Comparison of the effects of sedation and general anesthesia in surgically assisted rapid palatal expansion

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ABSTRACT

الأهداف: مقارنة نتائج التخدير المهدئ بنتائج التخدير العام بعد إجراء عملية توسيع الفك الجراحية، بالإضافة إلى معرفة مدى رضا المرضى والجراحين عن هذه النتائج.

الطريقة: أُجريت هذه الدراسة العشوائية الاستطلاعية في قسم جراحة الوجه والفكين، كلية الأسنان، جامعة مارمارا، اسطنبول، تركيا، وقد استمرت خلال الفترة من يناير 2008م إلى فبراير 2010م. شملت الدراسة 30 مريضاً ممن وُضعوا في لائحة إجراء عملية توسيع الفك الجراحية. قُسم المرضى إلى مجموعتين وهما: المجموعة م (عددها =15) وهي المجموعة التي أُعطيت التخدير المهدئ بكل من الميدازولام والفينتنيل، والمجموعة ع (عددها =15) وهي المجموعة التي تم تخديرها تخديراً عاماً، وبعد ذلك تم تسجيل المقاييس المتعلقة بديناميكية الدم، والفترة التي استغرقها التخدير، والجراحة، ووقت الإفاقة، ووقت الخروج من المستشفى، ومعدلات المقياس التماثلي البصري لقياس درجة الألم بعد العملية الجراحية بالأوقات التالية: 30 دقيقة، و ساعة واحدة، و4 ساعات، و12 ساعة و24 ساعة، بالإضافة إلى وقت استهلاك المسكن، والكمية الكلية للمسكنات المُتناولة، ومدى رضا المريض والجراح عن نتيجة العملية، والدوار، والقيء.

النتائج: أشارت نتائج الدراسة إلى أن وقت استهلاك المسكن قد كان أطول في المجموعة م (p=0.008)، بينما كان وقت الاستهلاك الكلي للمسكن أقل في المجموعة م من المجموعة ع (p=0.031). لقد كانت نسبة رضا المريض أعلى في المجموعة م (p=0.035) مقارنةً بالمجموعة الثانية. كانت معدلات المقياس التماثلي البصري في المجموعة م أقل منها في المجموعة ع وذلك بعد العملية بحوالي 30 دقيقة، وساعة واحدة، و12 ساعة، وبالمقابل لم يكن هناك فرقاً بين المجموعتين في معدلات المقياس التماثلي البصري بعد مرور 4 ساعات، و24 ساعة.

خاتمة: أثبتت الدراسة مدى فعالية استخدام التخدير المهدئ في عملية توسيع الفك الجراحية، حيث أن مثل هذا التخدير قد أدى إلى تخفيف درجات الألم وتقليل وقت الخروج من المستشفى، وتقليل نسبة استهلاك المسكنات، أضف إلى ذلك رضا المرضى عن مثل هذا التخدير.

Objectives: To compare the effects of sedation and general anesthesia for surgically assisted rapid palatal expansion (SARPE).

Methods: This randomized prospective study included 30 patients who were scheduled for SARPE performed between January 2008 to February 2010 in the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Marmara University, Istanbul, Turkey. Patients were allocated into Group S - midazolam + fentanyl sedation (n=15), and Group G - general anesthesia (n=15). Hemodynamic parameters, duration of anesthesia, surgery, recovery time, time to discharge, visual analogue scale (VAS) pain scores at 30 minutes (min), one hour (hr), 4 hours, 12 hours, and 24 hours, first consumption of analgesic time, total amount of consumption of analgesics, patient and surgeon satisfaction, nausea, and vomiting were recorded.

Results: Analgesic time was significantly longer in Group S (p=0.008), and total analgesic consumption was significantly lower in Group S than in Group G (p=0.031). Patient satisfaction was statistically higher in Group S (p=0.035). At 30 min, one hr, and 12 hrs, VAS satisfaction scores in Group S were statistically lower than those in Group G, and at 4 hrs and 24 hrs there was no statistical difference in VAS scores for both groups.

Conclusion: The use of sedation for outpatient SARPE resulted in lower pain scores at discharge, lower analgesic consumption, and greater patient satisfaction.

