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A meta-analysis of intraoperative neuromonitoring of recurrent laryngeal nerve palsy during thyroid reoperations

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Summary

Background: The rate of recurrent laryngeal nerve (RLN) palsy, a common complication of thyroid surgery, is especially high in thyroid reoperations. The present meta-analysis assesses whether intraoperative neuromonitoring (IONM) reduces the prevalence of RLN palsy in thyroid reoperations.

Design and methods: A systematic literature search was conducted in the PubMed, SCIE and Wan Fang databases for studies published up to 31 August 2016. All data were analysed using STATA (version 11) software. Publication bias was assessed using Begg's funnel plot and Egger's test, and sensitivity analysis was performed.

Results: Nine studies including 2436 at-risk nerves met the inclusion criteria. The results were presented as pooled relative risks (RRs) with 95% confidence intervals (CI). The overall RLN palsy rate was significantly lower in reoperations conducted with IONM than in those conducted without IONM (RR=0.434, 95% CI=0.206-0.916, P=.029). High heterogeneity was found (I^2=70.2%, P=.001). The rates of transient RLN palsy with and without IONM did not differ significantly (RR=0.607, 95% CI=0.270-1.366, P=.227). The heterogeneity was high (I^2=67.4%, P=.005). However, IONM was significantly associated with a reduction in permanent RLN palsy (RR=0.426, 95% CI=0.196-0.925, P=.031). No significant heterogeneity was found (I^2=13.7%, P=.325). Funnel plots for overall and transient RLN palsy showed a possible publication bias.

Conclusions: Intraoperative neuromonitoring (IONM) is associated with a reduction in overall and permanent RLN palsy in thyroid reoperations. However, given the limited sample size and heterogeneity in this meta-analysis, further studies are required to confirm our preliminary findings.

KEYWORDS
intraoperative neuromonitoring, recurrent laryngeal nerve palsy, thyroid reoperations

1 | INTRODUCTION

With the incidence of thyroid disorders rapidly increasing worldwide, the number of thyroid surgeries has inevitably risen in the last few decades. Generally, thyroid surgery is a safe operation, but postoperative complications including recurrent laryngeal nerve (RLN) palsy, hypoparathyroidism and tracheotomy may lead to a decrease in the overall quality of life.[1-3] Of these, RLN palsy is one of the most common serious complications and an important reason for malpractice suits after thyroid surgery.[4-6] Unilateral RLN palsy can lead to various problems including dysphonia, vocal fatigue and dyspnoea, while bilateral RLN palsy can be a life-threatening complication leading to airway obstruction.[7] Currently, RLN visualization has been considered the gold standard for the prevention of RLN palsy during thyroid surgery.[8] Despite meticulous anatomical identification during surgery, RLN palsy continues to occur, with a widely varying incidence after thyroidectomy (0.4%-7.2% for temporary palsy and 0%-5.2% for permanent palsy).[9-11] Intraoperative nerve monitoring (IONM) has commonly been applied during thyroid surgery in recent decades. The use of IONM during thyroid surgery has gained universal acceptance as a supplement to visual identification of the RLN. It is useful not only for localizing and identifying the nerve but also as a way to predict its function and clarify the mechanisms of RLN palsy.[12,13] Discouragingly, current research shows that the use of IONM does not decrease the incidence of RLN palsy in thyroid surgery. However, none of the published meta-analyses on this matter have reported the use of IONM only in reoperation patients. Thus, whether IONM helps reduce the RLN palsy rate in reoperations remains unclear.

Reoperations represent a major challenge in thyroid surgery as they are associated with a high rate of complications because of the extensive scarring and distortion of the usual anatomy caused by previous operations.[14] The RLN palsy rate in thyroid reoperations has been reported to be typically higher than that with first-time surgeries, at approximately 5% (range, 2%-12%).[15-19] Several studies have shown that IONM could reduce the incidence of nerve paralysis in reoperation and complex thyroid surgeries.[20-22] However, there is no overwhelming evidence to show that the use of IONM decreases the incidence of RLN palsy in reoperations. Thus, we carried out the present meta-analysis to evaluate whether IONM could reduce the prevalence of RLN palsy to a greater extent than RLN visual identification alone in thyroid reoperations.

