A Prospective Randomized Controlled Trial Comparing Dexmedetomidine and Propofol for Sedation and Analgesia for Incision and Drainage Procedure in Lactational Breast Abscess

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ABSTRACT

BACKGROUND

A lactational breast abscess is a localized accumulation of infected fluid in breast tissue, due to which many women stop breastfeeding. Lack of adequate anaesthesia is the most common factor limiting incision and drainage (I & D) in the Emergency Department (ED). The present study was planned to compare the efficacy of dexmedetomidine and propofol among patients undergoing incision and drainage (I & D) for lactational breast abscess.

METHODS

A total of 50 consenting patients in the age group of 18-40 years, American Society of Anaesthesiologists (ASA) I and II undergoing incision and drainage (I & D) of lactational breast abscess were included in the study. The patients were divided into two groups of 25 patients each. Group D received dexmedetomidine and Group P received Propofol. Sedation score, heart rate (HR), systolic blood pressure (SBP), requirement of rescue injection fentanyl, patient satisfaction, surgeon satisfaction and complications were recorded.

RESULTS

Baseline values of the mean heart rate and mean systolic blood pressure were comparable between the groups, but intraoperatively, there was a statistically significant reduction in the mean heart rate and mean systolic blood pressure. There was statistically significant fall in systolic blood pressure in group P [8 (32%) vs 2 (8%)]. There was statistically significant difference in requirement of injection fentanyl in group D [3 (6%) vs 12 (24)]. Both, patient satisfaction and surgeon satisfaction were significantly better in D group when compared to P group. Sedation score and time to achieve adequate RSS was comparable between both the groups.

CONCLUSIONS

Dexmedetomidine seems to be a better drug with minimal haemodynamic instability when compared to propofol.

KEYWORDS

Lactation, Breast, Abscess, Incision, Drainage, Dexmedetomidine, Propofol

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BACKGROUND

The benefits of breast feeding are well known, and the World Health Organization recommends exclusive breastfeeding for the first six months of life and continuing breastfeeding up to 2 years of age. Some women develop a breast abscess while breastfeeding, called a lactational breast abscess. A breast abscess is a localized accumulation of infected fluid in breast tissue. The treatment is to cure the abscess quickly and effectively, ensuring maximum benefit to the mother with minimal interruption of breastfeeding. However, many women stop breastfeeding due to lactational breast abscesses. Presently, lactational breast abscesses are commonly treated with antibiotics, incision and drainage (I & D) or ultrasound-guided needle aspiration, but there is no consensus on the optimal treatment.[1]

Lack of adequate anaesthesia is the most common factor limiting incision and drainage (I & D) in the Emergency Department (ED). In addition to limiting proper drainage, it is unethical to subject a patient to extreme pain when alternatives are available. It is often quite difficult to achieve local anaesthesia by direct infiltration because of the poor function of local anaesthetic agents in the low pH of infected tissue. Furthermore, distension of sensitive structures by a local injection is quite painful and hence poorly tolerated by most patients. Skin anaesthesia is usually possible, but total anaesthesia of the abscess cavity itself cannot generally be achieved. Currently, there is judicious use of preoperative sedation with IV opioids and sedatives or with nitrous oxide makes the procedure easier for both the patient and clinician. Ketamine, propofol, or a combination of these drugs is a popular option in the ED setting.[2]

Dexmedetomidine (Dextomid, Neon Laboratories Ltd, Mumbai, Maharashtra, India) is a centrally acting alpha-2 receptor agonist that can be titrated to the desired level of sedation without significant respiratory depression.[3,4,5] Dexmedetomidine has an analgesic-sparing effect, significantly reducing opioid requirements both during and after surgery.[6,7,8,9] In addition, dexmedetomidine has a sympatholytic effect that can attenuate the stress response to surgery, mitigating tachycardia and hypertension.[7,10] Because of its analgesic properties, "cooperative sedation," and lack of respiratory depression, dexmedetomidine is increasingly being used as a sedative for MAC.[4] There have been several reports on the successful use of dexmedetomidine as the primary sedative drug for orthopaedic, ophthalmic, dental, and plastic surgery, and for diagnostic procedures.[9,10,11]

Propofol (Propofol-Lipuro 1%, B Braun, Melsungen AG, Berlin, Germany) or 2,6-di isopropyl phenol is an intravenous anaesthetic unique in its structure and chemically unrelated to other sedative agents commonly used in sedation. It produces rapid onset of anaesthesia and a quick recovery. Since approval of propofol by the U.S. Food and Drug Administration and subsequent introduction into clinical practice in 1989, its popularity has increased immensely; this has occurred in conventional operating room settings and outside of the operating room.[12] First reported the use of propofol for sedating adult ED patients undergoing relatively short, painful procedures.[13]

Thus, the present study was planned to evaluate the efficacy of dexmedetomidine as analgesic, sedative with its haemodynamic effects among patients undergoing incision and drainage (I & D) for lactational breast abscess. Patient satisfaction, surgeon satisfaction and side effects were the secondary outcome.

