

## SPECIAL REPORT

### **Database application for patients with OSAS**

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## SUMMARY

Obstructive Sleep Apnea (OSA) results from upper airways (UA) collapse during sleep. It represents an increasing well recognized pathology associated with many diseases.

Here we describe the application of a database (DB) for patients with OSA syndrome (OSAS).

This work has different goals: to facilitate a good uniformity of the clinical assessment, to allow the use of the application even by non-ENT Specialists, to evaluate the results of medical and/or surgical treatments, to enable a statistical meta-analysis built upon the information retrieved from the data collected in many OSAS Medical Centres that will use it.

KEY WORDS: OSA, OSAS, Database, Software, Statistics.

## INTRODUCTION

Obstructive Sleep Apnea (OSA) is characterized by recurrent episodes ( $\geq 5/h$ ) of apnea or hypopnoea caused by partial or complete obstruction of the upper airways (UA). From an epidemiological point of view, its incidence is estimated to be 2% in women and 4% in men. This means that in Italy about 623.200 women and about 1.169.100 men are affected by it. However, OSA represents a major problem not only for its social impact but also from the health point of view. There is a recognized association between OSA and metabolic syndrome, designated syndrome Z<sup>1</sup>. It is now widely accepted that this pathology has a multifactor etiology and hence has to be treated with a multidisciplinary approach.

Since 2002, at the ENT Unit of the University of Siena, an outpatient Clinic for OSA surgery is operating. Here patients sent by GPs or also by non-ENT specialists as the Neurologist, Pneumologist, Endocrinologist, Cardiologist are evaluated.

At the very beginning, the implementation of a database (DB) exclusively devoted to the OSAS patient was suggested by the need to collect the patient information (personal data, clinical investigations) and to record the surgical follow-up. Afterwards, it was decided to develop a tool useful also for other Specialists and able, at the same time, to store some data with the related parameters, to automatically calculate some indexes and to extract homogeneous data for subsequent statistical analysis. This compelled the programmer to build not a simple desktop DB but a real DB application.

Purpose of this the work is to illustrate the “OSAS patient” application.

## METHODS

The DB was implemented with Microsoft Access Database application for Windows suite (2002-2003 version and 2007 version)<sup>2-6</sup>, a powerful and versatile software that allows storing, managing, importing or linking data (even stored in other applications or databases). The numerous and simple tools supplied by Access were integrated with more sophisticated programming languages, as for example the Structured Query Language (SQL)<sup>7,8</sup> and Visual Basic for Applications (VBA)<sup>9,10</sup>. The main objective was to design an application of DB which, automating quite all the operations employed to manage a DB, turns a complex set of instructions and commands into simple operations approachable even by inexperienced users.

The main form of the DB was designed taking into consideration the wide spectrum of data to store and also the necessity to offer an intuitive and simple tool of work. It consists of three sections:

- the first one dedicated to manage the available information (inserting, updating and extracting data);
- the second one to consult the data in respect to the single patient;
- the third one for programming and scheduling the surgery.

## DISCUSSION

A DB is a structured and ordered collection of information closely related to each other, stored on a mass storage device (eg a hard disk), organized to store, manage, update and retrieve large amount of data. When these operations on data are automated by the means of programming, so as to turn a complex set of instructions and commands into simple actions performable even by inexperienced users, you get a very sophisticated type of DB, called "DB application". The project named "OSAS patient" belongs to this category of DB and was implemented using Microsoft<sup>®</sup> Office Access software for the Windows desktop platform. Specific for the management of relational DB, Access was chosen in the 2002-2003 version because widely diffused and also for the fact that provides, among others, tools such as:

- Referential Integrity
- Active Data Object (ADO)
- Structured Query Language (SQL)
- Visual Basic for Applications (VBA)
- Object Linking and Embedding (OLE)
- Automatic Data Processing (ADP)

The DB Application “OSAS patient”, in fact, was designed and implemented to meet not only the initial objectives of the project, but also those that have become necessary during its development.

