

Research Article

Adult post-tonsillectomy pain management: Opioid versus non-opioid drug comparisons

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Abstract

Objective: The primary purpose of this retrospective study was to determine if a non-steroidal anti-inflammatory drug (diclofenac sodium) plus acetaminophen was as effective as alternative opioid drug regimens, +/- ibuprofen and acetaminophen, for pain management in adults following tonsillectomy.

Study design: Retrospective study.

Setting: 4 hospitals in Michigan associated with the Detroit Medical Center.

Subjects and methods: Medical records of adult tonsillectomy patients (age 18 to 50 Years) were reviewed. The incidences of unscheduled post-operative visits to either the ER or ENT clinic for uncontrolled throat pain and/or postoperative bleeding complications were reviewed.

Results: Of the 372 different patient charts reviewed for possible inclusion in this investigation, 302 individuals met the criteria for participation. These charts were divided into 3 post-operative treatment groups: 1. opioid medication plus acetaminophen for 10 days, 2. opioid medication for first 3 days, plus acetaminophen and ibuprofen regimens for next 7 days, or 3. diclofenac sodium for first 5 days plus acetaminophen for 10 days. Groups 1, 2, and 3 were composed of 217, 40 and 45 subjects, respectively. The overall frequency of ER visits for pain, ENT clinic visits for pain, and ER visits for bleeding complications across subjects from all 3 treatment groups was 47 (15.6%), 41 (13.6%), and 25 (8.3%), respectively. These findings suggested that there was a significant difference in ER visits across the intervention groups. Specifically, subjects in treatment Group 1 (opioids plus acetaminophen) were 4.7 times more likely to have an ER visit ($B = 1.55$, $p = 0.037$) than subjects in Group 2 (opioids plus ibuprofen/acetaminophen) and Group 3 (diclofenac sodium plus acetaminophen). Analyses did not demonstrate a significant difference in bleeding complications ($\chi^2 = 4.26$, $p = 0.119$) or ENT clinic visits for adjunctive pain medications across the 3 intervention groups ($\chi^2 = 4.26$, $p = 0.119$).

Conclusions: Results of this preliminary investigation support the administration of acetaminophen 500mg for 10 days with diclofenac sodium (NSAID) 50mg for 5 days for reliable and safe pain control in the post-tonsillectomy time frame, without significant concerns for complications like excessive bleeding or unscheduled ER or ENT clinic visits during the recovery period.

Use of opium for pain control dates back to ancient times. When consumed, this narcotic drug enters the bloodstream and quickly attaches to proteins called opioid receptors on nerve cells in the brain, spinal cord, and other parts of the body. This process blocks pain sensations from the body, in part by stimulating the release of dopamine within the brain. Although very effective as pain suppressors, opioid drugs can be highly addictive, especially if they are used over a long period of time. They often have the undesired effect of convincing the brain that for contented survival higher and higher doses are needed daily. This evolutionary dependency is classically defined as an addiction.

Presently, over 2 million Americans are addicted to opioids (NIDA report), and nearly 100 people die from overdoses every day in this country [1,2]. Within the last two decades, nearly one million people in the United States have died from opioid drug overdoses. Of these deaths, nearly 75% involved the use of prescription drugs, which originally had been obtained legally [3]. Because of these statistics, government officials and ordinary citizens have become increasingly concerned about the prevalence of opioid prescriptions by well-intentioned physicians and the potentially very harmful toll of these drugs on many unsuspecting patients. Notwithstanding



these alarming data, in 2015 it was reported that within the United States otolaryngologists alone wrote 134,000 opioid prescriptions for many different clinical populations [4].

