

Evaluation of Recovery Profile with Dexmedetomidine in Ambulatory Anesthesia

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Abstract

Context: The availability of rapid, shorter acting anesthetics, analgesics and muscle relaxant drugs has facilitated the recovery process and allowed more extensive procedures to be performed on ambulatory basis.¹ Dexmedetomidine is highly selective alpha 2 adrenoceptor agonist with sympatholytic, sedative, amnestic and analgesic properties. It provides unique conscious sedation where patient is easily arousable and analgesia without respiratory depression. **Aims:** To evaluate recovery profile with Dexmedetomidine in Ambulatory Anesthesia. **Settings and Design:** 60 female patients posted for Medical termination of pregnancy aged between 20 and 40 years were included in the study, and were randomly divided into two groups, Group M (Midazolam) and Group D (Dexmedetomidine) having 30 patients in each. **Methods and Materials:** All Group D patients received Inj. Ondansetron, Inj. Dexmedetomidine 0.25 ug/kg I.V. slowly over 10 minutes as infusion with hemodynamic monitoring, Inj. Fentanyl 1 ug/kg I.V. Induction was done with Inj. Propofol upto a maximum of 2 mg/kg in divided doses, titrated to effect. Dexmedetomidine infusion @ 0.25 ug/kg/hour was continued during the procedure if hemodynamic parameters were stable. **Statistical Analysis:** The statistical significance of difference was tested using Chi-square test, unpaired 't' test, repeated measures analysis of variance (ANOVA), The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 11.5, Inc. Chicago) for MS Windows. **Results:** Group D had better recovery profile than Group M, with Group D having shorter awakening (p -value 0.020). Orientation times of (p - value 0.001). Faster achievement of target Aldrete D (p - value 0.001). and Fastrack scores (p - value 0.001). and a rapid home readiness compared to Group M. **Conclusions:** Dexmedetomidine infusion in lower doses 0.2-0.3 mcg/kg/hr for short duration procedures can be a good choice in multimodal approach in Ambulatory Anesthesia.

Keywords: Dexmedetomidine; Ambulatory Anesthesia; Recovery Profile.

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Introduction

Dexmedetomidine, the pharmacologically active d-isomer of medetomidine is highly selective, specific and potent alpha 2 adrenoceptor agonist.^{1,2} It improves performance of several cognitive

tasks, which rely on prefrontal cortex.³ Because of its analgesic properties, 'co-operative' sedation and lack of respiratory depression, it is preferred as main component of the drug combinations in Ambulatory Anesthesia. We present the study of patients posted for MTP (Medical Termination of Pregnancy) in Ambulatory Anesthesia setting.

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Aim

To evaluate recovery profile with Dexmedetomidine in Ambulatory Anesthesia.

Objectives

1. To study hemodynamic changes with Dexmedetomidine;
2. To assess anesthetic and analgesic sparing effect of Dexmedetomidine;
3. To observe post-operative complications if any.

Materials and Methods

Study was conducted at the attached teaching hospital with the approval of the institutional Ethics committee. In a prospective randomized trial, total 60 female patients posted for MTP were divided into two Groups: Group M (Midazolam) and Group D (Dexmedetomidine) having 30 in each. Patients of ASA I-II between 20 and 40 years of age were included in the study.

Patients with persisting major systemic diseases and hemodynamic instability were excluded from the study. Patients lacking responsible adult attendant were also excluded from the study. Written informed consent was obtained. Baseline hemodynamic parameters were recorded and intravenous (I.V.) access was established with 20 G intracath.

Patients in Group M received Inj. Ondansetron 4 mg I.V., Inj. Midazolam 0.02 mg/kg I.V. Ramsay sedation score noted followed by Inj. Fentanyl

1 mcg/kg I.V. Induction was done with Inj. Propofol up to maximum of 2 mg/kg I.V. in divided doses, titrated to the effect. Supplemental doses of Inj. Propofol and Inj. Fentanyl were given as per requirement.

