

# Effect on pregnancy related discomfort concentrating on the back, pelvic and vaginal area through compression therapy with a support garment

## Clinical case series of 40 patients

R. Edler<sup>1</sup> • G. Speck<sup>2\*</sup> J. Brade<sup>3</sup>

<sup>1</sup>Dr. med. Rainer Edler, gynecologist, Georg-Kohl-Str. 1, 74336 Brackenheim

<sup>2</sup>Gabriele Speck, midwife, Hermann-Hesse-Str. 16, 75196 Neuenstadt; representing 10 more self-employed midwives who had been involved in this trial

<sup>3</sup>Joachim Brade, Data Processing Service Centre of Mannheim University Hospital, Th.-Kutzer-Ufer 1 - 3, 68167 Mannheim

Translation from German language, original published in: Die Hebamme 2005, 18: 244 - 247

## Summary

The safety and efficacy of a maternity support garment was examined prophylactically and therapeutically on 40 participating pregnant women with different complaints. The initial condition improved for 82% of the participants after a mean observation period of ten weeks up to the date of delivery. 6 of the test subjects experienced no change of state. The initial condition impaired in one case only. According to this, 87.2% of the participants evaluated their satisfaction with a support garment with very good or good. Due to the study results the use of this support garment seems suggestive in the event of weakness of the connective tissue, vulva varices, former complications in previous pregnancies and twin pregnancies, therapeutically in case of pain in the back, pelvic and symphysis area.

## Introduction

Midwives and doctors often experience that at the beginning of the sixth month, mothers-to-be often complain of typical and often painful back pain, abdominal discomfort, pelvic and vaginal pressure and painful ligaments across the pubic symphysis. The complaints are contingent upon the weight of the child and growing uterus, the child's position, the physiological and hormonal relaxation of the connective tissue and musculature, as well as the occurrence of partly monstrous vulva varices (1 - 4). These discomforts cause the well being of pregnant women to be sorely afflicted.

The symptoms can often barely be differentiated from vaginal pressure and early contractions. The consequence can be the provision of domestic help, disability, bedriddenness and referral.

Consequentially, these questions are to be examined:

- ▶ Is it possible for a special support garment, therapeutically prescribed, to medicate discomforts effectively in the support device area and the venous vascular system?
- ▶ Is a prophylactic prescription of such support garments indicated for problems in previous pregnancies or twin pregnancies, weakness of the connective tissue and vulva varices?

## Product Description

The support garment, used in the study (GraviBody; manufacturer: Tomed Dr. Toussaint GmbH, Bensheim; [www.tomed.com](http://www.tomed.com)), consists of a wide adjustable abdomen belt supporting the uterus, as well as a pair of fuselage fabric, individually adjustable in length and tension by brackets in order to distribute the uterus' weight equally. The equal distribution of the uterus' weight, even in the back, is achieved by wide straps dividing the narrow straps in the front.



Figure 1: GraviBody® support garment

The **strap's arrangement** ensures that the womb and the child are not being constricted and the weight pressure, concentrating on the vaginal musculature, is being reduced. When experiencing uterus

contractions, the elastic abdomen belt can be placed temporarily over the uterus until the contractions have stopped. The straps also relieve the lower spine area due to their arrangement. Two narrow bottom straps, set out from the back, merge to a wide perineum belt which is connected on the front side of the compression garment with the wide stomach belt through an easy detachable Velcro. The support garment thereby achieves a compression in the pelvic area.

Deducing from a study of 25 pregnant women about a loin and ligament support system in USA, the described support system does not have an acute influence on the **haemodynamic** conditions between mother and child (5).

The support garment is easy to put on and to wear. It is air-permeable and permits skin care. It can be worn with regular underwear and can even be worn during toileting. It is recommended by the manufacturer to hand-wash and air-dry the support garment.

## Method

In the course of the second half year of 2004, the participating midwives in the city and county of Heilbronn included 40 mothers-to-be into the case series. These women complained about pregnancy related back, pelvic or vaginal pain as well as vulva-varices. Women with anamnestic or current thrombophlebitis, thrombosis, thrombophilia or coagulation disorder as well as known back pain outside the pregnancy (suffering from an impairment of the motor nerves, distinctive scoliosis, disc prolapse) were not included.

8 twin pregnancies among the participants constituted a sub-group. The size of the support garment during the pregnancy was being used.

