Design of computerised database for clinical and basic management of uveal melanoma

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\textbf{A B S T R A C T}

\textbf{Purpose:} The uveal melanoma is the most common primary intraocular tumor in adults. The objective of this work is to show how a computerized database has been formed with specific applications, for clinical and research use, to an extensive group of patients diagnosed with uveal melanoma.

\textbf{Method:} For the design of the database a selection of categories, attributes and values was created based on the classifications and parameters given by various authors of articles which have had great relevance in the field of uveal melanoma in recent years.

\textbf{Results:} The database has over 250 patient entries with specific information on their clinical history, diagnosis, treatment and progress. It enables us to search any parameter of the entry and make quick and simple statistical studies of them.

\textbf{Conclusion:} The database models have been transformed into a basic tool for clinical practice, as they are an efficient way of storing, compiling and selective searching of information. When creating a database it is very important to define a common strategy and the use of a standard language.

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\textbf{Diseño de una base de datos informatizada para la gestión clínica y básica del melanoma uveal}

\textbf{R E S U M E N}

\textbf{Propósito:} El melanoma uveal es el tumor intraocular primario más frecuente en la edad adulta. El objetivo de este trabajo es mostrar cómo se ha construido una base de datos informatizada con unas aplicaciones, tanto clínicas como de investigación concretas, a un grupo extenso de pacientes diagnosticados de melanoma de la úvea.

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Métodos: Para el diseño de la base de datos se realizó una selección de categorías, atributos y valores, basándose en las clasificaciones y parámetros dados por diferentes autores en artículos que han tenido gran relevancia en el campo del melanoma uveal en los últimos años.

Resultados: La base de datos cuenta en la actualidad con más de 250 registros de pacientes, con información específica sobre su clínica, diagnóstico, tratamiento y evolución. Nos permite realizar búsquedas sobre cualquier parámetro del registro y hacer estudios estadísticos de los mismos de una forma rápida y sencilla.

Conclusión: Los modelos de bases de datos se han convertido en un arma fundamental para la práctica clínica, pues constituyen una forma eficaz tanto de almacenamiento como de recopilación y búsqueda selectiva de información. A la hora de realizar una base de datos, es muy importante la definición de una estrategia común y el uso de un idioma normalizado.

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Introduction

Uveal melanoma (UM) is the most frequent primary intraocular tumor in the adult age. Even though in Spain we have no data regarding its prevalence, other countries have published incidence rates of about 6 cases per million inhabitants and year. This tumor appears mainly in individuals having low pigmentation due to ethnicity, and among them those with lower amounts of melanine. It affects both sexes just about equally and generally expresses between the fifth and sixth decade of life, although increased rates have been recently identified in the population group under 40 years of age.

Clinically, it expresses as a pigmented choroidal mass with generally nodular morphology (80% of cases) and can appear in any part of the uveal tract (iris, ciliary body and choroids). It usually expresses with a loss of visual acuity or campimetric involvement, although many cases are diagnosed in routine ophthalmological assessments in patients who do not exhibit any symptoms.

In UM, the most important clinical and pathological characteristics with prognostic value are the ciliary body involvement, the mass size and cellular type, the presence of mitotic activity and lymphocytic infiltration, extracellular extension and certain characteristics of the extracellular matrix and the microvascular structure. Extraocular extension, local relapse and systemic disease are associated to an extremely poor prognosis. The main cause of demise in patients with UM is hepatic metastasis. Additional prognostic factors are based on molecular characteristics of the UM cells, such as cytogenetic changes (monosomy 3), alterations in the molecular pathways related to the cell cycle, loss of cell adhesion proteins or overexpression of apoptosis inhibitors. All these factors are beginning to be considered in the individual treatment for each patient. Even so, at present the prognosis of UM is uncertain in many cases and this requires the intensification of research about molecular prognostic factors (biomarkers).

