Accuracy and Consistency of Modern Elastomeric Pumps

Robyn S. Weisman, MD, Andres Missair, MD, Phung Pham, MD, Juan F. Gutierrez, MD, and Ralf E. Gebhard, MD

Abstract: Continuous peripheral nerve blockade has become a popular method of achieving postoperative analgesia for many surgical procedures. The safety and reliability of infusion pumps are dependent on their flow rate accuracy and consistency. Knowledge of pump rate profiles can help physicians determine which infusion pump is best suited for their clinical applications and specific patient population. Several studies have investigated the accuracy of portable infusion pumps. Using methodology similar to that used by Ilfeld et al, we investigated the accuracy and consistency of several current elastomeric pumps.

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Elastomeric pumps are a popular solution for providing patients with continuous peripheral nerve blockade (CPNB) because of their independence from electronic power supply, cost, disposability, and portability.[1–4] Patients with indwelling CPNB are often discharged home with elastomeric pumps for continued use in their own home, which highlights the need for pump safety and reliability. As recently as March 2013, Symbios Medical Products recalled their portable infusion pump, the GOPump, because of inaccurate flow rates.[5] We undertook this pump investigation to review the output from several different pumps, thus allowing the clinician to choose the optimum pump for their practice.

METHODS

Five elastomeric pumps (Fig. 1 and Table 1) used for CPNB were evaluated for flow rate accuracy, consistency, and the effect of positioning on measured output. The pumps tested were the ACTion Pump (Ambu, Glen Burnie, Maryland), GoBlock-SF (B. Braun, Bethlehem, Pennsylvania), ON-Q C-bloc (I-Flow, Lake Forest, California), MedFlo MultiRate (MR) (Acacia Inc, Brea, California), and the Infusor LV Multirate (Baxter, Round Lake, Illinois). In addition, 5 ACTion pumps, which have the capability of being refilled, were refilled and retrialed after their initial use.

The study apparatus consisted of 5 identical electronic mass balances (EMBs) M-Power; AZ4101 (Sartorius, Bohemia, New York). Each EMB had a weight capacity of 4100 g and a readability of 0.1 g, and a repeatability of ±0.1 g, according to the manufacturer's specifications. Before initiation of the study, all scales were calibrated with the same 2-kg mass, leveled, and the auto-zero function was disabled. The time-related drift was measured using a 100-g mass over 100 hours and found to have a drift of −0.8% to +0.2% at a temperature range of 23°C to 24°C. The scales were linked to a laptop computer via a RS232 (25 pin to USB) connecting cable. The software used to record serial masses into an Excel (Microsoft, Redmond, Washington) spreadsheet was WinWedge (Tal Technologies Inc, Philadelphia, Pennsylvania). The flow rates were calculated by subtracting the hourly mass [M (h + 1)] from that of the previous mass, [M (h + 1) − M (h)] = hourly flow (F). The percent of the flow rate was compared with the rate the pump was set to run at (Fset), such that F/Fset × 100% = percent of the set rate. The averaged percent set rates were compared from trial to trial. If the percent set rate was greater than 5%, a third trial was performed. Five identical empty reservoir bottles were placed on the top-loading portion of the EMBs. Using an 18-gauge blunt needle, a hole was bored into the screw caps of the reservoir bottles. A 20-gauge peripheral nerve block catheter (B. Braun) connected to the pump output, and the distal 20 cm of the catheter was threaded through the hole. The 20-gauge catheter was chosen for the study because this is the identical catheter used at our large academic center for CPNB. A seal was created in the reservoir bottle cap by melting a small amount of paraffin wax around the catheter insertion sites, to minimize evaporation (Fig. 2 and Table 1). Once the pump and total length of the catheter was primed with 0.9% normal saline, the scales were tared to zero. Each pump and regulator was placed at the same level as the scale unless specified by the trial. For the entire 100-hour measurement, an OM-73 temperature and humidity logger (Omega Engineering Inc, Stamford, Connecticut) recorded the ambient temperature surrounding the pumps and study apparatus.

