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The benefit of elastic abdominal binders after cesarean section in rural area: A Randomized Controlled Pilot Trial

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Abstract

Introduction: Cesarean section (CS) is the most common abdominal surgery procedure in the world. This study aims to determine the effectivity of abdominal binder use after cesarean section related to pain and mobilization.

Methods: This was a randomized controlled, single-site, pilot trial study conducted in RSUD SoE, Timor Tengah Selatan, East Nusa Tenggara, Indonesia. Women with singleton term pregnancy undergoing cesarean section in our hospital were eligible to participate in the study. We excluded patients with history of cesarean section, second stage dystocia, abnormal placenta, hemoglobin level preoperative less than 10 g/dL, chorioamnionitis, cesarean hysterectomy due to severe hemorrhage, organ injury, and outside spinal anesthesia during cesarean section. Data were analyzed using IBM SPSS version 20.

Results: There were 60 participants randomized into control and intervention (binder) group. There was no difference in age, height, weight, body mass index (BMI), gestational age, infant birth weight, and length between groups ($p>0.027$). The use of an elastic abdominal binder can speed up the rate of mobilization, shown by 2-minute walking test ($p<0.05$). Based on BPI-SF, the postoperative pain in elastic abdominal binder group had lower mean value than control group ($p<0.05$). Impact of pain to daily activities based on BPI-SF and SDS showed no difference between both groups ($p>0.05$).

Conclusion: This study showed the benefit of abdominal binder after CS is to enhance the mobilization and reduce postoperative pain.

Key words: Cesarean section, elastic abdominal binder, postoperative pain, mobilization

Introduction

Cesarean section (CS) is the most common abdominal surgery procedure in the world. WHO reported that the incidence of CS was approximately 32% in USA, 24% in UK, 27% in China, and 50% in Brazil.[1] Pain is the most common complaint associated with cesarean section which 50-70% of patients stated pain after delivery.[2,3] In the early phase of after cesarean section, pain influences the activities of daily living.[4] If it is not treated effectively, patients become afraid of surgery procedure, threefold increased risk of postpartum depression; therefore, it will impact to the bonding and caring for a newborn. Besides, immobilization due to pain raises the risk of thromboembolism and it disrupt to breastfeed to newborn.[5]

Injectable analgesics are the main sources of postoperative pain relief.[3] The inadequacy of analgesics for pain relief, cost, availability, and drug saving is several problems found in rural hospital. In the literature, non-pharmacologic intervention such as abdominal binder or known as "*gurita*" can reduce pain and improve mobilization.[5] Abdominal binder is a soft elastic band, which attaches around the abdomen and adjusts to different abdominal circumferences by overlapping and attaching it. It may increase the lung function after cesarean section through limiting the abdominal muscle movement.[6] The other benefits of abdominal binder are speeding the uterine and other organs involution, compressing the abdomen so that it helps tissue repair by increasing blood flow.[7]

Based on the economic cost of abdominal binder and limited availability of injectable analgesic drug in rural hospital, this study aims to determine the effectivity of abdominal binder use after cesarean section related to pain and mobilization. It hopes that this study is able to apply in this rural hospital to improve the quality service of reproductive women's health.

Methods

This was a randomized controlled, single-site, pilot trial study conducted in RSUD SoE, Timor Tengah Selatan, East Nusa Tenggara, Indonesia as a rural hospital. Sixty patients consisted of thirty intervention patients using abdominal binder and thirty comparison patients as control enroll to this study. This study has been approved by Ethical Committee Faculty of Medicine Universitas Nusa Cendana under number 81/UN15.16/KEPK/2022.

Women with singleton term pregnancy undergoing cesarean section in our hospital were eligible to participate in the study. Additional inclusion criteria included aged 15-40 years old, were able to read and understand Indonesian language, and body mass index (BMI) lower than 40 kg/m2. Meanwhile, we excluded patients with history of cesarean section, second stage dystocia, abnormal placenta (placenta previa or placenta accrete), hemoglobin level preoperative less than 10 g/dL, chorioamnionitis (intrauterine infection), cesarean hysterectomy due to severe hemorrhage, organ injury (cystotomy, enterotomy, or ureteral injury), and outside spinal anesthesia during cesarean section. We dropped out the patients if they refused to continue intervention before 24 hours.

