

The Future of the Perfusion Record: Automated Data Collection vs. Manual Recording

Jane Ottens BSc, Dip Perf, CCP(Aust);* Robert A. Baker, PhD, Dip Perf, CCP(Aust);†‡
Richard F. Newland, BSc, Dip Perf, CCP(Aust);† Annette Mazzone, BSc, Dip Perf†

*Ashford Hospital, Ashford, South Australia, Australia; †Flinders Medical Centre Bedford Park, South Australia, Australia; and ‡Flinders University, Bedford Park, South Australia, Australia

Presented at the 43rd International Conference of the American Society of Extra-Corporeal Technology, New Orleans, Louisiana, March 3–6, 2005

Abstract: The perfusion record, whether manually recorded or computer generated, is a legal representation of the procedure. The handwritten perfusion record has been the most common method of recording events that occur during cardiopulmonary bypass. This record is of significant contrast to the integrated data management systems available that provide continuous collection of data automatically or by means of a few keystrokes. Additionally, an increasing number of monitoring devices are available to assist in the management of patients on bypass. These devices are becoming more complex and provide more data for the perfusionist to monitor and record. Most of the data from these can be downloaded automatically into online data management systems, allowing more time for the perfusionist to concentrate on the patient while simultaneously producing a more accurate record. In this prospective report, we compared 17 cases that were recorded using both manual and electronic data collection techniques. The perfusionist in charge of the case recorded the perfusion using the manual technique while a sec-

ond perfusionist entered relevant events on the electronic record generated by the Stockert S3 Data Management System/Data Bahn (Munich, Germany). Analysis of the two types of perfusion records showed significant variations in the recorded information. Areas that showed the most inconsistency included measurement of the perfusion pressures, flow, blood temperatures, cardioplegia delivery details, and the recording of events, with the electronic record superior in the integrity of the data. In addition, the limitations of the electronic system were also shown by the lack of electronic gas flow data in our hardware. Our results confirm the importance of accurate methods of recording of perfusion events. The use of an automated system provides the opportunity to minimize transcription error and bias. This study highlights the limitation of spot recording of perfusion events in the overall record keeping for perfusion management. **Keywords:** electronic data, computerized data collection, data accuracy, record keeping, cardiopulmonary bypass.
JECT. 2005;37:355–359

The perfusion record is a legal record of the cardiopulmonary bypass (CPB) procedure and should be an accurate and legible document. Traditionally, the perfusion record has been handwritten, with the perfusionist documenting specific parameters and events, often every 5–10 minutes or when changes in monitored parameters occur or events dictate documentation (e.g., drug administration). This manual method of data collection produces a record that can be filed into the medical record; however, these records are often inadequate (1–3). The manual record cannot offer a complete picture of what has occurred

during the bypass period, with errors able to be introduced in a number of ways. These inadequacies include missing data, such as when the perfusionist is distracted by more pressing events; biased recording of information; transcription error; and subjectivity of observation.

The accuracy of recording intraoperative data has been examined in anesthesia, where computer-generated records have been compared with handwritten records, and the quality of the data collected examined (1–3). Each of these papers reported a bias in the handwritten records when blood pressures were recorded, finding that, when actual blood pressures were lower or higher than expected, the recorded data points were normalized toward the expected rather than the actual value. They concluded that the handwritten anesthetic record should not be relied on as a source of accurate data for research (3).

All of these issues give rise to the question of the integrity of the data documented manually. How accurate is

Address correspondence to: Robert A. Baker, PhD, Dip Perf, CCP, Dept. of Cardiac and Thoracic Surgery, Flinders Medical Center, Bedford Park, South Australia, Australia, 5042. E-mail: rob.baker@flinders.edu.au

The senior author has stated that authors have reported no material, financial or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

this record of events that actually occurred? The manual record only produces a snapshot of the CPB procedure, and it is not possible to extrapolate what has occurred between recorded events. In legal cases, expert perfusionists may be consulted to fill in the gaps of a manual record; however, the value of this input is questionable.