The infusate selected to run through the pumps was 0.9% normal saline. Normal saline was chosen because of its presumed similar viscosity to ropivacaine.[6] Viscosity data on ropivacaine remain unavailable from the manufacturer (personal communication with APP Pharmaceuticals, LLC, Schaumburg, Illinois, February 2014). Ropivacaine is a commonly used local anesthetic for CPNB.[6,7] Normal saline was also the choice test infusate in previous experiments using different pumps and study criteria.[1,2,6] The Baxter Infusor LV Multirate pump was tested and calibrated with a dextrose 5% solution because the manufacturer specifies that using normal saline will increase the flow rate by 10%.

Each pump trial was 100 hours in duration. After the first 2 trials, the accuracy and consistency of the pumps were reviewed (investigation A). Accuracy was defined as the closeness of the regulator setting to the measured flow rate (true value). Consistency was defined as the degree to which repeated flow rate measurements under unchanged conditions showed the same results. If the "average percent set rate," which is the difference in the actual pump flow rate from the expected flow rate of the pump was less than ±10%, a repeat trial was not indicated. If the percent set rate was greater than ±10% at any given time, a third trial was performed and then averaged with the initial 2 trials. The pumps were set at rates between 7 and 10 mL/h, and all pumps were unused and filled to the maximum volume designated by the manufacturer for each pump. The infusion rate was chosen based on the

University of Miami Miller School of Medicine, Department of Anesthesiology, Perioperative Medicine, and Pain Management, Miami, FL.
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Address correspondence to: Robyn S. Weisman, MD, Department of Anesthesiology, University of Miami, Miami, FL (e-mail: rweisman1@med.miami.edu).
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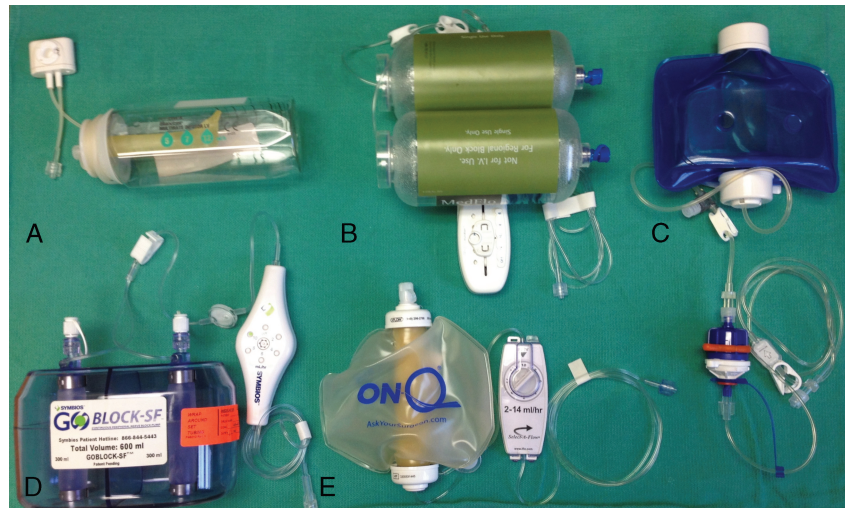

FIGURE 1. Elastomeric pumps tested. A, Infusor LV Multirate. B, MedFloMR. C, ACTion block pump. D, GoBlock-SF. E, ON-Q C-bloc.

