

Compression stockings prophylaxis of emergent varicose veins in pregnancy: a prospective randomised controlled study

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Summary

Questions under study: To determine the efficacy of compression stockings in preventing emergent varicose veins in pregnancy.

Methods: A prospective randomised controlled study in the outpatient department of the University Hospital of Zurich, Switzerland, including women with uncomplicated pregnancies <12 weeks at outset of study. A no-stockings control group (n = 15) was compared with two treatment groups: group 1 (n = 12) wore compression class I stockings (18–21 mm Hg) on the left leg and class II stockings (25–32 mm Hg) on the right; in group 2 (n = 15), the compression classes were reversed. Stockings were worn from study entry to term. Endpoints were emergence and worsening of superficial varicose veins, long saphenous vein reflux at the sapheno-femoral junction, and leg symptoms (pain, discomfort, cramps) during pregnancy.

Results: Both classes of compression stockings failed to prevent the emergence of superficial vari-

cose veins. However, long saphenous vein reflux at the sapheno-femoral junction was observed in the third trimester in only 1/27 treated women *vs.* 4/15 controls (p = 0.047); in addition, more treated women reported improved leg symptoms (7/27 *vs.* 0/15 controls; p = 0.045). Emergent varicose changes, however, did not differ significantly (7/14 controls *vs.* 5/12 in group 1 and 8/14 in group 2; 3 × 3 table, Fisher's exact = 0.94).

Conclusions: Although compression stockings do not prevent the emergence of gestational varicose veins, they significantly decrease the incidence of long saphenous vein reflux at the sapheno-femoral junction and improve leg symptoms. Our results also suggest that superficial varices and deep venous insufficiency may have a different aetiology.

Key words: pregnancy; varicose veins; randomised controlled trial

Introduction

Much remains unknown about the development of varicose veins. Cohort studies found long saphenous vein reflux in 10% of schoolchildren aged 11–18, with an incidence that increased with age [1]. Varicose veins of one kind or another are found in 40–50% of adults [2]. Although similarly distributed between the sexes in younger subjects [3], in older subjects they are more prevalent in women [4]. Pregnancy is a major contributor, most probably due to a hormonal environment which lowers venous tone combined with uterine compression of venous return, leading to (ir)reversible over-distension of the superficial (and deep) veins and valvular incompetence. One-third of primiparas and about 50% of multiparas have evidence of varicose veins after pregnancy [5, 6]. Emergent varicose veins occur in approximately 28% of

pregnancies [7]. Veins themselves possess oestrogen and progesterone receptors at concentrations which are increased in women, especially in the presence of varicose changes [8]; thus high oestrogen levels of pregnancy may directly predispose to formation of varicose veins.

Compression stockings improve the drainage of superficial venous blood, thereby reducing the risk of over-distension. In addition to general measures, e.g., exercise, elevation of the legs, and avoidance of prolonged standing and sitting, compression stockings decrease complications such as phlebitis, thrombosis, tension and pain in women with pre-existing varicose veins [9, 10]. In late pregnancy they also improve maternal circulatory problems in the standing position (uterovascular syndrome) [11]. The aims of the present study

were to determine, for the first time, whether compression stockings worn throughout pregnancy could also prevent or mitigate the emergence of varicose veins and, if so, to identify the compression class required: I (18–21 mm Hg) or II (25–32

mm Hg). Our expectation was that adequate compression would abolish or limit increased saphenous vein reflux in the sapheno-femoral junction, limit the emergence of varicose changes overall and relieve leg symptoms.

Patients and methods

Following local ethics committee approval, antenatal outpatients attending the Zurich University Hospital Obstetrics and Gynaecology department were recruited with their written informed consent into a prospective, partially blinded study in which they were randomised to one of three groups: a no-stockings control group (controls), and two compression-stockings treatment groups. Group 1 wore a compression class I stockings on the left leg and a class II stockings on the right; group 2 followed the reverse arrangement. The purpose of mirror division into two compression groups was to exclude a laterality bias in varicose vein emergence. In each woman, the contra-lateral leg was used as an internal control to compare the effects of compression classes I and II. Randomisation was performed at the stockings manufacturers (Ganzoni SA, St Gallen, CH-9014, Switzerland), with blinding of the investigators. Women were also stratified by venous status at study entry (slight varicose changes absent/present) to correct for baseline bias.

