COMMENTARY

ETHICS OF FREY SYNDROME: ENSURING THAT CONSENT IS TRULY INFORMED

Andrew G. Shuman, MD,[1,2] Carol R. Bradford, MD[1]

[1] Department of Otolaryngology – Head and Neck Surgery, University of Michigan Medical School, Ann Arbor, Michigan. E-mail: shumana@umich.edu
[2] Adult Ethics Committee, University of Michigan Medical School, Ann Arbor, Michigan

Accepted 22 February 2010
Published online 2 June 2010 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/hed.21443

Abstract: Frey syndrome is a widely recognized sequela of parotidectomy with a variable prevalence dependent upon diagnostic criteria. There exists a multitude of strategies for both prevention and treatment. Surgeons are obligated to engage patients in a frank and open discussion of the operative risks, benefits, and alternatives. Due to uncertainty regarding the significance of Frey syndrome postoperatively, the process of informed consent and preoperative decision-making pose a potential ethical quandary. This commentary is designed to heighten the awareness of the preoperative informed consent process by dissecting the ethical tenets underlying these patient encounters using Frey syndrome as an example, ensuring that patients are granted the opportunity to participate in their own care in accordance with the concept of individual autonomy. © 2010 Wiley Periodicals, Inc. *Head Neck* **32:** 1125–1128, 2010

Keywords: Frey syndrome; parotidectomy; autonomy; informed consent; surgical complication

Frey syndrome describes the phenomenon of sweating and hyperemia of the facial skin occurring during mastication. It typically occurs after parotidectomy for benign or malignant conditions, but may occur with any event (trauma, infection, and so on) that disrupts the parotid bed. The eponym honors Lucja Frey, the Polish neurologist who originally described its pathophysiology. The pathway involves parasympathetic fibers aberrantly reinnervating sweat glands and the subcutaneous vascular plexus rather than their original end-organ, the secretomotor cells of the parotid acini.[1]

The diagnosis of Frey syndrome after parotidectomy is controversial; its incidence varies depending upon diagnostic criteria. While objective testing indicates an extremely high prevalence, fewer patients report symptoms. Preventive and treatment strategies are wide-ranging. There is a dearth of quality data regarding the efficacy of various strategies for the prevention of Frey syndrome; no randomized or prospectively controlled studies have been published. This article does not purport to provide a comprehensive discussion of the various strategies for prevention of and treatment for Frey syndrome; the interested reader is referred to published reviews on this topic.[2]

Due to the unique facets of the condition and its management, Frey syndrome poses an

Correspondence to: A. G. Shuman

The authors have no financial interests, disclosures or conflicts of interest regarding the content of this original manuscript.

interesting model for a discussion of medical ethics with regard to surgical decision-making. To what extent should Frey syndrome be mentioned as a potential postoperative sequela given its near-ubiquity on objective tests and a lack of consensus regarding its actual impact upon patients? This article will attempt to define the controversies inherent to the discussion and dissect the ethical questions posed with regard to patient autonomy, the informed consent process, and patient involvement in preoperative decision-making.

The Diagnostic Conundrum. Objective measurements of Frey syndrome typically involve a version of the starch-iodine test originally described by Minor,[3] in which gustatory sweating causes a color change on the involved skin. Subjective reports of Frey syndrome are less straightforward. In surveys retrospectively asking postoperative patients about their symptoms, the reported incidence of Frey syndrome varies. In a review of 7 studies totaling 542 patients, the average rates of objective and subjective Frey syndrome, respectively, were 79% and 40%.[4] Another review article estimates a positive starch-iodine test in 95%, an affirmative answer to direct questioning in 35%, and unsolicited complaints in 10%.[2]

There is no ideal, validated instrument specifically designed to assess the impact of Frey syndrome upon quality of life. In a quality of life study that evaluated Frey syndrome, postoperative parotidectomy patients averaged a score of 93 on a 0 to 100 scale, with 0 representing intolerable symptoms of erythema and sweating, and 100 representing no symptoms.[5] Another study attempted to describe severity based upon the degree of the patients' symptoms and the affected surface area, using a numerical scale to subdivide "mild" versus "severe" Frey syndrome; slightly more than half were rated as severe.[4] A group of 173 postparotidectomy patients (of whom 13% developed subjective Frey syndrome) were asked an open-ended question about what they would change about their perioperative experience; 8% reported that "more information" would have been helpful.[6]

In general, Frey syndrome is likely under-recognized and under-reported. Some authors report that Frey syndrome is brought to the attention of medical providers only when patients are asked specifically about related symptoms. Designing a study to measure the percentage of patients who complain of Frey syndrome without prompting would be quite difficult from a methodologic standpoint. However, examining the number of patients who choose to undergo treatment of the condition sheds light onto this issue. One of the few articles to report this data estimated that 5% to 10% of patients request management of symptomatic Frey syndrome.[7]

