OSSCAR:
A Collaborative Project for Intelligent Patient Monitoring in Intensive Care and Anesthesia

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Abstract

The aim of the French project OSSCAR is to strengthen existing collaborations between medical doctors, scientists and manufacturers in order to define new tools for intelligent patient monitoring in anesthesia and intensive care. Two specific objectives are considered: false alarms reduction and development of tools to help clinical staff in data interpretation and decision making. In order to go ahead face to these well-known challenging objectives, we firstly adopt a common ontology and develop a centralized data repository where medical information, collected in respecting specific medical protocols, are systematically recorded. These information concern physiological data, alarms, and medical annotations. Various collaborative works are then realized: deep information analysis, evaluation of data processing algorithms and data mining with the ultimate goal of defining specific scenarios representative of typical scenes to be automatically recognized. We report some results obtained in this on-going project concerning the "intelligent data analysis" work-package.

1 The medical problem

Currently in Intensive Care Unit (ICU), an increasing number of devices are available for monitoring and treatment. Each individual device is designed carefully according to safety requirements and includes lots of alarms. In a recent review about alarms in ICU, we concluded that generally the apparatus *per se* is safe, but the mode of alarms generation is the source of many false alarms if we consider a false alarm as an alarm with no clinical relevance [5]. In the context of a complex treatment, where physicians and nurses have to control a vast amount of data coming from multiple devices, an integrated safety level is missing [7]. This requires multi-parametric data interpretation.

The proper extraction and interpretation of information contained in such massive data sets, which are often observed with high sampling frequencies, can hardly be done by experience only [8]. One way to give an answer to the problem of data interpretation is to use knowledge formalized from existing medical consensus and/or expertise. However, this knowledge, most often formalized by rules, is incomplete. Thus, this approach needs to be completed by a data-driven approach [21]. These problems are largely discussed in the relevant literature and in spite of several research efforts, remain challenging. In order to go ahead we started the OSSCAR[1] project sponsored by the French research ministry. The aim of OSSCAR is to strengthen existing collaborations between medical doctors, scientists and manufacturers in order to define new tools for intelligent patient monitoring in anesthesia and intensive care. The system under study is the mechanically ventilated adult patient. This is a complex biological system difficult to model. The approach we use combines data abstraction and knowledge representation. Our objective is to abstract the information that are contained (or hidden) in the data and to compare them to medical knowledge. The final goal is to provide a support for decision making during medical acute situations. Whether an alarm is detected by classic monitoring equipment or by our multi-parametric approach, the presentation of the most relevant information regarding the situation provides assistance to the medical staff for interpretation and decision making [15].

Based on a commonly shared ontology, we have at first collected physiological signals and several events annotated by an experimented observer. Then, based on this continuously growing data repository, we have evaluated different methodological approaches developed by the participants for data abstraction. As medical decision-making is often based on trend analysis of physiological parameters, different methodologies for trends extraction have been studied and confronted. Starting from physiological parameter values and from extracted information, data learning approaches are now used to detect inter-relations between parameters and eventually to construct specific scenarios representative of clinically relevant situations. To illustrate our approach we selected the episodes of desaturation as a major clinical event to be early detected.

2 Clinical data

Our experience showed that on-line data annotation is essential and must be performed very carefully in order to allow a proper exploitation of the collected parameters. We have looked at several categories of data, results of an observation:

1. physiological data (waveform and/or parameter) directly acquired from the monitors (ECG, systemic arterial pressure and SpO2) and ventilators (airway flow and pressure). They are used to characterize the patient's status.
2. events represent the entities that modify the patient's status and/or modify the devices settings. According to clinicians the following events, entered into the computerized system by the observer in charge, have been considered:
   - modifications concerning drug therapy: addition, suppression, increase and reduction of drugs with vaso-active or sedative effects,
   - modifications concerning ventilator settings,
   - blood or plasma filling,
   - investigations such as EEG, thorax X-ray, blood gas sampling, ..
   - presence of any person at the bedside for care or visit (nurses, doctors, physiotherapist, family),
   - calibration procedures of the monitors, arterial line flush,
   - clinical observations such as movements, anxiety...
3. alarms, that occur during the observation, are annotated using the following definitions:
   - a true positive alarm is an alarm occurring when a value of a parameter is outside the alarm threshold AND a medical or a technical action follows. In this last case the alarm is annotated as a technical true positive alarm.
   - a false positive alarm is defined as a value of a parameter out of the limits but leading to no action.
   - a false negative alarm is defined when an action is performed on the patient or device corresponding to a problematic situation without prior alarm.

