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#### Original article

## Frequency of Complications and Usefulness of the Minor Salivary Gland Biopsy<sup>☆</sup>

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#### ABSTRACT

Findings of specific antibodies and histopathology data are essential for the diagnosis of Sjögren syndrome (SS). Although the minor salivary gland biopsy (MSGB) is technically simple, it needs to be performed in a medical institution to avoid complications.

Objective: To determine the frequency of complications and the usefulness of this technique.

*Materials and methods*: Patients who underwent a minor salivary gland biopsy for a possible diagnosis of SS at Rivadavia Hospital between October 2007 and May 2010 where included. The patients were seen a week and a month after the procedure for follow-up.

*Results*: Frequency of acute complications (n=186): 15 patients; 8.1%, 95% CI: 4.7–13.2 (Bleeding 7.5%, syncope 3.2%, hematoma 2.7%. No accidents occurred). Medium term complications (n=164): 16 patients: 9.75%, 95% CI: 5.9–15.6 (pain 7.32%, inflammation 3.66%, sensitivity disorders 3.05%, granuloma 1.22%). No infections or suture dehiscence occurred. Microscopic results: 154 biopsy reports were received: glandular 90.9%, 95% CI: 85–95 (typical, sialadenitis, grade III and IV infiltration).

Conclusions: MSGB has very low frequency of medium term and acute complications and it has high usefulness.

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#### Frecuencia de complicaciones y rédito de la biopsia de glándula salival menor

RESUMEN

El hallazgo de anticuerpos específicos y datos histopatológicos son indispensables para llegar al diagnóstico de síndrome de Sjögren (SS). La biopsia de glándulas salivales menores (BGSM), si bien es un procedimiento sencillo, debe ser realizada en una institución a fin de evitar complicaciones.

Objetivo: Estimar la frecuencia de complicaciones mediatas e inmediatas y el rédito de la técnica.

*Materiales y métodos:* Se incluyeron los pacientes derivados al Hospital Rivadavia para realización de biopsia, entre octubre del 2007 y mayo del 2010. Los pacientes fueron citados a la semana y al mes del procedimiento para control de la lesión.

Resultados: Frecuencia de complicaciones inmediatas (n = 186): 15 pacientes: 8,1%, IC del 95%, 4,7–13,2 (sangrado 7,5%, lipotimia 3,2%, hematomas 2,7%; no hubo accidentes). Complicaciones mediatas (n = 164): 16 pacientes: 9,75%, IC del 95%, 5,9–15,6 (dolor 7,32%, signos inflamatorios 3,66%, trastornos de sensibilidad 3,05%, granuloma 1,22%). No hubo casos de infecciones, ni dehiscencia del punto de sutura. Rédito microscópico: total 154 biopsias: se obtuvo tejido glandular en el 90,9%, IC del 95%, 85–95 (típica, sialoadenitis, infiltrado grado III y IV).

Conclusiones: La BGSM presenta una baja frecuencia de complicaciones mediatas e inmediatas y un alto rédito en el estudio anatomo-patológico.

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#### Introduction

Sjögren's syndrome (SS) is a chronic systemic disease of autoimmune origin of the exocrine glands, manifested by symptoms that result from hyposecretion. SS may occur alone (primary SS [pSS]) or associated with other autoimmune diseases (secondary SS).<sup>1</sup>

The histopathology of the salivary glands as a part of diagnosis was proposed first in 1970 by Waterhouse, Chisholm, and Mason, the latter established a score based on inflammatory<sup>2</sup> cell aggregates.

According to the European-American<sup>3</sup> criteria for diagnosis of pSS, the presence of a SGB compatible with the disease and/or the presence of antibodies anti-Ro/anti-La is needed. The MSGB is also a method for diagnosing diseases such as infiltrative amiloidosis<sup>4</sup> and sarcoidosis.<sup>5</sup>

Numerous surgical techniques have been described. They vary according to size from 1.5 mm to 30 mm, the shape of the incision (elliptical, horizontal, vertical, and wedge), and localization. While this is an invasive procedure, it is easy to perform and has a low frequency complications. 7

Caporali et al. described transient adverse effects in 64 (12.7%) cases in their series of 502 procedures: paresthesias (57), hematoma (8), local swelling (27), and others (5).8 In other studies sensory disturbances (anesthesia, paresthesia) are described as the complications encountered with greater frequency, being transient in most cases. However, other authors have reported no complications.6

As for the sample collected, 99% is needed to be considered as the material is useful for study.<sup>8</sup>

Despite the simplicity of the technique, MSGB is not incorporated in daily practice in all centers. Although other authors have reported complication rates of the different techniques and usefulness of the procedure, we consider important to evaluate the safety and yield (obtaining suitable material for pathology) of the method in our center.

