Portable Infusion Pumps Used for Continuous Regional Analgesia: Delivery Rate Accuracy and Consistency

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Background and Objectives: Multiple benefits of postoperative perineural local anesthetic infusion have been shown including potent analgesia, decreased opioid requirements, and improved rehabilitation. Consequently, portable infusion pumps have been used with increasing frequency to provide perineural infusion for medically unsupervised ambulatory patients. We believe that the infusion rate accuracy and reliability of these pumps infusing potentially toxic doses of medication should be investigated independently. Therefore, we studied the flow-rate accuracy and consistency of various portable infusion pumps that have not been examined previously.

Methods: Using a computer/mass balance combination to record infusion rates, 6 pumps (3 electronic and 3 nonelectronic) were tested. Several factors that may influence pump performance were varied: temperature (ambient/skin), battery (replacement/addition), and catheter exchange (wound/perineural).

Results: Infusion rate accuracy differed significantly among the pumps, exhibiting flow rates within ±15% of their expected rate for 55% to 99% of their infusion duration. Furthermore, the profiles (infusion rate over time) of the various pumps differed significantly depending on the pump power source. Although elastomeric pump infusion rate increased with an increase in temperature, battery life was a limiting factor for one of the electronic pumps. Substituting wound catheters with commonly used perineural catheters did not significantly alter infusion profile.

Conclusions: Factors such as infusion rate accuracy and consistency, infusion profile, temperature sensitivity, and battery life affect the dose of medication administered by various portable pumps used for continuous regional analgesia. Health care providers should take these factors into consideration when choosing and using a portable infusion pump for local anesthetic administration. *Reg Anesth Pain Med 2003;28:424-432.*

Key Words: Ambulatory surgery, Continuous nerve block, Continuous regional analgesia, Patient controlled regional analgesia, Perineural infusion, Postoperative analgesia.

Multiple benefits of postoperative perineural local anesthetic infusion have been shown including potent analgesia,[1-3] decreased opioid requirements,[1,2,4,5] and improved rehabilitation.[4,6] Portable pumps enabling perineural infusion outside of the hospital have been used with increasing frequency for medically unsupervised ambulatory patients since first described in 1998.[7-10] Some of these portable units have been evaluated independently and the infusion accuracy and consistency were found to be different for each model.[11,12] For example, one study reported infusion accuracy to vary greatly among pumps, with flow rates within ±15% of their expected rate for 29% to 100% of their infusion duration, showing the high degree of variability among devices.[11] Because newer pumps that have not been evaluated independently are gaining acceptance and usage for medically unsupervised ambulatory patients,[5,13] we performed this investigation to evaluate the flow characteristics of these previously untested models.

Several factors may influence the infusion profile of the different pumps, depending on the model's power source. Using portable electronic pumps, ambulatory infusions of up to 98 hours have been described, raising the question of how battery dis-

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Table 1. Infusion Pump Manufacturers and Disposability

Pump	Manufacturer/U.S. Distributor	City	State	Power	Multi-use
Accufuser Plus	McKinley Medical	Wheat Ridge	CO	Elastomeric	No
AutoMed 3400	Ace Medical/Algos Medical	Salt Lake City	UT	Electronic	Yes
Infusor LV5	Baxter International	Deerfield	IL	Elastomeric	No
Microject PCEA	Sorenson Medical	West Jordan	UT	Electronic	Yes
Pain Care 3200	Breg, Inc.	Vista	CA	Spring	No
Pain Pump II	Stryker Instruments	Kalamazoo	MI	Electronic	No

charge affects infusion rate over time.[14] Relatively new, nonelectronic, elastomeric infusion pumps may provide a simple, disposable option for ambulatory infusion. However, their infusion is regulated with a temperature-dependent device that is calibrated to skin temperature. Therefore, the flow rate may vary over time with changing ambient or skin temperature. Lastly, 2 new pumps are calibrated to infuse local anesthetic via a catheter that is designed specifically for wound infusions and is included with the pump. The effect on the flow rate, if any, of altering catheter resistance by replacing the included wound catheter with one designed for perineural infusion with a different length and lumen radius is unknown.

