

378 Saliva sodium and chloride levels: a useful tool for cystic fibrosis (CF) diagnosis?

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Objective: To compare biochemical parameters of saliva from CF patients and healthy individuals.

Method: A cross sectional study including saliva samples of 42 CF patients from the Pediatric CF Reference Center of University Hospital of Campinas SP Brazil (UNICAMP) and 35 healthy individuals as controls. Saliva was collected with Salivet[®] (Sardest-Germany) cotton roll, chewed for a minute. The amount of saliva was measured and pH and concentrations of bicarbonate, sodium, chloride, potassium, glucose, calcium and lactate, were determined by ABL mod 835 Radiometer[®] (Denmark). Student's T and Mann Whitney tests were used for statistical analysis. The project was approved by the Research Ethics Committee.

Results: the mean age of samples was 15.03 years (\pm 6.92 years). Among individuals with CF the mean age was 12.3 years (\pm 7.02 years) and in the controls, 18.2 (\pm 5.24 years). Statistically significant difference between the two groups was observed for the variables: bicarbonate ($p < 0.001$), sodium ($p = 0.000$), chlorine ($p = 0.03$) and volume ($p = 0.000$). Averages of these variables in CF and control group, respectively, were: bicarbonate (4.72 mmol/L; 1.40 mmol/L) sodium (20.75 mmol/L; 10.50 mmol/L), chloride (30.41 mmol/L; 23.18 mmol/L) and volume (19.32 ml; 54.66 ml). No statistically significant difference was observed between the groups for pH, potassium, calcium, lactate and glucose.

Conclusion: Some biochemical salivary parameters seem to be influenced by CF. Other studies are necessary to confirm the usefulness of saliva as complementary, fast and inexpensive tool for CF diagnosis.

380 Cystic fibrosis in Libya: the experience of an international collaboration project

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Background: There are as yet no data about cystic fibrosis (CF) in Libya as a CF center did not exist in this country until 2008. In 2008 a CF Center started in accordance with an international collaboration between the CF Center of the Meyer Hospital and the Zahra Hospital (ZH).

Methods: According the agreement, ZH acquired facilities in performing sweat test, pancreatic and pulmonary function tests and microbiological culture. Doctor and physiotherapist were trained and started a management plan. Patients were regularly followed up; pharmacological and medical treatments were assured by Lybian Government.

Results: From July 2008 to December 2010, 31 patients were diagnosed of CF. Seventy percent were the product of consanguineous marriages 42% had other family members who also had CF (siblings) and in one family, more than two. Up to now 31 CF patients (14 females, 17 males) are regularly followed up at the Zahra Hospital). The mean age of patients was 8.9 yr (range 1–30 yr, median 7 yr) report; 15 were diagnosed outside of Libya, requiring the family to go abroad. The most commonly visited foreign country was Tunisia followed by Germany and Italy. Symptoms at presentation were respiratory and gastrointestinal in 75%. Dehydration was the first symptom in 20% and was severe enough to require multiple hospitalizations in the first years of life in 25% patients. Between July, 2008 and February, 2010, the mean number of follow-up visits/patient was 6.5.

Discussion: Our short experience in the ZH shows that families demonstrated good compliance, coming regularly for check-up and thus avoiding having to go to a foreign country for diagnosis and follow-up.

379 Utilization and healthcare charges in an insured US cystic fibrosis (CF) patient population

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Objective: To describe resource use, charges and medication adherence in US CF patients.

Methods: This retrospective analysis used a US insurance claims data set. CF patients were assigned an index date based on their first claim for dornase alfa (DA) (Pulmozyme) between 2006–2008. Included patients had ≥ 1 DA claim and were continuously enrolled in the health insurance plan ≥ 2 years. They were excluded if they had no claims for CF or had age < 4 . Patient characteristics over the 1-year preindex period and adherence to DA in the 1-year postindex period were examined.

Results: The final study included 934 patients. Mean age was 19.6 years (SD 11.6) and 49.0% were female. The specialties seen most frequently were pulmonology (35.5%) and primary care (29.4%). The cohort had a mean of 2.3 comorbid chronic conditions (SD 1.3), the most common were pancreatic insufficiency (80.8%), *P. aeruginosa* (77.4%), chronic sinusitis (24.0%), and diabetes (17.2%). Frequently used medications were inhaled antibiotics (58.0%), inhaled steroids (54.4%), and hypertonic saline (21.1%). 175 patients (18.7%) were hospitalized for respiratory exacerbations; mean length of stay was 13.9 days. Mean per patient annual healthcare charges were \$51,155 (SD 56,849) and charges related to respiratory exacerbations were \$10,295 (SD 33,343). The mean adherence (medication possession ratio) to DA in the postindex period was 0.59 (SD 0.30, median 0.58).

Conclusion: Resource use and healthcare charges are high in patients with CF, and adherence to dornase alfa is low. Future analyses will examine the relationship between medication adherence and subsequent health and economic outcomes.

381 Registration of clinical trials in cystic fibrosis

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Background: One supposed benefit of prospective registration of clinical trials is that it should discourage selective or delayed reporting of trials. We aimed to determine the proportion of registered clinical trials involving participants with cystic fibrosis that are published and how soon after study completion publication occurs.

Methods: In Jan 2011, we searched the register ClinicalTrials.gov for clinical trials involving participants with cystic fibrosis that were registered in January 2000 or later and that were completed by December 2008. For each trial identified, we searched Google Scholar using the names of the investigators and key terms for the study population and intervention to determine whether the trial had been published by the end of 2010.

Results: 240 trials involving participants with cystic fibrosis had been registered since 1999. Of these, 100 trials were reported on the register as having been completed by December 2008. Of the 100 completed trials, 64 had been published by December 2010. Of the remainder, 3 had been published as abstracts only and 2 had published secondary reports only, while 31 appeared unpublished. Among the 64 published trials, the mean period between completion and publication was 28 months (SD 21). The number of trials that were published within 2 years of their completion was 32.

Conclusion: Despite lodgement on a public register, many clinical trials in cystic fibrosis remain unpublished long after completion of the study. Half of those that are published are not published within 2 years of study completion.