

Compression in the treatment of chronic venous insufficiency: Efficacy depending on the length of the stocking

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Abstract:

BACKGROUND: Below knee two-component compression stockings (AD) have revealed as effective for compression treatment of venous leg ulcers. Upto groin, thigh length stocking (AG) may enhance clinical effects, however wear comfort of these stocking may be affected.

OBJECTIVE: venous haemodynamic in relation to the length of compression stockings.

METHODS: A two-component AD stocking (37 mmHg) and two thigh length stockings (AG 37, with an interface pressure of 37 mmHg; AG 45, with an interface pressure of 45 mmHg) were tested by 16 patients with CVI. Leg volume changes and venous ejection fraction and venous filling index were measured, whilst quality of life and wear comfort were surveyed by questionnaires.

RESULTS: Volume of both the lower limb and the thigh was reduced by AG stockings, whereas AD stockings reduced only the volume of the lower limb and increased thigh volume. Venous hemodynamic, ejection fraction and filling index were improved by AG and AD stockings, AG, however, was superior to AD. Quality of life and comfort of the stockings was assessed as good for AG 37mmHg, AG 45 mmHg and AD 37mmHg.

CONCLUSIONS: Thigh length two component stockings (AG) were shown to be superior to below knee stocking (AD) with regard to volume reduction and venous hemodynamic, yet

wear comfort was not impaired. These results imply that healing of trophic skin changes e.g. ulcers will be faster when thigh length two component stocking will be worn.

Keywords: chronic venous insufficiency, compression stocking, two-component compression stocking, thigh length compression stocking, below knee compression stocking, venous ejection fraction; venous filling index; leg volume

1. Introduction

The use of medical compression has a long history, is effective and the only conservative targeted therapy for the treatment of chronic venous insufficiency (CVI). This disease is characterized by a damage of venous valves, which leads to hypertension in leg veins and dermal capillaries of the foot [1]. Different leg related symptoms, such as discomfort, pain or heavy legs, are often stated by the patients and are of relevance for treatment [2]. Further multiple secondary disorders associated with the increased capillary pressure and microvascular damage can be described, such as oedema and skin changes [3]. An ulceration of the leg can occur at the final stage and as the most severe manifestation. The frequency of venous leg ulcers, however, has decreased down to 0,7% [4]. Severe stages of CVI are avoided by improved care: surgical or chemical ablation of insufficient leg veins and consequent use of compression hosiery to abolish venous and capillary hypervolemia and hypertension. Compression counteracts venous stasis through improved vascular flow rate by minimizing the diameter of the veins. Successful application of compression in the treatment of venous ulcerations are reported [5]. Depending on the clinical stage, different versions of a compression stocking can be selected. Two-component compression stockings have shown to be effective for the healing of venous leg ulcers [6].

The interface pressure of a medical compression stocking determines the pressure that is exerted on the leg. Moreover, the length of the stocking can be altered to treat different stages of CVI. However this may affect the wear comfort of the stocking [7]. As the improvement of haemodynamics and the clinical efficiency of a two-component below knee stocking has already been shown [8], the clinical efficacy with regard to edema reduction and effects to venous hemodynamics of a thigh length compression stocking should be elucidated here. Therefore this study is conducted to compare the effect on haemodynamics, wear comfort and clinical efficiency of three different compression stockings in patients with CVI.

2. Material and Methods

2.1 Study design

Each of the three compression stockings, AG 37 mmHg, AG 45 mmHg, AD 37 mmHg, was worn for one week, eight hours per day. Between these three wear periods, one week long lasting breaks without compression therapy were interposed. The first stocking is randomly assigned, followed by a screening that included anamneses, clinical examination, duplex ultrasound, checking of inclusion- and exclusion criteria (Table 1). Leg volume measurements occurred at the beginning and the end of the consecutive compression treatment periods. Venous hemodynamics without and with compression hosiery were measured at the beginning of the treatment periods. Quality of life and comfort of the stockings were investigated by questionnaires at the end of each compression treatment period (Fig. 1). The randomised controlled trial was approved by the Ethical Committee.

2.2 Patients

Patients were asked for comorbidities, medication, occupational leg oedema, thrombosis, phlebitis, hereditary dispositions, subjective complaints, phlebological treatments and the use of already present compression therapy. Clinical examination included inspection for corona phlebectatica paraplantaris and trophic skin changes due to CVI like atrophy blanche, hyperpigmentation, induration. Peripheral arterial occlusive disease was excluded by a crurobrachial index $> 0,8$. In addition an orientating status was documented to exclude other neurological, cardiac and orthopaedic diseases. By means of duplex ultrasound venous reflux of intra-, trans- and extrafascial leg veins were documented.