There has been a gradual evolution of electronic data output from monitoring devices available in the cardiac operating room, which facilitates the recording of this information into an electronic database (1). The variety of different technologies capable of outputting electronic data has expanded, now including most electronic devices in the operating room (e.g., anesthetic machines, blood gas analyzers, perfusion systems, and other point-of-care analyzers). In addition, the ability of electronically generated records to integrate with hospital information systems and databases is now common. Unfortunately, most of the technology available today has not been embraced with enthusiasm or used to its full capacity.

There are a number of heart lung machine systems that are able to generate an electronic record with the aid of data collection software. These systems have automatic data acquisition and integrate data from the pump system and other monitoring systems in the operating room. The management of the cardiac surgical patient in the operating room is increasing in complexity, with an increasing number of monitoring devices assisting in the management of patients before, during, and after CPB. This results in more data for the perfusionist to monitor, record, and respond to. If the data from these devices is recorded automatically, it allows more time for the perfusionist to concentrate on the conduct of CPB rather than on documenting the procedure manually. Manual entry is minimized with data collection software, being required only for events that are unable to be electronically detected and is often accomplished by simple single key-stroke entry.

Heart lung machine systems incorporating some degree of automatic data management have been available for many years; however, most clinical units using these systems have not fully used the technology available. Many prefer to record data manually (4). In addition, there are software solutions available that can be used in conjunction with manual data recording to integrate data such as PerfBase (<http://www.perfusion.com>) and Perfusion Data Solutions (West Terre Haute, IN) that allow charting, quality control, and reporting features (4). The integrity of the data in these systems may still be open to bias, because the data entry can be configured to require manual input.

In this prospective study, we compared two different methods of perfusion data collection: automatic data collection, using the Data Management System (DMS; Stockert, Munich, Germany), and the traditional manual perfusion record.

MATERIALS AND METHODS

We prospectively compared 17 cases that were recorded using both manual and automated electronic data collection techniques. All cases were elective coronary artery bypass surgery, except one case in which a repair of an atrial septal defect (ASD) was also performed and a second, which was an off-pump conversion to bypass.

Surgical and Perfusion Management

All patients received a moderate fentanyl-based anesthetic technique. CPB surgery was performed using the Stockert S3 (Munich, Germany) roller pump heart lung machine and Hemotherm heater cooler unit (Cincinnati Sub Zero, Cincinnati, OH). CPB was initiated after cannulation of the aorta (21-Fr cannula) and the right atrium (single 36-Fr dual-stage cannula) for venous drainage. Bicaval cannulation was used for the ASD repair (32-Fr cannula). The circuit consisted of a Capiiox SX25 (Terumo Corporation, Tokyo, Japan) membrane oxygenator, a Jostra 40- μ arterial filter (Hirrlingen, Germany), PVC tubing (Cobe, Denver, CO), and a crystalloid prime of 1600-ml (consisting of 100 ml Hartmann, 1000 ml plasmalyte 148, 500 ml gelofusine, 50 ml sodium bicarbonate [8.4%] and 10,000 U of heparin). Alpha stat blood gas management protocol was used. Activated clotting time (ACT) was measured using the Hemochron 401 (International Technidyne Corporation, Edison, NJ), and maintained above 400 seconds. Patients were allowed to drift to 34°C and received antegrade blood cardioplegia with an initial dose (500 ml) of tepid high potassium (30 mM KCl) blood cardioplegia (4:1, delivered at 250 ml/min at 32°C) to induce asystole. In addition, low potassium (15 mM KCl) blood cardioplegia was given to maintain asystole or at approximately 20-minute intervals. Mean arterial blood pressure (MAP) was maintained between 40 and 70 mmHg. No cases were vented; however, a pump sucker was used in the ASD repair. All cases were performed by one perfusionist (J.O.), one of two surgeons, and one of three anesthesiologists.

All routine functions such as rewarming, assessment of transfusion requirements, and administration of pharmacological and volatile agents were performed in the usual manner according to institutional protocol by the perfusionist in charge.

