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Effect of Intraoperative Intravenous Lidocaine on Postoperative Pain and Return of Bowel Function after Cesarean Sections: A Double-Blinded Randomized Control Study

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ABSTRACT

Background: After a Cesarean section (CS), postoperative discomfort is a typical side effect. Rapid mobilization and the mother-newborn attachment are typically impacted.

Objective: This study aimed to assess the impact of intravenous lidocaine during surgery on pain following surgery and on the prompt recovery of bowel movements after planned Cesarean sections.

Patients and methods: We recruited and randomly assigned 60 pregnant women who had planned for Caesarean sections into two groups: The experimental group, which obtained an intravenous injection of lidocaine beginning with the skin cut and continued until the skin closed, and the placebo group, which got 0.9% normal saline at the exact same rate as the experimental group. Using a visual analogue scale, the two groups' levels of discomfort, the need for pain killers, the time it took to detect normal intestinal noises for the first time, and the time it took for flatus to occur were all contrasted. Additionally, signs of lidocaine overdose were noted.

Results: Overall VAS score values at different times "baseline, 2, 4, 6 hours postoperatively, before and after analgesia" were statistically significantly lower among cases of lidocaine group compared to control group. On the other hand, no differences were noted between lidocaine and control group regarding time to 1st hearing of bowel sounds, flatus passing, duration of postoperative hospital stay and side effects of lidocaine.

Conclusion: Given its positive effects on postoperative pain scores and satisfaction among patients, iv lidocaine injections may be a helpful adjunct during spinal anesthesia. For post-caesarean section procedures, it is an effortless, secure, and side-effect-free supplementary analgesia treatment.

Keywords: Bowel function, Cesarean sections, Lidocaine, Postoperative pain.

INTRODUCTION

Nerve root or myofascial irritation at the abdomen wall is a usual source of soreness after procedures like Cesarean sections. Intense acute pain after a Cesarean delivery is associated with postpartum depression and persistent pain **(1).**

In order to prevent a number of adverse consequences, such as breathing issues, venous thromboembolism, and a lengthy stay in the hospital, analgesic therapy following surgery is essential. In addition to being suitable, pain management should be harmless for the nursing baby **(2).**

There are two types of pain from caesarean sections: visceral (from the uterus) and somatic (from the place of incision in the abdomen wall). Appropriately managing pain following surgery and reducing the administration of opioids has grown into the norm of care in several abdominal surgical fields, including the abdomen wall restoration **(3).** For postoperative pain management, systemic or neuraxial opioids are the go-to option because they work well against all factors. However, adverse symptoms like vomiting and nausea and respiratory depressions are frequently linked to opiates usage. Post-Cesarean pain may not be adequately relieved by non-steroid anti-inflammatory drugs **(4).**

Because of its impact on postoperative pain and recovery, intravenous lidocaine is frequently utilized. Nonetheless, if administered improperly, it can and has proven lethal. The sort of surgery and details about the patient like comorbidities (including chronic pain that already exists) affect the risk compared to benefit of intravenous lidocaine **(5)**. Therefore, assessing the effect of IV lidocaine during surgery on postoperative pain and the early recovery of bowel function after a scheduled Cesarean birth is the goal of the project.

PATIENTS AND METHODS

This randomized clinical trial included 60 pregnant women who attended at Obstetrics and Gynecology Department, Faculty of Medicine, Cairo University Hospitals through the period from August to December 2023.

Inclusion criteria: Age > 18 years. American society of anesthesiology (ASA) class II (Normal pregnancy, well controlled gestational HTN, non-preeclampsia, type A1 gestational DM). Singleton term pregnancy. Elective CS. Spinal anesthesia.

Exclusion criteria: Atypical postoperative care e.g. following Caesarean hysterectomy. Inflammatory bowel disease. Prolonged surgery >1.5 hours. Medical disorders e.g. liver or renal affection. Previous bowel surgery. History' of allergic reaction to lidocaine.