2.1 Data collection

We have defined two clinical contexts for data collection: the weaning from mechanical ventilation and the ending of sedative drugs administration. These contexts generate several unstable situations and alarms. Specific clinical protocols are followed during data collection approved by our ethical committee. Data collection is realized in real time without any interference with usual daily care. Any patient who meets the criteria required for the weaning procedure or who needs to be awaken is included in the study. Patient's characteristics such as age, gender, initial pathology are recorded. As usual, data are made anonymous before any diffusion. Recordings of the parameters or signals can be done as soon as the decision for weaning or stopping sedative drug is made by the physician in charge of the patient. Data collection (physiological data and annotation) starts one hour before the effective application of the relevant protocol (weaning or sedative drug stop) which lasts three hours. So each

[1]OSSCAR = French acronym for optimization of the medical strategies from cardio-respiratory signals in anesthesia and intensive care

record of annotated data was 4 hours long. The observer in charge of data collection is generally a non physician member of the OSSCAR project, but has a good physiological background and is aware of the importance of a correct annotation of the situations. Annotation correctness can be confirmed by the physician in charge of the patient. Two clinical sites are involved for data collection: Lille (LI) and Lyon (LY). Each site has its own ways for data collection,

1. In LI, the parameters coming from the cardiovascular monitor (UCW Spacelabs, Redmond USA) and the ventilators (Evita 2, 4 or Dura Dräger, Lübeck, Germany) are recorded on a personal computer (Aiddiag, [11]) using the serial link at a sampling rate of 5 seconds. Data annotation is made at the same time on the system using a pre-designed screen.

2. In LY, the waveforms (ECG, systemic arterial pressure and SpO2) delivered by the cardiovascular monitor (Datex 1606, Finland) and airway flow and pressure signals are connected through the Biopac MP100 system. AcqKnowledge software is used for signal acquisition at a sampling rate of 100Hz. The log file is used to enter the events following the predefined list of abbreviations. Then, these data are manually entered with a timing accuracy of a few seconds. The extraction of the physiological parameters is achieved later. It was done cycle by cycle using a program developed at the LAG [1]. The data are then re-sampled at 1Hz to be used as the raw data for the following procedures.

2.2 Distributed data sharing

We developed a specific software "NaineForge" to share the data, documents and procedures via the web (http://frodon.univ-lille2.fr). The access is protected using personal logins and passwords. Presently, it is rather a repository than a database. It looks like a file system. Some log functionalities have been developed in order to have a control on the use of the data that are available on the site. Any kind of data can be exchanged. Other facilities such as per-project forums, chat rooms and a "virtual distributed white board" are available to facilitate communication and collaboration between the research teams.

3 Data abstraction

We built a methodology for data abstraction that gradually allows the construction of scenarios. Data abstraction objective is :

- to transform numerical values, instant-point based, into symbolic values, time-interval based and,
- to generate several abstracted levels that synthesize parameters evolution.

Our methodology relies upon an incremental process handling three concepts: data, information and knowledge, based on an ontology. These three concepts are confused in the literature, so we prefer to re-characterize them. Data are the result of an observation or an experiment (here, numerical values of parameters); information is the result of the interpretation of data (here, for example, extracted trends); knowledge defines the way by which data and information are handled (here, clinical knowledge) [13]. This formalisation facilitates their manipulation in the abstraction process [19].

Because we are using real-time medical data, artefact detection is a pre-requisite step before any symbolic transformation [12]. We use a simple procedure for artifact detection based on the detection of outliers using absolute values. Absolute physio-pathological ranges for each parameter are defined. All the values out of the range are then replaced by a marked missing value. Gaps less than 60 seconds duration are filled with the mean surrounding values.

3.1 Numeric to symbolic conversion

Medical knowledge is most often expressed using rules such as "*IF parameter1 is increasing AND parameter2 is increasing AND parameter3 is increasing OR parameter3 is stable THEN conclusion...*" Thus, we take into account four categories: increase, decrease, stable and unstable.

At this step, for each parameter, we have to perform a series of operations to determine trends and then to split the time series in zones of predefined categories.

Numerical values, trends values will be then available to design more sophisticated abstractions.

