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Dissection with harmonic scalpel versus cold instruments in parotid surgery

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Abstract. *Dissection with harmonic scalpel versus cold instruments in parotid surgery. Background*: The harmonic scalpel (HS) has been used successfully in several head and neck surgical procedures. Some authors highlighted its advantages in reducing operative time, blood loss, and damages to surrounding tissue. In our study, we compared the results obtained during parotidectomy using the HS with the traditional approach to determine the benefits of the HS.
Methods: 130 patients with benign parotid tumors were enrolled and randomized into two groups for this prospective study. 63 patients underwent HS parotidectomy, and 67 patients received a parotidectomy using cold instruments and bipolar electrocautery hemostatic control (CI). 20 HS and 2 CI patients did not meet the inclusion criteria requirements, and were excluded.
Results: The admission time was significantly shorter in the HS group than the CI group (3.9±1.2 days and 4.7±1.4 days, respectively, $p< 0.01$). In the early post-operative period, 84% of HS patients and 60% of CI cases showed no facial nerve impairment ($p=0.01$). Significantly more CI patients than HS patients showed the onset of Frey's syndrome (29% and 9%, respectively, $p=0.01$). Multivariate stepwise regression analysis confirmed the reduction in admission length (Odds Ratio (OR): 0.62; $p=0.02$) and the lower risk of Frey's syndrome (OR: 0.29; $p=0.04$) in HS compared to CI parotidectomies.
Conclusions: In parotid surgery, the HS is useful in preventing Frey's syndrome and reducing early transitory facial nerve dysfunction and admission times, and results in decreased medical costs and increased quality of life.

Introduction

Major salivary gland tumors account for 5% of all head and neck neoplasms.[1] Benign and malignant salivary gland tumors mainly arise in the parotid gland. The main surgical concern while performing a parotidectomy is meticulous preservation of all facial nerve branches. Bleeding in the surgical field during dissection, especially adjacent to the nerve, can make the procedure tedious, and prolong surgical time.

Since its introduction in 1993, the harmonic scalpel (HS) has gained popularity in numerous surgical procedures, and it has been used successfully in the head and neck region for tonsillectomy, thyroidectomy, and oral cavity and oropharyngeal tumor resections.[2] The HS cuts and coagulates through ultrasonic vibrations of the blade at 55 kHz, provoking protein denaturation, and forming a coagulum, which seals small vessels; no electrical energy is transferred to the patient, therefore, the main advantage of the HS over monopolar and bipolar electrocautery resides in the lower thermal damage to surrounding tissue.[3] In fact, when using HS, the coaptive coagulation occurs at 50-100°C, while temperatures of 150-400°C are released with electrocautery.[4] The unique properties of the HS make it a useful device for procedures in which bleeding control, in a limited surgical field, is mandatory, in order to guarantee the preservation of important structures.

At our Institution, parotid surgery has always been performed with cold instruments and bipolar electrocautery hemostasis. After gaining experience with this device, we set a prospective study to compare results obtained by HS-assisted parotidectomy with the traditional approach. Comparisons were made in terms of intraoperative bleeding, operative time, facial nerve injury, time until facial recovery, and incidence of Frey's syndrome (measured during the two-year follow-up).

Materials and methods

The HS-assisted parotidectomy was introduced at our Institution in 2004. After two years of gaining confidence and expertise with this new instrument, all patients who planned to undergo superficial or

total parotidectomy for benign disease at the Otolaryngology and Head-Neck Surgery Department of the University of Florence, Italy, between January 2006 and December 2011, were screened for admission into this prospective study. Exclusion criteria included malignant diseases (confirmed postoperatively), preoperative facial nerve weak ness, other type of surgery than superficial or total parotidectomy, or surgical procedures where both HS and bipolar electrocautery were used simultaneously. Patients meeting inclusion criteria were randomized into two groups (stratified by age, gender, and clinical tumor size) using STATA (Stata software 9.2, College station, TX): the first group would receive HS-assisted parotidectomy, and the second group would undergo traditional parotidectomy using cold instruments and bipolar electrocautery (CI). All patients undersigned an informed consent, which was approved by the Institutional Review Board, and was in accordance with all accepted standards for human clinical research.

In order to avoid inter-operator differences, the senior Author (O.G.) performed all of the operations. Data recorded were: age, gender, admission time (in days), tumor size, definitive histology, difference between pre- and post-operative hemoglobin values (in g/dL), operative time, daily drainage production, timing of drainage removal, post-operative facial nerve evaluation (according to House-Brackmann Grading scale),[5] recovery time of post-operative facial nerve impairment,[6] and development of Frey's syndrome.

