RESEARCH ARTICLE

Comparison of Immediate Postsurgical Results in PatientsUndergoing Open Thyroidectomy vs Trans-oral Thyroidectomy (2-year experience) at the General Hospital IESS Ibarra Ecuador.

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ABSTRACT

Introduction: Conventional thyroid surgery has been used for several years without major changes in its technique, the vestibular oral endoscopic approach (TOTEVA) was described in 1997, the benefit is an excellent aesthetic result, adequate exposure of anatomical structures and results favorable cancer conditions, the objective of the present study was to compare immediate postsurgical results in patients undergoing thyroidectomy using the classical technique and TOETVA.

Methods: This is a retrospective cohort study, all cases in which thyroidectomy

INTRODUCTION

Conventional thyroid surgery has been used for several years without major changes in its technique since it was modified by Kocher in the 19th century, since then it is considered the standard technique [1].

The endoscopic approach for neck surgery was described in 1996 for a partial parathyroidectomy² and for thyroid surgery in 1997 [3], other remote minimally invasive procedures by transaxillary or retroauricular route, to name a few [4-5], have been published.

Miccoli⁶ described the: minimally invasive video assisted thyroidectomy (MIVAT) in 1998 which is approached through a single 2 cm incision in the neck without the use of endoscopic instruments. In 2008 Witzel [7] described for the first time the sublingual transoral approach in cadaveric models and in porcine models. In 2012, Nakajo [8] describes a new endoscopic technique for transoral thyroid surgery: video-assisted neck surgery (TOVANS), where mechanical retraction is used for exposure. In 2015, the first series of cases with a vestibular approach was reported: transoral endoscopic thyroidectomy vestibular approach (TOETVA) by Anuwong [9]. In Ecuador, the first surgery was performed using TOETVA in 2016 [10].

A potential benefit of TOETVA is the excellent cosmetic result, as well as favorable oncological results, and for some authors it has no longer been considered as an experimental technique [11]. Multiple centers have chosen to perform alternative procedures to the classical technique for thyroid surgery, in the same way, there are comparative studies where both techniques are shown to be safe with a difference in surgical time that was greater for TOETVA [12].

The main objective of the present study was to compare the immediate postsurgical results in patients who underwent thyroidectomy using the classical technique and TOETVA in a period of 2 years, taking into account the most frequent complications such as dysphonia and symptomatic

was performed using TOETVA and open technique were taken according to the inclusion criteria described, variables such as symptomatic hypocalcemia, dysphonia and duration of surgical time were analyzed.

Results: A total of 62 patients were obtained, of which 70% were open approach and 30% endoscopic, there was transient hypocalcemia and dysphonia for open surgery: 25% and 18.8% respectively, while for endoscopic surgery: 33% and 44.4%, statistically non -significant data, the duration of operative time was longer for TOETVA, significant data.

Conclusion: The presence of hypocalcemia and dysphonia was higher with TOETVA without statistical significance, the surgical time was longer with TOETVA, except for one major complication, TOETVA was safe.

Keywords: NOTES; Transoral thyroidectomy; Video-assisted minimally invasive thyroidectomy

hypocalcemia. surgical procedure in both techniques and the presence of other complications related to surgery.

METHODS AND MATERIALS

This is a retrospective cohort study, which included patients who underwent thyroidectomy by vestibular approach (TOETVA) and those who underwent open technique between 2014 and 2016, the data were obtained from the single integrated system of clinical records AS- 400 of the Ecuadorian Institute of Social Security.

The inclusion criteria were: those patients who have undergone thyroidectomy by either of the two techniques and with the following characteristics: thyroid gland with a diameter less than 10 cm, gland volume less than or equal to 45 ml, size of smaller nodules or equal to 50 mm, diagnosis of benign tumor, cyst or single or multiple nodular goiter, in cases of thyroid neoplasia with a Bethesda IV or V or with micropapillary carcinoma without evidence of metastasis.

