not used presented too short a period of treatment or too large interruptions in the practice of the EST. G1 comprised 16 patients (15 diaries used), G2 comprised 21 patients (20 diaries used) and G3 comprised 21 patients (21 diaries used). The characteristics of the sample are reported in Table 2.

In G1 a significant reduction in heavy legs ($p < 0.001$) and pain in the calves ($p = 0.02$) was observed between the start and end of treatment. The perimeters of the calves and the malleoli tended to decrease, but not significantly. The four scores calculated in the CIVIQ questionnaire decreased after treatment, and notably significantly for the feeling of generalised pain ($p = 0.04$) and psychological impact ($p = 0.03$). The level of pain decreased significantly for the five patients declaring the existence of pain before the treatment. This pain reduced by 74% in relation to its initial level. The proportion of patients declaring to feel heavy legs, primo-decubitus restless legs and cramps decreased, but not significantly. These results are reported in Tables 3 and 4.

In G2, a significant reduction in fatigue was observed between the start and end of treatment for fatigue ($p < 0.001$), heavy legs ($p < 0.001$), pain in the calves ($p < 0.001$) and oedema ($p = 0.02$). The perimeter of the calves reduced slightly by around 2 to 4 mm, while the perimeter of the malleoli reduced sharply and significantly by 8 to 9 mm ($p < 0.001$). The four scores calculated in the CIVIQ questionnaire fell significantly after the 21 days of treatment. The scale of the reductions reached 75 to 90% of the average levels observed before treatment. The level of pain reduced significantly for the17 patients in this group declaring the existence of pain before treatment ($p < 0.001$). Furthermore, the proportion of patients declaring to feel heavy legs and cramps reduced significantly after treatment ($p < 0.01$). The reduction was not significant with regard to primo-decubitus restless legs. These results are reported in Tables 3 and 4.

Table 1
Results of the preliminary study. Impact of the use of electrostimulation (EST) on foetal cardiac rhythm (FCR), uterine contractions (UC) and maternal uterine (UD) and foetal umbilical (OD) Dopplers.

| Parameter<br>Group A, $n = 16$ | Result | Population | Frequency (%) |
|---|---|---|---|
| FCR | Normal | 15 | 93.8 |
| | Hypo-oscillating | 1 | 6.3 |
| Uterine contractions | No UC before EST | 14 | 87.5 |
| | Presence of UC before EST | 2 | 12.5 |
| EST interferences on FCR/UC | *No change to recording* | *16* | *100.0* |
| | Changes to FCR and/or UC | 0 | 0.0 |
| Group B, $n = 14$ | | | |
| Umbilical Doppler | Normal | 13 | 92.9 |
| | Increased | 1 | 7.1 |
| Uterine Doppler | Normal | 9 | 64.3 |
| | Limited | 2 | 14.3 |
| | Increased | 3 | 21.4 |
| EST interference on OD/UD | *No change to Dopplers* | *14* | *100.0* |
| | Change to Dopplers | 0 | 0.0 |

Table 2

Characteristics of the sample

| | | G1 ($n$ = 16) | G2 ($n$ = 21) | G3 ($n$ = 21) |
|---|---|---|---|---|
| Age (years) | | 31.1 ± 2.9 | 32.7 ± 4.1 | 32.4 ± 3.6 |
| Current professional activity (%) | | 88 | 86 | 67 |
| Working conditions (%) | Sitting | 57 | 72 | 50 |
| | Standing | 36 | 22 | 43 |
| | Both | 7 | 6 | 7 |
| Means of transport (%) | Car | 69 | 47 | 54 |
| | Public transport | 31 | 41 | 31 |
| | Foot | 0 | 12 | 0 |
| | Other | 0 | 0 | 15 |
| Regular physical activity (%) | | 60 | 76 | 57 |
| Parity | | 1.7 ± 0.7 | 1.8 ± 0.9 | 2.0 ± 0.9 |
| Gestation | | 1.7 ± 0.8 | 2.0 ± 1.0 | 2.5 ± 1.4 |
| Term of pregnancy | Minimum | 23 weeks | 23 weeks three days | 23 weeks |
| | Maximum | 31 weeks three days | 33 weeks | 32 weeks two days |