Tonsillectomy and adeno-tonsillectomy are very common surgical procedures in children, but by comparison are much less common in adults. It has been well documented that ineffective pain management following tonsillectomy may result in patient discomfort and irritability, dehydration due to odynophagia, nausea, excessive bleeding, emergency room visits, and hospital re-admissions [5-7]. For adult patients, pain management is particularly challenging because they often take longer to heal than children, and as a result they not infrequently request pain medication for relief. Historically, to combat this comparatively protracted course of recovery in adults, which may last for as many as 2 to 3 weeks, treating surgeons and primary care physicians often prescribe one or more high-dose oral opioid pain medications such as hydrocodone & acetaminophen, oxycodone & acetaminophen, or hydromorphone & acetaminophen [8]. Because there are safe and effective non-addicting alternatives for pain management, such as steroidal (eg., dexamethasone) and non-steroidal anti-inflammatory drugs (NSAIDs), over the past few years at our institution we have begun to discontinue routine prescriptions of opioid drugs for many of our post-tonsillectomy patients. Instead, to regulate their pain we often administer an over the counter analgesic such as acetaminophen plus a prescription-strength NSAID medication.

The primary objective of this study was to perform a comparative analysis of our existing clinical data-base, wherein adult patients in the distant past who were routinely prescribed alternative dose regimens of opioid medication, +/-ibuprofen and/or acetaminophen, were compared with their surgery counterparts who instead were prescribed a regimen of non-opioid analgesic and NSAID medications for pain management following tonsillectomy. For the purposes of this investigation, we determined that poor post-operative pain control for any given patient would be behaviorally defined as an unexpected or unscheduled visit to the ER or ENT clinic to request additional pain medication.

Our primary null hypothesis was that following tonsillectomy use of analgesic and NSAID medications does not result in equally effective pain control when compared to use of opioid and analgesic medications. We secondarily examined whether within the first two-weeks post-operatively those patients in the opioid-based treatment groups experienced fewer bleeding complications than their study counterparts treated with non-opioid medications.

Methods

A retrospective research methodology was employed for this investigation. In-patient and out-patient medical charts from 4 hospitals of the Detroit Medical Center were examined in detail to identify adults who had undergone either a tonsillectomy or adeno-tonsillectomy procedure between the periods of January 2013 and July 2019.

Key variables of interest

Chart analyses of these individuals focused on several key variables including 1) sex, 2) age, 3) date of surgery, 4) pre-operative history of chronic tonsil infections, 5) pre-operative history of upper airway obstruction with related sleep apnea, 6) pre-operative history of tonsil malignancy, 7) pre-operative history of chronic pain complaints, 8) pre-operative history of repetitive use of pain medications, 9) history of post-operative bleeding complications, 10) history of post-operative Emergency Room visits for pain management, and 11) history of post-operative ENT clinic visits for pain management.

Power and IRB approval factors

We aimed to review thoroughly at least 250 subjects in accordance with our pre-investigation power analysis requirement. The charts of more than 300 subjects were ultimately examined. The study was authorized by our affiliated Wayne State University IRB as well as the Ethics committees of the 4 hospitals from which all charts were reviewed.

Criteria for Subject Participation

Inclusion criteria were as follows: 1) age 18 years or older, 2) pre-operative history of chronic benign tonsillar infections or hypertrophy with sleep apnea and other upper airway obstruction symptoms, and 3) tonsillectomy or adeno-tonsillectomy within the aforementioned 6 year time frame, wherein the surgical technique of monopolar electrocautery for coagulation was used. Exclusion criteria included 1) under 18 years of age, 2) tonsillar cancer, 3) history of pre-operative chronic pain syndrome (eg., fibromyalgia), 4) pre-operative history of opioid drug abuse, and 5) long-standing and regular pre-operative use of NSAID and/or analgesic medications, regardless of the causally-related medical conditions.

Judges

Three otolaryngologists served as chart reviewers. To conceal the identity of subjects, identification numbers were assigned before the judges reviewed the charts. All such reviews were conducted independently by these individuals without access to each other's key variable chart extraction data. One reviewer served as the primary judge; he reviewed the charts of all eligible subjects. Each of the other two reviewers only reviewed 40 charts, each one selected randomly from the overall eligible study population pool.

