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Research Article

Remifentanil and Dexmedetomidine Sedation for Office Oral Surgery Patients

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Abstract

Background: Our sedation service for an Oral maxillo facial surgeon was affected due to widespread drug shortages for regular sedation medications, fentanyl and midazolam, were not available for deep sedation. Procedural sedation was instead provided with dexmedetomidine (DEX) and remifentanil (REMI) along with propofol (PROP) supplementation as needed, in an outpatient oral surgery office.

Methods: After IRB approval a retrospective chart review was performed. The sedation regimen involved REMI at an infusion rate of 0.2 mcg/kg/minute with a loading dose of DEX, 0.7 mcg/kg. After 11 patients the starting REMI infusion rate was reduced to 0.1 mcg/kg/min. PROP boluses, were then administered starting 5 minutes after the DEX load had completed, the delay allowing time for the slower onset of DEX. A bispectral index (BIS) monitor was used when available. Statistical analysis was done using t-test, one-way ANOVA, Kruskal Wallis and Mann Whitney U tests.

Results: A total of 65 charts were reviewed. The mean dose of DEX was 0.7 mcg/kg and loading took 6 minutes. The mean number of supplemental PROP doses was 6, Patients were ready for discharge within 30 minutes. Average BIS reading during the procedure was 70, consistent with deep sedation. Higher than anticipated episodes of apnea, hypoxemia prompted the use of lower starting dose of REMI infusion.

Conclusions: A sedation regimen using DEX, REMI with PROP supplementation is safe for short term sedation and analgesia. The quick discharge times make it an attractive regimen to facilitate the quick disposition of patients from procedural sedation.

ABBREVIATIONS

MCI: Mild Cognitive Impairment; AD: Alzheimer's disease; SSRIs: Selective Serotonin Reuptake Inhibitors

INTRODUCTION

Deep sedation is often administered by oral maxillo facial surgeons (OMFS) for the extraction of third molar teeth in the office out-patient setting. In our department, these procedures are performed in a university pediatric dental office by an OMFS. Anesthesiology is provided by a group of pediatric anesthesiologists as part of a sedation training program with the dental school. These procedures are usually performed in teenagers and young adults and are most commonly sedated using midazolam, fentanyl with supplemental propofol as needed. This combination has proven to be a safe and effective regimen.

There are several newer sedation agents available today. Dexmedetomidine an alpha 2 agonist is an excellent sedation adjunct and appears to cause less respiratory depression than most other commonly used sedation agents. Dexmedetomidine [1] has a slower onset than the commonly used agents as rather than bolus administration it is administered using a loading dose, over 10 minutes to avoid severe bradycardia. It also has a half-life and redistribution kinetics that are somewhat longer than fentanyl and midazolam.

Remifentanil has a rapid onset and is an ultra-short acting synthetic opiate, with a short half-life, of about 8 minutes [2]. Its potency is about the same as fentanyl [3], however due to the risk of respiratory depression and rigidity it is usually administered as an infusion. The rapid onset of remifentanil also allows changes in the infusion rate to be quickly reflected as clinical changes in the depth of sedation or degree of analgesia.

It is possible that the lower risk of respiratory depression from dexmedetomidine could reduce the degree of respiratory depression when using remifentanil whose risk of respiratory depression, as with all potent opiates, is increased when administered along with propofol [4].

Both of these newer agents are quite expensive. Fentanyl (100 mcg) and midazolam (4mg) cost approximately $5. Dexmedetomidine (50 mcg) and remifentanil (200 mcg) costs approximately $37.

In 2012 and 2013 due to the serious shortages for many

anesthesia and sedation drugs we were unable to procure midazolam and fentanyl for a period of time. The newer, expensive, non-generic medications such as remifentanil and dexmedetomidine were still available. We decided to utilize the combination of remifentanil, Dexmedetomidine and propofol during this period of shortages as our new standard regimen.

The aim of the paper is to describe the report from our QA process on this regimen for third molar extractions in teenagers and young adults. Evaluating its safety, effectiveness and whether it is worth the extra cost, that we might consider it a new standard in the future.

