

The Flow Rate of the Elastomeric Balloon Infusor is Influenced by the Internal Pressure of the Infusor

The purpose of this study was to evaluate the flow rate of elastomeric balloon infusor composed of rubber or silicone materials. Two models were studied: the Baxter Twoday Infusor and Advance Silicone Infusor. Each infusion device has a preset flow rate of 2 mL/hr. Fifteen units of each device were filled with 100 mL of normal saline. The flow rate was measured gravimetrically using an electronic balance. The internal pressure of the balloon infusor was measured with a Digital pressure meter via the pressure transducer. The monitored internal pressure of the two kinds of infusor was not maintained uniformly during the entire delivery period, which was divided into 3 phases: the phase of decreasing, maintained, and increasing pressure during the delivery of drug. Both devices initially infused at a relatively high rate, followed by a somewhat steady flow rate. The flow rate distinctly increased in the small residual volume. The flow rate of the balloon infusor used in this study was not sustained uniformly during the entire delivery period and was in proportion to the internal pressure of the infusor regardless of the materials.

Key Words : Elastomers; Infusion Pumps; Flow rate

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INTRODUCTION

Patient-controlled analgesia (PCA) is a well established technique for providing pain control after surgery. PCA is generally provided by high-technology microprocessor-controlled infusion devices. A disposable device has been introduced and evaluated clinically (1-5). However, many PCA devices have been used without a single publication attesting to their safety and accuracy, and certain adverse incidents have led to calls for more rigorous testing (6, 7). The rationale for this study was to understand the general flow rate patterns of the balloon elastomer infusor. We studied the flow rate of two types of balloon infusors with somewhat different shapes and composed of different materials (rubber and silicone). Patients using these devices have reported that infusion times are prolonged, sometimes up to twice of the preset time as asserted by the manufacturers (8). Unfortunately, most of the previous studies on the infusion rate of the balloon-type infusor limited the observation period to the maximum delivery time illustrated by the manufacturers, so they could not show the flow rate pattern for the entire delivery period of drug (9-12). We observed the flow rate of the elastomeric balloon infusor during the entire drug delivery with measurements of the internal pressure of the infusor.

MATERIALS AND METHODS

Two disposable elastomer balloon-powered units, the Advance Silicone Infusor (Wooyoung, Korea) and Baxter Twoday Infusor (Baxter Health Corporation, U.S.A.) were used in this study (Fig. 1). Both infusion devices are designed to infuse drugs at a fixed rate (2 mL/hr) and have a maximum capacity of 100 mL of analgesic solution. Twenty-one Advance Silicone Infusors (group I) and nineteen Baxter Twoday Infusors (group II) were tested. After excluding the cases that could not complete the study because of the technical errors of the measurements and defects of the devices, the data obtained from fifteen each of the two infusion devices were analysed. There was one device in each group which stopped delivery during experiments. The flow rates and internal pressure of the infusors were measured as follows.

Measurement of the flow rate

The electronic balance was set at zero point after the infusor was put on the electronic balance (Mettler PM 2000, U.S.A.), and then the infusor was filled with normal saline on the electronic balance until the total weight became 100 g. The tube was clamped when the normal saline was filled

