MULTIMODAL ANALGESIA IN CHILDREN FOLLOWING DENTAL REHABILITATION UNDER GENERAL ANESTHESIA

A Thesis
Presented in Partial Fulfillment of the Requirement for
the Master’s Degree in the
Graduate School of the Ohio State University

By
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*****

The Ohio State University
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Purpose: To compare three analgesic regimens for managing postoperative pain after dental restorative treatment under general anesthesia.

Methods: Prospective, randomized, double-blind study. Patients undergoing dental rehabilitation under general anesthesia were randomly assigned to one of three analgesia regimens: 1.0 mg/kg IV Toradol (ketorolac) alone, 1.0 mg/kg IV Toradol + 0.1 mg/kg IV morphine, or 1.0 mg/kg IV Toradol + 7mg/kg (max) 2% Lidocaine with 1:100,000 epinephrine local anesthetic infiltration. Postoperative pain was evaluated using standardized Faces-Legs-Arms-Consolability-Crying (FLACC) scale and the Wong-Baker FACES scale.

Results: Sixty-seven children were included in final data analysis. Upon pair-wise analysis, it was determined that the Toradol-Local Anesthetic group responded significantly better for the FLACC-discharge than the Toradol-Morphine group (p=.004). The Toradol-Morphine group performed significantly better for the 24 hour FACES score (p=.015) than the Toradol-Local Anesthetic group.

Conclusions: Postoperative regimen significantly impacted pain scores upon discharge and at twenty-four hour follow up.
ACKNOWLEDGMENTS

I would like to extend a special thanks to my advisor, Dr. Sarat Thikkurissy, for his endless support for this project, and encouragement over the past six years. Your mentorship has helped realize my goal of becoming a pediatric dentist, and the time you have given me will never be forgotten.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>ii</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>iii</td>
</tr>
<tr>
<td>Vita</td>
<td>v</td>
</tr>
<tr>
<td>List of Figures</td>
<td>vii</td>
</tr>
<tr>
<td>List of Tables</td>
<td>viii</td>
</tr>
<tr>
<td>Appendices</td>
<td>32</td>
</tr>
<tr>
<td>A. Postoperative Data Sheet</td>
<td>32</td>
</tr>
<tr>
<td>List of References</td>
<td>36</td>
</tr>
</tbody>
</table>

## Chapters:

1. Introduction---------------------------------------------1
2. Methods-------------------------------------------------14
3. Results-------------------------------------------------18
4. Discussion-----------------------------------------------23
5. Conclusion-----------------------------------------------31
## LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Wong-Baker FACES Scale</td>
<td>11</td>
</tr>
</tbody>
</table>
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>FLACC Pain Assessment Tool</td>
<td>12</td>
</tr>
<tr>
<td>3.1</td>
<td>Demographic Data of Study Cohort</td>
<td>18</td>
</tr>
<tr>
<td>3.2</td>
<td>Demographic Data by Study Regimen</td>
<td>19</td>
</tr>
<tr>
<td>3.3</td>
<td>Dental Treatment Specifics by Study Group</td>
<td>20</td>
</tr>
<tr>
<td>3.4</td>
<td>Mean FLACC and FACES Scores by Study Group</td>
<td>21</td>
</tr>
<tr>
<td>3.5</td>
<td>ANOVA Analysis</td>
<td>21</td>
</tr>
</tbody>
</table>
CHAPTER 1

INTRODUCTION

There has been an increase in the number of surgeries performed at outpatient surgical centers.\textsuperscript{1} While the exact number of dental procedures performed under general anesthesia is unknown, it is estimated that between 100,000 and 250,000 pediatric dental sedations (including both oral sedations and general anesthesia combined) are performed each year.\textsuperscript{2} Various authors have attributed this trend to changes in parental attitudes, improved access to operating rooms and dental surgery centers, and increased safety.

**Parental Acceptance of General Anesthesia for Dentistry**

A review of literature demonstrates that parental acceptance of general anesthesia as a behavior management technique has increased. In a study conducted in 1984, parents were asked to rank behavior management techniques as “least and most” acceptable. Techniques compared included: general anesthesia, papoose board, oral sedation, hand-over-mouth, active restraint, tell-show-do, and voice control. In this study, parents viewed the papoose board and general anesthesia as the least acceptable techniques.\textsuperscript{3} A similar study was conducted in 1991, with general anesthesia ranked least acceptable by parents.\textsuperscript{4} When a third study was conducted in 2005, general anesthesia
was viewed as the third most acceptable behavior management technique after tell-
show-do and nitrous oxide sedation. Recent publications also report high parental
satisfaction with outcomes of dental rehabilitation under general anesthesia. In 2001
survey of 223 cases measuring perceived outcomes and parental satisfaction following
rehabilitation under general anesthesia, parents reported overwhelming satisfaction with
outcomes and overall care. In a 2003 study, parents perceived an increased quality of
life for their children after undergoing dental rehabilitation under general anesthesia.

**Pediatric Pain Management**

As the number of pediatric outpatient surgeries is on the rise, there is increased
attention to the need to determine the most effective way to manage the postoperative
pain and side effects that can accompany treatment. However, there are only a limited
number of studies on managing postoperative pain in the pediatric population, and many
of the published studies undertaken reveal inadequate management of pain. We know
that one of the most common types of pain experienced in the child patient is acute pain
resulting from medically necessary procedures. Yet, it is well documented that acute
pain in children is often inadequately assessed and treated. A survey conducted in 1983
reported that 40% of pediatric surgical patients experienced moderate-severe
postoperative pain, and that 75% of those patients had insufficient analgesia. In 1985, a
study of 40 children undergoing major surgery found that 38% of the children received
sub-therapeutic doses of analgesics, and only two of the children received all of the pain
medication prescribed.
Studies that directly compare adult versus pediatric pain management prove especially revealing. In 1983, Beyer conducted a study comparing postoperative pain management in 50 children and 50 adults who had undergone cardiac surgery. Children received only 30% of all analgesics administered, and six of the 50 children did not receive any analgesic prescriptions.11

