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Quality Management in the Doctor's Consulting Room

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Abstract

Clinical research and the measurement of quality in healthcare have similar properties. Clinical research is generally restricted to university and teaching hospitals because of it's time consuming nature while quality management and subsequent quality measurement are of interest to all medical doctors. To serve both purposes a Kaplan Meier satellite module was developed as an add-on to a medical workstation. Kaplan Meier survival statistics has interesting possibilities as a clinical tool for the measurement and graphic visualisation of quality of care. It does express the clinical behaviour of a patient population in terms of cumulative survival, patency or any other binary phenomenon. A vascular surgeon collected cumulative patency data on 340 vascular reconstructions with this Kaplan Meier module within 6 months without any perceptable influence on the normal outpatient clinic routines. The module is easy to operate, easy to maintain and very adaptable to any clinical question.

Keywords

Quality; Outcome measurement; Kaplan Meier, Medical Workstation

Introduction

The medical workstation is rapidly gaining popularity in The Netherlands, in 1996 great advances were realised [1]. Doctors expect from a medical workstation support for their various medical and administrative duties, most prominent of which is of course support for daily patient care. Since the beginning of 1997 a medical workstation of modular design is in operation in 10 hospitals in the Netherlands giving full retrieval of all relevant medical data from the Hospital Information System [1] for use by the practising specialist in the outpatient department [2].

One of the key issues in hospitals today is quality assurance of medical practice. Many Dutch national medical societies conduct extensive quality programs varying from peer review to formal examination of it's members. Measurement of outcome of care remains 'the bottom line' of quality assurance but it's realisation is very difficult for a non-researching medical unit pressed for time and staff.

Survival statistics are extensively used in oncology and vascular surgery for more than 30 years. The life table statistics and Kaplan Meier non-parametric studies on survival [3] describe time-honoured approaches to 'outcome' measurement given a disease and it's different ways of treatment, where 'outcome' was originally defined as survival from a disease. The strength and the simplicity of survival statistics make them extremely useful for outcome measurements in care and cure applied to other questions than survival. The far reaching possibilities of the Kaplan-Meier survival statistics for quality measurement and clinical research made us incorporate Kaplan Meier into the Medical Workstation.

Description of Kaplan Meier

The Kaplan Meier statistical method was originally adopted by medical scientists to quantify the mortality risk in patient populations and to study the effect of treatment schemes or disease related properties like the stage of the disease, on mortality. The Kaplan Meier statistics are since then increasingly used for a wide range of problems like e.g.. the patency of vascular reconstruction [4] the recurrence of stones in the urinary system after lithotripsy [5] or the recovery rate in traumatic sixth-nerve palsy [6].

If a cohort of subjects is followed in time for the occurrence of a certain event (e.g. death, patency of a graft, recovery of VI nerve palsy) all subjects may be observed for different lengths of time and also, events will not occur with every subject. Cases for which the event does not occur during the period of observation are called censored cases. To calculate Kaplan-Meier estimates of the survival, one evaluates the chance for survival at each of the time points where an event occurred. To compute the conditional probability of surviving at each time an event occurs, given that one is alive after the last event, one divides the number of cases alive just after the event by the number of cases alive just prior to that event. Censored cases do thus not contribute to the probability of surviving. In general, to calculate the cumulative survival probability for a particular period of observation time, one must multiply all individual probabilities up to and including the end of the observation time [7].