Methods

Pump Selection

Six small, portable pumps marketed for local anesthetic infusion were selected for testing and donated by their respective manufacturers (Table 1, Fig 1). The energy source to dispense an infusate varies among pumps and consists of elastic- (Accufuser Plus and Infusor LV5) or spring-based (Pain Care 3200) and electrical (AutoMed 3400, Microject PCEA, and Pain Pump II). The electronic pumps are programmable, which allows for various infusion rates, bolus doses, and lockout periods (Table 2). The spring and elastomeric pumps are available in various reservoir volume and infusion rate combinations. However, once manufactured, these attributes cannot be altered.

Infusate Selection

All pumps were unused previously and were tested using normal saline (NS) as the infusate. The electronic pumps were attached to a 1,000-mL bag of NS, whereas the nonelectronic pumps were filled to their recommended capacities with NS immediately before testing. Infusate viscosity potentially may influence the infusion rate of various pumps. Because ropivacaine is one of the most commonly used local anesthetics described in continuous regional anesthetic techniques,[3,5,8,14-19] NS was chosen as the infusate because its viscosity is similar to that of ropivacaine.[11,12] Of note, the Accufuser Plus and Infusor LV5 printed manufacturer information states that using sterile water or NS, respectively, will increase flow rate by 10%.

Study Apparatus

The following apparatus was used to record the infusion rate profiles. A polyamide multiport catheter (B. Braun Medical, Bethlehem, PA) was first attached to the infusion pump. The dispensed fluid was collected in an empty plastic bottle with a removable plastic cap. The distal end of the catheter was inserted through a hole in the plastic cap made with a 19-gauge needle except for the Pain Care 3200 wound catheter trials because of the larger 16-gauge catheter.

The infusion pumps were placed on the same surface as an electronic mass balance (Navigator Balance; Ohaus Corporation, Florham Park, NJ). The collection bottle was placed on the scale, and the distal end of the catheter tip was advanced to the bottom of the bottle. Data were logged onto an IBM-compatible personal computer (Dimension XPS 400; Dell Computer Corporation, Round Rock, TX) using an RS-232 cable once each test infusion began. A software program (Software Wedge; TAL Technologies, Philadelphia, PA) allowed entry from the serial port directly into a spreadsheet program (Excel 2000; Microsoft Corporation, Seattle, WA). Over the duration of the infusion, the mass of the infusate was measured every minute using the tared value of the bottle. The infusion period ended at 100 hours or when a pump had exhausted its fluid reservoir, whichever event occurred first. Subsequently, the hourly infusion rate was calculated by subtracting the mass at a given hour (M_x) from that obtained after the next hour ($M_{[x+1]}$), where x is the time in hours. That is, the hourly infusate volume equaled ($M_{[x+1]} - M_x$). This system has been shown to provide excellent accuracy and precision with the potentially confounding variables of time-related drift, evaporation, and temperature changes.[11]

