Prospective Study on Effectiveness of Facial Nerve Monitoring in Improving the Surgical Outcomes for Parotidectomy of Benign Parotid Tumours in a Tertiary Hospital in South India

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ABSTRACT

BACKGROUND

Salivary gland diseases are rare but an important group of disorders. Following surgeries involving the parotid gland, facial nerve paresis is a common postoperative complication. The reported worldwide incidence of facial nerve paresis following parotidectomy is approximately 20 - 60 %. We need to determine the incidence of facial nerve paresis in the post-operative period following superficial, adequate, or extra-capsular parotidectomy of benign parotid tumours with the use of intraoperative facial nerve monitoring.

METHODS

A non-randomised interventional trial was initiated once cleared by the institutional review board. With the calculated sample size of 44, the patients underwent nerve-monitoring for the identification of the branches of the facial nerve. Clinical grading of the nerve function was done using the House-Brackmann score on the postoperative days 2, 7, and 60. The findings were compared with the historical controls (HC) of 53 patients who underwent similar procedures but with no intraoperative facial nerve monitoring. All patients were recruited in continuity for over two years.

RESULTS

The incidence of facial nerve paresis was 30 - 40 % and 10 - 20 % in the historical control and nerve monitoring group, respectively (P = 0.07). The duration of surgery in the nerve monitoring group was 83 ± 30 minutes and 95 ± 15 minutes in the HC group. The incidence of nerve paresis was similar among the trainees and consultants suggestive of adequate training.

CONCLUSIONS

Intraoperative facial nerve monitoring is a useful adjunct to reduce the incidence of early postoperative facial nerve paresis. The technique would not prolong the duration of the procedure. The technique may be utilized safely on a routine basis even during surgical training.

KEYWORDS

Facial Nerve Monitoring, Parotidectomy, Benign Parotid Tumour, House-Brackmann Score

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BACKGROUND

Salivary gland diseases are rare but an important group of disorders. Neoplasms of the salivary glands, either benign or malignant, account for fewer than 3 % of tumours in the US and only 6 % of head and neck neoplasms.[1] Approximately 2500 new cases of salivary gland neoplasms are identified and diagnosed each year. Parotid neoplasms account for 80 % of salivary neoplasms. Of parotid lesions, 75 % are neoplastic; the remaining 25 % are non-neoplastic infiltrative processes, such as cysts and other inflammatory pathologies. Benign neoplasms account for approximately 70 - 80 % of all parotid tumours. Barring Warthin tumours, the benign tumours of the parotid gland are more common in women than in men. The median age for occurrence of these tumours is in the fifth decade of life. Parotid tumours occur more commonly in Caucasians. Although the aetiology of these tumours is unknown, the possibility of an adenoma gene being involved in the development of pleomorphic adenomas is being studied. Of all the benign epithelial tumours, pleomorphic adenoma is the most common. Mucoepidermoid carcinoma is the most common malignant parotid lesion.[1]

Benign neoplasm of the superficial lobe of the parotid gland can be treated by superficial, adequate parotidectomy, or extra-capsular parotidectomy. Following surgery, facial nerve paresis is a common postoperative complication. The reported worldwide incidence of facial nerve paresis following parotidectomy is approximately 20 - 60 %. In the US, there has been an increasing litigation associated with postoperative surgical complication such as temporary facial nerve paresis.[2] The effectiveness of facial nerve monitoring in benign parotid diseases can be debated and results have shown inconclusive data.[3,4,5] This had led to the use of facial nerve monitoring during parotidectomies.[2] Given the specialisation of surgical fields, the incidence of facial nerve paresis must be reduced to decrease the morbidity of the procedure.