Barriers to treatment include the following: 1) the myth that children, especially infants, do not feel pain the way adults do, or if they do, there is no untoward consequence; 2) lack of assessment and reassessment for the presence of pain; 3) misunderstanding of how to conceptualize and quantify a subjective pain experience; 4) lack of knowledge of pain treatment; 5) the notion that addressing pain in children takes too much time and effort; and 6) fears of adverse effects of analgesic medications, including respiration depression and addiction.8

The myth that children do not feel pain the way adults do is especially intriguing given what we know about pediatric physiology. Structural components necessary to perceive pain are present at 25 weeks in utero,12 and pain pathways and cortical centers are well developed in late gestation.13 Opioid receptors are more widely distributed in newborns. Infants are able to mount a graded hormonal stress in response to surgical interventions. Adequate intra- and postoperative analgesia will modify this response, and has been shown to reduce morbidity and mortality.12
Though many of these barriers to pain management still persist, our understanding and management of postoperative pain in the pediatric population seems to be improving. In 1974, Eland conducted a study of 25 children after surgery, of which 16% had no prescription for pain medication after surgery. Another author replicated this study in 1994, with all subjects matched by age and type of surgery. In this second study, all of the children were prescribed and received pain medication.

The importance of recognition and management of procedure-related pain in the pediatric population is gaining increased attention. Yet overall, our knowledge of pain management in this population is lacking. There is a need for further evaluation of which analgesic regimens should be employed to best manage postoperative pain, particularly after dental rehabilitation.

**Pediatric Analgesia Regimens**

Postoperative pain management involves the use of different classes of drugs, alone or in combination. The AAP has specific recommendations on managing procedure-related and operative pain. Local anesthetics should be considered to minimize distress. Opioids can be used to manage moderate-severe postoperative pain. Acetaminophen and nonsteroidal anti-inflammatory agents in combination with opioids can reduce the amount of opioid required. To best employ a multi-modal approach, an understanding of various classes of analgesics is paramount.

Lidocaine is an amide local anesthetic, and is available in topical, intravenous and injectable form. Its mechanism of action is to block fast voltage-gated sodium channels in the cell membrane, preventing depolarization at the pre-synaptic neuron. This
effectively prevents the initiation and propagation of impulses, ultimately preventing pain transmission. Its main indication for injectable use is for minor dental procedures, and the most common formulation used is 2% lidocaine with 1:100,000 epinephrine. A survey of pediatric dentists revealed that 83% of responding dentists used lidocaine most often. An absolute contraindication to the use of local anesthetic is a documented local anesthetic allergy, although an allergy to an amide local anesthetic is extremely rare. Sodium metabisulfite is added to the solution to function as a preservative of epinephrine. In patients with allergies to bisulfites, the use of a local anesthetic without epinephrine is indicated. Adverse drug reactions are rare, and most are associated with improper administration technique or dosing. The manufacturer’s maximum recommended dosage for 2% lidocaine with 1:100,000 epinephrine is 7mg/kg (not to exceed 500 mg). In the pediatric population, it is rarely necessary to administer this amount of drug to obtain adequate anesthesia.

There is limited evidence to support the intra-operative use of local anesthetic infiltration for postoperative pain management for pediatric patients undergoing dental rehabilitation under general anesthesia. Most studies have failed to demonstrate a reduction in postoperative pain, and results are conflicting at best. In a study of pediatric patients (age 2-6) undergoing extractions, intraligamentary injections provided significantly lower pain scores, however, there was no significant difference between groups receiving local infiltration versus no local anesthetic. In another study comparing postoperative pain after extractions (age 2-5), pain scores following the intraligamentary injection were significantly lower at five minutes after return from recovery as compared to no local anesthesia. At fifteen minutes, however, there were no
significant differences between the two groups.\textsuperscript{19} A third study evaluating postoperative pain after dental extractions in the same age group (age 2-6), found no significant difference in postoperative pain between children who did or did not have local anesthetic infiltrations.\textsuperscript{20} This is consistent with a fourth study by Coulthard, in which the authors found no significant differences in pain scores between local anesthetic infiltration and placebo groups following exodontias in children age 4-12.\textsuperscript{21} It is of note that most of these studies are comparing the use of local anesthetics after extractions. Another consideration is the notion that intraoperative local anesthetic can offer benefits beyond analgesia. Surgical stimulation, such as an extraction, can cause increases in blood pressure and heart rate. In a patient with ASA I status, this may not be concerning. However, in patients with certain cardiac conditions or poor perfusion, maintaining vital signs in a steady state becomes more critical. In addition, stimulating procedures may necessitate an increased delivery of gases or IV drugs to maintain depth of anesthesia.

Ketorolac (Toradol) is a non-steroidal anti-inflammatory (NSAID) in the family of propionic acids. Ketorolac can be administered through oral, ophthalmic, intramuscular, and intravenous routes. Ketorolac exhibits anti-inflammatory, analgesic, and antipyretic effects. It acts by inhibiting the synthesis of prostaglandins through competitive and non-selective blocking of the enzyme cyclooxygenase (COX). It is indicated in the management of mild-moderate pain on a short-term basis, and is especially effective in managing acute pain after minor procedures.
Contraindications include hypersensitivity to ketorolac, aspirin or other NSAIDS, nasal polyps, angioedema, bronchospastic reactivity, and a history of peptic ulcer disease or gastrointestinal bleeding. Administration should be avoided in patients with renal dysfunction, particularly those patients with fluid imbalances. It should be noted that ketorolac reversibly inhibits platelet aggregation.