I. **Sampling Method "systematic random sampling":** Patients included in this study (60 pregnant women) were subjected to randomization using a computer-based program. Closed envelopes and the data were documented in an Excel sheet with

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the number of the envelope and whether the patient received IV lidocaine or placebo. Patients were randomized using http://www.randomizer.org into 2 groups:

Group A (Lidocaine group): They were given IV infusion of 2 mg/kg per hour of lidocaine starting with skin incision, which was maintained until skin closure.

Group B (Control group): They received 0.9% normal saline at the same rate as that described in the 1st group.

II. Sample size justification:

Grady's (2012) work served as the basis for this investigation. The sample size was determined using Epi Info STATCALC [6], taking into account the following presumptions: 80% power and 5% error, with a 95% two-sided confidence level. 53 was the ultimate maximum sample size derived from the Epi-Info output. In order to account for potential dropout cases during follow-up, the sample size was subsequently raised to 60 individuals. The patients were split equally into two groups, with thirty patients in each group.

Safety and effectiveness: side effects of intravenous lidocaine administration include bluish lips, fingernails, or palms, double or blurred vision, chest pain or annoyance, cold, clammy & pale skin, persistent ringing or buzzing or other inexplicable noise in the ears, struggle breathing, difficult ingestion, and feeling lightheaded or feeling dizzy. Symptoms of lidocaine poisoning include headache, nausea, vomiting, tinnitus, anxiousness, and seizures. The anesthesiologist promptly halted the infusion and adjusted the treatment if there were any indications of toxicity. The mainstay of therapy for lidocaine overdose is supportive therapy, which may include atropine or cardiac pacer for bradycardia, benzodiazepines for seizure activity, and airway preservation for hypoxia. Intralipid 20%, an intravenous bolus injection of 1.5 ml/kg over one minute, was also used to treat serious poisoning, followed by an intravenous infusion of Intralipid 20% 15 ml/kg/h).

Study interventions and procedures:

1. The demographic maternal characteristics were extracted during their antenatal health care visit.
2. Patients were subjected to:
   a) **Complete history taking:** Personal history, menstrual history, obstetric history, contraceptive history, medical history & surgical history.
   b) **General & obstetric abdominal examinations** (Leopold maneuvers).
   c) **Investigations:** Routine investigations as complete blood picture, liver and kidney function tests, coagulation profile [Prothrombin time (PT), partial thromboplastin time (PTT) and international normalized ratio (INR)], viral hepatitis markers (hepatitis B and C viruses), Blood group (ABO) and Rh.
   d) **Antenatal ultrasound examination**, which included ultrasound measurements of classical fetal biometric parameters.
3. On the morning of surgery, patients were informed that the use of IV lidocaine in this context is off label. All patients received a single dose of prophylactic antibiotic in the form of cefotaxime 1 g intravenous (Eva Pharma CO., Cairo. Egypt) 1 hour prior to the Caesarean section.
4. Patients were then randomly assigned to either an experimental or a control group using simple randomization via computer-generated random numbers. Cesarean deliveries were performed under spinal anesthesia using Pfannenstiel incision. Investigators and patients were fully blinded to treatment allocation. The drug solutions were prepared by an anesthesiologist who was not involved in the management of the case.
   - **Experimental group (Group A):** Following the skin cut, they got an intravenous injection of lidocaine at a rate of 2 mg/kg per hour, which continued until the skin closed. Utilizing a syringe pump, 50 ml of regular saline was administered at a rate of 50 ml/hr with the determined dose of lidocaine added.
   - **Control group (Group B):** They received 0.9% normal saline at the same rate as that described in the 1st group.
5. Postoperative measures: Total operative time was recorded. Medications given and start-stop time of the study drug infusion were documented. A baseline visual analogue scale (VAS) score was obtained 2 hours postoperatively. Another VAS score was assessed immediately before the need for analgesic (diclofenac 75 mg IM together with acetaminophen 1 gm IV) and then every 15 minutes for 1 hour thereafter.

