2020

Do Abdominal Binders Placed after Cesarean Delivery Reduce Postoperative Pain?

Skyler Tuholski
Philadelphia College of Osteopathic Medicine

Do abdominal binders placed after cesarean delivery reduce postoperative pain?

Skyler Tuholski, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies

Philadelphia College of Osteopathic Medicine

Suwanee, Georgia

December 13, 2019

ABSTRACT

OBJECTIVE: The objective of this selective evidence based medicine review is to determine whether or not "Do abdominal binders placed after cesarean delivery reduce postoperative pain?"

STUDY DESIGN: Systematic review of three peer-reviewed studies written in English, published between the years 2016 and 2018.

DATA SOURCES: All three studies are randomized controlled trials found using PubMed database, and they were the only existing RCTs evaluating this objective published at the onset of this review.

OUTCOME MEASURED: The primary outcome measured in each study is self-reported pain on postoperative day 1 following cesarean delivery. Pain is measured on a scale from 0 to10 using the Visual Analog Scale or as part of the Brief Pain Inventory- Short Form.

RESULTS: Two of the three randomized controlled trials found significantly lower reported pain levels in the binder group. The study by Gustafson, Dong, Duong, and Kuhlmann (*Kans J Med.* 2018;11(2):48-53. PMID: 29796155) found significantly lower average level of pain at 24 hours post-op ($p= 0.024$). The study by Ghana, Hakimi, Mirghafourvand, Abbasalizadeh, and Behnampour (*Int J Gynecol Obstet*. 2017;137(3):271-276. doi:10.1002/ijgo.12134) reports significantly lower pain scores ($p<0.001$) at all time points postoperatively, measured up to 5 days. The third study did not find a significant difference in pain level on post-op day 1 ($p=0.33$) but cited the most weaknesses in experimental design (Gillier CM, Sparks JR, Kriner R, Anasti JN. *Int J Gynecol Obstet.* 2016;133(2):188-191. doi:10.1016/j.ijgo.2015.08.026).

CONCLUSIONS: Because two robust RCTs reported significantly lower postoperative pain levels in the binder group, and substantial limitations in the third study lessened the validity of those findings, this review finds stronger evidence to support using abdominal binders in multimodal reduction of post-cesarean pain.

KEY WORDS: abdominal binder, cesarean, postoperative pain

INTRODUCTION

Multimodal approaches to effective pain management after cesarean delivery that minimize opioid use and postoperative adverse events are being extensively explored, including the use of abdominal binders.[1] Abdominal binders are wide elastic belts that encircle the abdomen, providing flexible support to abdominal muscles and viscera at incision sites. Abdominal binders are commonly used and have been shown to improve mobility and ambulation distance; decrease the chance of wound dehiscence; and reduce discomfort associated with coughing, laughing, or positional changes following other major abdominal surgeries, such as ventral hernia repairs.[2] Cesarean deliveries are the most common major surgery performed in the United States, totaling over 1.2 million and accounting for 32% of all births in 2017.[3] Yet, binders are not routinely used after dividing all layers of the abdominal wall and incising the uterus in cesarean deliveries. Therapeutic standard of care for cesarean postoperative pain typically comprises of NSAIDs, acetaminophen, and/or opioids after relief from procedural anesthesia subsides.[4] Abdominal binders may be a cost-effective, non-pharmacologic adjunct to pain management for women who have had cesarean delivery. Non-pharmacologic treatments for this population are desirable because breast-feeding ability, need for early post-op ambulation, and maternal alertness must be considered. Women undergoing this invasive operation have unique postoperative needs due to their hypercoagulable state and the immediate care and bonding required by the infant.[5,6]

Physician assistants could easily employ the use of abdominal binders in the management of post-cesarean pain. Singular use of opioids for pain control following obstetric surgeries is positively correlated with increased cost, risk of opioid dependence, complications, and length of stay compared to multimodal approaches.[7] Abdominal binders can be purchased online or as

conveniently as the local grocery store for fifteen to twenty-five dollars on average if not provided during hospitalization. Physician assistants in any field may care for women with upcoming or postoperative cesarean deliveries, and they have the clinical ability to write opioid prescriptions and recommend use of an abdominal binder. Therefore, physician assistants can play a critical role in implementing effective multimodal post-cesarean pain management.

