

## **Major complications in thyroid surgery: utility of bipolar vessel sealing (Ligasure® Precise)**

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**SUMMARY:** Major complications in thyroid surgery: utility of bipolar vessel sealing system (Ligasure® Precise).

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*In the present study the Authors tried and assess the advantages of the standard sutureless thyroidectomy performed by the Ligasure® Vessel Sealing System, thanks to the use of the dedicated Precise handle. The Authors compared the efficacy of haemostasis and the economical impact of the device, in terms of drug administration and costs.*

*The Authors comparatively analyzed 120 total extracapsular thyroidectomies (TET) performed by the standard operative technique (Group A, control) and 70 TET achieved by the "sutureless technique" (Group B, case). There was a statistically significant decrease of transient post-operative hypocalcaemia (5,71% vs 7,5%) and also of mean operative time (about 20 minutes) in patients of the group B. Non significant decrease of other kind of complications (post-operative haemorrhage, transient and permanent inferior laryngeal palsy, stupor of the superior laryngeal nerve, seroma) were also observed.*

*The use of the Ligasure® Precise resulted easy, safe and efficient in the Authors' experience. It allowed the decrease of postoperative haemorrhages and mean operative time.*

**RIASSUNTO:** Complicanze maggiori in chirurgia tiroidea: utilità della pinza bipolare (Ligasure® precise)

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*In questo studio gli Autori hanno cercato di evidenziare i vantaggi della tiroidectomia "sutureless" eseguita con l'aiuto del Ligasure® Vessel sealing System, con manipolo preciso. Gli Autori hanno paragonato l'efficacia del dispositivo in termini di emostasi, inizio e consumo dell'apparecchio, somministrazione di farmaci nel post-operatorio e costi.*

*È stata effettuata un'analisi comparativa tra due gruppi randomizzati di pazienti, comprendenti 120 tiroidectomie totali extracapsulari (TET) eseguite con tecnica tradizionale (Gruppo A, controllo) e 70 TET eseguite con tecnica cosiddetta "sutureless" mediante Ligasure® (Gruppo B, casi). È stata registrata una sensibile riduzione dell'ipocalcemia transitoria post-operatoria (5,71% vs. 7,5%) così come del tempo medio operatorio (circa 20 minuti) nei pazienti del gruppo B. È stata altresì osservata una riduzione di altri tipi di complicanze (emorragia, paralisi transitoria o definitiva del nervo laringeo inferiore, stupore della branca inferiore del nervo laringeo superiore, sierosi), tuttavia statisticamente non significativa.*

*L'utilizzo del sistema di coagulazione Ligasure® è risultato semplice, sicuro ed efficace. ha consentito la riduzione del sanguinamento e del tempo operatorio medio.*

**KEY WORDS:** Ligasure® - Bipolar vessel sealing - Thyroid surgery - Thyroidectomy complications.  
Ligasure® - Pinza bipolare - Chirurgia tiroidea - Complicanze della tiroidectomia.

### **Introduction**

During the last years, several methods of achieving haemostasis have been developed, in order to

improve the efficacy and safety of conventional coagulation. Harmonic scalpel (DU Ultracision) and Ligasure® Vessel Sealing System (radiofrequencies bipolar electrothermal coagulation) have already been widely used in laparoscopic (1) and thoracoscopy surgery, as in digestive (2) and pelvic (3-5) traditional surgery.

The aim of this study is to assess the real advantages of the bipolar electrothermal coagulation (Ligasure®) in thyroid surgery, comparing surgical technique, results and costs with those of the traditional coagulation (use of electrocautery, sutures and

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stitches).