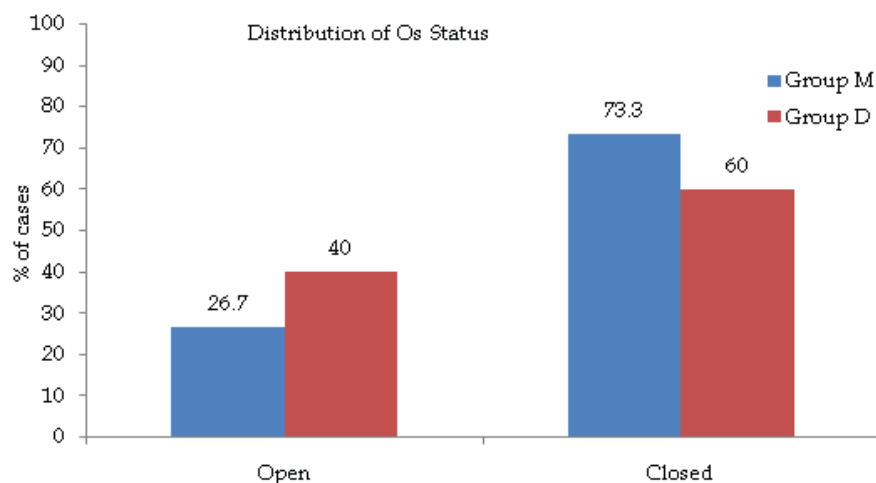
Patients in Group D received Inj. Ondansetron 4 mg I.V. followed by Inj. Dexmedetomidine 0.25 mcg/kg I.V. slowly over 10 min as infusion with hemodynamic monitoring and Ramsay score was noted. Inj. Fentanyl 1 mcg/kg I.V. was given and induction was done with Inj. Propofol up to 2 mg/kg I.V. in divided doses titrated to effect. Dexmedetomidine infusion @ 0.25 mcg/kg/hour was continued during the procedure if hemodynamic parameters were stable.

At the end of the procedure time to awakening, time to orientation by asking name and place, time to achieve an Aldrete score of 10, Fastrack score of 12, PADSS of 9 was noted in both groups. Monitoring of Ramsay sedation score, Visual Analogue Score and hemodynamic parameters continued up to one hour post-surgery. Any complications in post-operative recovery period were noted and home readiness was decided depending on PADSS.

Anticipated Risks: There exists a high risk of hypotension and bradycardia with the use of Dexmedetomidine, but in the low doses of 0.02 mcg/kg, under high vigilance, it is minimal.

Results

When the two groups were compared on the basis of age, weight, gestational age, parity of the patients, indication of emergency and os status, difference was statistically not significant.



Graph 1: Displays distribution of Os status

Gestational age amongst the two groups was comparable by unpaired *t*-test and statistically not significant [*p* value- 0.631 > 0.05]. Mean gestational age in group M is 8.3 ± 2.3 weeks and mean gestational age in group D is 8.6 ± 2.0 weeks. The difference in parity status was statistically not significant (*p* value-0.999) using the Chi -square test, displays (Graph 1).

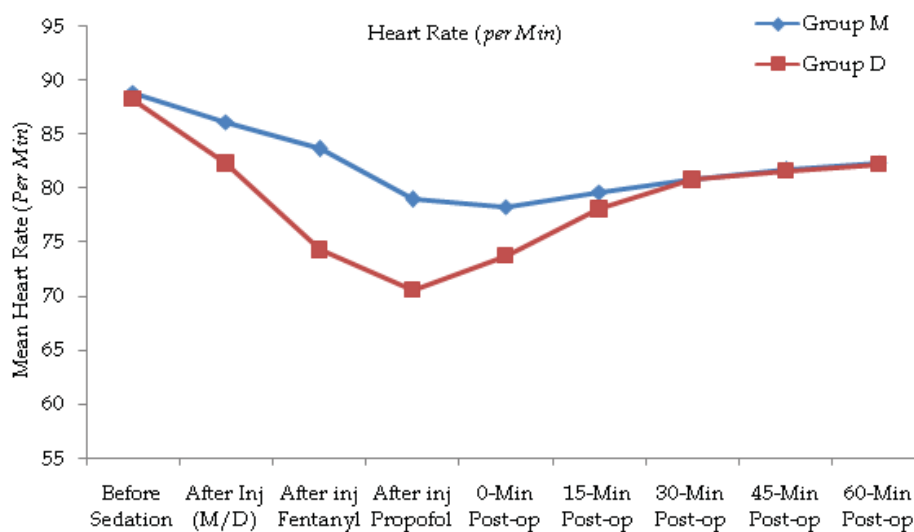
After Inj. Fentanyl the difference in heart rates amongst two groups (83.7 ± 10.9 in Group M and 74.3 ± 7.7 in Group D) was statistically significant (*p* value 0.001). After induction with Propofol the

difference in the heart rates amongst two groups (79.0 ± 11.3 in Group M and 70.6 ± 9.9 in Group D) was statistically significant (*p* value 0.003). However, at the end of surgery and thereafter, till 60 minutes post surgery the difference in heart rates amongst two groups was not significant (*p* value 0.093 at 0 minutes and *p* value 0.936 at 60 minutes), shows Table 1 and Graph 2.

