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Acceptance, compliance and effects of compression stockings on venous functional symptoms and quality of life of Italian pregnant women

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Aim. The rates of pregnant women with functional symptoms of venous insufficiency who accepted or refused to wear therapeutic compression stockings were evaluated and compared in relation to their clinical evolution and their compliance levels.

Methods. The observational study was conducted in pregnant women between 4 and 28 weeks of amenorrhea presenting a CEAP C0S to C3S venous disease. Therapeutic compression stockings (BSN medical, UltraSheer Maternity stockings, 15-20 mmHg) were offered to pregnant women satisfying the inclusion criteria during routine check visits, and both groups of patients (those who accepted as well as those who refused) were followed up until the end of the pregnancy. The clinical profiles of both groups and the evolution of the venous insufficiency were monitored and compared. The women were requested to indicate pain and further quality of life parameter by means of a specific questionnaire (CIVIQ).

Results. Ninety-eight women were included in the study and followed up; 30.6% (N.=30) of the women refused to wear compression stockings (Wr), 69.4% accepted 10.6% were not compliant to a daily wear (Wanc) and 58.8% wore them every day (Wac). Leg pain was more prominent in case of the Wac group (49.5 ± 21.3) than in case of the Wanc (42.1 ± 20.4) and Wr groups (36.6 ± 18). Their global quality also decreased (48.8 ± 15.7 vs. 43.6 ± 16.1 and 36.6 ± 15.6). Regular use of compression stockings led to decrease of pain (Wac -17 ± 10.1 vs. Wanc -10.3 ± 10.5 vs. Wr -4.2 ± 9.8 [$P < 0.0001$]) and enhanced total quality of life (Wac 13.5 ± 9.6 vs. Wanc 10.7 ± 11.3 vs. Wr -3.3 ± 9.4 [$P < 0.0001$]). Similar results were observed on the CIVIQ subscale (pain, psychological, social, physical impact of legs' pain on women quality of life).

Conclusion. In daily practice, more than two third of the pregnant women accepted to wear compression stockings. The use of compression stockings reduced the legs pain and increased the quality of life of pregnant women
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Key words: Stockings, compression - Pregnancy - Veins.

Pregnancy has a major impact on the venous system, initiating or increasing an existing ve-

nous insufficiency in many women. Various mechanisms may contribute to this alteration of the venous function.

The first corresponds to major hormonal modifications which are linked to the pregnancy and particularly, the increase of estrogens promoting the appearance of oedema and of progesterone levels inducing an important vasodilatation. Pregnancy has also an impact on the venous hemodynamic: a greater sedentary inducing venous stasis and the compression of the pelvic veins by the gravid uterus. These venous physical or functional troubles generally increase throughout pregnancy. The second factor influencing the beginning or the increase of the venous troubles during pregnancy is the number of previous pregnancies which reflect the persistence of the hemodynamic troubles induced by the former pregnancies.¹⁻³

Wearing compression stockings regularly may improve the venous system deficiency, however, very few data are available on the effect of wearing compression stocking on venous pain and quality of life of pregnant women in daily practice.

The objective of this prospective observational study was to describe the rate of pregnant women with venous functional symptoms (leg pain, leg heaviness and/or leg swelling) who accepted or refused to wear therapeutic compression stockings, to compare their clinical profile and quality of life and then their evolution according their compliance to the wearing of a 15-20 mmHg compression stockings.

Materials and methods

This study was a monocenter observational study conducted in a department of gynaecology under the supervision of angiologist specialists who were in charge of the venous symptoms evaluation. To be included in the study, the women were required to: 1) be pregnant, with an amenorrhoea period of at least 4 weeks and less than 28 weeks; 2) present a C0S to C3 CEAP venous disease with functional symptoms requiring compression stockings proposed by their medical practitioner; and 3) free to accept or to refuse to wear them. In order to respect the observational character of the study, exclusion criteria were limited to women with past history of venous thromboembolism, who should absolutely accept to wear an elastic compression.