While the rates of cesareans continue to climb in high-income countries, the rates of breast feeding initiation are significantly lower when compared with vaginal deliveries.[8] Several factors contribute to lower breast feeding rates after cesareans, including high levels of postoperative pain and limited mobility.[8] Pain can inhibit the milk let-down reflex, and limited mobility can affect the mother's ability to properly position the infant on the breast.[9] While the current gold standard of post-cesarean analgesia is opioids, the adverse effects of sedation, nausea, and vomiting can also limit breastfeeding.[10] Additionally, some new mothers would rather tolerate moderate pain than expose themselves or their breastfeeding infant to opioids, which do enter breast milk and pose health risks to the baby.[9,10] Multimodal approaches are needed to adequately control pain while allowing for safe completion of maternal activities of daily living and early ambulation to reduce thromboembolism risk.[9] Both pain and opioid-induced sedation can inhibit ambulation, which is critical because postpartum women have at least a 5 times higher risk of thromboembolism.[9] If abdominal binders can improve postoperative pain, then they could also reduce need for opioid use, facilitate early maternal ambulation to reduce thromboembolism risk, and improve breastfeeding rates to optimize infant nutrition.

OBJECTIVE

The objective of this selective evidence based medicine review is to determine whether or not "Do abdominal binders placed after cesarean delivery reduce postoperative pain?"

METHODS

This paper evaluates three randomized controlled trials (RCTs) that assess the effect of abdominal binders on maternal post-cesarean pain levels when used in conjunction with standard therapy compared to standard therapy alone. All patients were allowed to request pain medication as needed within the limits of physician orders, but the control group was not given an opportunity to wear the abdominal binder. The population studied is women greater than 18 years old that underwent cesarean sections; see Table 1 for specific inclusion and exclusion criteria of each study. There are slight variations between studies in regards to the onset and duration of abdominal binder use (Table 1) as well as specifically what constitutes standard therapy. Gillier et al.[5] describes the standard of care as ibuprofen, acetaminophen, ketorolac, codeine plus acetaminophen, oxycodone plus acetaminophen, hydrocodone plus acetaminophen, and/or morphine. Gustafson et al.[6] uses ibuprofen, ketorolac, oxycodone, oxycodone plus acetaminophen, hydrocodone plus acetaminophen, nalbuphine, hydromorphone, and/or morphine. The Ghana et al.[11] study does not specify which analgesics comprise the standard therapy. In each RCT, mothers self-reported numeric pain level (0-10) on postoperative day 1 with zero representing no pain and 10 representing the most severe pain. The experimenters measured pain levels at variable times, but all three studies report an average measurement on postoperative day 1, so results at that specific time point will be compared in this review. The statistics used to evaluate this outcome are mean pain scores with standard deviation, median pain scores with interquartile range, and p-values to determine if there are significant differences ($p < 0.05$) between groups' average reported pain levels.

This research question was investigated by the author using PubMed with the keywords "abdominal binder; cesarean OR caesarean; pain" to locate studies with relevant patient-oriented

outcomes. Additional inclusion criteria were controlled clinical trials or RCTs published within the last 10 years. The three selected articles for this review are all published in peer-reviewed journals and written in English. No reviews of the research question exist in the Cochrane Reviews Library at this time. Exclusion criteria were: disease-oriented outcomes, mothers younger than 18 years old, and studies published before 2008.

