



Rates of post-tonsillectomy haemorrhage between BiZact™ and bipolar tonsillectomy – a retrospective study

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Background: Tonsillectomy is a common procedure indicated in patients with recurrent tonsillitis or more commonly sleep-disordered breathing. Patient re-presentations to healthcare facilities occur due to complications such as pain, dehydration, and bleeding. Minimising these complications can significantly reduce the strain on local healthcare centres. The study identifies and compares the incidence of post-tonsillectomy haemorrhage (PTH) between BiZact™, a novel tonsillectomy device, and the traditional bipolar tonsillectomy.

Methods: A retrospective single surgeon cohort study of PTH between two tonsillectomy devices was performed during 2018–2022. A historical chart review of emergency department PTH re-presentations in Far North Queensland was correlated with the corresponding surgeon and tonsillectomy method. The severity of PTH was graded by the Stammberger classification. Patients of all ages receiving bilateral tonsillectomies were included in the study, however, tonsil biopsies and unilateral tonsillectomies were excluded. A two-tailed Fisher exact test was performed to identify differences in the PTH rates. All analyses used R version 4.2.1.

Results: In a study of 1,356 patients, the BiZact™ tonsillectomy technique showed a lower likelihood of PTH than the bipolar diathermy technique [P=0.04, odds ratio (OR) 0.64, 95% confidence interval (CI): 0.40–1.00]. The BiZact™ group had significantly reduced rates of secondary haemorrhage (P=0.003, OR 0.42, 95% CI: 0.23–0.76), and no cases of primary haemorrhage were reported. There was no significant difference in the timing of bleeding events between the two techniques. BiZact™ tonsillectomy also had a significantly lower rate of patients returning to theatre than bipolar tonsillectomy (P=0.02, OR 0.17, 95% CI: 0.02–0.85).

Conclusions: The BiZact™ tonsillectomy technique has become increasingly popular due to its ease of use and efficiency. Our study demonstrates a significant decrease in hospital readmissions, PTH, and the need for returning to the operating room, particularly among adult patients who undergo BiZact™ tonsillectomy.

Keywords: BiZact™ tonsillectomy; bipolar tonsillectomy; tonsillectomy; post-tonsillectomy haemorrhage (PTH)

Received: 14 June 2023; Accepted: 08 December 2023; Published online: 19 February 2024.

doi: 10.21037/ajo-23-25

View this article at: <https://dx.doi.org/10.21037/ajo-23-25>

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Introduction

Otolaryngologists strive to discover the optimal tonsillectomy technique. Traditional “cold dissections” (CD) methods involve using instruments to dissect palatine tonsils and ligating vessels with suture ties. In contrast, “hot dissection” (HD) methods employ electrocautery diathermy to remove tonsils while simultaneously providing haemostatic control. HD techniques have demonstrated advantages such as shorter operating times and lower intraoperative blood loss. Many studies argue that hot methods increase the risk of post-tonsillectomy haemorrhage (PTH) (1).

The BiZact™ tonsillectomy represents a novel approach to HD tonsillectomies. Developed by Medtronic (Mansfield, Massachusetts, USA), this innovative tissue-sealing device has gained attention for its marketed capabilities in reducing intraoperative bleeding and collateral thermal spread (TS). The BiZact™ features a trigger handle with opposing forcep tips that form a 3 mm soft tissue seal. A tissue-impedance feedback mechanism ensures the precise delivery of bipolar energy through clamped tissue (2). The energy delivered is derived from an algorithm within the diathermy unit. The design is based on the commonly used LigaSure™ (Mansfield, Massachusetts, USA) technology but features a curved jaw to facilitate easier access into the tonsillar bed. In contrast, traditional bipolar cautery utilises a fixed frequency and amplitude of electrical energy across two proximal electrodes forcep tips, to coagulate grasped tissue. The surgeon may adjust the distance between each bipolar electrode to provide various degrees of heat and coagulation to the clamped tissue. LigaSure™ sealing technology has been shown to cause less collateral thermal damage than bipolar cauterisation methods (3,4). The BiZact™ tonsillectomy is a safe method, with short operating times and a shallow learning curve (5). A surgeon’s familiarity with the BiZact™ device can directly influence surgical performance, with one study suggesting a plateaued learning curve after the 9th BiZact™ tonsillectomy (5,6). Technical advantages of bipolar diathermy include touch coagulation with precise haemostatic control, improved surgical visibility, and adjustable power settings between 10–40 W. Although some studies on BiZact™ have demonstrated comparable rates of PTH to other ‘hot’ techniques, it comes at a significantly higher cost compared to traditional bipolar devices and without a proven reduction in patient morbidity (7-9).

