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HEAD & NECK

The impact of platelet-rich plasma therapy on short-term postoperative outcomes of pediatric tonsillectomy patients

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Abstract

Introduction To compare the short-term outcomes of pediatric patients who underwent tonsillectomy alone vs. tonsillectomy plus platelet-rich plasma (PRP) therapy in terms of postoperative pain, appetite status, analgesia requirement, and bleeding complications.

Materials and methods This study included a total of 80 pediatric tonsillectomy patients (53.8% female, 46.2% male, aged 4–16 years), who were randomly allocated into tonsillectomy alone (TA group; $n=40$) and tonsillectomy plus PRP therapy (TPRP group, $n=40$) groups. Patient demographic data (age, gender) and postoperative data of visual analog scale (VAS) pain scores (postoperative 2nd hour, 1–10 days), appetite scores (postoperative 1–7 days), and analgesia requirement (postoperative 1–10 days) and bleeding complications were recorded.

Results A significant gradual decrease was noted in pain scores starting from the 3rd postoperative day reaching 0.0 ± 0.0 and 0.50 ± 0.88 on Day 10 in the TPRP and TA groups, respectively ($p<0.001$ for each). Compared to the TA group, the TPRP group was associated with significantly lower pain scores (Day 1 to Day 10), better appetite scores (Day 1 to Day 6), a lower requirement for analgesia (Day1 to Day 10) and fewer common bleeding complications (1 vs. 4 patients) in the postoperative period ($p<0.001$ for each).

Conclusion In conclusion, this study of pediatric tonsillectomy patients revealed the superiority of tonsillectomy with PRP over tonsillectomy alone in terms of effectiveness in reducing post-tonsillectomy pain and improving appetite status, together with a lower requirement for analgesia and a reduced risk of post-tonsillectomy bleeding during the first 10 postoperative days.

Keywords Tonsillectomy · Postoperative pain · Appetite · Analgesic need · Bleeding · Pediatrics

Introduction

Pediatric tonsillectomy is one of the most commonly performed surgeries in otolaryngology practice, being indicated for recurrent tonsillitis, obstructive sleep apnea and sleep disordered breathing [1–4].

Pediatric tonsillectomy has been associated with significant pain in the postoperative period that can last up to 14–21 days, together with a 2–4% risk of hemorrhage [5–9]. Given the association of poor pain control with decreased oral intake and increased likelihood of infection and secondary bleeding [10–12], adequate analgesic control is considered vital for a smooth post-operative recovery following pediatric tonsillectomy [4, 11, 13].

Accordingly, the search for measures to control post-tonsillectomy pain and bleeding has become an area of increasing interest in otolaryngology [11, 12, 14, 15]. However, amongst the variety of the methods attempted so far to improve post-tonsillectomy pain control, including surgical techniques (partial tonsillectomy, bipolar diathermy and plasma field dissection) [16], tonsillar bed injections (ketamine, ropivacaine, lidocaine, etc.) [17, 18], postoperative use of steroids [19] or honey [20, 21] and the use of topical solutions such as fibrin sealant [22] and fibrin glue [15], none has emerged as the optimum regimen and there remains a lack of consensus on the ideal pain management in tonsillectomy patients [5, 12, 15, 21].

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Given the recognition in recent years of platelet involvement not only in traditional hemostasis, but also in the wound healing process and immunomodulation [23, 24], platelet-rich plasma (PRP) has emerged as a potential adjuvant therapy and has been tested in many different clinical situations to improve the healing of surgical wounds and injuries [14, 24]. PRP is a concentrated volume of platelets that contains multiple growth and healing factors that are released upon activation of the platelets [14, 23, 24]. Although several basic scientific animal, and human studies have been conducted on the role of PRP as a novel treatment protocol in surgical wound healing, the results remain inconclusive due to a lack of high-level randomized studies [14, 24].

There are few studies in literature on the role of PRP in postoperative healing and pain control after tonsillectomy, and those that are available have shown inconsistent findings [14, 25, 26].

