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ORIGINAL ARTICLE

A COMPREHENSIVE APPROACH TO THE TREATMENT OF PATIENTS WITH PRIMARY GROWTH OF PLEOMORPHIC ADENOMA OF THE PAROTID SALIVARY GLAND

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ABSTRACT

Objective: The aim of the study is to develop a patient management algorithm for pleomorphic adenoma (PA) of the parotid salivary gland (PSG) based on a retrospective analysis of medical histories of patients with parotid gland tumors.

Materials and Methods: An analysis of archival data was conducted to determine the total number of patients with PA who were operated on from 2002 to 2021 (excluding the period from 2006 to 2008) at Department No. 8 of the Research Institute of Stomatology and Maxillofacial Surgery, St. Petersburg State Medical University named after Acad. I.P. Pavlov, Ministry of Health of the RF, as well as the conclusions from the postoperative dispensary follow-up of these patients.

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Results: 537 patients with neoplasms of the parotid salivary gland (PSG) were identified, of whom 253 (47.1%) were diagnosed with PA based on postoperative morphological findings. In 175 (32.6%) patients, no tumor growth was detected. The concordance rate between preoperative fine-needle aspiration biopsy (FNAB) under ultrasound (US) guidance and postoperative histological findings in patients with PA was 90.9%. During long-term follow-up ultrasound monitoring, recurrence of PA of the PSG was detected in 5 (14.7%) of the 34 examined patients. The average time to recurrence of PA of the PSG in patients with primary tumor growth was 8.9 years.
Conclusions: Based on the analysis of domestic and foreign sources, as well as the data from our study, a management algorithm for patients with primary growth of PA of the salivary glands was proposed. The key points include: mandatory preoperative FNAB under US guidance, exclusion of enucleation as a surgical treatment for PA, an alternative approach for superficially located PAs, removal of PA with a 0.9 cm margin from the fibrous capsule, and lifelong follow-up with ultrasound examination once a year.

Keywords: pleomorphic adenoma, parotid salivary gland, recurrence, fibrous capsule, enucleation, myxoid, morphometry

INTRODUCTION

Pleomorphic adenoma (PA) is the most common benign neoplasm of the salivary glands (SG), with an incidence of up to 80% in major salivary glands.[1] Pleomorphic adenoma occurs in all age groups but is most frequently observed in patients aged 40 to 60 years, with a higher prevalence among females.[2, 15]

PA is a mixed tumor composed of myoepithelial and epithelial cells, which, in turn, are classified into morphological subtypes.[3,4]

The primary preoperative clinical and instrumental diagnostic methods for patients with SG neoplasms include ultrasound (US),computed tomography (CT), and magnetic resonance imaging (MRI), as well as fine-needle aspiration biopsy (FNAB) under US guidance. FNAB is considered the method of choice for preoperative diagnosis and is performed at the initial diagnostic stage.[7]

According to several authors, the accuracy of FNAB under US guidance varies, with false-negative and false-positive rates ranging from 1% to 14%. The reliability of results for benign neoplasms (BN) and malignant neoplasms (MN) of the SG ranges from 81% to 98%, while the specificity of diagnostic methods is between 60% and 75%. False-negative diagnoses are primarily associated with factors such as improper sample collection and the ongoing development of SG tumor classification based on cytological studies.

For BN and MN of the SG, frozen section analysis of postoperative specimens is considered the most reliable method, with an accuracy of up to 98.7% for BN (excluding delayed cases) and up to 85.9% for MN.[5-7]

In recent years, there has been a growing trend toward revising surgical approaches for patients with benign salivary gland neoplasms (BSGN), focusing on organ-preserving surgery. However, the primary surgical treatment methods for BSGN, particularly pleomorphic adenoma, remain extracapsular enucleation/dissection, partial superficial parotidectomy, superficial parotidectomy, and total parotidectomy with or without facial nerve preservation. Additionally, a new trend has emerged involving the removal of salivary gland neoplasms using endoscopic-assisted visualization techniques.[6,7]

At the Congress of the European Society of Sialologists in 2010, a decision was made to divide the parotid salivary gland into five anatomical zones: I–upper lateral (superficial), II – lower lateral (superficial), III – lower deep, IV – upper deep, V – accessory lobe of the gland. The name of the surgical procedure on the parotid salivary gland should be formulated as either "parotidectomy" **or** "extracapsular dissection."