We analyzed the safety and the efficacy of the device in terms of haemostasis, decrease of mean operative time and costs (drug-economical analysis of the cost/benefits ratio), but also the efficacy of this kind of coagulation (which causes minimal lateral thermal spread) in preventing some complications of total thyroidectomy (such as transient or permanent palsy of the lower laryngeal nerve and transient or permanent hypocalcaemia) often caused by heating and charring of electrocautery; lastly, we reviewed the drug saving advantage (due to the decrease of mean operative time and the absence of foreign stuff of suture into the neck). The device used in this study was the "Ligasure® Bipolar Vessel Sealing System", an electrosurgical radiofrequency device allowing a perfect haemostasis with minimal thermal spread. The main advantages of this kind of coagulator are mostly related to:

- High current, but low voltage output with subsequent less thermal spread (1 mm), in contrast with other electrosurgical devices, even the harmonic scalpel (5, 10).
- The device diagnoses the type of tissues in the instrument jaws and delivers the appropriate amount of energy needed to effectively seal it: the "generator" measures the variation of impedance (by a feed-back system) in the tissues caused by radiofrequency and automatically stops its production. This mechanism avoids the use of an higher amount of energy (guesswork) in order not to cause charring, scab and sticking of the "target" tissue, but mostly not to damage the surrounding tissues (such as thin and delicate structures, i.e. nerves and small vessels). The haemostatic mechanism works applying a calibrated amount of energy, causing a biologic seal which closes tightly the vessels. In this way: 1) there is no need for foreign stuff (clips, sutures), thus reducing the infectious risk and the fibrosis due to the use of synthetic material (7); 2) allows the safe haemostasis of vessels up to 7 mm of diameter (10), withstanding three times systolic blood pressure. The seal allows a good flexibility of vessels, ensuring that the seal contains no thrombus. There are many differences with the standard coagulative systems, which cause excessive heating and charring of tissues with subsequent endovascular thrombi (6-9).
- Each cycle lasts few seconds: there is no need for further applications (as for other electrosurgical devices) with subsequent decrease of operative time.
- The translucent seal is well shown (there is no

blood flow in), thus allowing the clear recognition of the site to cut (6).

- Beyond the vessels, it is also possible to cut tissues, in order not to dissect them handly. The only limit is that the obliterated lumen of the vessel cannot be cut at the same time (like, for instance, ultrasound activated shears), but it must be cut with surgical seizures just after coagulation (11-13).

At the beginning of their experience with the Ligasure®, the Authors tried and use the same handle of abdominal surgery, but it was too big for the small spaces and structures in the neck. Particularly, it was of no advantage for the recognition and the sparing of the inferior laryngeal nerve. Yet, in these cases they used traditional electrocautery and vascular stitches. Subsequently, they used the Ligasure® Precise handle, which is dedicated for thyroid surgery. This allowed an easier haemostasis during all the steps of the intervention. The mean cost of the Ligasure® generator ranger between 20.000 and 25.000 Euro and each Precise handle costs 200-250 Euro.

## Patients and methods

Among a series of 200 thyroidectomies performed during the last year, the Authors reviewed charts from two groups, selected by a double blind, statistically designed study and again compared in a multivariate analysis (Stat 2000 ltd).

- 1) First group - 70 total thyroidectomies (may 2003 - may 2004)- 48 females, 22 males; mean age 46,7 years old) performed by the conventional surgical technique, but with the use of the dedicated small bipolar electro thermal coagulator (Ligasure®

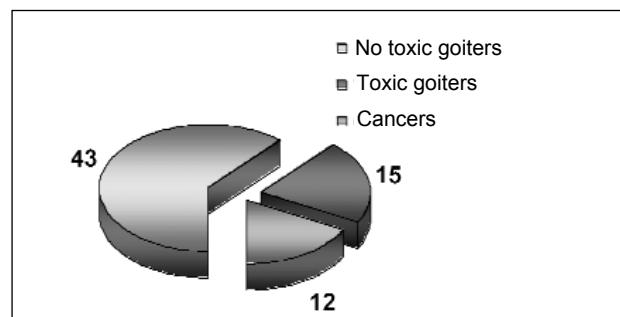


Fig. 1 - Total thyroidectomy performed by Ligasure® Precise (70 cases).