In group D, systolic blood pressure (*mmHg*) fell from a baseline of 120.1 ± 7.8 to 114.3 ± 6.1 after Inj. Dexmedetomidine (*p* value 0.001, statistically significant). After Fentanyl it further reduced to

Table 1: Displays Heart Rate (per Min)

Heart Rate (Per Min)	Group M (n = 30) per min	Group D (n = 30) per min	<i>p</i> -value [Inter-Group] (Group M v Group D)
Before sedation	88.9 ± 11.8	88.3 ± 11.7	0.844 ^{NS}
After Inj (M/D)	86.2 ± 10.5	82.3 ± 9.9	0.142 ^{NS}
After Inj Fentanyl	83.7 ± 10.9	74.3 ± 7.7	0.001
After Inj Propofol	79.0 ± 11.3	70.6 ± 9.9	0.003
0-Min Post-op	78.3 ± 10.1	73.8 ± 10.6	0.093 ^{NS}
15-Min Post-op	79.7 ± 8.9	78.1 ± 9.4	0.510 ^{NS}
30-Min Post-op	80.8 ± 8.9	80.8 ± 9.4	0.999 ^{NS}
45-Min Post-op	81.7 ± 8.9	81.6 ± 8.9	0.954 ^{NS}
60-Min Post-op	82.4 ± 8.1	82.2 ± 7.9	0.936 ^{NS}
P-value [Intra-Group]			
Before sedation v After Inj (M/D)	0.001	0.001	—
Before sedation v After Inj Fentanyl	0.001	0.001	—
Before sedation v After Inj Propofol	0.001	0.001	—
Before sedation v 0-Min Post-op	0.001	0.001	—
Before sedation v 15-Min Post-op	0.001	0.001	—
Before sedation v 30-Min Post-op	0.001	0.001	—
Before sedation v 45-Min Post-op	0.001	0.001	—
Before sedation v 60-Min Post-op	0.001	0.004	—



Graph 2: Displays Heart Rate (per Min)

108.3 ± 7.6 (*p* value 0.001, statistically significant). With induction with Propofol it was 99.8 ± 6.6 (*p* value 0.001, statistically significant). At the end of surgery it was 105.1 ± 7.2 (*p* value 0.001 statistically significant). At 15 minutes after surgery it was 111.9 ± 6.1 (*p* value 0.001, statistically significant). At 30 minutes post surgery it started recovering towards baseline and the difference was not statistically significant (*p* value 0.229). From there onwards it remained near pre-operative levels and was not statistically significant (*p* value 0.513 at 60 minutes post surgery), shows Table 2.

Group M also showed statistically significant fall

in systolic blood pressure and the difference was statistically significant for upto 15 minutes post surgery (*p* value 0.026 after Inj. Midazolam and 0.001 at 15 minutes post surgery).

The difference in the baseline systolic blood pressure values amongst two Groups was statistically not significant (*p* value 0.533). After Inj. Midazolam/Dexmedetomidine the fall in systolic BP amongst two groups was statistically significant (*p* value 0.013). After Inj. Fentanyl the fall in systolic blood pressure amongst two groups was statistically significant (*p* value 0.004). On induction with Inj. Propofol the systolic blood

Table 2: Comparison of systolic blood pressure amongst two groups

Systolic BP (mmHg)	Group M (n = 30)	Group D (n = 30)	<i>p</i> -value [Inter-Group] (Group M v Group D)
Before sedation	121.6 ± 10.9	120.1 ± 7.8	0.533 ^{NS}
After Inj (M/D)	119.3 ± 8.8	114.3 ± 6.1	0.013
After inj Fentanyl	114.8 ± 9.0	108.3 ± 7.6	0.004
After inj Propofol	104.3 ± 9.4	99.8 ± 6.6	0.035
0-Min Post-op	109.0 ± 8.8	105.1 ± 7.2	0.065 ^{NS}
15-Min Post-op	113.9 ± 8.0	111.9 ± 6.1	0.264 ^{NS}
30-Min Post-op	118.1 ± 9.1	118.4 ± 6.6	0.897 ^{NS}
45-Min Post-op	119.0 ± 6.9	118.9 ± 5.7	0.952 ^{NS}
60-Min Post-op	120.1 ± 6.9	119.1 ± 5.7	0.543 ^{NS}
P-values [Intra-Group]			
Before sedation v After Inj (M/D)	0.026	0.001	—
Before sedation v After Inj Fentanyl	0.001	0.001	—
Before sedation v After Inj Propofol	0.00	0.001	—
Before sedation v 0-Min Post-op	0.001	0.001	—
Before sedation v 15-Min Post-op	0.001	0.001	—
Before sedation v 30-Min Post-op	0.085 ^{NS}	0.229 ^{NS}	—
Before sedation v 45-Min Post-op	0.117 ^{NS}	0.429 ^{NS}	—
Before sedation v 60-Min Post-op	0.392 ^{NS}	0.513 ^{NS}	—

Table 3: Comparison of Diastolic blood pressure amongst two groups.

