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Comparison of postoperative pain severity between primary and repeated cesarean section: a prospective cohort study

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Abstract

Background The cesarean section was associated with moderate to severe postoperative pain. Uncertain differences exist between parturient who undergo a primary cesarean section and a repeat cesarean section in terms of post-operative pain.

Objective To compare the degree of postoperative pain in patients who had primary and repeat cesarean sections.

Method An institutional-based prospective cohort study was conducted on 336 patients who fulfilled eligibility criteria and underwent caesarian section under spinal anesthesia. Study participants were selected by a systematic random sampling technique. An independent sample t test and a Mann–Whitney U test were used to compare symmetric and asymmetric data, respectively. Time to first analgesic request was analyzed using log rank Kaplan–Meier survival curves and cox-regression for covariates. Comparisons of categorical variables between groups were done using the chi-square test. The significance was determined at a *P* value of < 0.05.

Results There was a high Risk of moderate to severe postoperative pain in repeated caesarean section compared to primary caesarean section in both incisional pain (RR, 1.364[95% CI, 1.12–1.66], $p = 0.002$) and visceral pain (RR, 1.66[95% CI, 1.40–1.66], $p = 0.001$). In comparison to the primiparas, parturient with repeated cesarean sections had highest post-operative pain severity in NRS with median NRS of 5(IQR, 3–5) at the 4th hour ($p < 0.001$) for the incisional pain and 6(IQR, 5–7) at the 8th hour for visceral pain, respectively, for the repeated group. The primiparas group had a longer median time to first rescue analgesic administration (median [minute], 875.7[95% CI, 750.3–1001]; $P < 0.001$)) than the repeated group (median [minute], 534.8 [95% CI, 426.8–642.8]; $P < 0.001$.

Conclusions Compared to primary CS, repeated cesarean had a high incidence of moderate to severe postoperative pain, both visceral and incisional; within 48-h. In future endeavors of crafting postoperative analgesic plans, it is imperative to take into account individual variations and distinctions.

Keywords Caesarean Section, Primary, Repeated, Postoperative pain, Parturient

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Introduction

The cesarean section stands as the most commonly performed surgical procedure, involving the delivery of a baby through an abdominal incision located just below the uterus and umbilicus [1]. On a global scale, there is a notable increase in the prevalence of cesarean sections. As per a recent report by the World Health Organization (WHO), the average worldwide cesarean section rate escalated from 12.4% to 18.6% between 1990 and 2014. North America reported the highest rate at 32.3%, while Africa exhibited the lowest at 7.3% [2]. According to EDHS (2016) figures, Ethiopia had a 29% total Caesarean section rate [3].

A Caesarean section is a typical major surgical procedure that produces significant postoperative pain [4]. Moderate to severe pain is frequently experienced for 48 h after a Caesarean section [5] It can be particularly challenging to treat postoperative pain in low-income countries for a variety of reasons. Patients' anticipated postoperative pain (which they do not try to alleviate by requesting medicines) and the low nurse-to-patient ratio that determines pain and administers the required analgesics [6].

For the past 20 years, spinal anesthesia has been the most widely utilized anesthetic approach for CS because it is simple, has a quick and predictable start, produces powerful blocks, exposes the fetus to little medication, increases patient awareness, and reduces postoperative pain as well as adding Adjuvants medications that work synergistically with local anesthetics helps to enhance the quality and efficacy of this regional techniques [7, 8]. Global health policy also considers the impact of uncontrolled pain and the resulting global burden because postoperative analgesia is still a serious medical concern [9]. Abdominal pain following a caesarean section appears to be a common but variable condition; comprehensive evaluations found incidences ranging from 4 to 42% [10].

Globally Previous research found that parturient who had CS had a 78.4–92 percent chance of experiencing moderate to severe pain globally [11].However, in Africa, very little is known regarding the severity of post-cesarean section pain and the risk factors that contribute to it in developing nations, particularly in sub-Saharan Africa, even if cesarean sections have the highest incidence of postoperative pain (> 80%) [12].The overall prevalence of moderate-to-severe postoperative pain after a cesarean section was 85.5% in Ethiopia [13].

