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The effects of using abdominal binder on pain intensity and mobility after cesarean section: A blind clinical trial

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Abstract

Cesarean delivery may be complicated by pain, bleeding, excessive use of painkillers, infection, or other issues. A potential non-pharmacological way to reduce post-operative pain is the use of an abdominal binder, which may also affect the mobility of patients. The present investigation was performed with the purpose of evaluating the effect of using an abdominal binder on pain intensity and mobility after caesarean section at Isfahan University of Medical Sciences. This study was a blind, two-group, one-stage parallel clinical trial with a control group. 184 pregnant women who met the inclusion criteria were randomized into two intervention and control groups with a block size of 4 and 6 and with an allocation ratio of 1:1. Each patient in the intervention group used an abdominal binder before leaving the operating room. Both groups received routine care and medication. Data collection was performed by using demographic information questionnaire, VAS scale, and recording of painkillers received. Mobility was evaluated by performing a six-minute walking test. Data analysis was done using SPSS version 24 software, independent T test and ANOVA test. A value of $P < 0.05$ was considered significant. 184 women candidates for cesarean section were divided in two groups of 92 people with the average age of the control group (27.7±7.3) and the intervention group (28.58±7.01). The results demonstrated that the two investigated groups were identical in terms of demographic characteristics. Based on the independent t-test, the pain intensity score of the intervention group at different times (6, 12, 18 and 24 hours after the operation) was significantly lower than the control group ($P<0.05$). In addition, 12 and 24 hours after the operation, the mean and standard deviation of the mobility score of the control group was significantly lower than the intervention group ($P=0.038$). The mean and standard deviation of the number of times receiving sedative by the intervention group was significantly lower than the control group ($P<0.001$). The use of abdominal binder after caesarean section was effective in reducing pain, improving mobility, and receiving sedatives in some periods of time.

Keywords: clinical trial, abdominal binder, caesarean section, pain, mobility.

1. Introduction

Cesarean delivery is the most common surgery worldwide (1). According to the reports of the World Health Organization, 1.5 million cesarean sections are performed annually in the world and its prevalence has tripled compared to the last 20 years (2). Cesarean delivery may be complicated by pain, excessive use of sedative drugs, infection, damage to pelvic organs, and maternal mortality (3, 4).

Pain is the most common symptom that affects the recovery of women after childbirth (5). Excessive pain after surgery is related to poor outcomes of postpartum nursing, such as mother- infant bonding disorder, breastfeeding problems, anxiety, distress, aggression and insomnia of the mother (6). On the other hand, insufficient movement after major abdominal surgeries such as cesarean section is also common and can increase complications such as atelectasis, deep vein thrombosis, and constipation (7).

Thromboembolism is one of the causes of maternal mortality. The highest time of its occurrence is immediately after delivery, but the risk of its occurrence continues up to 12 weeks after delivery. Lack of sufficient mobility after surgery is associated with an increased risk of thromboembolism, while having sufficient mobility increases bowel movements and reduces the length of hospitalization (8).

Pain and restriction of movement are both effective factors in delaying recovery and causing complications in patients (9). Although drug therapy is considered safe after cesarean section, many mothers prefer non-pharmacological methods (5). A potential non-pharmacological way to reduce postoperative pain and reduce postpartum bleeding is the use of an abdominal binder during the recovery period after

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surgery (10). Abdominal binder is a wide belt that surrounds the abdomen and supports the surgical site (11). Abdominal binder induces abdominal pressure, which subsequently increases blood flow and reduces inflammation at the incision site and facilitates rapid tissue repair (12). Currently, limited and contradictory studies are available regarding the effect of abdominal binder according to the type of abdominal surgeries. One of these studies is the study of Gillier et al (2016) about the use of abdominal binder in pain management and the level of mobility after cesarean section, which reported that the use of abdominal binder ineffective in reducing pain and distress after cesarean section (13). While the results of Gustafson's study (2018) show that the use of abdominal binder may be related to the pain improvement after cesarean surgery (14). Therefore, by reviewing numerous studies in this field and the with respect to their contradictory results, and since few studies have been conducted on patients undergoing cesarean section, the present study was performed with the purpose of investigating the effect of using abdominal binder on the amount of pain and mobility after cesarean section. It was performed on patients referred to the operating room of Shahid Beheshti Hospital in Isfahan in 2021.

2. Materials and Methods

The current research is a parallel clinical trial study (IRCT20211024052856N1), blind, with a control group. By referring to the gynecological department of Shahid Beheshti Hospital, Isfahan, Iran, women candidates for elective cesarean surgery were selected, who met the study entry criteria. The reason for choosing this hospital was the higher number of cesarean surgeries in them compared to other medical centers in the year 2021.

