Adding dexmedetomidine to morphine-based analgesia reduces early postoperative nausea in patients undergoing gynecological laparoscopic surgery: A randomized controlled trial

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Abstract

Purpose: Few studies have investigated the effect of dexmedetomidine on postoperative nausea and vomiting (PONV) in patients following gynecological laparoscopic surgery. We investigated if adding dexmedetomidine to a morphine-based patient-controlled analgesia (PCA) could reduce the incidence of PONV in this patient population. Methods: In this double-blind randomized-controlled trial,122 patients undergoing gynaecological laparoscopic surgery were randomly allocated to receive either a mixture of dexmedetomidine 1μg ml-1 and morphine 0.5mg ml-1 (Group Dex) or morphine 0.5mg ml-1 alone (Group Ctrl) for postoperative i.v. PCA. PCA pump was programmed as followed: bolus dose 2ml, lockout interval 8 minutes and background infusion at a rate of 1ml h-1. The primary outcome was the incidence of nausea and vomiting within 24 hours after operation. Results: The incidence of nausea and total PONV during the first 2h period was significantly lower in the Group Dex than in the Group Ctrl (10% vs 25%, P=0.031 and 0.031, respectively). There were no significant differences in regard to the total incidence of PONV (41% vs 52%, P=0.204), PONV score, time to first onset of PONV, or the need for rescue antiemetics in the first 24 hr following surgery between the two groups. Conclusions: For female patients undergoing gynecological laparoscopic surgery, adding dexmedetomidine to morphine-based PCA reduced the incidence of early postoperative nausea but not total PONV within 24h after surgery.

Background

Postoperative nausea and vomiting (PONV) is an unpleasant experience and distressing adverse events after general anesthesia, especially in the first 24 postoperative hours [1]. Patients after gynecological surgery are at particularly high risk and the incidence of PONV could even be as high as 80% in this population [2-3]. The Society for Ambulatory Anesthesia consensus guidelines recommended combination antiemetic therapy in high-risk patients population and adoption of prophylactic strategies to reduce the baseline risk of PONV [1]. Opioid-sparing technique is an integral part of enhanced recovery after major gynecological surgery protocol, because it not only reduces PONV but also decreases other opioid-related side effects that can have an influence on patients' recovery, such as sedation and postoperative ileus [4].

Dexmedetomidine is a highly selective α2-adrenoreceptor agonist which has sedative, anxiolytic, analgesic, sympatholytic properties and minimal depression of respiratory function. Due to benefits such as maintaining haemodynamic stability, reducing opioid consumption and improving the quality of recovery, it has been widely used in clinical anesthesia, postoperative analgesia and sedation in the intensive care unit [5]. Two meta-analyses demonstrated that intraoperative dexmedetomidine significantly lowered postoperative pain score and opioid consumption, and this could lead to a reduced opioid-related adverse events including PONV [6-7].

In our previous study, we demonstrated that intraoperative supplemental use of dexmedetomidine resulted in a lower incidence of nausea during the first 2 h postoperatively for patients undergoing gynecological laparoscopic surgery [8]. Other studies about susceptible patients who underwent

gynecological laparoscopic surgery were also focused on the intraoperative use of dexmedetomidine other than adding dexmedetomidine to patient-controlled analgesia (PCA) regimen [9-12].

A recent study found that adding dexmedetomidine to a fentanyl-based PCA reduced the frequency and severity of postoperative nausea during the time interval 1 to 3h postoperatively in patients underwent lumbar spinal surgery [13].

Thus, in this prospective, randomized, double-blind study, we aimed to evaluate the efficacy of adjunctive dexmedetomidine to morphine-based analgeia for PONV prophylaxis in women undergoing elective gynecological laparoscopic surgery. Our primary hypothesis was that adding dexmedetomidine to a morphine-based PCA would reduce PONV in this patient population in comparison to only morphine-based PCA.