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A major component of malocclusions is transverse maxillary discrepancy, which can be treated either by orthodontic forces in younger patients (<13 years), or by surgically assisted rapid palatal expansion (SARPE) in skeletally mature patients. Patients' quality of life (QoL) and satisfaction assessment are becoming increasingly important in health care delivery. There is evidence that better patient QoL and patient satisfaction might be associated with better medical outcome, including reduced hospitalization and reduced mortality.[1] The treatment of patients with complete skeletal maturity consists of SARPE, which is accomplished by diminishing the bone's resistance to palatal expansion, via the use of osteotomies in the walls and pillars of the maxilla, in addition to orthopedic devices (Haas or Hyrax) installed before surgery.[2] A combination of orthodontics and surgical procedures is used in the treatment of transverse deficiencies to increase maxillary arch diameter, correct posterior cross-bites, and widen maxillary hypoplasia and the dentoalveolar base. The SARPE promotes enlargement and widening, not only of the dental arch, but also of the nasal cavity, leading to an increase in nasal permeability.[1,2] The advent of and improvements in outpatient surgery, which dramatically changed the landscape of the profession, undoubtedly benefited patients and surgeons alike as it is convenient, safe, and cost-effective. The SARPE is usually performed as an outpatient surgery, and although it has primarily been performed under general anesthesia (GA),[1-3] it can also be performed under conscious sedation (CS). The CS is a medically controlled state of consciousness that maintains protective reflexes, retains the patient's ability in keeping the airway patent independently and continuously, and permits appropriate responses to physical stimulation and verbal command. Sedation, a technique where one, or more drugs are used to depress the central nervous system of a patient to his surroundings, is applied to ensure patient's safety, provide analgesia and amnesia, control behavior during the procedure, enable successful completion of the procedure, and return the patient to the pretreatment level of consciousness.[4-6] With these considerations, this study aims to compare the effects of CS and GA for SARPE in postoperative pain, and find out the patient's and surgeons satisfaction on the outcomes.

Methods. This prospective randomized study was performed in the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Marmara University, Istanbul, Turkey from January 2008 to February 2010. Thirty patients, American Society of Anesthesiologists (ASA) physical status I and II, 20-40 years old, and undergoing SARPE operation were included. Neither ethnic nor gender differences were considered. Patients with clinically significant respiratory, cardiovascular, neurological, and psychiatric diseases were excluded. In addition, patients with a history of drug or alcohol abuse, as well as those currently taking analgesic or sedative drugs were also excluded. The study protocol was approved by the institutional review board. All patients provided written informed consent. The patients were divided randomly into 2 groups by an assigning dentist using sealed envelopes, that is: Group S - midazolam + fentanyl sedation (n=15); and Group G - general anesthesia (n=15). Neither the patients nor the surgeon was aware of the group assignments. All patients were instructed to fast for 6 hours preoperatively, and were advised to have someone else take them home postoperatively. Blood pressure, pulse rate, respiratory rate, and oxygen saturation (SpO_2)were recorded before the drugs were administered, and at 5-minute intervals during the operation. The same surgeon, who was blinded to the group assignment performed all the operations. The intravenous (IV) sedation procedure was performed by an anesthetist. An IV cannula was inserted into a dorsal hand vein, and a continuous, free-flow infusion of 0.9% sodium chloride was started. After injecting the initial dose of 0.03 mg/kg midazolam (Dormicum [Roche, Basel, Switzerland]), the patients in Group S received one µg/kg fentanyl IV, and the midazolam administration was continued as required throughout the operation to maintain an adequate level of sedation (Ramsey score 3). At the end of the surgical procedure, 10 mg metoclopropamide was administered. General anesthesia was performed by an anesthetist. An IV cannula was inserted into a dorsal hand vein, and a continuous, free-flow infusion of 0.9% sodium chloride was started. The GA was started with 2 mg/kg propofol IV for induction, followed by one µg/kg fentanyl IV. Then, 0.1 mg/kg vecuronium bromide was administered, and intubation was performed. Sevoflurane (2-3%) and 50% O_2/N_2O were used for the maintenance of GA. At the end of the surgical procedure, 0.01 mg/kg IV atropine, 0.05 mg/kg IV neostigmine, and 10 mg IV metoclopramide were administered. After the reversal of muscle relaxation and reestablishment of adequate spontaneous ventilation, the trachea was extubated. After IV sedation and GA were achieved, 10 mL of local anesthetic (40 mg/mL articaine hydrochloride with 0.012 mg/mL adrenaline hydrochloride (2 mL [Ultracain® D-S Forte; Aventis, Bridgewater, NJ, USA]) was administered, and for 7-8 minutes (min.) waiting period, the surgery was started. To achieve effective local anesthesia, 2 mL of Ultracain® D-S Forte was applied as tuber anesthesia, 2 mL as a infraorbital anesthesia, and one mL of Ultracain® D-S Forte was administered along the planned incision. A horizontal incision is made through the mucoperiosteum above the mucogingival

