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Harmonic Scalpel in Multinodular Goiter Surgery: Impact on Surgery and Cost Analysis

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Abstract

Introduction: The aim of this study was to evaluate the potential advantages and the general operative cost of the Harmonic Scalpel (HS) in surgery for multinodular goiter (MNG).
Methods: Patients undergoing total thyroidectomy (TT) for MNG were prospectively allocated in a conventional tie-and-clip (TC) group ($n = 50$) and an HS group ($n = 50$). All pre- and postoperative data were recorded. The economic evaluation was based on a microcost measurement and aimed to consider all the resources consumed for each patient during the surgical procedure. To compare the results, we used the nonparametric unpaired two-tailed Mann-Whitney test.
Results: There were 81 women and 19 men (mean age, 55 $\pm$ 15 years). Mean preoperative TSH level was 1.2 (SD, 1.1) (TC) and 1.3 (SD, 2) (HS) (P = NS). Mean body mass index was 24.72 (SD, 8) (TC) and 25.6 (SD, 8) (HS) (P = NS). Four patients experienced a transient hypocalcemia (2 in each group). One patient had a postoperative hematoma requiring surgical evacuation (HS). One patient experienced a transient recurrent nerve palsy (TC). Mean length of surgery was 104 (SD, 32) (TC) and 84 minutes (SD, 17) (HS) ($P = .0001$). Mean length of hospitalization was 2 days in both groups (SD, 1) (P = NS). Mean operative cost per patient was 990 € (SD, 191) in the TC group and 1,024 € (SD, 143) in the HS group (P = NS).
Conclusion: Safety and efficiency of the HS is comparable to the tie-and-clip technique in thyroid surgery. The use of the HS in MNG surgery allows for a significant reduction in the length of the procedure with a comparable cost.

Introduction

Techniques in thyroid surgery have not significantly changed since Kocher's description. However, alternatives to conventional hemostatic techniques in surgery have been developed. Besides sutures and clips, the surgeon may use classical electrical devices. Recently, sealing devices using ultrasound energy, such as the Harmonic Scalpel (HS), have appeared. The HS uses high-frequency mechanical energy to cut and coagulate tissues and vessels. Its efficiency and safety are well known. Ultrasonically activated shears (UASs) are now available. A specific model has been designed for neck surgery. Hemostasis is a major concern in thyroid surgery, requiring a large amount of clamp-and-tie techniques and/or clips. For surgeons, the HS could represent advantages in terms of a reduction in operative time, with a comparable efficiency in patient morbidity. Thus, considerations in terms of cost minimization could be realized, despite the additional HS cost. The aim of this study was to evaluate the potential advantages of the HS in surgery for multinodular goiter (MNG) and to conduct the first economic evaluation based on prospective individual data, as well as a detailed observation of consumed resources during a surgical intervention.

Materials and Methods

We studied whether the use of the HS could present advantages in thyroid surgery in terms of operative time, length of hospitalization, morbidity, and global costs. The patients considered suitable for this evaluation all required a total, or near total, thyroidectomy for MNG. Patients with a preoperative diagnosis of thyroid cancer or Graves' disease were excluded. Patients requiring a less than near total thyroidectomy were also excluded. Over a 6-month period, patients undergoing total thyroidectomy (TT) for MNG were

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TABLE 1. TIME CHARACTERISTICS OF PROCEDURES

	HS group Mean (±)	P-*value*	*Control group Mean ± SD*
Operating room time (min)	140 ± 22	0.002	157 ± 32
Anesthesia time (min)	130 ± 25	0.004	146 ± 32
Surgery time (min)	84 ± 17	0.001	104 ± 32
Awakening room time (min)	83 ± 20	NS	80 ± 31