This study identifies and addresses the factors influencing PTH rates between BiZact™ and conventional bipolar tonsillectomies. We present this article in accordance with

the STROBE reporting checklist (available at <https://www.theajo.com/article/view/10.21037/ajo-23-25/rc>).

Methods

A single surgeon historical cohort study, examining 1,356 patients who underwent tonsillectomy procedures between January 2018 to December 2022 was conducted. In November 2020, the single surgeon who possesses dual fellowships in Otolaryngology from both the United Kingdom and Australia, and with a decade of consultant experience, underwent a complete practice transition. The transformation involved shifting from bipolar diathermy to BiZact™ tonsillectomies. The study separated the cohort into two groups. The bipolar group comprised of 551 patients who underwent bipolar tonsillectomies, between January 2018 to October 2020. The second, BiZact™ group comprised of 805 patients who underwent BiZact™ tonsillectomies, between November 2020 to December 2022. *Figure 1* presents a flowchart of the selection process.

The standard operative approach to the tonsillectomies is described as follows. Upon insertion of the Boyle Davis gag, the tonsil is retracted medially with a Denis Browne forcep. The superior mucosa is divided at the demarcated lateral tonsil with the BiZact device. The extracapsular plane is identified, and the tonsil is dissected within this plane in a superior to inferior manner. For a robust seal, minimal retraction is applied to the tonsil during clamping and coagulation to ensure adequate tissue bulk is present between the jaws of the device. Bipolar tonsillectomy is performed in a similar manner. The routine power setting is 12 W. At the end of the case, the tonsillar fossa is cooled with normal saline. Prophylactic antibiotics and tranexamic acid (in over 16 years old’s) were routinely administered. Post-operative care included paracetamol, ibuprofen, oxycodone and a full diet.

Ethical grant

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics board of Far North Queensland Human Ethics and Research Committee (QCH/90239). The individual consent for this retrospective analysis was waived.