Diastolic BP (mmHg)	Group M (n = 30)	Group D (n = 30)	P-value [Inter-Group] (Group M v Group D)
Before sedation	77.1 ± 7.8	74.1 ± 5.9	0.098 ^{NS}
After Inj (M/D)	76.7 ± 6.5	70.9 ± 5.1	0.001
After inj Fentanyl	71.8 ± 6.4	67.1 ± 4.2	0.001
After inj Propofol	65.4 ± 7.6	60.5 ± 6.2	0.008
0-Min Post-op	68.7 ± 7.2	65.1 ± 6.4	0.042
15-Min Post-op	72.5 ± 4.9	71.3 ± 5.1	0.354 ^{NS}
30-Min Post-op	73.4 ± 6.4	74.7 ± 5.1	0.401 ^{NS}
45-Min Post-op	75.1 ± 4.5	76.3 ± 4.5	0.338 ^{NS}
60-Min Post-op	75.3 ± 5.7	77.5 ± 4.8	0.120 ^{NS}
P-values [Intra-Group]			
Before sedation v After Inj (M/D)	0.699 ^{NS}	0.001	—
Before sedation v After Inj Fentanyl	0.001	0.001	—
Before sedation v After Inj Propofol	0.001	0.001	—
Before sedation v 0-Min Post-op	0.001	0.001	—
Before sedation v 15-Min Post-op	0.001	0.030	—
Before sedation v 30-Min Post-op	0.003	0.566 ^{NS}	—
Before sedation v 45-Min Post-op	0.151 ^{NS}	0.032	—
Before sedation v 60-Min Post-op	0.001	0.001	—

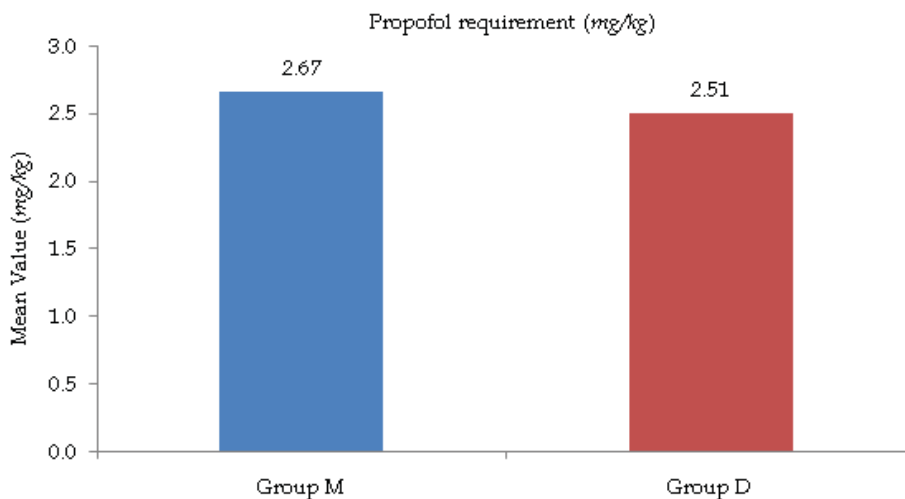
pressure further fell and the difference amongst two groups was statistically significant (p value 0.035). Thereafter, the systolic blood pressure showed a rising trend and the difference was statistically not significant from the end of surgery till 60 minutes post surgery (p value 0.543 at 60 minutes amongst two Groups). At 60 minutes post surgery the systolic blood pressure was near baseline levels for both the Groups and the difference was statistically not significant (p value 0.392 for group M and 0.513 for Group D), shows Table 3.

Group D showed a fall in diastolic blood pressure from 74.1 ± 5.9 to 70.9 ± 5.1 after Inj. Dexmedetomidine which was statistically significant (p 0.001). It further came down to 67.1 ± 4.2 with fentanyl (p 0.001, statistically significant) and it reached 60.5 ± 6.2 after induction with propofol (p 0.001, statistically significant). At the end of surgery the mean diastolic blood pressure reached 65.1 ± 6.4 (p 0.001, statistically significant) and then started rising thereafter, and reached 77.5 ± 4.8 , which was higher than the pre-operative value. This rise came out to be statistically significant (p 0.001).