TABLE 1. Elastomeric Pump Manufacturers and Disposability

Pump	Multiuse	Infusion Rate Tested, mL/h	Calibration Temperature, °C	Reservoir, mL	Infusion Rate, mL/h	Bolus Ability (Not Tested)	Error (%) by Manufacturer
Multirate Infusor LV, BAXTER Inc (Round Lake, Illinois)	No	7	33.3	300	5, 7, 12	Yes, optional	±10
MedFlo MR 500, Acacia Inc (Brea, California)	No	10	NA	500	6, 8, 10, 14	No	NA
ACTion Pump, AMBU Inc (Glen Burnie, Maryland)	Yes	10	22 ± 2	650	5–15 tested, 1–6 available	Yes, optional	±15
GO BLOCK-SF, B|Braun Inc (Bethlehem, Pennsylvania)	No	10	22.8	600	2, 4, 6, 8, 10	No	±15
ON-Q C-Bloc, I-Flow (Lake Forest, California)	No	10	22	400	2, 4, 6, 8, 10, 12, 14	Yes, optional	±20

typical infusion rate our institution uses for the CPNB pumps. The temperature was recorded hourly for the duration of each trial. The temperature of the trials was kept at ambient temperature, ranging from 21°C to 27.5°C. This temperature range is what would be expected for patients to experience in South Florida in an air-conditioned climate with CPNB. In addition, the manufacturer that recommended the pump device regulator to be taped to the skin (Infusor LV Multirate) was kept at room temperature and the manufacturer temperature-flow adjustments were made by the hourly temperature measurement. Analysis of individual pump performance was stopped once the pump flow decreased to less than 50% of the set flow rate. We conducted 1 trial (investigation B) consisting of the same study apparatus, duration, and temperature range with the pump and regulator 30 cm below the level of the scale. This was to determine if a vertical pressure gradient would affect the accuracy of the pump output. The manufacturer specifications for the Infusor LV Multirate state that flow will be decreased 0.5% for every inch the reservoir is positioned below the end of the tubing. Finally, we conducted investigation C to determine the impact of pump refill on flow rate. For this trial, refillable ACTion pumps were refilled to their specified maximum

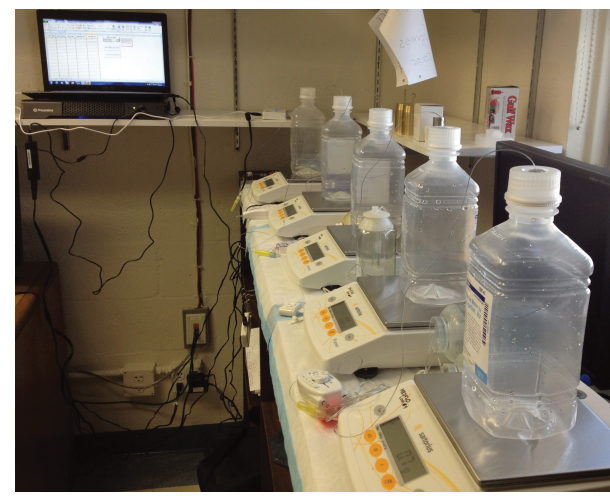

FIGURE 2. Study apparatus. All 5 pumps were tested at the same time under identical conditions for the 100-hour study period. Data were collected in a spreadsheet on a laptop computer.