Inclusion criteria

All patients who underwent a tonsillectomy, including

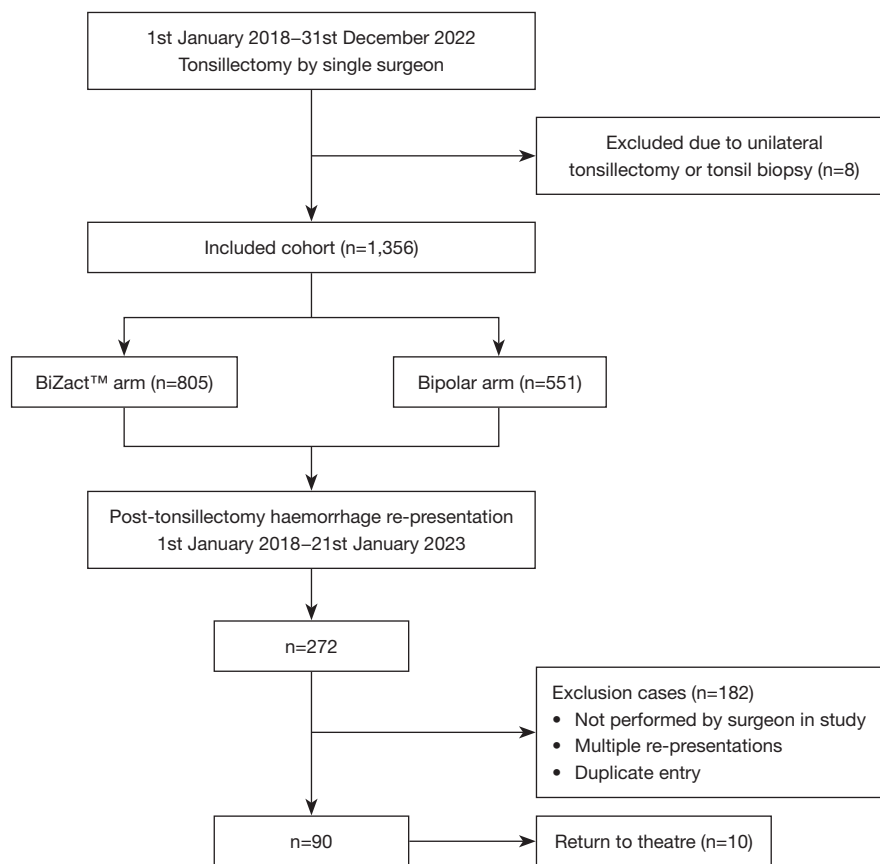


Figure 1 Flow chart of tonsillectomy and post-tonsillectomy haemorrhage selection and identification.

adenotonsillectomy, adenotonsillectomy and grommets, panendoscopy and tonsillectomy, and uvulopalatopharyngoplasty were included, regardless of indication.

Exclusion criteria

Surgical cases of unilateral tonsillectomy and tonsil biopsies were excluded due to oncological considerations such as wider margins or incisional biopsies. Cases of repeat presentation to healthcare facilities or return to theatres were excluded from the PTH data set. In these instances, only the first bleeding event or return to theatre event was included in the final analysis.

Data collection

To conduct a comprehensive analysis, SNOMED (Systematized Nomenclature of Medicine) and the Emergency Department Information System (EDIS) were utilised to gather data on post-tonsillectomy re-

presentations to healthcare facilities within the Cairns and Hinterland Health Service. An electronic database was created, compiling information on these re-presentations. A separate database was established to track the tonsillectomy procedures performed by the surgeon between 2018 and 2022. This database was generated by retrieving the tonsillectomy operative coding database during the specified time period. The patients from the surgical database were then cross-matched with the post-tonsillectomy re-presentations data to ensure accuracy and consistency.

Various independent variables were extracted from the patient’s electronic medical record, such as the method of tonsillectomy, age, gender, Stammberger bleeding classification (10), day of tonsil bleed and whether a theatre takeback was required.

Sample size

The calculations of sample size were based on previous PTH rates in bipolar tonsillectomy (11) and BiZact™

tonsillectomy (9). Using these probabilities, power calculations were conducted using G*Power software, with $\beta=0.1$ and $\alpha=0.05$. The calculations suggested a minimum sample size of 1,212 patients to provide adequate statistical power for a Fisher's Exact Test.

Statistics

The null hypothesis proposes no difference in PTH rates between bipolar and BiZact™ tonsillectomies. Significance was defined as $P<0.05$. A two-tailed Fisher's Exact Test was used to compare the incidence of PTH re-presentations between the two groups, unadjusted for covariates. This analysis was repeated excluding patients with Stammberger A1 bleeds (no clinical evidence of coagulum). A logistic regression model was used to provide estimates of bleeding incidence adjusted for demographic attributes and to

examine potential interactions between operative techniques and demographic attributes. All analyses used R version 4.2.1 (12).

Results

Out of the 1,356 patients who underwent a tonsillectomy procedure, there were 551 cases performed using the bipolar diathermy technique cases and 805 cases performed with the BiZact™ tonsillectomy technique. *Table 1* presents the baseline descriptive statistics for the cohort populations. The rates of post-tonsillectomy bleeds were compared using the Fisher Exact Test. The results are summarised in *Table 2*. BiZact™ group was much less likely to result in a hospital presentation with a post-tonsillectomy bleed [$P=0.04$, odds ratio (OR) 0.64, 95% confidence interval (CI): 0.40–1.0]. When Stammberger A1 events were excluded, the difference between the two groups was even more pronounced. The BiZact™ group demonstrated significantly reduced rates of clinical bleeds ($P=0.003$, OR 0.42, 95% CI: 0.23–0.76). It is worth noting that there were no reported cases of primary haemorrhage (haemorrhage event less than 24 hours from surgery), while the overall primary haemorrhage rate was 1.6% ($n=2$).