Morphine is a highly potent opiate analgesic, and is the gold standard against which all other opioids are tested. Morphine is an opioid receptor agonist, and its primary analgesic and sedative affects are due to strong and rapid binding to mu-opioid receptors distributed throughout the central nervous system. Morphine also exerts effects through binding or mu-opioid receptors in the gastrointestinal tract, and binds to kappa and gamma opioid receptors. Morphine is an effective analgesic used widely in hospital settings for the management of moderate to severe acute and chronic pain. It is used for epidural anesthesia, as an adjunct to general anesthesia, and as an anti-tussive and anti-diarrheal agent in chronic conditions. Morphine can cause respiratory depression therefore its use is contraindicated in patients with acute respiratory depression. Other contraindications include acute pancreatitis, renal failure, chemical toxicity, and raised intracranial pressure or head injury. It is also contraindicated in combination with alcohol, barbiturates and benzodiazepines, stimulants, MAO inhibitors, beta blockers, other opioids, hypnotics or sedatives. Morphine is highly physically and psychologically addictive and exhibits tolerance. Morphine can exhibit many unwanted side effects, more commonly nausea, vomiting, constipation, and itching.
Morphine is the most widely used analgesic for postoperative pain management in the pediatric population. In 2007, a systematic review was conducted to evaluate various pediatric postoperative pain regimens.22 Thirty-six randomized, double-blinded controlled clinical trials with forty-nine comparisons were examined. The study found that, overall, morphine did not provide superior analgesia, and had a higher incidence of side effects compared with active controls. Control drugs included ketorolac, tramadol, ketamine, methadone, meperidine, bupivacaine and lidocaine in various concentrations.

Surgical procedures examined in this review included adeno +/- tonsillectomy, orthopedic, abdominal, cardiac, and genitourinary surgeries. Only one of the included studies, conducted in 1996, examined various pain regimens after dental procedures. This study compared three different doses of IV ketorolac (0.75, 1.0, 1.5 mg/kg) with morphine (0.1 mg/kg) in pediatric dental surgical outpatients. This study found that ketorolac, in all doses, was as effective as morphine for managing postoperative pain associated with restorative dentistry.23

Many of the “non-dental” studies in this systematic review also evaluated analgesia and side effects of morphine as compared to ketorolac. In one study, IV ketorolac (0.75 mg/kg) was compared with IV morphine (0.1 mg/kg) + metoclopramide (0.15 mg/kg) for pediatric outpatient strabismus surgery. The authors found no difference in pain scores between groups, with less instances of postoperative vomiting in the ketorolac group.24 Another study evaluating postoperative pain after elective pediatric surgery yielded similar outcomes. In this study, there were no significant differences in pain scores or analgesic requirements after pediatric surgery, though patients receiving ketorolac (0.9 mg/kg) had less vomiting postoperatively than those
receiving morphine (0.1 mg/kg). \textsuperscript{25} In a study comparing IV ketorolac with morphine for postoperative pain in the pediatric population, analgesia with ketorolac (titration, 0.2 + 0.2 + 0.1 mg/kg) developed more slowly, but was sustained longer than morphine (titration, 0.1 mg/kg three successive doses). \textsuperscript{26}

A multimodal approach to pain management has been advocated. Proponents of combination regimens argue that drugs acting by different mechanisms will produce additive or synergistic results. NSAIDS act peripherally to reduce prostaglandin synthesis, while opioids act on centrally-located receptors within the CNS to attenuate pain signals. A perceived benefit of an opioid + non-opioid combination regimen would be production of an opioid-sparing effect. This can effectively reduce the occurrence of adverse affects that can accompany the administration of opioids.

Ketorolac has been co-administered with morphine without apparent adverse effects, and various studies have examined using ketorolac as an adjuvant to patient-controlled analgesia with morphine. In a study that evaluated the postoperative dosing requirements of patient-controlled analgesia with morphine, a single dose of IV ketorolac given intra-operatively (0.8 mg/kg) was opioid-sparing, produced fewer opioid-induced side effects, and demonstrated superior analgesia compared to the control group receiving patient-controlled analgesia with morphine alone. \textsuperscript{27} The same outcomes were realized in a study of postoperative pain after pediatric orthopedic surgery, where ketorolac (1 mg/kg) was given upon arrival in the PACU. \textsuperscript{28}
Patient-controlled analgesia is seldom used in the Post-Anesthesia Care Units (PACU) after dental rehabilitation under general anesthesia. While outcomes can be extrapolated and applied to evaluate post-operative analgesia, more research is needed to compare multimodal regimens that are used most often in same day surgery centers where dental rehabilitation is provided.

**Assessing Pain in the Pediatric Patient**

One barrier to adequate pain management is the lack of consensus and standardization in available research. There are conflicting reports in dental literature regarding the presence of pain. In a 1986 study, 37.6% of children ages 6 to 13 reported postoperative pain after dental extractions.\(^29\) In a 1992 study, 17% and 22% of children required postoperative analgesia following routine restorative dentistry and tooth extraction, respectively.\(^30\) In a 2007 study of 90 patients, 95% of the children undergoing dental rehabilitation under general anesthesia reported postoperative pain. Interestingly, only 72% of those patients were given analgesics by parents during the recovery period.\(^31\) These studies are often difficult to compare due to the use of different pain scales, variable statistics, different age groups, the number/types of procedure, duration of follow-up, sequelae evaluated, differences in intra-operative drug regimens, and differences in postoperative pain medications given by caregivers.\(^31\)

It is well understood that children feel pain, and its presence and severity needs to be adequately assessed by medical providers. The most reliable indicator of the presence and intensity of acute pain is self-reporting.\(^32\) However, challenges arise in a pediatric setting because children are often unable to verbalize pain adequately. It requires them to
communicate a subjective experience in a manner than can be quantified. A variety of measurement tools have been advocated. One measurement scale, the Wong-Baker FACES scale, was developed for the pediatric population (Figure 1.1). This self-report instrument is an example of a pain scale used by the Joint Commission for the Accreditation of Healthcare Organizations (JHACO). It is accepted as a common metric for measuring pain among children ages 2-7. Research has demonstrated validity and reliability for the faces scale as compared to five other pain assessment instruments.33

![Wong-Baker FACES scale](image)

Figure 1.1: Wong-Baker FACES scale.

