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The use of preoperative haemostasis and ABO blood typing tests in children: A retrospective observational study using a nationwide claims database

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Manuscripts

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3 **The use of preoperative haemostasis and ABO blood typing tests in children: A**
4 **retrospective observational study using a nationwide claims database**
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ABSTRACT

Objectives: To describe the prevalence and factors associated with preoperative haemostasis and ABO blood typing tests for children.

Design: A retrospective observational study.

Setting: Nationwide insurance claims database in Japan

Participants: Patients aged 1–17 years who underwent common paediatric surgeries between April 2012 and March 2018 were included. Patients with high-risk comorbidities for bleeding (n=175) and those with multiple eligible surgeries were excluded (n=2,121).

Main outcome measures: We described the proportions of each preoperative test performed within 60 days before an index surgery, including platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests. We also explored the associations between patient- and institutional-level factors and any preoperative tests, using multilevel logistic regression analysis.

Results: We included 13,018 patients (median [interquartile range] age, 5.2 [2.9–7.7] years; 8,276 [63.6%] boys) from 1,499 institutions. The overall proportion of each test was as follows: platelet count, 78.6%; PT, 54.4%; aPTT, 56.4%; and ABO blood typing tests, 50.4%. The proportion of patients undergoing any preoperative tests in the overall sample was 79.3%. Multilevel logistic regression analysis indicated that preoperative tests were associated with type of anaesthesia (general anaesthesia: adjusted OR, 7.06; 95% confidence interval [CI], 4.94–10.11), type of surgery (tonsillectomy: adjusted OR, 3.45; 95% CI, 2.75–4.33), and surgical setting (inpatient procedure: adjusted OR, 5.41; 95% CI, 3.83–7.66). There was one postoperative transfusion event (0.008%) in the entire cohort and 37 postoperative re-operation events for surgical bleeding after tonsillectomy (0.90%).

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3 **Conclusions:** In the largest Japanese cohort reported to date, preoperative haemostasis and
4 ABO blood typing tests were performed in a majority of children prior to common paediatric
5 surgeries despite the low postoperative adverse events. Preoperative tests were associated
6 with anaesthesia, surgical type, and surgical setting. Preoperative testing in this cohort should
7 be reconsidered.
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15 **Keywords:** preoperative test, hemostasis test, blood typing test, pediatrics, overuse
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first and largest study to investigate the epidemiology of preoperative testing among children undergoing non-cardiac surgery by using the nationwide insurance claims database.
- The study included children who have not typically been investigated in previous studies regarding preoperative testing.
- Baseline information about overuse of preoperative tests in Japan was established.
- Limitations of this study include its retrospective nature and generalizability to other countries with different clinical practices and health care systems.
- There are the absence of details information such as patients' symptoms and results of blood tests.

INTRODUCTION

The inappropriate use of medical service has gained much attention and has led to the Choosing Wisely (CW) initiative, which aimed to reduce unnecessary tests, treatments, and procedures.[1] As part of the CW campaign, the American Society of Anesthesiologists (ASA) recommends this: ‘Do not obtain baseline laboratory studies in patients without significant systemic disease undergoing low-risk surgery’.[2] Although practical guidelines and textbooks consistently describe the inappropriateness of routine preoperative tests,[3,4,5] they do not cover paediatric patients who will undergo elective procedures or surgeries. There is a paucity of data describing this important cohort of patients. In the guideline from the French Society of Anesthesiology and Intensive Care (SFAR), routine preoperative coagulation and ABO blood type screening tests for elective paediatric surgery were generally not recommended.[6,7] A recent national study conducted in France including 0.24 million children showed that even the re-operation rates for postoperative bleeding were very low, with a large number of patients undergoing the coagulation (49%) and ABO typing (50%) tests before adenoidectomy and tonsillectomy.[8] This French study suggested an inconsistency between the guidelines and real-world practice.[6,7,8]

In general, routine preoperative blood tests, without clinical indications, are representative of low-value care and cannot be justified.[5,9] Routine preoperative tests for children do warrant a reconsideration of their clinical utility, as they are costly, time consuming, and especially stressful (even painful) for children. Despite its clinical and public health importance, limited information is available regarding the frequency of these preoperative tests before elective paediatric surgery and the manner in which their utilisation is affected by individual patient- and institutional-level characteristics in a real-world setting. Hence, it is important to establish baseline data to understand the problem of low-value care.[10,11]

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3 Therefore, we aimed to estimate the proportion of children who underwent preoperative
4 haemostasis and ABO blood typing tests prior to common paediatric surgery in Japan.
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7 Moreover, we sought to identify the patient- and institutional-level factors associated with
8 preoperative tests.
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MATERIAL AND METHODS

No patient or public involvement in the development for design or implementation of this study. This retrospective observational study was conducted according to the ‘STrengthening the Reporting of OBservational studies in Epidemiology’ (STROBE) guidelines.[12] This study was approved by the Ethics Committee of our institution (Approval number: H2018-094), who waived the requirement for obtaining informed consent from the patients due to the anonymous nature of the data.

Data sources

The data were provided by a commercial database vendor, JMDC Co., Ltd (Tokyo, Japan).[13] The JMDC database is one of the largest commercial claims database available in Japan, with claims from >100 health insurance associations. This database has accumulated reimbursement data from 5.6 million insured individuals since 2005. In particular, the JMDC database contains claims data of employees as well as their families, who can access freely to health care facility under universal health coverage in Japan. The database contains the following information: patient demographic information (age and sex), medical and pharmacy claims data (inpatient and outpatient), clinical diagnoses coded using the International Classification of Diseases 10th revision (ICD-10), and medical procedures defined using Japan-specific standardised procedure codes (K codes).[13,14] This database was widely used in epidemiological studies, and details of the database have been previously described.[13,14,15,16]

Study population

We used these original Japanese K codes to identify the eligible common paediatric surgeries (otolaryngology, head and neck surgery, including tonsillectomy with or without adenoidectomy, ophthalmologic surgery [strabismus surgery or eyelid surgery for congenital

ptosis], superficial surgery [inguinal hernia or umbilical hernia], and urologic surgery [surgery of an undescended testis, hypospadias, or circumcision]; Online Supplementary Table S1) from April 1, 2012, to March 31, 2018. Included surgeries were commonly performed in children and based on the previous literature.[8] We especially chose tonsillectomy as the representative procedure in this study because tonsillectomy is one of the most commonly performed paediatric surgeries, a surgical procedure with relatively high risk of bleeding, and is a well-studied procedure in children.[8] We included patients aged 1–17 years with at least 12 months of insurance eligibility before their index surgery, who had at least 1 claim during the study period.[14] Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) who underwent an eligible procedure were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.[15]

Outcomes

Medical claims within 60 days before the index procedure (but not including the day of the index surgery) were used to identify our primary outcome, according to previous studies,[10,15] which included the receipt of any of the following preoperative blood tests: platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests.[8] The Japanese claims codes used in this study are provided in Online Supplementary Table S2.

To explore the clinical significance of these coagulation tests (PT or aPTT) more closely, we performed a supplementary analysis using a sub-cohort of restricting patients who underwent tonsillectomy with or without adenoidectomy, because their postoperative bleeding is relatively common, compared to other patients undergoing low-risk procedures. We

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3 examined the reoperation rate attributed to bleeding 1-14 days after surgeries.[17] We
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5 defined the reoperation after tonsillectomy as reoperation for haemostasis due to post-
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7 tonsillectomy bleeding (K377 and K367) based on the previous studies.[17,18] In addition,
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9 we collected red blood cell transfusions during the first two postoperative days (including the
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11 day of index surgery) as postoperative adverse events based on the previous study.[17]
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15 **Predictor variables of preoperative tests**

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18 We examined several predictors of preoperative tests, including patient demographics (age
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20 and sex), comorbidities, type of anaesthesia, surgical procedure, surgical setting, and medical
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22 facility status, based on clinical experience and previous literatures.[8,15]
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27 Diagnostic ICD-10 codes within the 360 days before an index surgery, except the month of
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29 the index surgery, were used to identify the presence of chronic comorbidities, including
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31 asthma, obesity, coagulopathy, and any malignancy, including leukaemia and
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33 lymphoma.[14,19] Based on the claims codes, the type of anaesthesia was categorised as
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35 general anaesthesia or not. The surgical procedure was categorised as tonsillectomy (with or
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37 without adenoidectomy) or other procedures. We used tonsillectomy procedures as a
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39 representative scenario to compare our study with previous investigations.[8] The surgical
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41 setting was classified as outpatient or inpatient procedure, based on the JMDC claims data.
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43 Hospital status was determined using the JMDC medical facility code and was classified
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45 according to the number of beds at the medical facility (<100, or \geq 100 beds). Teaching
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47 hospital was defined as university hospital and public hospitals with advanced
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49 functions.[14,15]
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55 **Statistical analysis**

Analyses were conducted based on the previously established methodology.[10,15,20] First, we performed a descriptive analysis to estimate the proportion of patients who received each kind and any of the specified preoperative tests, for the entire cohort and for each procedure category (tonsillectomy and other procedures). Continuous variables are presented as median (interquartile range), whereas categorical variables are presented as number (proportion).