The extent of parotid gland resection is determined by its localization within an anatomical zone and the designation of the removed non-glandular anatomical structure.[8]

When selecting the scope of surgical treatment for pleomorphic adenoma, factors such as tumor size, morphological subtype, integrity and thickness of the fibrous capsule, and the likelihood of satellite nodules must also be considered.[9, 15, 17]

Regarding postoperative follow-up, the 2014 Clinical Protocol for Medical Care of Benign Soft Tissue Tumors of the Head and Neck by the StAR Section "Association of Maxillofacial Surgeons and Dental Surgeons" recommends postoperative follow-up with a maxillofacial surgeon in a consultative and

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diagnostic outpatient clinic or a regional dental clinic. However, the protocol does not specify the timing and frequency of follow-up examinations .[10]

Additionally, the 2014 Clinical Guidelines of the Ministry of Health of the Russian Federation state that the minimum set of postoperative prevention and follow-up measures should include an examination by the attending physician and postoperative scar therapy no later than six months after surgery**,** but they do not specify the frequency of follow-up visits in the long-term postoperative period.[11]

The aim of the study is to develop a patient management algorithm for pleomorphic adenoma (PA) of the parotid salivary gland (PSG) based on a retrospective analysis of medical histories of patients with parotid gland tumors.

MATERIALS AND METHODS

In accordance with the objectives and tasks, an analysis was conducted of archival data from patients who underwent surgical treatment for maxillofacial tumors at the Oncology Department No. 8 (Maxillofacial Surgery) of the Maxillofacial Surgery Clinic at the I.P. Pavlov First St. Petersburg State Medical University of the Ministry of Health of the Russian Federation from 2002 to 2021, excluding the years 2006-2008.

RESULTS

Based on the analysis of the data obtained during this period, 537 patients (figure 1) were identified as having undergone surgical treatment for maxillofacial tumors, of which 364 (67.8%) were female and 173 (32.2%) males.

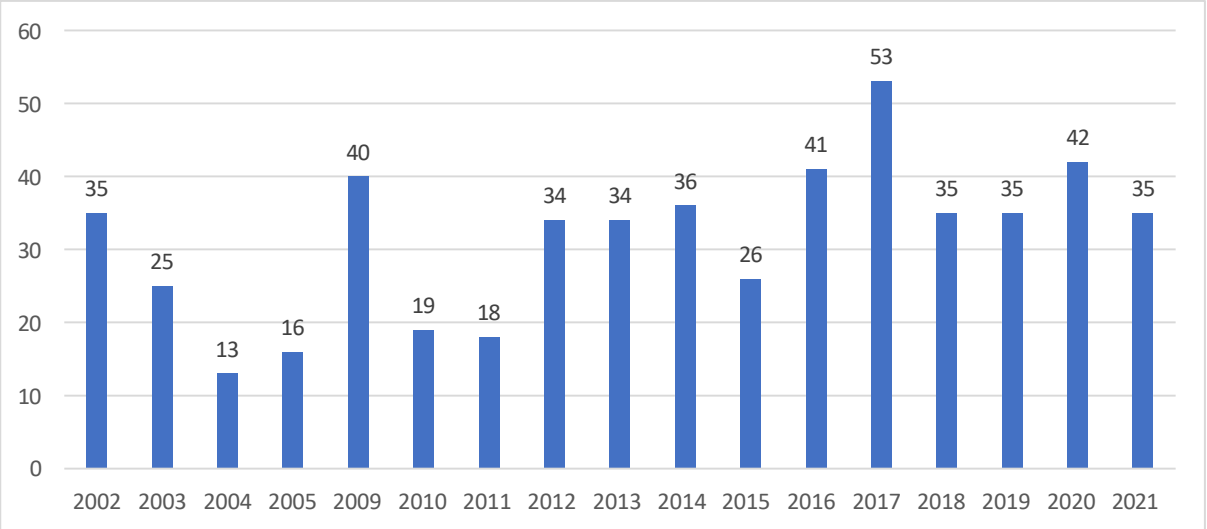


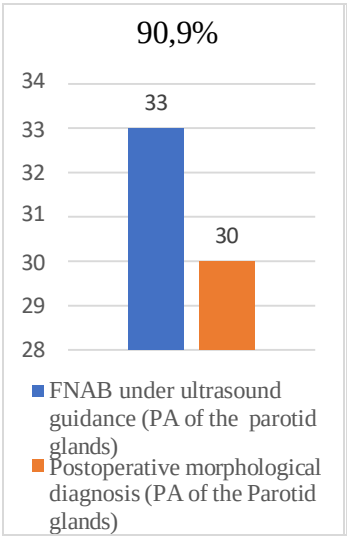
Figure 1. Distribution of 537 patients who received surgical treatment for neoplasms of the parotid gland by years from 2002 to 2021 (excluding 2006–2008).