The inclusion criteria were pregnancy <12 weeks, absence of long saphenous vein reflux at the sapheno-femoral junction, provision of informed consent, and willingness to wear compression stockings throughout pregnancy and keep a diary of stocking-wearing. Post-entry exclusion criteria were intolerance to the compression stockings components and miscarriage.

At study entry (visit 1), leg and ankle circumferences were measured, and legs examined for oedema and mild varicose changes, with photographs in the standing position to permit subsequent comparison. Doppler examination (Acuson 128 XP10) was performed to exclude long saphenous vein reflux at the sapheno-femoral junction and measure common femoral vein diameter. This included visualisation of the long saphenous vein at the junction in an upright position, positioning of the sample volume in the middle of the long saphenous vein, and repeated measurements using valsalva.

Group 1 and 2 members were each issued with three pairs of individually fitted compression stockings, numbered 1–3 to facilitate sequential wearing, together with a diary to record stocking-wearing which also included a leg symptom questionnaire. The same investigator (ET) conducted all preliminary examinations, documented the findings and fitted the stockings. Visits 2 and 3 took place in the second and third trimesters, and visit 4 and 5 one week and 6–8 weeks postpartum, respectively.

Primary outcome measures were the emergence of varicose veins of any kind (truncular and side-branch varices, spider naevi and reticular varices) during pregnancy, and Doppler ultrasound evidence of long saphenous reflux (>2 sec). A threshold value of 2 sec was used in order to exclude clinically irrelevant reflux symptoms. In the compression groups stockings were removed prior to Doppler measurement. Secondary measures were leg symptoms (pain, discomfort, cramps).

Statistical analysis was performed using STATA 6.0 for PC (Stata Corporation). Proportional differences were calculated using contingency tables and intra-individual interleg differences using a McNemar test, Pearson χ^2 test or Fisher's exact test, with $p < 0.05$. Statistical power calculations showed that 60 legs were required per group to demonstrate a reduction in emergent varicose veins from 30% to 10% with a power of 80% and an alpha error of 0.05 (one-sided) for a comparison between compressed and non-compressed legs [7]. A reduction of this order was defined as clinically relevant. Because there is no data on the possible effect of compression stockings this first randomised study was used to generate a hypothesis. Since compression class was being investigated at the same time, the study population was set at 45 pregnant women, divided into three groups although power decreased to 65%.

Results

The three groups did not differ at inclusion in age, parity, bilateral femoral vein diameter, bilateral ankle circumference, or absence/presence of mild varicose veins (table 1); they were also similar in average weight gain, birth weight and mode of delivery. All deliveries were at term.

There were three dropouts in group 1 (due to miscarriage, relocation abroad, and failure to re-attend), leaving 12 cases for evaluation compared with 15 in group 2 and 15 controls. Two women (control group and group 2) delivered elsewhere, so that postpartum venous status was only documented six weeks later. Nine women failed to attend the final visit (controls: $n = 3$; group 1: $n = 2$;

group 2: $n = 4$), but at least one postpartum venous status measure was obtained in each case.

Stockings-wearing compliance in group 1 was "very good" in six cases, "good" in three cases and "poor" in three cases *vs.* in six, six and three cases, respectively, in group 2 (3×3 table, Pearson χ^2 , $p = 0.71$). At postpartum interview no treated woman reported having confidently identified the more firmly compressed leg.

Emergent varicose changes were found in 7/14 controls *vs.* 5/12 in group 1 and 8/14 in group 2 (3×3 table, Fisher's exact, = 0.94), with no detectable side predilection (table 2). Direct comparison of class II compression *vs.* no compression

Table 1
Baseline characteristics in the study population.

