

Original Research

Efficacy of pelvic belt for back pain after delivery

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Abstract

The purpose of this study was to verify whether the wearing of a pelvic belt (Tocohan belt II) by postpartum women reduces back pain based on quantitative and functional evaluation.

The participants were women who delivered a single baby transvaginally at full term. There were 30 women wearing pelvic belts in the intervention group, and 11 women not wearing them in the control group. For evaluation, a visual analog scale and a function impairment evaluation scale were used. We investigated the number of occurrences of back pain at 1 week, 1 month, and 2 months after delivery.

As a result, the number of occurrences of back pain, lumbar pain and pelvic pain did not differ significantly between the 2 groups at any time point.

In the participants with low back pain at 1 week after delivery, both the quantitative and functional impairment evaluation results in the intervention group were reduced over time from 1 week to 2 months after delivery. On the other hand, in the control group, only functional impairment evaluation results from 1 month to 2 months were significantly reduced.

Key words : pelvic belt, back pain, lumbar pain, pelvic pain, postpartum women

Introduction

Pregnancy causes various physiological changes, including a 20-fold increase in the size of the uterus, which compresses pelvic organs, including the bladder and large intestine, and results in weight gain and postural changes (Murai, 2007). In addition, hormones such as relaxin that are secreted during pregnancy cause pelvic joints and ligaments to relax, increasing the range of motion of joints, which can stress the lumbar and pelvic regions (Tanaka, 1982). Symptoms such as lower back pain and pelvic pain are likely to persist during the puerperium (Murai, et al., 2005) because the duties of child care prevent the necessary rest and load further burdens.

Because these symptoms of discomfort do not directly affect the course of pregnancy, they have been considered a minor problem and therefore aggressive treatment or nursing care have

generally not been pursued. However, the need to address minor troubles is gaining recognition (Mori, 2010), because physical discomfort not only can continue for a long time but can also affect psychological health (Mori, 2010).

Yoga and other exercise therapies, aromatherapy, and the use of pelvic belts to support and stabilize the pelvis have been used to treat minor symptoms. The pelvic belt is thought to promote uterine restoration, prevent uterine prolapse, improve back pain, and prevent urinary incontinence (Aisaka, 2009; Hattori, et al., 1999; Ueno, et al., 2009). Pelvic belts are currently used by in of every five pregnant women. Some institutions actively recommend pelvic care with pelvic belts and some facilities incorporate them in standard care. However, most reports of the benefits of pelvic belts have been subjective evaluations; objective evaluations have not been adequately performed.

In this study, we evaluated the usefulness of the

pelvic belt, hypothesizing that “the pelvic belt reduces back pain after delivery.”

Materials and Methods

1. Research Period and Participants

This study included women with singleton pregnancy who consulted obstetric facilities in Shiga Prefecture from May to December 2010. Pelvic belts could be worn continuously. Exclusion criteria included high-risk pregnancy/high-risk parturition, delivery of a baby weighing 4,000 g or more at birth, a nonpregnant body mass index (BMI) of 25 kg/m² or more, and waist circumference less than 70 cm or greater than 120 cm, which exceeds the adjustment range of pelvic belts. Women with orthopedic diseases and other diseases considered to potentially influence the results and women with metal that could not be removed from the body were also excluded.

Although we planned to randomize participants to into study groups, recruiting for the control group in a facility that recommended pelvic belts was difficult. We confirmed that there were no differences in the implementation of postpartum care other than pelvic belt use at two facilities and allocated a wearing group (intervention group)

and non-wearing control group at each. Power analysis based on previous experimental results indicated that the experimental and control groups should each include 32 women.

2. Experimental Tools

The TocoChan Belt II (Aoba, Inc.; hereafter referred to as the pelvic belt) was used (Figure 1). The pelvic belt was positioned on the pubic symphysis (Watanabe, 2012), as reported in a previous study. Women are generally instructed to wear the pelvic belt at a pressure that feels comfortable, without verification of the actual pressure. In this study, we measured the pressure three times with a portable contact pressure-measuring instrument (Palm Q, product number : CR-490 ; Cape Co., Ltd.). The average pressure was 10.1 mmHg.