The study consisted of two visits: the first at the beginning of the pregnancy and the second at pregnancy term. During these two visits, the medical practitioner or the midwife filled in a form describing the age of the women, number of previous pregnancies, venous history, venous status according the CEAP classification, functional symptoms, agreement or refusal to wear an elastic thigh-high compression stockings (BSN medical Ultrasheer Maternity stocking 15-20 mmHg) and any other venous therapies prescribed. Then, the women were requested to evaluate their venous pain and discomfort on a visual analogic scale (VAS) and to measure their quality of life with a venous disease specific questionnaire (CIVIQ) (4). This questionnaire,

well validated and widely used in this field, comprises 20 questions to describe the impact of the venous disease symptoms in four quality-of-life domains: physical, psychological, social, and pain. Its score ranges from 0, the worst score, to 100, the best.

The statistical analysis describes and compares the clinical profiles of women either accepting or refusing to wear elastic compression stockings and then, compares the evolution of the venous insufficiency according the wearing or not of compression stockings and their compliance.

Quantitative data are described with mean and standard deviation, qualitative data with frequency and percentage. Comparisons of quantitative data are conducted with variance analysis and qualitative with χ^2 tests, or their non parametric equivalent if needed. The software is SAS version 9.2.

Results

Acceptance to wear therapeutic compression stockings and venous profiles of pregnant women

Hundred pregnant women were recruited by gynecologists and among them, 2 (2%) women did not indicate legs pain value on VAS at follow-up visit. For them it was not possible to calculate the legs' pain evolution and therefore they were excluded from the study. Therefore the study population covers 98 pregnant women.

TABLE I.—Comparison of the pregnant women's characteristics according to compression wearing or not.

	Women refusing to wear	Women accepting to wear	Test
Age	30.7±5.6	32±6.4	P-value=NS
Number of children	2.1±1.1	2.2±1	P-value=NS
Pregnancy month	3.6±0.9	4.1±1.3	P-value=0.0454
CEAP classification			
C0s	30% N.=9	14.7% N.=10	P-value=0.018
C1s	26.7% N.=8	14.7% N.=10	
C2s	23.3% N.=7	27.9% N.=19	
C3s	20% N.=6	42.7% N.=29	
Leg pain on EVA	36.6±18.5	48.6±21.1	P-value=0.0085
Quality of life: Civiq score			
Global	36.6±15.6	47.8±15.7	P-value=0.0016
Psychological impact	33.5±16.5	44±17.2	P-value=0.0059
Pain impact	42.7±16.3	54.5±17.9	P-value=0.0026
Social impact	33.6±16.3	44.9±15.3	P-value=0.0014
Physical impact	36.4±17.8	48.2±18.4	P-value=0.0040

Among them, 68 (69.4%) pregnant women accepted to wear therapeutic compression stockings and 30 (30.6%) did not accept.

The pregnant women's characteristics were compared according to compression wearing or not. Results shown in Table I indicate that women accepting to wear compression had a significantly more severe venous disease characterized by more frequent oedema, a higher level of pain and a more important impact of their venous disease on their daily quality of life either globally or on the four dimensions of the civiq score.

Evolution

All results concerning pain on EVA, the impact of the venous disease on the global quality of life according Civiq score and its psychological, pain, social or physical dimensions are illustrated in Figures 1 to 6.

COMPLIANCE

Compliance rate are not that high: 30.6% (N.=30) of the women refused to wear compression stockings. Among the 69.4% of pregnant women who accepted to wear compression stockings, 10.6% were not compliant to a daily wear but wear their compression stockings at least once every two days and 58.8% wore them every

day. The clinical venous profiles of the women at inclusion have been compared between their levels of compliance during the follow-up period. As shown in Figures 1 to 6 whatever the evaluation criteria (pain on EVA, or the global, psychological, pain, social or physical impact on quality of life), the level of compliance to elastic compression stockings wearing appears positively and significantly linked to the initial level of severity of the venous disease.

EVOLUTION OF PAIN

Legs pain evolution on EVA (mm, 0=No pain - 100= Maximal pain) according to compression wearing compliance is presented in graph 1 which shows than pain decrease was more important for women wearing compression every day (-17±10.1) than for women wearing it at least once every two days (-10.3±10.5) or for women who did not wear compression at all (-4.2±9.8) ($P<0.0001$). According the previous relation between compliance and symptoms intensity, is also noticeable than women having already severe symptoms are those who felt the greater improvement.

