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Evaluation of patient controlled sedation (PCS) during surgical removal of impacted lower third molars

Aktham Adel shoukry¹*, Mohamed Magdy bakr², Sameh Mekhemer³, Salah Yassin³

Abstract

Objective: The current study was conducted to evaluate the safety of patient-controlled sedation (PCS) and the efficiency of elastomeric infusion device during surgical removal of impacted lower third molars and its impact on patients regarding level of sedation, patients' satisfaction and psycho-motor recovery.

Material and Methods: Twenty patients were equally divided into two groups chosen randomly. In both groups, 0.03 mg/kg Midazolam and 0.5 mg/kg Propofol were administered IV as a bolus dose. Group 1 was then given 0.3 mg/kg/hr Ketamine and 1.2 mg/kg/hr Propofol as a maintenance dose delivered through the PCS pump. Group 2 was then given 0.3 μ g/kg/hr Fentanyl and 1.2 mg/kg/hr Propofol as a maintenance dose delivered through the PCS pump. For all patients' surgical procedure were done under local anesthesia. Before going to the operating theatre all patients were instructed about the PCS pump and familiarized with it. Patients in both groups were evaluated for hemodynamic stability, patient's &surgeon's satisfaction, psychomotor recovery and adverse effects.

Results: The results of this study showed no statistical difference between the two groups. The use of different drug combinations in both groups showed hemodynamic stability, patients'& surgeon's satisfaction and rapid psychomotor recovery. None of the patients in both groups suffered from any adverse reactions such as: nausea, vomiting, hallucinations, involuntary movements, or over-sedation.

Conclusion: PCS can be considered as a safe option in minor oral surgeries providing the majority of patients with high satisfaction and relaxation, also providing the surgeons with good operating conditions and the cooperation of the majority of the patients. Fentanyl-Propofol and Ketamine-Propofol combinations were both safe with respect to hemodynamic changes with rapid recovery of psychomotor functions in all patients.

Key words: Analgesia, Patient-Controlled, Impacted, Molar, Third, Tooth, Accufuser, Moderate Sedation

Introduction

Dental treatment often causes fear among patients, and although local anaesthetics make dental treatment easy and painless, dental operations arouse fear and anxiety (1) (2). Dental surgical procedures or even just the idea of having a tooth extracted are usually associated with patient discomfort and apprehension (3). This is in agreement with studies indicating that an extraction is considered to be highly distressing and that it belongs to the top 5 most fear-evoking procedures in dental treatment (4) (5)

Historically, general anaesthesia has been the usual pharmacological approach used in management of apprehensive patients. It is satisfactory and effective in sedation and pain control, but it has serious limitations as well as its technical hazards (6). General anaesthesia might be costly even in a freestanding outpatient surgery centre, and few dentists are familiar with procedures for functioning in the hospital environment (7). The use of some form of sedation is therefore common during dental operations.

Conscious sedation is medically controlled state of depressed consciousness that allows protective reflexes to be maintained, retains the patients' ability to keep an air-way patent independently and continuously, and permits appropriate responses to physical stimulation or verbal command. The field of patient-controlled sedation (PCS) is relatively young, and few practitioners have experience with this technique. The earliest report of PCS is that of Rudkin et al. in 1991 (8) who used a modified Graseby PCA pump to permit administration of propofol to patients undergoing third molar extraction. PCS describes delivery of sedative medications that is controlled by the patient throughout the procedure, including initiation of loading doses. The ability to modify the pain experience by simply pressing a button may be as potent an analgesic as the drug itself (9).

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¹ Ain Shams University, Dept. of anesthesia and intensive care, Cairo, Egypt

² October 6 University, Faculty of Oral and Dental medicine, Oral and Maxillofacial Department, Cairo-Egypt

³ Faculty of Oral and Dental medicine, Cairo University, Oral and Maxillofacial Department, Cairo-Egypt

^{*}Corresponding Author: Aktham Adel Shoukry E-mail: aktham.shoukry1@gmail.com

PCS provides adequate relief for patients, and allows them to vary the degree of sedation according to the amount f stress they feel from the operation and the environment. It is often used for sedation during procedures done under regional or local anaesthesia, and is the preferred technique because the total dose can be titrated according to the patients' needs and regulated according to their anxiety. It also lessens the risk of overdose and inadequate sedation. Many studies have shown that this technique is safe and satisfactory (2) (10).

