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EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY OF SUBMANDIBULAR STONES: EVALUATION AFTER 10 YEARS

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The use of extracorporeal shock waves in the treatment of submandibular stones is a minimally invasive approach for the treatment of this disease. Its clinical significance has been determined in a long-term retrospective study, performed as follow-up to the short-term results. From 1989 to 1994, 197 patients (88 female, 109 male; age range, 8 to 83 years) with symptomatic, sonographically detectable concretions of the submandibular gland were treated with extracorporeal shock wave lithotripsy. The review analysis was completed retrospectively in 2002 and included 191 patients with complete data. The period under review ranged from 8 to 13 years, with an average of 10.5 years. Altogether, 67 of the 191 patients (35%) either were free of stones or had no more symptoms from the residual sialoliths. Another 15% had a significant improvement in their symptoms and required no further therapy. The remaining 95 patients (50%) had residual stones; they had no symptoms in the short review period, but have had symptoms since. The therapeutic success was not influenced by the stone size, but rather by the stone location within the gland. After therapy, no severe side effects were identified. Extracorporeal shock wave lithotripsy is a possible treatment for stones in the submandibular gland. In combination with other gland-preserving methods, it now forms part of a multitherapeutic approach that renders submandibulectomy unnecessary in the majority of cases.

KEY WORDS — lithotripsy, salivary gland, shock wave, sialolithiasis, ultrasonography.

INTRODUCTION

Stones are estimated to occur within the major salivary glands in approximately 1.2% of the human population, and symptoms go on to develop in about 59 of every million people.[1,2] If a stone blocks the secretory duct of a salivary gland, it will cause saliva congestion in combination with a painful sialadenitis.[3] Of the stones formed in the major salivary glands, 80% occur in the submandibular gland and only 20% in the parotid gland.[4] This difference in lithogenesis is attributed to anatomic factors and to the differences in saliva composition between these two glands.[5,6] If it proves impossible to wash out the concretion by stimulating salivation through doses of sialagogues in combination with gland massage and, if necessary, duct bougienage, the remaining therapeutic methods include transoral removal,[7] endoscopic[8,9] or radiologically controlled[10] removal, extracorporeal shock wave lithotripsy (ESWL),[11] or the extirpation of the affected gland.

In 1989, we reported on the first successful use of ESWL therapy of a sialolith[11]; reports from other authors followed.[12-21] So far, however, there have been no long-term evaluations of a large survey of patients. In this study, we report on our findings concerning the application of ESWL to 197 patients; each had a single stone in the submandibular gland. We discuss the results of ESWL in association with other newly developed techniques of stone removal and propose guidelines for gland-preserving methods.

PATIENTS AND METHODS

Patients. Between January 1990 and March 1995, 451 patients with a sialolith in the submandibular duct were seen at the Department of Otorhinolaryngology–Head and Neck Surgery at the University of Erlangen-Nuremberg. After the patient's history was recorded and a clinical examination was performed, a sonogram of the affected gland was obtained (Sonoline SI 450, Siemens, Erlangen, Germany). Extracorporeal shock wave lithotripsy was applied according to defined criteria of inclusion and exclusion (Table 1). The need for repeated ESWL was indicated by

TABLE 1. INCLUSION AND EXCLUSION CRITERIA FOR EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY

Criteria for Inclusion	*Criteria for Exclusion*
Symptomatic disease	Impaired blood coagulation
At least 1 episode of purulent sialadenitis	Cervical spine problems with respect to posture during therapy
No recovery after 3 months of conservative therapy	At least 3 stones or size >12 mm
Exact sonographic location of concretions; 1 or 2 sialoliths	

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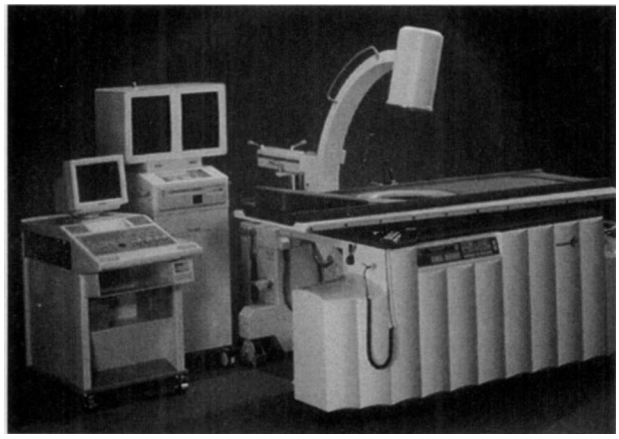