MATERIALS AND METHODS

As part of the QA process we collected data prospectively for 65patients receiving remifentanil, dexmedetomidine and propofol as their sedation regimen. Data collection involved patient demographics, drug dosing, drug times, sedation efficacy, cardio-respiratory parameters (every 5 minutes for up to 40 minutes), BIS monitor and complications. After we had completed the QA process and reported to the department we obtained IRB approval for a retrospective analysis of the QA database for publication.

The sedation regimen involved starting remifentanil at an infusion rate of 0.2 mcg/kg/minute [maximum dose based upon 85 kg, of 17 mcg/minute) followed by a loading dose of dexmedetomidine, 0.7 mcg/kg, (maximum dose based upon 85 kg, of 60 mcg], diluted into a total of 4 ml normal saline. The dexmedetomidine load was given as 4 divided doses over a period of 5 minutes the remifentanil infusion was then reduced to 0.1 mcg/kg/min. Subsequent dose changes were based upon the clinical needs. [of note, after the first 12 patients the initial infusion rate was lowered to 0.1 mcg/kg/minute] and all subsequent changes were based on clinical need. The remifentanil was continued until the final tooth had been extracted before the sutures were being placed. Propofol boluses, 10 mg each were then administered starting 5 minutes after the dexmedetomidine load had completed, the delay allowing time for the slower onset of dexmedetomidine. Propofol boluses were repeated as clinically indicated. A bispectral index (BIS) monitor was used (when available), all patients received supplemental oxygen as well as capnography, pulse oximetry, electrocardiograph (EKG) and non-invasive blood pressure (NIBP). The patient's sedation level was also assessed using the Richmond agitation sedation score (RASS) score (Table 1) at 5 minute intervals during the procedure. The surgeon assessed the appropriateness of the sedation using the surgeon assessment score [SAS] in Table (2). All complications and adjunct medications were noted. Patients were discharged home after they met our discharge criteria (Table 3).

Datawas analyzed using t test and one-way ANOVA for parametric data, chi square for binomial data and the Kruskal Wallis and MWU for non parametric datasets.

RESULTS AND DISCUSSION

The retrospective review of the QA database identified 65 patients who received dexmedetomidine, remifentanil and

Table 1: Richmond Agitation Sedation Score (RASS).

SCORE	TERM
+4	COMBATIVE
+3	VERY AGITATED
+2	AGITATED
+1	RESTLESS
0	ALERT & CALM
-1	DROWSY
-2	LIGHT SEDATION
-3	MODERATE SEDATION
-4	DEEP SEDATION
-5	UNROUSEABLE

Table 2: Surgeon Assessment Score (SAS).

SCORE	DESCRIPTION
0	CASE CANCELLED DUE TO UNCOOPERATION
1	AGGRESSIVE
2	MOVEMENT, PATIENT COMPLAINS
3	MOVEMENT, DELAY
4	MOVEMENT NO DELAY
5	APPROPRIATE
6	NOISY AIRWAY NO DELAY/INTEVENTION
7	INTERVENTION BEFORE AIRWAY PROBLEM, SLIGHT DELAY
8	INTERVENTION AFTER AIRWAY PROBLEM, MODERATE DELAY
9	ORAL AIRWAY, BMV, LONG DELAY
10	CASE CANCELLED DUE TO AIRWAY ISSUES

Abbreviations: BMV: Bag mask ventilation

Table 3: Discharge Criteria, after assessment by the anesthesiologist.

Minimum of 20 minutes post-procedure observation
Alert and orientated
Vital signs stable
No pain
No nausea
Able to stand unaided
Able to walk unaided
No supplemental oxygen required
Discharge criteria given
24 hour contact telephone number
Balance testing (Romberg test and straight line walking)

Table 4: Patient demographics.