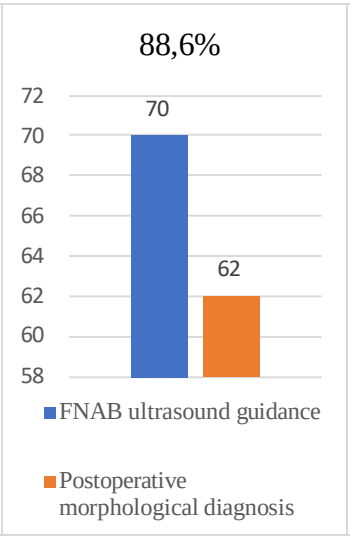
The average age was 51.7 (±15.2, 95% CI 1.29) years (men 51.3±15.5, 95% CI 2.37 years, women 51.9±15.1, 95% CI 1.55 years). All patients underwent ultrasound of the maxillofacial tumors upon admission. Among the aforementioned group of patients with benign maxillofacial tumors, analysis of the postoperative morphological examination reports, according to the 2017 WHO classification of head and neck tumors, revealed that 253 (47.1%) patients had primary pleomorphic adenoma, of which 176 were women and 77 were men. The average age of these patients was 48.2 (±14.4, 95% CI 1.79) years, with women being 49.7 (±14.0, 95% CI 2.08) years and men 44.7 (±14.8, 95% CI 3.42) years. In 143 (26.6%) patients, non-tumorous epithelial lesions of the maxillofacial tumors were identified (lymphoepithelial sialogadenitis, sclerosing polycystic adenosis, hyperplasia of the intercalated ducts) and other types of maxillofacial tumors, including patients with recurrence of pleomorphic adenoma, accounting for 141 (26.3%) patients who did not fall into the main research groups (Table 1).

Table 1. Distribution of patients by type of neoplasm of the parotid gland.

Histological Type	Number of Patients
Pleomorphic Adenoma	253
Non-Tumorous Epithelial Lesions	143
Other Tumors Not Included in the Study	141
Total	**537**

In the overall group of patients (537 individuals), only 70 patients (13%) underwent fine-needle aspiration biopsy (FNAB) under ultrasound guidance in the preoperative period. In 33 out of 70 cases (47.1%), pleomorphic adenoma was detected, while in 37 (52.9%) cases, other types of maxillofacial tumors were identified. Furthermore, an analysis of the cytological examination results revealed that in 30 out of 33 patients with pleomorphic adenoma, the preoperative cytological findings matched the postoperative morphological diagnosis, which is 91% (figure 2). At the same time, an analysis showed that in 175 patients (32.6%) out of 537, the preoperative clinical diagnosis did not match the postoperative morphological diagnosis. Additionally, during the study of preoperative cytological examination data under ultrasound guidance, it was found that the diagnostic accuracy for benign salivary gland tumors, particularly pleomorphic adenomas, was 30 (90.1%). In 3 (3%) cases, the postoperative histological findings revealed a malignant tumor. It is also worth noting that in 8 (11.4%) cases out of 70 cytological conclusions, including those with pleomorphic adenoma, the benign nature of the tumor was not confirmed according to the postoperative morphological diagnosis. Thus, when comparing the discrepancy between the preoperative clinical diagnosis in the overall patient group with the postoperative morphological diagnosis, excluding patients who underwent preoperative FNAB under ultrasound guidance, 175 (37.5%) out of 467 (from 537) patients had discrepancies. In contrast, the group of patients who underwent preoperative FNAB under ultrasound guidance showed significant differences, with a P-value <0.0001 (Fisher's exact test) figure 3,4).





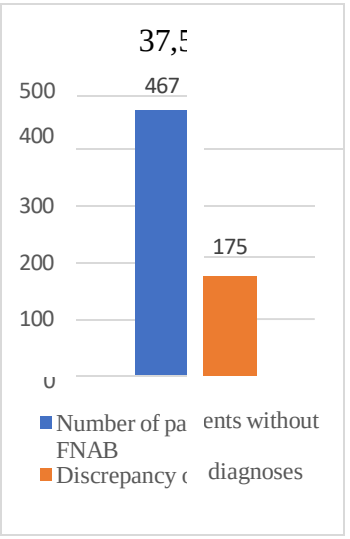


Figure 2. **Figure 3.** **Figure 4.**

Figure 2. Coincidence of the findings of preoperative FNAB and postoperative histological conclusions in patients with pleomorphic adenoma.

Figure 3. Coincidence of the findings of preoperative FNAB and postoperative histological conclusions in patients with neoplasm of the parotid gland.