The aim of this study was to compare the short-term outcomes in pediatric patients who underwent tonsillectomy alone vs. tonsillectomy plus PRP in terms of postoperative pain, appetite status, analgesia requirement and bleeding complications.

Materials and methods

Study population

This single blinded study included a total of 80 pediatric tonsillectomy patients (53.8% female, 46.2% male, aged 4–16 years), who were randomly separated into two groups of tonsillectomy alone (TA group; $n=40$) and tonsillectomy plus PRP therapy (TPRP group, $n=40$). Patients were excluded if they were aged <4 years or >16 years, had bleeding diathesis or hemorrhagic dyscrasias, any co-morbid disease (i.e., diabetes, cardiac disease, epilepsy), immune deficiency or were receiving immunosuppressive treatment, cleft palate, acute respiratory tract infection, poliomyelitis or no poliomyelitis vaccination.

Written informed consent was obtained from the parent or legal guardian of each patient following a detailed explanation of the objectives and protocol of the study which was conducted in accordance with the ethical principles stated in the "Declaration of Helsinki" and was approved by the Adana City Hospital, Ethics Committee for Clinical Research (18-KAEK-253).

Study parameters

Patient demographic data (age, gender) and the postoperative pain scores (postoperative 2nd hour, 1–10 days), appetite scores (postoperative 1–7 days), analgesia requirement (postoperative 1–10 days) and bleeding complications were recorded for both groups. Tonsil grade was scored between 1 and 4.

All the patients received i.v. paracetamol (10 mg/kg for per 6 h as needed) and amoxicillin (40 mg/kg per day) after the surgery. At the end of the operation all the patients received i.v. paracetamol (10 mg/kg) prior to their transfer to the recovery room. The oral food intake was forbidden for the first 4 h after the surgery. The pain levels were evaluated at the postoperative 2nd hour for the first time and second evaluation was performed at the 24th hour. The pain scales were evaluated before taking analgesic agent. After then, the pain evaluations were repeated for every 8 h and average of the three measurements was considered as the pain level of the that day. The Visual Analog Scale (VAS) and The Facial Pain Scale were used to evaluate the pain levels of the patients. The patients and/or their parents were informed about the pain evaluation surveys. The Facial Pain Scale was used for the patients that were younger than 7 years old. The evaluation of the Facial Pain Scale was performed according to instructions that were described in an article [27]. The patients older than 7 years scored their pain from 0 to 10 points (0 = no pain, 10 = unbearable pain). Postoperative appetite was classified as good, moderate and poor appetite status categories [28].

Tonsillectomy

The patients were hospitalized on the day of the operation and those without postoperative complications were discharged on the next day after clinical evaluation by the operating surgeon. None of the patients received oral premedication. Following general anesthesia with induction using volatile gases (sevoflurane) followed by IV propofol, the tonsillectomy operation was performed by the same surgeon using the classic cold dissection technique in all cases. Hemostasis was achieved using bipolar electrocautery where necessary. PRP was applied to both tonsillar beds at the end of the operation in the TPRP group and the operation was performed without the use of PRP in the TA group. Neither the patients nor the physicians who assessed the pain, appetite and analgesia requirement were informed about the group allocations.

PRP preparation

For PRP preparation, 25 ml of autologous blood was drawn from the patient during anesthesia induction and centrifuged in two sessions including soft spin (3000 rpm, 3 min) allowing separation of the blood into three layers [bottom-most erythrocyte layer, top-most platelet poor plasma (PPP) and the intermediate PRP layer (Buffy coat)] and then hard spin (4000 rpm, 3 min) allowing formation

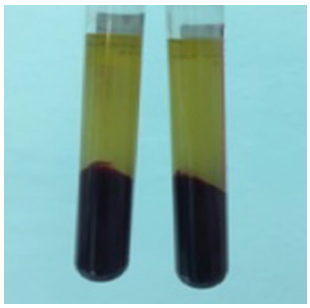

Fig. 1 Post-centrifugation: layers of centrifuged blood

of the PRP (Fig. 1). The PRP was then mixed with an equal amount of calcified thrombin for activation and was applied directly to the tonsil bed with a syringe where it formed a matrix resembling a blood clot (Fig. 2). Then, we applied a pressure to the matrix with a sponge to adhere to the wound tissue. Care was taken not to suction the matrix off during anesthesia. The presence of the matrix on the tonsil bed was checked in every 6 h in the first postoperative day.