METHODS

This prospective randomized single blinded study was carried out on all 50 consenting patients between the ages of 18 yrs. and 40 yrs. and American Society of Anesthesiologists (ASA) I and II, scheduled for incision and drainage (I & D) of lactational breast abscess in the Department of Anaesthesiology at Heema hospital from December 2017 to January 2018. Approval from Hospital Ethics committee was taken, and informed written consent was obtained from all the patients. We excluded patients with history of allergy, drug or alcohol abuse, currently taking sedative or analgesic drugs, American Society of Anesthesiologists (ASA) physical status greater than II, patient refusal to participate/uncooperative patient.

A routine pre-anaesthetic check was done before the surgery. Fasting period of 8 hours for solid food and 2 hours for clear fluids before surgery was advised. In the operation theatre pulse oximeter, non-invasive blood pressure (NIBP), electrocardiogram (ECG) was attached and baseline heart rate (HR), respiratory rate (RR), blood pressure (BP), Spo2 was recorded. A 20 G IV cannula was secured in the dorsum of the hand. An injection ondansetron 0.1 mg/kg was given as premedication to every patient in both the groups. Group D patients received IV inj. Dexmedetomidine 1 µg/kg bolus for 10 minutes followed by continuous infusion at the rate of 0.5 µg/kg/hr till the end of surgery. Group P patients received IV Inj. Propofol 100 µg/kg bolus for 10 minutes followed by infusion at the rate of 50 µg/kg/min till the end of surgery. Patient was maintained on spontaneous ventilation with 50% oxygen and 50% nitrous oxide. The vital parameters such as heart rate, systolic blood pressure (SBP), respiratory rate (RR), SpO_2, Ramsay sedation score (RSS) was observed and recorded. Target sedation level was defined as RSS ≥3. If RSS was less than 3, rescue sedation with propofol 100-300 mcg/kg/hr IV was given. Then surgeon proceeded to perform the surgery. Whenever patient complained of pain during the surgery, fentanyl 1 mcg/kg IV bolus was given as rescue analgesic. After completion of the surgery patients were shifted to the recovery room. 'How would you rate your experience with the sedation (or analgesia) you have received during surgery?' using a 7-point Likert verbal rating scale. This assessment of patient's satisfaction with sedation and analgesia was performed just before shifting to ward to minimize the effects of sedation on patient's judgement. Moreover, the surgeons were asked to rate their satisfaction

with operative conditions, using the same scale at the end of surgery, acceptable satisfaction score of both the patient and surgeon being 5-7. Adverse events like bradycardia (HR <50 beats/min), hypotension (SBP <90 mmHg), respiratory depression (respiratory rate ≤10 bpm), oxygen desaturation (SpO2<92%), nausea, vomiting were recorded.

Statistical Analysis

The recorded data are expressed as mean ± SD, percentage and numbers of patients. Statistical analysis was carried out using Microsoft Excel and Stat Graphic Centurion 16 for windows. The demographic data for categorical variables were compared using the $\chi 2$-test. Statistical significance in time-related variables was analysed using Student's t-test. A P value of less than 0.05 was considered statistically significant.