2 | MATERIALS AND METHODS

This meta-analysis has adopted throughout a systematic review using the Population Intervention Comparison and Outcome (PICO) model and following the guidelines proposed by the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement.[23] The PICO framework for this study was as follows: (P) patients undergoing thyroid reoperations; (I) patients operated using IONM of the RLN; (C) patients operated without IONM of the RLN; (O) and overall, transient and permanent palsy of the RLN.

2.1 | Search strategy

The PubMed, Web of Science and Wan Fang databases were systematically searched for studies published up to 31 August 2016. The keywords of the search strings were ([intraoperative nerve monitoring] OR neuromonitoring of recurrent laryngeal nerve) AND thyroid. Two reviewers (Sun W and Liu JH) independently performed the selection, and disagreements were resolved through discussion.

2.2 | Selection criteria

In this meta-analysis, studies were selected if they met the following criteria: (i) prospective or retrospective original literature; (ii) thyroid operations were carried out at least once, and vocal cord function was normal before reoperations; (iii) the previous surgical field including thyroid bed, ipsilateral central neck compartment and ipsilateral RLN was re-explored during reoperations. Studies were excluded from our meta-analysis if they met the following exclusion criteria: (i) the previous surgical field and ipsilateral RLNs were not exposed during reoperation; (ii) presence of RLN palsy after previous thyroid operation; (iii) first-time thyroid surgery or lack of complete clinical data or follow-up information.

2.3 | Data abstraction and quality assessment

In accordance with the selection criteria, relevant information including authors, publication years, study countries, study design, pre- or postoperative laryngoscopic details, age, sex, total nerves at risk, overall nerve palsy, transient nerve palsy, permanent nerve palsy, neuromonitoring system and electrodes for laryngeal electromyography were screened and extracted by two authors independently. The Newcastle-Ottawa Scale (NOS) was used to assess the quality of the included studies.[24]

2.4 | Statistical analysis

Our meta-analysis and statistical analyses were performed using STATA software (STATA, College Station, TX, USA). The results were presented as relative risks (RRs) with a 95% confidence interval (CI): a RR of >1 suggested that the use of IONM increased the risk of RLN palsy compared to that without the use of IONM, while a RR of <1 suggested that the use of IONM reduced the risk of RLN palsy compared to surgery without the use of IONM. $P<.05$ was considered statistically significant, except where otherwise specified. Moreover, the heterogeneity assumption was checked using the Q-test and I^2 test. An I^2 value of ≥50% indicates a moderate-high level of heterogeneity. The random-effects model was applied in this meta-analysis. Possible publication bias was tested using Begg's funnel plot and Egger's test (significance level, $P<.05$). Sensitivity analysis was performed to investigate whether the results were driven by one large study or by a single study with an extreme result.

3 | RESULTS

After a primarily electronic search, 806 studies were initially included in the meta-analysis. A total of 169 studies were excluded because of duplication and language. Approximately 590 studies were excluded after the titles and abstracts were carefully scanned. The remaining 47 articles were considered of potential value, and their details were evaluated. Finally, a total of nine studies and 2436 nerves at risk (1109 identified with IONM and 1327 identified without IONM) were included in our meta-analysis after the inclusion criteria were applied: two studies were prospective cohort studies and seven were retrospective cohort studies. To control for the quality of the studies selected for further analysis, we evaluated the quality of each study using the NOS. Each study included in our analysis rated above six on the NOS, indicating that data of a sufficiently high standard were collected (Table 1). We have also uploaded a PRISMA Checklist in the supplementary material.