Rater reliability measures

For the purpose of intra-rater reliability measures, all three judges re-reviewed (two weeks later) 50% of the charts they originally analyzed for comparative analyses with their original findings; 100% agreement with themselves on all original and subsequent chart data extractions was required for this reliability measure. Discrepancies were resolved by multiple re-reviews to ensure complete accuracy of all chart extractions. Additionally, findings from the two secondary reviewers were compared with the primary reviewer's results for the purpose of inter-rater reliability measurement; 100% agreement with



each other on all extractions of the key chart variables was required for inter-rater reliability. When discrepancies occurred in the data extractions all three judges re-reviewed the charts in question to resolve the differences between them without objection. We concluded in advance that if 100% agreements on these intra-rater and inter-rater reliability measurement outcomes were obtained upon completion of all chart reviews, we would use the data gathered by the primary reviewer to represent fully and reliably the results of this investigation.

Surgical procedures

In each case a supine position on the operating room table was established and general anesthesia was administered. After the subject was draped a shoulder roll was placed under the shoulder for neck extension, the mouth was then opened with a McIvor mouth gag and attached to a Mayo stand for oral access. Red rubber catheters were inserted into the nostrils to elevate the soft palate for adenoid visualization and removal if necessary. The tonsils were grasped using an Allis clamp. They were dissected out along their capsule using standard monopolar cautery techniques at a setting of 15. Hemostasis was achieved with a suction Bovie at a coagulation setting of 20. When adenoids were also removed the suction Bovie setting was 30. At completion of these procedures a 2 minute period was begun during which the mouth gag was let down from the Mayo stand. Re-suspension of the gag was conducted 2 minutes later for visual and manual inspection of the surgical sites for bleeding and any additional necessary cauterization. After stomach contents were suctioned the subject was unsuspended and awakened gradually by the anesthesiologist.

Post-surgical instructions

Prior to surgery each subject was instructed and agreed to cease all smoking behavior and alcoholic beverage consumption for at least 10 days post-operatively. Instructions were also given regarding a 10 day post-operative convalescence period, during which each subject agreed not to attend work or school and not to engage in any form of strenuous physical activity. A mechanically soft food diet was recommended; hot foods and beverages were strongly discouraged during the convalescence period. The importance of staying well-hydrated and nourished was emphasized to the subjects at discharge from hospital. After this rest time frame, subjects were allowed to return to their normal lifestyle routines if they felt able to do so. A follow-up clinic appointment was provided for 10 days to 2 weeks post-operatively.

Medication regimens

All subjects consented to their required surgery procedure. The plan in each case was for discharge home the same day of surgery. Virtually every subject was prescribed routine post-operative antibiotics. In all subjects intraoperative dexamethasone (10mg to 20 mg) was used. Post-operative prescribed medication regimens varied across the pool of subjects and were taken according to the following daily schedule:

Group 1) acetaminophen/codeine or hydrocodone/acetaminophen (5.0/325, 7.5/325, or 10.0/325mg), Q6 hourly for 7 to 10 days, or Group 2) hydrocodone/acetaminophen (5.0/325, 7.5/325, or 10.0/325mg), Q6 hourly for first 3 days only, followed by ibuprofen (600 mg), t.i.d. and intermittent acetaminophen (500mg) Q6 hourly for the next 7 days, or Group 3) acetaminophen (500mg), Q6 hourly for the first 10 days, plus diclofenac sodium (50mg) b.i.d. for the first 5 days.

The primary endpoint of the investigation was to establish overall whether those subjects who used one or the other of these two opioid medication regimens (Groups 1 & 2) experienced less pain complaints in the first 10 days post-operatively than their study counterparts who used the third non-opioid medication regimen for pain management (Group 3). Secondary endpoints of the investigation included whether the former groups of subjects (i.e., opioid drug users) had a) fewer bleeding complications, b) fewer unexpected ER visits, and c) fewer unscheduled ENT clinic visits in the first 10 days post-operatively than those individuals in the latter group of subjects (i.e., non-opioid drug users).

Data management

Significance of the data gathered was examined using Chi Square, One-Way ANOVA, and Logistic Regression statistical measures for comparative analysis of the study groups, relative to the previously defined primary and secondary endpoints, and whether the Null Hypothesis described at the end of the Introduction section was either rejected or accepted.