After obtaining informed consent, the patient was randomized one by one into 30 women to the intervention and 30 women to the comparison group. A sample of 30 for each group was considered adequate based on numerical sample calculation with standard deviation 1.5, clinically significant difference 2-point, power of 80%, and alpha of 0.05. Regarding improving pain control as primary outcome, this study used several parameters including Visual Analog Scale (VAS), Brief Pain Inventory Short Form (BPI-SF), Symptom Distress Scale (SDS), and objective test through 2-minute walking test.[8–10] For the question of VAS, the study used the instrument of 0-10 scale. BPI-SF was represented by 8 questions which question number 8 was divided into 7 points.

In the point of question number 8, there was two questions concerning breastfeeding and attachment to baby. If mother was separated with baby, these were not answered. This instrument used 0-10 scale which 0 described not ill at all and 10 for extremely ill. Meanwhile, the question of pain effect to activity, the study used 0 for no effect at all and 10 for very influential. For SDS, there were 9 questions and the study used 0-5 Likert scale. For item of nausea, insomnia, pain, fatigue, and cough, 1 signed as seldom and 5 as continuously. For appetite, scale 1 represented as good and 5 as cannot eat at all. Meanwhile, for item of digestion, concentration, respiration, scale 1 determined as normal and 5 as always not comfortable. Two-minute walking test described how far the respondents could walk after 24-hour cesarean section objectively. Head of research generated the allocation sequence and performed randomization which were concealed to research assistant who conducted the examination after 24-hour cesarean section. Random numbers were generated by computer in standard fashion.

All participants undergoing cesarean section were performed spinal anesthesia using bupivacaine 10-12.5 mg. Participants assigned to intervention group received an elastic abdominal binder immediately postoperative. They had to wear the binder minimally 24 hours after cesarean section. Meanwhile, participants in control group received usual postoperative care. Participants in both groups received pain medication consisted of ketorolac injection 30 mg/ 8 hour in the first 24-hour and whether they still complained of pain, another analgesic such as paracetamol injection 1 g/8 hour was given. After 24 hours, both groups were evaluated pain by research assistants using several parameters above. A medical record review included obstetrical history, reason for cesarean delivery, pain medication and dosages of 24-hour postoperative, also pain outcomes.

Data were analyzed using IBM SPSS version 20. Continuous variables included VAS, BPI-SF, SDS, and walking test 2 minutes were compared between intervention and control group using independent t-test if the data were normally distributed and non-parametric Mann-Whitney U test if the data were skewed. For categorical data in BPI-SF, we used Pearson's Chi-square or by Fisher's Exact tests when expected values in any cell less than five. All statistical analyses were two-sided and p-value of less than 0.05 was considered statistically significant.

Results

There were 60 participants randomized into control and intervention (binder) group. All participants completed the study after randomization. Figure 1 showed the step of participants recruitment in this study. In pain evaluation using 2-minute walking test, 27 participants in intervention and 25 participants in control group finished the test. Four patients refused to perform this objective evaluation due to pain and another one had burn injury on her feet. Meanwhile, in evaluation of BPI-SF on point of ability to breastfeeding and attachment to baby, only 20 participants in intervention group and 24 participants in control group completed the questionnaire. Participants who could not fill these questions because they were separated with the baby due to close observation in Neonatology room.

Demographic and clinical characteristics for participants were shown in table 1. The most common indication for cesarean section both in abdominal binder and control group was premature rupture of membrane (PROM) oligohydramnios (26.7% in abdominal binder group and 30.0% in control group). There was no difference in age, height, weight, body mass index (BMI), gestational age, infant birth weight, and length between groups ($p>0.05$).

