Technique for Improved Patient Care: Initial Experience with the GEM-6

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Abstract

(J. Extra-Corpor. Technol. 20[1]: p. 46-51 Spring 1988) **In our institution, a "stat" lab is not available in close proximity to the OR. The problem of receiving lab results quickly (within 5-8 minutes) while on cardiopulmonary bypass was a persistent problem. Therefore, the decision was made to evaluate the GEM-6, a relatively new on-line blood gas, electrolyte, and hematocrit monitor for the heart-lung machine. For the first 30 days of use, simultaneous results were obtained from the GEM-6 and the hospital lab. Our lag time receiving results was greatly reduced and the lab values compared favorably with the hospital lab. The least reliable value with the original cartridge and software was the hematocrit levels. Hematocrits measured by the GEM-6 consistently were 2-5% higher than the hospital lab results. This problem appears to be proportionately related to the patient's serum sodium level. Due to decreased work load on OR personnel, reliability, quickly obtainable results, and multiple parameters available with the GEM-6, we instituted use of the GEM-6 in January 1987. Through the use of Quality Assurance monitors and comparative Recovery Room first blood gases as QA monitors on open heart patients, documentation of improved patient care through the use of this on-line instrument is provided. Lab values readily available to the perfusionist can indeed result in the "fine tuning" of the pump run with improved patient care.**

Introduction

As in most hospitals, we continually strive to upgrade patient care. One area of concern was the usefulness of the lab work done during cardiopulmonary bypass. A "stat" lab is not available in the OR or in close proximity of the OR. Therefore, the lab results while on bypass were 10-30 minutes old when received back in the CV room. This is particularly a concern during the rewarming and final phases of the pump run. Several methods had been tried in the past to decrease this lag time. None of these methods were consistently successful. Therefore, the decision was made to evaluate other methods of obtaining reliable, prompt lab values while on cardiopulmonary bypass. This paper details our clinical experience with a relatively new on-line blood gas and chemistry monitor, the GEM-6 System by the Diamond Sensor company.[a] We have found this instrument to be user simple and reliable, and it provides hard copy results for the patients' charts. Improvement in patient perfusion care has resulted from the established use of this instrument.

The decision to evaluate the GEM-6 was made due to the following apparent advantages it had over current in-line sensor monitors available for use on pump:

1. One sample will yield an arterial and/or venous blood gas, hematocrit, serum potassium ($K+$), and ionized calcium (Ca^{++}). The blood gases can be temperature corrected either manually or automatically.
2. Lab results are available in approximately 2.5 minutes with hard copy documentation printed out with each result.
3. After initial setup, drawing lab work is a one-hand operation or can even be done automatically by the instrument.
4. The GEM-6 is an on-line instrument vs. an in-line sensor as are most other currently available monitors.[1] The sample is drawn from a continuous circulation line.
5. The GEM-6 is a self calibrating instrument with a

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a Diamond Sensor Systems, Ann Arbor, MI 48104.

2 point calibration being done each hour. Quality control solutions are available and are used to check performance of each cartridge.

6. The GEM-6 appeared to be cost effective. Table I summarizes the basic concepts of the GEM-6 system (Personal Communication from Cindy Flinn, Diamond Sensor Company).

TABLE I	DIAMOND SENSOR SYSTEMS, INC. GEM-6.*
UNDERLYING CONCEPT	ON-LINE ANALYSIS
MEASURED PARAMETERS	pH, PO_2, PCO_2, K^+, CA^{++}, HcT
CALCULATED PARAMETERS	BE, HCO_3, TCO_2, O_2SAT
DISCRETE SAMPLING CAPABILITY FOR PRE- & POST-PUMP ANALYSIS:	YES
INITIAL CALIBRATION METHOD:	AUTOMATIC
ACCURACY CONTROLLED: (DURING USE)	UPDATED REGULARLY VIA INTERNAL AUTOMATIC CALIBRATION
QUALITY CONTROL: CAPABILITY	STANDARDIZED SOLUTIONS PROVIDED WITH SYSTEM
USE LIFE OF DISPOSABLES:	36 HOURS/MULTIPLE PATIENT
HARD COPY PRINTOUT	YES

Material and Methods

To evaluate the effectiveness of the GEM-6, the Quality Assurance monitors and the Quality Assurance Manual, a patient care indicator done monthly by the Medical Perfusion department at Schumpert Medical Center, was utilized. By comparing the compliance of these monitors from previous months before the use of the GEM-6 and presently with the GEM-6, this would indicate the degree of ability to control those parameters usually monitored by the perfusionist during cardiopulmonary bypass.

