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Original Article

Fentanyl Transdermal Patches versus Transversus Abdominis Plane Block in Post Cesarean Section Pain control

Taher M. Mostafa [1*], Essam S. Abdelwahab[2]

[1] Department of Obstetrics and Gynecology, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

[2] Department of Anesthesiology and Intensive Care, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

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*Corresponding author

Email: taherelbarbari@gmail.com

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ABSTRACT

Background: Perioperative pain management planning is necessary. The transversus abdominis plane [TAP] block was first employed to produce a field block utilizing the Petit triangle as a landmark-guided method. Transdermal administration has been utilized for the delivery of medications such nitroglycerin, clonidine, and scopolamine.

The Aim of The work: An ultrasound-guided Transversus Abdominis Plane [TAP] block was compared to fentanyl patches for managing postpartum pain 24 hours after caesarean surgery.

Patients and Methods: A randomized controlled trial was conducted on 100 pregnant women who were scheduled for elective caesarean birth under spinal anesthesia. Following surgery, participants were randomly assigned to one of two equal groups. The first group got transdermal fentanyl patches at a rate of 50 µg/h [TFPs]. Following surgery, the second group had a transversus abdominis plane [TAP] block with 20 mL of 0.25 percent bupivacaine.

Results: In terms of the modified Observer's Assessment of Alertness/Sedation [OAA/S] Scale, statistical analysis of the current data revealed no statistically significant variation between the examined groups [p=0.101]. However, at 2, 4, 6, 12 and 24 hours, VAS score and pain threshold were significantly lower with TFPs than with TAP block [p=0.033, 0.024, 0.007, 0.002 and 0.002, respectively]. Hypotension was significantly more frequent with TFPs compared with TAP block [16 vs. 2%] p= 0.031.

Conclusion: Using transdermal fentanyl patches for postoperative analgesia after caesarean section was more effective than transversus abdominis plane block.

Keywords: Fentanyl Patches; Transversus Abdominis Plane Block; Cesarean Section; Pain.

INTRODUCTION

For effective post-operative pain control, pre-operative education and perioperative pain management planning that includes a preventative analgesic approach [e.g., incorporates multimodal therapies] are essential [1]. Since then, the transversus abdominis plane [TAP] block has been utilized to complete a field block using the Petit's triangle landmark-guided approach. The internal oblique and transverse abdominis muscles create a plane into which local anesthesia is given [2]. Nitroglycerin, clonidine, and scopolamine are just a few of the medications that have been administered transdermally in the past. In the hours and days following transdermal delivery, the concentrations of these medications in plasma are constant and stable [3]. No sufficient data are available comparing transdermal application to the TAP for post-cesarean pain control.

THE AIM OF THE STUDY

With this trial, the researchers hope to evaluate the effectiveness of an ultrasonic-guided Transversus Abdominis Plane [TAP] block to the efficacy of topical fentanyl patches in reducing post-cesarean section pain over a 24-hour period.

PATIENTS AND METHODS

Between November 2020 and November 2021, this randomized controlled trial was done on healthy pregnant women, who were scheduled for elective caesarean section in the labor ward of the obstetrics and gynecology department at Sayed Galal Hospital.

Inclusion criteria: Pregnant females between the ages of 18 and 35 years who are planning an elective caesarean birth under spinal anesthesia and who have a physical state classified as ASA Class I or II, as well as a body mass index [BMI] of less than 30 kg/m^2, are eligible for this procedure under certain conditions.

Exclusion criteria: Females between the ages of 18 and 35 who have central neuropathy, psychiatric illnesses, DM to rule out peripheral neuropathy, Drug addiction or chronic analgesic use in the past; allergy to study medicines; hepatic or renal impairment; BMI more than 30 kg/m2; coagulopathy or anticoagulant treatment; infection near the site of needle insertion; and other factors, chronic pain syndrome, or patient refusal to participate in the study.