To consider the nesting of all patients within medical institutions, we conducted a multilevel logistic regression analysis. We included all covariates except 'institution' as fixed effects; thus, age, sex, comorbidities, type of anaesthesia, surgical procedure, surgical setting, number of beds at the medical facility, teaching hospital status, and surgical volume quartile, were included based on clinical relevance and previous studies.[10,14,15] The institution was used as a random effect, to account for clustering effects in ordering preoperative tests across medical institutions.[10,15] The adjusted odds ratio (OR) and 95% confidence interval (CI) were reported, along with the P values. We summarised the inter-institutional variation in the utilisation pattern of preoperative tests between medical institutions in terms of the median odds ratio (MOR), which is the transformation of the random effect variance into an OR scale.[21,22,23] The MOR indicates heterogeneity in the ordering pattern of preoperative tests by comparing 2 individuals with the same covariates from 2 different randomly chosen medical institutions.[15] MOR can be directly compared to the OR of fixed-effect variables.[21,23] The 95% confidence interval for the MOR was calculated from 5,000 bootstrap resampled data sets.[22]

Subgroup analyses, as planned priori, were performed according to the type of anaesthesia (general anaesthesia vs. other anaesthesia) and the type of surgery (tonsillectomy vs. other procedures).

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3 Restricting the sub-cohort undergoing tonsillectomy procedure, we compared the patients
4 with coagulation tests (PT or aPTT) to those without such tests using the χ^2 test. Penalised
5 logistic regression analysis (Firth's penalised likelihood approach) [24] adjusted for patient
6 demographics (age, sex) was used to examine the association between preoperative
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coagulation tests and post-tonsillectomy bleeding.

All analyses were performed using SAS 9.4 for Windows (SAS Institute Inc.; Cary, NC, USA). A 2-sided α level of 0.05 was considered statistically significant.

RESULTS

Study cohort

Figure 1 shows the study flow diagram. The initial cohort undergoing eligible surgery consisted of 29,830 eligible procedures. The final cohort comprised 13,018 patients from 1,499 institutions between April 1, 2012, and March 31, 2018 (Figure 1).

Characteristics of the study cohort

Table 1 summarises the patient- and institutional-level characteristics. Among the patients included, 63.6% were male (n=8,276); the overall median (IQR) age was 5.2 (2.9–7.7) years. Moreover, 80.3% (n=10,454) and 82.1% (n=10,683) of the procedures were performed in an inpatient setting and under general anaesthesia, respectively. Tonsillectomy procedures accounted for 4,104 (31.5%) of all the procedures included.

Table 1. Characteristics of the study cohort according to the procedure type

Characteristics	Tonsillectomy procedure (n=4104)	Other procedures (n=8914)	Overall (n=13018)
Age, years			
Median (IQR)	5.9 (4.7–7.9)	4.4 (2.1–7.4)	5.2 (2.9–7.7)
1–3	507 (12.4)	4034 (45.3)	4541(34.9)
4–10	3044 (74.2)	3511 (39.4)	6555 (50.4)
11–17	553 (13.5)	1369 (15.4)	1922 (14.8)
Sex, male	2616 (63.7)	5660 (63.5)	8276 (63.6)
Comorbidity 12 months prior			

Asthma	1948 (47.5)	3435 (38.5)	5383 (41.4)
Obesity	19 (0.5)	16 (0.2)	35 (0.3)
Type of anaesthesia			
General anaesthesia	4098 (99.9)	6585 (73.9)	10683 (82.1)
Other anaesthesia	6 (0.2)	2329 (26.1)	2335 (17.9)
Surgical setting			
Inpatient procedure	4097 (99.8)	6357 (71.3)	10454 (80.3)
Outpatient procedure	7 (0.2)	2557 (28.7)	2564 (19.7)
Number of beds			
<100	108 (2.6)	2221 (24.9)	2329(17.9)
≥100	3996 (97.4)	6693 (75.1)	10689 (82.1)
Teaching hospital	558 (13.6)	1712 (19.2)	2270 (17.4)
Year of surgery			
2012	285 (6.9)	971 (10.9)	1256 (9.6)
2013	544 (13.3)	1784 (20.0)	2328 (17.9)
2014	643 (15.7)	1335 (15.0)	1978 (15.2)
2015	805 (19.6)	1391 (15.6)	2196 (16.9)
2016	843 (20.5)	1556 (17.5)	2399 (18.4)
2017	784 (19.1)	1520 (17.1)	2304 (17.7)
2018	200 (4.9)	357 (4.0)	557 (4.3)

Values are presented as frequencies (%) unless stated otherwise.

IQR, interquartile range

Prevalence of preoperative tests

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3 Table 2 shows the proportions of preoperative haemostasis and ABO blood typing tests for
4 the entire cohort and for each procedure and anaesthesia category. The proportion of any
5 preoperative test in the overall cohort was 79.3% (95% CI, 78.7%–80.0%). The overall
6 proportion of each test was as follows: platelet count, 78.6% (95% CI, 77.9%–79.3%); PT,
7 54.4% (95% CI, 53.5%–55.2%); aPTT, 56.4% (95% CI, 55.5%–57.2%); and ABO blood
8 typing tests, 50.4% (95% CI, 49.5%–51.3%). The overall proportions of each test in patients
9 undergoing tonsillectomy (4,104 patients) were higher than those undergoing other
10 procedures (platelet count, 95.5%; PT, 83.9%; aPTT, 85.7%; and ABO blood typing tests,
11 79.3%). The overall proportions of each test under general anaesthesia were higher than those
12 under other anaesthetic methods.
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Table 2. Proportions of preoperative haemostasis and ABO blood typing tests in the study cohort

Type of procedure	Tests; % of patients (95% CI)				
	Platelet count	PT	aPTT	ABO	Any tests
Overall (n=13018)	78.6 (77.9–79.3)	54.4 (53.5–55.2)	56.4 (55.5–57.2)	50.4 (49.5–51.3)	79.3 (78.7–80.0)
Procedure category					
Tonsillectomy procedure (n=4104)	95.5 (94.9–96.1)	83.9 (82.7–85.0)	85.7 (84.7–86.8)	79.3 (78.1–80.6)	96.7 (96.1–97.2)
Other procedures (n=8914)	70.9 (69.9–71.8)	40.8 (39.8–41.8)	42.9 (41.8–43.9)	37.1 (36.1–38.1)	71.4 (70.4–72.3)
Anaesthesia category					
Procedure under general anaesthesia (n=10683)	91.0 (90.5–91.6)	64.9 (64.0–65.9)	67.4 (66.5–68.3)	61.0 (60.1–61.9)	91.9 (91.4–92.4)
Procedure under other anaesthesia (n=2335)	21.8 (20.2–23.5)	5.9 (4.9–6.8)	5.8 (4.9–6.8)	1.8 (1.3–2.3)	22.0 (20.3–23.7)

aPTT, activated partial thromboplastin time; CI, confidence interval; PT, prothrombin time

Multilevel logistic regression analyses

Table 3 shows the adjusted OR of the patient- and institutional-level factors with any preoperative tests. Patient medical factors (older age or asthma) were associated with the preoperative tests, but their adjusted ORs were relatively weak. There were significant associations between any preoperative tests and the type of anaesthesia (general anaesthesia: adjusted OR, 7.06; 95% CI, 4.94–10.11) relative to the reference group of other anaesthesia, type of surgery (tonsillectomy: adjusted OR, 3.45; 95% CI, 2.75–4.33) relative to the reference group of the other procedures, and surgical setting (inpatient surgery: adjusted OR, 5.41; 95% CI, 3.83–7.66). The MOR for inter-institutional variation was 2.89 (95% CI, 2.69–3.24).

Table 3. Multilevel logistic regression analysis of the characteristics associated with any preoperative tests (haemostasis or ABO blood typing tests) for children undergoing common paediatric surgeries

Characteristic	Adjusted OR	95% CI	P value
Age, years			<0.001 ^a
1–3	Reference		
4–10	1.24	1.06–1.44	0.0059
11–17	1.59	1.28–1.97	<0.001
Sex			
Male	Reference		
Female	1.12	0.98–1.29	0.10
Comorbidities			
Asthma	1.29	1.12–1.48	<0.001
Obesity	1.30	0.28–6.05	0.73
Type of anaesthesia			
Not general anaesthesia	Reference		

General anaesthesia	7.06	4.94–10.11	<0.001
Type of procedures			
Other procedures	Reference		
Tonsillectomy procedure	3.45	2.75–4.33	<0.001
Surgical setting			
Outpatient procedure	Reference		
Inpatient procedure	5.41	3.83–7.66	<0.001
Number of beds			
<100	Reference		
≥100	1.91	1.41–2.57	<0.001
Teaching facility			
Teaching hospital	Reference		
Non-teaching hospital	0.77	0.55–1.09	0.14
Procedure volume quartile			0.0018 ^a
Q1 (lowest)	Reference		
Q2	1.18	0.91–1.52	0.22
Q3	1.63	1.10–2.40	0.015
Q4 (highest)	2.23	1.15–4.31	0.018
MOR ^b	2.89	2.69–3.24 ^c	

^a Overall P value.

