

Archives of Surgical Research | Original Research Communication

Preoperative Difficulty Index for Thyroidectomy (PreoDIT™): A Novel, Reliable, Content Valid, and Valuable Tool

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IMPORTANCE A thyroidectomy can be a complex operation, currently there are no preoperative tools available to predict cases which may prove to be challenging procedures, or tools to grade potential thyroid procedures according to difficulty, based on a pre-operative assessment. The aim of this study is to develop such a tool; the Preoperative Difficulty Index for Thyroidectomy (PreoDIT™) and assess its reliability and validity.

MATERIALS AND METHODS To define factors contributing to the complexity of a thyroidectomy, qualitative methods were used to retrieve qualitative data, in addition to an extensive literature review. A focus group was arranged in which a panel of 8 experts with extensive experience in thyroid surgery participated; and a tool, PreoDIT™, was developed. This tool was then utilized on 513 patients to test its reliability, validity and efficiency.

RESULTS PreoDIT™ scores strongly correlated with operative times, blood loss and postoperative complications; proving the reliability of this novel tool.

CONCLUSIONS PreoDIT™ is a reliable and valid tool to measure the difficulty index of a thyroidectomy. This tool was designed to help surgeons optimize and manage their teams, operation theatre resources and resident training in a more objective way, before committing to a procedure.

KEYWORDS thyroidectomy, endocrine surgery, surgical oncology, quality improvement

HOW TO CITE Waseem T, Zafar Z, Ahmad SZ, Ashraf MH. Preoperative Difficulty Index for Thyroidectomy (PreoDIT™): A Novel, Reliable, Content Valid, and Valuable Tool. *Archives of Surgical Research*. 2021, 2 (4):5-11. <https://doi.org/10.48111/2021.04.03>

Original Research

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092-333-8078705
<https://doi.org/10.48111/2021.04.03>

Thyroidectomy, once considered horrid butchery associated with high morbidity and mortality rates, has become quite safe when done with a methodical approach¹⁻⁸. In fact, Theodor Kocher was awarded the Nobel Prize for Medicine in 1909, for reducing mortality to a minuscule 1% in this testing operation, where compulsive haemostasis and meticulous dissection within planes is pre-requisite to avoid post and per-operative complications⁹. Surgeons have identified factors which add to the difficulty of a thyroidectomy; these included vascularity, inflammation, gland toxicity, friability, fibrosis and large size of the gland¹⁰. Schneider et al. developed a Thyroidectomy Difficulty Scale for preoperative assessment of difficult cases¹¹. This scale gives a good estimate of the pre-operative assessment of the difficulty of the thyroidectomy, however, there was still a need for a tool to predict the difficulty preoperatively to aid direction, planning and organization, in order to reduce postoperative complications.

In our opinion, there are multiple additional factors which contribute to increased difficulty in this operation, they were recently identified by Patoir et al. and many others^{4,12-15}. For example; extent of retrosternal extension, extent of operation, T staging of the cancer, type of cancer, range of neck extension available to operate around, pre-existing loss of the recurrent laryngeal nerve and BMI. These factors certainly play a role in our practice and add to the difficulty of the operation^{14,16-21}. Similarly, use of preoperative Lugol's iodine may decrease vascularity of the gland, which aids a surgeon^{15,22-25}. Hence, a scaling system is required which comprehensively encompasses all possible factors involved in a difficult thyroidectomy and which predicts, preoperatively, difficult cases for which an experienced team can be employed, to prevent possible complications, and further help in managing operation theatre times and assignment according to surgical training, more appropriately²⁶.

This study is intended first, to analyze all possible factors which could possibly make a thyroid operation difficult, and second, to develop a tool to help predict the difficulty of an operation, preoperatively. Such a tool would help surgeons plan in advance and help lower postoperative complications.

METHODS

The study consists of qualitative and quantitative clinical components to complement the findings of the data. Figure 1 shows study flow chart.

Qualitative Component of Study & Development of PreoDIT™ Application:

Extensive literature review was done to identify various factors responsible for the difficulty of a thyroidectomy operation. Based on literature review, a discussion guide was developed for a Focus Group Discussion (FGD), in which 8 endocrine surgeons, with extensive experience in endocrine surgery, participated. FGD was conducted as described previously²⁷ transcribed discussions were managed using QSR NVivo (V.9). Iterative analysis, following tenets of grounded theory, was used to identify themes and their inter-relationships. Researchers went through transcripts line by line to categorize and describe data, and then developed themes through selective and conceptual coding. Newer themes were subjected to subsequent use in e-Delphi consensus building²⁸. Analysis was run along the interviewing session. Thematic analysis was done and meaningful themes and subthemes were identified.

