Usefulness of the LigaSure Vessel Sealing System During Superficial Lobectomy of the Parotid Gland

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Objective: To evaluate the usefulness of the LigaSure Precise instrument in superficial lobectomy of the parotid gland.

Design: Prospective study of the surgical procedures in the LigaSure Vessel Sealing System and comparison with a conventionally treated control group.

Setting: Secondary care academic referral center.

Patients: Thirty-five patients with a parotid gland benign tumor were randomly allocated to 2 superficial lobe parotidectomy groups: 17 using the LigaSure procedure (group A) and 18 using the conventional method (group B).

Main Outcome Measures: During the past few years, different methods of achieving hemostasis in parotid gland surgery have been tested as means of decreasing operative time and facial nerve injuries by controlling bleeding. With the whole LigaSure Vessel Sealing System, we experienced the usefulness of the LigaSure Precise instrument in superficial lobectomy of the parotid gland.

Results: No statistically significant differences were noted between the 2 groups in mean age, tumor diameter, length of hospital stay, time to return to work, or number of adverse events during or after surgery. Operative time was significantly shorter in group A than in group B ($P < .001$). Total operative time for conservative partial parotidectomy with traditional excision ranged from 115 to 235 minutes (mean, 153.8 minutes). Using the LigaSure system, the mean operative time was 136.4 minutes. Salivary fistulas were more common in group A (3 of 17 patients), with no cases in group B.

Conclusions: The LigaSure method is comparable with but not superior to the conventional method. The main advantages of the LigaSure system are its "sutureless technique" and operative time savings; however, the cost is considerably higher.

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METHODS

PATIENTS

Thirty-five patients with a parotid gland benign tumor were treated between February 1, 2002, and December 31, 2003. The patient group consisted of 20 women and 15 men aged 28 to 73 years. Recruited patients were randomly allocated, by means of sealed envelopes, into 2 groups: in group A ($n = 17$), LigaSure procedures were used during surgery, and in group B ($n = 18$), conventional scissors, electric knives, and bipolar instruments were exclusively used. In group A, we performed a completely "sutureless technique"; no sutures were used, and all of the vessels were sealed using the LigaSure Precise instrument (Valleylab) in superficial lobectomy of the parotid gland.
sound examination of the parotid glands and neck lymph nodes, magnetic resonance imaging of the head and neck, and fine-needle aspiration biopsy of the lesion. Pathologic findings included 11 Warthin tumors, 2 lipomas, 1 myoepithelioma, and 21 pleomorphic adenomas involving the parotid gland.

Seventeen superficial lobe parotidectomies were performed using the LigaSure procedure, and 18 were performed using conventional methods by a single surgeon (G.C.) with the patient under general anesthesia.

After surgery, all patients were given a standard regimen of antibiotic therapy, and pain and edema were controlled by oral nonsteroidal anti-inflammatory drug treatment. Patients were instructed to score their pain daily on a linear analog pain scale from 0 to 10. Outpatient follow-up was continued weekly until the wounds were completely healed. Six months after surgery, a clinical evaluation was performed by an independent observer who was unaware of the type of surgery performed.

Using unpaired t tests, differences between the 2 groups were statistically analyzed for age, sex, duration of surgery, length of hospital stay, and complications.

**Surgical Procedure**

In both groups, a modified Blair incision was made, anteriorly elevating the superficial facial layer to expose the parotid gland and the mass; the gland was separated from the cartilaginous external auditory canal and the anterior border of the sternocleidomastoid muscle. The facial nerve trunk was identified after exposure of the tragal point. Dissection of the nerve from the gland was performed proximally to distally.

Thereafter, in group A, we performed a completely sutureless technique using the LigaSure system. The device was used successfully to coagulate small vessels and stroma of the parotid gland before cutting. In addition, larger vessels were successfully sealed using the LigaSure device, including the superficial temporal vessels and the retromandibular artery (Figure). In group B, dissection of the facial nerve and cutting of the parotid tissue were performed using traditional scissors, and electric bipolar instruments were used for the coagulation.