^b MOR indicates the inter-institutional variation of the utilisation of preoperative tests.

^c The 95% CI for MOR was calculated by bootstrap resampling method.

CI, confidence interval; MOR, median odds ratio; OR, odds ratio.

Postoperative adverse events

The incidence of postoperative transfusion events within postoperative 2 days was 1 patient (0.008%; 1 patient underwent hernia surgery) in the whole cohort. The incidence of postoperative re-operation for surgical bleeding after tonsillectomy was 0.90% (37 of 4,104); 31 of 3527 (0.88%) in patients undergoing preoperative coagulation tests and 6 of 577 (1.04%) in patients without preoperative tests (unadjusted OR, 0.84; 95% CI, 0.35–2.03,

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3 P=0.70). Penalised logistic regression analysis revealed that the adjusted OR of preoperative
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6 coagulation tests for postoperative re-operation was 0.74 (95% CI, 0.34–1.91, P=0.60).
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DISCUSSION

We found that the preoperative tests were performed in a majority of children before undergoing common paediatric surgeries. Preoperative testing was strongly associated with type of anaesthesia, type of surgery, and surgical setting. There were quite low postoperative transfusion events, and no statistically significant difference in postoperative re-operation for surgical bleeding was found between patients with or without preoperative coagulation tests.

Despite the increased overuse globally, problems of low-value care have not been well described, especially in the paediatrics.[9] To our knowledge, our study is the largest and most comprehensive population-based study investigating the preoperative tests before common paediatric surgeries. Our database could capture the whole series of preoperative tests ordered both at inpatient and outpatient settings. Therefore, our analysis can precisely describe the current preoperative testing status in Japan. Previous French nationwide cohort study did not have medical services data, including tests or procedures during inpatient episodes.[8] This recent French study showed that coagulation and ABO blood typing tests were performed in 49% and 50% of children before tonsillectomy, respectively.[8] Although the SFAR guideline did not recommend preoperative tests among children undergoing elective tonsillectomy,[6,7] there was still a high rate of unnecessary preoperative tests on paediatric patients.[8] Our results demonstrated that most children undergoing tonsillectomy underwent coagulation (PT, 84% and aPTT, 86%) and ABO blood typing (79%) tests, which were markedly higher compared to those of the recent French study.[8] Although not all of these preoperative tests are clinically inappropriate, preoperative coagulation tests for screening or predicting coagulopathy risk were not recommended. The predictive value of haemostatic tests (PT, aPTT, and platelet count) for determining perioperative bleeding risk of children undergoing tonsillectomy is generally poor, with a low sensitivity of <44% and a

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3 positive predictive value of <29%. [7] Abnormal results were not always associated with
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5 hereditary blood disease, such as haemophilia. [7,8] False positive results can trigger further
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7 tests, leading to inappropriate perioperative management and delay or cancellation of elective
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9 surgeries. [5,8] Furthermore, an increasing number of blood tests can worsen children and
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11 parents' discomfort.
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15 Regarding the association of preoperative tests, we found a markedly high adjusted OR for
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17 the type of anaesthesia and surgical setting. There was also a relatively high MOR for
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19 medical institutions (i.e., the odds of receiving preoperative tests between two randomly
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21 selected medical institutions varied by 2.89 times), suggesting inter-institutional variation in
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23 ordering preoperative tests in children. These results were consistent with our previous report
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25 on low-risk surgeries in Japan showing that preoperative blood tests performed in adult
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27 patients before undergoing low-risk surgery (e.g., cataract, superficial surgery) were strongly
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29 associated with the type of anaesthesia, patient characteristics, and medical facility
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31 status. [14,15,16] Especially, the type of anaesthesia was the most important predictors in our
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33 study focused in children and previous adult studies. [15] However, our findings were in
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35 opposition to the SFAR guidelines, which recommended that haemostasis tests should not be
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37 ordered regardless of anaesthesia type. [7] A guideline for preoperative tests has not been
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39 established in Japan, and there is little consensus on whether preoperative testing is required,
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41 leading to variations in ordering patterns. Moreover, certain hospital factors, including
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43 policies for preoperative management, provider preference, or the defensive medicine, may
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45 partially explain this overuse and inter-institutional variation. [14,15]
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53 Our supplementary analysis showed that the need for postoperative transfusion within 2 days
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55 was very rare. Moreover, re-operation incidence for post-tonsillectomy bleeding (objective
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57 and reliable end point for evaluating clinically relevant bleeding after tonsillectomy) [17,18]
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3 was low (0.9%), consistent with previous reports,[17,18] and there was no statistically
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5 significant difference between patients with or without preoperative coagulation tests. A
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7 previous randomised trial demonstrated that perioperative outcomes after low-risk surgery
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9 were not different in patients with or without preoperative tests.[25] Previous studies have
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11 investigated the utility of haemostasis tests in predicting bleeding risk among children
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13 undergoing tonsillectomy, and a majority of studies concluded that the predictive value of
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15 preoperative haemostasis tests was poor.[7] The efficacy of preoperative coagulation tests
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17 before paediatric surgery remains controversial and needs further investigation.
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23 In 2016, the Japanese government estimated that at least 2.4 million general anaesthesia cases
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25 were performed annually, with patients aged 5 years and younger accounting for 2.7% of
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27 total inpatient procedures performed under general anaesthesia (approximately 65,000
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29 cases).[26,27] It is apparent that increasing preoperative test overuse will burden the Japanese
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31 health care system in future. Our findings could provide valuable baseline data about
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33 preoperative testing overuse for not only clinicians but also for policymakers and promote the
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35 need for reconsidering the routine clinical practice and the cost of these tests.[8,14]
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40 This study has several limitations. First, our claims database lacked important clinical
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42 information, such as patients' and family history of bleeding, symptoms, or abnormal
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44 physical examination, which may have influenced the indication of preoperative tests. As we
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46 did obtain neither the patient's nor the family's history of bleeding, we excluded the patients
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48 with diagnostic codes indicating hereditary bleeding disorders. Second, how the abnormal
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50 results of preoperative tests have affected perioperative course was unknown. As our
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52 database did not have the results of the blood tests, we were not able to interpret whether the
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54 coagulation test results were normal or abnormal. Therefore, we did not analyse the sequela
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56 of these findings. Third, there may be a selection bias with the inclusion of only specific
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3 paediatric surgeries in this study. However, we carefully chose to include common paediatric
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5 surgeries based on the recent publications.[8,17] Additionally, we used tonsillectomy
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7 procedures as a representative scenario to compare our study with previous investigations.[8]
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10 Finally, this nationwide study limits the results' generalisability to other countries with
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12 different clinical practices and health care systems.[14,15] Compared to other developed
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14 countries, ambulatory surgery is not popular in Japan (only 0.8% of general anaesthesia cases
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16 underwent surgery in the outpatient setting).[26,27] Nevertheless, our study can add
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18 significantly to the growing evidence on the prevalence of medical overuse worldwide.
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21 **CONCLUSION**

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24 Preoperative haemostasis and ABO blood typing tests were performed in a majority of
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26 children before undergoing common paediatric surgeries despite the low postoperative
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28 transfusion and re-operation events. Preoperative tests were associated with the anaesthesia
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30 and surgical types, and surgical setting. It is necessary to reconsider routine preoperative
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32 testing in this cohort.
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Author Contribution

HY conceived the study, collected, analysed, interpreted the data and results, and drafted the manuscript. KI analysed the data and performed statistical analyses. HY, KI, YK, CT, YN, YM, MS, KK, and MK conceived the study and interpreted the data and drafted the manuscript. All authors critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

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Competing interest

The authors have no conflict of interest directly relevant to the content of this article within 36 months prior to submission. KK received honoraria from Shin Nippon Biomedical Laboratories, Ltd.; research funds from Bayer Yakuhin Ltd., CMIC Co., Ltd., Novartis Pharma K.K., Suntory Beverage & Food Ltd., Dainippon Sumitomo Pharma Co., Ltd., Stella Pharma Corporation; and holds stocks in School Health Record Center Co., Ltd. and Real World Data, Co., Ltd. There are no patent products under development or marketed products to declare, relevant to those companies.

Checklists for the appropriate reporting statement

This retrospective observational study was conducted according to the “STrengthening the Reporting of OBservational studies in Epidemiology” (STROBE) guidelines.

Patient consent for publication

Not required.