Methods

This prospective, randomized, double-blind clinical trial was performed between August 2018 to December 2018 at Peking University First Hospital. The trial was registered at Chictr.org.cn, Number ChiCTR 1800017172, on July 16 2018, http://www.chictr.org.cn/usercenter.aspx. Ethical approval for this study was provided by the Ethics Committee of Peking University First Hospital, Peking, China (Number 2018-130, principal investigator: Zhi Yu Geng) on 25 July 2018. Written informed content was obtained from all patients before enrollment.

Participants selection

We used the methodology previously described by our recent study [8]. Participant screening was performed the day before surgery. The inclusion criteria were: (1) female patients; (2) age between 18 and 65 years old; (3) scheduled for elective laparoscopic myomectomy or laparoscopy-assisted vaginal hysterectomy. Patients who met any of the following criteria were excluded: (1) American Society of Anesthesiologists physical status > II before surgery, (2) previous history of schizophrenia, Parkinson's Disease, epilepsy and myasthenia gravis, (3) unable to communicate due to comma, dementia and other diseases, (4) obesity defined as BMI (body mass index) > BMI > 30kg m^{-2}, (5) known sick sinus syndrome, severe bradycardia (heart rate < 50 beats per minute), or severe atrioventricular block without pacemaker before surgery, (6) pre-existing of severe hepatic disease (Child-Pugh class C), (7) pre-existing of chronic renal failure (receive renal replacement therapy preoperatively), (8)Neo-adjuvant chemoradiotherapy before surgery, (9) alcoholism or drug abuse, (10) any regimen of antiemetic, glucocorticoids or psychotropic drugs which are known to have an influence on the occurrence of PONV within 24h before surgery.

Randomisation and drug administration

Random numbers were generated by computer software in a 1:1 ratio. Patients were randomized to receive morphine 0.5mg ml^{-1} with or without dexmedetomidine 1μg ml^{-1}.Study drugs were prepared

according to the randomization results by a study coordinator. Anesthesiologist and the investigator responsible for the study outcomes assesssment were blinded.

For patients in the dexmedetomidine group (Group Dex), an initial loading dose of 0.4μg kg^{-1} dexmedetomidine was given by intravenous infusion 0.5 hour before the end of surgery. PCA was begun with 0.5mg ml^{-1} morphine plus 1μg ml^{-1} dexmedetomidine in 100 ml normal saline. While for patients in the control group (Group Ctrl), normal saline was given 0.5 hour before the end of surgery, and PCA was begun with 0.5mg ml^{-1} morphine in 100 ml normal saline. For all patients, PCA was programmed to deliver a 2ml bolus on-demand with a lockout time of 8 minutes and a background infusion at a rate of 1 ml h^{-1}.

The investigator assessing patients outcomes was blinded to group assignment and blinding was maintained throughout the study period.

Anesthesia and perioperative care

No pre-medication was administered before induction. Routine monitoring included non-invasive blood pressure, pulse oximetry, electocadiogram, Bispectral index and end-tidal carbon dioxide partial pressure were applied intraoperatively.

All patients received dexamethasone 5mg before induction. General anesthesia was induced intravenously with 0.03mg kg^{-1} midazolam, 2 mg kg^{-1} propofol, and target controlled infusion of remifentanil with an effect-site concentration of 3ng ml^{-1}. Rocuronium was administered to facilitate laryngeal mask airway insertion. Total intravenous anesthesia was provided with propofol and remifentanil. Bispectral index was maintained between 40 and 60 during surgery and blood pressure was adjusted within ±20% from baseline. Mechanical ventilation was maintained with a mixture of oxygen and air (FiO_2 0.5) and an end-tidal carbon dioxide partial pressure was adjusted between 4.6 and 7.3 kilopascals intraoperatively. Lactated Ringer's solution was infused at a rate of 6 ml kg^{-1} h^{-1} throughout the surgery.

Morphine 0.1mgkg^{-1} and parecoxib sodium 40mg were administered 0.5 hour before the end of surgery. Residual neuromuscularblock was reversed with neostigmine (0.04mg kg^{-1}) and atropine (0.02mg kg^{-1}) at the end of the surgery.