**Results**

Group A consisted of 17 patients, and group B consisted of 18. No significant differences were noted in mean age and tumor diameter between the 2 groups. Operative time was significantly shorter in group A (mean, 136.4 minutes; range, 95-235 minutes) than in group B (mean, 155.8 minutes; range, 115-235 minutes) \( (P < .001) \) (Table).

No cases of permanent facial palsy were observed in either group; 5 cases of facial weakness were observed in either group: 3 cases of facial weakness were noted in group A and 3 in group B. Four of these facial weaknesses were at the mandibular marginal branch of the facial nerve (2 in group A and 2 in group B), and 1 was at the buccal branch (in group B).

Quantitative analysis of facial motion was recorded (Table). No significant differences between the 2

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**Table. Characteristics of the Study Groups**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group A (LigaSure*)</th>
<th>Group B (Conventional)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range), y</td>
<td>45 (28-73)</td>
<td>49 (24-80)</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Sex, F/M, No.</td>
<td>9/8</td>
<td>11/7</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Tumor type, No.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleomorphic adenoma</td>
<td>11</td>
<td>10</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Warthin tumor</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Tumor diameter, mean (range), mm</td>
<td>29 (11-53)</td>
<td>31 (11-54)</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Operative time, mean (range), min</td>
<td>136.4 (95-235)</td>
<td>155.8 (115-235)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Complications, No.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facial nerve palsy</td>
<td>0</td>
<td>0</td>
<td>&lt;.05</td>
</tr>
<tr>
<td>Facial nerve weakness</td>
<td>2</td>
<td>3</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Salivary fistula</td>
<td>3</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>House-Brackmann mean value</td>
<td>1.11</td>
<td>1.16</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Hospital stay, mean, d</td>
<td>3.9</td>
<td>3.7</td>
<td>&gt;.05</td>
</tr>
</tbody>
</table>

*Valleylab, Boulder, Colo.
†Unpaired t test.
Bleeding control is one of the main goals in parotid gland surgery because of facial nerve dissection. There is no standardized technique for gland dissection: some surgeons prefer to use clamps for nerve dissection and ties for bleeding control, and others use several methods of achieving hemostasis, including ultrasonic, monopolar, or bipolar coagulation to speed up the dissection. Each method offers benefits and also has limitations. Use of electro-surgical coagulation decreases the operative time but, near the facial nerve, may lead to injuries. An electrothermal bipolar vessel sealer (LigaSure Vessel Sealing System) was developed as an alternative to ligatures, hemoclips, staplers, and ultrasonic coagulators for legating vessels and tissue bundles. It consists of a bipolar radiofrequency generator and forceps, and the instruments are designed to mimic standard surgical clamps.

The system diagnoses the type of tissue in the instrument jaws and delivers the appropriate amount of energy needed to seal it. This generator is designed to produce high-current (4 A), low-voltage (<200 V) output, and its effect is unique because it works by applying a precise amount of pressure and energy to transform the collagen and elastin in vessel walls to create a permanent seal for a width of several millimeters. The obliterated lumen is readily identifiable once the jaws of the instrument are released. As the energy is being applied, an audible signal informs the surgeon that the obliteration has been completed. The LigaSure system can safely seal and divide vessels that are up to 7 mm in diameter, unlike conventional bipolar vessel seals, which are reliable only in vessels smaller than 2 mm in diameter.¹,³,⁵ The LigaSure, therefore, is the only instrument currently available that can safely and reliably divide larger (4-7 mm) vessels. Vessels are typically sealed with 1 application.

Despite the high degree of heat produced between the jaws of the instrument, it does not produce a large amount of lateral heat, and damage to surrounding tissues is low, as is the smoke production. The LigaSure produces significantly less thermal spread compared with other existing bipolar instruments.²,⁴,⁸,⁹

A recent article¹ details the performance of the LigaSure device in an animal model and in nearly 100 major general surgical procedures. In a study of small-bowel resections in an animal model, 8 LigaSure seals could be performed per minute compared with only 2 ligations per minute. A recent study¹ comparing the LigaSure system with ultrasonic coagulation, surgical clips, and standard sutures showed that in patients who underwent the LigaSure procedure, the vessel sealing system created scars that were stronger than all other energy-based bipolar methods comparable in strength to a mechanical ligation technique. It has mainly been used in gastrointestinal and urologic procedures in humans.¹,⁰ In these branches, some researchers¹,⁹ estimated a reduction in operative time, with no adverse events either during or after surgery.