Ethics statement

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3 This study was by the Ethics Committee of Mie University Graduate School and Faculty of
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5 Medicine (approval number: H2018-094), who waived the requirement for obtaining
6
7 informed consent from the patients due to the anonymous nature of the data.
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10 **Provenance and peer review**

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12 Not commissioned; externally peer reviewed.
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14 **Data sharing statement**

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16 The data sets analysed in this study are available from the corresponding author on
17
18 reasonable request.
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21 **Acknowledgments:** We thank the staff at JMDC Co., Ltd, Tokyo, Japan, for their assistance
22
23 with data preparation. We also thank our colleagues from the Department of
24
25 Pharmacoepidemiology, Graduate School of Medicine and Public Health, Kyoto University
26
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29 (<http://www.editage.jp>) for English language editing.
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3 **Figure legends**
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6 Figure 1. Study flow diagram.
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10 **Supplementary material**
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12 Supplemental Table S1: A list of all the surgeries included in the study.
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14 Supplemental Table S2: A list of all the claim codes used to define the preoperative
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16 haemostasis and ABO blood typing tests included in the study.
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2 Eligible surgeries from April 1,
3 2012 to March 31, 2018
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5 N = 29,830
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8 16,812 excluded
9 N = 685
10 Patients < 1 y of age
11 N = 13,831
12 Patients ≥ 18 y of age
13 N = 2,121
14 Multiple surgeries
15 N = 175
16 Patients with high-risk
17 comorbidities
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21 Available data
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Supplemental Digital Content 1

Supplemental Table 1: Common pediatric surgeries included in the study cohort

Procedure type

Japanese K procedure code Details

Otolaryngology, head, and neck surgery

- | | |
|------|--|
| K309 | ● Tympanoplasty with tubing |
| K370 | ● Adenoidectomy |
| K377 | ● Tonsillectomy
(excluding the reoperation for post-tonsillectomy bleeding) |

Ophthalmologic surgery

- | | |
|------|---|
| K219 | ● Blepharoptosis repair
(eyelid surgery for congenital ptosis) |
| K242 | ● Strabismus surgery |

Superficial surgery

- | | |
|------|---|
| K633 | ● Inguinal hernia repair
● Umbilical hernia repair |
|------|---|

Urologic surgery

- | | |
|------|---|
| K819 | ● Hypospadias repair |
| K828 | ● Circumcision |
| K836 | ● Orchidopexy
(surgical correction of an undescended testis) |

Supplemental Digital Content 2

Supplemental Table 2: All the claim codes used to define the preoperative hemostasis and ABO blood typing tests included in the study

Any one of the following claim codes (during days 1–60 prior to the index surgery)	Description
Platelet count	
160008010	Complete blood count (CBC)
160061810	Calculation charges
Prothrombin time (PT)	
160012010	Prothrombin time
Activated partial thromboplastin time (aPTT)	
160012310	Activated partial thromboplastin time
ABO blood typing tests	
160039110	ABO blood typing
160039210	Rh phenotype determination

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1, 2	“retrospective observational study”
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2	“We described the proportions of each preoperative test performed within 60 days before an index surgery, including platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests. We also explored the associations between patient- and institutional-level factors and any preoperative tests, using multilevel logistic regression analysis.” “The overall proportion of each test was as follows: platelet count, 78.6%; PT, 54.4%; aPTT, 56.4%; and ABO blood typing tests, 50.4%. The proportion of patients undergoing any preoperative tests in the overall sample was 79.3%. Multilevel logistic regression analysis indicated that ”

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Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5	“Despite its clinical and public health importance, limited information is available regarding the frequency of these preoperative tests before elective paediatric surgery and the manner in which their utilisation is affected by individual patient- and institutional-level characteristics in a real-world setting.”
Objectives	3	State specific objectives, including any prespecified hypotheses	6	“we aimed to estimate the proportion of children who underwent preoperative haemostasis and ABO blood typing tests prior to common paediatric surgery in Japan. Moreover, we sought to identify the patient- and institutional-level factors associated with preoperative tests.”
Methods				
Study design	4	Present key elements of study design early in the paper	7	“This retrospective observational study was conducted”
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7	“The data were provided by a commercial database vendor, JMDC Co., Ltd (Tokyo, Japan)”

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Participants

6 (a) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls
Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants

7,
Supplementary
Table S1,
8

“We used these original Japanese K codes to identify the eligible common paediatric surgeries (otolaryngology, head and neck surgery, including tonsillectomy with or without adenoidectomy, ophthalmologic surgery [strabismus surgery or eyelid surgery for congenital ptosis], superficial surgery [inguinal hernia or umbilical hernia], and urologic surgery [surgery of an undescended testis, hypospadias, or circumcision]; Online Supplementary Table S1) from April 1, 2012, to March 31, 2018”

“We included patients aged 1–17 years with at least 12 months of insurance eligibility before their index surgery, who had at least 1 claim during the study period.[14] Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) who underwent an eligible procedure

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				were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.”
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9, Supplementary Table S2	“Medical claims within 60 days before the index procedure (but not including the day of the index surgery) were used to identify our primary outcome, according to previous studies” “We examined several predictors of preoperative tests, including patient demographics (age and sex), comorbidities, type of anaesthesia, surgical procedure, surgical setting, and medical facility status, based on clinical experience and previous literatures”
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8, Supplementary Table S2	“the receipt of any of the following preoperative blood tests: platelet count, prothrombin time (PT), activated partial thromboplastin

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				time (aPTT), and ABO blood typing tests.[8] The Japanese claims codes used in this study are provided in Online Supplementary Table S2.”
Bias	9	Describe any efforts to address potential sources of bias	8	“Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) who underwent an eligible procedure were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.”
Study size	10	Explain how the study size was arrived at		No relevant text

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why		No relevant text
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	10	“To consider the nesting of all patients within medical institutions, we conducted a multilevel logistic regression analysis.”
		(b) Describe any methods used to examine subgroups and interactions		No relevant text
		(c) Explain how missing data were addressed		No relevant text
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy		There were no follow-up cases. no relevant text
		(e) Describe any sensitivity analyses		No relevant text
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	12	“Figure 1 shows the study diagram.”
		(b) Give reasons for non-participation at each stage	Figure 1	Figure 1 gives reasons for non-participation at each stage.
		(c) Consider use of a flow diagram	12, Figure 1	“Figure 1 shows the study diagram.”
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	12, Table 1	“Table 1 summarises the patient- and institutional-level characteristics.”
		(b) Indicate number of participants with missing data for each variable of interest		No participants with missing data
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)		No relevant text
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	14, Table 2	“Table 2 shows the proportions of preoperative haemostasis and ABO blood typing tests for the entire cohort and for each procedure and anaesthesia category.”

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		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure		
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16, Table 3	“Table 3 shows the adjusted OR of the patient- and institutional-level factors with any preoperative tests. Patient medical factors (older age or asthma) were associated with the preoperative tests, but their adjusted ORs were relatively weak.”
		(b) Report category boundaries when continuous variables were categorized		
		© If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		

Continued on next page

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2	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14
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17	Discussion			
18	Key results	18	Summarise key results with reference to study objectives	19
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				between patients with or without preoperative coagulation tests.”
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21	“This study has several limitations.”
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	22	“Preoperative haemostasis and ABO blood typing tests were performed in a majority of children before undergoing common paediatric surgeries despite the low postoperative transfusion and re-operation events. Preoperative tests were associated with the anaesthesia and surgical types, and surgical setting. It is necessary to reconsider routine preoperative testing in this cohort.”
Generalisability	21	Discuss the generalisability (external validity) of the study results	22	“Finally, this nationwide study limits the results’ generalisability to other countries with different clinical practices and health care systems.[14,15] Compared to other developed countries, ambulatory

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surgery is not popular in Japan (only 0.8% of general anaesthesia cases underwent surgery in the outpatient setting).[26,27] Nevertheless, our study can add significantly to the growing evidence on the prevalence of medical overuse worldwide.”

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	23	“This work was supported in part by grants from the Pfizer Health Research Foundation.”
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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The use of preoperative haemostasis and ABO blood typing tests in children: A retrospective observational study using a nationwide claims database in Japan

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3 **The use of preoperative haemostasis and ABO blood typing tests in children: A**
4 **retrospective observational study using a nationwide claims database in Japan**
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ABSTRACT

Objectives: To describe the prevalence and factors associated with preoperative haemostasis and ABO blood typing tests for children because these tests might represent low-value care.

Design: A retrospective observational study.

Setting: Nationwide insurance claims database in Japan

Participants: Patients aged 1–17 years who underwent common non-cardiac surgeries between April 2012 and March 2018 were included. Patients with high-risk comorbidities for bleeding (n=175) and those with multiple eligible surgeries were excluded (n=2,121).

Main outcome measures: We described the proportions of each preoperative test performed within 60 days before an index surgery, including platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests. We also explored the associations between patient- and institutional-level factors and any preoperative tests, using multilevel logistic regression analysis.