Upon completion of surgery, laryngeal mask airway was removed and the patient was transferred to the post-anesthesia care unit (PACU) for one hour monitoring . The patient-controlled analgesia pump was started and continued until 24h after surgery.

Data collection

Data were collected by research personnel who were blinded to the randomization and not involved in the clinical care. The 24h observation period started at the time of removal of the laryngeal mask airway. The

researcher assessed the patients at 2, 6 and 24h postoperatively. Baseline characteristics of patients such as previous history of PONV, chronic smoking, primary risk score for PONV, co-existing systemic diseases and concurrent medication were recorded. Intra-operative parameters including duration of anesthesia and surgery, doses of anesthetics and analgesics, and total fluid administered were collected. Postoperative data including presence and severity of nausea and vomiting, visual analogue scale (VAS) pain scores, the cumulative dose of PCA morphine, requirement for rescue antiemetics, vital signs, sedation scores, and any adverse events were documented.

Outcome measures

The primary outcome was the incidence of PONV over the first 24h postoperative hours. Patients who experienced at least one episode of nausea, vomiting or retching or any combination of these during the first 24 h after surgery were considered to have PONV. Patients were asked to rate their degree of nausea using a four-point scale (0=none, 1=mild, 2=moderate, 3=severe) [14-15]. Postoperative vomiting was defined as at least one episode of vomiting or retching and the PONV score was rated as 4. Tropisetron 5mg was used as the rescue antiemetic. Rescue antiemetics were administered on the following conditions: two or more episodes of vomiting or retching, any nausea lasting for more than 30 min, a 'severe' degree of nausea or whenever treatment was requested by the patient.

The secondary outcomes included the VAS scores at 2, 6 and 24 h after surgery, the total 24 h morphine consumption, and the occurrence of adverse events during PACU stay. Pain intensity was assessed at PACU, 2 h, 6 h and 24 h postoperatively using an 11-point VAS on which 0 indicated no pain and 10 indicated the worst pain imaginable. In the PACU, supplemental morphine bolus of 2mg i.v. was administered for moderate pain (VAS≥4). Sedation levels were assessed using the Ramsay sedation scale (1=agitated and uncomfortable, 2=co-operative and orientated, 3=can follow simple directions, 4=asleep but strong response to stimulation, 5=asleep and slow response to stimulation and 6=asleep and no response to stimulation). Over sedation was defined as a sedation score ≥ 4 [16]. Agitation was evaluated using the Ricker sedation-agitation scale and emergence agitation was defined as a sedation-agitation score ≥ 5 [17].

Sample size calculation

Study sample size was calculated according to our previous studies [3,8], we estimated an incidence of PONV of 50% in the control group for this patient population. A sample size of 55 patients in each group was needed to detect a 50% reduction in the incidence of PONV (from 50 to 25%) with a power of 80% and a two-sided α error of 0.05. To allow for a possible dropout rate of 10%, we aimed to enrol 61 patients in each group.

Statistical analysis

Categorical data are expressed as number (percentage) and were analysed using the ^{2} test or the Fisher's exact test as appropriate. Continuous data are expressed as means (standard deviation [SD]) or medians

(interquartile range [IQR]) and were analyzed with the unpaired Student's t-test or Mann –Whitney U test as appropriate. A two-sided *P* value less than 0.05 was considered statistically significant. Statistical analysis was performed using the SPSS 22.0 software (SPSS, Inc., Chicago, Illinois, USA).

Results

Between August 2018 and December 2018, a total of 128 patients were enrolled and six patiens were excluded from the analysis. As a result, 122 patients completed the study: 61 in each group, a flowchart is shown in Fig.1. There were no significant differences with regard to patient's baseline characteristics and perioperative data including risk scores of PONV, durations of anesthesia and surgery, propofol and remifentanil doses, and intraoperative fluids between the two groups (Table 1,2).

The primary outcome was the incidence of PONV over the first 24h postoperative hours and we found no difference between the two groups (Group Dex *vs* Group Ctrl, 25 (41%) and 32 (52%), *P*=0.204) (Table 3).