Results

The purpose of this retrospective study was to determine if acetaminophen and diclofenac sodium (Group 3) in combination are equally effective (or better) for adult post-tonsillectomy pain management when compared to one or both previously described alternative opioid pain medication regimens. The dependent variable was defined as a visit either to the ER or ENT clinic within the first 2 weeks post-operatively for additional medication because of perceived uncontrolled throat pain, notwithstanding the drug regimen prescribed at discharge. The independent variables were the three aforementioned medication treatment group regimens; two covariates (gender and age) were also analyzed for effect.

After controlling for and including the two covariates, the statistical hypotheses were that the odds ratio for the non-opioid treatment group (#3) would be greater than or equal to the odds ratios of either or both of the two opioid treatment groups (#s 1 & 2). This would be interpreted as one group being more or less likely than the others to predict throat pain complaints that resulted in unexpected ER and/or ENT clinic visits. We initially identified 365 potentially eligible study participants. Of these, only 302 remained in the final data set due to the previously defined exclusion criteria. Figure 1 illustrates that there were 53 male and 249 female subjects, with an age range of 18 to 50 years (mean=27.1; SD=8.3). Figure 2 demonstrates that Group #1 (opioids plus acetaminophen drug regimen) consisted of 217 subjects. Group #2 (lower dose opioids plus ibuprofen/

acetaminophen) consisted of 40 subjects. Group #3 (diclofenac sodium plus acetaminophen) consisted of 45 subjects. Approximately 75% of the subjects in the opioid treatment groups (1& 2) were prescribed hydrocodone/acetaminophen 7.5/325 mg for post-tonsillectomy pain management.

To address the study hypotheses and to incorporate the covariates the statistical analysis measures of Chi-Square, One-way ANOVAs, and multiple logistic regression were employed by our biostatistician. After controlling for and including the two covariates, the statistical hypotheses were that the odds ratio for the non-opioid treatment group (#3) would be greater than or equal to the odds ratios of either or both of the two opioid treatment groups (#s 1 & 2). This would be interpreted as one group being more or less likely than the others to predict throat pain complaints that resulted in unexpected ER and/or ENT clinic visits.

Figures 3-5 illustrate the total number of post-operative bleeding complications and unscheduled ER and ENT clinic visits for the entire study population, respectively. Figure 6 shows more explicitly the differences in the number of ER visits for uncontrolled throat pain between the three drug treatment groups. Summarily, the overall frequency of ER visits for pain, ENT clinic visits for pain, and ER visits for bleeding complications across the entire study population was 47 (15.6%), 41 (13.6%), and 25 (8.3%), respectively. Below we address the statistical significance of these raw data.

A Chi-Square analysis was performed to determine whether males and females were represented across all 3 treatment groups proportionally to their numbers in the total sample. This measure produced a non-significant value ($X^2=.746, p=.689$), indicating that neither males nor females were over-represented in any of the 3 treatment group categories. Chi-square analyses

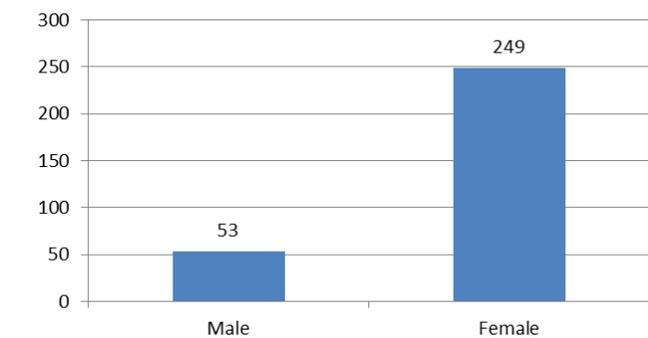


Figure 1: Gender ratio(302).