Results: We included 13,018 patients (median [interquartile range] age, 5.2 [2.9–7.7] years; 8,276 [63.6%] boys) from 1,499 institutions. The overall proportion of each test was as follows: platelet count, 78.6%; PT, 54.4%; aPTT, 56.4%; and ABO blood typing tests, 50.4%. The proportion of patients undergoing any preoperative tests in the overall sample was 79.3%. Multilevel logistic regression analysis indicated that preoperative tests were associated with type of anaesthesia (general anaesthesia: adjusted odds ratio [OR], 7.06; 95% confidence interval [CI], 4.94–10.11), type of surgery (tonsillectomy: adjusted OR, 3.45; 95% CI, 2.75–4.33), and surgical setting (inpatient procedure: adjusted OR, 5.41; 95% CI, 3.83–7.66). There was one postoperative transfusion event (0.008%) in the entire cohort and 37 postoperative re-operation events for surgical bleeding after tonsillectomy (0.90%).

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3 **Conclusions:** In the largest Japanese cohort reported to date, preoperative haemostasis and
4
5 ABO blood typing tests were performed in a majority of children prior to common paediatric
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7 surgeries. Preoperative tests were associated with anaesthesia, surgical type, and surgical
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9 setting.
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13 **Keywords:** preoperative test, haemostasis test, blood typing test, paediatrics, overuse
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is the first and largest study to investigate the epidemiology of preoperative testing among children undergoing non-cardiac surgery by using the nationwide insurance claims database.
- The study included children who have not typically been investigated in previous studies regarding preoperative testing.
- Baseline information about overuse of preoperative tests in Japan was established.
- Limitations of this study include its retrospective nature and generalizability to other countries with different clinical practices and health care systems.
- Detailed information such as patients' symptoms and results of blood tests was lacking.

INTRODUCTION

The inappropriate use of medical service has gained much attention and has led to the Choosing Wisely (CW) initiative, which aimed to reduce unnecessary tests, treatments, and procedures.[1] As part of the CW campaign, the American Society of Anesthesiologists (ASA) recommends this: ‘Do not obtain baseline laboratory studies in patients without significant systemic disease undergoing low-risk surgery’.[2] Although practical guidelines and textbooks consistently describe the inappropriateness of routine preoperative tests,[3,4,5] they do not cover paediatric patients who will undergo elective procedures or surgeries. There is a paucity of data describing this important cohort of patients. In the guideline from the French Society of Anesthesiology and Intensive Care (SFAR), routine preoperative coagulation and ABO blood type screening tests for elective paediatric surgery were generally not recommended.[6,7] A recent national study conducted in France including 0.24 million children showed that even the re-operation rates for postoperative bleeding were very low, with a large number of patients undergoing the coagulation (49%) and ABO typing (50%) tests before adenoidectomy and tonsillectomy.[8] This French study suggested an inconsistency between the guidelines and real-world practice.[6,7,8]

In general, routine preoperative blood tests, without clinical indications, are representative of low-value care and cannot be justified.[5,9] Routine preoperative tests for children do warrant a reconsideration of their clinical utility, as they are costly, time consuming, and especially stressful (even painful) for children. Despite its clinical and public health importance, limited information is available regarding the frequency of these preoperative tests before elective paediatric surgery and the manner in which their utilisation is affected by individual patient- and institutional-level characteristics in a real-world setting. Hence, it is important to establish baseline data to understand the problem of low-value care.[10,11]

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3 Therefore, we aimed to estimate the proportion of children who underwent preoperative
4 haemostasis and ABO blood typing tests prior to common paediatric surgery in Japan.
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7 Moreover, we sought to identify the patient- and institutional-level factors associated with
8 preoperative tests.
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MATERIAL AND METHODS

This retrospective observational study was conducted according to the ‘STrengthening the Reporting of OBservational studies in Epidemiology’ (STROBE) guidelines.[12] This study was approved by the Ethics Committee of our institution (Approval number: H2018-094), who waived the requirement for obtaining informed consent from the patients due to the anonymous nature of the data.

Data sources

The data were provided by a commercial database vendor, JMDC Co., Ltd (Tokyo, Japan).[13] The JMDC database is one of the largest commercial claims databases available in Japan, with claims from approximately 18% of all society-managed health insurance associations in Japan.[14] This database has accumulated reimbursement data from 5.6 million insured individuals since 2005. In particular, the JMDC database contains claims data of employees as well as their families, who can access freely to any health care facility (public and private) under universal health coverage in Japan. The database contains the following information: patient demographic information (age and sex), medical and pharmacy claims data (inpatient, outpatient, and emergency department), clinical diagnoses coded using the International Classification of Diseases 10th revision (ICD-10), and medical procedures defined using Japan-specific standardised procedure codes (K codes).[13,15] This database was widely used in epidemiological studies, and details of the database have been previously described.[13,15,16,17]

Study population

We used these original Japanese K codes to identify the eligible common paediatric surgeries (otolaryngology, head and neck surgery, including tonsillectomy with or without adenoidectomy, ophthalmologic surgery [strabismus surgery or eyelid surgery for congenital

ptosis], superficial surgery [inguinal hernia or umbilical hernia], and urologic surgery [surgery of an undescended testis, hypospadias, or circumcision]; Online Supplementary Table S1) from April 1, 2012, to March 31, 2018. Included surgeries were commonly performed in children and based on the previous literature.[8] We especially chose tonsillectomy as the representative procedure in this study because tonsillectomy is one of the most commonly performed paediatric surgeries, a surgical procedure with relatively high risk of bleeding, and is a well-studied procedure in children.[8] We included patients aged 1–17 years with at least 12 months of insurance eligibility before their index surgery, who had at least 1 claim during the study period.[15] Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) [18] who underwent an eligible procedure were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.[16]

Outcomes

Medical billing within 60 days before the index procedure (but not including the day of the index surgery) was used to identify our primary outcome, according to previous studies,[10,16] which included the receipt of any of the following preoperative blood tests: platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests.[8] The Japanese claims codes used in this study are provided in Online Supplementary Table S2.

To explore the clinical significance of these coagulation tests (PT or aPTT) more closely, we performed a supplementary analysis using a sub-cohort of restricting patients who underwent tonsillectomy with or without adenoidectomy, because their postoperative bleeding is relatively common, compared to other patients undergoing low-risk procedures. We

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3 examined the reoperation rate attributed to bleeding 1-14 days after surgeries.[19] We
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5 defined the reoperation after tonsillectomy as reoperation for haemostasis due to post-
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7 tonsillectomy bleeding (K377 and K367) based on the previous studies.[19,20] In addition,
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9 we collected red blood cell transfusions during the first two postoperative days (including the
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11 day of index surgery) as postoperative adverse events based on the previous study.[8]
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15 **Predictor variables of preoperative tests**

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17 We examined several predictors of preoperative tests, including patient demographics (age
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19 and sex), comorbidities, type of anaesthesia, surgical procedure, surgical setting, and medical
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21 facility status, based on clinical experience and previous literatures.[8,16]
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26 Diagnostic ICD-10 codes within the 360 days before an index surgery, except the month of
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28 the index surgery, were used to identify the presence of chronic comorbidities, including
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30 asthma, obesity, coagulopathy, and any malignancy, including leukaemia and
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32 lymphoma.[15,18,21] Based on the claims codes, the type of anaesthesia was categorised as
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34 general anaesthesia or not. The surgical procedure was categorised as tonsillectomy (with or
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36 without adenoidectomy) or other procedures. We used tonsillectomy procedures as a
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38 representative scenario to compare our study with previous investigations.[8] The surgical
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40 setting was classified as outpatient or inpatient procedure, based on the JMDC claims data.
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42 Hospital status was determined using the JMDC medical facility code and was classified
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44 according to the number of beds at the medical facility (<100, or \geq 100 beds). Teaching
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46 hospital was defined as university hospital and public hospitals with advanced
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48 functions.[15,16]
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54 **Statistical analysis**

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Analyses were conducted based on the previously established methodology.[10,16,22] First, we performed a descriptive analysis to estimate the proportion of patients who received each kind and any of the specified preoperative tests, for the entire cohort and for each procedure category (tonsillectomy and other procedures). Continuous variables are presented as median (interquartile range), whereas categorical variables are presented as number (proportion).

To consider the nesting of all patients within medical institutions, we conducted a multilevel logistic regression analysis. We included all covariates except 'institution' as fixed effects; thus, age, sex, comorbidities, type of anaesthesia, surgical procedure, surgical setting, number of beds at the medical facility, teaching hospital status, and surgical volume quartile were included based on clinical relevance and previous studies.[10,15,16] The institution was used as a random effect, to account for clustering effects in ordering preoperative tests across medical institutions.[10,16] The adjusted odds ratio (OR) and 95% confidence interval (CI) were reported, along with the P values. We summarised the inter-institutional variation in the utilisation pattern of preoperative tests between medical institutions in terms of the median odds ratio (MOR), which is the transformation of the random effect variance into an OR scale.[23,24,25] The MOR indicates heterogeneity in the ordering pattern of preoperative tests by comparing 2 individuals with the same covariates from 2 different randomly chosen medical institutions.[16] MOR can be directly compared to the OR of fixed-effect variables.[23,25] The 95% confidence interval for the MOR was calculated from 5,000 bootstrap resampled data sets.[24]

Subgroup analyses, as planned priori, were performed according to the type of anaesthesia (general anaesthesia vs. other anaesthesia) and the type of surgery (tonsillectomy vs. other procedures).