The facial nerve in the face traverses the parotid gland. The parotid gland develops in the space formed by the two major branches of the facial nerve. As the gland enlarges it covers these nerve trunks. As the superficial lobe and deep lobe fuse, the nerve comes to lie buried within the gland. The facial nerve emerges from the stylomastoid foramen, proceeds laterally to the styloid process and can then be exposed in the groove between the bony part of the external auditory meatus and the mastoid process. This has a useful surface marking, the tragal pointer of the ear, which is situated directly over the facial nerve. Just beyond this point the nerve dives into the deeper aspect of the parotid gland and bifurcates almost immediately into its two main divisions (occasionally it divides before entering the gland). The upper-division divides into temporal and zygomatic branches. The lower-division gives the buccal, mandibular and cervical branches. These two divisions may remain completely separate within the parotid, may form a plexus of communicating nerve branches. The branches of the nerve then emerges on the anterior aspect of the parotid to lie on the masseter, then passes to the muscles of the face.

Facial Nerve Monitoring

During the early 1980s, various new techniques such as nerve stimulators were creating new waves in terms of safe surgery. In 1979, Delgado became the first person to use electrophysiological monitoring of the facial nerve.[6] The use of intraoperative facial nerve monitors has resulted in improvement in facial nerve outcome for patients undergoing parotidectomies. The benefit of continuous Electromyography (EMG) monitoring is to provide immediate feedback on the proximity of the facial nerve to prevent serious or irreversible nerve damage. This is thought to be especially useful in training, as the resident is guided by the nerve monitoring system during dissection.[7] There are several drawbacks discussed in the literature with the use of facial nerve monitoring. These include that a nerve monitor may give a false sense of security, resulting in an aggressive dissection of tissues close to the nerves. Pensak and associates reported that in 7 % of ENT cases, the nerve monitor failed to warn the surgeon of an exposed facial nerve before its identification in the surgical field with the use of anatomic criteria.[8] Theoretically, more reliance on a facial nerve monitor for facial nerve identification could have resulted in a greater frequency of injury to the nerve. The nerve monitor may also frustrate and delay the surgeon with false-positive alarms. To prove the benefit of facial nerve monitoring in reducing the frequency of this complication, a prospective, randomized study of sufficient size and statistical power would be necessary. For example, to demonstrate the reduction in permanent facial nerve paralysis from 2 % to 1 % (a ¼ 0.05, power ¼ 0.8, 1 - tailed t - test), 1000 patients would be needed.[9]

It has been demonstrated that nerve monitoring reduces the risk of early postoperative facial nerve dysfunction in primary surgery, but not in redo parotid surgeries or surgeries for recurrences.[10] The psychological aspect of the severe facial nerve paresis or paralysis finds patients with degraded self-image, loss of self-confidence and self-esteem. Most patients experience at least a transient phase of depression, and social interaction as occupational status can be affected. Hence, the surgeons who operate in the anatomic areas traversed by the facial nerve would be welcoming the interventions that could reduce the morbidity of the surgery.

Objectives

1. To determine the incidence of facial nerve paresis in the post-operative period following superficial, adequate or extracapsular parotidectomy for benign parotid tumours with the use of intraoperative facial nerve monitoring.
2. To correlate the qualification of the surgeon with the grade of facial nerve paresis.
3. To correlate the duration of surgery with facial nerve paresis.

METHODS

A non-randomised interventional study with historical controls was conducted, from November 2014 to June 2016 in the Department of General Surgery, Unit 1 – Head & Neck Surgery, Christian Medical College, Vellore, Tamil Nadu, India, which is a 4000 bedded tertiary hospital and referral centre, after obtaining approval from the Institutional Review Board (IRB). Written informed consent was obtained from all patients.

Inclusion Criteria

All the patients undergoing superficial parotidectomy, adequate parotidectomy, or extra-capsular tumour excision with a pre-operative clinically benign or pathological benign parotid pathology.

