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Prospective Case Control Study for Efficacy of Methylene Blue Dye as an Aid for Safe Thyroidectomy

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Abstract:
BACKGROUND
Thyroidectomy is one of the most commonly performed surgeries. Thyroidectomy is procedure to removes either part of or the entire thyroid gland. There could be many reasons that required to remove a thyroid gland, including cancer, benign conditions or hyper-functioning glands(1-2). Injury to Parathyroids and Recurrent Laryngeal Nerve (RLN) are two of the complications of thyroidectomy that cause significant postoperative morbidity
MATERIAL AND METHOD:
Patients were randomized into two groups i.e. 20 patients in Group A (NOT USING DYE INTRAOPERATIVELY) and 20 patients in Group B (USING DYE INTRAOPERATIVELY).
RESULTS:
We found that for the Group A (without use of MBD), in 25 % case (5 out of 20) have developed complications. Postoperative incidences of hypocalcemia has been found in 10% cases (2 numbers) while incidence of RLN nerve palsy has been found in 15% cases (3 numbers).
Keywords: *Methylene blue dye, RLN, Hypocalcemia.*

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I. Introduction

Thyroidectomy is one of the most commonly performed surgeries. Injury to Parathyroids and Recurrent Laryngeal Nerve (RLN) are two of the complications of thyroidectomy that cause significant postoperative morbidity.

Selective in-vivo staining of the parathyroid glands by intravenous and intra-arterial administration of toluidine blue was used but it has been withdrawal from general use because of its negative side effects led.Embolisation of the nerve by doing intra-operative nerve monitoring, (IONM) is another alternative for identification of RLN, to improve the outcome (reduce complications) but again it's a expensive opinion(8-10).

Our aim in this study is to identify a promising alternatives to minimalize operative complications in a cost effective way. Methylene blue dye, which is a medication and dye that has been used for more than a century, is safe and readily available and is quite inexpensive. The previous study has found that methylene blue spray on the surgical field is absorbed by the parathyroid gland faster than in the perithyroidal area based on dense lymphovascular tissue of parathyroid gland. Methylene blue dye is a hetero-cyclic aromatic chemical compound whose use has been widely accepted in recent years in sentinel lymph node biopsies. For preventing injury to the parathyroid glands during thyroid surgeries, staining of the parathyroid glands was first described by Klopper et al. in 1966 (11-15). This study investigate the diagnostic value of methylene blue dye spray to identify the parathyroid gland and RLN during thyriodectomy.

II. Material and Method

The approval was taken from the ethical committee before initiating the study and informed consent was taken from the patients, we explained all surgical procedures and their possible consequences to the patients. The study was carried out on 40 euthyroid status patients who underwent thyroidectomy after taking detailed history and general examination. Study conducted in a single unit conducted at MGM Medical College and M.Y. Hospital, Indore (M.P.) between December 2018 to February 2019.Patients were randomized into two groups i.e. 20 patients in Group A (not used methylene blue dye) and 20 patients in Group B (used methylene blue dye). Each operation was conducted under general anesthetic with endo-tracheal intubation. Surgeries were

performed in the routine manner with a transverse midline incision for all cases. Anaesthesia team were also ready all the time for the rare risk of anaphylaxis.
Patients in whom methylene blue was used intra-operatively were considered cases and patients without dye were considered as controls.

After superior but before inferior pole ligation, methylene blue was sprayed over the thyroid lobe and perilober area. Tissues, especially parathyroid gland, and the recurrent laryngeal nerve, were identified and evaluated.We observed that the wash-out time of parathyroid glands was less than three minutes Within three minutes parathyroid glands washed out the blue stain and the original yellow color was regained. But for thyroid glands it was more than 20-25 minutes. We hypothesize and even observed that, the differences in time is due to the lympho-vascular pattern of the tissues.
Post operative study on each of these group conducted on Day1 and Day3 to evalaute the post operative complication.