EVOLUTION ON QUALITY OF LIFE IMPACT (CIVIQ)

Global impact of venous disease on women's quality of life according to frequency of compres-

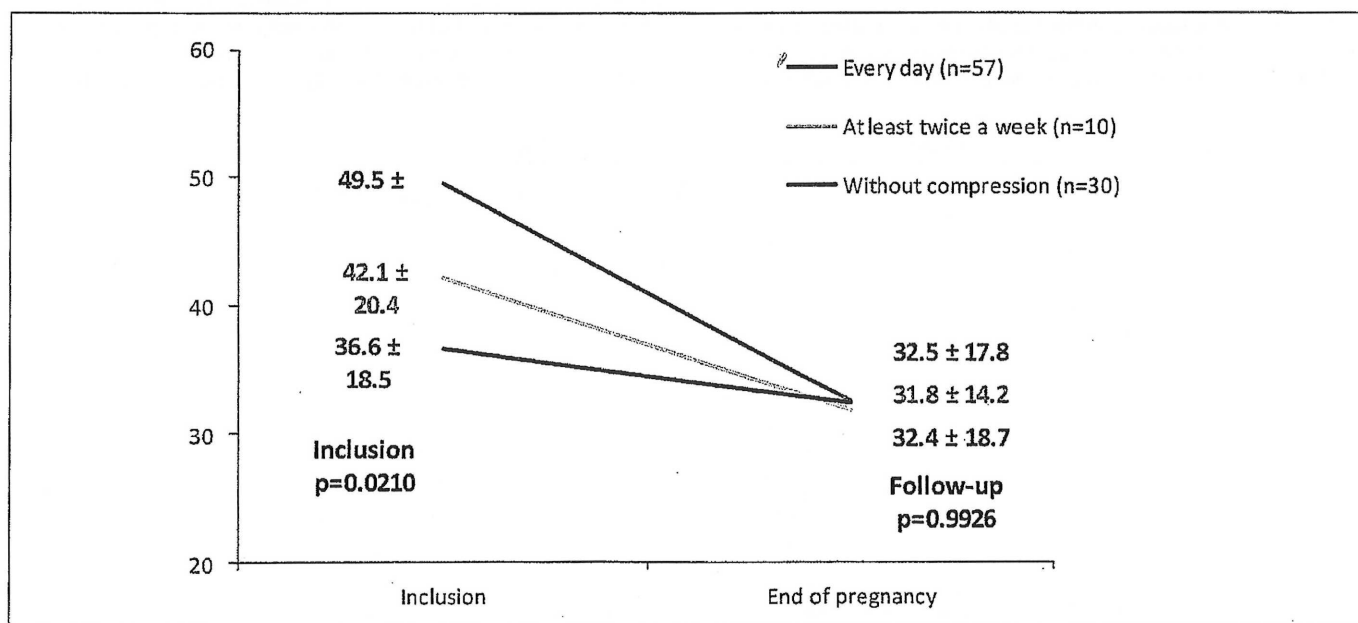


Figure 1.—Legs pain evolution on EVA (mm, 0=No pain - 100=Maximal pain) according to frequency of compression wearing.

sion wearing compliance decreased for women wearing compression every day (-13.5 ± 9.6) and for women wearing it at least once every two days (-10.7 ± 11.3) while it increased for women who didn't wear compression at all (3.3 ± 9.4 , $P < 0.0001$) (Figure 2).

