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Impact of body mass index on post-thyroidectomy morbidity

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Abstract

Background: The impact of obesity on total thyroidectomy (TT) morbidity (recurrent laryngeal nerve palsy and hypocalcaemia) remains largely unknown.

Methods: In a prospective study (NCT01551914), patients were divided into five groups according to their body mass index (BMI): underweight, normal weight, overweight, obese, and severely obese. Preoperative and postoperative serum calcium was measured. Recurrent laryngeal nerve (RLN) function was evaluated before discharge, and if abnormal, at 6 months.

Results: In total 1310 patients were included. Baseline characteristics were similar across BMI groups except for age and sex. Postoperative hypocalcaemia was more frequent in underweight compared to obese patients but the difference was not statistically significant in multivariate analysis. There was no difference between groups in terms of definitive hypocalcaemia, transient and definitive RLN palsy, and postoperative pain.

Conclusion: Obesity does not increase intraoperative and postoperative morbidity of TT, despite a longer duration of the procedure.

KEYWORDS
body mass index, obesity, postoperative complications, recurrent laryngeal nerve palsy, total thyroidectomy

1 | INTRODUCTION

Obesity and excessive weight are major public health issues in France as in most western countries. In 2016, the World Health Organization (WHO) declared that obesity had nearly tripled since 1975 worldwide. More than 1.9 billion adults were overweight (body mass index [BMI] ≥25 kg/m^2), among whom 650 million were obese (BMI ≥30).[1] Increased BMI is a major risk factor for morbidity, such as cardiovascular disease, diabetes, musculoskeletal disorders, and some cancer types such as endometrial, breast, ovarian, prostate, liver, kidney, and colon cancers.[2] Obese patients have a higher risk of thyroid cancer,[3,4] possibly due to alterations in the level of adipokines and sex hormones.[4] Furthermore, in case of macro-cancers, obese patients are at higher risk for locoregional recurrence or persistence.[5]

For endocrine surgeons, obesity is associated with technical intraoperative difficulties, leading to a potentially higher morbidity.[5] Preservation of the recurrent laryngeal nerve (RLN) needs a correct visualization, which can be altered by fatty tissue, even when using an intraoperative neurostimulation device.[6] Identification and preservation of parathyroid glands may also be difficult in obese patients.

Intuitively, one might think that obesity is a risk factor for postoperative complications. However, its impact remains controversial. Some studies demonstrated that obesity increases morbidity in elective spine surgery, emergency repairs of ventral hernia and in laparoscopic colorectal surgery.[7–9] On the other hand, obesity has been reported to be protective against mortality in a large review of 101 078 patients who underwent emergency abdominal operations.[10] Regarding obesity in thyroid surgery, literature data are limited. Prospective studies include a small number of patients (less than 400),[11,12] and the largest series do not evaluate thyroidectomy-specific complications, such as RLN palsies and hypocalcaemia.[13–15] The aim of this study was to evaluate the impact of obesity on postthyroidectomy morbidity in a prospective multicenter cohort.

2 | MATERIALS AND METHODS

In this study, we performed a preplanned analysis of data collected in the FOThyr clinical trial, published in a previous article.[16] Briefly, FOThyr is a prospective, randomized, multicenter, single blind study comparing a single-use hemostatic device to conventional hemostasis in total thyroidectomy (TT). All patients, aged 18 to 80 years, scheduled to undergo TT were eligible for inclusion if they had Graves' disease, toxic or non-toxic goiter, or any thyroid nodule requiring TT by cervicotomy. The exclusion criteria were thyroid cancer (to avoid lymph node dissection), serum calcitonin level >30 pg/mL, planned partial thyroidectomy, abnormal motility of vocal cords (based on abnormal voice), substernal goiter (>3 cm below the sternal notch), endoscopic thyroid surgery, and prior history of neck surgery. Preoperative serum calcium, phosphorus, calcitonin, thyroid stimulating hormone, and albumin were measured in all patients. Preoperative vocal cord examination was exclusively performed in case of voice abnormality as RLN dysfunction is exceptional in individuals with normal voice. Microcarcinomas were discovered during pathological analysis. A central neck dissection was performed if the extemporaneous exam was in favor of a malignant lesion. Decision of intraoperative central neck dissection depended on the surgeon's choice (either systematic or only in case of suspicious lymph node involvement).