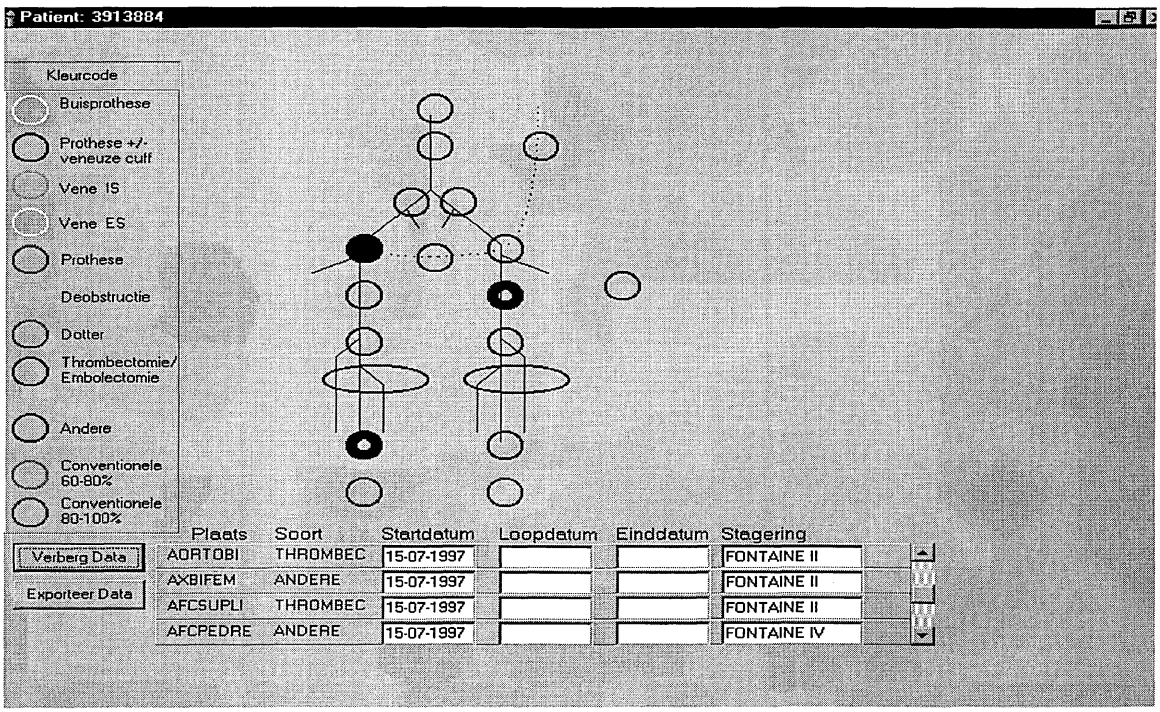

Figure 1 - The front-end of the vascular version of Kaplan Meier. The open circles represent the possible sites of operation, the closed circle means that an event has occurred [occlusion of a graft] while the bold circles indicate a re-operation before an occlusion occurred [assisted primary patency].

The survival graph presents the drawn line between the successive calculations of cumulative survival probability at each event.

Functional and Technical requirements

The architecture of the Medical Workstation Mirador is modular so that satellite systems and modules can be hooked to the main data retrieval system. A button in the main screen of Mirador connects to Kaplan Meier while

simultaneously passing on patient number and name to the relational database of Kaplan Meier. The Kaplan Meier module essentially consists of three parts ; a graphical

front-end for input and presentation of data, a series of relational tables for data storage and finally an output modality for exportation of the data to a statistical program for the computation of the survival. The program is written in Delphi and the relational database used is Paradox.

The graphical input screen in figure 1 presents a schematic picture of the vascular tree, the circles are the possible operation areas. The column on the left lists all operative procedures presented as coloured circles. The patient is added to the database with the mouse by dragging the coloured circles (procedure) to the vascular tree (site of operation). In the oncology version of the Kaplan Meier, figure 2, the doctor selects the organ harbouring the tumour. A table is then presented listing all possible treatment combinations, one click suffices to enter a

patient. In the vascular reconstruction example, figure 1, the focus is on one event: Is the reconstruction patent or not? In oncology, the second example, figure 2, three events are possible and addressed at each patient's visit: Is the patient alive? Are there sign's of local recurrence or distant metastases? The questions are given to the user in a dialogbox and answerable by one click of the mouse. The Kaplan Meier screen acts simultaneously as an input screen and gives important clues to the vascular history of the patient. In the oncology version the oncologist may have to act upon the occurrence of an event with a change in treatment policy, f.i. a local recurrence needs irradiation but the patient is alive without distant metastasis. These changes in therapy are recorded in the database without censoring the case for the non-events. Export of the data to a statistical program (SPSS) takes place by clicking on a button. The module offers it's user statistical analysis by choice on selections of the data or on all data. The data are either exported to a commercially available statistical program or made available locally for statistical computation

