How Reliable Is Sonography in the Assessment of Sialolithiasis?

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OBJECTIVE. The purpose of this study was to determine the value of sonography for the diagnosis of salivary gland calculi.

SUBJECTS AND METHODS. In this study, 82 salivary glands in 79 consecutively registered patients with acute or recurrent parotid or submandibular gland swelling were examined with 7.5-12 MHz linear probes. All sonographic examinations were performed by two experienced radiologists without knowledge of the final diagnosis. The reference standard was digital sialography and sialendoscopy with or without surgery for 54 salivary glands and digital sialography alone for 28 glands.

RESULTS. Sialolithiasis was present in 44 glands and was absent in 38 glands as confirmed by the final diagnosis. The overall sensitivity, specificity, accuracy, and positive and negative predictive values of sonography in the detection of calculi were 77%, 95%, 85%, 94%, and 78%, respectively. False-negative sonographic findings were associated with calculi with a diameter less than 3 mm in nondilated or dilated salivary ducts; most calculi with a diameter of 3 mm or greater were correctly identified. False-positive findings were caused by ductal stenosis with wall fibrosis, which was erroneously interpreted as lithiasis.

CONCLUSION. Because of its limited sensitivity and limited negative predictive value, sonography does not allow reliable exclusion of small salivary gland calculi. Therefore, further diagnostic investigations are recommended to detect calculi in patients with normal sonographic findings and suspected lithiasis.

Keywords: salivary glands, sialendoscopy, sialography, sialolithiasis, sonography

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Salivary calculi are a common cause of salivary gland swelling. They can occur in any of the major salivary glands and at almost any age [1–10]. Sialoliths cause symptoms resulting from obstruction of salivary flow. Sialoliths can either pass the papilla spontaneously or necessitate treatment, which is aimed at complete stone removal. If conservative measures fail, stone removal can be achieved by sialendoscopy, extracorporeal shock wave lithotripsy, percutaneous stone retrieval, or surgery [4, 11–20].

A variety of diagnostic tests are used to detect sialoliths [21–33]. These include radiographic sialography with iodinated contrast material, sonography, CT, MR sialography, cone-beam CT, and sialendoscopy [21–33]. Except for sonography and MR sialography, all of the these methods are invasive or require x-ray exposure. Because of its excellent delineation of the ductal system, many authors continue to consider radiographic sialography the reference standard for assessing pathologic conditions in the salivary ducts, including lithiasis [25, 29, 31]. Advantages of this technique include assessment of duct function as a response to a sialagogue and occasional therapeutic success of stone release after retrograde injection of contrast material. Limitations include use of ionizing radiation, dependence on the operator's technical skill for successful ductal cannulation, pain during and after the procedure, and the need to inject contrast material. Radiographic sialography also is contraindicated if the patient has acute salivary infection.

Detection of sialolithiasis with CT and cone-beam CT depends on the calcium content of the calculi. To our knowledge, there have been no reports of evaluation of the performance of these two imaging modalities against a reference standard in large series of cases [30, 32].

MR sialography is a noninvasive, nonirradiating alternative imaging technique of assessing ductal abnormalities without ionizing radiation or ductal cannulation. Although it has yielded promising results in the detection of sialolithiasis with reported sensitivities and specificities of 80–100% and 90–100% [28, 29, 33], MR sialography is not widely available.

Sialendoscopy performed with specially designed optic endoscopic devices requires local or general anesthesia, dilation of the ductal orifice with subsequent ductal cannulation, and flushing of the gland with saline solution for better visualization of the ductal system. It is not limited to diagnosis and may be used for treatment [11, 12, 19].

Because of its availability, lack of invasiveness, and low cost, sonography is widely used by both radiologists and clinicians to detect sialolithiasis and to monitor patients after treatment [7, 20, 21]. Nonetheless, robust scientific data concerning sensitivity, specificity, accuracy, and positive and negative predictive values based on comparison with a reference standard are limited, and the reported results are controversial, sensitivities varying between 71% and 94% [21, 25, 29].

The purpose of the current study was to evaluate the diagnostic performance of ultrasound in the detection of sialolithiasis by comparing the results of ultrasound studies against digital sialography with and without additional sialendoscopy and surgery, which was considered the reference standard.