Repeated cesareans increase the risk of uterine rupture, increased blood loss, blood transfusion-induced severe adhesion, organ injury, cesarean hysterectomy, wound infection, and postoperative pyrexia, making these patients high-risk. Because of their scarred uterus, these patients also experience additional surgical complications and need an additional surgery time, which increases the burden of moderate to severe pain on repeated CS mothers [14].

Multiparas women have a repeat cesarean delivery, on the other hand, are typically older, which has been related to less postoperative pain. There hasn't been much research that compares multiparas and primiparas in terms of postoperative pain control [15–17].

So far, no research has looked at whether acute and subacute postoperative pain scores and opioid intake differ between primary and repeat CD. It's possible that repeated CD patients take more opioids as a result of scar hyperalgesia, which has been linked to higher pain scores in these patients [18].

Therefore, the current study was included patients who are scheduled to undergo primary or repeated cesarean sections to investigate the potential difference in severity of postoperative pain, total analgesia consumption and first analgesia requirement between primary and repeated CS.

Methods and materials

Study design, period and area

A prospective cohort study was conducted from March 15 to June 30/2022 after obtaining Ethical approval from Institutional Review board of Wolaita Sodo University, College of Health Sciences and Medicine, with protocol unique No. CHSM/ERC/03/14. The exposed groups were mothers who gave birth by repeated caesarean section, and the non-exposed group would be primary caesarean section. The hospital serves over 100,000 outpatient visitors a year and has around 450 functional beds with an average admission rate of 800 per month. The total number of caesarean sections (spinal + general anesthesia) performed in the year 2021 (G.C.) was 1634.Thestudy was registered with the university research registry. The work has been reported in line with the STROCSS criteria [19].

Inclusion criteria

✓ Parturients with an ASA physical status scale of II-III who were scheduled to have an elective cesarean section with a transverse incision.

✓ Only those who were undergoing their first repeat cesarean deliveries were included in the recruitment for this study.

Exclusion criteria

✓ A history of chronic pain disorder, recent or chronic opioid use, substance abuse, heavy smoking (> 30 pack-years)

✓ Pregnancy Complications include pulmonary embolism, antepartum hemorrhage, severe preeclamp-

sia or eclampsia, Previous non CS uterine scar from myomectomy, previous abdominal surgery, and preoperative pain, parturient with regional block or local infiltration was used was excluded from our study

Operational definition

Postoperative pain: is defined as a patient complaining of pain and a pain score greater than zero within 48 h [20].

Inadequate analgesia (moderate to severe pain): defined as a therapy cutoff point for the NRS-11 ≥ 4 score(NRS 4–10), which was used to identify individuals with moderate to severe pain [21].

Time to first analgesia request: a time in minutes from the end of surgery to the first time analgesia is given.

Total post-operative analgesia consumption: total dose and type of medication administered in mg within the first 48 h following admission to the recovery room.

Primary caesarean section: a pregnant mother comes for her first caesarean section.

Repeated caesarean section: a pregnant mother undergoing her second caesarean section.

Censored: A pregnant woman who participated in the study and were followed up on but did not received analgesia.

Event (die censored): a pregnant women who participated in the study and were followed up on and received analgesia.

Lost follow up: a patient who did not receive full postoperative care during the first 48 h.

The severity of postoperative pain: it is postoperative pain intensity, measured by numerical rating scale (NRS).

Study variables

Dependent variables

➢ Severity of postoperative pain by NRS[primary outcome]
➢ Time to first analgesia request in minute [secondary outcome]
➢ Total analgesics consumption within 48 h[tertiary outcome]

Independent variables

Socio demographic variable

✔ Age,BMI, residence,marital status

Preoperative variables

✔ Anxiety,ASA status, blood group,baseline vital sign, previous history of CS

Intraoperative variable

✔ Dose of local anesthesia,Incisional vital sign, Intraoperative vital sign,Intraoperative analgesia,Blood loss, Duration of surgery

Postoperative variable

✔ Postoperative analgesia taken, Adjuvant drug used,Postoperative MAP, Postoperative heart rate

Sample size determination and sampling technique

Based on a previous study by Guiying Yang and his colleagues, repeated cesarean delivery predicts a higher risk of inadequate analgesia than primary cesarean delivery. We use the value of surgical duration for both the exposed group (repeated) (74.0 ± 21.2) and the control group (primary) (82.8 ± 25.9). To calculate the effect size, data was presented as mean ± SD [22]. We calculate our sample size by using G*Power version 3.1.9.

