Retrospective Comparison of the Safety and Effectiveness of Dexmedetomidine Versus Standard of Care Before and During Cesarean Delivery in a Maternity Unit in Zhengzhou, China

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Background: The objective of the present study was to test the hypothesis that intravenous dexmedetomidine is safe and effective when administered to women before and during cesarean section.

Material/Methods: The analysis included 392 women who received spinal anesthesia and no analgesia prior to undergoing elective cesarean delivery. Of them, 115 women received dexmedetomidine before anesthesia and during delivery (DX cohort), 109 received normal saline before anesthesia and during delivery and dexmedetomidine after delivery (SC cohort), and 168 received normal saline only before anesthesia and during delivery (CN cohort). Data about the women’s consumption of sufentanil and ondansetron during hospitalization, onset of lactation, and hospital stays were retrospectively collected and analyzed.

Results: Most of the women in the study were primiparous (362/392). The women in the DX cohort received less sufentanil during their hospital stays than those in either of the other 2 cohorts (SC comparison: 151.45±11.15 μg vs. 175.12±25.15 μg, P<0.0001, q=8.776; CN comparison: 151.45±11.15 μg vs. 185.42±37.45 μg, P<0.0001, q=13.911). Also, the women in the DX cohort received less ondansetron before discharge and had shorter times to first lactation and hospital stays than those in the SC and CN cohorts.

Conclusions: Administering dexmedetomidine before spinal anesthesia appears to be safe and effective for women undergoing elective cesarean delivery.

MeSH Keywords: Anesthesia, Spinal • Cesarean Section • Dexmedetomidine • Hemodynamics • Lactation • Sufentanil

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Background

Cesarean deliveries are common [1] and post-delivery pain [2], anxiety, and depression [3] are seen more often in women who deliver via cesareans than vaginally. Effective post-delivery pain relief affects the recovery of women after cesarean delivery [4]. General anesthesia often is used for cesarean deliveries because many of the procedures are emergent, but also based on patient choice [5]. Sufentanil (a selective agonist of the μ-receptor) [6] combined with non-opioid analgesics commonly is used for pain management after cesarean delivery [7]. Maternal treatment with analgesics and sufentanil combined before delivery induces neonatal respiratory depression [5].

Dexmedetomidine is a highly selective α-2 receptor agonist that has anti-sympathetic, sedative, and analgesic effects [7]. It reduces release of damage-transmitting substances and glutamate, leading to suppression of pain [8]. Dexmedetomidine affects the locus coeruleus and induces sleep [9]. It also increases the frequency of contractions of smooth muscles in the uterus [7]. These effects can be of benefit to women who have cesarean deliveries [7,10], whereas postoperative infusion of dexmedetomidine combined with sufentanil is effective for analgesia and sedation [4]. However, when combined with sufentanil, dexmedetomidine results in excessive sedation [7], and adverse effects include hypotension [5] and bradycardia [7]. The maternal and fetal effects of administering dexmedetomidine after delivery have not been thoroughly evaluated [2]. Stronger evidence is required about the drug’s analgesic and sedative actions in obstetric settings. Retrospective analysis also should be performed to evaluate the effects of administration of different regimens of dexmedetomidine before and during cesarean delivery and for post-cesarean pain management.

The objectives of the present retrospective study were to evaluate the effectiveness and safety profile of preoperative and intraoperative use of dexmedetomidine in women undergoing cesarean deliveries.

Material and Methods

Ethics approval and consent to participate

Protocol 2019-ZZH-189, dated March 28, 2020, was approved by the Zhengzhou University Review Board and the Chinese Society of Anesthesiology. Written approval was received before the data were collected. All of the women who participated or their legally authorized representatives signed informed consent forms prior to hospital admission, which included information about anesthesia, delivery, treatment, and publica-
Pain measurement

The women’s pain was assessed using a visual analog scale (VAS) with a range of 0 to 10, with 0 being no pain and 10 the maximum possible pain. Nursing staff with a minimum of 3 years of experience administered the VAS at 6 and 12 h and 1 day after delivery while the women were resting, having uterine contractions, and moving [7].

Pain management

The institute’s nursing staff, in consultation with an obstetrician who had a minimum of 3 years of experience, administered the VAS to the women at 6 and 12 h and 1 day after delivery while the women were resting, having uterine contractions, and moving [7].

Management of nausea and vomiting

Working in consultation with an obstetrician, nursing staff from the institute who were blinded to the treatments administered 4-mg ondansetron injections to women who experienced nausea and vomiting.