Different techniques [10; 20] can be used to perform the numeric/symbolic conversion. Presently, in OSSCAR two techniques are implemented:

- The first technique (A) extracts on-line temporal sequences from the data. Temporal sequences are semi quantitative information, explaining the temporal behavior of a variable, such as "*systolic blood pressure is steady at 120 mm Hg from time t_0 until time t_1; it increases from 120 mmHg to 160 mmHg from time t_1 to time t_2...*" The method uses a segmentation algorithm which consists of splitting the data into successive line segments of the form: $y(t) = p(t - t_0) + y_0$ where t_0 is the time when the segment begins, p is its slope and y_0 is the ordinate at time t_0. The segmentation algorithm determines on-line the moment when the current linear approximation is no longer acceptable and when the new line segment that now best fits the data should be calculated, using the least squares criteria. The technique used to detect whether the linear approximation is still acceptable is the cumulative sum (CUSUM) technique. This technique consists of integrating the difference between the observed value and the current model. It is very sensitive to behavior changes in data and ensures that the algorithm can react quickly when confronted with sudden changes. Once a new segment has been calculated by the segmentation algorithm, the segment forms a shape with the preceding one that can be classified using a hierarchical tree. The class it belongs to is calculated from the variation observed on the variable between the beginning and the end of the segment and from the value of the discontinuity between the current segment and the previous one. Information about the value at the beginning and at the end of the shape is associated with the shape to provide information of such kind: the variable is steady (increasing or decreasing) since t_0 (time at the beginning of the segment) from value v_0 (the value at the beginning of the segment) to the value v_1 (value at the end of the segment). The shape is then aggregated with the previous one, using simple aggregation rules such as "*increasing since time t_0 until time t_1 from value v_0 to value v_1*" followed by " *increasing since time t_1 until time t_2 from value v_1 to v_2*" becomes "*increasing since time t_0 until time t_2 from value v_0 to value v_2*." The method is tuned by seven parameters. Five are used to tune the segmentation algorithm, and two to tune the classification into temporal shapes. Among the five parameters tuning the segmentation, two tune the decomposition into segments and three the rejection of artifacts. The values of the tuning parameters are different from one variable to another, but do not change from one patient to another. For more details about the method, see [6].

- The second technique (B) is issued from the work performed by D. Calvelo [3; 4]. The trend is computed using linear regression on a window whose size is determined according the dynamics of the parameter under study and called "characteristic span". When computed in that way, the trend is comparable to a derivative. It is then possible to reconstruct filtered data by integration of the trend values. At any time and at characteristic span, the value of the parameter and its trend characterized by the slope of the regression line are given. The standard deviation is used as an index of stability. We then used the partitioning of the trend vs stability plan (or more precisely regression coefficient vs standard deviation) to determine the predefined categories (increase, decrease, steady and unstable). Partitioning can be done according to different modalities. At this stage, it is difficult to have objective criteria for comparison and validation. So, the computation can be done according to different modalities and validation requires medical expertise. In the present study, they have been determined on a set of eighteen records realized by L. Biot [2]. Partitioning is performed using a fixed value of the regression coefficient (decreasing/steady = -0.7, steady/increasing = + 0.7). The choice of the value for stable/unstable is computed as the value of percentile 95 of the standard deviation distribution.

3.2 A step further in data abstraction

Starting from physiological parameters and trends, we can develop new abstractions [18]. However, the abstraction process should rely upon reliable parameter values. In our application domain, parameter values are often erratic. Thus, we restrict the abstraction process validity domain to domains where the parameter behavior is considered as valid. Validity domains are based on the notion of stability: if a parameter is marked as unstable, we consider its numerical values as invalid. Our abstraction process consists in a few steps:

1. parameters labeling in terms of stable or unstable,
2. characterization of the stability interval by the mean and the standard deviation of the values labeled as stable,
3. aggregation of the intervals according to temporal relations, mean values or raw data variations. Intervals around an unstable zone can be aggregated and the mean of all the measured values assigned to the aggregation, and
4. numeric/symbolic transformation of these final segments.

As a result, we obtain for each parameter, a semi-qualitative information which synthesizes the parameter evolution in terms of "normal", "high but normal", "high and abnormal", "low but normal", "low and abnormal" and "unstable". All these information are given on temporal intervals.

Starting from this information, we can detect simple patterns for each parameter, which represent events such as desaturation, disconnection or cough. Such types of patterns are shown in Figure 1 for SpO2.

