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Surgical Management of Isolated Fractures of Zygoma under Local Anaesthesia and Intra Venous Midazolam.

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Research Article

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ABSTRACT

Fractures of the zygomatic complex are the second most common fractures of the middle third of the face. The treatment should aim at optimal reduction and fixation while taking into consideration patient satisfaction in terms of pain control, type of anaesthesia and treatment cost. This study is designed to assess the anxiolytic, sedative, amnesic properties as well as safety and efficacy of use of midazolam as intravenous sedation agent in treatment of isolated zygomatic fractures. The present study was conducted at an urban institute in Amritsar , Punjab from January 2011 to june 2012. The study was undertaken in 10 patients of isolated zygomatic fracture under local anesthesia and intravenous midazolam. The parameters evaluated were : blood pressure, heart rate, respiratory rate , oxygen saturation, airway, sedation, anxiety and surgeon's assessment. These were recorded pre-operatively, pre-procedure, peri-operative, immediately post-operative for 2 hours and late postoperative at 12 and 24 hours. The fracture was exposed using a combination of Gilles temporal incision, supra orbital incision, maxillary vestibular incision and crows foot incision. A 2 point fixation was done using 2mm stainless steel monocortical plates. The effect of midazolam was insignificant on blood pressure and respiratory rate , whereas it was statistically significant on the heart rate , oxygen saturation and anxiety. Appropriate sedation was achieved in 90% of the patients. The degree of amnesia ranged from mild to profound. Operative comfort was rated as "good" in 60% of the patients. Optimal reduction of the fracture was achieved in 70% of the patients. Midazolam as a conscious sedative agent can be very successful in treatment of fractures of the zygomatic bone in reducing patient hospitalization, patient morbidity, complications and lowering the overall cost of the patient by avoiding general anesthesia.

INTRODUCTION

Fractures of the zygomatic complex are the second most common fractures of the middle third of the facial skeleton. Open reduction and internal fixation (ORIF) should not only aim at optimal reduction and fixation but should also take into consideration patient satisfaction in terms of pain control, type of anesthesia and treatment cost. ORIF of zygomatic fracture may be carried out under local anesthesia (LA) with or without conscious sedation or under general anesthesia (GA). GA with its utilities has its own disadvantages in the post-operative period such as- inadequate reflexes, problems of airway maintenance, nausea, vomiting and possibility of gastric aspiration. Conscious sedation has become popular due to its advantage of supplementing local anesthesia, thus utilizing the benefit of consciousness and co-operation of the patient, along with verbal contact and protective reflexes and at the same time having no anxiety and recall. The present study was designed to assess the anxiolytic, sedative, amnesic properties as well as safety and efficacy of the use of midazolam on the various physiological parameters (cardiovascular, respiratory etc) in treatment of isolated zygomatic fractures.

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MATERIALS AND METHODS

The present study was undertaken in 10 patients of isolated zygomatic fractures reporting to the department of oral and maxillofacial surgery. Inclusion criteria for the study was ASA class I and II. Exclusion criteria was uncontrolled medical problems, LA sensitivity, bleeding disorders, chest infections, neurological or psychiatric illnesses and pregnancy.

A detailed clinical examination was carried out along with the requisite hematological, biochemical and serological investigations including urinalysis and an electrocardiogram.

Pre-anesthetic check up was done a day before surgery. Instructions regarding the scoring of anxiety (visual analogue scale, VAS) were given one day prior to the surgery. The parameters evaluated were 1) Hemodynamic parameters- (a) Blood pressure (b) Heart rate , 2) Respiratory parameters –(a) Respiratory-rate (b) Oxygen-saturation by pulse oxymetry (c) Airway , 3) Ramsey's sedation score, 4) Anxiety (VAS 0-100), 5) Adverse reactions and 6) Surgeon's assessment (Table-1).

