IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 8 Ser. 15 (August. 2019), PP 58-63
www.iosrjournals.org

A Comparative Study between Intravenous Dexmedetomidine and Propofol for Intraoperative Sedation During Regional Anaesthesia

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Abstract
Background*: To get ideal sedative state in patients undergoing surgery in local anesthesia is challenging for Anaesthesiologists.*
Aim*: To evaluate efficacy of intravenous Dexmedetomidine and intravenous Propofol infusion in patients undergoing surgery in regional anaesthesia.*
Material and Methods: *Ninety patients were randomly divided into two groups of 45 each. Group D patients were given I.V. Dexmedetomidine on initial loading dose of 1 µg/kg for 10 minutes period followed by 0.2-0.7 µg/kg/hr. Patients in group P were given I.V. Propofol 75 µg/kg/min for 10 minutes followed by maintenance dose of 12.5-75 µg /kg/min. Sedation level of patients was recorded regularly using Ramsay Sedation Scale. Besides that pulse, blood pressure, respiratory rate, saturation, rescue analgesia and any untoward effect was noted.*
Result: *Dexmedetomidine and Propofol provided adequate sedation needed for MAC but Propofol required rescue analgesia in three patients. Onset and recovery from sedation was earlier with Propofol. Mean heart rate was lower in Dexmedetomidine group and blood pressure was lower in the Propofol group. However both the drugs did not affect respiration. Patients of Dexmedetomidine group developed dryness of mouth.*
Conclusion: *Both Dexmedetomidine and Propofol were effective in providing monitored anaesthesia care but Dexmedetomidine was found to be a better drug as it provided hemodynamic stability, additional rescue analgesia and better sedation.*

Keywords*: Dexmedetomidine, Regional anaesthesia, Monitored Anaesthesia Care and Propofol*

Date of Submission: 17-08-2019 Date of Acceptance: 03-09-2019

I. Introduction

Regional anesthetic techniques can be used for a variety of surgical procedures and may offer certain advantages over general anaesthesia. Regional anesthetic technique also produces high level of stress, strain and discomfort to the patient with physiological, psychological and physiochemical alteration resulting in increased mortality and morbidity[1]. In order to improve patient acceptability and comfort and to reduce stress it is necessary to provide some form of sedation during the operation.

Sedation has become a viable alternative for general anaesthesia for certain procedures and can be administered to both adults and children. Sedation has been shown to increase patient satisfaction and acceptance and make it more convenient for the anaesthesiologist and the surgeon.[2] Regional anaesthesia is popular and offers several benefits to the patient. The top three from the patient's point of view are staying awake, early family contact and early food intake. This shows that patients are interested in postoperative landmarks and their importance regarding patient satisfaction.

Several drugs have been used till date for sedation during surgical procedures under regional anaesthesia including benzodiazepines, opioids, phenothiazines, propofol etc.[3] The search of ideal sedative agent continues; Ideal sedative drugs are those which provide sedation and analgesia without respiratory depression, maintain airway and hemodynamic stability, cost effective, less toxic, non allergic, having early onset and fast recovery and can attenuate stress response.[4]

Intravenous Dexmedetomidine is a FDA approved drug to provide conscious sedation in ICU in patients on ventilator. Dexmedetomidine is centrally acting α2 receptor agonist having property of analgesia and conscious sedation without respiratory depression and seems to be a drug of choice for procedural sedation. [5-7]

Propofol is widely used as a sedative hypnotic with rapid onset and offset along with antiemetic and

euphoric properties.[8] In this study we are comparing two drugs to produce moderate sedation intraoperative under regional anesthesia.

II. Material And Methods

This is a randomized double blind prospective study done in our institute after taking approval from institutional ethical committee. Ninety patients of ASA I and II aged 18–45 years of either sex undergoing surgery under regional anesthesia were enrolled in this study after taking informed consent.

Patients allergic to local anesthetics and the drugs under study, patients having cardiac disease, COPD, hepatic, renal insufficiency, metabolic and CNS disorder, addiction or on psychotic medication, history of sleep apnea, pregnant and lactating woman and obese patients were excluded from this study.

The patients were examined and evaluated on the day before surgery. Patients were fully explained about the procedure of anaesthesia to allay anxiety and apprehension. Informed consent was taken for the study. All the patients were pre-medicated with oral dose of Alprazolam 0.5 mg a night before surgery. On the day of surgery the baseline heart rate and blood pressure of the patient was recorded. After shifting the patient to the O.T, I.V access was obtained and monitors were connected.

