

Prospective Evaluation

Preoperative Fasting Before Interventional Techniques: Is It Necessary or Evidence-Based?

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Background: Interventional pain management is an evolving specialty. Multiple issues including preoperative fasting, sedation, and infection control have not been well investigated and addressed. Based on the necessity for sedation and also the adverse events related to interventional techniques, preoperative fasting is considered practical to avoid postoperative nausea and vomiting. However, there are no guidelines for interventional techniques for sedation or fasting. Most interventional techniques are performed under intravenous or conscious sedation.

Objective: To assess the need for preoperative fasting and risks without fasting in patients undergoing interventional techniques.

Study Design: A prospective, non-randomized study of patients undergoing interventional techniques from May 2008 to December 2009.

Study Setting: An interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Methods: All patients presenting for interventional techniques from May 2008 to December 2009 are included with documentation of various complications related to interventional techniques including nausea and vomiting.

Results: From May 2008 to December 2009 a total of 3,179 patients underwent 12,000 encounters with 18,472 procedures, with patients receiving sedation during 11,856 encounters.

Only 189, or 1.6% of the patients complained of nausea and 3 of them, or 0.02%, experienced vomiting. There were no aspirations. Of the 189 patients with nausea, 80 of them improved significantly prior to discharge without further complaints. Overall, 109 patients, or 0.9% were minimally nauseated prior to discharge. The postoperative complaints of continued nausea were reported in only 26 patients for 6 to 72 hours. There were only 2 events of respiratory depression, which were managed with brief oxygenation with mask without any adverse consequence of nausea, vomiting, aspiration, or other adverse effects.

Limitations: Limitations include the nonrandomized observational nature of the study.

Conclusion: This study illustrates that postoperative nausea, vomiting, and respiratory depression are extremely rare and aspiration is almost nonexistent, despite almost all of the patients receiving sedation and without preoperative fasting prior to provision of the interventional techniques.

Key words: Interventional pain management, interventional techniques, complications, relative risk, evidence-based medicine, preoperative fasting, nausea, vomiting, aspiration

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The evolution and growth of the specialty of interventional pain management and multiple interventional techniques have led to physicians considering various precautions to be taken prior to performing these procedures with safety and comfort (1-5). These include preoperative fasting, infection control, and sedation. Further, development of various techniques and increased utilization have led to physicians encountering patients with chronic, persistent pain associated with psychological problems presenting with anxiety and apprehension prior to undergoing interventional techniques (6-11). Thus, a significant proportion of patients receive sedation before multiple types of interventional techniques, specifically spinal injections (12-14). Patient anxiety prior to any type of interventional technique is considered the norm. However, psychological variables such as depression, anxiety, and excessive somatic symptoms are recognized as actively contributing to patients' perception of pain (15,16). Further, unrecognized and untreated psychopathology has been shown to interfere with the successful management of chronic pain and patient rehabilitation (17-19). In addition, psychopathology also has been shown to be predictor of poor surgical outcomes (18,20) and serves to perpetuate pain related dysfunction (21), with anxiety decreasing a patient's pain threshold and tolerance (22). In fact it has been illustrated that anesthesiologists are frequently inaccurate when assessing patients' anxiety and they tend to underestimate it (23). The majority of patients feel that spinal interventional techniques are painful (6,10-14,24).

Anxiety simply is an emotional reaction defined as tension, apprehension, nervousness, and concern caused by an intangible and diffuse advancing threat or approaching danger, accompanied by activation of the autonomous nervous system (25). Anxious patients may be uncooperative during interventional techniques and not only may not respond well, but may also complicate the procedures. Thus, conscious sedation is common for interventional techniques with minimal loss of consciousness, maintenance of verbal communication and cooperation, stable vital signs, and unobstructed and active reflex protectors intact (26). Conscious intravenous sedation is a safe alternative to general anesthesia for the control of intraoperative pain and anxiety for the majority of interventional techniques.

Based on the necessity for sedation and also the adverse events related to interventional techniques, preoperative fasting is practiced to avoid postoperative nausea and vomiting. The guidelines are well established for

the field of surgical anesthesia. Even though multiple physicians including anesthesiologists impose routine preoperative fasting instructions, there are no guidelines either for preoperative fasting or sedation during the procedures. In a survey of periprocedural protocols for interventional pain management techniques in U.S. pain centers, Ahmed et al (27) showed highly variable patterns practiced by physicians with preoperative fasting for over 94% of the patients for discograms, approximately 80% for radiofrequency neurotomy and stellate ganglion block, and approximately 60% to 70% for epidural and facet joint injections. Similarly, there was wide variation for sedation practices with over 90% of the patients being sedated for discography, approximately 80% for radiofrequency neurotomy, and as many as 65% for epidural injections and facet joint nerve blocks. Preoperative fasting as well as intravenous sedation was lower for intercostal nerve blocks and peripheral nerve blocks. Further, incidence and prevalence of postoperative nausea and vomiting have not been evaluated for interventional techniques.