In G3, a significant reduction was observed in heavy legs ($p = 0.03$). The perimeters of the calves and malleoli decreased significantly by around 4 to 7 mm ($p < 0.05$ for the four measurements). After the 21 days of treatment, the four scores calculated in the CIVIQ questionnaire fell significantly ($p < 0.05$). The reduction was between 43 and 67 % of the average levels observed before treatment. The pain also reduced significantly ($p < 0.001$) for the 18 patients who declared having pain before the treatment. This reduction was 63% of the initial level of pain declared. Before treatment, 90% of women in this group declared having heavy legs and 70% having cramps. After treatment, a significant reduction in these problems was observed, namely around 50% ($p < 0.01$). These results are reported in Tables 3 and 4.

When the three groups are compared, G1 shows less marked results than the two other groups. The beneficial effect of the treatment is most marked in G2 concerning subjective symptoms ($p < 0.001$), the results on the CIVIQ score ($p < 0.05$) and pain in the legs ($p < 0.05$). The effect of the treatment halved the number of patients declaring to have pain in the legs and/or cramps. This effect seems greater in G2 and G3, but the difference is not significant.

The efficacy of the treatment felt by the patients was the same for all three groups. It was considered good to excellent (Fig. 1). The tolerance to the treatment was also the same for all three groups. It was deemed excellent by all patients (Fig. 2). Lastly, 63% of patients of G1 and 86% patients of G2 and G3 declared that they were satisfied with the treatment by the EST device.

Table 3

Summary of the results obtained through the CIVIQ questionnaire between the start and end of treatment.

| | G1 | | | G2 | | | G3 | | |
|---|---|---|---|---|---|---|---|---|---|
| Criteria | Before ttt | After ttt | $p$ | Before ttt | After ttt | $p$ | Before ttt | After ttt | $p$ |
| Right calf (average in mm) | 355.9 | 354.7 | ns | 355.2 | 352.6 | ns | 359.8 | 355.0 | ***0.01*** |
| Left calf (average in mm) | 355.3 | 353.4 | ns | 352.2 | 348.8 | ns | 363.3 | 358.1 | ***0.02*** |
| Right malleolus (average in mm) | 229.4 | 227.2 | ns | 234.3 | 226.4 | < ***0.001*** | 236.7 | 232.4 | ***0.007*** |
| Left malleolus (average in mm) | 226.9 | 225.3 | ns | 233.3 | 224.3 | < ***0.001*** | 236.4 | 229.0 | ***0.005*** |
| Feeling of generalised pain Average AU (%) | 20.7 | 11.7 | ***0.04*** | 44.0 | 8.3 | < ***0.001*** | 47.9 | 26.5 | < ***0.001*** |
| Physical impact Average AU (%) | 15.6 | 11.3 | ns | 34.5 | 8.6 | < ***0.001*** | 34.5 | 19.6 | ***0.03*** |
| Psychological impact Average AU (%) | 14.1 | 5.4 | ***0.03*** | 28.3 | 3.2 | < ***0.001*** | 41.4 | 15.7 | < ***0.001*** |
| Social impact Average AU (%) | 8.3 | 2.5 | ns | 36.1 | 5.6 | ***0.0083*** | 32.6 | 10.6 | ns |
| Pain in lower limbs (average EVA) | 11.5 | 3.0 | ***0.05*** | 43.0 | 5.7 | < ***0.001*** | 43.9 | 17.3 | < ***0.001*** |
| Heavy legs ($n$ %) | 50.0 | 18.8 | ns | 71.4 | 28.6 | < ***0.01*** | 90.5 | 42.9 | < ***0.01*** |
| Primo-decubitus restless legs ($n$ %) | 25.0 | 6.3 | ns | 35.0 | 10.0 | < ***0.01*** | 15.0 | 0.0 | < ***0.01*** |
| Cramps ($n$ %) | 37.5 | 6.3 | ns | 50.0 | 5.0 | ns | 70.0 | 20.0 | ns |