TABLE 1 Basic characteristics of included studies

Author	Yr	Country	Study design	Pre- or postoperative laryngoscopic details	Permanent palsy definition	Neuromonitoring systems	Electrodes for laryngeal electromyography	Age		Sex (F/M)		Quality assessment
								With IONM	Without IONM	With IONM	Without IONM	
Marcin Barczynski[25]	2014	Poland	Retrospective cohort study	Pre- or postoperative	12	Neurosign 100 system (Inomed, Teningen, Germany) NIM2.0/3.0 (Medtronic, Jacksonville, USA)	Needle electrodes Endotracheal tube	54.6±13.2	54.0±13.6	247/590	440/108	9
Yu-Chuan Chuang[26]	2013	Taiwan	Retrospective cohort study	Preoperative	NA	NIM Response System (Medtronic, Jacksonville, FL)	Endotracheal tube	22.8-80.5	29.7-85.0	48/8	11/4	7
Piero F. Alesina[27]	2012	Germany	Retrospective cohort study	Pre- or postoperative	6	Neurosign (InoMed, Teningen, Germany) NIM Response 3.0 (Medtronic, Jacksonville, FL)	Needle electrode Endotracheal tube	55±12	55±13	78/11	131/26	8
Emmanuel Prokopakis[28]	2013	Greece	Prospective cohort study	Preoperative	NA	NIM Response System (Medtronic, Jacksonville, FL)	Endotracheal tube					7
Hu Hei[29]	2016	China	Cohort Study Prospective	Pre- or postoperative	6	NIM Response 2.0 (Medtronic Xomed, Jacksonville, FL)	Endotracheal tube	48.36±9.09	46.86±10.6	23/10	31/6	8
Wu Jiayu[30]	2016	China	Retrospective cohort study	Pre- or postoperative	6	NIM Response 3.0 (Medtronic Xomed, Jacksonville, FL)	Endotracheal tube					6
Zhang Shuwen[31]	2016	China	Retrospective cohort study	Preoperative	6	NIM Response 3.0 (Medtronic Xomed, Jacksonville, FL)	Endotracheal tube	54.36±13.09	52.59±13.74	53/24	32/19	7
Liu Yongjun[32]	2016	China	Retrospective cohort study	Pre- or postoperative	6	NIM Response 2.0 (Medtronic Xomed, Jacksonville, FL)	Endotracheal tube					6
Donald E. Yarbrough[33]	2004	American	Retrospective cohort study	Pre- or postoperative	6	EMG monitoring	Endoscopically applied hook-wire electrodes	51.1	50.4	33/19	37/22	8

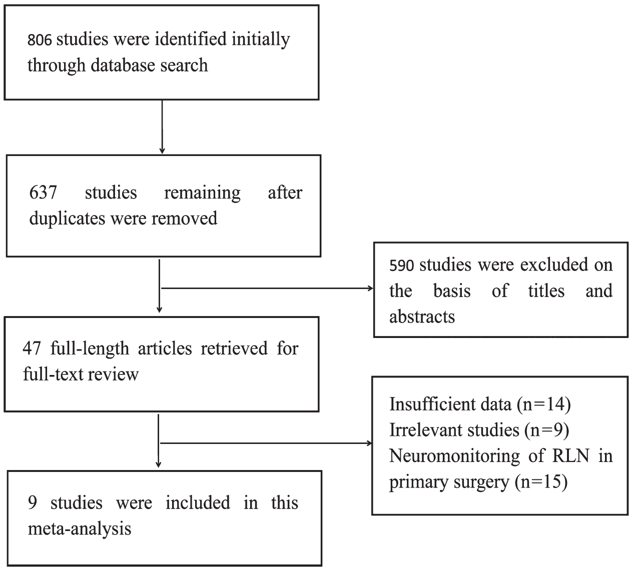

FIGURE 1 Flow chart of the study selection process

The flow chart of the study selection process is presented in Figure 1. The basic characteristics of the included studies are summarized in Table 1, and the corresponding numbers of total nerves at risk, overall nerve palsy, transient nerve palsy and permanent nerve palsy are shown in Table 2. All information on the neuromonitoring systems and electrodes for laryngeal electromyography is shown in Table 1.

3.1 | Overall RLN palsy

The overall palsy rate is the total number of RLN palsy cases (including cases of transient and permanent RLN palsy) divided by the total number of RLNs at risk. All nine studies presented follow-up data on overall RLN palsy and were therefore included in this analysis. Because of the heterogeneity (I^2=70.2%, *P*=.001), a random-effects model was applied. The overall rate of RLN palsy was 4.69% and 9.27% among patients who underwent reoperations conducted with or without IONM. The results indicated that patients who underwent surgery with the use of IONM showed a lower rate of RLN palsy (RR=0.434, 95% CI=0.206-0.916, *P*=.029) (Figure 2A).