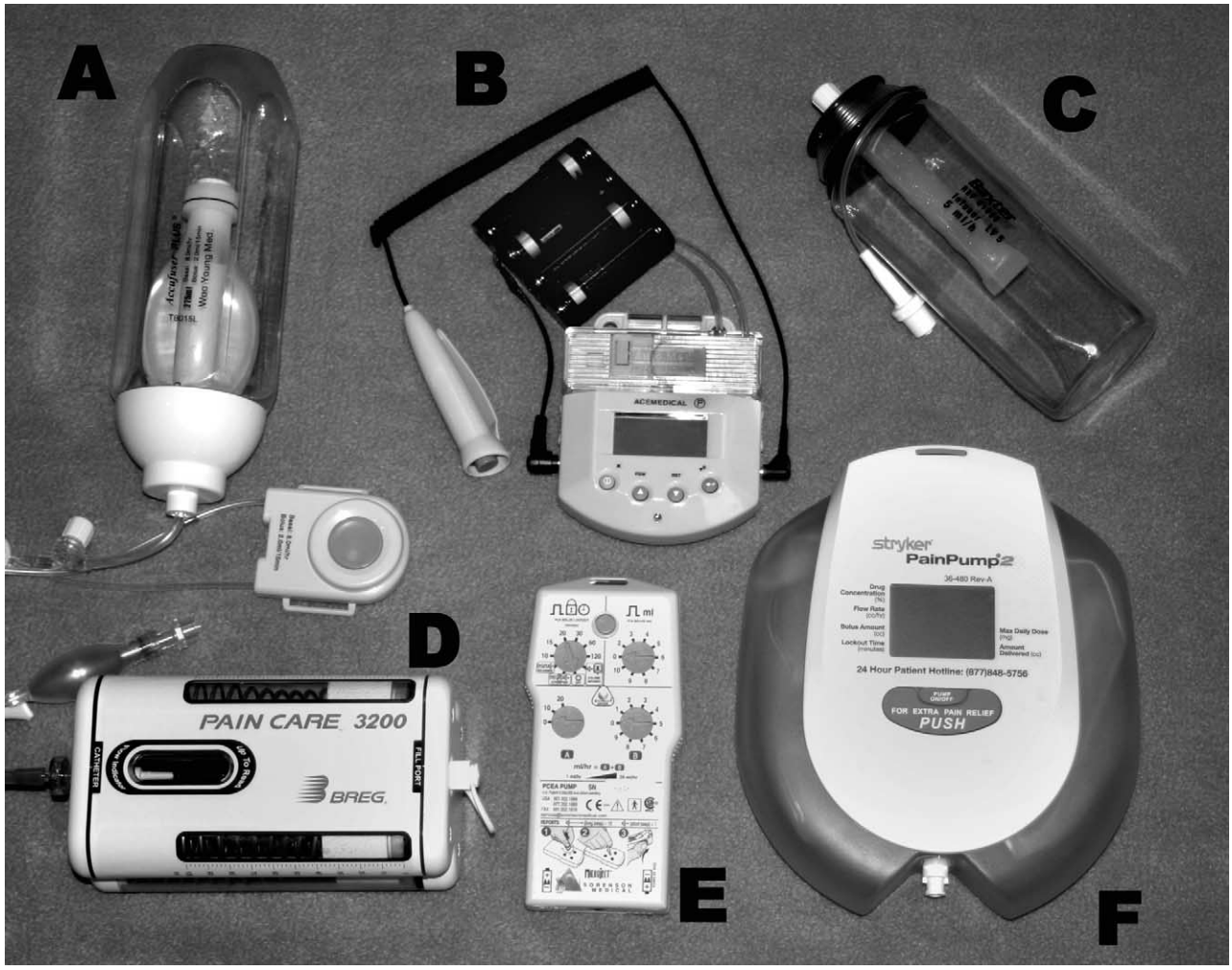

Fig 1. Portable infusion pump configurations as investigated. (A) Accufuser Plus, (B) AutoMed 3400, (C) Infusor LV5, (D) Pain Care 3200, (E) Microject PCEA, and (F) Pain Pump II.

Data Collection

For each pump, the first trial involved 100 hours of infusion, or until the local anesthetic reservoir was exhausted and the infusion rate dropped to 0. After this, an identical trial was run using a new infusion pump (and batteries, when applicable). If the infusion rate during the second trial was found to differ by more than ±10% of the original test at any point, then a third trial was performed. The trials were combined to produce a mean profile for

Table 2. Infusion Pump Attributes as Described by Manufacturers (As Tested)

Infusion Pump	Dimensions* (cm)	Weight* (g)	Reservoir (mL)	Basal Infusion (mL/h)	Bolus Dose (mL)	Bolus Lockout (min)
Accufuser Plus	18.8 × 7.0 × 6.0	109	275	8.0†	2†	15†
AutoMed 3400	8.5 × 8.0 × 2.7	325	NA	0-50	0-50	0-60
Infusor LV5	16.5 × 6.5 × 5.5	62	275	5.0†	NA	NA
Microject PCEA	13.2 × 6.1 × 3.7	148	NA	0-29	0-10	10-120
Pain Care 3200	15.0 × 7.5 × 6.5	283	200	5.7-2.9‡ (declining)	4-6†	40-80† (approximately)
Pain Pump II	18.2 × 15.6 × 5.3	410	400	0.5-10	0-5	15-120

*Including batteries and disposable cassette in electronic pumps; and excluding infusate for all pumps.

