SUPPLEMENTARY ONLINE MATERIAL

MATERIALS AND METHODS

Participants were enrolled from 2003-2013 at nine global sites [Argentina, People's Republic of China, Denmark, Japan, United Kingdom, India and the United States (3 sites)]. Registrants had to be at least 21 years old and have at least one of the following: a complaint of dry eyes or dry mouth; bilateral parotid enlargement; a recent increase in dental caries; a previous diagnosis of SS; or elevated titers of antinuclear antibodies (ANA), RF, and/or anti-SSA or anti-SSB. Informed consent was obtained from all participants in compliance with the Helsinki Declaration.

Each SICCA participant underwent a systematic and extensive assessment of symptoms and signs, and objective tests (serologic, ocular, and oral/salivary) related to SS using uniform protocol-driven data collection methods[1,2]. The data collection forms and standard operating procedures may be found at: http://sicca.ucsf.edu/.

Ocular and oral components. The ocular component of SS was assessed with the ocular staining score (OSS) (using lissamine green and fluorescein)[3]; Schirmer test; and dry eye symptoms. An OSS $\geq$3 was the criterion for SS-associated dry eye disease. The oral component of SS was assessed with the histopathology of a labial salivary gland (LSG) biopsy, with all slides read by the same pathologist[2]; unstimulated whole salivary flow (UWSF) rate; and dry mouth symptoms. Focal lymphocytic sialadenitis (FLS) with a focus score (FS)$\geq$1 foci/4 mm^2 was used as the LSG biopsy criterion for the oral component of SS[2].

Laboratory testing**.** Complete blood counts were performed at the local site while all other laboratory testing was performed centrally by Quest Diagnostics (Madison, NJ). Serologic measures of autoimmunity included serum anti-SSA and SSB, antinuclear antibody (ANA) titer, RF, immunoglobulin levels, C3 and C4. Anti-SSA and anti-SSB antibody testing was performed at Quest Laboratories prior to October 2007 with the Biorad Autoimmune EIA. After October 2007 the Biorad 2200 multiplex bead assay system was used to simultaneously detect antibodies to recombinant Ro52, native Ro60, and native SSB/La in a single tube. The presence of anti-Ro52 (recombinant antigen) and/or anti-Ro60 (native antigen) antibodies is reported as a combined anti-SSA/Ro result.

Disease classification. Registrants were classified with SS by the ACR and AECG criteria[4-5]. The AECG criteria were defined for SICCA participants using the specified oral/salivary, ocular, and systemic components, substituting the SICCA OSS for rose Bengal staining and a definition of participant-reported ocular and oral symptoms based on questions most closely matching the corresponding questions used in the AECG criteria.

REFERENCES FOR SUPPLEMENTARY MATERIAL

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