Characteristic	controls n = 15	group 1 n = 12	group 2 n = 15
Maternal age (years)	28.8 ± 5	29 ± 5	33 ± 4
Weight gain (kg)	12.9 ± 6.6	10 ± 6.7	13.25 ± 5.8
Parity	2 ± 1.4	1.7 ± 0.9	2.2 ± 0.8
Mode of delivery*	10 SV, 2 V, 3 SC	7 SV, 1 V, 1 F, 6 CS	9 SV, 1 V, 2 CS
Patients (n) with varicose veins at entry	9 total; 1 R, 2 L, 6 R+L	7 R+L	8 total; 1 R, 1 L, 6 R+L
Ø L femoral vein (mm)	1.1 ± 0.97	0.91 ± 0.96	0.81 ± 0.43
Ø R femoral vein (mm)	0.82 ± 0.8	0.75 ± 0.54	1.0 ± 0.73
Increase 1. to 3. trimester R ankle (mm)	2.6 ± 3.16	3.5 ± 4.2	1.9 ± 2.9
Increase 1. to 3. trimester L ankle (mm)	2.8 ± 3.65	3.5 ± 4.7	3.3 ± 4.4

* CS = caesarean section; F = forceps delivery; SC = secondary caesarean section; SV = spontaneous vaginal delivery; V = vacuum extraction; R = right; L = left

Table 2
Patients (n) with emergent varicose veins (one week postpartum).

	total	right leg only	left leg only	both legs
Group 1 n = 12	5	2	2	1
Group 2 n = 14	8	4	1	3
Controls n = 14	7	0	3	4

Table 3
Leg symptoms compliance (one week postpartum).

		controls n = 14	group 1 n = 12	group 2 n = 14	p
Leg symptoms	unchanged	6	8	7	0.030
	better	0	3	4	
	worse	8	1	3	

showed no stockings preventive effect: 13/27 class II compressed legs showed emergent varicose changes vs. 13/30 uncompressed legs (3×3 table,

Fisher's exact, p = 0.79). The difference remained non-significant even after excluding the poorly compliant women. Intra-individual comparison of class I vs. class II compression likewise showed no significant difference (emergent varicose changes in three class I-compressed legs vs. in two class II-compressed legs, McNemar, p = 0.08). However, emergent third trimester long saphenous vein reflux at the sapheno-femoral junction was observed in 4/15 controls vs. only 1/27 compressed women (p = 0.047) at visit 3. A statistical evaluation at visits 4 and 5 was not possible since we had too many drop outs at each visit. Similarly, leg symptoms improved significantly in treated women vs. controls (7/27 vs. 0/15, respectively; p = 0.045) at both visits 2 and 3.

The reticular and side-branch varices which emerged in one woman each virtually resolved within the first six weeks postpartum.

Discussion

Earlier studies have shown that sufficiently compressive stockings improve venous return from the legs in pregnancy and thus may prevent thrombosis in high risk patients [10, 12, 13]. Increased venous return is associated with an increase in venous flow rates and a decrease in oedema and leg symptoms. The hypothesis that compression stockings would also prevent the emergence of new varicose veins had been repeatedly advanced but never previously tested in a prospective study [9, 13].

Our results suggest that compression to a maximum of 32 mm Hg fails to prevent the emergence of superficial varicose veins. This somewhat disappointing result contrasts with the findings at the sapheno-femoral junction, where the emergence of reflux was significantly decreased. Reflux may be due to the 170% increase in venous cross-sectional area from the first to third trimester reported by several authors [14-16], despite differences in the estimated incidence of reflux itself: 5/38 cases [14] vs. 0/30 [17], possibly due to the use of differing limit values (2 vs. 0.5 sec, respectively).

It may be suggested that by preventing venous dilatation compression stockings also prevent the emergence of truncular varices and valvular incompetence. However, our group was too small to substantiate or exclude a benefit of this kind. A larger long-term study would be required to determine whether compression stockings prevent truncular varicosity in the long term.

The aetiology and morphology of the wall changes which are so prominent in the pathogenesis of varicose veins, and which lead to valvular incompetence and over-distension with increased reflux, are still to be elucidated. An aetiologically-based prophylaxis does not therefore exist. Our results suggest that superficial varices and deep venous insufficiency have different causes. Compression had little effect on the emergence of unsightly superficial varicose veins. Most emergent reticular and side-branch varices in fact vanished postpartum. On the other hand, compression largely prevented long saphenous vein reflux at the sapheno-femoral junction, while significantly decreasing leg symptoms.

Thus compression stockings may be ineffective in preventing superficial spider naevi, side-branch or reticular varices, but they alleviate leg symptoms in pregnancy and lower the incidence of long saphenous vein reflux at the sapheno-femoral junction. If the latter effect were to be associated with a lower incidence of long saphenous varices, compression stockings could make an important contribution to the prevention of deep varicose changes in pregnancy.

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