†Fixed during manufacture; various combinations of basal infusion, bolus dose, and bolus lockout period available for some models.

‡Basal infusion rate described as "4 mL/h continuous flow" on product packaging and marketing materials. However, product information contained within the instruction manual specifies that the rate is 5.7 mL/h at the beginning of the infusion, and steadily declines to 2.9 mL/h by reservoir exhaustion.

Abbreviation: NA, not applicable.

this first test. After the completion of these first tests of each pump, one factor that may influence each individual model's performance was altered, and the protocol described earlier was repeated. The factors altered for each pump are described below.

Battery Testing

For the pumps that use replaceable batteries (AutoMed 3400 and Microject PCEA), the first test involved 100 hours of infusion with only one set of batteries that was inserted into the units just before commencement of each infusion. After the initial set of trials, the changes made for the second set of trials are described below.

AutoMed 3400. This pump uses 4 internal, replaceable, AAA batteries. For the second set of trials, an optional external battery pack with 4 replaceable AA batteries was attached to the pump in addition to fresh internal AAA batteries (Fig 1).

Microject PCEA. This pump differs from the Microject PCA, which has been evaluated previously,[11,12] in that it provides for much larger bolus doses—often desired by practitioners during perineural local anesthetic infusion—than the original pump (Table 2). For the second set of trials, the 2 replaceable internal AA batteries were changed after 50 hours.

Temperature Testing

For the pumps with a temperature-dependent flow-rate regulator (Accufuser Plus and Infusor LV5), the rate-limiting device was placed within an adjustable heating unit (Microplate Incubator; Boekel Scientific, Feasterville, PA) set for the manufacturer's description of skin temperature (Accufuser Plus: 32°C; Infusor LV5: 33°C). Each test was performed twice with a new infusion pump unit. After the initial set of trials, the following changes were made for the second set of trials:

Accufuser Plus. This pump regulates the infusion flow rate using a temperature-dependent device calibrated to skin temperature located in the bolus button specifically designed to be worn around the patient's wrist. During a recent study, however, the present authors found that patients often prefer to remove this device from their wrist.[5] This action lowers the flow-regulating device to ambient room temperature. What effect, if any, this temperature decrease has on infusion rate was investigated by removing the temperature-sensitive flow-rate restrictor from the heating unit (ambient temperature, 20°C to 24°C). In addition, the possible effect of an increase in ambient temperature, such as occurs on a hot day, was investigated by placing the flow-rate restrictor in the heating unit set 4°C above skin temperature (36°C). Although reported on previously,[12] the Accufuser Plus, which was used in a recent study,[5] has a new bolus button design—and flow-rate regulator that is in the button unit—and therefore required further evaluation.

Infusor LV5. This pump regulates the infusion flow rate using a temperature-dependent device calibrated to skin temperature found near the connection between the pump tubing and catheter attachment, and is designed to be taped directly to the patient's skin. The possible effect of an increase in ambient temperature, such as occurs on a hot day, was investigated by placing the flow-rate restrictor in the heating unit set 4°C above skin temperature (37°C).

Catheter Testing

Two of the pumps are calibrated to be used with an included multiport catheter that is meant to be placed via an included noninsulated needle (Pain Care 3200 and Pain Pump II). This design is primarily for wound catheters. If a perineural catheter is desired, an adaptor may be used to allow the connection from the pump to the perineural catheter. Because the Contiplex (B. Braun Medical) system often is used for perineural catheter placement, we tested these pumps with the adaptor and Braun multiport catheter for the first set of trials.[3,5,8,15,20] After the initial set of trials, the following changes were made for the second set of trials:

Pain Care 3200. For the second set of trials, the catheter that was included with the pump was used.

Pain Pump II. For the second set of trials, the catheter that was included with the pump was used. Of note, the Pain Pump II is electronic but not reusable, unlike the other electronic pumps tested, and comes with its batteries presealed in the unit itself. The pump is designed to lock out once its 400-mL reservoir is exhausted, which occurs after approximately 50 hours with an 8-mL/h infusion rate. Because many patients require a longer duration of postoperative analgesia, 2 of the trial pumps were refilled to capacity when their reservoirs were depleted to 20 mL and before the pumps locked out. Note that the manufacturer does not recommend refilling the reservoir.