The Ocular Oncology Unit of the Ophthalmology Service of the Santiago de Compostela University Complex Hospital (designated as a reference unit by the Health Ministry according to RD 1302/2006, decision dated December 26, 2000 date for designating reference centers, services and units in the National Health System) is particularly interested in the research of molecular biomarkers for UM. Accordingly, at present molecular factors are being identified in the blood of patients to enable individual prognosis and therefore a precise adjustment of known treatments. Said research activity requires detailed and complete records of the clinical characteristics of each patient. To this end, in the course of the past year a computer database has been designed to facilitate a retrospective analysis of the clinical characteristics of UM patients and the correlation with the molecular findings obtained in the basic research carried out by our group.

A database is defined as a series of organized and interrelated values, which are collected and analyzed by information systems. Generally, databases applied to a series of humans affected by a specific type of disease must comprise a number of characteristics to enhance efficiency in information search, including logical and physical independence of data, minimum redundancy, concurrent access by multiple users, data integrity, optimized complex queries and access with standard programming languages. The entities (categories), attributes and keys are important concepts in databases. An entity is a general class of individuals, places or things (objects) for which data are collected, stored and maintained. In this task, the main entity of the database is the patient. An attribute is the characteristic of an entity, such as the color of a melanoma or the intraocular pressure of the patient. The specific value of an attribute, known as a data element, can be found with the registry fields that describe an entity. In the above case, the value or variable of the melanoma color attribute could be amelanotic, melanotic or orange, and any of these values could be taken for this attribute. A set of fields of a specific object represents a record. The objective of this paper is to demonstrate how a computer database has been built with specific clinical and research applications for a large group of patients diagnosed with UM. In addition, it describes the main practical uses of said computer tool.

Materials and methods

The first step in the database design was the choice of categories, attributes and values. The category comprised the patients diagnosed with UM. It was necessary to determine
OCT


Fig. 1 – Selection process example. Subcategory: OCT-diagnostic.

which attributes were going to be included in the database. To this end, we have followed classifications and parameters given by various authors in highly relevant outcomes in the field of UM in recent years, mainly in the series of publications related to the Collaborative Ocular Melanoma Study (COMS).11 Fig. 1 illustrates an example of the selection process. The first step was to choose a number of publications on a specific subcategory. In the case of the figure, the subcategory was “diagnostic test-OCT”. Subsequently, for each article we extracted the parameters applied by the authors to describe the study or establish its results. These are usually described in the “Material and methods” section or in “Results”. This procedure was continued with the remaining subcategories until the tables were completed. When the list of attributes was made, they were introduced in a work interface. The section has been dedicated for supplementary tests data such as ultrasound biomicroscopy (UBM),12,13 optic coherence tomography (OCT)14–16 and echography.17,18 We have given significant importance to the new predictive factors that emerged in recent years. In addition to the clinical19–21 and anatomopathological characteristics,3 we have also established the thin needle biopsy analysis and new markers.22–24 As discussed above, monosomy 3 and chromosome 8 alterations have a poor prognosis. These alterations can be determined by means of various techniques such as on-site fluorescent hybridization (FISH), MLPA (multiplex ligation-dependent probe amplification) or GEP (gene expression profile). The 2 latter techniques classify melanomas in 2 types (class 1 and class 2), class 2 being more aggressive and with higher risk of metastasis.25 All these tests appear in the Prognostic subcategory (molecular-genetic study-histology).

The computer program was FileMaker Pro Advanced 10.0 v1 (FileMaker Inc, Santa Clara, CA, USA), for designing and building databases with simple procedures for Windows, Mac and the Web. The platform used for processing was Windows Vista (Microsoft Corporation-Redmond, WA, USA), running in a Pentium Core2 Duo computer.