Mean One for the Exposed Group = 74, SD one for the exposed group = 21.2

The mean of the control group = 82.8, SD two for the control group = 25.9

By inserting this input, the effect size becomes 0.371826.

After that, we use: Test family (t-test).

Type of power analysis- A priori: computer required sample size given alpha = 0.05, power = 0.90, effect size = 0.37, and allocation ratio N2/N1 = 1.

With these assumptions, we determined the sample size for both groups, using the Mann–Whitney (two independent groups) settings with a two-tailed test).

Group 1 has a sample size of = 153 parturient.

Group 2 has a sample size of = 153 parturient.

The sample sizes for the primary and repeat groups were 153 and 153, respectively (total = 306 subjects). Taking a 10% non-response rate into account, a total of 336 participants were recruited in each group. Study participants were selected by a systematic random sampling technique.

Data collection tool and procedure

Structured check lists for patient safety assurance and data accuracy checkup and questionnaires were developed for this study in English and Amharic from literatures [10, 14, 22, 23]. Data collection was done using designed check lists and observational structured questionnaires. The data was collected from the anesthesia sheet by one anesthetist, while postoperative data was

collected by three nurses after getting training with the pain, anxiety, and depression assessment tools and the principal investigator supervised the completeness of the data daily.

Preoperative

Preoperative patient information was taken from the chart and patient by the first data collector. In the operation room, the patient was positioned in a supine position with an electrocardiogram, heart rate (HR), noninvasive blood pressure, and pulse oximetry attached for standard monitoring. Base line blood pressure, HR, and oxygen saturation (SPO2) were recorded before SA. After that, they positioned the patient in a sitting position and infiltrated the patient's skin at the entry point of L3/L4 with Lidocaine (2 mL of 2% plain after strict aseptic technique with iodine and alcohol).

A local anesthesia drug (Bupivacaine) was given to the patient with a (0.5*%)* concentration at L3–L4 in different positions after adequate CSF flow without barbotage by the anesthetist using more than 22 gauge spinal needles with a speed of injection of 0.2ml/sec. Immediately after they put the patient in the supine position, they inserted a pillow under the right hip to prevent aortocaval compression.

Just after they give the spinal, the anesthetist asses the level of block (alcohol drips for autonomic, pin prick for sensory & bromage scale of 3 for motor). Surgery was undergone after a sensory level of T5 or T6. Only patients with successful spinal blocks were included in the study.

Intraoperative

They started to monitor and record oxygen saturation, heart rate, and non-invasive blood pressure. They would have been monitored every 2 min for the first 10 min just after spinal anesthesia for early identification of spinal-related complications, but after that, they would monitor the vital signs at ten-minute intervals till the end of surgery.

Postoperative

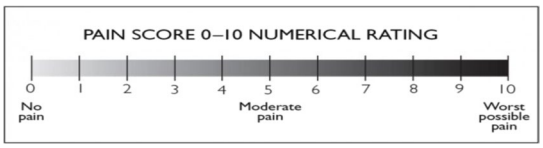
After the end of surgery, they was transfer the patient to PACU, the immediate NRS pain score of the patient in the PACU was taken in both at rest and cough and hand over the case to the nurse there. The PACU nurse follows the parturient's condition until the spinal block wears off, and after they assess the PACU discharge criteria, if the parturient fulfills it, they was transfer to the ward.