3.2 | Transient RLN palsy

A random-effects model was applied because of the heterogeneity (I^2=67.4%, *P*=.005). Seven studies were included in the analysis of the relationship between transient RLN palsy and the use of IONM. The rate of transient RLN palsy with and without the use of IONM was 3.98% and 6.63%, respectively. However, this difference was not statistically significant (RR=0.607, 95% CI=0.270-1.366, *P*=.227) (Figure 2B).

3.3 | Permanent RLN palsy

No significant heterogeneity was found in this subgroup (I^2=13.7%, *P*=.325). However, given the low numbers of included studies, a random-effects model was applied in this analysis. Seven studies

TABLE 2 Numbers of nerves at risk (total) and cases of overall nerve palsy, transient nerve palsy and permanent nerve palsy in the included studies

Author	Total nerves at risk		Overall nerves palsy		Transient nerves palsy		Permanent nerves palsy	
	With IONM	Without IONM	With IONM	Without IONM	With IONM	Without IONM	With IONM	Without IONM
Marcin Barczynski[25]	500	826	20	72	13	52	7	20
Yu-Chuan Chuang[26]	70	15	1	3			1	3
Piero F. Alesina[27]	128	161	8	5	8	4	0	1
Emmanuel Prokopakis[28]	60	61	1	6				
Hu Hei[29]	41	43	7	4	5	3	2	1
Wu Jiayu[30]	65	50	1	6	1	4	0	2
Zhang Shuwen[31]	77	51	2	12	2	8	0	4
Liu Yongjun[32]	96	41	1	4	1	4		
Donald E. Yarbrough[33]	72	79	11	11	9	8	2	3