First lactation time

The time from delivery to when at least 10 mL (2 tsp) of milk flowed from both breasts was defined as the first lactation time, based on self-reports by the women [7].

Other maternal outcomes after delivery

After delivery, episodes of hypertension (systolic blood pressure >180 mmHg), hypotension (systolic blood pressure <90 mmHg), bradycardia (heart rate <50 beats per minutes), tachycardia (heart rate >110 beats per minutes), respiratory depression (defined as a decline in respiratory rate to 10 times/min for more than 10 min), and hypoxia (peripheral capillary oxygen saturation <95%) were recorded and analyzed [7].

Hospital stays

A hospital stay was defined as the period from admission for delivery to discharge.
Table 1. Demographic and clinical characteristics and educational status of pregnant women at the time of admission and neonatal parameters.

| Characteristic            | 392 (91) | 115 (32) | 109 (27) | 168 (35) |
|---------------------------|----------|----------|----------|----------|
| **Age (years)**           | Minimum  | 20       | 20       | 21       |
|                           | Maximum  | 41       | 39       | 41       |
|                           | Mean±SD  | 30.36±5.48 | 30.42±4.45 | 29.47±6.41 | 31.08±4.55 |
| **Gestational age (weeks)** | Minimum  | 30       | 32       | 30       |
|                           | Maximum  | 42       | 40       | 39       |
|                           | Mean±SD  | 35.15±2.46 | 35.89±2.11 | 35.38±3.15 | 34.96±4.15 |
| **Ethnicity**             | Han Chinese | 358 (91) | 103 (90) | 100 (92) | 155 (92) |
|                           | Mongolian | 30 (8)   | 11 (9)   | 8 (7)    | 11 (7)   |
|                           | Tibetan  | 4 (1)    | 1 (1)    | 1 (1)    | 2 (1)    |
| **Maternal height (cm)**  | Minimum  | 158      | 160      | 159      |
|                           | Maximum  | 166      | 165      | 166      |
|                           | Mean±SD  | 161.53±5.14 | 161.15±5.41 | 162.37±4.49 | 160.95±5.48 |
| **Maternal weight (kg)**  | Minimum  | 50       | 50       | 51       |
|                           | Maximum  | 60       | 59       | 58       |
|                           | Mean±SD  | 54.95±3.25 | 55.15±3.12 | 54.89±2.55 | 54.88±4.15 |
| **Body mass index (kg/m²)** | Minimum  | 21.12±0.15 | 20.51±0.11 | 21.35±0.11 | 21.12±0.15 |
|                           | Maximum  | 23.12±0.78 | 22.75±0.95 | 22.95±0.88 | 23.12±0.86 |
|                           | Mean±SD  | 22.11±0.32 | 22.05±0.51 | 22.15±0.48 | 22.21±0.61 |
| **Educational status**    | Elementary school | 199 (51) | 54 (47) | 57 (52) | 88 (52) |
|                           | Undergraduate | 133 (34) | 37 (32) | 38 (35) | 58 (35) |
|                           | Graduate and above | 60 (15) | 24 (21) | 14 (13) | 22 (13) |
| **History**               | Nullipara | 362 (92) | 97 (92) | 100 (92) | 155 (92) |
|                           | Primipara  | 26 (7)   | 7 (7)    | 8 (7)    | 11 (7)   |
|                           | Multipara  | 4 (1)    | 1 (1)    | 1 (1)    | 2 (1)    |
| **Uterine scar**          | Yes        | 252 (64) | 72 (63) | 71 (65) | 109 (65) |
|                           | No         | 140 (36) | 43 (37) | 38 (35) | 59 (35) |
Statistical analysis

SPSS v25.0 (IBM, Inc., New York, NY, U.S.A.) was used for statistical analysis. Data are shown as a frequency (percentage) and continuous and ordinal data as mean±SD. One-way analysis of variance (ANOVA) [2] was performed on continuous data and Fisher’s exact test [7] was performed on constant and ordinal data. Tukey’s test (with a critical value q>3.326) was performed for post hoc analysis. The sample size was calculated on the basis of 80% power and a 5% margin of error [2]. All results were considered significant at a 95% confidence level.