In the postoperative period in the ward, the data collector started assessing and recording the severity of both the visceral and incision pain scores. These scores were assessed during a quiet breathing period or at rest (static NRS) and after a voluntary cough (dynamic NRS), and the women were asked to report their pain intensity on an 11-point numerical rating scale (NRS). Mild pain (NRS = 1–3), moderate pain (NRS = 4–6), and severe pain (NRS = 7–10)at (1st), (4th), (12th), (24hth), and (48th) hour spost surgery were recorded from the patient's chart, and the time to the first analgesic request was recorded from the patient's chart after admission to recovery, and total analgesic consumption was recorded for each patient. At the time of pain evaluation, the heart rate, the mean arterial blood pressure, the respiratory rate, and SPO2 are recorded.

Numerical pain rating scale (NRS)

A pain assessment tool in which the number assigned from 0- 10 to represent severity of pain.

- o 0 = no pain
- o 1-3 = mild pain
- o 4-6 = moderate pain
- o 7-10 = severe pain.



Data quality assurance

Training and orientation about the objectives and relevance of the study, each item included in the study tools, and the whole process of data collection were provided for data collectors and supervisors. A supervisor checked each questionnaire daily, with further cross-checking by the principal investigator for completeness and consistency of data. Data clean-up and cross-checking of missing data were done before entering EPI info and analyzing it in SPSS.

Data processing and analysis

Data was checked manually for completeness and then coded and entered in to EPI info version 4.6.1 then transferred to SPSS version 25computer program for analysis. The comparison of numerical variables between study groups was done using an independent t-test and the Mann–Whitney U test for symmetric and asymmetric data, respectively. Time to first analgesic request was analyzed using log rank Kaplan–Meier survival curves and cox-regression for covariates. Frequency and percentages to describe categorical variables and statistical differences between groups were expressed by using the chi-square test. *P*-value less than 0.05 were considered statistically significant.

Results

According to predefined inclusion and exclusion criteria, patients were accepted. 336 participants who were scheduled for elective cesarean sections with a transverse incision and spinal anesthesia were included in the study. Participants in the repeated and primary cesarean sections did not substantially differ in terms of socio-demographic characteristics between groups ($P > 0.05$).The mean age of repeated group's (Mean ± SD) was 28.30 ± 4.9,while the primipara group's mean age (Mean ± SD) was 27.48 ± 4.328 ($p = 0.102$). The results showed that the majority of the parturient was from urban 105(62.5%) in the repeated group and 90(53.5%) in the primary group. while majority of parturient, 157 (51.8%) in the repeated group and 146(48.2%) in the primiparas group were ASA II ($p = 0.231$) (Table 1).

Table 1 Distribution of Socio-demographic and perioperative characteristics of patient who under want caesarean section at WSCSH, 2022. ($n = 336$)

Variable		Group		*P* value
		Repeated	Primipara	
Patient age	Year	28.30 ± 4.9	27.48 ± 4.3	$P = 0.102$
BMI	Underweight *n* (%)	2(50.0%)	2(50.0%)	$P = 0.313$
	Normal *n* (%)	125(47.7%)	137(52.3%)	
	Overweight *n* (%)	20(55.6%)	16(44.4%)	
	Obese *n* (%)	13(54.2%)	11(45.8%)	
Marital status	Single *n* (%)	13(36.1%)	23(63.9%)	$P = 0.270$
	Married *n* (%)	148(52.5%)	134(47.5%)	
	Divorced *n* (%)	5(38.5%)	8(61.5%)	
	Widowed *n* (%)	2(40.0%)	3(60.0%)	
Residence	Urban *n* (%)	105(62.5%)	90(53.5%)	$P = 0.742$
	Rural *n* (%)	63(37.5%)	78(46.5%)	
ASA status	ASA II	157(51.8%)	146(48.2%)	$P = 0.231$
	ASA III	11(33.3%)	22(66.7%)	
Anxiety status	High	93(52.2%)	85(47.8%)	$P = 0.381$
	Low	75(47.5%)	83(52.5%)	

Hint: The values are presented as frequency (proportion), *BMI* Body mass index, *ASA* American Society of Anesthesiologists

Distribution of Intraoperative, postoperative data across the groups

All parturient received spinal anesthesia with bupivacaine at varied doses according to the data. The majority of them took 12.5mg, with a rate of repeated 152 (50.5%) and primiparas 149 (48.1%), $p = 0.356$. Surgical duration became statistically significant between groups, with a mean ± SD (42.97 ± 10.17), $p = 0.001$.Post-operative average mean arterial pressure and heart rate of the parturient was no statistical significance between the group, $p > 0.05$ (Table 2).