2.3 Compression materials

Three two-component stockings (Bauerfeind AG, Zeulenroda, Germany) consisting of an inner liner and an outer stocking, which are worn one on top of the other. Both components are worn

during daytime, the inner liner also during the night. The following three two-component compression stockings were used in the trial:

- Below knee two-component stocking (AD): liner (AD), 12 mmHg und outer stocking (AD) 25 mmHg, total interface pressure 37 mmHg
- Two-component AG stocking 45 (upto groin): AG liner stocking 20 mmHg und AD outer stocking 25 mmHg, total interface pressure 45mmHg
- Two-component AG stocking 37 (upto groin): AG liner stocking 12 mmHg und AD outer stocking 25 mmHg, total interface pressure 37 mmHg

2.4 *Volume*

Measurement of the volume of the lower and upper leg took place with Bodytronic 600 (Bauerfeind AG, Zeulenroda). It is a non-contact system with a rotating turntable that forms a virtual 3D model of the leg via projected beams of light that form a grid and are captured with a camera.

2.5 *Plethysmography*

Mercury strain gauge plethysmography was used to evaluate the effect of the stocking on the haemodynamic of the leg. Therefor a measuring routine described by Christopoulos et al. [9] and repeated by Riebe et al. [10] was followed to obtain the Ejection Fraction EF as a measure of the calf muscle pump and VFI to quantify the venous reflux. The system measures percental volume changes by calibrating the distension of the strain gauges, which are placed around the foot during testing.

2.6 *Wear comfort and quality of life*

Quality of life was measured using the TLQ-CVI [11]. It is a comprehensive questionnaire that contains a variety of aspects and items relevant to patients suffering from CVI. It is also a powerful measure to monitor compression therapy during a study. Adverse effects and wear comfort of the different stockings were recorded using a self-developed questionnaire. Donning

of the stocking was evaluated (qualities: reasonable, high, too high) and difficulties in donning were logged (qualities: yes/no). Further a variety of complaints were obtained (qualities: 0 = not present, 1 = low present, 2 = moderate present, 3 = highly present) - cold sensations, tingling, itching, warmth, sweating, burning, pain, restrictions of movement, tightness, constrictions.

2.7 *Data analysis and statics*

Mean and median values including standard deviation and interquartile range were calculated. Boxplots were used to visualize volume changes and hemodynamic parameters. Line diagrams were chosen to illustrate the results of the questionnaires. A significance level of $p < 0,05$ was determined to show high significance. The Fisher's exact test and the Kruskal test were used for data analysis. All statistics were calculated with the free statistic software "R".

3. Results

Nineteen subjects were recruited to the study. An overall number of three was excluded due to noncompliance and on behalf of the patient. A whole of twelve female and four male subjects finished the study according to protocol. An oedema was seen in most of the patients (CEAP: C3 = 13; C5 = 1; C6 = 2). Mean age was 48, with the female participants being younger than the male (Fig. 2).

The below knee stocking (AD) induced a non-significant volume increase of the thigh (mean: +0,062 l). On contrary thigh volume was reduced by both thigh length AG stockings (Table 2). Volume reduction was most pronounced by AG37 (mean: -0,055 l, $p < 0,10$ compared to AD). The volume of the lower limb was significantly reduced by the three stockings (Table 3, fig.4), AG37 was most effective.

Ejection Fraction was raised significantly by each stocking (Table 4, Fig. 5). Venous Filling Index (VFI) was reduced by each compression stocking (Table 5), most pronounced by AG45 (Fig. 6).

Besides the haemodynamic and clinical effects, wear comfort of the stockings was assessed and quality of life was monitored. Functional status was good in every day life and the patients showed few complaints with either of the three stockings. Least complaints occurred with the AG37, n.s. (Fig. 7). In addition all subjects declared overall satisfaction (Fig. 8). In addition comfort of all three compression stockings was assessed as good. The AD showed slight advantages, n.s. (Fig. 9), yet the donning of the stocking was not influenced. Only one of the sixteen subjects complained about a high time exposure in donning with all three stocking, no patient stated difficulties in donning.

