Comparison of the Modified Lumbar Pelvic Belt with the Current Belt on Low Back and Pelvic Pain in Pregnant Women

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ABSTRACT

Background: Low back pain is one of the most common problems for pregnant women during pregnancy. Most belts are designed for supporting the surface of the symphysis pubis or upper anterior iliac spine without any support in the lumbar region.

Objective: This study aimed to compare the related effects between the new design and the current belt on the pain and function of pregnant women.

Material and Methods: In this randomized control trial study, 48 pregnant women with pelvic and lumbar pain participated. The participants were randomly divided into three groups: current belt, modified belt, and control. Pain intensity assessment, pelvic girdle (PG), and Oswestry disability index (ODI) questionnaires were utilized at the beginning of the study and three weeks later.

Results: The pain intensity decreased more in the modified belt group than in the current belt group. ODI and PG scores decreased in two belt groups after three weeks of follow-up. However, this decrease was greater in the modified belt group, there was no statistically significant difference.

Conclusion: The disability decreased in both groups using the belts, and their function was improved. Accordingly, the use of a modified belt with lumbar and PG support can significantly reduce back and pelvic pain in pregnant women compared to the current pelvic belt.

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Keywords

Pregnancy; Low Back Pain; Pelvic Pain; Orthosis; Function

Introduction

One of the most common problems in pregnant women is back pain; accordingly, some studies reported that this issue might be contributed to 30% to 70% of their problems [1-3]. For this reason, about 30% of women may stop at least one of their daily activities during pregnancy [4,5]. A total of 19% of women who had experienced such pain during pregnancy did not want to get pregnant again due to fear of musculoskeletal problems [6]. In general, spine pain in pregnancy is classified as back or pelvic girdle (PG) pain or a combination of these pains [7].

During pregnancy, a large number of physical and hormonal changes occur in a woman's body, including weight gain, displacement of the body mass center, increased ligament relaxation, and changes in skel-

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etal alignment [8]. The average weight among these women is almost 9 to 14 kg [8,9], and the most weight is due to the enlargement of the uterus, fetus, and breasts [8].

Due to some of these changes, the mass center of the mother's body shifts upwards and forwards [8], leading to an increase in the number of forces over the intervertebral discs and spine [4,8,10,11]. Moreover, the changes in the shape and inertia of the lower trunk can also lead to postural adaptation, musculoskeletal disorders, and back pain [12-14]. Increasing the shear forces leads to pelvic pain in the pelvic joint [15-17].

Different studies have shown that low back pain associated with pregnancy can affect the quality of life. Low back pain can also create sleep disturbance and disruption of daily activities so that a pregnant woman's workability may decrease [18-20].

According to some studies on low-back pain problems, many interventions were investigated as follows: 1) conservative treatments, including physiotherapy, occupational therapy, osteopathic and chiropractic manipulation, pelvic belts, exercise therapy, and medication and 2) invasive treatments, including topical injections, intra-articular injections, and radiofrequency anesthesia [21-26].

Pelvic belts as an intervention have some advantages, resulting in correcting deformities, reducing spinal movements and mechanical forces on the trunk [18,27] stabilization of the lumbar-pelvic spine [28,29], improving the function of the muscles of the abdomen, spine, and pelvic [18,28], facilitating daily activities, such as walking [29,30], and decreasing pain by preventing muscle damage as well as muscle activity and fatigue [10].

A few studies have shown that belts can be effective in reducing sacroiliac joint relaxation and transmitting forces through the pelvic joint [28,31]. However, Bertuit, Kordi, Flack, and Cameron studies have shown the positive effect of belts on reducing pain and improving the function of pregnant women; however, the design and pattern of different belts may have different effects [15,29,32,33].

Falak et al. studied two different pelvic belts (hard and flexible) to reduce symphysis-related pregnancy pain and reported that after three weeks, the pain significantly improved in both groups using the hard and flexible belt; however, a flexible pelvic belt is more effective in reducing pain [32]. Bertuit showed that both two pelvic belts reduced pain with easier daily activities [29].

In another study of pregnant women between 20 and 36 weeks gestation, those women who used the new belt had a lower level of pain compared to others without any significant difference in the function [15].