Results

experience with a vascular surgeon

During the past 6 months the Kaplan Meier module was used during the outpatient office hours of a vascular surgeon for 9 hours a week. The database grew with an average of 14 new

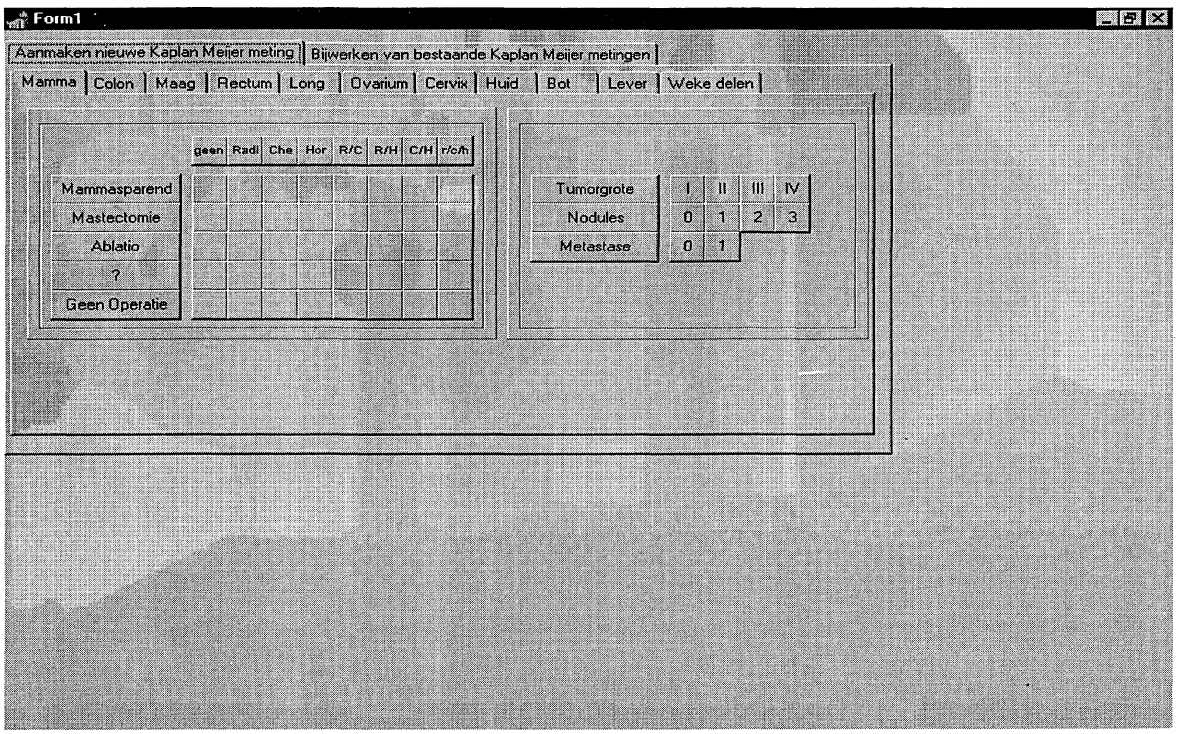

Figure 2 - The front-end of the oncology version of Kaplan Meier. The example given on breast cancer identifies five operative procedures for cancer of the breast and three non-operative treatment modalities. Only one cell needs 'clicking' for selection of the right treatment combination.

patients a week so that at present 263 cases are available for analysis distributed over all anatomical sites involving all types of operation [table 1].