High Dose (n=12)	AGE (years)	WEIGHT(kg)	GENDER(M/F)
Mean ± SD	17.7 ±2.1	68.5 ±10.4	8 / 3
Range	14 to 20	55to 85	
Low Dose (n=53)	**AGE (years)**	**WEIGHT(kg)**	**GENDER(M/F)**
Mean ± SD	17.3 ±2.0	73.2 ±18.9	30 / 23
Range	13 to 24	42 to 123	-

Abbreviations: SD: Standard Deviation

propofol for deep sedation. The sedation method changed with respect to the loading remifentanil infusion after the first 12 patients. The patient demographics for the two groups are shown in Table (4). In both groups the mean age was 17 years (t test: p = 0.406) with no differences in weight (t test: p = 0.425) or gender (chi square: p = 0.502. Sedation drug doses used are shown in Tables (5a) and (5b). The only difference between the two groups was the total dose/ kg of remifentanil which was significantly higher in the high loading dose group. The mean dose of dexmedetomidine was 50 mcg, about 0.7 mcg/kg, consistent with the dosing schedule. The intermittent dexmedetomidine loading took about 6 minutes. In the low dose group, the mean total remifentanil dose was about 200 mcg infused for 30 minutes, the median number of supplemental propofol doses required was 5, resulting in a total dose of about 0.9 mg/kg. The majority of the propofol was given during a 4-minute window; about 11 minutes after the remifentanil infusion had started.

Lidocaine 2% with epinephrine 1:200000 was administered to all patients, the median dose was 8 carpules (lidocaine 36 mg / carpule). All patients also received 0.5 mg/kg ketorolac IV and 10 mg dexamethasone IV, 66% received 4 mg ondansetron IV during the procedure.

Procedure times for both groups are shown in Table (6). In the low dose group, the time from starting the remifentanil infusion to starting the procedure (placement of local anesthesia) was 15 minutes. Local anesthesia took 4 minutes to complete and the surgical procedure lasted about 16 minutes. The times for the high dose group were not significantly different. The patients were ready for discharge after about 30 minutes.

The quality of sedation was assessed in several manners. The median and range for the RASS and SAS assessments for the low dose group are shown in Table (7). The patients were lightly sedated for the placement of the bite block and then deeply sedated for both the stimulating local anesthesia placement and the third molar extractions. The median surgeon assessment indicated that the level of sedation was appropriate. However, the SAS indicated, not unexpectedly, there was a significant range from both under to over-sedation for all three periods of the procedure.

The BIS monitor was also used in 34 patients to assess sedation (Figure 1). The BIS fell to the low 70's for the procedure. This is consistent with deep sedation and matches the changes in the RASS score during the procedure (Figure 2).

The mean heart rate (all patients) decreased during the initial 15 minutes as the patient was being sedated and then rose to slightly higher than baseline for the rest of the procedure (Figure 3). There were no significant changes in the systolic blood pressure (all patients) during the procedure (Figure 4). One patient in the high dose group had a systolic pressure < 80, no treatment was required. Respiratory depression was assessed using nasal cannula capnography (Figure 5). There was a significant increase in the ETCO2 (all patients), peaking during the procedure. Fifty percent of the patients had an ETCO2 > 55 mmHg documented during the procedure. There was no difference between the high dose and low dose groups for any of the cardio-respiratory parameters.

Table (8) shows complications from both the high and low doses. There was 1 episode of severe bradycardia (< 40, no treatment was required), however 20% of the patients did have a heart rate < 50, no treatment was required either, and this

Table 5: Drug Doses, The only significant difference in drug doses between the groups is the * total remifentanil dose mcg/kg *(p< 0.05)*.

