SLEEP DISORDERS

Database application for patients with obstructive sleep apnoea syndrome

Applicazione di database per i pazienti affetti da OSAS

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SUMMARY

Obstructive sleep apnoea syndrome (OSAS) results from upper airway collapse during sleep. It represents an increasingly recognized pathology associated with many diseases. Herein, we describe a database for patients with OSAS. This has different goals: to facilitate good uniformity in clinical assessment, to allow the use of the application even by non-ENT specialists, to evaluate the results of medical and/or surgical treatments and to enable a statistical meta-analysis derived from the data collected in many OSAS medical centres.

KEY WORDS: OSA • OSAS • Database • Software • Statistics

RIASSUNTO

La Sindrome delle Apnee Ostruttive del Sonno (OSAS), risultato del collasso delle strutture delle vie aeree superiori durante il sonno, rappresenta una patologia ormai ben definita, in continuo aumento a cui si associano molti altri disturbi e/o patologie. Lo scopo del seguente lavoro è quello di descrivere l'applicazione di un database per i pazienti affetti da Sindrome delle Apnee Ostruttive del Sonno. Gli obbiettivi sono pertanto di: facilitare una buona uniformità della valutazione clinica, per consentire l'utilizzo dell'applicazione anche dai non specialisti in Otorinolaringoiatria, di valutare in maniera obbiettiva e sistematica i risultati dei trattamenti medici e/o chirurgici e di avviare una meta-analisi statistica costruita sulla base delle informazioni recuperate dai dati raccolti nei centri medici OSAS che lo utilizzeranno.

PAROLE CHIAVE: *OSA • OSAS • Cartella clinica informatizzata*

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Introduction

Obstructive sleep apnoea (OSA) is characterized by recurrent episodes (≥ 5/h) of apnoea 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 OSA. However, OSA represents a major problem not only for its social impact, but also from a general health point of view. There is a recognized association between OSA and metabolic syndrome, designated syndrome Z [1]. It is now widely accepted that this pathology has a multifactorial aetiology, and hence must be treated with a multidisciplinary approach.

Since 2002, at the ENT Unit of the University of Siena, an outpatient Clinic for OSA surgery has been functioning where patients are referred by general practitioners or non-ENT specialists such as the neurologists, pneumologists, endocrinologists and cardiologists.

At the very beginning, the implementation of a database (DB) exclusively devoted to OSAS was suggested by the need to collect the patient information (personal data, clinical investigations) and to record surgical follow-up. Afterwards, it was decided to develop a tool that was also useful for other specialists, that would store data, automatically calculate selected indexes and extract homogeneous data for subsequent statistical analysis. This compelled the programmer to create not just a simple desktop DB, but a genuine DB application. Herein, the OSAS DB application is described.

Materials and methods

The DB was implemented using the Microsoft Access Database application for Windows (2002-2003 version and 2007 version) [2-6], which 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) [7 8] and Visual Basic for Applications (VBA) [9 10]. The main objective was to design a DB application which, automating all the operations employed to manage a DB, turns a complex set of instructions and commands into simple operations that are approachable even by inexperienced users.

Results

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

- the first dedicated to manage the available information (inserting, updating and extracting data);
- the second to consult data of individual patients;
- the third for programming and scheduling surgery.

In this way, the primary (to facilitate a good uniformity of clinical assessment) and secondary outcomes (to evaluate the results of medical and/or surgical treatment and to enable a statistical meta-analysis of data collected from different centres) could be easily attained.

Discussion

A DB is a structured and ordered collection of information closely related to each other, stored on a mass storage device (e.g. hard disk), organized to store, manage, update and retrieve large amounts of data. When these data operations are automated by programming, so as to turn a complex set of instructions and commands into simple actions performable even by inexperienced users, a sophisticated type of DB, called "DB application", is obtained. The project named "OSAS patient" is a DB application that was implemented using Microsoft® Office Access software for Windows. Specific for the management of the relational DB, Access was chosen in the 2002-2003 version because it is widely available and 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 became necessary during its development.

Opening the application launches a sagittal section of the head and neck (Fig. 1). This initial screen was designed to remind the non-ENT specialists involved in the diagnostic-therapeutic process that OSAS is a disease strongly associated with upper airway patency, and hence the otorhinolaryngologist's evaluation is an indispensable step.

By clicking on this image, the main form opens (Fig. 2), which is divided into three sections. The first section allows accessing the patient's personal information and investigations necessary for clinical assessment; in addition, it offers the possibility to extract all information concerning the patient in Excel format. The second and third sections of the form are conceptually equivalent: both allow retrieving the data through a so-called "report". A report, in fact, shows selected records in a user-designed format (predefined by the programmer in response to user's needs) and allows printing 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 surgical interventions (surgeries selected by date, etc.)