Results

Study population

From January 1, 2019 to December 15, 2019, 1198 women underwent delivery at 30 to 42 weeks’ gestation in the Department of Obstetrics of the School of nursing and health, Zhengzhou University, Zhengzhou, Henan, China and the Second Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China. Of them, 7 had emergency cesareans, 585 gave birth vaginally, and 1 woman reported having an α-2 receptor agonist allergy. In 51 women, obstetricians used analgesia before delivery and 162 women did not receive spinal anesthesia, based on a decision by an anesthesiologist in consultation with an obstetrician. Therefore, data on the previously described women were excluded from the analysis.

Data from 392 women were included in the analysis who received spinal anesthesia, did not receive predelivery analgesia, and underwent elective cesarean delivery based on a decision made by an obstetrician (Figure 1). The women were ages 20 to 41 years and the average gestational age was 35.15±2.46 weeks. The majority of women in the study were primiparous (362/392). Table 1 lists the demographic characteristics, clinical conditions, and educational status of the women at the time of their admissions.

Pain measurement

The same VAS score for pain was recorded in women in all of the cohorts during rest immediately after delivery (P=0.118). At 6 h after delivery, while resting, women in the DX cohort had significantly less pain than those in the SC cohort (P<0.0001, q=4.263) or the CN cohort (P<0.0001, q=7.064). While resting 6 h later, the women in the DX cohort (P<0.0001, q=8.437) and those in the SC cohort (P<0.0001, q=3.632) had significantly less pain than the women in the CN cohort. One day after delivery,
while resting, women in the DX cohort (P<0.0001, q=10.804) and in the SC cohort (P<0.0001, q=6.715) had significantly less pain than those in the CN cohort. Figure 2 lists detailed data about pain while resting after delivery in the patients.

One day after delivery, the women in the DX cohort had significantly less pain during uterine contractions than those in the CN cohort (P<0.0001, q=9.569) or the SC cohort (P<0.0001, q=6.931). Table 2 lists detailed data about pain during uterine contractions after delivery in the patients.

The women in the DX cohort also had significantly less pain on movement 1 day after delivery than those in the CN cohort (P<0.0001, q=8.460) or the SC cohort (P<0.0001, q=5.106). Table 3 lists detailed data about pain on movement after delivery in the patients.

Pain management

The women in the DX cohort received significantly less sufentanil during their hospitalizations than those in the SC cohort (151.45±11.15 μg vs. 175.12±25.15 μg, P<0.0001, q=8.776) or in the CN cohort (151.45±11.15 μg vs. 185.42±37.45 μg, P<0.0001, q=13.911). The women in the SC cohort received significantly less sufentanil before discharge than those in the CN cohort (P<0.0001, q=4.151, Figure 3).

Management of nausea and vomiting

The women in the DX cohort received significantly less ondansetron before discharge than those in the SC cohort (6.15±1.14 mg/woman vs. 7.52±2.14 mg, P<0.0001, q=6.016) or in the CN cohort (6.15±1.14 mg vs. 9.12±3.11 mg, P<0.0001, q=14.404). The women in the SC cohort received significantly less ondansetron before discharge than those in the CN cohort (P<0.0001, q=7.636, Figure 4).

Table 2. Measurement of pain during uterine contractions.

| Time after delivery | DX cohort (n=115) | SC cohort (n=109) | CN cohort (n=168) |
|---------------------|------------------|------------------|------------------|
| Immediately after delivery | 1.75±0.22 | 1.77±0.24 | 1.81±0.26 |
| 6 h after delivery | 3.47±0.24 | 3.55±0.26 | 3.51±0.28 |
| 12 h after delivery | 3.42±0.29 | 3.48±0.29 | 3.52±0.41 |
| 1 day after delivery | 2.23±0.15* | 2.31±0.17 | 2.38±0.21 |

Data are shown as mean±SD. One-way analysis of variance was performed followed by Tukey’s post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. * Significantly less than in the CN cohort.
**Table 3. Measurement of pain during movement.**

| Treatment cohorts | DX: Dexmedetomidine before and during delivery + normal saline after delivery | SC: Normal saline before and during delivery + dexmedetomidine after delivery | CN: Normal saline before, during, and after delivery |
|-------------------|------------------------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------|
| No. women included | 115                                                                          | 109                                                                       | 168                                                 |

| Time after delivery | DX vs. SC | DX vs. CN | SC vs. SN |
|---------------------|-----------|-----------|-----------|
| Immediately after delivery | 2.01±0.18 | 2.04±0.17 | 2.08±0.31 | 0.054      | N/A        | N/A        | N/A        |
| 6 h after delivery   | 4.15±0.18 | 4.19±0.17 | 4.21±0.32 | 0.135      | N/A        | N/A        | N/A        |
| 12 h after delivery  | 3.52±0.24 | 3.59±0.25 | 3.60±0.33 | 0.054      | N/A        | N/A        | N/A        |
| 1 day after delivery | 3.41±0.25*| 3.53±0.26 | 3.59±0.24 | <0.0001    | 5.106      | 8.460      | 2.775      |

Data are shown as mean±SD. One-way analysis of variance was performed followed by Tukey’s post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. N/A – not applicable. * Significantly less than in the CN cohort.

