Are we changing our inclusion criteria for the minimally invasive videoassisted thyroidectomy?



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AIM: The first cases treated with Minimally Invasive videoassisted thyroidectomy (MIVAT) were characterized by inclusion and exclusion criteria that are changing with the experience.

MATERIALS AND METHODS: We have analyzed the patients treated from july 2005 to december 2010 with MIVAT All these cases were treated in accord with Miccoli's technique with a minicervicotomy of 1.5-2 cm above the sternal notch. We have divided the cases on the surgical period highlighting changing in the inclusion criteria and the adverse events (0-211 cases; 212-300 cases). All the cases treated were followed up at days 7 (ambulatory visit) and days 30-12 months (ambulatory visit or telephone contactc). The patients classified in the II° period were chracterized by the exclusion of the clinical thyroiditis. We have related these cases with the cases treated with conventional thyroidectomy(CT).

RESULTS: No differences in postoperative pain, nerve palsy and hypocalcemia in MIVAT group and CT group. We have registered a postoperative pain at 24 hours lower in MIVAT group. The percentage of transitory nerve palsy in the MIVAT group in the first period was 2,84 % versus 1,12 % in the second period.

CONCLUSION: MIVAT technique is safe and reproducible, with an excellent cosmetic results. In our experience MIVAT remains the better surgical options for the patients that meet the inclusion criteria. These cases are 15% of patients treated with thyroidectomy in our Endocrine surgery Unit.

KEY WORDS: MIVAT, Nerve palsy, Thyroid disease, Thyroidectomy, Thyroiditis, Thyroid cancer

Introduction

The introduction in the last years of clinical and experimental miniinvasive procedures in endocrine surgery has introduced new surgical technical approaches to thyroidectomy ¹⁻⁸ and consequently new adverse events postthyroidectomy. These new extracervical approaches required more dissection than conventional open and videoassisted surgery; in accord with Henry ⁹ cannot be classified as minimally invasive surgery.

Minimally invasive videoassisted thyroidectomy (MIVAT) has demonstred a reduced surgical distress, a lower postoperative pain at 24 hours from the procedure compared to conventional thyroidectomy (CT) with a good pain control using paracetamole , an excellent cosmethic result and a reduced posthyroidectomy voice and swallowing symptoms ¹⁰⁻¹⁵. Several authors demonstred that the adverse events associated to MIVAT are the same or better related to postoperative hypocalcemia; no significant differences are reported compared to traditional surgical thyroidectomy in the incidence of nerve palsy, haemorrhage and cost effective analysis ¹⁶⁻¹⁷.

The first cases treated with MIVAT and described by Miccoli were characterized by inclusion and exclusion

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criteria that are changing with the experience of the endocrine surgeons as the indication to treat the Basedow disease ¹⁸.

The learning curve as in others miniinvasive surgical procedures is fundamental for the experienced endocrine surgeons ¹⁹⁻²⁰; besides the surgical MIVAT approach and anatomical vision are different in MIVAT respect to CT. We have analyzed the experience from our first 300 cases treated , analyzing the differences in the selection of the patients candidates to MIVAT and the change in inclusion criteria in our Unit.

Materials and methods

We have analyzed the patients treated from july 2005 to december 2010 with MIVAT. All the patients candidates to thryoidectomy were evaluated on a preoperative protocol study (Table I) accreditated on our ambulatory as a preoperative protocol before thyroidectomy.

All these cases were treated in accord with Miccoli's technique with a minicervicotomy of 1.5 - 2 cm above the sternal notch with subsequent dissection of prethyroidal muscles in vertical line. Isolation from the omolateral muscle of thyroid lobe, use of dedicated devices, and identification of superior pedicle vessels with the aim of 5 mm camera 30° degree, section of pedicle superior vessels with the use of Ultracision (Ethicon Endosurgery) and / or Single Use Automatic Clip Applier(Autosuture, Ethicon Endosurgery).

During the camera vision we identified the parathyroid glands and superior and inferior recurrent nerve. We dissected the vessels of inferior pedicle to remove the omolateral lobe. To perform a total thyroidectomy we have repeated all the steps of procedure in the controlateral thyroidal region.

We have registered all these cases in a dedicated data base; we have divided the surgical period highlighting the incidence of adverse events and the intra and postoperative course. After 24 hours all the patients were tested with a calcium level test.