Sedation protocol

All the patients were kept fasting for 6 hours before the surgery.One hour prior to the commencement of the procedure, the base line readings of all the parameters were recorded and tabulated. The patients were premedicated with Injection glycopyrrolate (30 mg) intramuscularly. An initial intravenous (i/v) dose of 0.03 to 0.07 mg/kg of midazolam was slowly administered over a period of one minute ,until the desired sedative end point of slurred speech, slow or inaccurate index finger to nose movements or ptosis was reached. If during the procedure the patient developed moderate anxiety or a sedation score of zero, incremental supplemental injection of midazolam (0.5 mg) was given IV.

All the parameters were recorded at 5 minute intervals throughout the surgical procedure. The surgical procedure was divided according to the time interval as - Baseline period (BLP) – 1 hour before the bolus dose of midazolam, Pre-procedure period (PPP) – the time from bolus dose till the time of incision, Peri-operative period (POP) – from the time of incision till skin closure, Immediate post operative period (Immediate POP) – upto 2 hours post operatively and Late procedure period (Late POP) – at 12 hrs and 24 hrs post operatively (Table-2).

Surgical protocol

A standardized surgical protocol was followed in all the patients. Local anesthesia was achieved using 2% lidocaine with 1: 200,000 adrenaline via the posterior superior alveolar, infra orbital and supra orbital nerve blocks. Local anesthetic agent was also infiltrated along the incision line and along the plane of placement of the bristow's elevator. The incisions used for reduction and fixation of the fracture were Gillies temporal incision, supra orbital incision, maxillary vestibular incision and crow's feet incision. After reduction, the fracture was fixed at a minimum of 2 points, preferably the fronto-zygomatic suture and the zygomatico-maxillary buttress using 2mm stainless-steel mono-cortical plates. The skin incision was closed in layers and the intra oral mucosa was closed in a single layer. The sutures were removed on the 7^{th} post operative day.

Post operative assessment

All the parameters were recorded every half hour for two hours. Criteria for street fitness was : 1) Stable vital signs for atleast one hour, 2) No evidence of respiratory depression or airway obstruction, 3) Well oriented to time place and person, 4) Ability to dress and walk at preoperative level, 5)Ability to take fluid orally and void urine, 6) Minimal nausea and vomiting. The patient was again assessed at 12 hours and 24 hours postoperatively.

The data was assessed for the efficacy of intravenous midazolam for supplementation of local anesthesia for conscious sedation in the surgical management of isolated zygomatic procedures.

OBSERVATIONS

Midazolam as an agent for conscious sedation was evaluated for its effect on the various parameters of the study.

Baseline mean systolic blood pressure (SBP) was 129.00 $\pm$ 9.94 mm of Hg, whereas the SBP during PPP was 127.27 $\pm$ 12.96 mm Hg, in POP was 133.51$\pm$15.98 mm Hg. In the immediate POP and late POP the SBP was 125.65$\pm$13.55 mm Hg and 122.80$\pm$16.72mm Hg respectively. These variations observed during the different periods were found to be statistically insignificant ($p>0.05$) (table 1) (figure 1).

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Table 1: Table Showing the Mean Systolic Blood Pressure (mmHg)

Time period	Systolic blood pressure (mmHg) Mean	S.D
Base line	129.00	±9.94
Pre-procedure	127.27	±12.96
Perioperative	133.51	±15.98
Immediate post procedure	125.65	±13.55
Late post procedure	122.80	±16.72