Manual Data Collection

The perfusionist in charge of conducting CPB recorded the procedure using the manual technique. The manual record was documented in accordance to institutional protocols, with patient parameters recorded every 5–10 minutes or if changes occurred. The parameters recorded were time and major events, MAP, venous pressure, line pressure, venous saturation, hematocrit, and nasopharynx-

geal, arterial, and venous blood temperatures. Blood gas analysis was undertaken approximately 10 minutes after the initiation of CPB, 3 minutes after cross-clamp removal when rewarming, and every 30 minutes. All information was transcribed temporally onto the pump sheet when possible. Data were collected in a routine manner from the prebypass period until the completion of CPB.

Automated Electronic Data Collection

A second perfusionist (A.M.), present for the entire procedure, entered relevant events into the electronic record using the DMS. The DMS was configured to collect data at 20-second intervals from the S3 heart lung machine (Stockert), S5 anesthetic monitor (Datex-Ohmeda, Helsinki, Finland), and the Biotrend venous saturation monitor (Medtronic, Minneapolis, MN). Data were also collected electronically from the ABL725 blood gas analyzer (Radiometer, Copenhagen, Denmark) after blood gas analysis. The DMS was run on a Compaq Armada E500 Pentium III laptop computer (Hewlett Packard, Palo Alto, CA) using a Windows 2000 operating system (Microsoft Corporation, Redmond, WA). Intraoperative data were collected from patient intubation until the CPB circuit lines were returned by the surgeon. Events, such as drug addition, were entered manually by keystrokes into the laptop. The blood gas result was accepted by a single keystroke to confirm that the perfusionist had seen the results and for data storage.

RESULTS

Analysis of the perfusion records generated manually and electronically highlighted significant variations in the type of information and the quantity of recorded information. We identified the following areas to show the most inconsistency, the most obvious being the difference in the number of time-points for which data were collected. The electronic record was configured to record data every 20 seconds, which for our average bypass time of 52 minutes, resulted in 156 sets of data during bypass (Figure 1). The manually recorded data were only recorded on average 15.5 times per case, with the time interval between entries ranging from 2.7 to 6.2 minutes.

There was also a large difference in the number of pro-

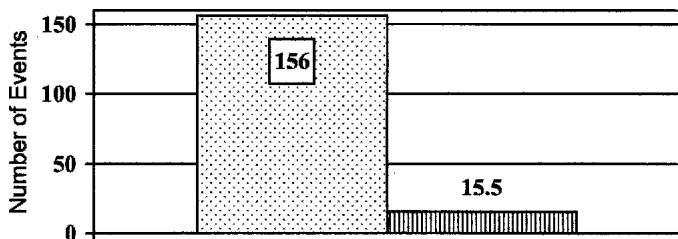


Figure 1. The average number of data points collected in the automatic (spotted bar) vs. manually (striped bar) collected records.

cedural events recorded. Most major events were recorded on the manual record during the procedure (e.g., X clamp application, drug administration, and blood gas results); however, on the electronic record, these events and many additional events (e.g., activation of electronic low level or air bubble alarms) were captured. These additional events were not documented on the manual record. Figure 2 shows the difference in the actual data recorded by both methods. Highlighted in this comparison of the MAP for an entire case is the failure of the manual record to capture the maximum and minimum pressures actually reached during bypass. This comparison also highlights that data were not collected from the initiation and weaning of CPB on the manual form, because the perfusionist was not able to record manually the parameters before bypass because of other duties.

MAP data for all cases are displayed in Figure 3. The minimum mean MAP recorded manually was 34.7 vs. 30.3 mmHg, which was recorded electronically ($p < .05$); the range of variation was 2 to -13 mmHg ($p = .001$), and the maximum manual pressure was 69.1 vs. 74.2 mmHg (range of variation, -4 to 25 mmHg; $p < .05$).