High Dose	DEX DOSE	DEX /KG	DEX LOAD	REMI TOTAL	REMI /KG	REMI RATE	DUR REMI	TOTAL PROP	PROP /KG
	(mcg)	(mcg /kg)	(mins.)	(mcg)	(mcg /kg)	(mcg/kg/ min.)	(mins.)	(mg)	(mg/kg)
Mean± SD	47.4±6.9	0.69±0.01	6.0±1.4	232±56	3.4±0.5*	0.09±0.02	32.6±5.2	72.7±40.3	1.0±0.5
Range	38.5 to 57.5	0.67 to 0.71	4.0 to 9.0	160 to 330	2.2 to 4.0	0.05 to 0.20	22.0 to 43.0	30 to 150	0.5 to 2.2
Low Dose	**DEX DOSE**	**DEX /KG**	**DEX LOAD**	**REMI TOTAL**	**REMI /KG**	**REMI RATE**	**DUR REMI**	**TOTAL PROP**	**PROP /KG**
	(mcg)	(mcg /kg)	(mins.)	(mcg)	(mcg /kg)	(mcg/kg/ min.)	(mins.)	(mg)	(mg/kg)
Mean ± SD	49.0 ±9.6	0.68±0.05	5.4 ±1.0	201 ±45	2.8 ±0.6*	0.09 ±0.02	31.3 ±6.0	60.4 ±30.2	0.9 ±0.5
Range	29.5 to 70.0	0.5 to 0.75	4.0 to 8.0	120 to 280	1.5 to 4.8	0.05 to 0.20	17.0 to 43.0	10 to 130	0.1 to 2.2

Abbreviations: DEX: Dexmedetomidine; REMI: Remifentanil; PROP: Propofol, DUR: duration of infusion

Table 6: Procedure times (minutes).

High Dose	SEDATION	LA	PROCEDURE	DISCHARGE
Mean ± SD	17.2 ±1.9	3.0 ±1.4	14.5 ±5.4	28.1 ±5.0
Range	14 to 20	1 to 6	3 to 23	20 to 38
Low Dose	**SEDATION**	**LA**	**PROCEDURE**	**DISCHARGE**
Mean ± SD	15.5 ±2.3	3.8 ±1.9	15.8 ±6.0	30.3 ±10.3
Range	11.0 to 21.0	11.0 to 11	7 to 38	20 to 60

Abbreviations: LA**:** Placement of local anesthesia block.

Table 7: Sedation Assessment, Low Dose Group.

	BITEBLOCK		LOCAL ANESTHESIA		PROCEDURE	
	RASS	*SAS*	*RASS*	*SAS*	*RASS*	*SAS*
Median	-1	5	-4	5	-4	5
Minimum	-1	5	-5	4	-5	2
Maximum	1	6	-1	7	-1	6

Abbreviations: RASS: Richmond Agitation Sedation Score; SAS: Surgeon Assessment Score

Table 8: Complications, Comparing High and Low Dose Groups.

	DESATURATION	OBSTRUCTION	APNEA	BRADYCARDIA
	< 90%	*INTERVENTION*	*STIM/ASSIST*	*< 40*
High Dose	5	7	2	0
Low Dose	9	12	0	1
p value	*0.03*	*0.02*	*0.03*	*NS*

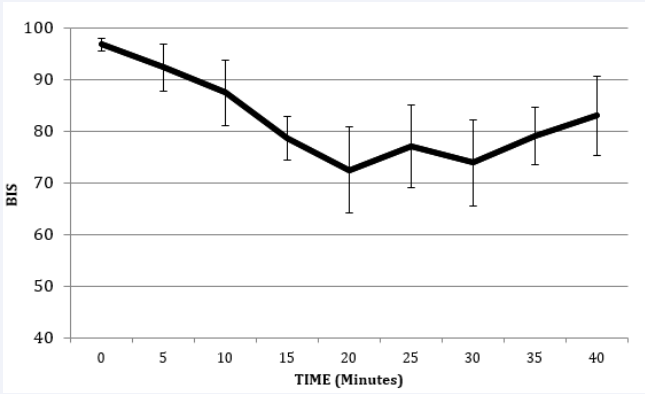

Figure 1 All patients, Mean BIS Scores, (+/- SD).
**p <0.01.* For all data points compared to baseline value.