Bolus-Dose Testing

For each pump that could provide patient-controlled bolus doses, the flow characteristics were tested 4 times: twice during the initial hour of infusion and twice during the latter part of the infusion. If programmable, the bolus was set for 4 mL.

Data Analysis

For purposes of data analysis, infusion duration (measured) for all laboratory trials was considered to end when the measured flow rate decreased below 50% of the set rate, or at 100 hours, whichever event occurred first. Data are reported as mean ± SD. Overall comparisons were made using repeated-measures analysis of variance with post hoc Tukey pairwise testing, if appropriate. A *P* value of less than .05 was considered to be statistically significant.

Results

The infusion-rate profiles for the 6 portable pumps tested are shown in Figure 2. All pumps infused without interruption until the reservoir was exhausted or 100 hours (excluding the battery discharge alarm).

Accuracy

For all pumps investigated, the infusion rate differed less than 10% between the first 2 trials for each test, thus negating the need for a third trial. However, 4 pumps showed superior consistency with a difference of less than 5% at any point between trials for each test: the Accufuser Plus, the AutoMed 3400, the Infusor LV5, and the Pain Pump II. The 2 remaining pumps had a difference of less than 10% between the first and second trails for each test (Microject PCEA and Pain Care 3200).

Accufuser Plus

This pump infused at a rate higher than expected initially, and then returned closer to its set rate for much of the infusion, only to increase again as its reservoir approached empty (Fig 2). However, the infusion remained within ±15% of its set rate for 99% of its duration (Table 3) when the flow regulator was held at skin temperature. This matches the manufacturer's printed information included with each pump regarding delivery profile and pump accuracy (presented as ±15% at skin temperature). This did not change significantly when the temperature was increased 4°C, an improvement over the manufacturer's printed information. However, when the flow regulator remained at room temperature, the infusion rate remained within ±15% of its set rate for only 76% of its duration, and was less than 85% of the set rate for 24% of its duration. This matches the manufacturer's printed information included with each pump regarding pump accuracy after a change of temperature (presented as increasing just under 2% per 1°C increase in temperature).

AutoMed 3400

The infusion rate of this pump was very consistent while the batteries held their charge. However, the batteries were exhausted after 40 to 45 hours of infusion when the internal batteries were used exclusively (Table 3). With the addition of the external batteries, the infusion was extended to between 80 and 85 hours. Although the manufacturer's information included with the pump did not comment on battery life, the stated delivery accuracy of ±5% must be compared with the observed delivery accuracy of ±5% to 10% found in this investigation.

Infusor LV5

This pump infused at a rate higher than expected initially, and then returned closer to its set rate for much of the infusion, only to increase again as its reservoir approached empty (Fig 2). However, the infusion remained within ±15% of its set rate for 90% of its duration (Table 3) when the flow regulator was held at skin temperature. This matches the manufacturer's printed information included with each pump regarding delivery profile and pump accuracy with the exception of the first 5 hours of infusion (presented as ±10% at skin temperature). When the temperature was increased 4°C, the infusion rate increased so that it was greater than 115% of its set rate for 20% of its duration and within ±15% of its set rate for 69% of its duration. Because of the increased rate, the reservoir was exhausted approximately 5 hours early, and therefore the infusion rate was less than 85% of the set rate for 11% of its duration. This also matches the manufacturer's printed information included with each pump regarding pump accuracy with a change of temperature (presented as increasing 2.3% per 1°C increase in temperature).

Microject PCEA

This pump's infusion rate was more variable than the other electronic pumps tested, but remained within ±15% of its set rate for 91% of the 100 hours of testing (Table 3). Although the Microject PCA infused at a rate of less than 85% for 9% of the infusion duration when the batteries were not changed, and only 4% of the duration when the batteries were changed at 50 hours, this difference was not statistically significant. The manufacturer's stated delivery accuracy of ±5% must be compared with the observed delivery accuracy of ±10% to 20% found in this investigation (presented expected battery life of 14 days at 10 mL/h).