It is a simple method to assess pain, and consists of six cartoon faces based on children’s perceptions of facial expression of no pain to worst pain. Children can understand this method, and it has been used in the evaluation of dental pain with success. In a cross sectional study of 601 school-aged children, the Wong Baker FACES scale was used to evaluate toothache severity. Severe pain was strongly associated with the presence of oral pathology, and the presence of reported high pain intensity was accompanied by high incidence of children who cried, were awakened by the pain, and were unable to carry out habitual tasks.34
Another method to measure pain in children is the FLACC (Face, Legs, Activity, Cry and Consolability) Pain Assessment Tool (Table 1.1). Each of the five categories is scored from 0-2, which results in a total score between zero and ten. Merkel et al conducted a study using the FLACC behavioral scale to score postoperative pain in young children undergoing a variety of surgical procedures. The FLACC scale demonstrated a high inter-rater reliability, and evidence of validity provided by a significant decrease in scores when analgesics were administrated.\textsuperscript{35} Manworren et al tested the validity of FLACC in preverbal patients. The authors measured changes in scores after administration of analgesics. Pre-analgesia FLACC scores were significantly higher than post-analgesia scores, and significantly higher for patients who received opioids than those who received non-opioid analgesics alone.\textsuperscript{36} FLACC has also been shown to have good validity and reliability in children with cognitive impairment.\textsuperscript{37}

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Face</td>
<td>No particular expression or smile</td>
</tr>
<tr>
<td>Legs</td>
<td>Normal position or relaxed</td>
</tr>
<tr>
<td>Activity</td>
<td>Lying quietly, normal position, moves easily</td>
</tr>
<tr>
<td>Cry</td>
<td>No cry (awake or asleep)</td>
</tr>
<tr>
<td>Consolability</td>
<td>Content, relaxed</td>
</tr>
</tbody>
</table>

Table 1.1: FLACC Pain Assessment Tool.
The FLACC behavioral scale was compared with the Wong-Baker FACES scale. In a study by Willis et al, the authors found significant correlations between the two scales for children ages 5-7, lending additional support for the validity of the FLACC Pain Assessment Tool.38

**Specific Aim**

“There is a need for more research to elucidate further the strategies for optimal pain management. Children deserve the benefit of research on the clinical efficacy and adverse effects of such medications”.8 The overall objective of this study was to investigate postoperative pain management in children undergoing general anesthesia for dental rehabilitation. The specific aim of this study was to compare the efficacy of three different drug regimens in controlling postoperative pain, evaluate their side effects, and assess the need for additional analgesics in the 24-hour postoperative period.
CHAPTER 2

METHODS

This was a prospective, randomized, double-blinded study. The study population included healthy children, age 18 months-8 years, with ASA I or II classifications. For those patients with ASA II classifications, the reason for this status was documented. Initial data collection included three asthmatics. However, due to potential interactions with drug regimens, patients with respiratory conditions (such as asthma) were excluded from the study after further consultation with the anesthesiologist. Subjects were free of any developmental delays or neurobehavioral conditions that could affect their ability to communicate. Because a follow-up interview was integral to this study, only patients/parents that had a telephone and were English-speaking were included.

The sample was drawn from patients scheduled for dental rehabilitation under general anesthesia in the Nationwide Children’s Hospital Dental Surgery Center. The typical patient profile included patients that could not tolerate dental treatment in an ambulatory setting due to behavior and/or scope of treatment. Each patient required a minimum of six involved primary teeth. At least two of the six teeth required some combination of pulpotomies, extractions, and/or crowns (including strip crowns, stainless steel crowns, or porcelain-veneered stainless steel crowns [PVSSCs]).
Prior to the treatment of their child, parents were informed of this IRB-approved study, and invited to participate. If parents declined participation, dental rehabilitation was completed as planned. If the child’s parents agreed to participate, written and verbal informed consent was obtained. Each subject meeting the study criteria was randomized into one of the three groups prior to the induction of anesthesia. Each group was given one of following three drug regimens:

1) 1.0 mg/kg IV Toradol (ketorolac) + 0.1 mg/kg IV Morphine Sulfate (morphine)
2) 1.0 mg/kg IV Toradol + 7.0 mg/kg (max) 2% Lidocaine (xylocaine) with 1:100,000 epinephrine local anesthetic infiltration
3) 1.0 mg/kg IV Toradol alone

The general anesthesia and dental rehabilitation proceeded as routinely performed in the Dental Surgery Center. The patient was intubated, and general anesthesia was induced using a combination of either: 1) nitrous oxide/oxygen + sevofluorane, or 2) oxygen + sevofluorane. Choice of induction agents was determined by the anesthesiologist’s training, and either regimen would not significantly effect the induction or outcomes of the study. Intravenous access was established, and routine monitoring continued throughout the case. The exact nature of dental rehabilitation was documented.
At 30 minutes prior to completion of the procedure, the analgesic drug or drug combination was given to the patient. As the patient woke from general anesthesia, they were transported to the Post Anesthesia Care Unit (PACU) immediately adjacent to the operating room. At that point, parents were invited to join the patient. Routine monitoring continued until the patient was ready for discharge. Typical recovery lasted between 20-30 minutes.

Once the patient was transported to the PACU, the post-operative pain was rated using two different rating scales. A designated, calibrated recovery nurse used the FLACC scale to rate the patient’s pain both post-operatively and immediately prior to discharge. Then, the recovery nurse instructed parents on the use of the Wong-Baker FACES pain scale. Immediately prior to discharge, parents were asked to use the Wong-Baker FACES scale to rate their child’s pain. The recovery nurse had been trained on these scales for use in a prior research project, and was blinded to the drug regimen.

