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## ORIGINAL ARTICLE

# Comparison of fasting and non-fasting patients receiving intravenous (IV) sedation

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anxiety, dentoalveolar, fasting, intravenous sedation

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**Abstract**

**Aim:** In 2015 the Intercollegiate Advisory Committee for Sedation in Dentistry published a national standard for the provision of conscious sedation in dentistry. This document highlighted the need for justification of the decision not to fast patients prior to administration of IV sedation. The aim of this case control study was to compare a fasting (F) and non-fasting (NF) group of patients undergoing oral surgery procedures under IV sedation, and to assess for sedation related complications in both groups.

**Material and methods:** A total of 228 patients were analysed, with 114 patients in each group.

**Results:** Mean age was 33 years for the F group and 30.2 years for the NF group. The average midazolam dose was 5.11 mg for the F group and 5.72 for the NF group ( $p = 0.03$ ). The mean recovery time was: 38.53 min for the F group and 36.57 min for the NF group ( $p = 0.14$ ). Extra measures required included: supplemental oxygen for 5 patients in the F group and 6 patients in the NF group, Oral glucose was given during the recovery period to 6 patients in the F group. 1 patient in the F group was unable to be cannulated.

**Conclusions:** Practicing minimal to moderate sedation in ASA 1 and 2 non-fasting patients is safe and in our study appears to give less complications than the fasting patients.

**Clinical relevance****Scientific rationale for study**

In 2015, the Intercollegiate Advisory Committee for Sedation in Dentistry published a national standard for the provision of conscious sedation in dentistry. This document highlighted the need for justification when taking the decision not to fast patients prior to administration of IV sedation. The aim of this audit was to compare a fasting (F) and non-fasting (NF) group of patients undergoing oral surgery procedures under IV sedation, and to assess for sedation-related complications in both groups.

**Principal finding**

Practicing minimal to moderate sedation in ASA 1 and 2 non-fasting patients is safe and in our study appears to give less complications than the fasting patients.

**Practical implications**

IV sedation is being more and more popular method of treatment for anxious patients as well as for not so anxious patients but patients that concern due to the complexity of the case. The need for fasting prior to dental treatment under conscious IV sedation is a subject of significant discussion and generates

controversy and it needs to be related with the sedation level.

## Introduction

A significant proportion of the population presents with dental anxiety. According to the United Kingdom (UK) Adult Dental Health Survey (2009), over one-third of adults (36%) were classified as having moderate dental anxiety, and 12% were classified as having extreme dental anxiety<sup>1</sup>.

One of the methods to manage dentally anxious patients is conscious sedation. Conscious sedation is being increasingly used in dental surgery. It is defined as a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation<sup>2-5</sup>.

Each patient must be assessed individually and there is no predetermined dosage. The correct dose for each patient is the smallest dose that achieves relaxation and cooperation during the procedure<sup>6</sup>. Conscious sedation must follow nationally agreed protocols and guidelines to minimise the risk of overdose and subsequent harm<sup>2,7,8</sup>. In 2015, the dental faculties of the Royal College of Surgeons and the Royal College of Anaesthetists published an update in standards for conscious sedation in the provision of dental care<sup>9</sup>. This document highlighted the need for justification when taking the decision not to fast patients prior to administration of intravenous (IV) sedation and has created some controversy between clinicians. In July 2015, after the new standards for conscious sedation<sup>9</sup> were published, the Oral Surgery department in the Edinburgh Dental Institute adopted the '6-4-2 fasting protocol' for patients requiring procedures under IV sedation. The 6-4-2 protocol is as follows: 6 h for solid food, 4 h for non-clear drinks (e.g. milk, orange juice, etc.) and 2 h for clear fluids like water. This protocol was gradually implemented for elective general anaesthetic cases after 1995 by national anaesthesia societies in Europe and the United States<sup>10-15</sup>. The previous, more rigid fasting routine was hoped to reduce the risk of anaesthesia-related pulmonary aspiration, which can lead to respiratory failure<sup>16</sup>. That has been challenged and found to be inaccurate<sup>17-19</sup>.

The aim of this case control study was:

1 to compare fasting (F) and non-fasting (NF) groups of patients undergoing oral surgery procedures under IV sedation

2 to compare sedation-related complications in both groups.

## Methods

The Quality Improvement Team at the Edinburgh Dental Institute granted study approval. This retrospective study involved a search of electronic and paper notes for all patients that had IV sedation treatment in the Oral Surgery outpatient department at the Edinburgh Dental Institute over an 8-month period between September 2015 and May 2016. All the patients were under the care of four different senior members of staff (e.g. consultants or specialists). During the period in which the fasting protocol was implemented, 114 patients underwent oral surgery procedures under IV sedation. A control group of non-fasting patient was selected from 114 consecutive patients within the 8 months period. All patients included in our study using the American Society of Anesthesiologists (ASA) classification were ASA 1 and ASA 2 and all patients were older than 16 years old.