All total thyroidectomies were performed according to the same protocol, except for the utilization of intraoperative neuromonitoring (IONM, Medtronic, Jacksonville, Florida), which was left to the surgeon's choice. Following cervical Kocher incision, infra-hyoid muscles were opened along the midline, and the muscles were divided as required. Vessels of the upper pole were ligated and cut, preserving the external branch of the superior laryngeal nerve whenever possible. Then, the parathyroid glands (whenever possible) and the RLN (mandatory) were visualized. Postoperative drainage was left to the surgeon's discretion. All surgeons had experienced in thyroid surgery (more than 30 surgeries per year) and used IONM for at least 1 year prior to the study. For all patients operated on with IONM, RLN was systematically tested via a sterile single-use pulse-generated monopolar stimulating probe with a stimulation level set to 1.0 mA. Thyroid hormone replacement therapy was introduced on postoperative day 1.

Postoperative RLN function was systematically evaluated by vocal cord examination with nasofibroscopy, carried out before hospital discharge and at 6 months postoperatively in case of postoperative abnormal motility. Blood calcium and albumin tests were performed in the laboratories of local hospitals. Postoperative hypocalcaemia was defined by a

serum calcium level <2.0 mmol/L corrected for albumin level at postoperative day 2. Permanent hypocalcaemia was defined as serum calcium level <2.0 mmol/L (corrected for albumin level) at 6 months, without receiving calcium or vitamin D supplementation. Clinical examination was performed during hospitalization to detect hematomas. Pain was evaluated at 4 hours, 18-24 hours, and 2 days after surgery using a numeric pain rating scale (0-10).

BMI was defined as the body mass in kilograms divided by the square of the body height in meters, and expressed in kg/m^2. Patients were divided into five BMI groups according to the WHO classification: <18.5 (underweight), 18.5-24.9 (normal weight), 25-29.9 (overweight), 30-34.9 (obesity), and ≥35 (severe obesity).[2]

The duration of the surgery was the time from skin incision to wound closure.

The study protocol was reviewed and approved by a regional ethics committee (Comité de Protection des Personnes Ouest IV N° 58/2012) and by the CNIL (Commission Nationale de l'Informatique et des Libertés N°1170319). The study was performed in accordance with the Good Clinical Practice Guidelines and the Declaration of Helsinki. All patients signed a written informed consent before inclusion. This study received a grant from the French Ministry of Health and was registered with ClinicalTrials.gov (NCT01551914).

2.1 | Statistics

Baseline characteristics in the five BMI groups were described and compared with Fisher exact test, Chi-square test, Student *t* test, Kruskal-Wallis test, or Wilcoxon signed-rank test, as appropriate. For all comparisons, if the global test of the five BMI groups was significant, 2 by 2 class comparisons were done.

Utilization of IONM, transient and definitive RLN palsy rates as well as transient and definitive hypocalcaemia rates were compared between groups using Chi-square test and Fisher exact test, as appropriate. The duration of procedures was compared using analysis of variance. Multivariate analysis was performed using a linear model with these variables (BMI, sex, age, cancer, hyperthyroidism, thyroiditis, and procedures). The normality assumption of the residuals was checked in the multivariate model. These variables were chosen by the relevance in the literature. A linear mixed model was used to compare postoperative pain severity between groups at 4 hours, 18-24 hours, and 2 days postoperatively (the patient was considered as a random effect). Univariate analysis was performed with Chi-square test for categorical variables.

A P value <.05 was considered statistically significant. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, North Carolina).