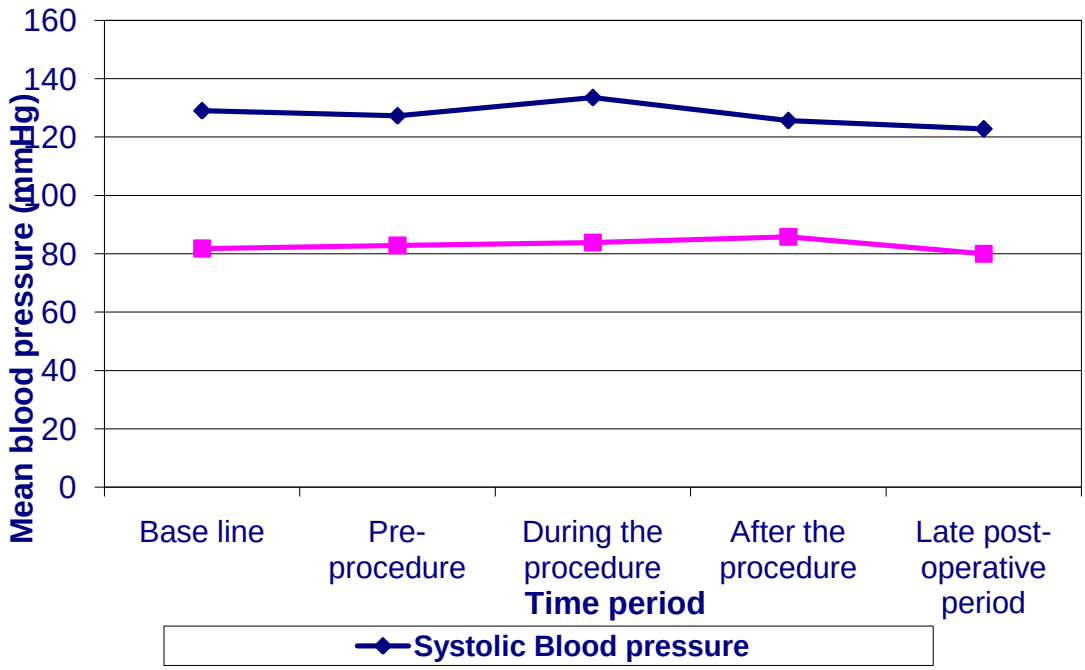
Statistical analysis of systolic blood pressure

Student's 't' test

	t-value	p-value
Baseline/Pre-procedure	0.34	>0.05
Baseline/Perioperative	0.78	>0.05
Baseline/Immediate post procedure	0.65	>0.05
Baseline/Late post procedure	1.04	>0.05

p>0.05 Not significant; p<0.05 Significant

Figure 1: Mean Systolic and Diastolic Blood Pressure during the Procedure



Similarly baseline mean diastolic blood pressure (DBP) was 81.80±3.33 mm of Hg while POP DBP was observed to be 83.85±10.84 mm Hg. In the immediate POP and the late POP the DBP was 85.80±9.41 mm Hg and 80.00 ± 3.65 mm Hg respectively. These variations were also found to be statistically insignificant (p> 0.05) (table 2) (figure 1).

Table 2: Table Showing the Mean Diastolic Blood Pressure (DBP) (mmHg)

Time period	Diastolic blood pressure (mmHg) Mean	S.D
Base line	81.80	±3.33
Pre-procedure	82.83	±7.22
Perioperative	83.85	±10.84
Immediate post procedure	85.80	±9.41
Late post procedure	80.00	±3.65

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Statistical analysis of systolic blood pressure

Student's 't' test

	t-value	p-value
Baseline/Pre-procedure	0.42	>0.05
Baseline/Perioperative	0.59	>0.05
Baseline/Immediate post procedure	1.30	>0.05
Baseline/Late post procedure	1.18	>0.05

p>0.05 Not significant; p<0.05 Significant

In the present study the average baseline respiratory rate (RR) was 20.90+4.18 per minute. The RR during the PPP was found to be increased (21.69+4.28). Whereas a slight decrease in RR during POP, immediate and late POP was observed (20.78+5.18, 19.58+4.75 and 18.80+3.68 respectively). These variations were however were found to be statistically insignificant (table 3) (figure 2).

Table 3: Table Showing the Mean Respiratory Rate (RR)

Time period	Respiratory rate (breaths/min)	
	Mean	S.D
Base line	20.90	±4.18
Pre-procedure	21.69	±4.28
Perioperative	20.78	±5.18
Immediate post procedure	19.58	±4.75
Late post procedure	18.80	±3.68