junction in the depth of the buccal vestibular, extending from the canine region to the mesial to first molar. Nasal mucosa is elevated gently from the nasal lateral wall. A horizontal low-level osteotomy is made through the lateral wall of the maxilla, 6 mm superior to the apexes of the anterior and posterior teeth, with tiny rounded burs and then a microsaw, on the same level as the occlusal plane extending from the inferolateral aspect of the piriform rim, posteriorly to the inferior aspect of the junction of the maxillary tuberosity and pterygoid plate. The maxilla is separated from the pterygoid plate with an osteotome. The maxilla are separated by malleting a thin osteotome between the central incisors. The forefinger is positioned on the incisive papilla to feel the redirected osteotome as it transects the deeper portion of the midpalatal suture. An osteotome is positioned in the central incisor interradicular space, and manipulated to achieve equal and symmetric mobilization of the anterior maxilla. The patients assessed their experience of the procedure, and at the end of the operation, the surgeon evaluated the procedure and operating conditions similarly by a 5-point Likert scale (LS) assigning a score from one to 5, which corresponded to 1 - poor, 2 - fair, 3 - good, 4 - very good, and 5 - excellent.[7] At the end of the operation, patients were accompanied to the recovery room, where a nurse collected the postoperative data, and determined the Aldrete score.[8] When the Aldrete score reached 10, patients were discharged. All side effects (nausea, vomiting, sore throat, drowsiness) that occurred during the 24-hour postoperative period were recorded. The patients were asked to score the overall pain encountered at 30 mins, and at one, 4, 12, and 24 hours on a 10-point visual analogue scale (VAS: 0 - no pain, and 10 - excessive pain). Following the operation, the patients were free to use analgesic tablets of flurbiprofen 100 mg (Majezik 100 mg [Sanovel Ltd, Istanbul, Turkey]), and the number of tablets used was recorded on the recall days. Patient sample sizes of 15 in Group S, and 15 in Group G achieved 82% power to detect a ratio in the group proportions of 0.0820. The proportion in Group S (the treatment group) is assumed to be 0.5330 under the null hypothesis, and 0.0437 under the alternative hypothesis. The proportion in Group G (the control group) is 0.5330. The test statistic used is the 2-sided Fisher's exact test. The significance level of the test was targeted at 0.0500. The significance level actually achieved by this design is 0.0164.

Statistical analysis was performed using Number Cruncher Statistical System (NCSS) 2007, and Power Analysis and Sample Size (PASS) 2008 Statistical Software (NCSS Inc., Kaysville Utah, USA). Parametric variables between the 2 groups were tested with Student's t-test, and the paired sample t-test for within group comparisons, non-parametric variables were tested using the Mann Whitney U test for between-group, and the Wilcoxon signed rank test for within group variables. $P<0.05$ was considered statistically significant.

Results. A total of 30 patients were enrolled in the study. Both groups were comparable with respect to age, body mass index, and gender (**Table 1**). The duration of anesthesia, surgery, recovery time, and time to discharge were significantly lower in Group G than in Group S ($p=0.01$). The time required for analgesia

Table 1 - Characteristics of patients in the 2 groups (n=15 each).

Characteristics	Group S	Group G	*P*-value
Age	22.86 ± 5.05	22.93 ± 4.40	0.970*
Body mass index	22.95 ± 2.28	23.73 ± 2.37	0.367*
Gender			0.713†
Male	9	8	
Female	6	7	

Data are expressed as mean ± standard deviation. *Student t-test, †Chi-square test, Group S - midazolam + fentanyl sedation, Group G - general anesthesia

Table 2 - Comparisons for the duration of anesthesia and operation, recovery and discharge time, first consumption of analgesic time, total amount consumption of analgesics, total intravenous fluid, intra-operative fentanyl, and time in operating theater.