TABLE 1- Demographics & Characteristics of Included Studies

RCT	# Pts	Age: (Experimental/ Control)	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
Gillier et al.[5] (2016)	155	**Range: 18-50** E: 30.1 +/- 5 C: 28 +/- 6.9	Women who underwent cesarean delivery by a low-transverse skin incision at St. Luke's University Hospital in Pennsylvania, USA between April 1-November 28, 2014.	General anesthesia, vertical incision, post-op drains	18	Abdominal binder applied immediately after delivery and used for 2 days with unmeasured breaks allowed
Gustafson et al.[6] (2018)	60	**Range: 18-39** E: 28.5+/- 4.7 C: 27.7+/- 4.4	Women from 2 clinics in Kansas, USA that delivered via scheduled cesarean at term, singleton gestation, aged 18-39 years old, literate in English, and prenatal BMI of 20-40 kg/m2	Bleeding disorder or use of anticoagulants, methadone usage, abnormal placenta, preoperative hemoglobin less than 10mg/dL, chorioamnionitis, treated for chronic pain, onset of labor occurred prior to the time when the cesarean was scheduled, or complications developed during the cesarean	2	Elastic abdominal binder applied immediately after delivery and worn for 24 hours
Ghana et al.[11] (2017)	178	**Range: 18-35** Cumulative: 26.3 +/- 5	Women undergoing non-emergent cesarean deliveries in Iran between January 22- October 23, 2015. Parity of 1 or 2, literate, uncomplicated term pregnancy, Pfannenstiel skin incision, BMI 18.5-25.9, hemoglobin >110 mg/L during first trimester.	Smokers or using opioids, experienced rupture of membranes for longer than 6 hours, self-reported underlying disease, surgical duration longer than 1 hour, had undergone any concurrent surgeries, had pre-eclampsia or eclampsia, severe hemorrhage, bleeding disorders or were using anticoagulants, emergency cesarean delivery, general anesthesia	3	Abdominal binder applied 2 hours after delivery and used for 2 days. Binder was opened between 10pm and 8am

OUTCOMES MEASURED

Mothers self-reported their average numeric pain level on postoperative day 1 on a scale of 0-10 using the Visual Analog Scale (VAS) or as part of the Brief Pain Inventory- Short Form.

RESULTS

In the study by Gillier et al.,[5] 180 women aged 18-50 were enrolled at a university hospital in Pennsylvania, USA, and the lead researchers assigned 92 participants to the experimental abdominal binder group and 88 to the control group.[5] This study allowed for inclusion of emergency cesareans because women planning to undergo vaginal delivery consented to the study early in the pregnancy.[5] Exclusion criteria were: general anesthesia, vertical incision, and the use of postoperative drains.[5] Computer-generated 1:1 randomization was used to allocate participants into either group, and their designation was drawn from an opaque envelope upon entering the operating suite.[5] No significant demographic differences or numbers of unscheduled cesareans existed between groups.[5] Five individuals were not included in the final data for the experimental group; of these, one person requested removal of the binder within 6 hours.[5] In the control group, 20 participants could not be included in final data because 17 participants requested to receive an abdominal binder within 6 hours of surgery.[5] The remaining unaccounted participants in each group had incomplete data collection.[5] Patients in the abdominal binder group were fitted with the binder immediately after surgery before leaving the operating room and were encouraged not to remove it, but were allowed unmeasured breaks.[5] The primary outcome measured is postoperative pain recorded on day 1 using the VAS.[5] Patients were asked to place a mark from 0-10 on a 10-cm line corresponding to the severity of their pain within the last 6 hours.[5] The mean VAS score +/- standard deviation in the experimental group was 3.1 +/- 2.1 compared to 3.4 +/- 2.3 in the control group with an insignificant p-value of 0.33

(Table 2).[5] Gillier and colleagues report the sample size offered an 80% power to detect a 1-cm difference in the VAS score between groups, which was deemed clinically approriate.[5]

Table 2: Average VAS Pain Scores on Post-Op Day 1 in Gillier et al Study

	Abdominal Binder (n=87)	Control (n= 68)
Mean +/- SD	3.1 +/- 2.1	3.4 +/- 2.3
P-value	0.33	

In the RCT conducted by Gustafson et al.,[6] research assistants assigned 60 women aged 18-39 to their respective groups using a computer generated 1:1 randomization, concealed to clinical investigators until the intervention occurred. There are much more specific inclusion and exclusion criteria than in the Gillier et al.[5] study, which are discussed in Table 1, but most notably the inclusion of advance scheduled cesarean deliveries of singleton gestation carried to at least 39 weeks.[6] An intention-to-treat analysis was performed on the 56 patients that completed the allocated intervention, 29 in the binder group and 27 in the control group.[6] Four other participants were excluded from results analysis.[6] Of these, two participants in the control group crossed over to the binder group, one by request and one by recommendation of medical staff.[6]