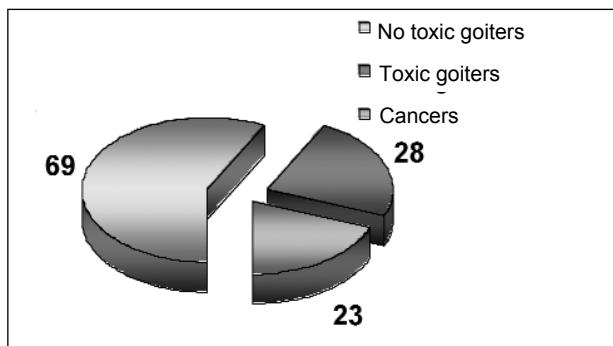
Precise).

The distribution of the different pathologies is showed in table I.

- 2) Second group - 120 total thyroidectomies performed during the previous year using the traditional monopolar electrocautery, linen or other non-absorbable stitches for the upper and lower vascular pedicles and absorbable sutures for all other vascular knots. Table 2 shows the incidence of the pathologies among this second group of patients.

Thirty cases were not taken into account, because mixed techniques of haemostasis were used (for instance, the abdomi-

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**Fig. 2 - Total thyroidectomy performed by traditional technique (120 cases)**

nal handle of the Ligasure®, when used, was not fit for thin spaces and structures, such as the lower laryngeal nerve, thus traditional electrocautery was necessary) in order to avoid the bias due to the learning curve and to effectively compare mean operative times between two homogeneous series.

The following parameters were analyzed: mean operative time, intra-operative bleeding, need for post-operative analgesic drugs, post-operative bleeding, seromas (deep or superficial), post-operative stay, incidence of transient or definitive laryngeal nerve lesions, uni- or bilateral(in case of dysphonic an early laryngoscopy was performed 10-15 days after surgery and it was repeated 3-6 months -usually after logopedy), incidence of permanent or transient hypocalcaemia (checked by daily serum calcemia, starting from the first post-operative day and 1, 3 and 6 months after surgery), costs of the different procedures.

## Results

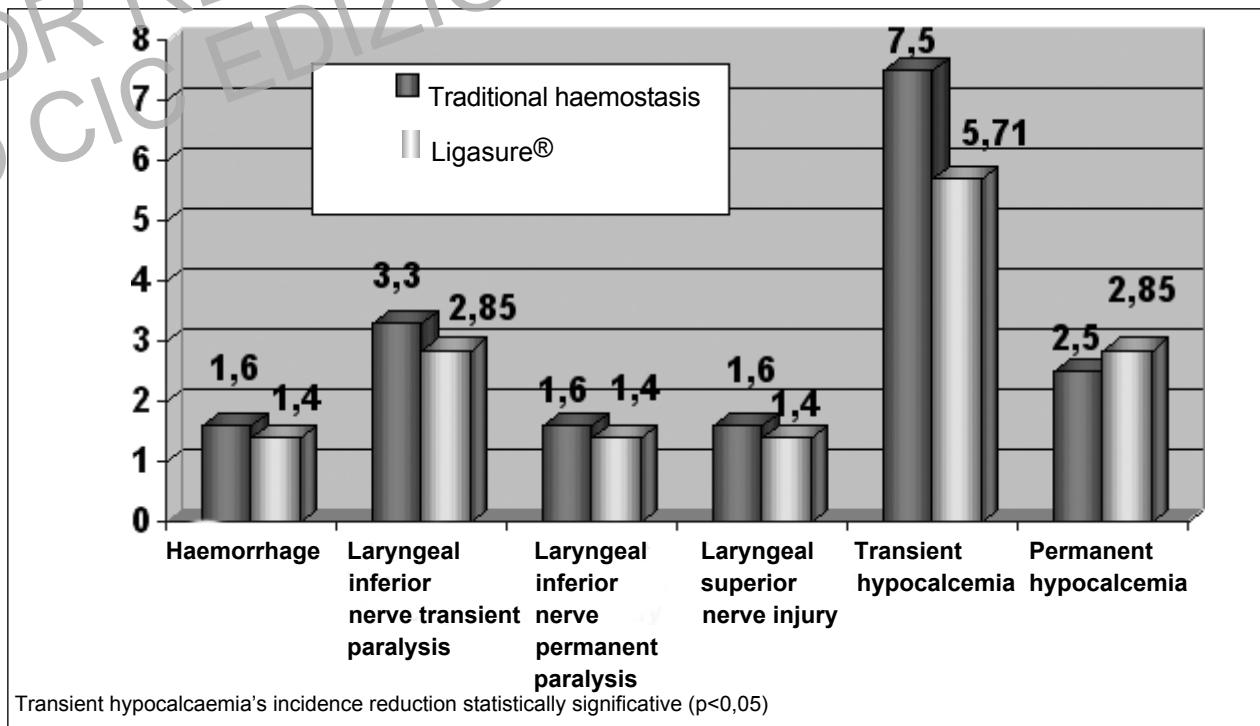
There were no statistically significant difference