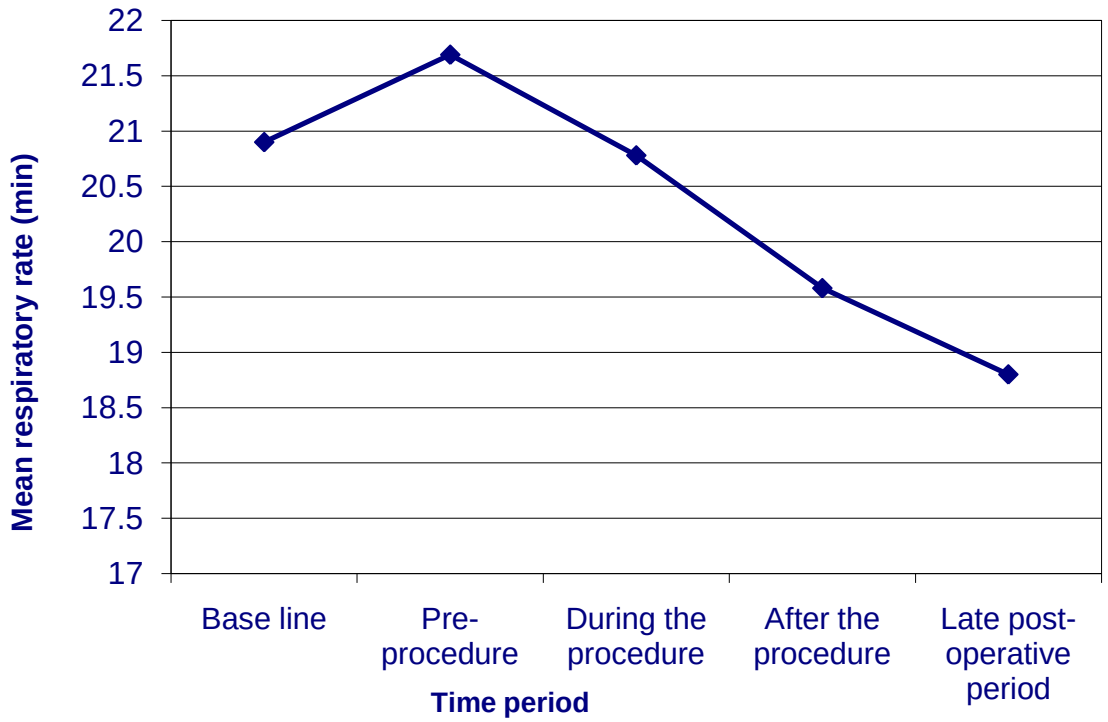
Statistical analysis of respiratory rate

Student's 't' test

	t-value	p-value
Baseline/Pre-procedure	0.43	>0.05
Baseline/Perioperative	0.06	>0.05
Baseline/Immediate post procedure	0.68	>0.05
Baseline/Late post procedure	1.23	>0.05

p>0.05 Not significant; p<0.05 Significant

Figure 2: Respiratory Rate during the Procedure



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The average baseline oxygen saturation (SPO_2) was 98.50+0.71%. The SPO_2 during PPP, POP, immediate and late POP period was observed to decrease. However, statistically significant decrease was observed only during POP and immediate POP. The saturation was found to fall below 91% in 2 patients. In one patient it occurred at the 55th minute (SPO2 89%, a fall of 11.89%) of the procedure after a top up dose of midazolam, and was corrected by tactile stimulation. In the second patient, the oxygen saturation was found to decrease immediately after the administration of the bolus dose of midazolam (SPO2 84%, a fall of 16% from baseline) and was corrected by insertion of a nasopharyngeal airway and oxygen supplementation (table 4) (figure 3).

Table 4: Table Showing the Mean Oxygen Saturation (SPO_2)

Time period	Oxygen saturation (%)	
	Mean	S.D
Base line	98.50	±0.71
Pre-procedure	97.63	±1.41
Perioperative	97.56	±1.05
Immediate post procedure	97.45	±1.23
Late post procedure	98.05	±1.21

