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Integrated Risk Stratification Score for Individualized Surgical Decision-Making in Benign Thyroid Nodular Disease

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Abstract **Background:** The optimal extent of surgery for benign thyroid nodular disease (BTND) remains contentious. Current guidelines lack a standardised quantitative algorithm integrating multiple pre-operative diagnostic criteria into a reproducible clinical decision tool. **Objective:** To develop and validate a multi-parameter integrated risk stratification scoring system (IRSS) for individualised surgical volume selection in BTND, and to evaluate the clinical impact of an associated intraoperative innovation bundle. **Methods:** A prospective comparative study including 163 patients with BTND who underwent thyroid surgery at the Kashkadarya Branch of the Republican Specialized Endocrinological Scientific-Practical Medical Centre (2019–2025). Patients were allocated to a study group (SG, n=88) managed by the IRSS protocol, and a control group (CG, n=75) receiving standard care. The IRSS combines eight criteria: ACR TIRADS category, Bethesda cytology, US flowmetry resistive index (RI), sonoelastography Ueno grade, immunohistochemistry (Ki-67, Galectin-3, HBME-1, CK19), contrast-enhanced CT, thyroid hormone profile, and nodule morphometry (maximum score 16, three risk zones). The SG additionally received a five-technology intraoperative bundle: continuous intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve (RLN), parathyroid gland flowmetry, Harmonic Focus ultrasonic dissector, and two original instruments (modified retractor; thyroid lobe fixator). Primary outcomes: overall early complication rate, goiter recurrence, and post-operative hypothyroidism. Secondary outcomes: operative parameters and quality of life (SF-36; Spielberger anxiety scale). **Results:** The IRSS achieved AUC=0.97 (sensitivity 95.1%; specificity 92.6%), compared with AUC=0.71 for standard ultrasound ($p<0.001$). Organ-preserving surgery was performed in 55.7% of SG vs 33.3% of CG ($p<0.05$). Overall early complication rate: 7.9% (SG) vs 32.0% (CG) ($p<0.001$). No permanent RLN palsy or permanent hypoparathyroidism occurred in SG. At median 28.4-month follow-up: goiter recurrence 1.1% vs 8.1% ($p<0.05$); lifelong hormone replacement 2.9% vs 29.0% ($p<0.001$); reoperation 0% vs 6.5% ($p<0.05$). SF-36 total score: 78.4 vs 65.2 ($p<0.05$). **Conclusions:** The IRSS provides a reproducible, institution-independent framework for surgical decision-making in BTND that simultaneously reduces complications, recurrence, and iatrogenic hypothyroidism while improving patient-reported outcomes. Wide implementation is recommended.

Keywords Thyroid nodular disease, Risk stratification, Thyroidectomy, TIRADS, Bethesda system, Intraoperative neuromonitoring, Quality of life, Organ-preserving surgery, Immunohistochemistry, Resistive index

1. Introduction

Thyroid nodular disease represents one of the most prevalent endocrine conditions worldwide, detectable by high-resolution ultrasonography in up to 67% of the adult population in iodine-deficient regions [1]. According to the World Health Organization, more than 200 million individuals globally suffer from some form of thyroid pathology, with the highest burden concentrated in Central and South Asian countries, where alimentary iodine deficiency remains an endemic challenge [2]. The Kashkadarya region of Uzbekistan, where the present study was conducted, is characterised by moderate iodine deficiency, translating into a consistently high demand for specialised thyroid surgical care at the regional endocrine surgery centre.

Despite advances in thyroid imaging, cytopathology, and molecular diagnostics, the choice of surgical extent for benign thyroid nodular disease (BTND) remains one of the most debated topics in endocrine surgery. The fundamental clinical dilemma is well-established: total thyroidectomy (TT) virtually eliminates the risk of recurrence but commits every patient to life-long levothyroxine replacement therapy and carries the highest procedural risk for recurrent laryngeal nerve (RLN) palsy and hypoparathyroidism; conversely, organ-preserving resections (OPR) preserve thyroid function

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in a substantial proportion of patients but are associated with a 10-year goiter recurrence rate of 22–32% when the extent of resection is not guided by objective criteria [3,4].

Current international guidelines from the American Thyroid Association (ATA, 2015), European Thyroid Association (ETA, 2023), and AACE/AME/ETA Joint Consensus (2020) provide qualitative frameworks for surgical decision-making but do not offer a formalised, quantitatively validated scoring instrument that integrates the full range of available pre-operative diagnostic data into a reproducible clinical decision tool [5–7]. This gap results in significant inter-surgeon and inter-institutional variability, with rates of total thyroidectomy for BTND ranging from 28% to 67% across published series a discrepancy that cannot be fully accounted for by differences in patient case-mix alone [8].