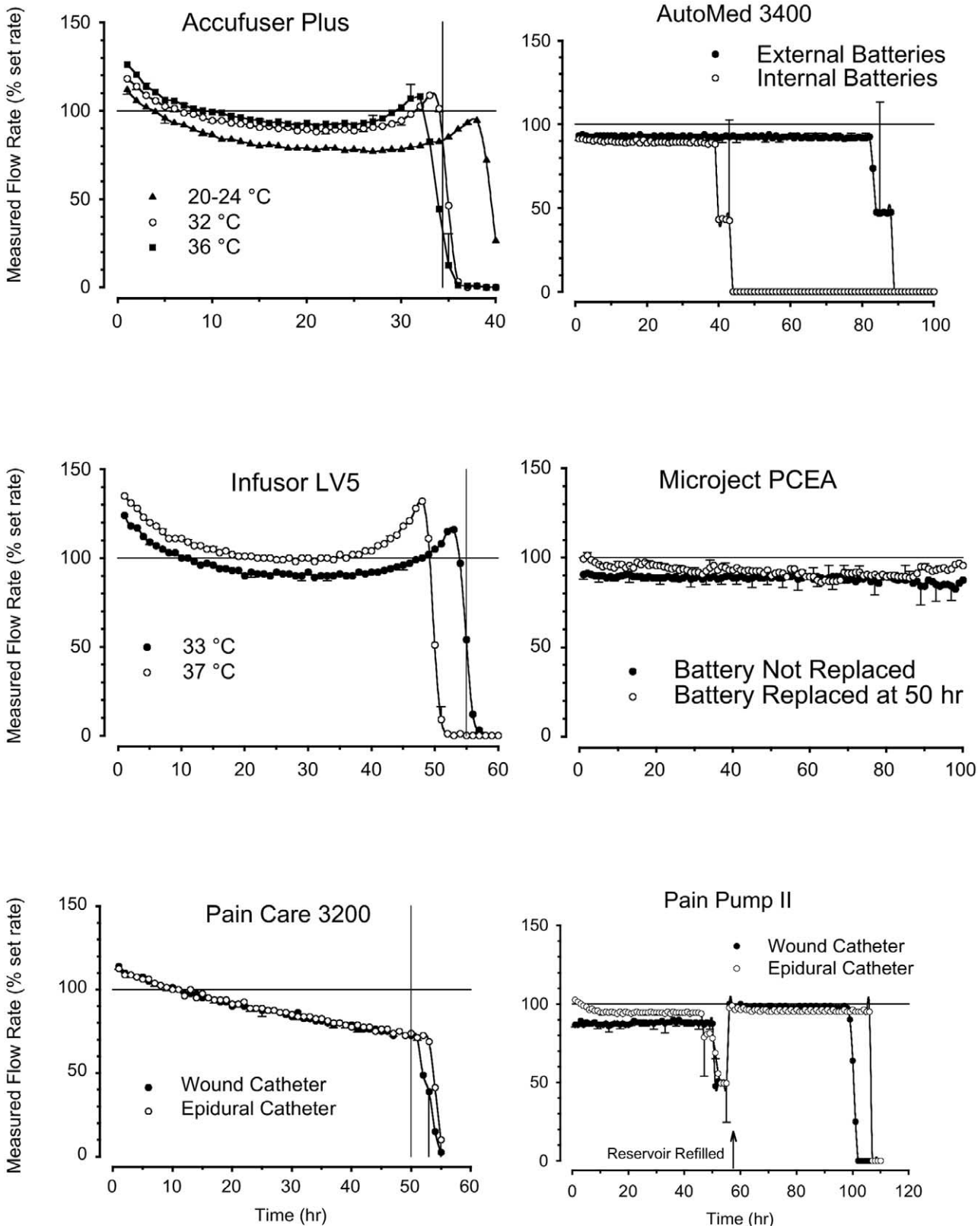

Fig 2. Performance over time for various portable infusion pumps as noted by title in each panel. Shown is the actual infusion rate as a fraction of the set infusion rate. The constant horizontal line represents the expected pump rate at 100% of set flow rate. The constant vertical line represents the expected infusion duration as calculated from the set rate and reservoir volume, except for the AutoMed 3400 and Microject PCEA, which use external reservoirs with variable volumes. The Pain Pump II was refilled to capacity for 2 of the trials when the reservoir was depleted to 20 mL. The axes' labels apply to all panels. Legends only apply to their respective panels. Data are expressed as mean ± SD. Representative error bars are inscribed for every fourth data point. Large error bars denote impending pump failure or reservoir depletion.