Variables	Group S	Group G	*P*-value
Duration of anesthesia, minutes*	112.00 ± 11.15	93.33 ± 4.08	0.001
Duration of operation, minutes*	91.33 ± 2.96	86.00 ± 2.80	0.001
Recovery time, minutes*	11.67 ± 3.09	5.00 ± 0.00	0.001
Discharge time, minutes*	80.33 ± 8.96	49.67 ± 5.16	0.001
First consumption of analgesic time†	3.80 ± 0.94	2.86 ± 0.74)	0.008
Total amount consumption of analgesics†	2.67 ± 0.81	3.33 ± 0.97	0.031
Total intravenous fluid*	853.33 ± 91.55	846.67 ± 118.72	0.865
Intra-operative fentanyl*	61.67 ± 18.58	95.00 ± 19.36	0.001
Time in operating theater*	132.00 ± 11.15	104.00 ± 6.32	0.001

Values are expressed as mean ± standard deviation. *Student t-test, †Mann Whitney U-test

was significantly longer in Group S (p=0.008), and total analgesic consumption was statistically lower in Group S in comparison with Group G (p>0.05). Time in the operating room was significantly longer in Group S than in Group G (p=0.01) (**Table 2**). No significant differences in heart rate, mean blood pressure, or SpO_2 were detected among the groups during the procedure (all p>0.05) (**Figure 1**). No patient in either group had hyper- or hypotension, and none had SpO_2 under 98% (**Figure 1**). Although surgeon satisfaction was significantly higher in Group G (p=0.06), patient satisfaction was significantly higher in Group S (p=0.035) (**Table 3**). The VAS pain scores in Group S at the 30 minutes, one hr, and 12 hrs were statistically lower than those in Group G, and at 4 hrs and 24 hrs, there was no statistical difference in VAS scores for both groups (**Table 4**). Nausea in Group S was statistically higher than in Group G (p=0.035). In Group G, 2 patients reported sore throat, one reported vomiting, and 8 reported drowsiness. No patients in Group S reported sore throat or vomiting, but 3 reported drowsiness.

Discussion. Intravenous sedation plus regional anesthesia can offer several potential advantages including: limiting the anesthetized area to the surgical site; avoiding common side effects of GA, such as nausea, vomiting, dizziness, and lethargy; minimizing the risks of aspiration pneumonitis; and minimizing the side effects of tracheal intubation (sore throat, croup, and hoarseness).[9] Although postoperative nausea and vomiting are almost always self-limiting and nonfatal, they can cause significant morbidity, including dehydration, electrolyte imbalance, suture tension and dehiscence, venous hypertension and bleeding, esophageal rupture, and life-threatening airway compromise, although more severe complications are rare.[10] Segal et al[9] compared the feasibility of local anesthesia with IV sedation versus GA for vaginal correction of pelvic organ prolapse, although postoperative nausea and vomiting are commonly associated with GA, this study did not reflect this. Squires et al[5] did not report any serious complications of GA or IV sedation in 296 endoscopic procedures. Malviya et al[11] stated that one sedation record indicated that nausea and vomiting occurred, after a child had been given chloral hydrate with his oatmeal. Song et al[12] in their study reported that the incidence of side effects, such as sore throat, drowsiness, and postoperative nausea and vomiting, as well as the

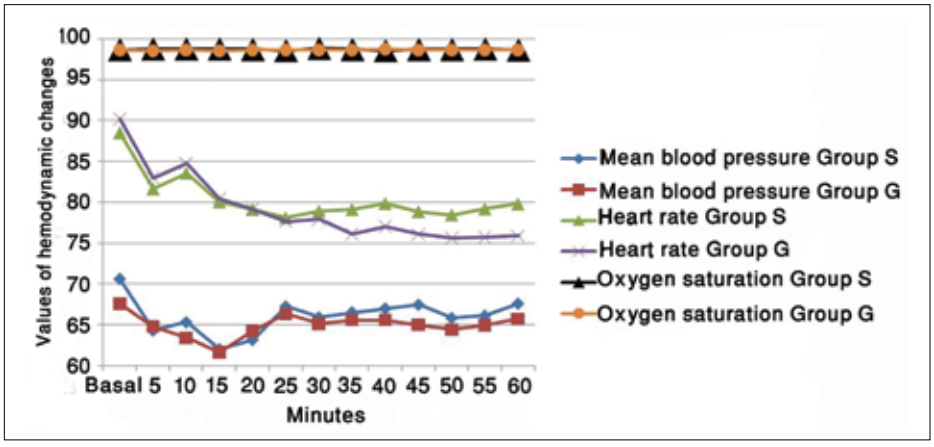

Figure 1 - Mean blood pressure in mm Hg, heart rate (beats per minute), and oxygen saturation among the groups during the operation.

