Initial experience with the world’s first digital drainage system.
The benefits of recording air leaks with graphic representation

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Abstract

Objective: To evaluate the clinical efficacy of a new digital drainage system, the DigiVent™ Chest Drainage System that gives accurate measurements of air leakage and pleural pressures and can display those measurements over time. Methods: The DigiVent™ Chest Drainage System was tested in three steps: Step 1; first clinical use in five patients, Step 2; management and acceptance in further 15 patients and Step 3; reliability in routine use in 50 patients. Result: The results from Steps 1 and 2 showed that the system was good enough for extended use. The results from Step 3 showed excellent clinical performance, however, we experienced device malfunctions in four cases without any consequences for the patients. The cause of the malfunctions was identified and steps taken to prevent their further occurrence. Conclusion: The ability of the DigiVent™ to measure airflow and present mean values for 1, 3 and 6 h proved to be very practical. The ability to save data and present curves for the entire course of treatment will be an advantage for research in the field of lung surgery.

Keywords: Postoperative pneumothorax; Chest drainage; Air leak; Chest tubes; Pleural drainage systems; Lung resection

1. Introduction

Postoperative air leaks are common after thoracic surgery. Reports have estimated their incidence ranging from 25 to 75% depending on the type of procedure performed [1—4]. Successful chest tube management and removal depends on accurate evaluation of the patient’s air leak. Inserting a chest tube is the standard treatment for several forms of pneumothorax and hydrothorax [5—8]. Conventional drainage systems rely on bubbling in the water seal to continuously track persistent air leakage over time. The monitoring of the applied negative pressure is indicated by either another water chamber or, in the so-called dry systems, by the position of a knob. However, in either type of device the real pressure in the pleura remains obscure [9—12]. The monitoring of air leakage volume has been possible to monitor only in the electrical pump, ‘Pneupump’, from Medela, which is not disposable and is expensive to buy and maintain. This system is no longer available.

In the Department of Thoracic Surgery at Sahlgrenska University Hospital, we have been closely involved in the development of a new drainage system, the DigiVent™ Chest Drainage System, by Millicore AB. Thus, it has been tailored to meet our needs in the field of drainage, resulting in a customized design for this intended use. The DigiVent™ Chest Drainage System is now commercially available in many countries after being accepted by the European regulatory authorities. This chest drainage system indicates actual airflow, records air leaks over time, shows true pressure levels, and displays the pressure variations with respiration, the ‘swing’. With the realisation that the new system has little resemblance to conventional devices, efforts have been made to render the device simple and intuitive to use.

The DigiVent™ System is shown in Fig. 1. The droplet-shaped uppermost part is the removable ‘brain’ of the system, which is called the controller unit.

1.1. Technical description

The DigiVent™ System is basically similar to conventional drainage systems with a 2000 cc collection chamber, a dry one-way valve, and a dry suction regulator that provides a steady level of applied intrapleural pressure. However, the DigiVent™ has a very low and compact design that allows it to be very stable when placed on the floor. The sensor electronics consists of two MEMS (Micro Electronic Mechanical System) sensors, one for measuring flow and one for...
measuring pressure, and two electronic circuit boards. The electronics provides sensor signal conditioning and compensation, data storage and data display. The electronics are battery powered (7 days) and are intended for one-time use only at this point. An LCD display is used to present measurement data.

The system also features:

- Measurements of airflow from 0 to 9 l/min.
- Pressure readings from +5 to –99 cm of water.
- Memory recording all air leaks from the start of treatment with the capability to retrieve customized curves of the whole treatment episode.
- Safety design—continued drainage function even if the controller unit is temporarily removed.
- Gravity drainage function, which allows certain mobility without a suction source.
- Flexible hangers.

1.2. Set-up and use

The controller unit is connected to the top of the DigiVent™. The drainage tube from the patient is connected to the drainage port on the top of the device. The drainage tube is then temporarily clamped, and the desired level of negative pressure is set by rotating the green knob while observing the digital display. Wall suction is set at –200 mmHg or –50 Pa. Accumulation of fluid is measured by the scales on the front of the device. Air leakage is read on the display. Accumulated values of air leakage for 1, 3 and 6 h can be obtained by pressing the 'Acc' button.

2. Methods

This validation study was performed in three steps. In Step 1, five units were used clinically for the first time with rigorous control from the surgeons and with the assistance of representatives from Millicore AB to ensure that the function in vivo was as good as in the laboratory.

In Step 2, the study was expanded to 15 consecutive patients constituting a test group to evaluate the acceptance of the system by the nurses who had been trained in handling it. A questionnaire with a battery of questions regarding ease of use, handling, and understanding of the system was distributed to the nurses (Table 1).

Another goal in Step 2 was to validate the clinical function of the system. The patients had chest tubes after thoracotomy and lung surgery (lobectomies or wedge resections), and were connected to the new digital chest drainage system. The progression of air leakage and intrapleural pressure was continuously displayed and tracked. To validate the effectiveness of the system, all patients had an X-ray examination after surgery as well as at the end of each treatment episode.

Step 3 consisted of 50 patients in whom the DigiVent™ was substituted for another drainage system being used on the patients in order to follow up the performance of the system as a routine treatment. The units were checked for quality of the manufacturing and all the chips from the control unit were collected for further analysis.

3. Results

3.1. Step 1

The initial test with five drains showed that the function was as expected. The experience was used to fine-tune the delay of the digital presentation of air leaks and of the pressure readings.