The accrual and randomization was closed at 130 patients, 63 received HS-assisted parotidectomy, while 67 patients were randomized for the CI group. Seven patients (five HS and two CI) were excluded after definitive histology revealed a malignant tumor, despite fine-needle aspiration cytology, which indicated a benign neoplasm; furthermore, 15 HS patients were excluded after the use of bipolar electrocautery was required, in order to control intraoperative bleeding. Finally, 108 patients met the study's inclusion criteria.

The mean age was 55±16 y/o (range 4-84); 49 males and 59 females; 43 patients underwent HS-assisted parotidectomy (20 males and 23 females), and 65 patients underwent CI parotidectomy (29 males and 36 females). The HS and CI groups were homogeneous for: age (mean 53±17 y/o and 56±15 y/o, respectively, $p=0.41$, t test), gender ($p=1$, Fisher's exact test), and tumor size (mean 2.8±1.1 cm and 2.9±1.3 cm, respectively, $p=0.53$, t test). The HS group registered 28 (65%) pleomorphic adenomas, 8 (19%) Warthin's tumors, 3 (7%) hemangiomas, 2 (5%) myoepitheliomas, 1 (2%) oncocytoma, and 1 (2%) cyst; the CI group registered 32 (49%) pleomorphic adenomas, 22 (34%) Warthin's tumors, 3 (5%) basal cell adenomas, 2 (3%) lipomas, 1 (2%) monomorphic adenoma, 1 (2%) myoepithelioma, 1 (2%) acinic cell adenoma, and 3 (5%) cysts. Only 9 (21%) patients in the HS group and 14 (22%) patients in the CI group underwent total parotidectomy for deep lobe pleomorphic adenomas.

After surgery, patients were evaluated for follow-up every two months for two years. Statistical analysis was performed using unpaired Student's t tests for continuous data, and Fisher's exact tests were used for categorical data. A stepwise regression analysis was calculated (STATA software 9.2, College station, TX). Continuous results for each group were expressed as means±standard deviation.

Surgical procedure

The Ultracision hook blade (Ethicon Endo-Surgery, Cincinnati, OH, USA) was used for HS-assisted parotidectomies. After identification of the main trunk of the facial nerve, the peripheral branches were dissected and separated from the parotid tissue with cold instruments in both groups (the hook blade was used as cold dissector in the HS group), then the glandular tissue was divided with either the HS or sharp instruments and bipolar bleeding control. A vacuum suction drain was routinely placed.

Results

The admission time was significantly shorter in the HS group than in the CI group (3.9±1.2 days and 4.7±1.4 days, respectively, $p<0.01$, t test; Fig. 1). The duration of operative time was not significantly different between groups (146.9±39.9 min and 151.6±54.1 min, respectively, $p=0.8$, t test). No statistical significance was found in the differences between the two groups for the difference in pre- and post-operative hemoglobin values (0.9±0.6 g/dL and 0.9±0.7 g/dL, respectively, $p=0.65$, t test), total drainage time (2.7±1.1 days and 2.9±1.3 days,

respectively, $p=0.41$, t test), and total drainage production (69±52 mL and 78±81 mL, respectively, $p=0.50$, t test).

Post-operative complete facial nerve paralysis was not encountered in this series. In the early post-operative period, there was no facial nerve impairment in 36 (84%) HS patients and in 39 (60%) CI patients ($p=0.01$, Fisher's exact test). Complete facial nerve function regained within three months in 6 (33%) HS patients (from grade II) and 19 (29%) CI patients (from grade II), and within 4-6 months in 1 (2%) HS patient (grade II) and 6 (9%) CI patients (three patients from grade II and one from grade III). 1 (2%) CI patient (grade IV) resolved facial nerve impairments in 14 months. There was no significant difference between groups in the time until complete facial recovery ($p=0.12$).

At two years follow-up consultation, no facial nerve impairment (House-Brackmann grade I) was seen in either group. Frey's syndrome was noted in 19 (29%) CI patients and 4 (9%) HS patients, showing a statistically significant difference ($p=0.01$, Fisher's exact test, Table 1).

Multivariate stepwise regression analysis confirmed both the reduction in admission length and the risk of appearance of Frey's syndrome using the harmonic scalpel (Table 1 and Figure 1).