4. Discussion

As venous pressure is maximal at the foot, compression stockings provide a degressive interface pressure profile with highest pressure at the distal lower limb, the interface pressure decreases towards the proximal leg segments. First clinical signs of chronic venous insufficiency concern the distal leg with reticular varicosis at the gaiter area (Corona phlebectatica paraplantaris) and edema formation of the lower limb. Calf compression counteracts increased venous pressure and has proven as appropriate in mild stages of CVI. With progress of the CVI, the gaiter area remains a critical region for skin ischaemia due to disturbed skin microcirculation [1]. Therefore below knee stockings with particular skin tolerability (inner liner) and short stretch properties (outer stocking) were developed which have been shown to be clinically efficacious. As in severe CVI valves of thigh and popliteal veins are usually also incompetent, compression of thigh could enhance the positive effects of compression stockings.

The here displayed results show a positive haemodynamic effect and volume reductions on the lower limb by all three compression materials. Compression hosiery, here three types of two-component stockings, reduces leg volume which means leg oedema. This favourable effect of compression has been shown by a variety of authors with regard to haemodynamics [9,10,12] and for the volume [13,14,15]. An increase of volume of the thigh, however, occurred when the below knee stocking was worn. On contrary the two upto groin stockings showed a volume

decrease also on the proximal leg at thigh level. This volume reduction of the thigh was achieved both by the 20 mmHg and by the 12 mmHg inner liner. This finding is consistent to Mosti et al [15], who neither detected a more pronounced effect on leg volume and circumference with increasing pressure. Having the same interface pressure as the below knee stocking the thigh length stocking AG37 was superior with regard to volume reduction and to venous hemodynamic. Obviously compression is more effective when larger segments of the leg are included. This is maybe due to valve incompetence of femoral and popliteal veins, which is compensated by thigh compression and due to effects to the skin microcirculation with the better transportation and removal of fluid and dermal lymphatic drainage through an overall consisting pressure exerted on the whole leg.

The revealed findings are supported by the haemodynamic effects of the stocking on reflux and drainage. They all showed a significant increase in EF, as a measure of the calf muscle pump. The results are consistent with the clinical effects on the volume reduction as an improved venous drainage leads to oedema reduction in the long term. Both thigh length compression materials, whilst having a pronounced effect on the volume also lead to an enhancement of the venous pumping function. Ejection Fraction cannot be further enhanced with AG45, may due to the congestive effect. Venous Filling Index (VFI) as a measure of the venous reflux was decreased by the use of all compression stockings ($p < 0,05$). Median reduction was here most pronounced with the AG 45 which is consistent with Partsch et al [16], who describe significant reduction of VFI only with higher pressure. Alongside those haemodynamic parameters and the clinical effect, it stayed unclear if the wear comfort, which influences patients' adherence, was impaired by thigh length compression stockings. Overall comfort was slightly (n.s.) better with the below knee stocking, patients' functional status, however, superior with the AG37 (n.s.). Further difficulties in donning and time required for donning were evaluated similarly for all three products.

A negative effect described by few patients of a two component stocking like the AD stocking

is a volume increase in the distal thigh, which leads to miss sensations and pain. Occasionally the grip top of the stocking strangles the edematous skin. With the displayed data, a distinct efficacy of the two component AG stocking can be shown. This impact was realized with an interface pressure of only 6 mmHg in the knee area by the liner stocking of the AG37.

In conclusion it was demonstrated that the therapeutic effect of the classic below knee compression stocking can be improved by a thigh length model which has a significant effect on the volume reduction on the upper leg. Hemodynamic parameters showed to be further improved, whilst the wear comfort is not impaired. Patients' adherence to compression therapy can even be enhanced by upto groin compression stockings which prevent edema formation and discomfort at the thigh level which leads to a better general well being by support of everyday life activities. On this account a better efficacy can also be expected with regard to healing of trophic skin changes e.g. ulcers.