An overall VAS test score was noted upon release. For the first twenty-four hours after surgery, the entire dosage, schedule, and method of analgesic delivery were documented. Auscultation was used to check for the existence or lack of intestinal sounds in each participant every two hours beginning four hours after surgery. The patients were told to notify when they experienced flatus. It was noted how long it took for the first flatus passing and the initial regeneration of normal intestinal noises. While in the hospital, all individuals were assessed for warning signs of lidocaine toxic effects, such as headache, nausea and vomiting, tinnitus, anxiety, seizure activity, and circumoral tingling. Figure (1) showed the visual analogue scale used to assess pain in our study.

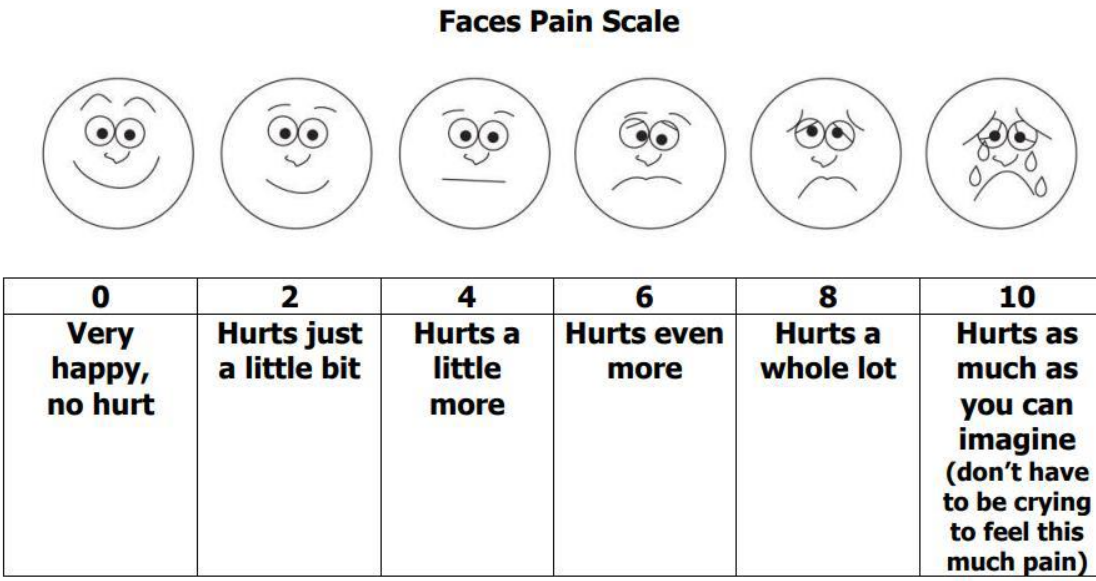

Figure (1): Visual analogue scale.

Study outcomes:

- **Primary outcomes:**
  1. Impact of intraoperative iv lidocaine on VAS pain scores among the two groups.
  2. Impact of intraoperative iv lidocaine on early return of bowel function assessed by the time to first hearing of intestinal sounds and the time to first flatus passing.

- **Secondary outcomes:**
  1. Occurrence of lidocaine toxicity with the standard dose given.
  2. Effect on patient's ambulation.
  3. Duration of hospital stay.

Ethical approval: The Ethics Committee of Faculty of Medicine, Cairo University approved this study prior to the start of the study. Throughout the whole research process, the Helsinki Declaration was applied. Written informed consents were obtained from all patients to take part in the research after being given a clear explanation of the purpose, magnitude, and potential outcomes of the clinical trial.