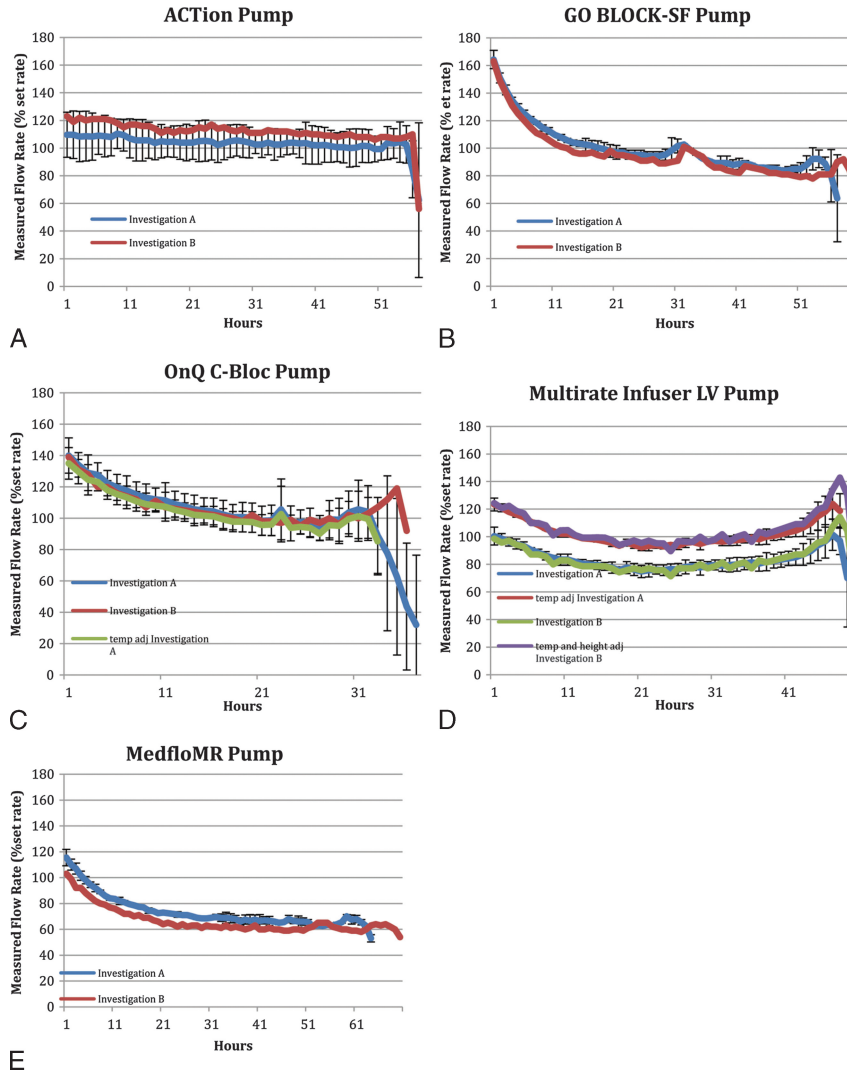

FIGURE 3. Graphs A to E show the pumps flow rate as a percentage of the rate at which the pump was set to run. The bars above and below the curve demonstrate the standard deviations between the first 3 trials when the pumps and the regulators were run on the same surface, investigation A. The graph of the trial of the pump regulators 30 cm below the reservoir, investigation B, is superimposed. If the manufacturer specified a calculated temperature adjustment, that graph was also superimposed and labeled.

volume, 650 mL, and retrialed with the same apparatus at the same level as the EMB.

RESULTS

The average percent set rate for each pump is shown graphically in Figures 3A to E. There were 3 trials performed for each pump with the exception of the MedFloMR pump, in which only 2 trials were performed because the second and first trials differed by no more that ±10% at any given time. The temperature for investigation A was consistently held within an ambient range of 21°C to 25.5°C (measured hourly). The frequencies of distributions of the pumps were charted in Figure 4. This graph demonstrates the hourly number of times the pump output varied from the percent set rate; for example, at 0%, the hourly pump output was equal to the set flow rate.

The GoBlock-SF and ACTion pumps were calibrated to the ambient temperature range of our study environment and, therefore, no temperature correction was necessary. Only the Infusor LV Multirate and ON-Q C-bloc pumps specified a change in flow rate based on change in temperature; these adjustments were taken into account (Figs. 3C, D and 4D, F).

The results of investigation B were superimposed in Figures 3A to E. The temperature range for investigation B was 24.5°C to 26°C.

The results for investigation C can be seen in Figure 5. The temperature range for investigation C was 24°C to 27°C.

DISCUSSION

Five pumps that are currently on the market for CPNB were evaluated for flow rate accuracy, consistency, and effect of pump height on flow rate. In addition, we tested the ACTion pump performance after it is refilled. The findings in this study are provided to assist clinicians in choosing a pump that best fits their practice.