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Tables

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
CEAP: C3 – C6	Peripheral arterial occlusive disease (PAOD)
Age: 18 – 85 years	Heart failure with dyspnea NYHA 4
Reflux and incompetence in the great or small saphenous veins	Medication with influence to edema (e.g. Diuretics)
	Non-compliance of the subject
	Limited mobility in the ankle joint (less the 5° of the Neutral Position)
	Comorbidities that influence the result of the study, especially diseases leading to increased edema
	Anamnestic indication for a liver or kidney disease

Table 2: Volume change (in l) of the upper leg by compression.¹

Stocking	mean	sd	media n	IQR	p-value
AD	0,062	0,201	0,01	0,120	0,874
AG37	-0,055	0,091	-0,04	0,105	0,018
AG45	-0,035	0,134	-0,08	0,125	0,162

¹ Volume reduction by the AG37 was significant compared to the volume increase by the AD, $p < 0,1$

Table 3: Volume change (in l) of the lower leg by compression.²

Stockin g	mean	sd	media n	IQR	p- value
AD	-0,065	0,069	-0,06	0,065	0,001
AG37	-0,075	0,091	-0,10	0,105	0,003
AG45	-0,068	0,107	-0,06	0,085	0,014

² Significant volume reduction on the lower leg with all three compression stockings, $p < 0,05$

Table 4: Change of EF (in %) by compression.³

Stocking	mean	sd	median	IQR	p-value
AD	28,258	45,189	17,222	47,227	0,018
AG37	60,115	90,624	28,456	63,378	0,021
AG45	60,377	68,775	47,678	62,910	0,003

³ Significant improvement of EF with all compression stockings, $p < 0,05$

Table 5: Change of VFI (in %/s) by compression⁴

Stocking	mean	sd	median	IQR	p-value
AD	-0,037	0,072	-0,007	0,030	0,037
AG37	-0,065	0,121	-0,014	0,076	0,045
AG45	-0,078	0,074	-0,059	0,077	0,001

⁴ Significant reduction of VFI with all compression stockings, $p < 0,05$

Figure captions

Figure 1: Flow chart illustrating randomization and course of the study

Figure 2: Age distribution by gender.

Figure 3: Volume change (l) of the upper leg. Significant volume reduction by the thigh length stocking AG37 compared to the below knee stocking AD, $p < 0,1$.

Figure 4: Volume change (l) of the lower leg. Significant volume reduction by all compression stockings, $p < 0,05$.

Figure 5: Change of Ejection Fraction (%). Significant increase of EF with all stockings, $p < 0,05$.

Figure 6: Change of Venous Filling Index (%/s). Significant reduction of VFI with all stockings, $p < 0,05$.

Figure 7: Functional status over the last seven days. Only slight complaints occurred with all stockings.

Figure 8: Satisfaction over the last 7 days. Overall well-being occurred with all compression stockings.

Figure 9: Negative experiences with compression over the last 7 days. Wear comfort was evaluated good with all stockings.