Result

Conceptually, the model of the designed database comprises 3 main constructions: objects, attributes and values. In some cases, the main categories can be divided into subcategories. In this database we started from the main category which is Patient Information, from which the remaining categories are derived. On the basis of the standard exploration of uveal melanoma patients we obtained the Clinic category (patient symptoms), Biomicroscopy category (slit lamp assessment) and the Ophthalmoscopy category (ocular fundus exploration data with direct and indirect ophthalmoscopy). An additional category was added to record the data from Additional Tests of patients (ecography, OCT and UBM). Within the Treatment category we found the subcategories of possible Complications and patient Evolution and Control. As
mentioned above, great importance has been given to the Prognostic category, with a detailed recording of all the parameters being studied currently in the uveal melanoma field. Fig. 2 schematically illustrates the entire internal configuration of subcategories with their attributes and respective variables.

The interface designed for the database is basically intuitive (Fig. 3). All the information can be displayed in one screen. Below the menu bar there is a frequent task bar with icons for Browse records, New Record, Delete Record and Search. An icon represented as a gray sphere in the upper part of the main menu indicates the number of clinical records that are archived or selected in the search. The information input fields follow the usual order of a conventional clinical records, i.e. firstly the patient identification data followed by basic as well as special anamnesis and ophthalmological assessment. Treatments and possible derived clinical complications have been placed at the end. The sections are separated with tabs that enable easy access to information. In addition, it is possible to introduce graphics and images from imaging and diagnostic tests which enable a better understanding of the information.

The information can be searched in any of the program fields and the search results are displayed in an individual table or by means of data exchange in an Excel spreadsheet (Microsoft and/or SPSS Statistical Package for the Social Sciences, Chicago, IL, USA) which enables the concentration of statistical analysis. In addition, the program can automatically generate a summary of the oncological history in the command format for printing or exporting at any time. This provides an immediate overview of an oncological patient history and provides an easy way to input data as well as a tool for generating brief reports.

At this time the database is in an individual account of the Ocular Oncology Unit of the University Hospital Complex of Santiago. Access to the database is exclusively limited to specialized physicians working in said unit. This restriction in the use of clinical data belonging to patients diagnosed and treated for UM is achieved by means of specific keys and access codes and is supported by the informed consent signed for this purpose by each patient. At present, the database has over 250 patient records (nevus and melanomas), which allows easy control of their evolution and clinical characteristics. The database is available through a local network. Automatic

![Fig. 2 – Schema of the entire internal configuration of categories and subcategories with attributes and variables. aCategory; bSubcategory.](image-url)
backups are made every day. To this date, no system failures or information losses have occurred.

**Discussion**

Database models have become a fundamental tool for clinical practice because they are an efficient way to collect, store and selectively search information. When designing a database it is very important to define a common strategy and utilize standardized language that can be understood internationally. The category of the study in this work was clear and defined, i.e. patients with UM. However, the selection of attributes is a researcher-dependent activity which is crucial for the pre-processing of data in order to develop a powerful and efficient database. In this work, the objective was the efficient selection of said attributes and their possible values to enable quick and easy conclusions. To this end, it was necessary to remove irrelevant and/or redundant attributes and to focus on those which were demonstrated in the course of time to be good assessment criteria. In this way, a growing source of standardized information was obtained which aggregates the necessary number of cases to extrapolate conclusions with statistical value. It is important to input most of the information by means of multiple choice tables with alphabetically determined searches and with dichotomic selection icons, as this significantly facilitates said input. In addition, it prevents grammatical changes which statistically can give rise to problems when carrying out searches and extracting reports. The software designed by our group facilitates the day-to-day management of patient data in clinical external practices and is an intuitive, user-friendly tool. Quick access to this information can facilitate clinical studies, assess the management thereof and—more importantly—reinforce the translation between basic and clinical research. It was designed to fulfill the specific needs of a multidisciplinary team that has the objective of diagnosing and treating UM, following the data extracted from the COMS and other related studies. In the near future, this will enable research that will contribute to improve the knowledge about UM. In addition, the development of computerized databases enhances the performance of clinical as well as basic research work in medicine.

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**Conflict of interests**

No conflict of interests has been declared by the authors.

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