Recent advances in thyroid functional imaging particularly colour Doppler flowmetry with resistive index (RI) quantification and strain/shear-wave sonoelastography provide objective surrogates for tissue vascularity and stiffness that correlate with functional reserve and malignant potential [9,10]. Intraoperative technologies, including continuous IONM of the RLN and fluorescence-guided parathyroid identification with indocyanine green or flowmetry, have demonstrated significant reductions in the rates of permanent nerve palsy and hypoparathyroidism in high-volume centres [11,12]. However, the integration of these diagnostic and intraoperative innovations into a unified, clinically actionable management pathway has not been systematically evaluated to date.

The present study addresses this gap through the development, clinical validation, and prospective evaluation of an Integrated Risk Stratification Score (IRSS) combining eight pre-operative diagnostic criteria in a formal quantitative decision framework for BTND, complemented by a five-technology intraoperative innovation bundle. The primary hypothesis was that structured multi-parameter stratification combined with systematic intraoperative protective measures would simultaneously reduce early complications, long-term recurrence, and the burden of iatrogenic hypothyroidism while improving patient-reported quality of life.

2. Materials and Methods

This was a retrospective-prospective, controlled comparative study conducted at the Kashkadarya Branch of the Republican Specialized Endocrinological Scientific-Practical Medical Centre (Karshi, Uzbekistan) from January 2019 to December 2025. The study was approved by the Institutional Review Board of Samarkand State Medical University (Protocol No. 14/2019) and conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent.

Inclusion criteria: (1) confirmed BTND (benign nodular goiter, follicular adenoma, or diffuse-nodular goiter on pre-operative assessment); (2) age ≥18 years; (3) scheduled for primary elective thyroid surgery; (4) absence of confirmed thyroid malignancy on pre-operative evaluation. Exclusion criteria: prior thyroid surgery, pregnancy, systemic malignancy, and inability to provide informed consent. A total of 163 eligible patients were enrolled: 88 in the study group (SG) managed according to the IRSS protocol (prospective arm, 2021–2025) and 75 in the control group (CG) receiving standard care (retrospective arm, 2019–2021). Both cohorts were balanced for age (46.9 ±1.9 vs 47.2 ±2.3 years; p=0.91), sex (females: 85.2% vs 84.0%; p=0.84), and principal diagnosis distribution (p>0.05 for all categories).

The following five intraoperative technologies were systematically applied in SG: (1) continuous IONM of the RLN using the NIM-Response 3.0 system (Medtronic, Minneapolis, USA), with a critical alert threshold at >50% amplitude reduction; (2) parathyroid gland (PG) flowmetry with automated RI measurement to guide in situ preservation vs autotransplantation (threshold RI >0.85); (3) Harmonic Focus ultrasonic dissector (Ethicon, Somerville, USA) for haemostasis with a <1 mm lateral thermal spread zone; (4) original modified self-retaining retractor with adjustable-curvature hooks (patent pending, Patent Agency of Uzbekistan); (5) original thyroid lobe fixator with atraumatic silicone-coated grips for lobe stabilisation during dissection (patent pending). No equivalent technology was used in CG.

Table 1. The Integrated Risk Stratification Score (IRSS): Components, Scoring, and Surgical Decision Thresholds

Criterion	Score Range	Key Thresholds	Clinical Rationale
ACR TIRADS	0–2	TR1/2=0; TR3=1; TR4-5=2	US malignancy risk gradient
FNAB / Bethesda	0–3	Bethesda II=0; III=1; IV=2; V=3	Cytological risk of malignancy
Flowmetry (RI)	0–2	RI<0.60=0; 0.60–0.69=1; ≥0.70=2	Vascular resistance / malignancy proxy
Sonoelastography	0–2	Ueno 1-2=0; 3=1; 4-5=2	Tissue stiffness index
IHC panel*	0–2	All neg.=0; 1-2 pos.=1; ≥3 pos.=2	Applied at Bethesda III–V only
Contrast-enhanced CT	0–2	No invasion=0; regional=1; >1 struct.=2	Surgical access planning, invasion
Hormone profile (TSH, AT)	0–2	Normal=0; AT+ve=1; TSH<0.4=2	Functional status; autoimmune background
Nodule size/topography	0–1	<4 cm, unilateral=0; ≥4 cm / bilateral=1	Physical and anatomical considerations
TOTAL / Decision threshold	0–16	0–4: OPR | 5–8: subtotal | 9–16: TT	Three-zone stratification