The *Accufuser* is a reliable, disposable device that has a continuous and accurate pre-fixed flow rate and elastomeric silicone reservoir without need for electrical power or extra equipment. The *Accufuser* is specially designed to deliver medications with continuous and bolus dose in the range of patient controlled analgesia infusion therapy. The *Accufuser* is designed for single-use in hospital, outpatient, and home care settings. The Accufuser was originally designed to be used in patient controlled analgesia (PCA) in many procedures. In our study, using the same concept of patient controlled analgesia, we used the Accufuser as a delivery pump for sedative drugs that is controlled by the patient.

Sedative-hypnotics and opioid analgesics are often used together to improve comfort and provide sedative, anxiolytic, and supplemental analgesia during outpatient operations under local anaesthesia. Propofol sedation is used frequently in local and regional anesthesia for its amnestic and anxiolytic effects (11) (12). Although propofol has the advantages of rapid awakening and minimal nausea and/or vomiting, its analgesic activity is insufficient; moreover, it may cause respiratory and cardiovascular depression (13). In minor surgery, propofol is combined with opioids, such as fentanyl, to achieve better analgesia (14) (15). Avramov et al. (16) reported that the propofol-combined opioid provides analgesia and amnesia, as well as reduces incidences of nausea, vomiting, and respiratory depression. Ketamine also causes minimal cardiovascular and respiratory depression, and at sub-anesthetic doses, it induces analgesia (17) (18) (19). Recent studies has been showed that low-dose ketamine in combination with propofol sedation, achieves adequate analgesia and preserves respiration (20) (21).

Patients and Methods

After we had ethics committee approval and informed patients' consent, 6 female and 14 male healthy patients (American Society of Anaesthesiologists grade I and II) aged between 18 and 34 who required surgical removal of impacted lower third molars were included to the study. The patients were selected from the outpatient clinics of the Oral and Maxillofacial Surgery Departments at the Faculties of Oral and Dental Medicine, at Cairo University and October 6 University in Egypt. All operations had the same degree of difficulty. Exclusion criteria included taking sedative, hypnotic, or psychoactive medication and serious musculoskeletal problems that would make the ballbearing test impossible. Before sedation all patients completed the ball bearing test to evaluate their psychomotor function. They were asked to pick up 40 beads with a tissue forceps from one cup and to carry them to another within 40 s. The numbers of beads carried were recorded as the score. This test was repeated at 15, 30, 45, and 60 min, postoperatively.

Before going to the operating theatre all patients were familiarized with the ACCUFUSER® pump (fig. 1) and were shown how to use it. For all the patients, the surgical procedure was performed under local anesthesia and I.V. sedation. A sterile syringe was filled with the sedatives to be dispensed into the pump reservoir. The filled syringe was then connected to the filling port of the pump and the sedatives were injected into the medication reservoir. The Accufuser module button was then fixed on the patient's wrist and the patient was instructed to press the button whenever he/she felt anxious, or whenever they felt that the level of sedation has decreased.



Figure 1: ACCUFUSER Pump

The two groups were chosen randomly. An IV cannula was inserted into a dorsal hand vein and a bolus dose of 0.03 mg/kg Midazolam and 0.5 mg/kg Propofol was administered as an induction dose in both groups of the study. The Accufuser pump was then connected to the IV cannula to deliver the sedative drugs after being prepared by the anaesthesiologist according to each group.

Group 1 was given 0.3 mg/kg/hr Ketamine and 1.2 mg/kg/hr Propofol as a maintenance dose delivered through the PCS pump. The PCS pump was prepared with 40 ml Propofol, 2 ml Ketamine and 3ml Xylocaine. Group 2 was given 0.3 μ g/kg/hr Fentanyl and 1.2 mg/kg/hr Propofol as a maintenance dose delivered through the PCS pump. The PCS pump was prepared with 40 ml Propofol, 2 ml Fentanyl and 3 ml Xylocaine.

After the 5th minute of sedation, 4 mL of local anesthetic [4% Articaine with 1/100 000 Adrenaline, 2 mL; UbistesinTM Forte (**3M Deutschland GmbH** Carl-Schurz-Strasse 1 DE-41453 Neuss Germany)] was given to anesthetize the inferior

alveolar, lingual and long buccal nerves. The efficacy of the local anesthetic was assessed by verbal questioning and by gently probing the buccal and lingual surfaces of the third molar. After ensuring the profoundness of the local anesthetic, the surgical procedure began. A full thickness mucoperiosteal flap was elevated to gain access to the impacted molar. Buccal and distal bone removal was performed down to the cervical line of impaction using surgical burs mounted on motor driven straight hand piece under copious irrigation. Tooth sectioning or decapitation was done to decrease the resistance, and a point of application was made. A suitable elevator was then applied to the application point to deliver the impacted tooth. The wound was then irrigated using warm saline to remove any debris. Then the wound was closed by interrupted sutures using (000) vicryl. All operations were done by the same surgeon using the same technique.