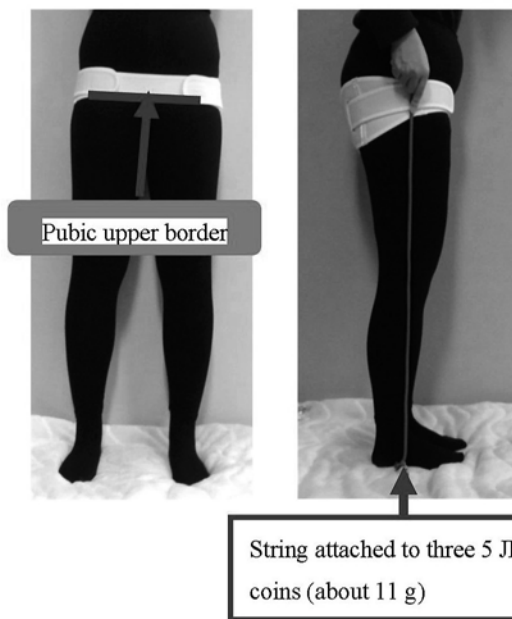
Because the capillary pressure in humans is 17 mmHg, the basic pressure was set to 10 to 15 mmHg in this study. Researchers received instructions for pelvic belt placement directly from the inventor of the TocoChan Belt II and also attended a lecture series, entitled : “Seminar for Pregnant Women, Basic Seminar Workshop”, offered by the NPO Maternal and Organization Study Group. To ensure the reproducibility of belt

Commercial product "Tokochan Belt II" made by Aoba Co, Ltd.

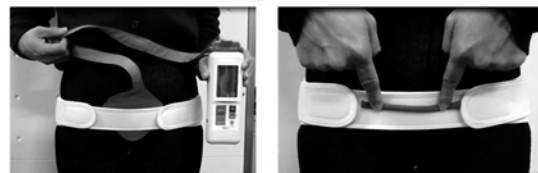
Waist circumference 70 to 120 cm is adaptive size



Wearing position



Basic pressure



Pressure: on pubic joint
(Palm Q made by Cape Corp.)
Standard pressure is 10 to 15 mmHg

Figure 1 I Wearing position of pelvic belt and basic pressure

positioning, we asked subjects to measure the vertical distance from the lower end of the pelvic belt to the floor with a cord and to wear the belt at the same position each time. We also taught women to use a string to measure the belt circumference so that the belt was worn at a standard pressure each time.

3. Participant Data

Data on participant age, height, weight, number of deliveries, number of years since delivery, nonpregnant height and weight, obstetric treatments, baby's condition, nursing situation, urinary incontinence, constipation, and exercise habits before and during pregnancy were collected from self-administered questionnaire surveys.

In this study, in order to evaluate back pain, which is one of the minor troubles, the function evaluation scale of disease-specific / patient-based chronic low back pain (Japan Low back pain Evaluation Questionnaire, hereinafter referred to as JLEQ) was used. JLEQ has been developed as a low back pain scale that reflects the living environment of Japan, it can be used to make international comparisons, and its validity has been verified with reliability ($\alpha=0.97$) (Shirato, et al., 2007).

JLEQ facilitates quantitative evaluation of the degree of back pain (hereinafter referred to as quantitative evaluation) and functional impairment evaluation associated with low back pain (hereinafter referred to as functional impairment evaluation).

For quantitative evaluation, when a straight line of 10 cm is drawn, the left end is "no pain", and the right end is "the most severe pain experienced so far". Participants placed a mark corresponding to their perceived level on the straight line. We measured the length from the left end to the mark and a score from 0 to 10 points (Visual Analogue Scale, hereinafter referred to as VAS) was used.

The functional impairment evaluation consists of 30 questions on "posture and movement while feeling back pain" (7 questions), "problems living with back pain (17 questions)" and "influence on mental health condition (6 questions)". Each question is allotted 0 to 4 points. The greater the severity based on quantitative and functional impairment evaluation, the higher the score.