Postoperative analgesia used and opioid consumption by the parturient during follow up period

Analgesia utilized during postoperative follow-up at 4, 8, 12, 24, and 48 h was not statistically significant between groups ($p > 0.05$). Within 48 h, the most common analgesics used to alleviate pain were diclofenac and tramadol. The total postoperative diclofenac intake in the postoperative analgesic primary group (mean rank = 41.6) was considerably lower than in the repeated group (mean rank = 62.4), p 0.001. The primary group's total postoperative opioid consumption (mean rank = 22.4) was also significantly lower than the repeated group's (mean rank = 38.5), p 0.001(Fig. 1).

Comparison of severity of postoperative pain at rest and during cough

The pain score during rest at PACU was not significant between the groups with $p = 0.255$. The highest median NRS of 5 (IQR, 3–5) was reported for Incisional pain at the fourth postoperative hour ($p = 0.001$). The highest median NRS of 6 (IQR, 5–7) at 4th hour and 6(IQR, 5–7) at 8TH hour with $p = 0.001$, were reported for repeated group during cough and 5(IQR, 3–6) at 8th hour with $p = 0.001$, were reported for primary group for visceral pain (Table 3).

Incidence of pain between the groups

The total incidence of inadequate analgesia on incision and visceral pain in repeated group was significantly higher than that in primiparas group, and the RR for multiparas to experience inadequate analgesia in both Incisional pain (RR, 2.45[95% CI, 1.98–3.02] at rest.Incidence of postoperative pain during cough after caesarean section in primipara and visceral pain (RR 1.73[95% CI, 1.49–2.02], $p = 0.001$) than in the primiparas group(Table 4).

Comparison of first analgesic request time between the group

A Kaplan–Meier survival analysis was used to compare the survival distribution of time to first analgesic administration between primiparas and repeated. In a log-rank test, it was discovered that the survival distributions of the two groups were statistically significantly different. The primiparas group had a longer median time to first rescue analgesic administration (median [minute], 875.7[95% CI, 750.3 -1001]; $P < 0.001$)) than the repeated group (median [minute], 534.8 [95% CI, 426.8 -642.8]; $P < 0.001$(Fig. 2).

Table 2 Distribution of Intraoperative, postoperative characteristic of the parturient who under want caesarean section at WSCSH in 2022. ($n=336$)

Intraoperative data		Group		*P* value
		Repeated	Primipara	
Bupivacaine dose	10 mg	2(25.0%)	6(75.0%)	0.356
	12.5 mg	152(50.5%)	149(49.5%)	
	15 mg	14(51.9%)	13(48.1%)	
Additive drug	Non	148(48.1%)	160(51.9%)	0.058
	Dexamethasone	7(70.0%)	3(30.0%)	
	Morphine	13(76.5%)	5(23.5%)	
Intraoperative analgesia used	Non	164(49.5%)	167(50.5%)	0.170
	Tramadol	2(100.0%)	00.0%	
	Morphine	2(75%)	1(25%)	
Intraoperative MAP	Mean ± SD	68.92 ± 7.98	71.28 ± 8.44	0.209
Intraoperative HR	Mean ± SD	81.47 ± 7.44	82.81 ± 8.14	0.116
Blood lose	Mean ± SD	519.82 ± 99.36	508.2 ± 103.3	0.296
Surgery duration	Mean ± SD	42.97 ± 10.17	39.38 ± 8.25	0.001**
Postoperative MAP	Mean ± SD	71.29 ± 5.87	72.27 ± 5.24	0.109
Postoperative HR	Mean ± SD	81.50 ± 6.58	80.82 ± 5.77	0.311

Hint: The values are presented as frequency (proportion) and Mean ± Standard deviation, *MAP* Mean arterial pressure, *HR* Heart Rate

** highly statistically significant

Discussion

The result of this study shows that patients undergoing primary caesarian section has decreased severity of post-operative pain, decreased post-operative analgesia consumption and prolonged time to first analgesia request than patient done repeated caesarian section in which the median time to first analgesia request in patients undergoing primary caesarian section is 875.7 [95% CI, 750.3 -1001] min than the repeated group 534.8 [95% CI, 426.8 -642.8]; $P<0.001$.