Fig 1. Piezolith 2500 piezoelectric lithotripter (R. Wolf Company, Knittlingen, Germany) with integrated ultrasonography for locating stones during therapy. Shock waves originate from piezoelectric elements at bottom of water-filled basin. Self-focusing elliptic device with integrated ultrasound scanner leads shock wave through water and latex membrane directly into focus zone of 5 × 5 × 15 mm.

lasting symptomatic disease.

Forty-seven of the 451 patients (10.4%) were free of symptoms and stones after 3 months of conservative therapy (gland massage, duct bougienage, sialagogues), so no further measures were required. Another 161 patients (36%) were treated by transoral removal of the stones. Thirteen patients (3%) took part in a study concerning laser lithotripsy of submandibular stones, and in 19 patients (4%) submandibulectomy was primarily performed because they did not fulfill the criteria in Table 1 (mainly because of multiple stones). Twelve patients (3%) had undergone 1 session of ESWL but were no longer available for the study after submandibulectomy was carried out elsewhere. One hundred ninety-seven of the 451 patients (44%) with stones of the submandibular gland fulfilled the criteria and were treated with ESWL.

The ages of the 197 patients in this study (88 female, 109 male) ranged from 8 to 83 years (average, 39 years). The duration of complaints at the time of the first appearance at the department was 23 months. The stones' diameters as detected by ultrasonography ranged from 3.5 to 12.0 mm (mean, 7.2 mm). We found 11% of the sialoliths in the distal part of Wharton's duct, 84% in the hilar region, and 5% in the intraparenchymatous duct system.

Shock Wave Generator. For shock wave generation, we used the piezoelectric lithotripter Piezolith 2500 (R. Wolf Company, Knittlingen, Germany; Fig 1). The technical data have already been published in the course of a first clinical trial.[13]

Treatment. Before and 1 and 24 hours after ESWL, B-mode sonography of the affected gland was carried out (Fig 2). Before and after treatment, all patients were also submitted to a pure tone audiogram in order to detect possible hearing damage caused by the therapy. No medication was administered before the application of shock waves.

The shock waves were applied without any sedation or analgesia. After ultrasonographic detection of the stone with the integrated B-mode scanner (7.5 MHz) of the lithotripter, a maximum of 3,000 shock waves were applied (frequency, 2.5 Hz; change in intensity depending on the patients' conditions; maximum focus pressure, 80 MPa). The treatment was terminated prematurely if the stone could no longer be located ultrasonographically or if increasing discomfort of the patient seemed to prevent an orderly application of shock waves.

All patients were first subjected to ESWL and then to auxiliary measures (gland massage for steady sali-