Figure 4 highlights the blood flow variation recorded in a single procedure. The manual record failed to capture

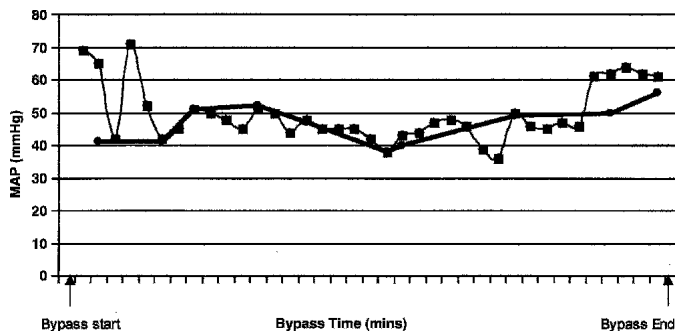


Figure 2. Example of MAP collected both manually and automatically. MAP is plotted against time for manual (●) and automatic (■) records.

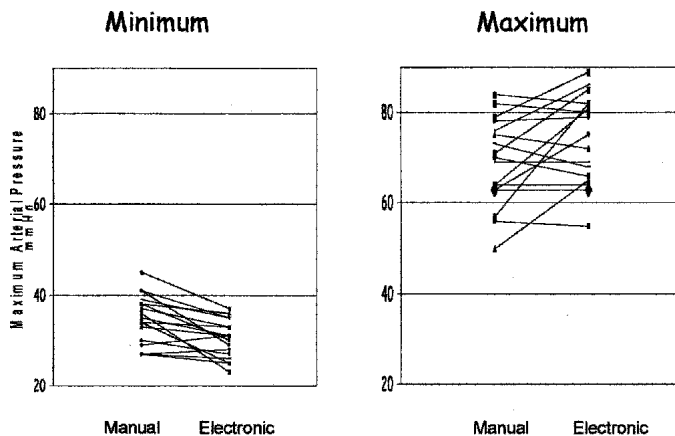


Figure 3. Scattergram of minimum and maximum MAP recorded manually and electronically.

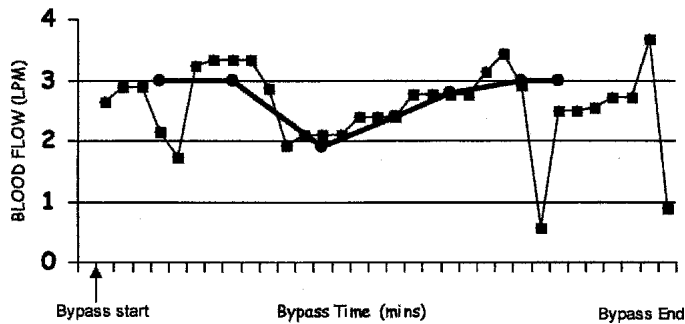


Figure 4. Example of blood flow collected both manually and automatically. Blood flow is plotted against the time for both the manual (●) and automatic records (■).

relevant information in relation to changes in blood flow. This was highlighted at the end of the procedure, when partial bypass was required and there were no manually reported data.

Figure 5 is a record of arterial outlet temperature, which is similar for either method; however, the manual data collection method failed to record extremes. There were differences in the rate of rewarming between the two records, and a failure to capture the maximum temperature and minimum temperature was evident. The arterial outlet temperature across all records (Figure 6) varied from 33.3°C (manual record) to 31.2°C (electronic); the range of variation was 0.7–6.9°C ($p = .002$). The maximum mean temperature recorded manually was 37.6°C, whereas electronically, temperatures in excess of 38°C were recorded, with temperature differences ranging from -1.3 to 0.1°C ($p = .001$). This inconsistency was also evident in the nasopharyngeal temperatures (Figure 7), with the mean minimum nasopharyngeal temperature recorded manually being 34.2°C compared with 33.7°C, which was recorded electronically. The range of the difference between records was -0.6°C to 3.2°C. The maximum nasopharyngeal temperature also showed variation, with a manual mean temperature of 36.4°C compared with 37.2°C being recorded electronically (range of difference, -1.6°C to 1°C; $p < .05$).