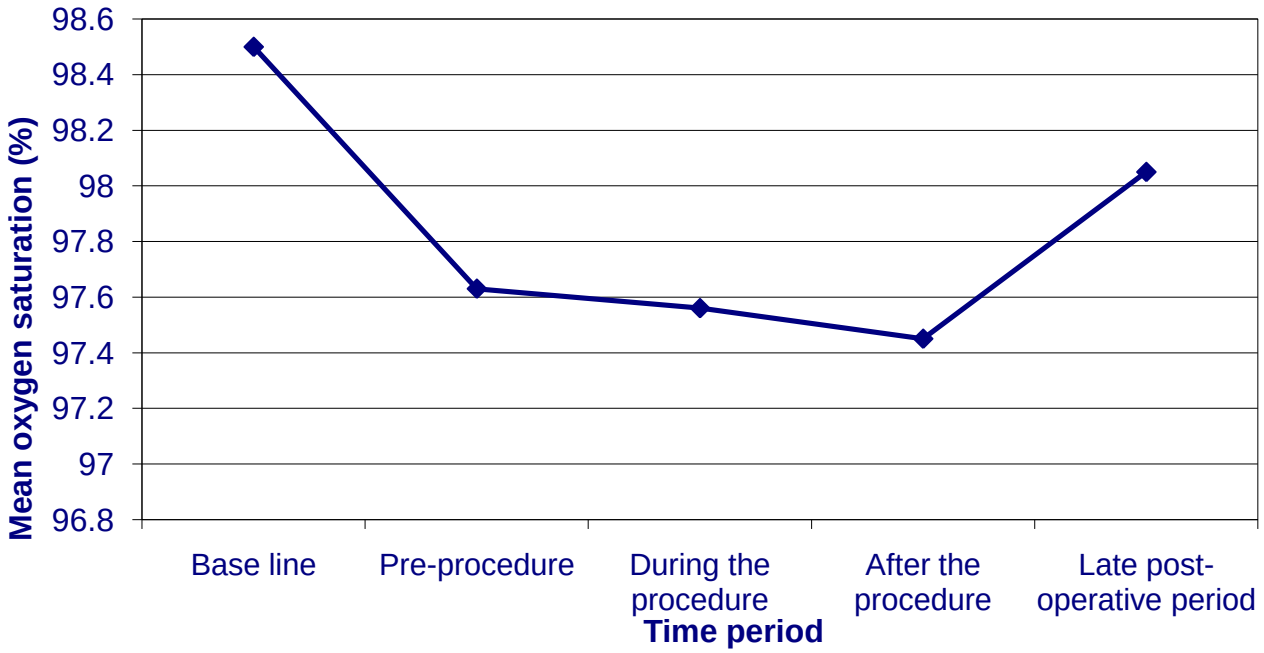
Statistical analysis of oxygen saturation

Student's 't' test

	't' value	p-value
Baseline/Pre-procedure	1.79	>0.05
Baseline/Perioperative	2.41	<0.05
Baseline/Immediate post procedure	2.40	<0.05
Baseline/Late post procedure	1.04	>0.05

p>0.05 Not significant; p<0.05 Significant

Figure 3: Mean Oxygen Saturation during the Procedure



The mean baseline heart rate (HR) was 79.70±7.12 beats per minute (bpm). During the PPP, POP and the immediate POP the HR was observed to increase, although the increase at every step was < 20% of the baseline HR. whereas during the late POP the mean HR was found to decrease (75.55±11.20). However, only during the POP the increase in the HR was found to be statistically significant (table 5) (figure 4).

For the purpose of statistical analysis of the anxiety score, all the patients were divided into 2 groups. Group I included patients with 'no' or 'mild' anxiety and group II included patients with 'moderate' and 'severe' anxiety. The results were evaluated using 'chi square test'. On comparing the baseline with PPP anxiety level, the values were statistically significant. It was noted that on comparison of baseline anxiety with the anxiety level during the procedure, most of the patients (7) had mild anxiety and 3 patients had moderate anxiety, this was found to be

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highly significant ($p < 0.001$). Whereas, significant difference ($p < 0.01$) was found on comparing the baseline anxiety with the anxiety level after the procedure and the late postoperative period (table 6).