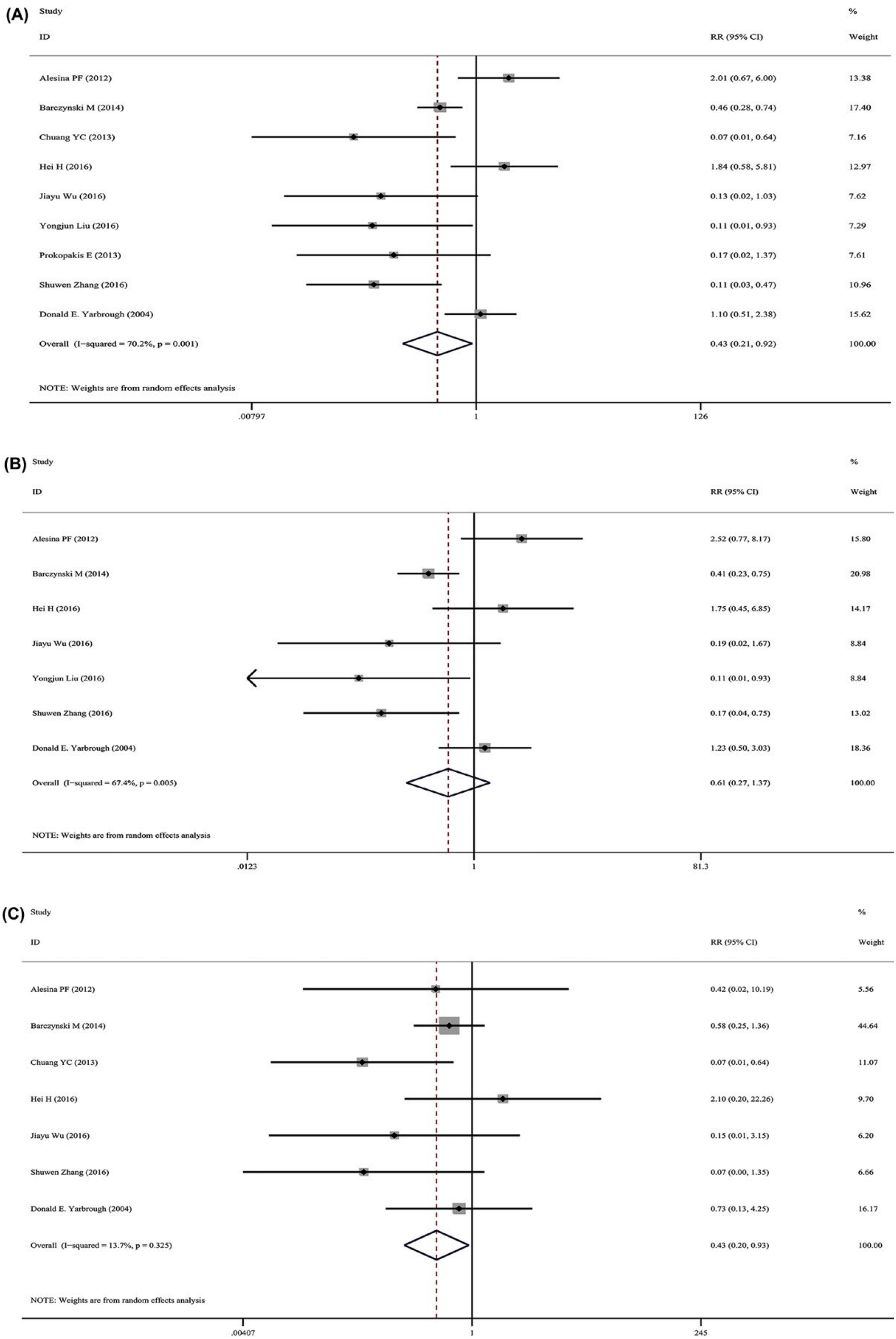

FIGURE 2 Forest plots of the association between intraoperative neuromonitoring (IONM) and recurrent laryngeal nerve (RLN) palsy in reoperations. (A) Overall RLN palsy. (B) Transient RLN palsy. (C) Permanent RLN palsy [Colour figure can be viewed at wileyonlinelibrary.com]

included follow-up data for the permanent RLN palsy group. Among patients who underwent thyroid reoperations, the rate of RLN palsy was 1.26% after surgery conducted using IONM and 2.78% after surgery conducted without IONM. The results indicate that IONM was significantly associated with preventing permanent RLN palsy (RR=0.426, 95% CI=0.196-0.925, *P*=.031) (Figure 2C).

3.4 | Publication bias

Begg's funnel plots were used to evaluate publication bias in this meta-analysis. As shown in Figure 3, no significant publication bias was found in the overall, transient and permanent RLN palsy groups. The results of Egger's test also showed no significant publication bias in this meta-analysis (*P*>.05). However, funnel plots for the overall and transient RLN palsy groups were not very symmetrical and extended well beyond the boundaries, indicating a possible publication bias (Figure 3).

3.5 | Sensitivity analysis

We performed a sensitivity analysis to evaluate the credibility and consistency of the results. As studies were omitted one by one, the pooled RRs were not materially altered from those in the overall, transient and permanent RLN palsy groups, indicating that our results were statistically robust (Figure 4).

4 | DISCUSSION

In 1938, Lahey first found that careful intraoperative dissection and exposure of RLNs decreased the incidence of palsy.[15] Since then, many prospective studies have confirmed this observation, and intraoperative exposure of the RLN has been advocated as the gold standard for preventing palsy after thyroid surgery.[34]

Despite rapid improvements in surgical techniques in the last few decades, the risk of RLN palsy during thyroid surgery has declined but not disappeared.[35] The rate of RLN palsy varies widely in the literature, from less than 1% to as high as 20%.[36,37] Identification of the RLN may be very difficult in some special types of operations, including reoperations, surgery for thyroid cancer, surgery in the presence of anatomical variants, and surgery in patients with a history of irradiation or inflammation.[34] Moreover, only 10% of nerve injury is detected visually by surgeons intraoperatively, indicating that structural continuity of the RLN

