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ORIGINAL RESEARCH

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Postoperative tonsil/adenoidectomy bleeding management in patients with diagnosed bleeding disorders

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Abstract

Objective: Tonsil/adenoidectomy (T/A) is a commonly performed procedure with an average post-tonsillectomy bleed (PTB) rate between 3 and 5%. Patients with bleeding disorders (BDs) are believed to have an increased risk of PTB. We hypothesize that our medical management of BD patients using a combination of DDAVP/antifibrinolytic agents has a similar PTB rate to control patients. This study suggests a standardized protocol for patients with BDs to avoid PTB.

Methods: A retrospective cohort study was completed for patients with BD who underwent tonsillectomy or T/A at Promedica Toledo or Flower Hospital between 2013 and 2020. Exclusion criteria included incomplete records, diagnosis of BD after surgery, and inability to find age and sex matched control. We defined the control group as patients who underwent T/A without BD. The following variables were collected: age, sex, medical history, BD severity, medications, type of surgery, indication for surgery, estimated blood loss (EBL), pre/postoperative medications, PTB status, and post-PTB intervention.

Results: A total of 164 patient charts were reviewed. There were 82 patients in both cohorts. The BDs represented were platelet function disorder (80.5%), von Willebrand disease (14.6%), and others such as Factor VII and IX deficiency (4.9%). Of the BD patients included, 13.4% had severe disease. There was no significant difference between the age, sex, EBL, and PTB rates. Of the 8 BD patients with PTB, 62% bled 9-10 days postoperatively and none had severe disease.

Conclusion: Our protocol to prevent PTB in patients with BDs produced similar bleed rates to control patients in this study. Further studies are required to assess postoperative length of antifibrinolytic treatment in BD patients.

Level of Evidence: III.

KEYWORDS
adenoidectomy, bleeding disorder, post-tonsillectomy bleed

1 | INTRODUCTION

Tonsillectomy with or without adenoidectomy (T/A) is the most commonly performed pediatric surgical procedure in otolaryngology, with nearly 289 000 reported operations in children less than 15-years of age in 2010.[1] T/A continues to be frequently recommended for children with recurrent tonsillitis and sleep-disordered breathing (SDB).[2] Additionally, T/A's incidence has dramatically increased over the years due to its utility in treating SDB.[3,4] Surgical treatment of SDB is often preferred to prevent feared complications, including hypertension, cognitive and behavioral disorders, nocturnal enuresis, and learning difficulties.[2] Although commonly performed, T/A is not without its own set of post-surgical complications.[5] Post-tonsillectomy bleed (PTB) is a serious complication and is reported to occur in 3%-5% of pediatric cases.[6-8] Additionally, patients with a known bleeding disorder (BD) may have a higher risk of developing PTB and should be strictly co-managed with a hematologist to prevent this dangerous complication.[9]

PTB in patients with BDs is a controversial topic in the current literature. Some studies conclude that patients with diagnosed BDs do not have an increased risk of PTB, and some suggest that appropriate pre-surgical treatment mitigates PTB's risk.[10-12] Others indicate that the risk of secondary PTB, defined by PTB after the first 24 postoperative hours, increases in this subset of patients with PTB rates around 8.7%-15.5%.[9,13,14] Although more research is needed to determine the true risk of PTB in patients with BDs, it is still imperative for children undergoing T/A procedures to obtain pretreatment medications to prevent potentially life-threatening bleeds.

Currently, there are no standardized medical protocols published in the literature for patients with wide ranges of BD severity. In this study, we propose a medical protocol using a combination of desmopressin (DDAVP) or factor replacement and an antifibrinolytic medication to prevent PTB in patients with mild-severe BDs. We hypothesize that our standardized medication protocol for patients with BDs undergoing T/A produced similar PTB rates when compared to a control patient population.

2 | METHODS

We conducted an IRB approved (IRB# 20-041) retrospective cohort study including a chart review of the ProMedica Health System electronic medical record (EMR) to identify patients who underwent total tonsillectomy with or without adenoidectomy (T/A) between 2013 and 2020 with diagnoses of a BD. Results from this search were confirmed by cross-referencing data from the ProMedica EMR with data from the American Thrombosis & Hemostasis Network (ATHN) database of patients from the Northwest Ohio Hemophilia Center. We then defined a control cohort as age and sex-matched patients from the ProMedica Physicians Ear, Nose, and Throat group who underwent T/A without a past medical history of coagulopathy. Notably, control patients were asked a set of intake questions to capture possible BDs before surgery related to a personal history of bleeding after surgery, a family history of BDs, menorrhagia, and easy bruising/bleeding. If a patient was positive for any of the screening questions, he/she was referred to Hematology for further evaluation and was excluded from the control group. The answers to these questions were clearly documented in the EMR.