There was no significant difference in the mean interval from the operation to the bleeding event between BiZact™ and bipolar cases, 7.7 and 7.3 days respectively ($P=0.70$). The results are illustrated in *Table 2*. Duration until a bleeding event was not affected by the type of surgery performed ($P=0.69$), gender ($P=0.46$) or age group ($P=0.09$).

To account for the covariates (age and gender), logistic regression was performed. As the effect of age was non-linear, the patients were grouped into three categories: children (ages <10 years), adolescents (ages 10–19 years), and adults (ages >19 years) (13). The sample sizes in each sex-age group combination are shown in *Table 1*.

The PTH (> Stammberger A1 events) adjusted by age and gender showed a significant 3-way interaction ($P=0.02$).

Table 1 Descriptive statistics of study cohort

Variables	Bipolar	BiZact™
Age, mean [range], years	13.3 [2–61]	13.0 [1–46]
Age groups, years		
Children <10	295 (54%)	456 (57%)
Adolescent 10–19	111 (20%)	187 (23%)
Adult >19	145 (26%)	162 (20%)
Male distribution	n=245	n=423
Children	155	274
Adolescent	36	85
Adult	54	64
Female distribution	n=306	n=382
Children	140	182
Adolescent	75	102
Adult	91	98

Table 2 Fisher exact test of post-tonsillectomy complications

Variables	BiZact™ (n=805)	Bipolar (n=551)	P value	OR (95% CI)
Re-presentation to hospital with bleed	5.3% (n=43)	8.2% (n=45)	0.04	0.64 (0.40–1.00)
> Stammberger A1 bleeding events	2.6% (n=21)	6.0% (n=33)	0.003	0.42 (0.23–0.76)
Return to theatre	0.2% (n=2)	1.5% (n=8)	0.02	0.17 (0.02–0.85)
Mean time to bleed in days	7.7	7.3	0.70	–

OR, odds ratio; CI, confidence interval.

Table 3 Analysis of deviance of the logistic regression adjusting for demographic attributes and potential interactions (Type 2 tests), and excluding Stammberger A1 events

Variables	LR Chi sq	dF	P value
Surgery	9.69	1	0.002**
Age group	11.26	2	0.004**
Gender	2.71	1	0.10
Surgery: age group	5.47	2	0.06
Surgery: gender	0.67	1	0.41
Age group: gender	2.54	2	0.28
Surgery: age group: gender	7.74	2	0.02*

*, P<0.05; **, P<0.01. LR, Likelihood ratio; Chi sq, Chi-square; dF, degrees of freedom.

Table 4 Percentage of > Stammberger A1 bleeds separated by age group and gender

Variables	Male (%)		Female (%)	
	BiZact™	Bipolar	BiZact™	Bipolar
Children <10 years	2.6	2.6	1.1	4.3
Adolescent 10–19 years	9.4	5.6	1.0	4.0
Adult >19 years	0.0	16.7	3.1	10.0

The various interactions between variables are shown in *Table 3*.

In the bipolar group, the adults were the highest risk group. Females across all age groups, particularly adults, experienced a reduction in bleeding risk with BiZact™ tonsillectomy. In males, the largest difference was observed in adults where no adult males in the BiZact™ group represented with a clinical bleed, despite a comparatively similar population size as the adults in the bipolar group (64 vs. 54 patients respectively). Adult males appeared to benefit the most from BiZact™ tonsillectomies. The results from the complex interactions are summarised in *Table 4*.

The same analysis was applied to the rate of patients requiring a return to theatre. Although the incidence of return to theatre was low in all groups, BiZact™ tonsillectomy demonstrated a significantly lower proportion of patients needing a return to theatre compared to bipolar tonsillectomy (P=0.02, OR 0.17, 95% CI: 0.02–0.85). Moreover, the benefit of BiZact™ appeared to be greater in adults than in younger age groups: in this case, the interaction did not achieve statistical significance (P=0.09).