Statistical analysis

Statistical analyses were made using IBM SPSS Statistics for Windows, Version 17.0 (IBM Corp., Armonk, NY). The continuity corrected Chi-square (χ^2) test was used for the comparison of categorical data. The Student's *t* test and Mann–Whitney *U* test were used for the parametric variables and the Friedman test and Wilcoxon Sign Rank test were used to analyze changes in the study parameters during the follow-up period. Data were expressed as mean ± standard deviation (SD), minimum, maximum values and number (*n*) and percentage (%) where appropriate. A value of $p < 0.05$ was considered statistically significant.

Fig. 2 Platelet-rich fibrin clot

Results

Patient demographic data and postoperative pain scores

The TPRP and TA groups were homogenous in terms of gender (females: 55.0% and 52.5%, respectively) and age (mean ± SD: 7.6 ± 2.9 vs. 7.1 ± 2.5 years, respectively) (Table 1). Additionally, tonsil grading scores was similar in each group (3.10 ± 0.70 vs. 3.05 ± 0.78).

Following a significant increase in pain scores from the postoperative 2nd hour to Day 1 (from 3.80 ± 1.26 to 4.60 ± 1.65 in TPRP and from 4.40 ± 1.52 to 7.55 ± 0.96 in TA groups, $p < 0.001$ for each), a significant gradual decrease was noted in the pain scores of both groups starting from the 3rd postoperative day, reaching 0.0 ± 0.0 and 0.50 ± 0.88 on Day 10 in the TPRP group and TA group, respectively ($p < 0.001$ for each) (Table 2; Fig. 3).

With the exception of the similar postoperative 2nd hour pain scores in both groups, the TPRP group had significantly lower pain scores than the TA group on each postoperative day from Day 1 to Day 10 ($p < 0.001$ for each) (Table 2; Fig. 3).

Post-operative appetite status

From postoperative Day 1 to Day 6, the appetite scores were better in the TPRP group than in the TA group ($p < 0.001$ for each). On Day 7, the appetite status was similar in both groups (Table 3).

There was a significant gradual increase in the percentage of patients with good appetite starting from the 3rd postoperative day with an increase from 50.0% on Day 3 to 92.5% on Day 7 in the TPRP group and from 7.5% on Day 3 to 72.5% on Day 7 in the TA group ($p < 0.001$ for each) (Table 3).

Table 1 Patient demographics and postoperative pain scores

	TPRP ($n = 40$)	TA ($n = 40$)	*p* value
Demographics			
Age (years), mean ± SD	7.6 ± 2.9	7.1 ± 2.5	0.488[a]
Gender, *n* (%)			
Male	18 (45.0)	19 (47.5)	0.999[b]
Female	22 (55.0)	21 (52.5)	