Statistics analysis

The data were coded, calculated, and analyzed using IBM SPSS (Statistical Package for the Social Sciences) v 23 for Windows (Chicago, USA). The qualitative data were presented as numbers and percentages. The mean ± SD was used to display quantitative variables. The Chi-square test was used to look at how categorical variables related to one another. The Fisher exact Test was substituted in four-cell tables if the anticipated cell number was below five. Two independent continuous variables with non-normal distributions were contrasted using the Mann-Whitney U test (z). The relationship between two independent normally distributed continuous groups' variables was examined using the independent sample t-test. P-value ≤ 0.05 was considered significant.

RESULTS

We applied our study on 60 patients who were divided into two groups: Lidocaine group (n=30) and control group (n=30), with the same inclusion and exclusion criteria. There was no statistically significant difference between lidocaine group and control group according to demographic data about age (years), number of previous CS and operative time (min), with p-value (P > 0.05) (Table 1).

Table (1): Comparison between lidocaine group and control group according to demographic data

	Lidocaine Group (n=30)	Control Group (n=30)	Test value	p-value
Age (years)				
Mean ± SD	24.83 ± 2.79	25.47 ± 2.53	-0.921	0.361
Range	21-30	22-33		
No of previous CS				
Median (IQR)	1 (0-2)	1 (1-2)	0.149	0.882
Range	0-3	0-3		
Operative time (min)				
Mean ± SD	59.50 ± 7.22	61.50 ± 9.08	-0.944	0.349
Range	45-71	45-75		

This table showed a statistically significant reduction in the VAS score in the two groups postoperatively compared to after 2 hours. While there was a reduction in the VAS score in the lidocaine group compared to the control group with a p-value ($p > 0.05$) (Table 2).

Table (2): Comparison between lidocaine group and control group according to VAS score

	VAS score	Lidocaine Group (n=30)	Control Group (n=30)	Test value	p-value
At 2 hours	Mean±SD	5.27±1.08	6.30±1.58	-2.958	0.004
	Median (IQR)	5 (4-6)	7 (5-8)		
	Range	4-7	4-9		
At 4 hours	Mean±SD	4.77±0.73	5.90±1.27	-4.243	0.001
	Median (IQR)	5 (4-5)	6 (5-7)		
	Range	4-6	4-8		
At 6 hours	Mean±SD	4.17±0.59	5.60±1.00	-6.738	0.001
	Median (IQR)	4 (4-5)	6 (5-6)		
	Range	3-5	4-7		
Before analgesia	Mean±SD	4.80±0.85	5.77±1.17	-3.676	0.001
	Median (IQR)	5 (4-5)	6 (5-7)		
	Range	4-7	4-8		
After analgesia	Mean±SD	3.80±0.81	4.87±0.90	-4.839	0.001
	Median (IQR)	4 (3-4)	5 (4-6)		
	Range	3-5	3-6		
Overall VAS score	Mean±SD	4.43±0.50	5.77±0.97	-3.938	0.001
	Median (IQR)	4 (4-5)	6 (5-6)		
	Range	4-5	4-8		

Time to 1st hearing of bowel sound was shorter in the lidocaine group (2.92 ± 0.72 hours) than in the control group (3.12 ± 0.83 hours). however, this was not statistically significant, with a p-value ($p>0.05$). Time to 1st flatus passing (hours) was longer in the lidocaine group (6.35 ± 2.15) than ln the control group (5.40±1.21), however this was not statistically significant, with a p-value ($p>0.05$). Duration of postoperative hospital stay (hours) was shorter in the lidocaine group (10.29 ± 3.36) than in the control group (11.74 ± 4.22), however this was not statistically significant, with a p-value ($p>0.05$). This table also showed an increase in the incidence of nausea in the control group of 3 patients (10%) compared to the lidocaine group of 2 patients (6.7%), however this was not statistically significant, with a p-value > 0.05.