3 | RESULTS

From March 2012 to June 2014, 1310 patients were enrolled at 14 sites. Their main characteristics are presented in Table 1. Mean BMI was 26.52 ± 5.55 kg/m^2. There were 1049 females (80.1%) and 261 males. Mean age was 50.74 ± 13.38 years. Baseline characteristics were similar in all groups except for age and sex: patients with BMI <18.5 were significantly younger than those from other groups ($P < .001$), and there were more women in the underweight and normal weight groups compared to the overweight and obese groups ($P < .001$). IONM was used in 800 patients (61.15%), more frequently in patients with BMI 18.5-24.9 (368 patients) compared to patients with BMI 25-29.9 (247 patients) ($P = .0185$) and BMI ≥35 (50 patients) ($P = .0041$). Preoperative levels of corrected serum calcium and albumin were not different between groups.

The primary analysis of the study showed that the rate of postoperative complications was not different between patients operated with conventional hemostasis and those operated with the single-use hemostatic device. The percentage of patients operated with each device was similar across all BMI groups, and close to 50% ($P = .951$).

Postoperative hypocalcaemia was diagnosed in 264 patients (20.15%) (Table 2). The only statistically significant difference ($P = .0120$) was observed between patients with BMI <18.5 (32.35%) and patients with BMI 30-34.9 (14.66%). However, in multivariate analysis, the difference was no longer significant ($P = .764$). There was no difference between the groups in terms of definitive hypocalcaemia ($P = .7643$), data were missing for 16 patients (out of 264 patients with postoperative hypocalcaemia). Postoperative abnormal vocal cord motility was diagnosed in 129 patients (9.91%), including 75 (5.76%) cases of hypomotility and 54 (4.15%) cases of immobility, with no difference between groups ($P = .7783$). Definitive RLN palsies were diagnosed in 11 patients (0.88%) with no difference between groups ($P = .7688$) but data were missing for 65 patients (50.38%). No reliable data were collected at 6 months regarding quality of voice. Sixteen patients (1.22%) had a postoperative compressive hematoma requiring emergent surgical evacuation, with no difference between groups ($P = .7705$). Three wound infections were observed: one in group BMI <18.5, one in group BMI 25-29.9, and one in group BMI 30-34.9 ($P = .050$). One patient was seen with cardiovascular non-lethal morbidity in group BMI 30-34.9. No other complications were reported (Table 3).

Data regarding the duration of the surgical procedure and postoperative pain are shown in Table 4. In univariate analysis, the duration of procedure was longer in overweight (103 ± 42.05 minutes) and obese (107 ± 46.30 minutes) patients compared to those with normal weight (96 ± 40.08 minutes)

TABLE 1 Baseline patients' characteristics

	BMI <18.5 No. of patients: 34 (2.6%)	BMI 18.5-24.9 No. of patients: 561 (42.8%)	BMI 25-29.9 No. of patients: 425 (32.4%)	BMI 30-34.9 No. of patients: 191 (14.6%)	BMI ≥35 No. of patients: 99 (7.6%)	Total no. of patients: 1310	*P* value
Age (y), mean (SD)	42.11 (13.21)[a]	49.01 (13.40)	52.86 (13.27)	52.51 (13.29)	50.92 (11.53)	50.74 (13.38)	<.001 for <18.5 vs all groups
Females No. of patients (%)	33 (97.0)[a]	488 (86.9)[a]	302 (71.1)	141 (73.8)	85 (85.9)	1049 (80.1)	<.001 for 18.5-24.9 vs 25-29.9 and 30-34.9
Procedures No. of patients (%). MD: 3	TT alone: 32 (94.1) TT + CND: 2 (5.9)	TT alone: 550 (98.4) TT + CND: 9 (1.6)	TT alone: 416 (98.1) TT + CND: 8 (1.9)	TT alone: 185 (96.9) TT + CND: 6 (3.1)	TT alone: 95 (96.0) TT + CND: 4 (4.0)	TT alone: 1278 (97.8) TT + CND: 29 (2.2)	.1480
Hyperthyroidism[b] No. of patients (%). MD: 75	12 (35.3)	102 (19.3)	87 (21.8)	29 (15.9)	22 (24.2)	252 (20.4)	.0728
Intraoperatively diagnosed cancer[c] No. of patients (%). MD: 1	9 (26.5)	113 (20.2)	89 (20.9)	53 (27.7)	21 (21.2)	285 (21.8)	.8045
Thyroiditis No. of patients (%). MD: 33	9 (26.5)	97 (17.6)	60 (14.5)	32 (17.4)	18 (18.7)	216 (16.9)	.6925