Subjects and Methods

This study was approved by the institutional ethics committee and was performed in accordance with the guidelines of the Helsinki II declaration. Over a period of 2 years, 83 consecutively registered patients with acute or recurrent postprandial salivary gland swelling and colicky pain were referred from the department of otorhinolaryngology because of suspected salivary calculi. All patients underwent pretreatment imaging with ultrasound followed by digital sialography as part of a routine diagnostic evaluation. Sialendoscopy with or without subsequent surgery was additionally performed when indicated for therapy. Conventional sialography was technically not feasible for four patients because of failure to cannulate the orifice of the Wharton duct. These patients were excluded from the study. The other 79 patients (46 men, 33 women; mean age, 46 years; range, 18–82 years) formed the study group.

In the 79 patients a total of 82 symptomatic salivary glands were examined (38 parotid glands, 44 submandibular glands). The standards of reference for assessing sialolithiasis were as follows: digital x-ray sialography with iodinated contrast material and sialendoscopy with or without endoscopic stone removal in 50 salivary glands (61%); digital sialography, sialendoscopy, and surgery in four salivary glands (5%); digital sialography alone in 28 salivary glands (34%). The final diagnoses were based on the digital sialographic findings, as noted in the original radiologic reports, and all available endoscopic, laboratory, surgical and pathologic records.

Examination Techniques

The ultrasound examinations of the salivary glands, which took approximately 20 minutes per patient, were performed with linear probe, high-frequency 7.5-12 MHz transducer (Acuson/Siemens Sequoia 512, Siemens Healthcare) in at least two perpendicular planes. In addition to gray-scale imaging, color Doppler and power Doppler modes were equally used to help differentiate dilated ducts from blood vessels and to better assess gland parenchyma. Examination on both sides was performed routinely to allow comparison of the symptomatic and nonsymptomatic sides. In addition, whenever necessary to better visualize calculi near the orifice of the Wharton duct (major salivary duct draining the submandibular gland) or the Stensen duct (major salivary duct draining the parotid gland), pressure was applied from within the oral cavity while the duct was palpated during the sonographic examination. All sonographic examinations were performed before conventional sialography by two radiologists with 10 and 7 years of experience in head and neck ultrasound.

Digital sialography was performed with standard fluoroscopy equipment (Digital Spot Imaging Diagnost 96, Philips Healthcare) immediately after the sonographic examination. To stimulate salivation, lemon juice was administered before the procedure. Anteroposterior and lateral oblique radiographs were obtained to detect large radiopaque calculi. Sialography was then performed with appropriate dilators, sialographic cannulas (Manashil type), polyethylene connecting tubes, 5-mL syringes, and a low osmolarity, water-soluble contrast agent (ioxaglate 2000 Hexabrix, Guerbet) [26–28]. After identification and dilation of the ductal opening, a cannula was advanced and 1–2 mL of contrast material was injected by hand under fluoroscopic control. The syringe containing the water-soluble contrast material was connected to the sialographic cannula with a connecting tube. Before cannulation, the entire system was flushed with contrast material to remove possible air bubbles. Particular attention was paid to having an air-free cannulation system to avoid injection of air bubbles into the salivary system.

Anteroposterior and lateral oblique spot radiographs were obtained to document optimal ductal filling. After administration of fresh lemon, evacuation radiographs were obtained to document ductal emptying. The procedure was performed by two radiologists with 20 and 8 years' experience in radiographic sialography. The sonographic and radiographic sialographic studies were performed on the same day for all patients. The radiologists performing the radiographic sialography procedure were not aware of the results of the sonographic examination.

Whenever necessary, sialendoscopy for stone retrieval or ductal dilation was performed within 2 weeks of the radiographic sialography procedure by a head and neck surgeon with 6 years' experience in the procedure. Under local anesthesia or with anesthesia standby, sialendoscopy was performed with an optic endoscopic device, various dilators, and specific baskets for stone retrieval (miniature endoscopes for diagnostic and interventional sialendoscopy, [Storz Marchal Mini Sialendoscopy Microendoscope, Karl Storz]).

Diagnostic Interpretation Criteria

The sonographic diagnosis of calculi was made according to accepted criteria in the literature, that is, the presence of hyperechoic linear, oval, or round formations casting an acoustic shadow behind them [1, 21–25] in normal or dilated salivary ducts. In the presence of ductal dilatation caused by a hyperechoic formation without an obvious acoustic shadow, the diagnosis of an obstructing calculus was also made [3, 21–24]. The position of calculi along the salivary ducts from the ostium to peripheral and intraglandular ducts was assessed.