The finding of this study shows that there is increased severity of post-operative pain in NRS in patient undergoing repeated caesarian section group than primpares with $p<0.05$.The finding of this study in line with study by Duan et al. [23] in which 67 primipares and 101 patients undergoing repeated c/s were followed for 48 post-operative hrs and patient undergoing repeated c/s had sever post-operative pain than primipares with relative risk for repeated caesarian Sect. 3.56 (95% CI: 1.05 to 12.04). This is due to the fact that Extensive adhesions resulting from prior surgeries were frequently unavoidable. Consequently, they pose heightened challenges during subsequent cesarean sections, leading to prolonged surgical durations and potentially eliciting more intense noxious stimuli. This heightened noxious stimulation is closely linked to an elevated severity of postoperative pain [14, 24–26]. Furthermore the finding of this study in line with previous study by Demelash et al. [13] in which 290 parturient undergoing caesarian section were evaluated and repeated caesarian section was highly associated with sever post-operative pain with (AOR: 2.3, 95% CI: 1.1, 5.0).

Current study demonstrated that post-operative total analgesia consumption is higher in repeated group than primiparas group and the finding of this study in line with retrospective cohort study by Yang et al. [22] in which 1142 patients undergone primary and repeated caesarian section was evaluated and the incidence of inadequate analgesia in the primiparas group was lower than that in the multiparas group (16.7% vs. 24.0%, $P<0.001$ and 16.1% vs. 23.5%, $P=0.002$; respectively. This is explained as patients in repeated caesarian section group had increased severity of post-operative pain due to scar hyperalgesia which in turn increase post-operative opioid consumption [18]. In contrary to this RCT study done in Xinqiao Hospital, in china [23] shows that there is no significant difference in post-operative analgesia consumption between the two groups. The difference might be due to population difference, post-operative pain management protocol and difference in study design in which cohort design used in current study.

The results of our survey showed that the primiparas group had a longer median time to first rescue analgesic administration than the repeated group (median time in [minute], 875.7 [95% CI, 750.3 -1001]; P 0.001. The finding of this study consistent with study by Ducan et al. [23] in which the repeated group has a longer time to experience pain after the procedure than the primary group,