Patients who underwent open thyroidectomy with pre-surgical characteristics other than those mentioned were excluded.

All patients underwent serum ionic calcium determination 10 hours after the procedure, physical examination in search of signs suggestive of hypocalcemia (paresthesia, chvostek or trousseau), dysphagia, dysphonia, cervical hematoma or other complications related to the surgery. Those who presented low ionic Ca values and any of the signs or symptoms described were classified as hypocalcemia; all cases were managed and adequate followup was provided.

A total of 62 patients were obtained and the analysis of the database was carried out with the statistical software SPPS version 25 in Spanish, for the hypothesis test a significance level of 5% is used, the variables involved in the study are qualitative and quantitative. For the presentation of the results, an exploratory analysis of the data is used with the use of tables according to the type of variable.

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RESULTS

A total of 62 patients were included, 90.3% (N = 56/62) female, and 9.7% (N = 6/62) male. The mean age was 49.96 ± 12.38 years, 95% CI (46.82; 53.11), the minimum age was 28 years and the maximum 74 years. Between the two techniques, the average duration of surgery was 137.01 ± 25.84 minutes, 95% CI (131.02; 144.14), the minimum duration of surgery was 80 minutes and the maximum was 210 minutes. As general post-surgical complications, asymptomatic transient hypocalcemia was reported in 17 patients (27.4%), transient dysphonia in 25.8%; both reversed before hospital discharge.

The mean age in the open technique was 52.00 ± 12.53 years with a 95% CI (48.18; 55.81) being the minimum of 31 years and the maximum of 74 years, with the highest concentration in the age group from 39 to 58 years of 47.72% (N = 21/44), in TOETVA the mean age was 39.64 ± 10.76 years with a 95% CI (39.64; 0.35) with an age minimum of 28 and maximum of 65 years, with the highest concentration in the age group of 28 to 58 years with 83% representativeness (N = 15/18). (Table 1)

25.0% of the patients with open technique and 33.3% with TOETVA presented low ionic Ca values in the first and clinical determination of hypocalcemia, which was transient and reversed in all patients with normal ionic Ca values prior to discharge and without symptoms; 6 patients with open technique and 2 with TOETVA required supplemental oral calcium; 18.8% and 44.4% of the patients with open thyroidectomy and TOETVA respectively presented dysphonia at 8 hours after surgery, in all cases it reverted before discharge. (Table 2 and 3)

With open technique, 63.63% (N = 28/44) required total thyroidectomy, 29.54% (N = 13/44), partial and 52.27% (N = 23/44) emptying. For TOETVA, 66.66% (N = 12/18) required total surgery, 33.33% (N = 6/18

partial surgery and 11.11% (N = 2/18) voiding; the voiding performed was of the central level in both techniques (Table 4)

The average surgical time in the open technique was 129.77 minutes with a standard deviation of \pm 21.40, a 95% CI (123.26, 136.27), the minimum time recorded was 80 minutes and the maximum time 180 minutes. For TOETVA, the mean was 156.67 minutes with a standard deviation of \pm 26.34 and a 95% CI (143.56; 169.78), the minimum time recorded was 120 minutes and the maximum was 210 minutes. (Table 5)

In order to perform hypothesis testing to analyze whether there are significant differences between the surgical time and ionic calcium between both techniques, normality tests were applied to verify the assumptions required by said techniques and thus be able to select the most appropriate; It was obtained that the surgical time and the ionic calcium for both techniques are not distributed in a normal way, with significance levels of 0.00 and 0.02 respectively, according to these results hypothesis tests are performed to analyze whether the TOETVA it is associated with the reduction of both the average duration and the ionic calcium, applying the Mann-Whitney U test of independent samples. For the average duration it is observed that if there is a significant difference between open thyroidectomy and trans-oral thyroidectomy with a p-value of 0.00; that is, the average time with open thyroidectomy is less than with TOETVA. For ionic calcium, the p-value was 0.810 higher than the significance level of 0.05, that is, there are no significant differences between both techniques. (Tables 6 and 7)