Statistical Analysis

- Data will be analysed using SPSS software and appropriate statistical tests

Table 01: Age Distribution

S. No.	Age Group	No.	Percentage %
1	24-35	18	45
2	36-45	11	27.5
3	46-60	11	27.5

Graph 01: Age Distribution

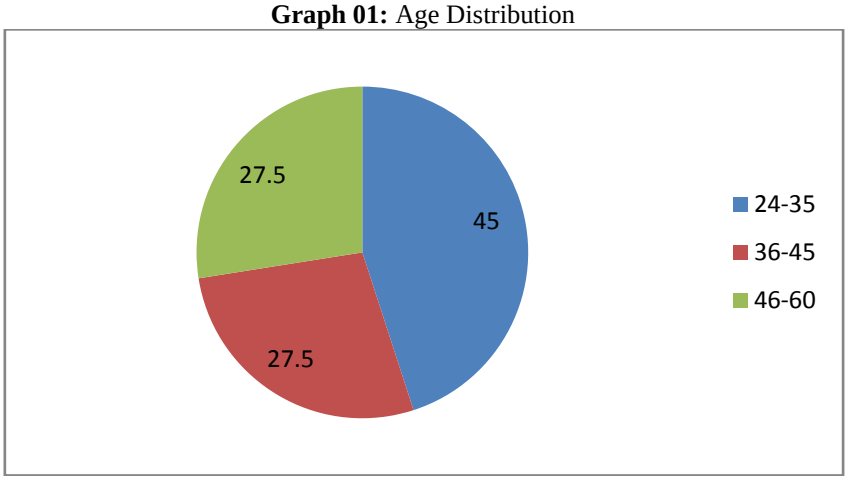


Table 02: Gender Distribution

S. No.	Gender	No.	Percentage %
1	Male	00	00
2	Female	40	100

Graph 02: Gender Distribution

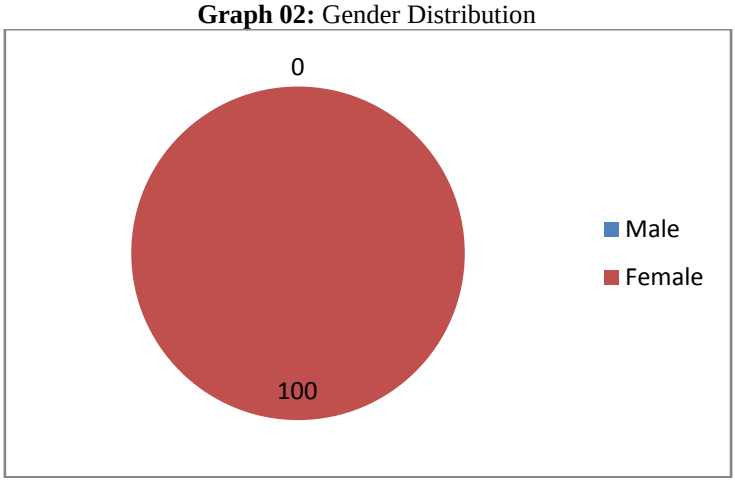


Table 03: Type of Thyroid Surgery

S. No.	Type of Thyroid Surgery	No.	Percentage %
1	Hemithyroidectomy	06	15
2	Lt. hemithyroidectomy	11	27.5
3	Rt hemithyroidectomy	11	27.5
4	Total Thyroidectomy	12	30