Discussion

PTH

A multitude of tonsillectomy techniques have been introduced with variable success. In the United Kingdom, a landmark National Prospective Tonsillectomy Audit highlighted HD as a risk factor for increased rates of PTH and levels of post-operative pain compared to CD (1,14-17). In Australia, there is no standardised technique and a combination of hot and cold techniques are often used, with a preference for monopolar diathermy in many institutions (18,19). With over 50,000 cases of tonsillectomies performed annually in Australia, even a small improvement in post-operative morbidity can have a significant impact on public health. The Australian national average of PTH has been stable over the decades but new data has shown a steady increase in adult populations (20).

In regional Far North Queensland, bipolar tonsillectomy and BiZact™ techniques are favoured. Initial smaller studies in South Australia, demonstrated the safety profile of BiZact™ (8), with a PTH rate of 4.3% comparable to a 2009 meta-analysis of 4,610 tonsillectomy papers citing an average PTH rate of 4.5% (21). Numerous papers have favoured traditional HD methods, such as monopolar diathermy, bipolar diathermy, harmonic scalpel and coblation tonsillectomy, demonstrating equivalent morbidity to CD and while concurrently decreasing operative time and intraoperative bleeding (22-26). A randomised control trial demonstrated reduced PTH rates with monopolar diathermy compared to CD (27). Another randomised control trial favoured BiZact™ over CD technique, reporting faster operative times, reduced bleeding and reduced day 1 and 3 pain scores (28). The debate between coblation and bipolar tonsillectomy has also been ongoing, with a meta-analysis showing no significant difference in PTH rates between the two techniques (29). However, a large retrospective analysis of 1,384 patients identified a reduced incidence of return to theatre with BiZact™ compared to coblation, 2.5% and 4.7% respectively (9).

This study is the first of its kind comparing bipolar with BiZact™ tonsillectomy PTH rates. Our study identified significantly lower PTH and return to theatre rates in BiZact™ tonsillectomy compared to other methods in the existing literature. Primary haemorrhage is classified as a bleeding event within 24 hours, these cases are rare and occur between 0.1–1.5% of tonsillectomies (7,14,30). Primary haemorrhage is often accompanied by a low threshold to return to theatre. Our study identified an

overall primary PTH rate of 0.16% with no cases seen in the BiZact™ group, which is lower than data from the National Tonsil Surgery Registry in Sweden which cites an incidence of 0.96% (31). Our BiZact™ return to theatre rate was 0.25% which is also lower than the national Australian average return to theatre rate of 1.63% (20).

Factors other than surgical techniques that increase morbidity include older patients, male patient gender and limited surgeon experience (7,20,31,32). This is consistent with our study where adult males who underwent bipolar tonsillectomy had the highest risk of bleeding. In our study, the surgeon had an advantageous familiarity with bipolar forceps throughout his career and underwent a learning period with BiZact™ during the referenced study time frame. Despite these setbacks, BiZact™ still outperformed bipolar tonsillectomy from a PTH reduction point of view.

Mechanical differences between BiZact™ and bipolar tonsillectomy

The BiZact™ device is designed to mitigate TS, leading to a reduction in pain and improved haemostatic control. Elevated levels of postoperative pain may stem from inadvertent injury to nearby soft tissue structures from TS. The severity of TS is classified by the lateral extent of histological soft tissue denaturing, which is seen when soft tissue is exposed to temperatures over 42 degrees. Variable degrees of TS can be appreciated depending on the device, as a result, the optimal device achieves a balance between thermal injury and haemostasis (33). Depending on the type of LigaSure™ device, lateral injury from TS can range from 0.9–2.7 mm (34–38). Newer surgical devices focus on reducing lateral TS in nerve-sparing operations, such as thyroidectomies or parotidectomies. LigaSure™ devices generate the least heat in short and sustained bursts compared to both monopolar and bipolar diathermy techniques.