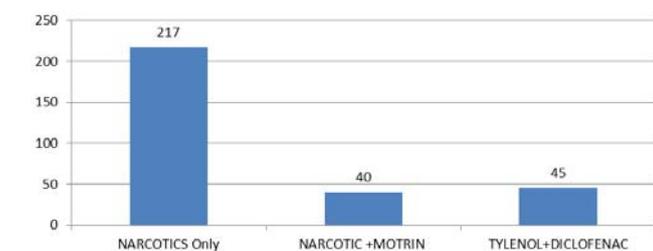


Figure 2: Intervention group(302).

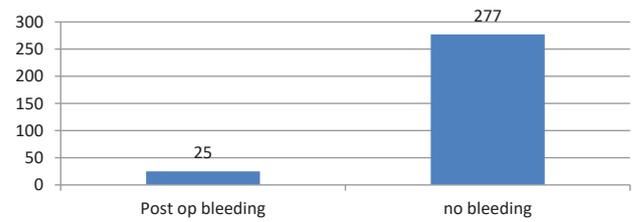


Figure 3: ER Visit for pain(302).

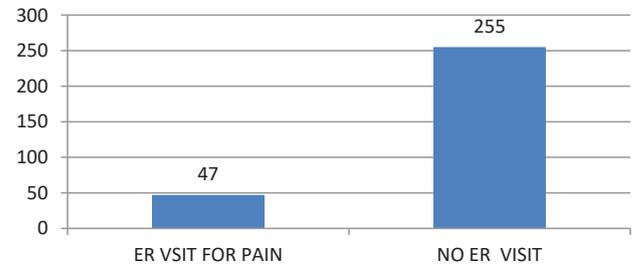


Figure 4: ENT clinic visit for pain(302).

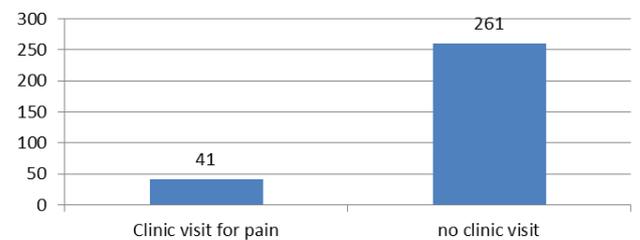


Figure 5: ENT clinic visit for pain(302)

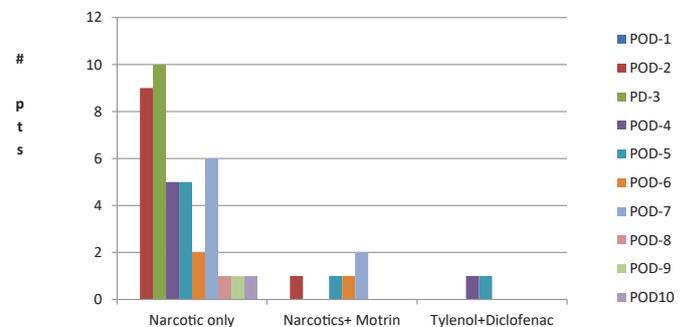


Figure 6: ER visits for uncontrolled post-tonsillectomy pain across all 3 treatment groups. Pts= patients POD= Post-Op Day.

were next conducted to determine whether males and females in the entire study population significantly differed in the number of post-operative bleeding complications, unscheduled ER visits, and/or unscheduled ENT clinic visits. The distribution of the data set produced non-significant Chi Square values for bleeding complications ($X^2= 2.057, p=.151$), ER visits ($X^2=2.451, p=.117$), or ENT clinic visits ($X^2=1.99, p=.158$), indicating that gender was not a factor relative to these categorical dependent variables. Because age is not a binary factor, one-way ANOVAs were performed to determine whether age of the subjects in each of the 3 treatment groups was a significant factor relative to the number of 1) bleeding complications, 2) unscheduled ER visits, and/or 3) unscheduled ENT clinic visits. Results revealed



no significant differences in any of these 3 dependent variables, respectively ($F= 2.34, p=.127$; $F=.036, p=.850$; $F=2.17, p=.147$) across the 3 treatment groups.