A standardized telephone interview was conducted within 72 hours of discharge. Two interviewers were used throughout the study, and they were blinded to the drug regimen chosen. Parents were asked to rate their child’s pain during the 24-hour post operative period using the Wong-Baker FACES pain scale. They were asked whether their child experienced any nausea and/or vomiting, itching, cheek, tongue, and/or lip biting, or any other problems. They were asked if the child was given additional analgesics after discharge to ensure adequate pain management. Analgesic given, dose given (in teaspoons or milligrams), and date and time of dosage were noted. The parents were also asked they had to miss work to bring their child to the appointment, and/or care for their child postoperatively.
For all subjects, the answers to telephone interview questions, as well as the demographics, dental treatment rendered, drug regimen, and pain scores were recorded on a Postoperative Data Sheet (Appendix A).

A power analysis was completed using the data provided. Using an alpha of 0.05 and a power of 0.8, it was determined that a minimum of 67 subjects would be required to demonstrate statistical significance to either reject or not reject the null hypothesis. The predictor variables included the drug or drug combination, the number of teeth involved, and the patient’s age. The outcome variables included the FLACC pain score measured post-operatively and immediately prior to discharge, the FACES pain score taken immediately post-operatively and 24-hours post-operatively, analgesic requirement after discharge, nausea and vomiting, itching, and cheek, tongue, and/or lip biting. Variables were analyzed using multivariate analysis of variance (ANOVA) and Tukey-Kramer pair-wise analysis, for both inter-group and intra-group analysis.

Because the anesthesiologist and the dental operator were responsible for delivering required drugs, they were not blinded to the drug regimen. However, all participants involved in rating pain (parents and recovery nurse), or conducting follow-up phone interviews, were blinded to the drug regimen chosen. Four anesthesiologists participated in this study. Ten dental operators, all full-time faculty or residents at the graduate program in Pediatric Dentistry at Ohio State University/Nationwide Children’s Hospital, performed the dental rehabilitation. Operators were not calibrated, but have similar practice philosophies and training in performing dental rehabilitation.
CHAPTER 3

RESULTS

Demographics

A total of 67 patients qualified for and were enrolled in this study. The mean age of the entire cohort was 51 months (14.8). There were 38 males (56.7%) and 29 females (43.2%). The mean weight of the cohort was 17.7 kg (5.4). Sixty children (89.6%) were classified as Class I by the American Society of Anesthesiologists rating scale, with the remaining 10.4% being ASA II. The Ethnic data were collected on 45 of the 67 patients. Ethnic composition of the cohort was as follows; 32/71.1% Caucasian, 8/17.8% African American, 3/6.7% Hispanic, 1/2.2% Somali and 1/2.2% Asian. Demographic data of study cohort is presented in Table 3.1.

<table>
<thead>
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<th>Age (m)</th>
<th>Weight (kg)</th>
<th>ASA</th>
<th>Gender</th>
</tr>
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<tr>
<td></td>
<td>51</td>
<td>17.7</td>
<td>60-ASA I</td>
<td>38- male</td>
</tr>
<tr>
<td></td>
<td>14.8</td>
<td>5.4</td>
<td>7- ASA II</td>
<td>29- female</td>
</tr>
</tbody>
</table>

Table 3.1: Demographic data of study cohort.
When analyzed by study regimen, there was no significant difference in distribution by age, gender or ASA status. Demographic data by regimen is presented in Table 3.2.

<table>
<thead>
<tr>
<th></th>
<th>Age (m)</th>
<th>Weight (kg)</th>
<th>ASA</th>
<th>Gender</th>
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<td>52.85</td>
<td>18.56</td>
<td>23 - ASA I</td>
<td>10- male</td>
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<tr>
<td></td>
<td>13.82</td>
<td>6.62</td>
<td>3- ASA II</td>
<td>16- female</td>
</tr>
<tr>
<td>Toradol + Local Anesthetic</td>
<td>49.00</td>
<td>17.38</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>16.41</td>
<td>5.31</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Toradol Only</td>
<td>50.70</td>
<td>16.98</td>
<td>20</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>14.05</td>
<td>2.77</td>
<td>0</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 3.2: Demographic data by study regimen.

**Dental Procedures**

Duration of treatment was defined as “throat pack in to throat pack out” time, as recorded on the anesthesia records. Fourteen cases (20.9%) were less than one hour in duration. Thirty-four cases (50.7%) were one hour in length. Twelve cases 17.9% were between 1-2 hours, and 10.4% of cases (7) were two hours or greater in length. The duration of case was significantly associated with nausea (p=.03) and vomiting (p=.002), although there were only five incidences of these, collectively. It is of interest to note that two of the five incidences of nausea and/or vomiting occurred following discharge on the car ride home, and two of the patients experienced nausea and/or stomach pain the following day. The duration of the case was also significantly related to the number of teeth worked on (p=.04). The mean number of total teeth worked on for the entire cohort
was 11.4 (3.1), and the range was from 7-20 primary teeth. In our cohort, there were no permanent teeth that required treatment. Table 3.3 demonstrates the dental case specifics for each regimen.

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Duration of Case</th>
<th># Teeth</th>
<th>Pulps</th>
<th>SSCs</th>
<th>PVSSC</th>
<th>Strip crns</th>
<th>Exts</th>
<th>Res/Amal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toradol + Morphine</td>
<td>1.28</td>
<td>11.35</td>
<td>2.08</td>
<td>5.58</td>
<td>0.15</td>
<td>1.19</td>
<td>2.38</td>
<td>1.88</td>
</tr>
<tr>
<td></td>
<td>0.46</td>
<td>3.33</td>
<td>1.59</td>
<td>2.62</td>
<td>0.77</td>
<td>1.71</td>
<td>2.11</td>
<td>2.26</td>
</tr>
<tr>
<td>Toradol + Local Anesthetic</td>
<td>1.04</td>
<td>12.24</td>
<td>1.38</td>
<td>5.29</td>
<td>0.43</td>
<td>0.86</td>
<td>3.71</td>
<td>1.57</td>
</tr>
<tr>
<td></td>
<td>0.42</td>
<td>3.12</td>
<td>1.50</td>
<td>3.19</td>
<td>1.09</td>
<td>1.39</td>
<td>3.33</td>
<td>1.65</td>
</tr>
<tr>
<td>Toradol Only</td>
<td>1.03</td>
<td>10.65</td>
<td>1.35</td>
<td>5.10</td>
<td>0.75</td>
<td>0.85</td>
<td>1.60</td>
<td>1.55</td>
</tr>
<tr>
<td></td>
<td>0.48</td>
<td>2.29</td>
<td>1.53</td>
<td>1.73</td>
<td>1.44</td>
<td>1.56</td>
<td>2.58</td>
<td>1.12</td>
</tr>
</tbody>
</table>

Table 3.3: Dental Treatment specifics by study group.

