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INTRANASAL FENTANYL IN PEDIATRIC PATIENTS UNDERGOING BILATERAL
MYRINGOTOMY AND TYMPANOSTOMY TUBE PLACEMENT

by

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Bachelor of Science in Nursing, Minot State University, 2010

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Abstract

Title: Intranasal Fentanyl in Pediatric Patients Undergoing Bilateral Myringotomy and Tympanostomy Tube Placement

Background: A 16 kg, 102 cm tall 26-month old male patient presented for bilateral myringotomy and PE (pressure equalization) tube placement. Bilateral myringotomy and PE tube placement is performed in more than two million children annually in the United States, making it the most common pediatric surgical procedure. Pain associated with this procedure is subjective to each child’s individual experience. Rectal Acetaminophen is a commonly used medication for this procedure, however the literature suggests that when used alone it does not provide adequate analgesia. An increasing number of anesthesia providers are turning towards an alternative analgesic such as intranasal Fentanyl (INF). Fentanyl is a lipophilic opioid agonist with an ability to be rapidly absorbed via respiratory mucosa.

Purpose: To conduct an extensive literature review of medications used in children undergoing bilateral myringotomy and tube placement (BMT), and to further determine which medication possesses the most optimal analgesic effects.

Process: A systematic literature review was conducted utilizing CINAHL, Cochrane Library, Scopus and PubMed for research articles that pertained to use of intranasal Fentanyl in pediatric patients undergoing BMT. The reviewed literature was synthesized to develop evidence-based recommendations for the use of intranasal Fentanyl in pediatric patients undergoing BMT.

Results: Administration of INF in healthy (ASA class 1 & 2) pediatric patients has been shown to be safe, effective, and well tolerated with minimal side effects when doses up to 2µg/kg are used. Use of INF in children with multiple comorbidities, impaired respiratory control, and airway obstruction should be evaluated on an individual basis.

Implications: Informed decision-making process should be utilized on a case-by-case basis regarding the use of INF in pediatric patients undergoing BMT. Anesthesia providers should be aware of the benefits and undesirable side effects associated with INF administration, along with the management of adverse effects. Whenever administering opioids to pediatric patients undergoing BMT procedure, standard monitors should be in place and frequent assessment of patient’s condition should be evaluated on a continuous basis.

Keywords: Pediatric patients, BMT, ear tubes, intranasal Fentanyl, INF.
**Background**

In 1649, while cleaning an ear canal with an ear-spoon, Jean Riolan the Younger accidentally pierced an eardrum in a patient complaining of hearing loss, which subsequently led to the patient’s improved hearing (Brusis, & Luckhaupt, 1996). Myringotomy, a procedure consisting of a surgical incision into the eardrum, has rapidly gained popularity amongst patients with hearing disabilities. It took years to realize healing tendencies of an eardrum, and in 1845 Martell Frank first described a grommet, tube surgically implanted in the eardrum, made of gold foil (Brusis, & Luckhaupt, 1996).

Bilateral myringotomy and pressure equalization (PE) tube placement is performed in more than two million children annually in the United States (Hippard et al., 2012), making it the most common pediatric surgical procedure (Galinkin et al., 2000). Myringotomy and PE tube placement is a relatively short procedure lasting less than 10 to 15 minutes. Typically, the anesthesia for this type of procedure consists of general anesthesia via mask ventilation without the placement on an intravenous (IV) line. Due to absence of an IV, alternative routes for medication administration may be necessary.

Inadequate pain control occurs when the pain experienced does not correlate to the received pain management (Mudd, 2011). Current literature demonstrates inadequate and unreliable pain control practices among pediatric patients (Mudd, 2011), where up to 87% of children undergoing BMT need rescue analgesia (Pestieau et al. 2011). Furthermore, retrospective studies show that up to 70% of pediatric patients undergoing BMT exhibit signs of pain (Rampersad, Jimenez, Bradford, Seidel & Lynn, 2010).

The use of intranasal Fentanyl (INF) in the pediatric population is controversial amongst anesthesia providers based on the perceived advantages and disadvantages of intranasal opioid
administration. Some anesthesia providers are reluctant to use INF in children without intravenous access due to the fear of potential undesirable side effects associated with opioid administration.

The purpose of this paper was to conduct an extensive literature review of medications used in children undergoing bilateral myringotomy and tube placement (BMT), and to further determine which medication possesses the most optimal analgesic effects. The reviewed literature analyzed current medication practices, advantages and disadvantages of those practices along with current recommendations. Ultimately, strong evidence is presented demonstrating the benefit of intranasal Fentanyl (INF) use in pediatric patients undergoing BMT procedure. Various methods for optimal medications administration are presented and practice recommendations are made in order to fully maximize the benefit of INF while minimizing any potential side effects.

**Case study**

A 16 kg, 102 cm tall 26-month old male patient presented for bilateral myringotomy and PE (pressure equalization) tube placement. The preoperative audiogram tympanogram showed persistent left sided middle ear effusion and conductive hearing loss. The patient’s medical history was obtained from the mother and was significant only for recurrent otitis media. The patient had had five ear infections in the past eight months. According to patient’s mother, the patient did not have any previous anesthesia history along with no family history of problems with anesthesia. The patient’s medication profile included Albuterol 1.25mg/3ml as needed for shortness of breath or wheezing. The last dose of Albuterol was two weeks prior to the scheduled procedure. The patient had no known allergies. Preoperative physical examination and baseline vital signs were unremarkable. Airway evaluation was limited due to patient’s level of
cooperation. The patient was assigned an American Society of Anesthesiologists (ASA) physical status 2. The patient had nothing by mouth for greater than eight hours.

Upon entering the operating room, an oxygen saturation monitor was applied to the patient’s foot. Standard ASA monitors, precordial stethoscope and facemask were applied to the patient. Sevoflurane was adjusted to 8% and Nitrous Oxide was adjusted to 50% in a mixture of oxygen 4 L/min and Nitrous Oxide 4 L/min. Once the patient was anesthetized, 12.5mcg of intranasal Fentanyl was administered bilaterally to each nare (total dose of 25mcg). Nitrous Oxide was then turned off and general anesthesia was maintained with Sevoflurane 3.2% expired concentration in a mixture of oxygen 2 L/min and air 2 L/min. Additionally, following the induction, 240mg rectal Acetaminophen was placed by the operating room Registered Nurse.