Table (3): Comparison between Lidocaine Group and Control Group according to postoperative data

Time to 1st hearing of bowel sounds (hour)	Lidocaine Group (n=30)	Control Group (n=30)	Test value	p-value	Sig.
Mean±SD	2.92±0.72	3.12±0.83	-0.964	0.339	NS
Range	1.5-4	2.1-4.9			
Time to 1st flatus passing (hour)	**Lidocaine Group (n=30)**	**Control Group (n=30)**	**Test value**	**p-value**	**Sig.**
Mean±SD	6.35±2.15	5.40±1.21	1.853	0.133	NS
Range	3-10	3.2-7			
Duration of postoperative hospital stay (hour)	**Lidocaine Group (n=30)**	**Control Group (n=30)**	**Test value**	**p-value**	**Sig.**
Mean±SD	10.29±3.36	11.74±4.22	-1.464	0.148	NS
Range	5.3-15.9	5.1-17.9			
Side effects	**Lidocaine Group (n=30)**	**Control Group (n=30)**	**Test value**	**p-value**	**Sig.**
None	28 (93.3%)	27 (90.0%)	0.218	0.640	NS
Nausea	2 (6.7%)	3 (10.0%)			
Side effects	**Lidocaine Group (n=30)**	**Control Group (n=30)**	**Test value**	**p-value**	**Sig.**
None	28 (93.3%)	27 (90.0%)	0.218	0.640	NS
Nausea	2 (6.7%)	3 (10.0%)			

DISCUSSION

Inflammatory and nerve-related pain can coexist in pain following surgery, which frequently manifests as heightened feeling of pain. I.V. lidocaine addresses these [4]**.** The injection of lidocaine is believed to affect a wide range of other clinically significant results, such as ileus, wound-healing, analgesia, coagulation, and postoperative cognitive impairment**.** The positive effects of iv lidocaine in the perioperative context suggest that it could provide a safe and effective substitute for epidural analgesia in enhancing perioperative outcomes [8]**.**

We recruited and randomly assigned 60 pregnant women who had optional Caesarean sections into two groups: The trial group, which obtained an IV infusion of lidocaine beginning with the skin cut and continued until the skin closed, and the placebo group, which got 0.9% normal saline at the identical rate as the group receiving the experimental treatment. The duration of the procedure, the drugs that were administered, the start-stop period for the study drug injection, the level of pain as graded by a visual analogue scale, the need for painkillers, the time that was taken for the normal bowel sounds recover, the time that was taken for the flatus to appear, and the signs of lidocaine toxic effects were all documented for each group.

Our research showed that the lidocaine group's entire VAS score values at various points in time (baseline, 2, 4, 6 hours postoperatively, before and after analgesia) were statistically considerably lower than those of the placebo group. Yet, there were no variations between the lidocaine and placebo groups in terms of the length of the postoperative hospitalization, the time to the first hearing of bowel sounds, flatus passage, or lidocaine adverse reactions, indicating that intravenous lidocaine had no influence on all of these outcomes.

In agreement with our findings, **Ndikontar and colleagues** [9] showed that adjuvant IV lidocaine can be utilized in gynecologic surgery having the benefits of improved pain relief following surgery, accelerated recovery, and fewer adverse effects. ASA 1 and 2 women who were taken in for optional gynecological surgery beneath general anesthesia (GA) were included in the research individuals. They were split into two categories of 17 patients: Those who received IV lidocaine and those who received normal saline as a placebo both during and after surgery as an adjuvant to conventional medical treatment. From the first postoperative hour to the third postoperative hour, participants in the lidocaine group claimed fewer discomforts than those in the placebo group.