Similar results were observed about:

— evolution of psychological impact of ve-

nous disease which decreased for women wearing compression every day (-12.2 ± 11.3) and for women wearing it at least once every two days (-6.5 ± 11.8) while it increased for women who did not wear compression at all (5.3 ± 11.9 , $P < 0.0001$) (Figure 3);

— evolution of pain impact of venous disease which decreased for women wearing

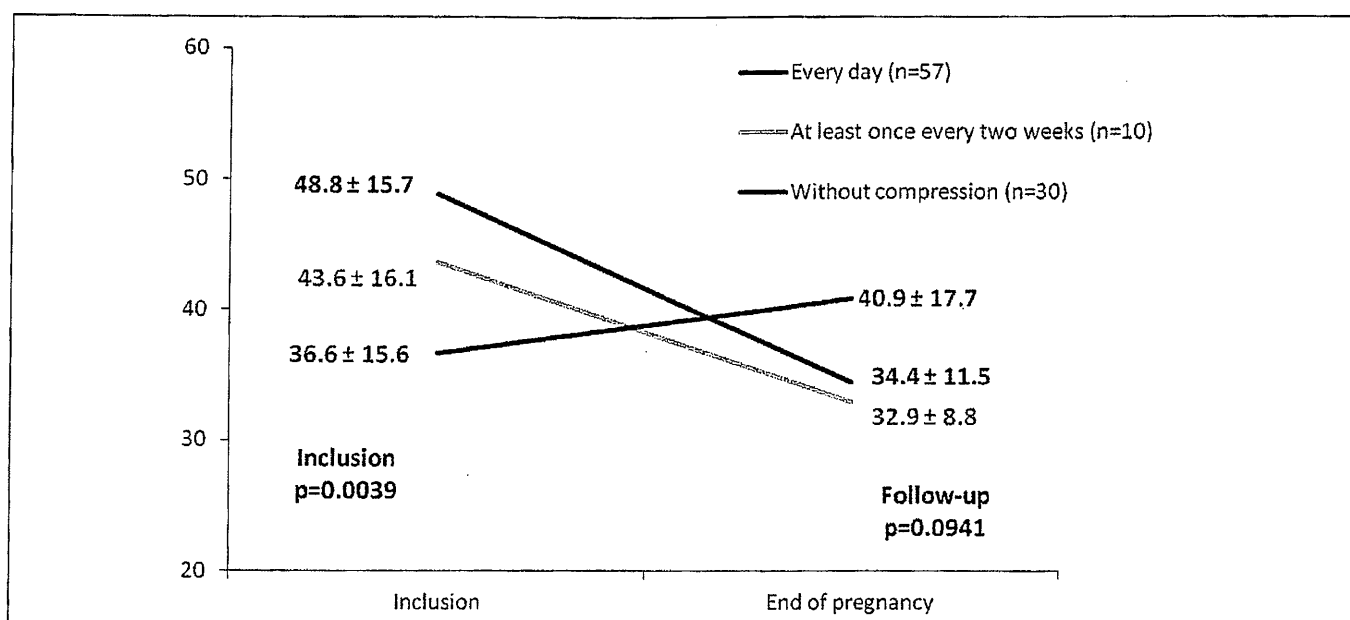


Figure 2.—Evolution of global impact of venous disease on women's quality of life according to frequency of compression wearing.