![Figure 3. Management of pain.](image1)

![Figure 4. Management of nausea and vomiting.](image2)

**Figure 3.** Management of pain. Data are shown as mean±SD. One-way analysis of variance was performed after Tukey’s post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. * Significantly less than in the CN cohort. # Significantly less than in the SC cohort. When a patient’s VAS score was >3 during rest, an injection of 50 μg of sufentanil was administered.

**Figure 4.** Management of nausea and vomiting. Data are shown as mean±SD. One-way analysis of variance was performed after Tukey’s post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. * Significantly less than in the CN cohort. # Significantly less than in the SC cohort. An injection of 4 mg of ondansetron was administered for nausea and vomiting.
Treatment cohorts

DX: Dexmedetomidine before and during delivery + normal saline after delivery
SC: Normal saline before and during delivery + dexmedetomidine after delivery
CN: Normal saline before, during, and after delivery

Table 4. Other maternal outcomes after delivery.

|                | DX cohort (n=115) | SC cohort (n=109) | CN cohort (n=168) | P values |
|----------------|------------------|------------------|------------------|---------|
| No. women included | 115              | 109              | 168              |         |
| Adverse effects |                  |                  |                  |         |
| Hypertension    | 3 (3)            | 7 (6)            | 11 (7)           | 0.297   |
| Hypotension     | 5 (4)            | 9 (8)            | 14 (8)           | 0.119   |
| Bradycardia     | 4 (3)            | 7 (6)            | 9 (5)            | 0.594   |
| Tachycardia     | 1 (1)            | 2 (2)            | 3 (2)            | 0.789   |
| Respiratory depression | 1 (1)        | 1 (1)            | 2 (1)            | 0.958   |
| Hypoxia         | 1 (1)            | 1 (1)            | 2 (1)            | 0.958   |
| Wound sepsis    | 1 (1)            | 1 (1)            | 2 (1)            | 0.958   |
| Dry mouth       | 5 (4)            | 7 (6)            | 18 (11)          | 0.121   |
| Death           | 0 (0)            | 0 (0)            | 1 (1)            | 0.513   |
| Total adverse characteristics | 21 (18)         | 35 (32)          | 62 (37)          | 0.998   |

Data are shown as frequencies (percentages). Fisher's exact test was performed for statistical analysis. P<0.05 was considered significant. Hypertension was defined as systolic blood pressure >180 mmHg. Hypotension was defined as systolic blood pressure <90 mmHg. Bradycardia was defined as heart rate <50 beats per min. Tachycardia was defined as heart rate >110 beats per min. Respiratory depression was defined as a respiratory rate 10 times/min lasting for >10 min. Hypoxia was defined as peripheral capillary oxygen saturation <95%.

Figure 5. Time to first lactation. Data are shown as mean±SD. One-way analysis of variance was performed after Tukey's post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. * Significantly less than in the CN cohort. # Significantly shorter than in the SC cohort. Time to first lactation was defined as the period from delivery to when at least 10 mL of milk flowed from both breasts.

Figure 6. Hospital length of stay. Data are shown as mean±SD. One-way analysis of variance was performed after Tukey's post hoc test for statistical analysis. P<0.05 and q>3.326 were considered significant. * Significantly less than in the CN cohort. # Significantly shorter than in the SC cohort. A hospital stay was defined as the time from admission for delivery to discharge.
First lactation time

Time to first lactation was significantly shorter in the women in the DX cohort than in those in the SC cohort (25.12±3.12 min vs. 27.45±2.12 min, P<0.0001, q=10.592) or in the CN cohort (25.12±3.12 min vs. 28.08±1.75 min, P<0.0001, q=14.863, Figure 5).

Maternal outcome after delivery

Incidence of adverse hemodynamic adverse events were the same in all of the study cohorts (P=0.998, Table 4).