3.2. Step 2

Fifteen consecutive patients were treated with DigiVent™ Chest Drainage Systems for a period of 1–4 days. The
progression of air leakage and intra pleural pressure was continuously displayed and recorded. Our observations were consistent with the literature as 4 of the 15 patients (26%) experienced postoperative air leakage. The patients with postoperative air leakage also showed signs of normal pressure variations during the breathing cycle. The other 11 patients (74%), patients had only an immediate air leak and then no signs of significant air leakage during the drainage period and the chest tubes were removed safely. One patient who was expected to have a normal compliance showed signs of excessive pressure variations even though there was no presence of air leakage. After X-ray examination it was obvious that the lung had not fully re-expanded. An increase in applied vacuum resulted in an immediate air evacuation and then the pressure variation ended indicating that the lung was fully re-expanded. In all other patients, the final X-ray examination revealed no residual pneumothorax or any pleural effusion.

The nursing staff completed the evaluation questionnaire. To summarize, the responses given by the nurses on all questions varied between 65% and 69% of the maximal possible score. No one disliked the system. We, therefore, conclude that the device is fairly easy to handle and understand. No problems with the new system were identified. The four pulmonary surgeons in our department have been very satisfied.

3.3. Step 3

The next 50 patients were treated uneventfully clinically, but four devices malfunctioned. In two units, there was a leak present in container lid, which caused a false indication of air leakage on the digital display even though it was observed that no air bubbled through a small volume of fluid in the tube. These devices were replaced. In another two devices, there was a compatibility problem between the container and the controller unit. The digital display showed the message ‘Err’ meaning ‘error’. This required that the drainage system, both the container and controller unit, be changed.

A minor problem was noted in some devices. From the beginning of the series there was a secure fit when the controller unit was attached to the container. But later in the series it was noted that the attachment of the controller unit was a little loose and moved with finger pressure. This had no influence on the function of the DigiVent™ and it has been corrected in later devices that we have used. The other problems also have been carefully evaluated and corrected. None of the malfunctions have had any negative consequences for the patients. After use, the controller units were collected and returned to Millicore for evaluation in their laboratory where different forms of graphic representations of the entire treatment period have been created (Figs. 2 and 3).

4. Discussion

A few malfunctions with operation of the DigiVent™ were noted during the total study of 70 patients. Millicore has since resolved these malfunctions and later devices have functioned satisfactorily. The DigiVent™ has now replaced the
older forms of drainage system at our clinic. It has also been used to satisfaction in two other Swedish centres. The feature that pleases us the most is the built-in memory for air leak. In the morning rounds at the ward the air leak meter may indicate zero leakage. As air leaks often are intermittent, with conventional units you have to come back later, maybe several times, to see if the air leak has really ceased. With the DigiVent™ you now press the ‘Acc’ button once to display total air leakage in the previous hour, twice to check for air leakage during the previous 3 h and three times to check air leakage during the previous 6 h. This is a very quick check. After this you can be convinced that the patient no longer has an air leak and make the immediate decision that the tube may be removed. This practice has proven to be very reliable for us. The benefit of this technique will be that the patient will get rid of drainage tubes earlier and speed up their mobilisation [13,14]. The overall cost savings in patient treatment will justify and offset the higher price for the DigiVent™.

In cases where we have an air leak, it is valuable to have a quantified air leak so that you can accurately assess trends in leakage rates and make a prognosis for when you can expect the air leak to cease. If you have a sustained air leak of several litres, for example, this information will enable you to decide to take active measures to treat it. The ability to accurately measure and record leaks may be most important in patients with prolonged postoperative air leakage [15—19].

There is an advantage of having a precise measurement of the applied negative pressure as the same time that you have exact measurements of the air leak. If, for example, you decrease the suction force you may soon notice an effect on the air leak. Perhaps this could constitute a form of fine-tuning of the suction. Theoretically, the representation of the respiratory ‘swing’ could give you a warning if the suction becomes too low to extract all air. If so, the ‘swing’ is expected to increase. However, we do not yet have enough experience to make any recommendations. The controller unit of the DigiVent™ is a precision instrument that makes older types of drainage units seem obsolete [20,21].

The indication of the normal respiratory variations, the ‘swing’, also serves as verification that the drainage tubes are patent. If there is doubt, the patient may be asked to cough, which causes a pressure wave from the pleura to be recorded on the digital display thus verifying patency. The magnitude and frequency of the respiratory pressure changes gives valuable information and it is possible that in future versions of the DigiVent™ that it could be recorded with actual figures on the display instead of a simple graphic representation. In the memory chip, the respiratory variations are already recorded exactly and can be presented as curves if you have a read-out device.

At the end of a prolonged drainage period, it might be an advantage to use DigiVent™ in a passive mode without an external suction source. The display will show the amount of accumulated negative pressure in the volume container. If there is a drop in pressure, active suction should be resumed [22].

The DigiVent™ will be an excellent research tool. In a university clinic, we must perform various clinical studies, for example, testing different ways to minimize air leaks postoperatively with glues or other methods [4,23—25]. With the DigiVent™, air leaks can be accurately evaluated and statistical analyses can be made, not only concerning days with drain but also in regards to quantifiable and true values for air leaks, thus eliminating several confounding factors.

To extract all information and construct curves for air leaks over time together with values for pressure in the pleura, the controller unit must be placed in a read-out device connected to a standard computer. The read-out device is available to us, but is not yet commercially available. For examples of possible curves, refer to Figs. 2 and 3.

One future possibility that is under consideration by Millicore AB is to make it possible to extract the information from the controller unit by using infrared technology directly to a handheld computer. The DigiVent™ will in that case be able to automatically send the patient information directly to the doctor’s PAD. Another option that is being considered is to make the controller unit reusable by purging it of prior use patient information before attaching it to another container. When the drainage technology goes digital, the possibilities only depend on programming. The system may in fact be customized in many ways.

References