Group M also showed a similar fall in diastolic blood pressure at various stages. After Inj. Midazolam the fall in diastolic blood pressure from a baseline of 77.1 ± 7.8 to 76.7 ± 6.5 was statistically not significant (p 0.699). After Inj. Fentanyl it reached 71.8 ± 6.4 (p 0.001, statistically significant). After induction with propofol it was 65.4 ± 7.6 (p 0.001, statistically significant). At the end of surgery it remained around 68.7 ± 7.2 (p 0.001, statistically significant). At 60 minutes post surgery the diastolic blood pressure was 75.3 ± 5.7 (p 0.001, statistically significant).

Considering the fall in two groups, the difference in fall was significant, but it was more in Group D (diastolic BP of 65.4 ± 7.6 in Group M and 60.5 ± 6.2 in Group D after propofol, p value 0.008 statistically significant). However, 60 minutes post surgery, there was no significant difference in the diastolic blood pressures amongst the two Groups (p 0.120, not significant), displays Graph 3.

The average Propofol requirement in Group D was slightly lower than in Group M, however, this difference was statistically not significant (p value 0.453), shows Table 4 and Graph 4.



Graph 3: The distribution of Propofol Dosage administered per kilogram of body weight across two intervention groups.

Table 4: Comparison of Recovery Variables Amongst two Groups

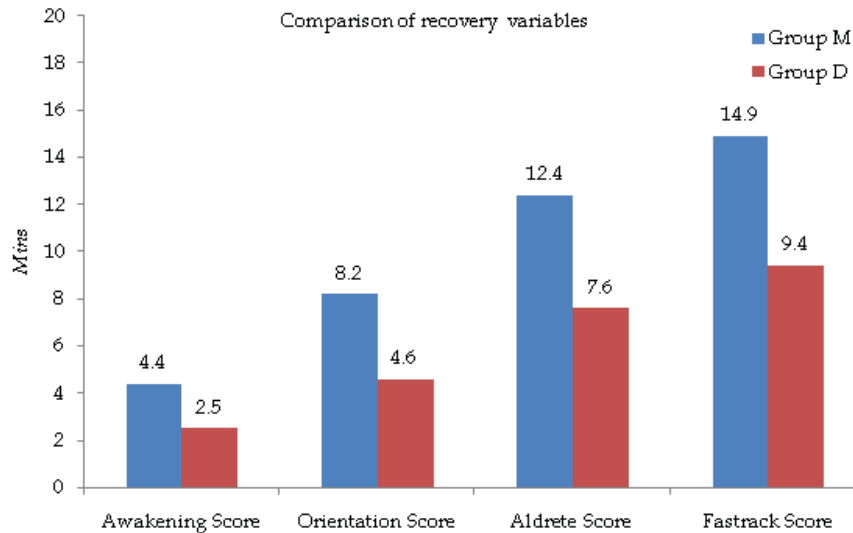
Recovery Variables Mins	Group M (n = 30) Mins	Group D (n = 30) Mins	p -value [Inter-Group] (Group M v Group D)
Time to Awakening	4.4 ± 3.65	2.5 ± 2.22	0.020
Time to Orientation	8.2 ± 4.44	4.6 ± 3.20	0.001
Time to Aldrete Score 10	12.4 ± 5.10	7.6 ± 3.84	0.001
Time to Fastrack Score 12	14.9 ± 6.11	9.4 ± 4.61	0.001

1. The average Time to Awakening (Awakening score) is significantly higher for Group M compared to Group D (p - value 0.020).
2. The average Time to Orientation (Orientation score) is significantly higher for Group M compared to Group D (p - value 0.001).
3. The average Time to Aldrete (Aldrete score) is significantly higher for Group M compared to Group D (p - value 0.001).
4. The average Time to Fastrack (Fastrack score) is significantly higher for Group M compared to Group D (p - value 0.001), p - values for Inter-group comparisons by unpaired t -test. p - values for Intra-group comparisons by repeated measures analysis of variance (ANOVA).