The findings of initial FGD were subjected to e-Delphi technique-based consensus building to develop a scoring system which was named as Preoperative Difficulty Index for Thyroidectomy (PreoDIT™). e-Delphi technique was administered as described previously²⁸. The relative importance of the factors was identified on a Likert Scale and consensus building was done with 80% cut-off value. The content validity of the items was assessed through estimation of Content Validity Index (CVI) (data not shown here)²⁹. Table 1 shows the relative values of various factors which were subsequently used in the PreoDIT™ Application. IT experts were involved to develop the scoring system online (accessible through <http://archivessr.com/calc/>) and in the form of a mobile phone application (accessible through Google Play Store). The difficulty associated with lobectomy & isthmectomy of a small non-toxic nodule without significant risk factors as described below was considered the baseline.

The maximum PreoDIT™ score can be up to 53. To make the score more user-friendly, and to compare with other scoring systems, scores were equated against PreoDIT™ Grades ranging from 1-5. The grading of the score was done

according to the criteria: Grade 1: ≤ 1 ; Grade 2: 1.1 – 3; Grade 3: 3.1-5.9; Grade 4: 6-8; Grade 5: 9+.

Prospective Blinded Clinical Piloting:

Patients undergoing thyroidectomy (n=513) were enrolled for the trial, in order to explore the reliability and strength of correlation with other scoring systems and difficulty parameters. Pre-operatively, PreoDIT™ scoring was done which was not revealed to the operating surgeons. Postoperatively, respective surgeons filled a survey to score difficulty of the preceding procedure (labelled as Postoperative Difficulty Index for Thyroidectomy—PostoDIT) on a Likert scale of 1-5 and were asked to fill in the Thyroidectomy Difficulty Scale items developed by Schneider et al. (with up to 20 possible score). General demographics and parameters related to operative procedures such as blood loss, operative time, hospital stay and complications were recorded.

Statistical Methods & Analysis:

SPSS Version 21 was used for statistical analysis. Means, averages, standard deviations were estimated as per standards. In e-Delphi technique inter-rater reliability and concordance was measured through intra-class coefficient kappa values. CVI for the e-Delphi was measured as described previously to assess the content validity of the scale^{28,29}. For the clinical component, the intra-rater and inter-rater reliability, intra-class coefficient were measured. For measuring correlations among the scoring systems and other parameters, Pearson, Spearman and Kendal Tau B were used as appropriate for the data. A correlation of 0.4-0.59 was considered moderate, 0.6-0.79 as strong and equal or above 0.8 was considered very strong. A p value of 0.05 was considered statistically significant.

RESULTS

Literature review identified various factors responsible for adding to the difficulty of thyroidectomy. Based on the literature review, these factors were further explored in a FGD. 12 factors were identified. Column 1-3 in Table 1 describe various themes identified and their representative statements.

e-Delphi was employed for developing consensus among the experts about the relative value of various factors identified before incorporating into the questionnaire and validating its construct and content validity (Table 1-Column 4,5).