TPRP tonsillectomy plus PRP, *TA* tonsillectomy alone

[a]Student's *t* test

[b]Continuity corrected Chi-square test

Table 2 The postoperative pain scores of the patients

		The Facial Pain Scale (≤ 7 years)			The Visual Analog Scale (> 7 years)			Total		
Time	Group	*N*	Mean	*p* value[1]	*N*	Mean	*p* value[1]	*N*	Mean	*p* value[1]
2nd hour	TPRP	27	3.77 ± 1.15	0.121	13	3.84 ± 1.51	0.301	40	3.80 ± 1.26	0.054
	TA	27	4.37 ± 1.57		13	4.46 ± 1.45		40	4.40 ± 1.52	
Day 1	TPRP	27	4.51 ± 1.52	**0.001**	13	4.76 ± 1.92	**0.001**	40	4.60 ± 1.65[a]	**0.001**
	TA	27	7.62 ± 0.79		13	7.38 ± 1.26		40	7.55 ± 0.96[a]	
Day 2	TPRP	27	3.92 ± 1.41	**0.001**	13	3.84 ± 1.72	**0.001**	40	3.90 ± 1.50	**0.001**
	TA	27	7.62 ± 0.79		13	7.38 ± 0.96		40	7.55 ± 0.85[a]	
Day 3	TPRP	27	2.66 ± 1.24	**0.001**	13	2.92 ± 1.55	**0.001**	40	2.75 ± 1.33[a,b,c]	**0.001**
	TA	27	6.51 ± 1.42		13	6.15 ± 1.72		40	6.40 ± 1.52[a,b,c]	
Day 4	TPRP	27	2.37 ± 1.24	**0.001**	13	2.00 ± 1.41	**0.001**	40	2.25 ± 1.30[a,b,c]	**0.001**
	TA	27	5.55 ± 1.50		13	4.76 ± 1.53		40	5.30 ± 1.54[b,c,d]	
Day 5	TPRP	27	2.00 ± 1.35	**0.001**	13	2.00 ± 1.15	**0.001**	40	2.00 ± 1.28[a,b,c,d]	**0.001**
	TA	27	4.07 ± 1.29		13	4.30 ± 2.13		40	4.15 ± 1.59[b,c,d,e]	
Day 6	TPRP	27	1.33 ± 1.2	**0.001**	13	1.53 ± 1.45	**0.001**	40	1.40 ± 1.30[a,b,c,d,e]	**0.001**
	TA	27	3.33 ± 1.75		13	3.23 ± 1.53		40	3.30 ± 1.67[b,c,d,e]	
Day 7	TPRP	27	0.81 ± 1.00	**0.001**	13	0.76 ± 1.01	**0.001**	40	0.80 ± 0.99[a,b,c,d,e,f]	**0.001**
	TA	27	2.44 ± 1.50		13	3.07 ± 1.32		40	2.65 ± 1.46[a,b,c,d,e,f,g]	
Day 8	TPRP	27	0.37 ± 0.79	**0.001**	13	0.30 ± 0.75	**0.001**	40	0.35 ± 0.77[a,b,c,d,e,f,g]	**0.001**
	TA	27	1.55 ± 1.28		13	2.30 ± 1.60		40	1.80 ± 1.42[a,b,c,d,e,f,g,h]	
Day 9	TPRP	27	0.14 ± 0.53	**0.001**	13	0.30 ± 0.75	**0.001**	40	0.20 ± 0.61[a,b,c,d,e,f,g]	**0.001**
	TA	27	1.03 ± 1.15		13	1.38 ± 0.96		40	1.15 ± 1.10[a,b,c,d,e,f,g,h]	
Day 10	TPRP	27	0.00 ± 0.00	**0.001**	13	0.00 ± 0.00	**0.001**	40	0.00 ± 0.00[a,b,c,d,e,f,g,h]	**0.001**
	TA	27	0.37 ± 0.79		13	0.76 ± 1.01		40	0.50 ± 0.88[a,b,c,d,e,f,g,h,i,j]	
p value[2]									**0.001**	

Statistically significant values are in bold

TPRP tonsillectomy plus PRP, *TA* tonsillectomy alone

a compared to 2nd hour, *b* compared to Day 1, *c* compared to Day 2, *d* compared to Day 3, *e* compared to Day 4, *f* compared to Day 5, *g* compared to Day 6, *h* compared to Day 7, *i* compared to Day 8, *j* compared to Day 9 ($p < 0.00045$)

[1]The comparisons between PRP treatment and tonsillectomy groups, Mann–Whitney *U* test, according to the Bonferroni Correction $p < 0.0045$ was considered statistically significant

