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Transdermal scopolamine for the prevention of a salivary fistula after parotidectomy

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Abstract

Our aim was to investigate whether perioperative transdermal application of scopolamine could help to prevent fistulas after parotidectomy, and to this end we retrospectively studied the records of all patients ($n = 645$) who had benign parotid tumours treated by partial parotidectomy between 2011 and 2016. We found that scopolamine led to a significant decrease in the incidence of salivary fistulas from 54/371 (15%) in the group not given it to 10/274 (4%) in the group given it ($p < 0.0001$). The “number needed to treat” was 9.17. There was a relatively low incidence of all adverse effects after scopolamine. Our results are encouraging. Thorough consideration of the contraindications and a knowledge of the potential adverse effects are crucial for its successful implementation.

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Introduction

The need to reduce postoperative morbidity after operations on the parotid gland (for example, facial nerve palsy and Frey syndrome) has led over the years to a considerable change in philosophy and to an increase in the use of less invasive surgical techniques. Recently there has been an increase in focus on the maintenance of the highest possible postoperative quality of life without any compromise of the oncological outcome.

We have used extracapsular dissection as a definitive surgical treatment for benign tumours of the parotid gland in our department for almost 20 years. The main point of this method

is to resect the tumour with a cuff of healthy parotid tissue, but without identification or exposure of the main trunk or branches of the facial nerve. If more parotid tissue was left in place than in conventional procedures, it could potentially lead to an increase in the incidence of salivary fistulas after parotidectomy, which would have a serious impact on the patients' quality of life.¹ Indeed, 10% of our patients developed salivary fistulas after extracapsular dissection, which led to considerable discomfort from saliva draining through the fistula, social stigma, a prolonged stay in hospital, and often required further expensive treatment.¹

This observation, and the need for further refinement of less invasive surgical techniques for the parotid gland, led us to introduce certain preventive measures to avoid the creation of a fistula without an increase in perioperative morbidity. Our generally favourable experience with scopolamine in the treatment of salivary fistulas^{2–5} led us to consider its prophylactic use.

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The main aim of the present study, therefore, was to evaluate its effectiveness as a prophylactic measure in a large group of patients.

Patients, material, and methods

We retrospectively studied the records of all patients who were operated on between 2011 and 2016 at an academic tertiary referral centre that specialises in conditions of the salivary glands (Department of Otorhinolaryngology, Head and Neck Surgery, University of Erlangen–Nuremberg, Erlangen, Germany). We restricted our analysis to benign tumours of the parotid gland by extracapsular dissection (resection of the tumour with a cuff of healthy parotid tissue without facial nerve dissection), partial superficial parotidectomy (dissection of the facial nerve and partial removal of the superficial lobe) or superficial parotidectomy (removal of the entire superficial lobe). Patients with incomplete data and those in whom scopolamine (hyoscine) was contraindicated (those with angle closure glaucoma, tachycardia, pyloric obstruction, paralytic ileus, prostatic hypertrophy, urinary bladder neck obstruction or myasthenia gravis) were excluded.

The main intervention was the transdermal application at the end of the operation of a scopolamine patch (Scopoderm TTS, Novartis, Munich, Germany) to a clean, dry, hairless area behind the opposite ear, which was left in place for three days. Each patch had an absorption surface of 2.5 cm² and contained 1.54 mg scopolamine that was released on to the skin at a rate of roughly 1.0 mg/72 hours.

Scopolamine was given as described to 274 cases (43%), while 371 cases (58%) had none.

Statistical analysis

The significance of differences between groups was assessed using the Chi squared test with the aid of the software program IBM SPSS Statistics for Windows (version 21, IBM Corp, Armonk, NY, USA). The number needed to treat (the number of patients who need to be treated to prevent one salivary fistula) as well as the number needed to harm (the number of patients who need to be treated for one patient to have a particular adverse effect) were calculated for those given scopolamine. Probabilities of less than 0.05 were accepted as significant.

Results

A total of 645 patients were included in the study (318 men and 327 women; male:female ratio 0.97:1), of whom 470 had an extracapsular dissection (73%), 133 partial superficial parotidectomy (21%), and 42 superficial parotidectomy (7%). The most common histological types were cystadenolymphoma (245/645, 38%) and pleomorphic adenoma

Table 1

Incidence of scopolamine-related adverse effects and number needed to harm for each side effect in the 274 patients given scopolamine.

Adverse effect	No. (%)	No. needed to harm
Blurred vision	20 (7)	13.7
Xerostomia	17 (6)	16.1
Accommodation deficit	17 (6)	16.1
Sleepiness	4 (2)	68.5
Constipation	3 (1)	91.3
Retention of urine	2 (1)	137
Tachycardia	2 (1)	137
Erythema	1 (0.3)	274
Dizziness	1 (0.3)	274

(220/645, 34%). The perioperative transdermal application of scopolamine was associated with a highly significant decrease in the incidence of postoperative salivary gland fistulas from 15% in the control group (54/371) to 4% in the group given scopolamine (10/274, $p < 0.0001$). In other words, this reduced the risk of fistulation by up to almost four times (odds ratio 3.99, 95% CI 2.07 to 7.69, $p < 0.0001$), and the number needed to treat was 9.17 (Table 1).

Discussion

Salivary fistula is a well-known and relatively common complication of operations on the parotid gland,⁶ and the reported incidence can be up to 14%.⁷ Experience has shown that many fistulas can persist for a long time after complete wound healing, which poses a challenge to the clinician. Laskawi et al reported persistent fistulas after parotidectomy in 4% of 223 patients.⁸

Interestingly, careful study of the relevant papers indicates that there is confusion about when increased salivary flow after parotidectomy is defined as a fistula and merits treatment. Some groups begin treating it as a complication as soon as the second postoperative day, while others wait (as in many cases it is self-limiting) without stating when they adopt more aggressive treatment; they therefore potentially underestimate the number of fistulas. We have found that salivary flow decreases considerably on the second or third postoperative day. Having taken into account the controversy among publications and our own observations, for the purposes of this study we have defined any increased salivary flow from the wound as a fistula as soon as it becomes relevant to the patient by resulting in a prolongation of their stay in hospital or repeated outpatient visits for postoperative care.

The more parenchyma of the gland that has been left in place after an operation on the parotid gland, the greater the possibility of persistent salivary leakage. Our experience during the last 17 years with less invasive procedures such as extracapsular dissection is that such operations have led to a considerable reduction in perioperative morbidity, except for the rate of fistulas that has increased. Intraoperative measures, such as closure of the parotid capsule, re-adaptation of the remaining capsule to the sternocleid-

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