We found that the incidence of nausea and total PONV during the first 0-2h after surgery was significantly lower in the Group Dex compared with the Group Ctrl (6 (10%) and 15 (25%), *P*=0.031). We did not find any differences in the incidence of nausea, vomiting and total PONV during the 2-6hr and 6-24h, PONV score, time to first PONV and the requirement of rescue antiemetics between two groups (Table 3).

The total consumption of morphine during 6-24h after surgery was significantly less in the Group Dex than in the Group Ctrl (*P*=0.009), but the cumulative consumption of morphine for the total 24h after surgery was not significantly different between the groups. The percentage of over sedation and bradycardia during the PACU stay was significantly higher in the Group Dex than in the Group Ctrl (*P*=0.040 and 0.036, respectively). There were no differences between the two groups regarding VAS score at every time point, the incidence of shivering, agitation and requiring rescue analgesic in the PACU (Table 4,5).

Discussion

Our study showed that for patients underwent gynecological laparoscopic surgery, adding dexmedetomidine to a morphine-based PCA decreased the incidence of nausea in the first 2 h postoperatively. Although adding dexmedetomidine to PCA decreased morphine consumption between 6 and 24 h, there was no difference regarding the incidence of PONV in this period between groups. Thus, no difference was found in the incidence of 24-hour PONV between the groups.

Intraoperative dexmedetomidine administration decreases postoperative pain intensity and opioids consumption compared with placebo. This opioid-sparing effect might lead to a reduction of opioid-related adverse events including PONV [6-7]. Adding dexmedetomidine to PCA seemed to have some beneficial effects on preventing PONV as well. Du and colleagues [18] used intravenous 0.5μg kg^{-1} dexmedetomidine as a loading dose and followed by continuous infusion as an adjunct to butorphanol PCA in patients undergoing total laparoscopic hysterectomy. Their result showed that dexmedetomidine

administration provided effective analgesia, significant butorphanol sparing and less nausea and vomiting. Another study investigated the effect of dexmedetomidine alone for intravenous PCA after gynecological laparoscopic operation. It was found that dexmedetomidine alone was effective for postoperative pain control and the incidence of PONV was significant lower in the Dex group [19].

In our present study, we chose the incidence of first postoperative 24h PONV as primary endpoint and demonstrated that dexmedetomidine combined with morphine only reduced early nausea of the first 2 h postoperatively. We suppose that the relatively low consumption of dexmedetomidine and morphine in this minimally invasive surgery may be responsible for the result. During the 24 h postoperative period, the cumulative PCA morphine consumption was 14.1 (1.8) mg and 14.3 (2.1) mg respectively. In Lin and colleagues' study [20], they investigated the effect of combining dexmedetomidine and morphine PCA in patients undergoing total abdominal hysterectomy. They demonstrated that patients receiving dexmedetomidine consumed 29% less PCA morphine and confirmed the analgesic effect of dexmedetomidine in clinical pain therapy. Since laparotomy surgery is more painful than laparoscopic surgery, the overall 24h doses of PCA morphine were 23.3 (10) mg and 32.8 (12.4) mg respectively in their study. And the total 24h dose of 28.2(3.5) μg dexmedetomidine in our study was much lower than their 116.5 (50) μg dose.

In our previous research about this PONV susceptible patient population, we found that intraoperative use of dexmedetomidine reduced the incidence of early nausea but not vomiting within 24h after gynecological laparoscopic surgery [8]. While in this subsequent trial, we focused on the preventive efficacy of postoperative dexmedetomidine when added to morphine PCA and obtained a similar result. The consistent result might be attributed to the initial loading dose of dexmedetomidine before the end of the surgery, since its terminal half-life is about 2h.