Graph 03: Type of Thyroid Surgery

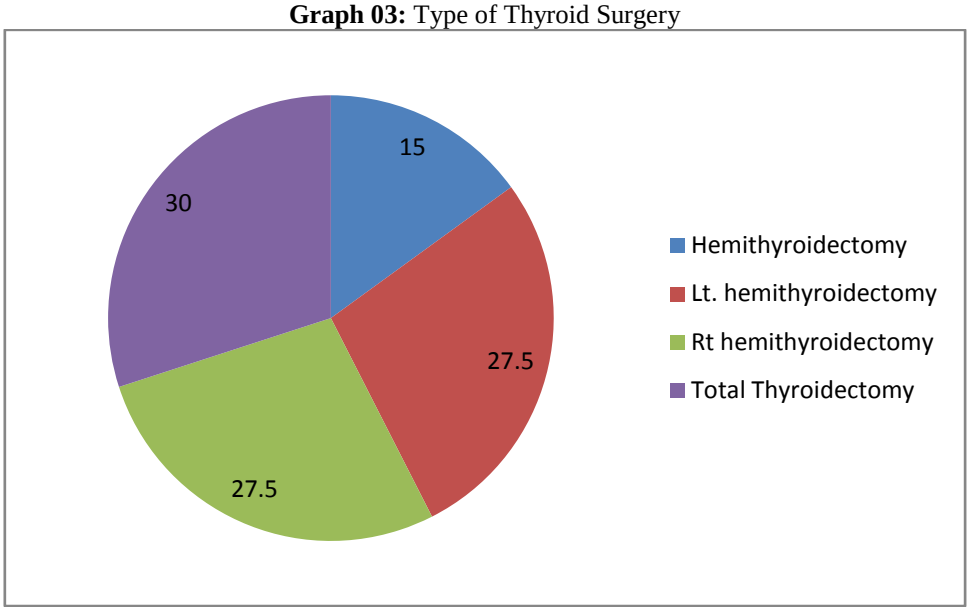


Table 04: Post of Voice Assessment

S. No.	Post of Voice Assessment	No.	Percentage %
1	No hoarseness	38	95
2	Hoarseness on D1 & D3	02	5

Graph 04: Post of Voice Assessment

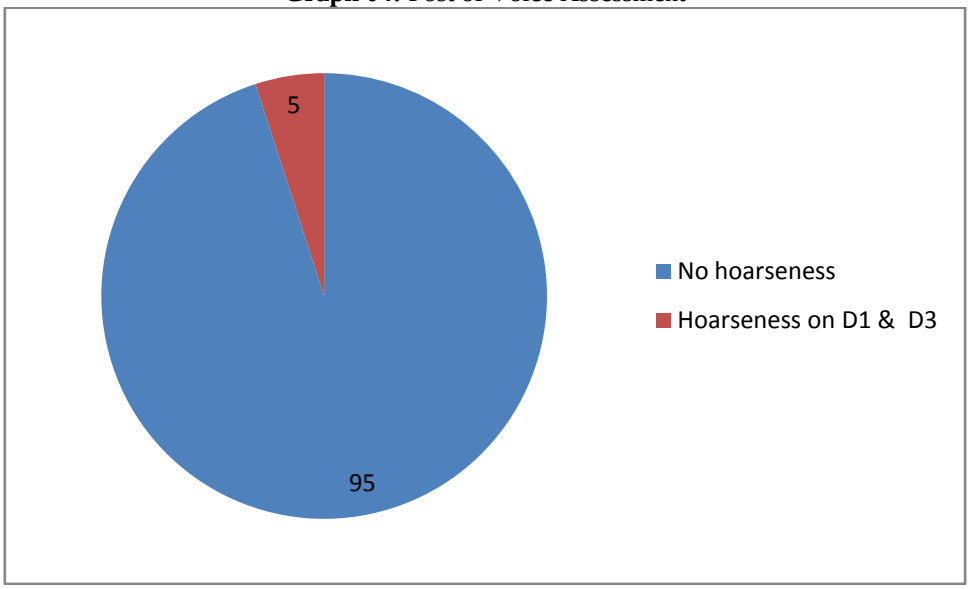


Table 05: Post op IDL

S. No.	Post op IDL	No.	Percentage %
1	Lt. Vocal cord immobilised	01	2.5
2	Rt. Vocal cord immobilise	01	2.5
3	WNL	38	95

Graph 05: Post op IDL

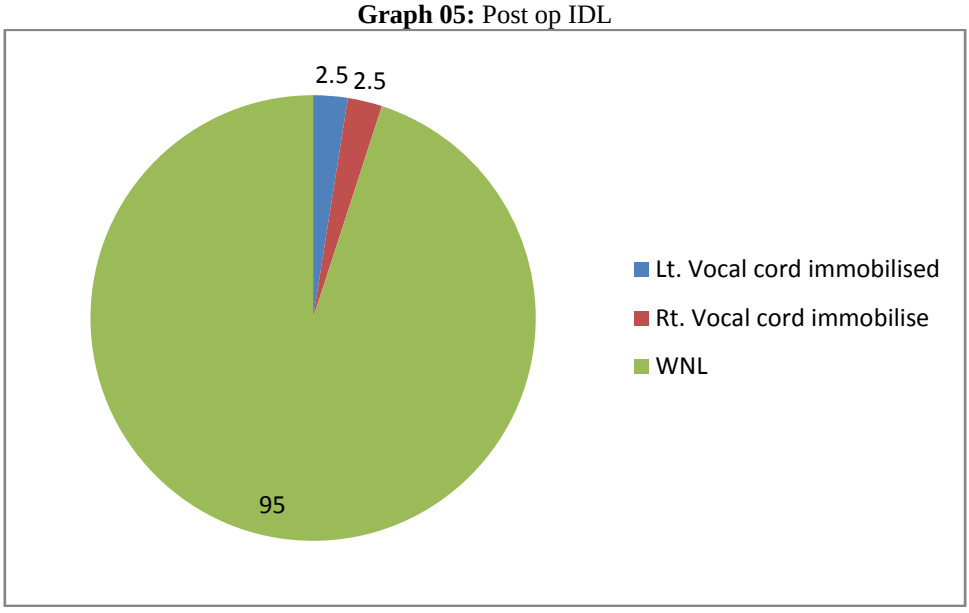
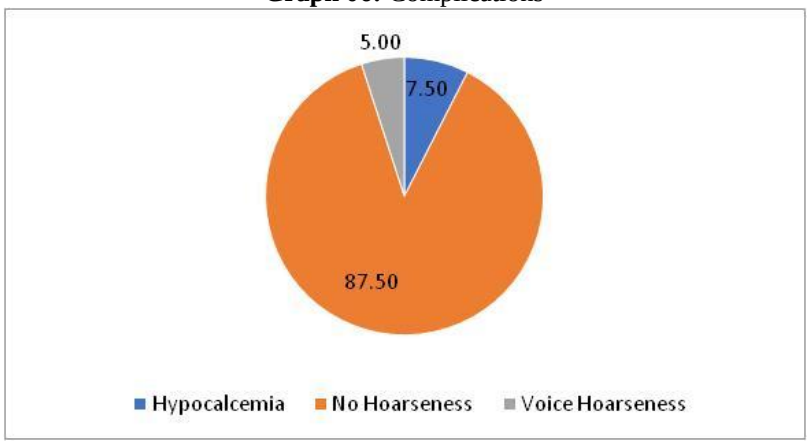


Table 06: Complications

S. No.	Complications	No.	Percentage
1	Hypocalcemia	03	7.5
2	No Hoarseness	35	87.5
3	Voice Hoarseness	02	5

Graph 06: Complications



III. Results

Sl. No.	Imperatives	Assesement Postoperative (Methylene Blue Dye Not Used prior to surgery Observed period		Assesment Postoperative Methylene Blue Dye is Used prior to surgery Observed period		Remarks (if any)
		Day 1	Day 3	Day 1	Day 3	
1	Patient Sample Size (Nos)	20		20		
2	Gender / Sex	Female		Female		
3	Age Group (20-60 Yrs)	24-50 Years		25 to 60 Years		
4	No. of incidence with post opeartive complications	5 (25%)		0 (0%)		Dye improved the outcome significantly.
4.1	Voice Hoarseness / IDL	3 (15%)		0		
4.2	Hypocalcemia	2 (10%)		0		
5	Serum Calcium Levels					
5.1	Mean of S. Calcium	8.55	8.54	8.85	8.79	
5.2	Range of (Min:Max) of S. Calcium	7.90 to 8.5	8.0 to 9.0	8.5 to 9.5	8.4 to 9.9	