A second means of comparison involves monitoring of the patient's first arterial blood gas in the OR recovery room as a QA monitor. Schumpert Medical Center performs approximately 450 open heart procedures annually. Random comparison of patients from April of 1986 and April of 1987 should be a valid comparison.

Materials used include the GEM-6 System consisting of the following components:

1. GEM-6, product #2300, electronic instrument.
2. Auto Sample Adaptor, pump unit which permits automatic sampling from the extracorporeal circuit.
3. Tube Set, product #2302, sterile and disposable tubing that connects the GEM-6 instrument to the extracorporeal circuit.
4. GEM-Pak, product #2301, disposable cartridge containing electrochemical sensors, calibrating and flush solutions and waste container.

Ancillary equipment used included:

System Mounting Bracket, product #2304, pole mount shelf.

GEM-Check, product #2306, aqueous controls that permit instrument quality control checks.

Discrete Sample adaptor, product #2305, disposable attachment that allows introduction of discrete blood samples and utilized for quality control checks. (*GEM-6 System, Instructions for Use*, page 4.)

The setup of the GEM-6 is simple and can be accomplished during the setup and priming of the extracorporeal circuit. The disposable cartridge of the GEM-6 system needs a warm-up time of 45 minutes. At one hour after insertion of the cartridge, the first two point calibration is completed and repeated once each hour thereafter. After priming the pump, the tube set is added to the circuit. The tube set is a disposable sterile set of lines which allows for on-line arterial and venous sampling. Arterial and venous blood are circulated from suitable sampling sites via the auto-sampler where a pair of stopcocks control either the arterial or venous sample. The blood is then circulated to a common return back to the extracorporeal circuit. This blood is circulated continuously so as to provide a current sample. A one-way valve on the arterial sampling line prevents the possiblity of blood flow back to the patient from the sampling line. In our pump circuit, both the arterial and venous blood via the common return line in the tube set are returned to the vented side of the cardiotomy. In the unlikely event that the cardiotomy should become pressurized, the common return line would not allow retrograde pressure on the sampling lines.

During setup, the patient and user ID are programmed. The GEM-6 contains the current date and time. Inserting the cartridge, installing the tube set into the extracorporeal circuit and programming the ID takes about 5 minutes. No additional work is needed for the GEM-6 during warmup. After the cartridge has completed warmup, a quality control solution can be run. This takes approximately 3 minutes. The hard copy printout of the quality control provided by the system can then be kept in a notebook for future reference. (GEM-6 Quality Control Manual, Medical Perfusion)

The GEM-6 operates in either a manual or automatic mode. The manual mode is used when quality controls are done and in doing discrete sampling. The automatic mode is used primarily for the on-line sampling done while on cardiopulmonary bypass. The automatic mode sampling can be programmed by the perfusionist to occur at "maximum allowed rate" or as needed when the "Start Sample" button is touched by the perfusionist. When the "Start Sample" button is pushed by the perfusionist, the GEM-6 will automatically turn the indicated stopcock (arterial or venous) and draw the sample from the sampling line. When drawn, the processing of a single sample takes approximately 2.5 minutes or 5.0 minutes for an arterial/venous pair. Blood gas, hematocrit, potassium, and ionized calcium levels are done on each sample. The GEM-6 can draw either an arterial or venous or arterial/venous pair that can be temperature corrected if the perfusionist so desires. Upon completion, a chart copy is printed by the GEM-6. Another function, oxygen consumption($\dot{V}O_2$), can be calculated by the GEM-6.

After each sample is done, the GEM-6 completes a rinse cycle. With the introduction of the extended standby cartridge in September 1987, this rinse cycle is shortened in both the single sample and the A/V pair sampling mode. A two-point calibration is done by the GEM-6 each hour. Currently, allowing for the rinses between samples and the 2 point calibration, approximately 6 arterial/venous pairs or 10 arterial and/or venous single samples can be done each hour. This has been adequate for our purposes.