Focus Group Discussion (FGD)		e-Delphi Technique Consensus Building on Relative Value of Factors	
Factor	Representative Statement	Preoperative Scale (PreoDIT™)	
1	Thyrotoxicosis "The gland I fear the most is not the big gland but a small gland with Graves' disease". "Gland is red hot like iron and has got enormous supply. The vessels are thin walled and they bleed like anything". "Operating a Graves' disease gland is the real test of surgeon's quality and gentleness of dissection" "The gland is friable like anything. If you scratch a small area, it won't forgive you especially if the patient has not taken Lugol's iodine preoperatively".	No Toxicity	0
		Primary Thyrotoxicosis	5
		Primary Thyrotoxicosis treated with Lugol's Iodine	2
		Secondary Thyrotoxicosis	4
		Secondary Thyrotoxicosis treated with Lugol's Iodine	2
		Tertiary Thyrotoxicosis	1
2	Retrosternal Extension/ Intrathoracic Goiter "Short neck people have higher chance of development of retrosternal extension and most of the time it is cervico-mediastinal extension". "More than 90% can be delivered trans-cervically. Difficulty of thyroidectomy is proportional to depth of extension into mediastinum" "Most of the extensions are into the anterior mediastinum and can be delivered trans-cervically". "Cervico-mediastinal extension into posterior mediastinum is unlikely to be delivered transcervically and would be better dealt with thoracotomy". "True intrathoracic goiter is rare but adds significant difficulty. All need thoracotomy."	No Extension	0
		Cervicomedial Extension (Below clavicle and sternum) Grade 1	1
		Cervicomedial Extension (up to left brachiocephalic vein) Grade 2	4
		Cervicomedial Extension (up to aortic arch) Grade 3 (Anterior Mediastinum)	6
		Cervicomedial Extension (behind major mediastinal vessels) Grade 3 (Posterior Mediastinum)	9
		Intrathoracic Goiter	11
3	Thyroiditis "Thyroiditis makes dissection more difficult and adds vulnerability to nervi and parathyroids"	No	0
		Yes	2
4	Carcinoma T staging "T1,2 lesions don't hurt much, it is the T3 or T4 lesions with direct spread into trachea, esophagus or carotid sheath and surrounding lymph nodes, that really adds difficulty to the operation". "T4 lesions are real challenge. The balance between oncological clearance and the safety comes with experience".	No	0
		Carcinoma T Stage 1	0
		Carcinoma T Stage 2	0
		Carcinoma T Stage 3	2
		Carcinoma T Stage 4	4
5	Carcinoma Type "Type certainly matters. Papillary and Anaplastic have higher degree of local invasion." "There are more chances of having a better clearance with T3 follicular lesions instead of papillary and anaplastic lesions".	Follicular Lesion	3
		Papillary Carcinoma	4
		Medullary Thyroid cancer	6
		Anaplastic Carcinoma	7
6	Recurrent Surgery "Redo is always a challenge". "It becomes difficult to explore immediately in first few weeks following surgery". "Fortunately many of the re dos are on the contralateral sides". "Ipsilateral redo are the hardest and increase the complication rates enormously".	No	0
		Contralateral Recurrent	3
		Ipsilateral Recurrent	6
7	Unilateral Palsy "Unilateral palsy makes you nervous and you don't have any chance". "The burden of one cord is too heavy for the thyroid surgeon to carry".	No	0
		Yes	4
8	Size of the Gland "There many other more important factors but size does matter". "Huge glands certainly add to complexity, longer operative times and blood loss".	Small (palpable only)	0
		Moderate (visible on deglutition)	0.5
		Large (visible)	3
		Massive	6
9	Extent of Thyroidectomy "Extent of Thyroidectomy really matters and adds to the difficulty of the procedure. Extent of resection and the surrounding nodes in form of neck dissection adds to the operative time and difficulty".	Lobectomy isthmectomy	1
		Subtotal Thyroidectomy	2
		Total Thyroidectomy	2.5
		Total Thyroidectomy with Central Neck Dissection	3
		Total Thyroidectomy with Block Neck Dissection	5
10	Limited Neck Extension "Fat people, and the patients having cervical spondylosis are likely to have limited neck dissection. This leads to difficulty in procedure as we lose the ease that we get when we extend the neck for better exposure".	Fully extendable	0
		Limited neck extension	1
		No neck extension	2
1	Short Neck "Short neck again adds to the difficult dissection."	No	0

1		"Mobilization of the superior and inferior poles becomes difficult due to limited space and retrosternal extension".	Yes	0.5
1	BMI	"High BMI is associated with short neck and limited neck extension with higher chances of the retrosternal extension".	Upto 35	0
2			>35	0.5

Table 1: Thematic analysis of qualitative assessment of factors involved in difficult thyroidectomy determined through FGD & PreoDIT™ Scoring Chart based on e-Delphi Consensus

This questionnaire formed the basis of development of this application. Thyrotoxicosis, retrosternal extension, gland size, fibrosis and malignant in-vasion were found to be the dominant drivers of operative difficulty with high relative im-portance scores. Other factors included T staging of the cancer, type of cancer, extent of surgery, unilateral RLN palsy, short neck, reduced neck extension, high BMI and preoperative use of lugol's iodine. The themes have been summarized in Table 1 along with their determined relative importance scores.

The findings of the qualitative components study were piloted in a huge cohort of the patients. The general characteristics of the patients have been summarized in Table 2 and 3.