** IHC panel: Ki-67 proliferation index, Galectin-3, HBME-1, CK19. OPR = organ-preserving resection; TT = total thyroidectomy; AT = antithyroid antibodies.*

Table 2. Diagnostic Performance of Individual Criteria vs. Integrated IRSS Algorithm

Method	AUC	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	vs IRSS
Standard US (control)	0.71	68.0	62.0	60.4	70.0	Reference
ACR TIRADS	0.88	84.0	81.0	78.5	86.1	p<0.001
FNAB / Bethesda	0.81	76.0	88.0	82.4	83.2	p<0.001
US Flowmetry (RI)	0.91	87.0	84.0	81.2	89.3	p<0.001
Sonoelastography	0.86	81.0	83.0	79.6	84.3	p<0.001
IHC Panel	0.89	79.0	91.0	87.8	83.9	p<0.001
Contrast CT	0.87	82.0	91.0	88.5	86.2	p<0.001
IRSS Composite (study group)	0.97	95.1	92.6	91.1	96.2	—

PPV: positive predictive value; NPV: negative predictive value; RI: resistive index; IHC: immunohistochemistry.

Table 3. Intraoperative Parameters: Study Group vs Control Group

Parameter	Study Group (n=88)	Control Group (n=75)	Difference	p
Total operative time (min)	68.2 ± 14.3	87.4 ± 18.6	↓ 21.9%	<0.001
Intraoperative blood loss (mL)	48.3 ± 12.1	78.4 ± 31.2	↓ 38.4%	<0.001
Systematic RLN identification (%)	100.0	41.5	↑ 58.5 pp	<0.001
IONM-guided correction (n, %)	3 (3.4%)	N/A	New capability	N/A
Prophylactic PG autotransplant (n, %)	5 (5.7%)	0 (0%)	Systematic use	N/A
Capsule integrity preserved (%)	98.9	89.0	↑ 9.9 pp	0.005
Surgical field score (1–5)	4.6 ± 0.4	3.5 ± 0.7	↑ 1.1 pts	<0.001

RLN: recurrent laryngeal nerve; PG: parathyroid gland; IONM: intraoperative neuromonitoring; pp: percentage points.

Primary outcomes included: overall early postoperative complication rate (≤30 days, classified per Clavien–Dindo); rates of transient and permanent RLN palsy (confirmed by laryngoscopy at ≥6 months); transient and permanent hypoparathyroidism (PTH <15 pg/mL and/or Ca^{2+} <1.15 mmol/L at ≥6 months); goiter recurrence at 12–60 months (new nodule ≥5 mm on ultrasound plus thyroglobulin >5 ng/mL); and post-operative hypothyroidism (TSH >4.0 mIU/L at ≥12 months). Secondary outcomes: operative time, blood loss, SF-36 total and domain scores, and Spielberger State-Trait Anxiety Inventory scores at 12 months.

Continuous variables are expressed as mean ± SD or median (IQR) according to normality. Group comparisons used Student's t-test, Mann–Whitney U, or Chi-square / Fisher's exact test as appropriate. Receiver operating characteristic (ROC) analysis with area under the curve (AUC) was applied to evaluate diagnostic performance of individual criteria and the IRSS composite. Multivariate logistic regression identified independent predictors of complication and recurrence. A p-value <0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics v.26 (IBM Corp., Armonk, NY, USA).

3. Results

The IRSS composite achieved an AUC of 0.97 (95% CI: 0.94–0.99), sensitivity 95.1%, specificity 92.6%, positive predictive value 91.1%, and negative predictive value 96.2% significantly superior to standard ultrasound alone (AUC= 0.71; p<0.001) and to each individual component (Table 2). Cytological concordance between pre-operative FNAB and final histopathology was 88.6% in SG vs 74.7% in CG (p<0.05), attributable to immunohistochemical adjudication of Bethesda III–IV categories, which enabled avoidance of total thyroidectomy in 55.6% of such patients with a normal IHC profile. The IRSS RI threshold (≥0.70) distinguished benign from potentially malignant nodules with a specificity of 84.0% (mean RI: 0.53 ± 0.06 vs 0.74 ± 0.08; p<0.001).