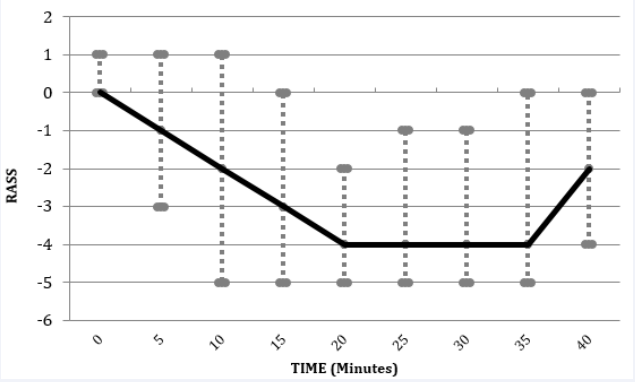

Figure 2 All patients, Median RASS (+/- range).
**p <0.01.* For all data points compared to baseline value

mostly occurred early during the dexmedetomidine load. There were 2 episodes of apnea, requiring verbal stimulation to remind the patient to breathe, during the loading phase in the high dose remifentanil group. This along with the higher than anticipated rate of desaturation and obstruction in the high dose remifentanil group, resulted in the change of our remifentanil loading strategy.

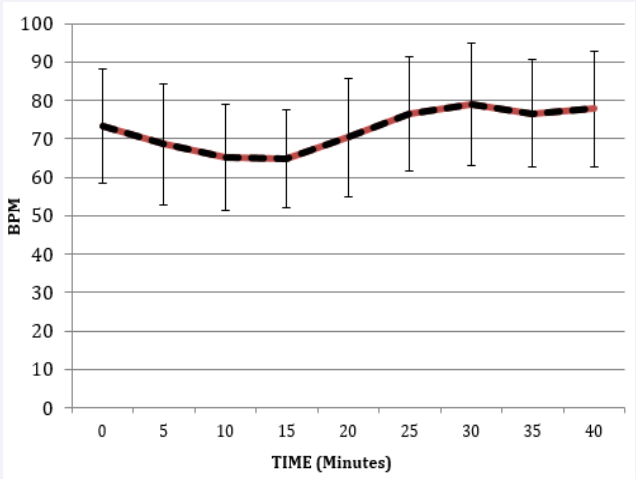

Figure 3 All patients, Mean Heart Rate (+/- SD)
**p <0.01.* For data points t=5 through t=15 minutes when compared to baseline value

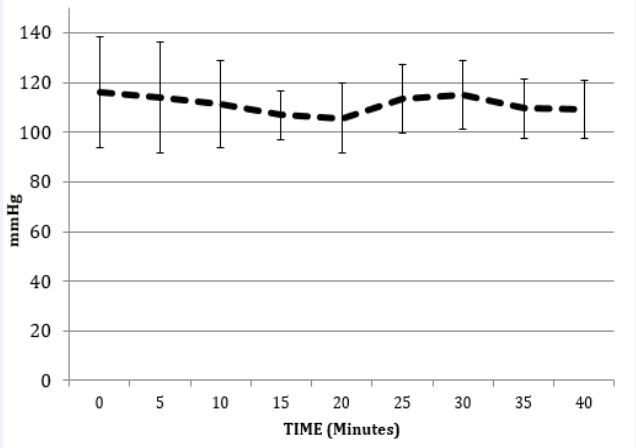

Figure 4 All patients, Mean Systolic Blood Pressure (+/- SD)
There was no significant change in blood pressure during the procedure

The reduced load resulted in a significantly reduced incidence of desaturation, obstruction and apnea.

Pharmacokinetic modeling for a remifentanil infusion, based upon published kinetic data demonstrates the more rapid increase in the remifentanil levels for the high dose group that may have contributed to the increased incidence of airway complication noted (Figure 6).

The remifentanil dose was adjusted if clinically indicated by 0.02 mcg/kg/minute. The dose was adjusted in the low dose group as follows: 17% required a decrease in the remifentanil infusion after a median time of 15 minutes. Two patients required an increase after a median of 25 minutes.

This review of using dexmedetomidine and remifentanil along with intermittent propofol boluses was performed as part of a QA report due to drug shortages in our dental clinic.