prospectively and successively allocated in a conventional tie-and-clip (TC) group (group 1:50 patients) and an HS group (group 2:50 patients). The allocation of a patient to one group or the other was based on the availability of the HS for the endocrine surgery team. The HS equipment is available for two different teams (vascular and endocrine Surgery, with four operating rooms). All patients were operated on by the two senior surgeons of the department. A scrub nurse was allocated for all surgeries, with or without a resident, depending on availability. In the TC group, the surgeon could use as many sutures, clips, and automatic clips as desired. In the HS group, ultrasonically activated shears were available, sutures and clips, but no automatic clips. The use of ties or clips (in both groups) and of the HS (in the HS group) depended on the surgeons' judgment. The surgeon used the HS as a coagulating and cutting device on any structure he estimated to deserve the HS. For vascular pedicles, vessels of less than 3 mm were eligible. A standardized security distance of 3 mm from the nerves and parathyroid glands was respected in order to avoid heat damage. All demographic and preoperative characteristics and follow-up (morbidity data) were studied and compared. Operating times (e.g., occupation of operating room, length of surgery and anesthesia, and occupation of awakening room) were precisely recorded prospectively for each patient.

The economic evaluation was a cost-minimization analysis and aimed to determine which of the two surgical procedures with comparable efficiency permitted a reduction in the global cost. The direct medical costs of the surgical intervention was evaluated for each included patient in the study. A microcost evaluation[1,2] was performed in order to precisely collect all the individual resources that were consumed for surgery during both periods: surgical act (in the operating room) and awakening time. A second step of the economic evaluation was to attribute appropriate monetary value, in euros, to the measured physical quantities. Real costs were considered in the analysis, instead of tariffs, in order to approximate the accurate value of consumed resources. The following cost factors were considered:

- cost of operating room use (including equipment, staff, and overheads)
- cost of awakening room use (including equipment, staff, and overheads)
- consumable cost

In order to calculate the above costs, the following physical quantities had to be collected for each patient:

- length of operating room use and length of awakening room use
- mobilized staff at each step of the intervention (i.e., during operating, anesthesia, and awakening time)
- consumable supplies, such as clips, sutures, ties, swabs, HS, bipolar electrocautery, drains, anesthesia products, and supplies.

Additional observation was needed aiming to precisely describe the equipment in both operating and awakening rooms.

Drug and consumable unit costs were average purchasing prices observed in the hospital. A cost for 1 minute of each room's use was calculated on the basis of initial purchasing prices of the listed equipment and its yearly depreciation (3, 5, or 7 years, according to the equipment). Maintenance charges and overheads of the hospital allocated on a pro rata basis were added. Average wages and mean yearly labor time for each staff type were used to calculate a 1-minute production cost. Costs were presented as the mean ± standard deviation for each group. Comparison of results was made by using the nonparametric unpaired two-tailed Mann-Whitney test. Statistical significance was defined as $P < 0.05$.

Results

There were 81 women and 19 men. There were no differences in sex ratios between both groups. Mean age was 53 years (SD, 15) in group 1 (TC) and 57 years (SD, 15) in group

TABLE 2. TOTAL COSTS AND MAIN FACTOR COSTS

	HS group	*CT group*	P-*value*
Operating room use (equipment and staff)	584 ± 136	655 ± 121	0.004
Surgical consumables	428 ± 15	323 ± 104	0.0001
Awakening use	12 ± 3	12 ± 5	NS
Total	1024 ± 143	990 ± 191	NS

NS, not significant.

2 (HS), with a significant difference ($P = 0.027$). Mean body mass index was 24.72 (SD, 8) (group 1, TC) and 25.6 (SD, 8) (group 2, HS) (P = NS). Mean preoperative TSH level was 1.2 (SD, 1.1) (group 1, TC), with 5 patients below the normal range, and 1.3 (SD, 2) (group 2, HS), with 3 patients below the normal range (P = NS). Six patients presented anti-TPO antibodies in group 1 and 5 in group 2.

Each surgeon operated on the same number of patients equally divided in both groups. During surgery, the inferior laryngeal nerves were identified in all patients. The mean number of identified parathyroid glands was 3 in both groups. Four patients experienced a transient postoperative hypocalcemia (2 in each group). One patient had a postoperative hematoma requiring surgical evacuation (group 2, HS). One patient experienced a transient recurrent nerve palsy (group 1, TC).