Once the initial myringotomy incision was made there was a noticeable increase in the patient’s heart rate from 95 to 110 beats per minute (bpm). After two minutes, the patient’s heart rate decreased to 98 bpm, while the second myringotomy incision did not cause any additional increase in heart rate. For the entire duration of the procedure the patient was masked without difficulty while breathing spontaneously. As the second myringotomy incision was made, Sevoflurane was turned off and patient was placed on 100% oxygen with oxygen flow of 8 L/minute.

Within minutes of the Sevoflurane being discontinued, the patient was awake, crying and making purposeful movements. Oxygen saturation was 99% and the patient was transferred to the Post Anesthesia Care Unit (PACU) with blow-by oxygen via mask. The patient remained hemodynamically stable and encountered no complications throughout the entire surgical procedure. During the postoperative visit, no signs of respiratory depression, hypoxia, nausea or vomiting were noted.
Discussion

Myringotomy & Pressure Equalization Tube Placement

Bilateral myringotomy and tympanostomy tube placement (BMT) is one of the most common surgical procedures performed among pediatric patients in the United States (Hippard et al., 2012 & Galinkin et al., 2000). Myringotomy and tympanostomy is indicated for patients with chronic serous otitis media or recurrent acute otitis media (Jaffe, 2014). Chronic serous otitis media is defined as a collection of fluid in the middle ear for greater than 3 months, while recurrent otitis media is defined as a series of six or more episodes of otitis media over a 12-month period (Jaffe, 2014).

BMT involves the patient being placed under general anesthesia typically without an airway device such as a laryngeal mask airway (LMA) or endotracheal tube. An ear speculum is inserted into the ear canal and any buildup of cerumen is removed. The tympanic membrane is inspected for any abnormalities, and myringotomy incision is placed. Myringotomy is a medical term indicating the placement of an incision in the tympanic membrane (Jaffe, 2014). In some instances, any fluid present in the middle ear following the tympanic membrane incision is suctioned. Once the surgical view of the middle ear is clear, a tympanostomy tube (pressure equalization or PE tube) is positioned within the tympanic membrane. Antibiotic eardrops are commonly inserted into the auditory canal. The patient’s head is then turned to the opposite side, the surgeon and the microscope are repositioned, and the entire procedure is repeated on the opposite ear (Jaffe, 2014).

Otitis Media

Acute otitis media (AOM) is an acute middle ear infection. The middle ear becomes inflamed, and in some instance an effusion can develop. Otitis media with effusion (OME), also
known as serous otitis media, indicates the presence of fluid in the middle ear without symptoms of acute ear infection (Grossman & Porth, 2014). Otitis media with effusion is more common than AOM and can develop spontaneously due to poor function of the Eustachian tubes (Grossman & Porth, 2014). In some instances, OME can accompany a viral upper respiratory tract infection or AOM. The pathophysiology behind acute otitis media (AOM) is believed to be the dysfunction of the eustachian tube which allows fluid and bacteria to move from the nasopharynx into the middle ear (Grossman & Porth, 2014). The incidence of AOM is more prevalent in infants and young children possibly due to two factors: 1) infants and younger children tend to have shorter, wider and more horizontal eustachian tubes compared to older children and adults; and 2) infants tend to spend more time in the supine position allowing easier spread of infection through the eustachian canal (Grossman & Porth, 2014).

Acute otitis media (AOM) can be either of bacterial or viral origin. The most common bacterial infection associated with AOM is Haemophilus influenzae, with Streptococcus pneumoniae being the second (Grossman & Porth, 2014). Since most cases of AOM proceed an uncomplicated URI (upper respiratory infection), respiratory viruses can also be a leading cause of AOM. Clinical manifestations of AOM include the following: acute onset of infants pulling on their ears, fever greater than 39 Celsius, hearing loss, middle ear effusion and evidence of middle ear inflammation (Grossman & Porth, 2014).

Otitis media with effusion (OME) is manifested with intact tympanic membranes and accumulation of fluid in the middle ear (Grossman & Porth, 2014). OME does not present with any signs or symptoms of infection, however individuals suffering from this condition can present with hearing loss. The accumulation of fluid in the middle ear can last from less than 3 weeks to more than 3 months (Grossman & Porth, 2014). Many cases of OME resolve
spontaneously, but recurrent episodes of OME occur as well. Persistent accumulation of fluid in the middle ear from OME can result in decreased motility of the tympanic membrane and impaired sound conduction (Grossman & Porth, 2014).

**Myringotomy/ BMT & Pain Levels**

Pain is a highly subjective and individualized experience. The amount of pain experienced by pediatric patients undergoing BMT procedure is highly debatable, yet most people agree that myringotomy is associated with a certain degree of discomfort. The tympanic membrane is very sensitive (Dewhirst et al., 2014), and the incision caused during the myringotomy can lead to patient discomfort. Despite the brief nature of the procedure, more than 50% of children experience significant pain following myringotomy and tube placement, indicating the need for adequate analgesic treatment (Kokki, 2003).

A review of retrospective studies found that up to 70% of pediatric patients undergoing BMT had either elevated heart rate, blood pressure, behavioral signs or complaints of pain (Rampersad, Jimenez, Bradford, Seidel & Lynn, 2010). Pestieau et al. (2011) found rescue analgesia to be necessary in up to 87% of children undergoing BMT. While the procedure itself is very brief, children will often exhibit pain related behaviors (Finkel et al., 2001). The data presented by Rampersad et al. (2010) and Pestieau et al. (2011) reveals the need for adequate analgesia in patients undergoing myringotomy and tube placement. In the past, BMT was performed without any intraoperative analgesia, which ultimately led to a high incidence of postoperative agitation, combativeness and a certain level of disorientation (Hippard et al., 2012). Some of these undesirable postoperative behaviors were attributed to intraoperative Sevoflurane use, while some of them were attributed to a lack of intraoperative pain management (Hippard et al., 2012).
It can be challenging to obtain a meaningful and accurate pain assessment in children experiencing BMT pain (Bolton et al., 2002). Current literature notes “inadequate and inconsistent pain control practices in pediatrics” (Mudd, 2011, p.316) despite the availability of various analgesics and opioids. Pediatric patients receive only a fraction of the recommended treatment options for pain management (MacLaren & Kain, 2008), likely due to the imprecise nature of pain scales used amongst young children. Ideally, the pain medication administration should be based on the child’s perception of pain. However, due to child’s lack of verbalization, cognitive participation in the assessment of their pain, and pain localization the child might not receive adequate analgesia (Derkay et al., 1998). The decision to administer pain medication is commonly dependent on the health care provider’s ability to interpret the child’s expression of pain (Knutsson, Tibbelin, & Von Unge, 2006).