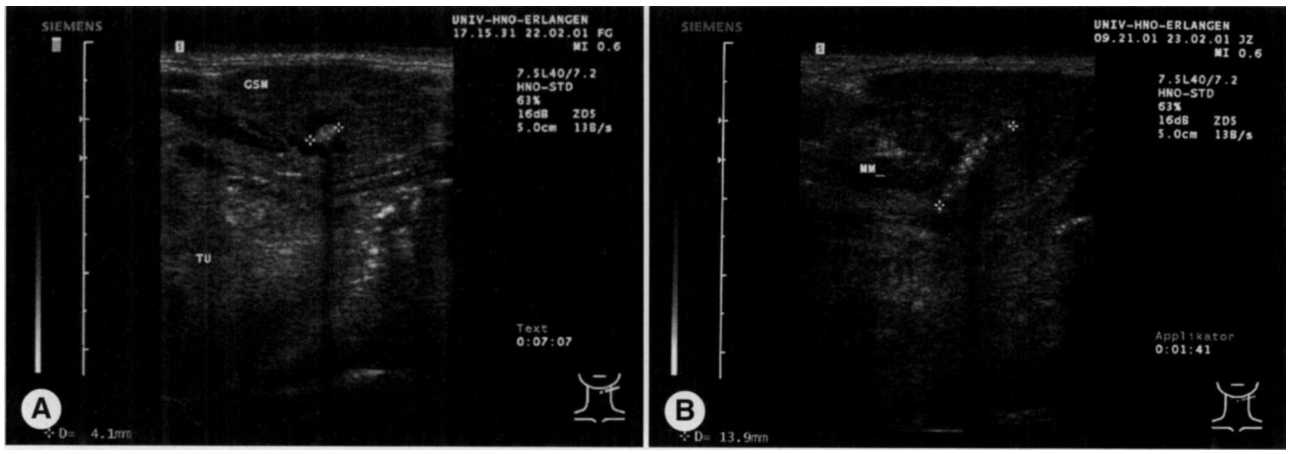

Fig 2. Ultrasonography. **A)** Stone (asterisks) within hilus of right submandibular gland (GSM) before extracorporeal shock wave lithotripsy. TU — tongue. **B)** Majority of patients show fragmentation of stone after extracorporeal shock wave lithotripsy. Fragments (asterisks) are located within main ducts and distributed along intraparenchymatous parts of salivary ducts. Fragments can be washed out completely or may stay inside duct for long period without causing problems. MM — mylohyoid muscle.

TABLE 2. SHORT-TERM RESULTS OF ESWL IN 197 PATIENTS WITH CONCRETIONS OF SUBMANDIBULAR GLAND

ESWL	*Free of Stones and Symptoms*	*Free of Symptoms; Residual Concretions*	*Residual Fragments; Improvement of Complaints*	*No Change in Symptoms*
First (n = 197)	44	111	33	6
Second (n = 42)	12	22	7	1
Third (n = 8)	2	6		
Total	58	139		

ESWL — extracorporeal shock wave lithotripsy.

vation, duct bougienage, Dormia basket extraction of stone fragments). We also administered an antibiotic agent (roxithromycin) and an antiphlogistic agent (diclofenac sodium) on the day of the treatment and 2 days thereafter.

If symptoms persisted after the first session, a second and third session were carried out 3 and 6 months, respectively, after the first session. Each patient had a maximum of 3 sessions.

Regular examinations took place 3 months and 1 year after the final ESWL session. After this period, the patients were asked to contact the clinic again if problems occurred. From 2000 to 2002 in a retrospective trial, all patients were contacted again and examined in the hospital or were given a detailed questionnaire.

RESULTS

Altogether, 197 patients underwent 259 ESWL treatments (Table 2). After termination of the treatment, 58 patients (29%) were free of stones. One hundred thirty-nine patients (71%) had ultrasonographically detectable residual concretions, but none of them reported any complaint in successive follow-up examinations (Fig 2B). The most acute effect of the therapy was that patients felt a slight shooting pain on the skin surface above the salivary gland treated. This discomfort was considered minor by the patients.

None of the patients had clinically detectable impairment of the facial nerve or the lingual nerve. In 55% of the cases, minor bleeding from the submandibular duct and/or easily reversible petechial bleeding occurred without permanent consequences. Damage to teeth or tooth fillings was not detected.

In 65% of all patients, a slight swelling of the gland, lasting at most 24 hours, developed immediately after ESWL therapy. In 4 cases, severe bacterial sialadenitis developed after the therapy and was controlled with intravenously administered antibiotics (ampicillin sodium–sulbactam sodium).

TABLE 3. LONG-TERM RESULTS OF ESWL

	Patients (n = 191)	
	No.	*%*
Successful ESWL	96	50.3
Without stones and/or without complaints	67	35.1
Significantly improved complaints; no treatment necessary	29	15.2
Unsuccessful ESWL	95	48.7
Further treatment necessary	23	12.0
Further treatment with transoral resection or submandibulectomy	72	37.7

Audiometric measurements did not support any case of hearing loss due to therapy.