At first, the steps of conducting the research and its purpose were explained to the research units participating in the study. They were assured that participating in the study will not prevent them from receiving adequate care and treatment, their information will remain confidential, and they will be given the right to withdraw from the study at any stage of the research. Then the informed consent form was provided to them to complete.

The inclusion criteria include not having any underlying disease (neuro-muscular disorders, high blood pressure, kidney disease, heart disease), spinal anesthesia, not using anti-anxiety, soporific and sedative drugs, first and second caesarean section, Body mass index was between 18.5 and 29.9, hemoglobin was higher than 10, term neonate, singleton pregnancy, pregnancy without complications such as the absence of eclampsia and preeclampsia, Pfannenstiel incision on the skin and Kerr incision on the uterus.

Exclusion criteria include uterine atony, the patient's intolerance to the abdominal binder, unwillingness to continue participating in the study, the need to perform simultaneous surgery such as hysterectomy, severe bleeding after surgery, damage to body tissues during cesarean surgery such as damage to the urinary tract and the digestive tube.

After the cesarean surgery, the demographic information form was completed based on the patients' medical records. Allocation of people in groups was done using random block with 4 and 6 block sizes and with 1:1 allocation ratio using RAS software. To hide the allocation, consecutively numbered opaque envelopes were used. In the intervention group, an abdominal binder was tied to the patient before leaving the operating room. The abdominal binder (Pak Saman, made in Tehran, Iran) was closed on the surgical incision in such a way that its upper edge was placed under the edge of the ribs, and it was ensured that the function of the lateral ribs and the diaphragm were not a problem. The abdominal binder was closed on the patient's body in the lower part of the abdomen so that the surgical incision is placed in its middle part. For more correct use of abdominal binder, before closing it, the abdominal circumference was measured with a meter and according to the size of the abdominal circumference, the appropriate abdominal binder (size Medium, Large) was closed for 24 hours after the operation. For the comfort of the patient, the abdominal binder was opened between 00:00 AM and 6:00 AM. No abdominal binder was used in the control group. Both groups received routine care and medication. In both groups, suppositories (diclofenac sodium 100 mg) and injectable sedative pethidine and acetaminophen were used within 24 hours after cesarean section if needed. VAS scale was used to check the patient's pain intensity. The VAS scale includes a 10 cm vertical ruler scale, where the number ten indicates the highest level of pain and the number zero indicates the lowest level of pain. The visual pain scale is used to measure pain intensity as a valid scale in the world. The validity of the VAS scale in the study by Azizi et al. (2018) was about 76-86% and its reliability was 60-70% (15).

The six-minute walk test was used to check mobility (16). According to the guidelines of the American Thoracic Association, this test was performed in a 30-meter long straight corridor on a hard surface (ground), where the two ends of the path were marked by two plastic cones for bypassing. The length of the walking path was marked for every 3 meters. The subjects were asked to refrain from vigorous physical activity 3 hours before the test. Before testing the research units, they sat on a comfortable chair for ten minutes, and then blood pressure variables, oxygen saturation percentage and heart rate were recorded at rest. The research units were told that the optimal goal of the test is to cover the maximum distance that they can cover in a round trip with the preferred speed of walking (not running). The time was recorded by a mobile stopwatch and was not stopped during rest. Heart rate variables, oxygen saturation percentage and blood pressure were measured at the end of the walking activity. The total distance traveled during the test (in meters) was considered as the patient's mobility score. The test (6MWT) was performed twice, 12 hours after cesarean surgery, when the patient first got out of bed, and 24 hours later.

Finally, information was collected and SPSS version 24 software and descriptive (mean and standard deviation) and inferential methods (independent t-tests, analysis of variance, chi-square and Pearson correlation) were used for data analysis.

2.1. Ethical Considerations

This study was approved by the ethics committee in biomedical research of Isfahan University of Medical Sciences with the code (IR.MUI.MED.1400.444). After stating the objectives of the research, the subjects were given the opportunity to cooperate and complete the informed consent. They were also assured about the confidentiality of the data. In addition, they had the right to withdraw from the study at any stage if they did not wish to continue their cooperation without any interruption in their follow-up care.

3. Results

In this study, 184 people (two groups of 92 people, test and control) from women candidates for elective caesarean surgery referred to the women's department of Shahid Beheshti Medical Training Center of Isfahan were included in the study, of which two people were in the intervention group due to heavy bleeding, and two people in the control group were excluded from the study due to their unwillingness to continue participating in the study. Finally, 180 people were examined until the end of the study.

The studied groups were similar in terms of demographic characteristics. Table 1 shows the frequency and percentage of demographic variables of the subjects.