Myringotomy is a painful procedure, and under ideal circumstances children undergoing this procedure should receive anesthesia or analgesia (Belmont, 2004). A patient’s response to injury can lead to enhanced catabolism, increased sympathetic activity, and can even lead to a certain degree of immunosuppression (Mudd, 2011). Effective analgesia plays an important role in the modification process of these physiological responses to injury, by minimizing the amount of stress experienced by the body (Mudd, 2011). “The evidence surrounding inadequate pain practices in children is substantial” (Mudd, 2011, p.321) and anesthesia professionals should do everything in their power to improve this practice.

**Myringotomy/ BMT & Alternative Medication Routes**

There are numerous challenging aspects of intraoperative pain management during a BMT. First, the procedure itself typically lasts only 10 to 15 minutes, therefore medications administered intraoperatively need to have a very quick onset and short duration of action. A
study published by Dewhirst et al. (2014) showed that BMT procedures, on average, lasted only 12 minutes, while a study published by Hippard et al. (2012) showed a mean procedure time of 7 minutes. Typically, an IV line is not placed in pediatric patients undergoing BMT. The rationales for this non-intervention include additional surgical time delay and potential for postoperative pediatric agitation related to IV presence. Furthermore, there are limited options for short-acting and effective pain medications for pediatric patients experiencing acute pain.

Orally administered medications for pain management of BMT procedures are often unpredictable with potentially altered absorption, slower onset, and prolonged duration of action. Delayed gastric absorption might explain why orally administered Acetaminophen or Ibuprofen one hour prior to induction failed to control post-operative pain behavior in pediatric patients undergoing BMT (Hippard et al., 2012). All pediatric patients undergoing any type of procedure or surgery typically have limited oral intake making the oral route of medication administration undesirable. In contrast, rectal medications provide a more rapid onset, however the utilization of this route is often undesirable. In many cases, pediatric patients undergoing BMT procedure receive rectal Acetaminophen (Dewhirst et al., 2014). The main drawback with rectal Acetaminophen is when administered alone, it does not provide sufficient analgesia (Dewhirst et al., 2014). Furthermore, the absorption of rectal Acetaminophen is highly variable, with an onset time of 45-60 minutes (Rampersad et al., 2010), while the peak effect is not reached for 2-3 hours following rectal administration (Finkel et al., 2001). Essentially, for rectal Acetaminophen to be effective, it should be placed 45 minutes prior to the procedure, and some evidence suggests that a larger dose (up to 60mg/kg rectally) than typically administered is needed to achieve a therapeutic effect (Finkel et al., 2001). Rectal medication placement in an awake child would create a certain amount of distress even before the actual procedure. The intramuscular
route might be quick and easy, but it also poses a challenge due to delayed onset, long duration of action, and pain associated with the injection site.

Some anesthesia providers might argue that intravenous (IV) route of medication administration offers rapid delivery of rescue analgesia, however it can be time consuming to start an IV in the operating room, especially when considering the total surgical time of BMT procedure is only 10 minutes. Hippard et al. (2012) analyzed several studies to discover that IV access did not provide any advantage in healthy children undergoing BMT, and in some instances, patients without an IV access had less pain, faster recovery and higher parental satisfaction scores. In addition to time constraint, IV placement in pediatric population is a mastered skill, which creates an additional challenge to the anesthesia provider. Due to brief nature of the procedure and no need of fluid replacement, children who undergo a BMT procedure typically do not need an IV access (Finkel et al., 2001).

**Intranasal Route**

The intranasal (IN) route is currently gaining a certain level of popularity along with some controversy. The intranasal route bypasses gastrointestinal first-pass metabolism, which allows for rapid absorption into the systemic circulation via highly vascular nasal mucosa (Corrigan, Wilson & Hampton, 2015). The avoidance of first pass metabolism results in greater bioavailability of administered medications compared to orally and rectally administered medications (Corrigan, Wilson & Hampton, 2015).

The respiratory mucosa contains a rich capillary network that receives more blood flow per unit of tissue compared to brain, liver or muscles (Corrigan, Wilson & Hampton, 2015). The cribriform plate of the skull, located in the upper portion of the nasal cavity, contains olfactory cells that extend directly into the cranial cavity (Corrigan, Wilson & Hampton, 2015).
Medications administered via intranasal route can be delivered directly to the cerebral spinal fluid and brain via the olfactory nerve pathway, which is located in the olfactory mucosa (Corrigan, Wilson & Hampton, 2015). Once the lipophilic drugs with low molecular weight come in contact with the very vascular and large surface area of the nasal cavity, the absorbed medication can produce serum concentrations similar to those achieved with intravenous administration (Finkel et al., 2001). Intranasally administered medications can completely bypass the difficult to penetrate blood-brain barrier, making this route of administration very effective (Corrigan, Wilson & Hampton, 2015).

The intranasal route provides for a very quick, painless and a simple mode of medication administration (Corrigan, Wilson & Hampton, 2015). In contrast, there are several disadvantages of IN administration. Patients undergoing BMT can present with upper respiratory infections (URI) and chronic rhinitis, which could potentially interfere with medication absorption and efficacy (Dewhirst et al., 2014), however the presence of a URI does not seem to have any effect on nasal absorption (Corrigan, Wilson & Hampton, 2015). Any type of nasal- septal abnormality along with copious amount of nasal secretions of blood or mucus may present a barrier to absorption by not allowing the medication to reach its site of action (Corrigan, Wilson & Hampton, 2015).