Based on pain outcome using several parameters such as VAS, BPI-SF, SDS, and 2- minute walking test, evaluation of VAS score 24 hours postoperative showed there was no significant difference between

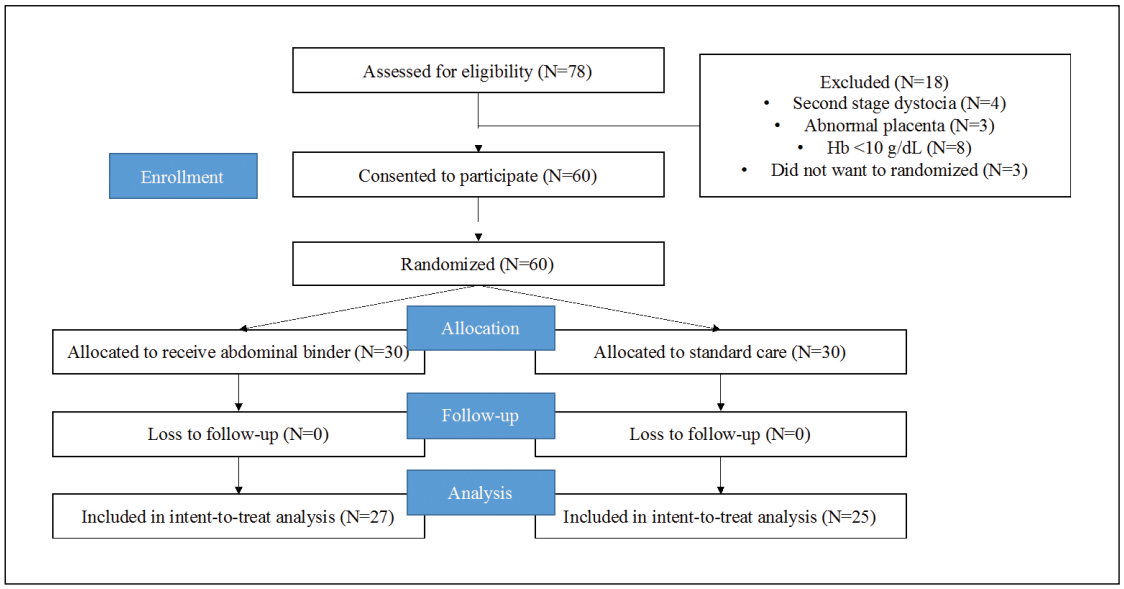

Figure 1. Step of randomization.

groups (p=0.208; 95% CI -1.5 – 0.3). Meanwhile, 2-minute walking test showed statistically significant between groups which intervention group could walk farther than control group (p=0.027; 95% CI 0.7-11.2). They were shown in table 2. Evaluation using BPI-SF, pain experience between groups was not different (p=0.353). Meanwhile, figure 2 depicted the difference between the worst and lightest pain in the last 24 hours, average pain and pain right now. In improvement of pain after analgesic for the last 24 hours, it did not differ significantly (mean 34.7% and 41.0% in abdominal binder group and control group; respectively; p=0.184). Table 3 showed the postoperative pain assessment question to the daily life. Table 4 stated the postoperative pain evaluation based on symptom distress scale (SDS) after 24-hour cesarean section.

Regarding to adverse events or side effects in each group, only one participant in abdominal binder group complained that the binder was too tight; nevertheless, she could finish until 24 hours. There were no other side effects reported in either group.

Discussion

Early mobilization after CS is essential for the return of physiological features to pre-pregnancy levels. A large number of patients refused to early mobilization due to fear of pain and damage to surgical area. This is the first randomized controlled clinical trial conducting in rural hospital with limited availability of analgesic injection. This study estimated that use of elastic abdominal binder as a cost-effective, easily accessible, controllable, safe, and available could be an alternative solution to overcome this problem.

In this study, the use of an elastic abdominal binder can speed up the rate of mobilization which shown by the difference of 2-minute walking test between intervention and control group (p<0.05). The worst, lightest, and average pain in elastic abdominal binder group had lower mean value than control group (p<0.05). Although, based on VAS score after 24-hour postoperative was not different significantly, the mean in elastic abdominal binder was lower than control group. Impact of pain to daily activities based on BPI-SF and SDS showed no difference between both groups (p>0.05).

Table 1. Demographic and clinical characteristics of participants in this study.