Pump Investigation

The ACTion pump was the most accurate pump as it infused within ±15%, from the beginning to the end of investigation A (Fig. 3A). This was consistent with the manufacturer's specified

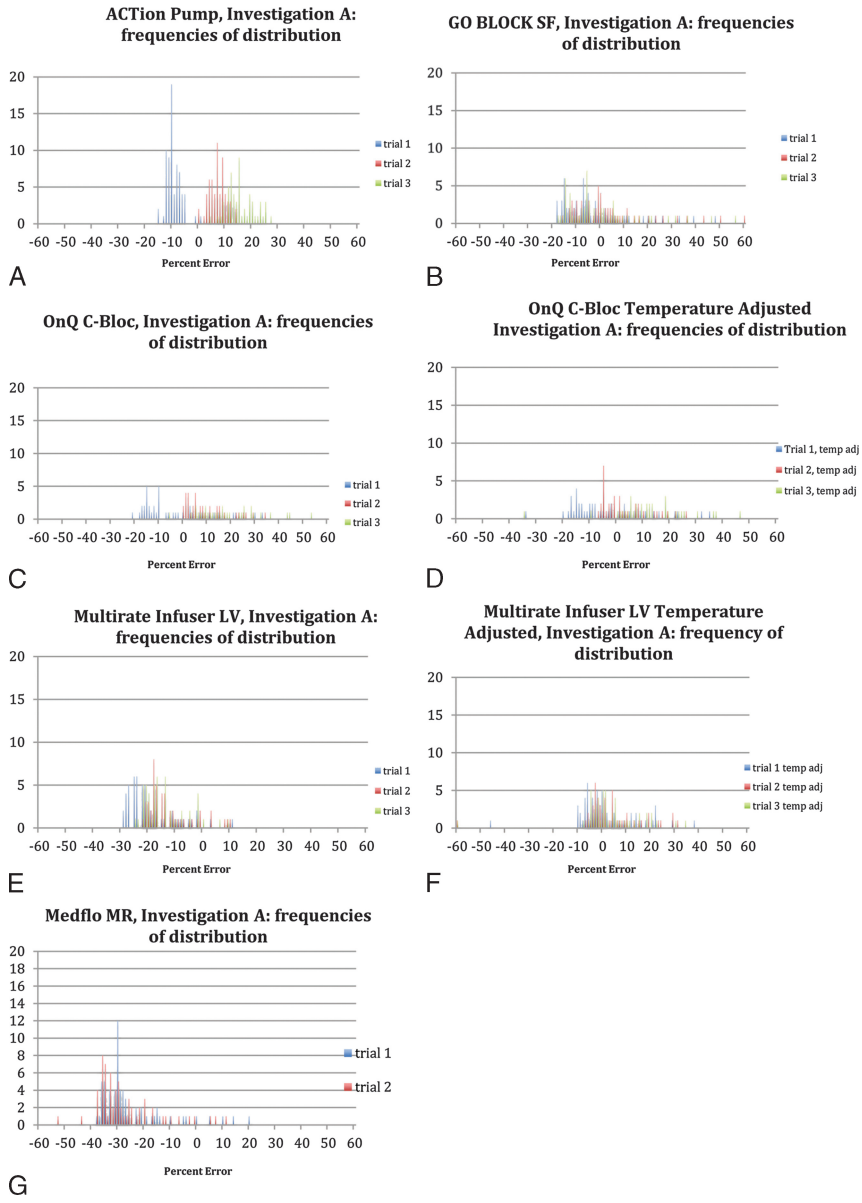

FIGURE 4. Graphs A to G represent the frequencies of distribution for the pumps for investigation A. The *y* axis represents the number of times a pump performed above or below its set rate, as a percentage. On the *x* axis, zero represents no error above or below the set rate as a percentage. The negative numbers on the *x* axis represent the pumps performance was less than the set rate and the positive numbers represent flows above the set rate, as a percentage. Graphs D and F show the adjusted frequency of distribution for the temperature based on the manufacturers' specifications.