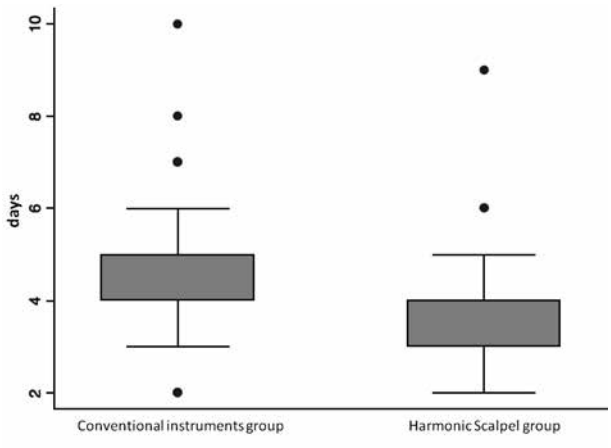

Figure 1
Patients who underwent parotidectomy using harmonic scalpel had lower duration of admission than patients who underwent parotidectomy using convention instruments. $p<0.01$.

Discussion

The rich vascularization of the parotid gland, and its intimate association with the facial nerve, requires precise dissection and meticulous hemostasis during parotid surgery, in order to minimize the risk of facial nerve injury. Thus, parotidectomy constitutes an ideal surgical field for the hemostatic and tissue friendly characteristics of the HS. Two pilot studies in parotid surgery, conducted by the same group, demonstrated that using the HS diminished operative time, intraoperative blood loss, postoperative drain production, and incidence of facial nerve injury, in comparison to cold scalpel dissection.[7,8] However, data regarding the time of facial nerve recovery and incidence of Frey's syndrome were not reported in detail.

In our study, we were unable to demonstrate a reduction in operative time; however, our data confirm that the HS is a safe alternative to CI dissection for both superficial and total paroti-

Table 1
Patient characteristics

	HS group	CI group	*p*
Age (y/o)	53±17	56±15	0.41
Gender (M/F)	20/23	29/36	1
Tumor size (cm)	2.8±1.1	2.9±1.3	0.53
Admission time (days)	**3.9±1.2**	**4.7±1.4**	***<0.01***
Operative Time (minutes)	146.9±39.9	151.6±54.1	0.8
Difference in pre- and post- operative hemoglobin values (g/dL)	0.9±0.6	0.9±0.7	0.65
Total drainage time (days)	2.7±1.1	2.9±1.3	0.41
Total drainage volume (mL)	69±52	78±81	0.50
Frey's syndrome	**4 (9%)**	**19 (29%)**	***0.01***

HS: harmonic scalpel; CI: cold instrument.

dectomy. The shorter admission length in the HS group reduces the hospitalization costs and improves patient satisfaction. At our Institution, this shorter hospitalization time slightly outweighed the intraoperative costs of the device, making HS-assisted parotidectomy no more expensive than the traditional surgical approach.

Our report confirms the ability of the harmonic scalpel to minimize facial nerve injury. The incidence of transient nerve paresis after superficial parotidectomy varies between 12.1-40%.[9,10] In our series, 7/43 (16%) patients who underwent HS parotidectomy presented a transient facial weakness, but they recovered within six months. The reduced incidence of post-operative facial nerve weakness in the HS groups was statistically significant ($p<0.01$). The decreased incidence of Frey's syndrome in HS patients (10%, $p=0.03$) may be due to a higher rate of thermal-related definitive fibrosis at the remaining glandular surface, thus, reducing abnormal re-innervation of sudoriparous glands.

16 HS patients were excluded from this study, since bipolar electrocautery had to be used, in order to control intraoperative bleeding. This result indicates that the HS hook blade may not be sufficient for effective intraoperative hemostasis in up to one fourth of the cases; in fact, some larger arterioles, which are encountered during parotidectomy, are not always successfully sealed with the hook blade, making ligature or bipolar electrocautery necessary. This aspect of HS-assisted parotidectomy creates a substantial bias in our study concerning the evaluation of drainage production. This bias might have been overcome if we had chosen to add the use of the HS scissors in the HS group; in fact, the HS scissors guarantee a high hemostatic power,[11,12] but this would have risen the intraoperative costs. Nevertheless, we feel that that this aspect does not represent a significant drawback.

After the conclusion of this study, and based on the evidence provided by our data analysis, the standard technique for parotid surgery has evolved in our institution; we have moved from the traditional CI approach to a combined dissection using the HS hook blade with the bipolar control of hemostasis, if necessary. In conclusion, the HS represents a valuable tool in parotid surgery, with some advantages over CI dissection, including shorter admission length, lower incidence of Frey's syndrome, and faster complete facial nerve recovery.

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