Figures

Figure 1

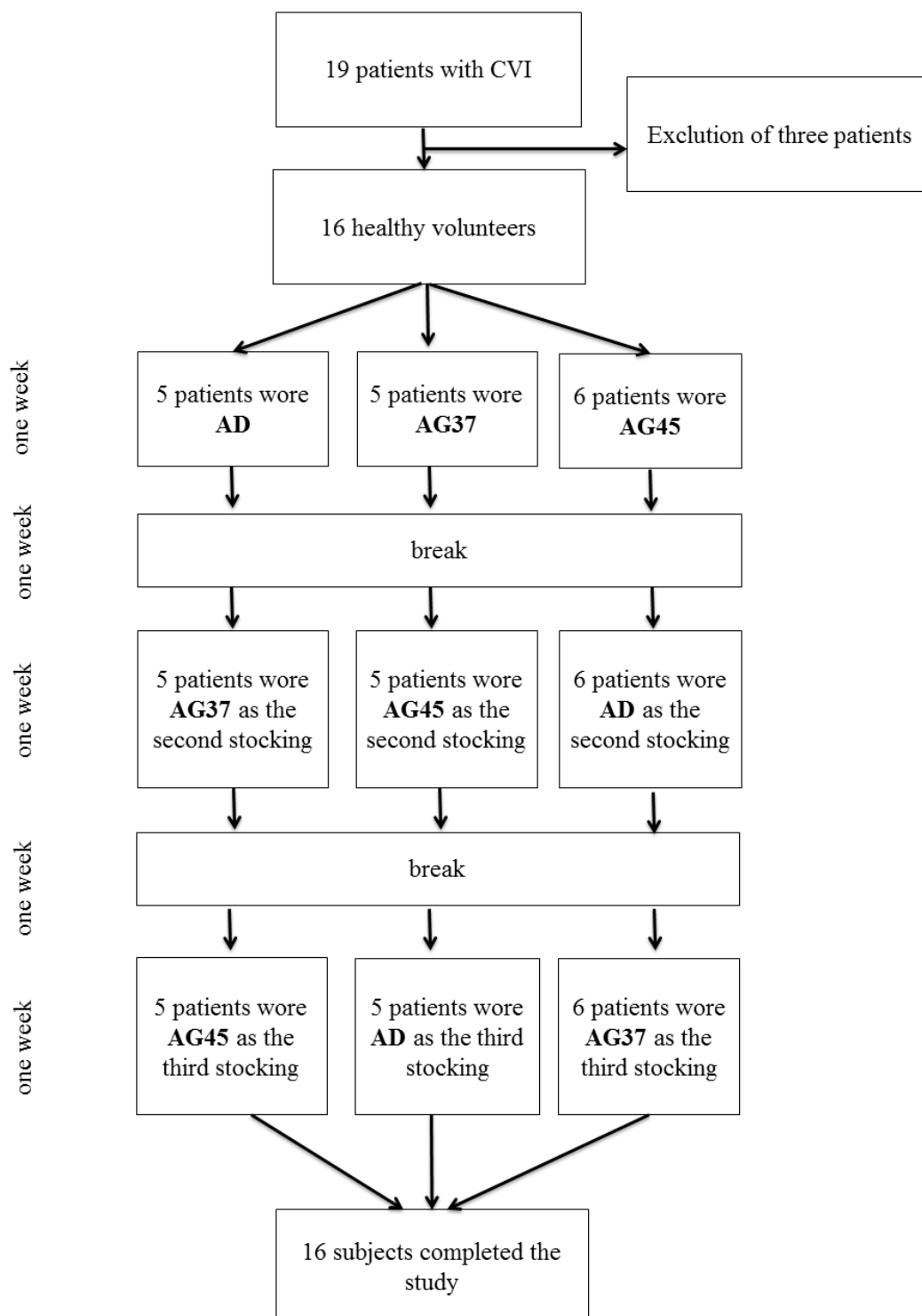
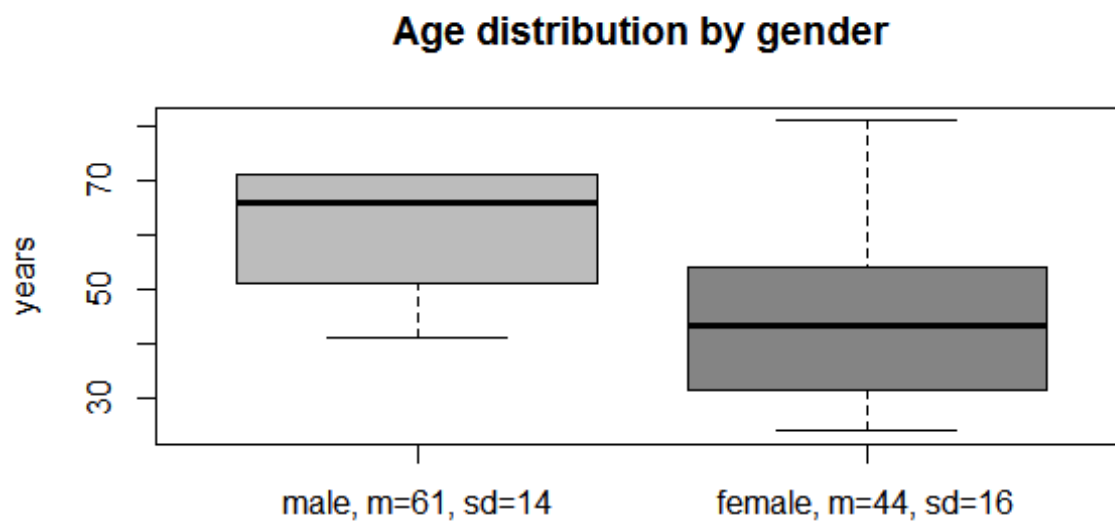