Mean length of surgery was 104 (SD, 32) (group 1, TC) and 84 minutes (SD, 17) (group 2, HS), ($P = 0.0001$). Mean length of anesthesia was 146 (SD, 32) (group 1, TC) and 130 minutes (SD, 25) (group 2, HS) ($P = 0.004$). Mean length of occupation of the operating room was 157 (SD, 32) (group 1, TC) and 140 minutes (SD, 22) (group 2, HS) ($P = 0.002$). Mean length of hospitalization was 2 days (SD, 1) in both groups (P = NS). Results are summarized in Table 1.

Mean procedure cost was 990 € (SD, 191) in group 1 (TC) and 1,024 € (SD, 143) in group 2 (HS) (P = NS). Major cost factors were operating room use (staff and equipment) and surgical consumables (clips, sutures, and HS device). Results are summarized in Table 2.

Discussion

We performed a prospective economic evaluation aiming to analyze the cost advantages of HS use in surgery for MNG, when compared to a conventional TC procedure. Allocation to each group was based on the availability of the HS equipment (one was shared between two teams and four operating rooms). This corresponded to a "real life" situation, which could support an economic rationale. Even if it does not correspond to a blind randomization, hazard allocation reached two comparable groups. First, we showed that morbidity with the HS seemed at least equivalent to our current practice in thyroid surgery, as observed in different teams.[3–6] During all operations, we tried to respect a standardized security distance (3 mm) to neural structures and parathyroid glands because of thermic diffusion of the HS. Regarding length of surgery and anesthesia, we observed a significant reduction of about 20 minutes (19%). A similar reduction time of surgery was observed in different teams.[3,5,7] We had also expected to see an amplified reduction in the length of anesthesia and awakening room stay; however, this was not observed. As this represented our initial experience, our anesthesiologists did not modify their protocol, and we could probably also expect a reduction in length of time of these phases. What is also expected, in the near future, is a more significant reduction in length of time of surgery. At the time of this study, both surgeons had only experienced about 50 neck procedures with the HS. We believe that with increasing experience, time of surgery could be reduced by 30–40%.[8] Our ongoing experience is confirming that we are increasingly reducing the length of time of surgery with the HS. Reducing time of surgery means that additional cases could be treated in the same operating session, or that the staff or the equipment could be dedicated to another activity.

With UAS, most procedures could be achieved by a surgeon and another helper (i.e., a resident or scrub nurse). In this study, procedures performed by only two people were 5 in the TC group and 4 in the HS group. This means that we did not use all the potential of the UAS in reducing the staff necessary for a thyroidectomy. Finally, the development of new devices will probably lead to faster, more powerful, and ergonomic UAS. All these anticipations, regarding time of surgery, reduction of staff, and additional cases, should be validated by further ongoing studies.

In the cost-minimization analysis, we showed that mean estimated total costs were not statistically different between both groups. Major cost factors were surgical consumables (UAS in the HS group and sutures, clips, and, especially, automatic clips in the TC group) and cost induced by operating room use (equipment and staff). This latter factor is totally dependant on the length of time of surgery.

In our study, we chose to analyze the cost of the surgical procedure, because we hypothesized that the use of the HS could only influence these aspects in the global management of patients. Indeed, no difference between both groups, in terms of hospitalization duration during follow-up, was observed, which could have greatly influenced the cost differences. Our costs presented the advantage to be representative of the real economic value of the consumed resources, because the methodology we used was a microcost evaluation recommended by health economists[1,2] as the most appropriate way of the calculation of the costs. Moreover, unit costs calculated in our study were according to charges, prices, and wages in our institution, instead of national tariffs, which are not specific to the studied patients. Such an accurate estimation showed that the additional cost of HS use was almost entirely compensated for by the avoided consumption of a part of surgical consumables, as well as the cost reduction of equipment and staff mobilization, due to the reduction in operative times.

Conclusion

The use of the HS is increasing throughout the different fields of surgery. The HS offers the surgeon a reliable hemostatic and cutting device in the same instrument and at the same time. With respect to a security distance (thermic diffusion), it is a safe instrument. After an initial evaluation of the HS in thyroid surgery in our department, the HS appears to present an advantage in significantly reducing operating times and in offering equivalent morbidity, safety, and cost comparisons to traditional techniques. These results could probably be overtaken, especially with increasing experience of the surgeons with this device and technical evolution of UAS. This will need additional studies.

Disclosure Statement

No competing financial interests exist.

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