between the two groups for distribution of age, sex, epidemiological characteristics, type of pathology etc. The incidence of major complications in thyroid surgery in the two groups (total thyroidectomy performed by traditional technique and by Ligasure®), in total and for pathology as well as compared with the data of the literature (18-22), is brought in the figures 3, 4 and 5.

We haven't recorded, globally considering the complications, meaningful percentages differences in the two groups in relationship both to those greater and to those smaller, made exception for transitory hypocalcaemia, more elevated in the group related to the interventions performed with "traditional method"; it's to signal, in comparison to the group of control, also a light reduction of the incidence of hemi lateral transient laryngeal inferior nerve injury, even if such relief doesn't enjoy, certainly, of the same statistic signify (Tab.1).

With regard to the intraoperative bleeding, valued approximately by means of the calculation of the gauzes used to maintain dry the operating field and by means of the determination of their weight, this datum deposes for a further advantage of the thyroidectomy with Ligasure®, the haemostatic action of the tool is conducted, besides, on the whole vascular and glandular tissue and not only on the vessels isolated in the context of same tissue (Tab. 1).

With regard to the duration of the operations, (Tab. 2 and Fig. 5), the mean time of the exeresis with



**Fig. 3 - Traditional total thyroidectomy complications (120 cases) vs total thyroidectomy by LigaSure Precise complications (70 cases).**