Table1. Determining and comparing the demographic characteristics of the control and intervention groups

	Control (n=90)	Intervention (n=90)	Statistics	P
	Mean ± Standard Deviation			
Age	27.7 ± 7.23	28.58 ± 7.01	-0.82	0.41
Gestational Age	38.5 ± 0.53	38.49 ± 0.54	0.07	0.944
BMI	25.3 ± 2.55	25.43 ± 2.59	-0.36	0.718
Number of Pregnancies	2.37 ± 1.1	2.37 ± 1.05	0.11	0.998
Frequency (percentage)				
Number of children				
Girl	51 (56.67)	41 (45.56)	2.22	0.136
Boy	39 (43.33)	49 (54.44)		
History of caesarean section				
Yes				
No	63 (70)	60 (66.67)	0.23	0.631
	27 (30)	30 (33.33)		
Education level:				
Elementary	17 (18.89)	17 (18.89)	0.75	0.861
Secondary	20 (22.22)	18 (20)		
High school	30 (33.33)	27 (30)		
University	23 (25.56)	28 (31.11)		
Job:				
Housewife	65 (72.22)	60 (66.67)	0.89	0.64
Student	3 (3.33)	5 (5.55)		
Employed	22 (24.45)	25 (27.78)		
Accommodation:				
City	73 (81.1)	77 (85.56)	0.64	0.424
Rural	17 (18.9)	13 (14.44)		

Based on the independent t-test, the pain intensity score of the intervention group at different times of 6, 12, 18 and 24 hours was significantly lower than the control group ($p<0.05$) (Table 2). The follow-up test showed that the pain intensity scores are significantly different at 6 to 12 hours ($p<0.001$), 6 to 18 hours ($p<0.001$), 6 to 24 hours ($p<0.001$), 12 to 24 hours ($p<0.001$) and 18 to 24 hours ($p<0.001$) after the operation. This means that with the passage of time, pain intensity has decreased significantly (Table 2).

Table 2. Determination and comparison of the average pain intensity score between the control and intervention groups at 18, 12, 6 and 24 hours

Pain Intensity Score	Control	Intervention	Statistics	P
After 6 hours	8.33 ± 1.58	7.61 ± 1.58	3.05	0.003
After 12 hours	6.46 ± 1.58	5.67 ± 1.39	3.69	< 0.001
After 18 hours	5.44 ± 1.38	4.42 ± 1.26	5.19	< 0.001
After 24 hours	4.38 ± 1.32	3.17 ± 1	6.89	< 0.001

Based on the results of independent t-test, 12 hours after the operation, the mean and standard deviation of the mobility score of the control group (75.85±25.43), is significantly lower than the intervention group (84.6 ± 30.36) (P=0.038). In addition, 24 hours after the operation, the mobility score of the control group (115.46±19.52) was significantly lower than the intervention group (125.5±27.32) (P=0.005) (Table 3). According to the walking test, the average mobility is different in the control group at 12 and 24 hours after the intervention, and it is statistically significant (p<0.001), in fact, with the passage of time, the mobility of the control group has increased.

Table 3. Determining and comparing the average mobility score between the control and intervention groups at 12 and 24 hours

Walking Test Score	Control	Intervention	Statistics	P
12 hours after delivery	75.85 ± 25.43	84.6 ± 30.36	-2.09	0.038
24 hours after delivery	115.46 ± 19.52	125.5 ± 27.32	-2.84	0.005

Based on the t-test, mean and standard deviation, the number of acetaminophen ampoules consumed at different times between the two intervention and control groups is not statistically significant (p<0.05). According to the results of the t-test, the mean and standard deviation of the number of diclofenac sodium suppositories consumed 6 hours after the operation between the two intervention and control groups is not statistically significant (p=0.096), but 12, 18 and 24 hours after the operation, the number of diclofenac sodium suppositories consumption in the intervention group was significantly lower than the control group (p<0.001) (Table 4).

Table 4. Determination and comparison of sedative drugs received between control and intervention groups at 6, 12, 18 and 24 hours

Variable		Control	Intervention	Statistics	P
Diclofenac sodium	6 hours	1.46 ± 0.721	1.3 ± 0.507	1.67	0.096
	12 hours	1.12 ± 0.615	0.72 ± 0.475	4.88	< 0.001
	18 hours	0.66 ± 0.544	0.31 ± 0.466	4.56	< 0.001
	24 hours	0.31 ± 0.466	0.11 ± 0.318	3.33	< 0.001
Acetaminophen	6 hours	0.03 ± 0.18	0.03 ± 0.18	0.01	0.98
	12 hours	0.11 ± 0.316	0.06 ± 0.23	1.34	0.179
	18 hours	0.01 ± 0.105	0	0.99	0.319
	24 hours	0	0	0	0