Abbreviations: BMI, body mass index; MD, missing data; No., number; TT, total thyroidectomy; TT + CND, total thyroidectomy and central neck dissection.
[a]Statistically significant difference ($P < .001$) compared to the other groups.
[b]Patients who did not have hyperthyroidism were in euthyroidism.
[c]Median tumor size was 6 mm.

($P = .0054$ and .0029, respectively). Table 5 shows results of multivariate analysis, considering patients with a BMI ≥35 as a reference. In multivariate analysis, these differences remained statistically significant ($P = .0090$; Table 5). BMI had no impact on postoperative pain ($P = .8975$) at 4, 18-24, and 48 hours postoperatively. The mean length of stay was 2.7 ± 0.9 days. There were no difference between the groups in function of BMI and no ambulatory procedures.

4 | DISCUSSION

This is the largest prospective study evaluating the impact of BMI on specific morbidity following TT. The distribution of BMI categories in the study population is the same as in the general French population.[17] We showed that obesity did not increase postoperative RLN palsy rates or postoperative hypocalcaemia. The lack of difference in RLN palsy rates between BMI groups suggests that obesity did not increase the rate of nerve injury. In this study, there were slight differences of IONM use between groups. Indeed, IONM was less used in patients with the higher BMI. However, it has been previously reported that the utilization of IONM does not significantly prevent RLN palsy.[6]

The mean duration of surgical procedure was slightly shorter in normal weight patients than in those with overweight and obesity. However, severely obese (BMI ≥35) patients did not have a significantly longer operative time compared to other patients. The low number of severely obese patients in our series (n = 99) may explain a type 2 error with an underestimation of the operative time in this group. Another explanation might be the size of the incision in severely obese patients, that is, the surgeon might have used a larger incision to facilitate the visualization of the

TABLE 2 Postoperative and definitive RLNP and hypocalcaemia rates according to BMI (univariate analysis)

	BMI <18.5 No. of patients: 34 (2.6%)	BMI 18.5-24.9 No. of patients: 561 (42.8%)	BMI 25-29.9 No. of patients: 425 (32.4%)	BMI 30-34.9 No. of patients: 191 (14.6%)	BMI ≥35 No. of patients: 99 (7.6%)	Total no. of patients: 1310	*P* value
Postoperative RLNP							.7783
No. of patients (%)	4 (11.76)	52 (9.32)	40 (9.48)	25 (13.16)	8 (8.16)	129 (9.91)	
Hypomotility	1 (2.94)	32 (5.73)	19 (4.50)	20 (10.53)	3 (3.06)	75 (5.76)	
Immobility	3 (8.82)	20 (3.58)	21 (4.98)	5 (2.63)	5 (5.10)	54 (4.15)	
Definitive RLNP							.7688
No. of patients (%)	0 (0)	3 (0.56)	5 (1.22)	3 (1.70)	0 (0)	11 (0.88)	
Hypomotility	0 (0)	1 (0.19)	2 (0.49)	2 (1.14)	0 (0)	5 (0.40)	
Immobility	0 (0)	2 (0.37)	3 (0.73)	1 (0.57)	0 (0)	6 (0.48)	
Postoperative hypocalcaemia							.0120
No. of patients (%)	11 (32.35)	129 (22.99)	79 (18.59)	28 (14.66)	17 (17.17)	264 (20.15)	
Definitive hypocalcaemia							.7643
No. of patients (%)	1 (3.03)	11 (1.99)	9 (2.14)	2 (1.05)	3 (3.06)	26 (2.01)	

Note: There were 8 missing data for postoperative vocal cord examination, 65 missing data for late (6 months) vocal cord examination. There were no missing data for postoperative hypocalcaemia, and 16 missing data for definitive hypocalcaemia.
Abbreviations: BMI, body mass index; No., number; RLNP, recurrent laryngeal nerve palsy.