Autonomy and Informed Consent. The overriding theme with regard to contemporary medical ethics involves the respect for patient autonomy, in which patients serve as active decision-makers in their own care, eschewing the historic tradition of paternalism. Legally, this was established by a decision of the New York Court of Appeals in 1914, stating that "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[8] The development of the doctor-patient relationship underlies all such encounters. Parker[9] describes a model involving the creation of a partnership between physician and patient with honest, open lines of communication, coupled with deliberation of choices, alternatives, and outcomes, with both clinician's and patient's input, assimilated into a workable and practical solution that is in accordance with the patient's preferences.

The concept of preoperative informed consent is descended from the theme of patient autonomy. Patients with sufficient capacity are expected to be engaged in a conversation involving the risks and benefits of, and viable alternatives to, a proposed intervention. While medical providers should participate in this decision-making process with their patients, including providing medical opinions based upon their own expertise, the decision itself rests with the patient or their designated proxy. The consent process begins with the determination of capacity, and does not end with a signature on a consent form, but rather encompasses the entire process whereby patients and care providers engage in an ongoing discussion of their care.[10]

In the United States, obtaining surgical consent has been mandated through the courts. While legal matters are of obvious importance, they are secondary to the crux of the physician–patient partnership. From an ethical standpoint, disclosure of risk is in many ways relative to the nature of the consequence itself. Thus, rare but dire complications (such as facial nerve transection) should be discussed. If a sequela

has more trivial consequences but is relatively common (ie, a numb earlobe after parotidectomy), it may be discussed at the discretion of the surgeon. Frey syndrome poses a quandary given uncertainty with regard to both incidence and perceived severity.

Patients do not always understand or retain the information provided during the consenting process, despite the best efforts of the individual obtaining consent. In a study by Hekkenberg et al,[11] the overall recall rate of complications from a preoperative discussion of the risks of head and neck surgery was 48%. In patients undergoing parotidectomy, only 27% of patients remembered the risk of Frey syndrome 2 months after their surgery. Poor recollection is not always related to seemingly unlikely complications; in the same study, only 19% of patients undergoing thyroid/parathyroid surgery recalled the possibility of having an unsightly scar.

One might argue that Frey syndrome is only significant if it is noticed by the patient, while others might contend that it is only truly worth discussing if patients not only notice its presence, but are bothered by it. In this case, it is worth mentioning simply so that patients are not scared or confused by its presence, especially if its etiology is not immediately apparent. Patients may not complain of Frey syndrome postoperatively simply due to the fact that they do not associate it with their surgery; often, it develops months after surgery, and even when counseled preoperatively, the majority of patients do not remember it being mentioned as a potential risk.

Patient Roles in Operative Decisions. There are practical limitations with regard to preoperative informed consent. Minute details of a surgical procedure (the decision to tie or clip vessels, for example) are reasonably expected to be inherent to the procedure itself and left to the discretion of the surgeon. In contrast, major decisions (the decision to sacrifice a functional facial nerve involved with neoplasm, for example) typically require patient involvement. Patient characteristics also play an important role; those who are more involved and educated with regard to their own medical situation may require a more detailed discussion than patients without such interest or knowledge. In certain cases, providing too much information or offering patients an inordinate number of choices may become overwhelming or add to their confusion. That said, while a patient's ignorance is not an excuse to circumvent the consent process, these factors can and should influence the give-and-take of the doctor–patient relationship.

With regard to prevention strategies for Frey syndrome, the data concerning efficacy remain inconclusive. Reported techniques for prevention involve raising a thicker skin flap, leaving a portion of the parotid gland undissected, tissue rearrangements (muscle/fascia flaps), or implanting autologous, allogeneic, or other biologic materials. Similarly, multiple treatment options exist, including reassurance, topical or systemic anticholinergics/antiperspirants, subcutaneous injection of Botulinum toxin, or a variety of surgical procedures.

Further complicating the discussion is the fact that some of these strategies are also utilized to provide an aesthetic improvement in the operative defect. Many of the recommended preventative techniques involve inherent risk. Implantable materials increased the risks of poor wound healing in one study,[12] and the use of any biologic material carries an inherent theoretical risk (albeit low) of rejection/extrusion and/or disease transmission. In addition, local tissue rearrangements or flaps that add bulk to the surgical site might delay early recognition of tumor recurrence. An author of 1 of the earlier articles describing local tissue rearrangements to prevent Frey syndrome wrote an editorial sharply condemning the use of any type of surgical implant due to the potential risks, which he deemed unjustified given the rare and minor consequences of the complication itself.[13] Nevertheless, the absence of quality research obviates a definitive answer, and surgical practice is largely based upon individual judgment.