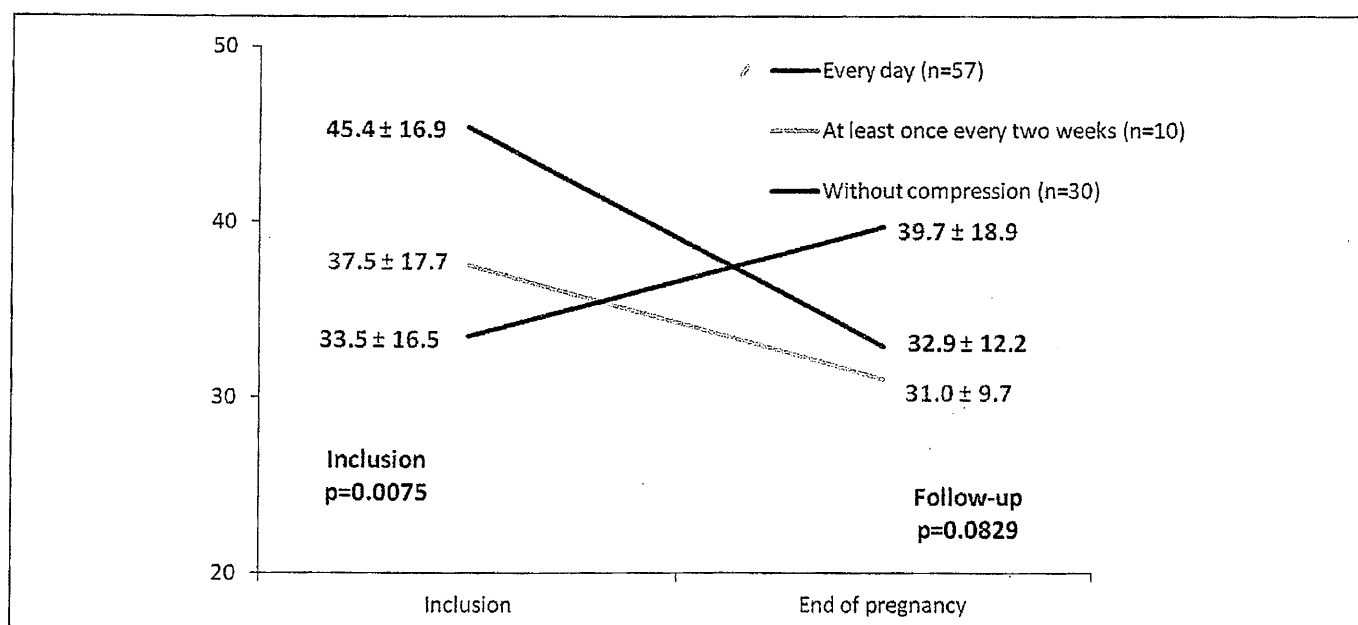


Figure 3.—Evolution of psychological impact of venous disease on women's quality of life according to frequency of compression wearing.

compression every day (-16.9 ± 12.5) and for women wearing it at least once every two day (-13.8 ± 14.4) while it increased for women who didn't wear compression at all (1.3 ± 8.9 , $P < 0.0001$) (Figure 4);

— evolution of social impact of venous disease which decreased for women wearing compression every day (-12.6 ± 10.4) and

for women wearing it at least once every two days (-9.2 ± 11.4) while it increased for women who did not wear compression at all (4.2 ± 11.5 , $P < 0.0001$) (Figure 5);

— evolution of physical impact of venous disease which decreased for women wearing compression every day (-13.4 ± 13) and for women wearing it at least once every two days