AU: arbitrary unit; ttt: treatment

Table 4
Summary of the results obtained through the diary between the start and end of treatment.

| | G1 | | | G2 | | | G3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Start | End | *p* | Start | End | *p* | Start | End | *p* |
| Fatigue Average AU | 43.1 | 38.3 | ***0.07*** | 50.8 | 37.2 | < ***0.001*** | 48.7 | 47.4 | 0.46 |
| Heavy legs Average AU | 29.2 | 21.4 | < ***0.001*** | 39.2 | 20.4 | < ***0.001*** | 43.1 | 38.3 | ***0.03*** |
| Pain in calf Average AU | 13.5 | 6.6 | ***0.02*** | 20.9 | 11.8 | < ***0.001*** | 26.8 | 24.9 | 0.72 |
| Oedema Average AU | 15.1 | 15.9 | 0.61 | 19.7 | 14.4 | ***0.02*** | 24.9 | 24.4 | 0.68 |

AU: arbitrary unit

## 4. Discussion

In this study, the average parity and the average number of gestations increased from G1 to G3. The known impact of pregnancy on the onset of circulatory problems tallies with this result and seems to indicate a good distribution of pregnant women within the three groups.

The symptoms of lower limbs venous insufficiency are a very common problem in daily obstetrical practice, namely heavy legs, cramps, varicose veins, oedema of the lower limbs and varices [4,5]. These problems tend to aggravate during pregnancy and with the number of pregnancies, and regress in variable proportions after delivery [5]. The treatments currently available are principally phlebotonic agents and elastic hosiery on the lower limbs. In a recent press review concerning treatment of lower limbs venous insufficiency during pregnancy [1], it was found that rutoside offered an improvement in symptoms in comparison to a placebo. However, although widely used, this drug is not recommended during pregnancy as things currently stand. Elastic hosiery also improves the symptoms of lower limbs venous insufficiency [1]. However, wearing elastic hosiery is often tiresome for the patients (discomfort, difficulties in putting it on) and is often not well tolerated when it is hot. The result is a rather poor observance in daily practice.

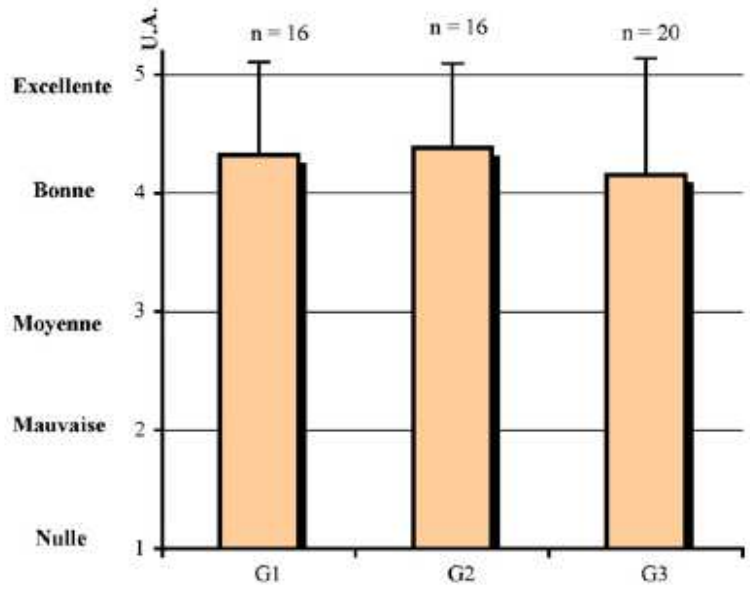


Fig 1. Overall assessment by the patients of the efficacy of electrostimulation
Excellent
Good
Medium
Poor
No effect