Figure 2



Mean and standard deviation by gender

Figure 3

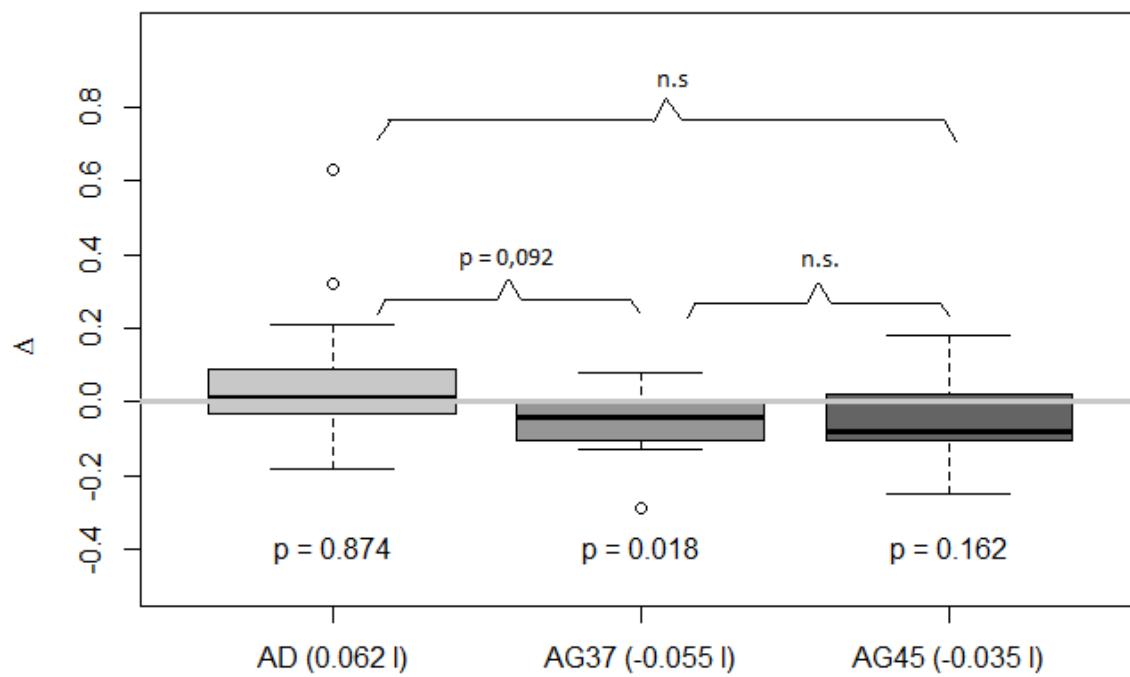


Figure 4