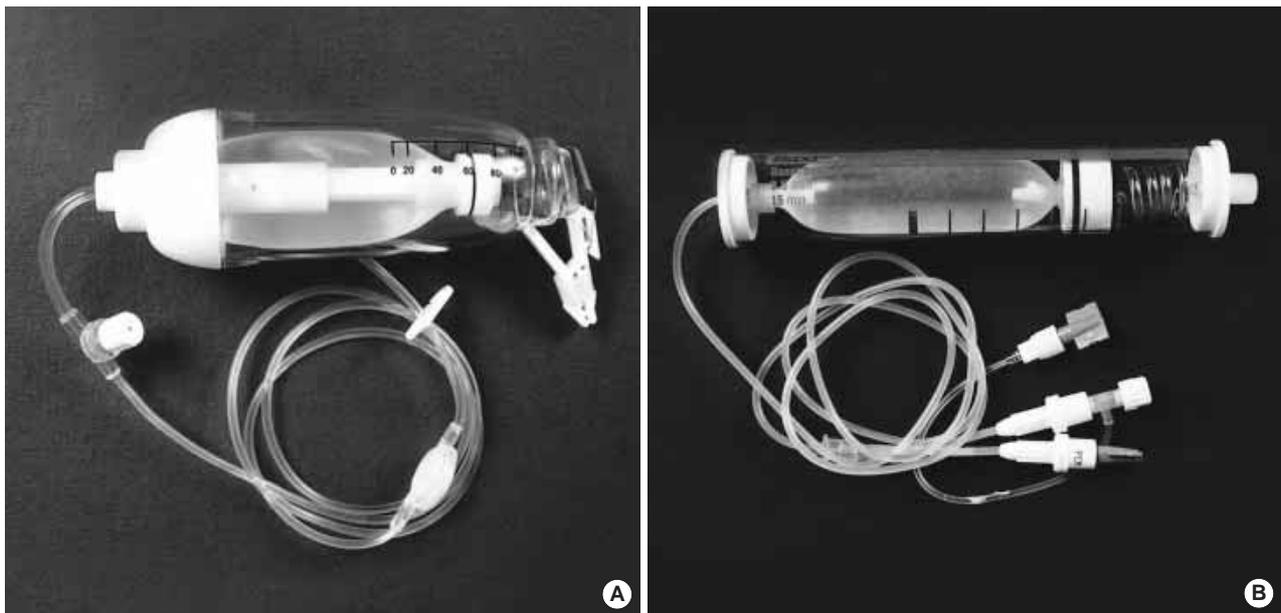


Fig. 1. (A) Advance Silicone Infusor; (B) Baxter Twoday Infusor.

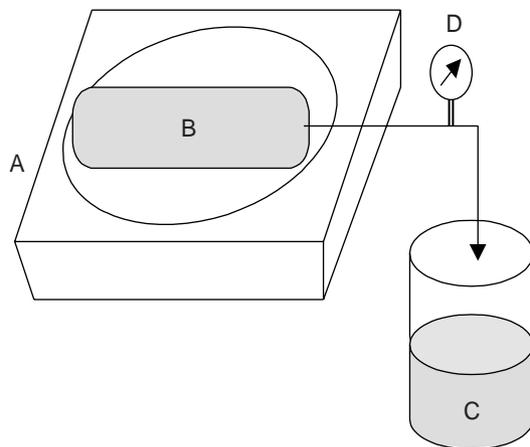


Fig. 2. Diagram representing the experimental method. (A) Electronic balance (Mettler PM 2000, U.S.A.); (B) Infusor; (C) Beaker; (D) Digital Pressure meter 207[®] (Dynatech Nevada Inc., U.S.A.). The flow rate was determined by the change of the weight of infusor hourly.

up to the end of the delivery tube. The flow rate was determined by the change of the weight of infusor per unit time after declamping of the delivery tube (Fig. 2). The experiments ended when the residual weight of the infusor did not change further. The room in which the experiments were conducted was air-conditioned and maintained at a constant room temperature. The results are expressed as mean \pm S.D. Data were analyzed by one-way repeated measures analysis of variance (ANOVA) followed by Dunnett's with the software Sigma Stat. The significance level was set at $p < 0.05$.

Measurement of the internal pressure of the infusor

The internal pressure of the balloon infusor was measured with a Digital Pressure Meter 207[®] (Dynatech Nevada Inc., U.S.A.) via the pressure transducer attached to the 16-gauge needle inserted into the delivery tube of the infusor before the Luer body which restricts the flow rate. Based on the preliminary study, the internal pressure was repeatedly measured at every filling of the infusor with 2 mL of normal saline until the weight of the infusor became 20 g. After that, every 10 mL of normal saline was filled into the infusor until a total of 80 mL of normal saline was filled within the reservoir. Again, the internal pressure was measured at every filling of 2 mL of normal saline until the total weight became 100 g. This procedure was repeated vice versa during the removal of the normal saline from the balloon infusor filled with 100 mL of normal saline.

RESULTS

The internal pressure of the infusor

The internal pressure pattern of the infusor showed a hysteresis-like phenomenon during the process of filling and emptying in the infusor with normal saline. However, we evaluated the internal pressure of the infusor during the decrease of the infusor volume because it could affect the delivery of analgesic drug to the patient. When the drug delivery began, the internal pressure of the infusor decreased according to the decrease of the infusor volume. However, the internal pressure sustained uniformly after the volume

of the infusor had reached to about 80 mL. The internal pressure increased again when the infusor volume reached to about 10 mL. This pressure pattern was observed both in the group I and in the group II. The range of the internal pressure of the group I was about 110-140 mmHg, and that of the group II was about 380-450 mmHg during the relatively uniform pressure state (Fig. 3).