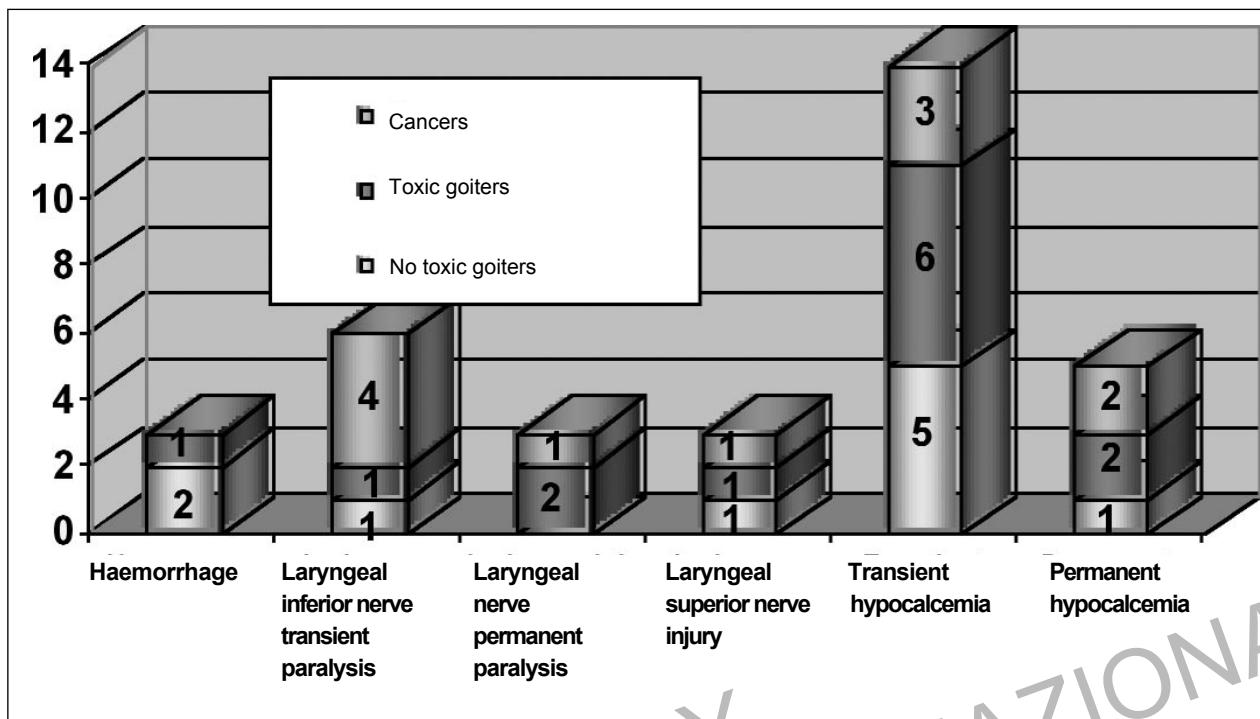


Fig. 4 - Total thyroidectomy complications (patients number for pathology).

radiofrequency in comparison to the conventional exeresis has been, certainly, reduced in average of 20 minutes around. It's needful, in fact, to notice that in the group relative to the use of Ligasure® the greater part of the operations has been concluded between 60 and 80 minutes, while in traditional group the greater part of the operations has had a duration between the 80 and the 100 minutes, and this thing has statistic signify.

This haemostatic method results, moreover, particularly fast in the opening phase of the thyroid seat in comparison to traditional method; besides in the conventional technique difficulties of haemostasis, with consequent increase of the operative mean times, are determinated not so much to load of the most greater vases, how much of the "suffuse bleeding" coming from the tissue of the band or pre thyroid scabbard, that asks for numerous electro coagulations and numerous thin bindings. This is confirmed by the relief that emerges by the analysis of the operative times of the sample excluded by the study (use of mixed haemostatic technique) in which, in fact, there are not important differences in comparison to the conventional technique, in relationship not so much to the initial negative interferences dictated by necessary curve of practical learning, as for her already signalled difficulty, in base to the dimensions of the it stings, of the use of the Ligasure® for abdominal surgery during the phases of dissection and

binding of the inferior vascular shank and the thyroid scabbard behind the laryngeal inferior nerve, when to techniques of traditional haemostasis however.

With the use Ligasure® Precise, a lower application of analgesics there has been in the postoperative period, in relationship perhaps, to the greater delicacy and cleaning of the ungluing phase of the surgical wound edges; nevertheless it is not possible to express certain data around such parameter, missing uniformity around the different volumes of the samples of thyroidectomy and around possible variables (recurrence, immersion, neoplasia) that can make the operations more difficult.

With regard to the presence of superficial (subcutaneous) and/or deep (in the thyroid seat) serum-haematic picked, identified in base of clinical and echographic relieves and treated by means of the emptying by puncture or least opening of the wound, it's relievable the same incidence in the two different groups - 6 cases in the first group (5%) vs 3 cases in the second group (4,3%) - and also the true postoperative haemorrhage, such that to require (generally between 2 and 18 hours) a new operation, has proved a similar incidence in the two different groups (A- 1,6%: 2 cases; B-1,4%: 1 case); in each of these three cases it has treated of delayed haemorrhages (insurgent to distance of 6-12 hours from the intervention) and originated from the thyroid seat (deep), particularly in 1 case from the inferior vascular shank,

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TABLE 1 - MAJOR COMPLICATIONS IN THYROID SURGERY (TOTAL THYROIDECTOMY).