The back pain location survey form was prepared by researchers based on the classification by Ostgaard (1994) in order to evaluate the presence and type of back pain. the first

question was: "Have you experienced back pain in the past few days?", and then participants answered with "Yes" / "No". If they answered "Yes", the next question was "the pain location(s) was/were A: back, B: lumbar region, C: pelvic region." Since the location may not have been limited to one place, two or three locations could be chosen.

4. Methods of Analysis

Analysis was performed with statistical software PASW Statistics 22.0 for Windows. The significance level was set at $p<0.05$ for comparisons between the wearing and control groups. Normality was examined using the Shapiro-Wilk test. The difference in the means between the wearing and the control groups was examined using Student's *t* — test and the Mann — Whitney U test. The difference in the ratios between the wearing and control groups was examined using Fisher's exact test and the Wilcoxon signed-rank test.

Ethical Considerations

This study was approved by the Shiga University of Medical Science Ethics Committee. We explained the measures for the protection of personal information and data and the rights of participants to all subjects at the time of recruitment. We performed this study with consideration of participants' physical and psychological health.

Results

Thirty-three participants in the wearing group and 13 control participants agreed to participate in the study. Figure 2 shows the change in the number of participants. Attributes of each group are shown in Table 1. There was a significant difference only in BMI. There were no significant differences in other attributes.

Validation of Hypothesis

In order to test the hypothesis that "Wearing a pelvic belt reduces back pain after delivery," we compared the number of occurrences of back pain, type of back pain, and degree of back pain in the wearing versus control group at 1 week, 1 month, and 2 months after delivery.