Table 3. Measured Infusion Pump Performance Compared With Manufacturer-Described Infusion Rate

Pump	Variable	Percent Infusion Duration With Measured Rate: <85% Set Rate	85% to 115% Set Rate	>115% Set Rate
Accufuser Plus	20°C to 24°C	24.0 ± 0.0	76.0 ± 0.0	0.0 ± 0.0
	32°C	0 ± 0.0	99.0 ± 0.0	1.0 ± 0.0
	36°C	1.0 ± 1.4	97.0 ± 1.4	2.0 ± 0.0
AutoMed 3400	Internal batteries	59.0 ± 2.8	41.0 ± 3.0	0.0 ± 0.0
	External batteries added	15.0 ± 4.2	85.0 ± 4.2	0.0 ± 0.0
Infusor LV5	33°C	1.8 ± 0.0	90.0 ± 1.3	8.2 ± 1.3
	37°C	10.9 ± 0.0	69.1 ± 0.0	20.0 ± 0.0
Microject PCEA	1 set of batteries	9.0 ± 12.7	91.0 ± 12.7	0.0 ± 0.0
	Battery change at 50 hours	3.5 ± 4.9	96.5 ± 4.9	0.0 ± 0.0
Pain Care 3200*	Included wound catheter	36.4 ± 1.0	54.6 ± 0.9	0.0 ± 0.0
	Braun perineural catheter	35.5 ± 3.9	55.5 ± 3.7	0.0 ± 0.0
Pain Pump II	Included wound catheter	2.5 ± 0.7	97.5 ± 0.7	0.0 ± 0.0
	Braun perineural catheter	2.0 ± 2.8	98.0 ± 2.8	0.0 ± 0.0

*Basal infusion rate described as "4 mL/h continuous flow" on product packaging and marketing materials.

Pain Care 3200

The infusion rate of this pump declined throughout its entire duration, remaining within ±15% of its set rate of 4 mL/h for 55% of its duration. Although the advertised rate of 4 mL/h is accurate for only a proportion of the infusion duration, the profile of the infusion matches the manufacturer's printed information included with each pump (5.7-2.9 mL/h, declining continuously). Replacing the included wound catheter for the Braun perineural catheter did not significantly alter this profile.

Pain Pump II

The infusion rate of this pump was very consistent, and remained within ±15% of its set rate for 98% of its duration (Table 3). Although the manufacturer's information included with the pump does not comment on battery life, the stated delivery accuracy of ±10% must be compared with the observed delivery accuracy of ±5% to 12% found in this investigation. When the Braun perineural catheter replaced the included wound catheter, this stability was unchanged. When the reservoir was refilled after the first 380 mL infusion, the pump continued to infuse at this stable rate for an additional 50 hours during both trials (Fig 2).

Bolus Dosing

The 3 electronic pumps all provided 4 mL for each bolus dose as programmed, and the basal infusion rate did not vary after the bolus dose. The 2 nonelectronic pumps that provided for patient-controlled bolus dosing (Accufuser Plus and Pain Care 3200) also provided their preset volume for each bolus dose. However, after each bolus, the basal rate decreased to 0 until the bolus bladder refilled at the basal rate. For the Accufuser Plus, this provided an approximately 15-minute lock-out, but also a cessation of basal flow for the same duration. For the Pain Care 3200 it took between 40 and 80 minutes to refill the bladder and restart the basal infusion, depending on the point of infusion.