[2]The comparisons between follow-up times within each study group, Wilcoxon Sign Rank test, according to Bonferroni Correction with $p < 0.025$ considered statistically significant

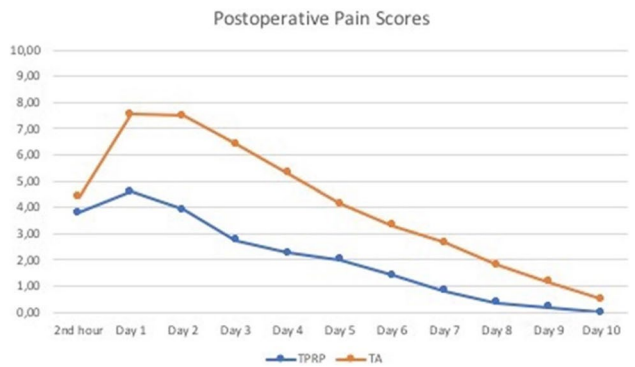

Fig. 3 Postoperative pain scores

Postoperative analgesia requirement

A significantly lower number of analgesics was needed in the postoperative period, from Day 1 to Day 10 in the TPRP group than in the TA group ($p < 0.001$ for each) (Table 4; Fig. 4).

In both groups, there was a significant gradual decrease in the number of analgesics needed starting from postoperative Day 3 with a decrease from 1.78 ± 0.83 on Day 3 to 0.00 ± 0.00 on Day 10 in the TPRP group and from 3.53 ± 0.60 on Day 3 to 0.45 ± 0.81 on Day 10 in the TA group ($p < 0.001$ for each) (Table 4; Fig. 4).

Table 3 Post-operative appetite status

	TPRP ($n=40$)			TA ($n=40$)			p value[1] TPRP vs. TA
	Appetite			Appetite			
	Fair	Moderate	Poor	Fair	Moderate	Poor	
Postoperative							
Day 1	5 (12.5)	23 (57.5)	12 (30.0)	1 (2.5)	9 (22.5)	30 (75.0)	**0.001**
Day 2	7 (17.5)	23 (57.5)	10 (25.0)	0 (0.0)	14 (35.0)	26 (65.0)	**0.001**
Day 3	20 (50.0)[a,b]	18 (45.0)	2 (5.0)	3 (7.5)[a,b]	21 (52.5)	16 (40.0)	**0.001**
Day 4	27 (67.5) [a,b]	13 (32.5)	0 (0.0)	5 (12.5)[a,b]	27 (67.5)	8 (20.0)	**0.001**
Day 5	30 (75.0) [a,b]	10 (25.0)	0 (0.0)	12 (30.0)[a,b,c]	21 (52.5)	7 (17.5)	**0.001**
Day 6	35 (87.5) [a,b,c]	5 (12.5)	0 (0.0)	21 (52.5)[a,b,c,d,e]	17 (42.5)	2 (5.0)	**0.001**
Day 7	37 (92.5) [a,b,c]	3 (7.5)	0 (0.0)	29 (72.5)[a,b,c,d,e]	9 (22.5)	2 (5.0)	0.017
p value[2]	**0.001**			**0.001**			

Statistically significant values are in bold

a compared to Day 1, *b* compared to Day 2, *c* compared to Day 3, *d* compared to Day 4, *e* compared to Day 5

[1]The comparisons between PRP treatment and tonsillectomy groups, Mann–Whitney *U* test, according to Bonferroni Correction with $p<0.0071$ considered statistically significant

[2]The comparisons between follow-up times within each study group, Wilcoxon Sign Rank test, according to Bonferroni Correction with $p<0.0012$ considered statistically significant