The following details were recorded for each group: ASA category, nature and duration of procedure, midazolam dose, recovery time, and any related complications/special measures required. The data were analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Descriptive statistics were used to present mean values with standard deviations and 95% confidence intervals where appropriate. Independent t-tests were used for continuous numerical variables and chi-square tests were used for categorical variables. Significant was tested at the alpha level of 0.05.

## Results

A total of 228 patients were treated under local anaesthetic and midazolam for IV sedation. There were 114 patients in F group (91 females and 23 males) and 114 in the NF group (86 females and 28 males). The F group had 69 patients with ASA 1 and 45 ASA 2 and the NF group contained 64 patients ASA 1 and 50 ASA 2. The mean age in years was 33 (SD=11.2) years for the F group and 30.2 (SD=10.3) years for the NF group. For baseline values, there was no statistically significant difference for gender ( $P = 0.43$ ) and ASA grading ( $P = 0.50$ ). There was a statistically significant difference between the two groups for mean age ( $P = 0.03$ ). (Table 1).

For the outcomes, there was a statistically significant difference between the two groups for

midazolam dose ( $P = 0.03$ ) with the average midazolam dose 5.11 mg (SD=2.0) for the F group and 5.72 mg (SD=2.2) for the NF group. There was no statistically significant difference for the length of the procedure between the two groups ( $P = 0.36$ ), with 15.6 min (SD=10.7) for the F group and 17 min (SD=11.6) for the NF group. No statistical difference was found at recovery time between the groups ( $P = 0.18$ ); where recovery time was 38.53 min (SD=9.92) for F group and 36.57 (SD=9.48) min for the NF group. Complication rates for the two groups showed no statistically significant difference ( $P = 0.14$ ). The extra measures required

due to complications included: supplemental oxygen for five patients (4.3%) in the F group and six patients (5.2%) in the NF group and in all cases oxygen saturation was between 90% and 95%. Oral glucose was given during the recovery period to six patients from the F group patients. Failure to cannulate occurred in one patient (0.9%) from the F group. (Figures 1 and Table 2).

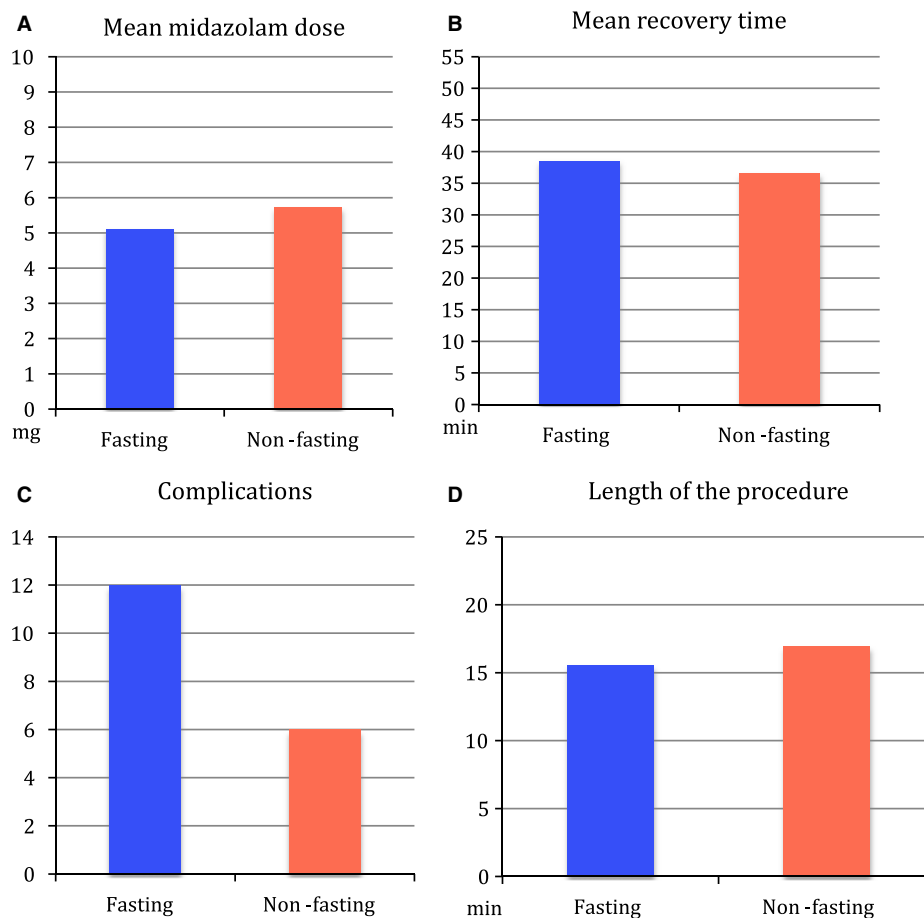
### Discussion

IV sedation is a common adjunct for anxious patients and in cases where anxiety may be heightened due to the complexity of the case. There are also medical conditions where the patient wishes to cooperate with dental treatment finds it almost impossible to do so; for example, patients with Parkinson’s disease, patients with learning difficulties or patients with a strong gag reflex<sup>20</sup>.