By clicking on the icon "Insert and up-to-date patient data", it is possible to access the area reserved to 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 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) and neck and waist circumference. It is well known, in fact, that obesity is the major risk factor for OSAS [11]. In subjects with BMI > 30, the incidence of sleep apnoea reaches 40-60%, and circumference of the neck is the parameter that best correlates to obesity OSAS [12]. As mnemonic help, by positioning the mouse on the corresponding field, the measures considered pathological are suggested. Also, for the Epworth Sleepiness Scale (ESS), it is easy to read that a score > 10 is considered pathologic [13]. Next, polysomnographic data and cephalometric values can be entered.

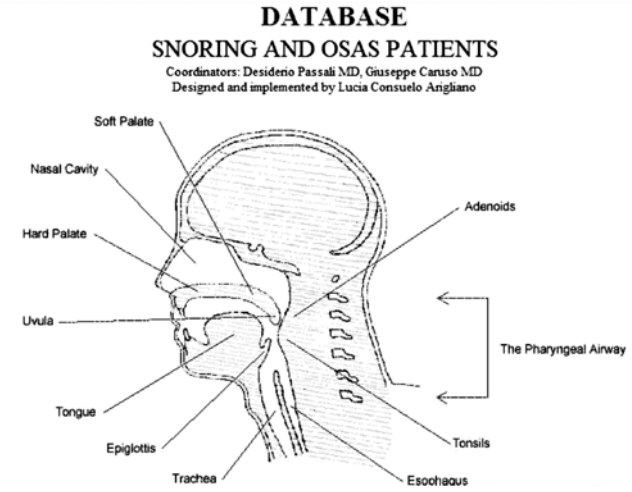

Fig. 1. Sagittal section of the head and neck: start-up form of the DB.

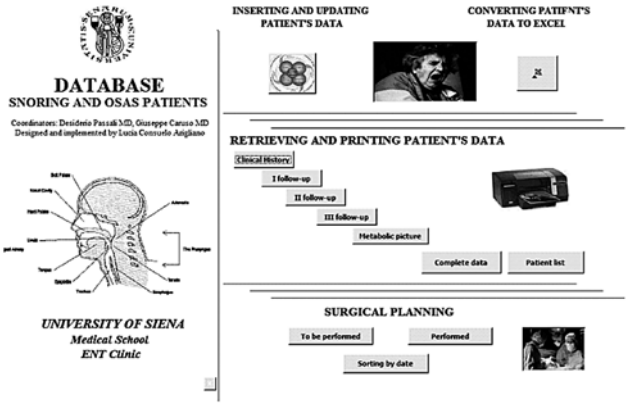

Fig. 2. Main form of the DB.

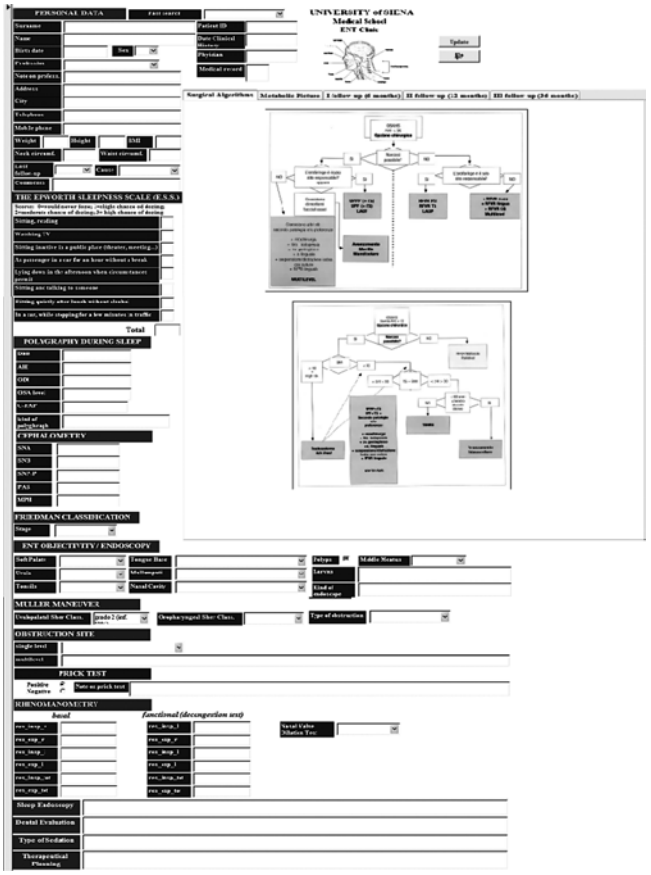

Fig. 3. Area for personal data and clinical-instrumental evaluation.

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 the possibility to enter the different levels and types of obstruction according to the Sher classification [14 15]. Alongside these data, Friedman staging [16] can be entered as well as the Mallampati score. Nasal evaluation may be completed by the results of skin prick tests and 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 [17 18].