Song and colleagues [13] investigated the effect of combining dexmedetomidine and fentanyl analgesia in patients undergoing lumbar spinal surgery. They found that the Dex group experienced less nausea during 1 to 3 h postoperatively and the intensity of nausea was was similar between groups during the first 48 h. Although less PCA fentanyl was required in the Dex group up to 12 h, there was no statistical significance in the incidence of vomiting between the groups. In addition, in our study, although the cumulative consumption of morphine during 6-24 h after surgery was statistically greater in the Group Ctrl, the incidence of nausea and vomiting was not significantly different between the groups. Since postoperative opioid is one of the primary drivers of PONV, it appears that the intensity of opioid-sparing effect of dexmedetomidine might be crucial to decreasing nausea and vomiting.

The stimulation of nausea and vomiting originates from the inputs of visceral, vestibular and chemoreceptor trigger areas, which are mediated by serotonin, dopamine, histamine and acetylcholine, respectively. Nauseogenic stimulus activates nucleus suchas amugdala, putamen and locus coeruleus, which converted into fear conditioning and emotional triggering. This eventually leads to a strong sensation of nausea [21]. In our study, dexmedetomidine showed some weak and short-lived anti-nausea effect that may be explained by the properties of α2 agonist. As PONV may be triggered by high

catecholamine concentration, it may produce a direct anti-nausea effect through activating the α2-adrenoceptor and decreasing sympathetic tone. Furthermore, dexmedetomidine has concentrate dependent sedative and hypnotic effects that mediated through activation of central α2-receptors in the locus coeruleus. The sedative property might be involved in reduing nausea just as benzodiazepines since in our research more patients in the Group Dex were over sedated during the PACU stay.

Dexmedetomidine may increase the risk of postoperative bradycardia [6]. When dexmedetomidine combined with sufentanil PCA was used in patient undergoing radical gastrectomy, the incidences of oversedation and bradycardia increased significantly and these side effects were dose-dependent [22]. Despite the low dose regimen of dexmedetomidine in our study, the percentage of patients who experienced bradycardia and over sedation in PACU was significantly higher in the Group Dex. Thus, when determine the optimal dose of dexmedetomidine for postoperative analgesia, the potential increased risk of significant hypotension, bradycardia, respiratory depression and over sedation should be balanced against the maximal beneficial analgesic effect.

There are several limitations of this study. First, in our study PCA was programmed to deliver bolus with a background basal infusion of morphine with or without dexmedetomidine. This continuous infusion dose of morphine might have masked the difference of opioid demands between groups. Second, we only chose one dose and the concentration of dexmedetomidine (1μg ml^{-1}) was relatively small in PCA. Further dose finding studies of dexmedetomidine are required to confirm the optimal efficacy and safety outcomes for these PONV susceptible patients.

Conclusions

In conclusion, adding dexmedetomidine to morphine-based PCA could reduce the incidence of early nausea but not total PONV within the first 24h after surgery in patiens undergoing gynecological laparoscopic surgery.

Abbreviations

PONV : Postoperative nausea and vomiting; PCA: Patient-controlled analgesia;

PACU: Post-anesthesia care unit; VAS: Visual analogue scale

Declarations

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Author's contributions

Study design and supervision: Z.Y. G, H.J. L

Data collection: S.L

Data analysis:Z.Y. G, X.Y.L

Drafting/ writing paper: H.J. L

Revising manuscript: Z.Y.G

Final approval of manuscript: all authors

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Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to patient confidentiality but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Ethics Committee of Peking University First Hospital approved the study protocol (Number 2018-130). Written informed consent was obtained from each recruited parturient after providing them with adequate explanations regarding the aims of this study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1.Clinical characteristics (n=61)

	Group Dex	Group Ctrl	*P* value
Age (years)	44.0 (8.1)	44.2 (8.4)	0.896
Height (cm)	161.3 (5.8)	160.6 (5.5)	0503
Weight (kg)	61.0 (8.8)	60.8 (8.8)	0.885
BMI (kg m^{-2})	23.5 (3.1)	23.5 (2.8)	0.872
ASA status I/II (n)	34/27	31/30	0.586
Smoking (n/%)	3 (5)	3 (5)	1.000
History of motion sickness (n/%)	19 (31)	22 (36)	0.565
History of PONV (n/%)	4 (7)	7 (11)	0.343
Risk score for PONV (n/%)			0.492
1	0	0	
2	3 (5)	1 (2)	
3	38 (62)	36 (57)	
4	20 (33)	24 (41)	
Average number of risk scores	3.3 (0.6)	3.4 (0.5)	0.679

Data are presented as mean (SD) or n (%). BMI: body mass index.