Complications of Intranasal Administration

The most serious drawback of IN administration is the potential of laryngospasm. Laryngospasm is a reflex leading to glottic closure as a result of noxious stimulation of the superior laryngeal nerve (Nagelhout & Plaus, 2014). The laryngeal inlet closes by the actions of supraglottic folds, true and false vocal cords, essentially leading to airway obstruction. The management of laryngospasm consists of three essential steps: removal of noxious stimuli,
increasing the depth of anesthetic and application of positive pressure ventilation in conjunction with direct application of pressure toward the laryngospasm notch (Nagelhout & Plaus, 2014). If none of the aforementioned interventions manage to break the laryngospasm, the last resort is the administration of Succinylcholine, which causes vocal cord relaxation within 60 seconds (Nagelhout & Plaus, 2014). The lack of IV access in most children undergoing BMT is not an issue since Succinylcholine 4mg/kg can quickly and safely be administered via intramuscular route into the deltoid muscle (Nagelhout & Plaus, 2014).

Despite the aforementioned drawbacks, current literature demonstrates that the presence of any complications associated with IN medication administration is minimal compared to its benefits (Galinkin et al., 2000). In a clinical trial conducted by Galinkin et al. (2000), 265 children, ASA class 1 or 2, received INF for their BMT procedure. The study found there were no adverse effects of laryngospasm, postoperative respiratory depression, bronchospasm or hypoxemia noted in any subjects. Recent research describes intranasal delivery of medications as safe, effective and a convenient alternative to other routes of drug administration (Corrigan, Wilson & Hampton, 2015).

**Pharmacological Options for Intranasal Pain Management**

The search still remains for an ideal analgesic for pediatric patients that would offer simple and painless administration, adequate pain relief, rapid onset, and minimal adverse effects (Mudd, 2011). Current literature review discovered the following two primary drugs being administered via intranasal route for BMT procedures: Fentanyl and Dexmedetomidine.

**Fentanyl**

In 1960, Dr. Paul Janssen managed to synthesize the drug called Fentanyl, and we have since seen its utilization increase steadily (Stanley, 1992). In the past, Fentanyl was only used as
In the operating room (OR). However, more recently Fentanyl has gained popularity in the management of acute and chronic pain outside of the OR environment. Intravenous Fentanyl is commonly administered to inpatient individuals experiencing acute pain, while transdermal Fentanyl patches are increasingly being used in the management of chronic pain (Grape, Schug, Lauer & Schug, 2010).

Lately, the intranasal route has been gaining popularity amongst healthcare providers for the management of acute pain in the OR and emergency room department in adult and pediatric patients. Fentanyl is currently the most widely investigated intranasal opioid in various clinical and pharmacokinetic trials (Hansen, Mathiesen, Trautner & Dahl, 2012). In Australia, INF administration is widely accepted and utilized by all major pediatric emergency room departments (Crellin, Ling & Babl, 2010). Additionally, there are currently several clinical trials testing the effectiveness of intranasal Fentanyl (INF) for the management of chronic cancer pain and results thus far are very promising (Hansen, Mathiesen, Trautner & Dahl, 2012).

Fentanyl is an analgesic approximately 100 times more potent than Morphine (Stoelting & Hillier, 2006) and its rapid onset and short duration of action make it very effective. Fentanyl is a synthetic opioid agonist, which primarily exerts its action on mu receptors with some activity seen on delta and kappa receptors (Stoelting & Hillier, 2006). All opioid receptors can be classified into three main categories: mu, delta and kappa. Mu-1 receptors are primarily responsible for analgesia and euphoria. Activation of Mu-2 receptors primarily causes respiratory depression, physical dependence, constipation and some euphoria. Stimulation of delta receptors primarily causes analgesia, however respiratory depression and minor constipation can be observed as well. Lastly, kappa receptors are responsible for analgesia, sedation, dysphoria and miosis (Stoelting & Hillier, 2006). Due to extensive first-pass metabolism, oral administration of
Fentanyl is not an option; however due to its high lipophilicity and potency, Fentanyl can be administered in a variety of routes (Grape, Schug, Lauer & Schug, 2010). The high lipophilicity of Fentanyl allows for rapid diffusion into the central nervous system structures via the largely lipophilic nasal mucosa, making the intranasal route of Fentanyl very effective (Corrigan, Wilson & Hampton, 2015).

To date, most research on the use of intranasal Fentanyl has been done on the pediatric population, and the data shows it to be safe and effective (Corrigan, Wilson & Hampton, 2015). Intranasal Fentanyl (INF) offers an advantage of needle-free, rapid, and simple administration of an opioid. The onset of INF is 6-8 minutes and the duration of analgesia is less than 1 hour, making it a great choice for the management of acute pain (Hansen, Mathiesen, Trautner & Dahl, 2012), which is commonly seen in BMT procedures. Based upon randomized controlled trials, its efficacy in the pediatric population has been proven to be very similar to intravenous Morphine (Crellin, Ling & Babl, 2010).

A prospective, observational study conducted in the Emergency Room department by Crellin, Ling and Babl (2010) analyzed the effectiveness of INF among children presenting with upper limb injury. Even though this study contained only 36 children undergoing fracture reductions, the main benefits of INF administration were clearly described. A total of 21 children received adequate pain relief from INF administration, and no further analgesia was required. The median dose of administered INF was 1.4µg/kg, and during this study no adverse effects were observed. There were no hypotensive episodes, hypoxic events nor unarousable events, which clearly demonstrates the safety profile of INF. The study concluded INF administration to be safe and effective for children in the emergency room department presenting with acute injuries.
INF has been proven to be very effective and well tolerated with minimal side effects when administered in doses of 1-2µg/kg (Mudd, 2011). INF administered at 2µg/kg results in a significant decrease in postoperative agitation (Mudd, 2011 & Rampersad et al., 2010), which can occur in up to 67% of children undergoing BMT with Sevoflurane alone (Finkel et al., 2001). Galinkin et al. (2000) noted that 25-50% of children who undergo BMT emerge from anesthesia with a certain degree of restlessness, disorientation, and inconsolability. Postoperative agitation can be attributed to multiple factors such as: pain, delirium, agitation, parental separation, hunger, thirst, etc. (Shi et al., 2015). Regardless of the cause, administration of Fentanyl provides analgesia and sedation leading to a disruption in the patient’s agitation and crying, and a subsequent decrease in the incidence of postoperative agitation (Shi et al., 2015). Likewise, Galinkin et al. (2000) noted decreased incidence of severe agitation and decreased heart rate in children receiving intranasal Fentanyl for BMT procedure.