The diagnosis of calculi at digital sialography was made whenever an irregularly shaped, ovoid, or rounded filling defect was identified within the dilated or nondilated ductal system [21–24, 28].

At sialendoscopy, the presence or absence of salivary calculi, sludge, ductal narrowing, and ductal inflammation was assessed before endoscopic extraction of calculi whenever necessary. When the size of the calculi made extraction impossible by an endoscopic approach alone, a combined endoscopic and surgical approach was used.

Statistical Evaluation

The sonographic findings were compared with the final diagnoses determined at sialography or sialendoscopy with or without surgery. Sensitivity, specificity, positive and negative predictive values, and overall accuracy of sonography in the detection of sialolithiasis were calculated. The 95% CIs were calculated with GraphPad Quick Calc 2012 (GraphPad Software). Statistical analysis of sensitivities depending on the size of calculi was performed with a two-tailed Fisher exact test.

Results

At final diagnosis, 53 calculi were present in 44 salivary glands (33 submandibular glands, 11 parotid glands), and no calculus was found in 38 salivary glands. The diameter of the calculi was less than 3 mm in 10 glands (23%), 3

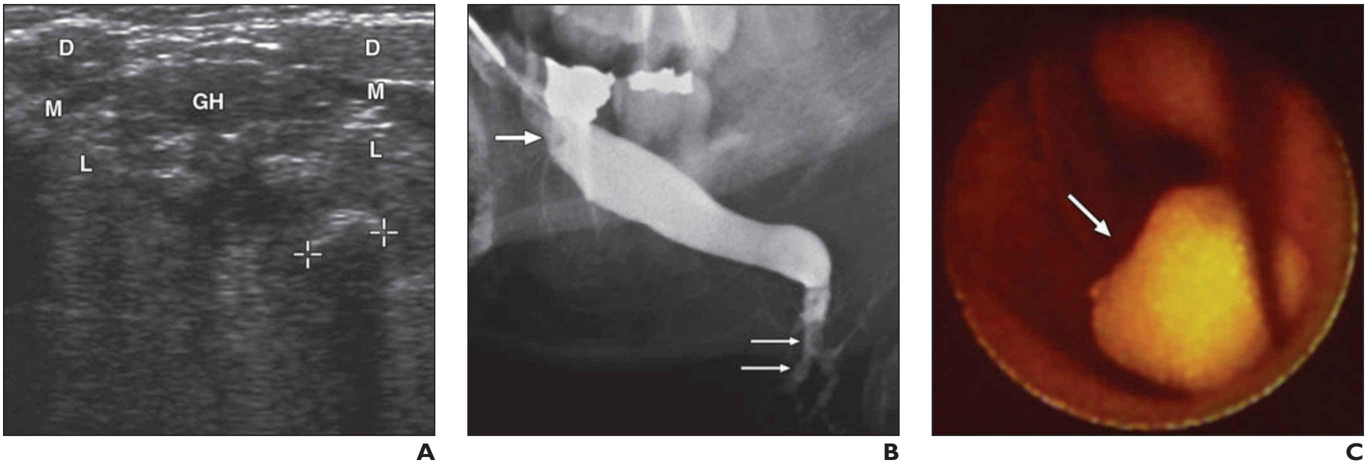

Fig. 1—26-year-old woman with recurrent submandibular gland swelling during mastication. True-positive ultrasound assessment for 4-mm large salivary calculus.
A, Coronal sonographic image of submandibular gland (view through floor of mouth) shows 4-mm calculus (*calipers*) within Wharton duct at level of floor of mouth near meatus. Calculus has rounded appearance and characteristic dorsal acoustic shadowing. Because image is in transverse plane, Wharton duct is not depicted in its entire length but only at level of obstructing calculus. D = anterior belly of digastric muscle, M = mylohyoid muscle, GH = geniohyoid muscle, L = sublingual glands.
B, Lateral oblique digital sialographic image shows major dilatation of Wharton duct and confirms diagnosis of distal sialolithiasis close to meatus (*large arrow*). Two additional small calculi (*small arrows*) in intraglandular branches were not seen at sonography.
C, Sialendoscopic image shows anteriorly located calculus (*arrow*). Two small calculi more distal in ductal system were found at conventional sialography (not shown). All calculi were retrieved endoscopically.

mm in nine glands (20%), greater than 3 mm but 6 mm or less in 18 glands (41%), and greater than 6 mm in seven glands (16%). A single calculus was present in 37 salivary glands, and multiple calculi were found in 7 of the 44 affected glands (16%). Three patients had simultaneous involvement of two major salivary glands (4%). Calculi were located in the major ducts in 29 glands (66%), and they were located in peripheral ducts in 15 glands (34%).