Computer-generated table of random numbers was used for randomization. The patients were randomly allotted into two groups of 45 patients each. Patients in study group D were given I.V. Dexmedetomidine initial loading dose 1 μg/kg over 10 minutes followed by 0.2-0.7 μg/kg/hr. Patients in study group P were given I.V. Propofol 75 μg/kg/min over 10 minutes followed by maintenance dose of 12.5-75 μg /kg/min. Drug was prepared by one of the authors who was not involved in the monitoring process. Maintenance drugs were given by infusion pump.

On achieving adequate sedation grade; surgery was started and infusion dose was adjusted to maintain the adequate sedation grade 2 to 4 of Ramsay scale. Oxygen 2L/min by nasal cannula was given throughout the surgery. Efficacy of sedation using Ramsay sedation score, pulse, blood pressure, respiration, oxygen saturation and any other untoward effect was noted. Patients were monitored before administering the drug, after giving the loading dose and every 15 minutes till the end of the surgery. In the recovery room, sedation assessment was recorded at minutes 5, 10 and 15 thereafter for 90 minutes. 24 hours follow up was made to assess patient satisfaction with sedation for their surgical procedure.

Side effects were treated symptomatically. Hypotension (systolic BP fall below 30% of previous value was treated with slowing down of drug infusion, intravenous fluids and if needed drug Mephentermine 6mg. Bradycardia (heart rate below 60/min) was treated with intravenous drug Atropine 0.6 mg. Respiratory depression was treated by reducing drug infusion and increasing oxygen support. Drug Ondensetron was used for nausea and vomiting and for rescue analgesia Fentanyl was given as per the need. At the end of the surgery the infusion was discontinued.

Statistical analysis: The data was analyzed using MiniTab Version 17.0, appropriate univariate and bivariate statistical analysis was carried out using the Students 't' Test for the continuous variables and two-tailed Fisher Exact Test or Chi-Square Test for categorical variables.

III. Result

No difference was found between the two groups based on the demographic data. They were comparable in age, sex, weight and ASA as shown in Table1.

Table 1: Demographic characteristics of the study population

Parameters	Dexmedetomidine (n = 45)	Propofol (n = 45)	't' Value	P Value
Age	31.16 ± 12.21	31.02 ± 11.05	0.054, df=88	0.957, NS
Weight	52.98 ± 6.74	54.44 ± 6.99	-1.012, df=88	0.314, NS
ASA Grading Grade I Grade II	 35 (77.8%) 10 (22.2%)	 39 (86.7%) 6 (13.3%)	$\chi 2$=1.216, df=1	0.270, NS
Gender Female Male Male : Female	 20 (44.4%) 25 (55.6%) 1.25 : 1	 20 (44.4%) 25 (55.6%) 1.25 : 1	$\chi 2$=0.000, df=1	1.000, NS

Values were expressed as number and percentage or mean+SD, n: number of patients; NS: Nonsignificant; S: Significant; SD: Standard deviation

As shown in Table 2: In group D 38 patients achieved target Ramsay scale 2-3 in 10 minutes after loading dose whereas 42 patients in group P achieved the same in 10 minutes. In group D, 7 patients had inadequate sedation after loading dose as compared to 3 patients in group P which were managed by increasing

the infusion rate. 3 patients of group P needed additional rescue analgesia in the form of Fentanyl 1µg/kg. No patients of group D went in deep sedation any time as compared to group P where 3 patients were found to be in deeper level and needed tapering of drug infusions.

Table 2: Sedation Score

	Group D (n=45)	Group P (n=45)	P Value
No. of patients achieved target sedation after loading dose	38	42	0.744 NS
Patients having inadequate sedation after loading dose	7	3	0.229 NS
Patients needed rescue analgesia intra-operative	0	3	0.088 NS
Deep level sedation	0	3	0.088 NS

n: number of patients; NS: Nonsignificant; S:Significant

There was no statistical difference found in mean heart rate between the two groups as shown in Table 3. Heart rate remained low in intraoperative period in group D. There was not much fall seen in group P.