**Relationship of treatment variables to pain scores**

Table 3.4 presents the mean FLACC and FACES scores by study group. The FLACC scores recorded were immediately upon awaking and at the time of discharge from the Surgery Center PACU. The FACES scores were noted the day of surgery (while child was still in the PACU) and at the follow-up phone call. The follow-up phone calls did not exceed 72 hours after surgery.
<table>
<thead>
<tr>
<th>Study Group</th>
<th>FLACC awake</th>
<th>FLACC discharge</th>
<th>FACES surgery</th>
<th>FACES 24 hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toradol + Morphine</td>
<td>2.00</td>
<td>1.15</td>
<td>2.38</td>
<td>1.19</td>
</tr>
<tr>
<td></td>
<td>2.94</td>
<td>2.01</td>
<td>3.37</td>
<td>2.08</td>
</tr>
<tr>
<td>Toradol + Local Anesthetic</td>
<td>1.43</td>
<td>0.38</td>
<td>2.67</td>
<td>1.62</td>
</tr>
<tr>
<td></td>
<td>2.22</td>
<td>0.79</td>
<td>3.23</td>
<td>2.80</td>
</tr>
<tr>
<td>Toradol Only</td>
<td>0.85</td>
<td>0.95</td>
<td>1.90</td>
<td>0.80</td>
</tr>
<tr>
<td></td>
<td>1.28</td>
<td>1.47</td>
<td>2.14</td>
<td>1.17</td>
</tr>
</tbody>
</table>

Table 3.4: Mean FLACC and FACES scores by study group

An Analysis of Variance was used to detect any relationship between scores and regimen. The ANOVA table is presented as Table 3.5.

<table>
<thead>
<tr>
<th></th>
<th>ss</th>
<th>df</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLACC-Awake</td>
<td>6.28</td>
<td>133</td>
<td>1.97</td>
<td>0.163</td>
</tr>
<tr>
<td>FLACC-Discharge</td>
<td>37.6</td>
<td>133</td>
<td>23.2</td>
<td>.004*</td>
</tr>
<tr>
<td>FACES-Day of Surgery</td>
<td>5.85</td>
<td>133</td>
<td>1.17</td>
<td>0.281</td>
</tr>
<tr>
<td>FACES- 24 hours post-op</td>
<td>16.5</td>
<td>133</td>
<td>6.1</td>
<td>.015*</td>
</tr>
</tbody>
</table>

Table 3.5: ANOVA analysis.

Upon pair-wise analysis, it was determined that the Toradol-Local Anesthetic group responded significantly better for the FLACC-discharge than the Toradol-Morphine group (p=.004). The Toradol-Morphine group performed significantly better for the 24 hour FACES score (p=.03) than the Toradol-Local Anesthetic group. There
were no other significant differences noted. It should be noted that of the three children (4.4% of total cohort) that reported lip biting, two were in the local anesthesia group, with the remaining one in the Toradol only group. There were no reported incidences of cheek or tongue biting.

**Relationship of Treatment Variables to Time in Post-Anesthesia Care Unit (PACU)**

Recovery time in the PACU was compared between the three drug regimens. All times (as measured from time in PACU until discharge time) were less than 30 minutes. The Toradol only group had the shortest time in the PACU at 23.7 minutes. The other groups averaged 28.5 minutes. Pair-wise analysis was used to compare drug regimens to time until discharge from the PACU. Time in PACU was significantly greater in the Toradol-Local Anesthetic group versus the Toradol only group.

**Associated Morbidity**

Of the 67 caregivers who were contacted, 64 responded to a question as to whether they missed work beyond what they anticipated (i.e., day of surgery) as a result of their child’s treatment. The majority of parents (47/73.4%) missed no work beyond what they had anticipated. Eleven caregivers (17.2%) missed one additional day of work, and 6 (9.4%) missed two additional days of work as a result of their child’s treatment. There was no significant relationship between parents missed time of work and ASA status of child (p=.41), or total number of teeth treated (p=.15).
CHAPTER 4

DISCUSSION

The overall objective of this study was to investigate postoperative pain management in children undergoing general anesthesia for dental rehabilitation. The specific aim of this study was to compare the efficacy of three different drug regimens in controlling postoperative pain, evaluate their side effects, and assess the need for additional analgesics in the 24-hour postoperative period.