Methodology

Pregnant women were randomly allocated to one of two equal groups in the study, which had 100 participants. Randomization was accomplished through the use of a computer-generated randomization sheet. One hundred opaque envelopes were serially numbered, and the matching letter denoting the assigned group was placed in each envelope according to the randomization table. After then, all envelopes were sealed and placed in a single box. When the first patient was delivered, the initial envelope was opened and the patient was assigned based on the contents of the letter. The Ethical Committee of the Department of Obstetrics and Gynecology, Faculty of Medicine, Al-Azhar University, approved this study. Prior to executing any study-related operations on a patient, the investigator obtained written, signed informed permission from the subject. The investigator preserved the signed informed consent form in its original form. All data were acquired in a secure manner. All ladies were advised about the potential negative effects of the research procedure. The confidentiality and safety of participants were safeguarded according to the Helsinki declaration. As soon as the protocol for the study has been authorized, women were included in the research based on inclusion and exclusion criteria. The patient's medical and surgical histories were evaluated in order to determine the best course of action. A complete blood count, prothrombin time and activity, hepatic and kidney function tests were all performed as part of the clinical examination. It was possible to continually monitor the heart rate and rhythm using electrocardiography. Systolic, diastolic and mean arterial pressure, as well as peripheral oxygen saturation levels, were measured using pulse oximetry. A lactated Ringer's solution was administered by an 18-gauge cannula.

Participants were divided into two groups at random, each with 50 patients: the first received 50 µg/h transdermal fentanyl patches [TFPs-50] after surgery [Durogesic®, Janssen Pharmaceutics, Belgium]. An untrained nurse administered the patches without knowing anything about the study's procedures. Following surgery, the second group [50 patients] had a transversus abdominis plane [TAP] block with 20 mL of 0.25% bupivacaine in the transversus abdominis plane [TAP]. Vital indicators [heart rate, blood pressure, breathing rate, and oxygen saturation] were monitored in post-anesthesia care unit. A modified Observer's Assessment of Alertness/Sedation [OAA/S] Scale was utilized to measure the degree of sedation, with 1 indicating awake/alert and 5 indicating sleep/unarousable, at rest and while moving. A visual analogue scale [VAS] was utilized to estimate pain, which was then repeated 1, 2, 4, 6, 12, and 24 hours later. When the VAS was more than 3 or at the patient's request, 1 g IV paracetamol was given every 8 hours to all patients, and 0.1 mg/kg IV morphine was given when the VAS was more than 3 or at the patient's request. The key outcomes were the time required to obtain analgesia for the initial time and the total quantity of analgesics ingested in the first 24 hours. Secondary outcomes were nausea, vomiting, hypotension, bradycardia, or cardiac arrhythmia, as well as the standard postoperative hospital stay.

Statistical analysis: Data entered into the computer was analyzed with the aid of IBM SPSS software version 20.0, which is a statistical analysis application developed by IBM. IBM Corporation is based in Armonk, New York. The phrases number and percent were utilized to express qualitative data in order to avoid ambiguity. For the purpose of determining whether or not the distribution was normally distributed, the Kolmogorov-Smirnov test

was performed. Range [minimum to maximum], mean, standard deviation, were all utilized to describe the quantitative data. Following the previously mentioned criteria, the statistical significance of the acquired results was assessed at a level of significance of 5 percent.

RESULTS

In the current work, patients in groups A and B were comparable regarding demographic data and anthropometric measurements [Table 1]. In addition, there was no significant difference between groups A and B as regard to blood pressure and results of laboratory investigations [Table 2].

Regarding assessment of assessment of alertness/ sedation, it was higher among group A than group B [2.7±0.46 vs 2.54±0.50]. However, the difference was statistically non-significant [Table 3]. The visual analogue scale [VAS] showed non-significant difference between groups A and B at first postoperative hour. Subsequently from the second to the end of the 24th hour after surgery, there was significant reduction of pain score in group A than group B [Table 4]. The reported side effects were in the form of nausea and vomiting and both were higher among group A than group B [48.0%, 26.0% vs 41.0% and 20.0% respectively]. However, the difference was statistically non-significant [Table 5].