All the cases treated were followed up at days 7 (ambulatory visit) and days 30-180 (ambulatory visit or telephone contact). We have recorded the postoperative pain making use of a visual score from 0 to 10, at 1 and 24

TABLE I - Preoperative protocol

Endocrinological visit Cervical ecothomography (evaluation of Thyroid volume) FNAC(if indicated by ecographical result) Serological evaluation (TSH, FT4, Calcitonine, Thyreoglobulin, PTH, Serum calcium) Vocal cords evaluation

*Scyntigrpahy, TC and/or NMR if necessary.

TABLE II - Inclusion and exclusion criteria

Inclusion

Thyroid volume < 30 ml Nodule < 3,5 cm Goiter Hyperfunctioning thyroid Follicular lesion Low risk carcinoma

Exclusion Absolute Short neck in obese patient Previous neck surgery Laterocervical nodes metastases Clinical thyroiditis*

Relative Previous neck radiotherapy Nodes at VI level

*Hormonal therapy, positive cervical ecothomography.

hours after surgery, the mean operative time, the postoperative calcemia values, the postoperative nerve palsy and the haemorrhage. We have defined a definitive nerve palsy all the cases with palsy after 6 months from thyroidectomy.

We have divided the patients into two periods.

The first period was published regarding the first 211 cases treated and characterized by the learning curve with the standard inclusion and exclusion criteria (19-22).

The second period (from 211 to 300 pts) was characterized by a new classification on inclusion and exclusion criteria (Table II).

The data of MIVAT cases were matched with CT conducted always from the same two experienced surgeons and then they were matched with data registered in data base. The data were analyzed with statistic methods t student and chi-square; the p values lower than 0.05 were considered positive.

Results

From july 2005 to december 2010 we have consecutively treated 300 patients with MIVAT technique on 1573 pts thyroidectomized (19.07 %).The patients candidates to MIVAT were affected by follicular lesions in 104 cases, by papillary carcinoma 105 cases, by Plummer's adenoma 20 cases,by Basedow disease 12 cases,by toxic goiter 21 cases and by goiter 38 cases. We have performed 9 cases of videoassisted central compartment nodes prophylactic dissection (Table III).

From march 2009 to december 2010 we identified a second period in our experience treating 558 cases with CT and 89 with MIVAT technique (15.9%).

TABLE III - Case treated with MIVAT

Preoperative diagnosis in 300 Disease	MIVAT cases N°cases
Follicular lesions	104
Papillary carcinoma	105*
Plummer's adenoma	20
Basedow disease	12
Toxic goiter	21
Goiter	38

*9 cases of videoassisted central compartment nodes dissection

The MIVAT cases were enrolled with new inclusion criteria excluding short neck in obese patient and clinical thyroiditis. We have analyzed this last period of our surgical experience in videoassisted thyroidectomy (Table IV). The postoperative pain at 1 hours from procedure was no statistically significant matched with the CT; the postoperative pain at 24 hours was statistically different (p<0,001) as in the previous experience.

The incidence of transitory nerve palsy occurred in 9/469 (2,84%) in CT group and 1/89 (1,12%) in MIVAT group (n.s). We registered a case of reintervention for postoperative bleeding in the CT. Symptomatic hypocalcemia presents an incidence of 8,1% in MIVAT group and 13,9% in CT group (n.s.). No differences in postoperative pain and hypocalcemia in MIVAT group and CT group in the two periods; the postoperative pain at 24 hours was lower in MIVAT group in both periods. The mean surgical time was in MIVAT cases statistically positive (p<0.05) between the first period (58,6 minutes) and second period (46,9 minutes). The percentage of transitory nerve palsy in the MIVAT group in the first period was 2,84% versus 1,12% in the second period. No definitive hypocalcemia in al cases after 12 months.

Discussion

The use of MIVAT technique is increasing in Europe, North America and Asia(23).In our article we don't discuss on the efficacy of this technique that today is demonstred to be safe, reproducible with excellent cosmetic results; we discuss if the changing in inclusion and exclusion criteria is related to an improved result.

What we have changed? The size of nodule is the same <3.5 cm of diameter, the thyroid volume is < 30 ml. We candidates to MIVAT the benign disease and malignant low risk carcinoma. We have as absolute contraindication the previous neck surgery, laterocervical nodes metastases, clinical thyroiditis and short neck in obese patient.

The relative contraindications remain previous neck irradiation and suspect nodes at VI level. We have changed the indications to MIVAT in case of clinical thyroiditis (no more as relative but as absolute controindications) and for obese patients.

These two criteria have similar difficulties: the short neck in obese patient doesn't permit a correct intraoperative position, with the real problem to mantain a correct plane in operative room and the consequent difficulty to use correctly the dedicated devices.