<i>Complication</i>	<i>Incidence (in literature)</i>	<i>Rosato et al. (9,599 TT- traditional) 2003</i>	<i>Parmeggiani et al. (120 TT- traditional) 2001-2002</i>	<i>Parmeggiani et al. (70 TT- Ligasure®) 2002 june/2003</i>
Transient hypocalcemia	0,5-83	8,3%	7,5%	5,71%
Permanent hypocalcemia	0 - 7,4	7%	2,5%	2,85%
Laryngeal superior nerve injury	1,4 - 10	3,7% (suspected) 0,4% (documented)	1,6%	1,4%
Laryngeal inferior nerve transient paralysis	0,2 - 5,77	2,4%	3,3%	2,85%
Laryngeal inferior nerve permanent paralysis	0,1 - 3,85	1,3%	1,6%	1,4%
Bilateral laryngeal inferior nerve paralysis	0,4	0,6%	0%	0%
Haemorrhage	1,2 - 6,7	1,6%	1,6%	1,4%

in 1 case from a big average thyroid vein and in 1 case from the whole operating bed in form of conspicuous bleeding. The new operation has foreseen, for the first two cases, the apposition of double binding using slow absorption material, in the last case, instead, an accurate and meticulous revision of the haemostasis. Probably the genesis of such haemorrhagic phenomena is to ascribe not so much to the native haemostatic methods, as for hypertensive woodpeckers not checked in the immediate postoperative period, such to frustrate the haemostasis however gotten, and to remove both accurate bindings and coagulations mono- or bipolar with radiofrequency, apparently well "sealed".

There haven't been meaningful differences with regard to the duration of the postoperative hospitalization, because that's tightly dependent, in absence of complications tied to the surgical wound, on the variations of the calcemia (the greater part of the patients, in the two groups, has been dismissed in III postoperative day and the hospitalization has never exceeded the VI day p.o.).

With regard to the major complications, we have not meaningfully founded, in the two groups, different incidences of lesions of superior laryngeal nerve [2 cases in the traditional group (1.6%); 1 case in the Ligasure® group (1.4%)], and of laryngeal inferior nerve, both transitory (4 cases equal to him 3.3% vs 2 cases equal to him 2.85%) and permanent, or rather

persistent to 6 months from the operation (2 cases equal to the 1.6% vs 1 case equal to 1.4%).

The safeguard of the innervations is certainly to compare to a suitable surgical behaviour, with identification and respect of the nerve in his passage toward the point of entry in larynx and the constant, even though least, percentage of damages relievable in the different casuistic it's to impute to anomalies of elapsed, hardly determinable.

Instead results meaningful a lower incidence in the group treated with Ligasure® of transitory hypocalcaemia (or rather of sub clinic hypocalcaemia or clinic hypocalcaemia resolved within one month), caused by transitory stunning of the parathyroid glands, while almost unmodified has resulted the incidence of definitive hypocalcaemia, caused by permanent hypoparathyroidism, without modify the therapeutic attitude that we follow in cases of the kind, that foresee the substitution with calcium (EV) in case of symptomatic hypocalcaemia; the administration, instead, of salts of calcium and precursors of the Vitamin D3 (os) in the cases of subclinic hypocalcaemia (values < 8 mg%); and, overall, the immediate postoperative hormonal substitutive therapy, being we convinced that one of the most meaningful elements that induce an post-thyroidectomy hypocalcaemia is represented by the thyroid hormonal deficit and that, instead, a precocious correction of the hypothyroidism, induced by the total thyroidectomy, drastically reduces the cases

TABLE 2 - OPERATIVE MEAN TIMES.