Flow rate

We observed that the flow rate was related to the internal pressure of the infusor. So the average flow rate was obtained according to the infusor volume based on our preliminary study about the internal pressure of the infusor and on the data obtained in this study. The group I showed a flow rate of 1.9 mL/hr, 1.6 mL/hr, and 2.2 mL/hr, corresponding to the infusor volume of 100-80 mL, 80-10 mL, and 10-0 mL, respectively. The flow rates of the group II were 2.0 mL/hr, 1.7 mL/hr, and 2.4 mL/hr during the corresponding delivery periods (Table 1). The actual flow rate was plotted against the infusor volume. The flow rate was significantly higher in the early phase and the late phase of the drug delivery than in the intermediate delivery phase (Fig. 4, 5). The instabili-

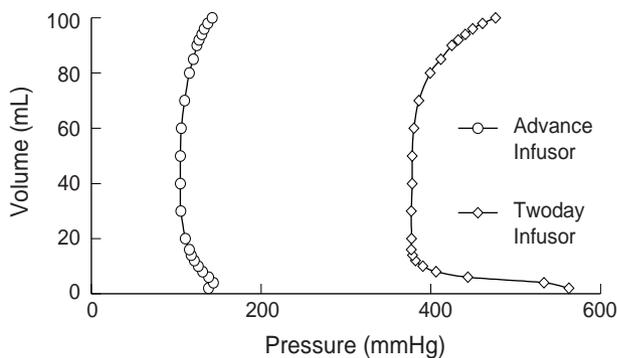


Fig. 3. Internal pressure-infusor volume curve in the elastomeric balloon infusor. The monitored internal pressure of the infusor decreased, was maintained, and increased according to the infusor volume.

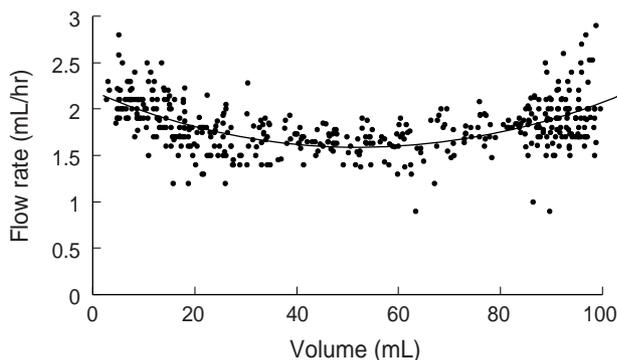


Fig. 4. Flow rate versus infusor volume curve in the Advance Silicone Infusor.

ty of the flow rates during the early and late phases of the delivery was also observed in both kinds of infusors. The variability of the flow rates among 15 products was also increased during the early and late phases. The group I showed the lowest flow rate in the about 50-60 mL of the infusor volume and the group II showed a decreasing tendency of the flow rates during the intermediate delivery phase (80-10 mL).

DISCUSSION

The two balloon elastomeric infusion devices used in this study are based on the same principle, although they have different shapes and are composed of different materials. It consists of a drug reservoir, outer housing, non-kinking delivery tube, filter that removes bacteria and air bubbles, and Luer body that houses a size-controlled orifice or filament and acts as a valve responsible for the maintenance of the preset flow rate and filling port through which the drug is filled into the reservoir. The balloon reservoir serves a sustained internal pressure as a driving force and the Luer body makes a resistance as a flow control device. So, the flow rate of these devices is determined by the constant pressure in the elastomeric membrane of the reservoir coupled with various flow control devices (13). Usually, these devices are recommended to use at room temperature (below 38°C), and in some products the flow rate in the state the Luer body contacts with the patient's skin is illustrated. This may be due

Table 1. Flow rates according to the infusor volume

	Volume of the infusor		
	100-80 (mL)	80-10 (mL)	10-0 (mL)
Advance Silicone Infusor (mL/hr)	1.9 ^{††} ±0.2	1.6 ^{††} ±0.1	2.2 ^{††} ±0.2
Baxter Twoday Infusor (mL/hr)	2.0 ^{††} ±0.3	1.7 ^{††} ±0.3	2.4 ^{††} ±0.5

*: *p*<0.05 compared to the 100-80 mL range, †: *p*<0.05 compared to the 80-10 mL range, ††: *p*<0.05 compared to the 10-0 mL range by one-way repeated measures ANOVA.