Figure 4. Discrepancy between the conclusions of preoperative clinical diagnosis in patients without preoperative FNAB and postoperative histological conclusion in patients with neoplasm of the parotid gland.

A detailed analysis of the data from patients with primary pleomorphic adenoma growth also revealed that in 222 (87.7%) patients, the tumor was located in the superficial lobe of the parotid gland. As a result, 129 (50.9%) patients underwent extracapsular enucleation/dissection, 97 (38.3%) patients underwent superficial parotidectomy or subtotal parotidectomy, as the tumor was located at the upper or lower pole of the parotid gland. Complete removal of the parotid gland (extirpation) with preservation of the branches of the facial nerve was performed in 18 patients, where the tumor was located in the deep lobe of the parotid gland. In 4 (1.5%) patients, endoscopic-assisted tumor removal was performed (figure 5).

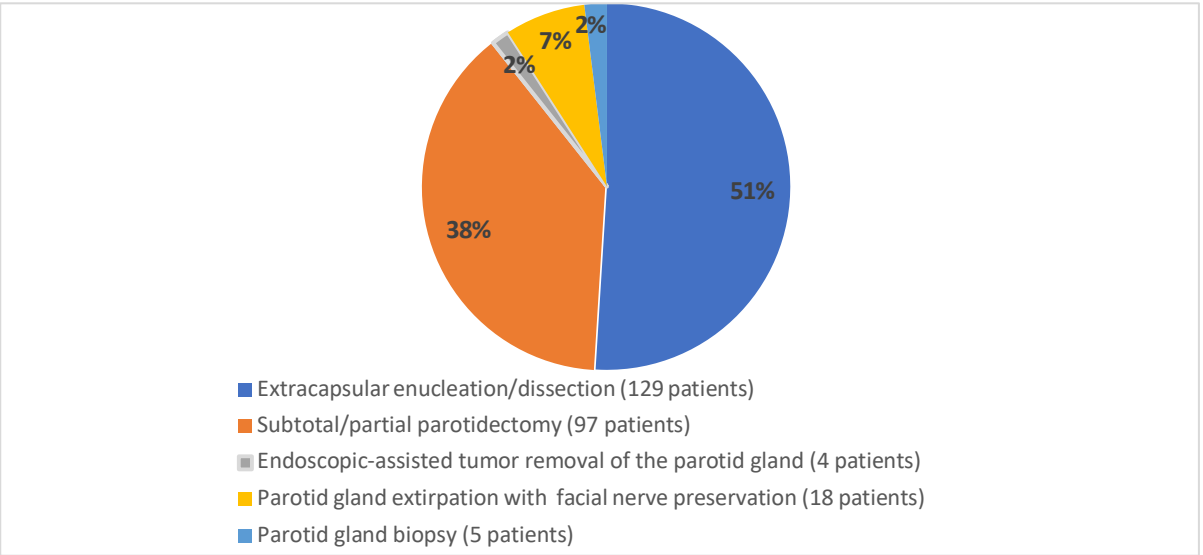


Figure 5. Analysis of the data from patients with primary pleomorphic adenoma

DISCUSSION

Despite the existence of the clinical protocol for medical care in soft tissue head and neck tumors (STAR) from 2014, as well as the clinical guidelines for benign tumors and tumor-like lesions of the parotid gland by the Ministry of Health of the Russian Federation from 2017, the need for improvement and refinement of the existing recommendations remains relevant.

Analyzing archival data from patients with primary tumor growth, particularly pleomorphic adenoma, who underwent surgery in Department No. 8 of the Institute of Stomatology and Maxillofacial Surgery at the I.P. Pavlov First St. Petersburg State Medical University of the Ministry of Health of the Russian Federation, and reviewing publications by foreign authors, we observe the following pattern: preoperative diagnostics, such as ultrasound or MRI, are of limited value in verifying tumor growth in the parotid gland. Based on this, we recommend including mandatory fine-needle aspiration biopsy (FNAB) under ultrasound guidance in the preoperative diagnostic protocol for patients with parotid gland tumors, not only to identify the nature of the tumor growth but also to more accurately plan the surgical treatment strategy.

The analysis of archival data also revealed that 129 (50.9%) patients with primary pleomorphic adenoma underwent extracapsular enucleation, which in turn increases the risk of recurrence. Comparing these data with the recommendations from the European Society of Sialogists from 2010 and our previous research, which indicates that the probability of recurrence of pleomorphic adenoma in the parotid gland is influenced not only by the volume of surgery but also by factors such as the integrity and thickness of the fibrous capsule of the adenoma and the presence of satellite nodules (satellites), which are located 0.5 to 0.85 cm from the fibrous capsule of the adenoma[12-14, 16], we recommend abandoning the extracapsular enucleation approach for removing pleomorphic adenomas.