In recent years, preoperative fasting has been revised and prolonged preprocedure fasting is considered as unnecessary in many settings. Liberal preoperative fasting routines have been implemented in most countries with clear fluids up to 2 hours before anesthesia and light meals up to 6 hours before (28). The same guidelines have been applied for children and pregnant women not in labor. Further, the concept of preoperative oral nutrition using a special carbohydrate-rich beverage also has gained support and been shown not to increase gastric fluid volume or acidity. These guidelines eluded to the fact that controversy still exists for procedures done under deep sedation. Further, none of these guidelines are based on evidence.

Most interventional techniques are performed under intravenous or conscious sedation (6,11-14,29). The American Society of Anesthesiologists (ASA) has developed a definition of the sedation continuum, which described the range of responses to sedatives and anesthetics from the awake state through general anesthesia (30). They described minimal sedation or anxiolysis with normal response to verbal stimulation with no effect on airway, spontaneous ventilation, or cardiovascular function. In contrast, moderate sedation and analgesia also known as conscious sedation includes purposeful response to verbal or tactile stimulation with no intervention required for airway, adequate spontaneous ventilation, and usual maintenance of cardiovascular function. Finally, deep sedation and

analgesia includes inadequate spontaneous ventilation with potential need for intervention. A number of organizations, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have adapted this definition.

Preoperative fasting for intravenous conscious sedation has been questioned and has been determined that it was not based on evidence (31). Proponents of preoperative fasting argue that benzodiazepines and opioids have respiratory depressive effects and a minute volume of gastric contents which are acidic leading to aspiration can be devastating. The opponents argue that aspiration is extremely rare even under general anesthesia (32,33). Overall incidence of aspiration syndrome was reported as one in 2,131 patients with mortality after aspiration at 5% (33). Further, there is very little evidence within published medical literature which concludes that preoperative fasting results in a decreased incidence of adverse effects in patients undergoing conscious sedation. The risk of aspiration during conscious sedation has not been quantified and there are no reports of such cases in the literature. The studies permitting clear fluids 2 hours prior and solid foods 6 hours prior have illustrated reduced preoperative thirst, headaches, irritation, discomfort, and postoperative nausea and vomiting apart from other deleterious effects with insulin metabolism (34,35). In fact, there is no indication that fluids permitted up to 90 minutes preoperatively prior to general anesthesia lead to an increased risk of regurgitation and aspiration (36). Finally, it is commonly thought that stress and anxiety increase gastric acid secretions and also may delay gastric emptying. McKenna and Manton (31) concluded that sedation and general anesthesia, even though linked historically, are different and the review of the literature shows that there is little evidence to support fasting prior to intravenous sedation.

Consequently, we sought to assess if there was any risk of nausea, vomiting, aspiration, and respiratory depression requiring resuscitation with intravenous conscious sedation in patients undergoing interventional techniques in a prospective non-randomized evaluation.

METHODS

The study was conducted in the United States in a private interventional pain practice and specialty referral center based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (37-39). The Institutional Review Board (IRB) approved the study protocol. This study was conducted with internal resources of the practice without any external fund-

ing either from industry or elsewhere. The study is registered with the U.S. Clinical Trial Registry NCT00625248. The results of this prospective non-randomized study of bleeding risk have been published (5).

Participants

All patients undergoing interventional techniques from May 2008 to December 2009 were included.

Interventions

This study was performed prospectively on patients without change in their normal course of treatment. Thus, the IRB waived the requirements for specific consent for inclusion in the study. However, all the patients were informed about the nature of the study with adherence to all confidentiality and Health Insurance Portability and Accountability Act (HIPAA) requirements.

Pre-Enrollment Evaluation

The patients provided the history of medical issues, antithrombotic therapy, and previous experience from interventions.

Inclusion and Exclusion Criteria

All the patients receiving interventional techniques during the time period were included, except those undergoing intrathecal implantables.

Description of Interventions

Either diagnostic or therapeutic interventional techniques of various types were performed on all participants. The procedures were performed by 3 physicians in sterile operating rooms located in an ambulatory surgery center, using fluoroscopy except for intraarticular injections and peripheral nerve blocks.