The recorded volume of cardioplegia delivered was in-

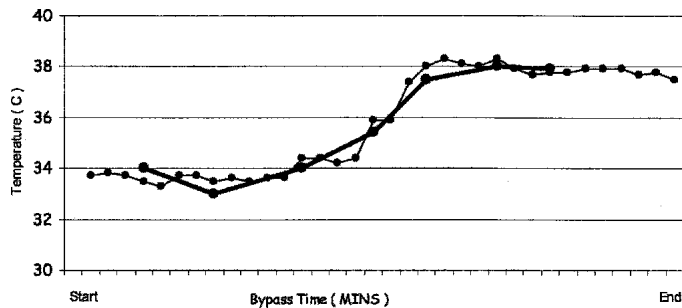


Figure 5. Example of arterial blood temperature measurement collected both manually and automatically. Arterial blood temperature is plotted against time for both the manual (●) and automatic records (■).

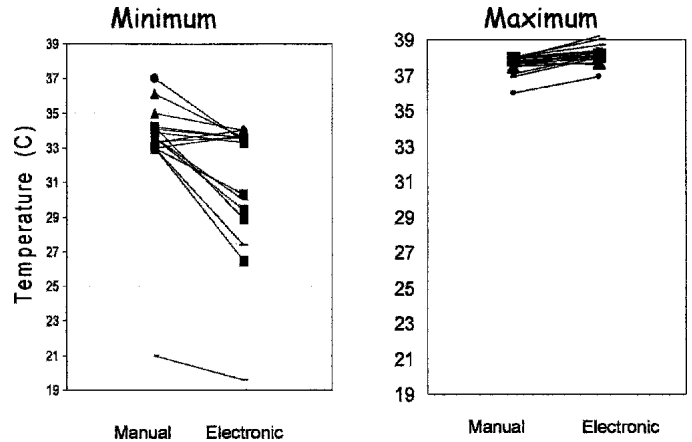


Figure 6. Scattergram of minimum and maximum arterial outlet temperatures recorded manually and automatically.

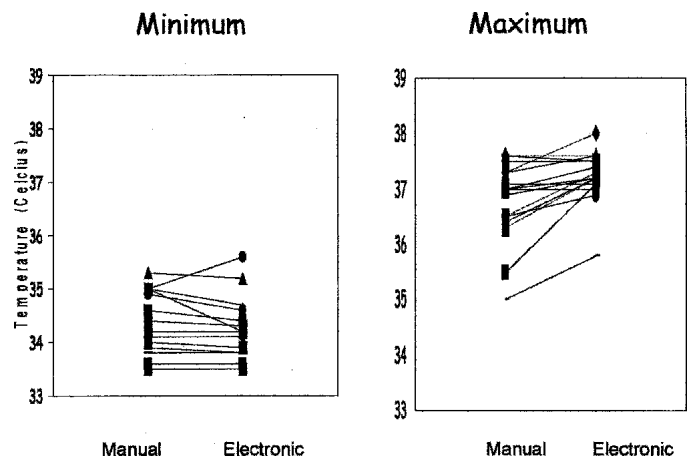


Figure 7. Scattergram of minimum and maximum nasopharyngeal temperature recorded manually and automatically.

consistent between the two records (Figure 8). This is highlighted by the difference in the volume of cardioplegia delivered that is recorded. The volume reported varied by as much as 70 ml (range, 0–70 ml).

There were limitations to the electronic system. We found that in the recording of gas flow data, the manual record was more accurate, with more data entry occurring in the manual record for events relating to gas flow than on the electronic record. Because we have not integrated an electronic gas blender, electronic data acquisition of gas flow values was not possible.