In this series, we did not perform stone-by-stone analysis because we believe that a gland-by-gland approach is clinically more relevant. Therefore, whenever a calculus was found within a salivary gland at sonography, the sonographic examination finding was considered true-positive for lithiasis. Results of sonography for the detection of sialolithiasis on a gland-by-gland basis included 34 true-positive (Figs. 1 and 2) and 36 true-negative assessments of lithiasis.

False-negative readings occurred in 10 glands and false-positive readings in two glands. Ten calculi in 10 glands were missed at ultrasound examinations. Nine of these calculi had a diameter less than 3 mm, and one had a diameter of 3 mm. The calculi with a diameter less than 3 mm were located within the Wharton duct at the level of the anterior floor of the mouth (close to the caruncle), at the posterior floor of the mouth (mylohyoid muscle border and submandibular gland hilum), or within the submandibular or parotid gland parenchyma (Fig. 3). They did not cast an acoustic shadow, and no ductal dilatation was visible on the sonographic images. The 3-mm stone missed at sonography was erroneously interpreted as a short stenotic area within the slightly dilated Stensen duct because no hyperechoic structure was seen within the ductal lumen. All 10 calculi missed at sonography were seen at digital sialography and sialendoscopy. They were retrieved endoscopically in nine cases, and in one case the 2-mm calculus was expelled spontaneously after a diagnostic conventional sialographic procedure.

False-positive assessments were rare in this study, resulting in a high specificity of sonography for the assessment of sialolithiasis. The only two false-positive sonographic assessments were caused by stenoses of the Stensen duct with major fibrosis in longstanding sialodochitis. These lesions were erroneously interpreted to be lithiasis (Fig. 4).

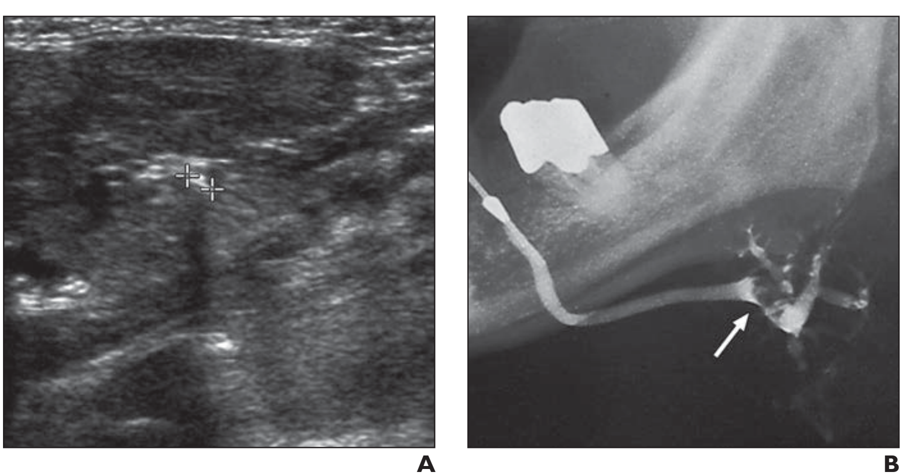

Fig. 2—60-year-old man with intermittent submandibular gland swelling after meals. True-positive sonographic findings of 2.3-mm large salivary calculus.
A, Sonographic image of submandibular gland (submental lateral oblique view) shows 2.3-mm-long calculus (*calipers*) within submandibular gland parenchyma at posterior floor of mouth. There is no dilatation of Wharton duct. Meatus (not visible on this sagittal oblique image) is located on right side of image. Calculus is therefore located 4–5 cm from meatus.
B, Lateral oblique digital sialographic image confirms diagnosis of sialolithiasis (*arrow*). Calculus is located at same level as on sonographic image. Patient underwent sialendoscopy, and 2.3 mm calculus was retrieved endoscopically.