Bipolar electrocautery seals by compressing vessels and producing a proximal thrombus, whereas the BiZact™ creates a translucent seal of denatured proteins (34). There is a paucity of research on the effects of TS in tonsillectomies. *Ex-vivo* tonsil capsule studies show branching vessels within 1 mm of the capsular plane to be smaller than $133.6 \pm 78.6 \mu\text{m}$ in diameter (39). Considering specimen shrinkage, adequate haemostasis of intracapsular vessels of this calibre is attainable by both BiZact™ and the bipolar devices. Clinically, animal studies have demonstrated improved haemostatic control and reduced TS with LigaSure™

devices compared to bipolar electrocautery (40). Human studies on bipolar electrocautery TS are non-existent likely due to a lack of standardisation in cauterisation variables such as timing, pressure and voltage applied. In addition, most bipolar electrocautery tonsillectomies are performed between 5–20 watts whereas most existing literature on bipolars are performed above 20 watts. The maximum temperatures reached in all devices are similar, but LigaSure™ devices consistently outperform 20–40 watts bipolar electrocautery in the time taken to cool (41). Methods to reduce TS include saline irrigation and heat sinks, with irrigation being the more feasible option and is also routinely performed by our surgeon during tonsillectomies (42). There is an argument for the preferential use of BiZact™ and other LigaSure™ devices over bipolar electrocautery from a thermal injury perspective.

Costs

BiZact™ devices have not achieved mainstream adoption in the public sector due to high inventory costs. The cost of each BiZact™ unit is \$275 AUD, which is considerably more expensive than \$30 AUD bipolar forceps (43). Bipolar tonsillectomies average 15–20 minutes of operative time (44–46). In comparison, BiZact™ tonsillectomies are faster, with operative times averaging between 4–7.5 minutes (5,8,28). Currently, the elective operating theatres in Australia cost \$42 AUD per minute (47). Once the runnings costs of an operating room is considered, the slower bipolar device may be more expensive for the healthcare system.

There is a growing demand for inpatient care in Australia, with presentations to the emergency department (ED) increasing by 6.9% year over year (48). Post-tonsillectomy morbidity poses a strain on bed availability and available resources. The average cost of an emergency department re-presentation from tonsillectomy complications is \$1,420 USD or \$2,055 AUD, as such a small reduction of morbidity from changing tonsillectomy practises may have drastic implications (49). Hospital administration should look beyond the immediate equipment expenses to appreciate the potential overall cost savings.

Limitations

Existing data on PTH is often limited by researcher interobserver variability and a lack of standardised definitions. In our retrospective study, we relied on well-documented clinical re-presentations of our patients in the

emergency department. Still, some re-presentations may have been missed if patients sought healthcare providers outside our audited healthcare district. BiZact™ device occasionally cannot achieve full haemostasis, and, in these instances, bipolar diathermy may have been additionally utilised intraoperatively by our surgeon. The final study limitation includes the fact that this is a single-surgeon study. Although a single-surgeon study provides consistent results, the experience, volume of practice and learning curve may differ between surgeons. The learning curve and proficiency of our single surgeon with BiZact™ may not be reflected in trainees nor across other surgeons. A multi-surgeon and multi-institution prospective trial may provide better insight into confirming the study results.

Conclusions

BiZact™ tonsillectomy has been gaining popularity over recent years due to its ease of use and speed. The null hypothesis is rejected at the 5% significance level, and we show that BiZact™ tonsillectomies result in a reduction in hospital re-presentations, PTH and return to theatres, especially in adults. Further studies on the cost-benefit analysis of the BiZact™ device are required for mainstream adoption.

Acknowledgments

Our sincere gratitude to the Emergency Departments of Cairns and Hinterland Health Service for not only providing the dataset required for this study but for their ongoing care and dedication to the management of post-operative otolaryngology patients across regional Far North Queensland.

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <https://www.theajo.com/article/view/10.21037/ajo-23-25/rc>

Data Sharing Statement: Available at <https://www.theajo.com/article/view/10.21037/ajo-23-25/dss>

Peer Review File: Available at <https://www.theajo.com/article/view/10.21037/ajo-23-25/prf>

Conflicts of Interest: All authors have completed the ICMJE

uniform disclosure form (available at <https://www.theajo.com/article/view/10.21037/ajo-23-25/coif>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics board of Far North Queensland Human Ethics and Research Committee (QCH/90239). The individual consent for this retrospective analysis was waived.

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doi: 10.21037/ajo-23-25

Cite this article as: Chuang F, Jones R, Quail G, Whitfield B, Ahluwalia S. Rates of post-tonsillectomy haemorrhage between BiZact™ and bipolar tonsillectomy—a retrospective study. *Aust J Otolaryngol* 2024;7:5.