DISCUSSION

Significant differences in reported data were apparent on a number of the parameters (e.g., MAP, temperature), as well as the range of values reported, between the two methods of reporting, indicating the large variability between techniques. These findings do raise questions, such as “how important is it to accurately report what is occur-

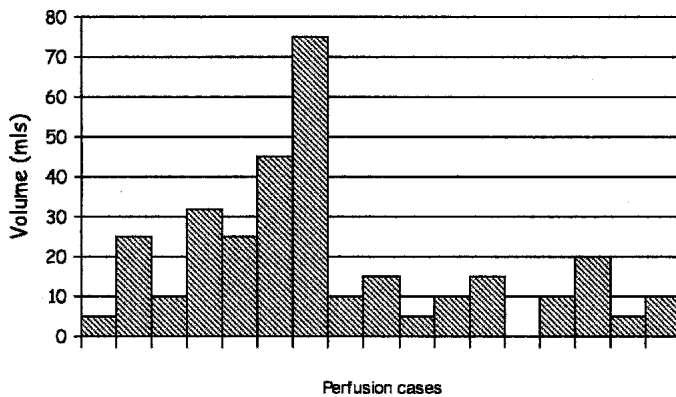


Figure 8. With all 17 cases, the difference in volume delivered between the manual record and the electronic record.

ring during bypass?,” “is the minimum pressure reached during a case important?,” and “is it acceptable to report a pressure that has an error of 50%?” The answer to these questions is complex; however, there can be no surrogate for accurate record keeping during cardiac surgical procedures. Our findings reflected those reported in similar studies evaluating record keeping in anesthesia. For example, with MAP values, the extremes seen in the electronic record were minimized in the handwritten record (1–3).

These results show the improved accuracy of recording perfusion events using an electronic data acquisition system and highlight the inadequacies produced by spot recording, with the manual record failing to capture critical events, such as maximum and minimum MAPs and temperatures. The integrity of the data from automatic data acquisition removes the bias that is produced in the manual record.

The ease at which events can be documented in the electronic record, such as a few keywords or keystrokes, gives the perfusionist greater ability to concentrate on performing CPB. This facilitates optimal patient management because it removes the task of manually documenting routine parameters, especially when more urgent events happen. In fact, if “emergency” events do occur, the automated record provides data for the period that may otherwise not be available. This can aid in analysis of the event and the development of strategies to better cope with perfusion emergencies, such as oxygenator failure.

The collection and recording of an accurate electronic record should be seen as beneficial, providing support for clinical practices. The premise is that if CPB is being performed according to institutional protocol, the data collected will reflect this. When an adverse outcome occurs, the electronic record additionally should be a valuable source of information because it records actual time-related events that have occurred and does not require “expert advice” to speculate on what “may have” actually happened.

There are, however, limitations to automatic data acquisition, such as recording of artefacts. For example, the flushing of a central venous pressure (CVP) monitoring line would produce a false CVP reading. This can be overcome by either a manual entry made at the time of the artefact or producing data analysis filters that reject artefacts (e.g., CVP > 50). In this study, artefacts were filtered manually in the evaluation of the data. Similarly, our system did not incorporate an electronic gas flow monitor, resulting in a second perfusionist occasionally recording this information into the DMS. An electronic flow meter or blender would rectify this. As per our clinical protocol, whenever the gas flow was altered, this change was documented.

The use of an automated system provides the opportunity to minimize transcription error and remove observer bias. Its potential at this time seems limitless, with one major application being the development of “real time” feedback for the perfusionist during the case, resulting in a potential change in patient management during bypass and the use of the collected data for the purpose of quality control.

REFERENCES

1. Cook RI, McDonald JS, Nunziata E. Differences between handwritten and automatic blood pressure records. *Anesthesiology*. 1989;71:385–90.
2. Thrush DN. Are automated anesthesia records better? *J Clin Anesth*. 1992;4:386–9.
3. Hollenberg JP, Pirraglia PA, Williams-Russo P, et al. Computerized data collection in the operating room during coronary artery bypass surgery: A comparison to the hand-written anesthesia record. *J Cardiothorac Vasc Anesth*. 1997;11:545–51.
4. Riley J. Electronic perfusion. *AmSECT Today*. 2004;7:6–7.