acceptable error (Table 1). The GoBlock-SF and the ON-Q C-bloc exhibited the highest error at the start of investigation A as indicated by the most pronounced parabolic-shaped flow profile (Figs. 3B, C). Both the ON-Q C-bloc and GoBlock-SF pumps demonstrated flow rates greater than 120% of their programmed settings during the trial. This performance was observed in both pump models during the first 7 hours of their infusion, with the most dramatic increase recorded during minutes 0 to 120. Accuracy is perhaps the most important criteria evaluated in this study, as overinfused medications could be potentially dangerous.

Adjusting the flow to the manufacturer's temperature calibration improved the accuracy of the Multirate Infusor LV pump. For most of investigation A, the differences between the first and second trials were less than ±10%. Adjustment for temperature calibration shifted the frequency of distribution from predominantly less than anticipated flow rates to higher than anticipated flow rates (Figs. 4E, F). After temperature correction, the percent error shifted from −30% to −5% to a range of −10% to +5%. This range is more consistent with the published error range of ±10%. The ON-Q C-bloc pump manufacturer specifies that the flow rate will increase 1.4% per 0.6°C increase in temperature higher than 22°C, or decrease 1.4% per 0.6°C decrease in temperature lower than 22°C. This was accounted for and graphed with its standard deviation error bars. There was minimal change after making the adjustments because the ON-Q C-bloc pump is calibrated closely within the temperature range that was tested (Figs. 4C, D).

The most consistent pump we tested was the MedFloMR; only it had less than ±10% error from the first to the second trial. These results differ from the study by Ilfeld et al,[6] in which the MedFloMR exhibited greater than ±10% flow variability between

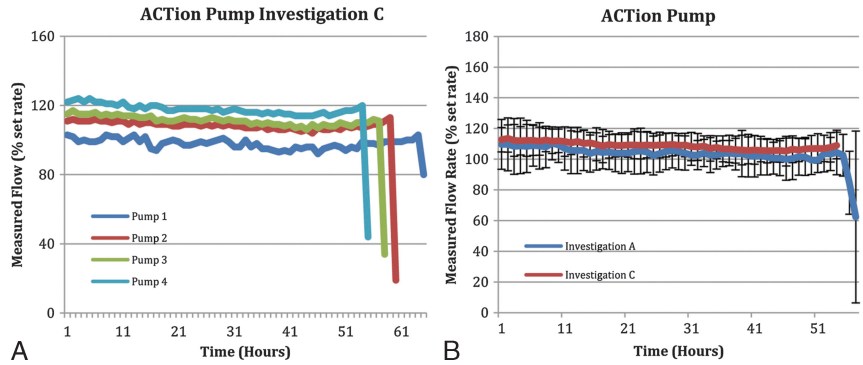

FIGURE 5. Graph A depicts the ACTion pump flow profiles after the pumps had been filled to the maximum set volume, allowed to empty, and then the pumps were refilled and retested, investigation C. Graph B shows the comparison between investigation A and investigation C.

the first 2 trials of investigation A. One possible explanation for this finding relates to the infusion rate selected: our trials were conducted at 10 mL/h, whereas the study by Ilfeld et al[6] performed evaluations at 5 mL/h. After averaging the differences between the first and second trials percent of the set rate for the pumps tested, the MedFloMR pump demonstrated the greatest consistency followed by the Go Block-SF, the Infusor LV Multirate, the ON-Q C-bloc, and lastly the ACTion pump. A study limitation was that the donated pumps came from the same lot from each of the manufacturers; therefore, selection bias could not be ruled out. The MedFloMR was the only pump that was not donated directly from the manufacturer, and it performed the most consistently.