**Minimum Effective Concentration**

The effectiveness of intranasal Fentanyl is closely associated with its absorption and subsequent plasma concentration levels. Since it’s difficult to obtain subjective pain scores in the pediatric population, it would be logical that blood concentration of Fentanyl would provide insight on the correlation between the serum levels and efficacy of analgesia. Currently there are no publications citing a minimum effective concentration of Fentanyl needed for adequate analgesia in children. However, Galinkin et al. (2000) cited a study where adults receiving Fentanyl patient-controlled analgesia following intra-abdominal procedures needed a minimum effective concentration of 0.63±0.25ng/ml in order to achieve adequate analgesia. In its own study, Galinkin et al. (2000) obtained 26 blood samples of children receiving 2µg/kg INF for BMT procedure in order to determine their mean Fentanyl concentration. This study discovered
that 10 minutes following the administration of INF 2mcg/kg, children undergoing BMT had mean fentanyl concentrations of 0.8±0.28 and 34 minutes following the administration the children had mean fentanyl concentration of 0.64±0.25ng/ml. Both of the obtained serum Fentanyl concentrations indicated serum levels associated with adequate analgesia. There are some limitations with this presented information such as the researchers compared the data between the two different age groups. Furthermore, values presented for adults represented the steady state concentration of Fentanyl, while values presented for children described their mean Fentanyl concentration. Despite these limitations, the goal of this study was to provide a more scientific explanation behind the effectiveness of INF. Galinkin et al. (2000) tried to demonstrate INF effectiveness in children, and that INF administration will result in Fentanyl serum levels that are associated with adequate analgesia in adults. Regardless of the evaluation method used, whether it is serum level or behavior pain scale used in the PACU, current literature review agrees on INF being able to provide adequate analgesia.

INF Administration Techniques

In the United States, the standard concentration of intravenously administered Fentanyl is 50mcg/ml. Since there is no standard formulation of Fentanyl specifically intended for intranasal administration, the very same medication used for the intravenous administration is simply administered into the nares (Mudd, 2011). It is important to note that nasal mucosa has a small surface area, so when administering INF, smaller volumes of medication should be used in order to avoid runoff into the nasopharynx (Grape, Schug, Lauer & Schug, 2010).

Intranasally administered Fentanyl should be dripped slowly into each nostril at least one minute following the induction to ensure adequate anesthetic depth, with patient’s head turned to the side (Finkel et al. 2001). The lateral head position ensures that the Fentanyl stays in contact
with the lateral surface of the nasal cavity thus minimizing the medication runoff, while the adequate anesthetic depth will minimize the potential of laryngospasm (Finkel et al., 2001). Another potential solution to medication runoff into the posterior nasopharynx is the use of mucosal atomizers when administering INF. The main advantage of mucosal atomizers is the increased mucosal coverage, improved medication absorption, and decreased amount of medication run off into the oropharynx and nasopharynx (Mudd, 2011). When utilizing a mucosal atomization device, the provider should keep in mind that there is 0.1ml of dead space, therefore an additional 0.1ml of medications should be drawn up to compensate for this dead space (Corrigan, Wilson & Hampton, 2015). Minimizing the amount of drug reaching the posterior nasopharynx would significantly decrease the potential of laryngospasm. Patients with nasal congestion should have their nostrils suctioned prior to intranasal Fentanyl administration (Galinkin et al., 2000). The best way to optimize the bioavailability of intranasally administered medications is to minimize the barriers to absorption, minimize the volume by using a higher concentration of medication if possible and to maximize the absorptive surface of the nasal mucosa by using the device that maximizes drug dispersion while minimizing drug runoff (Corrigan, Wilson & Hampton, 2015).

INF Side Effects

Fentanyl exhibits all common opioid related adverse effects such as pruritis, nausea and vomiting, urinary retention, and respiratory depression. The most common side effect is nausea and vomiting, while the most serious adverse effect of Fentanyl administration is the dose-dependent respiratory depression (Grape, Schug, Lauer & Schug, 2010). Rampersad et al. (2010) noted nausea and vomiting occurrence in 12% of individual receiving INF for BMT procedure, yet when compared to other treatment groups this incidence did not have any statistical
significance. Providers concerned with potential emesis should be aware of a correlation between the peak serum concentration and incidence of emesis. When administered intravenously, Fentanyl has the highest incidence of emesis at its peak serum concentration. As a result, providers should be aware that intranasally administered Fentanyl has a peak serum concentration occurring at 10 to 20 minutes post administration (Seith, Theophilos & Babl, 2012), therefore at that time, providers should be more vigilant of the potential side effects.

Likewise, the incidence of nausea appears to be correlated to the dose of administered medication. Pestieau et al. (2011) noted that in children undergoing BMT, INF doses of 1mcg/kg were associated with a 3.9% incidence rate of vomiting, while INF 2mcg/kg was associated with 12% incidence of vomiting. In contrast, Galinkin et al. (2000) found the incidence of postoperative vomiting, hypoxemia and decreased respiratory rate not to be increased with the administration of INF at 2µg/kg. Generally speaking, INF is considered to be safe with low incidence of emesis due to a lack of histamine release (Seith, Theophilos & Babl, 2012).

Mudd (2011) stated Fentanyl’s most serious adverse effect of respiratory depression being linked to higher doses exceeding 2µg/kg. Despite the lack of literature being able to link the administration of INF to respiratory depression, anesthesia providers should be aware of solutions to this potential problem. Naloxone, an opioid antagonist, is occasionally used to reverse the undesirable side effects of opioid administration such as respiratory depression, depressed mental status, uncontrollable pruritus, nausea, and vomiting. Prudent anesthesia providers should be aware of the potential and undesirable side effects of INF and thus consider regular and frequent assessments observing for presence of any adverse effects or signs of inadequate analgesia. Intranasal Naloxone, which comes supplied as 1mg/ml, has been found to be effective in the reversal of opioid induced respiratory depression when administered at a dose
of 2mg (Corrigan, Wilson & Hampton, 2015), thus eliminating the need of intravenous access. Intranasal Naloxone can be easily installed into the nostrils, however providers concerned with higher volumes of medication reaching the posterior nasopharynx can also opt to use the intramuscular route. The intramuscular Naloxone 0.8mg (supplied as 0.4mg/ml) is just as effective as intranasal Naloxone, and it may provide a better clinical outcome compared to IN Naloxone (Corrigan, Wilson & Hampton, 2015).