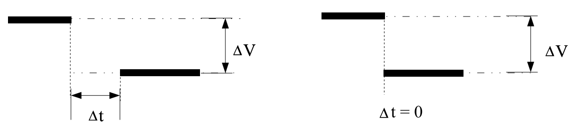

Figure 1: Two specific patterns for SpO2 parameter. Left: a temporal gap Δt separates two stable periods (bold lines). Right: meeting of two stable periods. A difference ΔV between their mean values can be measured. Depending on the values of Δt and ΔV specific SpO2 situations can be detected, a disconnection (right) or a desaturation (left)

4 Clinical validation

Initial validation is made during data collection for the annotation of the true and false alarms. The next step of validation concerns the trends calculation. It is performed by asking the expert to document *a posteriori* the raw data, in term of stable, unstable, increase or decrease of a parameter. This is done at two time scales. We first choose to present the parameter by successive periods of half an hour. The physician has to say if the variable has changed or not during this period and when. We do so to preserve the on line aspect of our treatments and prevent the physician from looking at further values to analyze the trend. Then the four hours record is presented and it is asked to the clinician to split the evolution of the global trend in relevant episodes. These episodes can be then related to external events. For the other abstraction steps, a specific tool is developed to allow the visualization of all abstractions and facilitate their validation by the clinical expert.

5 Preliminary results

Data collection is still going on. It started in March 2002. We collected 68 hours of observations on 17 patients (11 for weaning protocol, and 6 for sedative protocol). The data were imported and stored on the web site we created to facilitate the exchange of data.

We applied the above described methodologies on 6 physiological parameters: systolic arterial pressure (SAP), heart rate (HR), oxygen saturation (derived from pulse oximetry SpO2), minute ventilation (VE), respiratory rate (RR) and tidal volume (VT). An illustration of the results is presented in Figure 2 using SpO2 parameter.

The results obtained by the two filtering methodologies are quite similar (Fig 2-A, top = technique A, bottom = technique B). Short variations are discarded with the two approaches (around 2000). The larger one are preserved with the two methodologies but with distortion when using characteristic span.

Concerning the symbols (Fig 2-B) the top graph is directly constructed from the reading of the filtering signal obtained by the segmentation technique (technique A) and using the three qualitative values: increase, decrease or steady. The results of the symbolization according to trend vs stability partitioning (technique B) indicate some increase/decrease that don't seem significant on the signal at the represented scale. However, all periods of disconnection (short and large) appear as unstable.

Abstractions based on the two techniques (Fig 2-C) allow to detect four episodes (marked a, b, c and d) of disconnection when using unstability-stability information and one episode of desaturation.

The comments by the three physicians, when reading the record by successive periods of 30 minutes duration were the following: at time 2080 seconds, there is a transient modification that can be related to a tracheal suction. This short transient was filtered by both methods but found with the abstraction method, because the method B has detected it as an unstable period (marked "a" on Fig 2-C). The same event was detected at time 7000 seconds however lasting longer than the previous one, followed by a true episode of desaturation starting around 7600 and ending 8600. Two other episodes of disconnection around 10600 and 11200 were detected (marked "c" and "d" on Fig 2-C). Disconnection in 7000 is not identified as such. It is aggregated with the start of the desaturation. The end of the desaturation episode is recognized as a disconnection (marked "b" on Fig 2-C) by the abstraction process.

6 Discussion

Our clinical objective is to improve the clinical monitoring in anesthesia and critical care, by providing tools for false alarms reduction and for assistance in interpretation and decision making.

The involvement of medical experts since the beginning of the project has been central at several levels:

1. before data collection, to define all the events that must be reported in order to properly interpret the waveforms or the parameters evolution *a posteriori*, that is to say when the patient is not present any more. This constituted the basis for the domain ontology definition.
2. during the development stage, to define the limits of normal, low and high values of the physiological parameters required by some methodologies for artifact detection or rejection,
3. during the validation stage, to draw trends from the raw data and to compare them to the results of our procedures,
4. and finally, to determine episodes of clinical relevance through the visual multi-parametric analysis of all the signals. Such episodes are used for scenarios construction which eventually will be recognized on the fly by an automatic system.

When taking care of a patient, the first information the physician wants to obtain is whether the patient is stable or not. The next step is not to give a diagnosis, even if some clinical events could be detected automatically, but to present to the physician the data in such a way that this helps him to make a diagnosis or to take a decision. This requires to develop a high level of interpretation of all the data available from traditional monitoring and ventilators. The development and validation of new methodologies require an access to high quality and validated physiological data obtained in a variety of pathological conditions. Thus, we have firstly focused our efforts to the development of an annotated repository shared by the partners. From this we have validated two techniques to assess the stability and unstability of the parameters.