**Postoperative Pain & Analgesics**

At some point during their recovery, 41 of the 67 patients (62%) experienced postoperative pain as reported by their parents. 32 of the patients (48%) reported pain upon awakening from surgery. 23 of the (34%) patients reported pain on the day following surgery. 14 of the patients (21%) reported pain both immediately postoperatively, and on the following day. 62% is lower than the 95% prevalence rate reported in a recent study evaluating postoperative pain after general anesthesia.\(^{31}\) However, reports of postoperative pain after dental rehabilitation vary widely in the literature. In one study of 98 children undergoing dental rehabilitation, the authors reported that none of their subjects experienced postoperative pain.\(^{39}\)
Parents were asked if their children received additional analgesics after leaving the Post-Operative Care Unit (PACU). The drug, dose, and time(s) of administration were recorded. Forty-three of the 67 patients (64%) were given postoperative analgesics by their parents. Of those patients who received analgesics, twenty-three took acetaminophen only, nineteen took ibuprofen only, no patients took “other medication(s)”, and one patient took both acetaminophen and ibuprofen. Unless requested, parents were not given instructions on which over-the-counter pain medications to select. It is interesting to note that the majority of parents chose to give acetaminophen rather than ibuprofen. Acetaminophen has anti-pyretic and analgesic properties, but lacks the anti-inflammatory benefits that an NSAID can provide for alleviation of acute pain. There was also a wide variation on dosing. The majority of parents stated that they followed the directions on the bottle for to determine amount of medication to dispense, and it was not within the scope of this study to determine if the doses given were appropriate for age and/or weight. However, date and time of administration was tracked in this study. It appears from the results that parents were dispensing medications on an as-needed basis, rather than dosing at regular intervals. In young children, it is recommended that analgesics should not be given on an as-needed basis when postoperative pain is anticipated because of the difficulty in reporting pain. The American Academy of Pediatrics recommends that when moderate to severe pain is expected to persist, dosing at fixed intervals is recommended, and rarely would an as-needed regimen be indicated.
It is interesting to note that the patients who experienced pain did not necessarily correlate to the patients who received postoperative analgesics from their parents. Forty-one patients reported pain at some point in their recovery, and forty-three patients received pain medication. Seven patients who received analgesics had no reports of pain. However, the pain medications may have prevented the onset of pain. Five of the patients who reported pain were not given analgesics by their parents, and there was a variation in the severity of pain experienced. Immediately after the surgery, one patient was given a Wong-Baker pain scale rating of 8/10, another was given a rating of 4/10, and the remaining three had ratings of 0/10. All five of these parents reported a rating of 2/10 on the Wong-Baker FACES pain scale on the day following surgery. Parents were not questioned as to why they did or did not provide analgesics. In a study evaluating the incidence of postoperative pain and use of analgesia in children, 17% of children undergoing restorative treatment, and 22% of children requiring extraction(s) required postoperative analgesia.  

Postoperative Sequelae

Five of the 67 patients experienced either nausea and/or vomiting. Specifically, three of the patients vomited, and two of the patients reported nausea or stomach pain without any vomiting. Two of those patients experiencing nausea/vomiting on the car ride home, another experienced nausea at home on the day of surgery, and two patients reported stomach pain on the day following surgery. It is estimated that postoperative nausea and vomiting occurs in 20-30% of all patients undergoing general anesthesia, and may also occur within 24 hours of an uneventful discharge. The etiology is multi-
factorial, but commonly recognized factors include inhalational agents, the use of opioids, and postoperative pain. In our study, the use of anesthetic agents did not vary significantly, but nausea and vomiting was significantly associated with the duration of case. Opioids are commonly associated with increased nausea and vomiting. Morphine constricts the distal sphincter of the stomach, causing decreased gastric emptying, and increased incidence of nausea and vomiting. In this study cohort, four of the five patients that experienced postoperative nausea and/or vomiting were in the Toradol + morphine group, therefore received an opioid analgesic prior to discharge. The fifth patient was in the Toradol only group. This patient reported that his “belly hurt”, and he had a headache. It would be interesting to compare a morphine only to a morphine + Toradol group. There were no groups in our study that received morphine only, so we may have witnessed less nausea and vomiting than expected due to an opioid-sparing effect of a combined regimen.

Of the three children (4.4% of total cohort) that reported lip biting, two were in the local anesthesia group, with the remaining one in the Toradol only group. This is similar to a study involving 142 pediatric patients undergoing extractions. In this study, four of the patients with reported lip/cheek biting were in a group that was given local anesthetic intra-operatively, and one patient was in a placebo group. Many of the studies evaluating pain management after the intra-operative use of local anesthetic did not report on the incidence of cheek, lip, or tongue biting as post-operative sequelae, so it is difficult to compare the results of this study to those studies completed previously.
Patients were also asked at the follow-up interview if their child experienced any itching following treatment. This question was included in our follow-up survey due because pruritis is a reported side effect of opioids. It is estimated that up to 13% of patients receiving IV opioids experience pruritis post-operatively, and it is likely that there is significant under-reporting. Proposed mechanisms include histamine release from mast cells, or a direct central effect via opioid receptor binding. The second mechanism is supported by the observation that opioid antagonists have been able to reverse pruritis. Only one patient in the study cohort experienced any itching postoperatively. This patient experienced itching on arms and legs that began 24-hours postoperatively, and resolved with hydroxyzine taken every six hours as directed by her pediatrician. Interestingly, this patient was in the study group that received Toradol (ketorolac) + local anesthetic, and did not receive any opioids.

**Time in Post-Anesthesia Care Unit (PACU)**

It is interesting to note that patients who received local anesthetic had discharge time prolonged by an average of five minutes. This was statistically significant when comparing Toradol-Local Anesthetic group to Toradol only group, but may not be of clinical significance. If patients were more comfortable, they have spent more time sleeping in the PACU, until being awakened from stimulation, demonstrated alertness, and then subsequently discharged. It would be interested to evaluate this in a future study, especially because some clinicians argue that giving local anesthesia to a child may cause agitation upon awakening from general anesthesia.
The Toradol-morphine group did not vary significantly from the other two regimens. This finding may be clinically relevant, as some anesthesiologist argue against giving opioid pain medication for fear of prolonged discharge time. In our study, this was not the case.

Methods of Pain Assessment

The 2-8 year old age range meant that the vast majority patients had twenty primary teeth, and in this study, none of the permanent required dental treatment. The intention of the study design was to select for patients that would be undergoing dental procedures of comparable invasiveness. For this reason, a minimum of six involved teeth with at least two of the teeth needing pulpotomies, crowns, and/or extractions was required.