Moreover, stress can trigger or aggravate an acute episode of a medical condition such as ischaemic

**Table 1** Baseline data

	Fasting (F)	Non-fasting (NF)	P value
Gender (M/F)	23/91	28/86	0.43
Mean age in years (SD)	33.0 (11.2)	30.2 (10.3)	0.03
ASA (Grade 1/Grade2)	69/45	64/54	0.50



**Figure 1** (a–d) Outcomes for the fasting (F) and the non-fasting (NF) groups.

heart disease, asthma and epilepsy. Patients with a history of one of the above conditions, together with anxiety as a result of dental treatment are more likely to suffer an acute episode of their medical condition. Thus, sedation should be considered for patients at risk of medical emergencies during their medical or dental treatment.<sup>21,22</sup>

The ASA defines three levels of sedation<sup>23</sup> (Table 3), but there are other systems to define sedation levels (Table 4)<sup>24</sup>. In summary, when we pass from minimal to moderate followed by deep sedation, and finally to general anaesthesia, there is increasing depression of other physiological systems. The likelihood of adverse events increases if this is not managed accordingly, and effectively. Thus, the increasing depth of sedation should therefore be accompanied by an escalation in the level of competency required to ensure safe sedation practice<sup>25</sup>.

Sedation is preferable to general anaesthesia for the following reasons:

1. the complications associated directly with the administration of general anaesthesia are avoided. These are not negligible and include cardiopulmonary affects, airway and positional nerve injuries
2. avoidance of general anaesthesia could reduce the chance of developing a deep-vein thrombosis or a pulmonary embolism
3. reduced incidence of post-operative nausea vomiting (POVN), which means that patients can usually eat and drink sooner and have a faster recovery, as well as avoidance of PONV complications (dehydration, electrolyte disturbances and aspiration)<sup>26</sup>
4. as fewer drugs are used for sedation, there are fewer drug-induced side-effects post-operatively

**Table 2** Complications in fasting (F) and non-fasting (NF) groups

Complications	Fasting group (F)	Non-fasting group (NF)
Supplemental oxygen	5	6
Oral glucose, feeling faint	6	0
Failing to cannulate	1	0

**Table 3** Continuum of depth of sedation: levels of sedation ASA 2009<sup>23</sup>

	Minimal sedation/anoxiolysis	Moderate sedation/analgesia (conscious sedation)	Deep sedation/analgesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response after repeated or painful stimulation
Airway	Unaffected	No intervention required	Intervention may be required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained

\*Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

5. the whole procedure costs very little in comparison with general anaesthesia, as the costs of the operating theatre team, anaesthetic machinery and other equipment are obviated<sup>27</sup>.

The need for fasting prior to dental treatment under conscious IV sedation is a subject of significant discussion and generates controversy. Some authorities in dentistry and emergency medicine consider it as unnecessary as the airway reflexes are assumed to be maintained during moderate and minimal sedation, unlike patients under general anaesthesia where it is lost<sup>28,29</sup>.

On the other hand, Murphy *et al.* showed that it is not clear where the point of loss of reflexes lies or if such a point exists<sup>30</sup>. The argument is that using minimal and moderate sedation airway reflexes are maintained but this does not consider the potential for inadvertent over-sedation and loss of the protective airway reflexes.

The aetiology of why fasting is such an important and controversial subject is that fasting can prevent a rare but serious complication with high mortality rate known as aspiration pneumonitis which was first reported in obstetric patients.

Pulmonary aspiration can occur during deep sedation where airway protective reflexes are lost and materials such as pharyngeal secretions or stomach contents enter the larynx. Consequences vary from no injury at all, to chemical pneumonitis or pneumonia and that depends on the volume, the chemical composition and the health status of the patient.