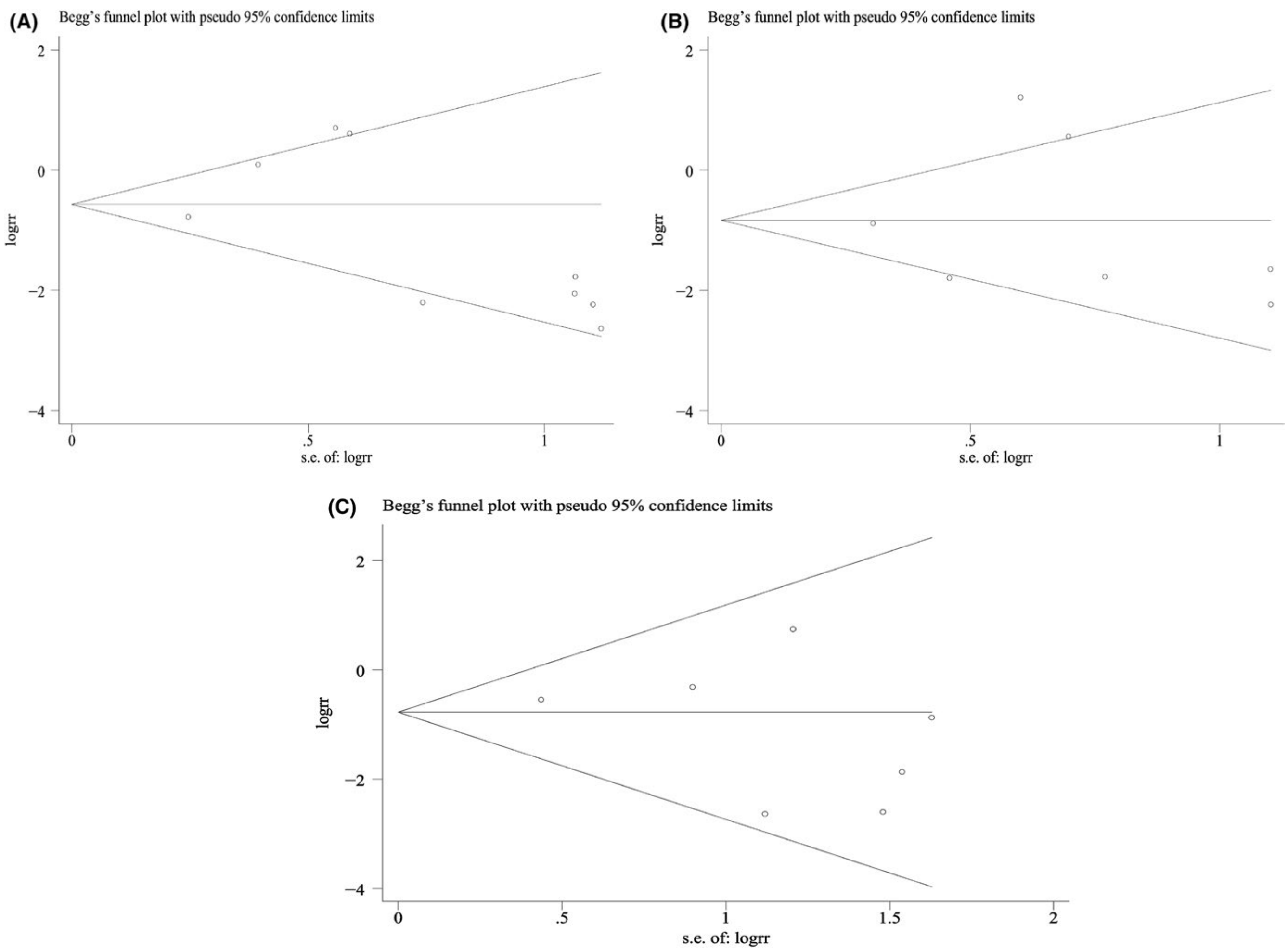

FIGURE 3 Begg's funnel plots. (A) Overall recurrent laryngeal nerve (RLN) palsy. (B) Transient RLN palsy. (C) Permanent RLN palsy