Table [1]: Comparison between the studied groups as regard to patient demographics and anthropometric data

		Group A [n=50]	Group B [n=50]	Test	P
Age [years]	Range	19 – 35	19 – 35	t=0.743	0.459
	Mean ± SD	26.16 ± 5.23	26.92 ± 4.99		
Parity	Nulliparous	19 [38.0%]	14 [28.0%]	χ^2=1.131	0.395
	Multiparous	31[62.0%]	36[72.0%]		
Previous abortion		5[10.0%]	7 [14.0%]	χ^2=0.379	0.760
Surgical history	None	26[52.0%]	35 [70.0%]	χ^2=3.405	0.100
	CS	24[48.0%]	15[30.0%]		
Comorbidity	Non	45 [90.0%]	43[86.0%]	χ^2=2.469	0.291
	Hypertension	3[6.0%]	4[8.0%]		
Weight [kg]	Range	58.5 – 85	59 – 87	1.604	0.112
	Mean ± SD	70.9 ± 6.38	73 ± 6.7		
Height [cm]	Range	157 – 173	157 – 173	1.737	0.085
	Mean ± SD	163.36 ± 4.32	164.98 ± 4.98		
BMI	Range	23.1 – 30	23 – 30	0.702	0.459
	Mean ± SD	26.54 ± 1.79	26.79 ± 1.86		

Table [2]: Comparison between the studied groups as regard Blood pressure and laboratory investigation

		Group A[n=50]	Group B [n=50]	t	P
Systolic BP[mmHg]	Range	110 – 170	110 – 170	0.712	0.478
	Mean ± SD	124 ± 12.12	122.2 ± 13.14		
Diastolic BP [mmHg]	Range	70 – 100	70 – 100	0.768	0.444
	Mean ± SD	76.6 ± 6.58	75.6 ± 6.44		
Mean arterial Pressure [MAP] [mmHg]	Range	83.3 – 116.7	83.3 – 116.7	0.883	0.380
	Mean ± SD	92.4 ± 7.13	91.13 ± 7.28		
Hemoglobin [mg/dl]	Range	10.8 – 12.6	10.8 – 12.6	0.867	0.388
	Mean ± SD	11.83 ± 0.52	11.73 ± 0.61		
Platelets [x10^3]/ml	Range	126 – 246	120 – 250	0.206	0.837
	Mean ± SD	187.88 ± 34.29	189.38 ± 38.48		
WBCs[x10^3]/ml	Range	4.7 – 7.6	4.7 – 7.6	0.001	0.99
	Mean ± SD	6.22 ± 0.84	6.22 ± 0.86		
INR	Range	0.7 – 1.1	0.7 – 1.1	0.476	0.635
	Mean ± SD	0.89 ± 0.16	0.88 ± 0.13		
PT [seconds]	Range	11.9 – 13.7	11.9 – 13.7	1.624	0.107
	Mean ± SD	12.77 ± 0.52	12.94 ± 0.55		
ALT [U/dl]	Range	10 – 40	9 – 40	1.170	0.245
	Mean ± SD	26.12 ± 9.84	23.88 ± 9.3		
AST [U/dl]	Range	12 – 45	12 – 45	0.029	0.977
	Mean ± SD	27.04 ± 10.24	26.98 ± 10.48		
Urea [mg/dl]	Range	5 – 20	5 – 20	0.250	0.803
	Mean ± SD	12.16 ± 5.05	12.4 ± 4.55		
Creatinine [mg/dl]	Range	4.5 – 9.2	4.5 – 9.3	1.252	0.214
	Mean ± SD	6.79 ± 1.55	6.41 ± 1.46		

Table [3]: Comparison between the studied groups as regard OAA/S score [modified Observer's Assessment of Alertness/Sedation [OAA/S] Scale]

OAA/S score	Group A [n=50]	Group B [n=50]	t	P
Range	2 – 3	2 – 3	1.654	0.101
Mean ± SD	2.7 ± 0.46	2.54 ± 0.5		

Table [4]: Comparison between the studied groups as regard VAS score

		Group A [n=50]	Group B [n=50]	t	P
First hour	Range	1.7 – 4.8	1.9 – 4.8	1.789	0.077
	Mean ± SD	3.2 ± 0.96	3.51 ± 0.8		
Second hour	Range	1.5 – 4.8	1.8 – 4.7	2.163	0.033*
	Mean ± SD	2.99 ± 0.96	3.37 ± 0.81		
Fourth hour	Range	1.2 – 4.7	1.6 – 4.6	2.297	0.024*
	Mean ± SD	2.81 ± 1	3.23 ± 0.82		
Sixth hour	Range	0.7 – 4.6	1.4 – 4.5	2.774	0.007*
	Mean ± SD	2.52 ± 1.01	3.04 ± 0.85		
12th hour	Range	0.7 – 4.1	1.2 – 4.4	3.158	0.002*
	Mean ± SD	2.25 ± 0.98	2.84 ± 0.86		
24th hour	Range	0.6 – 3.6	0.7 – 4.2	3.159	0.002*
	Mean ± SD	1.78 ± 0.9	2.36 ± 0.95		