All patients with a primary diagnosis of storage pool disease (SPD) before T/A received a standardized medication protocol consisting of DDAVP 0.3 mcg/kg preoperatively and 12 hours postoperatively. The second dose of DDAVP was held if the sodium level was <135 mEq/L 2 hours before the second dose. Notably, these patients underwent a DDAVP challenge prior to administration of the protocol to ensure the appropriateness of this intervention. Patients were also prescribed the antifibrinolytic agent Amicar 100 mg/kg IV or PO every 6 hours for 10 days post-surgery (Figure 1). One patient received the antifibrinolytic agent tranexamic acid, instead, at a dose of 650 mg (<12 years age) or 1300 mg PO every 8 hours post-op for 10 days due to insurance issues. One patient with a primary diagnosis of factor IX (FIX) deficiency received Alprolix, instead of DDAVP, to reach a FIX level of 60 to 100 IU/dL with a repeat dose at 6-10 hours and then daily for the first 3 days. This one patient also received Amicar at the standard dose for 10 days post-surgery. This medication regimen was adapted from protocols implemented in previous studies.[13,15-17] Patients with BDs were explicitly not given Non-steroidal Anti-inflammatory Drugs (NSAIDs) for post-operative pain. Instead, these patients were counseled to take over-the-counter acetaminophen. Patients in our control group Thi were encouraged to alternate between acetaminophen and ibuprofen for postoperative pain control. Opioids were only prescribed, with great caution and counseling, to parents that requested them for their children in either cohort.

We recorded the following variables from the chart review: patient age, sex, medical history—paying particular attention to known risk factors for PTB, indication for surgery, medications affecting hemostasis, estimated blood loss (EBL), surgery type (tonsillectomy vs tonsillectomy and adenoidectomy), presence of other concurrent surgical procedures (eg, turbinate reduction, maxillary antrostomy, balloon sinuplasty, etc.), preoperative medications, postoperative medications, presence or absence of PTB, other post-surgical complications (eg, infection, dehydration, etc.), need for medical intervention after PTB, and need for surgical intervention after PTB. A "PTB" was defined as any amount of bleeding from the nose or throat documented in the EMR. We implemented this broad definition of PTB to address unconscious bias and promote consistency when reviewing patient charts. For the patients with diagnosed BDs, we also collected specific information regarding the type of BD and disease severity including platelet function defect, primary dense granule deficiency (<2 dg/plt = severe, 2-3 dg/plt = moderate, 3-4 dg/plt = mild), and von Willebrand's disease, ristocetin cofactor (<30% severe, 30%-47%-mild), factor VII activity, factor VIII activity, and factor IX activity.

Data was compiled in an excel sheet and exported to SPSS Software (version 26, IBM SPSS Statistics for Windows, IBM Corp). The continuous variables analysis was analyzed using the Mann-Whitney *U* test or Student's *t*-Test, where applicable. Categorical data analysis was completed using a X^2 test and Fisher's Exact test.

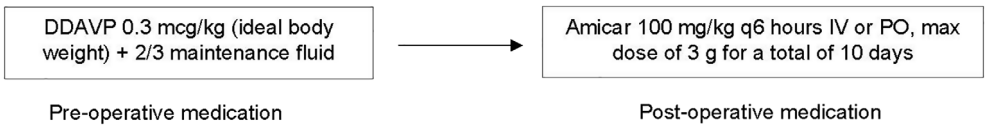

FIGURE 1 Simple flow chart of the medication protocol for BD patients with a primary diagnosis of SPD or vWD. Tranexamic acid is an antifibrinolytic agent that can be used as an appropriate substitute for Amicar

TABLE 1 Baseline and procedural characteristic comparison between coagulopathy and control groups