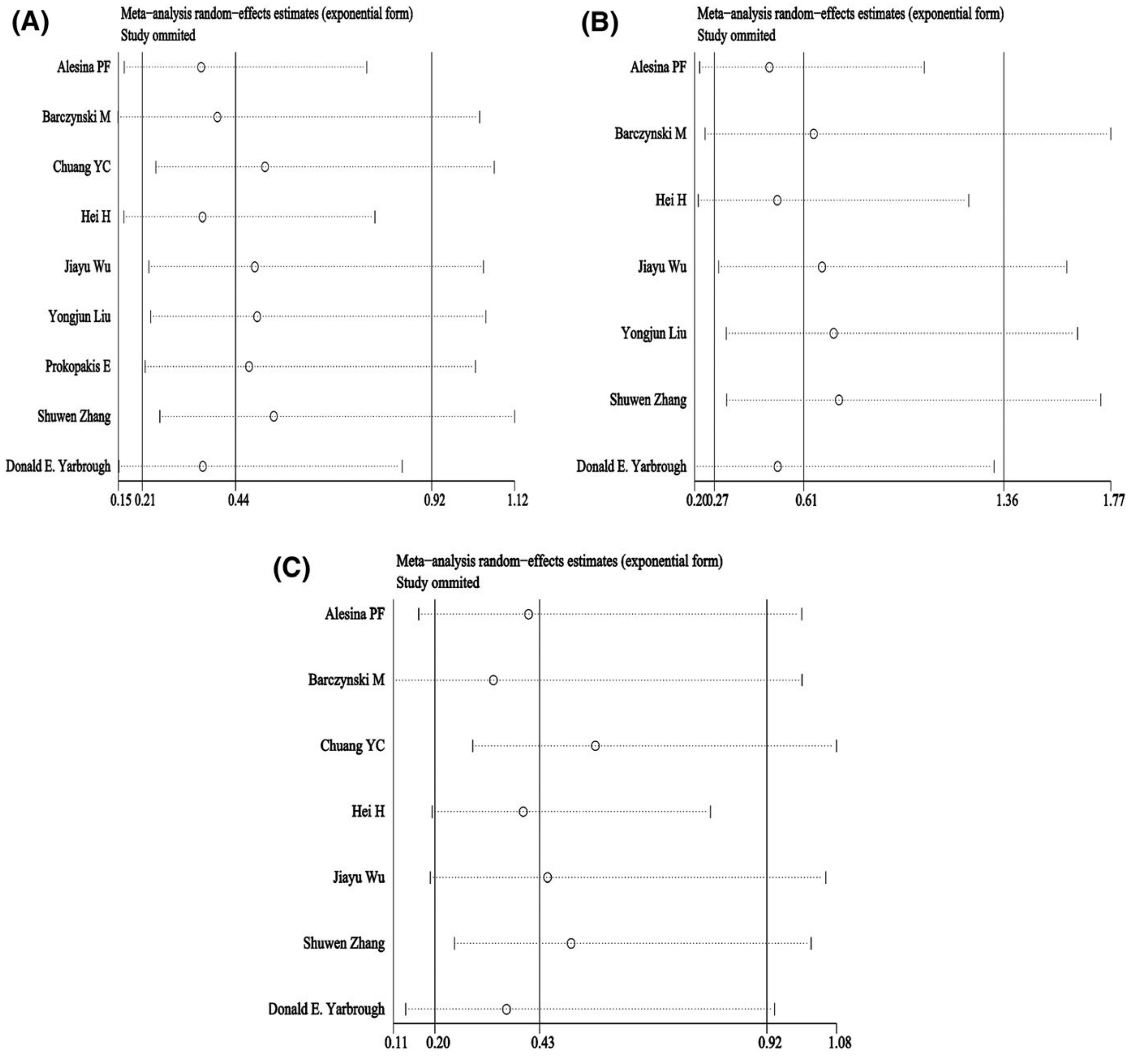

FIGURE 4 Sensitivity analysis. (A) Overall recurrent laryngeal nerve (RLN) palsy. (B) Transient RLN palsy. (C) Permanent RLN palsy

does not indicate functional integrity. Compression, crushing, ischaemia, ligature, thermal injury and stretching can cause RLN palsy without anatomical interruption of the nerve.[11,38] Given the difficulties in identifying the nerve and determining whether it is functioning properly, IONM was introduced by Shedd in 1966 as an adjunct to assist with identification of the RLN and predicting its functioning after dissection.[39] IONM also has some other potential advantages: (i) For patients requiring bilateral surgery, once unilateral functional impairment of the RLN has been confirmed, the contralateral operation should be abandoned to avoid the risk of bilateral damage. (ii) When a potentially harmful procedure is being conducted on the RLN, feedback from the neuromonitoring system will guide surgeons on whether to stop or modify the method, which will in turn improve surgical techniques and surgeons' confidence. (iii) IONM systems enable documentation both before and after thyroid resection, which is of great importance given the increase in lawsuits in recent times. However, the critical controversy surrounding the application of IONM pertains to whether it really is useful for reducing the RLN palsy rate. Two recent systematic meta-analyses comparing surgery conducted with and without IONM suggested no statistically significant benefit of IONM compared to visualization alone towards the outcomes of overall, transient or permanent RLN palsy when analysed per nerve at risk during thyroid surgery.[40,41] In contrast, another meta-analysis demonstrated the merits of IONM in preventing transient palsy during thyroidectomy, but found no advantage with regard to permanent palsy.[42] However, all published meta-analyses that report the use of IONM in thyroid surgery include patients who have undergone primary surgery as well as reoperations. None of them has examined the use of IONM in thyroid reoperations alone.

