Intra-Operative Purabond Haemostats: A Comparative Trial in Adult Tonsillectomy

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BACKGROUND

Tonsillectomy is one of the most common surgical procedures and accounts for 17% of elective workload. Despite it forming a large part of early surgical training amongst juniors, primary and secondary bleed rates carry significant morbidity and mortality. The national GIRFT study identified an adult tonsillectomy readmission rate of 18.4% with bleeding readmissions at 13.0%.

It has been well documented that the use of electrocautery increases secondary bleed rates following tonsillectomy in both adult and paediatric populations, with significant reductions noted in the studies evaluating the efficacy of intra-capsular coblation tonsillectomy. However, post-operative outcome analysis still dictates that extracapsular dissection is required in those with recurrent infective tonsillitis.

Intra-operative or post-operative tranexamic acid has been considered as potential solutions to reduce adult bleed rates, and level 5 evidence demonstrates the benefit of intra-operative pillar suturing in preventing post-tonsillectomy haemorrhage. However, such measures can post coagulopathic or intra-oral complications. More recently, the use of topical haemostats have been considered as a safe alternative.

Purabond is a synthetic matrix delivered in a pre-filled syringe with no required preparation time with studies confirming sufficient haemostasis within 15 seconds of topical application. Whilst its application has been well documented in vascular surgery, the role of Purabond in adult tonsillectomy has yet to be evaluated.

METHODS

Our single-centre, retrospective study compares the readmission, pain and bleeding rates of adult tonsillectomy with and without the use of intra-operative PuraBond. Between March 2019 – February 2020, 164 adult tonsillectomy cases were analysed and compared with a trial study of 21 adult tonsillectomies with intra-operative PuraBond. The haemostat was applied at the final point of surgery with no change in intra-operative haemostasis from usual clinical practice. This study was approved by departmental and clinical governance leads. Patients were consented to receive adequate management of intra-operative haemorrhage with topical, electrocautery or suturing modalities as required and were blinded to whether they received the topical haemostat.

DEMOGRAPHICS

	WITHOUT PURABOND	WITH PURABOND
TOTAL CASES	164	21
AVERAGE AGE	32	23.3
FEMALE	111 (67.7%)	18 (85.7%)
DAY CASE	151 (92.1%)	21 (100%)

INDICATIONS

	WITHOUT PURABOND	WITH PURABOND
HISTOLOGY	57 (34.8%)	1 (4.8%)
TONSILLITIS	101 (61.6%)	17 (81.0%)
QUINSY	4 (2.4%)	3 (14.3%)
OBSTRUCTIVE SLEEP APNOEA	2 (1.2%)	0