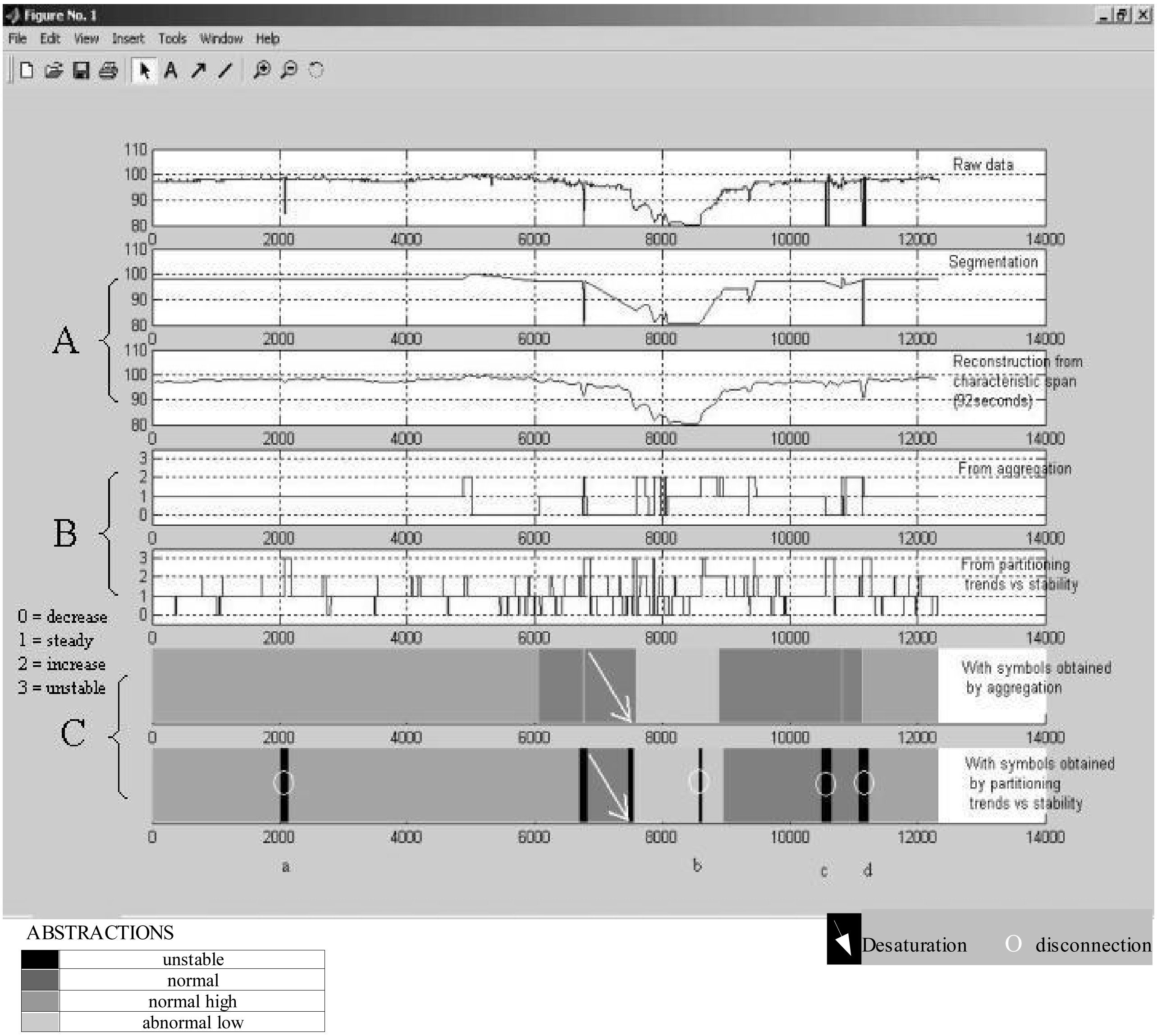

Figure 2: Example of the data abstraction process applied to SpO2 parameter. Part A shows the filtering signals according to the two techniques used (segmentation and characteristic span); part B shows the results of the numeric-symbolic conversion according to the two techniques and part C shows the results of the abstraction process. The desaturation episode is detected whatever the technique used for trend detection. The technique using characteristic span and stability/unstability allows the detection of disconnection episodes a ,b, c ,d (see text for more details).