As additional complications in one patient, there was a tracheal perforation diagnosed on the 4th postoperative day with the TOETVA technique, which was managed with the placement of a trachestome for 3 weeks without subsequent complications, 1 cervical hematoma with open technique and with TOETVA without ventilatory compromise that was drained on

Table 1	Age	distribution	according	to the	Surgical	Technique Applied
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Surgical technique	Ν	Half	Standard deviation	Standard error of the mean
Open	44	52	12.53	1.88
Trans-oral	18	Four. Five	10.76	2.53

N: 62 patients for both techniques

Fable 2 Distribution	ı of dysphonia	according to the	surgical technic	jue used (> j	p = 0.05)
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	Surgical t	echnique	
Dysphonia	Open	Trans-oral	Total
No N,%	36 (81.81)	10 (55.55)	46 (74.19)
Without,%	8 (18.18)	8 (44.44)	16 (25.80)
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N 18,8% of patients for open technique and 44,4% for Trans-oral technique

Table 3 Distribution of hypocalcemia according to the surgical technique used (p = 0.810)

TT 1 '	Surgical	echnique	
Hypocalcemia	Open	Trans-oral	lotal
No N,%	33 (75.0)	12 (66.67)	45 (72.58)
Without,%	11 (25.0)	6 (33.33)	17 (27.74)

N: 25,0% of patients for open technique and 33,3% for Trans-oral technique

Table 4 Distribution of the type of surgery according to the Surgical Technique

Surgical technique	Total Surgery		Partial Surgery		Emptying	
	Yes	No	Yes	No	Yes	No
Open thyroidectomy	28	16	13	31	2.3	twenty-one
Trans-oral thyroidectomy	12	6	6	12	2	16

Table 5 Statistics for Surgical 7	Time according to Surgical	Technique (<p 0.005)<="" =="" th=""></p>
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Surgical technique	Ν	Half	Standard deviation	Standard error of the mean
Open	44	129.77	21.40	3.22
Trans-oral	18	156.66	26.34	6.20

N: 62 patients for the both techniques

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Table 6 Normality Tests (verification of assumptions)

Normality tests					
Shapiro-Wilk					
Surgical technique	Variable	Statistical	gl	S.I.G.	
	Duration	0.358	44	0.00	
Open	Ionic Calcium	0.284	44	0.00	
	Duration	0.211	18	0.02	
l rans-oral	Ionic Calcium	0.326	18	0.00	

Sig: statistical significance p 0,00 to open technique and p 0,02 to Trans-oral technique

 Table 7 Hypothesis tests for the means of duration and ionic calcium.

	Mann-Whitney U test Duration		Mann-Whitney U test		
Surgical technique			Ionic Calcium		
	Half	p-value	Half	p-value	
Open	129.77		6.32	- 0.010	
Trans-oral	156.66	- 0.000	4.14	- 0.810	

 Table 8 Other complications according to the surgical technique used

	Surgical technique		
Other complications	Open	Trans-oral	
TRACHEOSTOME PLACEMENT FOR COMPLICATED TRACHEAL FISTULA WITH NECROSIS OF TRACHEAL CARTILAGES	0 (0.0)	1 (5.6)	
CERVICAL HEMATOMA REQUIRING DRAINAGE AND CONTROL OF HEMOSTASIA IN IMMEDIATE POST-SURGICAL	1 (2.3)	1 (2.3)	
CONVERSION TO OPEN SURGERY DUE TO DIFFICULT ACCESS OF TUMORATION IN THE RIGHT LOBE	1 (2.3)	0 (0.0)	
DYSPHAGIA DURING HOSPITALIZATION, WHICH RESOLVES	1 (2.3)	0 (0.0)	
PATIENT ADMITTED FOR RESPIRATORY INSUFFICIENCY REQUIRING POST-SURGICAL INTENSIVE THERAPY	2 (4.6)	1 (5.6)	