In this paper we estimate the percentage of mediate and immediate complications of MSGB and frequency of obtaining suitable material for pathology.

#### **Material and Methods**

We designed a prospective, observational, descriptive, and longitudinal study.

We included patients referred with suspected SS and who underwent MSGB. Patients should have no evidence of coagulation disorders and a platelet count within normal within 1 month before the procedure.

Exclusion criteria were: use of aspirin or other NSAIDs 1 week before the study, clinical signs of local infection, patients on anti-coagulants, and those who refused inclusion in the protocol.

The study was approved by the Ethics Committee of the hospital. All patients signed an informed consent.

We prospectively studied MSGB conducted between October 2007 and May 2010, at the Rheumatology Service of Hospital Bernardino Rivadavia City of Buenos Aires, Argentina.

All patients underwent minor salivary gland biopsy with the surgical technique described by Caporali et al.<sup>8</sup>

The material obtained was preserved in 10% formalin and sent for analysis to pathology.

We analyzed the characteristics of the incision and any complications during the procedure and after it. The patient was followed up a week and a month after the procedure. The yield was evaluated through the results of the pathology.

Measurements: immediate complications: bleeding that obstructs the proceedings, fainting, accidents due to health staff

 Table 1

 Clinical and Serologic Characteristics of Patients Evaluated.

Manifestations	Absolute Value/Percentage
Male/female gender	9/177 (4.8/95.2)
Age, median (year)	53 (IQR 45-60)
Time since onset of symptoms, median (years)	1 (IQR 0.64-3)
Xerostomy	155 (83.3)
Xerophtalmia	168 (90.3)
Positive syalometry (n=170)	62 (36.5)
Anti-Ro positive (n=122)	40 (32.8)
Anti-La positive (n=115)	20 (17.4)
ANA>1:80 (n=138)	91 (65.9)
Rheumatoid factor≥30 (n=109)	42 (38.5)
Pylocarpin (n=177)	4 (2.2)
Glucocorticoids<20 mg prednisone (n=179)	25 (13.9)
Hydroxicloroquine	27 (14.5)
Immunosuppressants	14 (7.5)

IQR: interquartile range.

while performing the procedure. Mediate complications: surgical wound infection, suture dehiscence, sensory disturbances (dysesthesia, anesthesia, paresthesia), defective wound healing, as defined by the presence of granuloma or keloid scarring at the site.

#### **Statistical Analysis**

Complications were studied with a frequency analysis and calculation of confidence intervals of 95%.

#### Results

We included 186 procedures performed between October 2007 and May 2010, of which 29 were performed to confirm the diagnosis of secondary SS and the rest of pSS. Among patients with suspected secondary SS, 21 had a diagnosis of rheumatoid arthritis (RA), 3 systemic lupus erythematosus (SLE), 3 primary biliary cirrhosis (PBC), 1 mixed connective tissue disease (MCTD) and 1 of cryoglobulinemic vasculitis. The clinical and serological features are described in Table 1.

Of the 14 (7.5%) patients receiving immunosuppressive therapy at the time of the procedure, 11 received methotrexate (9 of them had a diagnosis of RA), 1 leflunomide and 1 azathioprine.

All patients tolerated the procedure and no serious adverse events were recorded. 15 patients had postoperative complications (8.1%, 95% CI, 4.7–13.2). Complications included: bleeding 7.5%, fainting 3.2%, hematoma 2.7%. There were no accidents (Table 2).

There were 164 patients who attended follow-up visits a week and a month after the procedure. Mediate complications were

**Table 2**Immediate and Mediate Complications.

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Immediate complications	15 (8.1%, 95% CI, 4.7-13.2)
Bleeding	14(7.5%)
Fainting	6(3.2%)
Hematoma	5 (2.7%)
Accident	0
Mediate complications	16 (9.75%, 95% CI, 5.9–15.6)
Pain	12 (7.32%)
Inflammation	6 (3.66%)
Sensitivity abnormalities	5 (3.05%)
Granuloma	2 (1.22%)
Suture dehiscence	0
Infection	0

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