Belts were mostly designed to cover the surface of the symphysis pubis or upper anterior iliac spine, showing no support lumbar region [29,30,32-34]. According to the hypothesis of this study, extending the belt to the lumbar region and turning the belt into a flexible lumbar-sacral orthosis may further reduce low back pain and improve function better with the support of the lumbar region and PG. To the best of our knowledge, there is no evidence with concern to this new design in this field. Therefore, this study aimed to compare the related effects between the modified and the current belt on the pain and function of pregnant women.

Material and Methods

Subjects

Forty-eight pregnant women with pelvic and lumbar pain, aged under 40 years participated in this randomized control trial study. According to the inclusion, non-inclusion, and exclusion criteria listed in Table 1, individuals were included in the study.

The participants were randomly divided into three groups: A) women who had a current belt during pregnancy, B) women who had a modified belt during pregnancy, and C) those who do not wear a belt during pregnancy as

Table 1: Inclusion, non-inclusion, and exclusion criteria

Inclusion criteria	Non-Inclusion criteria	Exclusion criteria
Pregnant women from the 20th week of pregnancy	Pregnant women with a history of surgery on the spine or pelvis	Inability to attend follow-up study
Pregnant women with moderate to severe pain (Pain intensity 40 and above in VAS)	Pregnant women with a history of back pain and pelvic pain before pregnancy	Patient dissatisfaction with cooperation, lack of proper patient cooperation, and patient fatigue so that they are unable and unwilling to continue working
Age under 40 years	Systemic diseases, such as restrictive lung diseases, heart disease, and diabetes	History of any skin reactions when using the belt
Single pregnancy	Any signs of high-risk pregnancy	
Clinical diagnosis of low back pain or pelvic pain based on the individual's statement, the negative answer to research questions, and positive result of at least one of the following tests:1) Patrick's/Faber Test, 2) posterior pelvic pain provocation, 3) modified Trendelenburg test with direct palpation of the symphysis pubis, and 4) Active straight leg raise test	The common use of NSAIDs or any medication containing corticosteroids in the last 30 days	
	Depression	
	Twin pregnancy	
	Neurological diseases	

VAS: Visual Analogue Scale

the control group.

The patient recruitment was entered to study between January to July 2021 in Kowsar specialized and sub-specialized clinic, Arak, Iran. All participants in the study signed the informed consent form.

Ethical considerations

All participants in the study signed the informed consent form; the study was approved by the ethics committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran (reference number: IR.USWR.REC.1399.161) and IRRCT Code is IRCT20200925048833N1.

Intervention

In this study, two types of belts were used for pregnant women. The used current pelvic belt was flexible, soft, and comfortable and made of three-dimensional fabric with anti-allergy fiber. The current belt was placed around the pelvis at the level of the anterior superior iliac spine and under the abdomen (Figure 1).

The modified belt had four main parts as follows: the first part was the abdominal part, made of three-dimensional fabric, which was soft and comfortable and had anti-allergy fibers and proper ventilation, preventing sweating in the abdomen. The abdominal part placed under the abdomen of the body causes to bear the weight of the fetus, reduces weight, and prevents possible injuries to the fetus. The second part was the lumbar part made of lacquer fabric with good strength and elasticity for proper fitting and extended from the lower angle of the scapula to the gluteal bulge. The lumbar region has two plastic spring reinforcements on either side of the spine. Since the lumbar region covers a large part of the spine, it was designed to distribute forces properly in the lumbar region, help proper muscle activity, and reduce loads on the spine. The third part was a pelvic part with a polyester pelvic band, designed to include the pelvic ring, gentle compression, reduction of laxity, and shear forces, supporting pelvic girdle, stabilizing the sacroiliac joint, and reducing pelvic pain. A coccygeal pad was also added to the pelvis part to improve the distribution of forces and minimize pain in this area when sitting. The fourth part was the shoulder straps to better suspend the belt and distribute the appropriate load on the shoulders, leading to easier use of the belt and fixing the belt over the trunk during moving, sitting, and getting up.

Figure 1: The current belt

The modified belt, which is soft and comfortable to use and designed in three sizes to fit, covers the lumbar region and pelvic girdle. In addition, it is stretched to the desired size by the belt elasticity; accordingly, no worry about wearing and fitting is needed since it can be used easily until late pregnancy (Figure 2).