At this ambulatory surgery center, over 100,000 interventional techniques were performed until 2008. The routine has been not to advise the patients to fast preoperatively.

Objective

To investigate the risk of lack of preoperative fasting in patients undergoing various types of interventional techniques in managing chronic pain under usual circumstances.

Outcomes

Eight nurses were trained to evaluate the above outcomes. Each participant was contacted postoperatively within 48 hours.

Statistical Analysis

Data were recorded in a database using Microsoft Access (Microsoft Corporation, Redmond, WA) by a person not participating in the study. The SPSS 9.0 statistical package (IBM Corporation, Armonk, NY) was used to generate the frequency tables. Pearson chi-square test was carried out in the comparisons of proportion between antithrombotic with no antithrombotic. Results were considered statistically significant if the P value was less than 0.05.

RESULTS

Participant Flow

Table 1 illustrates the baseline characteristics. The study period lasted from May 2008 to December 2009 (20 months) with a total number of participants of 3,179 with 12,000 encounters and 18,472 procedures. The number of encounters performed with intravenous sedation was 11,856.

Procedural Characteristics

The total number of epidural procedures was 10,261, facet joint interventions was 7,482 (multiple levels and/or bilateral), and other procedures was 729 of which 199 were sacroiliac joint interventions, 114 were lumbar sympathetic blocks, 150 were stellate ganglion blocks, and the remaining were intercostal nerve blocks, occipital nerve blocks, intraarticular injections, and peripheral nerve blocks.

None of the patients were fasting. The preoperative fasting patients had solid food up to 2 hours prior

to the procedure and the majority of them had liquids until 15 minutes prior to the procedure.

Nausea, Vomiting, and Aspiration

During 15.4% of the encounters (1,848), patients were given an antiemetic during their stay at the ambulatory surgery center. They were provided with antiemetics based on the feeling of nausea and previous history of nausea or vomiting following sedation, interventional techniques, or general anesthesia. Among the patients receiving antiemetics 72% of the patients received Phenergan, whereas 28% received Zofran® (Ondansetron Hydrochloride).

Of the 12,000 encounters, overall, 189 or 1.6% of the patients complained of nausea and 3 of them or 0.02% experienced vomiting. However, there were no aspirations. Of the 189 patients with nausea, 80 of them improved significantly prior to discharge without further complaints. Thus, 109 patients or 0.9% were minimally nauseated prior to discharge. Postoperative complaints of continued nausea were reported in only 26 patients for 6 to 72 hours.

Respiratory Depression

Of the 11,850 encounters receiving intravenous sedation, brief oxygenation with mask was required in 2 patients without any adverse consequences of nausea, vomiting, aspiration, or other adverse effects.

DISCUSSION

This prospective non-randomized evaluation of approximately 3,200 patients, with approximately 12,000 encounters receiving intravenous sedation for interventional techniques illustrated minor complications with 0% aspiration, 1.6% nausea, and 0.02% episodes of vomiting. In this evaluation, none of the patients were provided with instructions to fast with all of them taking solids up to 2 hours and liquids until 15 minutes prior to the procedure. Approximately 15% of the patients were provided with antiemetics prophylactically and for management.

It continues to be a common practice among interventionalists to implement strict preoperative fasting guidelines with nothing by mouth after midnight and occasionally nothing 8 hours prior to the procedure if they are scheduled in the afternoon. Even though we are considered to be in the era of evidence-based medicine and there are no scientific reasons to keep a patient in preoperative fasting prior to interventional techniques with intravenous sedation, this routine con-

Table 1. Patient demographics based on encounter.

Gender	Male	36.1% (4,336)
	Female	63.9% (7,664)
Age	Mean ± SD	50.5 ± 13.00
Height	Mean ± SD	65.8 ± 7.95
Weight	Mean ± SD	184.2 ± 54.94
Smoking	Yes	59.4% (7,124)
	Quit	4.3% (518)
	None	36.3% (4,358)
Antithrombotic	Yes	25.7% (3,087)
	Discontinued	44.6% (1,376)
	Continued	55.4% (1,711)

tinues with cancellation of the patients who do not follow the instructions, resulting in increased costs and undue burden for the patients who travel or take off work.

Even though there are organizations and individual practitioners advocating preoperative fasting prior to monitored anesthesia care, there are no such guidelines or protocols for interventional techniques. The risk of aspiration of gastric contents has been shown to be minimal even under general anesthesia (31-33). Further, if such questions are raised, a patient may be prophylactically administered with one of multiple agents such as cimetidine, ranitidine, famotidine, metoclopramide, etc. prior to performing the procedure (40-43).