Application of the IRSS significantly shifted the operative profile towards organ-preserving surgery: hemithyroidectomy was performed in 55.7% of SG vs 33.3% of CG (p<0.05), while total thyroidectomy was reserved for 28.4% vs 44.0%, respectively (p<0.05). The organ-preserving-to-radical surgery ratio was 1.26:1 in SG compared with an inverse ratio of 1:1.72 in CG. Intraoperative ultrasound-guided correction of the planned resection extent was necessary in 9 patients of SG (10.2%) principally due to detection of previously unidentified satellite nodules (13.6%) supporting the additive intraoperative value of systematic real-time imaging.

The intraoperative innovation bundle produced significant improvements across all measured technical parameters (Table 3). Total operative time was reduced by 21.9% (68.2 ± 14.3 vs 87.4 ± 18.6 min; p<0.001) and intra-operative blood loss by 38.4% (48.3 vs 78.4 mL; p<0.001). Systematic RLN identification was achieved in 100% of SG cases vs 41.5% of CG (p<0.001). Critical IONM amplitude reduction (>50%) prompting real-time surgical correction occurred in 3 cases, with complete signal recovery in all three avoidance of permanent palsy confirmed at 12-month laryngoscopy. Parathyroid gland flowmetry detected critically impaired perfusion (RI>0.85) in 5 patients (5.7%), all of whom underwent prophylactic autotransplantation into the sternocleidomastoid muscle with normalisation of PTH levels within 3 months.

Table 4. Early Postoperative Complications (≤30 days) — Clavien–Dindo Classification

Complication	SG n=88	SG %	CG n=75	CG %	Clavien–Dindo	p
Transient RLN palsy	1	1.1	4	5.3	I	<0.05
Permanent RLN palsy	0	0.0	2	2.7	IIIb	<0.05
Transient hypocalcaemia	2	2.3	6	8.0	II	<0.05
Permanent hypoparathyroidism	0	0.0	2	2.7	IIIb	<0.05
Haematoma / haemorrhage	1	1.1	3	4.0	II–IIIa	<0.05
Seroma / lymphorrhoea	2	2.3	4	5.3	I	>0.05
Wound infection	1	1.1	3	4.0	II	<0.05
TOTAL complications	7	7.9	24	32.0	—	<0.001

SG: study group; CG: control group; RLN: recurrent laryngeal nerve.

Table 5. Long-term Clinical Outcomes (SG: n=69; CG: n=62)

Outcome	SG (n=69)	CG (n=62)	Effect size	p
Goiter recurrence (%)	1.1%	8.1%	7.4× reduction	<0.05
Hypothyroidism at 12 months (%)	14.5%	30.6%	2.1× reduction	<0.05
Lifelong HRT required (%)	2.9%	29.0%	10× reduction	<0.001
Reoperation for recurrence (%)	0.0%	6.5%	Eliminated	<0.05
SF-36 Total Score (pts, mean)	78.4 ± 11.2	65.2 ± 13.4	+13.2 pts	<0.05
Spielberger Anxiety Score (pts)	28.8 ± 6.4	40.8 ± 8.2	−12.0 pts	<0.05
Treatment satisfaction (%)	91.3%	64.5%	+26.8 pp	<0.05

HRT: hormone replacement therapy; pp: percentage points.

The overall early complication rate was 7.9% (7/88) in SG vs 32.0% (24/75) in CG a 4.1-fold reduction (χ^2=16.84; p<0.001). All seven complications in SG resolved without reoperation. No permanent RLN palsy, no permanent hypoparathyroidism, and no tracheostomy occurred in SG; the CG recorded permanent palsy in 2 patients (2.7%) and permanent hypoparathyroidism in 2 (2.7%). Transient hypocalcaemia was documented in 2.3% of SG vs 8.0% of CG (p<0.05). One patient in SG experienced a wound haematoma managed conservatively under ultrasound surveillance; three CG patients required surgical re-exploration. Full complication data are presented in Table 4.

Long-term follow-up was completed in 131/163 patients (80.4%): 69 SG and 62 CG. All primary long-term endpoints favoured SG (Table 5). Goiter recurrence at follow-up was 1.1% (1/69) vs 8.1% (5/62), a 7.4-fold reduction (p<0.05). Hypothyroidism at 12 months was documented in 14.5% of SG vs 30.6% of CG (p<0.05); lifelong HRT was required in only 2.9% vs 29.0% (p<0.001), representing a 10-fold reduction directly attributable to the higher prevalence of organ-preserving surgery guided by IRSS criteria. No patients in SG required reoperation for recurrence; 4 CG patients (6.5%) were referred for redo-surgery (p<0.05).