Table [5]: Comparison between the studied groups as regard Complications

Complications	Group A [n=50]		Group B [n=50]		$\chi 2$	P
	No.	%	No.	%		
Nausea	24	48.0	21	41.0	0.364	0.546
Vomiting	13	26.0	10	20.0	0.508	0.476
Hypotension	8	16.0	1	2.0	5.98	0.031

DISCUSSION

There has never been a comparison of TFPs and TAP block for pain control following CS. The basic demographic, anthropometric, and laboratory data, statistical analysis of the current results revealed no significant variation in age, parity, previous abortions, surgical history, comorbidities [hypertension and diabetes], weight, height, and BMI between the studied groups. In addition, laboratory investigations showed similar results.

The current study agreed with Sevarino and colleagues. They conducted a placebo-controlled double-blind experiment to determine the transdermal treatment system's safety and effectiveness [TTS] of fentanyl administration in the postoperative environment, as well as its prospective clinical use. 95 women were given TTS patches that released 25 or 50 mg/hr. or a placebo, one hour before abdominal gynecologic surgery under general anesthesia. They claimed that there were no disparities in demographic data between research groups [4].

Research conducted by Sandier and colleagues in a double-blind, randomized, placebo-controlled design has been confirmed by the current study. This study was designed to examine the analgesic, pharmacokinetic, and clinical respiratory effects of 72-hour treatment with two different transdermal fentanyl [TTSF] patch sizes for abdominal hysterectomy patients. Two hours before having an abdominal hysterectomy under general anesthesia, 120 women were given TTSF patches providing 50 mg/h [TTSF-50] or 75 mg/h [TTSF-75] fentanyl or a placebo patch. The procedure was performed under general anesthesia. Postoperatively, supplemental morphine was available to all patients via patient-controlled analgesia pumps. They noted that there were no significant variations in age [33-36 years], weight [61-64 kg], length of anesthesia [112-115 minutes], or duration of PACU monitoring time between the three groups [169-184 min] [5].

According to Broome and his colleagues, who conducted a double-blind, randomized research including 81 patients It was determined if postoperative analgesia utilized by transdermal fentanyl delivered at 25, 50, or 75pg/h for 72 hours was superior to that produced by a placebo in women who had full abdominal hysterectomy. According to the researchers, there were no statistically significant variations detected between the four groups in terms of age, height, or weight between them [6].

The current investigation corroborated Jadon and colleagues' findings in a randomized controlled trial evaluating the analgesic effectiveness of TAP block for post-caesarean analgesia. After gaining informed agreement, 139 women undergoing caesarean birth were randomly assigned to have TAP block with either 20 ml 0.375 percent ropivacaine or 20 ml saline. All individuals had a conventional spinal anesthetic and were given diclofenac for post-operative discomfort. According to them, maternal traits [age, height, weight, parity and gestational age] were similar in both the groups [7].

Alemnew and Lemma compared the analgesic effectiveness of TAP [Transversus Abdominis Plane Block] to wound site infiltration after caesarean delivery

under spinal anesthesia. At Debre Tabor General Hospital, 62 parturient planned for elective caesarean birth under spinal anesthetic were evaluated in a hospital-based prospective cohort study. They found that demographic and perioperative variables including age, gestational age, and higher sensory level following spinal anesthesia were equivalent in both groups [p > 0.05] [8].

When the current data were analyzed statistically, it was discovered that there was no statistically significant variation between the tested groups on the modified Observer's Assessment of Alertness and Sedation [OAA/S] Scale [with p=0.101]. The current study concurred with Sevarino and colleagues, who claimed that no significant variation in sleepiness or dizziness was seen across study groups [4].

Broome and his colleagues said that when total sedation ratings were examined in a same manner, there was no discernible variation between the groups [6].