Research shows that the most reliable indicator of reporting pain is self-reporting. Due to the agitation children can experience upon emergence from general anesthesia, it would have been difficult to request self-reports of pain under the circumstances. Instead, parents were asked to assess pain. Because the dental rehabilitation is provided on an outpatient basis, the 24-hour post-operative pain rating was again provided by the parents the following day. For this reason, we adopted a simpler method, the Wong-Baker FACES scale, for the parents/guardians to utilize.
The recovery nurse rated the patient’s pain using the FLACC scale. The nurse was trained on this scale for use in prior research projects, and uses it routinely in the Post-Anesthesia Care Unit (PACU) prior to discharging patients. By using only one recovery nurse to assess immediate post-procedure pain, standardized data collection and rater reliability was assured.

The FLACC scale is a behavioral scale used for rating postoperative pain, and is useful in a preverbal, pediatric population. It provides a simple, consistent method for providers to quantify pain for clinical and research purposes, and is a reliable tool for evaluating changes in pain in response to administration of analgesics. It provides a more sensitive rating system than the Wong-Baker FACES pain scale, yet both scales have good correlation.

**Calibration**

One aim of the study was to include enough subjects to achieve statistical significance. In order to collect as much data as possible, ten dentists and four anesthesiologists participated in this project. All the dentists were either full time faculty or dental residents at the Nationwide Children’s Hospital Dental Surgery Center. Due to similar training and treatment philosophies, the dental operators would have treatment planned and performed procedures in a similar manner, and would not have affected the outcomes of this study to a significant degree.

Because the drug regimens for pain management were standardized, using different anesthesiologists should not have affected the outcome of the study. The four anesthesiologists used a similar induction method and the same inhalational gases as
discussed previously. The depth of anesthesia was understood to be similar between anesthesiologists based on recovery and turn around time in the PACU. Of particular concern was the possibility of increased nausea and vomiting as a result of general anesthetic gases rather than any opioids used. Nausea \(p=.03\) and vomiting \(p=.002\) was significantly associated with duration of anesthesia, and this could be attributed to the hangover effect. Both general anesthesia and opioids can cause nausea and vomiting.

Sixty-two of the follow-up telephone interviews were conducted by the study coordinator, and the remaining five were conducted by a research assistant. The research assistant was utilized only when the study coordinator worked as the dental operator. In those instances, it was necessary to involve the research assistant for the phone interview since the study coordinator/operator would not have been blinded to the drug regimen used.

**Randomization**

On a handful of occasions, the dental operator and/or anesthesiologists removed subjects from study that were not selected for the Toradol/Local Anesthetic Group. Some providers expressed the opinion that the patients treatment planned for a large number of extractions would have less postoperative pain and/or decreased likelihood of tachycardia if they were given local anesthesia just prior to extractions. Exclusion from group was based on qualified opinion, not quantified criteria (i.e. more than four extractions), and cast some doubt on true randomization.
CHAPTER 5

CONCLUSIONS

In conclusion, the outcomes of this study reveal significantly better FLACC score upon discharge in the Toradol-local anesthetic group, and significantly better FACES score @ 24 hours post-op in the Toradol-morphine group. It would have been interesting to evaluate a fourth group with a drug regimen of Toradol + local anesthetic + morphine.

The intent of this study was to provide clinicians with some evidence when deciding what drug regimen to use for the management of postoperative pain. Much of the existing literature discusses the use of different drug regimens after patients who have undergone extractions. However, many pediatric dental patients are undergoing general anesthesia for restorative rehabilitation, which may or may not include extractions. In addition, there is limited data in published literature comparing multimodal drug regimens after dental treatment. In this study, lower postoperative pain scores were observed when multimodal pain regimens were employed.
APPENDIX A

POSTOPERATIVE DATA SHEET
POSTOPERATIVE DATA SHEET

Demographics

Age ____ y _____ mo

Weight (kg) _______

Child systemic health ASA I / ASA II

If ASA II, list reason: _________________

Gender (circle one):  male    female

Race (circle one):  Caucasian  AA  Hispanic  Somali  Asian  Other ____________

Duration of case in hours (circle one):      ½ hour      1         1 ½        2          2 ½         3

Total number of PRIMARY teeth involved: __________

Please list procedures in chart below:

<table>
<thead>
<tr>
<th>Max arch</th>
<th>Pulp</th>
<th>SSCs/Kinders</th>
<th>Ext</th>
<th>Res/Amal</th>
<th>Man arch</th>
<th>Pulp</th>
<th>SSCs/Kinders</th>
<th>Ext</th>
<th>Res/Amal</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>K</td>
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<td></td>
<td></td>
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<td>Category</td>
<td>Scoring</td>
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<td>0</td>
<td>1</td>
<td>2</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face</td>
<td>No particular expression or smile</td>
<td>Occasional grimace or frown, withdrawn, disinterested</td>
<td>Frequent to constant quivering chin, clenched jaw</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legs</td>
<td>Normal position or relaxed</td>
<td>Uneasy, restless, tense</td>
<td>Kicking, or legs drawn up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>Lying quietly, normal position, moves easily</td>
<td>Squirming, shifting back and forth, tense</td>
<td>Arched, rigid or jerking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cry</td>
<td>No cry (awake or asleep)</td>
<td>Moans or whimpers; occasional complaint</td>
<td>Crying steadily, screams or sobs, frequent complaints</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consolability</td>
<td>Content, relaxed</td>
<td>Reassured by occasional touching, hugging or being talked to, distractible</td>
<td>Difficult to console or comfort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FLACC scale. Each of the five categories (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between zero and ten.

FLACC Score: __________

Wong-Baker FACES scale.
Immediately After Surgery:_______  Day After Surgery:_______

Analgesics required? (circle)  Yes or No

If yes, please write the name of the drug, the dosage, date/time. Please include every time an analgesic was given:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage</th>
<th>Date/time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Any nausea or vomiting? (circle)  Yes or No

Any itching? (circle)  none  nose  lip  other  _______________

Any lip biting? (circle)  Yes or No

Any cheek biting? (circle)  Yes or No

Any tongue biting? (circle)  Yes or No

Any other problems? (circle)  Yes or No

If yes, please describe:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
LIST OF REFERENCES