**Dexmedetomidine**

Dexmedetomidine is a highly selective Alpha-2 agonist that produces dose dependent analgesia and sedation with only mild depression of ventilation (Stoelting & Hillier, 2006). The administration of Dexmedetomidine provides multiple beneficial effects such as the following: analgesia, sedation, improved quality of local anesthetics used for IV regional anesthesia, attenuation of hemodynamic responses related to tracheal intubation, and decreased perioperative requirements for opioids and inhaled anesthetics (Stoelting & Hillier, 2006). The preservation of respirations while providing the sedative properties is the main benefit of Dexmedetomidine. The general side effects of Dexmedetomidine are bradycardia and hypotension (Stoelting & Hillier, 2006), both of which can be detrimental in pediatric patients (Nagelhout & Plaus, 2014). When administered intranasally, Dexmedetomidine is dosed 0.5-1 mcg/kg (Nagelhout & Plaus, 2014), while some studies recommend a dose of 1-2mcg/kg (Pestieau et al., 2011). The administration of intranasal Dexmedetomidine is not associated with respiratory depression, however Dexmedetomidine alone does not produce adequate sedation and analgesia (Hitt, Corcoran, Michienzi, Creighton & Heard, 2014). Furthermore, unlike INF, which has rapid peak plasma concentration within minutes of administration, IN Dexmedetomidine has a relatively slow onset of 45 minutes and plasma peak effect at 90-150 minutes (Dewhirst et al., 2014). Anesthesia
providers should be aware of the potential for bradycardia, which would necessitate prolonged monitoring before and after the procedure (Pestieau et al., 2011).

A double-blinded, randomized controlled trial guided by Pestieau et al. (2011) examined the effect of Dexmedetomidine in 160 children undergoing BMT. The trial randomized children into four groups: the first group received IN Dexmedetomidine 1mcg/kg, the second group received IN Dexmedetomidine 2mcg/kg, the third group received IN Fentanyl 2mcg/kg, and the fourth group received placebo saline drops. The study had to be terminated early due to significantly extended PACU stay of children receiving IN Dexmedetomidine 2mcg/kg. The review of children receiving IN Fentanyl demonstrated adequate analgesia and reduced postoperative agitation, while children receiving saline demonstrated higher pain scores and higher requirements for analgesia in the PACU. The trial concluded that in children undergoing BMT, higher doses of IN Dexmedetomidine were associated with significantly longer PACU stays. Furthermore, in terms of pain, IN Dexmedetomidine was not superior to IN Fentanyl in children undergoing BMT.

A study published by Dewhirst et al. (2014) compared the effectiveness of intranasal Dexmedetomidine (1µg/kg) to intranasal Fentanyl (2µg/kg) in 100 ASA class 1 or 2 patients ranging from 1 to 7.7 years, undergoing bilateral myringotomy and tympanoplasty tube placement (BMT). In this randomized clinical trial, all patients received rectal Acetaminophen 40mg/kg, and the first 50 patients were additionally medicated with oral Midazolam. The study analyzed four individual groups: intranasal (IN) Fentanyl alone, IN Fentanyl with Midazolam premedication, IN Dexmedetomidine, and IN Dexmedetomidine with Midazolam premedication. The study showed no clinically significant difference in terms of pain relief when IN Fentanyl (2µg/kg) and IN Dexmedetomidine (1µg/kg) when compared alone. However, the study did
conclude that intranasal Dexmedetomidine alone was associated with a significantly lower heart rate among patients and prolonged PACU stays. In conclusion, the administration of IN Dexmedetomidine did not offer any advantage over administration of IN Fentanyl.

**Intranasal Fentanyl Versus Morphine**

Morphine has long been the standard in which all other opioids are compared. Several studies have compared Morphine to INF for BMT procedures. Mudd (2011) reviewed 12 studies comparing the pain relief of INF to Morphine administration via oral (PO), intravenous (IV) and intramuscular (IM) routes. One of these studies concluded that the children’s parents perceived the intranasal route of Fentanyl administration to be significantly better to intramuscular Morphine administration. Two studies noted decreased postoperative agitation in children receiving INF, and three studies concluded that administration of INF provided a significantly faster onset to analgesia compared to IV Morphine. One study showed a 3.9%-12% increased incidence of vomiting in children receiving INF compared to placebo, however this finding was not reported in any other studies. The remaining studies found comparable results between INF and Morphine administration. No serious side effects of INF administration were noted in any of the 12 analyzed studies.

The randomized, double-blinded, placebo controlled clinical trial described by Hippard et al. (2012) analyzed the effectiveness of INF, IV Morphine and IM Morphine among 171 pediatric patients undergoing BMT. All 171 pediatric patients were randomized into 3 different groups. Group 1 received INF 2µg/kg with IV and IM placebo saline, group 2 received IV Morphine 0.1mg/kg with nasal and IM placebo, and group 3 received IM Morphine 0.1mg/kg with nasal and IV placebo. All participating pediatric patients received general anesthesia with Sevoflurane, Nitrous oxide and oxygen. The study concluded no difference in postoperative pain
efficacy, PACU discharge time, side-effect profile or emergence delirium among children receiving INF, IV and IM Morphine. Despite the already mentioned findings, the study recommended the intramuscular (IM) route of medication administration. The explanation behind the IM administration was the simplicity of administration, avoidance of potential time delay associated with IV placement and avoidance of potential vocal cord irritation associated with INF. In essence, this recommendation was based upon the risk of laryngospasm triggered by INF administration, even though there were no incidents of laryngospasm noted in this study. The review of literature concluded that INF was equivalent or superior to Morphine administration via all routes (PO, IV, IM) for management of children’s acute pain (Mudd, 2011).