Data collection

Visual analog scale (to assess pain intensity), PG questionnaire (to assess the symptoms

Figure 2: The modified lumbar pelvic belt

and disabilities of pelvic pain), and Oswestry disability index (ODI) questionnaire (to assess the limitations and daily activities in low back pain) were utilized at the beginning of the study and three weeks later for the three groups. After three weeks, all questionnaires were completed by three groups again.

Data analysis

The frequency distribution, mean, and standard deviation were applied to describe the data. Analysis of covariance (ANCOVA) was used to compare post-test scores in the groups of this study (test of between-subject effects). All statistical analysis was performed using SPSS 26 software (IBM SPSS Statistics 26.0, 2019), and a statistically significant level was considered.

Results

A total of 48 pregnant women with lumbar and pelvic pain were divided into three groups in the study: current belt (n=14) modified belt (n=14) and control (n=20); the characteristics of the study samples are shown in Table 2. The sample size was computed by the following formula:

$$n_c = \frac{2s^2\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2}{\Delta^2} = \frac{2\times 15.16\times(1.96+0.84)^2}{3.5^2} \cong 20; n_{I1} = n_{I2} = \frac{20}{\sqrt{2}} \cong 14;$$

where n_c is defined as a sample size in the control group; n_{I1} and n_{I2} are considered the sample sizes in intervention in groups 1 and 2, respectively. s^2 (variance) and Δ (the minimal detectable difference between the two means) were obtained based on the GEMMA study [12]. In addition, 1-α/2 and 1-β are confidence level and power of the test set to 80% and 95%, respectively.

According to Table 3, means of pain intensity, ODI scores, and PG scores decreased in both belt user groups after three weeks. How-

Table 2: The basic characteristics of the study samples (mean± SD (Standard deviation))

Groups	Number	Age (mean± SD)	Height (mean± SD)	Week of pregnancy T1 (mean± SD)	Week of pregnancy T2 (mean± SD)	Mass T1 (mean± SD)	Mass T2 (mean± SD)
Current belt	14	28.86±2.71	163.35±3.29	28.00±1.66	32.00±1.66	72.18±3.734	74.03±3.71
Modified belt	14	29.64±2.56	161.89±3.99	28.14±1.70	32.14±1.70	72.03±3.875	73.85±4.06
Control	20	29.60±2.41	162.20±3.90	28.55±1.70	32.55±1.70	73.22±4.03	75.32±4.06

SD: Standard deviation, T1: At the basic time; T2: After three weeks follow up

Table 3: Descriptive variables of pregnant women with lumbar and pelvic pain

Group	VAST1	VAST2	ODIT1	ODIT2	PGT1	PGT2
Current belt	72.93±10.50	71.93±9.54	30.43±4.03	28.64±3.45	51.21±8.39	49.14±6.87
Modified belt	78.14±10.67	71.07±10.48	29.64±4.60	26.86±3.46	48.64±8.54	44.29±6.58
Control	74.70±11.09	79.45±11.58	28.70±6.40	32.50±5.41	46.70±8.41	55.50±7.64

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, PG: Pelvic girdle, T1: At the basic time; T2: After three weeks follow up

ever, in the control group, all variables increased after three weeks of follow-up.

The results of the ANCOVA test (Table 4) showed significant differences in all variables between the three groups. According to the pairwise comparisons between three variables (Table 5), the current belt group and the modified belt group were significantly different from the control group (p-value<0.001). In ODI and PG scores, the difference between the current belt group and the modified belt group was not significant (p-value =0.339, p-value=0.077). Indeed, ODI and PG scores decreased in two belt groups after three weeks of follow-up. However, this decrease was greater in the modified belt group, there were no statistically significant differences; in addition, there was a significant difference between the current belt group and the modified belt group in pain intensity (p-value<0.001), i.e. the pain intensity decreased more in the modified belt group than the current belt group.

Table 4: Tests of between-subjects effects based on ANCOVA (Analysis of covariance)

Variables		DF	Mean Square	F	p-value
VAST2	VAS.T1	1	4682.40	428.86	<0.001
	group	2	554.43	50.78	<0.001
	Error	44	10.92		
ODIT2	ODI.T1	1	698.12	180.89	<0.001
	group	2	194.70	50.45	<0.001
	Error	44	3.86		
PGT2	PG.T1	1	1797.51	161.39	<0.001
	group	2	741.90	66.61	<0.001
	Error	44	11.14		

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, PG: Pelvic girdle, T1: At the basic time; T2: After three weeks follow up, DF: Degree of freedom, F: F statistics, Statistically Significant (p-value <0.05)

Discussion

This study aimed to compare the modified lumbar pelvic belt with the current belt for low back and pelvic pain in pregnant women. All participants in this study had low back and pelvic pain, included in the study from the 20th week of pregnancy.