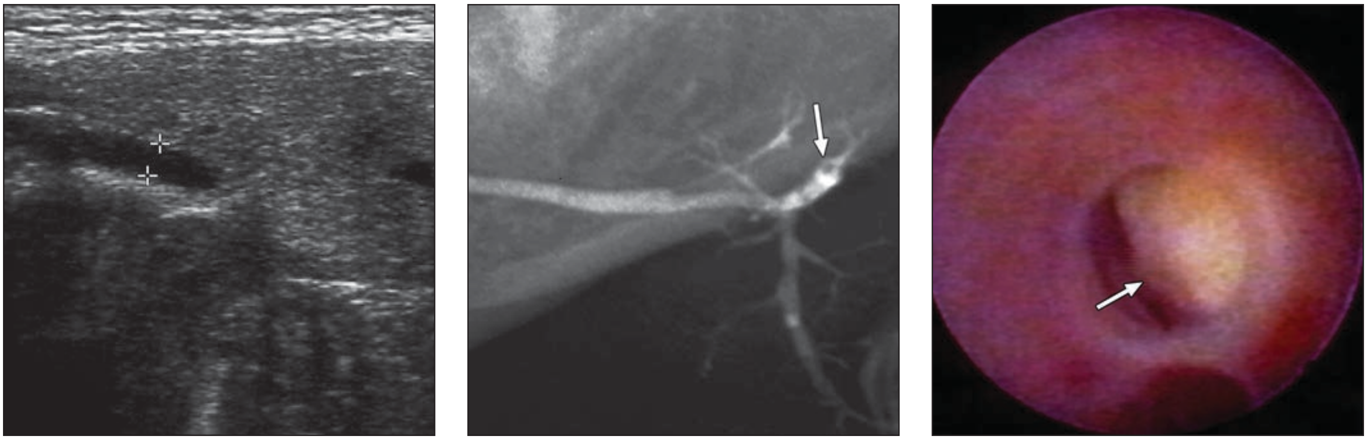

Fig. 3—45-year-old woman with recurrent submandibular gland swelling during mastication. False-negative sonographic findings despite presence of 2-mm large calculus.
A, Submental lateral oblique sonographic image of submandibular gland shows normal findings. There is no dilatation of ductal system, nor were any calculi seen within gland parenchyma. Calipers indicate mylohyoid muscle.
B, Conventional sialographic image (lateral oblique view) shows 2-mm calculus (*arrow*) in intraglandular branches. Size of ducts proximal to calculus is normal.
C, Sialendoscopic image obtained after digital sialography confirms presence of 2-mm distal calculus (*arrow*), which was retrieved endoscopically.

The overall sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of sonography in the detection of lithiasis were 77% (CI, 63–87), 95% (CI, 82–99), 94% (CI, 81–99), 78% (64–87), and 85% (76–92), respectively.

The sensitivity of sonography for the detection of sialolithiasis depended on the diameter of calculi. Sonography depicted calculi in one of 10 salivary glands with calculi smaller than 3 mm (sensitivity, 10%) and in 33 of 34 glands with calculi 3 mm or larger (sensitivity, 97%). The gland-by-gland statistical analysis with the two-tailed Fisher exact test showed that the sensitivity of sonography in the detection of calculi 3 mm and larger was significantly higher than for calculi smaller than 3 mm ($p = 0.0039$).

Discrepancy regarding the exact location of a calculus as assessed with sonography and digital sialography was noted in 11 cases and was caused by displacement of an anteriorly placed ductal stone into a posterior location after active filling of the ductal system with contrast material during digital radiographic sialography. In the seven patients with multiple salivary gland calculi, sonography enabled depiction of the correct number of calculi in only three cases. Four calculi were missed in the other four patients with multiple calculi.

Discussion

Sialolithiasis is defined as the presence of one or more calculi within the salivary glands. It mainly affects adults, and it appears to have no relation to the formation of calculi in the biliary tree or the kidney [6–9]. There is no correlation between water hardness and the formation of salivary gland calculi [5]; however, tobacco consumption, the use of diuretics, and the presence of primary hyperparathyroidism may be predisposing factors in sialolithiasis [9, 10].

Submandibular glands appear to be affected more often than parotid glands because of differences in the salivary secretions. Submandibular secretion is more viscous, whereas parotid secretion is more serous [1–4]. Although salivary gland calculi are usually solitary, multiple stones are not exceptional [12–14]. In our series, calculi were multiple in 7 of the 44 affected glands, and three patients had simultaneous involvement of two major salivary glands.