Overall there has been a tendency to reduce the preoperative fasting time based on evidence (32). Preoperative fasting is mandatory before general anesthesia to reduce the volume and acidity of the stomach contents to decrease the risk of regurgitation and aspiration recognized as Mendelson's syndrome (44). Multiple precautions have been developed to avoid regurgitation and aspiration including preoperative fasting and administration of various drugs to reduce gastric acidity and volume. However, in the era of evidence-based medicine, there are no scientific reasons to keep a patient in prolonged preoperative fasting. This routine was questioned and shown to be unnecessary for most patients. As a result, many anesthesia societies have changed their guidelines and currently recommend intake of clear fluids until 2 hours before surgery and anesthesia (45). Many anesthesiologists and also those physicians practicing interventional techniques tend to believe that fasting from midnight is safer. However, the excessive fasting has been shown not only unnecessary but also may represent additional stress (46), with development of insulin resistance (47,48) with modification of normal metabolism with a pronounced insulin resistance illustrated to develop after completion of surgery (49,50). Conventional preoperative fasting time may aggravate insulin resistance and influence the elevation of glycemia (51), especially because it is frequently longer than the expected 6 to 8 hours and may be as long as 10 to 16 hours (52). In addition, overnight fasting may cause variable degrees of dehydration depending on the ultimate duration of the fasting period. Thus, even for general anesthesia, shorter preoperative fasting has been considered safer in several randomized controlled trials and meta-analyses (53-59). In otherwise healthy adults scheduled for elective surgery oral intake of water and other clear

fluids up to 2 hours before induction of anesthesia has been shown not to increase gastric fluid volume or acidity (53-59).

Moderate sedation occupies one portion of the sedation continuum and is defined as a drug-induced depression of consciousness during which patients remain able to respond purposefully to verbal commands, either alone or when accompanied by light tactile stimulation. It is important to note that spontaneous ventilation remains adequate and the patient requires no intervention to maintain an airway. The patient's cardiovascular status remains stable. In contrast, deep sedation is a drug-induced depression of consciousness during which patients are not easily aroused, but do respond purposefully following repeated or painful stimulation. Reflex withdrawal from a painful stimulus is not considered a purposeful response. With deep sedation, patients may require assistance in maintaining an airway, spontaneous ventilation may be inadequate to prevent hypoxemia or hypercarbia, but cardiovascular function usually remains acceptable without intervention. While it is not always possible to predict how an individual patient will respond, moderate sedation is ideal for interventional techniques other than implantables. Moderate sedation is also utilized for interventional radiology procedures (60).

At the ambulatory surgery center, over 100,000 interventional procedures were performed without any significant adverse effects without preoperative fasting. Postoperative nausea and vomiting is considered as a common complication of surgery even in ambulatory surgery patients. Thus, it can lead to increased recovery room time, expanded nursing care, and potential hospital admission – all factors that may increase total health care costs. Further, postoperative nausea and vomiting increase patient discomfort and dissatisfaction (61). It also has been reported that avoidance of postoperative nausea is of greater concern than avoidance of postoperative pain and patients are willing to spend additional amounts of money to control it (62,63). It has been reported that approximately 25% of patients continue to experience postoperative nausea within 24 hours of surgery (64,65). Further, among high-risk patients, the incidence of postoperative nausea can be as frequent as 70% to 80% (66). In this evaluation only 109 of approximately 12,000 patients or less than 1% experienced post operative nausea; thus, despite the lack of statistics available for interventional techniques in reference to nausea and vomiting in patients receiving sedation, this is extremely low compared to reported postopera-

tive nausea in ambulatory surgery patients.

The limitations of this study include its prospective nature and it being a single center study, even though a large proportion of patients were included. Further, the study was performed in a setting where the majority of the nursing personnel are trained in advanced cardiac life support systems and all the physicians are anesthesiologists. Thus, in a setting without trained personnel and equipment, the results may be different.

Thus, extensive, expensive, and burdensome restrictions may reduce access to interventional techniques. Utilization of interventional techniques has been increasing over the past several years (1-3,67-71). Even though the effectiveness of multiple interventional techniques continues to be debated (69-76), these techniques are widely used with moderate evidence presented from randomized trials (77-92), systematic reviews (93-99), guidelines (4,100), and expert consensus.

CONCLUSION

Intravenous sedation without preoperative fasting provides a safe environment for patients undergoing interventional techniques without risk of increased levels of nausea, vomiting, any risk of aspiration, and without increased risk of respiratory depression. However, it is essential that all the monitoring equipment be available and the personnel are trained in advanced cardiac life support systems, including the physician.

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