

A Shared Decision-Making Intervention to Guide Opioid Prescribing After Cesarean Delivery

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OBJECTIVE: To assess whether a shared decision-making intervention decreases the quantity of oxycodone tablets prescribed after cesarean delivery.

TECHNIQUE: A tablet computer-based decision aid formed the basis of a shared decision-making session to guide opioid prescribing after cesarean delivery. Women first received information on typical trajectories of pain resolution and expected opioid use after cesar-

ean delivery and then chose the number of tablets of 5 mg oxycodone they would be prescribed up to the institutional standard prescription of 40 tablets.

EXPERIENCE: From April 11, 2016, to June 10, 2016, 105 women were screened, 75 were eligible, and 51 consented to participate; one patient was excluded after enrollment as a result of prolonged hospitalization. The median number of tablets (5 mg oxycodone) women chose for their prescription was 20.0 (interquartile range 15.0–25.0), which was less than the standard 40-tablet prescription ($P < .001$).

CONCLUSION: A shared decision-making approach to opioid prescribing after cesarean delivery was associated with approximately a 50% decrease in the number of opioids prescribed postoperatively in this cohort compared with our institutional standard prescription. This approach is a promising strategy to reduce the amount of leftover opioid medication after treatment of acute postcesarean pain.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT02770612.

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See related editorial on page 7.

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Cesarean delivery is the most common inpatient surgical procedure in the United States, and prescription opioids are one of the mainstays of pain management after discharge.¹ Survey data suggest that the amount of prescription opioid dispensed after cesarean delivery frequently exceeds what women use by a significant margin, leading to large amounts of leftover opioid medication.² Leftover opioids from legitimate prescriptions represent a primary source of misused or diverted opioids.^{3–5} Strategies to align the number of prescription opioids dispensed with the amount used for acute indications are needed to reduce the quantity of leftover opioids introduced into communities.



Over the past two decades, shared decision-making has been demonstrated to improve outcomes and patient satisfaction in a variety of clinical settings.⁶⁻⁹ We sought to assess the effects of an interactive shared decision-making session based on a decision aid delivered by a tablet computer on women's choice regarding the number of 5-mg oxycodone tablets they would be prescribed at discharge after cesarean delivery. We hypothesized that this intervention would decrease the amount of opioids prescribed as compared with our institution's standard while maintaining effective postcesarean delivery pain management.

TECHNIQUE

After approval from the Partners institutional review board, we reviewed medical charts of women undergoing cesarean delivery daily (on the day before hospital discharge) to identify eligible patients. Women with a history of chronic pain or chronic opioid use, including methadone or buprenorphine, were not eligible for participation. Additional exclusion criteria were age younger than 18 years, non-English-speaking, postoperative hospitalization greater than 7 days, use of oral opioids other than oxycodone postoperatively, and contraindications to acetaminophen or nonsteroidal anti-inflammatory drugs.

After providing written informed consent, women participated in an approximately 10-minute shared decision-making session in which a clinician (obstetrician [M.P.] or anesthesiologist [E.M.-H.]) reviewed information verbally while the participants viewed a tablet computer-based decision aid (Appendix 1, available online at <http://links.lww.com/AOG/A955>). The clinicians who facilitated the sessions followed a script and observed each other to ensure consistency in presentation. The decision aid was developed by the study investigators based on the standards of the International Patient Decision Aid Standards Collaboration¹⁰ and included 1) information on anticipated patterns of pain in the first 2 weeks after cesarean delivery, 2) expected outpatient opioid use after cesarean delivery,² 3) risks and benefits of opioid and non-opioid analgesics, and 4) information on opioid disposal and access to refills if needed. At the conclusion of the session, participants chose the number of tablets (5 mg oxycodone) they would be prescribed on discharge, from zero to 40 tablets; 40 tablets was the standard number of tablets prescribed by obstetric providers at our institution at the time of the study. The number of oxycodone tablets prescribed was confirmed by chart review. Two weeks after enrollment,

telephone follow-up was performed by one of two investigators (M.P. and E.M.-H.).

Because obtaining additional opioid after discharge requires returning to the hospital or clinic to obtain a new prescription, our primary safety concern was ensuring that participants were provided adequate pain control. We planned an a priori interim analysis with follow-up data on 25 patients to assess the need for refills with a plan to modify the study procedure if more than 50% of patients required an additional prescription after discharge. At the interim analysis, four (16%) patients required an additional prescription, and no changes were made to the study methodology.