Up to 6 Visits (Visit 1: admittance; Visit 6: completion) that took place according to the pregnancy age on admittance in a 2 – 3 week distance were being polled and the answers documented.

- ▶ Discomforts in the support device area
- ▶ Vaginal pressure
- ▶ Pain/burning in the symphysis area
- ▶ Mean wearing period of the support garment by day
- ▶ Well-being during physical activity
- ▶ Wearing comfort
- ▶ Vulva varices

Each evaluation was being documented by **visual analog scales** with score values from 1 to 6. A score of 1 thereby signified no pain, (resp.) very good, (resp.) without discomforts. A score of 6 however signified massive discomforts, (resp.) severe pain, (resp.) not possible, (resp.) very bad.

In a **concluding discussion** the participating women evaluated together with their midwives the wearing comfort and application of the support garment.

Statistics: The statistical evaluation took place at the data processing service centre of Mannheim University. For purposes of the comparing statistics, the t-test for associated samples as well as the Wilcoxon rank-sum test was being performed without present Gaussian distribution. The standard parameters N (number of observations), average value (arithmetic mean), min, median, standard deviation and max were assigned within the descriptive statistics.

A patient who was first being provided post-partum with the indication "symphysis relaxation" with the support garment had to be excluded. Consequentially, the test population consists of 39 evaluative patients (the success of wearing the support garment for this patient was excellent so that an indication appears given even post-partum).

The pregnant women, enrolled into this study, were on average in the 28<sup>th</sup> week of pregnancy at Visit 1 and in the 38<sup>th</sup> week of pregnancy at the completion Visit 6.

## Results

Each recorded patient complained initially about discomfort in the support device area, ligament and vaginal area as well as vaginal pressure. Referrals to compression pain (66%) and discomfort of curvature of the spine (84%) were reported frequently. Vulva-varices were initially stated by 26% of the pregnant women, by the end of the study even by 30%.

Table 1: Reported pain (frequency in %)

Description and Localization	Visit 1 (%)	Visit 6 (%)
Vulva-varices	26.3	30.6
Pain through curvature of spine	66.7	45.7
Pressure pain of spine	46.2	40.0
Pain through flexion	84.6	48.6
Pain through rotation	71.8	40.0
Pain through extension	74.4	45.7

Throughout the observation period, a significant improvement has shown for all pain relevant parameters for both, in the occurrence frequency as well as in its characteristic. A considerable improvement of the physical activity impairment, existing on enrollment into the study, has thereby been outlined.

The pain symptoms reduction achieved a significant level in the support device area, ligament and vaginal area, as well as vaginal pressure.

Table 2: Change of state

	Visit 1 Mean value ± SD Median	Visit 6 Mean value ± SD Median	P-value (t-Test)	p-value (Wilcoxon-Test)
Support device	3.2 ± 1.55 4.00	2.01 ± 1.06 2.00	< 0.0001	< 0.0001
Ligament and Vaginal area	3.44 ± 1.77 4.00	2.03 ± 1,8 2.00	< 0.0001	< 0.0001
Vaginal pressure pressure	2.87 ± 1.72 3.00	1.92 ± 1.14 2.00	0.0083	0.0068
Physical Activity	3,2 ± 1.23 4.00	2.31 ± 1.19 2.00	< 0.0001	< 0.0001

The occurrence of vulva-varices could not be avoided by wearing the support garment but vaginal pain could be reduced.

Table 3: Influencing pain characteristic

	Visit 1 Mean value ± SD Median	Visit 6 Mean value ± SD Median	P-value (t-Test)	p-value (Wilcoxon-Test)
Compression pain of spine	3.46 ± 1.79 4.00	2.19 ± 1.05 2.00	0.0244	0.0161
Pressure pain of spine	3.56 ± 1.92 4.00	1.68 ± 0.72 1.75	0.0543	0.0625
Pain through flexion	3.30 ± 1.74 4.00	2.06 ± 0.75 2.00	0.0018	0.0039
Pain through rotation	3.43 ± 1.79 3.00	1.79 ± 0.89 2.00	0.0043	0.0078
Pain through extension extension	3.59 ± 1.84 4.00	1.75 ± 0.86 2.00	0.0016	0.0039

- ▶ The **wearing comfort** of the support garment was evaluated as good throughout the entire observation period (Visit 6: mean value 2.24 ± 1.37, median 2.00).
- ▶ The **daily utilization period** declined from visit 2 to visit 6. This however was primarily explained by 8 women being pregnant with twins. They felt constricted by the support garment because of substantial size and weight increase. Thereby they wore the device shorter or not at all

respectively. The solution could be, to find remedy in wearing a bigger size of the support garment which was not performed in the study.