Table 5: Table Showing the Mean Heart Rate (HR)

Time period	Heart rate (beats/min)	
	Mean	S.D
Base line	79.70	±7.12
Pre-procedure	83.61	±8.64
Perioperative	88.63	±11.29
Immediate post procedure	85.68	±13.43
Late post procedure	75.55	±11.20

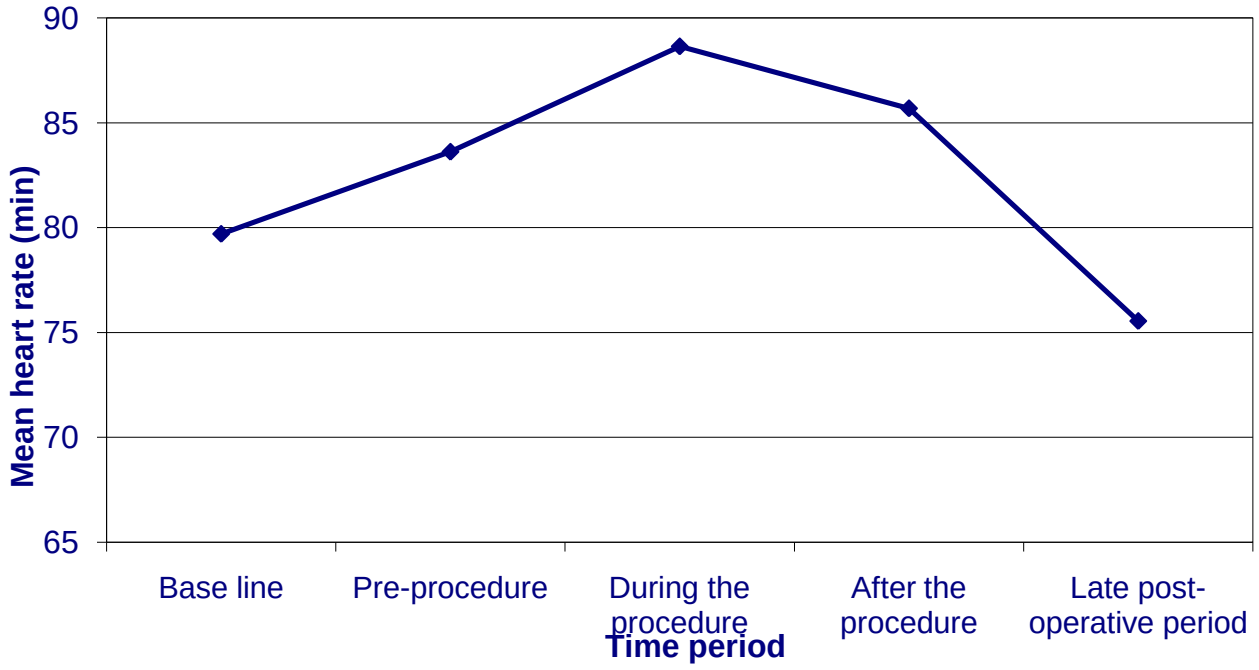
Statistical analysis of heart rate

Student's 't' test

	t-value	p-value
Baseline/Pre-procedure	1.13	>0.05
Baseline/Perioperative	2.17	<0.05
Baseline/Immediate post procedure	1.28	>0.05
Baseline/Late post procedure	1.02	>0.05

p>0.05 Not significant; p<0.05 Significant

Figure 4: Mean Heart Rate during the Procedure



The sedation levels achieved during the study in the patients was found to be appropriate (stage I and II) in 09 patients. One patient however was found to be deeply sedated (stage IV) with a grade III airway and required the insertion of a nasopharyngeal airway and oxygen supplementation (table 7).

The degree of amnesia was found to range from mild to profound. Two patients were found to have mild amnesia. Five patients had moderate amnesia whereas three patients had profound amnesia. The operative comfort and the patients co-operation was rated as 'good' in 60% patients and 'fair' in 40% of the patients (table 8). Optimal reduction of the zygomatic complex fractures was achieved in 70% of the patients (table 9).