1) Number of Occurrences of Back Pain

The number of occurrences of back pain in the

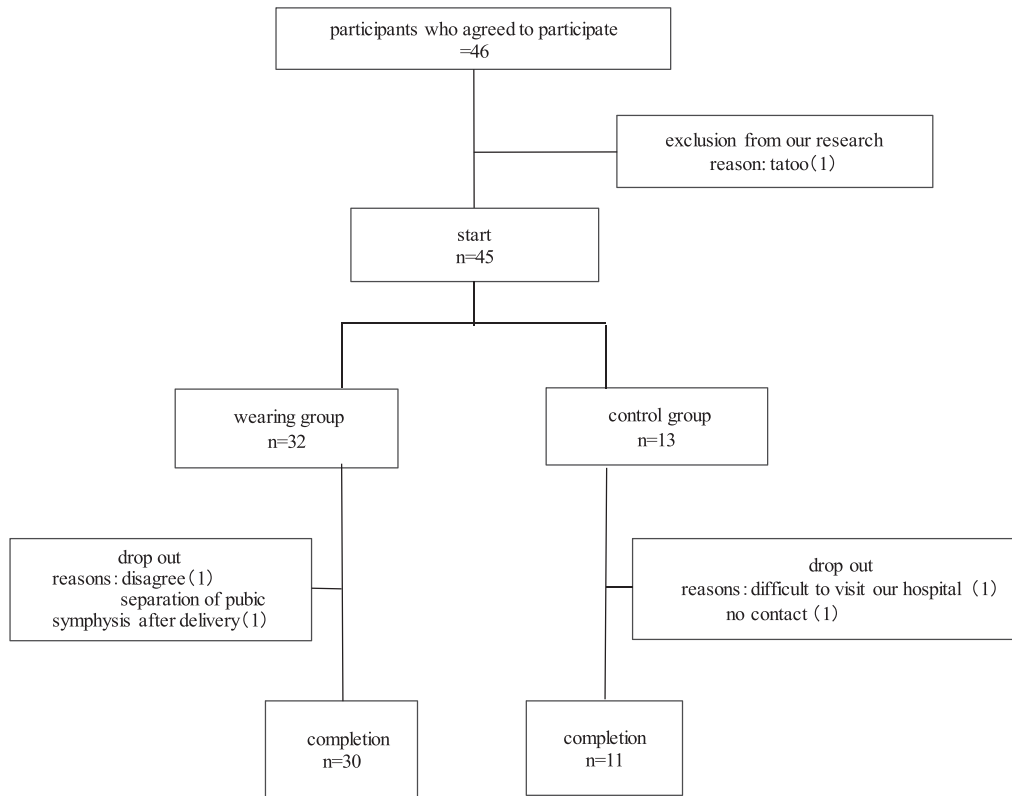


Figure 2 Change in number of participants

Table 1 Attributes

			wearing group n=30	control group n=11	p-value
age (years)	mean ± standard deviation		32.4 ± 4.4	30.3 ± 4.7	0.20 ¹⁾
	minimum-maximum		26–41	25–40	
non-pregnancy BMI	mean ± standard deviation		19.5 ± 1.8	20.8 ± 1.8	0.04 ¹⁾
	minimum-maximum		16.4–23.8	18.4–24.3	
number of deliveries (person (%))	1st time		18 (60.0)	3 (27.3)	0.13 ²⁾
	2nd time		10 (33.3)	6 (54.5)	
	Third or more		2 (6.7)	2 (18.2)	
delivery time (minutes)	primipara	mean ± standard deviation	609.6 ± 441.0	579.0 ± 487.0	0.91 ¹⁾
		minimum-maximum	175–1730	142–1104	
	multipara	mean ± standard deviation	312.8 ± 212.8	314.4 ± 169.9	0.99 ¹⁾
		minimum-maximum	76–826	90–655	
obstetric treatment (person (%))	suction delivery	done	0 (0.0)	0 (0.0)	1.00 ²⁾
		nondone	30 (100.0)	11 (100.0)	
	labor-inducing drug	done	4 (13.3)	1 (9.1)	0.97 ²⁾
		nondone	26 (86.7)	10 (90.9)	
	Kristeller maneuver	done	6 (20.0)	0 (0.0)	0.17 ²⁾
		nondone	24 (80.0)	11 (100.0)	
baby's condition	weight (g)	mean ± standard deviation	2998.7 ± 307.5	3209.0 ± 272.6	0.53 ¹⁾
		minimum-maximum	2408–3640	2790–3615	
	head circumference (cm)	mean ± standard deviation	32.6 ± 1.5	33.2 ± 1.1	0.23 ¹⁾
		minimum-maximum	29.0–35.0	32.0–35.0	

1) Student's *t*-test

2) Fisher's exact test

wearing versus control group was compared at 1 week, 1 month, and 2 months after parturition. The results are shown in Table 2. There was no significant difference in the incidence of back pain at any of time points.

2) Number of Back Pain Occurrences According to Type of Back Pain

At 1 week, 1 month, and 2 months after parturition, the number of back pain occurrences according to the type of back pain was compared between the wearing versus control group. The results are shown in Table 3. There were no significant differences between groups in the number of occurrences of upper back pain, lower back pain, or pelvic pain at any time point.

3) Comparison of Degree of Back Pain

Quantitative evaluations of the degree of back pain and evaluation of functional impairment associated with back pain were compared in the wearing versus control group at 1 week, 1 month,

and 2 months after parturition. This analysis included the 24 wearing-group women (80%) and eight control-group women (73%) who had back pain at 1 week after parturition.

(1) Quantitative Evaluation of Pain

The 24 women in the wearing group reported medium pain scores of 5.0 (interquartile range [IQR] 2.5–7.0) at 1 week, 3.0 (IQR 1.6–5.8) at 1 month, and 1.5 (IQR 0.5–2.5) at 2 months after parturition (Figure 3). The differences in quantitative evaluations at 1 week versus 1 month after delivery and at 1 month versus 2 months after delivery were both significant ($p < 0.025$, $p < 0.005$, respectively).

Similarly, the eight control-group women reported medium pain scores of 4.0 (IQR 2.1–5.8) at 1 week, 2.6 (IQR 2.0–4.3) at 1 month, and 1.8 (IQR 0.6–2.0) at 2 months after parturition. There was no significant difference in quantitative evaluation at 1 week versus 1 month after delivery or at 1 month versus 2 months after delivery in the control group.