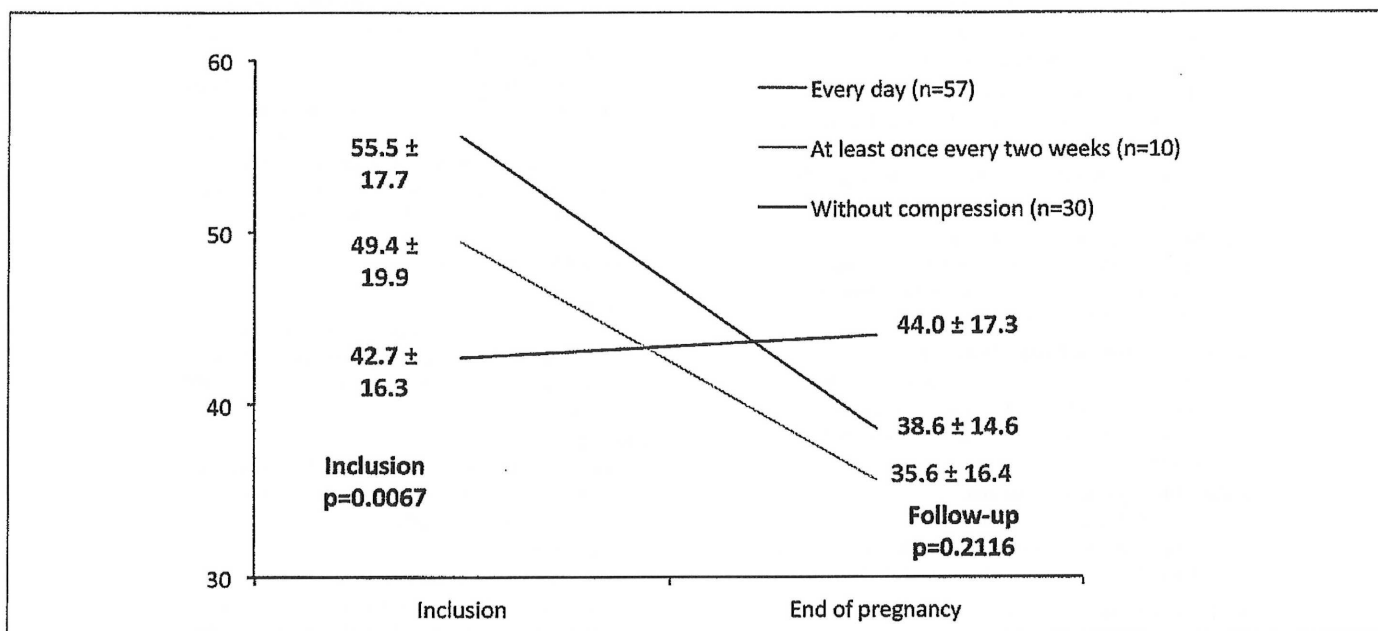


Figure 4.—Evolution of pain impact of venous disease on women's quality of life according to frequency of compression wearing.

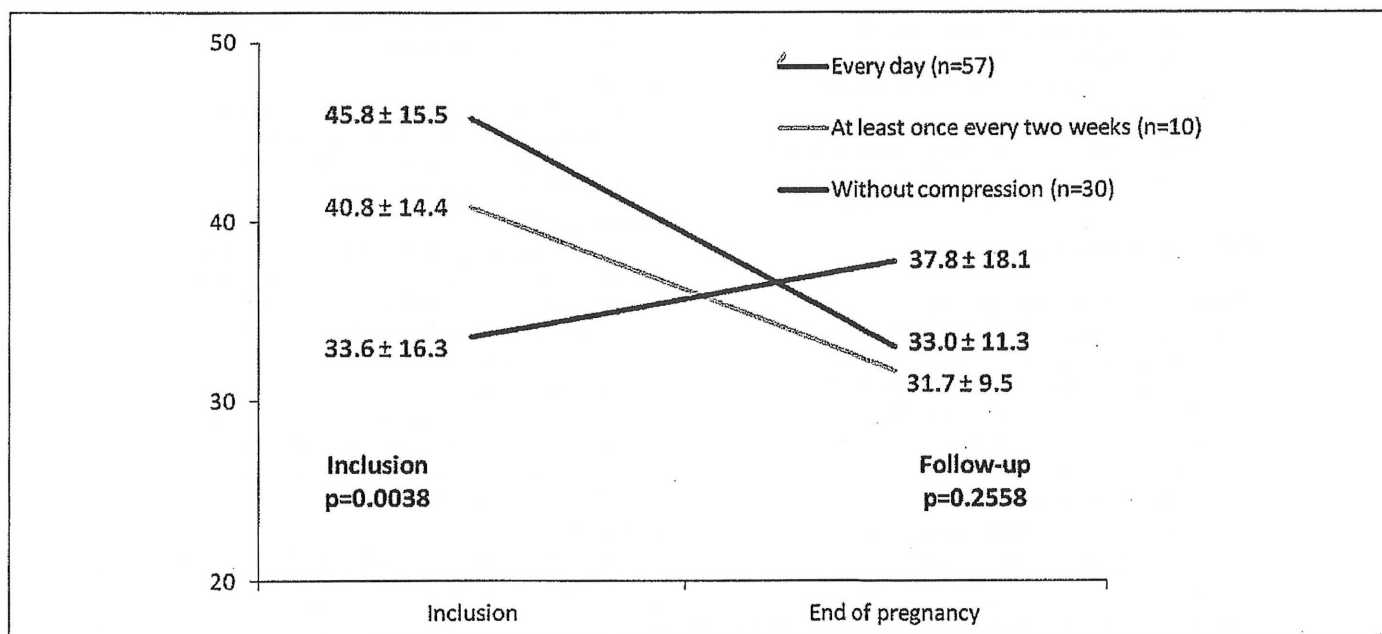


Figure 5.—Evolution of social impact of venous disease on women's quality of life according to frequency of compression wearing.