Finally, a field dedicated to sleep endoscopy, if carried out, is available. There is also a free field to enter data for dental evaluation. As a further help, in the middle part of this form, the slightly modified surgical algorithms suggested in the "Guidelines in ENT OSA Surgery" [19] 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 therapeutic planning and by four dedicated pages: the first to metabolic assessment (Fig. 4) and the last three to follow up (Fig. 5). These pages were included to reach several goals. One of the first objectives of the DB, in fact, was to improve quality and uniformity of the diagnostic process in 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. Thus, the metabolic form was included, which allows 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-1β, IL-6 and TNF-α. 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 [20]. Finally, the follow-up consists of three clinical controls at 6, 12 and 36 months. A correct evaluation to define success of various surgical procedures, in fact, should provide a follow-up that is not limited to just 6 months, but extended to 36 months. At each control visit, the same clinical-instrumental tests applied during the first observation are repeated.

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

Finally, from a statistical point of view, a very structured analysis has been already designed. The possibility, in fact, to easily convert data stored in Access to 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 centres, 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 copyright number DEP634353565069085969.

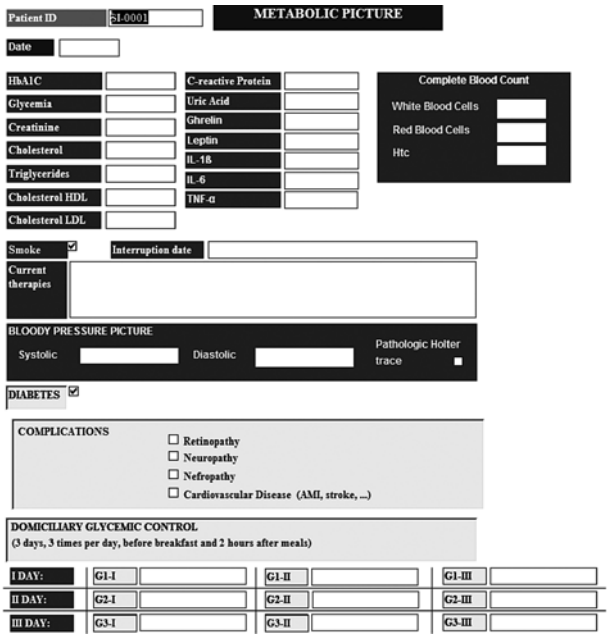

Fig. 4. Metabolic assessment of the patient.

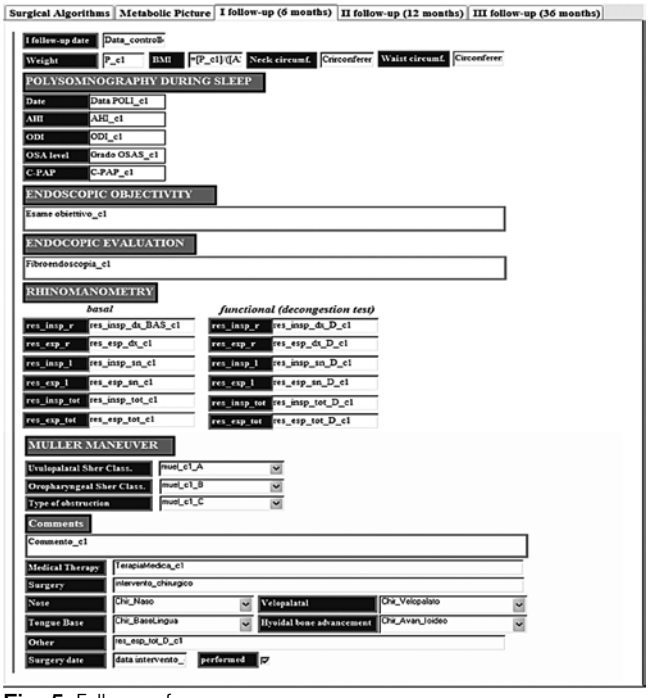

Fig. 5. Follow-up form.

Conclusions

The main objective in designing the DB presented here was to supply ENT Specialists and other colleagues involved in the therapeutic and diagnostic process of OSAS with a very simple and intuitive tool. Despite the ease of use, this DB application goes far beyond the simple storage of the patient data and surgical/therapeutic follow-up.

The expected effects from distributing the DB are a more homogeneous behaviour in diagnostic planning; improvement of diagnostic accuracy; an increased collaboration among the specialists for health and research; rationalize costs linked to diagnosis; and finally, the possibility to collect data for homogeneous and consistency statistical analysis.

For the treatment of OSAS, a multidisciplinary approach is needed to best serve the health and quality of life of these patients. A DB application specifically dedicated to OSAS can offer a vigorous contribution.

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