The primary outcome of postoperative pain was assessed using the Brief Pain Inventory-Short Form at 24 hours postoperatively after continuous binder use. The specific question of interest to this review is the average level of pain reported from 0-10, though effects of pain on maternal activities of daily living were also evaluated by the researchers. When comparing the mean +/- standard deviation, the binder group reported significantly lower pain scores, 3.45 +/- 1.74, than the control group, 4.48 +/- 1.6 (p=0.024, Table 3).[6]

Table 3: Average Pain Scores at 24 hrs Post-Op in Gustafson et al Study

	Abdominal Binder (n= 29)	Control (n=27)
Mean +/- SD	3.45 +/- 1.74	4.48 +/- 1.6
P-value	0.024	

In the RCT conducted by Ghana et al.,[11] 178 women aged 18-35 that had uncomplicated non-emergent cesareans in an Iranian hospital were randomized to groups of 89 by a researcher masked to the experiment. This study had the most specific inclusion and exclusion criteria due to their research on the effects of abdominal binders on postpartum hemorrhage (Table 1). Two participants in total were lost from the binder group because one requested removal of binder and the other experienced hemorrhage.[11] The data was analyzed on an intention-to-treat basis.[11] Binders were applied 2 hours after delivery and worn for 2 days, but were opened between 10pm and 8am.[11] Pain measurements using the VAS were recorded 15 minutes before routine administration of pain medication, and were taken at baseline and every 6 hours for 48 hours, then again once on day five.[11] There was no difference in the baseline pain score between groups, yet the pain scores for patients in the binder group were significantly lower than those of the control group at 24 hours and all other time points ($p<0.001$, Table 4).[11]

Table 4: Median VAS Pain Scores at 24-hours Post-Op in Ghana et al Study

	Abdominal Binder (n=89)	Control Group (n=89)
Median (Interquartile Range)	3 (3-4)	6 (6-5)[a]
P-value	<0.001	

[a]Data reported as in original study, though it appears Q1 and Q3 may be reversed within parentheses

Table 5: Adverse Events Reported in Binder Groups

Study	Binder Group Size	Adverse Event
Gustafson et al.[6]	29	Itchiness (n=2)
Ghana et al.[11]	89	Hemorrhage (n=1)

DISCUSSION

The strengths of the reviewed studies are their randomized controlled designs and implementation of a simple, inexpensive, non-pharmacologic intervention with few contraindications and minimal potential adverse effects.[5] Additionally, valid and reliable measures of pain were used with straightforward statistical analysis. There were no significant

differences in sociodemographic variables between experimental and control groups in any study. All subjects who entered these trials were accounted for and attributed at their conclusions, with less than 5% lost to follow-up. Only three adverse events were reported (Table 5), and no similar occurrences of hemorrhage were found in literature.[11]

These studies also shared several limitations. Because of the nature of the intervention, it is impossible to mask the participants, researchers, and clinicians to the group allocation, allowing for biases to potentially influence reporting. It is notable that 17 out of 88 participants, or 19%, in the control group in the Gillier et al.[5] study requested an abdominal binder within 6 hours of their surgery. This implies that women may have a presumed bias towards the ability of the binder to reduce pain, or at least that they are interested in this potential therapy. Care providers may have also expressed their biases regarding binder use. Additionally, pain is a complex multifaceted experience; affected by psychosocial, behavioral, emotional, and environmental influences[11] that cannot be controlled and could affect scores, particularly in small sample sizes.