Measurement Parameter	Patients undergoing Thyroidectomy (n=513)
Age	48.58±11.46
Gender	
Female	418 (81.5%)
Male	95 (18.5%)
Clinical Diagnosis	
Follicular Lesion	32 (6.2%)
MNG	21 (4.1%)
MNG involving Single Lobe	30 (5.8%)
Papillary CA	229 (44.6%)
Primary Thyrotoxicosis	16 (3.1%)
Suspicious Solitary Nodule	161 (31.4%)
Toxic MNG	24 (4.7%)
Histological Diagnosis	
Benign Follicular Lesion	170 (33.1%)
Benign Hyperplastic Glands	45 (8.8%)
Suspected Follicular Carcinoma	40 (7.8%)
Primary Thyrotoxicosis	16 (3.1%)
Papillary Carcinoma	240 (46.7%)
Hashimoto's Thyroiditis	2 (0.03%)
Clinical Status	
Euthyroid	435 (84.8%)
Hypothyroid	5 (1%)
Toxic Adenoma	40 (7.8%)
Toxic MNG	33 (6.4%)
ASA Status	
ASA-I	456 (88.9%)
ASA-II	26 (5.1%)
ASA-III	21 (4.1%)
ASA-IV	10 (1.9%)
Gland Size WHO Classification (1974)	
WHO Class I	21 (4.1%)

WHO Class II	8 (1.6%)
WHO Class III	409 (79.7%)
WHO Class IV	74 (14.4%)
Type of surgery	
Lobectomy and Isthmectomy	191 (37.2%)
Total Thyroidectomy	265 (51.7%)
Completion Thyroidectomy	21 (4.1%)
Total thyroidectomy + Neck Dissection	36 (7%)

Table 2: General Characteristics of the Patients participating in the study

Measurement parameter	
Mean length of surgery (minutes)	118.17±39.57
Peri-operative mean blood loss	44.07±24.53
Postoperative Drain Output	53.55±38.51
Mean length of postoperative stay (Hours)	34.88±12.82
Mean pain score (maximum = 10)	3.2±1.3
Median postoperative analgesic requirements as per WHO pain ladder	Level II
Complications	
Wound infection	0.9%
Hematoma requiring drainage	3/513 (0.5%)
Seroma formation requiring drainage	5.3%
Transient hypocalcemia	58 (11.3%)
Permanent hypocalcemia	1/513 (0.19%)
Transient recurrent laryngeal Nerve compromise	32 (6.23%)
Permanent recurrent laryngeal nerve compromise	3/513 (0.5%)
Recurrence (Over period of at least 6 months- 7 years)	2/513 (0.38%)

Table 3: Patient Surgery Characteristics including Complications

The scoring systems were explored in terms of their intra-rater and inter-rater reliability and their correlation with each other. PreoDIT™ scores and grades have strong intra-rater and inter-rater reliabilities as measured by the intra-class coefficients (Table 4).

Scoring System	Agreement / Concordance measured by Intra-Class Coefficient	
	Intra-rater reliability	Inter-rater reliability
PreoDIT™ Score	0.991 (0.989-0.992); p<0.000	0.992 (0.991-0.994); p<0.000
PreoDIT™ Grade	0.969 (0.963-0.974); p<0.000	0.950 (0.941-0.958); p<0.000
PostoDIT Score	0.953 (0.936-0.965); p<0.000	0.846 (0.713-0.906); p<0.000
TDS Scoring	0.884 (0.834-0.967); p<0.003	0.763 (0.723-0.841); p<0.004

Table 4: Scoring systems and their respective intra-rater and inter-rater reliability measured by intra-class coefficient.

PreoDIT™ scores and grades have a strong correlation with postoperative surgeon assessment, measured as PostoDIT (Table 5).

	Correlation Among Various Scoring Systems	
	Correlation Coefficient	P Value
PreoDIT™ Score vs PreoDIT™ Grade	0.809	0.000
PreoDIT™ Grade vs. PostoDIT Score	0.848	0.000
PreoDIT™ Score vs TDS Scoring	0.576	0.000
PreoDIT™ Grade vs. TDS Scoring	0.526	0.000

Table 5: Strength of Correlation among the PreoDIT™ Score, PostoDIT Score, PreoDIT™ Grade and TDS Score

Correlation with Schneider's TDS was however moderate at best. PreoDIT™ proved to be a reliable and valid tool in gauging the complexity of a planned thyroid procedure. Scores and grades attained through PreoDIT™ correlated with operative times, operative blood loss and complications moderate to strongly (Table 6), and thus helped in both, pre-operative and post-operative management.