After cardiopulmonary bypass is completed, the GEM-6 can be used either for discrete sampling or can be put into a standby mode to lengthen the utilization life of the cartridge. The disposable cartridge has an active running time of 8 hours or 50 samples. Current software with 28 hours standby time permits a cartridge life of 36 hours. Therefore, by utilizing the standby mode, one cartridge can be used for several patients depending on pump times and caseload. There is no danger of cross contamination between patients for two reasons. One, the sterile disposable tube set is discarded after each patient. More importantly, all blood drawn form the extracorporeal circuit and rinse solutions are retained within the cartridge itself. Once entered into the GEM-PAK cartridge, no blood or solution is returned to the outside.

Results

A 30 day evalution of the GEM-6 system was begun in December 1986. By comparing simultaneous results with our hospital lab during this time, the GEM-6 yielded reliable results. Being able to obtain results quickly, yielded information about the pump runs that was previously unavailable. Critical values on CPB including hematocrit, potassium, ionized calcium, arterial and/or venous blood gases became readily available. The GEM-6 system appears to be cost effective. Before the use of the GEM-6, the number of personnel required to draw and perform blood gases, hematocrit, and chemistries was considerable. We have a large hospital lab where each of these parameters is tested by separate departments. Both an OR and lab secretary need to load and unload results from the computer. All of these steps added costly time to lab work. The average number of arterial blood gases completed while on CPB during April-May 1986 was 2.28 per case. After established use of on-line monitoring, the average number of completed blood gases during April-May 1987 on CPB rose to 5.0 per case. Further studies are needed for a more detailed analysis for cost effeectiveness of the GEM-6 system. In Vitro testing of the GEM-6 system has proven it to be equivalent to other current lab instruments.[2] We have been using the GEM-6 system since mid December 1986 and have found it to be a consistently reliable instrument involving bood gases and electrolytes. However, the hematocrit levels with the initial cartridge did at times read an average of 2-5% higher than lab values. The method of measurement by the GEM-6 involves a conductivity analysis, the sodium ion being the most important conductive ion in this process. Therefore, patients with low preoperative sodium levels tend to read a false high hematocrit GEM-6. Addition of large amounts of albumin, a non-conductive molecule, also caused the GEM-6 to produce a false high reading.

Approximately 350 open heart procedures (through August 1987) have been performed using the GEM-6. The ability to "fine tune" the pump runs has increased. This further improves the margin of patient safety. Laboratory information is now readily available. One set charge per patient allows lab work to be done as often as needed without added cost to the patient.

The main question to be answered is "Have we improved patient care through the use of on-line monitoring?" To evaluate this, two areas of patient care involving the CPB and lab work were compared.

At this institution, quality assurance monitors are performed monthly to insure consistent patient care, identify possible problems and seek solutions to these problems. One of the Medical Perfusion Department's intraoperative criteria to be met for each patient is: "The final arterial blood gas at completion of CPB will have a base excess of not greater than -4.0 with a pH between 7.35-7.59." These are values at 37 degrees Centrigrade. Every patient's perfusion record for each Monday and Wednesday is checked against this criteria and compliance recorded. For the period of May 1986 through November 1986, the average compliance was