Table 3 - Results of patients' and surgeons' satisfaction by Fisher's exact and Chi-square test.

Characteristics	Group S	Group G	*P*-value
	n (%)		
Patients' satisfaction			0.035
Good	1 (6.7)	7 (46.7)	
Excellent	14 (93.3)	8 (53.3)	
Surgeons' satisfaction			0.006
Good	7 (46.7)	0 (0.0)	
Excellent	8 (53.3)	15 (100.0)	

Group S - midazolam + fentanyl sedation, Group G - general anesthesia

Table 4 - Visual analogue scales scores in the groups at different time intervals.

Time	Group S	Group G	*P*-value*
30th minute	2.86 ± 0.83	3.40 ± 0.63	0.032
First hour	3.46 ± 0.51	4.13 ± 0.64	0.007
Fourth hour	3.86 ± 0.91	4.13 ± 0.83	0.417
Twelfth hour	3.53 ± 0.91	4.46 ± 0.64	0.005
Twenty-fourth hour	2.73 ± 1.03	3.20 ± 0.67	0.175

*Mann Whitney U-test, Group S - midazolam + fentanyl sedation, Group G - general anesthesia

maximum VAS nausea scores were significantly higher in the GA group. In our study, nausea in Group S was statistically higher than that in Group G (p=0.035). In Group G, 2 patients had sore throat, one patient had vomiting, and 8 patients had drowsiness. In Group S, no patients had a sore throat or vomiting, and 3 patients experienced drowsiness.

Patient and surgeon satisfaction were other important points examined in this study. Song et al[12] stated that patient satisfaction in the ilioinguinal hypogastric nerve block-monitored anesthesia care (IHNB-MAC) was significantly higher, and was associated with lower pain scores at discharge compared with a general anesthetic technique. In our study, the reason for higher patient satisfaction in Group S may have been the lower incidence of side effects, as well as because patients' VAS pain scores in Group S in general were statistically lower than those in Group G. Although surgeon satisfaction was significantly higher in Group G, surgeon satisfaction in Group S also was described as good to excellent. These differences in surgeon satisfaction are related to patient discomfort in Group S during osteotomies, especially during pterygomaxillary junction osteotomies, during which patients increase the movements of the head and legs, resulting in greater difficulty for the surgeon compared with GA. Although the patient may disturb the surgeon by moving around during sedation, the incomplete muscle relaxation has the benefit of preventing the formation of deep vein thrombosis.[13] Although we did not see any complications of deep vein thrombosis in either group, sedation might be advantageous in patients with this risk.

Pellicano et al[14] reported that the mean operative time in the sedation group was clinically lower than that in the group that underwent surgery under GA. However, in our study, the duration of the operation was significantly lower in Group G than in Group S. This difference between studies might have been caused by the patient's movement during the osteotomies in our study, which negatively affected surgeons' work. Recovery time and time to discharge were significantly higher in Group S, and this is contrary to the findings of Song et al[9] and Pellicano et al,[14] and it might be because midazolam tends to make patients sleepier after the operation. Pellicano et al[14] reported that the need for additional analgesia was significantly lower in the sedation group. In addition, Song et al[12] showed lower percentages of patients in the sedation group taking oral pain medication in the postoperative period, and after discharge. In our study, the time until first analgesic administration was statistically significantly longer in Group S, and the total analgesic consumption was statistically lower in Group S than in Group G.

We cannot effectively detect the differences in the incidence of side effects, due to the small sample size of each group in our study, and this is our limitation.

In conclusion, the use of sedation for outpatient SARPE resulted lower pain scores at discharge and lower analgesic consumption, greater patient satisfaction, and lower associated incremental costs compared with GA. Future studies should focus on increasing surgeon's satisfaction during pterygomaxillary junction osteotomies in SARPE operations, if sedation is the only option.

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