The results of a systematic review by **Kraken and colleagues** [10], which demonstrated that individuals in the lidocaine group did not require additional doses of pain relievers, provide definitive proof for the efficacy of IV lidocaine for alleviating discomfort following surgery in a variety of surgical procedures**.**

Our findings similarly support those of **Koppert and colleagues** [11] who showed that continuous intravenous infusion of lidocaine significantly reduced severity of pain after open digestive tract surgery. Similarly, a different comprehensive analysis by **García-Navia and colleagues** [12] found that when IV lidocaine infusion are used in addition to general anesthetics during gynecological laparotomy, perioperative pain is decreased. **Islam and colleagues** [13] concurred with us, reporting that a safe dosage of lidocaine infused during surgery reduces postoperative degree of pain without producing any notable adverse reactions. **Mendonça and colleagues** [14] reported that intraoperative lidocaine administration considerably reduced postoperative discomfort. The results of studies by **Groudine and associates** [15] and **Kaba and colleagues** [16] demonstrated a remarkable impact on postoperative pain with a decrease in total pain levels relative with placebo groups following colorectal procedures, which are also supported by our research. According to **Weibel and coworkers** [17], the pain relieving impact of intravenous lidocaine infusions (IVLI) was noticeable at early (1-4 hours) and intermediate (24 hours) post-operatively when juxtaposed with control or usual care; however, no evidence was identified at afterwards**.**

In our study, the administration of IV lidocaine did not show an advantage in the recuperation of GIT motion. This contradicts the results of **Grady and colleagues** [6] who discovered that during surgery IVLI at 2 mg/kg/hour, lasting a mean of 57 minutes, throughout laparoscopic gynecologic surgery speeds up the recurrence of the initial flatus while leaving the untreated group's time to the first bowel movements unchanged. They believed that by preventing systemic inflammation in response to surgical stress, IV lidocaine, administered as one dose or as an ongoing infusion, helps to preserve intestinal motility [6]**.**

When it came to intestinal function, **Moeen and her colleagues** [18] also opposed with us. They came to the conclusion that improving the recovery pathway with an iv lidocaine administration boosted preoperative and postoperative bowel activity. The lidocaine group experienced considerably shorter mean durations [For restoration of bowel movements (23.7 vs. 26.7 hours), their first flatus was 76.5 vs. 86.5 hours, their first feces was 92.7 vs. 106.9 hours, and their return to a regular diet was 80.7 vs. 92.8 hours] than the placebo group.

Contrary to our findings, **Elhafz and associates** [19] discovered that intravenous lidocaine infusions (IVLI) greatly speeds up the recovery of intestinal motility following a laparoscopic procedure.

Additionally, **Herroeder and colleagues** [20] differed with us and showed that IVLI (2 mg/minute) administered right away following tracheal intubation till 4 hours postoperatively had a considerably shorter hospitalization after open surgical procedures and expedited the restoration of intestinal motility. This might be because IVLI was administered for four hours following the conclusion of the procedure**.**

Our results revealed rare perioperative lidocaine infusion toxicity events in the perioperative period. Similar to us, **Jendoubi and associates** [21] experienced negligible or no negative consequences when receiving lidocaine injection**.**

There were no research investigations that addressed the impact of IV lidocaine administration during planned Cesarean deliveries, according to a summary of the available research. This could be the reason why our findings and those of other studies about the impact of lidocaine on the restoration of intestinal motility are inconsistent. However, our findings support the notion that intraoperative IV lidocaine greatly lowers discomfort following surgery. The current investigation can advance our understanding and provide some insight into prospective future research with bigger sample numbers and greater follow-up to reevaluate our results.

CONCLUSION

Given its positive effects on postoperative pain ratings and satisfaction among patients, our study suggested that intraoperative lidocaine injections could be a helpful adjuvant during spinal anesthesia. For post-caesarean section procedures, it was an easy, safe, and side-effect-free supplementary analgesia treatment. Yet, the length of the postoperative hospitalization and the time required for the recovery of intestinal sounds were unaffected by the intraoperative lidocaine administration.

For all straightforward operations, intraoperative lidocaine administration is advised for pain relief following the procedure.

The manuscript's creators affirm that:

1) The work is not being considered anywhere else,
2) Neither of its sections have been released before, and
3) The paper has been reviewed and accepted by all writers.

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