Table 4 Number of additional analgesics in both study groups and follow-up times

	Number of additional analgesics,		p value[1]
	TPRP ($n=40$) mean ± SD	TA ($n=40$) mean ± SD	
Postoperative			
Day 1	2.73 ± 0.75	3.83 ± 0.38	**0.001**
Day 2	2.43 ± 0.71	3.85 ± 0.36	**0.001**
Day 3	1.78 ± 0.83[a,b]	3.53 ± 0.60[a]	**0.001**
Day 4	1.18 ± 0.68[a,b,c]	3.25 ± 0.63[a,b]	**0.001**
Day 5	0.88 ± 0.69[a,b,c]	2.88 ± 0.61[a,b,c]	**0.001**
Day 6	0.68 ± 0.69[a,b,c,d]	2.58 ± 0.87[a,b,c,d]	**0.001**
Day 7	0.38 ± 0.49[a,b,c,d,e,f]	2.08 ± 1.10[a,b,c,d,e,f]	**0.001**
Day 8	0.18 ± 0.38[a,b,c,d,e,f]	1.50 ± 1.09[a,b,c,d,e,f,g]	**0.001**
Day 9	0.10 ± 0.30[a,b,c,d,e,f]	1.00 ± 0.99[a,b,c,d,e,f,g]	**0.001**
Day 10	0.00 ± 0.00[a,b,c,d,e,f,g]	0.45 ± 0.81[a,b,c,d,e,f,g,h]	**0.001**
p value[2]	**0.001**	**0.001**	

Statistically significant values are in bold

a compared to Day 1, *b* compared to Day 2, *c* compared to Day 3, *d* compared to Day 4, *e* compared to Day 5, *f* compared to Day 6, *g* compared to Day 7, *h* compared to Day 8 ($p<0.00056$)

[1]The comparisons between PRP treatment and tonsillectomy groups, Mann–Whitney *U* test, according to Bonferroni Correction $p<0.005$ was considered statistically significant

[2]The comparisons between follow-up times within each study group, Wilcoxon Sign Rank test, according to Bonferroni Correction with $p<0.025$ considered statistically significant

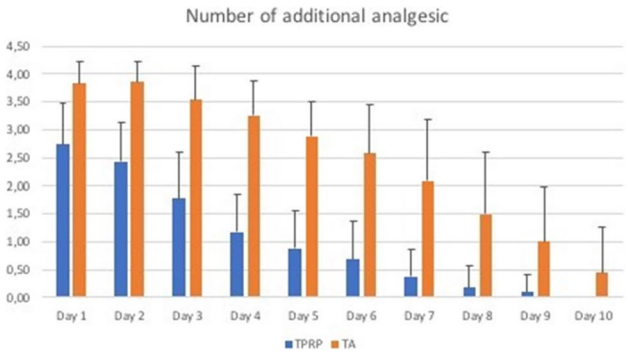

Fig. 4 The analgesia requirement in the tonsillectomy plus PRP and tonsillectomy alone groups

Postoperative bleeding complications

No bleeding was occurred in the TPRP group in the early and late term.

Mild bleeding occurred in two patients on postoperative 7th and 9th days. Bleeding control was provided with ice-cooling method in one patient, and with bipolar cautery in one patient.

Discussion

The findings of this study of a cohort of pediatric tonsillectomy patients revealed a significant improvement in pain scores and appetite status together with a gradual decrease in the analgesia requirement from the early postoperative

period to 7–10 days in both the TA and TPRP groups. More favorable outcomes in terms of postoperative pain, appetite, analgesia requirement and bleeding risk during the entire postoperative period were observed in the TPRP group.

Data from this TA group are consistent with the natural course of postoperative tonsillectomy pain which follows a gradual decline during the first postoperative week and a more rapid decline after this period [12]. Persistent and severe post-tonsillectomy pain has been associated with the likelihood of complications such as poor oral intake and dehydration, morbidity and delayed recovery [21, 29]. Better control of post-tonsillectomy pain in the TPRP group during the entire period of 10-day follow-up seems notable in this regard emphasizing the potential role of PRP as an adjunct therapy to aid faster postoperative recovery [30].