Table 3: Comparison of the study group in terms of Heart Rate

Heart Rate	**Dexmedetomidine [Mean ±SD]**	**Propofol [Mean±SD]**	**'t' Value**	**P Value**
At 0 min	80.89 ± 11.52	84.51 ± 10.84	-1.536, df=88	0.128, NS
At 10 min	80.60 ± 10.90	83.67 ± 9.97	-1.393, df=88	0.167, NS
At 25 min	79.71 ± 11.10	87.53 ± 9.89	-3.528, df=88	0.001*
At 40 min	76.38 ± 12.29	84.93 ± 10.06	-3.613, df=88	0.001*
At 55 min	76.73 ± 12.74	84.64 ± 11.14	-3.136, df=88	0.002*
At 70 min	75.71 ± 12.69	83.31 ± 11.81	-2.941, df=88	0.004*
End of surgery	75.20 ± 12.46	83.31 ± 13.62	-2.947, df=88	0.004*

As shown in Table 4 there was a fall in systolic BP with statistical difference found in both the groups at various time intervals. However fall in diastolic BP was not found to be significant. (P >0.05)

Table 4: Comparison of intra-operative blood pressure values between the study groups

	Blood Pressure	Dexmedetomidine [Mean ±SD]	Propofol [Mean±SD]	P Value
Basal	Systolic Diastolic	114.38 ± 11.17 75.33 + 9.27	113.24 ± 7.02 74.13 + 8.53	0.566 NS 0.228 NS
At 10 min of infusion	Systolic Diastolic	120.11 ± 11.38 72.42 ± 8.28	115.11 ± 6.70 71.48 ± 6.74	0.013 S 0.556 NS
At 20 min	Systolic Diastolic	111.40 ± 10.17 69.69 ± 8.30	107.91 ± 4.21 68.38 ± 6.93	0.036 S 0.418 NS
At 30 min	Systolic Diastolic	110.11 ± 8.49 66.47 ± 6.47	106.53 ± 5.52 65.20 ± 5.76	0.020 S 0.328 NS
At 40 min	Systolic Diastolic	111.11 ± 9.23 66.58 ± 8.19	107.51 ± 4.63 64.82 ± 6.76	0.022 S 0.269 NS
At 60 min	Systolic Diastolic	110.69 ± 8.49 65.51 ± 9.69	108.58 ± 5.45 63.20 ± 7.44	0.164, NS 0.208 NS
End of Surgery	Systolic Diastolic	110.73 ± 8.29 66.84 ± 8.68	108.58 ± 4.96 64.87 ± 6.80	0.138, NS 0.233 NS

Values were expressed as number and percentage or mean+SD, n: number of patients; NS: Nonsignificant; S:Significant; SD: Standard deviation

As shown in Table 5 none of the patients had respiratory depression at any time. Saturation was maintained more than 95% in both the groups.

Table 5: SpO_2 (%) in dexmedetomidine and propofol group

SpO_2	Dexmedetomidine [Mean ±SD]	Propofol [Mean±SD]	't' Value	P Value
At 0 min	99.71 ± 0.63	99.33 ± 0.93	2.262, df=88	0.026*
At 10 min	99.78 ± 0.52	98.64 ± 1.43	4.991, df=88	0.000*
At 25 min	99.60 ± 0.69	98.38 ± 1.54	4.857, df=88	0.000*
At 40 min	99.60 ± 0.65	98.20 ± 1.67	5.228, df=88	0.000*
At 55 min	99.60 ± 0.65	98.11 ± 1.54	5.968, df=88	0.000*
At 70 min	99.60 ± 0.65	98.13 ± 1.62	5.638, df=88	0.000*
End of surgery	99.60 ± 0.65	98.20 ± 1.56	5.506, df=88	0.000*

Values were expressed as number and percentage or mean+SD, n: number of patients; NS: Nonsignificant; S:Significant; SD: Standard deviation

With regards to adverse effect as shown in Table 6: 2 (4.5%) patients of Dexmedetomidine group had bradycardia who responded well by reducing drug infusion. 10 (22.2%) patients from Group P had hypotension. Out of those 6 patients recovered by reducing drug infusion and rest 4 needed fast intravenous fluid infusion. Two (4.5%) patients of Group D had hypotension who responded well by reducing drug infusion. Three (6.6%) patients of Group D and 1 (4.5%) patient of Group P had nausea and were given intravenous Ondensetron. Two (4.5%) patients of Group P experienced pain on injection in the form of discomfort. Nine (20.0%) patients of Group D and 2 (4.5%) patients from Group P had dry mouth.