Alternative Analgesic Options to Intranasal Fentanyl

The various modalities available for pain management of pediatric patients undergoing BMT include but are not limited to the following: oral and rectal Acetaminophen, Ibuprofen, intranasal Fentanyl, intramuscular Ketorolac, intramuscular Morphine, topical 2% Lidocaine ear drops and regional anesthesia. Voronov et al. (2008) conducted a double blinded, randomized controlled trial (RTC) in 200 children undergoing myringotomy and tube placement. The goal of this RTC was to compare the effectiveness of INF 2µg/kg to a nerve block of the auricular branch of the Vagus (Nerve of Arnold) using 0.2ml of 0.25% Bupivacaine with 1:200,000 Epinephrine. The auricular branch of the Vagus innervates the external auditory meatus and the inferior portion of the tympanic membrane, an area where the incision for PE tube placement is carried out. In order to perform this block, the tragus is everted and a 30G needle is advanced until the cartilage is pierced. The needle is aspirated to rule out intravascular placement, followed by injection of 0.2ml 0.25% Bupivacaine with 1:200 000 Epinephrine. In addition, both groups
received 20mg/kg of rectal Acetaminophen suppository. The RTC concluded no difference in pain scores between the administration of INF and the nerve block of the auricular branch of the Vagus. Additionally, there was no difference between the two groups in incidence of nausea and vomiting, wake-up time or discharge time (Voronov et al., 2008).

Rampersad et al. (2010) analyzed three different methods of analgesia for 228 children undergoing BMT procedure. One group received only rectal Acetaminophen 40mg/kg, the second group received intramuscular Ketorolac 1mg/kg in conjunction to rectal Acetaminophen 40mg/kg, and the third group received rectal Acetaminophen 40mg/kg along with INF 1mcg/kg. All children were premedicated with oral Versed 0.5mg/kg and they all received inhalational induction and maintenance with Sevoflurane, Oxygen and Nitrous Oxide. The use of intramuscular (IM) Ketorolac in this randomized controlled trial implies that IM Ketorolac 1mg/kg could also be considered as an option for acute pain management in pediatric patients. The drawback of intramuscular Ketorolac administration was bruising at the site of injection, which was present in 4 out of 69 subjects and a slower onset time of 20-25 minutes. In current practice, the use of IM Ketorolac in children is controversial and there is inconsistent data regarding its pain efficacy in the pediatric population. Rampersad et al. (2010) primarily focused on the incidence of emergence agitation among the three groups, yet they also noted no significant difference in pain scores or side effects. It is worth mentioning that similar pain scores were attributed to oral premedication with Midazolam. Due to premedication, the real benefit of this study was not to compare the efficacy of the three different types of analgesia, but instead to offer a possible alternative to INF use.
**Conclusion**

The review of literature demonstrates a variety of pain management techniques currently utilized in pediatric patients undergoing BMT procedures. The intranasal route offers a time efficient, simple, fast and painless mode of medication delivery without the need for intravenous access. Administration of INF in the pediatric population has been shown to be safe, effective, and well tolerated with minimal side effects when doses up to 1-2µg/kg are used. Furthermore, INF at 2µg/kg causes a significant decrease in postoperative agitation among pediatric population, however, this higher dose (2mcg/kg) did demonstrate a potential for the increased risk of respiratory depression. Use of INF in children with multiple comorbidities, impaired respiratory control, and airway obstruction should be evaluated on an individual basis.

Anesthesia providers should be aware of the benefits and undesirable side effects associated with INF administration, along with the management of adverse effects. When administering INF, it is recommended to use mucosal atomization devices in order to minimize the potential of laryngospasm. Undesirable side effects such as nausea and vomiting, are associated with higher doses of INF, therefore anesthesia providers are advised to administer the minimal amount of medication needed to achieve adequate analgesia. Standard monitors should be in place when administering opioids to pediatric patients undergoing BMT and frequent assessment of the patient’s condition should be evaluated on a continuous basis. Occurrence of any unexpected side effects following the administration of INF should be treated with 0.8mg intramuscular Naloxone. In conclusion, multiple benefits of INF administration outweigh its potential drawbacks, therefore anesthesia providers should strongly consider the use of INF in healthy pediatric patients undergoing BMT procedures.
Reference


**Introduction to Intranasal Fentanyl**

- The most commonly performed surgical procedure among pediatric population in the US.
- **Indication:** Chronic serous otitis media (defined as a collection of fluid in the middle ear for greater than 3 months) & recurrent otitis media (defined as a series of six or more episodes of otitis media over the 12-month period).
- Anesthetic technique is fairly standardized, however use of analgesics greatly varies among anesthesia providers.
- Use of intranasal Fentanyl is somewhat controversial.
- Review of literature on use of INF (Intranasal Fentanyl) in healthy pediatric patients (ASA 1 & 2) undergoing BMT will be examined.

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**Case Information**

- **Surgical Procedure:** bilateral myringotomy and PE (pressure equalization) tube placement
- **Age:** 26 month old
- **Weight:** 16 kg
- **Height:** 102 cm
- **Gender:** Male
- **ASA:** 2

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**Pre-operative Evaluation**

- **Past Medical Hx:** 5 ear infections in the past 8 months.
- **Surgical Hx:** None
- **Pre-op VS:** HR 97, SpO2 98% on RA
- **Pertinent Test:** preoperative audiogram tympanogram showed persistent left sided middle ear effusion and conductive hearing loss
- **Airway Evaluation:** Limited due to patient's age
- **Current Medications:** Albuterol 1.25mg/3ml PRN for SOB/wheezing.

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**Anesthetic Course**

- **Technique:** mask technique - patient breathing spontaneously during the case
- **Induction:** Sevoflurane 8% and N2O at 50% (4lpm O2 and 4lpm N2O)
  - Once anesthetized N2O turned off and anesthesia maintained with expSevo at 3.2%.
- **Drugs:** 12.5mcg Fentanyl (1.56 mcg/kg) applied to each nare & Rectal Acetaminophen 240mg.

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**Intraoperative Issues**

- Once the initial myringotomy incision was made there was a noticeable increase in the patient's heart rate from 95 to 110 beats per minute (bpm). After two minutes, the patient's heart rate decreased to 98 bpm, while the second myringotomy incision did not cause any additional increase in heart rate.
- **No intraoperative issues noted.**
**PACU**
- Transport to the PACU was uneventful - patient transported with blow by oxygen.
- Hemodynamically stable throughout stay in PACU - SpO2 99% on RA HR 98
- During the postoperative visit, no signs of respiratory depression, hypoxia, nausea or vomiting were noted.

**IntraNasal Fentanyl??**
- Should we use intra-nasal Fentanyl in pediatric patients undergoing BMT procedures?
- Is it safe?
- What are the benefits/advantages of it?
- What are the possible side effects?
- What does the literature say?
- What are any other alternative analgesics that we can use?