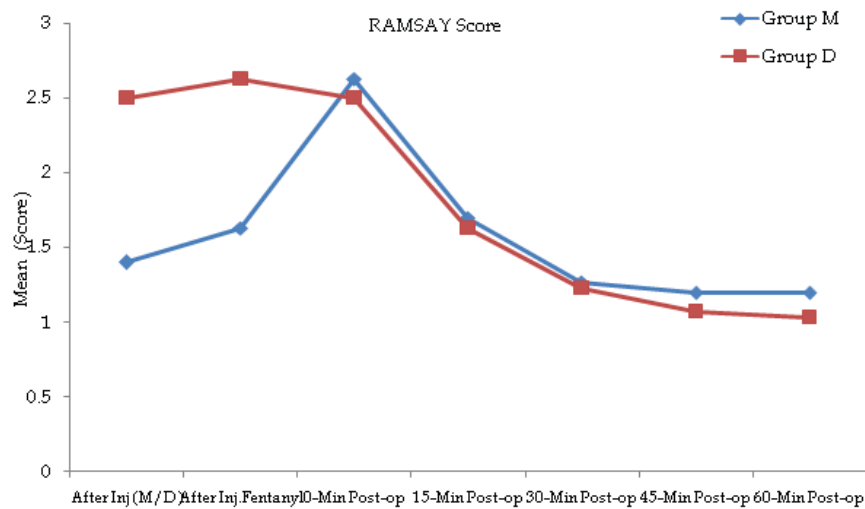
In group D, there was no significant difference in the Ramsay sedation score after Inj. Fentanyl to immediately after surgery (0 minute post-op p - value was 0.595, not significant). At 15 minutes post-surgery the average Ramsay Score had reduced from pre-operative value of 2.63 ± 0.62 to 1.63 ± 0.85 , a difference which was statistically significant (p value 0.001). It continued to decrease to 1.03 ± 0.18 at 60 minutes post-surgery. This fall was statistically significant (p value 0.001).

Group M showed, a similar fall in Ramsay values from a baseline value of 1.63 ± 0.49 after Inj. Fentanyl to 1.20 ± 0.41 at 60 minutes post-surgery (p value 0.001, statistically significant).

Between the two groups there was a statistically significant difference in Ramsay sedation scores at



Graph 4: Distribution of Recovery variables amongst two groups



Graph 5: Distribution of RAMSAY scores amongst two groups

before induction (p value 0.001) and at 60 minutes post surgery (p value 0.045) the average sedation being less in Group D (1.03 ± 0.18) than Group M (1.20 ± 0.41). Difference in average SpO₂ after induction up to 60 min post-operatively was not significant by unpaired t -test [p value 0.241], shown in Table 5 and Graph 5.

There was a statistically significant reduction in VAS scores in both groups at 15 minutes and

30 minutes post surgery (p value 0.001). However, the difference between the groups was statistically not significant (p 0.699, p 0.447 and p 0.398 at 0,15 and 30 minutes post-surgery), displays Graph 6.

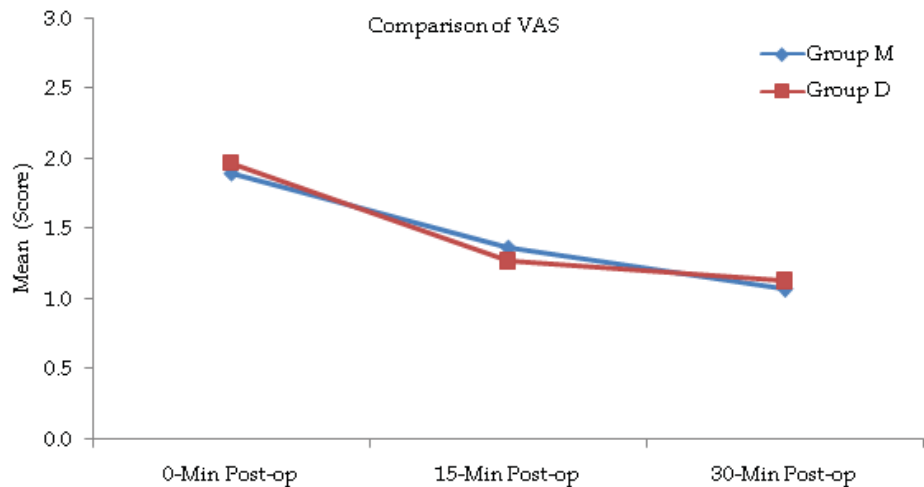
p - values for Inter-group comparisons by unpaired t -test. p - values for Intra-group comparisons by repeated measures analysis of variance (ANOVA).

Table 5: Comparison of RAMSAY score across two groups.