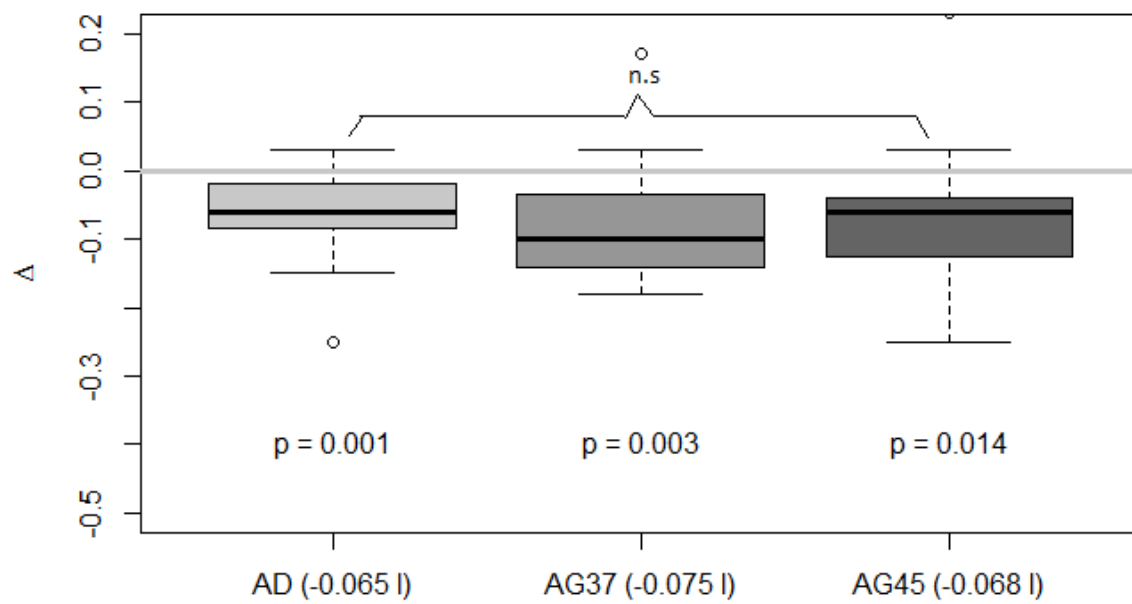


Figure 5

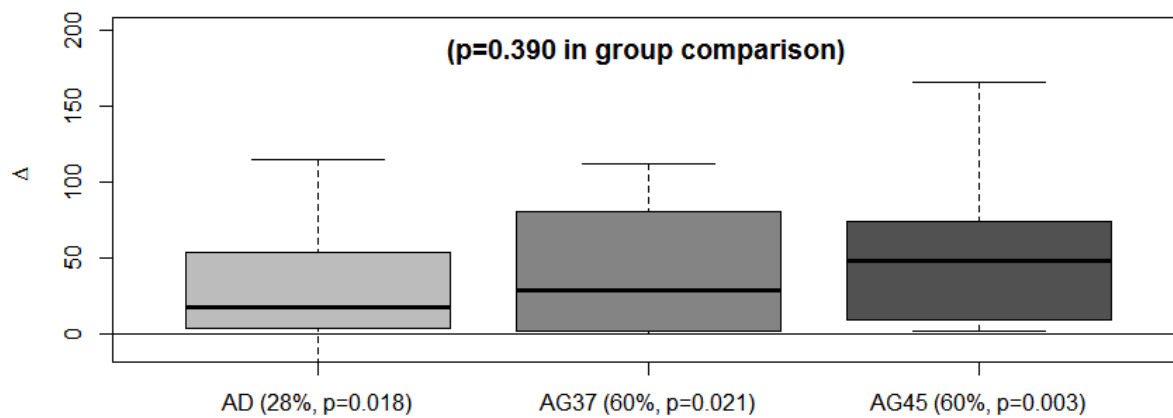


Figure 6

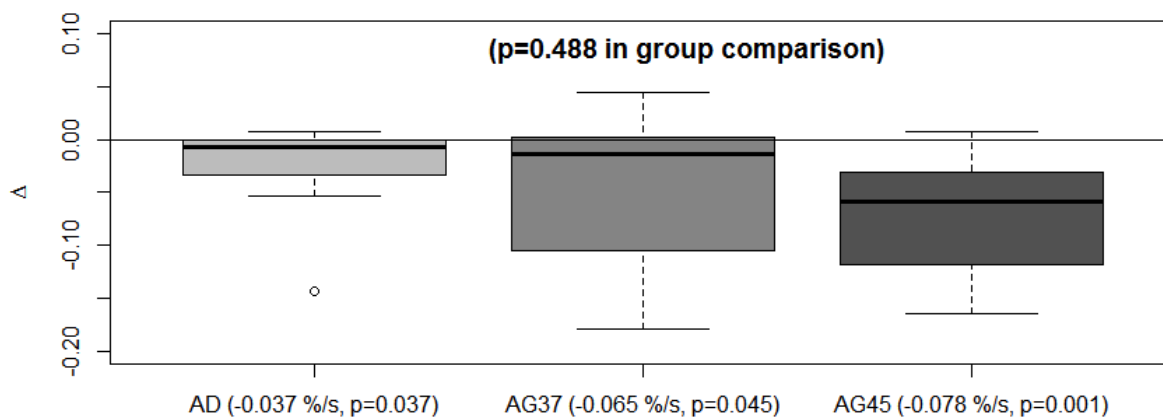