By launching the application it appears a sagittal section of the head and neck (Fig. 1). This initial screen was designed in order to remind the non-ENT specialists involved in the diagnostic-therapeutic process that OSAS is a disease strongly associated with upper airways patency and hence the otorhinolaryngologist’s evaluation is an absolutely indispensable step.

By clicking on this image, the main form (Fig. 2 ), divided into three sections, opens. The first section allows accessing the patient’s personal information and also the investigations necessary for the clinical assessment; besides, it offers the possibility to extract all the information concerning the patient in Excel format. The second and the third sections of the form are conceptually equivalent: both allow retrieving the data through the means of the so-called “report”. A report, in fact, shows selected records in a user-designed format (the format is predefined by the programmer in response to user’s needs) and allows to print data streams, extracted from one or more forms or queries. In our case, there are two types of reports: those dedicated to the patient (clinical history, first follow-up, etc.) and those to the planning of the surgical interventions (surgeries selected by date, etc..)

By clicking on the icon "Insert and up-to-date patient data" it is possible to access into the area reserved to the personal data of the patient and his/her clinical-instrumental evaluation (Fig. 3).

The user is supplied with several tools to enter, update and store the information, but also to link each record to an external file, such as, for example, a medical record. The first clinical data evaluated are weight and height of the patient, BMI (automatically calculated by the application), neck and waist circumference. It is well known, in fact, that obesity is the major risk factor for OSAS <sup>11</sup>. In subjects with BMI (Body Mass Index) > 30 the incidence of sleep apnea reaches 40-60% and the circumference of the neck is the parameter that best correlates to obesity OSAS <sup>12</sup>. As mnemonic help, by positioning the mouse on the corresponding field, the measures considered pathological by the literature are suggested. Also for the Epworth Sleepiness Scale (ESS) it is immediate to read that a score > 10 is considered pathologic <sup>13</sup>. Then polysomnographic data and cephalometric values can be entered. For the latter, only some parameters were implemented, in particular, we reported the analysis of the Stanford group: SNA, SNB, SNP-P, MP-H. Also for these parameters, the application automatically suggests the standard value (a deviation of + / - 2 represents the range of normality).

Endoscopic examination with Muller manoeuvre offers a detailed description of the various sites of the UA and also the possibility to enter the different levels and types of obstruction according to the Sher classification <sup>14,15</sup>. Alongside these data, Friedman staging <sup>16</sup> can be entered as well as the Mallampati score. Nasal evaluation may be completed by the results of skin prick tests and by

rhinomanometry. The most recent literature confirms the importance of a complete nasal evaluation, considering that the combination of high Mallampati score and nasal obstruction represents a greater risk factor for worsening of OSA as well as a predisposing factor for OSAS<sup>17,18</sup>.

Finally, a field dedicated to sleep endoscopy, if carried out, is available. There is also a free field to enter data for dental evaluating. As a further help, in the middle part of this form, the slightly modified surgical algorithms suggested in the “Guidelines in ENT OSA Surgery”<sup>19</sup> were embedded.

Clinical assessment, OSA staging, nasal evaluation and the possibility to follow widely accepted surgical algorithms should ensure uniformity in the diagnostic-therapeutic process.

The patient form is then completed by considerations on the therapeutic planning and by four pages dedicated: the first to the metabolic assessment of the patient (Fig. 4) and the last three to his/her follow up (Fig. 5). These pages were included to reach several goals. One of the first objectives of the DB, in fact, is to improve quality and uniformity of the diagnostic process of the Italian Medical Centers involved in OSAS; another goal is to have an useful tool not only for the ENT specialists but also for other specialists who deal with OSAS. This suggested us to insert the metabolic form, which allows the storage of routine blood tests, ECG evaluation, Holter trace, some hormones such as leptin and ghrelin, and the dosage of the inflammatory cytokines such as IL-1 $\beta$ , IL-6 and TNF- $\alpha$ . As it is now well known, sleep loss is associated with a dysregulation of neuroendocrine control of appetite with a reduction of the satiety factor, leptin, and an increase in the hunger-promoting hormone, ghrelin<sup>20</sup>. Finally, the follow-up consists of three clinical controls at 6, 12 and 36 months. A right evaluation to define success of various surgical procedures, in fact, should provide a follow-up not limited to just 6 but extended to 36 months. In each control, the same clinical-instrumental tests applied during the first observation are repeated.