CHARACTERISTICS	ABDOMINAL BINDER N=30	CONTROL N=30	P
Age (mean (SD)) (y.o)	30.7 (6.8)	33.1 (7.7)	0.201[a]
Height (med (min-max)) (cm)	152.0 (145-170)	150.0 (138-164)	0.081[b]
Weight (med (min-max)) (kg)	51.5 (42-70)	50.0 (38-74)	0.571[b]
BMI (med (min-max)) (kg/m2)	21.9 (17.3-31.5)	21.6 (19.0-34.7)	0.933[b]
Gestational age (med (min-max) (weeks)	38.5 (37-42)	39.0 (37-41)	0.536[b]
Infant birth weight (mean (SD)) (grams)	2993.9 (438.6)	2801.7 (462.5)	0.180[a]
Infant birth length (med (min-max)) (cm)	49.0 (47-51)	48.5 (46-53)	0.304[b]
Reason for caesarean section			
• Active phase dystocia	7 (23.3%)	3 (10.0%)	
• Severe preeclampsia	3 (10.0%)	5 (16.7%)	
• Malpresentation	3 (10.0%)	7 (23.3%)	
• Uncontrolled asthma	1 (3.3%)	0	
• PROM oligohydramnios	8 (26.7%)	9 (30.0%)	
• CPD	5 (16.7%)	0	
• Fetal distress	1 (3.3%)	4 (13.3%)	
• Condyloma acuminata	1 (3.3%)	0	
• HIV not on ARV	1 (3.3%)	2 (6.7%)	
Additional pain medication within the first 24 hours			
• Paracetamol 1 gram (IV)	3 (10.0%)	1 (3.3%)	

*p-value was calculated based on normality test of Shapiro-Wilk test
[a]Independent t-test
[b]Mann-Whitney U test
SD: Standard deviation; BMI: Body mass index; PROM: Premature rupture of membrane; CPD: Cephalopelvic disproportion; HIV: Human Immunodeficiency Virus; ARV: Anti Retroviral

Table 2. Evaluation of pain using VAS and 2-minute walking test.

	ABDOMINAL BINDER N=30	CONTROL N=30	P	95% CI
VAS (mean (SD))	6.4 (1.7)	6.9 (1.5)	0.208[a]	-1.5 – 0.3
2-minute walking test (mean (SD))	38.0 (10.1) N = 27	32.0 (8.7) N = 25	0.027[a]	0.7 - 11.2

[a]Independent t-test

Abdominal binder was believed to alleviate the postoperative pain. The pressure caused by the binder can generalize pain over the abdomen rather than just the incision line itself.[11,12] The discomfort feeling during standing and walking is lesser after using this binder. Several studies has shown that use of an elastic abdominal binder reduces postoperative pain and distress.[7,13,14] Postoperative pain also influenced breastfeeding and infant care.[15] Our study showed the decrease of pain in abdominal binder;

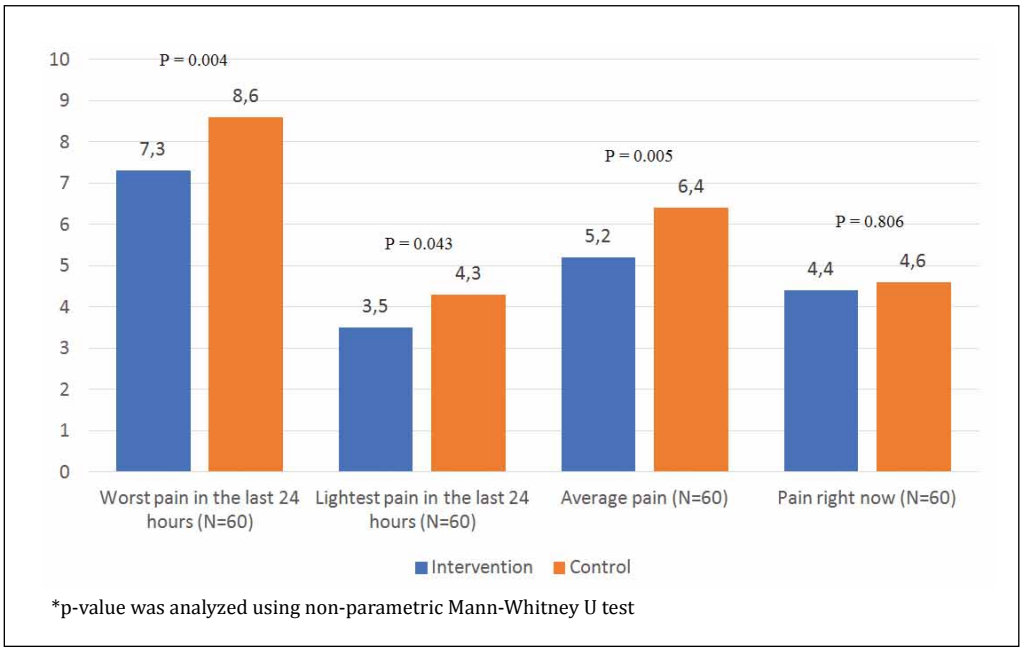

Figure 2. Pain scores based on BPI-SF.