**INF**
- Review of retrospective studies found that up to 70% of pediatric patients undergoing the procedure had either elevated heart rate, blood pressure, behavioral signs or complaints of pain (Rampersad, Jimenez, Bradford, Seid & Lynn, 2010).
- Pestieau et al. (2011) found rescue analgesia to be necessary in up to 87% of children undergoing BMT.
- More than 50% of children experience significant pain following myringotomy and tube placement (Kotob, 2001).

**Bilateral Myringotomy Tube Placement**
- Hippard et al. (2012) analyzed several studies to discover that IV access did not provide any advantage in healthy children undergoing BMT, and in some instances, patients without an IV access had less pain, faster recovery and higher parental satisfaction scores.
- Premedication with oral medications is unpredictable (delayed onset) patients NPO.
- One of the most commonly administered analgesics is rectal Acetaminophen but...

**Rectal Acetaminophen**
- When administered alone, it does not provide a sufficient analgesia (Dewhurst et al., 2014).
- The absorption of rectal Acetaminophen is highly variable, with an onset time of 45-60 minutes (Rampersad et al., 2010).
- Peak effect is not reached for 2-3 hours following the rectal administration (Finkel et al., 2001).
- Evidence suggests that a larger dose (up to 60mg/kg rectally) is needed to achieve a therapeutic effect (Finkel et al., 2001).

**The Intranasal Route**
- It bypasses gastrointestinal first-pass metabolism, which allows for rapid absorption into the systemic circulation via highly vascular nasal mucosa.
- The avoidance of first pass metabolism results in greater bioavailability of administered medications compared to orally and rectally administered medications (Corrigan, Wilson & Hampton, 2015).
- The respiratory mucosa contains the rich capillary network that receives more blood flow per unit of tissue compared to brain, liver or muscles (Corrigan, Wilson & Hampton, 2015).
INTRANASAL FENTANYL IN PEDIATRIC PATIENTS UNDERGOING BMT

The Intranasal route

- Medications administered via intranasal route can be delivered directly to the cerebral spinal fluid and brain via the olfactory nerve pathway, which is located in the olfactory mucosa (Cronin, Wilson & Hamptom, 2015).
- The absorbed medications produce serum concentrations similar to ones achieved with intravenous administration.

Problems With IN Route & Recommendations:

- Nasal-septal abnormality along with copious amount of nasal secretions or blood may present a barrier to absorption
- Laryngospasm (PPV vs Succinylcholine 4mg/kg IM) Galinkin et al. (2000): 265 children received INF and there were no instances of laryngospasm
- Goal: minimize barriers to absorption, minimize the volume, and maximize the absorptive surface

IN Fentanyl Vs. IN Dexmedetomidine

<table>
<thead>
<tr>
<th>Medication</th>
<th>IN Fentanyl</th>
<th>IN Dexmedetomidine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>10mg/kg</td>
<td>2mg/kg</td>
</tr>
<tr>
<td>Category</td>
<td>Alpha 2 agonist</td>
<td>Alpha 2 agonist</td>
</tr>
<tr>
<td>Circuit</td>
<td>18 minutes</td>
<td>45 minutes</td>
</tr>
<tr>
<td>Mean plasma concentration</td>
<td>14 minutes</td>
<td>40-150 minutes (Kawahara et al., 2016, p. 1394)</td>
</tr>
</tbody>
</table>

Side effects: N/V, Respiratory depression

IN Fentanyl

- High lipophilicity of Fentanyl allows for rapid diffusion into the CNS structures via the largely lipophilic nasal mucosa
- Rampersad et al. (2010): nausea and vomiting occurrence in 12% of individuals receiving INF for BMT procedure
- Pestieau et al. (2011): IN Fentanyl doses of 1mg/kg = 3.9% incidence rate of vomiting, while INF 2mg/kg = associated with 12% incidence of vomiting (significance?)
- Galinkin et al. (2000): Incidence of PONV, hypoxemia and decreased respiratory rate has not increased with INF use
- Main advantage: quick onset, short duration, no histamine release, minimal hemodynamic impact, decrease in post-operative agitation

IntraNasal Fentanyl

- Respiratory depression concern:
- Grape et al. (2010) - there were no reports linking respiratory depression to INF
- Mudd (2011) respiratory depression being linked to higher doses exceeding 2mg/kg
- There is a lack of evidence to support respiratory depression in doses up to 2mg/kg
- Treatment: IN Naloxone (1mg/ml) or IM Naloxone 0.8mg (recommended).
**Alternative Pharmacological Options for BMT**

- Oral or Rectal Acetaminophen
- Ibuprofen
- IM Ketorolac 1mg/kg (slow onset, controversy)
- PO/IM/IV Morphine
- 2% Lidocaine ear drops
- IN Dexametomidine
- Regional anesthesia...

**Regional Anesthesia for BMT procedure?**

- Nerve block of the auricular branch of the Vagus (Nerve of Arnold) using 0.2ml of 0.25% Bupivacaine with 1:200 000 Epinephrine.
- The auricular branch of the Vagus innervates the external auditory meatus and the inferior portion of the tympanic membrane, an area where incision for PK tube placement is carried out.

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**Recommendations**

- When possible, use mucosal atomization devices to minimize the potential of laryngospasm & turn patient’s head to the side.
- Undesirable side effects such as nausea and vomiting are associated with higher doses of INF; therefore administer the minimal amount of medication needed to achieve adequate analgesia.
- Use of INF in children with multiple comorbidities, impaired respiratory control, and airway obstruction should be evaluated on an individual basis.
- Standard monitors should be placed when administering opioids to pediatric patients undergoing BMT and frequent assessment of patient’s condition should be evaluated on a continuous basis.

**Conclusion**

- Administration of INF in healthy (ASA class 1 & 2) pediatric patients has been shown to be safe, effective, and well tolerated with minimal side effects when doses up to 2mg/kg are used.
- The intranasal route offers a time efficient, simple, fast and painless mode of medication delivery without the need of intravenous access.
- “Current evidence suggests that INF is a safe and effective method of pain management for children in a variety of clinical settings” (Modell, 2011, p. 316).

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**Reference**

Thank You
Are There Any Questions?