N 11.5% to open technique and 13.5% to Trans-oral technique

the floor and was reviewed in the operating room without subsequent complications, a case of TOETVA required conversion to open surgery without subsequent complications, the presence of dysphagia in a patient with an open technique that reversed with general measures and swallowing therapy, 3 patients presented difficulty respiratory tract (2 in open technique and 1 in TOETVA) that required support for 24 hours in ICU secondary to post-extubation laryngospasm, which evolved adequately in the following days.(Table 8)

DISCUSSION

The use of the TOETVA vestibular technique offers advantages in certain cases and good hemostatic control as well as results comparable to the classical technique12; In thyroidectomies performed under specific circumstances, such as in Graves' disease, cases of conversion have been reported due to hypervascularity secondary to said disease. [13] In our series, conversion was chosen in one patient due to the presence of a right lobe closely adhering to the posterior planes.

The endoscopic approach offers adequate visualization and favorable control of hemostasis, 9 offering adequate exposure for patients requiring total thyroidectomy with emptying, as reported in the results of the study where a central dissection could be completed in those patients in whom the macroscopic characteristics of the gland in the intraoperative period led to the decision to complement the thyroidectomy with dissection through the vestibular approach; other minimally invasive techniques offer the same advantages as TOETVA and are safe in benign pathologies [14].

Regarding certain complications such as hypocalcemia evidenced in a not

inconsiderable percentage of thyroidectomies, [15] TOETVA does not seem to be a risk factor for its development according to the series reported by Anuwong9; in comparative studies in patients with thyroid neoplasia and with adequate selection criteria to perform TOETVA, postoperative complications as well as the oncological result were favorable and even comparable with classical thyroidectomy techniques [16], in the same way it is a technique with good results and few complications in patients with a diagnosis of papillary thyroid microcarcinoma, [17] data that are similar to those reported in our study, taking into account the appropriate selection criteria and that were similar for both techniques.

The minimally invasive approach was described for neck surgery approximately 25 years ago, as an option and alternative in those patients where a favorable cosmetic result can be obtained without altering an adequate procedure and resolution of the pathology [18], we evidence a low level of pain and since it is a NOTES technique, the esthetic result is excellent, except for a small 5 mm scar when a drain was placed.

Complications such as recurrent laryngeal nerve injury, infection, bleeding, superior laryngeal nerve injury occur in a similar way in this technique.[19] In our patients, no recurrent laryngeal nerve injuries were reported in either of the two groups, taking into account the criteria of selection applied and that patients who needed a more radical surgery and with a higher risk for major complications or associated injuries were not included; it was possible to identify and preserve important structures such as the laryngeal nerves and the parathyroid glands, with adequate vascular control and hemostasis. On the other hand, no spacers or special equipment are required for its realization.

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In a general context and according to the data published for TOETVA, major complications occur in less than 5%, and infections are usually rare. [20] In the present study we had a greater complication than with a favorable evolution, according to reported statistical data.

In short, several authors agree that thyroidectomy by TOETVA in selected patients is comparable to the conventional technique in terms of complications and results [21-22-23], our work shows that the time is shorter with the open technique than with TOETVA, variable attributable to the curve and the increase in cases resolved by the latter, since compared to the first cases, there was a significant reduction in the duration of surgery at the beginning of applying TOETVA and currently, in the period of two years.

CONCLUSION

The use of TOETVA is safe and the results obtained do not show a higher rate of immediate complications compared with conventional surgery and with other reported series; hypocalcemia and dysphonia were evidenced in both groups in a similar proportion to the global data with a predominance for TOETVA however the results were not statistically significant. Surgical time was longer for TOETVA statistically significant data. Total and central emptying procedures can be performed in selected patients with TOETVA.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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