Clearly, there is no accepted consensus regarding the utility of preoperative prevention strategies. In these cases, it is imperative to involve the patients in the discussion. Physicians should explain the rationale behind, in addition to the risks and benefits of, the various options to their patients. All options need not be painstakingly explained so long as patients are an integral part of the decision-making process and given sufficient opportunity to exercise their own autonomy.

Surgeon preference can and should frame the conversation, as individual surgeon experience and anecdotal evidence is potentially helpful in dictating care and informing the treatment paradigm for clinical questions lacking quality data.

For example, if a surgeon notices that a larger proportion of patients are complaining of Frey syndrome, it may behoove him/her to critically appraise his/her outcomes and consider changes in technique or treatment. The senior author of this article, based upon her personal experience with approximately 200 parotidectomies over the past decade, believes that Frey syndrome is common, bothersome, and preventable in a safe and efficacious fashion. She routinely recommends placement of Alloderm (Lifecell, Branchburg, NJ), and counsels patients regarding the associated risks, benefits, and uncertainties.

Patients should have the opportunity to weigh options under their surgeon's guidance, especially with regard to comparatively riskier and unproven strategies such as the use of implantable materials. In general, physicians are not obligated, either ethically or professionally, to offer unproven and potentially harmful treatments to patients. Thus, any discussion of strategies to prevent Frey syndrome should include a discussion of their inherent potential risk.

Recommendations. Based upon available data, Frey syndrome is noticed by a significant number of patients, and bothersome in an unknown subset. Nevertheless, patients can and should expect their surgeons to be honest and forthright about what can be reasonably expected in the postoperative period. Clinicians should be candid with patients, stressing that Frey syndrome is quite common when testing is performed, but that its clinical significance is not well established. Surgeons should also include their patients in preoperative decision-making with regard to deciding upon the use of preventative strategies for Frey syndrome.

CONCLUSION

Physicians and patients must embark upon a trust-based partnership in order to foster a mutually beneficial and ethical relationship. Patients rely upon the opinions and expertise of their physicians, and likewise, doctors must routinely take their patients' individual preferences into account. These issues are applicable not only to Frey syndrome and parotidectomy, but highlight themes common within the informed consent process for a wide variety of procedures. Whereas the slope from autonomy to paternalism may be slippery, we owe it to our patients to be prudent and sure-footed.

REFERENCES

1. Frey L. The syndrome of the auriculo-temporal nerve (French). Rev Neurol 1923;2:97–104.
2. de Bree R, van der Waal I, Leemans CR. Management of Frey syndrome. Head Neck 2007;29:773–778.
3. Minor V. A new procedure for the clinical investigation of gustatory sweating (German). Dtsch Z Nervenheilkd 1927;101:302–308.
4. Luna-Ortiz K, Sansón-RíoFrío JA, Mosqueda-Taylor A. Frey syndrome. A proposal for evaluating severity. Oral Oncol 2004;40:501–505.
5. Erkan AN, Yavuz H, Ozer C, Ozer F, Ozluoglu L. Quality of life after surgery for benign disease of the parotid gland. J Laryngol Otol 2008;122:397–402.
6. Marshall AH, Quraishi SM, Bradley PJ. Patients' perspectives on the short- and long-term outcomes following surgery for benign parotid neoplasms. J Laryngol Otol 2003;117:624–629.
7. Linder TE, Huber A, Schmid S. Frey's syndrome after parotidectomy: a retrospective and prospective analysis. Laryngoscope 1997;107(11 Pt 1):1496–1501.
8. Schloendorf v. Society of New York Hospital, 211 N.Y. 125, 129 (1914).
9. Parker M. A conversational approach to the ethics of genetic testing. In: Case Analysis in Clinical Ethics. Ashcroft R, Lucassen A, Parker M, et al, editors. NY: Cambridge Univ Press, 2005.
10. Bernat JL, Peterson LM. Patient-centered informed consent in surgical practice. Arch Surg 2006;141:86–92.
11. Hekkenberg RJ, Irish JC, Rotstein LE, Brown DH, Gullane PJ. Informed consent in head and neck surgery: how much do patients actually remember? J Otolaryngol 1997;26:155–159.
12. Dulguerov P, Quinodoz D, Cosendai G, Piletta P, Marchal F, Lehmann W. Prevention of Frey syndrome during parotidectomy. Arch Otolaryngol Head Neck Surg 1999;125:833–839.
13. Kornblut AD. The fallacy of preventing Frey syndrome during parotidectomy. Arch Otolaryngol Head Neck Surg 2000;126:556–557.