Throughout the study blood pressure, pulse rate, peripheral oxygen saturation (SaO2) were monitored non-invasively. Monitoring was done and recorded before the procedure, and was repeated every 5 minutes throughout the procedure. Assessment of sedation level was recorded at the 5th minute of sedation using modified five-levelled sedation scale (Table 1) (22).

 Table 1: Picture showing sedation level scale.

| Secation | Definition |
|----------|---|
| Scale | |
| 1 | Fully awake and oriented |
| 2 | Drowsy, eyes open |
| 3 | Drowsy, eyes closed but rousable |
| 4 | Drowsy, eyes closed arousable on mild stimulation |
| 5 | Unarousable on mild physical stimulation |
| | |

To evaluate the patient's opinion about the procedure under sedation a modified visual analogue scale from 0 to 10 was applied (0 is totally calm & 10 is worst fear imaginable) (Fig. 2) (23).

Figure 2: Picture showing modified visual analogue scale.



Assessment was repeated every 10 minutes throughout the procedure. The condition of the patient during the surgery under PCS was evaluated by the surgeon on a scale from 1 to 5 (1= patient is calm and cooperative and 5= patient is very nervous and very resistant towards the procedure). Assessment was recorded on the injection of the local anesthetic and during the operation. An object was shown to the patients after 20 minutes of sedation, they were asked to identify it and identify its colour. To evaluate the level of amnesia at 60 minutes and one week postoperatively, the patients were asked whether they remember the injection of the local anaesthetic, the operation and the suturing. They were also asked whether they remember the object that they had been shown during the procedure or not.

The patients were observed for any adverse reactions such as, nausea, vomiting, hallucinations, involuntary movements or drowsiness. The numbers of presses recorded by the digital counter were documented to evaluate the efficiency of sedation.

The collected data were revised, coded, tabulated and introduced to a pc using statistical package for social science (SPSS 22.0 for windows; IBM USA).

Description of quantitative (numerical) variables was performed in the form of mean \pm SD. Description of qualitative (categorical) data was performed in the form of number of cases and percent. Error bars represent 95% confidence interval. Analysis of unpaired numerical variable was performed using the unpaired Student t-test, whereas analysis of paired numerical variables was performed.

Results

The study was conducted on 20 patients [14 males (70%) and 6 females (30%)]. The minimum age was 18 years; maximum was 34 years with a mean age of 24.6 \pm 4.2 years. Patients were randomly divided into two equal groups, Group 1 (Ketamine – Propofol group): consisted of 10 patients distributed as 10 males and no females. The mean age was 23.4 \pm 5.5 years. Group 2 (Fentanyl – Propofol group): consisted of 10 patients distributed as 4 males and 6 females. The mean age was 25.8 \pm 3.9 years.

Preoperative heart rate value was recorded for all the patients in each group and considered as the base line value. There was insignificant increase in the intra-operative value when compared with the preoperative heart rate in both groups (Table 2, 3).

 Table 2: Showing group 1 Pre-operative and Intra-operative mean heart rate values.

| | Time | Pre-operative | | Intra-operative | | | |
|------------------|--------|-----------------------------|----------|-----------------|----------|--|--|
| Group | | Mean | \pm SD | Mean | \pm SD | | |
| Ketamine-Propfol | | 71.6 | 11.9 | 71.9 | 8.8 | | |
| Mean differences | | Pre-operative – Intra-opera | | | ative | | |
| P-value | -value | | | 0.9342 | | | |

 Table 3: Group 2 Pre-operative and Intra-operative mean heart rate values

| Time | Pre-operative | | Intra-o | operative |
|------------------|---------------------------------|----------|---------|-----------|
| Group | Mean | \pm SD | Mean | \pm SD |
| Fentanyl-Propfol | 73.9 | 13.7 | 75.2 | 10.19 |
| Mean differences | Pre-operative – Intra-operative | | | erative |
| P-value | 0.8061 | | | |

On comparing the two groups together by using the t-test, there was no statistically significant difference between the mean heart rate in the two groups (Fig. 3).



Figure 3: Graph comparing mean preoperative and intra-operative heart rate values between two groups. Bars represent Mean±SD

The preoperative systolic blood pressure was recorded for the patients in each group and was considered as the baseline value. There was insignificant decrease in the intra-operative values when compared with the preoperative SBP in both groups (Table 4, 5).