Because of obstruction of salivary flow by a calculus, secondary infection with subsequent duct strictures may eventually occur, leading to progressive parenchymal inflammation, atrophy, and fibrosis. For years, the traditional treatment of salivary stones has been surgical intraoral extraction, usually with meatotomy, whereas recurrent postobstructive sialadenitis was usually treated with sialadenectomy [4, 12–16]. Sialadenectomy performed for sialolithiasis and sialadenitis has a complication rate of 35% [15]. These complications include facial and mandibular nerve paralysis, lingual nerve deficit, scarring, and reduced salivation [15, 16]. Submandibular glands removed for sialolithiasis appear to be affected by fibrosis and atrophy in only 41% of cases; the other 59% of glands may be normal histologically or may have only minor inflammation [13].

Several minimally invasive, organ-preserving techniques such as extracorporeal sialolithotripsy and percutaneous and endoscopic stone removal have been developed to treat sialolithiasis [11–20]. The smaller the diameter of calculi, the higher is the success rate of these techniques, in particular of sialendoscopy [11, 12, 14]. Therefore, current treatment strategies emphasize the need to diagnose salivary gland calculi in early stages of the disease, when they have not caused major parenchymal damage and fibrosis and when endoscopic or percutaneous retrieval is easier [19, 20].

Ultrasound is widely used as a first-line examination to assess the presence or absence of salivary gland calculi [18, 21–23, 25] because it is noninvasive and readily available at low cost. Moreover, there is no radiation exposure with sonography. However, reported data concerning its sensitivity, specificity, accuracy, and positive and negative predictive values based on comparison with a standard of reference are very scarce [21, 25, 29]. In addition, the few reported data on the performance of sonography for the detection of sialolithiasis are controversial. In a review article on sonography of the major salivary glands, Gritzmann [21] reported a sensitivity of 94% but did not report the size of the calculi detected with sonography. In contrast, Diedrich et al. [25] reported a sensitivity of only 71%, and on the basis of results in a series of 20 patients with suspected submandibular gland lithiasis, Jäger et al. [29] reported a sensitivity of 80%. In our series, the overall sensitivity of sonography was lower than that