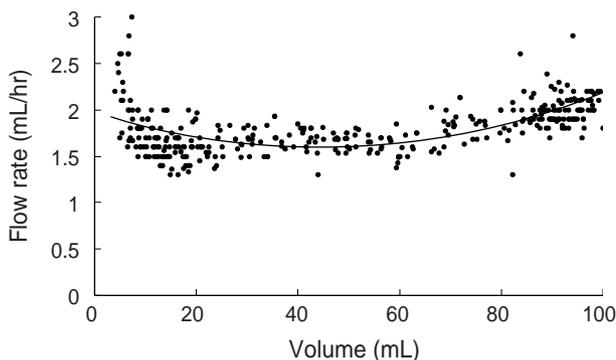


Fig. 5. Flow rate versus reservoir infusor volume curve in the Baxter Twoday Infusor.

to the expansion or constriction of the reservoir or Luer body by the change of the temperature. We tried to conduct the experiments at a constant room temperature, but there was a room for a small change in temperature. In the practical use, the devices are used at room temperature, and we could apply our results to the clinical settings. At a relatively constant room temperature, if the internal diameter of the Luer body does not change, the internal pressure of the infusor will decide the flow rate of the elastomeric balloon infusor.

The driving force in the elastomeric balloon infusor is the elasticity of the material, which has been already determined in the process of sulfuration or bridging process in the rubber or silicone (14, 15). The internal pressure in the group II was higher than that in the group I. This may be due to the larger stress caused by the larger strain in the rubber than in the silicone. Theoretically, the internal pressure of the infusor must be maintained uniformly up to the preset reservoir volume limit. However, in this study, the internal pressure of the infusor varied with the elapse of the delivery time. Some factors might have influenced this pressure pattern. The strain might increase owing to the abrupt increase of volume when the reservoir was filled with normal saline 100 mL, resulting in the increase of the internal pressure. During the intermediate delivery phase, the internal pressure was sustained at a somewhat decreased level for the uniform elasticity of the material. Then, the internal pressure distinctly increased again by the effect of increased depth itself of the material when the infusor volume outstandingly decreased. The depth of the material could increase because of the decreased surface area during the delivery of drug. We think that it is important to maintain the ratio of the surface area to the volume during the drug delivery and that it is necessary to have a concern about this problem in the development of the shape of the balloon infusor. The decrease in the internal pressure of the infusor might be observed for the decreased membrane stress in the thin-walled pressure vessel shape caused by the decreased internal force, radius, and increased depth during the delivery ($\sigma \propto P \cdot r/t$, σ : membrane stress, P: internal force, r: radius, t: depth of membrane) (16, 17). This can be compensated by the elasticity in the elastomeric balloon infusor. Coley et al. showed that the mean flow rate of the balloon infusors during the first two hours was significantly higher than during the last two hours (10), but they could not observe the increased flow rate during the final period because they limited the duration of the study. Veal et al. reported the residual volume of the infusor at the end of delivery in the study about the flow rates of the infusors, however, they also restricted the observation period (12) and did not investigate further. Mackey et al. observed that as the infusor became exhausted, the delivery increased to a maximum value, ranging from 118% to 137% of normal, before falling to zero (18). In a clinical situation, it may be important to know the increased flow rate during the terminal phase of the delivery, because it cor-

responds to the decreased analgesic demand of the patients. The studies about the flow rate of elastomeric balloon infusor have shown common results of the unstable and relatively high flow rates during the early infusion period (13, 18). This might be explained by the process of stabilization after relaxation of the high molecular strain in rubber or silicone due to the acutely increased infusor volume (14). The group II tended to have a somewhat decreased flow rate during the intermediate phase. This might be partly explained by the change of the elasticity of the material with the elapse of the infusion time. Thus, it is important to sustain the elasticity during the total infusion period in the use of over 48 hr.

Many factors can influence the flow rate, such as environmental temperature, fluid viscosity, and type of the venous access (18, 19). However, the intent of this study was to examine the change of the driving force and flow rates according to the volume of the infusor. Conclusively, in applying the elastomeric balloon infusor to the patients, we must keep the fact in mind that the balloon infusors do not provide uniform drug delivery.

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