- ▶ The physical condition as well as the **utilization** of the support garment for and by the mothers-to-be was evaluated during the final exam (see below fig. 2 and 3). The condition improved for 32 out of 39 (82%) of the examined patients, for 6 (15.4%) pregnant women reported no effect and one only case (2.6%) stated an impairment of the original condition.
- ▶ By the end of the study, the participants evaluated the utilization of the support garment accordingly. 87.2% of the pregnant women rated the utilization from Good to Very Good.
- ▶ The results of the women being pregnant with twins differed from each other marginal. A significant reduction of the pain symptoms characteristic could also be documented. For 6 out of 8 patients, the final evaluation resulted in an improvement of the condition, 2 of the patients experienced no change

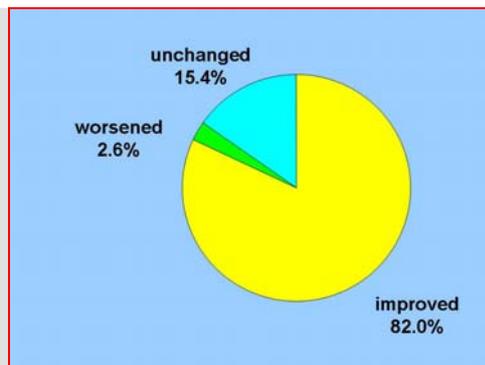


Figure 2: Change of state at visit 6 compared to visit 1 (N = 39)

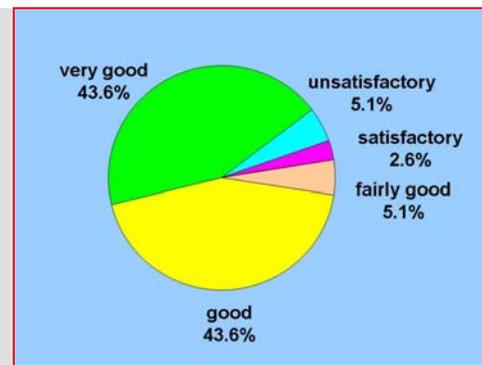


Figure 3: Overall benefit assessment at final visit 6 (N = 39)

## Discussion

Within the case series, the support garment lead to a considerable improvement of the discomfort and the level of activity. Merely one case observed impairment. 82% of the participants stated an improvement. By tendency, the results of the subjective pain scale agree with the objective results of the physical examination. Particularly back- and compression pain had been clearly improved by wearing the support garment. The support garment has no influence on the development of vulva-varices. However, discomfort in the ligament and vaginal area had been significantly reduced. By the end of the observation period, the participants rated the wearing comfort as good. This also shows in a mean wearing period of about 8 hours.

## Conclusion

- ▶ Back- and ligament discomforts can be reduced or even avoided by wearing the investigated support garment. No side affects or risks for mother and child occur.
- ▶ Therapeutic use is thereby recommended
  - **prophylactic** for weakness of the connective tissue, vulva-varices, former complications in previous pregnancies as well as twin pregnancies
  - **therapeutic** of discomforts in back, pelvic and vaginal area, as well as
  - **post-partum** for symphysis relaxation

## Literature

1. Scultetus AH, Villavicencio JL, Rich NM, Das weibliche Beckenvenensyndrom - eine Übersicht, Phlebologie 2003, 32: 37 - 44
2. Carlson HL, Carlson NL, Pasternak BA et al., Understanding and managing the back pain of pregnancy, Curr Womens Health Rep 2003, 3: 65 - 71
3. Forrester M, Low back pain in pregnancy, Acupuncture in Medicine 2003, 21: 36 - 41
4. Rost CC, Jacqueline J, Kaiser A et al., Pelvic pain during pregnancy, Spine 2004, 29: 2567 - 2572
5. Beaty CM, Bhaktaram VJ, Rayburn WF et al., Acute hemodynamic effects of a lumbar support, J of Reprod Medicine 1999, 44: 1007 - 1011