	BD[a]	Control	*P*-value
Age	8.5 ± 5.4	8.5 ± 5.5	0.97
Sex, M	37 (45.1%)	38 (46.3%)	0.88
Obesity	6 (7.3%)	7 (8.5%)	0.77
ADHD	11 (13.4%)	3 (3.7%)	0.025
Procedure, T/A[b]	70 (85.4%)	72 (87.8%)	0.65
EBL[c]	6.0 ± 4.7	6.9 ± 5.8	0.30
Preoperative medication	82 (100%)	0 (0%)	<0.01
Postoperative medication	82 (100%)	0 (0%)	<0.01
Postoperative bleed	8 (9.8%)	6 (7.3%)	0.58
Postoperative blood transfusion	1 (1.2%)	0 (0%)	N/A
Medical intervention	4 (4.9%)	4 (4.9%)	0.73
Surgical intervention	1 (1.2%)	1 (1.2%)	1

[a]Bleeding disorder.
[b]Tonsillectomy/adenoidectomy.
[c]Estimated blood loss.

3 | RESULTS

Two-hundred twelve patients with BDs were evaluated for inclusion in this study. We excluded patients when we were unable to find a matched control or if patients had insufficient surgical data in the EMR. Ultimately, 164 charts were retrospectively reviewed for this study. The two groups were equally divided, with 82 (50%) BD patients and 82 (50%) control patients. There were a total of 89 (54.3%) females and 75 (45.7%) males. Other demographic information for the two groups can be found in Table 1.

3.1 | Power analysis

The study design was unique compared to previous studies and therefore, we did not calculate a sample size before collecting data. A post hoc power analysis was performed using GPower 3.1 after our study was completed to obtain the achieved power. Additionally, when using the proportions found in our study, an a priori power analysis shows a necessity of over 1300 patients for each group to be considered well powered. A threshold difference of 2% is required to obtain clinical significance.

3.2 | BD results

In the BD, the average age was 8.5 ± 5.4 years. There were 37 (45.1%) males and 45 (54.9%) females. The different BD frequencies were 66 (80.5%) SPD, 12 (14.4%) vWD, and 4 (4.9%) other coagulopathies such as Factor VII, VIII, or IX deficiency. A total of 11 (13.4%) subjects were considered to have severe disease. The remaining subjects either had mild (41.5%) or moderate (45.1%) disease severity. Most of the coagulopathy subjects underwent T/A (85.4%) compared to tonsillectomy alone (14.6%). A small fraction (4.9%) underwent another surgery simultaneously as the T/A procedure. The average estimated blood loss (EBL) was 6.0 ± 4.7 mL. There was a 100% rate of preoperative and postoperative medication administration. Of the 8 (9.8%) BD subjects who bled, 4 (50%) required medical intervention for the PTB, 1 (12.5%) required surgical intervention, and 3 (37.5%) had no added intervention, as shown in Table 2. No patients with a severe BD experienced a postoperative bleed.

3.3 | Control results

In the control group, the average age was 8.5 ± 5.5 years. There were 38 (46.3%) males and 44 (53.7%) females. The most common

TABLE 2 Characteristics of coagulopathy patients that experienced post-tonsillectomy bleed

Patient	Age/sex	PMH[c]	Disease severity	Indication for surgery	Post-Op bleed day	Medical intervention	Surgical intervention
1	5/F	SPD	Moderate	SDB[a], RT[b]	13	Amicar 100 mg/kg ×2 q6H for 2 days	N/A
2	6/F	SPD	Moderate	RT	13	N/A	N/A
3	22/F	SPD, ADHD, Ehlers-Danlos	Moderate	RT	15	N/A	N/A
4	10/M	SPD	Mild	RT	3	N/A	Cauterization
5	11/M	SPD	Mild	SDB	9	Amicar continuation then D/C, readmitted for anemia on POD #17 and #18 – received iron and 1-unit PRBC, respectively	N/A
6	5/F	SPD, Obesity	Moderate	SDB	12	Amicar for 5 days	N/A
7	9/F	SPD	Moderate	SDB	14	N/A	N/A
8	10/M	vWD,type 1	Mild	SDB	5	Afrin (nosebleed with unclear origin)	N/A

[a]Sleep disordered breathing.
[b]Recurrent tonsillitis.
[c]Past medical history.