RESULTS

The present study was successfully completed on 50 adult consented patients and the efficacy of intravenous dexmedetomidine and propofol in reducing haemodynamics parameter during incision and drainage (I & D) for lactational breast abscess was examined as well as its safety and satisfaction. As in group P, 6 patients required more than a single dose of rescue analgesic and in group D for 1 patient surgery time was more than 1 h and hence these 7 patients were excluded from the study. So, at the end data were available for 50 patients. The demographic data of age, weight, ASA physical status, and duration of surgery were comparable between the groups (Table 1). Baseline values of the mean heart rate were comparable between the groups, but intraoperatively, there was a statistically significant reduction in the mean heart rate compared with the baseline value in group D ($P < 0.05$), with bradycardia (heart rate <60 beats/min) found in one patient, who promptly responded to intravenous atropine 0.5 mg. At 5, 10 and 15 min, the heart rate was found to be higher in patients of the group P than group D (Table 2). The baseline mean systolic blood pressure was comparable between the groups, but it was lower during surgery in patients of group D, with statistically significant difference at 5 and 15 min (Table 3). There was statistically significant fall in systolic blood pressure in group P (8 (32%) vs 2 (8%)) (Table 4) which was treated with I.V. fluid and incremental dose of ephedrine. Sedation score was comparable between the both groups and time to achieve adequate RSS was (10.46±2.62 min) in group D, whereas in group P, it was (10.93±3.02 min) which are also comparable (Table 5). In group D only 3 (6%) patients required injection fentanyl thus showing a significant difference between two groups. Both patient satisfaction and surgeon satisfaction were significantly better in D group when compared to P group (Table 6). Respiratory rate and peripheral oxygen saturation (SpO2) were comparable with no episode of respiratory depression and desaturation at any time.

Parameters	Group D (n=25)	Group P (n=25)
Age (years)	29.7 ± 8.3	31.2 ± 6.7
Weight (kg)	55.7 ± 17.8	54.81 ± 16.6
ASA status I/II	22/03	19/06
Surgical time (min)	13.8 ± 7.7	15 ± 6.4

Table 1. Demographic Characteristic of 50 Patients

Data are presented as mean ± SD or number of patients; ASA, American Society of Anaesthesiologists; *p< 0.05 is statistically significant.

Heart Rates (Beats/Min)	Group D	Group P
Baseline	92.43 ± 12.28	94.6 ± 11.8
After induction	72.41 ± 7.35	86.2 ± 6.75
2 min	66.83 ± 8.93	74.24 ± 10.59
5 min	68.25 ± 9.43*	77.4 ± 10.33
10 min	71.33 ± 11.7*	90.67 ± 7.79
15 min	86.41 ± 1.86*	96.15 ± 11.19

Table 2. Changes in Heart Rate during Anaesthesia

Data are presented as mean ± SD; *P < 0.05 is statistically significant.

SBPs (mmHg)	Group D	Group P
Baseline	124.4 ± 18.4	128.2 ± 13.56
After induction	102.3± 4.5	114.5 ± 6.4
2 min	104.8 ± 8.8	109.4 ± 4.6
5 min	94.81 ± 4.5*	102.77 ± 5.6
10 min	102.66 ± 2.7	106.76± 5.3
15 min	110.43 ± 12.8*	130.32 ± 12.4

Table 3. Changes in Systolic Blood Pressure during Anaesthesia

Data are presented as mean ± SD; SBP, systolic blood pressure;
*P < 0.05 is statistically significant

Complications	Group D (n=25) (%)	Group P (n=25) (%)
Nausea	4 (16)	3 (12)
Vomiting	1 (4)	1 (4)
Hypotension	2 (8)	8 (32)*
Bradycardia	1 (4)	0

Table 4. Complications

Values were expressed as number and percentage.
*P <0.05 is statistically significant

Parameter	Group D (n=25)	Group P (n=25)
Ramsay Sedation Score(RSS)	3.18±0.19	3.03±0.21
Time to achieve RSS of ≥3	10.46±2.62	10.93±3.02

Table 5. Ramsay Sedation Score

Values were expressed as number and mean ± SD

	Group D	Group P
Degree of patient satisfaction (Likert scale)	6.4±0.5 *	4.9±1.4
Degree of surgeon satisfaction (Likert scale)	5.6±0.67 *	4.05±0.9
No. of patients required fentanyl intraoperative	3 (6) *	12 (24)

Table 6. Intraoperative Clinical Data and Measured Particular Times

Values were expressed as number and percentage or mean ± SD.
*P < 0.05 is statistically significant.