Demographic information and medical history were abstracted from the medical record. Study data were collected and managed using REDCap, which is a secure, web-based application designed to support data capture for research studies.¹¹

Data were analyzed in Stata 14. We used summary statistics to describe study participants and performed a one-sided, one-sample Wilcoxon test comparing the median (interquartile range) number of oxycodone tablets chosen and prescribed with the institutional standard of 40 tablets. The sample size of 50 women was based on 90% power to show a reduction in the mean oxycodone prescription from 40 to 35, assuming a standard deviation of 12 and $\alpha=0.05$. The study was registered with Clinicaltrials.gov, NCT02770612.

EXPERIENCE

From April 11, 2016, to June 10, 2016, we assessed 105 women for eligibility: 30 (28.6%) were ineligible for the study and 24 (22.9%) declined participation (Fig. 1). One woman was initially enrolled but was subsequently excluded because she had a prolonged postdelivery hospitalization. Of the remaining 50 women enrolled, none were lost to follow-up. The median maternal age of participants was 33 years and, consistent with the patient population at our institution, the majority were white, privately insured, and healthy (Table 1). Seventy percent of participants underwent a primary cesarean delivery, and median (interquartile range) postoperative length of stay was 4.0 (3.8-4.4) days.

The median (interquartile range) number of 5-mg oxycodone tablets selected was 20.0 (15.0-25.0), which was lower than the 40 tablets usually prescribed ($P<.001$) (Table 2). For six patients, the number of tablets prescribed was different from the number chosen by the patients such that the overall median (interquartile range) number of tablets dispensed was



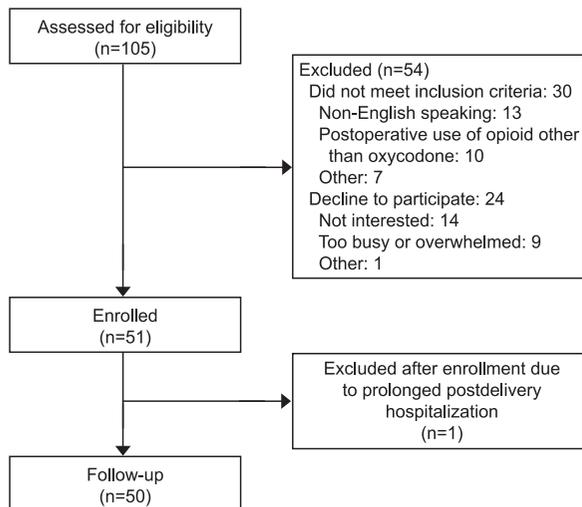


Fig. 1. Study flowchart.

Prabhu. *Decision Aid for Opioids After Cesarean Delivery*. *Obstet Gynecol* 2017.

20.0 (20.0–30.0) ($P<.001$, compared with 40). Whether this was a deliberate choice based on clinical judgment or simply accidental noncompliance with the study protocol is not known. The median (interquartile range) oxycodone used was 15.5 (8.0–25.0) tablets over the first 2 weeks after discharge, and the median (interquartile range) number of leftover oxycodone tablets was 4.0 (0.0–8.0).

Overall, 26 (52.0%) women were satisfied and 19 (38.0%) women were very satisfied with pain management. Forty-three (86.0%) women found the intervention valuable to their postoperative care. These women were asked about which elements of the intervention they found helpful (response choices were not mutually exclusive); 20 (46.5%) cited the education regarding expectations for their outpatient course and 19 (44.2%) cited the education surrounding the risks and benefits of oxycodone.

Four women (8.0%) required refills of oxycodone; their initial choice for oxycodone prescription was 5, 30, 30, and 40 tablets. Three of these women had complications that likely resulted in greater than usual postoperative pain and one patient had continued postoperative pain for which the initial prescription was inadequate. These patients were prescribed between 20 and 30 additional tablets of oxycodone.

Among the 32 participants with unused oxycodone tablets who did not receive a refill and were not using oxycodone at the time of follow-up, plans for disposal included: flushing the pills (11 [34.3%]), returning pills to a disposal station (10 [31.3%]), and no plan (11 [34.3%]). Additional analyses of oxycodone

Table 1. Baseline Characteristics of Participants

Characteristic	Value
Patient demographic	
Age (y)	33.0 (29.0–37.0)
Nulliparous	26 (52.0)
Race–ethnicity	
White	27 (54.0)
Black	0 (0)
Hispanic	8 (16.0)
Asian	14 (28.0)
Other	1 (2.0)
Insurance	
Private	36 (72.0)
Medicaid	14 (28.0)
Current nonopioid drug abuse	1 (2.0)
Current alcohol or tobacco use	2 (4.0)
Cesarean delivery characteristics	
Type	
Primary	35 (70.0)
Repeat	15 (30.0)
Planned	
Yes	19 (38.0)
No	31 (62.0)
Anesthetic mode	
Spinal or combined spinal–epidural	19 (38.0)
Epidural	29 (58.0)
General	2 (4.0)
Use of neuraxial morphine	46 (92.0)
Postoperative length of stay (d)	4.0 (3.8–4.4)
Postoperative pain characteristics	
Pain scores with activity	
Postoperative day 1	7.0 (5.0–8.5)
Postoperative day 2	5.0 (4.0–6.0)
Postoperative day 3	4.0 (3.0–5.0)