There are a number of discussion points that contribute to the lack of significant findings in the Gillier et al.[5] study, perhaps because this was the first known RCT to investigate this particular research question. There were 28% more people in the experimental group due to high rates of initial dropout in control group because of inability to mask participants' allocation.[5] The experimenters asked participants to rate their average pain level from the last 6 hours, but there was no standardized time to administer the VAS on post-op day 1.[5] This potentially caused widely varied pain scores based on the time of day and events of the previous 6 hours, including when the last pain medication was dispensed. Additionally, because unmeasured break time from

binder use was allowed, the likely variable duration of usage diminishes its power to affect outcomes.

The primary limitation in the Gustafson et al.[6] study is the small sample size, but otherwise has several unique strengths discussed below. It is worth noting that pain interference with feeding the baby was lower in the binder group with results nearing significance (p=0.078) as measured by the modified Brief Pain Inventory- Short Form.[6] The Ghana et al.[11] study described the nightly 10 hour opening of the binder as a limitation, however it may be a strength, as abdominal binders are intended to reduce discomfort associated with positional changes. Perhaps opening the binder during a measured interval overnight allowed for improved comfort while sleeping and should be replicated in future studies. Other strengths in the Ghana et al.[11] study were the large equal group sizes, efforts made to conceal randomization, standardized times for recording pain measurements before giving medication, and comparison of baseline pain levels.

Both the Gustafson et al.[6] and Ghana et al.[11] studies used strict inclusion criteria which may minimize risk of adverse events, such as non-emergent singleton gestation pregnancies delivered at full term. The Ghana et al.[11] study further excluded smokers, those with an overweight BMI >25.9, and self-reported underlying disease. These are all factors known to be associated with increased risk of surgical complications. By standardizing the study population to generally low-risk pregnancies in healthy women, the researchers may have been able to control for adverse events that could cause increased pain levels, including the emotional component of pain in cases of poor infant outcomes. Gustafson and colleagues found no significant between-group difference in the average dose of pain medication used within the first 24 hours, lending further validity to the significant effect of the abdominal binder on pain reduction.[6]

CONCLUSION

Based on the objective findings of these three randomized controlled trials, there is some conflicting evidence as to whether or not abdominal binders placed after cesarean delivery reduce postoperative pain. However, given that the 2 stronger RCTs found significant evidence in favorable support[6,11] and the remaining study is limited by many sources of variability and bias acknowledged by its authors,[5] there is more substantial evidence to suggest yes, abdominal binders do reduce post-cesarean pain. The findings of these studies are not yet generalizable to the entire population of pregnant women undergoing cesarean deliveries because there are wide differences in the inclusion and exclusion criteria, and there is overall varying and limited evidence based on subjective data. More investigation that includes objective measures of pain control and addresses additional clinical implications of binder use is needed to generalize the answer to this question and provide evidentiary support for financing widespread implementation of binders. New research has already been added to the growing body of literature on this topic since beginning this review.

In a 2019 quality improvement project, a work group at a Pennsylvania hospital implemented a comfort bundle that included abdominal binders with the intention of reducing opioid consumption after cesarean deliveries.[4] The comfort bundle was incredibly successful, achieving a 61% reduction in morphine milliequivalents.[4] Subsequently, a 2019 RCT reports "ambulation exacerbated pain in patients not wearing binders to a greater degree than in patients wearing binders, while statistically controlling for medication use."[1] The researchers ultimately supported use of abdominal binders as a safe nonpharmacologic option to provide comfort after cesarean birth.[1] Most recently, a research hospital in Turkey published an RCT that demonstrated significantly reduced VAS pain levels on post-op day 1 in the binder group as well as

significantly increased walking distance during a 6-minute walk test in the postoperative 8th hour.[12] None of these studies resulted in adverse events,[1,4,12] and participants reported minimal to no discomfort[1] while wearing the binder. The findings of this newly published global literature add support to this review's conclusion favoring use of abdominal binders for multimodal post-cesarean pain reduction.