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3 Restricting the sub-cohort undergoing tonsillectomy procedure, we compared the patients
4 with coagulation tests (PT or aPTT) to those without such tests using the χ^2 test. Penalised
5 logistic regression analysis (Firth's penalised likelihood approach) [26] adjusted for patient
6 demographics (age, sex) was used to examine the association between preoperative
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coagulation tests and post-tonsillectomy bleeding.

All analyses were performed using SAS 9.4 for Windows (SAS Institute Inc.; Cary, NC, USA). A 2-sided α level of 0.05 was considered statistically significant.

Patient and public involvement

This study has no patient or public involvement in the development of its design or implementation.

RESULTS

Study cohort

Figure 1 shows the study flow diagram. The initial cohort undergoing eligible surgery consisted of 29,830 eligible procedures. The final cohort comprised 13,018 patients from 1,499 institutions between April 1, 2012, and March 31, 2018 (Figure 1).

Characteristics of the study cohort

Table 1 summarises the patient- and institutional-level characteristics. Among the patients included, 63.6% were male (n=8,276); the overall median (IQR) age was 5.2 (2.9–7.7) years. Moreover, 80.3% (n=10,454) and 82.1% (n=10,683) of the procedures were performed in an inpatient setting and under general anaesthesia, respectively. Tonsillectomy procedures accounted for 4,104 (31.5%) of all the procedures included.

Table 1. Characteristics of the study cohort according to the procedure type

Characteristics	Tonsillectomy procedure (n=4104)	Other procedures (n=8914)	Overall (n=13018)
Age, years			
Median (IQR)	5.9 (4.7–7.9)	4.4 (2.1–7.4)	5.2 (2.9–7.7)
1–3	507 (12.4)	4034 (45.3)	4541(34.9)
4–10	3044 (74.2)	3511 (39.4)	6555 (50.4)
11–17	553 (13.5)	1369 (15.4)	1922 (14.8)
Sex, male	2616 (63.7)	5660 (63.5)	8276 (63.6)
Comorbidity 12 months prior			

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3	Asthma	1948 (47.5)	3435 (38.5)	5383 (41.4)
4				
5	Obesity	19 (0.5)	16 (0.2)	35 (0.3)
6				
7				
8	Type of anaesthesia			
9				
10	General anaesthesia	4098 (99.9)	6585 (73.9)	10683 (82.1)
11				
12	Other anaesthesia	6 (0.2)	2329 (26.1)	2335 (17.9)
13				
14				
15	Surgical setting			
16				
17	Inpatient procedure	4097 (99.8)	6357 (71.3)	10454 (80.3)
18				
19	Outpatient procedure	7 (0.2)	2557 (28.7)	2564 (19.7)
20				
21				
22	Number of beds			
23				
24	<100	108 (2.6)	2221 (24.9)	2329(17.9)
25				
26	≥100	3996 (97.4)	6693 (75.1)	10689 (82.1)
27				
28	Teaching hospital	558 (13.6)	1712 (19.2)	2270 (17.4)
29				
30				
31	Year of surgery			
32				
33	2012	285 (6.9)	971 (10.9)	1256 (9.6)
34				
35	2013	544 (13.3)	1784 (20.0)	2328 (17.9)
36				
37	2014	643 (15.7)	1335 (15.0)	1978 (15.2)
38				
39	2015	805 (19.6)	1391 (15.6)	2196 (16.9)
40				
41	2016	843 (20.5)	1556 (17.5)	2399 (18.4)
42				
43	2017	784 (19.1)	1520 (17.1)	2304 (17.7)
44				
45	2018	200 (4.9)	357 (4.0)	557 (4.3)
46				
47				
48				

Values are presented as frequencies (%) unless stated otherwise.

IQR, interquartile range

Prevalence of preoperative tests

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3 Table 2 shows the proportions of preoperative haemostasis and ABO blood typing tests for
4 the entire cohort and for each procedure and anaesthesia category. The proportion of any
5 preoperative test in the overall cohort was 79.3% (95% CI, 78.7%–80.0%). The overall
6 proportion of each test was as follows: platelet count, 78.6% (95% CI, 77.9%–79.3%); PT,
7 54.4% (95% CI, 53.5%–55.2%); aPTT, 56.4% (95% CI, 55.5%–57.2%); and ABO blood
8 typing tests, 50.4% (95% CI, 49.5%–51.3%). The overall proportions of each test in patients
9 undergoing tonsillectomy (4,104 patients) were higher than those undergoing other
10 procedures (platelet count, 95.5%; PT, 83.9%; aPTT, 85.7%; and ABO blood typing tests,
11 79.3%). The overall proportions of each test under general anaesthesia were higher than those
12 under other anaesthetic methods.
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Table 2. Proportions of preoperative haemostasis and ABO blood typing tests in the study cohort

Type of procedure	Tests; % of patients (95% CI)				
	Platelet count	PT	aPTT	ABO	Any tests
Overall (n=13018)	78.6 (77.9–79.3)	54.4 (53.5–55.2)	56.4 (55.5–57.2)	50.4 (49.5–51.3)	79.3 (78.7–80.0)
Procedure category					
Tonsillectomy procedure (n=4104)	95.5 (94.9–96.1)	83.9 (82.7–85.0)	85.7 (84.7–86.8)	79.3 (78.1–80.6)	96.7 (96.1–97.2)
Other procedures (n=8914)	70.9 (69.9–71.8)	40.8 (39.8–41.8)	42.9 (41.8–43.9)	37.1 (36.1–38.1)	71.4 (70.4–72.3)
Anaesthesia category					
Procedure under general anaesthesia (n=10683)	91.0 (90.5–91.6)	64.9 (64.0–65.9)	67.4 (66.5–68.3)	61.0 (60.1–61.9)	91.9 (91.4–92.4)
Procedure under other anaesthesia (n=2335)	21.8 (20.2–23.5)	5.9 (4.9–6.8)	5.8 (4.9–6.8)	1.8 (1.3–2.3)	22.0 (20.3–23.7)

aPTT, activated partial thromboplastin time; CI, confidence interval; PT, prothrombin time

Multilevel logistic regression analyses

Table 3 shows the adjusted OR of the patient- and institutional-level factors with any preoperative tests. Patient medical factors (older age or asthma) were associated with the preoperative tests, but their adjusted ORs were relatively weak. There were significant associations between any preoperative tests and the type of anaesthesia (general anaesthesia: adjusted OR, 7.06; 95% CI, 4.94–10.11) relative to the reference group of other anaesthesia, type of surgery (tonsillectomy: adjusted OR, 3.45; 95% CI, 2.75–4.33) relative to the reference group of the other procedures, and surgical setting (inpatient surgery: adjusted OR, 5.41; 95% CI, 3.83–7.66). The MOR for inter-institutional variation was 2.89 (95% CI, 2.69–3.24).

Table 3. Multilevel logistic regression analysis of the characteristics associated with any preoperative tests (haemostasis or ABO blood typing tests) for children undergoing common non-cardiac surgeries

Characteristic	Adjusted OR	95% CI	P value
Age, years			<0.001 ^a
1–3	Reference		
4–10	1.24	1.06–1.44	0.0059
11–17	1.59	1.28–1.97	<0.001
Sex			
Male	Reference		
Female	1.12	0.98–1.29	0.10
Comorbidities			
Asthma	1.29	1.12–1.48	<0.001
Obesity	1.30	0.28–6.05	0.73
Type of anaesthesia			
Not general anaesthesia	Reference		

1				
2				
3	General anaesthesia	7.06	4.94–10.11	<0.001
4				
5	Type of procedures			
6				
7	Other procedures	Reference		
8				
9	Tonsillectomy procedure	3.45	2.75–4.33	<0.001
10				
11	Surgical setting			
12				
13	Outpatient procedure	Reference		
14	Inpatient procedure	5.41	3.83–7.66	<0.001
15				
16	Number of beds			
17	<100	Reference		
18	≥100	1.91	1.41–2.57	<0.001
19				
20	Teaching facility			
21				
22	Teaching hospital	Reference		
23	Non-teaching hospital	0.77	0.55–1.09	0.14
24				
25	Procedure volume quartile			0.0018 ^a
26				
27	Q1 (lowest)	Reference		
28	Q2	1.18	0.91–1.52	0.22
29	Q3	1.63	1.10–2.40	0.015
30	Q4 (highest)	2.23	1.15–4.31	0.018
31				
32	MOR ^b	2.89	2.69–3.24 ^c	
33				

^aOverall P value.

^bMOR indicates the inter-institutional variation of the utilisation of preoperative tests.

^cThe 95% CI for MOR was calculated by bootstrap resampling method.