Data are median (interquartile range) or n (%).

tablets chosen, used, and remaining, stratified by type of cesarean delivery (primary compared with repeat) and timing (planned compared with unplanned), are shown in Appendix 2, available online at <http://links.lww.com/AOG/A956>.

Table 2. Oxycodone Use After Discharge and Satisfaction With the Pain Regimen

Outcome	Value
No. of oxycodone tablets chosen*	20.0 (15.0–25.0)
No. of oxycodone tablets used	15.5 (8.0–25.0)
No. of oxycodone tablets remaining	4.0 (0.0–8.0)
Need for oxycodone refills	4 (8.0)
Satisfied with outpatient pain management	26 (52.0)
Very satisfied with outpatient pain management	19 (38.0)

Data are median (interquartile range) or n (%).

* For six patients, the number of tablets prescribed was different from the number chosen such that the median (interquartile range) number of tablets dispensed was 20.0 (20.0–30.0).



DISCUSSION

The use of a shared decision-making intervention to optimize postcesarean delivery pain management was associated with a reduction in the number of prescribed oxycodone tablets by approximately half among patients who participated in the study compared with our institution's standard. The refill rate was low, and 90% of participants reported being satisfied or very satisfied with their outpatient pain management. Use of this approach to guide opioid prescribing after cesarean delivery represents a novel strategy to reduce the amount of left-over opioids available for misuse and diversion without compromising the effective treatment of pain.

Our study's strengths include the application of a multifaceted shared decision-making intervention to acute pain management after cesarean delivery, the most commonly performed inpatient surgical procedure in the United States.¹ In addition to decreasing the median number of oxycodone tablets prescribed, two thirds of patients had plans to dispose of unused opioids. Of note, flushing opioids was included as a potential disposal strategy, because this is endorsed by the U.S. Food and Drug Administration as reasonable to permanently remove potentially harmful medications from the community. However, the U.S. Environmental Protection Agency recommends the disposal of medications by other methods as a result of potential concerns for the safety of the water supply.^{12,13}

Our pilot study is subject to limitations inherent in its design. We cannot isolate the influence of each component within our intervention, including the relative effect of the contents of the decision aid, the time spent with an obstetrician or anesthesiologist, or the patient engagement in the decision on their satisfaction. Immediately after the session, 79% of patients noted either improved expectations regarding their outpatient postoperative course or education about pharmacologic options for pain management, suggesting that perhaps education was a key factor driving the choice for a lower number of oxycodone tablets. Future studies testing the individual components of the shared decision-making intervention and incorporating measures of decision quality are needed to establish which components are most effective. Also, although the frequency of refill was low and satisfaction scores high, future randomized evaluations with a control group receiving routine care will be necessary to fully define the effect of this approach on these

measures. Also of note, one third of eligible patients declined participation. Nonparticipation may influence generalizability of our findings; because we did not have institutional review board approval to conduct chart reviews once women declined participation, we cannot comment on the characteristics of this population or their motivations for declining beyond what they reported. Additional studies are needed to establish the feasibility of these approaches in clinical settings with variable resources and diverse patient populations to determine generalizability and identify strategies to maximize participation. However, if the consent rate and proportion of patients excluded are generalizable, this intervention would be expected to result in a 25% overall reduction in the number of opioid tablets dispensed after cesarean delivery.

In conclusion, our study demonstrates that shared decision-making is a promising strategy to align opioid prescribing with patient needs after cesarean delivery and thus may reduce the number of unused opioid tablets in the community while still ensuring adequate pain control and patient satisfaction.

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Harold A. Kaminetzky Award

The American College of Obstetricians and Gynecologists (the College) and *Obstetrics & Gynecology* established the Harold A. Kaminetzky Award to recognize the best paper from a non-U.S. researcher each year.

Dr. Harold A. Kaminetzky, former College Secretary and President, as well as Vice President, Practice Activities, had a long career as editor of major medical journals. His last editorship was as Editor of the *International Journal of Gynecology and Obstetrics*. Dr. Kaminetzky also had a long interest in international activities.

The Harold A. Kaminetzky Award winner will be chosen by the editors and a special committee of former Editorial Board members. The recipient of the award will receive \$2,000.

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