Referencing the combined strengths of these RCTs, future studies should aim to analyze large equal group sizes, mask group allocation as much as possible, use standardized times for applying the binder as well as recording pain measurements before giving analgesic medication, and compare baseline pain levels and dispensed morphine-equivalent doses. Experimenters should follow a script during recruitment to remain impartial, and they should allow set hours of overnight binder opening. Participants should be selected using strict inclusion criteria which may minimize risk of adverse events, such as non-emergent singleton gestation pregnancies delivered at full term. Exclusion criteria should include obesity, chronic pain, comorbidities, concurrent surgeries, and substance abuse. If significant results are consistently found among this controlled population, inclusion criteria can then be expanded and exclusion criteria minimized to test generalizability. Finally, future studies should use a modified Brief Pain Inventory- Short Form as in Gustafson et al.[6] to additionally assess how much pain interferes with sleep, mood, walking ability, feeding, and infant bonding between binder and control groups. Measuring these outcomes can provide data to determine if the clinical effect of using abdominal binders for post-cesarean pain reduction has additional implications, such as improved breast feeding rates, infant bonding, and ambulation during a hypercoagulable state.

REFERENCES

1. Tussey C, Kelly LA, Oja KJ, Bay RC, Makarova N. Reducing discomfort after cesarean birth using abdominal binders. *MCN Am J Matern Child Nurs*. 2019; 44(6): 310-316. doi:10.1097/NMC.0000000000000571.

2. Cheifetz O, Lucy SD, Overend TJ, Crowe J. The effect of abdominal support on functional outcomes in patients following major abdominal surgery: A randomized controlled trial. *Physiother Can.* 2010; 62(3): 242-253. doi:10.3138/physio.62.3.242.

3. Martin JA, Hamilton BE, Osterman MJK, Driscoll AK, Drake P. Births: Final data for 2017. Centers for Disease Control and Prevention, National Vital Statistics Reports. 2018; 67(8):1-50. https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_08-508.pdf. Accessed November 15, 2019.

4. Burgess A, Harris A, Wheeling J, Dermo, R. A quality improvement initiative to reduce opioid consumption after cesarean birth. *MCN Am J Matern Child Nurs.* 2019;44(5): 250-259. doi:10.1097/NMC.0000000000000549.

5. Gillier CM, Sparks JR, Kriner R, Anasti JN. A randomized controlled trial of abdominal binders for the management of postoperative pain and distress after cesarean delivery. *Int J Gynecol Obstet.* 2016;133(2):188-191. doi:10.1016/j.ijgo.2015.08.026.

6. Gustafson JL, Dong F, Duong J, Kuhlmann ZC. Elastic abdominal binders reduce cesarean pain postoperatively*:* A randomized controlled pilot trial. *Kans J Med.* 2018;11(2):48-53. PMID: 29796155.

7. Hansen RN, Pham AT, Lovelace B, Balaban S, Wan GJ. Comparative analysis of inpatient costs for obstetrics and gynecology surgery patients treated with IV acetaminophen and IV opioids versus IV opioid-only analgesia for postoperative pain. *Ann Pharmacother*. 2017; 51(10):834-839. doi:10.1177/1060028017715651.

8. Beake S, Bick D, Narracott C, Chang Y. Interventions for women who have a caesarean birth to increase uptake and duration of breastfeeding: A systematic review. *Matern Child Nutr*. 2017;13(4):e12390. doi: 10.1111/mcn.12390.

9. Fahey JO. Best practices in management of postpartum pain. *J Perinat Neonatal Nurs.* 31(2):126-136. doi:10.1097/JPN.0000000000000241.

10. Schyns-van den Berg AM, Huisjes A, Stolker RJ. Postcaesarean section analgesia: Are opioids still required? *Curr Opin Anaesthesiol.* 2015;28(3):267–274. doi: 10.1097/ACO.0000000000000195.

11. Ghana S, Hakimi S, Mirghafourvand M, Abbasalizadeh F, Behnampour N. Randomized controlled trial of abdominal binders for postoperative pain, distress, and blood loss after cesarean delivery. *Int J Gynecol Obstet*. 2017;137(3):271-276. doi:10.1002/ijgo.12134.

12. Karaca I, Ozturk M, Alay I, et al. Influence of abdominal binder usage after cesarean delivery on postoperative mobilization, pain and distress: A randomized controlled trial. *Eurasian J Med*. 2019;51(3):214–218. doi:10.5152/eurasianjmed.2019.18457.