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Frey's syndrome after superficial parotidectomy: role of the sternocleidomastoid muscle flap: a prospective nonrandomized controlled trial

Maria Grosheva, M.D.[a,*], Luisa Horstmann[a], Gerd Fabian Volk, M.D.[b], Claudia Holler, M.D.[c], Laura Ludwig, M.D.[a], Verena Weiß, M.Sc.[d], Mira Finkensieper, M.D.[b,1], Claus Wittekindt, M.D.[c], Jens Peter Klussmann, M.D.[c], Orlando Guntinas-Lichius, M.D.[b], Dirk Beutner, M.D.[a]

[a]Department of Otolaryngology, Head and Neck Surgery, University of Cologne, Kerpener Straße 62, Cologne 50937, Germany; [b]Department of Otolaryngology, Head and Neck Surgery, Jena University Hospital, Jena, Germany; [c]Department of Otolaryngology, Head and Neck Surgery, University of Giessen, Giessen, Germany; [d]Institute of Medical Statistics, Informatics and Epidemiology, University of Cologne, Cologne, Germany

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Prospective trial

Abstract

BACKGROUND: The prevalence of Frey's syndrome (FS) after superficial parotidectomy in correlation to the sternocleidomastoid muscle flap (SCMMF) interposition is analyzed.

METHODS: A prospective nonrandomized controlled multicenter trial included 130 patients. During superficial parotidectomy, SCMMF was dissected, if excised specimens' volume exceeded 25 mL (SCMMF group). Follow-up examinations took place after 6, 12, and 24 months and included a Minor's test.

RESULTS: SCMMF was dissected in 30 (23.1%) patients. A total of 104, 80, and 68 patients completed the 1st, 2nd, and the 3rd follow-up, respectively. FS was detectable with nonvarying prevalence (46.3%, 45.6%, and 43.4%, respectively) during follow-up. The prevalence was higher in the SCMMF group (59.9%) than in the non-SCMMF group (41.8%; $P = .92$). The sweating area increased during follow-up ($P = .12$). Overall, 89.5% of patients characterized FS as not disturbing after 2 years.

CONCLUSIONS: FS occurred with a steady and high prevalence after superficial parotidectomy. In particular, SCMMF did not lower the risk of FS.

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The authors declare no conflicts of interest.

Trial registration: The study was registered in the German Clinical Trials Register (ID: DRKS00008972, URL: http://apps.who.int/trialsearch/.) in agreement with the Ethics Committees of participating universities.

* Corresponding author. Tel.: +49-221-478-4795; fax: +49-221-478-1422500.

E-mail address: maria.grosheva@uk-koeln.de

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[1] Present address: Department of Otolaryngology, Head and Neck Surgery, St. Anna Clinic, Vogelsangstraße 106, 42,109 Wuppertal, Germany.

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Frey's syndrome (FS) was first described by Lucja Frey, a Polish neurologist, in 1923.[1] The etiology of the syndrome, also known as auriculotemporal syndrome or gustatory sweating, is not exactly understood.[1] The theory of aberrant regeneration of parasympathetic fibers is commonly described.[2,3] However, it appears to be one of the most common postparotidectomy complication with an incidence of up to 80% reported in retrospective analyses.[2,4] The significance of various surgical techniques preventing FS was reported.[2,3,5–9] The dissection of the sternocleidomastoid muscle flap (SCMMF), the preservation of the superficial musculoaponeurotic system (SMAS), the higher thickness of the skin flap, and transplantation of autologous tissue or xenografts are described to prevent gustatory sweating.[2,3,6–10] Varying or even contradictory results may be mainly because of the retrospective inhomogeneous character of the clinical trials. The aim of this prospective multicenter trial was to analyze the prevalence of FS after superficial parotidectomy for benign parotid lesions and to correlate it to SCMMF dissection.

Methods

A prospective interventional nonrandomized controlled multicenter study was carried out. The Ethics Committees of University of Cologne (leading approval, ID 10-171), of University of Jena and of University of Giessen approved this trial. The study was registered in the German Clinical Trials Register (ID: DRKS00008972, URL: http://apps.who.int/trialsearch/). The participants were enrolled after giving informed written consent for the study.

From September 2010 to May 2012, 160 patients from 3 university-based tertiary referral centers (Ear, Nose and Throat Hospitals of Cologne, Jena and Giessen; all in Germany) were consecutively included. Patients who underwent a total parotidectomy or surgery for malignant lesions, and patients with revision surgery or with preoperative facial nerve dysfunction were excluded. Only adult patients, who underwent a primary superficial parotidectomy for benign tumor of the parotid gland, were included for further analysis. Data on their gender, age, hospitalization period, duration of surgery (time from skin incision to suture in minutes), and histology of parotid specimen, its volume (volume of the excised parotid tissue including the tumor in cm^3) and mass in grams (g) were assessed during hospitalization.

Surgery

All enrolled patients underwent a superficial parotidectomy. The standardized surgery method under general anesthesia was previously described by Guntinas-Lichius et al.[11] It was mandatorily applied using an operating microscope or binocular loupe and visual facial nerve monitoring in all participating hospitals.[12] The SMAS was integrated into the skin flap in all patients. After the identification of the main trunk of the facial nerve and dissection of all peripheral facial nerve braches, the superficial parotid gland tissue including the tumor was removed. Because of the study protocol, the SCMMF was mandatorily dissected in patients with a higher resection extent. To determine the specimens' volume during surgery, the removed specimen was measured by displacement of formaldehyde (in mL) in a normed container. The minimum displacement volume of 25 mL was required for SCMMF interposition. The SCMMF interposition was not performed in patients with displacement volume less than 25 mL. This specific number was set, based on the data from a previous investigation on specimens' measurements during superficial parotidectomy in the participating study centers.[12] The SCMMF was dissected using this method in each participating study center. Therefore, the proximal part of the sternocleidomastoid muscle was mobilized. After identification of the accessory nerve, one-third of the muscle was dissected and rotated toward the main trunk of the facial nerve, covering the facial fan. The muscle tissue was sutured without tension to the surrounding fat tissue. All patients received an intravenous single-shot antibiotic treatment before surgery. Surgeons of comparable education level, at least 5th educational year in 5-year profession training, performed all surgeries.

Follow-up examinations

The presence of early postoperative complications was evaluated during hospitalization. The facial nerve function on the last day was graded by reference to the House–Brackmann (HB) as Stennert facial nerve grading scale (Stennert-index).[13,14] Follow-up examinations were carried out after 6, 12, and 24 months. At each visit, each patient filled in a questionnaire, which included the validated patient reported outcome measures "parotidectomy outcome inventory 8" (POI-8)[15] and additional questions regarding the impact of FS on daily routine. Using the POI-8 scale, the patients classified the symptom "gustatory sweating" on a numeric scale from 0 ("no problem at all") to 5 ("it could not be worse"). After the Ear, Nose and Throat-examination, the facial function was analyzed and photo documented in case of dysfunction. The iodine-starch test (Minor's test)[2] was performed to detect FS and photo documented in all patients at each follow-up visit (Fig. 1). A blinded investigator (L.H.; blinded to surgery extent, histology of the tumor, and the SCMMF dissection) analyzed all photographs at the end of the trial. L.H. rated the Minor's test as positive if color changes of the analyzed skin area were visible. Then, the sweating area was measured in cm^2 using the ImageJ application, version 1.47 v (Wayne Rasband, NIH, USA) and averaged more than 3 measured areas. The calculations were performed for each patient at each follow-up visit.