Regarding Kahsay and colleagues, the present investigation overlapped with theirs because they were examining whether a transversus abdominis plane [TAP] block may be utilized in a resource-constrained for pain management strategy after CS. Patients with ASA-I and II scheduled for CS under spinal anesthesia were randomly allocated to one of two groups: the TAP block group or the control group. According to the study's findings, the TAP block decreased the likelihood of patients experiencing score 1 sedation [11.5 percent vs. 32.7 percent; p = 0.01]. On the other hand, there was no statistically significant variation in score 2 sedations [0 percent vs. 1.9 percent; p = 0.43] [9].

The new investigation supported the findings of Jadon and colleagues that there was no variation in sedation between the two groups in the previous trial [7].

In terms of VAS score, statistical analysis of the current data revealed that TFPs resulted in a lower VAS score and pain threshold when compared to TAP block at 1, 2, 4, 6, 12 and 24 hours with p= 0.077, 0.033, 0.024, 0.007, 0.002 and 0.002 respectively.

Current study agreed with Sevarino and his colleagues who stated that at 24 hours, individuals receiving the 50 mg/hr. patch had significantly lower VAS pain scores upon ambulation than those receiving placebo. Compared to placebo, a greater proportion of group 3 [50 mg/hr] patients were assessed by the investigator as having superior or good analgesia [P < 0.05] [4].

Sandier and colleagues' findings that the TTSF-50 group did not vary significantly from the placebo group in terms of rest or movement pain were refuted in this study. Early postoperative VAS pain levels were high in all three groups during the first few days after surgery. There was no statistically significant variation in VAS pain levels between the three groups when they were at rest or when they were moving. These discrepancies might be explained by the fact that the study was conducted using a different methodology and population criteria [5].

The current investigation corroborated Miguel and colleagues' findings in which they examined two transdermal delivery systems for fentanyl at two different strengths: 70-80 and 90-100 mg/kg/hr. Both dosages were assessed for pain management during gynecologic exploratory laparotomy in 143 patients. The trial utilized a prospective, randomized, placebo-controlled, double-blind design at four sites. Group 1 received two placebo patches, while group 2 received a 40-cm^2 fentanyl patch and a 60-cm^2 placebo, while group 3 received two 60-cm^2 fentanyl patches and two 40-cm^2 placebos, according to the study's protocol. On many instances, the mean VAS ratings reported by patients in group 3 were considerably lower than those reported by patients in groups 1 and 2. In five of the ten evaluation periods, patients' global self-assessment of analgesia indicated significantly superior pain reduction compared to individuals in group 1. Individuals in group 2 reported considerably better pain alleviation than patients in group 1 during one of the ten evaluation times. Between patients in groups 2 and 3, there were no statistically significant variations [10].

The current study corroborated with Broome and colleagues' findings that the placebo group had the highest linear analogue pain ratings and the 75 mg/hr. group had the lowest. The combined transdermal fentanyl groups had substantially lower overall pain ratings than the placebo group [p < 0.007]. Additionally, unpaired t-tests across the groups revealed significant variations [6].

Finally, the current study contradicted Lehmann and colleagues, who stated that pain relief was comparable in both groups 8, 16, 24, and 36 hours after patch application, as measured by a VAS both at rest and when moving The purpose of this trial was to see if a transdermal fentanyl administration device for post-operative pain management was safe and effective. In a non-blinded, non-crossover, 40 patients scheduled for abdominal surgery under general anesthesia were randomly allocated to one of two groups in a placebo-controlled study. Patients in group I were administered a transdermal patch containing 0.16 mg/cm 2 fentanyl. A second group of twenty patients got similar-sized placebo patches [11].

Onishi *et al*. Researchers investigated if transversus abdominis plane [TAP] block provides additional analgesic advantages in post-cesarean women when compared to epidural morphine alone, and the current study validated their findings. The test subjects were parturients undergoing a caesarean section under a combined spinal epidural anesthesia. Morphine [2 mg] was administered into the spinal space once the surgery was completed. TAP was assigned to women who demonstrated an interest in becoming a part of it. Women who did not get TAP block formed the control group. TAP block, they said, enhanced the analgesic effects of epidural morphine. The TAP group had a longer median time between their first morphine request and their first morphine request [555 vs 215 minutes] and a lower median 24-hour total morphine consumption [5.3 vs 7.7 mg] than the control group [12].