When patients have an indwelling CPNB, pump height in relation to the patient catheter varies on patient activity and placement of the pump by the patient. In 2 of the 5 pumps, the MedFloMR and the GO Block-SF, the height of the pump decreased the pump output when the pump was 30 cm lower than the height of the catheter, (investigation B, Figs. 3B, E). This suggests to the clinician that, when using those pumps, the patient should be instructed to keep the pump at the level of catheters. The clinician must also expect height-related changes with the Multirate Infusor LV that can be calculated using the manufacturer's specifications. More studies would need to be conducted to determine whether the pump height above the reservoir would also change the pump output.

The only pump that was tested in which the manufacturer specified a change in flow rate based on reservoir height was the Infusor LV Multirate. The specifications for the height variation on flow are a decrease of 0.5% for every inch the reservoir is below the tubing. We took this into account and adjusted the flow rate by the temperature and height variation to create an adjusted profile for the Infusor LV Multirate pump (Fig. 3D). Before correcting for height and temperature, the flow profile fell within the standard deviation of the averaged uncorrected flow profile. After making the adjustments for temperature and height specified by the manufacturer, the flow profile fit within the standard deviation of the temperature corrected average flow profile curve of investigation A.

The ACTion pump was found to be consistent in investigation C, the flow profiles from investigations A and C fit within the same standard deviation (Fig. 5B). A reliable refillable pump is a significant advantage because it can lead to potential cost savings and a smaller environmental footprint.

Study Limitations

One of the limitations of the study was the number of pumps that were tested. For investigation A, the first and second trial were compared and if the preset set flow rate was greater than 10% at any point in the trial, a third trial was performed, with results subsequently averaged together; the same method was used by Ilfeld et al[1,6] in determining the number of pumps that needed to be tested. However, for investigation B, this was only tested once because of limited pump supply. More trials are needed to determine the statistical significance of the effects of lowering the pump height on the flow rates.

Some of the pertinent study limitations we encountered included small variations in ambient temperature which could affect flow rates by as much as 10% and these were not accounted for in our study.[6] We do not feel this was clinically relevant because the study apparatus and pumps were intended to run at room temperature to better approximate the expected ambient temperature range patients are exposed to. Another study limitation was that time-related drift was evaluated in only one of the 5 EMBs (−0.8% to +0.2%). The EMB manufacturer's specifications reported ±0.1 g. The EMB position was not evaluated for static interference, but all EMBs were assumed to have the same because of their similar locations in the laboratory. Evaporation was not taken into consideration because all reservoirs were sealed with melted paraffin wax at the catheter insertion site.

Another limitation to this study is that the pumps were tested in vitro. There are numerous factors that cannot be controlled for when testing in vivo pumps such as tissue resistance at the tip of the catheter, patients placing additional pressure on the soft casing of their pumps, patient tampering with pumps, kinked tubing, and catheters clogged by clots or tissue.[3]

Clinical Implications of Study Findings

Patients are routinely sent home with elastomeric pumps, and it is important for the pump to be reliable and accurate to ensure patient comfort and safety. An ideal pump would demonstrate both high levels of consistency and accuracy in terms of flow rate profile. Overinfusion is a greater concern than underinfusion because of morbidity and mortality associated with local anesthetic systemic toxicity. There was a recent report of the death from cardiac arrest of a patient who had a CPNB with an ON-Q PainBuster that prematurely emptied; the authors speculated that the rapid overinfusion after patient tampering with the pump may have contributed to that patient's death.[8] Although complications from overinfusion can occur, it seems to be uncommon or underreported in the literature. At our institution, we have also witnessed pumps that empty sooner than expected; however, the affected patients other than premature return of pain experienced no adverse events. More common problems with elastomeric pumps in vivo seem to be underinfusion or failure of the pump to deflate, leading to inadequate analgesia.[3] After investigating some of the elastomeric

pumps currently available on the market, we have provided the in vitro flow profiles for the pumps evaluated and reliable estimates of pump reservoir emptying time.

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