Next, Chi-Square analyses were performed to determine whether there were significant relationships between the 3 intervention groups and the aforementioned 3 dependent variables (bleeding complications, unscheduled ER visits, and unscheduled ENT clinic visits). Results revealed no relationships between 1) bleeding and intervention group ($X^2=4.55, p=.103$), 2) ER visits and intervention group ($X^2= 5.87, p=.053$), or 3) ENT clinic visits and intervention group ($X^2=4.55, p=.103$).

Because of the marginally significant value for the above mentioned second categorical variable (ER visits), a logistic regression analysis was conducted. This statistical measure can be used when the dependent target variable (eg., an unscheduled ER visit) is binary (ie., occurred [1] or not [0]) and there is a desire to establish or predict the probability of observing this variable in the presence of a nominal measurement variable (eg., a specific drug). As such, a logistic regression was performed to predict the occurrence of an unscheduled ER visit. The covariates of age and gender were entered along with two dummy coded variables. Results revealed a significant change in the probabilistic statistical model following entry of the dummy code variables ($X^2= 6.97, p= 0.031$), which explained the addition 4% of the variance. This finding suggested that there was a significant difference in ER visits across the intervention groups. Specifically, subjects in treatment Group #1 were 4.7 times more likely to have an ER visit ($B= 1.55, p= 0.037$) than subjects in the other two treatment groups. Conversely, no significant difference in the presence of an ER visit ($B= 1.07, p= 0.221$) was determined when subjects in the low dose opioid plus ibuprofen/acetaminophen treatment group (#2) were purposely compared with those from treatment Group 1 (opioids plus acetaminophen) and Group 3 (diclofenac sodium plus acetaminophen). It is important to note that virtually all of the unscheduled ER visits for adjunctive pain relief measures occurred within the first 7 days post-operatively.

A logistic regression was performed predicting presence of bleeding, and the covariates of age and gender were considered. Results revealed no significant difference in bleeding complications a) between subjects in the opioids plus acetaminophen Group (#1) and those in the low dose opioids plus ibuprofen/acetaminophen (#2) or diclofenac sodium plus acetaminophen (#3) treatment groups [$B=1.33, p= 0.203$], or b) between subjects in Group #2 and the other two groups ($B=1.94, p= 0.081$).

A logistic regression was also performed predicting going to the ENT clinic for additional pain relief. The covariates of age and gender were again considered. Results revealed no difference in the presence of an ENT clinic visit for adjunctive pain medications a) between subjects in Group 1 and the other two treatment groups ($B=0.65, p= 0.245$), or b) between subjects in Group 2 and the other two treatment groups ($B=-.69, p= 0.449$). An incidental finding was that older subjects were more likely to appear for unscheduled ENT clinic visits for pain relief than their younger counterparts.

Based on the findings obtained we were able to reject the primary NULL hypothesis of this investigation that use of non-opioid medications to manage post-tonsillectomy pain in adults does not result in equally effective pain control when compared to use of popular opioid-based drug regimens. In fact, we demonstrated that subjects within the former treatment group of this investigation were significantly less likely to make unscheduled ER visits for adjunctive pain medication than many of their study counterparts who were prescribed opioid drugs post-operatively. We also demonstrated that there were no differences in 1) bleeding complications, or 2) unscheduled ENT clinic visits for uncontrollable pain complaints between any of the 3 treatment groups of this investigation within the first two weeks post-operatively. These results support the suggestion that diclofenac sodium plus an analgesic is at least as effective as opioid drugs (+/- ibuprofen/acetaminophen) relative to these two study variables.

Discussion

The previously described escalating opioid epidemic demands that the entire medical community identify and evaluate alternative drugs for various clinical populations who require dependable yet non-addictive medication for pain relief. Achieving this objective is of paramount importance; for patients, their loved ones, and society at large. Although the incidence of tonsillectomy in adults has declined steadily over the past decade it is still relatively common, with approximately 100,000 cases annually in the United States [9]. Because significant but decreasing pain is expected, treating physicians very often prescribe opioid drugs in synchrony with over the counter NSAIDs for relief during the first 7 days to two weeks following surgery [10,11]. In October 2017, the Secretary of Health and Human Services (USA) issued an emergency declaration urging physicians to employ strict limitations when prescribing opioid medications. Since then, we have been experimenting with reasonable alternative non-opioid drug regimens for managing various clinical populations who require pain control.