Thyroid reoperations are obviously associated with a higher rate of complications because the adjacent tissue is scarred and the anatomy distorted from the previous surgery. Scarring makes dissection more difficult, and bleeding further compromises the operation field. Many studies claim that neuromonitoring is a promising tool for nerve identification and protection in extended thyroid operations and reoperations.[8,36] However, some prospective and retrospective studies found that IONM did not seem to reduce the incidence of RLN palsy in thyroid reoperations.[29,33] Thus, there is no consensus on the benefits of using IONM in thyroid reoperations. The present meta-analysis was therefore appropriate to determine whether IONM plays a critical role in thyroid reoperations.

Meta-analysis of the nine studies finally included showed that the rate of overall RLN palsy for patients who underwent surgery with and without IONM was 4.69% and 9.27%, respectively. The RR was 0.434, indicating that this monitoring technique was a significant protective factor against RLN palsy in thyroid reoperations. To further investigate the effect of IONM in thyroid reoperations, we divided RLN palsy into transient and permanent. We found that patients who underwent surgery with IONM had a significantly lower rate of permanent RLN palsy than those who underwent surgery without IONM.

Our study revealed a significant effect of IONM in preventing permanent RLN palsy, with an RR of 0.426. The rate of permanent RLN palsy was 1.26% in patients who underwent surgery with IONM and 2.78% in those who underwent surgery without IONM. In the case of transient palsy, although the rate was lower in patients who underwent surgery with IONM than in those who underwent surgery without IONM, the difference was not statistically significant. Permanent RLN palsy differs from transient RLN palsy as it significantly affects the quality of the patient's entire life. A possible explanation for our results is that when IONM started being used to identify the RLN, complete transection of the RLN, which causes permanent palsy, became increasingly rare. However, clamping, stretching, electrothermal injury, ligature entrapment or ischaemia may lead to transient RLN palsy in thyroid reoperations. Therefore, IONM is more useful in preventing permanent RLN palsy than transient RLN palsy. To the best of our knowledge, this is the first meta-analysis to compare the effects of IONM on RLN palsy rates during thyroid reoperations.

Our systematic review and meta-analysis have some limitations. First, no randomized controlled trial was included in this study. Second, the heterogeneity in the overall RLN palsy and transient RLN palsy groups was high, for which we considered two interpretations. First, surgeons of different skill or experience levels may produce different results. For instance, for inexperienced young doctors, IONM may provide great assistance in decreasing RLN palsy rate in reoperations. However, skilled surgeons can minimize the possibility of RLN palsy even without the use of IONM. Second, the different primary diseases (toxic multinodular goitre, Graves' disease, hyperparathyroidism, differentiated thyroid cancer and medullary thyroid cancer) warranting the previous thyroidectomy may also have led to the relatively high heterogeneity seen in this meta-analysis. The final limitation of this study is that although we carefully searched the current literature, only nine studies met the inclusion criteria, and some studies had a small sample size. More prospective or retrospective studies are therefore needed to confirm our findings. We should also realize that there was no exact evidence illustrating that a postoperative laryngoscopy was applied to evaluate RLN palsy in three of the included studies, which may lead to a bias in this study.

5 | CONCLUSIONS

In summary, IONM not only helps surgeons identify the RLN and confirm its function but is also associated with a reduction in overall RLN palsy and permanent RLN palsy in patients undergoing thyroid reoperations. We believe IONM is a valuable tool and should routinely be applied in thyroid reoperations. However, because of the limited data included in this study and the relatively high heterogeneity among studies included, our results should be approached with caution. Further studies including high-quality, multicentre, prospective, randomized trials are required to confirm our findings.

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