	<i>Traditional total thyroidectomy</i>	<i>Total thyroideectomy by Ligasure®</i>
60-80 minutes	45 operations	47 operations
80-100 minutes	60 operations	17 operations
Over 100 minutes	15 operations	6 operations
Mean time	91,35 minutes	72,07 minutes
Standard deviation	12,90 minutes	12,49 minutes

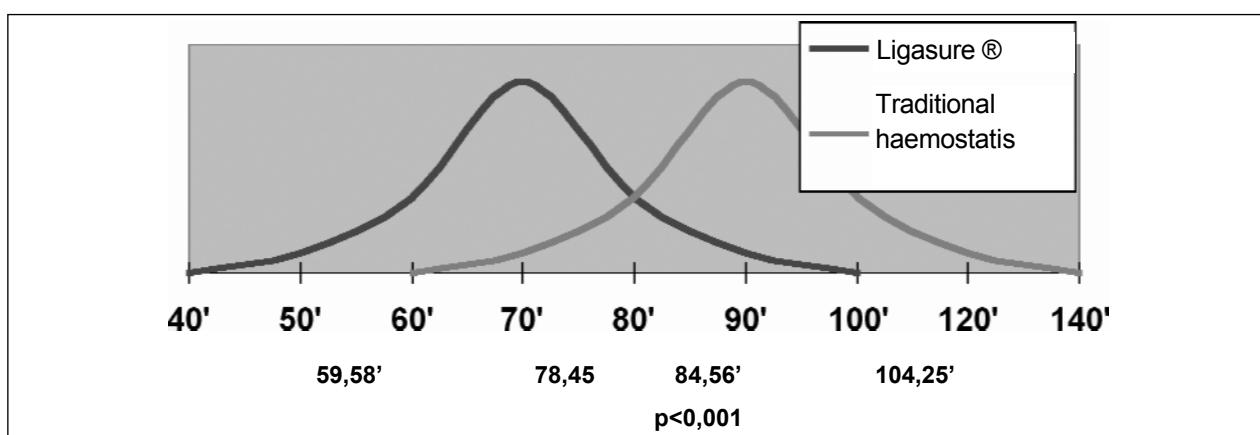
of hypocalcaemia.

Even if it's true that the safeguard of the parathyroids and of their vascular supply puts aside from the exeretic method and it's founded upon precise anatomo-surgical norms, it's undeniable that a transitory "stupor" can be facilitated by the injurious action of the heat transmitted during electro coagulations performed in proximity of such structures; to be able to have a so precise tool for the haemostasis, able not to spread the heat, especially in the delicate phase of binding of the branches of inferior vascular shank, where, usually, are lodged the inferior parathyroid glands, has certainly produced the smaller incidence of transitory hypoparathyroidism.

In both casuistic, finally, the negative influence of some varying, represented by the mediastinum immersion, by the surgical recurrence, by the neoplasia (overall with regards to the lesions of the recurrent nerve; all of our cases introduced such anatomic

varying, single or in partnership) as well as of the hyperfunction and of the presence of autoimmune phenomenon (it is clearly more elevated in percentage the incidence of hypocalcaemia, transitory or that extended, in the hyperfunctioning cases and with autoimmune thyroiditis) has been confirmed.