Because the scientific literature is not replete with investigations of post-tonsillectomy pain management alternatives for adults, we did not discover unequivocally useful information regarding the best non-opioid treatment regimen to employ with our patients. Magdalena and her associates reported no significant differences in pain control whether they used tramadol plus NSAIDs or prednisolone plus NSAIDs in their patients [12]. Sanders and his associates discovered no benefit to the use of gabapentin for their post-operative patients [13]. Whereas Lachance and her colleagues found that dexamethasone did not adequately relieve pain in their patients [14], Stewart, et al. reported that piroxicam coupled to dexamethasone significantly reduced pain in their patients versus either of these drugs alone [15]. Salonen and his associates reported that ketoprofen plus acetaminophen and codeine provided good pain control for their patients, but resulted in an unacceptable increase in bleeding complications [16]. Similarly, Attia showed that administration of acetaminophen and ibuprofen caused too many bleeding complications to warrant this drug



combination for pain control [17]. Curiously, Hatami and her co-authors suggested that honey and acetaminophen worked synergistically to regulate pain in their post-tonsillectomy patients [18]. Husband and Davis reported that diclofenac sodium given prior to surgery proved effective in reducing post-operative pain [19]. Kotecha and his associates discovered that patients who were given a single dose of intramuscular diclofenac injection post-operatively experienced good pain control [20]. To our knowledge only one investigation of acetaminophen and diclofenac sodium for analgesia following tonsillectomy was previously published [21]. Results revealed that this combination drug regimen proved minimally more effective than either of these two drugs alone.

The chief aim of the current investigation was to discover a non-addicting and effective medical approach to comfort care in the immediate post-operative period for adult patients who undergo a tonsillectomy procedure. Specifically, we examined whether a non-opioid medication regimen of acetaminophen and diclofenac sodium (a prescription strength NSAID) was as effective as opioid-based treatment methods for pain control. Although the exact mechanism of action of diclofenac is not fully understood, it is thought to work by inhibiting the expression of various hormones and pain receptors within the body that normally regulate inflammation and pain (eg., cyclooxygenase [COX-1 and COX-2], P-glycoprotein, peroxisome proliferator activated receptor gamma cells, N-methyl & D-aspartate receptors) [22,23]. Because of these therapeutic properties we elected to use this drug for our study. It should be noted that at the dose administered none of our patients exhibited significant known side effects while taking this drug, such as gastrointestinal bleeding, ulcers, or cardiovascular thrombotic events.

Our data base at the Detroit Medical Center enabled us to study a relatively large population of adults who underwent tonsillectomy between 2013 and 2019. In the earlier years of this time frame, we routinely prescribed at hospital discharge 10 days of opioid medications +/- acetaminophen to these patients (Group #1). The primary objective for this approach was to provide maximum pain relief and to thwart causally related post-operative complications such as dehydration, hemorrhage, and bleeding [7,11]. Over the past few years, we discontinued this post-tonsillectomy standard treatment regimen in favor of lower dose opioids plus an alternating regimen of ibuprofen/acetaminophen (Group #2), or diclofenac sodium plus acetaminophen (Group #3). The existence of the latter group of patients in our medical center data base permitted us to conduct a comparative analysis of post-surgical outcomes in these 3 treatment group populations, most specifically with regard to bleeding complications and pain control.

Clinical researchers have reported a 6% bleeding complication rate in their subjects post-tonsillectomy [7]. Our overall finding of a mean rate of 8% across all 3 treatment groups was generally consistent with those reports; no significant differences were determined between our 3 treatment groups for this complication factor. Within and between these treatment groups, neither gender nor age was

a significant factor relative to post-tonsillectomy bleeding complications.