Table 2 Number of Occurrences of Back Pain

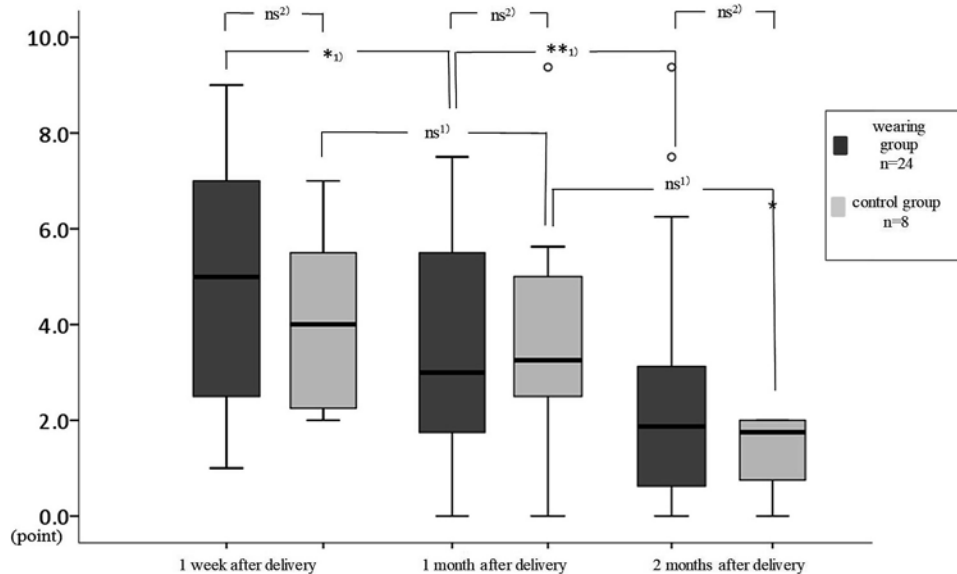
			wearing group n=30	control group n=11	total n=41	<i>p</i> -value
back pain (person (%))	1 week after delivery	with	24 (80.0)	8 (72.7)	32 (78.0)	0.68
		without	6 (20.0)	3 (27.3)	9 (22.0)	
	1 month after delivery	with	22 (73.3)	7 (63.6)	29 (70.3)	
		without	8 (26.7)	4 (36.4)	12 (29.7)	
	2 months after delivery	with	14 (46.7)	5 (45.5)	19 (46.3)	
		without	16 (53.3)	6 (54.5)	22 (53.7)	

Fisher's exact test

Table 3 Number of Back Pain Occurrences According to type of Back Pain

			wearing group group n=30	control group n=11	total n=41	<i>p</i> -value
upper back pain (person (%))	1 week after delivery	with	1 (3.3)	0 (0.0)	13 (31.7)	0.54
		without	29 (96.7)	11 (100.0)	28 (68.3)	
	1 month after delivery	with	3 (10.0)	0 (0.0)	10 (24.4)	
		without	27 (90.0)	11 (100.0)	31 (75.6)	
	2 months after delivery	with	1 (3.3)	1 (9.1)	7 (17.1)	
		without	29 (96.7)	10 (90.9)	34 (82.9)	
lower back pain (person (%))	1 week after delivery	with	16 (53.3)	6 (54.5)	22 (53.7)	0.95
		without	14 (46.7)	5 (45.5)	19 (46.3)	
	1 month after delivery	with	14 (46.7)	7 (63.6)	21 (51.2)	
		without	16 (53.3)	4 (36.4)	20 (48.8)	
	2 months after delivery	with	10 (33.3)	5 (45.5)	15 (36.6)	
		without	20 (66.7)	6 (54.5)	26 (63.4)	
pelvic pain (person (%))	1 week after delivery	with	10 (33.3)	3 (27.3)	13 (31.7)	0.71
		without	20 (66.7)	8 (72.7)	28 (68.3)	
	1 month after delivery	with	9 (30.0)	1 (9.1)	10 (24.4)	
		without	21 (70.0)	10 (90.9)	31 (75.6)	
	2 months after delivery	with	6 (20.0)	1 (9.1)	7 (17.1)	
		without	24 (80.0)	10 (90.9)	34 (82.9)	