The thyroiditis is associated with a difficult to exposure of the anatomical region for the endoscopic approach with an excessive medial traction of the thyroid lobe by the dedicated retractors with a tension on recurrent nerve and thyreotracheal plane.

The thyroiditis determines an objective difficulty to free the lobe from soft tissue; so it's more difficult to mobilize the lobe under camera vision. This is an obstacle to a correct identification of vascular-nervous system increasing the risk of laryngeal lesions.

With these new inclusion criteria we have reduced the incidence of nerve palsy as showed from the analysis of two periods reported in Table IV (from 2005 to march 2009, from march 2009 to December 2010); we have

	Clinical hypocalcemia %	Postoperative pain at 1 hour	Postoperative pain at 24 hours	Transitory nerve palsy	Mean surgical time (minutes)
MIVAT (300 cases)	7,58 (8,1)	2.54+/-1.15 (2,56+/-1,19)	1,04 +/-0.83 (1.13+/-0.92)	6(1)	58.6 (46.9)*
CT (1273 cases)	12,4 (13,9)	2,89 +/-1,39 (2,93+/-1,46)	2.05+/-1.08 (2.23+/-1.06)	7(9)	-
Р	n.s. (n.s.)	n.s. (n.s.)	p<0.001 (p<0.001)	n.s n.s.	-

TABLE IV - Analysis of adverse events from July 2005 to March 2009 related to cases treated from April 2009 to December 2010.

(..) Data related to II° period; *p<0.05

observed a lower incidence in percentage of nerve palsy in MIVAT technique related to the first period.

We believe that our controindications to treat with MIVAT the clinical thyroiditis can be correlated to the lower incidence of nerve palsy. We have reduced the percentage of MIVAT on total thyroidectomy from 20,7 % in the first period to 15,9 % in the second period as others authors 24 .

The others data as postoperative calcemia,post operative pain are the same in all cases with MIVAT treatment. The significant statistical difference in postoperative pain at 24 hours ,in our opinion, is related to the neck hyperestension in CT that determines an higher postoperative pain and not to extension of skin incision.

If we examine the mean surgical time we have a statistical difference between the two periods but in the first cases treated we had a longer surgical time justified by the learning curve.

Conclusion

MIVAT sec. Miccoli's technique is safe and reproducible, with an excellent cosmetic results. This minimally invasive procedure is more safe if the endocrine surgeon doesn't candidate to videoassisted procedure the clinical thyroiditis. In our experience MIVAT remains the better surgical options for the patients that meet the inclusion criteria. These cases are today the 15% of patients treated with thyroidectomy in our Endocrine surgery Unit. The surgeon experienced in endocrine surgery can use safely in selected cases this miniinvasive procedure

Riassunto

SCOPO: I primi casi di tiroidectomia trattati con tecnica videoassistita (MIVAT) erano caratterizzati da criteri di inclusione ed esclusione che sono stati modificati con l'esperienza.

MATERIALI E METODI: Abbiamo analizzato i pazienti trattati consecutivamente dal luglio 2005 al dicembre 2010 con tecnica MIVAT. Tutti i casi sono stati trattai in accordo con la tecnica di MIccoli con una minicervicotomia di 1,5 - 2 cm al di sopra del giugulo. Abbiamo divisoi casi in base al periodo di trattamento evidenziando i criteri di inclusione e gli eventi aversi (casi da 0 a 211; casi da 212 a 300). Tutti i casi trattati sono stati seguiti a 7 giorni mediante visita ambulatoriale ed a 30 e 12 mesi con visita ambulatoriale o contatto telefonico. I pazienti classificati nel secondo periodo furono caratterizzati dall'esclusione dei pazienti affetti da tiroidite clinica. Abbiamo correlato questi casi con quelli trattati con tiroidectomia convenzionale (CT).

RISULTATI: Non abbiamo registrato differenze in base al dolore postoperatorio, paresi del nervo, ipocalcemia tra il gruppo MIVAT e quello CT.Abbiamo registrato un dolore postoperatorio a 24 ore inferiore nel gruppo MIVAT. La percentuale di paresi del laringeo inferiore del gruppo MIVAT nel primo periodo era di 2,84% verso 1,12% nel secondo periodo.

CONCLUSIONI: La tecnica MIVAT è sicura e riproducibile, con un eccellente risultatao cosmetico. Nella nostra esperienza la MIVAT è la migliore opzione chirurgica per quei pazienti che incontrano i criteri di inclusione. Questi casi sono il 15% dei pazienti trattai con tiroidectomia nella nostra Unità di endocrino chirurgia.

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