We arbitrarily defined pain complication as an unexpected ER or ENT clinic visit for additional pain medication. Previous researchers have reported a complication incidence figure of approximately 10% for post-tonsillectomy pain [10-12]. Comparatively, in our investigation the pain complication rate ranged from 18% in Group 1 to 4% in Group 3, with approximate means for the entire study population of 16% for ER visits and 14% for ENT clinic visits. These ER data proved to be the only statistically significant difference between our 3 treatment groups relative to all dependent variables (ie., ER visits, ENT clinic visits, and bleeding); suggesting that subjects in Group 1 (high dose opioids plus acetaminophen) were nearly 5 times more likely to go to the ER for pain complaints than subjects in either of the other two treatment groups. Within and between these 3 treatment groups, neither gender nor age was a significant factor relative to post-tonsillectomy ER or ENT clinic visits.

All of these results helped us to reject the null hypothesis of this investigation. The non-opioid pharmacologic treatment regimen employed for Group 3 subjects proved to be at least as effective in controlling pain and bleeding complications as the alternative opioid drug regimens administered to subjects in Groups 1 and 2. Paradoxically, the poorest results on all variables measured were generally obtained from subjects in the high dose opioids plus acetaminophen treatment group (#1).

In this day and age of patient care, with the incidence of opioid addiction on the rise, it is of paramount importance that physicians judiciously administer medications for pain to all clinical populations. In our practices we are exceedingly careful not to prescribe automatically opioid-based drugs to patients who complain of pain because of certain medical conditions or treatments they have received. Results of this investigation have taught us that it is not unreasonable when treating these patient populations to prescribe the strong NSAID diclofenac sodium, plus a synchronized daily course of acetaminophen, in lieu of commonly used opioid drugs. For our post-tonsillectomy study subjects, we discovered that this alternative approach to pain management was quite effective in the vast majority of cases.

Limitations

As with most retrospective chart reviews this investigation was also riddled by some important limitations. First and foremost, none of the charts contained a validated pain scale measurement tool, which would have enabled us to grade the actual levels of pain that a subject may have complained about during the post-operative period. Second, we were not able to control for personality differences among the 3 drug treatment groups. It is well understood that people often differ from one another with regard to their pain thresholds. Some individuals may consider themselves stoic, capable of coping with even moderate to severe degrees of pain without complaining. These types of people might not be inclined to reach out for or use many



pain management drugs during their course of recovery from treatment. Others individuals, may have low tolerance levels for any discomfort; especially significant pain, as is often the case following tonsillectomy. We were unable to differentiate these potentially influential personality variables within or between our 3 treatment groups. Third, we don't know whether subjects in each group actually followed the drug regimen as prescribed. It is not inconceivable that some, if not many, individuals were not compliant; they may have taken more or less of the drugs recommended on any given day, depending upon their perceived levels of pain. These possibilities could have negatively (or positively) influenced the results reported per treatment group. Finally, our sample size was not even across all treatment groups. This discrepancy may have skewed the data and the findings of fact.

Notwithstanding our study limitations, we are unaware of any other scientific publication that offers a more robust set of findings regarding the success of a non-opioid drug regimen in the management of pain following tonsillectomy. However, as the common research adage always warns: a randomized prospective treatment design should be constructed to overcome these limitations, and perhaps to ensure the discovery of an even more efficacious pharmacologic treatment paradigm for the comfort and safety of post-tonsillectomy patients.

Conclusions

Adult tonsillectomy surgery is one of the most painful same day elective otolaryngology procedures. Most patients require many days of analgesic pharmacologic management post-operatively. There is no known standard, efficacious, and safe drug regimen for this clinical population. Results of this preliminary investigation support the administration of acetaminophen 500mg for 10 days with diclofenac sodium (NSAID) 50mg for 5 days for reliable and safe pain control in the post-tonsillectomy time frame, without significant concerns for complications like excessive bleeding or inconvenient and costly unscheduled ER or ENT clinic visits during the recovery period. Additionally, these preliminary findings argue in favor of avoiding use of opioid-based analgesics because the aforementioned non-addicting NSAID plus acetaminophen combination pharmacologic regimen may prove as effective in regulating pain following tonsillectomy.

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