RAMSAY score	Group M (n = 30)	Group D (n = 30)	p - value [Inter-Group] (Group M v Group D)
After Inj (M/D)	1.40 ± 0.49	2.50 ± 0.51	0.001
After Inj.Fentanyl	1.63 ± 0.49	2.63 ± 0.62	0.001
0-Min Post-op	2.63 ± 1.61	2.50 ± 1.14	0.712 ^{NS}
15-Min Post-op	1.70 ± 0.99	1.63 ± 0.85	0.780 ^{NS}
30-Min Post-op	1.27 ± 0.52	1.23 ± 0.50	0.802 ^{NS}
45-Min Post-op	1.20 ± 0.41	1.07 ± 0.25	0.133 ^{NS}
60-Min Post-op	1.20 ± 0.41	1.03 ± 0.18	0.045
P-value [Intra-Group]			
After Inj (M/D) v Inj.Fentanyl	0.006	0.043	—
After Inj (M/D) v 0-Min Post-op	0.001	0.999 ^{NS}	—
After Inj (M/D) v 15-Min Postop	0.119 ^{NS}	0.001	—
After Inj (M/D) v 30-Min Postop	0.293 ^{NS}	0.001	—
After Inj (M/D) v 45-Min Postop	0.083 ^{NS}	0.001	—
After Inj (M/D) v 60-Min Postop	0.083 ^{NS}	0.001	—
After Inj.Fentanyl v 0-Min Post-op	0.003	0.595 ^{NS}	—
After Inj.Fentanyl v 15-Min Postop	0.745 ^{NS}	0.001	—
After Inj.Fentanyl v 30-Min Postop	0.009	0.001	—
After Inj.Fentanyl v 45-Min Postop	0.001	0.001	—
After Inj.Fentanyl v 60-Min Postop	0.001	0.001	—

Table 6: Comparison of PADSS Score amongst two groups

PADSS Score	Group M (n = 30)	Group D (n = 30)	p - value [Inter-Group] (Group M v Group D)
30-Min Post-op	5.93 ± 0.37	6.00 ± 0.00	0.321 ^{NS}
60-Min Post-op	7.63 ± 0.81	8.33 ± 0.48	0.001
90-Min Post-op	8.53 ± 0.68	8.90 ± 0.31	0.009
120-Min Post-op	9.00 ± 0.37	9.40 ± 0.49	0.001
180-Min Post-op	9.97 ± 0.18	10.00 ± 0.00	0.321 ^{NS}
p -value [Intra-Group]			
30-Min v 60-Min	0.001	0.001	—
30-Min v 90-Min	0.001	0.001	—
30-Min v 120-Min	0.001	0.001	—
30-Min v 180-Min	0.001	0.001	—



Graph 6: Distribution of VAS scores amongst two groups

Discussion

Dilatation and evacuation is the most frequently performed minor surgery in ambulatory set-up. Propofol is widely used sedative hypnotic agent with minimal analgesic properties. It causes respiratory depression and this effect is potentiated in presence of opioids like Fentanyl.⁴ By decreasing hypoxic drive, Midazolam also produces respiratory depression and this effect is exaggerated in presence of opioids and other CNS depressant drugs. Benzodiazepines also depress the swallowing reflex and decrease upper airway activity.⁵ On this background, Dexmedetomidine is a highly selective alpha 2 adrenoceptor agonist with sympatholytic, sedative, amnestic and analgesic properties. It provides unique conscious sedation where patient is readily arousable and analgesia without respiratory depression.⁶ Thus, it can be a good addition to existing combinations.

Statistically significant fall in HR after Dexmedetomidine was observed and continued up to 15 min post-surgery. However, it started rising thereafter, one patient (3%) in Group M as compared to 13% (4) in Group D had bradycardia (HR < 60 bpm) but did not require Inj. Atropine as it was transient. Tomar GS *et al.*⁷ had similar finding of drop in HR by 18.66% by 5 min which was transient not requiring Atropine.

Both the groups displayed statistically significant fall in BP intra-operatively transiently and 15 min post-surgery showing rising trends. Systolic BP achieved baseline values by 60 min post-surgery. However, diastolic BP continued to remain low in Group M which was statistically significant

[*p* value- 0.001]. On the other hand, diastolic BP in Group D reached higher than baseline by 60 min post-surgery which was statistically significant [*p* value 0.001]

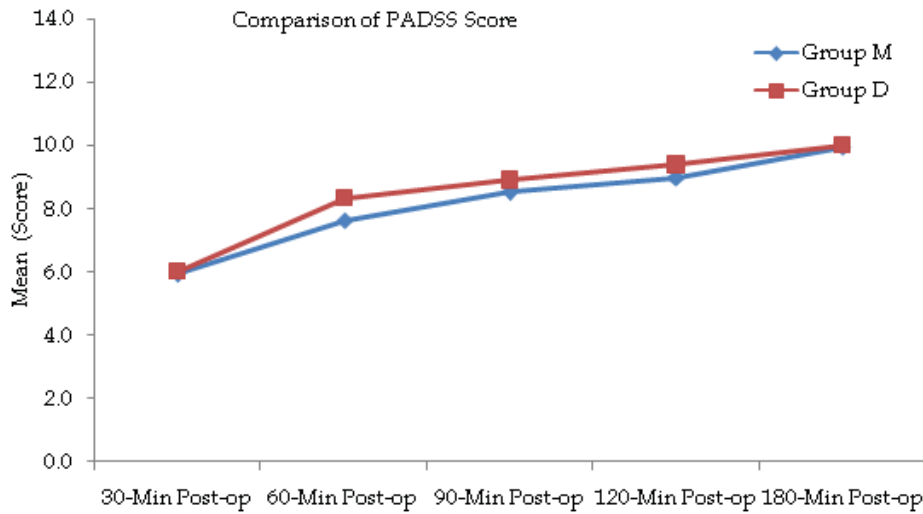
We did not find significant difference in mean saturation levels amongst two groups. Dexmedetomidine is unique in that it does not cause respiratory depression because its effects are not mediated by the gamma aminobutyric acid system.⁷