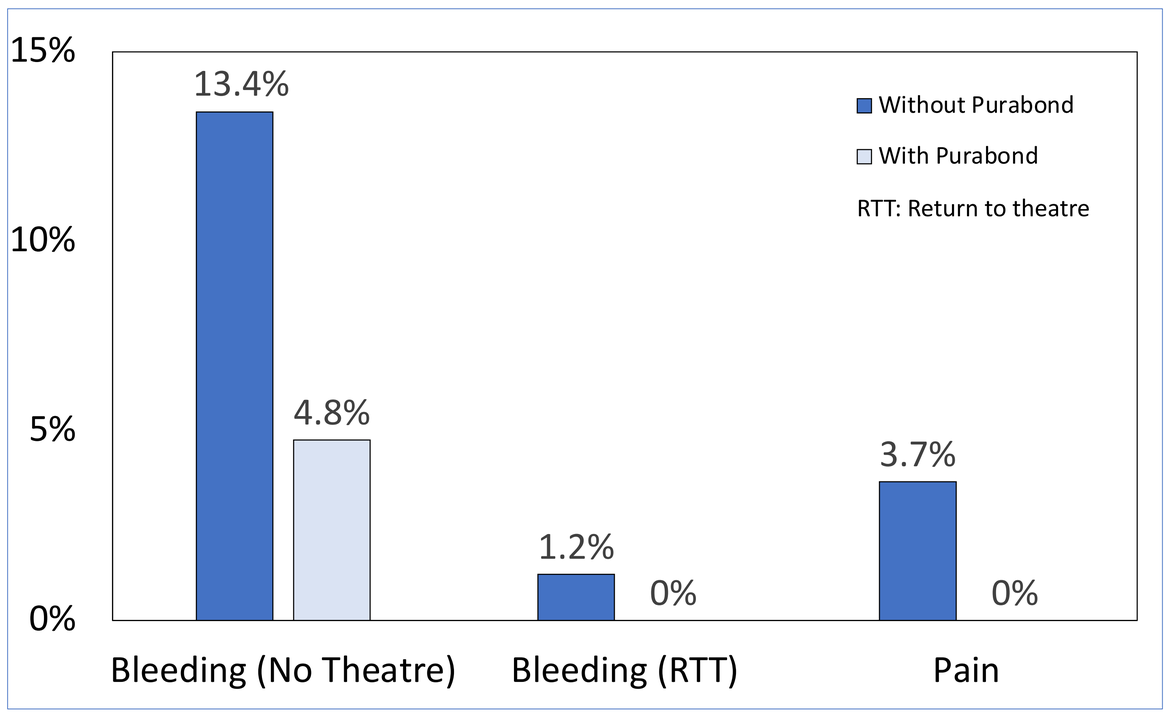
RESULTS

Data was collected as a collaborative effort amongst authors with secondary evaluators recruited to confirm reliability. Analysis was performed on Microsoft Excel 2010 with data stored in accordance with local trust information governance policy.

Preliminary results demonstrated a readmission rate of 4.8% and 18.9% for with and without PuraBond adult tonsillectomies respectively. 100% of these readmissions were due to bleeding in the PuraBond cohort, with no patients requiring a return to theatre. Conversely, 77.4% of the without PuraBond readmissions were due to bleeding with just 2 readmissions (6.5%) requiring a return to theatre. The remaining readmissions were secondary to pain.

Secondary haemorrhage was seen in 14.6% patients (1.2% requiring theatre) without Purabond and 4.8% patients with Purabond application.

RESULTS



DISCUSSION

Our study identifies a benefit from intra-operative Purabond application to the tonsillar bed by means of reduced bleed rate and need for surgical intervention as well as reduced readmission rates for post-operative pain.

Limitations to this study include a small sample size in our treatment arm and variable operator technique and ability. This data was not collected and therefore may show differences between each cohort.

Furthermore, it's important to recognise that post-operative pain is depending not only on surgical technique but the type and frequency of analgesics used outside of the hospital setting.

CONCLUSION

This study demonstrates the benefit of Purabond as a means of reducing secondary haemorrhage and readmission for pain relief in adults undergoing tonsillectomy. Further data sampling is requiring to strengthen our data with additional analysis of post-operative pain between cohorts.

REFERENCES

Marshall A (2019) Ear, Nose & Throat Surgery – GIRFT Programme National Specialty Report
Fonseca (2018) Am J Otolaryngol. 39; 445-47 – Effect of changing post-operative pain management on bleeding rates in tonsillectomy patients
Mitchell R (2016) Otolaryngol Clin North Am. 49; 615-26 – Hemostasis in tonsillectomy
Li B et al., (2022) Laryngoscopy Investig Otolaryngol. 23; 1204-16 – Can intraoperative suturing reduce the incidence of post-tonsillectomy haemorrhage? A systematic review and meta-analysis
Morshuis M, Final Clinical Study Report: A Single-Centre, Single Arm Post-Market Clinical Follow-Up to Confirm the Safety and Performance of PuraStat Absorbable Haemostatic Material for the Management of Bleeding After Left Ventricular Assist Device (LVAD) Implantation