In a previous study of pain and behavior changes in children following elective surgery, it was noted that 73% of the children (aged 2–12) exhibited peak incidence of pain and problematic behavior on day 2 after hospital discharge [31]. Given the significant reduction in postoperative pain and increase in appetite scores in each group in the current study by the 3rd postoperative day, the superiority of PRP over TA in terms of pain control and appetite from the first postoperative day seems important in this regard, emphasizing the likelihood of better long-term functional outcomes and higher patient and family satisfaction [30].

Previous studies on the effectiveness of PRP on post-tonsillectomy pain have revealed inconsistent findings with the amelioration of postoperative pain starting from day 1 to day 3 with the application of PRP in a study of adult patients [14], the prevention of hemorrhage and pharyngeal pain attenuation after tonsillectomy with PRP in another study [26], and no significant difference in the pain scale between PRP patients and control patients in a pediatric study with a high dropout rate (17.1%) [25]. Additionally, it was suggested that repetitive applications of the PRP may reduce the postoperative pain [25]. On the hand, the pressure on the PRP matrix may lead to stabilization of the matrix on the tonsil bed and the increased surface area of the matrix may prevent irritation of the wound by the saliva. Decreased irritation may be the reason of the lower pain scores in the TPRP group in current study. Beside this, we observed no dropout of the PRP matrix.

In a study of 40 adult tonsillectomy patients, the effectiveness of PRP applied to the tonsillar bed (test side vs. control side in the same patient) was investigated, and PRP applied immediately after tonsillectomy on the tonsil bed was shown to accelerate the healing process and to decrease postoperative pain and analgesia requirement, together with a potential role in decreasing the incidence of bleeding [14].

In another study comparing a PRP group (80 tonsillar niches) with a control group (110 tonsillar niches), a lower risk of hemorrhage (none in PRP, nine cases in control) and less severe pain was reported after local use of PRP, and thus the use of PRP in the region of the postoperative wound was stated to be effective in the prevention of hemorrhage and pharyngeal pain attenuation after tonsillectomy [26].

However, in a study of 70 pediatric patients, PRP application was reported to have no impact on postoperative pain or recovery in terms of medication use, days to normal diet, and follow-up visits compared to the control group [25].

The findings of this study revealed more effective pain control and a lower requirement for analgesia in the TPRP patients than in the TA group throughout the entire 10-day follow up, together with more favorable appetite status in the TPRP group within the first 6 postoperative days. Postoperative bleeding was observed similar in the postoperative 0–3 days in each group. On the other hand, late-term bleeding was only occurred in the TA group and this situation may be associated with the rapid wound healing effect of the PRP on the tonsillar beds. The potential role of PRP in reducing the risk of post-tonsillectomy bleeding in this cohort seems important given that hemorrhage after tonsillectomy is considered to be the most reported (range 2–9%) and potentially dramatic complication of tonsillectomy [32].

Therefore, these findings emphasize the potential role of PRP in the amelioration of post-tonsillectomy pain, improvement of appetite status and reduction of postoperative analgesia need and bleeding risk in pediatric tonsillectomy patients. This seems notable given that PRP is a completely safe product, prepared via collection and concentration of the patient's own blood, and then immediately applied to the tonsil bed to accelerate the healing process [14].

Conclusions

In conclusion, this study in pediatric tonsillectomy patients revealed the superiority of tonsillectomy with PRP over tonsillectomy alone in terms of the effect in reducing post-tonsillectomy pain and improving appetite status, together with a lower requirement for analgesia and a reduced risk of post-tonsillectomy bleeding during the first 10 postoperative days. There is a need for further larger scale studies addressing the use of PRP in tonsillectomy patients with different operation techniques and in different age groups to confirm the potential utility of PRP as an adjunct therapy in post-tonsillectomy pain management and wound healing.

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Compliance with ethical standards

Conflict of interest The authors do not have any commercial or other association that might pose a conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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