Fisher's exact test



The upper and lower sides of the box are the first (25% tile) and third (75% tile) quartiles respectively, the median line of the box is the median, and the upper and lower limits of the beard are 1.5 times values of the first and third quartiles. A white circle indicates an outlier of 1.5 times or more and less than 3 times, and a black star indicates an outlier of 3 times or more.

- 1) Wilcoxon signed-ranks test Bonferroni
* $p < 0.025$, ** $p < 0.005$ ns=not significant
- 2) Mann-Whitney *U* test
ns=not significant

Figure 3 Comparison of quantity evaluation of wearing group/control group at each time point after delivery

There was no difference in the quantitative pain score between the wearing and control groups at any time point.

(2) Evaluation of Function

The evaluation of functional impairment among the 24 women in the wearing group revealed medium scores of 27.0 (IQR 21.0-41.8) at 1 week, 6.5 (IQR 3.3-15.8) at 1 month, and 2.5 (IQR 0.3-9.8) at 2 months after parturition (Figure 4). There were significant decreases in functional impairment from 1 week to 1 month after delivery and from 1 to 2 months after delivery ($p < 0.005$ for both).

Similarly, the medium functional impairment of the eight control-group women was 27.0 (IQR 8.3-39.0) at 1 week, 6.0 (IQR 3.0-21.0) at 1 month, and 2.0 (IQR 0.3-17.5) at 2 months after parturition. A significant decrease in functional impairment was found only between 1 and 2 months postpartum ($p < 0.025$).

There were no significant differences in functional impairment scores between the wearing and control groups at any time point.

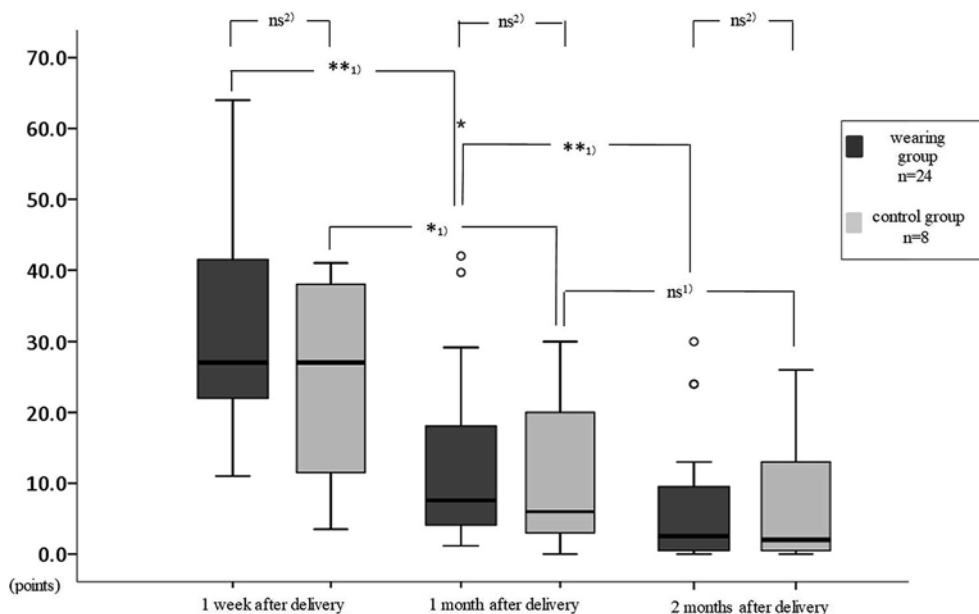
Women in the wearing group who had back pain at 1 week after parturition showed reductions in both the quantitative pain score and functional impairment from 1 week to 2 months

after delivery. In contrast, women in the control group showed a significant reduction only in functional impairment from 1 to 2 months after delivery.