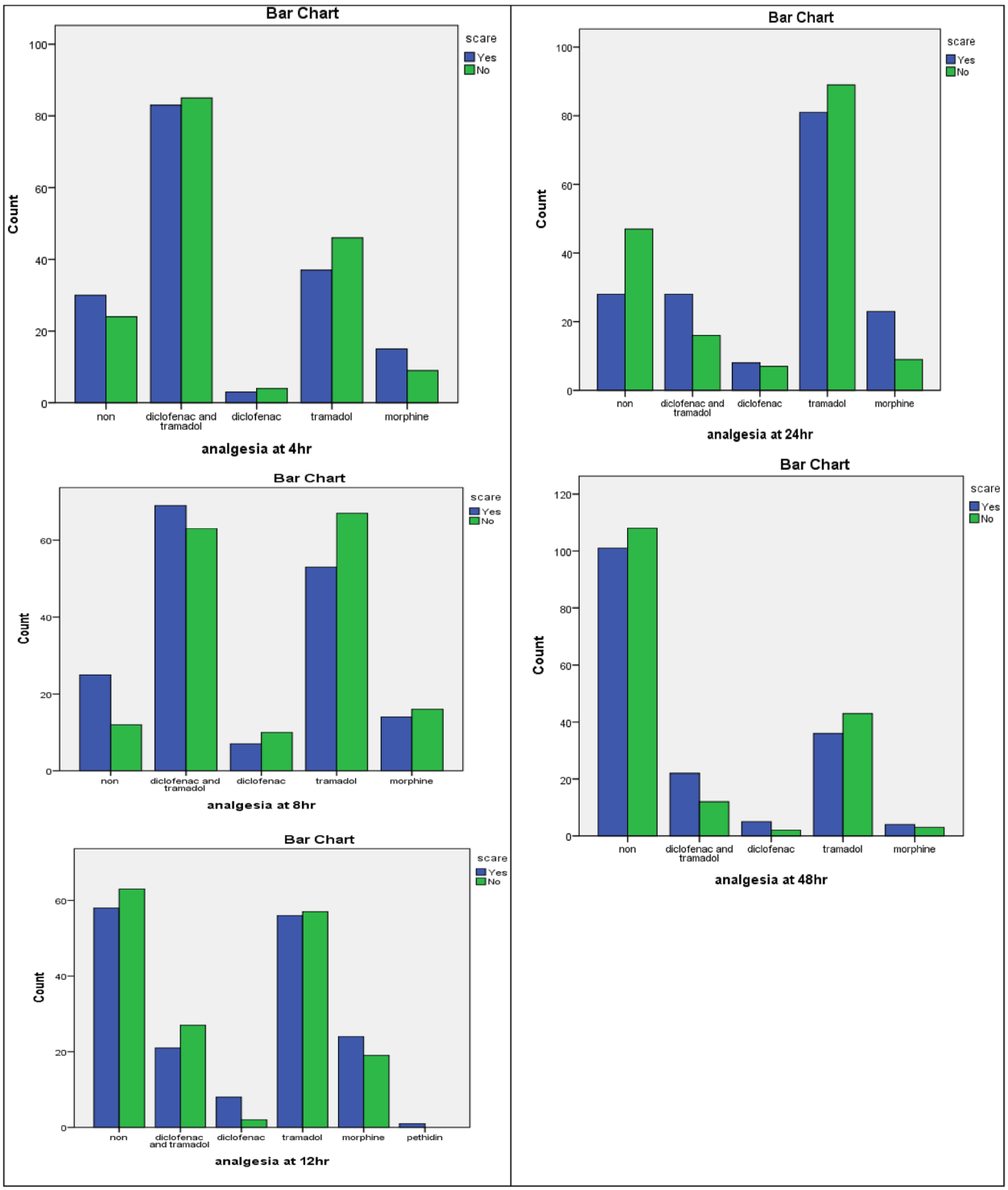


Fig. 1 Comparison of type of analgesia used during postoperative period

with 4 h and 3 h respectively. This is due to the fact that, previous surgery history might increase the patients 'post-operative pain sensitivity so patients with repeated caesarian section requests analgesia earlier than primiparas [18, 27, 28].The study's strengths include the fact that it is the first of its kind in the region and the country as

Table 3 Compares the severity of postoperative pain by NRS at rest and during cough ($n=336$)

Hour	NRS at rest		*P* value	NRS during cough		*P* value
	Repeated	Primary		Repeated	Primary	
0 h at PACU	0(0–1.75)	0(0–1)	0.255	1(0–2)	0(0–2)	0.075
4h	5(3–5)	3(2–5)	0.001**	6(4–6)	4(3–6)	0.001**
8h	3(2–5)	3(2–5)	0.638	6(5–7)	5(3–6)	0.001**
12h	3(1–5)	3(1–4)	0.165	4(2–7)	3(2–4)	0.006
24h	3(2–5)	2(1–3)	0.006	4(3–5))	3(2–4))	0.004
48h	2(1–4)	1(1–3)	0.065	4(2–6)	2(1–4)	0.001**

Hint: The values are presented as median (IQR)*PACU* Post Anesthesia Care Unit, *NRS* Numeric Rating Scale

** = highly statistically significant,

Table 4 Incidence of moderate to severe postoperative pain at rest and during cough, WSCSH 20, 2022

	Group	Moderate-sever postoperative pain		Risk ration 95% CI	*P* value
		No	Yes		
At rest	Repeated	21(12.5%)	147(87.5%)	2.45(1.98–3.02)	*P* = 0.001**
	Primary	108(64.3%)	60(35.7%)		
During cough	Repeated	15(8.9%)	153(91.1%)	1.73(1.49–2.02)	*P* = 0.001
	Primary	80(47.6%)	88(52.4%)		