PONV: postoperative nausea and vomiting.

Dex: dexmedetomidine, Ctrl:control.

Table 2.Comparison of intraoperative variables (n=61)

	Group Dex	Group Ctrl	*P* value
Duration of anaesthesia(min)	133 (59)	131 (52)	0.837
Duration of surgery(min)	112 (59)	112 (49)	0.969
Intraoperative propofol($mg \cdot kg^{-1} \cdot h^{-1}$)	5.4 (1.2)	5.4 (0.8)	0.784
Intraoperative remifentanil ($\mu g \cdot kg^{-1} \cdot h^{-1}$)	7.3 (1.4)	7.1 (1.2)	0.367
Intraoperative fluids (ml)	1285 (433)	1239 (417)	0.545

Data are presented as mean (SD)

Dex: dexmedetomidine, Ctrl:control

Table 3. Comparison of overall postoperative nausea and vomiting outcomes (n=61)

	Group Dex	Group Ctrl	*P* value
Nausea (n/%)			
0-2hr	6(10)	15(25)	0.031
2-6hr	7(11)	11(18)	0.307
6-24hr	21(34)	17(28)	0.434
Vomiting (n/%)			
0-2hr	3(5)	6(10)	0.488
2-6hr	3(5)	5(8)	0.715
6-24hr	8(13)	7(11)	0.809
PONV (n/%)			
0-2hr	6 (10)	15 (25)	0.031
2-6hr	7 (11)	13 (21)	0.142
6-24hr	20 (33)	17 (28)	0.555
Total 24h PONV (n/%)	25 (41)	32 (52)	0.204
PONV score	0 (0, 2.5)	1 (0, 4)	0.226
Time to first PONV (hr)	0(0,4)	0.5(0,3)	0.430
Rescue antiemetics (n/%)	7(11)	10(16)	0.433

Data are presented as mean (SD), median (lower quartile, upper quartile) or n (%).

Dex: dexmedetomidine, Ctrl:control.

PONV: postoperative nausea and vomiting.

Table 4.Comparison of PCA morphine consumption and adverse events in PACU (n=61)

	Group Dex	Group Ctrl	*P* value
VAS at PACU	2 (1,3)	2 (2,3)	0.442
VAS at 2h	2 (1,3)	2 (1,3)	0.498
VAS at 6h	1 (0,1)	1 (0,1)	0.800
VAS at 24h	0 (0,1)	0 (0,1)	0.191
Total morphine consumption (mg)			
0-2h	2.8 (1.5)	2.8 (1.5)	0.907
2-6h	2.3 (0.6)	2.2 (0.6)	0.280
6-24h	9.0 (0.1)	9.3 (1.3)	0.009
0-24h	14.1 (1.8)	14.3 (2.1)	0.524
Use of rescue analgesic (n/%)	10 (16)	9(15)	0.803

Data are presented as mean (SD) or n (%).

Dex: dexmedetomidine, Ctrl:control.

PCA: patient controlled analgesia, PACU: postanaesthesia care unit.

Table 5 Adverse events in PACU (n=61)

	Group Dex	Group Ctrl	*P*value
Hypertension (n/%)	2 (3)	2 (3)	0.611
Hypotension (n/%)	0	1 (2)	1.000
Respiratory depression (n/%)	0	0	
Bradycardia (n/%)	6(10)	0(0)	0.036
Agitation (n/%)	1(2)	3(5)	0.611
Over sedation (n/%)	10 (16)	3 (5)	0.040
Shivering (n/%)	7 (11)	10 (16)	0.433

Data are presented as n (%).

Dex: dexmedetomidine, Ctrl:control.

PACU: postanaesthesia care unit.

Supplementary Files

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