 Table 4: Group 1 Pre-operative and Intra-operative mean systolic blood pressure values

| Time | Pre-operative | | Intra-operative | | |
|----------------------|---------------------------------|----------|-----------------|----------|--|
| Group | Mean | \pm SD | Mean | \pm SD | |
| Ketamine- Propfol | 121.9 | 11.4 | 117.8 | 7.05 | |
| Mean differences | Pre-operative - Intra operative | | | | |
| P-value | 0.3497 | | | | |

 Table 5: Showing: group 2 Pre-operative and Intra-operative mean systolic blood pressure values.

| Time | Pre-operative | | Intra-operative | | |
|----------------------|---------------------------------|----------|-----------------|----------|--|
| Group | Mean | \pm SD | Mean | \pm SD | |
| Fentanyl- Propfol | 116.6 | 14.1 | 111.6 | 7.05 | |
| Mean differences | Pre-operative – Intra-operative | | | | |
| P-value | 0.3949 | | | | |

On comparing the two groups together by using the t-test, there was no statistically significant difference in the mean systolic blood pressure between the two groups (Fig 4).

Preoperative diastolic blood pressure was recorded for patients in each group and was considered as the baseline value. There was insignificant decrease in the intra-operative value when compared with the preoperative DBP in both groups (Table 6, 7). doi



Figure 4: Graph comparing mean intra-operative systolic blood pressure values between the two groups of the study. Bars represent Mean±SD

Table 6: showing: group 1 Pre-operative and Intra-operative mean diastolic blood pressure values.

| Time | Pre-operative | | Intra-operative | |
|------------------|---------------------------------|----------|-----------------|----------|
| Group | Mean | \pm SD | Mean | \pm SD |
| Ketamine-Propfol | 72.5 | 7.7 | 71.4 | 5.4 |
| Mean differences | Pre-operative – Intra-operative | | | |
| P-value | | 0.721 | 5 | |

| Table 7: showing: group 2 Pre-operative and Intra-operative |
|---|
| mean diastolic blood pressure values |

| Time | Pre-operative | | Intra-operative | |
|------------------|---------------------------------|----------|-----------------|----------|
| Group | Mean | \pm SD | Mean | \pm SD |
| Fentanyl-Propfol | 73 | 11 | 67.2 | 5.12 |
| Mean differences | Pre-operative – Intra-operative | | | tive |
| P-value | 0.1520 | | | |

On comparing the two groups together by using the t-test, there was no statistically significant difference in the mean diastolic blood pressure between the two groups (Fig 5).



Figure 5: Graph comparing mean intra-operative diastolic blood pressure values between two groups. Bars represent Mean±SD

There was insignificant increase in the intraoperative oxygen saturation when compared with the preoperative value in group 1, (Table 8) while there was insignificant decrease in the intra-operative oxygen saturation when compared with the preoperative value in group 2 (Table 9).

 Table 8: Showing: group 1 Pre-operative and Intra-operative mean oxygen saturation values.

| Time | Pre-operative | | Intra-c | perative |
|------------------|---------------------------------|----------|---------|----------|
| Group | Mean | \pm SD | Mean | \pm SD |
| Ketamine-Propfol | 98.9 | 0.9 | 99.2 | 0.4 |
| Mean differ. | Pre-operative – Intra-operative | | | |
| P-value | 0.3549 | | | |

 Table 9: showing: group 2 Pre-operative and Intra-operative mean oxygen saturation values.

| Time | Pre-operative | | Intra-operative | |
|------------------|---------------|------------|-----------------|----------|
| Group | Mean | \pm SD | Mean | \pm SD |
| Fentanyl-Propfol | 99 | 0.6 | 98.7 | 0.46 |
| Mean differ. | Pre | -operative | - Intra-op | erative |
| P-value | 0.3711 | | | |

On comparing the two groups together by using the t-test, there was statistically significant difference in the mean oxygen saturation between the two groups where [P value = 0.0331] (Table 10).

Sedation level was assessed by the anaesthesiologist at the 5^{th} minute of sedation, with all patients in both groups falling in the mild to moderate level of sedation. None of the patients in both groups were under sedated or fell into a level of deep sedation (Table 11).

1, and 2.52 ± 3.1 for Group 2 (Fentanyl – Propofol group). On comparing the two groups together by using the t-test, there was no statistically significant difference in the mean score of the modified visual analogue scale between the two groups where [*P* value = 0.2859] (Table 12).