5.3	Standard Deviation S. Calcium	8.60	8.60	8.85	8.80	
5.4	Median of S. Calcium	0.35	0.28	0.23	0.18	
5.5	p* value Significance (without MBD and with MBD sample)	D1 vs D1 : 0.0027 D3 vs D3 : 0.0018				Null Hypothesis is Not True
5.6	Significance	Significant differnec in samples of with MBD and without MBD				

A statistical test (t-test and p-value significance) to compare the sample of D1 and D3 for the group A (without MBD) and Group B patient (with MBD). P value suggest that D1 and D3 samples for same group are similar (as expected), while, D1- D1 and D3 - D3 for different group (A&B) are different (P value <0.5 at 95% CI level) indicating that significant variation due to the procedure(as expected).

IV. Summary and Conclusions

Spraying methylene blue dye to identify RLN and Parathyroid gland is a good screening tool in a very cost effective way and is rapid and also safe method.

Methylene blue dye can readily be used as an good alternative in hospital setups where other means of identification of RLN and Parathyroid gland like Intra-operative nerve monitoring, IV Photodynamic detection of normal Parathyroid gland using 5-ALA, etc, are not readily available.

As compared to other sophisticated techniques of identification, spraying methylene blue dye do not require much technical skills tolearn ,i.e. have easy learning.

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