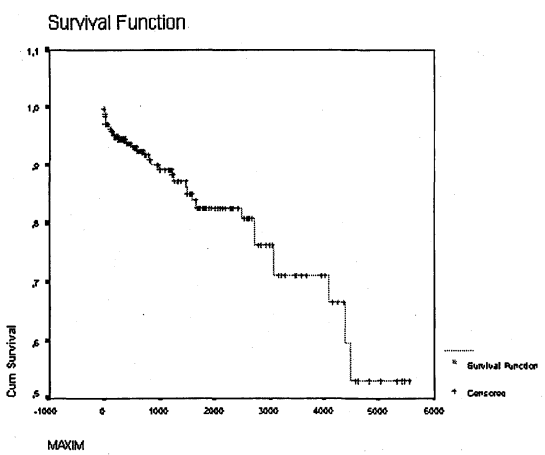

Figure 3 - The plotted cumulative patency of all cases. The patency of all graft and operations after more than 5000 days was 50%..In Table 1 the first three and the last three patients are presented, the tiny vertical lines are the censored cases.

Thirty five events (occlusion of a vascular reconstruction) were recorded , the maximal length of observation was 5544 days (15 years). The plotted cumulative patency of all reconstructions is shown in *figure 3.* Tailored to area of interest of the user, selections by operation site or operative procedure can be put through the statistical program.

The input and updating routines did not noticeably influence the workload of the vascular surgeon during his outpatient hours, the number of new and repeated patient visits in the period before and after the introduction of Kaplan Meier did not change. Subjectively, input of the operation and updating the duration of observation did not in any way disrupt normal procedures in the vascular clinic.

Discussion

Quality and quality assurance of healthcare has become an important issue in public health policy in many countries and most medical organisations and professional societies developed programs towards this goal. Improvement of medical education and structural changes in the organisation of healthcare are generally the instruments available for quality management. Professional medical societies in the Netherlands usually carry out peer review programs [8] and in some instances formal examinations take place among members of their societies. All these activities are important determinants to quality by giving form to the way medicine is conducted but in the evaluation of quality management the measurement of quality [9] is of paramount necessity. Measurement of outcome of care and clinical

research such as clinical trials are not synonymous but closely related and overlapping clinical tools. Doctor's time honoured curiosity in the effectiveness of medical care is expressed as clinical research and can also be seen as a measurement of outcome of care. If a medical workstation provides a clinical tool which would enable the doctor routinely to study his patients it would serve all mentioned purposes. Outcome measurements and clinical research are time consuming if carried out by studying medical dossiers so if doctors are to be interested in systematic study of their patients in terms of survival, patency of grafts, recurrence of cancer etc. the medical workstation should provide them with a user-friendly and time-saving method. The Kaplan Meier survival statistics, originally developed for the calculation of survival [3], can be used for a wide range of clinical questions [4,5,6] , it's only limitation

Table 1 - output from the SPSS Kaplan Meier procedure giving anatomical sites (column 1), time at risk (column 2) , event x=yes, cumulative survival (column 4), number of events (column 5), number remaining in obeservation (column 6). Only the first three and last three of the 263 cases are presented.

anatomical site of operation	time of graft at risk	x= event	cumulative survival	cumulative events	number remaining
AFCSUPLI	,00	x	,9962	1	262
AFCCRURE	,00			1	261
AFCINFLI	,00			1	260
.....	.....	.....	.....	...	.....
ILLI	5397,0			35	2
Aortobi	5455,0			35	1
AFCINFLI	5544,0			35	0
number of cases 263		*censored 228*		*events 35*	

being that the answer should have a binary form. The measurement results are easy to interpret and several statistical ways are available to test for significant statistical difference between two or more Kaplan Meier functions [7] . The satellite Kaplan Meier module with data input, presentation and output facilities proved to function extremely well under the busy conditions of a vascular outpatient clinic without notable impairment of it's routines.

A second important requirement for it's success as a clinical tool lies in the general applicability of the module to all the various possible binary questions which theoretically could become an unlimited number. The vascular surgery and the oncology versions made use of the same relational database with hardly any modifications needed. This was not the case for the data input screen of both versions. It became apparent that a fully graphic input screen had added value when anatomy and a large list of surgical procedures determined the input of data because an input table, used for inputting the oncology data, would have become too large for practical purposes. The Kaplan Meier module proved to be easy to operate and easy to maintain. It is expected that the Kaplan Meier module will be in routine use within the coming year.

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