Exclusion Criteria

Patients under 16 years of age, preoperatively diagnosed to have malignant pathology that required total conservative parotidectomy or recurrent tumours irrespective of benign or malignant tumour pathology were excluded from the study. The sample size was calculated based on historical data and results. Two Proportions - Hypothesis Testing - Large Proportion - Equal Allocation Proportion in group I - 0.05, Proportion in group II - 0.2 with an estimated risk difference - 0.15. The Power (1- beta) % - 80 with an Alpha error (%) – 5. The sample size in each arm was 44.

Study Method

Patients were recruited on the day of admission or the day before surgery after giving consent and explained about the procedure. The anaesthesiologists were informed about the nerve monitoring and were requested to provide deep sedation under general anaesthesia, without the use of skeletal muscle relaxants. At induction, a small dose of muscle relaxant was permissible, but the rest of the surgery was conducted under an intravenous Propofol infusion. After induction, the electrodes were placed in the region of the frontalis, orbicularis oculi, orbicular oris, and platysma. (Figure 1)

Figure 1. Placement of Electrodes in the Frontalis, Orbucularis Oris and Platysma

During the dissection, the bipolar electrode was used to locate the nerve by stimulating in its likely vicinity with 0.5 mA current and the corresponding muscle was observed for contractions. These contractions could be visualised in the form of a graph or heard as an audio signal from the main console. Traction and direct contact with the nerve or its branches were avoided. (Figure 2)

Figure 2. A Nerve Monitoring Device (Nicolet Endeavor CR)

Data Collection

Post-operative data collection started from day 2 and during an outpatient visit, either on postoperative days 6, 7 or 8. On postoperative day 60, either via telephonic conversation, email or at the outpatient clinic, the facial nerve weakness was recorded. Available complete data of 53 historical controls from 2007 to 2012 were analysed.

All Grade 1 and 2 House-Brackmann scores were categorised as mild, Grade 3 and 4 as moderate, and Grade 5 and 6 as severe. The various parameters measured were facial nerve paresis – House Brackmann score, comorbid illnesses, duration of surgery and designation of a surgeon.

Statistical Analysis

The data were recorded in epidata version 3.1 and imported to IBM SPSS Statistics for Windows, version 21 (IBM Corp., Armonk, N.Y., USA). Unpaired T-test analysis was used. The two-tailed significance and standard deviation were measured. Two-sided P values were considered for statistical analysis.

RESULTS

In the study population, 30 (68 %) were males and 14 (32 %) were females. The mean age was 40 years (33 - 70 years). The most commonly diagnosed benign parotid tumour was pleomorphic adenoma. (Table 1).

Table 2 compares the incidence of facial nerve paresis on postoperative day 2. On postoperative day 2, the zygomatic branch showed a 36% decrease in facial paresis with the use of monitoring and the temporal branch showed a 30 % reduction in facial nerve paresis with the use of nerve monitoring. The marginal mandibular nerve, which was the most commonly affected nerve, showed a 10 % decrease in facial nerve paresis with facial nerve monitoring. The buccal and cervical branches were excluded from analysis because of the non-availability of data from the historical database. Table 3 chart depicts facial nerve paresis on the postoperative day 6 / 7 / 8. There was a 32 % decrease in paresis of the temporal branch, 34 % decrease in paresis with the zygomatic branch and a 20 % decrease in paresis with the marginal mandibular nerve, in the historic data group. The P values were not statistically significant. Table 4 had no data available for comparison for postoperative day 60 in the historical data set.