	Correlation Among Various Scoring Systems	
	Correlation Coefficient	P Value
PreoDIT™ Score vs Operative Time	0.813	0.001
PreoDIT™ Score vs. Blood Loss	0.795	0.000
PreoDIT™ Score vs Complications	0.647	0.000
PreoDIT™ Grade vs Operative Time	0.623	0.000
PreoDIT™ Grade vs. Blood Loss	0.763	0.000
PreoDIT™ Grade vs Complications	0.611	0.000

Table 6: Correlation of PreoDIT™ Score and Grade with complications, operative times and blood loss

DISCUSSION

Thyroidectomy still remains a delicate and demanding operation which sometimes proves to be difficult owing to varying reasons³⁰⁻³². Thyroidectomy difficulty scale (TDS) proposed by Schneider et al. correlates well with operative times and complications of thyroidectomy^{10,11,33}. This scale calculates difficulty index based on surgeon's peri-operative assessment hinging on four important parameters, toxicity,

tissue friability, size and fibrosis of the visible thyroid gland. There are however two important limitations of this scale. Firstly, it is a subjective as-assessment which can only be made once the patient is anesthetized and dissected, with the surgeon ready to operate. Secondly, this scale does not regard multiple other important factors like retrosternal extension, cancer stage, RLN palsy, neck extension and BMI, which significantly influence the difficulty of operation¹². However, it would be infinitely more beneficial for both patient and surgeon, to make an assessment preoperatively so that operation theatre resources and surgical staff are managed more appropriately.

Operative difficulty is a subjective assessment and remains intuitively variable and non-uniform. To develop an application which objectively measured the difficulty of an operation preoperatively with the added goal of making it reproducible and uniform among users, we needed to rely on solid, objective preoperative assessment. Carefully considering the aforementioned dozen factors and their relative contribution to the difficulty of a thyroidectomy was important as it would provide us with objective data to predict the operative difficulty before the operation was initiated. Qualitative and consensus methods were used to know the relative value of these factors and their content validity. As we explored the relative value of these factors, it became quite apparent that toxicity of the gland, retrosternal extension, gland size and adhesions either due to redo-related fibrosis or malignancy-related local invasion played a dominant role in determining the difficulty of the operation. As data points are relatively objective, the results were uniform, leading to strong intra-rater and inter-rater reliability. PreoDIT™, therefore, provides comprehensive estimates in the form of more reliable and objective scores. To assess and compare the relative value of PreoDIT™ scores and grades to postoperative measurements such as PostoDIT and TDS score statistical correlation was studied, this was moderate to strong in most instances. Similarly, PreoDIT™ scores and grades strongly correlate with operative time, peri-operative blood loss and complications, demonstrating their value in clinical application. The PreoDIT™ scores are better predictive measures as opposed to PreoDIT™ grades, however, grades were more user-friendly.

Limitations: This study has many limitations. Converting a subjective assessment into objective data is al-ways difficult. The scores and relative values selected for various scores have been derived from the experience of only 8 endocrine surgeons and more input, especially in clinical settings, by even more surgeons, is crucial in optimizing the scoring system and in improving its sensitivity and specificity. Furthermore, surgeon experience and the volume of surgeries performed also influences outcomes¹². This score has been applied to only 2 surgeons and 1 clinical set up where surgeons had similar technique and operative conditions, wider application in diverse set ups and their

feedback is important in its optimization to assess and improve its external validity.

CONCLUSION

PreoDIT™ is a content valid, novel tool which promises to be helpful for endocrine surgeons to prepare and measure preoperatively, the difficulty of their planned thyroid operation. The tool takes into consideration a dozen factors

which make a thyroid procedure complex, out of which thyrotoxicosis, retrosternal extension, size of gland and adhesions due to either redo-related fibrosis or local malignant invasion play a pivotal role. This information can be useful for sur-geons to optimize and manage their teams, OR resources and resident training preoperatively. This may also aid in development of application aided referral services for better patient care. Overall, PreoDIT™ predicted the difficulty of a thyroid procedure accurately and proved to be a tool which helped in maximizing efficiency both inside the operation theatre, and outside of.

ARTICLE Accepted for Publication: November 18, 2021 Published Online: December, 2021.

<https://doi.org/10.48111/2021.04.03>

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The article has been previously published in Journal of American College of Surgeons as an abstract.

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Financial Support and Sponsorship: Nil.

Conflicts of Interest: There are no conflicts of interest

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