however, it was not different for SDS and BPI-SF in terms of pain's impact to daily life. It could be due to low educational background of patients so that they could not fully understand of Likert scale for these parameters. Besides, this study only evaluated once 24-hour after postoperative. This result was in accordance to study by Giller CM, et al.[5] which suggested that using an abdominal binder did not have an impact on VAS scores or SDS.

Postoperative pain was lower in assistance of

Table 3. Postoperative Pain Assessment Questions Based on BPI-SF

IMPACT OF PAIN TO YOUR:	ABDOMINAL BINDER N=30	CONTROL N=30	P
General activity (mean (SD))	4.6 (2.3)	4.3 (2.4)	0.387[a]
Mood (mean (SD))	1.4 (2.0)	2.2 (2.8)	0.296[a]
Walking ability (mean (SD))	4.3 (2.3)	5.4 (2.4)	0.101[a]
Relationship with others (mean (SD))	0.6 (1.3)	0.8 (1.7)	0.662[a]
Sleeping (mean (SD))	2.9 (2.4)	4.3 (2.9)	0.063[a]
Ability to breastfeeding (mean (SD))	1.4 (2.4) N=20*	2.7 (3.1) N=24*	0.128[a]
Attachment to baby (mean (SD))	1.2 (2.2) N=20*	1.8 (2.5) N=24*	0.238[a]

[a]Non parametric Mann-Whitney U test
*The sample was less than 30 because baby was separated from the mothers or mothers did not breastfeed

Table 4. Postoperative Pain Assessment Questions Based on SDS.

SYMPTOM DISTRESS SCALE	ABDOMINAL BINDER N=30	CONTROL N=30	P
Nausea (N(%))	Seldom (30; 100%)	Seldom (29; 97%)	0.317[a]
Appetite (N(%))	Good (28; 93%)	Good (29; 97%)	0.570[a]
Insomnia (N(%))	Seldom (22; 73%)	Seldom (21; 70%)	0.721[a]
Pain (N(%))	Once (15; 50%)	Once (16; 53%)	0.371[a]
Fatigue (N(%))	Seldom (25; 83%)	Seldom (29; 97%)	0.088[a]
Digestion (N(%))	Normal (17; 57%)	Normal (21; 70%)	0.389[a]
Concentration (N(%))	Normal (30; 100%)	Normal (27; 90%)	0.078[a]
Respiration (N(%))	Normal (29; 97%)	Normal (28; 93%)	0.557[a]
Cough (N(%))	Seldom (23; 77%)	Seldom (24; 80%)	0.821[a]

[a]Non parametric Mann-Whitney U test

abdominal binder; therefore, it makes patients more comfortable to mobilization.[16] Several studies showed the mobilization postoperatively was longer in abdominal binder group than casual fashion through objective walking distance test.[11,12,17,18] Early postoperative mobilization has several benefits including enhancing recovery of intestinal peristalsis and reducing the risk of immobilization complication such as venous thromboembolism.[17]

Abdominal binder has other potential advantages such as enhancing healing of the scar and prevention of hematoma also seroma in the surgical area. Our study did not detect significant side effects or adverse events around surgical area. Discomfort is known as a complaint by the user of elastic abdominal binder. The mechanism is due to the increment of abdominal pressure which may reduce the observed lung capacity.[19]

The limitation of this randomized controlled clinical trial was a smaller sample size and potential reporting bias due to inability to blind the patients. Apart from that, we did not evaluation for more than 24-hour postoperative. Thus, we cannot determine the long-term benefit of elastic abdominal binder use in cesarean section. In addition, the strength of this study is the randomized control trial with limited loss of follow-up. This study was conducted in rural hospital which limited resources; therefore, it is applicable in other areas with similar setting.

Conclusion

This study showed the benefit of abdominal binder after CS is to enhance the mobilization and reduce postoperative pain. It is cost-effective as non-pharmacologic intervention to reduce postoperative pain after CS.

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