Figure 7

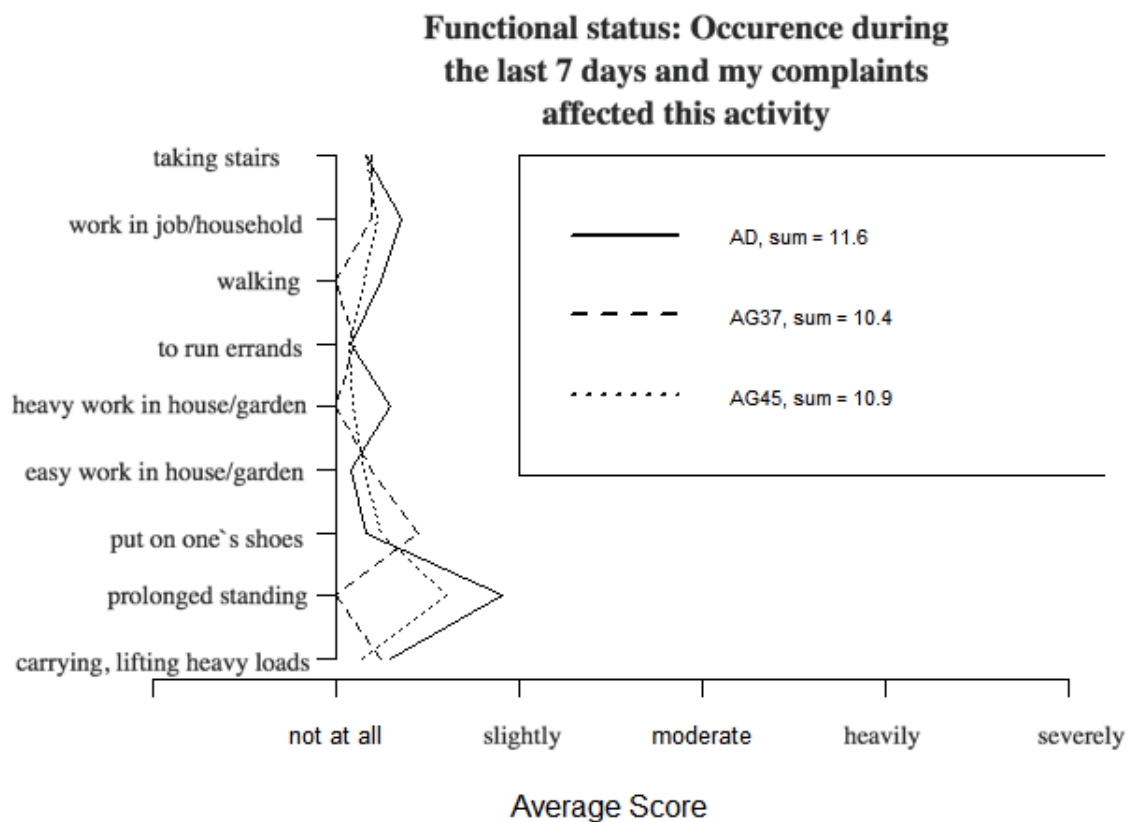


Figure 8

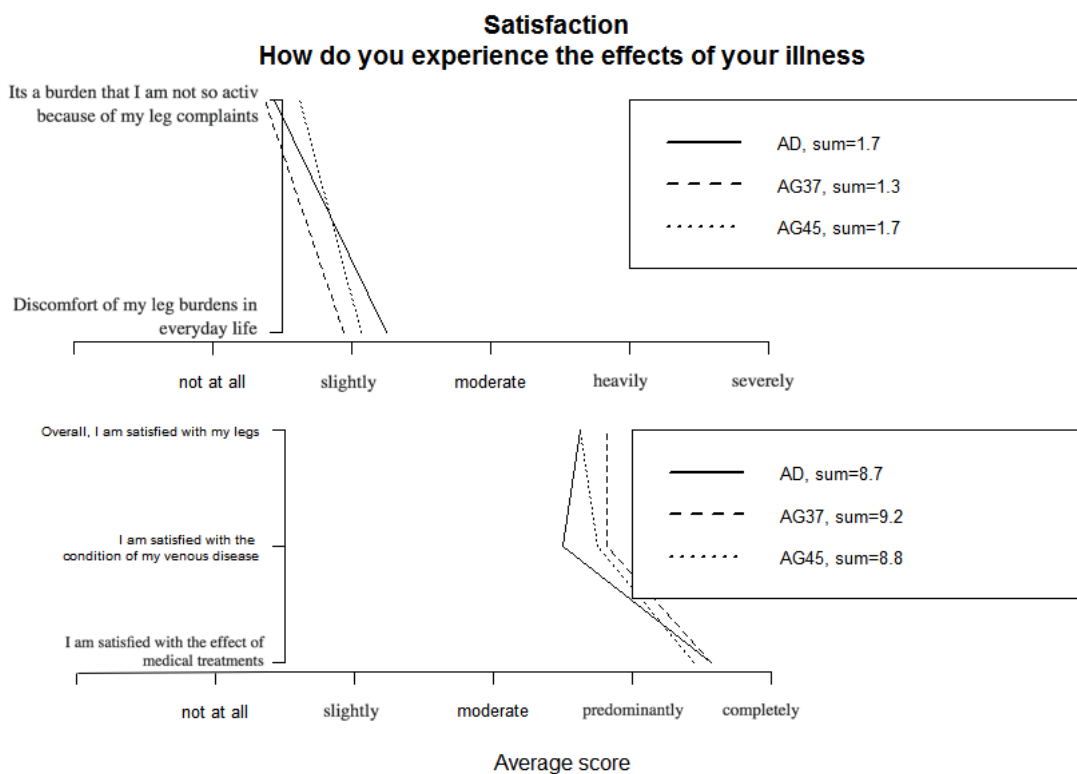


Figure 9