Average Propofol requirement in Group D was significantly lower than group M, statistically not significant [*P* value 0.453]. Post-operative recovery parameters were better in Group D with statistically significant difference.

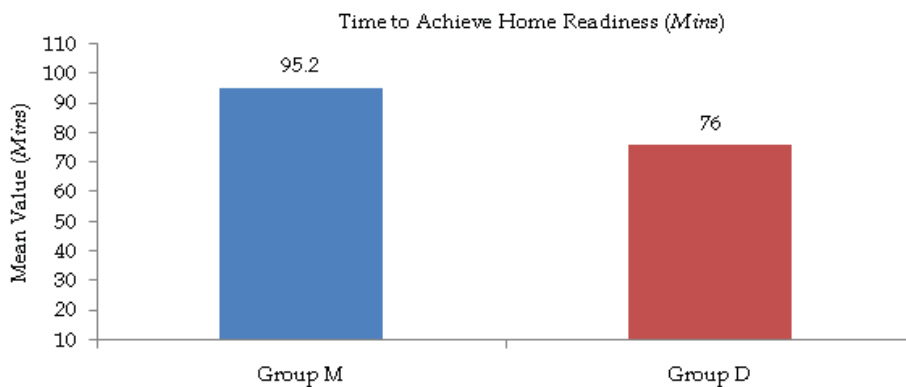
Tufanogullaris B *et al.*⁸ summarized the anesthetic and analgesic effects of Dexmedetomidine infusion; 0.2-0.8 mcg/kg/hr facilitated early but not late recovery of morbidly obese patients undergoing bariatric surgery. Infusion rate of 0.2 mcg/kg/hr is recommended to facilitate early recovery while minimizing adverse peri-operative cardiovascular side effects.

Ramsay sedation score was significantly higher in Group D [*p* value-0.001]. Favourable sedation scores were maintained till 15 min post-surgery; thereafter, sedation weaned off rapidly at 60 min. Since, the procedure is short and post-operative pain is not that severe, analgesic property could not be appreciated well and no significant difference in VAS amongst the two groups could be observed.

Group D achieved higher PADSS score at 60 min post-surgery than Group M [*p* value-0.001]. Steady rise in scores up to 120 min was observed



Graph 7: Displays Comparison of PADSS Score



Graph 8: Displays Time to Achieve Home Readiness (Mins)

[*p* value-0.001]. At 3 hours, the difference in PADSS scores amongst the two groups was not significant [*p* value-0.321]. Average time to home readiness was significantly lower [*p* value-0.002], shown in Table 6 and displays in Graph 7 and 8.

Summary

Intra-operative higher incidence of hypotension and bradycardia was seen in Group D. No airway problem was seen with Dexmedetomidine Group; but one patient developed post-operative airway obstruction in Midazolam Group which was managed successfully with jaw manipulation and oxygen. The sedation scores were comparable in both Groups, but patients in Group D achieved higher sedation scores prior to induction, which were maintained intra-operatively with no adverse effect on discharge times. This could be attributed

to the unique profile of conscious sedation of Dexmedetomidine

Dexmedetomidine provides better hemodynamic profile and faster recovery in short duration ambulatory surgery with minimal respiratory depression. When used in low doses of 0.2-0.3 mcg/kg I.V. the bradycardia and hypotension is not clinically unsafe. Reduction in mean Propofol dosage in Group D reflects anesthetic sparing property.

Limitation

Pharmacokinetics vary with the duration of infusion of Dexmedetomidine and context sensitive half-life changes from 4 minutes after 10 minutes duration of infusion to 250 minutes after 8 hours duration of infusion. Therefore, results of this study are not applicable to longer duration of infusion of Dexmedetomidine.

Conclusion

Dexmedetomidine infusion in lower dosage 0.2–0.3 mcg/kg/hr for short duration procedures can be a good choice in multimodal approach in Ambulatory Anesthesia. Rapid awakening, quicker time to home readiness are unique recovery profiles.

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