Two different aspiration syndromes were first described by Mendelson in 1946 following analysis of patients who had aspirated during obstetric anaesthesia: aspiration of solid material, caused by an obstructive reaction which potentially resulted in asphyxia and death and aspiration of gastric fluids, caused an asthmatic type reaction resulting in bronchoconstriction and inflammation in the lower airways<sup>31</sup>. It was only after Mendelson conducted animal experiments and concluded that regurgitated

gastric acid was responsible for the pulmonary damage observed with aspiration syndrome, that fasting prior to general anaesthesia was introduced. Other latest studies have shown other risk factors for aspiration pneumonitis including pregnancy, obesity, diabetes, peptic ulcer disease, incompetent lower oesophageal sphincter, narcotic medication due to delayed gastric emptying and regurgitation<sup>32,33</sup>. A minimum volume and pH of gastric contents required to produce aspiration pneumonitis has not been determined, but it has been reported that even a minute volume of gastric contents in some patients can lead to aspiration<sup>34</sup>. A retrospective study investigating the need for fasting in patients before cataract surgery, who are probably more similar to oral surgery patients, by Sanmugasunderam and Khalfan 2009 showed no incidence of aspiration in non-fasting group and they did not routinely cancel patient if they had not fasted<sup>35</sup>.

Patient's comorbidities, the nature of the procedure as well as the limitations of the environment should be taken into consideration. The need for anaesthetic support should be considered for ASA 3 and ASA 4 patients as well as patients with high risk of aspiration.

In our study, all patients who received IV sedation with midazolam maintained sedation levels 2–4. In the literature, the complication rate with sedation in previous studies was from 3% to 9%<sup>5,24</sup>. Complications can be classified according to severity (Table 5). In our study, all the complications were minor with the F group having a 10% complication rate and the NF group 8% for the NF. (Table 2) The non-fasting group appeared to have six patients in one type of complication, need for supplemental oxygen, whereas in the fasting group there were other types of complications apart from the need for supplemental oxygen, such as feeling faint and failed to cannulate.

Desaturation followed by the need for supplementary oxygen was the most common complication noticed overall and is usually caused by upper airway obstruction during sedation. During sedation, the pharyngeal muscles commonly relax resulting in upper airway obstruction, which occurs in the supra-glottic structures due primarily to the soft palate and base of the tongue falling back to the posterior pharynx. This can usually be easily resolved by placing the patient in the early morning sniffing position, by applying jaw thrust or chin lift or even by inserting a nasopharyngeal airway<sup>36</sup>.

It was only on the fasting group that six patients required oral glucose intake or complaint for feeling faint. Considering that in clinical practice some

patients might be fasted for more than 6 h hypoglycaemia is commonly observed. Generally, hypoglycaemia is defined as a serum glucose level below 70 mg/dl, whereas symptoms typically appear at levels below 60 mg/dl. Symptoms arise from an inadequate supply of glucose to the brain and include from tremor and tachycardia to blurred vision, drowsiness, neurological facilities and seizures. Blood sugar levels should be monitored in all diabetic patients prior to anaesthesia to ensure normoglycaemia. That group of patients should also be advised to carry a form of glucose that they can take in case of symptoms of hypoglycaemia that will not cause surgery to be cancelled, for example, a clear, sugar-containing drink<sup>37</sup>. Although blood sugar levels are not monitored routinely in non-diabetic patients, it may be advisable to measure the blood sugar in patients feeling faint, along with patients fasting for more than 10 h<sup>38</sup>.

Failure to cannulate occurred in the fasting group only. The association between difficult venous access (DVA) and dehydration has been reported previously. Fasting from fluids for several hours could make veins less visible and tangible and thus cannulation more challenging<sup>39</sup>.

**Table 4** Description of sedation levels<sup>24</sup>

Level of sedation	Description
1	Awake and anxious
2	Awake not anxious
3	Partial ptosis and/or slurred speech
4	Eyes closed, responds to speech
5	Eyes closed, responds to mild stimulation (shaking)

**Table 5** Type of complications and their characteristics<sup>24</sup>

Type of Complication	Characteristics
Minor	1 Managed in clinic
	2 Treatment completed
	3 Patient discharged home
	4 Example: faint, respiratory depression with SaO <sub>2</sub> ≤ 90% managed with oxygen supplementation, transient hypotension, transient bradycardia
Moderate	1 Managed in clinic
	2 Treatment completed
	3 Prolonged recovery/medical advice sought
	4 Patient discharged home
Severe	5 Example: over-sedation requiring reversal
	1 Treatment stopped
	2 Medical intervention required
	3 Patient admitted to hospital
	4 No long-term sequelae
	5 Example: loss of consciousness

## Conclusion

To our knowledge, this is the only study that looked into differences and complication between fasting and non-fasting patients prior to IV sedation in an outpatient dental setting. Our study has shown that practicing minimal to moderate sedation in ASA 1 and ASA 2 non-fasting patients is safe and appears to give less complications than the fasting patients.

Taking into consideration the increase in need for IV sedation and the benefit of the sedation in comparison with general anaesthesia, there is a need for further studies and more specific randomised control trials to provide clear evidence or guidance as it will reduce the bias of a retrospective study.

## Conflict of interest

The authors confirm that they have no conflict of interest.

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