Short-Term Results (1 Year). After the first treatment, 44 of the patients (21%) were free of stones, and 111 (53%) were free of discomfort but had residual stones. Forty-two patients underwent a second ESWL treatment, and 8 patients a third. After the second and third ESWL treatments, respectively, another 28% and 25% were free of stones, and 50% and 75% were free of complaints. The data and the results of ESWL of submandibular stones within the first year after treatment are listed in Table 2.

If the aim of the treatment is defined as "living without stones," the success rate was 28%, and if it is defined as "living without symptoms," it was 92%. Neither the result "free of stones" nor the persistence of discomfort or complaints was influenced by the stone size (Table 3). The location of the stone within the submandibular duct, however, did influence the results. Distally located stones were more easily dealt with — 40% free of stones and 60% free of symptoms — than were stones of the hilus or the intraglandular parts of the duct system.

Long-Term Results (7 to 12 Years). In this follow-up examination, complete data were obtained for 191 patients. The records of 6 patients who were free of symptoms but who had residual concretions were unobtainable and were considered lost to follow-up. Sixty-seven patients (35%) were free of concretions, and another 29 (15%) had residual concretions confirmed; they suffered from a sometimes slight, painless swelling of the gland, but felt no need for further therapy even though they were informed of possible risks of infection. During the years, the same symptoms as were present before lithotripsy had developed in 23 patients (13%), but they did not have any other medical investigation until they were contacted again for the study. Because of the reappearance of symptoms, 72 patients (38%) were treated either with sub-

mandibulectomy or with transoral removal of the stones.

In comparison to the immediate results, 50% of the patients with residual concretions but no discomfort did in fact require therapy again after the long-term follow-up examination.

DISCUSSION

The introduction and establishment of the treatment of sialoliths with ESWL in 1989 fundamentally changed the guidelines for sialolith treatment. This is particularly the case with respect to parotid stones, as the incidence of parotidectomy due to sialolithiasis has decreased to less than 5%.[22]

Although the number of shock waves required for total destruction was determined to be dependent on stone size in in vitro studies,[23] our initial clinical experience,[13] in accordance with the findings of other authors,[14] did not reveal a connection between stone size, the number of shock waves, and the rate of patients' being free of stones. Considering this and our experimental results, the number of shock waves we selected per treatment ranged from 2,500 to at most 3,000, irrespective of stone size. Other authors chose between 1,300 and 7,500 shock waves per treatment.[14,17,19] In contrast to other groups,[12,17] after a first clinical trial[13] our aim of treatment in the case of submandibular stones was to, at the very least, fully relieve patients of their symptoms in no more than 3 repeated treatments.

Although as a rule the application of ESWL can be carried out without the administration of sedatives or analgesia, and therefore as an outpatient treatment, we do not recommend more than 3 treatments; on this point we agree with other authors.[14] In other reports, the electromagnetic system Minilith (Storz Medical, Kreuzlingen, Switzerland) is used for as many as 5 sessions. However, this system has a lower pressure within the focus volume.[17,19] Even at the onset of ESWL application, the effects on submandibular stones were significantly different from those on parotid stones.[22] All in all, it is not easy to compare the different results because of the use of different shock wave generators, various numbers and intensities of shock waves, various stone sizes, and different numbers of stones per patient.

From 1992 to 2002, several studies with a short-term review of either piezoelectric or electromagnetic lithotripsy of submandibular stones have been produced; 14% to 63% of the patients were free of stones. If the criterion for successful treatment is defined as patients' being free of stones and/or discomfort, as in our study group, between 56% and 97% of the patients reached this goal.[12-21]

Even though not all of our patients underwent second and third treatments, we can conclude that the short-term results are comparable to those levels and especially to our own previous study[11] with a smaller group of patients who underwent 3 successive sessions of ESWL. Therefore, we conclude that just 1 session of ESWL could be sufficient for treatment.