The initial high dose loading resulted in higher remifentanil levels during the initial 15 to 20 minutes (Figure 6). This was

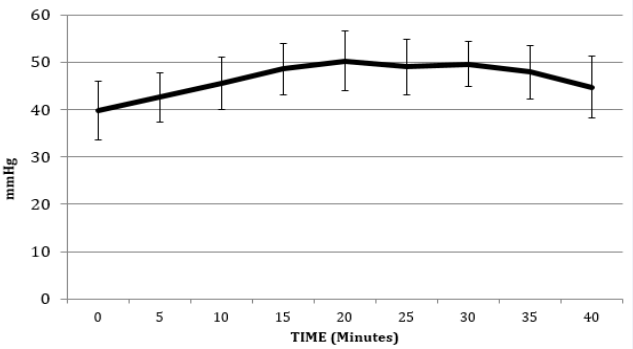

Figure 5 All patients, Mean End Tidal CO2 (+/- SD)
*p <0.01. For all data points compared to baseline value.

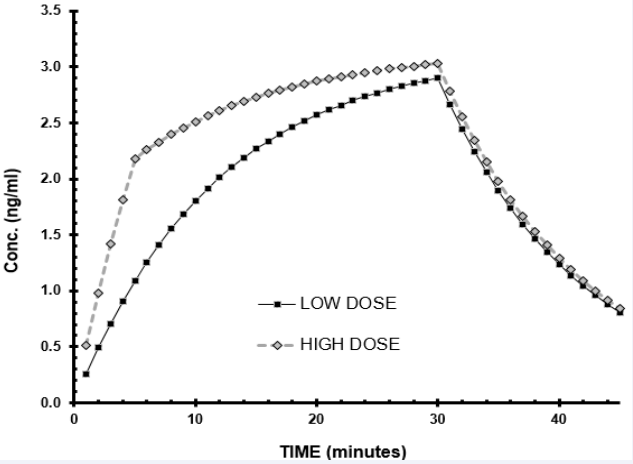

Figure 6 Pharmacokinetic model of Remifentanil Infusion, low and high dose.
Results per dose Key: A: 70 kg patient, Volume distribution 27l, K-elimination 5.13, Half-life 8.4 minutes; HIGH DOSE: 0.2 mcg/kg/minute for 5 minutes followed by 0.1 mcg/kg/minute for 25 minutes; and LOW DOSE: 0.1 mcg/kg/minute for 30 minutes.

the time period during which the complications occurred. This is probably related to the initial dosing of propofol a potent respiratory depressant when combined with opiates [5]. Both remifentanil and propofol have significant depressant effects on minute ventilation, however when they are combined the synergistic effect can increase the respiratory depression, resulting in a higher ETCO2 as well as a flattened response to the hypercapnia [6].

The quality of the sedation by this technique appears very good, the surgeon was very satisfied by the level of sedation with minimal interruptions to the surgical procedure due to over or under-sedation. The RASS were mostly in the -4 range, the occasional -5, difficult to arouse but no treatment was required. No airway interventions beyond chin lift or jaw thrust were required. The BIS scores appeared a little higher than we anticipated from our previous experience, this may be due to the fact that remifentanil may only have minimal effects on the BIS [6] and as such the BIS reflected just the low dose of propofol and dexmedetomidine, which will cause the BIS to fall into the low 70's using the full recommended dosing [7]. The RASS and SAS scores may be influenced by the variability from the observer (either an anesthesia or ICU fellow)or surgeon (all procedures were performed by one surgeon). That is why we also used the non-subjective nature of the BIS monitor (when available) to confirm our depth of sedation. The BIS monitor itself can have errors, due to signal quality issues as well as pharmacology dependent errors. The BIS may actually increase with ketamine [8] and with nitrous oxide the BIS may not accurately reflect the depth of sedation [9]. In our cases the BIS and the RASS seemed to be in agreement during the procedure.