Besides, in compliance with privacy laws, the DB is protected by password.

Finally, from the statistical point of view, a very structured analysis has been already designed. The possibility, in fact, to easily convert data stored in Access to standard Excel format (see the Excel icon in Fig. 2), will supply not only a large amount of data but also homogeneous information. Even from several OSAS Centers, the method used to collect the data allows overcoming some of the recognized problems of retrospective meta-analyses.

The DB application has been registered with the copyright number DEP634353565069085969.

## CONCLUSIONS

The main objective in designing the DB presented here was to supply the ENT Specialists and all the other Colleagues involved in the therapeutic and diagnostic process of OSAS patient with a very

simple and intuitive tool. Despite the ease of use, this DB application goes far beyond the plain storage of the patient personal data or of his/her surgical and therapeutic follow-up.

The expected effects from distributing the DB are: a more homogeneous behaviour in the diagnostic planning; improvement of the diagnostic accuracy; an increased collaboration among the Specialists of different branches both for health and research; to rationalize the costs linked to the diagnostic step; and finally, the possibility to collect data for homogeneous and consistency statistical analysis. For the treatment of OSAS multidisciplinary is needed so the health and quality of life of these patients can best be served. The application of DB specifically dedicated to OSAS can offer a vigorous contribute.

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Fig. 1 Sagittal section of the head and neck: start-up form of the DB