TABLE 3 Postoperative and definitive RLN palsy, hypocalcaemia, and hematoma according to BMI (multivariate analysis)

	Odds ratio [confidence interval]	*P* value
Hypocalcaemia	0.75 [0.23; 2.40]	.7643
Postoperative abnormal vocal cord motility	1.01 [0.26; 3.95]	.7783
Definitive RLNP	0.76 [0.18; 3.24]	.7688
Hematoma	5.03 [0.39; 64.13]	.7705

Note: Multivariate analysis was performed using a logistic model.
Abbreviations: BMI, body mass index; RLNP, recurrent laryngeal nerve palsy.

RLN and the parathyroid glands in severely obese patients. Unfortunately, the incision length has not been reported in our study or in previously published ones.[11,12] Finel et al reported that the duration of TT was longer in patients with BMI ≥25 compared to that normal weight patients (103.7 minutes vs 91.55 minutes, $P = .007$).[12] Milone et al confirmed this result with no difference in postoperative hypocalcaemia (1.9% for BMI ≥25 and 3.7% for BMI <25), or postoperative RLN palsy rate (2.8% for BMI ≥25 and 2.4% for BMI <25).[11] Rate of hypocalcaemia are lower than ours, but Milone et al included total and partial thyroidectomies.[11] Unfortunately, Finel et al and Milone et al did not distinguish results among patients with BMI >25.[11,12]

Surprisingly, postoperative pain severity was not different between groups. One might suppose that more cervical stretching is required in obese patients than in other patients, resulting in more pain, which could also be increased by a longer and more difficult procedure. Perhaps obese patients had a larger incision than normal weight patients. This explains less important stretching forces. In this study, the greatest difference in mean operative time was only 11 minutes between obese and normal weight patients.

The American College of Surgeons National Surgery Quality Improvement Program (ACS NSQIP) provided data from 18 825 patients undergoing thyroidectomy between 2005 and 2008.[13] The authors evaluated global morbidity but not thyroidectomy-specific morbidity including RLN palsy and hypocalcaemia. They reported that morbid obesity was an independent predictor for urinary complications. They also showed that BMI 25-29.9, BMI 30-34.9, and BMI ≥35 were independent predictors for spending a longer time in the operative room due to anesthetic problems or intraoperative difficulties. However, the authors did not draw any conclusions about RLN palsy or hypocalcaemia. In the present series, no urinary complications or deep venous thrombosis was reported, despite the absence of thromboprophylaxis. These two complications are classical postoperative complications in obese patients. In 2014, Abraham et al published retrospective data collected from ACS NSQIP between 2005 and 2010.[14] RLN palsy and hypocalcaemia were still not evaluated. In multivariate analysis, the factors significantly associated with postoperative morbidity were diabetes, hypertension, age >70 years, steroid use, chronic obstructive pulmonary disease, and dialysis, but not BMI.[14] Updated ACS NSQIP data were recently published by Caulley et al, who retrospectively compared data from 40 025 thyroidectomies, and concluded that BMI

TABLE 4 Duration of the procedure and postoperative pain according to BMI (univariate analysis)

	BMI <18.5 No. of patients: 34 (%)	BMI 18.5-24.9 No. of patients: 561 (%)	BMI 25-29.9 No. of patients: 425 (%)	BMI 30-34.9 No. of patients: 191 (%)	BMI ≥35 No. of patients: 99 (%)	Total no. of patients: 1310 (%)	*P* value
Mean length of procedure in minutes (SD), MD: 40	99.66 (35.39)	95.99 (40.08)	103.45 (42.05)	107.36 (46.30)	104.09 (42.47)	100.81 (41.94)	.0072 .0054 for 25-29.9 vs 18.5-24.9 .0029 for 18.5-24.9 vs 30-34.9
Postoperative pain (0-10), mean (SD), MD: 93							
At 4 h	2.69 (2.13)	2.79 (2.10)	2.77 (1.98)	2.95 (2.17)	2.84 (1.95)	2.81 (2.06)	.8975
At 18-24 h	1.87 (1.82)	2.02 (1.78)	1.93 (1.77)	2.08 (1.94)	2.02 (1.89)	2.00 (1.82)	
At 48 h	1.65 (1.92)	1.19 (1.63)	1.21 (1.46)	1.27 (1.72)	1.18 (1.59)	1.22 (1.59)	

Abbreviations: BMI, body mass index; MD, missing data; No., number.