Discussion

This investigation shows the variable infusion-rate accuracy and consistency of portable pumps often used to provide postoperative continuous regional analgesia (Table 3). Furthermore, the profiles (infusion rate over time) of the various pumps differed significantly, depending on the pump power source. Both the elastomeric- and spring-powered pumps infused at higher than expected rates initially, with infusion rates decreasing over the infusion duration. The electronic pumps infused at a consistently lower than expected rate, although their flow had less variability than the nonelectronic pumps. Raising flow-regulator temperature increased infusion rates by approximately 10% in one of the elastomeric pumps (Infusor LV5), but less than 5% in the other (Accufuser Plus). The higher than expected infusion rates led to a decreased total infusion duration (Table 3). Continuous battery discharge did not affect infusion accuracy for the electronic pumps, and only the AutoMed 3400 required a change of batteries before 100 hours. Replacing the included wound catheters with commonly used Braun perineural catheters did not significantly alter the infusion profile for either the Pain Pump II or the Pain Care 3200.

These differences in flow-rate accuracy may have implications for patient care when applied to continuous regional analgesia. Although there is nothing inherently wrong with an infusion rate that varies over time as these pumps provide, health

care providers must be aware of the infusion profile to maximize patient safety and benefit. There are potential advantages and disadvantages to all of the infusion profiles described in this study, and the pump profile must be matched adequately to the situation/indication. For example, because surgical pain generally decreases over time, a pump that provides a declining rate of infusion (e.g., Pain Care 3200) may be appropriate for an adult patient receiving a perineural local anesthetic infusion for postoperative analgesia. However, this profile may provide a subtherapeutic infusion rate during the latter portion of the infusion period, and, consequently, unsatisfactory analgesia.

It also should be noted that the electronic pumps' infusion rate and bolus dose volume may be tailored to individual patient requirements. This allows a decrease in the infusion rate as postoperative pain resolves,[14] or an increase if analgesia is inadequate.[19] For example, the AutoMed 3400 consistently infuses at 90% to 95% of the programmed rate. Clinically, it is rare that this degree of difference would influence analgesia. However, if it did, simply reprogramming the pump could increase the infusion rate. When choosing the proper infusion pump for a given application, several clinical factors must be accounted for, including, but not limited to, acceptable infusion rate accuracy, patient-controlled bolus availability, desired infusion duration, and total local anesthetic volume requirement.

The degree to which the temperature sensitivity of a given pump should influence a decision regarding its use is highly situation dependent. For example, our institution is located in Florida, where summer temperatures commonly reach 39°C, increasing skin and ambient temperature that affect the flow regulators of various infusion pumps. After this study, we now instruct our patients to remain in air-conditioned environments when using a temperature-sensitive infusion pump during the summer months. This investigation only varied temperature with an increase of 4°C. A larger increase theoretically should increase the flow rate to a greater extent than reported here, while a temperature decrease theoretically should result in a flow-rate decrease. However, this speculation is based on the physics of the flow-regulator technology and requires additional investigation for confirmation.

Although infusion rate accuracy and consistency are important factors, these are not the only variables that should be taken into account when deciding on an optimal pump for a given indication. Such factors include patient and health care provider convenience, size, weight, cost, reliability, ease of use, reprogrammability, as well as the previously mentioned clinical factors (e.g., desired infusion duration). For example, for a 2-day, 5-mL/h intra-articular local anesthetic infusion in an adult, it may be desirable to use the nonelectronic Infusor LV5 for its simplicity and disposability. In this example, a 15% to 25% infusion rate change may be clinically insignificant, and infusion rate accuracy may be outweighed by other factors. Although commenting on every variable is beyond the scope of this discussion, health care providers should take all of these into account when deciding on an infusion pump for a specific circumstance.

To investigate the effect of an increase in temperature on the elastomeric pumps, we included only the infusion-rate regulator in the heating unit. To simulate a temperature increase, we increased the temperature of the heating device, but the ambient room temperature of the infusion pumps remained constant. Therefore, it is unknown what the effect of increasing the temperature for both the flow regulator and the pump would have on the flow rate, as would actually occur on a very hot day. Furthermore, how reliable each infusion pump model is cannot be estimated from the data collected for this investigation: large series of pumps would have to be studied to draw these conclusions.

In conclusion, factors such as flow-rate accuracy and consistency, infusion profile, temperature sensitivity, and battery duration should be taken into consideration when choosing and using a portable infusion pump for local anesthetic administration. Controlled clinical studies are needed to investigate how local anesthetic infusion rate variability affects patient analgesia.

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