	Total Number of Operated Cases N = 44 Year 2015 - 2016	N = 53 Year 2007 - 2012
Pleomorphic adenoma	22 (50.0)	45 (84.9)
Warthin's tumor	9 (20.5)	5 (9.4)
Mucoepidermoid ca	3 (6.8)	0
TB	1 (2.3)	0
Salivary gland cyst	2 (4.5)	0
others	7 (15.9)	3 (5.6)

Table 1. Type of Tumour

POD 2	Temporal	Zygomatic	Buccal	Marginal	Cervical
Mild	p=0.50	p =0.40		p=0.63	
Monitored	36 (67.9)	34 (64.1)	NA	35 (66)	NA
Non-monitored	43 (97.7)	44 (100)	40 (90.9)	35 (79.5)	34 (77.3)
Moderate				P = 0.07	
Monitored	1 (2.3)	0 4 (9.1)	8 (18.2)	9 (20.5)	
Non-monitored	NA	16 (30.1)	NA	16 (30.1)	NA
Severe				P = 0.8	
Monitored	0	0	0	1 (2.3)	1 (2.3)
Non-monitored	3 (5.6)	3 (5.6)	NA	2 (3.7)	NA

Table 2. Postoperative Day 2 Facial Nerve Paresis

N (%), N = total number of cases with paresis
2015 - 2016: Nerve monitoring
2007 - 2012: Non-nerve monitoring

POD6,7,8	Temporal	Zygomatic	Buccal	Marginal Mandibular	Cervical
Mild Monitored	36 (67.9)	35 (66)	NA	34 (64.1)	NA
Non-monitored	44 (100)	44 (100)	42 (95.5)	36 (81.8)	38 (86.4)
Moderate Monitored	0	0	2 (4.5)	p =0.9 7 (15.9)	6 (13.6)
Non-monitored	14 (26.4)	15 (28.3)	NA	17 (32)	NA
Severe Monitored	0	0	0	p = 0.8 1 (2.3)	0
Non-monitored	3 (5.6)	3 (5.6)	NA	2 (3.7)	NA

Table 3. Postoperative Day 6 / 7 / 8 Facial Nerve Paresis

N (%), N = total number of cases with paresis
2015-2016: Nerve monitoring
2007-2012: Non-nerve monitoring

POD 60 Monitored	Temporal	Zygomatic	Buccal	Marginal Mandibular	Cervical
MILD	44 (100)	44 (100)	44 (100)	43 (97.7)	0
MODERATE	0	0	0	1 (2.3)	0
SEVERE	0	0	0	0	0

Table 4. Postoperative Day 60 Facial Nerve Paresis

N (%), N = total number of cases with paresis
2015 - 2016: Nerve monitoring
2007 - 2012: Non-nerve monitoring

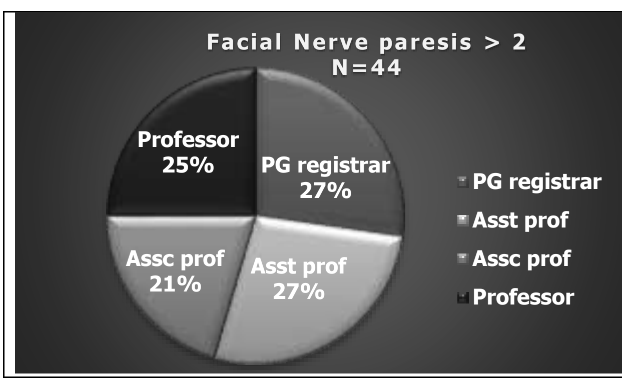

Figure 3. Facial Nerve Paresis Vs Surgeon Cadre

Qualification of the Surgeon Vs Facial Nerve Paresis

On postoperative day 6, those with facial nerve paresis of 2 or more were included in this analysis. The incidence of facial nerve paresis between the different levels of surgeons as per the qualifications was similar. (Figure 3). The number of cases operated by various cadres of surgeons was similar. There was no significant rise in paresis caused by junior surgeons during the study. All trainees and consultants had used nerve monitoring.

Duration of Surgery and the Incidence of Facial Nerve Paresis

On postoperative day 2, the mean duration of surgery using nerve monitoring resulting in nerve paresis was 83 minutes with a standard deviation of 30 minutes. The mean duration of surgery in the historical control group was 95 with a standard deviation of 15 minutes. The prolonged duration of surgery in the historic controls without nerve monitoring may have a role in increased nerve paresis. (P = 0.22).