The use of remifentanil as part of the sedation regimen brings several important factors into play. There are some unique pharmacokinetic properties of remifentanil that must be considered. Remifentanil is rapidly metabolized by nonspecific esterases to an inactive metabolite [10]. The half-life of remifentanil is much shorter than other clinically used opiates and as such usually requires an infusion to maintain a steady blood level. The half-life of remifentanil does not change with longer infusions, and so accumulation is not a concern, patients are not at risk of delayed awakening. It is supplied as a powder and must be reconstituted to the desired concentration. This does increase the risk for error. We routinely use a 20 mcg/ml solution (1 mg dissolved in 50 ml normal saline). Also due to the rapid termination of effect, the remifentanil dose does not need to be weaned down towards the end of the procedure and should be maintained until the painful stimulus has finished. Also related to the quick offset, preemptive dosing of post-operative analgesia is warranted; as such we gave a dose of ketorolac early during the procedure for postoperative pain control. Remifentanil has been given by repeated bolus method [11], however the risk of respiratory depression is greater and maintaining a stable blood concentration can be difficult [12]. We felt that it was safer and more efficacious to use the infusion pump for the remifentanil and load the Dexmedetomidine using a 4 repeated bolus method.

Dexmedetomidine also has some specific properties when

used that are important to review. The loading dose is usually recommended over 10 minutes [1], however there are reports of a quicker 5-minute load without any problems [13]. In fact, up to 0.5 mcg/kg has safely been given by a bolus method [14]. We chose to give 0.7 mcg/kg divided into 4 doses, administered over about 5 minutes. We did note bradycardia occurring, however only one patient had a heart rate less than 40, who did not require treatment. The majority of the patients' heart rate fell during the first 10 minutes. Remifentanil could augment this bradycardic effect. Usually after the dexmedetomidine load, an infusion is recommended, however with our relatively short procedures we felt that the loading kinetics more closely matched our therapeutic needs for the dexmedetomidine. When higher doses of dexmedetomidine are used, prolonged recovery has been noted. This could also occur if an infusion was used. The most painful part of the procedure is during the placement of the local anesthetic blocks. During this phase of the procedure we had the highest levels of the dexmedetomidine. Dexmedetomidine also has analgesic properties [15], which may have helped with the management of postoperative pain control with using the short acting remifentanil. Several papers [7] have noted hypotension during the dexmedetomidine load. We did not find this even with a rapid load. Dexmedetomidine has been reported to have little effect on $ETCO_2$ [7], however in our patients the combination of remifentanil and propofol caused significant increases of $ETCO_2$. As such the dexmedetomidine does not appear to protect the patient from respiratory depression. Also when comparing dexmedetomidine to propofol for deep sedation using MRI imaging of the pharyngeal structures there was no difference in the degree of airway collapse between dexmedetomidine and propofol [16].

Dexmedetomidine as a solo agent can be utilized, however deep sedation may be difficult. A report on successful moderate sedation for OMFS procedures using dexmedetomidine in combination was associated with a discharge time of 90 minutes [17]. Also the recovery from dexmedetomidine can demonstrate the non-stimulus dependent nature of the obtained sedation. Patients will wake up and be orientated when stimulated, however fall to sleep when left alone, delaying recovery [7].

The cost of this sedation regimen must be considered (US Dollar, 2017, non hospital contract purchase cost). The actual cost/mg difference is about $32 per case, however unless you are able to do multiple cases, the cost could increase to the full vial cost for each drug, which would be approximately $175 per case.

After we had changed our loading dose for the remifentanil we did not experience more airway complications that could be considered more than is anticipated when performing deep sedation for oral surgical procedures. The high dose load was associated with apnea, a complication one wishes to avoid if the patient's airway is not controlled and the surgeon is operating in that vicinity. The lower dose complications were all easily managed with chin lift and jaw thrust.

CONCLUSION

Should this new regimen become our standard of care? It is definitely effective enough, the complications were not increased and the discharge time was very quick, facilitating a rapid office throughput if necessary. The OMFS also stated that this was his favorite sedation method. The bolus dose of dexmedetomidine was safe and effective. The low dose infusion rate for the remifentanil was appropriate in 80% of the patients. The need for an infusion pump, and the increased costs of the sedative agents could limit its application in general, however for a busy schedule we feel that it is an appropriate method to use.

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