Our study was designed to evaluate the LigaSure procedure in parotid gland surgery. The data emerging from this investigation reveal advantages of the LigaSure procedure over traditional methods concerning operative procedures and operative time only. No significant differences were reported between the 2 groups regarding complications, facial palsy or weakness, and duration of hospital stay. The LigaSure Precise has thinner tips than the standard LigaSure instrument, and in parotid gland surgery, it can be used as a dissector as well as a coagulator. This aspect could be the cause of the reduced operative time in total or superficial parotidectomy. Total operative time for conservative partial parotidectomy with traditional excision ranged from 115 to 235 minutes (mean, 155.8 minutes). Use of the LigaSure system reduced the length of the operation to a mean of 136.4 minutes. In all cases, the mean operative time was reduced by 15 minutes. The LigaSure Precise instrument shows some advantages because it reduces (1) adhesions and thermal spread and (2) the number of applications (1 is usually enough). The absence of blood in the operative field is such that no time is required to secure hemostasis, resulting in the mean operating time decrease.

Operative time depends not only on the size of the tumor but also on the tumor position, the pattern and size of the facial nerve branches, the training and experience of the surgeon, and the history of surgery in the area. In the present study, all superficial parotidectomies were performed by the same surgeon to control the variable of surgeon experience and training. Moreover, the surgical team was the same in all cases.

Regarding postoperative pain and the need for analgesia, there was no significant difference between groups in postoperative pain. Moreover, less local edema and the reduction or absence of necrosis of surrounding tissues have been noted. Owing to the minimal thermal spread, the incidence of facial nerve and other nerve branch palsy was low but comparable with that of the standard procedure. A higher incidence (3 of 17 patients) of salivary fistulas was recorded in group A. Postparotidectomy fistula is a common occurrence, ranging from 8% to 14%.¹⁰,¹²

In the present study, we hypothesize that the LigaSure device produced a smaller amount of heat and less damage to surrounding glandular tissue so that in the early postoperative period it was regularly functioning. Also, many more minor ducts could be sealed during such operations, and, therefore, poor wound healing could lead to drainage via the pathway of less resistance: the wound site. Several methods are mentioned for the treatment of parotid fistulas; however, the use of a pressure dressing is the best choice after parotidectomy. In our patients, as in the literature,¹⁰,¹² all of the fistulas healed with time and pressure dressing. Concerning hemostasis, the results were good, but we recorded no significant differ-
ences in postoperative bleeding and no significant reduction in early facial nerve weakness. House-Brackmann values were similar in both groups. Data analysis suggested that the use of the LigaSure system was not a risk factor for the development of facial nerve injuries. In fact, its thermal spread to surrounding tissues is low and heat damage to the nerve is less than or equivalent to that of bipolar electrocautery.

Sometimes “mosquito” clamps are required when using the LigaSure procedure for dissection of the finest facial nerve branches. In some cases, LigaSure Precise tips are not as thin as mosquito clamp tips and are inadequate for dissection.

This new technique is safe, easy to learn, bloodless, and rapid to perform, but it is not followed by a significantly shorter hospital stay, earlier return to work, or reduction in adverse events during or after surgery. Also, LigaSure has considerably higher costs. In fact, in addition to the cost of the entire device, each operation requires a new “Precise” handle replacement. The cost per procedure for the LigaSure open instruments (Standard and Precise devices) is approximately €100 for each superficial parotidectomy. Considering that the traditional bipolar coagulation running cost is less than €10 per surgery, the LigaSure Vessel Sealing System would not be a cost-effective alternative for achieving hemostasis. This method is comparable with but not superior to conventional methods. The main advantages of LigaSure are the ability to perform a sutureless technique and the decreased operative time.

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REFERENCES