The mean surgeon's satisfaction value for Group 1 (Ketamine – Propofol group) was 1.4 ± 0.69 , and 1.6 ± 1 for Group 2 (Fentanyl – Propofol group). On comparing the two groups together by using the ttest, there was no statistically significant difference in the mean score of the surgeon's satisfaction between the two groups where [P value = 0.6278]. About 70% of patients in both groups were calm and cooperative throughout the procedure, while only one patient in the Fentanyl - Propofol group that became very nervous (Fig 6, 7). Evaluation of amnesia was done after 60 minutes and one week post-operatively by asking the patients if they remembered the injection of local anaesthetic, removal of bone and suturing, and if they remembered the object that had been shown to them during the surgical procedure. After 60 minutes 30 to 40 % percent of patients in both groups had some degree of amnesia, with no statistical difference between the two groups. After one week postoperatively, revaluation showed a slight increase in the degree of amnesia in both groups, but this increase was statistically insignificant.

There was no statistical difference between the two groups after one week (Table 13).

 Table 10: Comparing mean oxygen saturation values of the two groups together by using the t-test. * Statistically significance

| Casara | Ketamine - Pr | opfol | Fentanyl- Propfol | | | | |
|----------------------|---------------|----------|-------------------|----------|---------|--|--|
| Variable | Mean (n =10) | \pm SD | Mean (n =10) | \pm SD | Р | | |
| Oxygen Saturation | 99.2 | 0.42 | 98.7 | 0.46 | 0.0331* | | |

Table 11: Number of patients in each group and their sedation score.

| Grou | p Ketamine-Propofol | Fentanyl-Propofol |
|--|---------------------|----------------------|
| Sedation scale | No. of pa | tients in each group |
| 1.Fully awake and oriented | 0 | 0 |
| 2. Drowsy, eyes open | 5 | 4 |
| 3. Drowsy, eyes closed but rousable | 5 | 6 |
| 4. Drowsy, eyes closed, rousable on mild stimulation | 0 | 0 |
| 5. Unrousable on mild physical stimulation | 0 | 0 |

Table 12: Comparing mean values of the modified visual analogue score for the two groups together by using the t-test.

| Group | Ketamine-Propfol | | Fentanyl-Propfol | | D l | |
|--------------------------------|------------------|----------|------------------|----------|---------|--|
| Variable | Mean (n =10) | \pm SD | Mean (n =10) | \pm SD | P-value | |
| Modified visual analogue scale | 1.38 | 1 | 2.52 | 3.1 | 0.2859 | |

Table 13: Showing the number of the patients who remembered the intra-operative events and the object shown after 60 min and 1 week (n = 10 in each group).

| | After 60 minutes | | P-value | After 1 week | | P-value |
|--------------------------------|------------------|---------|---------|-----------------|---------|---------|
| | Group 1 | Group 2 | | Group 1 | Group 2 | |
| | No. of patients | | | No. of patients | | |
| Injection of local anaesthetic | 6 | 7 | 0.3574 | 4 | 6 | 0.2674 |
| Removal of bone and suturing | 6 | 7 | 0.3574 | 6 | 5 | 0.3606 |
| Object | 4 | 6 | 0.2674 | 5 | 6 | 0.3606 |

The mean visual analogue scale (VAS) value

for Group 1 (Ketamine – Propofol group) was 1.38 ±

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Table 14: Showing comparison between postoperative scores for the ball bearing test with the preoperative score for each group. * Statistically significant

| | Ketamine – Propofol group | | | Fentanyl – Propofol group | | |
|------------------|---------------------------|------|---------|---------------------------|------|---------|
| | Mean | + SD | P-value | Mean | + SD | P-value |
| | (n =10) | ± 5D | | (n =10) | ± 5D | |
| Preoperative | 18.4 | 3 | | 19.4 | 2.1 | |
| After 15 minutes | 16.7 | 2.1 | 0.1623 | 17.8 | 2.8 | 0.1758 |
| After 30 minutes | 17.7 | 2.4 | 0.5795 | 19.5 | 1.2 | 0.8995 |
| After 45 minutes | 20.1 | 2 | 0.1571 | 19.5 | 2 | 0.9161 |
| After 60 minutes | 20.5 | 1 | 0.0494* | 20.2 | 1.3 | 0.3239 |

The mean preoperative score for the ball bearing test for Group 1 (Ketamine – Propofol group) (Table 14) was 18.4 ± 3 . There was a statistically insignificant decrease in the 15 minutes postoperative mean score of the ball bearing test 16.7 ± 2.1 when compared to the preoperative score, where [P value =0.1623]. also there was a statistically insignificant decrease in the 30 minutes postoperative mean score of the ball bearing test 17.7 ± 2.4 when compared to the preoperative score, where [P value = 0.5795]. There was a statistically insignificant increase in the 45 minutes postoperative mean score of the ball bearing test 20.1 ± 2 when compared to the preoperative score, where [P value = 0.1571]. On the other hand there was a statistically significant increase in the 60 minutes postoperative mean score of the ball bearing test 20.5 ± 1 when compared to the preoperative score, where [P value = 0.0494].