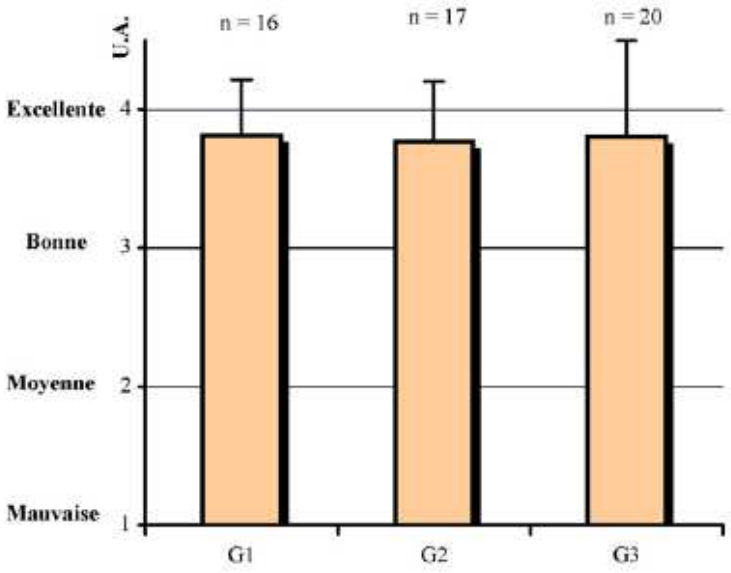


Fig 2. Overall assessment by the patients of the tolerance of electrostimulation
Excellent
Good
Medium
Poor

In a previous study [2], it was demonstrated that EST in practice restored a physiological venous flow and drained the muscle of the blood that had accumulated there. A significant improvement in the quality of life of the patients using EST was also found, particularly in terms of fatigue and psychological energy. The use of the EST device has even been reported in the treatment of a chronic leg ulcer, for which the usual treatment does not offer recovery. After the use of EST in addition to local treatment recovery was obtained, and the ulcer began to recur when the patient stopped EST for personal reasons. Resumption of the treatment led to recovery [6].

EST of the sacral roots in rats at high doses seven hours per day for almost the whole duration of pregnancy did not cause miscarriage (even though the roots for the cervix were stimulated), retarded growth or deformity [7]. The authors of this study concluded that EST of the sacral roots as part of the neurological vessels could not as a rule be responsible for miscarriage or deformity in the human species in the event of unwitting use at the beginning of pregnancy. Furthermore, transcutaneous electrical nerve stimulation (TENS) has been widely used in the past, applied in the lumbar and suprapubic regions, to relieve the pain of labour without harmful effect for the mother or the foetus [3-10]. Some authors have tried to instigate the work in women over 40 weeks in using EST on certain acupuncture points (foot and ankle). The latent time to obtain contractions was four hours, but no patient went into labour [11]. Lastly, the improvement in Dopplers and foetal growth after transcutaneous EST was reported in mothers of foetuses presenting intra-uterine growth retardation of vascular origin, in comparison to the foetuses of mothers treated with rest alone [12].

In this study which evaluated a particular population, i.e. pregnant women for whom the therapeutic arsenal is poor, we show that EST of the lower limbs can improve the objective and subjective symptoms of venous insufficiency and the general condition, resulting in a significant reduction in the feeling of generalised fatigue. These effects are particularly marked in the group constituted of patients with moderate problems (G2). The effect is less marked on G3, constituted of patients with significant problems, maybe due to the fact that the study duration was too short. Unfortunately in this preliminary study we did not perform venous Dopplers of the lower limbs at the end of treatment in order to evaluate whether or not there was an improvement in the parameters measured by Dopplers.

## 5. Conclusion

EST seems in the short term to be an effective and well-tolerated treatment of the symptoms of lower limbs venous insufficiency in pregnant women. Its use during pregnancy has no impact on the foetus. The Veinoplus® EST device should be able to advantageously complement the poor therapeutic arsenal for problems linked to venous insufficiency in pregnant women. A longer study should demonstrate that this method could contribute in the long term to the obtaining of general wellbeing in pregnant women suffering from functional venous problems.

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