The problem of the costs, certainly, wouldn't seem to depose for the use of the Ligasure®, in consideration both of the start-up cost of the source, and of the cost of the single pliers, rigorously "single use", on indication of same manufacturing house; the cost of operation with Ligasure® Precise, at the moment, can be quantified in a superior cost of about 10 times to that of an operation performed with traditional haemostasis. It's need, logically, to keep in mind this thing in relationship to the actual business economic politic inclined to sanitary saving, even if it's necessary to consider the possibility, thanks to the undeniable reduction of the operative times in comparison to conventional technique, to be able to program, in the same session, a greater number of operations in such way to amortize in enough rapid times the general expense. With an average of 20 minutes of saving for operation, every 4 operations it's possible to earn 1 operation; in a Surgery Division that effects at least 80 operations in one year it's possible to earn, at least, 20 interventions in more. The comparison between the two groups, in terms of costs, must be performed, therefore, in relationship to the operating duration and so doing to 100 operations by traditional haemostasis it needs to compare 125 total thyroidectomies with Ligasure® Precise; in our experience, if the cost of the haemostasis with traditional technique can oscillate between 50 and 75 euro, the general expense amounts, in this group, to a cost inclusive among 5000 and 7500 euro (50-75 operations), clearly inferior to the cost of the haemostasis in the "Ligasure® Precise group" in which, besides the



start-up cost of the source (20.000-25.000 euro), we've to consider the cost of the hand piece Precise (200-250 euro), for a general cost of the haemostasis inclusive among 45.000 and 57.250 euro.

If we consider that the DRG for a Total Thyroidectomy can vary among 2000 and 3500 euro (variability of regional DRG), executing with the Ligasure Precise downright 25 interventions in more we can esteem an profit inclusive among 50.000 and 87.500 Euro: in conclusion that signifies a net gain oscillating among 10.000 and 37.750 euro, working off, therefore, the cost of the source entirely.

## Discussion

Total thyroidectomy has by now a prominent place in the thyroid surgery, representing the intervention of election over that in malignant neoplastic pathology (where, already, from many years it has a fundamental and almost exclusive role) (14,15,24), also in benign full gland pathology, normal functioning or hyper-functioning (diffused or nodular), or, finally, on self-immune basic (16-18). In support of such formulation there are numerous contributions in literature in which, thanks to progressive get sharper of surgical technique, there is almost over impossible incidence of complications after total and subtotal interventions, with differences of morbidity statistically not significative (23). Besides total thyroidectomy resolves in absolute the recidivist's problem (the "instalment surgery" results undesirable to the patient and it's burdened by a greater number of complications) and simplifies postoperative hormonal therapy. The study of the complications has assumed more and more importance, because it yields: to make use of suitable instruments and procedures to reduce these at the least; to treat these, if present, in best way; to furnish, also, to the patient adjusted information. Within thyroid surgery the use of the radio fre-

quency as technique of haemostasis (bipolar electro thermal coagulation as Ligasure® bipolar vessel sealing system), the method is simple and of easy application, has shown effectiveness and safety in terms of haemostasis, with clean reduction of intraoperative bleeding and of the operating middle times (19).

## Conclusions

Our experience (70 cases) confirms such data, in the comparison with the now consolidated technique of so-called traditional thyroidectomy (haemostasis with monopolar coagulation and vascular bindings). The relief in our experience with Ligasure®, among the most greater complications, of a lower incidence of transitory hypoparathyroidism (because of transitory "dizziness" of the parathyroids), as well as of a reduction, even though light and less remarkable from statistic point of view, of the cases of transitory unilateral recurrential paralysis, invites to valorise and to subsequently improve the technique with the purpose to avoid or to reduce to the minimum two most dangerous complications of the thyroid surgery or rather transitory or permanent lesions of the parathyroidis and/or of the recurrent nerve.

A disadvantage is represented by the necessity to manually section however the vase or the coagulated structure, while in others methodical, as for instance the ultrasounds dissector, that contemporarily happens with the use of the same device (11-13) but, in comparison to it, it also has the advantage to consent the choice of the level of section, besides also in vessels of superior calibre, and, if this doesn't offer enough safety, to widen with a second taking the sealed zone. The limit perhaps more important to an steady employment of the methodic one is represented by the tall cost of the equipment. This can quickly be amortized by minor duration of the intervention if the use of the equipment is extensive, that is when it's employed in centres with **tall** number of thyroid interventions (>100/year).

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