The importance to construct documented database is not new. In 1996, as part of the IMPROVE (EU/BIOMED-1) project, an annotated database was realized. The IMPROVE Data Library [14] consists of digital recordings of continuous monitored signals (ECG, systemic blood pressure (SAP), pulmonary arterial pressure(PAP), central venous pressure (CVP), airway flow and pressure and concentration of oxygen and carbon dioxide in the airway gases), clinical patient data and continuous patient state annotations. This data library is commercially available. More recently, Goldberger et al. [9] presented PhysioNet, which offers free access via the web to large collections of recorded physiological signals (PhysioBank) and related open-source software (http://www.physionet.org/). PhysioBank is a large and growing archive of well-characterized digital recordings of physiological signals. Among them, there are multi-parameter databases concerning ICU such as MGF/MF waveform database [17] and MIMIC database [16]. Continuous hemodynamic signals such as SAP, PAP are available. Only few continuous respiratory signals are available (end tidal CO2, respiratory impedance). Documentation includes waveform annotation and/or monitor alarms. However, our concern is much more about the interpretation of physiological parameters as they are provided by the monitoring devices to the clinician, not about waveform analysis.

We initially thought to be able to collect information once a week, leading to integrate around fifty patients for the two sites until December 2002. Unfortunately, this was not possible according to many factors: some are directly linked to the ICU environment where you have to combine the availability of the person in charge of the data collection and the possibility for the patient to be weaned or no more sedated. It is indeed impossible for a person working in the ICU to manage properly its clinical activity and the protocol, even if he (she) is coming only for the protocol. So we had to call a person with no usual activity in the ICU, to be sure not to be solicited by any other medical action. So the collection was done properly according the list, but only few cases were recorded. However, according to our objective to provide relevant information related to events of clinical relevance, collected data and annotations made according to the list are not sufficient to validate our results. The only way to obtain this clinical relevance is to ask medical experts to read again the records in order to make an interpretation. The main problem at this stage is to determine at which scale to re-read the records. This interpretation can be refined according to the annotations.

Concerning data treatment, the question is: should the parameters be pretreated or not before further analysis ? If we are just interested in the patient's status, the artifacts should be removed from the data. If the objective is to detect some events, raw data should be used. So, both should probably be done. Some events such as drawing blood samples or measuring cardiac output, or making zeros lead to values that are outlier values, but are representative of an event. It is not a problem of sensor or measurement but mainly a problem related to an external action. From the point of view of measurement, the values provided by the sensor are correct. But at this time of external event, the measurement is no more representative of the system to monitor.

At this stage, it is not possible to compare the results of the methodologies used for trend detection. Too few signals have been analyzed by the physicians. Currently, a complete comparison could be performed at the end of the treatment only, by comparing the number of false alarms detected by each method. The two methods have been conceived for on-line real-time implementation. The segmentation approach needs no learning period, but needs the determination of predetermined thresholds according clinical expertise. The use of a characteristic span needs a learning period. This approach is made in order to take into account the proper dynamics of each parameter, so it is hypothesized that small changes that can occur in a patient's physiology over long periods of time could also be detected. The information about the variance of the parameter is lost by the segmentation algorithm. This information may be useful to make an interpretation during an alarm. This information is conserved with the characteristic span method, since when the variance of the parameters is large the parameter is quoted as unstable. This approach is only data-driven.

A higher level of abstraction is provided taking into account the numerical value, the trend and some heuristics based on medical knowledge. It relies on the notion of parameter validity based on the stability-unstability measurement. The two techniques we have used for the trends detection allow to detect the desaturation episode. The technique B using unstability/stability allows the detection of four disconnetion episodes (marked a, b, c and d on Fig 2-C bottom). It is more sensitive than the A technique and only a false disconnection is detected (b). The next step is the development of multi-parametric approaches that are necessary to build the models to be confronted with medical knowledge. Different approaches will be considered but have not yet been explored on the available data set.

7 Conclusion

The work we have started in the "intelligent data analysis" work-package of OSSCAR project is at the stage of academic researches and involves mainly medical doctors and scientists. We have created a tool to promote data exchanges between different laboratories. A lot of work is to be done for data collection and development of new methodologies, but we have created the environment allowing to go further.

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