Hint: values are presented in frequency (proportion), *CI* Confidence Interval, ** statistically significant

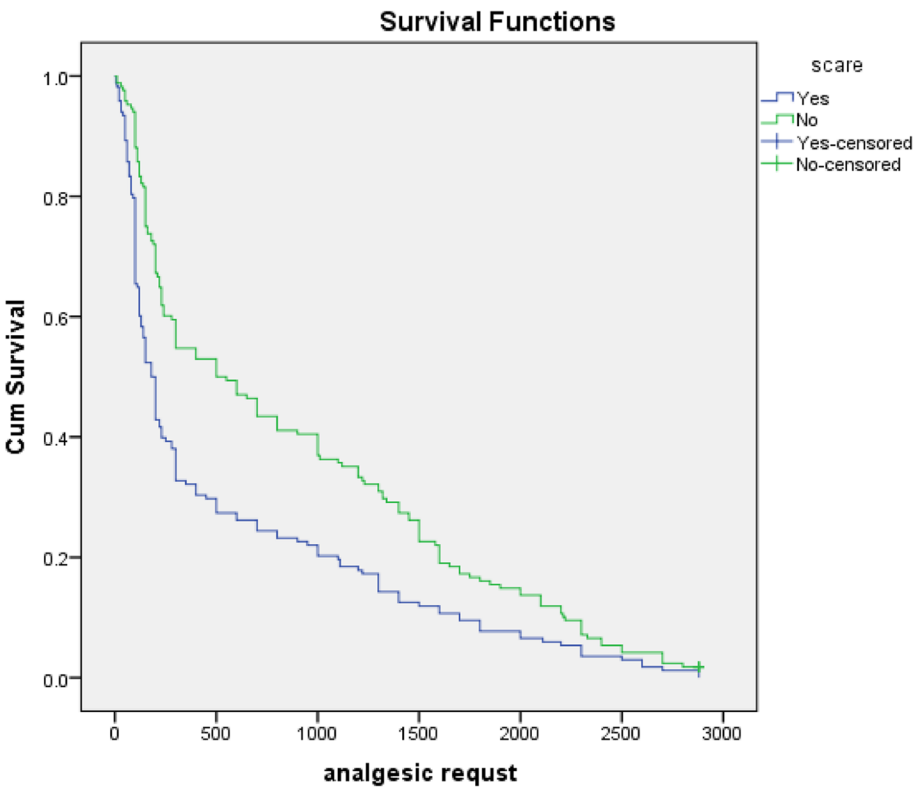


Fig. 2 The Kaplan–Meier curve of survival function for the comparison of time to the first rescue analgesic administration. Supportive document: questioner docx

a whole but more reliable results would have come from a randomized control trial, large sample size, and multicenter study.

Conclusion

In conclusion, when compared to primiparas, multiparas undergoing a repeat cesarean delivery were considerably more prone to experiencing moderate to severe postoperative pain so individual distinctions between primiparas and multiparas should be considered in the future when developing a postoperative analgesic plan following cesarean delivery.

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Authors' contributions
ZG and MK were responsible for data collection, statistical analysis and interpretation, wrote the manuscript. AU,GA,HG,MT,AZ,MK,TD,MI andAS interpreted and supervised statistical analysis and edited the manuscript. All authors have read and approved the manuscript.

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Data availability
The data that support the findings of this study are available from the author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained from Institutional Review board of Wolaita Sodo University, College of Health Sciences and Medicine, with protocol unique No. CHSM/ERC/03/14 and submitted to wolaita sodo comprehensive specialized hospital. Informed consent was waived by Institutional Review board of Wolaita Sodo University, College of Health Sciences and Medicine. A formal letter of cooperation was written to Wolaita Sodo University Comprehensive Specialized Hospital and permission was obtained from hospital administrators. Information confidentiality was maintained by avoiding the use of any personal or identifying information**.** Informed written consent was obtained from every participant. All methods were carried out in accordance with declaration of Helsink.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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