DISCUSSION

In the previous years, an average of 70 - 80 patients presented annually to the unit for the treatment of parotid tumours. Out of these, benign tumours accounted for 50 - 60 cases while 10 - 20 cases being diagnosed as malignant. The incidence of facial nerve paresis from 2007 to 2012 was 30 - 40% which had decreased to 10 - 20 % with the use of facial nerve monitoring.

The technique of reducing iatrogenic facial nerve injury in parotid surgery remains with knowledge of anatomy and surgical dissection. At its best, intraoperative facial nerve monitoring can only provide information. It is not an antidote for poor surgical exposure, lack of experience, bad judgment, or inferior technique. In our institution, we have an overall incidence (2007 - 2015) of 25 – 30 % facial nerve paresis and less than 1% incidence of facial nerve paralysis. In this study, the incidences of males undergoing surgery for benign parotid tumours were more than females. The average duration of surgery was 80 - 90 minutes. There was a mild increase in the incidence of facial nerve paresis with the increasing duration of surgery.

Most surgeons across all levels of experience, especially junior surgeons, found nerve monitoring useful. None of the patients had any procedure-related complications or adverse effects like burn marks and pain at the insertion of the electrodes. The previous surgical approach towards benign parotid tumour surgery did not use intraoperative facial nerve monitoring. Many centres in the US and Europe have adopted intraoperative facial nerve monitoring.

The use of it in malignant tumour surgery has been successful, but its use in benign parotid surgeries is debatable. On all post-operative days of assessment, there was near significant (P = 0.07) decrease of facial nerve paresis in all comparable groups of nerves. Clinically there was a 10 – 30 % decrease in facial nerve paresis with the use of intraoperative monitoring.

There seems to be a similar incidence of facial nerve paresis concerning the surgeon qualification and experience with slightly higher rates of moderate and severe House-Brackmann score among the surgical residents, assistant, and associate professors as compared to professors. The reasons could be a professor operating the cases with a higher degree of difficulty that might have been even more challenging to junior doctors. The number of cases operated by postgraduate registrars without compromising on the morbidity outcome of nerve paresis, in a range similar to those achieved by the senior surgeons, is reflective of good general surgical training in the department.

CONCLUSIONS

There has been a positive impact of facial nerve monitoring during this study. Despite not having statistically significant data, the clinical incidence of facial nerve paresis has decreased. There have not been any complications because of the nerve monitoring device and probe placement. It increased the confidence among the junior surgeons when in doubt of the nerve anatomy. There may have been various confounding factors skewing the data. Hence large, multi-institutional studies with randomisation would be necessary. The cost accounting factor along with the availability of the nerve monitoring facility would play a role in defining it along with a protocol for benign parotid tumours. Further modification of the device to simplify it would cut down costs and increase usage.

The ability of the head and neck surgeon to use these nerve monitoring advancements in surgery has only added to the armamentarium of the surgeon. A procedure involving a monitor requires the additional time, and therefore the additional cost, of setting up the monitor at the start of the case, as well as the cost of technical staff to observe it intraoperatively.

Limitations

This study has certain acknowledged limitations due to which the results may have to be interpreted with discretionary caution. They are -

1. The study compared non-randomised prospectively collected data with historical data with its inherent limitation of incompleteness.
2. As the study was non-blinded, surgeon bias during the use of facial nerve monitoring can be presumed inherent in the prospectively monitored cases and the surgeon being more careful during the identification and dissection of the nerve due to the Hawthorne effect.
3. Due to technical advances and recent understanding, the types of procedures being done for superficial parotid benign tumours have changed over the years. Therefore, historical superficial parotidectomies were a poor match for the increasing numbers of adequate parotidectomies and extra-capsular excisions of benign parotid tumours being offered for smaller lesions in the superficial lobe. The apparent advantage of nerve monitoring may have been confounded by this fact.

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