As an alternative, we propose that in cases where the pleomorphic adenoma is located in the superficial lobe of the parotid gland and has a size of ≤2.5 cm, the tumor should be removed with a margin of 0.9 cm from the fibrous capsule into the "safe zone" with regard to the presence of satellite nodules.

Additionally, the analysis of archival data revealed the following pattern: postoperative follow-up should not have a time limit and should be conducted for life, with annual ultrasound examination of the parotid gland. Based on the analysis of all the above data, we developed a management algorithm for patients with primary tumor growth in the parotid gland, particularly pleomorphic adenoma (figure 6).

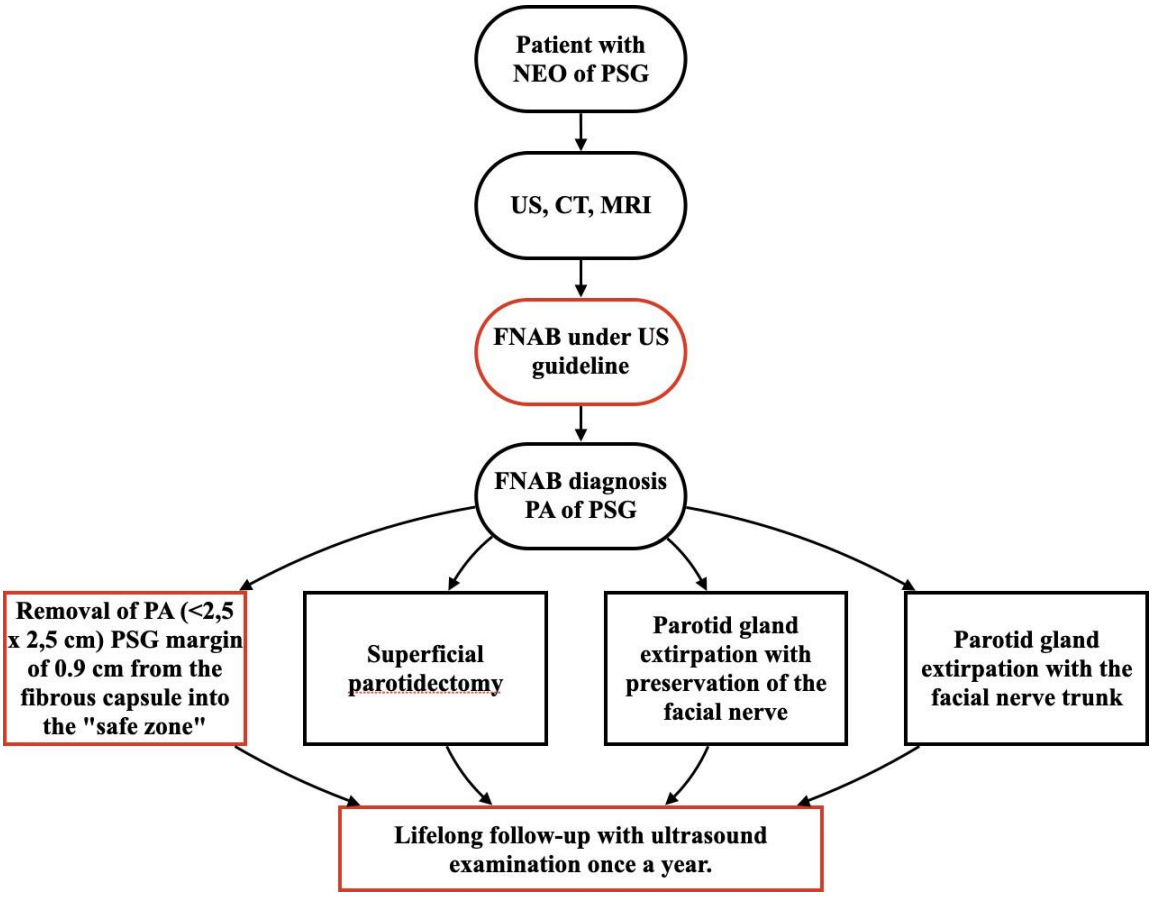


Figure 6. Algorithm for choosing the management and surgical treatment of patients with pleomorphic adenoma of the parotid gland.

DECLARATIONS

Conflicts of interest and financial disclosures: The authors declare that they have no conflicts of interest, and there was no external source of funding for this research.

Ethical approval: The study was approved by the Institutional Ethics Committee and was conducted in accordance with the Declaration of the World Medical Association.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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