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Table 6: Table Showing the Anxiety Score

Time period	Anxiety			
	No	Mild	Moderate	Severe
Base line	-	9	-	1
Pre-procedure	-	9	-	1
Perioperative	-	7	3	-
Immediate post procedure	8	2	-	-
Late post procedure	10	-	-	-

Statistical analysis of anxiety score

Chi-square

	X^2	p-value
Baseline/Pre-procedure	-	>0.05
Baseline/Perioperative	12.53	<0.001
Baseline/Immediate post procedure	10.63	<0.01
Baseline/Late post procedure	10.63	<0.01

p<0.05 Significant; p<0.001 Highly Significant: >0.05 Not significant

Table 7: Table Showing the Sedation Level

Time period	Sedation				
	0	I	II	III	IV
Base line	-	-	-	-	-
Pre-procedure	1	8	1	-	-
Perioperative	-	3	6	-	1
Immediate post procedure	-	9	-	1	-
Late post procedure	10	-	-	-	-

Table 8: Table Showing the Degree of Amnesia

Range	Degree of amnesia	No. of patients
4-8	Mild	2
8-12	Moderate	5
12-16	Profound	3

Table 9: Table Showing the Surgeon's Assessment

Surgeon's assessment	Number of patients	
	Fair	Good
Operative comfort	4	6
Patients co-operations	4	6
Ability to achieve optimal reduction	3	7

DISCUSSION

Fractures of the zygomatic complex are the second most common fractures of the middle third of the face. The treatment should aim at optimal reduction and fixation while taking into consideration patient satisfaction in terms of pain control, type of anaesthesia and treatment cost. Open reduction and internal fixation of zygomatic fractures may be carried out under general anaesthesia or local anaesthesia with sedation.

Benzodiapines (Midazolam) has been used as a conscious sedation agent in minor gyanecological procedures, oesophago-gastro-duodenoscopy, gastroscopy, spinal anesthesia, plastic surgery and in field of dentistry. [1, 3, 13, 28] It is a water soluble imidazobenzodiazepine, with a short plasma elimination half life [8, 25] and high lipid solubility. At physiological pH it has a rapid brain entry and hence, a relatively fast onset of action. [8] However, the duration of action is short due to rapid metabolic inactivation [7] resulting in a short recovery period.

Various methods for drug administration have been documented in the literature. The drug can either be administered by the anaesthetist (anaesthetist controlled sedation, ACS) [20] or by the patient (patient controlled sedation, PCS) [5, 20, 23]. It may be given as bolus, a bolus dose followed by incremental top up doses for titration and

maintenance, a bolus dose followed by infusion, continuous infusion titrated till sedation end point with or without supplementation.

In the present study, bolus dose ranged from 0.03 mg/kg to 0.07mg/kg, which has also been reported by many researchers. [3, 14, 26] However; a few researchers such as Bijl et al [2] and McClure et al [13] have reported the bolus dose as high as 0.1 mg/ Kg. Incremental top up dosages of 0.5-1.5 mg used in the present study was comparable to the work done by other researchers in plastic surgery and minor oral surgical procedures.

The guidelines for anesthetic dosing are based primarily on patient weight, duration of the procedure, HR, SBP, patient anxiety and gender.

In the present study no significant relationship was seen between body weight and midazolam dosage, which concurs with the work done by some other researchers [15, 17, 22]

Although a longer procedure generally leads to an increased dose in the form of more incremental doses for maintenance, we did not find any increase in the dose requirements in the procedures carried out for more than one hour when compared with those with a duration of less than one hour. This in turn proves the benefit of choosing midazolam over other sedatives in treating cases of isolated zygomatic fractures.

Decreased heart rate has been associated with intravenous sedation using midazolam. [14] We observed a perioperative increase in the heart rate (1.2%) from the baseline and it was progressive till 30 minutes following the bolus injection of midazolam. Subsequently the heart rate was found to decrease but the baseline levels were not achieved throughout the surgical procedure. Similar results have been reported by McClure et al [13] and Jerjes et al [10] using midazolam , and by White et al [28] using multi drug induced sedation. Although the increase in the heart rate during multidrug sedation was reported to be significantly higher (25 – 28 %)

Although a decrease in the blood pressure has been reported following the injection of intravenous midazolam [13, 19, 20] , we observed a clinically and statistically insignificant decrease in blood pressure (1.34%) in our study.