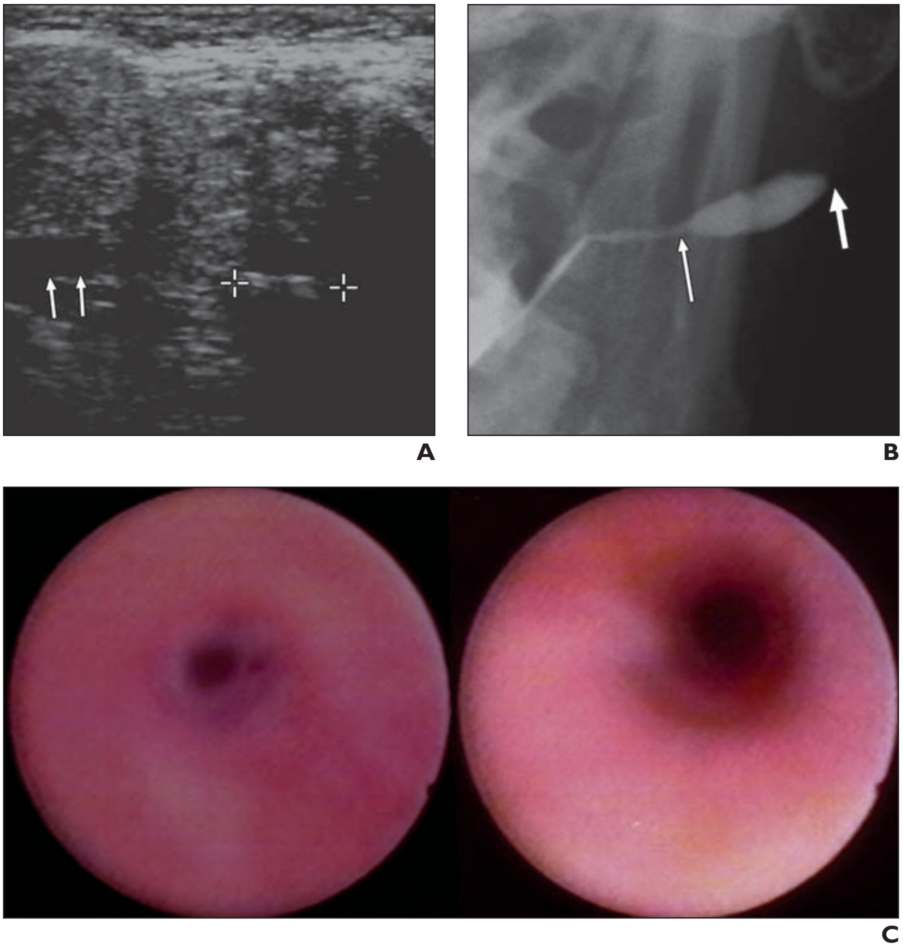

Fig. 4—35-year-old old woman with recurrent parotid gland swelling during mastication and false-positive sonographic findings of lithiasis.
A, Axial oblique sonographic image of parotid gland (parallel to hard palate) shows dilatation of Stensen duct (*arrows*). Portion overlying masseter muscle shows hyperechoic area (*calipers*) with acoustic shadow. Although this hyperechoic area does not have typical curvilinear appearance of larger calculi, it was interpreted as calculus.
B, Anteroposterior conventional sialographic image shows stenotic distal duct (*thin arrow*) close to ostium. More proximal ductal dilatation is evident between thin and thick arrows. This portion of dilated duct is depicted in **A.**
C, Sialendoscopy after digital sialography confirmed presence of two tight stenoses of Stensen duct with extensive wall fibrosis: distal stenosis closer to meatus corresponding to thin arrow in **B** and proximal short stenotic area corresponding to thick arrow in **B.** No calculus was present. Sialendoscopic images show Stensen duct at level of distal stenosis close to ostium before dilation (*left*) and after successful endoscopic balloon dilation (*right*). Hyperechoic area with acoustic shadowing in **A** corresponds to stenotic ductal wall and is most probably caused by duct wall fibrosis.

reported by Gritzmann and similar to that reported by Jäger et al., that is, 77%.

The results in our series clearly show that the sensitivity of sonography for the detection of sialolithiasis mainly depends on the size of the calculi. In our series, in 19 glands (43%), calculi had a diameter of 3 mm or less. In 10 of 19 (53%) of these glands, calculi were missed at sonography because they did not produce a dorsal acoustic shadow or because they were not hyperechoic with regard to surrounding structures. As some authors suggest [21–24], the lack of a dorsal acoustic shadow may depend not only on the size but also on the chemical composition of calculi. In our series, all calculi with a diameter greater than 3 mm and most calculi with a diameter of 3 mm were correctly diagnosed at sonography. Our findings may explain the discrepant results in the literature. In series with a large percentage of calculi with a diameter of 3 mm or greater, the sensitivity of sonography approaches 100%. However, when the number of calculi with a diameter less than 3 mm is large, the corresponding sensitivity of sonography decreases. The size of the calculi may therefore be a determining factor for the performance of sonography to detect calculi.

The reported specificity of sonography in the literature also varies dramatically. Whereas Gritzmann [21] reported a specificity of 97%, Jäger et al. [29] reported a specificity of only 80%. As suggested by several authors [1–3, 21–23], stenoses, phleboliths, arterial vascular calcifications, and calcified lymph nodes may mimic salivary gland calculi and cause false-positive assessments. The specificity of sonography in our study was 95%. The only two false-positive assessments were caused by ductal stenoses with wall fibrosis mimicking calculi. These stenoses were easily identified at sialography and sialendoscopy (Fig. 4).

A different problem encountered with sonography in our study was difficulty correctly assessing the precise number of calculi in patients with multiple calculi. This was mainly due to nonvisualization of small distal calculi in dilated ducts. Pretreatment assessment of the location of calculi in the ductal system and whether a single calculus or multiple calculi are present may, however, play a role in planning endoscopic procedures (duration of the procedure, local vs general anesthesia).

In summary, the results of our study indicate that when signs of sialolithiasis are found at sonographic examination, a calculus is probably present, as reflected by the high positive predictive value (94%). However, in a patient with suspected sialolithiasis, normal sonographic findings do not appear sufficiently reliable for excluding small calculi, because the negative predictive value of sonography is only 78%. Therefore, at our institution, this subset of patients with normal findings at sonographic examination usually undergo an additional diagnostic study. We prefer conventional sialography or MR sialography if the degree of suspicion is low and interventional sialendoscopy if the degree of suspicion is high.

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