In principle, every sialolith can be fragmented by means of extracorporeal shock waves, whatever its mineralogical composition. This was proved by in vitro analyses.[23] This clinical study also showed signs of concretion disintegration after every treatment. Whether, however, the fragmented stone pieces can be detached by means of ESWL and washed out through the secretory duct obviously depends on how firmly the stone is embedded in the secretory duct system, possibly as a consequence of past inflammatory events. Thus, in our opinion, the rate of patients' being free of stones after treatment is in correlation with the surrounding structure of the respective stones, rather than with the composition of the sialoliths themselves. The studies of other authors have also failed to establish a proven connection between stone size and results after ESWL treatment. This, however, is only valid for a stone size of up to approximately 12 mm in diameter. For stones of a greater size, elimination is only possible in special cases.[17]

The assumption that the percentage of patients who are free of stones is essentially influenced by the relationship between the stone and its surrounding structures would also explain why the success rate of ESWL treatment of stones in the submandibular gland is considerably lower than that of parotid stones.[15-18] The ascending course of the secretory duct and the more viscous (seromucous) saliva of the submandibular gland are more likely to promote the "impacting" of a concretion in the secretory duct system. Moreover, the extent to which a stone is impacted is nowadays clearly discernible when the salivascope is used for diagnostic or therapeutic measures.[8]

In this context, one aspect deserves special attention. In none of our patients who became free of stones by means of ESWL therapy was a recurrent concretion diagnosed during the follow-up period of up to 13 years. This is quite remarkable, because ESWL therapy is not aimed at the cause of the stone disorder, ie, the dyschylia, but only at the resulting concretion and symptoms. Because of the short follow-up periods, there are no reports available on that subject written by other authors.

Being free of stones can be considered as a sole and lasting criterion for successful therapy. Presum-

ably, the lack of symptoms despite identifiable residual concretions will only last for a defined period of time. It is certain that a lack of complaints from residual concretions after lithotripsy results from the fact that the saliva forces a course through the fragmented stone pieces to the ostium. During the follow-up period, about half of our symptom-free patients with residual sialoliths developed a recurrence of symptoms. This observation has not yet been reported by other authors. To date, one cannot predict exactly when symptoms will appear again. From our point of view, this reflects exactly what we know from the patient's history before treatment: the time period from the beginning of the stone's development until the occurrence of the first symptoms may last from months to years.[24]

Nevertheless, taking into account the long-term results of our patients, who form the largest group ever reviewed of those who have undergone ESWL, 35% are apparently free of stones, and another 15% have minor symptoms. Within a mean follow-up period of 10 years, about 50% of the patients were treated successfully, as compared to 93% of patients with parotid sialoliths.[22]

To summarize the significance of ESWL in the treatment of submandibular stones in long-term follow-up, we believe that it can lead to complete recovery in about one third of all patients, that another third will remain symptom-free for years, and that a third will gain at most short-term relief of their symptoms.

This application of ESWL has had a great impact on improving other methods of organ-preserving therapy. Beginning in 1994, we had already used it in the extended transoral removal of submandibular stones with success rates greater than 90%, even in cases with hilar or parenchymal location of the stones.[7] Other techniques, such as ultrasonographically or radiologically controlled basket extraction[10] and endoscopically controlled stone removal,[8,9] have also been gradually developed.

If intensive conservative measures such as duct bougienage, gland massage, and sialagogues have failed to eliminate the stone, the following methods, depending on stone size and location, have proven practical in cases of submandibular lithiasis. 1) Sialoliths in the distal section of the secretory duct, independent of size, should be removed by the duct-slitting method. This also applies to all stones that are further proximal within the hilus or intraparenchymatous duct system and are transorally palpable. 2) Stones as large as 8 mm in diameter that are not palpable transorally and are within the hilus or intraparenchymatous duct system are suitable for ESWL. 3) Submandibulectomy is recommended in cases of intraglandular stones greater than 8 mm in diameter, in cases with evidence of more than 2 stones, or when ESWL or transoral removal has been unsuccessful.

CONCLUSIONS

Extracorporeal shock wave lithotripsy currently forms an integral part of organ-preserving therapy in treating submandibular stones. When conservative therapies such as gland massage or duct bougienage fail, we consider it to be the therapy of choice for small stones located within the hilus or more proximal in the intraparenchymatous duct system. The use of this noninvasive strategy that may include ESWL has made submandibulectomy necessary in less than 5% of all cases of sialolithiasis. The salivary gland function can completely recover after stone removal, and the rate of stone recurrence is less than 5%.[7,25,26]

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