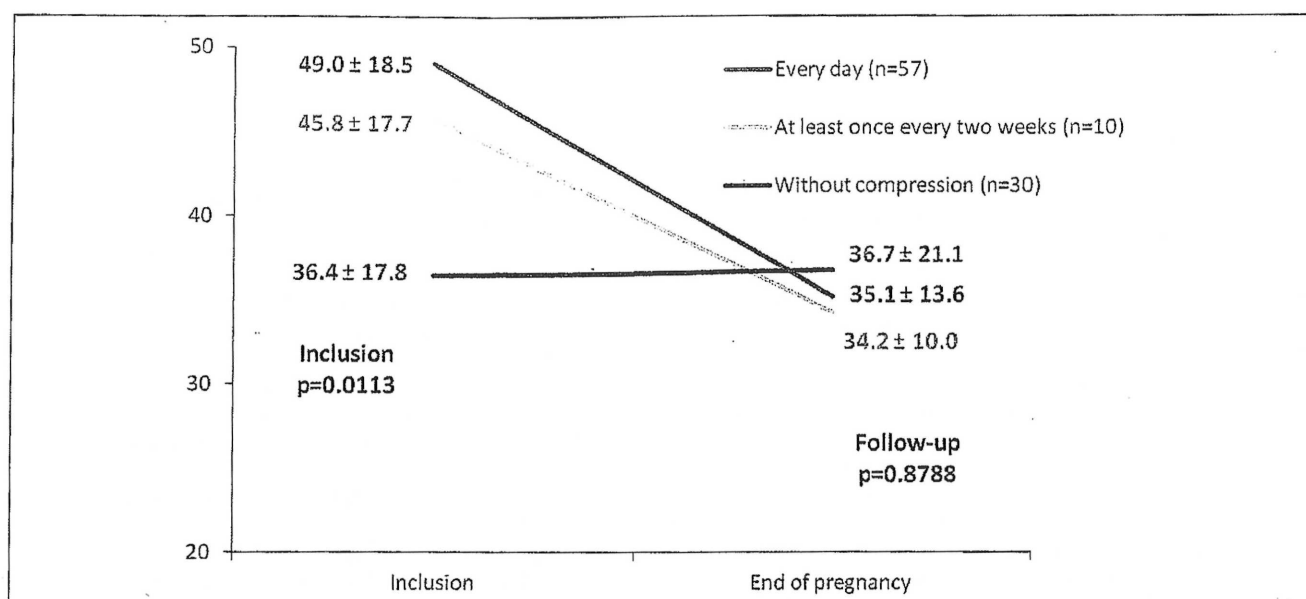


Figure 6.—Evolution of physical impact of venous disease on women's quality of life according to frequency of compression wearing.

(-11.7±13.7) while it was stable for women who did not wear compression at all (0.3±11.9, $P<0.0001$) (Figure 6).

As previously, in accordance with relation between compliance and symptoms intensity, is also noticeable than women having already severe symptoms are those who felt the greater improvement.

SAFETY

Any significant difference was observed between women wearing or not elastic compression stocking and only two women in the group wearing compression describes itching.

Discussion

The first result to highlight is that more than two third (69.4%) of the pregnant women accepted to wear elastic stockings supporting the idea that when the advantage to wear compression elastic is explained to the patients, their acceptance rate may be quite high. This results is very similar to the results observed in a French cohort of pregnant women where a rate of 72.1 was described.⁵ It is also noticeable that as in the French cohort women accepting to wear it had more severe pain than women who refused.

it: 58.4 vs. 46.1 ($P<0.01$) on a same VAS from 0 to 100. Our results show also that the women who are suffering the most are those who felt the greater improvement and that may appear as a consequence of both elastic compression efficacy and compliance. Therefore, medical practitioner and midwives should not hesitate to propose this to all pregnant women presenting already a venous disease or predisposing conditions.