In this study, pain intensity was reduced in both two groups that used belts after three weeks of follow-up. In similar studies, the pain was reduced by using pelvic belts [10,29,33,34]. However, the pain intensity was significantly lower in the modified belt group than in the current belt group. The lumbar region and PG are surrounded by a modified belt as a unit structure, leading to transferring forces better and reducing pressure on the spin; accordingly, back and pelvic pains decrease.

In contrast, the pain increased in the control group (who did not wear belts) due to physical changes in pregnancy, such as weight gain, protrusion of the abdomen, and changes in skeletal alignment, leading to increased pres-

Table 5: Results of between-group comparisons

	Current belt VS modified belt		Current belt VS control		Modified belt VS control	
	Mean Difference (95% Confidence)	p-value	Mean Difference (95% Confidence)	p-value	Mean Difference (95% Confidence)	p-value
VAST2	5.78±1.27	<0.001	-5.85±1.15	<0.001	-11.63±.1.16	<0.001
ODIT2	1.20±0.74	0.339	-5.14±0.69	<0.001	-6.34±0.68	<0.001
PGT2	2.93±1.27	0.077	-9.73±1.19	<0.001	-12.66±.1.17	<0.001

VAS: Visual Analogue Scale, ODI: Oswestry Disability Index, PG: Pelvic girdle, T1: At the basic time; T2: After three weeks follow up, VS: Versus

sure on the spine [8].

Based on functional disability in low back pain and disabilities regarding pelvic pain measured by ODI and PG questionnaires, disability decreased and function improved after three weeks in both groups with belts. However, among the two groups with the belt, the disability rate was lower in the modified belt group compared to in the current belt group, which was not significant.

However, the third group that did not use the belt had a significant increase in functional disability and disability due to pelvic pain, this increase is considered due to the increase in the number of weeks of pregnancy and physical changes in pregnancy, leading to disability and functional limitation in pregnant women [29]. The reduction of these variables in other groups shows the positive effect of belts, especially the modified belt since any decrease in the rate of functional disability in pregnant women is considered from a clinical point of view; although this reduction is not statistically significant.

Two systematic reviews investigated the positive effect of supporting belts on improving the function of pregnant women [35,36], which was in line with the results of the current study. In addition, one study showed that there is no significant difference in the function of pregnant women that use two different belts [15].

In this study, in the control group who had more pain, the rate of functional disabilities was also higher; accordingly, with enlargement of the abdomen and increasing lumbar lordosis in clinically view leading to increased pain, the disabilities increased in pregnant women [8,12].

In the present study, sample collection was very difficult and the participation of pregnant women in the study was low due to the prevalence of COVID 19 disease. Future studies should investigate the effect of long-term use of the modified belt on pregnant women with low back and pelvic pain and the impact of using this belt on the activity of the lumbar and pelvic muscles in this group.

Conclusion

In this study, the use of a modified belt with lumbar and PG support can significantly reduce back and pelvic pain in pregnant women compared to the current pelvic belt. Belts also help improve function and reduce the disability of pregnant women. The modified belt in comparison with the current belt can reduce disability and improve the function of pregnant women. However, this reduction was not statistically significant, its improvement can be considered, clinically.

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Authors' Contribution

Zh. Heidari collected data, analyzed, interpretation of data, and drafting of the manuscript. Gh. Aminian provided data modeling, drafting of the manuscript, critical revision of the manuscript for important intellectual content, and editing. A. Biglarian carried out statistical analysis and drafting of the manuscript. M. Shokrpour referred the patients and manuscript drafting. M. Mardani conceived the original idea, studied the concept and design, and drafting of the manuscript. All the authors read, modified, and approved the final version of the manuscript.

Ethical Approval

The study was approved by the ethics committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran (reference number: IR.USWR.REC.1399.161) and IRRCT Code is IRCT20200925048833N1.

Informed consent

All participants in the study signed the informed consent form.

Conflict of Interest

None

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