CI, confidence interval; MOR, median odds ratio; OR, odds ratio.

Postoperative adverse events

The incidence of postoperative transfusion events within postoperative 2 days was 1 patient (0.008%; 1 patient underwent hernia surgery) in the whole cohort. The incidence of postoperative re-operation for surgical bleeding after tonsillectomy was 0.90% (37 of 4,104); 31 of 3527 (0.88%) in patients undergoing preoperative coagulation tests and 6 of 577 (1.04%) in patients without preoperative tests (unadjusted OR, 0.84; 95% CI, 0.35–2.03,

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3 P=0.70). Penalised logistic regression analysis revealed that the adjusted OR of preoperative
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6 coagulation tests for postoperative re-operation was 0.74 (95% CI, 0.34–1.91, P=0.60).
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DISCUSSION

We found that the preoperative tests were performed in a majority of children before undergoing common non-cardiac surgeries. Preoperative testing was strongly associated with type of anaesthesia, type of surgery, and surgical setting. There were quite low postoperative transfusion events, and no statistically significant difference in postoperative re-operation for surgical bleeding was found between patients with or without preoperative coagulation tests.

As the increased overuse globally, problems of low-value care have gained more attention recently.[9] To our knowledge, our study is the largest and most comprehensive population-based study investigating the preoperative tests before common paediatric surgeries. Our database could capture the whole series of preoperative tests ordered both at inpatient and outpatient settings. Therefore, our analysis can precisely describe the current preoperative testing status in Japan. Previous French nationwide cohort study did not have medical services data, including tests or procedures during inpatient episodes.[8] This recent French study showed that coagulation and ABO blood typing tests were performed in 49% and 50% of children before tonsillectomy, respectively.[8] Although the SFAR guideline did not recommend preoperative tests among children undergoing elective tonsillectomy,[6,7] there was still a high rate of unnecessary preoperative tests on paediatric patients.[8] Our results demonstrated that most children undergoing tonsillectomy underwent coagulation (PT, 84% and aPTT, 86%) and ABO blood typing (79%) tests, which were markedly higher compared to those of the recent French study.[8] Although not all of these preoperative tests are clinically inappropriate, preoperative coagulation tests for screening or predicting coagulopathy risk were not recommended. Standard haemostatic assessments (PT, aPTT, and platelet count) cannot help in detecting the most common congenital bleeding disorders, such as von Willebrand disease or haemophilia A, and cannot help in predicting perioperative

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3 bleeding risk. The predictive value of haemostatic tests (PT, aPTT, and platelet count) for
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5 determining perioperative bleeding risk of children undergoing tonsillectomy is generally
6
7 poor, with a low sensitivity of <44% and a positive predictive value of <29%. [7] In walking-
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9 age children, a standardized questionnaire (personal or family history of haemorrhagic
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11 diathesis) and physical examination are more sensitive than laboratory tests in the detection
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13 of bleeding risk. [7,27] Abnormal results were not always associated with hereditary blood
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15 disease. [7,8] False positive results can trigger further tests, leading to inappropriate
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17 perioperative management and delay or cancellation of elective surgeries. [5,8] The increasing
18
19 number of blood tests can burden children and parents. As children consider phlebotomy as
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21 one of the most frightening and painful health-related events, frequent experiences can lead
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23 to increased distress in future procedures and development of needle fears, potentially leading
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25 to health care avoidance behaviours. [28]

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31 Regarding the association of preoperative tests, we found a markedly high adjusted OR for
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33 the type of anaesthesia and surgical setting. There was also a relatively high MOR for
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35 medical institutions (i.e., the odds of receiving preoperative tests between two randomly
36
37 selected medical institutions varied by 2.89 times), suggesting inter-institutional variation in
38
39 ordering preoperative tests in children. These results were consistent with our previous report
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41 on low-risk surgeries in Japan showing that preoperative blood tests performed in adult
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43 patients before undergoing low-risk surgery (e.g., cataract, superficial surgery) were strongly
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45 associated with the type of anaesthesia, patient characteristics, and medical facility
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47 status. [15,16,17] Especially, the type of anaesthesia was the most important predictors in our
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49 study focused in children and previous adult studies. [16] However, our findings were in
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51 opposition to the SFAR guidelines, which recommended that haemostasis tests should not be
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53 ordered regardless of anaesthesia type. [7] A guideline for preoperative tests has not been
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55 established in Japan, and there is little consensus on whether preoperative testing is required,
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3 leading to variations in ordering patterns. Moreover, certain hospital factors, including
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5 policies for preoperative management, provider preference, or the defensive medicine, may
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7 partially explain this overuse and inter-institutional variation.[15,16]
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11 Our supplementary analysis showed that the need for postoperative transfusion within 2 days
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13 was very rare. Moreover, re-operation incidence for post-tonsillectomy bleeding (objective
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15 and reliable end point for evaluating clinically relevant bleeding after tonsillectomy) [19,20]
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17 was low (0.9%), consistent with previous reports,[19,20] and there was no statistically
18
19 significant difference between patients with or without preoperative coagulation tests. A
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21 previous randomised trial demonstrated that perioperative outcomes after low-risk surgery
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23 were not different in patients with or without preoperative tests.[29] Previous studies have
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25 investigated the utility of haemostasis tests in predicting bleeding risk among children
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27 undergoing tonsillectomy, and a majority of studies concluded that the predictive value of
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29 preoperative haemostasis tests was poor.[7] The preoperative coagulation tests before
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31 paediatric non-cardiac surgery are largely unnecessary. It is important to reduce these tests
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33 unless there is a clear indication not only because of the low-value care, which provides little
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35 or no benefit at all, but also increasing cost of related health care. In 2016, the Japanese
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37 government estimated that at least 2.4 million general anaesthesia cases were performed
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39 annually, with patients aged 5 years and younger accounting for 2.7% of total inpatient
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41 procedures performed under general anaesthesia (approximately 65,000 cases).[30,31] It is
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43 apparent that increasing preoperative test overuse will burden the Japanese health care system
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45 in future. Our findings could provide valuable baseline data about preoperative testing
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47 overuse for not only clinicians but also for policymakers and promote the need for
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49 reconsidering the routine clinical practice and the cost of these tests.[8,15]
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3 This study has several limitations. First, our claims database lacked important clinical
4 information, such as patients' and family history of bleeding, symptoms, or abnormal
5 physical examination, which may have influenced the indication of preoperative tests. As we
6 did obtain neither the patient's nor the family's history of bleeding, we excluded the patients
7 with diagnostic codes indicating hereditary bleeding disorders. The exclusion of patients with
8 high-risk comorbidities for bleeding was based on ICD-10 codes using components of the
9 Elixhauser comorbidities index.[18] Although the Elixhauser comorbidities index is a
10 validated measure of comorbidities in insurance claims databases, similarly to that used in
11 this study,[32] the diagnostic accuracy of each component was not validated in Japan. Thus,
12 misclassification of comorbidities can lead to underestimation. Second, how the abnormal
13 results of preoperative tests have affected perioperative course was unknown. As our
14 database did not have the results of the blood tests, we were not able to interpret whether the
15 coagulation test results were normal or abnormal. Therefore, we did not analyse the sequela
16 of these findings. Third, there may be a selection bias with the inclusion of only specific
17 paediatric surgeries in this study. However, we carefully chose to include common paediatric
18 surgeries based on the recent publications.[8,19] We used tonsillectomy procedures as a
19 representative scenario to compare our study with previous investigations.[8] Fourth, we
20 could not access the data from the physician who ordered the preoperative tests and could not
21 investigate the effects of clinician-related practice pattern. A previous study of low-risk
22 surgery revealed that the practice patterns of the physicians were more likely associated with
23 the preoperative testing rather than patients' comorbidities.[22] In future exploration, it is
24 necessary to determine whether the degree of variation is rooted at the institutional or
25 individual provider levels.[33] Given that our MOR for inter-institutional variation was 2.89,
26 it would be important to compare institutions with high and low orders for these tests to
27 investigate the reasons for their practice variation. Finally, this nationwide study limits the
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3 results' generalisability to other countries with different clinical practices and health care
4 systems.[15,16] Nevertheless, our study can add significantly to the growing evidence on the
5 prevalence of medical overuse worldwide.
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9 10 **CONCLUSION**

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13 Preoperative haemostasis and ABO blood typing tests were performed in a majority of
14 children before undergoing common paediatric surgeries despite the low postoperative
15 transfusion and re-operation events. Preoperative tests were associated with the anaesthesia,
16 surgical type, and surgical setting.
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Author Contribution

HY conceived the study, collected, analysed, interpreted the data and results, and drafted the manuscript. KI analysed the data and performed statistical analyses. HY, KI, YK, CT, YN, YM, MS, KK, and MK conceived the study and interpreted the data and drafted the manuscript. All authors critically revised the manuscript for intellectual content. All authors read and approved the final manuscript.