TABLE II — OR RECOVERY ROOM FIRST ARTERIAL BLOOD GAS POST CPB — 1986

ph	pco2	po2	BE	hco3	Hct	ph	pco2	po2	BE	hco3	Hct
7.16	62.5	229	−6.3	22.7	43.0	7.40	40.8	116	1.2	25.5	28.3
7.33	37.5	81	−4.3	20.3	38.6	7.51	25.7	175	0.3	21.0	28.3
7.40	40.9	174	1.6	25.9	30.0	7.45	28.5	92	−2.0	20.1	38.1
7.33	40.4	97	−3.5	21.5	18.1	7.33	40.8	54	−3.2	21.9	33.4
7.47	31.7	158	1.4	23.6	21.2	7.43	31.8	181	−1.1	21.6	30.1
7.45	30.1	199	−1.2	21.1	30.2	7.43	25.4	221	−4.4	17.4	32.5
7.37	38.7	113	−1.8	22.6	25.9	7.29	47.2	92	−2.9	23.2	27.3
7.34	36.4	95	−4.1	20.3	32.7	7.39	34.2	103	−2.6	20.9	35.1
7.31	38.7	103	−5.7	19.5	41.0	7.40	34.7	98	−1.4	22.0	3.1
7.40	34.9	79	−1.3	22.2	30.1	7.38	37.0	55	−1.7	22.3	34.0
7.38	36.2	62	−2.2	21.7	20.8	7.50	27.0	114	0.2	21.4	28.6
7.47	31.7	92	1.3	23.5	32.6	7.40	33.6	250	−2.1	21.3	27.7
7.27	44.7	59	−5.1	21.1	39.4	7.49	32.9	92	3.4	26.0	32.9
7.31	42.5	70	−3.4	22.1	36.8	7.26	40.5	73	−7.2	18.7	35.5
7.34	42.2	86	−2.1	23.0	28.0	7.47	31.7	158	1.4	23.6	21.2
7.35	40.6	82	−2.0	22.8	27.6	7.38	33.6	70	−3.1	20.5	28.1
7.40	33.7	91	−2.1	21.3	26.6	7.44	29.6	108	−1.6	20.6	21.5
7.37	34.6	133	−3.4	20.4	30.8	7.39	34.9	129	−2.2	21.4	29.3
7.29	32.6	261	−8.8	16.0	18.1	7.25	44.7	63	−6.4	20.1	29.6
7.49	30.0	135	1.6	23.4	30.3	AVERAGES					
7.41	30.5	113	−3.2	19.6	35.0	7.381	36.143	118.9	−2.25	21.405	29.573

TABLE III — OR RECOVERY ROOM FIRST ARTERIAL BLOOD GAS POST CPB — 1987

ph	pco2	po2	BE	hco3	Hct	ph	pco2	po2	BE	hco3	Hct
7.41	34.0	66	−1.0	22.2	29.7	7.42	36.3	102	0.8	24.2	32.2
7.48	29.0	84	0.2	21.9	31.1	7.45	34.0	104	1.4	24.1	35.2
7.37	37.6	103	−2.2	22.0	36.5	7.43	33.8	92	−0.2	22.8	27.2
7.34	39.6	106	−3.3	21.5	31.2	7.37	35.1	110	−3.2	20.7	26.5
7.44	31.7	89	−0.7	21.8	31.5	7.31	43.8	64	−2.8	22.8	27.8
7.41	36.0	67	−0.5	23.0	31.9	7.41	39.3	51	1.4	25.4	28.4
7.27	54.7	90	−1.8	25.4	34.8	7.35	43.0	89	−1.1	24.0	30.0
7.43	33.4	64	−0.5	22.4	32.4	7.40	36.9	138	−0.6	23.2	31.2
7.29	51.0	206	−1.8	24.8		7.31	42.2	49	−3.9	21.6	30.2
7.42	37.5	88	0.7	24.4	31.5	7.32	39.6	96	−4.7	20.5	33.4
7.36	35.4	68	−3.7	20.3	36.5	7.36	39.2	79	−1.9	22.6	29.5
7.49	32.3	106	2.8	24.9	32.5	7.45	33.6	126	1.2	23.9	24.8
7.44	37.7	105	2.5	25.9	31.9	7.41	33.0	95	−1.5	21.6	34.1
7.42	34.4	113	−0.3	22.8	31.6	7.46	29.2	123	−0.6	21.3	35.3
7.37	36.5	308	−2.6	21.4	28.2	7.47	28.9	208	0.0	21.7	24.4
7.38	40.1	130	−0.7	23.8	27.4	7.32	40.6	69	−4.1	21.2	33.8
7.45	29.5	207	−1.3	20.8	35.2	7.44	34.2	58	0.8	23.7	33.7
7.44	36.7	174	2.2	25.5	22.5	7.46	30.6	104	−0.2	22.1	29.5
7.37	47.1	108	2.1	27.5	29.1	7.33	39.8	127	−3.4	21.5	34.7
7.43	37.9	130	2.5	26.0	26.0	AVERAGES					
7.47	32.7	138	1.7	24.0	35.1	7.399	36.948	110.85	−.708	23.133	30.208

93%. During the evaluation period of the GEM-6, mid-December 1986 through January 1987, the average compliance to stated criteria rose to 95%. From February 1987 through May 1987, the compliance continued to rise to an average of 98% (Quality Assurance Summary, Medical Perfusion, Schumpert Medical Center, June 1987). Although a 5% increase in compliance to a stated goal may seem small, this may be directly related to the improved ability to monitor and adjust patient parameters while on pump. No other changes in our protocol occurred during this time.