Score	Response
1	Anxious or restless or both
2	Cooperative, orientated and tranquil
3	Responding to commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

Table 7. Ramsay Sedation Scale

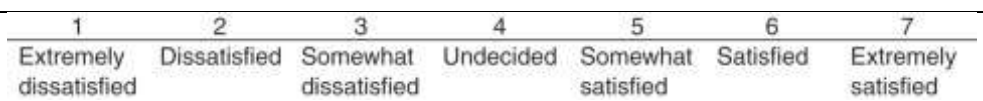

Figure 1. A 7-point Likert-like Verbal Rating Scale for Assessment of Patients' Satisfaction with Intraoperative Sedation/Analgesia

DISCUSSION

The successful use of dexmedetomidine as the primary sedative drug for orthopaedic, ophthalmic, dental, plastic surgery and for diagnostic procedures have been reported. Dexmedetomidine is increasingly being used as a sedative for monitored anaesthesia care, due to its properties like analgesia, cooperative sedation and lack of respiratory depression.[10,14,15]

In present study, the depth of sedation was determined by Ramsay sedation scores (RSS) and results showed comparable sedation scores. The results are similar to those of Recart et al, patients who receive dexmedetomidine are quite comfortable and are still arousable and responsive to stimuli.[16] Target RSS of ≥3 was achieved at almost similar time with dexmedetomine (10.46±2.62 minutes) and propofol (10.93±3.02 minutes) after starting study drug. Yavuz Demiraran et al, found onset time of sedation with dexmedetomidine as 10 minutes which was comparable with our study having onset time of 10.46 min showing that induction time in dexmedetomidine sedation are suitable for short surgical procedures. Contrary to our study, Arain et al, evaluated the intraoperative sedative effects of dexmedetomidine and propofol, and demonstrated that although sedation with dexmedetomidine was achieved slowly.[6]

In the present study, HR decreased and comparatively stable SBP values were observed with use of dexmedetomidine. In dexmedetomidine group, HR was significantly lower than the baseline values during procedure at all time intervals. With dexmedetomidine, bradycardia (HR<50 bpm) occurred in two patients, which was transient, and HR recovered after giving atropine. Our results were similar with other studies in terms of haemodynamic effects in patients sedated with dexmedetomidine, which shows that HR is significantly lower in dexmedetomidine treated patients.[17] Bradycardia is a major side effect of dexmedetomidine (α2 agonist) that is mediated by the activation of α2-adrenoceptors in the ventrolateral medulla and solitarius nucleus tract and part by an increase in vagal activity may also be involved in the haemodynamic effects of dexmedetomidine.[18]

In our study, SBP was more stable in the dexmedetomidine group compared to propofol showing that dexmedetomidine has clinical advantages in controlling haemodynamic variability and respiration. In propofol group, there was a higher incidence of decrease in SBP compared to baseline during sedation. These hypotensive episodes were clinically managed by intravenous fluid and incremental dose of ephedrine. Our results were similar to study by Taniyama et al, in which statistically significant lower HR was found in the dexmedetomidine group and lower MBP and SpO2 was seen in the propofol group.[19] As dexmedetomidine inhibits the central sympathetic outflow and inhibits the norepinephrine release by stimulation of α-2 adrenoceptor, it is expected to decrease MAP as observed by Ghali et al, in their studies.[20,21,22,23] However, we observed that patients receiving propofol had significantly decreased levels of SBP as same observed by Arain and Ebert.[6] This may be due to the powerful inhibitory effect of propofol on sympathetic outflow. Dexmedetomidine group had decreased requirement of rescue analgesic perioperatively, which is similar to the findings of Arain and Ebert.[6] This reduced requirement of injection fentanyl as rescue analgesic in group D explains the analgesic property of dexmedetomidine.

Both surgeon comfort and patient satisfaction regarding sedation was more in group D. Better patient and surgeon satisfaction may be related to early recovery and minimum adverse effects seen with dexmedetomidine. Moreover, dexmedetomidine also have analgesic properties resulting in better pain relief in patients as indicated by less requirement of rescue analgesia during procedure. Our results were in agreement to that of Arain and Ebert, and that of Takimoto et al where patients were more satisfied with dexmedetomidine than propofol for sedation.[6,24] But Ghali et al, observed in their study that surgeon satisfaction was equal for both groups as they compared the dexmedetomidine with propofol for vitreoretinal surgery under sub tenon's anaesthesia and the reason may be the different type of surgery.

CONCLUSIONS

Both dexmedetomidine and propofol provide adequate levels of sedation without clinically significant respiratory depression in the perioperative period, but use of propofol is associated with increased requirement of intraoperative rescue analgesic and increased haemodynamic instability (hypotension). On the basis of the findings of the present study, dexmedetomidine seems to be a better drug for monitored anaesthesia care with minimal haemodynamic instability when compared to propofol.

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