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Competing interest

The authors have no conflict of interest directly relevant to the content of this article within 36 months prior to submission. KK received honoraria from Shin Nippon Biomedical Laboratories, Ltd.; research funds from Bayer Yakuhin Ltd., CMIC Co., Ltd., Novartis Pharma K.K., Suntory Beverage & Food Ltd., Dainippon Sumitomo Pharma Co., Ltd., and Stella Pharma Corporation; and holds stocks in School Health Record Center Co., Ltd. and Real World Data, Co., Ltd. There are no patent products under development or marketed products to declare, relevant to those companies.

Checklists for the appropriate reporting statement

This retrospective observational study was conducted according to the “STrengthening the Reporting of OBservational studies in Epidemiology” (STROBE) guidelines.

Patient consent for publication

Not required.

Ethics statement

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3 This study was by the Ethics Committee of Mie University Graduate School and Faculty of
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5 Medicine (approval number: H2018-094), who waived the requirement for obtaining
6
7 informed consent from the patients due to the anonymous nature of the data.
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10 **Provenance and peer review**

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12 Not commissioned; externally peer reviewed.
13

14 **Data sharing statement**

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16 The data sets analysed in this study are available from the corresponding author on
17
18 reasonable request.
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22
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Figure legends

Figure 1. Study flow diagram.

Supplementary material

Supplemental Table S1: A list of all the surgeries included in the study.

Supplemental Table S2: A list of all the claim codes used to define the preoperative haemostasis and ABO blood typing tests included in the study.

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Eligible surgeries from April 1,
2012 to March 31, 2018
N = 29,830

16,812 excluded
N = 685
Patients < 1 y of age
N = 13,831
Patients ≥ 18 y of age
N = 2,121
Multiple surgeries
N = 175
Patients with high-risk
comorbidities

Available data
N = 13,018

Supplemental Digital Content 1

Supplemental Table 1: Common pediatric surgeries included in the study cohort

Procedure type

Japanese K procedure code Details

Otolaryngology, head, and neck surgery

- | | |
|------|--|
| K309 | ● Tympanoplasty with tubing |
| K370 | ● Adenoidectomy |
| K377 | ● Tonsillectomy
(excluding the reoperation for post-tonsillectomy bleeding) |

Ophthalmologic surgery

- | | |
|------|---|
| K219 | ● Blepharoptosis repair
(eyelid surgery for congenital ptosis) |
| K242 | ● Strabismus surgery |

Superficial surgery

- | | |
|------|---|
| K633 | ● Inguinal hernia repair
● Umbilical hernia repair |
|------|---|

Urologic surgery

- | | |
|------|---|
| K819 | ● Hypospadias repair |
| K828 | ● Circumcision |
| K836 | ● Orchidopexy
(surgical correction of an undescended testis) |

Supplemental Digital Content 2

Supplemental Table 2: All the claim codes used to define the preoperative hemostasis and ABO blood typing tests included in the study

Any one of the following claim codes (during days 1–60 prior to the index surgery)	Description
Platelet count	
160008010	Complete blood count (CBC)
160061810	Calculation charges
Prothrombin time (PT)	
160012010	Prothrombin time
Activated partial thromboplastin time (aPTT)	
160012310	Activated partial thromboplastin time
ABO blood typing tests	
160039110	ABO blood typing
160039210	Rh phenotype determination

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 2	“retrospective observational study”
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2	“We described the proportions of each preoperative test performed within 60 days before an index surgery, including platelet count, prothrombin time (PT), activated partial thromboplastin time (aPTT), and ABO blood typing tests. We also explored the associations between patient- and institutional-level factors and any preoperative tests, using multilevel logistic regression analysis.” “The overall proportion of each test was as follows: platelet count, 78.6%; PT, 54.4%; aPTT, 56.4%; and ABO blood typing tests, 50.4%. The proportion of patients undergoing any preoperative tests in the overall sample was 79.3%. Multilevel logistic regression analysis indicated that ”

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Introduction

Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5	“Despite its clinical and public health importance, limited information is available regarding the frequency of these preoperative tests before elective paediatric surgery and the manner in which their utilisation is affected by individual patient- and institutional-level characteristics in a real-world setting.”
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Objectives	3	State specific objectives, including any prespecified hypotheses	6	“we aimed to estimate the proportion of children who underwent preoperative haemostasis and ABO blood typing tests prior to common paediatric surgery in Japan. Moreover, we sought to identify the patient- and institutional-level factors associated with preoperative tests.”
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Methods

Study design	4	Present key elements of study design early in the paper	7	“This retrospective observational study was conducted”
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7	“The data were provided by a commercial database vendor, JMDC Co., Ltd (Tokyo, Japan)”

1				
2	Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	7,
3				Supplementary
4				Table S1,
5			<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case	8
6			ascertainment and control selection. Give the rationale for the choice of cases and controls	
7			<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of	
8			participants	
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For peer review only

“We used these original Japanese K codes to identify the eligible common paediatric surgeries (otolaryngology, head and neck surgery, including tonsillectomy with or without adenoidectomy, ophthalmologic surgery [strabismus surgery or eyelid surgery for congenital ptosis], superficial surgery [inguinal hernia or umbilical hernia], and urologic surgery [surgery of an undescended testis, hypospadias, or circumcision]; Online Supplementary Table S1) from April 1, 2012, to March 31, 2018”

“We included patients aged 1–17 years with at least 12 months of insurance eligibility before their index surgery, who had at least 1 claim during the study period.[15] Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) who underwent an eligible procedure

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				were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.”
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8, 9, Supplementary Table S2	“Medical billing within 60 days before the index procedure (but not including the day of the index surgery) were used to identify our primary outcome, according to previous studies” “We examined several predictors of preoperative tests, including patient demographics (age and sex), comorbidities, type of anaesthesia, surgical procedure, surgical setting, and medical facility status, based on clinical experience and previous literatures”
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8, Supplementary Table S2	“the receipt of any of the following preoperative blood tests: platelet count, prothrombin time (PT), activated partial thromboplastin

				time (aPTT), and ABO blood typing tests.[8] The Japanese claims codes used in this study are provided in Online Supplementary Table S2.”
Bias	9	Describe any efforts to address potential sources of bias	8	“Patients with high-risk comorbidities for bleeding (i.e., patient with coagulopathy including hereditary bleeding disorders, or with any malignancy, including leukaemia and lymphoma) who underwent an eligible procedure were also excluded.[8] To eliminate the effects of within-subject correlation among patients with multiple eligible surgeries, only the first surgery per person was considered.”
Study size	10	Explain how the study size was arrived at		No relevant text

Continued on next page

1				
2	Quantitative	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which	No relevant text
3	variables		groupings were chosen and why	
4				
5	Statistical	12	(a) Describe all statistical methods, including those used to control for confounding	10
6	methods			
7				“To consider the nesting of all
8				patients within medical institutions,
9				we conducted a multilevel logistic
10				regression analysis.”
11			(b) Describe any methods used to examine subgroups and interactions	No relevant text
12			(c) Explain how missing data were addressed	No relevant text
13			(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	There were no follow-up cases.
14			<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed	no relevant text
15			<i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling	
16			strategy	
17			(e) Describe any sensitivity analyses	No relevant text
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19	Results			
20	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined	12
21			for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
22			(b) Give reasons for non-participation at each stage	Figure 1
23				Figure 1 gives reasons for non-
24				participation at each stage.
25			(c) Consider use of a flow diagram	12,
26				Figure
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28				“Figure 1 shows the study
29	Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on	12, Table 1
30			exposures and potential confounders	
31				“Table 1 summarises the patient-
32				and institutional-level
33			(b) Indicate number of participants with missing data for each variable of interest	No participants with missing data
34			(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	No relevant text
35	Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	14, Table 2
36				“Table 2 shows the proportions of
37				preoperative haemostasis and ABO
38				blood typing tests for the entire
39				cohort and for each procedure and
40				anaesthesia category.”
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		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure		
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures		
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	16, Table 3	“Table 3 shows the adjusted OR of the patient- and institutional-level factors with any preoperative tests. Patient medical factors (older age or asthma) were associated with the preoperative tests, but their adjusted ORs were relatively weak.”
		(b) Report category boundaries when continuous variables were categorized		
		© If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		

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2	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14
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18	Discussion			
19	Key results	18	Summarise key results with reference to study objectives	19
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				between patients with or without preoperative coagulation tests.”
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22	“This study has several limitations.”
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	23	“Preoperative haemostasis and ABO blood typing tests were performed in a majority of children before undergoing common paediatric surgeries despite the low postoperative transfusion and re-operation events. Preoperative tests were associated with the anaesthesia and surgical types, and surgical setting.”
Generalisability	21	Discuss the generalisability (external validity) of the study results	22,23	“Finally, this nationwide study limits the results’ generalisability to other countries with different clinical practices and health care systems.[15,16] Nevertheless, our study can add significantly to the

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growing evidence on the prevalence of medical overuse worldwide.”

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24	This work was supported in part by grants from the Pfizer Health Research Foundation and the Japanese Society of Anesthesiologists.
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.