TABLE 3 Characteristics of control patients that experienced post-tonsillectomy bleed

Patient	Age/sex	PMH[c]	Indication for surgery	Post-Op bleed day	Medical intervention	Surgical intervention
1	15/M	N/A	RT[a]	9	N/A	N/A
2	9/F	N/A	RT	6	Cold water	N/A
3	6/M	ADHD	SDB[b]	8	Observation in ED	N/A
4	7/M	N/A	SDB	5	Cold water + observation in ED	N/A
5	10/F	Down syndrome	SDB	6	Cold water	Cauterization
6	24/F	N/A	RT	3	Cold water	N/A

[a]Recurrent tonsillitis.
[b]Sleep disordered breathing.
[c]Past medical history.

procedure was tonsillectomy and adenoidectomy (87.8%), followed by tonsillectomy alone (12.2%). A total of 9 (11.0%) control subjects underwent another procedure at the time of T/A. The average EBL was 6.9 ± 5.8 mL. None of the patients were given pre- or postoperative medications. There were 6 (7.3%) subjects who had a postoperative bleed. Of those that bled, 4 (66.7%) required a medical intervention for the PTB, 1 (16.7%) required surgical intervention, and one patient required no additional intervention (16.7%), as shown in Table 3.

3.4 | Comparison of two groups

When the two study groups were compared, ADHD was significantly more prominent in the BD group compared to the control group (χ-squared = 4.99, df = 1, Fisher's Exact Test *P*-value <.05). Additionally, the indication for surgery between both groups no statistical significance (χ-squared = 0.88, df = 2, Fisher's Exact Test *P*-value = .465). There was no statistical significance found for the remaining variables tested. These results are represented as a *P*-value in Table 1.

4 | DISCUSSION

PTB is a daunting complication of T/A. A 2013 review by Subramanyam et al shared that PTB is both the most frequent fatal and non-fatal cause of T/A-related complications.[18] Therefore, it is vital that the effects of risk factors for PTB are appropriately managed and addressed before this procedure.

PTB is a general term commonly divided into two bleeding patterns: primary and secondary. Primary PTB, occurring within the first 24 hours after surgery, occurs when a patient's responsiveness, airway protective mechanisms, mean arterial pressure undergo compromise and/or inadequate surgical techniques are utilized.[19,20] Secondary PTB, typically occurring 5-10 days after T/A, is thought to occur when eschars slough from the underlying granulation tissue in the tonsillar bed.[19,20] In this study, both the control and BD group patients experienced secondary PTB, a more difficult-to-predict side effect of wound healing. We believe that the lack of primary PTB in these cohorts was likely due to strict monitoring of the risk factors associated with primary PTB in Toledo institutions. These include, but are not limited to, proper anesthetic dosing, careful intraoperative blood pressure monitoring, and postoperative orogastric tube decompression.

The current literature provided valuable but limited evidence regarding the utility of a standardized medication regimen in patients with BD undergoing T/A.[13,15] A retrospective case series including data from 12 patients with vWD published by Shah et al in 2009 utilized preoperative DDAVP or factor VIII concentrated followed by postoperative Amicar for 10 to 14 days in children undergoing otolaryngologic surgeries. This protocol implemented at the University of California San Francisco was shown to minimize bleeding complications in patients with vWD. Though convincing, this study did not address this protocol's use in patients with other hematological disorders and included patients undergoing procedures other than T/A.[15] In 2012, García-Matte et al published a study to evaluate PTB incidence in children with mild bleeding disorders (platelet function disorder, vWD, factor VII deficiency) undergoing T/A. In general, they defined a PTB prophylaxis protocol, including preoperative DDAVP, followed by Tranexamic acid postoperatively for 10 days after surgery. This study did not evaluate this protocol against a control group and did not extend the protocol to moderate-severe BD patients. However, they concluded that the protocol could likely be safely implemented in patients with BD.[16] Lastly, a 2017 retrospective study performed by Patel et al studied PTB outcomes in 45 patients with BD vs a control cohort matched for age, sex, and indication for surgery. These patients had a more comprehensive range of diagnoses, including platelet dysfunction, vWD, and factor deficiencies. The protocol outlined in this study included preoperative DDAVP administration plus postoperative Amicar prescribed for 10 days after T/A surgery. Although this study included patients diagnosed with BD both pre- and postoperatively, resulting in a non-standardized duration of Amicar treatment among the BD cohort patients, they concluded that their protocol decreased PTB rates in patients with BD.[13]

Unfortunately, the circumstances surrounding each patient's PTB were challenging to assess thoroughly due to inconsistencies in EMR documentation. As a result, we could not comment on patient factors or potential confounders that contributed to bleeding episodes- particularly in those requiring surgical intervention from severe PTB. Additionally, we reported a PTB rate in both cohorts that were above the commonly reported trends in the literature.[6-8] We defined a PTB as any bleed post T/A regardless of timing, quantity, or intervention needed for the sake of completeness. Perhaps our broad definition of PTB contributed to slightly higher than average PTB rates in this study.[21] It is also unclear why patients with only mild to moderate BDs experienced PTB v. those with severe BD. Perhaps the patients with severe BD underwent optimal surgical resection and perioperative medical correction of their underlying BDs. It could also suggest that the sample size of our severe BD patients was small, or that the severe BD patients were more compliant with their medical regimen and/or diet.