The mean preoperative score for the ball bearing test for Group 2 (Fentanyl – Propofol group) (Table 14) was 19.4 ± 2.1 . There was a statistically insignificant decrease in the 15 minutes postoperative mean score of the ball bearing test 17.8 ± 2.8 when compared to the preoperative score, where [*P* value = 0.1758]. Also there was a statistically insignificant increase in the 30 minutes postoperative mean score of the ball bearing test 19.5 ± 1.2 when compared to the preoperative score, where [*P* value = 0.8995]. There was a statistically insignificant increase in the 45 minutes postoperative mean score of the ball bearing test 19.5 \pm 2 when compared to the preoperative score, where [*P* value = 0.9161]. Also there was a statistically insignificant increase in the 60 minutes postoperative mean score of the ball bearing test 20.2 \pm 1.3 when compared to the preoperative score, where [*P* value = 0.3239] (table-14).



Figure 8: Graph showing the mean number of presses in both groups

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The mean number of pump presses for Group 1 (Ketamine – Propofol group) was 3.6 ± 2.6 , and 2.7 ± 4.5 for Group 2 (Fentanyl – Propofol group) On comparing the two groups together by using the t-test, there was no statistically significant difference in the mean number of presses between the two groups where [P value = 0.5932] Fig (8).

None of the patients in this study suffered from any adverse reactions such as, nausea, vomiting, hallucinations, involuntary movements, or oversedation.

Discussion

Procedural sedation and analgesia refers to the technique of administering sedatives or dissociative agents with or without analgesics to induce an altered state of consciousness that allows the patient to tolerate painful or unpleasant procedures while preserving cardio-respiratory function. (24) Sedation depths of "mild," "moderate," and "deep" levels of altered consciousness are frequently cited in the medical literature (25).

Moderate sedation, previously known as conscious sedation, is a pharmacologically induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, spontaneous ventilation adequate. and is Cardiovascular function is usually maintained. (24) (25) (26)Several methods can be used to produce conscious sedation. One of these, patient-controlled sedation (PCS), provides adequate sedation for patients' requirements and enables the patient to vary the degree of sedation depending on the degree of stress caused by the procedure and environment. (27) (28). It provides the opportunity to titrate the drug to individual patients' requirements by setting the dose given as a bolus with "lockout period" between successive bolus doses to avoid the risk of over sedation. Irwin et al (29) stated that as with any bolus-based concept, PCS may produce unwanted peak effects and an unstable sedation profile, which can be avoided using a basal infusion giving the patient the option to have some boluses.

In the present study the surgical removal of impacted lower third molars was chosen to evaluate the efficiency and safety of ACCUFUSER® ELASTOMERIC INFUSION DEVICE in patientcontrolled sedation (PCS) as the third molar operations are the most painful, highly distressing and belongs to the top 5 most fear-evoking treatment procedures in dental situations.

Propofol sedation is used frequently in local and regional anaesthesia has the advantages of rapid awakening and minimal nausea and/or vomiting, its analgesic activity is insufficient; moreover, it may cause respiratory and cardiovascular depression (13). to achieve better analgesia propofol is combined with fentanyl (14)and sub-anesthetic dose of Ketamine (17) (19) ketamine-propofol and fentanyl-propofol combinations were evaluated in patients undergoing lower third molar surgery with respect to sedation, hemodynamic stability, side effects, recovery of psychomotor functions, and patient and surgeon satisfaction.

Both groups showed hemodynamic stability throughout the procedure, with insignificant increase in the mean heart rate value and insignificant decrease in the systolic and diastolic blood pressure with respect to the preoperative values. Changes in the heart rate, though not statistically significant, were elevated in each group due, in part, to the use of 1/100 000 Adrenaline local anaesthetic.

It is accepted that induction of anaesthesia with propofol is associated with significant decreases in arterial blood pressure due to its vasodilating effect as well as decrease in cardiac output after induction with propofol. In addition, fentanyl, known for its potential to decrease systemic vascular resistance, probably contributed to the cardiovascular effect of the drugs used in this study. The addition of low dose ketamine has been shown to attenuate the cardiovascular and respiratory depressing effect of propofol (21).