Hospital stays

Women in the DX cohort had significantly shorter hospital stays than those in the SC cohort (3.01±0.15 days vs. 3.51±1.15 days, P<0.0001, q=3.964) or the CN cohort (3.01±0.15 days vs. 3.85±1.81 days, P<0.0001, q=7.356, Figure 6).

Discussion

Administration of dexmedetomidine before and during cesarean delivery resulted in less pain post-delivery in women during rest, uterine contractions, and while moving compared with post-delivery administration of normal saline combined with sufentanil. These outcomes parallel those reported in randomized trials [2,11]. Administration of dexmedetomidine before anesthesia has been shown to decrease post-delivery pain due to an opioid-sparing effect [7]. In the present study, post-delivery administration of dexmedetomidine combined with sufentanil resulted in less post-delivery pain at during rest in the SC cohort than was seen in the CH cohort with post-delivery administration of normal saline combined with sufentanil. These results also parallel those reported in randomized trials [4,7,12]. Post-delivery administration of dexmedetomidine with sufentanil has been shown to decrease pain associated with delivery [2]. The results of the present study suggest that dexmedetomidine may enhance the analgesic effect of sufentanil in the setting of cesarean delivery.

Women in the DX cohort received less sufentanil and ondansetron before discharge than those in the SC and CN cohorts. Those results parallel outcomes reported in some [2,5,7] but not all randomized trials [4]. The smaller sample size in the present study may be the reason for the contradictory results. Dexmedetomidine administration has been shown to decrease requirements for sufentanil [2,7]. The drug’s α-receptor agonist action reduces nausea and vomiting [7] by reducing the minimum alveolar concentration of anesthetics [5]. Dexmedetomidine also reduces the need for administration of sufentanil, which can cause nausea and vomiting [6,7]. Dexmedetomidine administration may decrease nausea and vomiting after cesarean delivery.

Time to first lactation was shorter in women who received dexmedetomidine before and during delivery, but not in the same was not true in those who received the drug after delivery. Those results are consistent with reports from randomized trials [2,4,7]. Stress caused by delivery increases release of dynorphin and dopamine, which decreases release of prolactin and delays time to first lactation [2]. Therefore, time to first lactation is delayed in women who undergo cesarean delivery [13]. Dexmedetomidine improves time to first lactation by decreasing depression after delivery [14]. Because plasma dexmedetomidine levels were no higher in the women in the SC cohort than in those of the DX cohort, time to first lactation was not lengthened in the former cohort [4,7]. Difficulty in breastfeeding that is associated with cesarean delivery may be overcome by administering dexmedetomidine before and during delivery.

In the present study, there were no differences in hemodynamic parameters among the cohorts. These results parallel those reported in randomized trials [2,4,5,7] and in a prospective, observational study [5]. Administration of dexmedetomidine before delivery is safe for maternal health but further research is required to study its effects on neonates.

Hospital stays were shortest in the women who received dexmedetomidine before and during delivery. Long hospital stays are correlated with poor recovery in women who undergo cesarean delivery [16] and administration of dexmedetomidine before the procedure improves quality of life in these patients.

The present study has several limitations, the most important being that the analysis was retrospective and there was no randomization. The sample size was calculated on the basis of maternal outcomes rather than outcomes of hemodynamic parameters. Emergency cesarean deliveries were excluded and only data from elective cesarean deliveries were included. Data regarding milk volume during hospital stays were not evaluated. Dexmedetomidine is a highly selective α2-receptor agonist and has anti-sympathetic, sedative, and analgesic effects. The reduction in the amount of sufentanil administered, from 175 μg to 150 μg, was not clinically significant because it did not amount to a difference equal to eliminating a full dose. The difference in time to lactation of 25 min versus 27 min also was statistically but not clinically significant. A number of confounders were introduced into the study, such as use of nicardipine, esmolol, and paracetamol, which were not addressed. The present study was conducted at a single maternity unit in China with established clinical protocols and methods of patient assessment, such as not using the Ramsay sedation score. In addition, the effects of dexmedetomidine on...
neonates were not evaluated. Most of the women in the study (362/392) were primiparous; therefore, they may have been more sensitive to pain than multiparas. Further studies of dexmedetomidine should be conducted with subgroup analysis.

Conclusions

Administration of dexmedetomidine combined with sufentanil can decrease post-caesarean pain, nausea, and vomiting, and help stimulate lactation, particularly if the drugs are given before the procedure. This treatment decreases lengths of hospital stays. Administering dexmedetomidine before spinal anesthesia is safe for women undergoing cesarean delivery.

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Conflict of interest

None.

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