Our study also aimed to determine if the indication for surgery—for example, recurrent tonsillitis (RT), sleep-disordered bleeding (SDB)—independently contributed to the incidence of PTB in either or both cohorts of patients. We ultimately found that the indication for surgery did not contribute significantly to PTB rates in either group of patients. Notably, the baseline characteristics of both patient groups were similar in this study with two exceptions: need for pre- and postoperative medication delivery and past medical history of ADHD in the BD patients. Importantly, though, the presence of ADHD did not contribute to increase in PTB as there was only one patient in each cohort with ADHD that experienced a PTB.

This study had several ethical and non-ethical limitations. To combat the obvious ethical dilemma of withholding medications that could prevent postoperative bleeding, we considered defining a sample cohort as patients who were diagnosed with a BD postoperatively. This would have allowed us to compare PTB rates in patients with BDs who did and did not receive our medical protocol. After a thorough search of the ATHN database, we found that only nine patients were diagnosed with BD postoperatively and this would have led to an underpowered study. Although our sample size was larger than similar studies of this type, it was still relatively small. We were limited to a smaller sample size because this study was conducted at a small academic institution without a dedicated otolaryngology department. This led to an underpowered study that could not be adjusted due to lack of sample and control subjects. The small sample size may have also contributed to our higher-than-average bleed rates. Between these limitations, we could not provide a concrete protocol. Instead, we hoped to provide the foundation for a study to test our protocol at a larger institution. Another limitation of this study relates to number of providers performing the T/A procedures. The BD group consisted of patients treated at the Northwest Ohio Hemophilia Center and were all treated with the standardized medication regimen described in this study. Therefore, not all patients were treated by the same surgeon. As a result, 11 surgeons were involved in the treatment of these BD patients compared to one otolaryngologist who performed the T/A surgeries for all control patients. The slight variability amongst the surgeons in T/A techniques in the BD cohort can be considered another limitation of this study. Another common limitation is loss to follow-up. These patients may have been seen at other facilities outside of our hospital system. Lastly, the pain regimen for both BD and control patients in this study was not standardized—except for the fact that BD patients were not prescribed non-steroidal anti-inflammatory drugs (NSAIDs) postoperatively. While our pain regimen was not standardized in this study, previous studies have shown that postoperative opioid and NSAID use is not associated with greater incidence of PTB.[22-24] Despite the lack of evidence suggesting that opioids and NSAIDs affecting PTB rates, future studies should utilize a standardized pain regiment in all T/A patients to reduce the number of variables.

To our knowledge, this is the first study to analyze the rates of PTB and specific patient factors that contribute to PTB in BD patients treated with a standardized medication regimen vs a control cohort. It is also one of the more extensive studies evaluating how a standardized medical protocol can potentially improve outcomes in BD patients. Despite this fact, a future study consisting of even larger cohorts of patients is necessary to determine causes more precisely for the lack of PTB in patients with severe BDs. Additionally, four patients in the BD group experienced PTB after the 10-day postoperative antifibrinolytic treatment schedule ended. A prospective study treating a cohort with 10 days of postoperative antifibrinolytic treatment vs 14 days may provide insights into the

optimal treatment duration in these patients. Finally, additional known risk factors for PTB include older age (>11-12 years-old), obesity, attention deficit hyperactivity disorder (ADHD), and chronic tonsillitis.[8] In the present study, we did not find that these variables affected the risk of PTB. In future studies, with a larger cohort of patients, we could also determine if this medication regimen would be beneficial in lowering PTB rates in patients with these risk factors.

5 | CONCLUSION

The medical regimen described in this study explicitly established for patients with BD produced PTB rates comparable to those seen in a control patient cohort without BD. It may be beneficial to conduct more extensive prospective trials to refine the treatment length in PTB patients to optimize these results further and justify applying this protocol nationwide.

CONFLICT OF INTEREST

The authors of this study have no financial or non-financial disclosures. This research did not receive funding from not-for-profit agencies, public sector entities, or private sector firms.

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