TABLE 5 Duration of the procedure—multivariate analysis adjusted to age, sex, procedure, hyperthyroidism, cancer, and thyroiditis (linear regression model)

	Estimate	95% confidence interval	Overall *P* value	*P* value
BMI <18.5	−9.10	[−25.61; 7.42]	.009*	.279
BMI 18.5-24.9	−9.16	[−18.39; 0.06]		.051
BMI 25-29.9	−1.71	[−11.17; 7.76]		.723
BMI 30-34.9	1.82	[−8.64; 12.29]		.732
BMI ≥35 (ref)	0.00			

Abbreviations: BMI, body mass index; Ref, reference.
*P value <.05: 25-29.9 vs 18.5-24.9 ($P = .008$) and 18.5-24.9 vs 30-34.9 ($P = .002$).

increased postoperative complications only in patients over 70 years of age.[15] The aim of this work was not to precise the feasibility of ambulatory surgery in TT. A high BMI was not a contraindication for outpatient thyroidectomy in the literature.[15] In France, outpatient thyroid surgery is rarely performed. However, our data suggest that a high BMI (without comorbidities) should not be a contraindication for outpatient surgery. A randomized designed study is necessary to definitively conclude.

Although our series was large (1310 patients), prospective, and had few postoperative missing data, it has limitations. This study had no data regarding preoperative blood vitamin D levels, whereas vitamin D deficiency is a predictive factor for postoperative hypocalcemia.[18] The differences of hypocalcemia between patients with BMI <18.5 and those with BMI 30-34.9 may be due to the level of preoperative vitamin D level. Nevertheless, the difference was not statistically significant using multivariate analysis. Data regarding intraoperative difficulties were not collected. However, one may estimate that the duration of the procedure indirectly reflects intraoperative difficulties. Our results cannot apply to patients with invasive cancers or substernal goiter, who were excluded from the present study. We excluded these patients in order to include a more homogeneous population and avoid stratification on TT indication, as surgery is more difficult in case of thyroid cancer. In addition, lymph node dissection increases the rate of hypocalcemia, which would have added confusion in the analysis of our primary endpoint. Approximately half of the patients with postoperative RLN palsy refused the 6-month laryngoscopy, resulting in a possible underestimation of the rate of definitive RLN palsy. However, it has been shown that the rate of definitive palsies is correlated to the rate of immediate postoperative palsies.[19]

5 | CONCLUSION

In conclusion, obesity does not increase intraoperative and postoperative morbidity following TT, despite a longer duration of the procedure. This large prospective study encourages endocrine surgeons to reassure obese patients scheduled for TT, as the postoperative morbidity rate is similar to that of normal weight patients.

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CONFLICT OF INTERESTS

The authors declare no potential conflict of interest. The study protocol was reviewed and approved by a regional ethics committee (Comité de Protection des Personnes Ouest IV N° 58/2012) and by the CNIL (Commission Nationale de l'Informatique et des Libertés N°1170319). The study was performed in accordance with the Good Clinical Practice Guidelines and the Declaration of Helsinki. All patients signed a written informed consent before inclusion.

AUTHOR CONTRIBUTIONS

C.B. and S.B. collected and analyzed the data, wrote and revised the manuscript. F.P., L.B., N.C., M.D., J.-M.P., A.H., G.L., M.M., N.C., J.-C.L., H.-P.D., F.S., E.B., A.B., and C.J. collected the data and revised the manuscript. V.-P.R. and C.V. analyzed the data. E.M. and C.C. designed the research study, supervised the study, wrote, and edited the manuscript. All of the authors approved the final version of the manuscript.

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