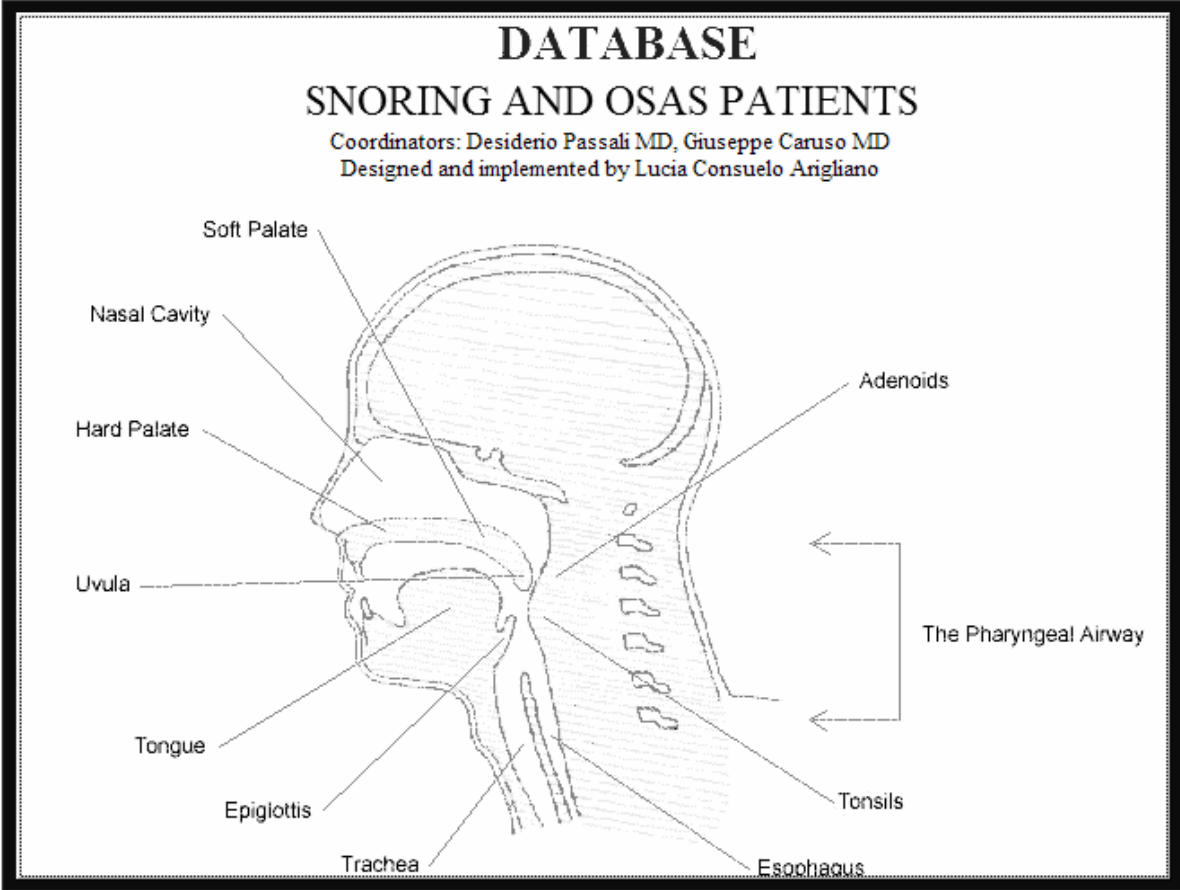



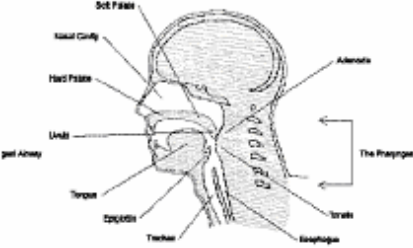
Fig. 2 Main form of the DB



## DATABASE


### SNORING AND OSAS PATIENTS

Coordinators: Desiderio Passali MD, Giuseppe Caruso MD  
Designed and implemented by Lucia Consuelo Arigliano





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#### INSERTING AND UPDATING PATIENT'S DATA



#### CONVERTING PATIENT'S DATA TO EXCEL



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#### RETRIEVING AND PRINTING PATIENT'S DATA


Clinical History

I follow-up

II follow-up

III follow-up

Metabolic picture



Complete data

Patient list


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#### SURGICAL PLANNING

To be performed

Performed

Sorting by date



**Fig. 3** Area for personal data and clinical-instrumental evaluation

**PERSONAL DATA**

Fast search:

Suriname:  Patient ID:

Name:  Date Clinical History:

Birth date:  Sex:

Profession:  Physician:

Note on profess.:  Medical record:

Address:

City:

Telephone:

Mobile phone:

Weight:  Height:  BMI:

Neck circumf.:  Waist circumf.:

Last follow-up:  Cause:

Comments:

**THE EPWORTH SLEEPINESS SCALE (E.S.S.)**

Scores: 0=would never doze; 1=slight chance of dozing; 2=moderate chance of dozing; 3=high chance of dozing

Sitting, reading:

Watching TV:

Sitting inactive in a public place (theater, meeting...):

As passenger in a car for an hour without a break:

Lying down in the afternoon when circumstances permit:

Sitting and talking to someone:

Rising quickly after lunch without alcohol:

In a car, while stopping for a few minutes in traffic:

Total:

**POLYGRAPHY DURING SLEEP**

Drain:

AHI:

ODI:

OSA level:

C-EAP:

Kind of polygraph:

**CEPHALOMETRY**

SNA:

SNS:

SNP-P:

PAS:

MPH:

**FRIEDMAN CLASSIFICATION**

Stage:

**ENT OBJECTIVITY/ ENDOSCOPY**

Soft Palate:  Tongue Base:  Polyps:  Middle Meatus:

Uvula:  Molluscapiti:  Larynx:

Tonsils:  Nasal Cavity:  Kind of endoscope:

**MULLER MANEUVER**

Unilateral Shev. Class.:  Oropharyngeal Shev. Class.:  Type of obstruction:

**OBSTRUCTION SITE**

single level:

multilevel:

**PRICK TEST**

Positive:  Note on prick test:

Negative:

**RHINOMANOMETRY**

basal:  functional (decongestion test):

res\_insp\_r:  res\_exp\_r:  Nasal Valve Dilation Test:

res\_insp\_l:  res\_exp\_l:

res\_insp\_tot:  res\_exp\_tot:

res\_insp\_at:  res\_exp\_at:

res\_insp\_tot:  res\_exp\_tot:


Sleep Endoscopy:

Dental Evaluation:

Type of Sedation:

Therapeutical Planning:

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Update

Print

Surgical Algorithms | Metabolic Picture | I follow up (6 months) | II follow up (12 months) | III follow up (36 months)

**Flowchart 1: Nasal possible?**

Start: OSAS (AHI > 20) / Discrepanza

Decision: Nasal possible?

If NO: L'obstruzione è il solo sito responsabile? → NO → OSAS (AHI > 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

If SI: L'obstruzione è il solo sito responsabile? → SI → OSAS (AHI < 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

If NO: L'obstruzione è il solo sito responsabile? → NO → OSAS (AHI > 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

If SI: L'obstruzione è il solo sito responsabile? → SI → OSAS (AHI < 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

**Flowchart 2: Nasal possible?**

Start: OSAS (AHI > 20) / Discrepanza

Decision: Nasal possible?

If NO: OSAS (AHI > 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

If SI: OSAS (AHI < 20) / Discrepanza → CPAP (+ ES) / LAUP → Avanzamento Maxillo-Mandibolare

**Fig. 4** Metabolic assessment of the patient

|   |                      |   |                      |   |                             |
|---|----------------------|---|----------------------|---|-----------------------------|
| Patient ID  |                      | SI-0001   |                      | <b>METABOLIC PICTURE</b>  |                             |
| Date  |                      |   |                      |   |                             |
| HbA1C   |                      | C-reactive Protein                                      |                      | <b>Complete Blood Count</b><br>White Blood Cells <input type="text"/><br>Red Blood Cells <input type="text"/><br>Htc <input type="text"/> |                             |
| Glycemia  |                      | Uric Acid   |                      |   |                             |
| Creatinine  |                      | Ghrelin   |                      |   |                             |
| Cholesterol   |                      | Leptin  |                      |   |                             |
| Triglycerides   |                      | IL-1 $\beta$  |                      |   |                             |
| Cholesterol HDL   |                      | IL-6  |                      |   |                             |
| Cholesterol LDL   |                      | TNF- $\alpha$   |                      |   |                             |
| Smoke <input checked="" type="checkbox"/>   |                      | Interruption date <input type="text"/>                  |                      |   |                             |
| Current therapies   |                      | <input style="width: 100%; height: 40px;" type="text"/> |                      |   |                             |
| <b>BLOODY PRESSURE PICTURE</b>  |                      |   |                      |   |                             |
| Systolic  | <input type="text"/> | Diastolic   | <input type="text"/> | Pathologic Holter trace   | <input type="checkbox"/>    |
| DIABETES <input checked="" type="checkbox"/>  |                      |   |                      |   |                             |
| <b>COMPLICATIONS</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Retinopathy</li> <li><input type="checkbox"/> Neuropathy</li> <li><input type="checkbox"/> Nefropathy</li> <li><input type="checkbox"/> Cardiovascular Disease (AMI, stroke, ...)</li> </ul> |                      |   |                      |   |                             |
| <b>DOMICILIARY GLYCEMIC CONTROL</b><br>(3 days, 3 times per day, before breakfast and 2 hours after meals)  |                      |   |                      |   |                             |
| I DAY:  | G1-I                 | <input type="text"/>                                    | G1-II                | <input type="text"/>  | G1-III <input type="text"/> |
| II DAY:   | G2-I                 | <input type="text"/>                                    | G2-II                | <input type="text"/>  | G2-III <input type="text"/> |
| III DAY:  | G3-I                 | <input type="text"/>                                    | G3-II                | <input type="text"/>  | G3-III <input type="text"/> |