As previously stated, a second means of comparison involved monitoring first patient arterial blood gases in the OR Recovery Room. Tables 2 and 3 list the patient's first arterial blood gas result upon arrival in the OR Recovery Room. The average values are listed at the bottom of each table. Though the average values appear improved during April 1987 (after utilizing the GEM-6), the true difference can be seen on a per patient basis. Statistical analysis of data reveal the following information:

1. The base excess (BE) and the bicarbonate ion (HCO_3) concentration were both dramatically and significantly improved in 1987 (utilizing the GEM-6) compared to 1986.
2. Other parameters: pO_2, pCO_2, pH, hematocrit, though not significantly different, did exhibit a reduced and tighter standard deviation for April 1987 when compared to April 1986. Tables 4-9 illustrate these comparisons. The metabolic (perfusion) state of the patient in the OR Recovery Room after the introduction of on-line monitoring did improve significantly.

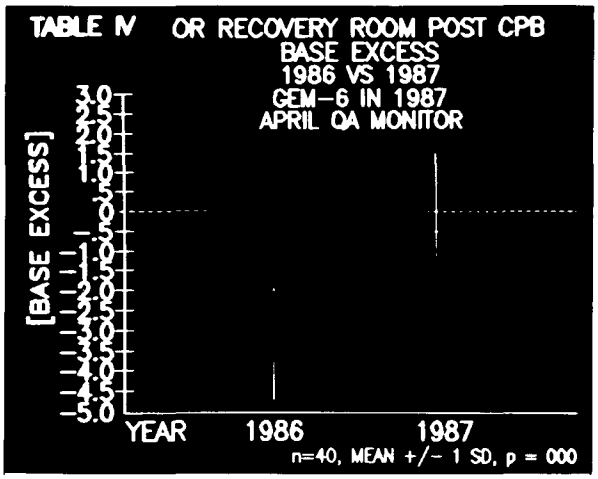
Discussion

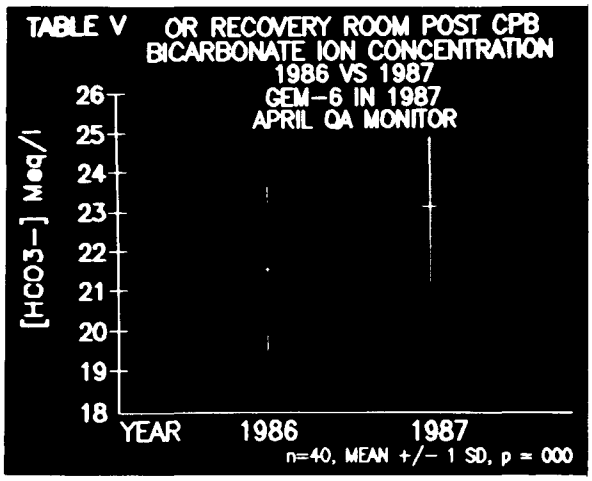
The initial reasons for investigating an on-line blood gas and electrolyte monitor involved the lag time experienced in getting lab work performed on CPB. Because of the number of personnel involved in completing lab work, there were several points at which the lab work could become "bogged down." If the hospital computer went down, those times could be further increased. A paper by ECRI regarding CPB and lab values suggests that "chemistry (pH and electrolytes) and blood gases should be available on a "stat" basis (within 5 minutes)."[3]

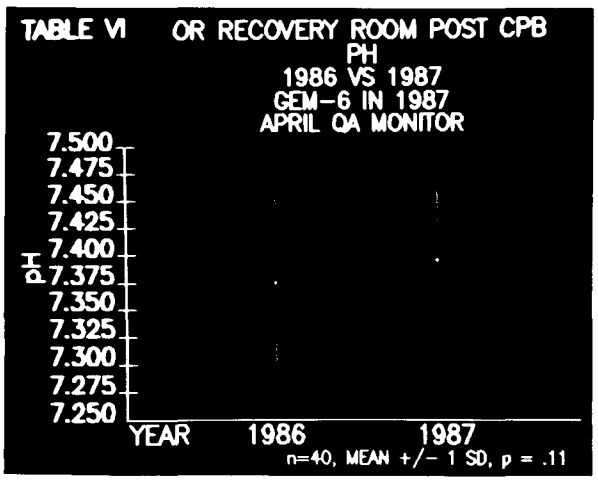
During the rewarming phase of the procedure, the GEM-6 has proved to be particularly helpful. In some patients dramatic changes can take place in the very final stages of rewarming. Previously, lab work had to be drawn 15-20 minutes before completion of bypass in order to receive results before termination of CPB. The final stage changes that occur in some patients were possibly being missed. Now lab work can be done every 6-7 minutes if needed. With results available within 2.5 minutes (5 minutes for A/V pair), adjustments may be made and repeat lab work can then be done before termination of bypass to insure that the adjustments were adequate. Discrete sampling is available while the patient is in the OR after completion of CPB.