However, the observation of high acceptance levels, of wearing elastic compression for pregnant women suffering from venous disease must not be considered sufficient in and of itself. It reflects more a symptomatic treatment attitude than a real prevention action. Information on the effect of pregnancy on the venous system must be reinforced to the pregnant women as well as to the medical practitioner and midwives who may still have a passive attitude towards this risk.

One other finding of the study shows the importance of the venous functional symptoms evolution during pregnancy. The link between venous disease and pregnancy is well known, but has rarely been systematically described and thus, we do not find papers to discuss our results from a symptomatic point of view. One of the weaknesses of our study is also that our results only concerned functional symptoms and not objective signs.

Some Medline reference papers, however, have described the effect of pregnancy on the lower limb venous system from a hemodynamic point of view and give a physiopathological substratum to the clinical evolution described in our study.

Sparey C (6) conducted a study on 57 pregnant women, among whom 43 completed the full assessment to six weeks postpartum. The veins were assessed in both lower limbs using color flow duplex scanning at 12, 20, 26, 34, 38 weeks of gestation and 6 weeks postpartum. The results show that no new reflux developed in any of the veins studied. In the superficial system, the maximum change was seen in the Great saphenous vein at 34 weeks. On the left side, the vein diameter failed to return to baseline size. Significant change also occurred in the superficial femoral vein. Dilatation of the deep veins of the calf was observed being greater in the left posterior tibial and the left peroneal at the mid-calf point. The evolution of the women who already presented a venous insufficiency has also been published and shows similar results.⁷ It is also noticeable that in the study conducted by Boivin P, Cornu-Thenard A⁸ on 66 pregnant women, the diameter of the largest varicose dilatations of the GSV, its tributaries and non-saphenous networks increased between the first and third trimester ($P < 0.001$) and decreased between the third trimester and the postpartum period ($P < 0.001$).

This last paper may contribute to explain the fact that contrary to the French study, the symptoms of the women who did not accept to wear compression stockings did not seriously increase. Most of the women were at the end of their first pregnancy trimester and perhaps are we faced to two populations: women whose venous system will strongly suffer from hormone changes and those who are less sensitive. It may suggest that in women without past history of venous disease, the end of the first trimester is the most appropriate period to propose to wear compression stockings to the pregnant women. The purpose of the elastic compression is to contribute to support the venous flow which is impaired by the effect of hormones on the venous wall and the mechanic blocage induced by the gravid uterus.

Our results clearly shows that in women presenting already venous functional symptoms

and who therefore accept to wear it, elastic compression decreases leg pain and improves the quality of life of the women. It seems also important to point out that these results are obtained with relatively light level of compression. It is well known that more the pressure is high, more the stocking is difficult to slip on and less the women, and particularly the pregnant women bothered by their abdomen, will be compliant. Rather than prescribing higher compression classes that will not be worn, the use of a light moderate compression may contribute to obtain good results.

Although we do not find any clinical research conducted in the treatment of the venous disease of the pregnant women, the results of our study contribute to support the benefit of prescribing elastic compression to pregnant women. It has many methodological limits due to the fact that it is an observational study and not a controlled, double-blind study and the main problem induced by the lack of randomisation is that we compare patient groups with different level of severity at baseline but in the other hand, this observational conditions were the only possibility to answer to one of our main questions: what are the percentages of pregnant women who accept to wear an elastic compression, what are their profile and what are the venous evolution of women who wear it or not. Obviously the grade A demonstration of elastic efficacy will need a real randomised clinical trial. However, the results of this observational study provides arguments to convince women about the risks of venous disease increasing/worsening during pregnancy if they do not wear elastic compression, and supports the principle that the use of compression stockings throughout pregnancy in women with pre-existing disease and in those at higher risk may be a justifiable recommendation.

Conclusions

Results show that elastic compression was prescribed and accepted by pregnant women whose venous insufficiency was more important than in women who didn't wish to wear it. At the end of the study and under the effect of compression, this initial difference decrease and globally women wearing compression were released of

their pain while women who do not wear it had a slight increase of their functional symptoms. Similar results were observed for women quality of life which confirms a real benefit of wearing elastic compression during pregnancy by women who required it. Moreover it was noticeable that the effect of elastic compression was proportional to the regularity of the elastic compression wearing.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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