Similarly, an insignificant increase of 3.78% was observed in the respiratory rate after the administration of midazolam , following which an insignificant decrease in the respiratory rate from the baseline was seen throughout the procedure. Short et al [24], Bijl et al [2] and White et al [28] have also reported no significant difference in the respiratory rate from the baseline, using intravenous midazolam sedation.

Conscious sedation with midazolam has been documented to induce arterial oxygen desaturation. [1, 2, 12, 18, 27] In our study, a significant decrease of 0.95% in the oxygen saturation was observed during the perioperative period. A physiologically significant drop in oxygen saturation of 9.2% (SPO_2 89%) and 13.4% (SPO_2 84%) from the baseline was seen in 2 patients, which was corrected by verbal stimulation and oxygen supplementation. Similarly, we observed a significant decrease of 1.06% from the baseline in oxygen saturation during the recovery phase in the present study. The decrease in oxygen saturation during recovery is unrelated to the use of midazolam and has been attributed to increased tissue oxygen consumption due to increased catecholamine levels because of stress [12].

Anterograde amnesia is a well known property of midazolam [6, 21, 22, 23], and both are related in a dose dependent manner. [16, 28] All patients included in the study had anterograde amnesia along with a dose dependant relation between the degree of amnesia and midazolam. Patients administered doses >5 mg showed 40% more amnesia than patients who were administered <5mg. Although, majority of the patients were able to recall the surgical steps of reduction of the fracture, all the patients reported amnesia for local anaesthesia administration. [11].

The utility of conscious sedation with midazolam for anxiety is due to its relatively short duration of action and minimal perturbations of the normal physiological functions. It has been proved to be an effective anxiolytic with the anxiety scores consistently lower after its administration [2, 28]. However, in the present study there was a highly significant increase in the intraoperative anxiety, which may be attributed to the change in environment and heightened anticipation, resulting in increased anxiety levels. [22] On the other hand, postoperative anxiety levels were found to be significantly decreased. [11] One of our patients was unresponsive to midazolam, this was probably a dose related phenomenon as the high anxiety level of the patient required a higher dose of midazolam. Jerjes et al, [10] have reported unresponsiveness to midazolam and attributed it to the increased cortisol levels leading to increased stress and anxiety.

Midazolam has been shown to be superior to diazepam in relation to sedation. [4, 13, 28] In our study all the patients were adequately sedated with no loss of verbal contact except one patient who was deeply sedated, but responded to physical stimulation. The degree of sedation achieved has been reported to be good or excellent in the majority of cases. [2, 4, 11, 13, 22, 24]

We observed the average onset time of sedation to be 14 minutes; this may be due to the use of a smaller bolus dose in our study. The time of onset has been reported to be ranging from 45 seconds to 7 minutes [3, 19, 22, 27] in the literature. However, EEG studies have shown that the maximum changes can take 5-10 minutes to develop after sedative doses of intravenous midazolam. [9]

The unresponsiveness to midazolam in one patient, followed by a deeply sedated state seen in the present study may be due to dose stacking which may lead to over sedation with midazolam, as the full effect of closely spaced doses is observed some time after the last dose. [23]

The sedative and anxiolytic effects of midazolam aid the surgeon by providing conducive working conditions. [2, 11, 17, 19] Accurate anatomic reduction of the fracture was achieved in 70% of the cases in the present study. Good patient co-operation and operative comfort was observed in 60% patients our study.

CONCLUSION

Midazolam as a conscious sedative agent can be very successful in treatment of fractures of the zygomatic bone in reducing patient hospitalization, patient morbidity, complications and lowering the overall cost of the patient by avoiding general anesthesia.

The combination of local anesthetic and sedative using midazolam when assessed against cardio-respiratory parameters, sedation, amnesia and anxiolysis were favourable. The parameters BP, HR, RR and SPO_2 were minimally affected. Good operative comfort and optimal fracture reduction was seen in the majority of the patients. The present study concludes that considering overall advantages and cost-analysis, midazolam as an agent of conscious sedation with local anesthetic (especially in resource challenged countries) should be the modality suggested in treating patients of zygomatic fractures. The final decision of utilizing general anesthesia or local anesthesia should, however, be decided on the basis of the working clinical assessment and the institutional/ personal experience of the treating surgeon.

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