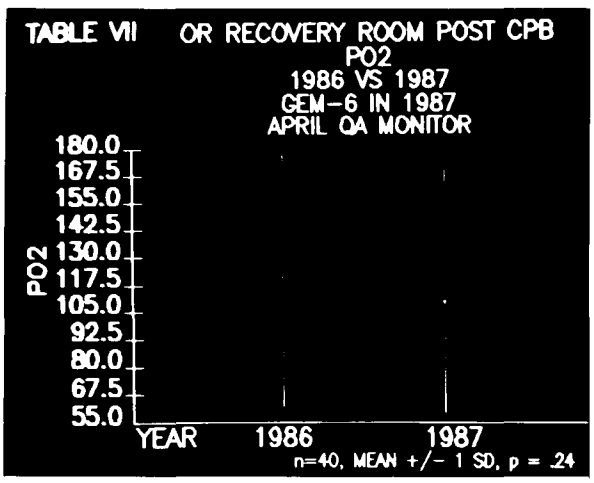
The improved metabolic status of the patient upon arrival in Recovery Room has been more consistent and improved since the implementation of on-line blood gas, electrolyte, and hematologic monitoring while on CPB.

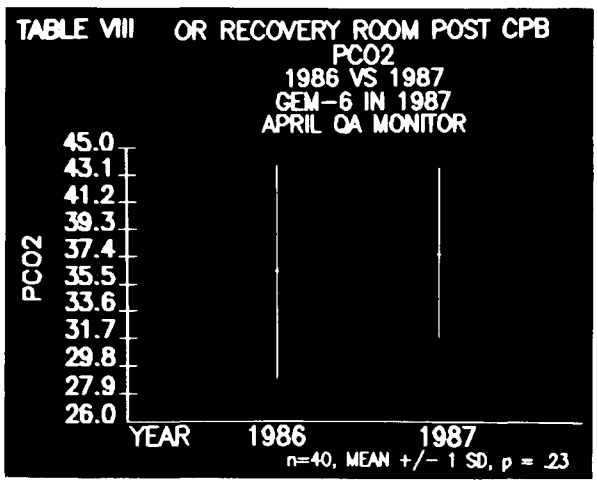
While the importance of blood gas values obtained with the GEM-6 has been stressed, it is the GEM-6's ability to also provide a hematocrit, potassium, and ionized calcium that sets this on-line monitoring equipment apart from those currently available. We are constantly learning through the use of this device. In the area of Risk Management, documentable results are obtained with the GEM-6. By obtaining readily available and reliable results, safety margins for all those involved are increased. Quality Assurance indicators for all types of patient care including perfusion care are recognized measurable indicators of care delivered. Therefore, an increase in compliance to these indica-

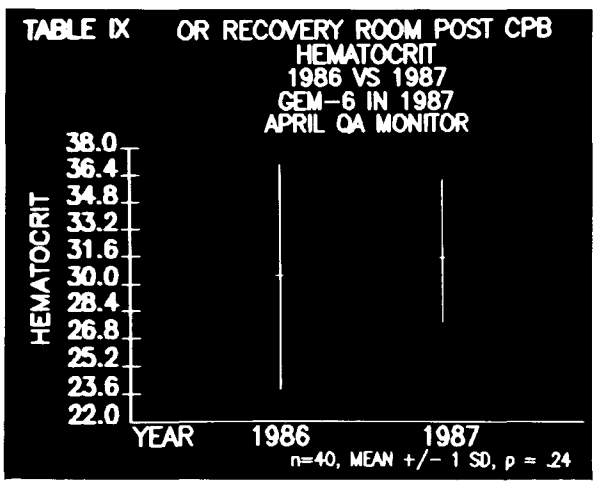












tors both during the intraoperative and the immediate postoperative phase does reflect an improvement in care delivered.

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