Table 6: Adverse Events

Adverse Events	Group D		Group P	
	No	%	No	%
Bradycardia	2	4.5	0	0.0
Hypotension	2	4.5	10	22.2
Nausea	3	6.6	1	2.2
Pain on injection	0	0.0	2	4.5
Dry mouth	9	20.0	2	4.5

No: number of patients; NS: Nonsignificant; S:Significant; %: percentage

IV. Discussion

Regional anesthetic techniques can be used for a variety of surgical procedures and may offer certain advantages over general anaesthesia. Patient management is a vital component of regional anaesthesia. In order to improve patient acceptability and comfort and to reduce stress it is necessary to provide some form of sedation during the operation.

Alpha 2-adrenoceptor agonists are being increasingly used in anaesthesia and critical care as they not only decrease sympathetic tone and attenuate the stress responses to anaesthesia and surgery; but also cause sedation and analgesia. They are also used as adjuvant during regional anaesthesia. Dexmedetomidine is the most recent agent in this group approved by FDA in 1999 for use in humans for analgesia and sedation. Dexmedetomidine and propofol has been implemented as a sedative and hypnotic for patients undergoing procedures without the need for tracheal intubation.

The major findings of our study were:

Demographic data were comparable in both the groups, thus we were able to provide uniform platform for our study.

All patients achieved targeted sedation levels; however, patients receiving Propofol for sedation achieved levels of sedation more rapidly than those receiving Dexmedetomidine. The early onset of sedation in the Propofol group compared to Dexmedetomidine group occured because Propofol is highly lipophilic and distributes rapidly into the central nervous system. Arain, et al [11] noted that the target sedation was achieved within 10 min with Propofol as compared to 25 min with Dexmedetomidine. Similar results were obtained by Abdelkareim et al [12] as shown in Table 2, number of patients who achieved target sedation in group D was 38

as compared to 42 patients of group P. We noted that more number of patients required rescue analgesia in group P whereas rescue analgesia was not required in group D, which is consistent with the findings of Arain and Ebert [11]. This explains the analgesic property of Dexmedetomidine.

Deep level of sedation was observed in 3 patients of Group P and none in Group D. Reason being Dexmedetomidine causes conscious sedation and patient remains arousable under Dexmedetomidine sedation whereas Propofol being more lipophilic crosses blood brain barrier readily and produces deep sedation.

We observed that 2 patients of Group D developed bradycardia which was managed by reducing infusion rate. This is due to sympatholytic and vagal mimetic effects of Dexmedetomidine and it is correlated with Al-Mustafa et al [14] and Mahmoud et al. [15]

Blood pressure was significantly decreased in Group P as compared to Group D. The fall in blood pressure in patients receiving propofol could be attributed to direct powerful inhibitory effect of propofol on sympathetic outflow causing vasodilatation. Dexmedetomidine is also known to decrease sympathetic outflow and circulating catecholamine levels and would, therefore, be expected to cause a decrease in MBP similar to those of propofol. However, larger doses of dexmedetomidine have a direct effect at the postsynaptic vascular smooth muscle to cause vasoconstriction and it is possible that the sympathoinhibitory effects of dexmedetomidine were slightly opposed by direct α-2 mediated vasoconstriction. Results similar to our study were observed by Arain et al., [11] Al-Mustafa et al [14] and Mahmoud et al. [15]

Use of propofol has been associated with local anesthetic injection pain in the form of patient discomfort or patient movement. [16,17] We observed that 2 patients of Group P had discomfort to Propofol infusion.

Dry mouth is a known side effect of α-2 agonists. We also observed that more patients (20%) in Group D complained of dry mouth as compared to those in Group P (4.5%). [18]

V. Conclusion

It is concluded from our study that both Dexmedetomidine and Propofol were effective in providing adequate level of sedation. However, Dexmedetomidine has an excellent sedation for the procedures carried out under regional anaesthesia. Propofol provides early onset of sedation, requires rescue analgesia and results in lower blood pressure intraoperatively as compared to Dexmedetomidine. Neither Dexmedetomidine nor Propofol influence respiration. Thus Dexmedetomidine proves to be a better drug for sedation in patients undergoing surgery under regional anaesthesia.

CONFLICT OF INTEREST

No conflicts of interest.

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Shashank Shekhar. "A Comparative Study between Intravenous Dexmedetomidine and Propofol for Intraoperative Sedation During Regional Anaesthesia." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 8, 2019, pp 58-63.