4. Discussion

The present findings have demonstrated that the average pain intensity score in the intervention group was lower than the control group (P<0.001) and the intervention group had reported less pain than the control group during the investigated times. Hassan et al. (2021) investigated the effect of abdominal binder on pain, distress, mobility and satisfaction of women after cesarean section. The results of this study showed that the pain score in the first 8, 24, 48 hours after delivery and after one week was lower in the intervention group than in the control group (P<0.001) (17). In addition, Rothman et al. (2014) showed in their study that the use of abdominal binder after cesarean delivery had a great effect in reducing the pain score in the abdominal binder intervention group compared to the control group. According to the researchers, this may be due to the effect of the abdominal binder, which provides direct support to the abdominal muscles and minimizes the direct pressure on the cesarean section and leads to a reduction in pain (18). In the study of Singdaeng et al. (2020), the results showed that the wound pain score with the visual pain scale was significantly lower in the abdominal binder group at 6, 24 and 48 hours after delivery compared to the control group, and this difference is It was statistically significant. (P>0.005, F=78.30) (19). The results of our study are in line with the mentioned studies and all these studies reported the effect of using abdominal binder in reducing pain after cesarean section. However, the findings of some studies have shown that the use of abdominal binder has not been associated with a significant reduction in postoperative pain (9, 14, 20). which is not consistent with the results of the present study. One of the reasons for the difference between the results of these studies and the present study can be the different time intervals for measuring the pain level and the urgency of the procedures investigated by other researchers.

Comparison of the average motor power score between the control and intervention groups at 12 and 24 hours after the intervention showed that the 12- and 24-hour walking test scores between the control and intervention groups were statistically significant (P<0.05). In fact, 12 hours after the operation, the mean and standard deviation of the motor power score of the control group was significantly lower than the intervention group (P=0.038). In addition, 24 hours after the operation, the motor power score in control group was significantly lower than the intervention group (P=0.005)

(Table 4). Cheifetz et al. (2010) investigated the effect of using abdominal binder on the functional results of patients after major abdominal surgery. In this study, the walking distance was compared with the six-minute walking test on days 1 and 5 after the operation, and the results showed that the distance traveled was significantly longer in the group that used the abdominal binder (10). Karaca et al. (2019) investigated the effect of using a abdominal binder after cesarean delivery on postoperative mobility in Turkey. In all time periods, the distance covered by the intervention group was more than the control group. In this study, the motor power in the first 8 hours after the operation in the intervention group was higher than the control group, and the motor power on the first and second day after the cesarean operation was not different between the two control and intervention groups (P=0.001) (21). While in our study, there was a difference between the control and intervention groups in the first 12 and 24 hours after delivery. However, the results of the Karaka study showed that the use of an abdominal binder after cesarean section increases mobility. which was consistent with the results of the present study. Saeed et al. (2019) investigated the use of abdominal binder after major abdominal surgery. There was no statistically significant difference between the control and intervention groups on the first day after surgery (p=0.0762) in the six-minute walk test. But this difference was significant on the fourth day (p<0.001) and the seventh day after surgery (p<0.001). However, researchers in this study reported that the use of abdominal binder after surgery improves mobility in patients (22). In the mentioned study, the walking test between the control and intervention groups on the first day after surgery was not reported to be significant, which was not consistent with the results of the present study, and the reason for this discrepancy can be attributed to the difference in the statistical population and the type of surgery. In our study, the patients are women who underwent cesarean section, but in the two mentioned studies, the statistical population consisted of women and men who underwent major abdominal surgery, including emergency laparotomy, abdominal hernia repair, etc. However, following a cesarean section, many patients are reluctant to move because they are afraid of damaging the wound site and stitches and increasing pain from movement. But the use of abdominal binder can be useful in facilitating mobility after surgery and leads to faster recovery of patients.

Final Conclusion: Based on the results of the present study, the use of abdominal binder can be suggested as a low-cost, low-complication, and non-pharmacological method after cesarean surgery, because it has a positive effect on reducing pain and reducing the use of sedatives. It improves the physical activity of patients by increasing their mobility.

Conflict of interest

The authors declared no conflict of interest.

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Authors' contributions

Concept: F.A., S.B., Design: F.A., S.B., Data Collection or Processing: T.K.B., Analysis or Interpretation: T.K.B., Literature Search: F.A., S.B., Writing: F.A., S.B.

Ethical statement

This study was approved by the ethics committee in biomedical research of Isfahan University of Medical Sciences with the code (IR.MUI.MED.1400.444).

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