The TAP block group had considerably decreased postoperative pain ratings [p 0.05] at all time periods, both at rest and during stressors, according to Kahsay and colleagues [on deep inhale, purposeful coughing, and movement] [9].

Alhosainy et al. investigated the effectiveness and safety of bilateral continuous TAP block against continuous wound infiltration for post-operative pain management in a recent research. Elective spinal cord stimulation was planned for forty of the participants in this randomized controlled research, all of them had ASA physical status I or II [ASA]. TAP block was much more effective than CWI while moving, opioid intake was significantly lower in the TAP group compared to the CWI group, and the time of first analgesic request was significantly earlier in the CWI group compared to the TAP group [13].

The study supported Jadon and colleagues' findings, which revealed that pain scores in the TAP block group were considerably lower than those in the placebo group throughout the trial, both at rest and during movement [7].

According to Alemnew and Lemma's findings, there was no statistically significant variation in pain severity measured by the Numeric Rating Scale immediately upon arrival in the recovery room compared to the third hour following caesarean surgery. The current study largely confirmed these findings. However, when the NRS was given as the median and interquartile range with a p-value less than 0.05, a statistically significant variation in NRS was seen [8].

In terms of complications, statistical analysis of the existing data revealed that hypotension was substantially more common with TFPs than with TAP block [16 vs. 2%, p=0.031]. On the other hand, there were no significant variations in nausea or vomiting between the two groups [p= 0.546 and 0.476, respectively]. The present study concurred with Sevarino and colleagues, who reported that there were no significant variations in nausea, vomiting, respiratory depression, urine retention, or itching across study groups [4].

According to Sandier and colleagues, there was no significant variation in the prevalence of adverse effects such as nausea, vomiting, pruritus, or mean hourly apnea rate, or in the mean number of episodes of slow respiratory rate [SRR]/h, between the groups during the 8-hour preoperative monitoring period [5]. Previously published findings by Miguel and colleagues, showing the prevalence of nausea and vomiting was high in all groups and that there were no statistically significant variations between groups in terms of nausea and vomiting, were corroborated by the current research. Group 3 participants were more likely than the rest to suffer pruritus. Three patients in group 1, eleven in group 2, and six in group 3 ceased taking their medications as a result of their symptoms, despite the fact that their pruritus was generally modest in each of the three groups [variation not statistically significant]. Patients in group 2 exhibited a little increase in erythema compared to the other groups, but it was small and did not need any additional therapy. Despite the fact that respiratory depression was seen in all groups, it was substantially more common in group 3 than in group I [10].

There were substantial variations in systolic arterial pressure at 4 hours and 64 hours, as well as respiration rate at 4, 32, 36, and 60 hours following the application of a transdermal delivery system, according to the findings of Broome and colleagues. When it came to respiration rates throughout these times, the placebo group had the highest rate, whereas the 75 mg/hr. transdermal fentanyl group had the lowest rate. There was no statistically significant variation between the groups in terms of pulse rate, diastolic blood pressure, the prevalence of nausea or vomiting, or the usage of antiemetic drugs [6].

In terms of TAP block, the present study agreed with Kahsay and his colleagues, who reported that there were no adverse effects or problems associated with TAP block injection. Despite the fact that the control group had more postoperative nausea and vomiting, the two study groups had no statistically significant variations; nausea [5.8% vs. 1.9%] and vomiting [7.7% vs. 0%; p = 0.06], respectively [9].

The current study disputed Jadon and colleagues, who stated that the study group's nausea scores were significantly decreased [p 0.05] only during the trial's latter half [10, 12, 18, and 24 hours] [7]. Finally, the current study largely agreed with Alemnew and Lemma, who stated that there was no statistically significant variation between two groups in the prevalence of nausea and/or vomiting within 24 hours after caesarean delivery [p > 0.05] [8].

Conclusion : For postoperative analgesia, in women who had a caesarean delivery, transdermal fentanyl patches outperformed transversus abdominis plane block.

Study limitations: the small sample size is a limiting step against generalization of results. A future large scale studies are warranted.

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