Fig. 5 Follow-up form

| Surgical Algorithms   | Metabolic Picture                                  | I follow-up (6 months)                | II follow-up (12 months)                       | III follow-up (36 months)                             |
|---|--|---------------------------------------|--|---|
| I follow-up date <input type="text" value="Data_controll"/> |  |                                       |  |   |
| Weight  | <input type="text" value="P_c1"/>                  | BMI                                   | <input type="text" value="=[P_c1]/([A"/>       | Neck circumf. <input type="text" value="Circonfere"/> |
| <b>POLYSOMNOGRAPHY DURING SLEEP</b>                         |  |                                       |  |   |
| Date  | <input type="text" value="Data POLI_c1"/>          |                                       |  |   |
| AHI   | <input type="text" value="AHI_c1"/>                |                                       |  |   |
| ODI   | <input type="text" value="ODI_c1"/>                |                                       |  |   |
| OSA level   | <input type="text" value="Grado OSAS_c1"/>         |                                       |  |   |
| C-PAP   | <input type="text" value="C-PAP_c1"/>              |                                       |  |   |
| <b>ENDOSCOPIC OBJECTIVITY</b>                               |  |                                       |  |   |
| <input type="text" value="Esame obiettivo_c1"/>             |  |                                       |  |   |
| <b>ENDOSCOPIC EVALUATION</b>                                |  |                                       |  |   |
| <input type="text" value="Fibroendoscopia_c1"/>             |  |                                       |  |   |
| <b>RHINOMANOMETRY</b>                                       |  |                                       |  |   |
| <i>basal</i>  |  | <i>functional (decongestion test)</i> |  |   |
| res_insp_r  | <input type="text" value="res_insp_dx_BAS_c1"/>    | res_insp_r                            | <input type="text" value="res_insp_dx_D_c1"/>  |   |
| res_exp_r   | <input type="text" value="res_esp_dx_c1"/>         | res_exp_r                             | <input type="text" value="res_esp_dx_D_c1"/>   |   |
| res_insp_l  | <input type="text" value="res_insp_sn_c1"/>        | res_insp_l                            | <input type="text" value="res_insp_sn_D_c1"/>  |   |
| res_exp_l   | <input type="text" value="res_esp_sn_c1"/>         | res_exp_l                             | <input type="text" value="res_esp_sn_D_c1"/>   |   |
| res_insp_tot  | <input type="text" value="res_insp_tot_c1"/>       | res_insp_tot                          | <input type="text" value="res_insp_tot_D_c1"/> |   |
| res_exp_tot   | <input type="text" value="res_esp_tot_c1"/>        | res_exp_tot                           | <input type="text" value="res_esp_tot_D_c1"/>  |   |
| <b>MULLER MANEUVER</b>                                      |  |                                       |  |   |
| Uvulopalatal Sher Class.                                    | <input type="text" value="muel_c1_A"/>             |                                       |  |   |
| Oropharyngeal Sher Class.                                   | <input type="text" value="muel_c1_B"/>             |                                       |  |   |
| Type of obstruction   | <input type="text" value="muel_c1_C"/>             |                                       |  |   |
| <b>Comments</b>   |  |                                       |  |   |
| <input type="text" value="Commento_c1"/>                    |  |                                       |  |   |
| Medical Therapy   | <input type="text" value="TerapiaMedica_c1"/>      |                                       |  |   |
| Surgery   | <input type="text" value="intervento_chirurgico"/> |                                       |  |   |
| Nose  | <input type="text" value="Chir_Naso"/>             | <b>Velopalatal</b>                    | <input type="text" value="Chir_Velopalato"/>   |   |
| Tongue Base   | <input type="text" value="Chir_BaseLingua"/>       | <b>Hyoidal bone advancement</b>       | <input type="text" value="Chir_Avan_Ioideo"/>  |   |
| Other   | <input type="text" value="res_esp_tot_D_c1"/>      |                                       |  |   |
| Surgery date  | <input type="text" value="data intervento"/>       | <b>performed</b>                      | <input checked="" type="checkbox"/>            |   |