The most common problem encountered during patient-controlled sedation is respiratory depression, observed as decrease in the oxygen saturation. In the present study, both groups showed an insignificant decrease in the mean intra-operative values of oxygen saturation when compared to the preoperative values. The possibility for a decrease in oxygen saturation emphasizes the need for close during patient-controlled sedation, monitoring particularly when opioids are added to the sedative agents. On comparing the two groups together, the mean oxygen saturation of the fentanyl-propofol group was significantly lower than the ketaminepropofol group from a statistical point of view, while there was no clinical significance to this difference as the mean value of both groups was above the normal level of oxygen saturation.

The degree of sedation was monitored in both groups the sedation levels were mild to moderate, with no incidence of deep sedation or under sedation.

The patient satisfaction and surgeon's satisfaction are one of the most important aims of sedation. In this study, the values of the modified visual analogue scale were indicative of high patient satisfaction in both groups. The patients in both groups were cooperative and relaxed during the surgical procedure, with no statistically significant difference between the two groups, except for one patient in the fentanyl-propofol group which became uncooperative and resistant to the procedure due to increased difficulty and duration of the surgical procedure. In studies that compared anaesthetistcontrolled sedation with patient-controlled sedation, found that the patients were more comfortable with patient-controlled sedation (30) (31) (32) while in another study, (33) almost an equal number preferred

each technique. In addition, the operators have assessed the operating conditions as good with good cooperation from patients (8)(31)(33)(32).

The anterograde amnesia was greater for the ketamine-propofol group than for the fentanylpropofol group, but the difference was not statistically significant. Considering total of both groups, 60 to 70 % had some degree of amnesia at different events of the surgery. The level of amnesia may be related to the midazolam induction dose rather than the maintenance drugs used in both groups.

The psychomotor function had improved by the 45th minute postoperatively in the ketaminepropofol group and 30th minute in the fentanylpropofol group, which allowed for early discharge of all patients from the hospital.. The preoperative scores of the ball bearing test were surprisingly found to be lower than the post-operative scores in both groups. These results were similar to those of Zuhal Küçükyavuz et al, (34) evaluating the effect of lowdose midazolam with propofol in patient-controlled sedation for apicectomy, suggesting that preoperative stress and anxiety possibly reduces the patients' concentration.

The mean number of pump presses in the fentanyl-propofol group was less than that of the ketamine-propofol group, but the difference was of no statistical significance. It has also been observed that when patients require an increment during the procedure, some press the button many times because they are so eager to receive the drug as soon as possible and to get to a deeper level of sedation, thus the number of pump presses may not be the most reliable test to evaluate the sufficiency of the sedative dose.

Conclusion

PCS can be considered as an efficient and safe option in minor oral surgeries providing the majority of patients with high satisfaction and relaxation, also providing the surgeons with good operating conditions and the cooperation of the majority of the patients. Fentanyl-Propofol and Ketamine-Propofol combinations were both safe with respect to hemodynamic changes with rapid recovery of psychomotor functions in all patients