Discussion

There were no significant differences between the wearing ($n=30$) and control ($n=11$) groups in age, number of deliveries, obstetric treatment, or birth status. The nonpregnant BMI in the control group was significantly higher than that in the wearing group; however, both groups were within the standard range, and the influence of this difference on study results was considered to be small.

To test the hypothesis that “Wearing a pelvic belt reduces low back pain after parturition for postpartum women,” we compared the number of occurrences of back pain according to the type of pain, the quantitative evaluation of low back pain, and functional impairment scores of women in the wearing versus control group at 1 week, 1 month, and 2 months after parturition. We found no difference between groups in the number of occurrences of low back pain or the location of pain at any time point. In addition, among women



The upper and lower sides of the box are the first (25% tile) and third (75% tile) quartiles respectively, the median line of the box is the median, the upper and lower limits of the beard are 1.5 times values of the first and third quartiles. A white circle indicates an outlier of 1.5 times or more and less than 3 times, and a black star indicates an outlier of 3 times or more.

- 1) Wilcoxon signed-ranks test Bonferroni
* $p < 0.025$, ** $p < 0.005$ ns=not significant
- 2) Mann-Whitney U test
ns=not significant

Figure 4 Comparison of Quantitative Evaluation of wearing group/control group at each time point after delivery

in the wearing group with low back pain at 1 week after parturition, both the quantitative evaluation of pain and functional impairment scores fell from 1 week to 2 months after delivery. In contrast, only functional impairment scores showed a significant decrease from 1 to 2 months after delivery in the control group.

In this study, pain reduction was observed over time in both the wearing and control group², because the cause of pain improved in the 2 months after parturition. Low back pain during pregnancy and in the puerperium is generally lumbar pain resulting from weight gain and lumbar lordosis, and pelvic relaxation caused by hormones such as relaxin, which cause relaxation of lumbar and pelvic ligaments early in pregnancy (Kunoki, 1999). The reduction in lumbar pain is thought to result from the uterine size and weight returning to those of the nonpregnant state, whereas pelvic pain reduction is thought to result from reversal of pelvic relaxation.

The finding of clear pain reduction in the wearing group may be attributed to the fact that low back pain was subjectively evaluated in our study. The wearing group completed a survey on wearing the pelvic belt for 2 months and was not

blinded. Members of the wearing group had the pelvic belt recommended to them in the obstetric facility and knew about it from the Internet and maternity magazines. Therefore, the participants themselves were interested in the effect of the pelvic belt and actively participated in the research, which may have resulted in the Hawthorn effect.

Our findings did not support the hypothesis that “wearing a pelvic belt reduces back pain.”

In this study, randomization was planned for distribution of participants to the wearing and control groups, however, but this was not possible. The number of participants required for each group was 32; however, at the time of recruitment, many women had already decided to use pelvic belts and corsets, which made it difficult to select subjects for the control group. Therefore, the statistical power was weakened. In the future, it will be necessary to collect additional data for randomization and control group recruitment.

The JLEQ used in this study to evaluate low back pain is a scale designed for a general adult population and was not developed for evaluation of the puerperal period. Therefore, this scale does not specifically evaluate low back pain unique to

the puerperium. In the future, it will be necessary to consider evaluation methods designed for each phase of the perinatal period.

Conclusion

We assessed the hypothesis that “wearing a pelvic belt reduces low back pain” by comparing the type and degree of low back pain of 30 women who wore a pelvic belt versus 11 women who did not at 1 week, 1 month, and 2 months after delivery. We found no significant difference between the groups in the number of occurrences of back pain or in occurrences of lumbar pain or pelvic pain at any time point.

Among women with low back pain at 1 week after parturition, both the quantitative pain score and functional impairment score decreased in the wearing group from 1 week to 2 months after delivery. In contrast, the control group showed a significant reduction only in functional impairment from 1 to 2 months after delivery.

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Conflict of interest

This research received a donation from Aoba Co., Ltd.

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