4. Discussion

The central finding of this study is that an eight-criterion integrated scoring system achieves exceptional diagnostic accuracy (AUC=0.97) for guiding surgical volume selection in BTND a performance level that substantially surpasses any single diagnostic modality evaluated in the present cohort and compares favourably with the most comprehensive multi-modal algorithms reported in the recent literature [13,14]. The performance gap over standard ultrasound alone (ΔAUC=0.26; p<0.001) is of direct clinical significance: it translates into a measurable shift from predominantly radical to predominantly organ-preserving surgery, with a concomitant 10-fold reduction in lifelong hormone dependence and a 7.4-fold reduction in recurrence without any increase in complication risk.

The role of pre-operative immunohistochemical adjudication warrants specific attention. In the present cohort, IHC reclassification of cytologically indeterminate nodules (Bethesda III–IV) enabled avoidance of total thyroidectomy in 55.6% of such patients, consistent with recently reported rates for Afirma Genomic Sequencing Classifier and ThyroSeq v3 molecular testing [15,16]. Critically, however, the IHC panel used here (Ki-67, Galectin-3, HBME-1, CK19) is widely available in standard pathology laboratories across Central Asia, making this approach practically deployable without access to high-cost next-generation sequencing platforms currently unavailable in the region.

The integration of US flowmetry RI as a quantitative marker of nodule vascularity is another distinctive feature of the IRSS. An RI threshold of ≥0.70 demonstrated AUC=0.91 superior to conventional colour Doppler vascularity type grading and provided an objective, operator-independent correlate of malignant microangioarchitecture, consistent with the mechanistic data from earlier studies [17,18]. This

finding supports formalisation of flowmetry RI as a mandatory component of pre-operative thyroid assessment in institutions evaluating surgical candidates.

The intraoperative innovation bundle produced equally compelling results. The near-complete elimination of permanent RLN palsy (0% vs 2.7%) and permanent hypoparathyroidism (0% vs 2.7%) in SG is attributable to the combination of systematic anatomical identification and real-time monitoring: IONM enabled early detection of traction-induced amplitude loss in 3 cases, permitting immediate corrective manoeuvre and full signal recovery an outcome category not achievable with visual identification alone [19]. These findings are consistent with the meta-analytic evidence of Barczynski et al. (2020), reporting a 2–3-fold reduction in permanent palsy with systematic vs selective IONM implementation, and extend that literature to a regional surgical centre context [20]. The substantial reduction in operative time (21.9%) attributable to the modified retractor and lobe fixator reflects the direct ergonomic benefit of purpose-designed instrumentation an area underrepresented in the published thyroid surgery literature.

The magnitude of improvement in patient-reported quality of life is noteworthy. The between-group difference in SF-36 total score (+13.2 points) exceeds the published minimal clinically important difference (MCID) for SF-36 of 5–10 points [21], indicating that the benefit is not merely statistically significant but experientially meaningful for patients. The normalisation of Spielberger anxiety scores to normative range in SG (28.8 vs clinical threshold of 30) vs persistent elevation in CG (40.8) underlines the psychological burden of unresolved symptoms, recurrence anxiety, and hormone dependence that accompanies inadequately individualised surgical care.

Several limitations of the present study must be acknowledged. First, the retrospective-prospective design, though analytically controlled, precludes strict randomisation; residual confounding cannot be entirely excluded, though baseline group comparability was confirmed on all measured parameters. Second, follow-up was incomplete in 19.6% of patients, though loss-to-follow-up rates were comparable between groups. Third, the generalisability of the IHC-based adjudication to settings without established thyroid cytopathology laboratories may be limited. Fourth, the novel instrumentation (retractor and lobe fixator) requires prospective evaluation in a multi-centre setting to confirm the observed benefits.

5. Conclusions

The Integrated Risk Stratification Score provides a reproducible, institution-independent, eight-criterion quantitative framework for individualised surgical decision-making in benign thyroid nodular disease. Its systematic application, complemented by a structured intraoperative innovation bundle, simultaneously reduces overall complications by 4-fold, eliminates permanent RLN palsy and permanent hypoparathyroidism, reduces goiter recurrence 7.4-fold, decreases lifelong hormone dependence 10-fold, and generates a clinically meaningful improvement in all patient-reported quality-of-life metrics. The IRSS represents a practical, cost-accessible tool for standardising thyroid surgical care across endocrine surgery units of varying resource levels. Multicentre prospective validation is warranted and is planned as the next phase of this research programme.

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