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References

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- Garip H, Abali O, Goker K, Gokturk U, Garip Y. Anxiety and extraction of third molars in Turkish patients. Br J Oral Maxillofac Surg 2004; 42:551-4.
- Kucukyavuz Z, Cambazoglu M. Effects of low-dose midazolam with propofol in patient-controlled sedation (PCS) for apicectomy. Br J Oral Maxillofac Surg 2004; 42:215–20.
- 3. Anaesthesia, Grattidge R.: Patient-controlled sedation using propofol in day surgery. and 683-85., 47:,1992.
- 4. Earl P: Patients' anxieties with third molar surgery. Br J Oral Maxillofac Surg 32:293, 1994.
- Yusa H, Onizawa K, Hori M, et al: Anxiety measurements in university students undergoing third molar extraction. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 98:23, 2004.
- O'Neil R and VerrillP J. Intravenousdiazepam in minor oral surgery. Br .J Oral Surg and 12-14., 7, 1969.
- 7. EJ, Smilack ZH and Florucci RD. Sedation with intravenous diazepam. J Oral Surg 1972; 332., 30:.
- 8. Rudkin GE, Osborne GA, Curtis NJ: Intra-operative patient controlled sedation. Anaesthesia 1991; 46:90-92.
- 9. Koyama T, McHaffie JG, Laurienti PJ, et al. The subjective experience of pain:where expectations become reality. Proc Natl Acad Sci U S A 2005; 102:12950–12955.
- Esen E, U⁻⁻ stu⁻n Y, Balciog⁻lu O, Alparslan ZN. Evaluation of patient-controlled remifentanil application in third molar surgery. J Oral Maxillofac Surg 2005; 63:457–63.
- Sa Rego MM, Watcha MF, White PF. The changing role of monitored anesthesia care in anesthesiology. Anesth Analg 1997; 36., 85:1020-.
- Smith I, Monk TG, White PF, Ding Y. Propofol infusion during regional anaesthesia: sedative, amnestic, and anxiolytic properties. Anesth Analg 1994; 313–9, 79:.
- Smith I, White PF, Nathanson M, Gouldson R. Propofol: an update on its clinical use. Anesthesiology 1994; 43., 81:1005-.
- Smith C, McEwan AI, Jhaveri R, et al. The interaction of fentanyl on the Cp50 of propofol for loss of consciousness and skin incision. Anesthesiology 1994; 8., 81:820 -.
- Vukyk J, Lim T, Engbers FH, Burm AG, Vletter AA, Bovill JG. The pharmacodynamic interaction of propofol and alfentanil during lower abdominal surgery in women. Anesthesiology 1995; 22., 83:8 -.
- Avramov MN, White PF Use of alfentanil and propofol for outpatient monitored anesthesia care: determining the optimal dosing regimen. Anesth Analg. 1997; 85(3):566-572.
- 17. White PF, Way WL, Trevor AJ. Ketamine—its pharmacology and therapeutic uses. Anesthesiology 1982; 36., 56:119-.
- Suzuki M, Tsueda K, Lansing PS, et al. Small-dose ketamine enhances morphine-induced analgesia after outpatient surgery. Anesth Analg 1999; 103., 89:98 -.
- Sadove MS, Shulman M, Hatano S, Fevold N. Analgesic effects of ketamine administered in subdissociative doses. Anesth Analg 1971; 7., 50:452 -.
- 20. Frey K, Sukhani R, Pawlowski J, Pappas AL, Mikat-Stevens M, Slogoff S. Propofol versus propofol-ketamine sedation for retrobulbar nerve block:comparison of sedation quality, intraocular pressure changes, and recovery profiles. Anesth Analg 1999; 21, 89:317-.
- Badrinath S, Avramov MN, Shadrick M,Witt TR, Ivankovich AD. The use of a ketamine-propofol combination during monitored anesthesia care. Anesth Analg 2000; 62., 90:858-.

- 22. Herrick IA, Craen RA, Gelb AW, Miller LA, Kubu CS, Girvin JP, Parrent AG, Eliasziw M, Kirkby J.,Propofol sedation during awake craniotomy for seizures: patient-controlled administration versus neurolept analgesia. Anesth Analg. 1997 Jun; 84(6):1285-91.
- 23. Oliveira AM, Batalha LMC, Fernandes AM, Gonçalves JC, Viegas RG. Uma análise funcional da Wong-Baker Faces Pain Rating Scale: linearidade, discriminabilidade e amplitude. Revista de Enfermagem Referência. 2014;serIV(3):121-30.
- 24. Godwin SA, Caro DA, Wolf SJ, et al. American College of Emergency Physicians. ACEP clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005; 45:177-196.
- 25. Centers for Medicare & Medicaid Services (CMS). Revised appendix A, interpretive guidelines for hospitals— state operations manual, anesthesia services. Effective December 2, 2011.
- American Society of Anesthesiologists. Continuum of depth of sedation: definition of general anesthesia and levels of sedation/ analgesia. October 21, 2009.
- Rodrigo C, Chow KC. Patient-controlled sedation: a comparison of sedation prior to and until the end of minor oral surgery. Aust Dent J 1996; 41:159–63

- doi http://dx.doi.org/10.17546/msd.20288
- Thorpe SJ, Balakrishan VR, Cook LB. The safety of patientcontrolled sedation. Anaesthesia 1997; 52:1144—50.
- 29. Irwin MG, Thompson N, Kenny GN. Patient-maintained propofol sedation. Assessment of a target-controlled infusion system. Anaesthesia 1997; 525–30, 52:.
- Park WY, Watkins PA: Patient-controlled sedation during epidural anesthesia. Anesth Analg 1991; 72:304-307.
- Osborne GA, Rudkin GE, Curtis NJ, Vickers D, Craker AJ. Intra-operative patientcontrolled sedation. Anaesthesia 1991; 553-556., 46:.
- Ganapathy S, Herrick IA, Gelb AW, Kirkby J: Propofol patientcontrolled sedation during hip or knee arthroplasty in elderly patients. Can J Anaesth 1997; 44:385-389.
- 33. Rodrigo MRC, Tong CKA: A comparison of patient and anaesthetist controlled midazolam sedation for dental surgery. Anaesthesia 1994; 49:241-244.
- Zuhal Küçükyavuz, Mine Cambazo glu:Effects of low-dose midazolam with propofol in patient-controlled sedation (PCS) for apicectomy. British Journal of Oral and Maxillofacial Surgery (2004) 42, 215—220.

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